National Institute for Health and Care Excellence

Final

Community pharmacy: promoting health and wellbeing

Evidence reviews for providing information on health and wellbeing

NICE guideline NG102

Evidence review 1

August 2018

Final

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

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ISBN: 978-1-4731-3048-7

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Review question 1c. How can information on health and wellbeing (including information provided as part of awareness raising campaigns) be provided in a cost effective way by community pharmacy staff? For example, are booklets containing self-help material cost effective?

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 (The positive pharmacy care law: an area-level analysis of the relationship between community pharmacy distribution, urbanity and social deprivation in England Todd et al. 2014).

Community pharmacies can help raise awareness of health conditions, improve health, and reduce both health inequalities and individual health risks by providing advice and services to everyone entering their premises. This includes people who do not visit GPs or other healthcare services. In addition, they may support other primary care services, such as GP practices.

The risk of many health conditions can be reduced by people adopting healthier behaviours. These include: type 2 diabetes, cardiovascular disease, respiratory diseases such as chronic obstructive pulmonary disease, and conditions related to obesity and smoking.

The aim of this review was to determine which information provision interventions are effective and cost-effective for self-care to promote health and wellbeing in community pharmacy and whether information provision is acceptable to users of community pharmacy.

This review also aims to explore whether the effectiveness and cost-effectiveness of information provision interventions varies by the characteristics of the intervention, the person delivering the intervention, or the person receiving the intervention. It will also aim to explore how information provision interventions 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 1a, 1b and 1c on provision of information

PICO Element	Details		
Population	Anyone who may use community pharmacy services		
Intervention	Any intervention delivered by community pharmacy staff that provides information on health and wellbeing, including: • Posters • Leaflets • Self-help booklets • TV or computer screens • Counter cards • SMS messaging • Verbal information given by staff • Product displays • Any other intervention that provides information or awareness raising to users of community pharmacy services		
Comparator	• No intervention • Any other approach to providing information on health and wellbeing by community pharmacy staff.		
Outcomes	*Review question 1a*	*Review question 1b*	*Review question 1c*
	• Behavioural outcomes - Action • Modifying factors or determinants of behaviour - Awareness - Knowledge - Attitudes - Intentions	• Preferences and experiences of people using the service • Qualitative element of quality of life	• Costs, saving and cost-effectiveness - Cost per quality adjusted life year - Cost per unit of effect - Net benefit

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 include 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 5 primary studies of effectiveness were included in review 1 (Table 2).

Table 2. Summary of effectiveness evidence for provision of information

Study	Setting and country	Intervention	Health area	Outcomes
Hariri et al. 2000	Community pharmacies London, UK	Interactive kiosk displaying a CardioPharm multimedia health promotion package Health promotion leaflet display	Cardiovascular disease	Leaflet uptake Health promotion enquiries
Lloyd-Williams 2003	Community pharmacies North Staffordshire, UK	Leaflet display in a prominent position and targeted distribution of leaflets. Leaflets used a question and answer arrangement.	Heartburn and indigestion	Leaflet uptake Health promotion enquiries
Meijer et al 2005	Community pharmacies The Netherlands	Stickers about folic acid place on boxes of oral contraceptives dispensed to women. Leaflet about folic acid also provided	Folic acid supplementation (Women's health)	Knowledge Intention
Sharma et al.1998	Community pharmacies London, UK	Information displays including information from the Health Authority on sexual health services and emergency contraception.	Sexual health	Leaflet uptake Health promotion enquiries
Slater et al. 2013	Community pharmacies	Informational pamphlet containing evidence-based information about lower back pain	Orthopaedic disorders	Back beliefs Physical activity related fear

Study	Setting and country	Intervention	Health area	Outcomes
	Perth, Australia	management, consistent with current recommendations Information highlighted the need to stay active, positive and engaged at work and socially.		Work-related fear Pain Activity impairment

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 I^2 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

Quality domain	Description
	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 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.

GRADE 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 by outcome.

The evidence for the effectiveness outcomes included in this review was all low to very low in quality. This is because the included studies had either serious or very serious risk of bias. Additionally, included studies had serious or very serious imprecision due to lack of data reporting making imprecision incalculable or due to small sample sizes.

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 provision of information

Outcome		Quality of evidence
Action	Folic acid uptake	Low
Awareness	No evidence identified	No evidence identified
Knowledge	Back beliefs Folic acid uptake	Low to very low
Attitudes	Physical activity related fear Folic acid	Low to Very low
	Work-related fear Folic acid uptake	Very low Low
Intentions	Leaflet uptake	Very low
	Health promotion enquiries	Very low
Clinical measurements	Pain	Very low
	Activity impairment	Very low

Acceptability evidence

To assess the acceptability of providing information based interventions 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 informational 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 such as leaflets, posters or product displays were of interest. 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

1 study met the qualitative inclusion criteria. It was conducted in the UK and assessed the acceptability of information services related to cardiovascular disease risk factors. The study met some of the of the quality assessment checklist criteria.

First Author, Year	Design & Analysis	Country	Health area	Population	Outcomes	Quality rating
Saramunee 2016	Cross-sectional survey with open-ended qualitative component	UK	CVD	General public (219 comments)	Acceptability	+

Saramunee (2016 [+]) conducted a face-to-face, telephone and mail out cross-sectional survey with 2,661 members of the general public. 219 comments were received in response to free-text questions to explore views on promotional methods for community pharmacy public health services. The themes identified include desirability of promoting services and factors that will influence behaviour change.

See appendix D for full evidence tables.

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.
-	Few or no checklist criteria have been fulfilled and the conclusions are likely or Very likely to alter.

The included study had some deficiencies in reporting the context in which the qualitative information was collected and the data was not rich or detailed.

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

Action

Evidence statement 1.1 – Provision of information increases folic acid consumption in pregnant women or women who are intending to become pregnant [GRADE profile 1]

- Low quality evidence from 1 randomised controlled trial found in a subgroup of 72 women who were pregnant or intending to become pregnant those who received a sticker asking if they were planning to have a baby and a leaflet about folic acid supplementation were more likely to be taking folic acid at 6 weeks follow-up (6.3% vs. 4.9%, p=0.048) than women who did not receive information.

Awareness

Evidence statement 1.2 - No evidence was identified for the effect of provision of information on awareness [GRADE profile 2]

- No evidence was identified for the effect of provision of information on awareness.

Knowledge

Evidence statement 1.3 – Provision of information increases positive back beliefs in community pharmacy users with lower back pain [GRADE profile 3]

- Very low quality evidence from 1 randomised controlled trial with 215 participants found that there is a difference in back belief scores between participants provided with information on lower back pain compared to those who are not, 2 weeks after information has been provided (mean difference of 2.2, 95% CI 0.47 to 3.93), although this was not a clinically important increase. Low quality evidence indicates this is no longer the case at 8 weeks post information provision (mean difference of 0.3, 95% CI -1.54 to 2.14).

Evidence statement 1.4 Provision of information increases knowledge about folic acid supplementation in women

- Very low quality evidence from 1 randomised controlled trial with 528 participants found that women who received a sticker asking if they were planning to have a baby and a leaflet on folic acid were more likely to have knowledge on how to prevent neural tube defects (48.1% vs. 37.2%,), know to start taking folic acid before pregnancy (69.8% vs.58.5%) than women who did not receive any information. The groups were similar in terms of knowing the correct time period in which to start taking folic acid supplementation (18.7% vs. 12.8%).

Attitudes

Evidence statement 1.5 – No evidence of effectiveness that provision of information decreases physical activity related fear in community pharmacy users with lower back pain [GRADE profile 4]

- Very low quality evidence from 1 randomised controlled trial with 215 participants found that there is no difference in physical activity related fear scores between participants provided with pamphlets containing information on lower back pain compared to those

who are not, 2 weeks after information has been provided (mean difference of -1.3, 95% CI -2.8 to 0.2), or 8 weeks after information has been provided (mean difference of -1.4, 95% CI -2.8 to 0.0).

Evidence statement 1.6 – No evidence of effectiveness that provision of information decreases work related fear in those with lower back pain [GRADE profile 4]

- Very low quality evidence from 1 randomised controlled trial with 215 participants found that there is no difference in work related fear scores between participants provided with information on lower back pain compared to those who are not, 2 weeks after information has been provided (mean difference -1.0, 95% CI -4.1 to 2.2) or 8 weeks after information has been provided (mean difference of -2.1, 95% CI -5.3 to 1.1).

Evidence statement 1.7 – Provision of information increases the proportion of women who would recommend taking folic acid to other women

- Very low quality evidence from 1 randomised controlled trial with 528 participants found that women who received a sticker asking if they were planning to have a baby and a leaflet on folic acid were more likely to recommend taking folic acid to other women (63.2% vs. 50.0%) than women who had not received any information.

Intentions

Evidence statement 1.8 – Provision of information increases leaflet uptake [GRADE profile 5]

- Very low quality evidence from 1 before and after study with 847 participants indicated that there is an increase in health promotion leaflet uptake per week after the provision of information on cardiovascular disease compared to no provision of information (mean difference of 29 more leaflets/week), although the certainty of the point estimate is incalculable.
- Very low quality evidence from 1 before and after study with 698 participants indicated that there is an increase in health promotion leaflet uptake per week after the provision of information on sexual health compared to no provision of information (mean difference of 261 more leaflets/week), although the certainty of the point estimate is incalculable.
- Very low quality evidence from before and after 1 study with 619 participants indicated that there is an increase in leaflet uptake per week whilst an information provision campaign on sexual health is ongoing within a pharmacy, compared to when there is no information provision (mean difference of 89 more leaflets/week), although the certainty of the point estimate is incalculable.
- Very low quality evidence from 1 before and after study with 1141 participants indicated that there is an increase in leaflet uptake per week after the conclusion of an information campaign on sexual health, in comparison to the period during an information provision campaign (mean difference of 172 more leaflets/week), although the certainty of the point estimate is incalculable.

Evidence statement 1.9 – Targeted active provision of information on heartburn and indigestion is more effective at increasing leaflet uptake than passive provision of information [GRADE profile 5]

- Very low quality evidence from 1 non-randomised controlled trial with 382 participants indicated that targeting leaflets at community pharmacy users, either with or without an additional offer of advice (mean difference of 41 leaflets/month with and 3 leaflets/month without) is more effective at increasing leaflet uptake than displaying leaflets, although the certainty of the point estimates is incalculable.

