National Institute for Health and Care Excellence

Community pharmacy: Promoting health and wellbeing

Evidence reviews for offering advice or education to promote health and wellbeing

NICE guideline NG102

Evidence review 2

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Final

These evidence reviews were developed by the Public Health Internal Guidelines Team

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Introduction

This review aims to determine which interventions are effective and cost-effective for offering advice or education to promote health and wellbeing in community pharmacy and whether providing information is acceptable to users of community pharmacy.

This review focuses on the effectiveness, acceptability and cost-effectiveness of advice or education that is tailored to an individual, rather than information that is provided to a group of users of community pharmacy services.

The review aims to explore whether effectiveness and cost-effectiveness varies by the characteristics of the intervention, the person delivering the intervention, or the person receiving the intervention. It will also explore how interventions could be made more acceptable to users of community pharmacy services.

Community pharmacies are able to 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. 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).

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 inclusion criteria for offering advice or education to promote health and wellbeing in community pharmacies (RQ2)

	Criteria
Population	Studies of people accessing or using community pharmacy services
Intervention	Any intervention delivered by community pharmacy staff that offers advice or education to promote health and wellbeing, including: • Brief advice • Very brief advice • Face to face advice • Face to face education • Tailored SMS messaging

	Criteria		
	• Any other form of advice or education that is tailored to an individual		
Comparators	• No intervention. • Any intervention provided by community pharmacy staff that provides information. • Any other intervention provided by community pharmacy staff that offers advice or education to promote health and wellbeing		
Outcomes	• Clinical measurements or health outcomes • Behavioural outcomes ○ Action • Modifying factors or determinants of behaviour ○ Intention ○ Attitudes ○ Knowledge ○ Awareness • Wellbeing • Quality of life	• Preference and experience of people using the service • Qualitative element of quality of life	• Costs, savings and 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 or quasi-experimental studies such as non-randomised controlled trials or before-after studies
- Systematic reviews of studies of effectiveness where the review question matched the review question were also included. 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.
- Were conducted in the UK, Australia, Canada, Republic of Ireland, the European Union (including Norway and Switzerland), Chile and New Zealand.
- Published between 1990 and 2016
- Published in English language

The health areas of interests included: alcohol use, cancer awareness, prevention of cardiovascular disease, diabetes, substance misuse or falls, mental health and wellbeing, orthopaedic conditions, sexual health, smoking and smokeless tobacco or weight management.

Excluded studies

Papers were excluded if they:

- Were non-systematic literature reviews, case-control or cross-sectional studies, quantitative surveys, study protocols, opinion pieces, commentaries, editorials or letters.
- Assessed the effectiveness of screening, health checks or testing as recommendations on screening are made by the National Screening Committee.
- Were studies on vaccination.

- Did not include comparative data, that is to say, 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.
- Only included interventions delivered by distance-selling (online) pharmacies.

  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 12 primary studies of effectiveness were included in review 2 (Table 2).

Table 2 Summary of included effectiveness primary studies for offering advice or education to promote health and wellbeing in community pharmacies (RQ2a)

First author, year	Setting and Country	Intervention	Health area	Outcome
Burford et al. 2013	Community pharmacies Perth, Western Australia	Age progression photography, with and without hypothetical smoking cessation	Smoking cessation	- Smoking cessation - Fagerström score
Guirguis et al. 2001	Community pharmacies Edmonton, Canada	Diabetes Education delivered by pharmacist with specialist certification in this area	Diabetes	- Diet - Exercise - Quality of Life
Kritikos et al. 2005	High schools Orange, Australia[a]	Pharmacists (working in pairs) led education based on awareness, empowerment, and social learning	Asthma	Asthma knowledge
Lloyd-Williams 2003	Community pharmacies Staffordshire, UK	Leaflets with pharmacists offering to provide advice	Heartburn and indigestion	Advice seeking
Mehuys et al 2011	Community pharmacies Belgium	Advice and education during medication refills	Diabetes	Diabetes knowledge Diet Physical activity Foot care Smoking

First author, year	Setting and Country	Intervention	Health area	Outcome
Petkova et al 2006	Community pharmacies Bulgaria	5 intensive education sessions	Diabetes	Blood glucose Hypo/ Hyperglycaemia Quality of Life
Saini et al. 2004	Community pharmacies Australia	Six step asthma care model including: patient appointments, needs analysis, individually tailored interventions, goal setting, collaborating with other healthcare practitioners and monitoring at 1, 3 and 6 months post intervention	Asthma	Asthma knowledge
Saini et al. 2011	Community pharmacies Australia	3-4 pharmacy visits over 6 months to assess educational needs. Targeted information on asthma triggers (e.g. smoking) and counselling on trigger factors provided	Asthma	Asthma knowledge
Sarkadi et al 2004	Community pharmacies Sweden	12 month group education	Diabetes	Blood glucose level
Skrowron 2011	Community pharmacies Poland	12 sessions of education along with pharmacotherapy monitoring, detecting and solving drug related problems	Hypertension	Hypertension knowledge Arterial blood pressure
Slater et al. 2013	Community pharmacies Perth, Australia	Group 1: Information pamphlet on low back pain (LBP) and verbal reinforcement on pamphlet content Group 2: Pamphlet only	Orthopaedic conditions	- Back-pain belief - Physical activity related fear - Work related fear - Pain - Activity impairment - Usefulness of education
Watman et al. 2002	GP practice London, UK	Health screening interview with advice on nutrition and	Cardiovascular disease	- Number of cigarettes/ cigars smoked

First author, year	Setting and Country	Intervention	Health area	Outcome
		well-being by community pharmacy.		

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 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

Quality domain	Description
	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.

GRADE rating	Description
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 quality of the evidence from the effectiveness studies ranged from very low to moderate in quality, with the majority very low. This is because the studies had either serious or very serious risk or bias and imprecision in measurement of outcome, and there was uncertainty about the cases included for some of the analysis (**Error! Reference source not found.**).

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 (Priority)		Quality of evidence
Clinical measurements or health outcomes (Critical)	Fagerström score Activity impairment Asthma severity Pain severity Blood glucose level Hypo-/ hyperglycaemia Medication use Arterial blood pressure	Low to Very low Very low Very low Very low Very low Very low Low Low
Action (Critical)	Smoking cessation Diet Exercise Foot care	Moderate to Very low Moderate & Very low Moderate & Very low Moderate
Intention (Important)	Advice seeking	Very low
Attitudes (Important)	Back pain belief Physical activity belief Work related fears	Very low Very low Very low
Knowledge (Important)	Asthma knowledge Diabetes knowledge	Very low Moderate to low
Awareness (Important)	No evidence identified	No evidence identified
Wellbeing (Not important)	Physical function Mental well-being	Very low Very low
Quality of life (Not important)	Descriptive findings	Very low

See appendix F for full GRADE tables.

Acceptability evidence

To assess the acceptability of providing education or advice 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 advice or education 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 included providing brief advice, face to face education or tailored SMS messaging. 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 Republic of Ireland, were included. See Appendix A for full details of review protocol.

Summary of acceptability studies included in the review

Seven studies met the qualitative inclusion criteria. Five UK studies assessed the acceptability of alcohol consumption services in community pharmacy (with two studies also looking at the patient experience). One UK study assessed the acceptability and experience of pharmacy based health checks with advice on lifestyle. One study conducted in Australia assessed the acceptability and client experience of community pharmacists providing advice and education on sleep disorders. Six studies met very few of the quality assessment checklist criteria and it is possible the conclusions could be altered. One study met some of the qualitative appraisal quality assessment criteria.

First Author, Year	Design & Analysis	Country	Health Area	Population	Outcomes	Quality Rating
Dhital 2010	Face to face interview Inductive analysis	UK	Alcohol consumption	102 pharmacy service users	Acceptability	-
Chauhan, 2012	Semi-structured phone interviews, Thematic analysis	UK	General health (Health checks and lifestyle/diet advice)	14 community pharmacy users	Experience Acceptability	-
Fuller 2011	Cross-sectional survey with a few open ended questions Method of analysis not described	Australia	Sleep disorders	Up to 325 (Number not specified)	Acceptability Experience	-
Krska 2014	Phone interview	UK	Alcohol consumption	10 pharmacy service users	Acceptability Experience	-

First Author, Year	Design & Analysis	Country	Health Area	Population	Outcomes	Quality Rating
	Thematic analysis					
Mackridge 2016	Mixed methods ethnographic observations and interviews. Constant comparative technique	UK	Alcohol consumption	16 pharmacy service users	Acceptability	+
Gray 2014	Telephone interviews Thematic analysis	UK	Alcohol consumption	16 pharmacy service users, 7 pharmacy staff	Acceptability Experience	-
Urban 2015b & Urban 2015c	Open ended questionnaire Thematic analysis	UK	Alcohol consumption	62 service users, 30 pharmacy staff (across 2 sites)	Acceptability	-

See appendix D for full evidence tables.

Chauhan (2012 [-]) conducted semi-structured phone interviews with 14 pharmacy service users (5 male, 7 female, age range 41 to 66 years, 50% White European, 43% South Asian) to explore their experiences with having received pharmacy based health checks with advice on lifestyle. Positive and negative aspects of the experience and acceptability of the intervention were reported.

Dhital (2010[-]) conducted face to face interviews with 102 pharmacy service users (62% female, 85% White) to investigate the potential uptake of alcohol screening and brief interventions. Key themes that emerged related to appropriateness of pharmacists providing health promotion services, communication, environment and information.

Fuller (2011[-]) conducted a before after study with an open-ended question component with pharmacy service users presenting with sleep related issues (53% female, Mean BMI 29.9) to evaluate a pharmacist led sleep health awareness education program. The patient experience and acceptability was reported.

Krska (2014[-]) conduced telephone interviews with 10 pharmacy service users (50% male) to evaluate a pilot pharmacy based alcohol screening and advisory service. Key themes surrounding the role of the pharmacist and privacy emerged using thematic analysis.

