#### **National Institute for Health and Care Excellence**

# Community pharmacy: promoting health and wellbeing

Evidence reviews for signposting and referral to other services and support

NICE guideline NG102

Evidence review 4

August 2018

Final

These evidence reviews were developed by the Public Health internal guidelines team



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## Signposting and referral to other services and support

#### **Review question**

**Review question 4a**: What is the most effective way for community pharmacies to refer or signpost people to other services or support?

**Review question 4b**: Is offering signposting and referral acceptable to users of community pharmacy services?

**Review question 4c**: What is the most cost effective way for community pharmacies to refer or signpost people to other services or support?

#### Introduction

Community pharmacies are well positioned to promote health and wellbeing to their local community as 90% of people overall, and over 99% of people in the most deprived communities, live within a 20-minute walk of a community pharmacy (<a href="The positive pharmacy care law: an area-level analysis of the relationship between community pharmacy distribution, urbanity and social deprivation in England">England</a> Todd et al. 2014).

As well as promoting healthy lifestyles, community pharmacy contractors are required to signpost members of the community to appropriate services. This involves providing information on other health and social care providers or support organisations to people who need support, advice or treatment that cannot be provided by the pharmacy.

The aim of this review was to determine the most effective and cost-effective way for community pharmacy staff to refer or signpost people from community pharmacy to other services or support, and whether offering signposting and referral is acceptable to users of community pharmacy services.

This review also aims to explore whether the effectiveness and cost-effectiveness of signposting and referral varies by the characteristics of the intervention, the person providing the signposting and referral, or the person being signposted or referred. It will also explore how signposting and referral could be made more acceptable to users of community pharmacy services.

The review focused on identifying studies that fulfilled the criteria specified in Table 1. For full details of the review protocol, see Appendix A.

#### PICO table

Table 1. PICO table for review questions 4a, 4b and 4c on signposting and referral

PICO Element	Details
Population	Anyone who may use community pharmacy services
Intervention	<ul> <li>Any type of referral made by community pharmacy staff from community pharmacy services to other services or support. This includes formal referrals made by community pharmacy staff to other services, such as lifestyle weight management programs, social prescribing for debt management, or domestic violence helplines.</li> </ul>
	<ul> <li>Any type of signposting done by community pharmacy staff to other services or support.</li> </ul>
Comparator	<ul><li>No intervention.</li><li>Any signposting or referral done by community pharmacy staff.</li></ul>

PICO Element	Details		
Outcomes	Review question 4a	Review question 4b	Review question 4c
	Uptake of interventions or services to promote, maintain and improve health and wellbeing	Preference and experience of people using the service	<ul> <li>Costs, savings and effectiveness</li> <li>Cost per quality adjusted life year</li> <li>Cost per unit of effect</li> <li>Net benefit</li> </ul>

#### Effectiveness evidence

#### Included studies

Papers were included if they met the PICO and were:

- Randomised controlled trials, before and after studies, or any other type of comparative study design.
- Systematic reviews of randomised controlled trials or other comparative studies, if the majority of included studies met the PICO. If the majority of studies did not meet the PICO, individual studies included in the systematic review were considered separately for inclusion in this evidence review.
- Conducted in the UK, Australia, Canada, Republic of Ireland, the European Union (including Norway and Switzerland), New Zealand and Chile.
- Published between 1990 and 2016.
- Published in English language.

#### **Excluded studies**

Papers were excluded if they:

- Did not include comparative data, that is, they did not included data either comparing an intervention to another active intervention or a control intervention, or comparing data before and after an intervention.
- Were related to treatment of diseases and acute medical conditions, such as dispensing, other medicine or device services, self-care to improve the use of medicines or devices, urgent care.
- Were related to vaccinations.
- Only included interventions delivered by distance-selling (online) pharmacies.
- Only looked at the effectiveness of screening, checks and testing, such as blood glucose checks, blood pressure checks, cardiovascular risk assessments, cholesterol checks, medicine use reviews, mole checking services, NHS Health checks.
- Included interventions delivered by people other than community pharmacy staff.
   Studies that were delivered by a mixture of community pharmacy staff and other healthcare professionals were only included if results for the services provided by community pharmacy staff were reported separately.

See appendix K document for a full list of excluded studies.

#### Summary of effectiveness studies included in the evidence review

In total 14,652 references were found across the four review questions. Full-text papers of 361 citations seemed potentially relevant. In total 4 primary studies of effectiveness and 1 qualitative study was included in review 4.

Table 2. Summary of the effectiveness evidence for signposting and referral

Study	Setting and country	Intervention	Health area	Outcomes
Evans et al. (1997)	Community pharmacies  South-East Wales, UK	Advised to seek advice from elsewhere regardless of any changes in presenting symptoms  Advised to seek advice only if presenting symptoms worsen or do not improve	Any	Uptake of GP appointment
Michie et al. (2014)	Community pharmacies  Edinburgh, UK	Empty box of emergency contraception to take to family planning clinic  Verbal and written advice on methods of contraception, including locations of family planning clinics	Sexual health	Uptake of appointment with sexual health clinic or other contraception provider
Perraudin et al (2015)	Community pharmacies France	Information brochure along with estimated risk of obstructive sleep apnea syndrome. Signed letter for GP referral for further diagnostic testing	Obstructive Sleep Apnea Syndrome (OSAS)	Diagnostic test for OSAS
Sriram et al. (2016)	Community pharmacies  Perth, Australia	Referral letter to GP based on Jodi Lee Test and pharmacist opinion  Referral letter to GP based on pharmacist opinion	Cancer awareness	Uptake of GP appointment

See appendix D for full evidence tables.

## Synthesis and quality assessment of effectiveness evidence included in the review

Studies included in this review were a mix of experimental and observational study designs. Studies with a control group were assessed for risk of bias using the Cochrane Effective Practice and Organisation of Care (EPOC) checklist as referenced in Appendix H of the NICE methods manual. The Effective Public Health Practice Project (EPHPP) QA Checklist was applied to assess risk of bias in uncontrolled before-and-after studies.

GRADE methodology was used to appraise the evidence across five potential sources of uncertainty: risk of bias, indirectness, inconsistency, imprecision and other issues. Overall ratings start at 'High' where the evidence comes from RCTs, and 'Low' for evidence derived from observational studies. Meta-analysis was not undertaken within this review and results are presented from single studies only, thus the inconsistency domain of GRADE was largely not applicable. Details of how the evidence for each outcome was appraised across each of the quality domains is given below.

Quality domain	Description
Risk of bias	Limitations in study design and implementation may bias the estimates of the treatment effect. Major limitations in studies decrease the confidence in the estimate of the effect. Examples of such limitations are selection bias (often due to poor allocation concealment), performance and detection bias (often due to a lack of blinding of the patient, healthcare professional or assessor) and attrition bias (due to missing data causing systematic bias in the analysis). Where there are no study limitations, evidence is assessed as having 'no serious' risk of bias. Alternatively, evidence may be downgraded one level ('serious' risk of bias) or two levels ('very serious' risk of bias).
Indirectness	Indirectness refers to differences in study population, intervention, comparator and outcomes between the available evidence and the review question. Where the evidence is directly applicable to the PICO, it is assessed as having 'no serious' risk of indirectness. Alternatively, evidence may be downgraded one level ('serious' risk of indirectness) or two levels ('very serious' risk of indirectness).
Inconsistency	Inconsistency refers to an unexplained heterogeneity of effect estimates between studies pooled in the same meta-analysis. The I² statistic describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance). As meta-analysis was not performed within this review downgrading for inconsistency was not applicable.
Imprecision	Results are imprecise when studies include relatively few patients and few events (or highly variable measures) and thus have wide confidence intervals around the estimate of the effect relative to clinically important thresholds. 95% confidence intervals denote the possible range of locations of the true population effect at a 95% probability, and so wide confidence intervals may denote a result that is consistent with conflicting interpretations (for example a result may be consistent with both public health benefit AND public health harm) and thus be imprecise.
	Imprecision was assessed with reference to minimally important difference (MID) thresholds for individual outcomes (smallest change in an outcome that is considered important by patients or health care professionals). Established MIDs are published in previous literature and seen and accepted in clinical community. It was decided that the point measure would be used to decide whether or not the result was clinically important, and that the 95% confidence intervals would indicate certainty of this importance. Uncertainty is introduced where confidence intervals crossed the MID threshold. If the confidence interval crosses either the lower or upper MID threshold this indicates 'serious' risk of imprecision. Crossing both MID thresholds indicates 'very serious' risk of imprecision in the effect estimate. Default MIDs are used where no established MID's for individual outcomes are found (0.75 and 1.25 for dichotomous outcomes and 0.5*SD of control group at baseline for continuous outcomes). If the MID could not be calculated (e.g. because standard deviation of outcome measure at baseline was not reported in the paper) then we downgraded by 1 level as it was 'not possible to calculate imprecision from the information reported in the study'. Where data was pooled in analyses, the study with the largest weight was used as the control group for MID calculations.  Where the 95%CI does not cross either MID threshold, the evidence is assessed as having 'no serious' risk of imprecision unless the effect estimate is derived on the basis of few events and a small study sample (that is, less than 300 events for dichotomous outcomes or total sample size less than 400

Quality domain	Description
	for continuous outcomes). In that case the results were downgraded one level for 'serious' imprecision to reflect uncertainty in the effect estimate.
Other issues	Publication bias is a systematic underestimate or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies. A closely related phenomenon is where some papers fail to report an outcome that is inconclusive, thus leading to an overestimate of the effectiveness of that outcome.
	Sometimes randomisation may not adequately lead to group equivalence of confounders, and if so this may lead to bias, which should be taken into account. Potential conflicts of interest, often caused by excessive pharmaceutical company involvement in the publication of a study, should also be noted.

Details of how the 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) were appraised for each outcome are given below in the GRADE tables. Publication or other bias was only taken into consideration in the quality assessment if it was apparent.

<b>GRADE</b> rating	Description
High	Further research is very unlikely to change our confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very Low	Any estimate of effect is very uncertain.

See Appendix F for full GRADE tables.

The evidence from the effectiveness studies was all very low in quality. This is because all of the included studies had either serious or very serious risk of bias and most of the studies had serious indirectness and small numbers of events.