Evidence statement 1.10 – Mixed evidence of effectiveness that provision of information increases the number of health promotion enquires [GRADE profile 5]

- Very low quality evidence from 1 before and after study with 847 participants indicated that there is an increase in the number of health promotion enquiries per day after provision of information on cardiovascular disease compared to when there is no provision of information (mean difference of 1 enquiry/day), although the certainty of the point estimate is incalculable.
- Very low quality evidence from 1 before and after study with 59 participants indicated that there is a decrease in the number of health promotion enquires per week after an information provision campaign on sexual health compared to when there is no provision of information (mean difference of 11 enquiries/week), although the certainty of the point estimate is incalculable.
- Very low quality evidence from 1 before and after study with 162 participants indicated that there is an increase in the number of health promotion enquiries per week whilst an information provision campaign on sexual health is ongoing within a pharmacy, compared to when there is no information provision (mean difference of 11 enquiries/week), although the certainty of the point estimate is incalculable.
- Very low quality evidence from 1 before and after study with 141 participants indicated that there is a decrease in the number of health promotion enquires per week after the conclusion of an information provision campaign on sexual health, compared to the period during an information provision campaign (mean difference of 21 enquiries/week), although the certainty of the point estimate is incalculable.

Evidence statement 1.11 – Mixed evidence that targeted provision of information is more effective at increasing the number of health promotion enquires than passive provision of information [GRADE profile 5]

- Very low quality evidence from 1 non-randomised controlled trial with 382 participants indicated that targeting leaflets providing information on heartburn and indigestion at community pharmacy users without an additional offer of advice is more effective at increasing the number of people making health promotion enquiries than displaying leaflets (21% difference in enquiry number/month), although the certainty of the point estimate is incalculable. There is no clinically important difference in the number of health promotion enquiries per month when targeting leaflets compared to displaying leaflets (RR 0.96, 95% CI 0.57 to 1.64).

Evidence statement 1.12- No evidence of effectiveness that provision of information changes intention to start folic acid uptake

- Low quality evidence from 1 randomised controlled trial found there was no difference in intention to start taking folic acid in a subgroup of 72 women who were pregnant or intending to become pregnant and received a sticker asking if they were planning to have a baby and an information leaflet about folic acid than women who did not receive information (2.5% vs. 4.3%).

Clinical measurements

Evidence statement 1.13 – No evidence of effectiveness that provision of information decreases pain severity in those with lower back pain [GRADE profile 6]

- Very low quality evidence from 1 randomised controlled trial with 215 participants suggests that there is no difference in pain severity score 2 weeks after provision of information on lower back pain (mean difference of 0.4, 95% CI -2.1 to 2.9) or at 8 weeks post provision of information (mean difference of -0.1, 95% CI -0.8 to 0.6).

Evidence statement 1.14 – No evidence of effectiveness that provision of information decreases activity impairment in those with lower back pain [GRADE profile 6]

- Very low quality evidence from 1 randomised controlled trial with 215 participants suggests that there is no difference in activity impairment score 2 weeks after provision of information on lower back pain (mean difference of 0.1, 95% CI -0.6 to 0.8), and no difference in score 8 weeks after provision of information (mean difference of -0.2, 95% CI -0.9 to 0.5).

Evidence statement 1.15 – No evidence was identified for which characteristics of the person delivering the intervention affect its effectiveness

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

Evidence statement 1.16– No evidence was identified for how the way the intervention is delivered affects its effectiveness

- No evidence was identified that directly compares interventions delivered in different ways by community pharmacy staff.

Evidence statement 1.17 – No evidence was identified for which characteristics of the person receiving the intervention affect its effectiveness

- No evidence was identified that directly compares different people receiving the same intervention delivered by community pharmacy staff.

Acceptability evidence statements

Evidence statement 1.18- There are mixed sentiments around the role of community pharmacies providing information services for public health promotion

One cross-sectional UK study [+[3]] assessing the pharmacy characteristics perceived as desirable and promotional methods that would likely influence behaviour in members of the general public found there were mixed sentiments about community pharmacists promoting their services. Some participants indicated they felt things such as posters would be valuable and would enhance the user experience "*I do not feel the pharmacy services are advertised at all – I didn't realise until recently just what they can offer – I have recently found their services a huge help…a relief as I didn't have to visit a doctor"* On the contrary some respondents disagreed with pharmacists promoting their services as they felt it could lead to the commercialisation of health "*I don't believe healthcare should be advertised in a manner which would be more appropriate for soap powder*". Factors such as the quality of the service provided were deemed important factors in public health promotion *"Good pharmacist will have more influence than any advertising".* Additionally it is vital the motivations of the pharmacists were genuinely altruistic as evidenced in this quote *"So long as the service being advertised is for the sole benefit of the user and not to boost trade".*

[3] Saramunee 2016 (+)

Recommendations

Evidence discussion

Interpreting the evidence

The outcomes that matter most

The committee agreed that action was a critical outcome for this review. They also agreed that intentions, attitudes, and knowledge and awareness were important outcomes. All 5

effectiveness studies addressed these outcomes across health areas including cardiovascular disease, heartburn and indigestion, folic acid supplementation, sexual health, and orthopaedic issues. Awareness was also considered an important outcome within this review, however no evidence was identified which investigated the effect of provision of information on this outcome [ES 1.2]. One qualitative UK study assessed the general public's views on the acceptability of pharmacists providing promotional materials on cardiovascular disease risk factors [ES 1.18]. No evidence was identified that directly considered variations in the effectiveness of interventions by the characteristics of the person delivering it [ES 1.15], the format of the intervention [ES 1.16], or the characteristics of the person having it [ES 1.17].

The committee acknowledged that one of the outcomes reported in the evidence was how many people took a leaflet in a community pharmacy [ES 1.8]. The committee agreed that taking a leaflet alone may not reflect an outcome of interest, such as intention. However they noted based on other evidence reviewed that if the pharmacist (or pharmacy staff member) explained the importance of the leaflet when handing to customers and opened up dialogue with the receiver, the information would then have the potential to be more personalised and targeted to their needs [ES 1.9 and 1.11]. The committee agreed that giving information in this active way may encourage a change in intention and more likely lead to an outcome of action by the customer.

The committee were aware that leaflets may be given to carers, family/friends or a delivery person on an individual's behalf, for example when collecting prescriptions. The committee highlighted that in these circumstances taking a leaflet may be less likely to reflect an outcome of interest as the benefit of giving a leaflet in this way may be reduced. It was also noted that there is no evidence to suggest that leaflets collected by another person are ineffective and leaflets given this way can be influential, particularly if the person collecting is more suitable for encouraging the use of the information. For example if a carer/family/friend prepares meals for an individual then information on diet may be best given to that person. The committee agreed that steps should be taken to maximise the chance that the information would be passed to the intended recipient, such as through placing a leaflet inside the bag of dispensed medicines, rather than handing it to the other person separately.

The committee noted that 1 study included in the review reported clinical measurements as an additional outcome [ES 1.13-1.14]. The committee agreed that this evidence would not be used to inform a recommendation as no clinically important effect was reported. However it was emphasised that the intervention was on the pathway to change and may have required a more intense approach.

The quality of the evidence

The quality of the effectiveness evidence ranged from low to very low, with the evidence for most outcomes being very low. The only qualitative study within the review was of moderate quality. This prevented the committee from making strong recommendations for or against using specific information interventions in community pharmacies, and they were unable to make strong recommendations on how to make these information interventions more effective. The main factors that reduced quality were bias, indirectness and precision due to study design, outcomes reported and low sample sizes.

The committee noted that one RCT study showed a clinically important uptake of folic acid after the provision of information in the form of a leaflet and the use of a sticker asking if women were planning on becoming pregnant [ES 1.1]. The same study indicated that the provision of information increased the knowledge about folic acid supplementation in women [ES 1.4] and the proportion of women who would recommend others to take it [ES 1.7] but not the intention to start folic acid uptake [ES 1.12]. This RCT which was of low quality indicated that information delivered in this active way, was of more benefit than if delivered in a passive way. The committee noted that the study had a large sample size and could easily be applied in a community pharmacy setting, however there was some uncertainty due to

potential contamination as some subjects in the control group recalled receiving the intervention. The committee agreed this may only have reduced the relative size of effect and thus did not alter their certainty that this active approach was highly plausible in this and other scenarios [ES 1.9] and so extrapolated this to other health areas.

The committee noted that 1 of the studies used an interactive touch screen kiosk giving lifestyle health promotion resulting in a significant increase in the number of leaflets taken and health queries made to pharmacy staff [ES 1.8]. However, committee members noted that installing a kiosk in a pharmacy does not ensure that all members of the public use it and more detailed estimates of pharmacy activity would be needed to warrant its use. They also agreed it may not be cost effective without further evidence of effect. Despite this, the committee highlighted that the internet is increasingly used in day to day life to provide health and wellbeing information and raise awareness of health promotion services due to the high volume of people that use internet based technology. Thus it was decided that it would not be unreasonable to extrapolate this evidence to other accessible information resources such as smartphones.

Whilst there were some gaps in the evidence the committee agreed that leaflets should form part of a progressive approach potentially leading to education, advice or behavioural interventions where warranted and thus did not recommend further research in this area.

Benefits and harms/advantages and disadvantages of providing advice and education

The committee agreed with the evidence that targeted health promotion campaigns which provide information for customers in an active way would be beneficial within these settings.

Information on lower back pain increased positive back beliefs [ES 1.3], however there was no effect on change in pain severity and activity impairment [ES 1.13-1.14], physical activity fear [ES 1.5] or work related fear [ES 1.6]. Provision of information on cardiovascular disease and sexual health was also found to increase the number of health enquiries made [ES1.10]. However, the committee agreed that linking any information given to the reason people are accessing the pharmacy for example would be better than offering general information not linked to the needs of the person.

The committee noted that although there was a lack of high quality evidence within this review area, there was no indication from the available data to suggest that information resources within community pharmacies caused any harm or disadvantages to those who used them. The committee agreed that any awareness raising campaigns or information should follow the agreed evidence based principles for facilitating behaviour change and thus recommended they are delivered in line with previous NICE guidance on behaviour change individual and general approaches.

Cost effectiveness and resource use

No cost effectiveness evidence was identified for this review.

The committee agreed that actively providing health and wellbeing information may involve a small amount of additional staff time to ensure that the relevance and importance of information is highlighted to an individual during discussion of the information. This may be associated with an opportunity cost to the pharmacy. However this cost may be offset by the improvement in health outcomes by the information given or by the person seeking further advice or other interventions to prevent ill health or generally improve their health and wellbeing. This would likely save resources elsewhere in the healthcare system. Despite the uncertainty here, the committee agreed that this downstream improvement would be the likely scenario based on the limited evidence of effect available.

The committee agreed that if staff are appropriately trained to deliver information in this way then there should be no significant cost implications. The committee anticipated that this

would likely be the case given the training available to staff as a minimum requirement [EP 1] plus that available through other sources. For example some pharmacy staff, such as those who have become Health Champions, are competent to provide information in this way because they are trained in general healthy living [EP 3]. Pharmacists or pharmacy technicians receive or have access to some training on communication and consultation skills as part of their undergraduate and pre-registration training programmes and The Centre for Pharmacy Post Graduate Education provides free professional development learning to pharmacists and pharmacy technicians which is funded by Health Education England (HEE).