Mackridge (2016[+]) conducted a mixed methods ethnographic observational study of 3,299 pharmacy customers and in-depth semi-structured follow-up interviews with 16 pharmacy customers. The participant experience and acceptability was reported.

Gray (2014[-]) conducted semi-structured telephone interviews with 16 service users and 7 members of pharmacy staff (4 pharmacists, 3 other staff members) to evaluate a pharmacy based alcohol identification/brief advice service in the Northwest. The participant and staff experience and acceptability was reported.

Urban (2015b & Urban 2015c[-]) conducted open ended questionnaires in 62 pharmacy users and 30 pharmacy staff members following delivery of a pharmacy based alcohol identification/brief advice service in two areas of the UK (Calderdale- Urban 2015b, Kirklees- Urban 2015c). The participant and staff experience and acceptability was reported.

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.

All seven studies had some deficiencies in reporting or conduct of their study design, data collection and trustworthiness. Methods of analysis were not reliable and the data was limited in its richness

Economic evidence

Included studies

Papers were included if they met the PICO and were:

- Based on effectiveness and cost data from the UK, Australia, Canada or the Republic of Ireland.
- Published between 1990 and 2016.
- Published in English language.

The health areas of interests included: alcohol use, cancer awareness, prevention of cardiovascular disease, diabetes, substance misuse or falls, mental health and wellbeing, orthopaedic conditions, sexual health, smoking and smokeless tobacco or weight management.

Excluded studies

Papers were excluded if they:

- 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 cost 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 cost effectiveness studies included in the review

One cost effectiveness study was included in this evidence review. Table 4 provides the details of this study.

Table 4. Summary of cost effectiveness evidence for behavioural support

Study	Design	Setting and country	Intervention	Health area	Outcomes
Burford et al. 2013	Cost effectiveness analysis	Community pharmacies Australia	Photo ageing software	Smoking cessation	Cost effectiveness ratio Cost-offset

See appendix H for full evidence tables.

Economic model

Due to the lack of published economic evidence on behaviour change interventions in the community pharmacy setting, 2 new economic analyses were undertaken, 1 of which included a photo-ageing intervention for smoking cessation. Full details of the economic model are provided in evidence review 3 and in the health economic modelling appendix. Briefly, the model comprises 3 main health states (current smoker, former smoker and dead), and has 6 comorbidity states (e.g. asthma), with former smokers facing a lower comorbidity risk than smokers. Costs included delivery of the intervention and NHS costs of managing comorbidities. Outcomes were evaluated over a person's lifetime, and were discounted annually by 3.5% to account for societal time preference.

The model found that the photo-ageing software intervention delivered in a community pharmacy setting is likely to be a cost-effective use of resources compared with not using it. The intervention was predicted to generate more QALYs per person at a lower total cost, and would have to cost substantially more than its base case estimate to become cost-ineffective.

Evidence statements

Clinical measurements or health outcomes

Evidence statement 2.1- No evidence of effectiveness for information leaflets plus education for low back pain for reducing activity impairment [GRADE profile 1]

- Very low quality evidence from 1 cluster randomised controlled trial with 128 participants found no difference in change in activity impairment scores relative to usual care as measured by an 11 point Numerical Rating Scale (NRS) at 2 or 8 weeks, mean difference of -0.20 (95%CI -1.12 to 0.72) and -0.60 (95%CI -1.57 to 0.37) respectively. The same study found no difference in activity impairment with leaflet plus education relative to receiving leaflets only, mean difference of -0.30 (95%CI -1.13 to 0.53) at 2 weeks and -0.40 (95%CI -1.36 to 0.56) at 8 weeks.

Evidence statement 2.2- Patient education and regular review reduced patient reported asthma severity [GRADE profile 1]

- Very low quality evidence from 1 randomised controlled trial with 72 participants found that individuals receiving education and regular review of their condition had lower mean asthma severity scores as measured by patient reported symptom frequency at 6 months relative to individuals receiving standard care (1.6 ± 0.7 vs 2.7 ±0.7[control group 1] / 2.4 ± 0.5 [control group 2]), $p<0.05$.

Evidence statement 2.3- No evidence of effectiveness for information leaflets plus education for reducing the severity of low back pain [GRADE profile 1]

- Very low quality evidence from 1 cluster randomised controlled trial with 128 participants found no difference in change in pain severity scores with leaflets plus education relative to usual care as measured by an 11 point Numerical Rating Scale (NRS) at 2 or 8 weeks with mean difference of 0.0 (95%CI -0.81 to 0.81) and -0.70 (95%CI -1.62 to 0.22) respectively. The same study found no statistically significant difference in pain severity with leaflets plus education relative to leaflets only with mean difference of -0.40 (95%CI -1.19 to 0.39) at 2 weeks and -0.60 (95%CI -1.54 to 0.34) at 8 weeks.

Evidence statement 2.4- Photo-ageing education decreased Fagerström nicotine dependency score [GRADE profile 1]

- Low quality evidence from 1 randomised controlled trial with 160 participants found that a photo-ageing smoking cessation service was effective at increasing the number of individuals with a decreased Fagerström nicotine dependency score (RR =3.73, 95% CI 2.07 to 6.72). The same study found the photo-ageing intervention was effective at decreasing the number of individuals with an unchanging Fagerström score (RR =0.57, 95% CI 0.45 to 0.73). Very low quality evidence from the same study did not show effectiveness at decreasing the number of individuals with an increasing Fagerström score (RR =0.33, 95% CI 0.01 to 8.06).
- Very low quality evidence from the same randomised control trial with 160 participants found a mean difference of -0.69 in Fagerström score comparing control and intervention groups at 1 month follow-up and a mean difference of -0.96 in Fagerström score at 3 month follow-up, however the confidence in this estimate cannot be determined. A mean difference of -1.62 in Fagerström score at 6 month follow-up was determined ($p<0.001$).

Evidence statement 2.5- Patient education reduced blood glucose levels for individuals with diabetes [GRADE profile 1]

- One very low quality randomised controlled trial with 64 participants with type 2 diabetes found that blood glucose levels were lower at 6 months ($p=0.047$) and 24 months ($p=0.008$) follow-up after undergoing a 12 month group experience based educational program. Blood glucose level did not differ significantly from baseline at the 12 months of follow-up time-point ($p=0.240$). Participating in the intervention decreased blood glucose levels by 0.4% at 24 months after baseline.
- One very low quality before-after study with 24 participants with type 2 diabetes found that blood glucose levels did not change after undergoing five intensive diabetes education sessions at 1, 3 or 6 months follow-up.

Evidence statement 2.6- Patient education reduced incidents of hypo- or hyperglycaemia in individuals with diabetes [GRADE profile 1]

- One very low quality before-after study with 24 participants with type 2 diabetes found that incidents of hypo/ hyperglycaemia decreased 33%, 46% and 58% at 1, 3 and 6 months follow-up respectively after undergoing five intensive diabetes education sessions. No p-values were reported for this outcome.

Evidence statement 2.7- Advice and education reduced diastolic blood pressure but not systolic blood pressure in individuals with hypertension [GRADE profile 1]

- One low quality randomised control trial with 84 participants with hypertension found that diastolic blood pressure decreased, [mean difference -5.00 mmHg (95%CI -9.39 to -0.61)] at 12 month follow-up for individuals receiving 12 educational sessions relative to those only receiving 2 session. However this same study found there was no decrease in systolic blood pressure, [mean difference -4.00 mmHg (95%CI -10.91 to 2.91)] at 12 month follow-up.

Action

Evidence statement 2.8- Patient advice reduces cigarette and/or cigar smoking [GRADE profile 2]

- Low quality evidence from 1 before after study with 110 participants found that individuals who received a health screening interview along with advice on nutrition and well-being had a reduction in the mean daily number of cigarettes and/or cigars smoked at two years, mean difference -3.50 (95% CI 5.58 to 1.42), p<0.01.

Evidence statement 2.9- There is mixed evidence of effectiveness for advice and education improving diet [GRADE profile 2]

- Very low quality evidence from 1 randomised controlled trial with 49 participants found that individuals who received a health screening interview with emphasis on nutrition and well-being had no improvement in diet as measured by the Summary of Diabetes Self-Care activities scale relative to individuals receiving usual care, mean difference -0.04 (95% CI -0.32 to +0.24).

- Moderate quality evidence from 1 randomised control trial with 280 participants found there was no change in general diet (e.g. prescribed or generally helpful diet) as measured by the Diabetes Self Care Activities questionnaire, [mean difference 0.10 (95%CI -0.36 to 0.56)] that participants with diabetes who received 5 education sessions relative to those receiving standard care at 6 months follow-up. However, there was an improvement in specific diet consumption (e.g. relating to fruit and vegetable and high fat foods) [mean difference 0.60 (95%CI 0.24 to 0.96)] for those receiving the 5 educational sessions at 6 months follow-up.

Evidence statement 2.10- Mixed evidence of effectiveness for patient advice or education increasing exercise participation [GRADE profile 2]

- Very low quality evidence from 1 randomised controlled trial with 49 participants found that individuals who received a health screening interview with emphasis on nutrition and well-being had no increase in exercise as measured by the Summary of Diabetes Self-Care activities scale relative to individuals receiving usual care, mean difference 0.10 (95%CI -0.24 to +0.44), p=0.57.

- Moderate quality evidence from 1 randomised controlled trial with 280 participants with diabetes found there was no change in exercise levels as measured by the Diabetes Self Care Activities questionnaire, mean difference 0.0 (95%CI -0.55 to 0.55) for individuals receiving 5 education sessions relative to those receiving standard care at 6 months follow-up.