A summary of the quality of the evidence for each type of outcome is provided in table 3. Table 3. Summary of the quality of the evidence for each outcome for signposting and referral

Outcome		Quality of evidence
Uptake of services	Uptake of GP appointment	Very low
	Uptake of appointment with family planning clinic or other contraception provider	Very low
	Diagnostic test for obstructive sleep apnea syndrome	Very low

#### Acceptability evidence

## To assess the acceptability of providing signposting or referral services in community pharmacy settings, the views and experiences of pharmacy service users were sought from the qualitative literature. Included studies

Studies were included if they sought out to determine the acceptability of providing signposting or referral services to pharmacy users or explored how these types of interventions could be made more acceptable to users of community pharmacy services. Anyone who may use a community pharmacy was eligible for participation and specific types of interventions providing formal referrals to other services such as lifestyle weight management programs, debt management or domestic violence helplines were included. Any type of signposting done by community pharmacy staff to other services or support was also included. Outcomes of interest were respondent preferences and experience and also quality of life. Data needed to be collected using either interviews (face to face, telephone, SMS or online) or focus groups. Only studies conducted in the UK, Australia, Canada and the Republic of Ireland were included. See Appendix A for full details of review protocol.

#### Summary of acceptability studies included in the evidence review

One study conducted in the UK met the inclusion criteria. This study assessed the barriers and facilitators of providing pharmacy based interventions to increase uptake of emergency contraception.

First Author, Year	Design & Analysis	Countr	Health Area	Population	Outcomes	Quality Rating
Michie, 2016	Face to face semi-structured interviews	UK	Sexual Health	12 female emergency contraceptive users	Acceptability Barriers & facilitators	+
	Thematic analysis					

**Michie (2016 [+])** conducted semi-structured face to face interviews with 12 females (mean age 26 years) requiring emergency contraception about barriers and facilitators of providing pharmacy based interventions to increase uptake of effective contraception following emergency contraception. Themes around the usefulness and acceptability of the approach were emerged.

#### Quality assessment of acceptability studies included in the evidence review

Included studies were rated individually to indicate their quality, based on assessment using a checklist. The tool used to assess the quality of studies was selected from appendix H in the methods manual. The quality ratings used for included studies are outlined below:

++	All or most of the checklist criteria have been fulfilled, and where they have not been fulfilled the conclusions are Very unlikely to alter.
+	Some of the checklist criteria have been fulfilled, and where they have not been fulfilled, or are not adequately described, the conclusions are unlikely to alter.
1	Few or no checklist criteria have been fulfilled and the conclusions are likely or Very likely to alter.

The included acceptability study was of moderate quality due to limitations in the lack of clarity on the role of the researcher and lack of rigour in data analyses. Subsequently there are likely to be issues with the reliability of the findings and the conclusions may be inadequate.

#### **Economic evidence**

#### Included studies

No studies on the cost effectiveness of information provision by community pharmacy staff were identified.

#### **Excluded studies**

See appendix K document for a full list of excluded studies.

#### **Economic model**

No new economic modelling was done for this review question

#### **Evidence statements**

## Evidence statement 4.1 – Advice to make a GP appointment based on presenting symptoms increased uptake of GP appointments [GRADE profile 1]

 Very low quality evidence from 1 observational cohort study with 40 participants found that asking participants to go to their GP based on presenting symptoms resulted in a clinically important increase in the number of participants attending the GP appointment compared to asking participants to go to their GP if presenting symptoms do not improve or get worse (RR 5.25, 95% CI 1.93 to 14.25).

## Evidence statement 4.2 – No evidence that referral to GP based on results of Jodi Lee test for bowel cancer increased uptake of GP appointments [GRADE profile 1]

Very low quality evidence from 1 before and after study with 41 participants found that
a standard referral letter after using the Jodi Lee test for bowel cancer symptoms may
not increase the uptake of GP appointments compared to a standard referral letter
based on pharmacist opinion of bowel cancer symptoms (RR 6.22, 95% CI 0.90 to
43.09).

## Evidence statement 4.3 – Advice to attend family planning clinic using an empty box of emergency contraception increased uptake of appointments with family planning clinics or other contraception providers [GRADE profile 1]

Very low quality evidence from 1 randomised controlled trial with 61 participants found
that asking participants to attend a family planning clinic with an empty box of
emergency contraception resulted in a clinically important increase in the uptake of
appointments at family planning clinics or other contraception providers compared to
providing verbal and written advice on methods of contraception and locations of family
planning clinics (RR 3.72, 95% CI 1.58 to 8.74).

# Evidence statement 4.4- Providing information brochures with advice and a written referral to customers deemed to be at increased risk for obstructive sleep apnea syndrome (OSAS) to consult with their GP increases uptake of OSAS diagnostic testing [GRADE profile 1]

Very low quality evidence from one cohort study conducted in France with 782
participants who were overweight or obese and on drug based antihypertensive
therapy found that community pharmacists providing an information brochure, brief
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advice and a written referral to consult with a GP resulted in a clinically important increase uptake of diagnostic testing for OSAS (OR 2.24, 95% 1.25 to 4.01).

## Evidence statement 4.5 – No evidence was identified for what characteristics of the person delivering signposting and referral interventions affect their effectiveness

 No evidence was identified that directly compares intervention delivered by different members of staff working for a community pharmacy.

#### Acceptability evidence statements

## Evidence statement 4.6 Rapid referral programs to family planning clinics fills a health service provision gap for women requiring emergency contraception

One UK study [+4] examining the barriers and facilitators of community pharmacists providing referrals to a family planning clinic to women requiring emergency contraception found that women cited difficulties in or reluctance to accessing GP services for emergency contraception and viewed referral from a community pharmacist as a vital service "I don't want to trouble my GP for minor health concerns so I prefer to self-medicate or go to the pharmacy across from where I live". Furthermore the possibility of having a rapid access appointment for contraception was welcomed and could potentially influence future contraception behaviour change especially if it enabled quicker access to consultations and potentially more specialist support "Getting emergency contraception can kick start your brain to thinking about wanting to get on the pill or something"

## Evidence statement 4.7 There are mixed views on the appropriateness of community pharmacists providing short-term supplies of hormonal contraception

One UK study [+4] examining the barriers and facilitators of community pharmacists providing a one month supply of progesterone only pills reported that some women found a one month supply of contraception to be a "waste of time" and indicated it could put women off using hormonal methods as a one month supply may not provide sufficient time to fully understand how their body would react or what the risks and benefits of using the product were. This was particularly highlighted by women who had no previous experience using hormonal contraception "I think for women like me who have never tried hormones it is not a good idea". Some women also indicated there were questions they wanted to ask the community pharmacist but did not feel they were able and may have preferred to discuss options with a GP. Conversely some respondents indicated they felt speaking to a pharmacist was a good alternative "as some people can be hesitant going on it and asking about it from their GP, so if they are offered they can try it. It is easier to ask the GP for more rather than to start on it". Women also thought that the time between presenting for emergency contraception and having an appointment would allow time to reflect on their experience and seek appropriate clinical and emotional support if needed.

#### Recommendations

**Evidence discussion** 

Interpreting the evidence

The outcomes that matter most

<sup>4.</sup> Michie 2016 [+]

<sup>&</sup>lt;sup>4.</sup> Michie 2016 [+]

The committee agreed that uptake of interventions or services to promote, maintain and improve health and wellbeing was a critical outcome for this review. Four out of five effectiveness studies addressed either the uptake of GP appointments or the uptake of an appointment with a family planning clinic or other contraception provider [ES 4.1-4.3]. Health areas these studies targeted included sexual health, cancer awareness and overall health. One effectiveness study assessed the uptake of obstructive sleep apnea syndrome (OSAS) diagnostic testing in those at risk who were referred to a GP by a pharmacist [ES 4.4]. No evidence was identified which investigated the cost effectiveness of interventions within this review.

One qualitative UK studies assessed the general public's views on the acceptability of pharmacists providing signposting or referral services. The committee agreed that the views and experiences of pharmacy service users and the perceived barriers and facilitators of providing pharmacy based interventions to increase uptake of referrals were both important outcomes [ES 4.6].

The committee acknowledged that no evidence was identified that directly considered variations in the effectiveness of interventions by the characteristics of the person delivering it, the format of the intervention, or the characteristics of the person receiving it [ES 4.5].

#### The quality of the evidence

There is evidence from only 4 effectiveness studies. Of these studies, one was carried out in France and one in Australia. Both qualitative studies were conducted in the UK. Seven evidence statements were generated across this review which were related to a range of health areas including sexual health, OSAS, cancer awareness and overall health [ES 4.1-4.8].

The committee agreed that the certainty in the effectiveness evidence was very low due to the high risk of bias and small number of events. Three effectiveness studies had fewer than 100 participants overall [ES 4.1-4.3]. One study found the provision of information brochures with advice and a written referral to a GP to be effective in increasing diagnostic testing amongst 783 subjects who were risk of OSAS [ES 4.4]. The committee agreed that as other evidence within this area was limited, the intervention should be given as an example to underpin a more generalised recommendation about how community pharmacies ought to work alongside other health care services to integrally support improved health and well-being. The committee noted that the evidence indicated patients are more likely to make an appointment with their GP if a pharmacist spends time with the person explaining the importance and relevance of the service being referred to.

The committee agreed that the UK study was not relevant to the guideline [ES 4.1]. The study was an old, retrospective study designed to determine whether pharmacists should give 'watch and wait' advice, rather than which forms of referral or signposting are effective. Although this study was not powered to show any harm the committee felt that practise within community pharmacies has changed substantially since publication of the study and therefore it should not be used to inform a recommendation.

The committee acknowledged that the study from Australia may not apply to the UK [ES 4.2]. It covered bowel cancer screening for all those aged 18 and over rather than older people. In addition, it was not clear whether the screening tool used had been validated, and, more importantly, whether it has been validated in the UK. The committee noted that there is a national GP programme for bowel cancer screening in the UK where eligible people are invited, and therefore it may not be something for community pharmacies to deliver. Despite this the committee agreed that pharmacy staff should raise awareness of cancer screening services where appropriate.

The committee noted that 1 study of very low quality indicated that referral is more effective for increasing uptake of appointments than signposting. Evidence from this study suggested

that using a token to refer people to other services could increase uptake of those services. For example, asking participants to attend a family planning clinic with an empty box of emergency contraception increased the uptake of appointments compared to providing verbal and written advice on methods of contraception and locations of family planning clinics [ES 4.3]. The committee agreed that having a formal referral process in place rather than a token per se that was the plausible mechanism of action and made recommendations in light of this.

The committee noted the usefulness and acceptability of UK pharmacy based interventions to increase uptake of effective contraception following emergency contraception. Rapid referral programs to family planning may fill a service provision gap for women requiring emergency contraception as they were viewed as a vital service [ES 4.6]. However there were mixed views on the appropriateness of community pharmacists providing short-term supplies of hormonal contraception, as some women agreed that a one month supply may not provide sufficient time to fully understand the personal suitability of the product or the risks and benefits of using it [ES 4.7]. The committee noted that the acceptability evidence had limitations in regard to the lack of clarity on the role of the researcher, lack of rigour in data analyses and the lack of detailed verbatim.