Other factors the committee took into account

The committee noted that although there was a paucity of evidence within this review, the evidence available did suggest a positive direction of effect between information and awareness raising within pharmacies and the impact on health and wellbeing of pharmacy users. It was agreed that community pharmacy staff should make use of existing information resources available to them to reduce any additional costs.

The committee discussed their own experience of delivering these kinds of interventions in pharmacy settings and agreed that examples of the use of community pharmacy services and the benefits observed, whilst not recorded as formal evidence, should be taken in to consideration.

Linked expert testimony (see appendix M)

EP 1- EP 1- Expert Paper 1 – Training and competencies of community pharmacy staff

EP 3 – Expert Paper 3 – Healthy Living Pharmacies

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 1a – Effectiveness of awareness raising and provision of information

Field	Content
Review question 1a	How can information on health and wellbeing (including information provided as part of awareness raising campaigns) be provided in an effective way by community pharmacy staff? For example, are booklets containing self-help material effective?
Type of review question	Intervention
Objective of the review	This review aims to determine which interventions are effective for providing information on health and wellbeing in community pharmacy. This includes information that is provided as part of a wider health promotion campaign, such as specific awareness raising campaigns requested by NHS England. This review will focus on the effectiveness of information aimed at a group of users of community pharmacy services, rather than interventions that are tailored to an individual. 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 criteria - population	Anyone who may use community pharmacy services See common elements section for further details.
Eligibility criteria - interventions	Any intervention delivered by community pharmacy staff that provides information on health and wellbeing, including: • Posters • Leaflets • Self-help booklets

Field	Content
	• TV or computer screens • Counter cards • SMS messaging • Verbal information given by staff • Product displays • Any other intervention that provides information or awareness raising to users of community pharmacy services Exclusions: • Interventions delivered by anyone who is not working for a community pharmacy • Interventions delivered by distance-selling (online) pharmacies See common elements section for further details.
Eligibility interventions - comparators	No intervention. Any other approach to providing information on health and wellbeing by community pharmacy staff. See common elements section for further details.
Outcomes and prioritisation	1 Behavioural outcomes - Action 2 Modifying factors or determinants of behaviour - Awareness - Knowledge - Attitudes - Intentions See common elements section for further details.
Eligibility criteria – study design	- Systematic reviews of studies of effectiveness - Studies of effectiveness, including: o Randomised controlled trials o Quasi-experimental studies, such as non-randomised controlled trials and before and after studies 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. 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: I. What characteristics of the person delivering the intervention (for example their job role and competencies, or being a

Field	Content
	health champion) affect its effectiveness in community pharmacy? 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? III. What characteristics of the people receiving the intervention (for example, age or gender) affect its effectiveness in community pharmacy? 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 – 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 1b – Acceptability of providing information

Field	Content

Review question 1b	Is providing information acceptable to users of community pharmacy services?
Type of review question	Views and experiences
Objective of the review	The review aims to determine whether providing information (including information provided as part of awareness raising campaigns) is acceptable to users of community pharmacy services. This includes information that is provided as part of a wider health promotion campaign, such as specific awareness raising campaigns requested by NHS England. This review will focus on the acceptability of information provided to a group of users of community pharmacy services rather than interventions that are tailored to an individual. This review 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 intervention delivered by community pharmacy staff that provides information on health and wellbeing, including: • Posters • Leaflets • Self-help booklets • TV or computer screens • Counter cards • SMS messaging • Verbal information given by staff • Product displays • Any other intervention that provides information or awareness raising to users of community pharmacy services Exclusions: • Interventions delivered by anyone who is not working for a community pharmacy • Interventions delivered by distance-selling (online) pharmacies See common elements section for further details.
Eligibility criteria - comparators	No intervention. Any other information intervention delivered by community pharmacy staff. See common elements section for further details.
Outcomes and prioritisation	Preferences and experiences of people using the service Quality of life 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: I. How can information 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 – 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 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	Ella Novakovic (Senior Technical Analyst) Daniel Tuvey (Information Specialist)

Review question 1c – Cost effectiveness of providing information

Field	Content
Review question 1c	How can information on health and wellbeing (including information provided as part of awareness raising campaigns) be provided in a cost effective way by community pharmacy staff? For example, are booklets containing self-help material cost effective?

Field	Content
Type of review question	Cost effectiveness
Objective of the review	This review aims to determine which interventions are effective and cost effective for providing information on health and wellbeing in community pharmacy. This includes information that is provided as part of a wider health promotion campaign, such as specific awareness raising campaigns requested by NHS England. This review will focus on the cost effectiveness of information provided to a group of users of community pharmacy services rather than interventions that are tailored to an individual. 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 intervention delivered by community pharmacy staff that provides information on health and wellbeing, including: • Posters • Leaflets • Self-help booklets • TV or computer screens • Counter cards • SMS messaging • Verbal information given by staff • Product displays • Any other intervention that provides information to users of community pharmacy services Exclusions: • Interventions delivered by anyone who is not working for a community pharmacy • Interventions delivered by distance-selling (online) pharmacies See common elements section for further details.
Eligibility criteria - comparators	No intervention. Any other approach to providing information on health and wellbeing by community pharmacy staff. See common elements section for further details
Outcomes and prioritisation	Costs, saving and cost effectiveness - Cost per quality adjusted life year - Cost per unit of effect - Net benefit See common elements section for further details
Eligibility criteria – study design	- Systematic reviews of cost-effectiveness studies - Economic evaluations - Cost-utility studies - Cost benefit studies - Cost-effectiveness studies - Cost minimisation studies

Field	Content
	- Cost-consequence studies 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: 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? 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? III. What characteristics of the people receiving the intervention (for example, age or gender) affect its cost effectiveness in community pharmacy? 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 – 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,	For details please see section 6.2 of Developing NICE guidelines: the manual.

Field	Content
selective reporting bias	
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 referral or signposting by community pharmacy staff to other services or support will be included in review 4. This includes:

- studies of referral or signposting to services or support offered by other NHS services, such as NHS stop smoking services
- studies of referral or signposting to services or support offered by non-NHS services, such as those provided by charity organisations
- studies of referral or signposting 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:
  - alcohol misuse
  - 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)
  - early signs and symptoms of any cancer, such as blood in urine or stools
- cardiovascular disease prevention, including:
  - lifestyle factors
- diabetes prevention, including:
  - lifestyle factors
  - healthy eating
  - physical activity
- substance misuse prevention, including:
  - needle and syringe exchange programmes, including disposal and injecting equipment
  - 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
  - physical activity
- mental health and wellbeing, including
  - getting a good night's sleep
  - 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
  - diet
- sexual health, including:

  - emergency contraception
  - safer sex practice, including use of condoms
  - methods of contraception
  - preventing unwanted pregnancies
  - pregnancy testing
  - sexually transmitted infections, including testing
  - information on HIV testing
- smoking and smokeless tobacco, including:
  - stopping use
  - harm reduction
  - nicotine-containing products
  - the importance of smoke free homes
- weight management, including:
  - maintaining a healthy weight
    - why maintaining a healthy weight is beneficial
    - how to maintain a healthy weight
    - checking weight
  - nutrition:
    - healthy eating
    - vitamin D
    - sugar
    - salt
    - saturated fat
    - folic acid
    - child and maternal health
  - 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

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 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.

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 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

1. Hariri S, Goodyer LI, Meyer J, Anderson C (2000) Assessment of a touch-screen health promotion system in independent community pharmacies. Health Education Journal, vol 59, p99 to 107
2. Lloyd-Williams F. (2003) The effect of an intervention programme to improve health education leaflet uptake and distribution in community pharmacies. Patient Education and Counselling, vol 49, p27-33
3. Meijer, WM. de Smit, DJ. Jurgens, RA. (2005) Improved periconceptional use of folic acid after patient education in pharmacies: promising results of a pilot study in the Netherlands, vol 13, p47-51
4. Saramunee K, Dewsbury C, Cutler S, Mackridge A, Krska J (2016) Public attitudes towards community pharmacy attributes and preferences for methods for promotion of public health services. Public Health. 140: 186-195
5. Sharma S, Anderson C. The impact of using pharmacy window space for health promotion about emergency contraception. Health Education Journal. 1998 Mar 1;57(1):42-50.
6. Slater H, Briggs AM, Watkins K et al. (2013) Translating evidence for low back pain management into a consumer-focussed resource for use in community pharmacies: a cluster-randomised controlled trial. PLoS ONE. Vol 8 (8) e71918

Appendix Di – Effectiveness evidence tables

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Hariri S, Goodyer LI, Meyer J, Anderson C (2000) Assessment of a touch-screen health promotion system in independent community pharmacies. Health Education Journal, vol 59, p99 to 107

Quality score
-

Study type
Before and after
Location and setting
3 pharmacies in London, England

Aims
To assess the characteristics of users of CardioPharm within an independent community</td>
<td>Health area
Cardiovascular disease

Number of participants
847 started, 262 completed intervention (assuming only 1 interaction from each participant)

Participant characteristics
The ratio of males to females was 1:1.7 during observation periods. No statistically significant difference between the stores in the gender distribution of the pharmacies (p=0.537).

<20yrs: 250 users
20-40yrs: 324yrs
40-60yrs: 181 users
>60yrs: 91 users

Inclusion criteria
Any pharmacy users that used an interactive kiosk.

Exclusion criteria</td>
<td>Intervention
June-Sep 1996

Pharmacy managers received the study protocol and training on data collection sheets and for the kiosk and CardioPharm program and asked to train other staff.

The CardioPharm kiosk was available for use in the pharmacy during the 4 week intervention period.
Mean time spent on the kiosk was 5.7minutes

Comparator
Before the intervention, each pharmacy was observed for 4</td>
<td>Recruitment:
A sample of 3 community pharmacies was chosen, using purposive sampling. This achieved recruitment of 2 high street pharmacies – the first 44 square metres with 2000-3000 prescriptions per month; the second 150 square metres with 1000-2000 prescriptions per month and 1 pharmacy in a residential area (150 square meters with 3000-4000 prescriptions per month)

Data collection:
8 type of health promotion leaflet were displayed during the second 4 weeks of the study.

The study period was extended in Pharmacy 2 to compensate for shorter opening hours.

Number of enquiries regarding cardiovascular risk factors were recorded by pharmacists daily with a data record sheet.

Analysis:

Normality of the data was assumed and an unpaired 2 sample t-test was used.</td>
<td>Number of users and percent completed in each age group for completed interactions was: below 20 years=250 (20% completed), 20 to 40 years=324 (33% completed), 40 to 60 years=181 (35% completed), and above 60 years= 91 (41% completed). In pharmacy 3 there was a statistically significant association between age groups and completing the program (p=0.002).

Overall, 34% of females and 26% of males completed the program (p>0.05) - between pharmacies p=0.25, and difference from baseline p>0.05.

Difference in BMI between the 3 pharmacies - p=0.002. Users with BMI of above 30 were less likely to complete the program.

Health promotion activity
None of the pharmacies recorded data for the full eight week period and all omitted some days.