Evidence statement 2.11- Patient education increased smoking cessation rates for smokers in a general population groups but not smokers with diabetes [GRADE profile 2]

- Low quality evidence from 1 randomised control trial with 160 participants found that a photo-ageing smoking cessation intervention was effective at increasing self-reported smoking cessation rates, comparing intervention and control groups at 6 month follow up (RR=4.4, 95% CI 1.75 to 11.04). Moderate quality evidence from the same study found that the photo-ageing intervention was effective at increasing carbon monoxide verified smoking cessation, comparing intervention and control groups at 6 month follow up (RR=11.0, 95% CI 1.45 to 83.21).
- Moderate quality evidence from one randomised control trial with 280 participants with diabetes found no change in smoking rates [RR=0.83 (95%CI 0.51 to 1.34), for individuals

receiving 5 education sessions relative to those receiving standard care at 6 months follow-up.

Evidence statement 2.12- Patient education improved foot care for individuals with diabetes [GRADE profile 2]

- Moderate quality evidence from one randomised control trial with 280 participants with diabetes found that foot care as measured by the Diabetes Self Care Activities Questionnaire improved for individuals receiving 5 education sessions relative to those receiving standard care, mean difference 0.60 (95%CI 0.11 to 1.43) at 6 months follow-up.

Intention

Evidence statement 2.13- No evidence of effectiveness for information leaflets handed out by pharmacists with offer to provide advice for increasing health seeking behaviour [GRADE profile 3]

- Very low quality evidence from one non-randomised controlled trial with 384 participants found that 19% of individuals who had a leaflet passed to them by their pharmacist with an offer to provide advice sought advice. The proportion of individuals who took a leaflet from a display in the pharmacy and sought advice was not documented therefore.
- Subgroup analysis found no difference in seeking advice in individuals who took a leaflet that instructed them to seek advice vs individuals who had the leaflet handed to them form the pharmacist without offer of advice, RR=0.96 (95% CI 0.57 to 1.64). Additionally there was no difference in seeking health advice in individuals who had a leaflet with instructions to seek advice handed out by pharmacist vs those receiving the same leaflet but without direct offer from the pharmacist to provide advice, RR= 0.88 (95%CI 0.51 to 1.54).

Attitude

Evidence statement 2.14- No evidence was identified for the effect of advice or educations on attitudes [GRADE profile 4]

- No evidence was identified for the effect of advice or education on attitudes.

Knowledge

Evidence statement 2.15- Patient education increased asthma knowledge [GRADE profile 5]

- Very low quality evidence from 1 before-after study with 92 high school students found that individuals receiving peer led education increased asthma knowledge immediately post-intervention, mean difference 4.39 (95%CI 3.67 to 5.11) p<0.001.
- Very low quality evidence from 1 before-after study with 212 participants with asthma found that individuals who received 3 education visits had a statistically significant increase in asthma knowledge, mean difference 1.09 (95% CI 0.65 to 1.53) p<0.001 relative to standard care. This study also found that individuals receiving four visits also had a significant increase in knowledge at six months post-intervention, mean difference 1.18 (95%CI 0.73 to 1.63) p<0.001.

- Subgroup analysis found no difference in knowledge increase in individuals who received four education visits vs individuals who received three education visits, mean difference 0.38 (95%CI -0.04 to 0.80).

Evidence statement 2.16- Patient education plus review increased asthma knowledge [GRADE profile 5]

- Very low quality evidence from 1 randomised controlled trial with 89 participants with asthma found that individuals receiving education and regular review had an increase in asthma knowledge, mean difference 2.80 (95%CI 0.59 to 5.01) p<0.05 relative to those receiving standard care only at six months follow-up.

Evidence statement 2.17- Patient education increased diabetes knowledge [GRADE profile 5]

- Moderate quality evidence from 1 randomised control trial with 280 participants with diabetes found that diabetes knowledge as measured by the Diabetes Self-Care Activities questionnaire was higher for individuals receiving 5 educational sessions relative to those receiving only usual care at 6 months follow up, mean difference 11.4 (95%CI 6.68 to 16.12).
- Low quality evidence from 1 randomised control trial with 84 participants with diabetes found that diabetes knowledge was higher in individuals receiving12 education sessions relative to those receiving 2 education sessions, mean difference 1.7 (95%CI 0.56 to 2.84).

Beliefs

Evidence statement 2.18- No evidence of effectiveness for information plus education for decreasing negative beliefs about back pain [GRADE profile 6]

- Very low quality evidence from one cluster randomised controlled trial with 128 participants found no difference in change in negative beliefs about lower back pain as measured by scores on the Back Beliefs Questionnaire (BBQ) in participants who received leaflets plus education relative to individuals who received usual care: Mean difference at 2 weeks 2.10 (95%CI -0.34 to 4.54), Mean difference at 8 weeks 0.90 (95%CI -1.80 to 3.60).
- There was also no difference in back beliefs relative to individuals who received leaflets only: Mean difference at 2 weeks -0.10 (95%CI -2.57 to 2.37), Mean difference at 8 weeks 0.60 (95%CI -2.19 to 3.39).

Evidence statement 2.19- No evidence of effectiveness for information plus education for decreasing physical activity related fear about low back pain [GRADE profile 6]

- Very low quality evidence from one cluster randomised controlled trial with 128 participants found no difference in change in negative beliefs about lower back pain as measured by scores on the Fear Avoidance Beliefs Questionnaire (FABQ-physical activity) in participants who received leaflets plus education relative to individuals who received usual care: Mean difference at 2 weeks 0.10 (95%CI -1.86 to 2.06), Mean difference at 8 weeks -1.00 (95%CI -3.06 to 1.06).
- There was also no difference in back beliefs relative to individuals who received leaflets only: Mean difference at 2 weeks 1.40 (95%CI -0.82 to 3.62), Mean difference at 8 weeks 0.40 (95%CI -1.99 to 2.79).

Evidence statement 2.20- No evidence of effectiveness for information plus education for decreasing work related fear about low back pain [GRADE profile 6]

- Very low quality evidence from one cluster randomised controlled trial with 128 participants found no statistically significant difference in change in negative beliefs about work related fear as measured by scores on the Fear Avoidance Beliefs Questionnaire (FABQ-work) in participants who received leaflets plus education relative to individuals who received usual care: Mean difference at 2 weeks -2.70 (95%CI -6.97 to 4.57), Mean difference at 8 weeks -2.30 (95%CI -6.41 to 1.81).

- There was also no difference in back beliefs relative to individuals who received leaflets only: Mean difference at 2 weeks -1.70 (95%CI -5.92 to 2.52), Mean difference at 8 weeks -0.20 (95%CI -4.05 to 3.65).

Awareness

Evidence statement 2.21- No evidence was identified for the effect of advice or education on awareness [GRADE profile 7]

- No evidence was identified for the effect of behavioural interventions on well-being.

Well-being

Evidence statement 2.22- No evidence of effectiveness for education for increasing well-being (physical aspects) [GRADE profile 8]

- Very low quality evidence from one randomised controlled trial with 49 participants with diabetes found no improvement in well-being physical composite scores as measured by the SF-12 at six months in individuals who received diabetes, nutrition and exercise education and advice relative to those who received standard care, mean difference 2.20 (95%CI -2.66 to 7.06).

Evidence statement 2.23- Education increased well-being (mental aspects) [GRADE profile 8]

- Very low quality evidence from one randomised controlled trial with 49 participants with diabetes found an improvement in mental well-being composite scores as measured by the SF-12 at six months in individuals who received diabetes, nutrition and exercise education and advice relative to those who received standard care, mean difference 6.60 (95%CI 1.49 to 11.71), p=0.01.

Quality of life

Evidence statement 2.24- No evidence of effectiveness for education improving quality of life [GRADE profile 9]

- Very low quality evidence from one before after study with 24 participants with diabetes found there was no change in the following facets of quality of life: Positive mood [OR=1.84 (95%CI 0.39 to 8.77)], Days being easy [OR=1.67 (95%CI 0.40, 6.87)], Social activity [OR=1.0 (95%CI 0.18 to 5.53)], Feeling rested [OR=1.0 (95%CI 0.22 to 4.56)], or increase in physical activity [OR= 1.84 (95%CI 0.39 to 8.77)] for individuals who received 5 education sessions. The measure used to assess quality of life was not reported in the study.

Factors affecting effectiveness

Evidence statement 2.25– No evidence was identified for what 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 2.26 –Photo-ageing smoking cessation intervention is effective when given to younger individuals [GRADE profile 1]

- Very low quality evidence from 1 randomised controlled trial with 160 participants found that younger participants were more likely to achieve a decrease in Fagerström nicotine dependency score following a photo-ageing smoking cessation intervention, compared to older participants (p=0.001).

Evidence statement 2.27- Photo-ageing smoking cessation intervention is effective when given to heavy smokers [GRADE profile 1]

- Very low quality evidence from 1 randomised controlled trial with 160 participants found that individuals at baseline smoking >10 cigarettes per day were more likely to achieve a decrease in Fagerström nicotine dependency score than individuals smoking 0-5 or 6-10 cigarettes per day (χ^2_2=26.2, p<0.001).

Evidence statement 2.28- No evidence of a difference in effectiveness of a photo-ageing smoking cessation intervention when given to males or females [GRADE profile 1]

- Very low quality evidence from 1 randomised controlled trial with 160 participants found that there was no difference in the effectiveness of a photo-ageing smoking cessation intervention according to participant gender (p=0.34).

Acceptability of intervention

Evidence statement 2.29- There is evidence to support the provision of advice and education on sleep disorders in community pharmacy settings

One Australian study [-[3]] found that the majority of pharmacy service users felt positive about a sleep disorder program being provided in a community pharmacy setting and would recommend the service to a friend *"I found it helpful to sit down and talk to the pharmacist and discover changes to improve the number of hours I sleep…the written information was wonderful".* The program may also increase knowledge about factors that may influence sleep patterns and lead to participants getting more sleep *"I am far more aware of things which affect my sleep patterns e.g. TV in room, radio, suduko, reading, getting up and using toilet each time I wake up. Following the service I average 30-50 minutes extra sleep per night"*.