#### Advantages and disadvantages of providing referral and signposting

The committee acknowledged that there was a paucity of evidence within this area. A number of studies indicated that referral and explaining the importance of accepting referrals to other services were effective and acceptable, but the lack of quality and consistency reduced the overall certainty in the evidence [ES 4.1-4.6]. However, they did agree that community pharmacies should progress to become health and wellbeing hubs as part of the local care network, increasing the likelihood of referral processes being in place and thus improving outcome for patients. Integrating community pharmacies into the patient care pathway is in line with the integration of health and care through the NHS sustainability and transformation partnerships (STPs) and the Five Year Forward View.

The committee agreed that some evidence indicated that referral by community pharmacy teams increased service uptake more than signposting, however there was not enough evidence to strongly recommend how to effectively refer in and out of pharmacies to improve patient outcomes. It was noted that if community pharmacies do offer such a service it would need to match that provided by GPs and other services, which would mean fast referrals for those in need and ensuring people referred on are not re-assessed when they enter the care pathway. The committee decided to provide examples of the types of issues that community pharmacists could make referrals on, based on the evidence of effect as well as their expert opinion.

The committee noted that the evidence suggested there were no direct harms or disadvantages of delivering referral and signposting within community pharmacy settings and therefore should be considered as an important approach to improving health and well-being in individuals, particularly those who may not access healthcare elsewhere such as underserved groups or those from deprived communities. The committee agreed that further research to support the effectiveness and cost effectiveness of formal referrals within community pharmacies would strengthen the current evidence base.

#### Cost effectiveness and resource use

No cost effectiveness evidence was identified for this review

The committee noted that establishing links with other health and care organisations may result in upfront costs such as the time it takes to develop pathways and the time it takes to make a referral. However it was agreed that this may be offset by several downstream benefits including more efficient use of resources in the wider system, better continuity of

care and quicker access to the right treatment for some groups who do not access health services elsewhere (such as those from underserved or underprivileged communities).

#### Other factors the committee took in to account

The committee acknowledged that the referral process may work two ways within a community pharmacy. Members of the public may be referred in to a pharmacy from an external healthcare provider, or they may be referred to an external service by a pharmacy team. Expertise on local community pharmacy health services in the North Manchester region [EP 4] revealed the importance of including community pharmacy in to existing care pathways where formal referral links with other health and care providers are established and consistently managed. Based on their expert opinion, the committee agreed that community pharmacy teams should consider being involved in formal referrals to other organisations for broader health and wellbeing support as some people will benefit from particular services that are not available in the pharmacy. They noted that having a seamless service model in place will ensure effective continuity of care, improved efficiency of services and will result in better outcomes for the local population.

The committee noted that where an effective agreed referral process with another provider is not in place, signposting to other may still be important, but should, however not be recommended as usual practise.

The committee recognised that social prescribing would be an important concept to consider when signposting and referring within pharmacies. However, the committee were unable to recommend this specifically as the concept is very complex where evidence in regard to its effectiveness or acceptability within these settings is limited. Although there is not yet a universally agreed definition of what this term means, it may be described as a process whereby health care professionals refer individuals to non-clinical services within the community which may help improve health and well-being. The committee considered it an area for further evaluation and thus made a research recommendation on how it may be of benefit within pharmacy referrals.

#### Linked expert testimony (see appendix M)

EP 4 – Expert Paper 4 – Community Pharmacy to promote health and well-being

EP 6 – Expert Paper 6 – Five year forward view for Pharmacy

## **Appendices**

#### Appendix A – Review protocols

A number of elements within the protocols are common across two or more of the review questions. To reduce repetition these details have been included below the protocols, and will not be repeated in each protocol.

The elements common across reviews 1 to 4 are:

- Eligibility criteria population
- Eligibility criteria interventions
- Eligibility criteria comparators
- · Outcomes and prioritisation
- Eligibility criteria study design
- · Other inclusion or exclusion criteria
- · Selection process duplicate screening
- Data management (software)
- · Information sources databases and dates
- Methods for assessing bias at outcome or study level

See common elements across reviews 1 to 4 for more details.

Review question 4a - Effectiveness of signposting and referral

Field	Content
Review question	What is the most effective way for community pharmacies to refer or signpost
4a	people to other services or support?
Type of review question	Intervention
Objective of the review	This review aims to determine the most effective way for community pharmacy staff to refer or signpost people from community pharmacy to other services or support.
	The review will also explore whether effectiveness varies by the characteristics of the intervention, the person delivering the intervention, or the person receiving the intervention.
Eligibility oritoria	Anyone who may use community pharmacy services
Eligibility criteria - population	See common elements section for further details
Eligibility criteria - interventions	Any type of referral made by community pharmacy staff from community pharmacy services to other services or support. This includes formal referrals made by community pharmacy staff to other services, such as lifestyle weight management programs, social prescribing for debt management, or domestic violence helplines.
	Any type of signposting done by community pharmacy staff to other services or support.

Field	Content
	<ul> <li>Exclusions:</li> <li>Studies of the effectiveness of the services or support that the person is referred or signposted to.</li> <li>Interventions delivered by anyone who is not working for a community pharmacy</li> <li>Interventions delivered by distance-selling (online) pharmacies</li> </ul>
	See common elements section for further details
Eligibility criteria - comparators	No intervention.  Any signposting or referral done by community pharmacy staff.
Outcomes and prioritisation	See common elements section for further details.  1 Uptake of interventions or services to promote, maintain and improve health and wellbeing
Eligibility criteria – study design	See common elements section for further details.  Systematic reviews of studies of effectiveness  Studies of effectiveness, including:  Randomised controlled trials  Quasi-experimental studies, such as non-randomised controlled trials and before and after studies
Other inclusion or exclusion criteria	See common elements section for further details.  Only papers published in English will be included. Only studies undertaken in the UK, Australia, Canada and Republic of Ireland will be included.  See common elements section for further details.
	March 15, 2017: The committee requested that in addition to the initially agreed 4 countries the effectiveness review be expanded to include studies from the European Union (including Norway and Switzerland), New Zealand and Chile. Change approved by NICE QA on March 28, 2017
Proposed sensitivity or subgroup analysis	Where evidence allows, the review will also answer the following sub questions:
	<ul> <li>I. What characteristics of the person delivering the intervention (for example their job role and competencies, or being a health champion) affect its effectiveness in community pharmacy?</li> <li>II. How does the way the intervention is delivered, for example, the medium used, when, how often, or where the intervention takes place (such as in a consultation room, over the counter, in someone's home, or electronic communication) affect its effectiveness in community pharmacy?</li> <li>III. What characteristics of the people receiving the intervention (for example, age or gender) affect its effectiveness in community pharmacy?</li> </ul>
	Subgroup analysis by the health area (for example, physical activity, smoking cessation) may be undertaken, if appropriate.

Field	Content
Selection process  – duplicate screening	See common elements section for details.
Data management (software)	See common elements section for details.
Information sources – databases and dates	See common elements section for details.
Methods for assessing bias at outcome or study level	See common elements section for details.
Criteria for quantitative synthesis	For details please see section 6.4 of Developing NICE guidelines: the manual
Methods for quantitative analysis – combining studies and exploring inconsistency	Data from different studies will be meta-analysed if the studies are similar enough in terms of interventions, comparators and outcomes.
Meta-bias assessment- publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual.
Confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual
Review staff	Rachel Walsh (Technical Analyst)
	Ella Novakovic (Senior Technical Analyst)
	Daniel Tuvey (Information Specialist)

Review question 4b - Acceptability of signposting and referral

Field	Content			
Review question 4b	Is offering signposting and referral acceptable to users of community pharmacy services?			
Type of review question	Views and experiences			
Objective of the review	The review aims to determine whether offering signposting and referral is acceptable to users of community pharmacy services. It will also explore how interventions could be made more acceptable to users of community pharmacy services.			
Eligibility criteria - population	Anyone who may use community pharmacy services  See common elements section for further details			

Eligibility criteria - interventions	Any type of referral made by community pharmacy staff from community pharmacy services to other services or support. This includes formal referrals made by community pharmacy staff to other services, such as lifestyle weight management programs, social prescribing for debt management, or domestic violence helplines.
	Any type of signposting done by community pharmacy staff to other services or support.
	<ul> <li>Exclusions:</li> <li>Studies of the effectiveness of the services or support that the person is referred or signposted to.</li> <li>Interventions delivered by anyone who is not working for a community pharmacy</li> <li>Interventions delivered by distance-selling (online) pharmacies</li> </ul>
	See common elements section for further details.
Eligibility criteria - comparators	No intervention.  Any signposting or referral done by community pharmacy staff.
	See common elements section for further details.
Outcomes and prioritisation	Preference and experience of people using the service
Fliade lite and and	See common elements section for further details.
Eligibility criteria – study design	Interviews – unstructured and semi-structured (face to face, via telephone or SMS, or online).
	Focus groups.
	See common elements section for further details.
Other inclusion or exclusion criteria	Only studies undertaken in the UK, Australia, Canada and Republic of Ireland will be included.
	Only studies published in English will be included.
	See common elements section for further details.
Proposed sensitivity or subgroup analyses	Where evidence allows, the review will also answer the following sub question:
	How can signposting and referral be made more acceptable to users of community pharmacy services?
	Subgroup analysis by the health area (for example, physical activity, smoking cessation) may be undertaken, if appropriate.
Selection process  – duplicate screening	See common elements section for details.
Data management (software)	See common elements section for details.
Information sources –	See common elements section for details.

databases and dates	
Methods for assessing bias at outcome or study level	See common elements section for details.
Criteria for qualitative synthesis	For details please see section 6.4 of Developing NICE guidelines: the manual
Methods for qualitative analysis – combining studies and exploring inconsistency	Data from different studies will be summarised using narrative synthesis.
Meta-bias assessment- publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual.
Confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual
Review staff	Rachel Walsh (Technical Analyst)
	Ella Novakovic (Senior Technical Analyst)
	Daniel Tuvey (Information Specialist)

Review question 4c - Cost effectiveness of signposting or referral

Field	Content
Review question 4c	What is the most cost effective way for community pharmacies to refer or signpost people to other services or support?
Type of review question	Cost effectiveness
Objective of the review	This review aims to determine the most cost effective way for community pharmacy staff to refer or signpost people from community pharmacy to other services or support.
	The review will also explore whether cost effectiveness varies by the characteristics of the intervention, the person delivering the intervention, or the person receiving the intervention.
Eligibility criteria - population	Anyone who may use community pharmacy services  See common elements section for further details.
Eligibility criteria - interventions	Any type of referral made by community pharmacy staff from community pharmacy services to other services or support. This includes formal referrals made by community pharmacy staff to other services, such as lifestyle weight management programs, social prescribing for debt management, or domestic violence helplines.