Number of health promotion interventions
<table>
<tr><th></th><th>Pharmacy</th><th>Health promotion enquiries</th><th>Days of data collection</th></tr>
<tr><td rowspan="3">Before</td><td>1</td><td>24</td><td>13.0</td></tr>
<tr><td>2</td><td>34</td><td>18.0</td></tr>
<tr><td>3</td><td>46</td><td>17.5</td></tr>
<tr><td rowspan="3">After</td><td>1</td><td>54</td><td>18.0</td></tr>
<tr><td>2</td><td>49</td><td>18.0</td></tr>
<tr><td>3</td><td>66</td><td>20.0</td></tr>
</table>
<table>
<tr><th></th><th>Mean no. enquiries/day across all pharmacies</th><th>Mean difference in enquiries/day</th></tr>
<tr><td>Before</td><td>2.13</td><td rowspan="2">0.88</td></tr>
<tr><td>After</td><td>3.01</td></tr>
</table>
Table calculated by NICE technical team
Number of health promotion leaflets picked up
<table>
<tr><th></th><th>Pharmacy</th><th>Duration (weeks)</th><th>Total no. of leaflets</th><th>Mean number of leaflets per week (SD)</th><th>Percentage increase</th></tr>
</table>
</td>
</tr>
</table>

pharmacy settings, and to examine the effect on the public's use of their community pharmacy as a source of health information.

Length of follow up
Immediate

Source of funding
None reported

All interactions that did not reach the BMI were excluded from analysis as children were observed interacting with the kiosk but not fully participating.

Data which could not be defined as an 'interaction', were excluded – 357 events

hours on 2 separate occasions to record the number of males and females visiting the pharmacy.

Baseline data was collected for 3 weeks in pharmacies 2 and 3 and 4 weeks in pharmacy 1.

An 'interaction' was defined as when a user started CardioPharm and proceeded to enter their details in order to obtain an estimate of BMI. A 'complete' interaction was defined as when a user reached the pharmacists' summary screen at the end of the program. Users also had a choice of going on to a quiz section, which consisted of 10 questions giving them more advice regarding a healthy lifestyle.

Before	1	4	109	27 (12)	-
	2	3	107	36 (10)	-
	3	4	153	38 (13)	-
After	1	4	213	53 (12)	95
	2	4	245	61 (3)	71
	3	3	216	72 (22)	87

Pharmacies 1 and 2 showed a significant increase ($p<0.05$) in the number of leaflets taken. Pharmacy 3 did not show a significant increase ($p=0.053$).

	Mean leaflet uptake/week across all pharmacies	Mean difference in leaflet uptake/week
Before	33.7	28.5
After	62.2	

Table calculated by NICE technical team

Limitations identified by authors
Users could have used the program more than once. Not possible to determine if the recorded interactions were all from customers that were genuinely interested in the content of the program – some children used the kiosk and were observed to leave the program after a few screen touches, so all interactions that did not reach the kiosk screen for entering information related to BMI were excluded from data analysis.
Not possible to determine if users were responding truthfully to the questions, and may have provided answers that they knew would produce favourable feedback from the program.
Consultations with the pharmacist relies on reporting by the pharmacist.
Increase in uptake of leaflets may not be as a result of presence of CardioPharm – pharmacists and staff may have been motivated by being chosen for the project and increased attention could have contributed to observed increase (Hawthorne effect). This effect could have been reduced with a longer data-collection period.
Limitations identified by review team
It is not clear whether pharmacy users who were not using CardioPharm could take leaflets, and whether this would be counted in the results as an action resulting from the CardioPharm kiosk.
The kiosk was not switched on for the full 60 day period in any of the pharmacies because of bank holidays, hardware problems, being too busy to turn it on, the presence of locum pharmacists and vandalism from children.
8 leaflets were on display, and the content of these leaflets is unknown. This increases the likelihood of multiple leaflets being picked up by 1 participant thus it is likely participant numbers are an over-estimate. It also doesn't allow information on intent to change specific behaviour to be evaluated.
Other comments
The authors thank Merton, Sutton and Wandsworth Area Health Authority and Mr Norman Evans (Pharmaceutical Advisor) for help and support in the project. It is not clear whether financial support was received.
Data for interactions initiated by a pharmacist were included in study results but not considered an outcome of interest for this guideline as this does not reflect an intention to change behaviour as picking up a leaflet does.

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Lloyd-Williams F. (2003) The effect of an intervention programme to improve health education leaflet uptake and distribution in community pharmacies. Patient Education and Counselling, vol 49, p27-33

Quality score
-

Study type
Non-randomised controlled trial

Location and setting
Community pharmacies in North Staffordshire, UK

Aims
To enhance the uptake by, or distribution to, pharmacy clients of health-related leaflets and to enhance the utilisation of pharmacists' health knowledge, and expertise by clients, through seeking the formers' advice on health matters.

Length of follow up
1 month

Source of funding</td>
<td>Health area
Heartburn and indigestion

Number of participants
12 community pharmacies
Number of pharmacy users not reported.

Participant characteristics
9 single proprietor pharmacists, 3 small multiple proprietors

9 pharmacies were in an urban residential area, 2 in a village, 1 in a city centre.

Inclusion criteria
None reported

Exclusion criteria
None reported</td>
<td>Intervention 1 – leaflet display, no offer of advice
Displaying leaflet in a prominent position

Intervention 2 – leaflet display, with offer of advice
Same as intervention 1, but with an offer in the leaflet to pharmacy users to seek pharmacists' advice on the health matter dealt with in the leaflet

Intervention 3 – targeted leaflet distribution, no offer of advice
Leaflets directly handed to pharmacy users seeking advice on or purchasing medication relating to the issue dealt with in the leaflet. No offer of advice contained in leaflet.

Intervention 4 – targeted leaflet distribution, with offer of advice
Same as intervention 3, but with offer of advice by the pharmacist in the leaflet.

Leaflets used a question and answer arrangement. It was developed in consultation with a representative number of pharmacists. Pharmacists in interventions 2, 3 and 4 were also provided with a booklet with comprehensive heartburn and indigestion</td>
<td>Recruitment:
12 out of 15 pharmacies approached agreed to take part.

Assignment to intervention was based on conditions and layout in the pharmacies (all were visited by the researcher), such as availability of space for the display of leaflets and/or provision of advice to clients.

Intervention 1= 2 pharmacies

Intervention 2= 3 pharmacies

Intervention 3= 3 pharmacies

Intervention 4= 4 pharmacies

Analysis:
No analysis reported.</td>
<td>Primary outcomes:

<table>
<tr><th>Intervention</th><th>Total number of leaflets provided</th><th>Leaflets taken/distributed</th><th>Leaflet recipients requesting advice</th></tr>
<tr><td>Intervention 1 Leaflet display, no advice</td><td>100</td><td>72* (72%)</td><td>0* (0%)</td></tr>
<tr><td>Intervention 2 Leaflet display, with advice offer</td><td>150</td><td>97* (65%)</td><td>19* (20%)</td></tr>
<tr><td>Intervention 3 Targeted leaflet, no advice</td><td>150</td><td>75* (50%)</td><td>16* (21%)</td></tr>
<tr><td>Intervention 4 Targeted leaflet, with advice offer</td><td>200</td><td>138* (69%)</td><td>26* (19%)</td></tr>
<tr><td>All interventions combined</td><td>600</td><td>384* (64%)</td><td>61*/384* (16%*)</td></tr>
</table>
Statistical significance and p values of differences not reported. * Denotes figure calculated by the NICE technical team.

<table>
<tr><th></th><th>Leaflet display (with advice offer)</th><th>Leaflet targeting (with advice offer)</th><th>RR (95% CI)*</th></tr>
<tr><td>Number of leaflet recipients requesting advice</td><td>19</td><td>26</td><td>0.96 (0.57 to 1.64)</td></tr>
</table>
* Denotes figure calculated by the NICE technical team using Review Manager 5.3</td>
</tr>
</table>

None reported.		information to refer to in case users requested advice. Booklet was derived from valid sources and verified by members of an advisory group (including GP, dietician, public health specialist). Interventions took place over 1 month. Pharmacists in interventions 1 and 2 were provided with holders for displaying leaflets. Each pharmacy was supplied with 50 leaflets.		One of the pharmacies in intervention 3 only distributed 25% of the leaflets available to them, reducing the overall figure. In the targeted leaflet interventions (interventions 3 and 4), only 7 users declined to accept the leaflet, compared to 203 that accepted the leaflet. Occasionally, leaflets were not issued together with medication purchased by a user, especially when busy (n not reported). **Secondary outcomes:** Users' reactions were sought via a postal questionnaire and were "generally favourable". They reported that the leaflet had provided them with new information, with many expressing an intention of adjusting their eating and/or drinking habits in the light of what the leaflet had conveyed to them. Clients who had approached their pharmacists for additional advice expressed a high degree of satisfaction with the advice received and were clearly willing to continue to seek advice from pharmacists on other occasions.
Limitations identified by authors Rationale for taking leaflets not explored – may be that users were taking them out of 'idle curiosity or boredom' whilst waiting for service. **Limitations identified by review team** Allocation was not randomised – pharmacies were allocated based on the availability of resources in the pharmacy. Allocation was not concealed – the researchers decided which intervention the pharmacy would be allocated to. Baseline outcome measures and characteristics were not reported. Knowledge of allocated intervention was not prevented, however, outcomes were objective. **Other comments** The number of people taking leaflets and receiving advice was not reported – this has been calculated by the NICE technical team but assumes that users did not take more than 1 leaflet (either in the same visit or at a subsequent visit).				

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Meijer et al. 2005
Quality score
-
Study type
Randomised controlled trial

Location and setting
Community pharmacies in the Netherlands
Aims
To evaluate the effect of information on folic acid on women's knowledge and attitudes, in particular among those planning a pregnancy
Length of follow up
6 months
Source of funding
Scientific Institute Dutch</td>
<td>Health area
Folic acid supplementation
Number of participants
n=845 participants
7 pharmacies (4 assigned to intervention, 3 to control)

Participant characteristics
<table>
<tr><th></th><th>Intervention (n=579)</th><th>Control (n=266)</th></tr>
<tr><td>Age</td><td>33.2 years (SD 3.40), range 27 to 39</td><td>32.6 (SD 3.51), range 22 to 39</td></tr>
<tr><td>Nulligravida</td><td>133 (36.5%)</td><td>88 (53.7%)</td></tr>
<tr><td>Received sticker on contraceptives</td><td>272 (74.7%)</td><td>20 (12.2%)</td></tr>
<tr><td>Received leaflet as part of intervention</td><td>176 (48.4%)</td><td>11 (6.7%)</td></tr>
</table>
Statistically significant differences in age (p=0.02), nulligravida status (p<0.01), received intervention – stickers (p<0.01) and received intervention – leaflets (p<0.01).
Inclusion criteria
Not reported
Exclusion criteria
Not reported</td>
<td>Intervention
Stickers about folic acid were added to boxes of oral contraceptives dispensed to participants. The stickers said "Are you planning to have a baby? Ask for information about folic acid in pregnancy."