[3.] Fuller 2011 [-]

Evidence statement 2.30- There is some evidence to support the acceptability of pharmacists providing health checks with lifestyle advice in community pharmacies

One UK study [-[1]] assessed the experiences of pharmacy service users receiving health checks with lifestyle advice. They found that some individuals reported that the length of and person centred delivery of these types of consultations exceeded their expectations. They appreciated the pharmacists providing health checks and liked the convenience of the location and lack of waiting time. They also reported they felt the information and advice provided about lifestyle was adequate and would enable those who perceived change was needed to consider modification of diet, exercise and smoking habits especially when the information is tailored to meet specific cultural needs (e.g. differences in South Asian cooking practices). A minority of participants felt that a nurse or GP would be more appropriate intervention provider. No direct quotes were reported to support these assertions.

[1.] Chauhan 2012 [-]

Evidence statement 2.31- There is mixed evidence to support the provision of advice and education to reduce alcohol consumption in community pharmacy settings

Five UK studies [-[2],-[6], +[8,] -[9,] -[10]] found that respondents held positive views of the alcohol information and advice service which also included pre-screening with the AUDIT or AUDIT-C questionnaire. Overall they felt that pharmacists were professional and the service was useful *"They were very sincere and very friendly, they don't look down on people like ourselves…it should be available in every pharmacy so that people are aware about what alcohol actually does"[6].*

Some respondents thought of pharmacists as being more accessible to the public than GPs and felt they could credibly provide alcohol advice "*Pharmacist has training and is used to talking to the general public"*[2]*. However,* the opposite opinion was also voiced by some participants *"Not sure how much pharmacists will know about alcohol, not sure about their alcohol training".* Respondents who questioned the appropriateness and level of training of the pharmacist delivering this sort of intervention indicated they would rather speak with a GP *"Prefer to discuss alcohol use with GP"*[2]*.* On the contrary other respondents indicated a preference to communicating with a pharmacist *"Easier to talk to a pharmacist than a doctor"*[2]*.* The desire to communicate with a pharmacists was also influenced by personal characteristics of the pharmacists *"Pharmacists talk to you like normal human beings*"[2]. On the contrary some respondents may be hesitant in communicating with their pharmacists *"Would depend on the personality of the pharmacist, how approachable they were*"[2].

Having a private environment to provide the intervention was also deemed to be important as some individuals indicated they may be less likely to participate during the screening with the AUDIT-C if there were other customers around "*There were no customers in so it wasn't too bad but if it had been busy I wouldn't have done it… Just like err may be a private screened area just like you know like a photo booth style curtain or something just at the end of the counter- nothing more than that- I'm not talking about a private room or anything"*[6]. Assurances about patient record confidentiality were also mentioned as something participants would consider if they were to participate in this type of program "need to know if the service is totally anonymous or not"[2]. Some subjects also felt that the alcohol information and advice service could be improved by offering more leaflets to support the advice. Leaflets that were given as additional support were deemed as useful "Great leaflets and info provided on calories and units was useful"[10].

[2]. Dhital 2010 [-]

[6]. Krska 2014 [-]

[8]. Mackridge 2016 [+]

[9]. Gray 2012 [-]

[10]. Urban 2015b and Urban 2015c [-]

Cost-effectiveness evidence

Evidence statement 2.32- evidence of cost-effectiveness of photo-ageing smoking cessation interventions

- High quality evidence from 1 cost utility analysis indicated that a photo-ageing smoking cessation intervention had an incremental cost effectiveness ratio (ICER) per additional quitter of AU$46 (£31). Sensitivity analysis accounting for time the pharmacist spent on the intervention, the exchange rate and the pharmacy intervention discount, indicated that the best case ICER per additional quitter is AU$41 (£27) and the worst case is AU$71 (£48). The same study indicated an ICER per additional lifetime quitter of AU$74 (£50), with the same sensitivity analysis indicating the best case ICER per additional lifetime quitter at AU$64 (£43) and the worst case at AU$113 (£76).
- The same study used a model to indicate that a photo-ageing smoking cessation intervention provided a cost offset of AU$2144 (£1434) from a reduction in healthcare costs, with sensitivity analysis indicating best case as AU$2660 (£1780) and worst case as AU$1867 (£1249). A model also indicated that net total cost savings of AU$1778 (£1190) would be made, with sensitivity analysis indicating best case as AU$2346 (£1570) and worst case as AU$1316 (£880).
- One directly applicable cost–utility analysis with potentially serious limitations, developed for this guideline, found a photo-ageing intervention for smoking cessation dominated usual care. The intervention produced 0.12 incremental QALYs per person, and

incremental costs of -£347 per person, making it a dominant strategy compared with not using photo-ageing software. This result was found to be robust to univariable sensitivity analyses. Probabilistic sensitivity analysis was not undertaken.

Evidence statement 2.33- evidence of cost-effectiveness of advice and education for type-2 Diabetes

Low quality evidence from 1 before after study from Bulgaria found that the cost-effectiveness ratio calculated on the basis of the decrease in blood glucose level per patient was €7.5 (£5.23) for achieving one intermediate clinical outcome (€6 [£4.19]: 0.8 mmol/l). The long term clinical outcomes could not be calculated during the six month project but the steady decrease of blood glucose level, decrease in hypogylcemic incidents and increase in overall QoL are prerequisites for achieving such improvements. At the end of the program no incidents were matched that €10/patient, which is the cost paid by the Bulgarian health insurance fund for the consultation of a patient with specialists. For 58% of the observed patients that report having such incidents at the beginning such savings were €140 (£97.68) and thus benefit to cost ratio is at least about 1:1 (€140 to €142.80 [£97.68 to £99.63]) if there are no other expenses.

Recommendations

Evidence discussion

Interpreting the evidence

The outcomes that matter most

The committee agreed that clinical measurements or health outcomes and actions were critical outcomes for this review. Nine effectiveness studies addressed these outcomes [ES 2.1-2.12]. Committee members agreed that intentions, attitudes, knowledge and awareness were also important outcomes, with wellbeing and quality of life being less important outcomes. One effectiveness study addressed the intention of health seeking behaviour with the use of leaflets and advice [ES 2.13], and five effectiveness studies addressed knowledge as an outcome [ES 2.15]. One effectiveness study addressed wellbeing in individuals who received diabetes, nutrition and exercise education/advice [ES 2.22-2.23], and one effectiveness study addressed quality of life in those with diabetes who received an education intervention [ES 2.24]. It was important to note that some studies addressed multiple outcomes.

No evidence was identified for the effect of advice and education interventions on attitudes and awareness [ES 2.14, 2.21], or for the influence of the characteristics of the person delivering the intervention on its effectiveness [ES 2.25]. One study addressed the influence of the characteristics of the person receiving a photo-ageing app for smoking cessation [ES 2.26-2.28]. Seven qualitative studies (4 UK) assessed the acceptability of providing education or advice interventions in community pharmacy settings [ES 2.29-2.31] and two studies investigated the cost-effectiveness of interventions within this review [ES 2.32-2.33].

The committee noted that beliefs were an additional outcome uncovered from the evidence. One study investigated the effectiveness of information plus education for decreasing negative beliefs about low back pain, decreasing physical activity related fear about low back pain, and decreasing work related fear about low back pain. [ES 2.18-2.20].

The committee acknowledged that some of the evidence indicated that education sessions and advice resulted in positive effects on clinical outcomes, action, knowledge, and well-being within certain health areas [ES 2.2, 2.4-2.6, 2.8, 2.11, 2.12, 2.15-2.17, and 2.23]. The acceptability evidence also revealed data to support the provision of advice and education on

sleep disorders and the reduction of alcohol consumption [ES 2.29-2.31]. However there were concerns with the quality, applicability and generalisability of individual studies which are discussed in further detail below.

The quality of the evidence

The committee noted that the evidence for all health areas ranged from moderate to very low in quality. Reasons for downgrading included high risk of bias, imprecision in the measurement of an outcome and uncertainty about the cases included for some of the analyses. The evidence indicated that in some cases clinically important outcomes occurred but due to uncertainty resulting from overall quality, limited quantity and lack of consistency in the evidence, recommendation strength and detail of the intervention components was restricted.

The committee noted a study which found the use of a photo-ageing software to be of benefit for smoking cessation [ES 2.4-2.5] which was also more effective when given to younger individuals [ES 2.26] and heavy smokers [ES 2.27]. The committee agreed that these groups may benefit proportionally more from the intervention and so recommended it as an example of an effective way to support education and advice in this area. Other advice and education interventions for smoking cessation yielded mixed findings [ES 2.8], [ES 2.11], however it was acknowledged that this was a recognised approach in general and showed promise in this setting, despite some uncertainties in the evidence.

One RCT which evaluated 12 educational sessions within community pharmacies for 84 subjects with hypertension found a clinically important reduction in diastolic blood pressure at 12 months follow up [ES 2.7]. Similarly, the evidence in relation to diabetes showed positive overall outcomes across a number of key areas [ES 2.5-2.6, ES 2.15-2.17]. However the committee agreed that sample sizes were small and thus there was a lack of overall certainty in the evidence.

The committee agreed that the UK acceptability evidence in relation to alcohol consumption was of mixed quality, all five studies found that respondents held positive views of the alcohol advice service [ES 2.31]. However, due to the limited effectiveness evidence they agreed to recommend that any brief alcohol intervention was delivered in line with appropriate recommendations in other guidelines as a means to assess needs and referral to other services if necessary. The acceptability evidence from the UK also highlighted the importance of having a private area to apply an educational intervention [ES 2.31]. However as 90 percent of pharmacies within the UK already have a private area and it is part of the pharmacy contract to be mindful of the importance of using these facilities, recommendations were not plausible.