Field	Content
	Any type of signposting done by community pharmacy staff to other services or support.
	<ul> <li>Exclusions:</li> <li>Studies of the effectiveness of the services or support that the person is referred or signposted to.</li> <li>Interventions delivered by anyone who is not working for a community pharmacy</li> <li>Interventions delivered by distance-selling (online) pharmacies</li> </ul>
	See common elements section for further details.
Eligibility criteria - comparators	No intervention.
Comparators	Any signposting or referral done by community pharmacy staff.
Outrous	See common elements section for further details.
Outcomes and prioritisation	Costs, savings and cost effectiveness  Cost per quality adjusted life year
prioritioation	Cost per quality dajusted life year     Cost per unit of effect
	Net benefit
	See common elements section for further details.
Eligibility criteria –	Systematic reviews of cost-effectiveness studies
study design	Economic evaluations
	Cost-utility studies
	Cost benefit studies     Cost offerthis page studies
	<ul><li>Cost-effectiveness studies</li><li>Cost minimisation studies</li></ul>
	Cost-consequence studies
	·
Other inclusion or	See common elements section for further details.
Other inclusion or exclusion criteria	Only papers published in English will be included. Only studies undertaken in the UK, Australia, Canada and Republic of Ireland will be included.
	See common elements section for further details.
Proposed sensitivity or subgroup analysis	Where evidence allows, the review will also answer the following sub questions:
	<ul> <li>I. What characteristics of the person delivering the intervention (for example their job role and competencies, or being a health champion) affect its cost effectiveness in community pharmacy?</li> <li>II. How does the way the intervention is delivered, for example, the medium used, when, how often, or where the intervention takes place (such as in a consultation room, over the counter, in someone's home, or electronic communication) affect its cost effectiveness in community pharmacy?</li> <li>III. What characteristics of the people receiving the intervention (for example, age or gender) affect its cost effectiveness in community pharmacy?</li> </ul>
	Subgroup analysis by the health area (for example, physical activity, smoking cessation) may be undertaken, if appropriate.

Field	Content					
Selection process  – duplicate screening	See common elements section for details.					
Data management (software)	See common elements section for details.					
Information sources – databases and dates	See common elements section for details.					
Methods for assessing bias at outcome or study level	See common elements section for details.					
Criteria for quantitative synthesis	For details please see section 6.4 of Developing NICE guidelines: the manual					
Methods for quantitative analysis – combining studies and exploring inconsistency	Data from different studies will be meta-analysed if the studies are similar enough in terms of interventions, comparators and outcomes.					
Meta-bias assessment- publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual.					
Confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual					
Review staff	Ella Novakovic (Senior Technical Analyst)					
	Daniel Tuvey (Information Specialist)					

#### Common elements across reviews 1 to 4

The following aspects are common across two or more of the review questions.

#### Eligibility criteria - population

Studies of people who have access to or are using community pharmacy services in any setting are included. This means that studies of people using community pharmacy services in commercial settings (such as high streets or supermarkets), healthcare settings (such as general practices), or community settings (such as care homes, places of worship) will be included. Studies of community pharmacy services provided in any area, including healthy new towns, will be included.

Studies of people using community pharmacy services in their own home, for example, if community pharmacy staff deliver medicines to their home, will be included.

Studies of people using distance selling pharmacies (also known as online pharmacies) will be excluded from this review.

#### Eligibility criteria - interventions

#### Inclusions

Studies of interventions delivered by community pharmacy staff will be included. This includes studies of interventions provided outside of a community pharmacy premises if the intervention is provided by community pharmacy staff. For example, a study of leaflets provided by community pharmacy staff in a place of worship would be included. Studies of interventions provided by staff who are not community pharmacy staff will be excluded, even if the intervention is delivered in community pharmacy premises. For example, a study of an intervention delivered by a GP that has rented a room in a community pharmacy but is working as an out of hour's service would be excluded. Studies that describe public health interventions provided by a 'clinical pharmacist' will be included if these studies were performed in a community pharmacy setting. Studies of interventions delivered by pharmacy students, within a community pharmacy setting, will be included.

Studies of health promotion campaigns from NHS England and Public Health England (such as Change4Life, One You, Eatwell Guide) will be included if they are delivered by community pharmacy staff. Studies of other initiatives, such as Men's Health Week, will be included if they are delivered by community pharmacy staff.

Studies of interventions that provide checks and testing to monitor the outcomes of interventions as part of behavioural support will be included in review 3.

Studies of any type of signposting and referral by community pharmacy staff to other services or support will be included in review 4. This includes:

- studies of signposting and referral to services or support offered by other NHS services, such as NHS stop smoking services
- studies of signposting and referral to services or support offered by non-NHS services, such as those provided by charity organisations
- studies of signposting and referral to other community pharmacies that offer services that are not available at the community pharmacy that the person presented to, such as chlamydia screening

Studies of signposting or referral to any service or support by community pharmacy staff will be included in review 4. This may include:

- disease management programs
- lifestyle weight management programs
- alcohol treatment services
- substance misuse services, including self-help groups
- sexual health services, including STI clinics and services that offer full range of contraceptive methods
- support services for smoking cessation, such as NHS Stop Smoking services
- social prescribing for debt management, domestic violence helplines, housing support, befriending.

#### **Exclusions**

The effectiveness of screening, checks and testing will not be assessed in this review. This includes the effectiveness of:

- blood glucose checks
- blood pressure checks
- · cardiovascular risk assessments
- cholesterol checks (including point of care tests)

- medicine use reviews
- mole checking services
- NHS Health Checks

NICE is unable to make recommendations on screening as these are provided by the National Screening Committee. Studies that look at the effectiveness of health promotion information and advice provided during screening (such as lifestyle advice), checks or testing will be included.

Studies of vaccinations will not be included in this review. Recommendations on vaccinations are provided by other NICE guidelines, such as Flu vaccination – increasing uptake (in development) and Immunisations: reducing differences in uptake in under 19s (PH21). Studies that look at the effectiveness of health promotion information and advice provided during a vaccination appointment, such as advice on sunlight exposure for people receiving vaccinations for travel abroad, will be included.

Studies of interventions provided by people who are not community pharmacy staff will be excluded. For example, studies of leaflets provided by district nurses would be excluded. Studies of interventions provided by pharmacy students, outside of the community pharmacy setting will be excluded. For example, an educational seminar led by pharmacy students directed at peers would be excluded.

Studies of interventions that are delivered in part by community pharmacy staff and in part by other healthcare professionals, such as GPs, will only be included if the study reports the results for community pharmacy staff separately. If results are not presented separately for community pharmacy staff then the study will not be included.

#### Health areas

Studies of interventions in any health area will be included. This includes the following health areas:

- alcohol use, including:
  - o alcohol misuse
  - o recommended levels of alcohol consumption
- cancer awareness (all cancers), including:
  - risks and benefits of behaviours including:
    - sunlight exposure
    - use of sun care products
    - approaches to protecting skin (clothing, shade and sunscreen)
  - o early signs and symptoms of any cancer, such as blood in urine or stools
- · cardiovascular disease prevention, including:
  - lifestyle factors
- diabetes prevention, including:
  - o lifestyle factors
  - healthy eating
  - physical activity
- substance misuse prevention, including:
  - o needle and syringe exchange programmes, including disposal and injecting equipment
  - o harm reduction services, including advice on safer injecting practices

- provision of, or access to services for, blood-borne virus testing, and treatment, including hepatitis B, hepatitis C and HIV
- falls prevention including:
  - correctly fitted footwear
  - using handrails
  - hydration and diet
  - o physical activity
- · mental health and wellbeing, including
  - o getting a good night's sleep
  - o physical activity in green spaces, such as how and where to do this locally
- orthopaedic conditions (such as osteoporosis, osteoarthritis and lower back pain), including:
  - physical activity
  - o diet
- sexual health, including:
  - o emergency contraception
  - o safer sex practice, including use of condoms
  - o methods of contraception
  - preventing unwanted pregnancies
  - pregnancy testing
  - sexually transmitted infections, including testing
  - o information on HIV testing
- smoking and smokeless tobacco, including:
  - o stopping use
  - o harm reduction
  - o nicotine-containing products
  - the importance of smoke free homes
- weight management, including:
  - o maintaining a healthy weight
    - why maintaining a healthy weight is beneficial
    - how to maintain a healthy weight
    - checking weight
  - o nutrition:
    - healthy eating
    - vitamin D
    - sugar
    - salt
    - saturated fat
    - folic acid
    - child and maternal health
  - o physical activity
    - benefits of physical activity
    - appropriate local opportunities to be more active
    - recommended levels of physical activity

- weight reduction programmes
  - over the counter weight management products
  - healthy eating
  - physical activity

#### Eligibility criteria - comparators

Studies with comparators provided outside of a community pharmacy premises are to be included only if the comparator is provided by community pharmacy staff. For example, a study that uses leaflets provided by community pharmacy staff in a place of worship as a comparator would be included.

Studies with comparators that are delivered in part by community pharmacy staff and in part by other healthcare professionals, such as GPs, will only be included if the study reports the results for interventions delivered by community pharmacy staff separately. If results are not presented separately for interventions delivered by community pharmacy staff then the study will not be included.

Studies that compare the effectiveness of different types of community pharmacy staff to deliver an intervention will be included. For example, studies that compare leaflets provided by community pharmacy staff who are health champions to leaflets provided by community pharmacy staff who are not health champions.

Studies that compare the way the intervention is delivered will be included. For example, studies that compare face to face with electronic communication, or studies that compare one-off interventions to interventions delivered at every contact with staff, will be included.

Studies that compare the effectiveness of interventions in different groups of people using community pharmacy services will be included. For example, studies comparing the effectiveness of self-help booklets in men and women would be included.

#### Outcomes and prioritisation

Health outcomes may include clinical measurements, such as physiological and biochemical measures related to risk factors, such as blood pressure, body mass index, or blood glucose levels. It may also include mortality.

Examples of actions include behavioural outcomes such as smoking cessation or changes to levels of physical activity. It can include uptake, continuation and completion of services. 'Action' also includes intermediary steps to enacting a healthier behaviour, such as picking up a leaflet.