Pharmacies were also asked to give a leaflet about folic acid at least once to every woman with a prescription for oral contraceptives during the intervention period.

Comparator
Usual care.</td>
<td>Recruitment:
February 2002 to July 2002
6 months after the intervention, a random sample of women who had received an oral contraceptive during the study period received a postal questionnaire from their pharmacist. Sampling was done from lists of dispensed prescriptions using a random number table. After 2 weeks, reminders were sent to non-responders.

Analysis:
Chi squared tests</td>
<td>880 questionnaires were sent out but 35 were returned because the woman was no longer traceable at that address. Response rates were 364/579 (62.9%) in the intervention group and 164/266 (61.7%) in the control group. The number of missing responses is not reported, but said to be 'few'.
Comparison of Knowledge and Intention for Intervention and control groups*
<table>
<tr><th></th><th>Intervention (n=364)</th><th>Control (n=164)</th><th>Chi-square test</th></tr>
<tr><td>Knowledge – prevents neural tube defect</td><td>175 (48.1%)</td><td>61 (37.2%)</td><td>X2 = 5.42 p=0.02</td></tr>
<tr><td>Knowledge – correct time period</td><td>68 (18.7%)</td><td>21 (12.8%)</td><td>X2 = 2.79 0.09</td></tr>
<tr><td>Knowledge – start before pregnancy</td><td>254 (69.8%)</td><td>96 (58.5%)</td><td>X2 = 6.40 0.01</td></tr>
<tr><td>Would recommend folic acid to other women</td><td>230 (63.2%)</td><td>82 (50.0%)</td><td>X2 = 8.13 P<0.001</td></tr>
</table>
Null gravidae and women with previous pregnancy women who were pregnant or intending to become pregnant behaviour and intention*
<table>
<tr><th></th><th>Intervention (n=44)</th><th>Control (n=28)</th><th>Chi-square test</th></tr>
<tr><td>Currently using folic acid</td><td>23 (6.3%)</td><td>8 (4.9%)</td><td>X2 = 3.92 P=0.048</td></tr>
<tr><td>Intending to start using folic acid</td><td>9 (2.5%)</td><td>7 (4.3%)</td><td>X2 = 0.20 P=0.65</td></tr>
</table>
Participants did not specify whether the leaflet that was the source of knowledge was part of the intervention or another leaflet provided by the pharmacy (or other healthcare professional).
*Summary findings calculated by NICE technical team using Excel and online chi-statistics calculator (http://www.socscistatistics.com/tests/chisquare/Default2.aspx.)</td>
</tr>
</table>

Pharmacists (WINAp) provided financial support				
Limitations identified by authors Pilot study – may have been underpowered to detect differences between subgroups All women in intervention group should have received a leaflet as well as the sticker, but only about half said they received a leaflet. Some participants in control group reported receiving a sticker and/or leaflet. No information available on non-responders to questionnaire. **Limitations identified by review team** It is unclear whether allocation was concealed and how missing data were accounted for. Outcomes were not measured at baseline. There were statistically significant differences in baseline characteristics between the groups (age and null gravida status). There was evidence of contamination – some participants in the control group reported receiving the intervention. **Other comments** It is clear from the data that are reported that some women received information from sources other than the intervention of interest.				

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Sharma S, Anderson C. The impact of using pharmacy window space for health promotion about emergency contraception. Health Education Journal. 1998 Mar 1;57(1):42-50.
Quality score
-
Study type
Before and after

Location and setting
Ealing, Hammersmith and Hounslow Health Authority; major chain pharmacy branches and independent pharmacies
Aims
To evaluate the impact of</td>
<td>Health area
Sexual health

Number of participants
20 participating pharmacies
15 pharmacies participated in collecting customer surveys.
13 pharmacies completed the leaflet evaluation
15 pharmacies participated in the log book evaluation
160 participants completed customer surveys

Participant characteristics
4 pharmacists employed by major multiple branch pharmacies; 16 were independent pharmacists.
The majority of the 160 survey respondents were in the age group 12-25yrs</td>
<td>Intervention
Display of literature on boards, either in a window display (16/20) or within the pharmacy (4/20).
Display material included credit-style cards containing information from the Health Authority including family planning clinic addresses, the Health Education Authority poster on emergency contraception and other messages as detailed below:

“Morning After the Night Before

Did you know that:
- If you have had unprotected sex
- If you think your contraception failed

You have:
- Up to 72 hours to use emergency pills (sometimes called the morning after pill)
- Up to 5 days to be fitted with an IUD (sometimes called the coil)
- You can get emergency contraception from any GP who provides contraceptive</td>
<td>Data collection
Data collected for 2 weeks before, during the 4 week campaign and 2 weeks after the campaign. Pharmacists collected data in a log book with a simple tick-box system, recording the numbers of enquires received about sexual health

Data was collected on the number of leaflets picked up</td>
<td>Number of leaflets taken:
<table>
<tr><th>Title of leaflet</th><th>Before campaign, n (%)</th><th>During campaign, n (%)</th><th>After campaign, n (%)</th></tr>
<tr><td>Your guide to safer sex and the condom</td><td>9 (7)</td><td>67 (53)</td><td>51 (40)</td></tr>
<tr><td>Choosing & using your method of family planning: diaphragm and caps</td><td>19 (13)</td><td>53 (36)</td><td>75 (51)</td></tr>
<tr><td>Contraception after childbirth</td><td>3 (2)</td><td>62 (47)</td><td>66 (51)</td></tr>
<tr><td>Choosing & using your method of family planning: natural methods</td><td>11 (8)</td><td>45 (34)</td><td>78 (58)</td></tr>
<tr><td>Emergency contraception</td><td>20 (9)</td><td>98 (47)</td><td>93 (44)</td></tr>
<tr><td>Choosing & using your method of family planning: male and female condoms</td><td>3 (3)</td><td>29 (30)</td><td>64 (67)</td></tr>
<tr><td>A guide to family planning services: choosing a service to meet your needs</td><td>0</td><td>43 (49)</td><td>44 (51)</td></tr>
<tr><td>Your guide to contraception</td><td>8 (5)</td><td>78 (45)</td><td>88 (50)</td></tr>
<tr><td>Condoms, pills and other useful things: a young person’s guide to contraception and STDs</td><td>15 (12)</td><td>56 (46)</td><td>51 (42)</td></tr>
<tr><td>*TOTAL - all leaflets</td><td>88</td><td>531</td><td>610</td></tr>
<tr><td>*Mean leaflets/week</td><td>44</td><td>133</td><td>305</td></tr>
</table>
<table>
<tr><th>Time period</th><th>Mean difference leaflets/week</th></tr>
<tr><td>Before vs after campaign</td><td>261.0</td></tr>
<tr><td>Before vs during campaign</td><td>88.8</td></tr>
<tr><td>During campaign vs after</td><td>172.3</td></tr>
</table>
Table calculated by NICE technical team

Number of enquires:</td>
</tr>
</table>

<table>
<tr>
<td>using pharmacy window space to educate the public about emergency contraception

Length of follow up
6 weeks (4 weeks while campaign was on-going and 2 weeks post intervention)

Source of funding
Unknown</td>
<td>Three quarters of survey respondents visited a pharmacy either more than once a week or between once a week and once a month.

The majority of respondents visited a pharmacy in relation to medicines; fewer than 10% utilise the pharmacist for health advice

Inclusion criteria
None reported
Exclusion criteria
None reported</td>
<td>services. It need not be your own GP
- You can get emergency contraception from local clinics
- Pick up a free leaflet inside or ask your pharmacist in confidence for further information

Information provided by Ealing, Hounslow and Hammersmith Health Authority and the West London Health promotion Agency”

Comparator
2 week period before the implementation of displays and 2 weeks post intervention</td>
<td>The customer survey had 10 questions and took about 5 minutes to complete.</td>
<td>
<table>
<tr><th>Enquiry</th><th>Before campaign n (%)</th><th>During campaign, n (%)</th><th>After campaign, n (%)</th></tr>
<tr><td>Emergency contraception</td><td>14 (22)</td><td>43 (67)</td><td>7 (11)</td></tr>
<tr><td>Coil</td><td>1 (11)</td><td>7 (78)</td><td>1 (11)</td></tr>
<tr><td>Contraceptive advice</td><td>3 (15)</td><td>14 (70)</td><td>3 (15)</td></tr>
<tr><td>Pregnancy</td><td>22 (26)</td><td>55 (65)</td><td>8 (9)</td></tr>
<tr><td>Abortion</td><td>0</td><td>3 (100)</td><td>0</td></tr>
<tr><td>*TOTAL – all enquiries</td><td>40</td><td>122</td><td>19</td></tr>
<tr><td>*Mean enquiries/week</td><td>20.0</td><td>30.5</td><td>9.5</td></tr>
</table>
<table>
<tr><th>Time period</th><th>Mean difference enquiries/week*</th></tr>
<tr><td>Before vs after campaign</td><td>-10.5</td></tr>
<tr><td>Before vs during campaign</td><td>+10.5</td></tr>
<tr><td>During campaign vs after</td><td>-21.0</td></tr>
</table>
Table calculated by NICE technical team
*Denotes figures calculated by NICE technical team

Acceptability
The majority of customers indicated that they considered the emergency contraception display to be good or very good.
</td>
</tr>
<tr>
<td colspan="5">Limitations identified by authors
The reliability of self-reporting in the log book evaluation may be questioned as it relies on self-reporting
Pharmacists in the study may not have logged as many enquires in the post-campaign phase, since they may not have realised the importance of logging enquiries once the display had been removed
The survey was random, however, many of the pharmacists or sales staff carrying out the survey may have approached regular customers
Limitations identified by review team
Display of health promotion leaflets within an accessible area in the pharmacies was implemented form the start of the study period – including in the 0-2 week control ‘before’ study period. The data collection focuses on whether there was an increase in enquiries for sexual health advice during the intervention study period (weeks 3-6) due to the addition of a window poster. However, the recent implementation of leaflets may have affected the actions of participants both up to and during the intervention period. The control period for number of enquires therefore may have been influenced.</td>
</tr>
</table>

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention and comparator</th><th>Methods and analysis</th><th>Results</th></tr>
<tr>
<td>Reference
Slater H, Briggs AM, Watkins K et al. (2013) Translating evidence for low back pain management into a consumer-focussed resource for use in community pharmacies: a cluster-randomised controlled trial. PLoS ONE. Vol 8 (8) e71918