The committee noted that the intervention of providing heath checks and lifestyle advice which included one-to-one consultation was well received and enabled those who used the service to consider lifestyle changes to reduce CVD risk [ES 2.30]. However, a minority of participants felt that a nurse or GP would be more appropriate intervention provider therefore the committee agreed this was for local decision making based on discussion with relevant partners such as CCG and Health and Wellbeing boards. The committee also questioned the generalisability of the qualitative evidence from Australia because it provided limited contextual information and direct quotes [ES 2.29].

A number of evidence statements did not impact on recommendations [ES 2.1, 2.3, 2.13, 2.18-2.20] they were not used for a variety of reasons including lack of clinically important outcomes, too much uncertainty in the evidence, and limited applicability to the UK setting.

Advantages and disadvantages of providing advice and education

The committee acknowledged that some of the evidence indicated that advice and education interventions were beneficial in terms of improving health and well-being within community pharmacies.

Overall the advantages included the potential for reduction in hypertension that is considered clinically important [ES 2.7] reducing patient reported asthma severity [ES 2.2] and knowledge [ES 2.15, 2.15], reduction in blood glucose levels [ES 2.5], and incidents of hypo- or hyperglycaemia [ES 2.6], improved foot care [ES 2.12] and knowledge [ES 2.17] in individuals with diabetes. There were also improvements in smoking behaviours [ES 2.4, 2.8, 2.11], nutrition habits [ES 2.9] and exercise participation [ES 2.10] although some of this evidence was mixed.

The committee agreed that the evidence suggested there were no direct harms or disadvantages of delivering advice and education within community pharmacy settings, and therefore should be considered as an approach to improving health and wellbeing in individuals. The committee agreed that where evidence was weak but showed positive directions of effect, reference to other NICE guidance on related health areas would be appropriate, if available. The recommendations cross referred to within these guidelines are strong recommendations.

Cost effectiveness and resource use

One Australian study investigating advice and education for smoking cessation found that photo-ageing education had an incremental cost-effectiveness ratio (ICER) of AU$46 [£31] (overall range AU$41 [£27] to AU$71 [£48]) for each person who stopped smoking. Photo-ageing education also showed a cost-offset of AU$2144 [£1434] (range AU$2660 [£1780] to AU$1867 [£1249]) from reduction in healthcare costs and net total savings of AU$1778 [£1190] (range AU$2346 [£1570] to AU$1316 [£880]).

A new economic evaluation was performed to assess the cost-effectiveness of behaviour change interventions for smoking cessation in the community pharmacy setting. This analysis included 1 photo-ageing software intervention, in a comparison with usual care (i.e. no photo-ageing intervention). The lifetime model captured 6 comorbidities, with their incidence dependent on smoking status (either current or former), and smoking-related mortality. The main health outcome was QALYs, and costs included delivery of the intervention and management of comorbidities. The committee did not consider the cost of implementing photo-ageing software to be prohibitive. The model found the photo-ageing intervention to be highly cost effective compared with usual care, producing more 0.12 QALYs per patient at reduced overall costs. This finding was robust to scenario and sensitivity analyses. The committee agreed that these recommendations would reduce the variation in delivery of advice and education within community pharmacies which is currently seen in practice. It was noted that pharmacy teams that provide the least advice and education services are likely to have the biggest expenditure as a result of implementing them.

The committee agreed that if staff are appropriately trained to deliver advice and education then there should be no significant cost implications. The committee agreed with expert testimony that some staff (such as pharmacists and pharmacy technicians) will be competent to deliver these interventions as they are trained in core public health priorities and some will be trained in healthy living (for example, the Royal Society for Public Health Level (RSPH) level 2 award in improving health). Some staff may also become qualified health champions who have completed the RSPH Level 2 award [EP 1, 3].

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 2a - Effectiveness of advice or education

Field	Content
Review question 2a	What are the most effective ways for community pharmacy staff to offer advice or education to promote health and wellbeing to users of community pharmacy services?
Type of review question	Intervention
Objective of the review	This review aims to determine which interventions are effective for offering advice or education to promote health and wellbeing in community pharmacy. This review will focus on the effectiveness of advice or education that is tailored to an individual, rather than information that is provided to a group of users of community pharmacy services. 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 offers advice or education to promote health and wellbeing, including: • Brief advice • Very brief advice • Face to face advice • Face to face education • Tailored SMS messaging

Field	Content
	• Any other form of advice or education that is tailored to an individual 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 intervention provided by community pharmacy staff that provides information. Any other intervention provided by community pharmacy staff that offers advice or education to promote health and wellbeing. See common elements section for further details.
Outcomes and prioritisation	1 Clinical measurements or health outcomes 2 Behavioural outcomes - Action 3 Modifying factors or determinants of behaviour - Intention - Attitudes - Knowledge - Awareness 4 Wellbeing 5 Quality of life 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
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 2b - Acceptability of advice or education

Field	Content

Review question 2b	Is offering advice or education acceptable to users of community pharmacy services?
Type of review question	Views and experiences
Objective of the review	The review aims to determine whether offering advice or education is acceptable to users of community pharmacy services. This review will focus on the acceptability of advice or education that is tailored to an individual, rather than information that is provided to a group of users of community pharmacy services. The 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 offers advice or education to promote health and wellbeing, including: • Brief advice • Very brief advice • Face to face advice • Face to face education • Tailored SMS messaging • Any other form of advice or education that is tailored to an individual 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 intervention provided by community pharmacy staff that provides information. Any other intervention provided by community pharmacy staff that offers advice or education to promote health and wellbeing. See common elements section for further details.
Outcomes and prioritisation	Preference and experience 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 advice or education 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	Rachel Walsh (Technical Analyst) Ella Novakovic (Senior Technical Analyst) Daniel Tuvey (Information Specialist)

Review question 2c - Cost effectiveness of advice or education

Field	Content
Review question 2c	What are the most cost effective ways of offering advice or education to promote health and wellbeing by community pharmacy staff?
Type of review question	Cost effectiveness
Objective of the review	This review aims to determine which interventions are cost effective for offering advice or education to promote health and wellbeing in community pharmacy. This review will focus on the cost effectiveness of advice or education that is tailored to an individual, rather than information that is provided to a group of users of community pharmacy services. 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 offers advice or education to promote health and wellbeing, including: • Brief advice • Very brief advice • Face to face advice • Face to face education • Tailored SMS messaging • Any other form of advice or education that is tailored to an individual 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 intervention provided by community pharmacy staff that provides information. Any other intervention provided by community pharmacy staff that offers advice or education to promote health and wellbeing. See common elements section for further details.
Outcomes and prioritisation	Costs, savings 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

Field	Content
	• Cost benefit studies • Cost-effectiveness studies • Cost minimisation studies • 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.

Field	Content
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)

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 Table5 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 5: Prioritisation and minimal important difference for each outcome

Outcome	Priority	Minimal important difference
Review question 1a (information and awareness raising)		
Action	Critical	25% reduction in relative risk
Intention	Important	25% reduction in relative risk
Attitudes	Important	25% reduction in relative risk
Knowledge	Important	25% reduction in relative risk
Awareness	Important	25% reduction in relative risk
Review questions 2a (advice or education) and 3a (behavioural support)		
Clinical measurements or health outcomes	Critical	25% point change in relative risk
Action	Critical	25% point change in relative risk
Intention	Important	25% point change in relative risk
Attitudes	Important	25% point change in relative risk
Knowledge	Important	25% point change in relative risk
Awareness	Important	25% point change in relative risk
Wellbeing	Less important	25% point change in relative risk
Quality of life	Less important	25% point change in relative risk
Review question 4a (signposting and referral)		

Uptake of interventions or services to promote, maintain and improve health and wellbeing	Critical	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. Change 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 evidence study selection

1. Burford O, Jiwa M, Carter O, Parsons R, Hendrie D. (2013) Internet-based photoaging within Australian pharmacies to promote smoking cessation: randomized controlled trial. Journal of medical Internet research. 15(3):e64.

2. Dhital R, Whittlesea CM, Norman I, Milligan P. (2010) Community pharmacy service users views and perceptions of alcohol screening and brief intervention. Drug and Alcohol Review. 29; 596-602

3. Chahuan A, Hiles S, Patel, N et al (2012) Pharmacy-based health checks – acceptable and feasible. Primary Care cardiovascular Journal. 5; 74-76

4. Fuller J, Wong K, Krass I et al (2011) Sleep disorders screening, sleep health awareness and patient follow-up by community pharmacists in Australia. Patient Education and Counseling. 83 325-335

5. Gray JN, Wilson SE, Cook PA, Mackridge AJ, Blenkinsopp A, Prescott J, Stokes LC, Morleo MJ, Heim D, Krska J, Stafford L (2012) Understanding and optimising an identification/brief advice (IBA) service about alcohol in the community pharmacy setting. Liverpool: Liverpool Primary Care Trust. http://clok.uclan.ac.uk/5972/3/Final%20full%20report%2025th%20october%202012.pdf

6. Guirguis LM, Johnson JA, Farris KB et al. (2001) A pilot study to evaluate the impact of pharmacists as certified diabetes educators on the clinical and humanistic outcomes of people with diabetes. Canadian Journal of Diabetes Care, 25 (4) 266-276

7. Kritkos V, Saini B, Bosnic-Anticevish SZ et al (2005) Innovative asthma health promotion by rural community pharmacists: a feasibility study. Health Promotion Journal of Australia, 16 (1) 69-73

8. Krska J and Mackridge A (2014) Involving the public and other stakeholders in development and evaluation of a community pharmacy alcohol screening and brief advice service. Public Health, 128: 309-316

9. Lloyd-Williams F (2003) The effect of an intervention programme to improve health education leaflet uptake and distribution in community pharmacies. Patient Education and Counseling, 49 (1) 27-33

10. Mackridge AJ, Krska J, Stokes EC, Heim D (2016) Towards improving service delivery in screening and intervention services in community pharmacies: a case study of an alcohol IBA service. Journal of Public health Advance Access, p1-7

11. Mehuys E, Van Bortel L, De Bolle L et al (2011) Effectiveness of a community pharmacist intervention in diabetes care: a randomized controlled trial. Journal of Clinical Pharmacy and Therapeutics:36, 602-613