Studies may report patient activation, which refers to the knowledge, skills and confidence a person has in managing their own healthcare. Patient activation will be included as an outcome in the existing outcomes listed in the review protocols above.

Outcomes with longer timescales will be prioritised over shorter outcomes, e.g. body mass index at 12 months will be prioritised over body mass index at 3 months.

See table i. for the prioritisation and minimal important differences for each outcome in review questions 1a, 2a, 3a and 4a. These will be used to inform the GRADE profiles.

Table i. Prioritisation and minimal important difference for each outcome

Outcome	Priority	Minimal important difference		
Review question 1a (information	and awareness raising)			
Action	Critical	25% point change in relative risk		
Intention	Important	25% point change in relative risk		

Attitudes	Important	25% point change in relative risk
Knowledge	Important	25% point change in relative risk
Awareness	Important	25% point change in relative risk
Review questions 2a (advice or	education) and 3a (behaviour	al support)
Clinical measurements or health	Critical	25% point change in relative risk
outcomes		
Action	Critical	25% point change in relative risk
Intention	Important	25% point change in relative risk
Attitudes	Important	25% point change in relative risk
Knowledge	Important	25% point change in relative risk
Awareness	Important	25% point change in relative risk
Wellbeing	Less important	25% point change in relative risk
Quality of life	Less important	25% point change in relative risk
Review question 4a (signposting	and referral)	-
Uptake of interventions or	Critical	25% point change in relative risk
services to promote, maintain		
and improve health and		
wellbeing		

#### Eligibility criteria - study design

Systematic reviews will only be included if the review question in the paper matches the review question in the evidence review for the guideline. Systematic reviews that do not answer a review question of interest may be used for citation searching if primary searches do not yield a substantial amount of evidence. Systematic reviews must have clear inclusion/exclusion criteria and report critical appraisal of included studies to be included.

For review questions 1a, 2a, 3a and 4a (effectiveness) primary studies will only be included if they are comparative. This includes:

- Studies that compare a group that receives an intervention to another group that does not receive an intervention,
- Studies that compare a group that receives an intervention to another group that receives a different intervention,
- Studies that compare the same group before and after an intervention.

Studies that compare the same intervention in different groups will be included to answer the sub question on whether the characteristics of the people receiving an intervention (for example, age or gender) affect its effectiveness.

Qualitative studies that relate to interventions of interest will be included for data on quality of life and preference and experience of people using the services. Only qualitative studies from the UK, Australia, Canada and the Republic of Ireland., will be included.

In the event of more evidence being identified than is feasible to consider in the time available, priority will be given to using RCTs and nRCTs to identify data for comparative outcomes.

The following types of papers will not be included:

- Non-systematic literature reviews
- Case-control studies
- Cross-sectional studies
- Quantitative surveys
- · Study protocols
- · Opinion pieces

- Commentaries
- Editorials
- Letters

#### Other inclusion or exclusion criteria

The committee agreed that Australia, Canada and the Republic of Ireland, have community pharmacy services that are similar enough to the UK that studies from these countries can be used to make recommendations for UK practice. On March 15, 2017 the committee requested that in addition to the initially agreed 4 countries the effectiveness review be expanded to include studies from the European Union (including Norway and Switzerland), New Zealand and Chile. This change was approved by NICE QA on March 28, 2017. The committee felt that the community pharmacy services in other countries are too dissimilar to the UK to allow evidence from those countries to be used to make recommendations for UK practice.

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#### Selection process - duplicate screening

10% of the search results will be blind-screened by a second reviewer. Any disagreements will be resolved by the two reviewers, and escalated to a third reviewer if agreement cannot be reached. If the initial level of agreement is below 90%, a second round of blind-screening will be considered.

All data extraction and critical appraisal will be checked by a second reviewer. Any disagreements will be resolved by the two reviewers, and escalated to a third reviewer if agreement cannot be reached.

In the event of more evidence being identified than is feasible to consider in the time available, priority will be given to:

- evidence with critical or highly important outcomes
- number of participants (n>100) or number of sites in the study.

These criteria were agreed by the committee at the Public Health Advisory Committee (PHAC) 0, however, further discussion of the criteria with PHAC will take place if necessary.

A date cut off of the year 1990 will be used. This is because this is when the National Health Service and Community Care Act 1990 was put in place and health authorities were given responsibility for managing their own budgets. Using 1990 is also consistent with the date that is used in the review question on pharmacists in the Acute Medical Emergencies in adults and young people services guidance that is currently in development by NICE.

#### Data management (software)

EPPI Reviewer will be used:

- to store lists of citations
- to sift studies based on title and abstract
- · to record decisions about full text papers
- to store extracted data.

If meta-analysis is undertaken, Cochrane Review Manager 5 will be used to perform the analysis.

Qualitative data will be analysed using EPPI Reviewer. Qualitative data will be summarised using GRADE-CERQUAL (if appropriate) or narrative synthesis.

#### Information sources - databases and dates

The following sources will be searched:

- Medline
- Embase
- Cochrane Library
- PsycINFO
- Cinahl
- ASSIA
- EconLit
- EconPapers
- PharmLine
- Health Services Research in Pharmacy Practice

The following grey literature sources will also be searched:

- · Social policy and practice
- NIHR journals library
- Academic centres (Pharmacy Schools): Aston, Bath, Birmingham, Bradford, Brighton, Central Lancashire, Sunderland, Durham, De Montfort, East Anglia, Greenwich, Hertfordshire, Huddersfield, Keele, Kingston, Lincoln, Liverpool John Moores, University College London, King's College London, Portsmouth, Reading, Sussex, Manchester, Nottingham, Wolverhampton, Robert Gordon, Strathclyde, Cardiff, Queen's University Belfast, Ulster (Coleraine).
- Healthwatch England
- Community Pharmacy Futures
- Pharmaceutical Services Negotiating Committee
- Centre for Pharmacy Postgraduate Education
- Royal Pharmaceutical Society
- Community Pharmacy Northern Ireland
- Community Pharmacy Scotland
- Community Pharmacy Wales
- Public Health England
- Department of Health
- Welsh Assembly
- Scottish Government
- NHS England

The following limits will be applied to the search:

- Date limit of 1990 to 2016
- English language

A study filter will not be applied.

Citation searching of included studies will be undertaken.

Results will be saved to an EndNote database and de-duplicated. Results will be provided to the Public Health team as RIS files, suitable for import into EPPI Reviewer

A record will be kept of number of records found from each database and of the strategy used in each database. A record will be kept of total number of duplicates found and of total results provided to the Public Health team.

#### Methods for assessing bias at outcome or study level

Standard study checklists will be used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual

Where appropriate, the risk of bias across all available evidence will be evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/.

#### Appendix B - Literature search strategies

See separate appendix B document.

## Appendix C – Effectiveness and acceptability included evidence

- Evans SW, John DN, Bloor MJ, Luscombe DK. Use of non-prescription advice offered to the public by community pharmacists. International Journal of Pharmacy Practice. 1997 Mar 1;5(1):16-25.
- 2. Michie L, Cameron S, Glasier A et al. (2014) Pharmacy based interventions for initiating effective contraception following the use of emergency contraception: a pilot study. Contraception, vol 90 (4), p447-453.
- 3. Michie J, Cameron ST, Glasier A et al (2016) Provision of contraception after emergency contraception from the pharmacy: evaluating the acceptability of pharmacy for providing sexual and reproductive health services, 135: 97-103
- 4. Perraudin C, Fleury B, Pelletier-Fleury N. (2015) Effectiveness of intervention led by a community pharmacists for improving recognition of sleep apnea in primary care- a cohort study, 24: 167-173
- 5. Sriram Deepa, McManus Alexandra, Emmerton Lynne M, Parsons Richard W, and Jiwa Moyez (2016) A model for assessment and referral of clients with bowel symptoms in community pharmacies. Current medical research and opinion 32(4), 661-7.

### Appendix Di – Effectiveness evidence tables

Study details	Population	Intervention and	Methods and analysis	Results			
		comparator					
Reference	Health area	Direct suggestion of	Recruitment:	Primary outco	omes:		
Evans SW, John	Any	GP appointment:	A random selection of 6	Uptake of app	<u>ointment</u>		
DN, Bloor MJ,		Where a client is	independent community				
Luscombe DK.	Number of participants	advised to seek	pharmacies in south-east Wales			ents made by th	
Use of non-	N=98 participants	advice from	were sent an invitation to			appointment m	
prescription		elsewhere regardless	participate			between the tim	
advice offered to	215 fulfilled entry criteria; 34	of the outcome of the				d by the pharma	acist and the
the public by	subsequently excluded as	presenting symptoms	Individuals were approached as	time of intervie	ew (4-8 days la	ter).	
community	ineligible; 98 were successfully		they were leaving the pharmacy if	_	T	•	
pharmacists.	interviewed	Conditional	they fulfilled the inclusion criteria		Number of	Number of	Uptake %
International		suggestion of GP	and asked to participate.		people	appointmen	
Journal of	4 pharmacies	appointment:				ts attended	
Pharmacy		Where a client is	Methods:	Direct	10	7	70.0
Practice. 1997	Participant characteristics	advised to seek	Telephone interviews were	suggestion			
Mar 1;5(1):16-25.	Age	advice only if another	undertaken with clients 4-8 days	Conditional	30	4	13.3
	18-40 40	criterion is met, for	after their pharmacy visit using a	suggestion			
Quality score	41-60 32	example, if the	structure instrument which mainly				
-	61+ 24	presenting symptom	consisted of closed questions.				
04 1 4	Gender	worsens or does not	O(**				
Study type	Female 79	improve	Questions were asked to				
Observational -	Male 19		determine client adherence with				
cohort study	_		any advice on making an				
l a sation and	Participants presented with a		appointment with a GPI.				
Location and	wide range of conditions,		All recentled when receipt alient				
setting	including: eye, skin, respiratory,		All recorded pharmacist-client interactions which fulfilled the				
High street and	pain, gastrointestinal tract, oral						
village	and other miscellaneous		entry criteria were timed and				
pharmacies situated in south-	conditions		transcribed verbatim, as were the researcher-client interviews.				
east Wales			researcher-chefft lifterviews.				
east wates	Inclusion criteria		Analysis:				
Aims	Individuals who had requested		4 statistical tests were used,				
To establish	advice or presented at the		namely the Kruskal-Wallis test,				
whether members	pharmacy describing symptoms		the Mann-Whitney U test, the				
of the public			Chi-squared test and Pearson's				
utilise the specific	An individual who was advised		product moment correlation.				
aunac ine apecinic	by a pharmacist regarding a		product moment correlation.				