Quality score
+

Study type
Randomised controlled trial
Location and setting
Community pharmacies in Perth, Australia
Aims
To determine the effectiveness of a consumer lower back pain pamphlet compared to usual pharmacy care in improving lower back pain related beliefs among community pharmacy users with lower back pain</td>
<td>Health area
Orthopaedic – lower back pain
Number of participants
317 pharmacy users from 35 pharmacies
Pamphlet only= 111 users from 11 pharmacies
Control group= 104 users from 13 pharmacies
Participant characteristics
Pharmacy characteristics:
<table>
<tr><td></td><td>Intervention 2</td><td>Control</td></tr>
<tr><td>N (%) female</td><td>72 (64.9%)</td><td>63(60.6%)</td></tr>
<tr><td colspan="3">Duration of current LBP episode (n,%)</td></tr>
<tr><td><3 months</td><td>15 (13.5%)</td><td>24 (23.1%)</td></tr>
<tr><td>≥3 months intermittently</td><td>34 (30.6%)</td><td>23 (22.1%)</td></tr>
<tr><td>≥3 months continuously</td><td>61 (55.0%)</td><td>57 (54.8%)</td></tr>
<tr><td>24 hour pain severity (0 to 10, mean, SD, range)</td><td>5.0 (2.3), 0 to 10</td><td>5.7 (2.0), 2 to 10</td></tr>
<tr><td>24 hour activity impairment (0 to 10, mean, SD, range)</td><td>4.3 (2.7), 0 to 10</td><td>4.9 (2.7), 0 to 10</td></tr>
<tr><td>Back beliefs (9 to 45, mean, SD, range)</td><td>25.7 (7.5), range 9 to 42</td><td>25.0 (6.6), range 12 to 38</td></tr>
</table>
</td>
<td>Intervention
Usual care and pamphlet with evidence-based information on low back pain, e.g. need to stay active, stay positive and stay engaged.
Key messages of the pamphlet:
- ‘there is a lot you can do yourself to manage your pain’
- ‘Most people recover fully’
- ‘stay active if possible’
- ‘moving helps reduce pain’
- ‘maintain your usual activities’
- ‘stay at work if possible’
- ‘stay positive’</td>
<td>Recruitment:
35 community pharmacies between May- Aug 2011, based on an expression of interest issued by the Pharmaceutical Society of Western Australia.

Participants recruited by:
- Those with a prescription for analgesia related to low back pain
- Requested non-prescription medication for low back pain
- Inquired about the study after seeing study posters in the pharmacy

Cluster allocation by pharmacy. All eligible users in each pharmacy were included.
Pharmacies from different socioeconomic areas were equally distributed amongst the groups.
Allocation of pharmacies concealed from Pharmaceutical Society of Western Australia and study author KW. Allocation was not concealed at individual user level.
Blinding done by 1 study author (JC) – generated random allocation sequence, enrolled clusters and assigned clusters to intervention groups.

Analysis:
Questionnaires were completed at baseline, 2 weeks post intervention and 8 weeks post intervention.
<u>Measures:</u>
Beliefs: Back Pain Beliefs Questionnaire.
Fear avoidance and beliefs and attitudes: Fear Avoidance Beliefs Questionnaire.</td>
<td>*Denotes figures calculated by NICE technical team using Review Manager 5.3
Back beliefs (higher score= more positive beliefs, range 9-45, n=206)
<table>
<tr><td>Time</td><td>Intervention</td><td>Control</td><td>*Mean difference (95% CI)</td></tr>
<tr><td>2 weeks</td><td>27.1 (6.3)</td><td>24.9 (6.6)</td><td>2.2 (0.47 to 3.93)</td></tr>
<tr><td>8 weeks</td><td>26.1 (7.0)</td><td>25.8 (6.8)</td><td>0.3 (-1.54 to 2.14)</td></tr>
</table>
Physical activity related fear (higher= higher fear avoidance beliefs, range 0-24 n=206)
<table>
<tr><td>Time</td><td>Intervention</td><td>Control</td><td>*Mean difference (95% CI)</td></tr>
<tr><td>2 weeks</td><td>13.7 (5.5)</td><td>15.0 (5.5)</td><td>-1.3 (-2.8 to 0.2)</td></tr>
<tr><td>8 weeks</td><td>13.4 (5.8)</td><td>14.8 (4.9)</td><td>-1.4 (-2.8 to 0.0)</td></tr>
</table>
Work-related fear (higher score= higher fear avoidance beliefs, range 0-42, n=203)
<table>
<tr><td>Time</td><td>Intervention</td><td>Control</td><td>*Mean difference (95% CI)</td></tr>
<tr><td>2 weeks</td><td>17.6 (11.07)</td><td>18.6 (12.2)</td><td>-1.0 (-4.1 to 2.2)</td></tr>
<tr><td>8 weeks</td><td>15.6 (11.3)</td><td>17.7 (12.8)</td><td>-2.1 (-5.3 to 1.1)</td></tr>
</table>
Pain severity (0=no pain, 10=worst pain, n=210)
<table>
<tr><td>Time</td><td>Intervention</td><td>Control</td><td>*Mean difference (95% CI)</td></tr>
</table>
</td>
</tr>
</table>

Length of follow up
8 weeks
Source of funding
Funded in part provided by the Department of Health, Government of W. Australia (including pamphlet production). In kind support from Curtin University. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Physical activity-related fear (0 to 24, mean, SD, range)	15.7 (5.3), 2 to 24	15.7 (6.1), 0 to 24
Work-related fear (0 to 42, mean, SD, range)	17.9 (11.9), 0 to 42	17.5 (12.5), 0 to 42

Inclusion criteria
For pharmacies: willingness of proprietor to be involved and staff to complete training on verbal reinforcement of pamphlet.
For users: currently experiencing low back pain; 18-65yrs; read and comprehend English
Exclusion criteria
For pharmacies: proprietor did not agree to be involved in the study
For users: none

- 'avoid prolonged bed rest'
- 'X rays or other imaging is usually not required'

Comparator
Usual care alone.

Users received the pamphlet at completion of the study.

Pain: *11 point severity scale*
Activity impairment: *11 point severity scale*

Power calculation estimated that the power of the study to detect minimal important differences in back beliefs (2 points on scale) with a minimum of 11 pharmacies in each intervention and at least 10 users in each pharmacy was 78%.

Change from baseline was estimated using paired t-tests. Linear mixed models were used to determine mean effects of intervention on beliefs, pain and activity impairment. Users with missing follow up data were included in the models.

2 weeks	4.7 (2.1)	4.3 (2.4)	0.4 (-2.1 to 2.9)
8 weeks	4.3 (2.5)	4.4 (2.5)	-0.1 (-0.8 to 0.6)

Activity impairment (0=no effect on daily living, 10=unable to perform any activities of daily living, n=210)

Time	Intervention	Control	*Mean difference (95% CI)
2 weeks	3.7 (2.1)	3.6 (2.8)	0.1 (-0.6 to 0.8)
8 weeks	3.5 (2.5)	3.7 (2.7)	-0.2 (-0.9 to 0.5)

Perceived usefulness of pamphlet (GIPU score)

	Intervention	Between group difference
2 weeks	5.3 (SD 2.1)	0.9 (-0.1 to 1.9)
8 weeks	4.9 (SD 2.5)	0.9 (-0.1 to 1.9)

Difference between groups pooled over time= 0.9 (95% CI 0 to 1.8)

Limitations identified by authors
Selection bias may have occurred as pharmacies and users were self-selected. Not all pharmacies in Perth are members of the PSWA.
Non-responding members were significantly younger – may affect generalisability of the results to the younger population.
Data were based on self-report measures.
Substantial proportion (33.8%) did not respond to 2 week or 8 week follow up, but the proportion was similar across the three groups.
Limitations identified by review team
Criteria to establish low back pain were not used – authors considered this would have been a barrier to implementation.
Pharmacies and users were not blinded to intervention.
No specific measure of fidelity for pharmacist-delivered interventions was used, but staff were trained on which key messages to reinforce.
Missing follow-up data was included in analysis, but not stated how this was included.
Other comments

Competing interests: one of the authors is a proprietor of a community pharmacy that was recruited to the trial, but they were not actively involved in data collection or analysis. Pharmacies were paid $AUD10 for each participant recruited into the trial. Proportion of non-responders was similar across groups (32.9% for pamphlet plus education, 39.3% pamphlet only, 29.9% control). No significant differences between responders and non-responders at baseline except age (non-responders were significantly younger than responders [39.8 years vs. 46.5 years]).

Appendix Dii – Acceptability evidence table

<table>
<tr><th>Study details</th><th>Research Parameters</th><th>Inclusion/ Exclusion criteria</th><th>Population</th><th>Results</th></tr>
<tr>
<td>Author name and year
Saramunee et al. 2016

Quality score
+

Study type
Cross-sectional survey

Aim of the study
To identify attitudes towards pharmacy characteristics and promotional methods for selected pharmacy public health services (lifestyle advice and screening for cardiovascular risk factors) among different sectors of the general public.

Location and setting
15 areas of England

Source of funding
This study was financially support by School of Pharmacy and Biomedical</td>
<td>Intervention
Focused on services related to CVD risk factors: smoking cessation, sensible drinking, losing weight, heart health advice, blood pressure, blood sugar, and cholesterol checks. Data collection was not in relation to a particular intervention but for CVD services provided by pharmacies in general.

Data collection
Instrument was developed iteratively by research team, based on previous qualitative work with members of the public. Development included testing the instrument for face validity to evaluate content and understanding with 10 non-pharmacist volunteers. Further piloting was conducted to test content validity and instrument reliability in 2 ways: using interviewer-assisted and self-completion with 100</td>
<td>Members of the general public aged 18 years or older were included.

Anyone working as a healthcare professional was excluded.</td>
<td>2661 responses were available for analysis – 1946 face to face, 301 telephone and 407 paper questionnaires. Estimated response rates were 18.7% face to face, 25.1% telephone and 18.3% paper. However, only 219 comments were received in response to the free-text questions and it's not clear which methods of demographic characteristics were in this group.

<table>
<tr><th></th><th>Study data</th><th>National data</th></tr>
<tr><td>Female</td><td>57.04%</td><td>50.7%</td></tr>
<tr><td><25 years</td><td>24.2%</td><td>11.7%</td></tr>
<tr><td>25 to 34 years</td><td>11.7%</td><td>17.5%</td></tr>
<tr><td>35 to 44 years</td><td>11.3%</td><td>16.7%</td></tr>
<tr><td>45 to 54 years</td><td>13.6%</td><td>18.0%</td></tr>
<tr><td>55 to 64 years</td><td>16.9%</td><td>14.3%</td></tr>
<tr><td>65+ years</td><td>22.0%</td><td>21.8%</td></tr>
<tr><td>White</td><td>84.5%</td><td>86.0%</td></tr>
<tr><td>Asian</td><td>7.4%</td><td>7.5%</td></tr>
<tr><td>Black</td><td>4.1%</td><td>3.3%</td></tr>
<tr><td>Mixed</td><td>2.1%</td><td>2.2%</td></tr>
<tr><td>Chinese</td><td>1.1%</td><td>NR</td></tr>
<tr><td>Other</td><td>0.7%</td><td>1.0%</td></tr>
<tr><td>School educated</td><td>30.3%</td><td>55.4%</td></tr>
<tr><td>Further education</td><td>27.3%</td><td>12.5%</td></tr>
</table>
</td>
<td>Questionnaire included rating agreement with statements, the results of which are not reported here. It elicited additional comments on promotional techniques perceived as likely to succeed through an open question, the results of which are reported here.