12. Petkova VB, Petrova GI (2006) Pilot project for educatin of patients with type 2 diabetes by pharmacists. Acta Diabetol;43: 37-42

13. Saini B, Krass I, Armour C (2004) Development, implementation, and evaluation of a community pharmacy-based asthma care model. The Annals of Pharmacotherapy, 38 (11) 1954-1960

14. Saini B, LeMay K, Emmerton L et al (2011) Asthma disease management- Australian pharmacists' interventions improve patients asthma knowledge and this is sustained. Patient Education and Counseling, 83 (3) 295-302

15. Sarkadi A, Rosenqvist U (2004) Experience-based group education in Type 2 diabetes A randomised controlled trial, 53:291-298

16. Skowron A, Polak S, Brandys J (2011) The impact of pharmaceutical care on patients with hypertension and their pharmacists. Pharmacy Practice (Internet):9(2):110-115

17. 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. 8(8) 1-13

18. Urban R (2015b) Calderdale Alcohol Identification and Brief Advice Service Evaluation 1st November 2013 – 31st October 2014. Community Pharmacy West Yorkshire. http://www.cpwy.org/doc/916.pdf. Urban R (2015c) Kirklees Alcohol Identification and Brief Advice Service Evaluation March 2013 – October 2014. Community Pharmacy West Yorkshire. http://www.cpwy.org/doc/972.pdf

19. Watman GP and Jepson M (2002) Patient screening by a community pharmacist located in a GP practice. Journal of Social and Administrative Pharmacy 19(3) 105-114

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
Burford O, Jiwa M, Carter O, Parsons R, Hendrie D. Internet-based photoaging within Australian pharmacies to promote smoking cessation: randomized controlled trial. Journal of medical Internet research. 2013;15(3):e64.

Quality score
++

Study type
RCT

Location and setting</td>
<td>Health area
Smoking cessation

Number of participants
160 – 80 assigned to control and intervention groups
8 pharmacies
(1259 CP users screened for eligibility; 213 eligible and 160 recruited)

77.5% 6 month follow up for control
72.5% 6 month follow up for intervention

Participant characteristics
No statistically significant differences between control and intervention groups o demographic or smoking dependence variables at baseline. Greater proportion of intervention group were concerned about appearance (82.5 vs 67.5%, p=0.03) and believed that facial wrinkles were associated with smoking (98.8 vs 85.0%, p=0.002). There was no difference in the proportion of participants in each group who made at least 1 attempt to quit smoking in the past (68.4 vs 70.9%, p=0.73)
<table>
<tr><th>Variable</th><th>Control</th><th>Intervention</th><th>P value</th></tr>
<tr><td>Male, n (%)</td><td>35 (43.8)</td><td>25 (31.3)</td><td>0.10[a]</td></tr>
</table>
</td>
<td>Intervention
APRIL Face Aging software is an Internet-based 3D age progression software package that creates aged images of faces from a standard digital photograph. Participants were photographed and their images were digitally aged as both a smoker and non-smoker and invited to view the images, which were also sent to their email within 24hrs.

Comparator</td>
<td>Recruitment:
Participants recruited when presenting to collect prescribed medications or over the counter medications in each CP. Participants were assigned to different arms of the study on alternate weeks.

Data collection:
Baseline questionnaire was used to collect demographic data, Fagerström Smoking Dependence Score (0-10), attitudes towards personal appearance, opinions on health risks associated with smoking and perceived barriers to quitting smoking. Intervention group was screened for body dysmorphia.

Willingness to pay for the aged imaging was assessed by questionnaire, at the time of intervention.

Follow-up surveys were undertaken via telephone at 1, 3 and 6 months. This measured successful quits, quit attempts and progression along the trans theoretical stages of change model and nicotine dependence using the Fagerström scale. Self-reported quits at 6-months were validated with a CO breath test.
Those lost to follow up were assumed to be continuing to smoke at 6 months and included in the analysis.</td>
<td>Clinical outcomes:
<table>
<tr><th>Variable</th><th>Control (n=80)</th><th>Treatment (n=80)</th><th>P value[a]</th><th>RR [95% CI]*</th></tr>
<tr><td colspan="5">Quit smoking at 6 months, n (%)</td></tr>
<tr><td>Self-reported</td><td>5 (6.3)</td><td>22 (27.5)</td><td><0.001</td><td>4.4 [1.75 to 11.04]</td></tr>
<tr><td>CO validated</td><td>1 (1.3)</td><td>11 (13.8)</td><td>0.003</td><td>11.0 [1.45 to 83.21]</td></tr>
<tr><td colspan="3">Change in Fagerström smoking dependence score at 6 months, n (%)</td><td><0.001 [b]</td><td></td></tr>
<tr><td>Reduced dependence</td><td>11 (13.8)</td><td>41 (51.3)</td><td></td><td>3.73 [2.07 to 6.72]</td></tr>
<tr><td>No change</td><td>68 (85.0)</td><td>39 (48.8)</td><td></td><td>0.57 [0.45 to 0.73]</td></tr>
<tr><td>Increased dependence</td><td>1 (1.3)</td><td>0</td><td></td><td>0.33 [0.01 to 8.06]</td></tr>
</table>
<table>
<tr><th></th><th>Control (n=80</th><th>Treatment (n=80)</th><th>P value</th><th>Mean difference</th></tr>
<tr><td colspan="3"><i>Change in mean Fagerström score from baseline to follow up</i></td><td><i><0.001</i>[c]</td><td></td></tr>
<tr><td>1 month</td><td>-0.14</td><td>-0.83</td><td></td><td>-0.69</td></tr>
<tr><td>3 months</td><td>-0.38</td><td>-1.34</td><td></td><td>-0.96</td></tr>
<tr><td>6 months</td><td>-0.26</td><td>-1.88</td><td></td><td>-1.62</td></tr>
</table>
[a] Chi-square values unless otherwise stated
[b] Fisher's Exact test, χ^2_2=26.2
[c] Repeated measures analysis including all available surveys</td>
</tr>
</table>

8 metropolitan community pharmacies located geographically around Perth city centre, Western Australia. **Aims** To test the efficacy and cost-effectiveness of an intervention based on personalised vivid illustrations of "smokers face" among young smokers (18-30 years). **Length of follow up** 6 months (Intervention Jan-Dec 2010; follow-up completed June 2011). **Source of funding**	Female, n (%)	45 (56.2)	55 (68.7)		Control group did not receive an offer of photo-aging.	**Analysis:** Baseline data was compared between groups using Fisher's exact test and Pearson's chi-square test for categorical variables and Student's t-test for continuous variables. End points were analysed using chi-square tests to compare percentages of quitters, or t-tests to compare smoking dependence. Self-reported and CO validated quits were compared. A logistic regression model was used to analyse percentage of quitters after adjustment for possible differences based on demographic or baseline data. A repeated measures analysis was used to identify changes in Fagerström dependence score at 1, 3 and 6 months. Data were analysed using SAS v9.2 software with $p<0.05$ taken as statistically significant. Customers perceptions about the value of the intervention was analysed using simple descriptive statistics Cost effectiveness from a health sector prospective as incremental cost per additional quitter and per additional lifetime quitter was measured. Costs were calculated based on time taken to provide the service (pharmacist time valued based on published recommended rate of pay in W.Australia) and the cost to a pharmacy of using the software (based on market price). Time taken that was protocol driven was excluded. Potential cost offsets from a reduction in healthcare costs of quitters were used to calculate net intervention costs (using Quit Benefits Model). Cost offsets were discounted at a rate of 3%.	***** Denotes figure calculated by NICE technical team, using Review Manager 5.3 Random effects regression model was used to model the mean change in Fagerström score from baseline by using data from all follow-up surveys. The control group did not experience a significant drop in Fagerström score over the study (p=0.36), the intervention group dropped by an average of 1.9 points (p=0.002) The difference in quitting between control and treatment groups was still statistically significant (p=0.003 for self-reported quit and p=0.03 for CO validated quit) after adjustment for: intervention group containing a larger population responding to the question "I care about how people think I look"; group differences in gender and nicotine dependence. **Change in effects due to characteristics of person receiving intervention:** Control groups had no association between change in score and age (p=0.14), gender (p=0.72) or baseline consumption (p=0.49). The intervention group showed a significant association in change of score with age (p<0.001) and baseline consumption (p<0.001), but gender was not (p=0.34). Older participants were less likely to reduce their score than younger participants (p=0.001). Participants who smoked more than 10 cigarettes per day showed a significant drop in Fagerström score of at least 1 point (p<0.001), independent on age. Participants smoking 6-10 cigarettes per day obtained a lower score but this was not statistically significant (p=0.07) whereas light smokers (0-5 cigarettes per day) showed no change in score. **Cost effectiveness:** **Item (AU$) | Base case | Best case | Worst case**
	Mean age (SD)	25.1 (4.1)	24.2 (4.1)	0.16[b]		
	Education, n (%)			*0.71[a]*		
	Year 10	15 (19.0)	17 (21.3)			
	Year 12	31 (39.2)	29 (36.3)			
	Technical and further education	17 (21.5)	22 (27.5)			
	Degree	16 (20.3)	12 (15.0)			
	Cigarettes per day over past 30 days, n (%)			*0.35[a]*		
	1	11 (13.8)	19 (23.8)			
	2-5	9 (11.3)	10 (12.5)			
	6-10	21 (26.3)	14 (17.5)			
	11-20	27 (33.8)	29 (36.3)			
	>21	12 (15.0)	8 (10.0)			
	Fagerström score, mean (SD)	2.96 (2.52)	2.87 (2.48)	0.82[b]		
	Fagerström dependency score, n (%)			*0.92[a]*		
	0-2	39 (48.8)	39 (49.4)			
	3-4	19 (23.8)	18 (22.8)			
	5	8 (10.0)	10 (12.7)			

APRIL Face Aging software supplied the progression software license per gratis for the study.