advice offered by	minor ailment and/or an over	Values for these tests were
community	the counter medicine	considered statistically significant
pharmacists and		if the probability was = 0.005</td
adhere with	An individual who was offered	l l l l l l l l l l l l l l l l l l l
advice offered on	advice intended for their own	l l
referrals	use or for someone under their	l l
	care	l l
Length of follow		l l
up	Exclusion criteria	l l
4-8 days	Professional carers, seeking	l l
	advice for an individual they	l l
Source of	care for.	l l
funding		l l
Welsh Pharmacy	Those who reported not having	l l
Practice Research	a telephone	l l
Enterprise		
Scheme	Those not available for	
Limitationa identifi	interview	

#### Limitations identified by authors

As recordings of the pharmacist-client interaction were made with the pharmacist knowledge, the possibility of the Hawthorne effect cannot be discounted 16 of those invited to participate in the study were found not to have a telephone and so a possible sample bias could have been introduced

#### Limitations identified by review team

It is unknown whether the participants who were given conditional appointment later fulfilled the conditions set by pharmacists to warrant a GP visit. This is an observational study and thus the intervention could not be properly controlled or regulated across sites. The follow up time is short and inconsistent (4-8 days), and no data is collected on intent to seek appointment. It is possible that individuals who received 'conditional appointment' were more likely to have a longer delay between suggestion of appointment and uptake. Participant selection was not randomised. Baseline characteristics of the groups were not compared. Outcomes were self-reported. 54% of participants were successfully followed up but it is not clear how many eligible community pharmacy users were recruited into the study. The consistency of the intervention across different sites or different days was not measured.

#### Other comments

Medicine related outcomes are also reported in this study, but have been excluded from this review

Study details	udy details Population		Intervention	Methods and analysis	Results						
					and comparator						
Reference	Health area				Intervention	Cluster randomisation by		POP group	Rapid	Access	Standard
Michie L,	Sexual healt	th			(n=58)	pharmacy. Restricted			group		care
Cameron S,					'Rapid access'.	randomisation used to ensure	Allocated	56	58		54
Glasier A et al.	Number of participants				Participants were	balance between study arms	Lost to	17	30		19
(2014)	n=168 pharmacy users				told to take their	in respect to emergency	follow up				
Pharmacy	11 pharmacists from 11 pharmacies			acies	empty packet of	contraception dispensing	Analysed	39	28		35
based					emergency	figures and the deprivation	In POP group 35/39 (90%) reported using pills provided. To				rided. Two
interventions for	Participant characteristics				contraception to	category.	women didn't use pills because they were not currently				
initiating	Mean age of all participants= 23 years			3 years	the local			e, one did not get			
effective	(SD 5.2)				specialist family	4 pharmacies were		d about side effec			
contraception					planning centre	randomised to intervention		pill reported compl			
following the	Mean age of participants completing the			leting the	to discuss	and 3 to standard care. Four	between 7 and 14 pills; 3 delayed starting and had not fin				
use of	telephone interview:				contraception, as	months into the study, a	the pack at time of interview.				
emergency	POP group:	22 years	(SD 5.2),	range 18	soon as	pharmacist in the standard	'				
contraception: a	to 44				possible. Women	care arm retired, so the	In rapid access intervention group, 9/28 (32%)			32%) won	vomen
pilot study.					were seen on the	pharmacy was replaced with	attended the family planning clinic – 3 on the day they obtain				
Contraception,	Rapid access group: 25 years (SD 5.6),			(SD 5.6),	day they	another pharmacy.		ontraception and th			
vol 90 (4),	range 18 to 40				presented			lost common reas			
p447-453					without having to	Recruitment:					
	Standard care=23 years (SD 4.5), range			.5), range	book an	April 2012 to December 2012	access contraception was 'pressure of time' (n=10, 53%). Additional reasons included 'prefer to see GP' (n=1), 'still				
Quality score	18 to 36	18 to 36		appointment,			ontraceptive option				
+				and were offered	Analysis:	too far away' (n=1), 'forgot' (n=1), 'not sexually activ					
	Contraception at time of recruitment:		all methods of	Some women using hormonal	and 2 women stated that 'the option was not clearly explain						
Study type		POP	Rapid	Control	contraception to	contraception were	to them'.				,
Randomised		group	access		start	accidentally recruited and so	10 11101111				
controlled trial			group		immediately.	were excluded from the	8 (23%) wome	en in the standard	care arm	said they	received
	None	13	8	12	Pharmacists	analysis (n=3 in intervention		om the pharmacist			
Location and		(33%)	(28%)	(34%)	provided written	and 4 in standard care arm).		on available or wh			
setting	Condoms	26	17	19	information	,		. 8 (23%) said they			
Community		(67%)	(61%)	(54%)	about the	Power calculation was not		n methods availabl			
pharmacies in	Other	0	3	4	location and	performed. Aimed to recruit		ny information ab			
Edinburgh, UK			(11%)	(12%)	opening hours of	180 women from 10 to 12	contraception		out whole	andy oou	ia got
	Statistical sign	nificano			the family	pharmacies.	Contraception	•			
Aims	Statistical significance and p values for differences between groups at baseline				planning clinic.		Method of contraception use at 6 to 8 weeks:				
To determine	not reported.			Proportions in each cluster	11.561154 51 661	in acception acc at	POP	Rapid	Standard		
the feasibility of	1.5t reported	•			Progesterone	using effective contraception			group	Access	Care
a larger study,	Inclusion c	riteria			Only Pill (POP)	compared using two-sample t			group	group	Carc
investigating	Pharmacy us				group (n=56)	tests.			1	group	
whether either	,	aged 16	or over								
	- WOITIEII	ayeu 10	OI OVEI		<u> </u>	l .	L				

intervention resulted in an increased proportion of women selfreporting use of effective ongoing contraception at 6 to 8 weeks after emergency contraception use, compared to standard care.

#### Length of follow up 6 to 8 weeks

# Source of funding See 'other comments' below.

- Presenting for emergency contraception who had been using either no contraception or barrier method
- Women eligible for emergency contraception according to patient group directive criteria with no medical contraindications (e.g. unexplained vaginal bleeding, pregnancy, severe hepatic dysfunction, severe malabsorption syndrome, previous unprotected sexual intercourse in the same menstrual cycle or unprotected sex over 72 hours earlier)
- UK resident
- Not requiring language interpreting services

Pharmacists who had previous experience in research or dispensed 10 or more courses of emergency contraception a month.

#### **Exclusion criteria**

Pharmacy users: Already using hormonal contraception.

Packet of 35 POP provided by pharmacist using locally approved patient group directive (PGD) at no cost to women as a bridging method of contraception giving them 1 month to attend their usual healthcare provider for ongoing contraception. PGD allows pharmacist to dispense certain approved medications without a prescription. Comparator (n=54)'Standard care'. **Pharmacists** 

(n=54)
'Standard care'.
Pharmacists
dispensed
emergency
contraception
and could
provide usual
verbal and/or
written
information on
contraception. All
pharmacies have
leaflets detailing
location and
services of local

78% of recruited participants were contactable by phone 6 to 8 weeks later and 102 (61% of all participants) completed the interview. There was no significant difference in age between women contacted and those not contacted (no other data were available for those not contacted). Lost to follow up: decline interview (n=11 in intervention group, n=10 in standard care), no answer to phone all (n=5 in intervention group, n=4 in standard care), no/wrong phone number (n=11 intervention group, n=5 in standard care), no consent form (n=1 in intervention) or not in country (n=1 in intervention).

Participants using the same form of contraception at follow up at baseline were excluded from the analysis – 3 people in intervention and 4 people in standard care.

'Effective' contraception	All effective methods	22 (56%)	13 (52%) **	5 (16%)
	Long-acting reversible contraception	3 (8%) **	5 (20%) **	0
No/barrier meth	17 (44%)	12 (48%)	26 (84%)	

<sup>\*\*</sup> p<0.01 vs. standard care

Relative risk of using effective contraception at 6 to 8 weeks RR= 2.57 (95% CI 1.55 to 4.27), p=0.006 Rapid referral group RR= 3.13 (95% CI 1.90 to 5.13),

Relative risk of using long-acting reversible contraception 6 to 8 weeks after emergency contraception was 20% in intervention compared to 0% in standard care group (p=0.004).

If assume baseline observation carried forward, there would still be a significant increase in the use of an effective method in intervention vs. standard care (22% vs. 9%, p=0.043).

	family planning	
	clinics.	

#### Limitations identified by authors

Loss to follow up was high, including lack of willingness to be interviewed at follow up. Contraception use at 6 to 8 weeks was self-reported. Lacking robust data on women who were not recruited to the study – cannot rule out selective recruitment. Intended sample size was not recruited and telephone interviews only completed in 60% of participants.

#### Limitations identified by review team

It is unclear how the allocation sequence was generated. It is unclear if the allocation was concealed. The baseline outcome measurements and characteristics appear to be similar between groups, however, statistical significance and p values are not reported. It is unclear whether outcomes were assessed blindly.

#### Other comments

This study also included 'intervention 1' which was a 30 day supply of hormonal contraception, however, this is not a relevant intervention for this review question and so is not presented here. This was a pilot study. Pharmacists were compensated £10 per participant recruited. The Edinburgh and Lothians Health Foundation provided funding for this study. In addition, a research grant was provided by HRA Pharma which enabled LM to be funded as a clinical research fellow at The University of Edinburgh. Both STC and AG currently and in the past have received research support from and undertaken consultancies for pharmaceutical companies working to develop emergency contraception.