Results from 219 comments reported here.

66 (30%) of comments were in favour of promotion generally, or increasing promotion, of public health services

33 (15%) provided comments on method of promotion – 12 indicated word of mouth was preferred method. Several expressed views on the need for doctors to support pharmacy services. Other suggestions included posters in public places and using social media. Seventeen (8%) concerned promotional material content, including prices, opening hours/rotas need or being up to date, and promoting the pharmacist's availability.

45 (12%) of comments were against promotion of pharmacy services, expressing concerns about the costs of such activities that promotion was unprofessional or intrusive with no guarantee of quality. Others expressed the need for caution in the way services are promoted, including potential for conflict with doctors and the need for regulation and constraint. 18 (8%) comments indicated other factors were more influential, in particular convenience, recommendations from doctors or quality of services.

Need for increased promotion
"Only know of smoking cessation from a friend, don't know what else is offered" (white male, 55 to 64 years old, college education, not working, infrequent pharmacy user)

"I do not feel the pharmacy services are advertised at all – I didn't realise until recently just what they can offer – I have recently found their services a huge help…a relief as I didn't have to visit a doctor" (white female, 35 to 44 years old, college educated, working full-time, frequent pharmacy user)

Disagree with promoting services</td>
</tr>
</table>

<table>
<tr><th>Study details</th><th>Research Parameters</th><th>Inclusion/ Exclusion criteria</th><th>Population</th><th>Results</th></tr>
<tr>
<td>Sciences, Liverpool John Moors University and Medway School of Pharmacy, The Universities of Greenwich and Kent at Medway.</td>
<td>members of the public recruited in a city centre location and cognitive interview with 15 further members of the public.

Questionnaire included rating agreement with statements, the results of which are not reported here. It elicited additional comments on promotional techniques perceived as likely to succeed through an open question, the results of which are reported here.

Data collection took place in multiple locations throughout England during 2011 and 2012 using various recruitment methods to maximise diversity of the sample, including face to face interviews, telephone interviews and self-completion of the questionnaire.

Method of analysis
Free-text comments were analysed by developing categories using a constant comparison approach</td>
<td></td>
<td>
<table>
<tr><td>University</td><td>40.1%</td><td>14.5%</td></tr>
<tr><td>None</td><td>2.3%</td><td>15.5%</td></tr>
<tr><td>Employed</td><td>50.1%</td><td>74.1%</td></tr>
<tr><td>Retired</td><td>27.3%</td><td>NR</td></tr>
<tr><td>Not working</td><td>22.5%</td><td>NR</td></tr>
<tr><td>Deprivation status 1 (highest)</td><td>32.2%</td><td>19.9%</td></tr>
<tr><td>Deprivation status 2</td><td>18.4%</td><td>19.9%</td></tr>
<tr><td>Deprivation status 3</td><td>21.0%</td><td>20.0%</td></tr>
<tr><td>Deprivation status 4</td><td>17.8%</td><td>20.0%</td></tr>
<tr><td>Deprivation status 5 (lowest)</td><td>10.5%</td><td>20.1%</td></tr>
</table>

Authors state that sample may have been over representative of people aged 25 years and younger and those of university level education.

<table>
<tr><td>Frequency of pharmacy use</td><td>% of responders</td></tr>
<tr><td>Once a week</td><td>7.9</td></tr>
<tr><td>Once a fortnight</td><td>10.2</td></tr>
<tr><td>Once a month</td><td>30.7</td></tr>
<tr><td>Once every 2 to 3 months</td><td>25.1</td></tr>
<tr><td>Once every 6 months</td><td>16.4</td></tr>
<tr><td>Never/less than 6 monthly</td><td>8.5</td></tr>
<tr><td>Not sure</td><td>1.2</td></tr>
</table>
</td>
<td>“I don’t believe healthcare should be advertised in a manner which would be more appropriate for soap powder” (white male, 55 to 64 years told, university education, working part-time, frequent pharmacy user)

“I feel advertisements do not necessarily guarantee quality of services” (white female, 35 to 44 years old, university educated, working full-time, infrequent pharmacy user)

Important factors to consider –
“Good pharmacist will have more influence than any advertising” (white male, 55 to 64 years old, school educated, not working, frequent pharmacy user)

“So long as the service being advertised is for the sole benefit of the user and not to boost trade.” (white female, 55 to 64 years old, university educated, working full-time, infrequent pharmacy user)

*These are the only quotes reported in the paper</td>
</tr>
</table>

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
	then assigning each to a category.			
Limitations identified by author Young people and those with a degree were slightly over represented. Proportion of infrequent pharmacy users lower in this study than previous studies, suggesting possible bias towards people that use pharmacies. Non-respondent bias is of concern. Interviewer assisted approaches may be further concern. **Limitations identified by review team** The characteristics of the participants providing free-text comments were not reported separately. Authors do not report how many researchers were involved in analysing and interpreting the free-text comments.				

Appendix E – Forest plots

No forest plots were created for this review.

Appendix F – GRADE tables

GRADE profile 1: Outcome: Action

Quality assessment										
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**No. of participants**	**Effect**	**Quality**	**Outcome rating**
Folic Acid- % women currently using folic acid at 6 month follow-up [ES1.1]										
1[1]	Randomised controlled trial	Very serious[a]	Not applicable	No serious	No serious	No	72	6.3% vs. 4.3% X^2= 3.92, p=0.048 Favours intervention	Low	Critical

1 Meijer 2005

a. Downgraded 2 levels as study may have been underpowered, contamination occurred, allocation concealment unclear

GRADE profile 2: Outcome: Awareness

No evidence identified [ES 1.2].

GRADE profile 3: Outcome: Knowledge

Quality assessment										
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**No. of participants**	**Effect**	**Quality**	**Outcome rating**
Back knowledge (higher score indicating more positive beliefs; score range 9-45)										
Pamphlet only vs control (2 weeks post-intervention) [ES 1.3]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	No serious	Very serious[b]	No[c]	215	Mean difference of 2.2 (0.47 to 3.93) p value not reported	Very low	Important
Pamphlet only vs control (8 weeks post-intervention) [ES 1.3]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	No serious	Serious[d]	No[c]	215	Mean difference of 0.3 (-1.54 to 2.14) p value not reported	Low	Important
Folic Acid knowledge										
Folic acid prevents neural tube defect (% women answering correctly) at 6 months follow-up [ES1.4]										
1[2]	Randomised controlled trial	Very serious[e]	Not applicable	No serious	No serious	No	528	48.1% vs. 37.2% X^2= 5.42, p=0.02 Favours intervention	Low	Important

Correct period of use for taking folic acid (% women answering correctly) at 6 months follow-up [ES1.4]										
1[2]	Randomised controlled trial	Very serious[e]	Not applicable	No serious	No serious	No	528	18.7% vs. 12.8% X^2= 2.79, p=0.09	Low	Important
Know to start taking folic acid before pregnancy acid (% women answering correctly) at 6 months follow-up [ES1.4]										
1[2]	Randomised controlled trial	Very serious[e]	Not applicable	No serious	No serious	No	528	69.8% vs. 58.5% X^2= 6.40, p=0.01 Favours intervention	Low	Important

1 Slater 2013
2. Meijer 2005

a. Downgraded by 1 level as outcomes are assessed by non-blinded pharmacy users, using self-reported measures which are subjective with no objective validation of the self-reported measures performed.
b. Downgraded 2 levels as confidence intervals cross the minimal important difference (0.5*SD of control group at baseline) and total sample size is less than 400.
c. Confidence interval calculated by NICE technical team, assuming that the number of participants at baseline is equal to the number of participants included in the follow-up analysis; this may be an over-estimation of the number of participants and thus confidence intervals may be wider than reported here. However, the quality rating has not been downgraded based on this.
d. Downgraded 1 level as total sample size is less than 400.
e. Downgraded 2 levels as study may have been underpowered, contamination occurred, allocation concealment unclear

GRADE profile 4: Outcome: Attitudes

Quality assessment										
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**No. of participants**	**Effect**	**Quality**	**Outcome rating**
Physical activity related fear (higher score indicating higher fear avoidance beliefs; score range 0-24)										
Pamphlet only vs control (2 weeks post-intervention) [ES 1.5]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[b]	Serious[c]	No[d]	215	Mean difference of -1.3 (-2.8 to 0.2) p value not reported	VERY LOW	Important
Pamphlet only vs control (8 weeks post-intervention) [ES 1.5]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[b]	Serious[c]	No[d]	215	Mean difference of -1.4 (-2.8 to 0.0) p value not reported	VERY LOW	Important
Work-related fear (higher score indicating higher fear avoidance beliefs; score range 0-42)										
Pamphlet only vs control (2 weeks post-intervention) [ES 1.6]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[e]	Serious[c]	No[d]	215	Mean difference of -1.0 (-4.1 to 2.2) p value not reported	VERY LOW	Important
Pamphlet only vs control (8 weeks post-intervention) [ES 1.6]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[e]	Serious[c]	No[d]	215	Mean difference of -2.1 (-5.3 to 1.1) p value not reported	VERY LOW	Important
Folic acid (% women who would recommend folic acid to other women) at 6 months follow-up [ES1.7]										
1[2]	Randomised controlled trial	Very serious[f]	Not applicable	No serious	No serious	No	528	X^2= 8.13, p<0.001 Favours intervention	Low	Important

1 Slater 2013

2. Meijer 2005

a. Downgraded 1 level as outcomes are assessed by non-blinded pharmacy users, using self-reported measures which are subjective, with no objective validation of the self-reported measures performed.

b. Downgraded 1 level as physical activity related fear does not have any clear link to an outcome specified in the review protocol, although most closely represents an attitude.

c. Downgraded 1 level as the total sample size is less than 400.

d. Confidence interval calculated by NICE technical team, assuming that the number of participants at baseline is equal to the number of participants included in the follow-up analysis; this may be an over-estimation of the number of participants and thus confidence intervals may be wider than reported here. However, the quality rating has not been downgraded based on this.

e. Downgraded by 1 level as work-related fear does not have any clear link to an outcome specified in the review protocol, although most closely represents an attitude.

f. Downgraded 2 levels as study may have been underpowered, contamination occurred, allocation concealment unclear