6-7	10 (12.5)	10 (12.7)	
8-10	4 (5.0)	2 (2.5)	

[a] Chi-square
[b] t-test

Inclusion criteria
- Aged 18-30
- Smoker (1 or more a day)
- Able to give consent
- Available for 6 month follow-up
- No beards, moustaches or non-removable facial accessories
- No body dysmorphia (assessed by - Body Dysmorphic Disorder Questionnaire)
- Not using NRT or oral drugs for nicotine dependence

Exclusion criteria
None specifically reported

All costs were expressed in 2011 AUS dollars. Cost of tokens was converted from American to AUS dollars based on 2011 average exchange rate. Number of lifetime quitters was calculated assuming long-term smoking relapse of 37% within 10yrs.

Scenario sensitivity analysis were performed according to table below:

Item	**Base case**	**Best case (change from base)**	**Worst case (change from base)**
Pharmacist's time	4.8 mins	-25%	+25%
Exchange rate*	0.9687 AU$	lowest level in 5yrs	highest level in 5yrs
Discount rate	3%	-3%	+2%

* for converting cost of tokens from American to AUS dollars

Mean cost per participant	5.79	5.07	8.93
Total cost[a]	463	406	714
ICER per additional quitter	46	41	71
ICER per additional lifetime quitter	74	64	113
Cost offset from reduction in healthcare costs	2144	2660	1867
Net total cost savings	1778	2346	1316

[a] total cost for all 80 participants
(Best case and worst case taken from table in methods and analysis column)

Cost effectiveness results with conversion to UK pounds sterling (conversion based on AUS dollars to UK pounds at 01/07/2011 [bankofengland.co.uk]):

Item (AU$)	**Base case**	**Best case**	**Worst case**
Mean cost per participant	3.87	3.39	8.93
Total cost[a]	310	272	478
ICER per additional quitter	31	27	48
ICER per additional lifetime quitter	50	43	76
Cost offset from reduction in healthcare costs	1434	1780	1249
Net total cost savings	1190	1570	880

[a] total cost for all 80 participants
(Best case and worst case taken from table in methods and analysis column)

				Acceptability Mean amount willing to pay for service (SD): 20.25AU$ (15.32) Median amount willing to pay for service (SD): 20.00AU$ (10.00, 20.00) More than 80% of participants thought their friends would be willing to pay for the service and all but 2 participants said they would recommend the photo-aging intervention to 1 or more friends who were smokers.

Limitations identified by authors
The participants and researcher could not be blinded to the study group. Allocation to groups was not performed as eligible participants were recruited, but according to the treatment being used at the pharmacy during that week.
Follow-up to 12 months would have been preferable, but was impractical in this case.
Few participants in the control group agreed to CO verification. It is possible that these participants continued to smoke, or they were not as engaged in the project as the intervention group and were less amenable to follow up.
Self-reported smoking status is likely prone to socially desirable responses.
Limitations identified by review team
Inclusion criteria was defined as self-report (smoking 1+ cigarette per day; not using NRT or drugs for nicotine dependence; age)
Unclear who delivered the intervention, whether it was a member of community pharmacy staff or an external researcher utilising the pharmacy premises.
Other comments
None.

Study details	**Population**	**Intervention and comparator**	**Methods and analysis**	**Results**
Reference Guirguis 2001 **Quality score** - **Study type** RCT **Location and setting** Community pharmacies in Edmonton, Canada	**Health area** Diabetes care **Number of participants** n=62 participants 1 pharmacy with 2 certified diabetes educator pharmacists 21 control pharmacies (number of pharmacists not reported) **Participant characteristics** Only reported for program completed (n=49).	**Intervention** (n=33) Diabetes care from 1 of 2 pharmacists with a certified diabetes educator designation. 1 pharmacist followed 18 participants, 1 followed 8 participants. Pharmacists met with each participant for an average of 6.9 (SD 1.0) visits, with 2 visits in the first month and then	**Recruitment**: Over 5 months from January 1999. **Analysis**: Method of randomisation not reported. Methods of allocation concealment (if any) not reported.	13 (21%) participants dropped out – comparable between groups (7 from intervention and 6 from control). Reasons for drop out in intervention group: pharmacy location (n=1), felt could receive similar services in own community (n=1), health reasons (n=1), unable to meet regularly with CDE pharmacists (n=4). Reasons for drop out in the control group: health reasons (n=1), lost to follow up (n=4), did not complete baseline data collection (n=1). Final study sample consisted of 49 participants.

	Change from baseline at 6 months			
Outcome	Intervention (n=26)*	Control (n=23)*	Change in intervention vs. change in control	Effect size

Aims
To measure the impact of Certified Diabetes Educator pharmacists in the community setting on clinical and humanistic outcomes of people with type 2 diabetes.

Length of follow up
6 months

Source of funding
Canadian Diabetes, Shoppers Drug Mart, and the Alberta Pharmaceutical Association. Bayer Inc., LifeScan, Medisense and Roche contributed monitoring devices and test strips for study participants.

	Intervention (n=26)	Control (n=23)
Age	57.1 years (SD 12.4)	61.9 (SD 9.4)
Gender	13 (50%) male	13 (57%) males
Duration of diabetes	7.4 years (SD 7.3)	6.3 years (SD 5.8)
Method of treating diabetes		
Diet alone	8 (31%)	2 (9%)
Pills	14 (54%)	19 (82%)
Insulin	4 (15%)	2 (9%)
Insulin and pills	0	0
Total DAS (1 to 5)	4.1 (SD 0.7)	4.1 (SD 0.4)
Total lifestyles form (1 to 5)	3.0 (SD 0.5)	3.5 (SD 0.6)
MCS12 (1 to 100)	44.8 (SD 12.7)	52.0 (SD 8.5)

Similar between groups, except method of diabetes treatment – control group more likely to use medications to treat diabetes ($p<0.05$) and had a statistically significantly higher total lifestyles form score ($p<0.01$) and mental component scale score ($p<0.05$).

approximately 1 visit per month for the next 5 months.

Over 80% of all participants received education. Around 85% of participants received education on nutrition, 85% on diabetes and its complications, 80% on exercise and 65% on foot care. Over 90% received education on hypoglycaemia. [All of these data are interpreted from a bar graph and may not be accurate]

Comparator (n=29)
Control pharmacies providing 'usual care'. Likely to vary from pharmacy to pharmacy, from minimal medication dispensing and counselling to one to one disease management, including monitoring of outcomes.

To assess care provided, pharmacists in the intervention group documented care on a follow up form and 1 pharmacist from 18 control pharmacies were interviewed (1 pharmacy refused to participate because of store policy, 2 pharmacies had scheduling difficulties).

Missing data were replaced with mean of available scores, however, if more than half of the items in a scale were missing for a participant that scale score was treated as missing data.

SDSCA diet	-0.02 (SD 0.5)	0.02 (SD 0.5)	p=0.78	-0.08
SDSCA exercise	0.05 (SD 0.05)	-0.05 (SD 0.7)	p=0.73	0.13
QoL (PCS12)	-2.2 (SD10.6)	-4.4 (SD 6.5)	P=0.99	0.23
QoL (MCS12)	5.6 (SD11.5)	-1.0 (SD 6.29)	P=0.026	0.78
Mean Difference (95%CI)** Diet: -0.04 (95% CI -0.32 to +0.24), p=0.78 Exercis: +0.10 (95%CI -0.24 to +0.44), p=0.57 QoL (PCS12): 2.20 (95%CI -2.66 to 7.06), p=0.38 QoL (MCS12): 6.60 (95%CI 1.49 to 11.71), p=0.01				

SDSCA Summary of diabetes self-care activities
* Complete cases only
**- Mean difference (95% CI) and p-values calculated by NICE technical team using Review Manager
PCS- Physical Composite Score
MCS- Mental Composite Summary

P values for change from baseline to 6 months in self-care ranged from 0.54 to 0.81 when controlled for HbA1c, duration of diabetes and baseline health-related quality of life at baseline [study does not clearly report which p value relates to which outcome].

Limitations identified by authors

Sample size was small and statistical analyses underpowered.
Withdrawal rate of 21%.
Data was not available from all participants who did not complete the study, to determine if differences existed.
Pre-test sensitisation, use of self-report questionnaires and the Hawthorne effect may have reduced the difference in change.
Participants may not have been representative of all persons with type 2 diabetes, because included participants were ready to change.
Differences in diet therapy at baseline suggest control group may have less well controlled diabetes at baseline.
Not clear if participants in control group received a higher level of care similar to the intervention group.

Limitations identified by review team

The method of randomisation is not reported and it is not clear how participants were allocated to groups. It is not clear if allocation was concealed. Baseline measurements for the outcomes of interest were not reported. There were statistically significant differences between the groups in methods of diabetes treatment, local lifestyles score and mental component scale score at baseline but these factors were not controlled for in the analysis. Missing data were replaced with mean available scores, however, it's not clear how many participants had missing data.

Other comments

All participants were supplied with a blood glucose meter and 200 testing strips. Participants received education on monitoring blood glucose levels, insulin devices and medication use but this is not reported here. Other outcomes, including HbA1c, were reported but are not presented here as the intervention included activities not of interest (medication changes, device services) that would have affected these results.