Study details	Population		Intervention and	Methods and analysis	Results				
				comparator					
Reference			Intervention	Recruitment:		Primary outcomes:			
Perraudin	Obstructive Sleep Apnea Syndrome			Patients provided with	Pharmacists recruited on	<u>Underwent diagnostic test for OSAS (N=782)</u>			
2015	(OSAS)			OSAS detailed brochure	voluntary basis. Each		Intervention	Control	Statistical
Quality score				with comments from	pharmacist asked to include		Group	Group	test
+	Number of pa	articipants		community pharmacists	at least 4 patients each.		(N=88)	(N=694)	
Study type				to inform about	INTERVENTION GROUP	N (%)	20	79 (11.4%)	X <sup>2</sup> test
Cohort	88 pharmacy	clients (seen by	y 31	consequences if OSAS	-Made aware of OSAS		(22.7%)	,	P=0.003
	pharmacists)			left untreated. At end of	screening campaign through				
Location and	Participant cha	aracteristics		encounter, given the	posters displayed on window.	Adjusted OR	=2.24 (95%CI 1	.25-4.01) for 1	those in the
setting		Intervention	Control	estimated pretest risk of	During visits by regular		group to underg		
France,		group	Group	OSAS, pharmacists	overweight patients coming		se in the contro		
Community		(N=88)	(n=694)	advised participants to	to renew their anti-			• .	
pharmacies	Women	28 (32%)	278	consult their GP. A letter	hypertensive prescription the	Secondary of	outcomes:		
			(40%)	to the doctor, signed by	pharmacist would ask if they	none			
Aims	Age	62.2 (12.6)	62.7	the pharmacist given to	snored. Eligible patients				
To assess the	(Mean, sd)		(11.7)	patients, explaining that	included consecutively.				
feasibility and	BMI	30.3 (4.6)	30.6	the patient was involved	Anthropometric data, SES				
effectiveness	(Mean, sd)	, ,	(4.6)	in a research study. All	and medication history data				
of community	Education			data collected were	collected.				
pharmacist led	Primary	28.4%	45.1%**	attached to letter and	CONTROL GROUP				
intervention	Secondary	55.7%	41.1%	stressed need for GP-	-Patients selected from the				
for improving	& higher			pharmacists	Health Social Protection				
recognition of	ed			collaboration and urged	Survey (ESPS) which is a				
Obstructive	>High ed	15.9%	13.8%	GP to continue	panel survey conducted by				
Sleep Apnea	Retired	61.4%	57.8%	investigations for these	the French Institute for				
Syndrome	Epworth			patients at risk of OSAS.	Research and Information in				
(OSAS) in	score			Dationto monitored for 0	health Economics every two				
primary care and increase	<10	63.6%	44.7%	Patients monitored for 6 months. Pharmacists	year. Aim of ESPS is to provide a detailed picture of				
the use of	>=10	25.0%	21.9%	were to call participants	state of health, health-care				
diagnostic	**- p<0.05		<u> </u>	at 1,3 & 6 months.	utilization and level of health				
tests.	-			Comparator	insurance. In 2008 questions				
icolo.	Flow of participants in INTERVENTION		No intervention. To test	concerning sleep disorders					
Length of	GROUP (n=88)		whether these	were included for people					
follow up	In intervention group 70/88 (79.5%)			individuals underwent	aged 16 years or older. All				
6 months	consulted their GP		diagnostic testing they	respondents who met the					
	-61/70 (87%) gave letter to GP (9 did			were asked "Have you	inclusion/ exclusion were				
Source of	not give letter	to GP)		ever had a sleep	included in the control group.				
funding				recording performed at					
iananig	l			1 . c c c a m g por lor mod dt		1			

None reperted	40/70 (E70/) ware referred to along	the beenitel or of	Analysis	
None reported	-40/70 (57%) were referred to sleep	the hospital or at	Analysis:	
	specialist (21 not referred to sleep	home?"	t-test and chi-square tests to	
	specialist)		compare continuous and	
	-20/40 (50%) performed diagnostic test		categorical variables. Logistic	
	-17/20 (85%) had a positive diagnosis		regression adjusted to	
	(3 had a negative diagnosis)		gender, age, BMI, education,	
			Employment status and	
	Inclusion criteria		Epworth score to analyse the	
	Pharmacists: No a priori criteria		independent effect of	
	Pharmacy clients:		intervention on the primary	
	-Taking one or more antihypertensive		outcome of interest.	
	drugs, being overweight (BMI >=25)			
	and snoring almost every night. Pretest			
	probability of having OSAS estimated			
	at 82% in this population			
	Exclusion criteria			
	-Patients under OSAS treatment, not			
	having a referent GP, having a long-			
	term illness and not having the capacity			
	to sign an informed consent			
1 !!4 - 4! ! -! -	natifical last assets and	· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·	·

#### Limitations identified by authors

Pharmacists reported difficulties in recruiting patients due to lack of time and having to recruit patients directly at the counter with two-thirds indicating there were no private consultation areas. Way in which patients were recruited to intervention group could lead to selection bias as researchers were not sure recruitment was always consecutive as instructed. No information available on the individuals who declined to participate in the intervention arm. Follow-up period lasted for only six months which could have lead to an underestimation of the proportion of diagnostic test. 20 patients referred by their GP to sleep specialist but did not undergo testing. Perhaps if research period was longer they may have had the chance to go for testing.

### Limitations identified by review team

Possible that individuals selected for the intervention may have also been respondents to the national survey from which the control population was drawn.

Study details	Population		Intervention and	Methods and analysis	Results
			comparator		
Reference	Health area		Intervention	Recruitment:	Primary outcomes:
Sriram Deepa,	Cancer awareness		Jodi Lee Test (JLT)	A convenience sample of 21	Uptake of referral:
McManus			guide was used in	pharmacies was recruited	Attendance rate for general practitioner consultation
Alexandra,	Number of participants		decision-making		was higher during the intervention phase:
Emmerton Lynne	Usual	Intervention	during the	Pharmacy staff recruited clients	
M, Parsons	practice		pharmacist's	seeking advice for bowel	Usual practice Intervention
Richard W, and			consultation with	symptoms or seeking medicines	

Jiwa Moyez (2016) A model for assessment and referral of clients with bowel symptoms in community pharmacies. Current medical research and opinion 32(4), 661-7

### **Quality score**

-

Study type Uncontrolled before and after

# Location and setting

Perth metropolitan area and regional towns covering a range of socioeconomic areas.

#### **Aims**

To examine the feasibility and effectiveness of the use of the Jodi Lee Test (JLT) as a guide to pharmacy staff to identify clients with bowel symptoms warranting general

Pharmacy	21	19
no.		
Recruited	84	80
Referred	17	30 (38%)
	(20%)	
No.	14	27
referred		
followed		
up		

### Participant characteristics

Pharmacist characteristics:
122 pharmacy assistants
62 pharmacists
7 pre-registered pharmacists

	Usual practice	Intervention
Male	24 (29%)	26 (33%)
Female	60 (71%)	54 (68%)

#### Inclusion criteria

18+ years

Able to give written informed consent, including contact by the researcher for follow-up

## **Exclusion criteria**

None specified

clients. The JLT is a paper-based questionnaire comprising 8 questions, which was self-completed by clients in a private or semiprivate area in the pharmacy, if available, with assistance of the staff member, if required. On reviewing the completed JLT, the attending pharmacy assistant decided whether or not to refer the client to the pharmacist: likewise, the pharmacist applied his/her clinical judgement regarding referral to the client's general practitioner. If referred, the pharmacist completed details on a standard referral letter. issued to the client with the completed JLT.

Comparator
Usual practice:

normally used to treat diarrhoea, constipation or haemorrhoids during both usual care and intervention phases of the study, over a 12 week period during usual care and 20 weeks for intervention phases.

#### Methods:

Follow up of the recruited clients during usual practice took place 4 weeks following their pharmacy visit. Clients were contacted by telephone to determine if their referrals were acted upon. Participants not contactable for follow-up after 3 attempts were deemed lost to follow-up.

For the intervention group, recruitment started 4 weeks after the completion of the usual practice phase. Clients who were referred for consultation with a general practitioner were contacted by the researcher 4 weeks after their pharmacy visit to determine if they had visited the GP.

Intervention pharmacies were those that completed the usual practice phase.

### Analysis:

The effectiveness of the JLT intervention was determined by comparison of general practitioner attendance rates for clients referred to the general

Number referred	14	27
Uptake number	1	12
Uptake rate	6%*	40%*

\*Reported as 7% and 44% in the study paper, but calculated as 6% and 40% by NICE technical team.

RR 6.22 (95% CI 0.90 to 43.09) for uptake for usual practice vs. intervention [calculated by NICE technical team]

practitioner	Referrals for further	practitioner following use of the						
assessment.	investigation if	JLT compared to usual practice.						
	required. The	Differences in referral rates and						
Length of follow	participants were	the general practitioner						
up	advised of the	consultations were assessed						
4 weeks	need for a medical	using the Chi-square and						
	consultation and	Fisher's exact test. A p-value						
Source of	given a referral	<0.005 was interpreted as						
funding	letter to take to the	indicating a statistically						
Supported by a	general	significant association.						
Jodi Lee	practitioner.							
Foundation PhD								
scholarship								
Limitations identified by authors								
The study protocol was not consistently applied in some pharmacies.								
Adherence to the study protocol by individual staff was not able to be controlled.								
Limitations identified by review team	Limitations identified by review team							

Low participant numbers
Other comments

None

# Appendix Dii – Acceptability evidence tables

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
Author name and year  Michie, 2016  Quality score  +  Study type  Qualitative  Aim of the study  Pilot study to identify barriers and facilitators of providing pharmacy based interventions to increase uptake of effective contraception after emergency contraception (EC).  Location and setting  Edinburgh, UK, Community pharmacies	Intervention  Cluster RCT where pharmacies provided: A) One month supply of packet of progesterone only pills (POP) with option to arrange ongoing contraception B) Invite to present empty EC pack to family planning clinic for contraceptive advice (rapid access) C) Standard care  Sample frame  49 women asked to participate, 26 (53%) agreed, purposive sample of 12 interviewed.  Data collection  Face to face semi-structured interviews lasting about 1 hour and conducted between Aug-Nov 2012. Used topic guide to facilitate the generation of data that could be and allow women to raise issues that were important to them and inform future development of research and	emergency contraception according to patient group directive criteria with no medical contraindications (e.g. unexplained vaginal bleeding, pregnancy, severe hepatic dysfunction, severe malabsorption syndrome, previous unprotected sexual intercourse in the same menstrual cycle or unprotected sex over 72 hours earlier)  UK resident	Health Area Sexual Heath  12 women - Mean age 26 (SD 5.5) - Depcat score	Experience/ Acceptability  Women cited difficulties with accessing GP appointments for EC and thinking that it would not be seen as a priority for your GP to discuss   "I don't want to trouble my GP for minor health concerns so I prefer to self-medicate or go to the pharmacy across from where I live where they operate a drop-in system to suits me better"- standard care group"  Provision of month supply of POP  Mixed views articulated. Some women thought one month supply was sufficient to make a follow-up appointment to access further supply or discuss other methods some women felt one month supply was a "waste of time" or put women off using hormonal methods  "I think it will be useful for other women but for myself and others it will take a while for the pill to settle, so a month supply may not be worth it as it may not give a good indication of side effects "- (standard care grp)  Some felt being offered POP at pharmacy was a good alternative to accessing it only at the GP or the Family Planning Clinic  "It is good to do this because some people can be hesitant going on it and asking about it from their GP. So if they are offered they can try it. It's easier to ask the GP for more rather than to start on it. A month supply should be enough to make an appointment with their GP"- (POP group)