GRADE profile 5: Outcome: Intention

Quality assessment										
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**No. of participants**	**Effect**	**Quality**	**Importance of outcome**
Leaflet uptake/week										
Baseline vs post-intervention [ES 1.8]										
1[1]	Before and after	Serious[a]	Not applicable	No serious	Serious[b]	No	847	Mean difference of 29 more leaflets per week post-intervention p value not reported	VERY LOW	Important
1[2]	Before and after	Very serious[d]	Not applicable	No serious	Serious[b]	No[c]	698	Mean difference of 261 more leaflets per week post-intervention p value not reported	VERY LOW	Important
Baseline vs during intervention [ES 1.8]										
1[2]	Before and after	Very serious[d]	Not applicable	No serious	Serious[b]	No[c]	619	Mean difference of 89 more leaflets per week during intervention p value not reported	VERY LOW	Important
During intervention vs post-intervention [ES 1.8]										
1[2]	Before and after	Very serious[d]	Not applicable	No serious	Serious[b]	No[c]	1141	Mean difference of 173 more leaflets per week post-intervention p value not reported	VERY LOW	Important
Leaflet uptake/month										
Leaflet display vs targeting (without offer of advice) [ES 1.9]										
1[3]	Non-randomised controlled trial	Serious[e]	Not applicable	Serious[f]	Very serious[g]	No[c]	147	Mean difference of 3 leaflets per month favouring targeting p value not reported	VERY LOW	Important
Leaflet display vs targeting (with offer of advice) [ES 1.9]										
1[3]	Non-randomised controlled trial	Serious[e]	Not applicable	Serious[f]	Very serious[g]	No[c]	235	Mean difference of 41 leaflets per month favouring targeting p value not reported	VERY LOW	Important
Health promotion enquires/day										
Baseline vs post-intervention [ES 1.10]										
1[1]	Before and after	Very serious[i]	Not applicable	No serious	Serious[b]	No	847	Mean difference of 1 increase in enquiries per day post-intervention p value not reported	VERY LOW	Important
Health promotion enquires/week										

Baseline vs post-intervention [ES 1.10]										
1[2]	Before and after	Very serious[d]	Not applicable	No serious	Very serious[g]	No[c]	59	Mean difference of 11 fewer enquiries/week post-intervention p value not reported	VERY LOW	Important
Baseline vs during intervention [ES 1.10]										
1[2]	Before and after	Very serious[d]	Not applicable	No serious	Very serious[g]	No[c]	162	Mean difference of 11 more enquiries/week during intervention p value not reported	VERY LOW	Important
During intervention vs post-intervention [ES 1.10]										
1[2]	Before and after	Very serious[d]	Not applicable	No serious	Very serious[g]	No[c]	141	Mean difference of 21 fewer enquiries/week post-intervention p value not reported	VERY LOW	Important
Number of people making health promotion enquires/month										
Leaflet display vs targeting (without offer of advice) [ES 1.11]										
1[3]	Non-randomised controlled trial	Serious[e]	Not applicable	No serious	Very serious[h]	No[c]	147	21% difference, favouring targeting (0% vs 21%)	VERY LOW	Important
Leaflet display vs targeting (with offer of advice) [ES 1.11]										
1[3]	Non-randomised controlled trial	Serious[e]	Not applicable	No serious	Very serious[j]	No[c]	235	1% difference, favouring display (20% vs 19%; RR 0.96 [0.57 to 1.64])	VERY LOW	Important
Folic Acid- % women intending to start using folic acid at 6 month follow-up [ES1.12]										
1[2]	Randomised controlled trial	Very serious[k]	Not applicable	No serious	No serious	No	72	X^2= 0.20, p=0.65 Favours intervention	Low	Important

1 Hariri 2000
2 Sharma 1998
3 Lloyd-Williams 2003
4. Meijer 2005

a. Downgraded 1 level. There was a large number of withdrawals, with 31% of those starting the intervention completing it and an unknown percentage of total pharmacy users starting the intervention; there is no assessment of the validity or reliability of the data collection tool.
b. Downgraded 1 level as it is not possible to calculate imprecision from the information reported in the study.
c. Number of participants estimated from number of leaflets picked up or enquiries made during relevant data collection period or in relevant study arm, as the number of participants is unknown. However, the quality rating has not been downgraded based on this.
d. Downgraded 2 levels. Data collection shows potential bias as pharmacist self-reported outcomes used with a high risk of misreporting; there is no characteristics data presented, therefore unable to ascertain if there is a bias coming from differences between before and after group demographic; cannot ascertain how many individuals were exposed to the intervention.
e. Downgraded 1 level as pharmacy allocation was not randomised and chosen by researchers based on available resources in each pharmacy.
f. Downgraded 1 level as leaflet uptake is considered an intention to change behaviour, however this is more likely to be representative of intention in leaflet display groups than targeted leaflet groups.

g. Downgraded 2 levels as it is not possible to calculate imprecision from the information reported in the study and the total sample size is less than 400.
h. Downgraded 2 levels as it is not possible to calculate imprecision from the information reported in the study and the number of events is less than 300.
i. Downgraded 2 levels. Method of data collection relies on pharmacist self-report with no effort to validate this method; data collection was not recorded for everyday of the study period; there was a high proportion of withdrawals from the intervention (69%)
j. Downgraded 2 levels as confidence intervals cross the minimally important difference (0.75 and 1.25) and number of events is less than 300.
k. Downgraded 2 levels as study may have been underpowered, contamination occurred, allocation concealment unclear

GRADE profile 6: Outcome: Clinical measurements

Quality assessment								Effect	Quality	Outcome rating
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No. of participants			
Pain (scored 0 ['no pain'] to 10 ['worst pain])										
Pamphlet only vs control (2 weeks post-intervention) [ES 1.13]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[b]	Very serious[c]	No[d]	215	Mean difference of 0.4 (-2.1 to 2.9) p value not reported	VERY LOW	Less important
Pamphlet only vs control (8 weeks post-intervention) [ES 1.13]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[b]	Serious[e]	No[d]	215	Mean difference of -0.1 (-0.8 to 0.6) p value not reported	VERY LOW	Less important
Activity impairment (scored 0 ['no effect on activities of daily living'] to 10 ['unable to perform any activities of daily living'])										
Pamphlet only vs control (2 weeks post-intervention) [ES 1.14]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[b]	Serious[e]	No[d]	215	Mean difference of 0.1 (-0.6 to 0.8) p value not reported	VERY LOW	Less important
Pamphlet only vs control (8 weeks post-intervention) [ES 1.14]										
1[1]	Randomised controlled trial	Serious[a]	Not applicable	Serious[b]	Serious[e]	No[d]	215	Mean difference of -0.2 (-0.9 to 0.5) p value not reported	VERY LOW	Less important

1 Slater 2013

a. Downgraded 1 level as outcomes are assessed by non-blinded pharmacy users, using self-reported measures which are subjective, with no objective validation of the self-reported measures performed.
b. Downgraded 1 level as clinical outcomes do not show a clear link between provision of information and an outcome and are thus not included as an outcome of interest in the review protocol
c. Downgraded 2 levels as the confidence interval crosses the minimally important difference (0.5*SD of control group at baseline) and the total sample size is less than 400.
d. Confidence interval calculated by NICE technical team, assuming that the number of participants at baseline is equal to the number of participants included in the follow-up analysis; this may be an over-estimation of the number of participants and thus confidence intervals may be wider than reported here. However, the quality rating has not been downgraded based on this.
e. Downgraded 1 level as the total sample size is less than 400.

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.

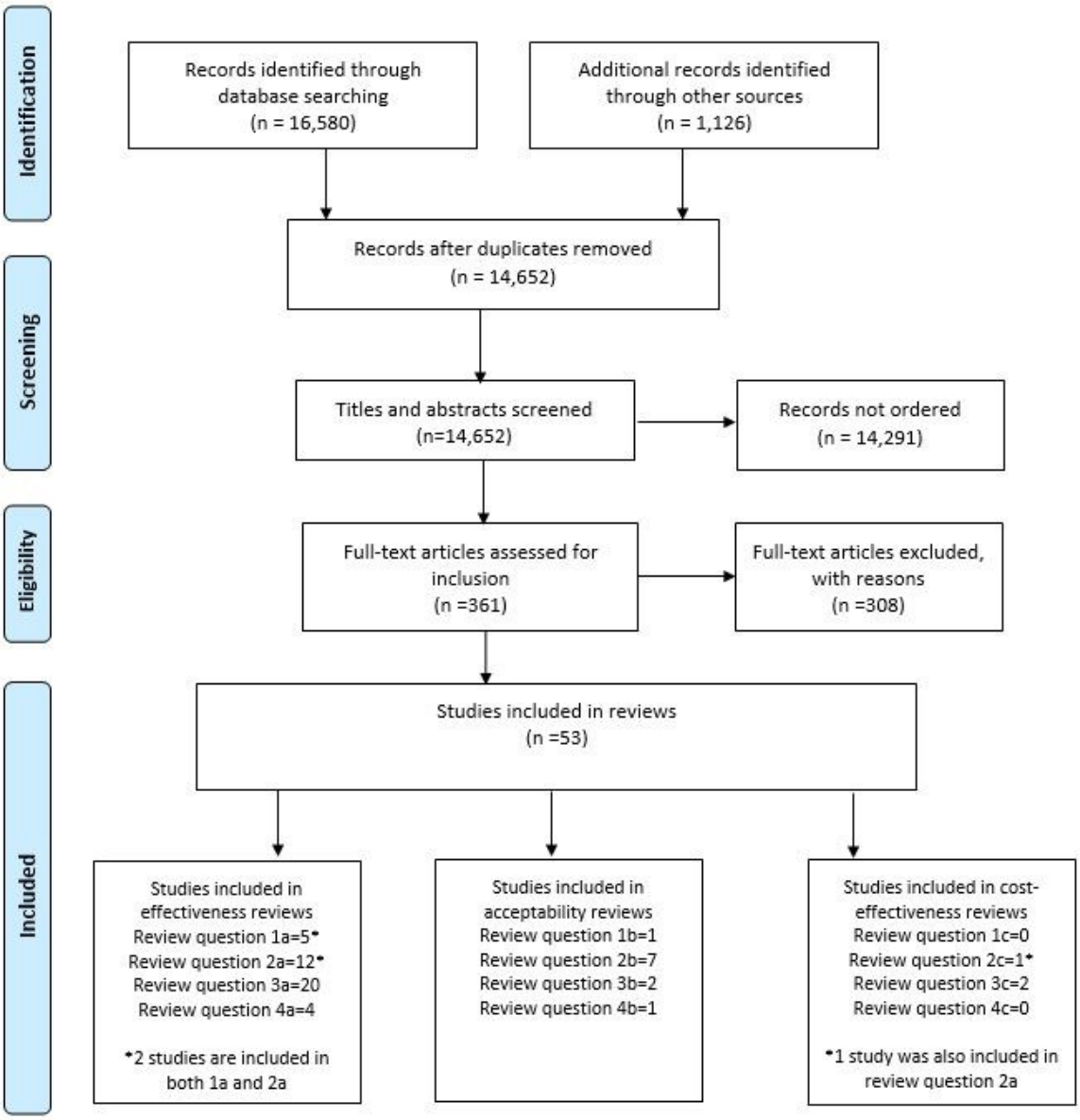
Appendix L – Research recommendations

No research recommendations were formed from this review

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). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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