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
Source of funding  Edinburgh & Lothians Health Foundation,  HRA Pharma funded lead author for clinical fellowship	clinical implementation of interventions. Interviews audiorecorded and transcribed verbatim. Research log used by research team to record operational issues.  Method of analysis  Cross-sectional indexing and thematic analysis.	Exclusion - Women already on hormonal contraception		Some had reservations about starting a new hormonal method at the time of presenting for EC. Some women questioned if it was the role of the pharmacist to undertake contraception consultations  "I think for women like me who have never tried hormones before it is not a good idea. I want to speak to someone about different options and health implications of hormones before I take them. My GP was surprised when I mentioned that I was given the pills at the pharmacy, it was not a good method for me" – (POP group)  All 4 women in POP arm said they were provided with info by pharmacists and given opportunity to ask questions about POP but 3 felt they went away having questions about POP which they did not feel able to ask at the time.  PROVISION OF RAPID ACCESS (RA) APPOINTMENT  All women liked the idea of being provided with an RA appointment as it enabled quicker access to consultations and potentially more specialist support that can help match women to suitable and effective methods of contraception  "Getting EC can kick start your brain to think about wanting to get on the pill or somethingan appointment to see someone quickly to discuss more will be really helpful" (standard care group)  "having an appointment to see someone quickly to discuss more will be really helpful" (Standard care group)  Time between presenting for EC and having appointment would allow time to reflect on her experience and seek appropriated clinical and emotional support

Study details Research Parameters Inclusion/ Exclusion criteria Population Results	
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#### Notes

## Limitations identified by author

Difficult to conduct high quality research in this setting. Was difficult to retain pharmacists during the study and slow recruitment of women into the study. This is a small study with a small sample of women from a single urban site so results may not be applicable to rural pharmacies.

Limitations identified by review team

# **Appendix E – Forest plots**

No forest plots were created for this review.

## Appendix F - GRADE tables

## **GRADE** profile 1: Uptake of services

	Quality assessment								Quality of	
No. of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No. of participants	Effect	evidence for outcome	Importance of outcome
Uptake of	GP appointment									
Suggestic	n of GP appointm	nent for any heal	Ith condition base	ed on presentin	ig symptoms vs. s	suggestion based	on symptoms	not improving or worsening		
1 <sup>1</sup>	Observational cohort study	Very serious <sup>a</sup>	Not applicable	Serious <sup>b</sup>	Serious <sup>c</sup>	No	40	RR 5.25 (95% CI 1.93 to 14.25) favouring presenting symptoms	Very low	Critical
Standard referral letter based on results of Jodi Lee test for bowel cancer symptoms vs. standard referral letter based on pharmacist opinion of bowel cancer symptoms										
1 <sup>2</sup>	Before and after study	Very serious <sup>d</sup>	Not applicable	No serious	Very serious <sup>e</sup>	No	41	RR 6.22 (95% CI 0.90 to 43.09)	Very low	Critical
Uptake of	appointment with	family planning	clinic or other co	ontraception pro	ovider					
Empty box	Empty box of emergency contraception to take to family planning clinic vs. verbal and written advice on methods of contraception, including locations of family planning clinics									
1 <sup>3</sup>	Randomised controlled trial	Serious <sup>f</sup>	Not applicable	Serious <sup>g</sup>	Serious <sup>c</sup>	No	61	RR 3.72 <sup>h</sup> (95% CI 1.58 to 8.74) favouring empty box	Very low	Critical
Uptake of	Jptake of diagnostic test for Obstructive Sleep Apnea Syndrome (OSAS)									
OSAS bro	DSAS brochure with brief education and referral for OSAS diagnostic testing vs. No intervention									
14	Cohort study	Serious <sup>i</sup>	Not applicable	Serious <sup>j</sup>	No serious	No	782	OR 2.24 (95%CI 1.25 to 4.01) favouring intervention	Very low	Critical

CI Confidence intervals

- 1. Evans et al. 1997
- 2. Sriram et al. 2016
- 3. Michie et al. 2014
- 4. Perraudin et al 2015

- Downgraded by 1 level as people were only recruited to study if they approached pharmacist about minor ailment or OTC medication.
- <sup>c</sup> Downgraded 1 level as number of events is less than 300.

- <sup>e</sup> Downgraded 2 levels as confidence intervals crosses the upper minimally important difference (1.25) and number of events is less than 300.
- Downgraded 1 level. It is unclear how the allocation sequence was generated. It is unclear how the allocation was concealed. It is unclear whether primary outcomes were assessed blindly.
- <sup>9</sup> Downgraded 1 level. Outcome is use of 'effective contraception', defined as contraception that is not barrier method and not no contraception (so therefore hormonal or LARC). There will be other people who took up the service who decided not to use 'effective' contraception.
- h Only includes data from participants with follow up data. Overall quality not downgraded.
- i. Downgrade 1 level. Selection bias into study likely to have occurred
- j. Downgrade 1 level. Uncertainty how applicable results are to UK setting and population

<sup>&</sup>lt;sup>a</sup> Downgraded 2 levels. Baseline characteristics of the groups were not compared. Outcomes were self-reported. 54% of participants were successfully followed up but it is not clear how many eligible community pharmacy users were recruited into the study. The consistency of the intervention across different sites or different days was not measured.

d Downgraded by 2 levels. Very likely to be different participants in before and after group. No comparison of characteristics in before and after groups, except gender. Outcome assessors likely to be aware of intervention status of participants. Self-reported uptake of referral.

## Appendix G – Economic evidence study selection

No relevant economic studies were identified.

# **Appendix H – Economic evidence tables**

No studies were identified for inclusion in the economic review.

# Appendix I – Health economic evidence profiles

N/A

## Appendix J – Health economic analysis

N/A

## Appendix K – Excluded studies

See separate appendix K document.

# Appendix L - Research recommendations

Is referral from a community pharmacy within a formal local care pathway framework more effective and cost effective than signposting alone in improving access to, and uptake of services by underserved groups and the general population?

#### Rationale

Community pharmacies have to be integrated within the patient care pathway, with inward and outward referrals established and consistently managed. This is in line with the NHS sustainability and transformation partnerships (STPs) and the Five Year Forward View, to better integrate healthcare services in the UK. But there is no evidence to show whether it is effective and cost effective for them to offer a broad or narrow set of services. It is also not clear how to effectively refer in and out of pharmacies to improve patient outcomes.

Some evidence showed that referral by community pharmacies increased service uptake more than signposting, but more research is needed to support this. Establishing cost-effectiveness evidence for this in pharmacies is important because the resource impact for making and receiving referrals is greater than for signposting. For example, there may be cost implications for the time needed to make or accept individual referrals and for setting up the overall process.

Criterion	Explanation
Population	General population and underserved groups

Intervention	Referral within a formal local care network
Comparators	Signposting alone
Outcomes	Access to services elsewhere in the network
	Uptake of services or interventions
	elsewhere within the network
	Costs, savings and effectiveness
Study design	Study designs could include cost- effectiveness studies and RCTs of specific referral interventions or other types of evaluation with the purpose of ascertaining the effect of formal referrals in improving service uptake. It will also be important to gain public and staff feedback as part of any studies so a mixed methods approach to include qualitative elements may also be appropriate.
Timeframe	No specific timeframe

How effective and cost effective is it for community pharmacy teams to provide local social prescribing interventions? What is the differential impact in both effectiveness and cost effectiveness of community pharmacies carrying out this activity or acting only as a referral or signposting element of the approach?

### Rationale

The committee noted that social prescribing is an important concept to consider when referring and signposting people from community pharmacies. Social prescribing schemes can involve various activities to support people's social, emotional or practical needs. Examples include volunteering, arts activities, group learning, debt counselling, gardening, befriending, cookery and sports.

The main goal of social prescribing is to promote better patient outcomes. It may also help to reduce referrals to the acute sector or uptake of more costly interventions. But currently there is no evidence on its effectiveness – or acceptability – in community pharmacies.

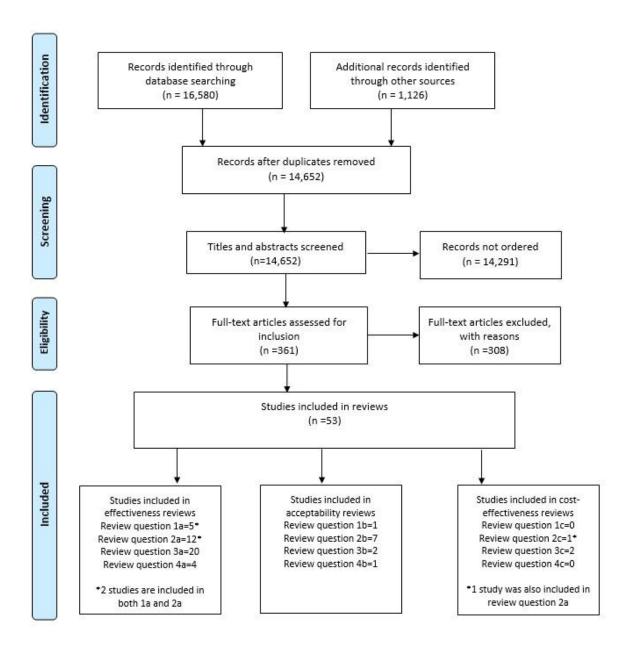
Criterion	Explanation
Population	General population and underserved groups
Intervention	Social prescribing. This could include UK-specific social prescribing referrals and

	interventions which are already being provided in community pharmacies, but do
	not currently have an evidence base.
Comparators	Social prescribing by others in the local care network
	Other non-social prescribing interventions
	Signposting verses referral for social prescribing
	No intervention
Outcomes	Uptake of social prescribing interventions
	Clinical measurements or health outcomes
	Behavioural outcomes (action)
	Modifying factors or determinants of behaviour (awareness, knowledge, attitudes, intentions)
	Wellbeing, Quality of Life
	Costs, savings and effectiveness
Study design	Study designs could include cost- effectiveness studies and RCTs of specific interventions or other types of evaluation with the purpose of ascertaining what interventions are effective at providing social prescribing, specifically within a UK context. It will also be important to gain public and staff feedback as part of any studies so a mixed methods approach to include qualitative elements may also be appropriate.
Timeframe	Studies would require sufficient follow up time to capture impacts on health and wellbeing

# **Appendix M – Expert testimony**

See separate appendix M document.

# Appendix N - PRISMA diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.