Study details	Population	Intervention and comparator	Methods and analysis	Results
Reference Kritikos 2005 **Quality score** - **Study type** Uncontrolled before and after study **Location and setting** Orange, Australia **Aims**	**Health area** Asthma **Number of participants** N=92 Year 11 students were trained (26.3% of total Year 11 population in the 3 high schools) 7 community pharmacists were trained as Triple A educators 3 of the 5 high schools in Orange participated **Participant characteristics** Not reported	**Intervention** Triple A program – community pharmacists were trained ('pharmacists required minimal training') as Triple A educators and implemented step 1 of the Triple A to Year 11 students at 3	**Recruitment**: September 2002 to March 2003 **Analysis**: Year 11's asthma knowledge was assessed on the training day pre- and post-delivery of the program using a validated asthma	**Primary outcomes:** Mean asthma knowledge scores of Year 11 students in each high school after Triple A delivery: | | Before Triple A | After Triple A | P for before vs. after | |---|---|---|---| | High School 1 (n=36) | 19.0 (SD 2.6) | 22.2 (SD 2.9) | p<0.001 | | High School 2 (n=42) | 18.7 (SD 3.3) | 23.0 (SD 1.7) | p<0.001 | | High School 3 (n=14) | 19.1 (SD 1.7) | 25.1 (SD 2.1) | p<0.001 | *Overall Mean difference: 4.39 (95%CI 3.67 to 5.11), p<0.001 *Caclculated by NICE technical team using formula for pooled mean and standard deviation. Overall, significant increase in mean asthma knowledge over time (p<0.001).

<table>
<tr>
<td>To assess the feasibility of using community pharmacists to deliver 2 asthma outreach programs and assess the programs' impact on asthma knowledge and requests for information at the community pharmacy.

Length of follow up
Immediately after intervention

Source of funding
Commonwealth Department of Health and Ageing</td>
<td>Inclusion criteria
Year 11 students at high school in Orange

Exclusion criteria
None stated</td>
<td>high schools.
Pharmacists trained Year 11 students as asthma peer leaders.

Pharmacists worked in pairs to deliver the program.

Triple A program is a 3 step, evidence-based, peer-led asthma education program based on awareness of asthma-related issues, empowerment, education and social learning.</td>
<td>knowledge questionnaire.

Asthma-related pharmacy visits were monitored with a data collection form. Data relating to patient demographics, circumstances for visit (e.g. prescription) and patient-initiated requests for information were recorded.

F test used for increase in mean asthma knowledge over time.</td>
<td>No statistically significant differences between high schools (p>0.05).

Asthma-related pharmacy visits:
<table>
<tr><th></th><th>Before Triple A</th><th>After Triple A</th></tr>
<tr><td>No requests for information</td><td>70.8%</td><td>72.2%</td></tr>
<tr><td>Asthma information requests</td><td>25.6%</td><td>19.1%</td></tr>
<tr><td>Device information requests</td><td>3.6%</td><td>8.6%</td></tr>
</table>
Statistical significance of differences before and after Triple A not reported.

Secondary outcomes:
Important points gained by students:
The symptoms of asthma
The triggers of asthma
Awareness of what it is like to have asthma
First aid for an asthma attack
How to prevent exercise-induced asthma
Asthma can be controlled by regularly using a preventer
Smoking is bad for asthma
What students liked in particular:
First aid for an asthma attack
Interactive sessions were interesting and exciting
The activities, discussions, videos and the role plays
Educators (pharmacists) were excellent
Friendly and approachable pharmacists
Easy communication and relaxed approach of educators
A great experience</td>
</tr>
<tr>
<td colspan="5">Limitations identified by authors
None reported.
Limitations identified by review team
It is not clear how Year 11 participants were selected to be peer educators, and it's not clear how many were approached before agreeing to participate.
It is not clear how participants were selected to be peer educators, and it's not clear how many were approached before agreeing to participate.
It is not clear if any participants dropped out of the study.
It is not clear if all participants who agreed to take part received the intervention or not
The intervention was delivered by different pharmacists and the consistency of the intervention was not measured.
Other comments
This study also reports a public forum on asthma with a panel of experts, however, it is not clear if this panel were community pharmacists, and so the results from this part of the study (such as asthma-related pharmacy visits) are not presented here.</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
Lloyd-Williams 2003

Quality score
-

Study type
Non-randomised controlled trial

Location and setting
Community pharmacies in North Staffordshire, UK

Aims</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</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</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.</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 [A]</td><td>100</td><td>72* (72%)</td><td>0* (0%)</td></tr>
<tr><td>Intervention 2 Leaflet display, with advice offer [B]</td><td>150</td><td>97* (65%)</td><td>19* (20%)</td></tr>
<tr><td>Intervention 3</td><td>150</td><td>75* (50%)</td><td>16* (21%)</td></tr>
</table>
</td>
</tr>
</table>

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** None reported.	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	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 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	Intervention 1= 2 pharmacies Intervention 2= 3 pharmacies Intervention 3= 3 pharmacies Intervention 4= 4 pharmacies Analysis: No analysis reported.	<table><tr><td>Targeted leaflet, no advice [C]</td><td></td><td></td><td></td></tr><tr><td>Intervention 4 Targeted leaflet, with advice offer [D]</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><tr><td colspan="4">RR (95%CI)* B vs D: RR=0.96 (95%CI 0.57 to 1.64), p=0.89 C vs D: RR= 0.88 (95%CI 0.51 to 1.54), p=0.66</td></tr></table> *Relative risk (95% CI) and p-values calculated by NICE technical team using Review Manager 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.

		pharmacy was supplied with 50 leaflets.		

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).

Study details	Population	Intervention and comparator	Methods and analysis	Results
Reference Mehuys et al. 2011 **Quality score** ++ **Study type** Randomised controlled trial **Location and setting**	**Health area** Diabetes **Number of participants** N=288 participants (135 in control group, 153 in intervention group) 66 community pharmacies (31 in control group, 35 in intervention group) **Participant characteristics** Intervention: Male 51.0%; Age 62.3 years (45 to 79) Control: Male 53.7%; Age 63.0 years (40 to 84)	**Intervention** (n=153) At start and at each prescription-refill visit for hypoglycaemic medication during 6 month study period: Education about type 2 diabetes and its complications Education about the correct use of oral hypoglycaemic	**Recruitment:** January 2006 to October 2006 Each pharmacy asked to recruit 5 patients. Recruitment in each pharmacy was consecutive. **Analysis**: Knowledge about diabetes was evaluated using a validated Dutch translation of the Brief	Nearly all participants completed the study (132/135 in control group and 148/153 in intervention group). Reasons for non-completion were hospitalisation (n=2), cancer diagnosis (n=1), cardiovascular accident (n=1), objection of the GP (n=1), patient no longer motivated (n=1) and lost to follow up (n=2). Knowledge test scores (%, from 0 to 100) Intervention (n=148): Baseline 60.0% (SD 18.2); 6 months 72.7% (SD 18.4); Mean change +12.7 (+9.3 to +16.1) p<0.001 Control (n=132): Baseline 58.3% (SD 16.8); 6 months 61.3% (SD 21.5); Mean change +3.0 (-0.2 to +6.1) p=0.069

Community pharmacies in Belgium

Aims
To study the effectiveness and sustainability of effects of a community pharmacist intervention in diabetes care in Belgium.

Length of follow up
6 months

Source of funding
The study was funded by Ghent University. Lifescan Belgium donated the glucose meters used in the study.

BMI	30.5 (23.3 to 42.3)	31.0 (23.4 to 44.5)
Metformin	50.7%	48.4%
Sulphonylureas	33.9%	35.8%
Glinides	6.3%	4.1%
Other	9.1%	11.7%
Oral hypoglycaemic agents per patients	1.8 (0 to 3)	1.5 (0 to 3)
Insulin users	11.4%	6.8%
Fasting plasma glucose	153.9 mg/dL (81.7 to 332.3)	154.1 mg/dL (86.5 to 310.0)
HbA1c*	7.3% (5.6 to 11.1)	7.7% (5.7 to 12.9)

*only available for 57.0% of control group and 42.5% of intervention group

No statistically significant differences between the groups.
Inclusion criteria
Type 2 diabetes
Prescription for oral hypoglycaemic medication
45 to 75 years old
BMI 25 kg/m2 or greater
Treatment with oral hypoglycaemic medication for at least 12 months
Regular visitor to the pharmacy (not defined)

Exclusion criteria
Solely on insulin treatment

agents (timing in relation to food)
Facilitation of medication adherence (by counselling)
Healthy lifestyle education (diet, physical exercise, and smoking cessation)
Reminders about annual eye and foot examinations

Intervention
pharmacists underwent a training session on pathophysiology of type 2 diabetes and its management (pharmacological and non-pharmacological) according to current treatment guidelines).

Comparator
(n=135)
Usual pharmacist care (not defined)

Diabetes Knowledge Test of the Michigan Diabetes Research and Training Centre.
Self-care activities of the patients were assessed with a validated Dutch translation of the Summary of Diabetes Self-Care Activities questionnaire (self-report) that measured levels of self-management for general diet, specific diet, physical exercise, foot care, and smoking.

Randomisation was at pharmacy level – predetermined using randomisation table.

Paired t-tests were used for continuous variables. Chi-squared tests were used for categorical variables. Answers on domains 1 to 4 of the self-care questionnaire were evaluated with the Wilcoxon signed ranks test (time effect) and a Mann Whitney U-test (study group effect).

Difference from baseline between groups= 9.7% (5.1 to 14.4), p<0.001
*Mean Difference 11.4 (95%CI 6.68, 16.12), p<0.001

Self-care activities
General diet (0 to 7)

	Baseline	6 months	Mean change
Intervention (n=148)	4.5 (SD 2.3)	4.8 (SD 1.8)	p=0.159
Control (n=132)	4.8 (SD 2.3)	4.7 (SD 2.1)	p=0.538

Difference from baseline between groups p=0.226
*Mean Difference 0.10 (95%CI -0.36, 0.56), p=0.67

Specific diet (0 to 7)

	Baseline	6 months	Mean change
Intervention (n=148)	4.0 (SD 1.7)	4.5 (SD 1.5)	p=0.008
Control (n=132)	4.0 (SD 1.7)	3.9 (SD 1.6)	p=0.904

Difference from baseline between groups p=0.052
*Mean difference 0.60 (95%CI 0.24, 0.96), p=0.001

Physical exercise (0 to 7)

	Baseline	6 months	Mean change
Intervention (n=148)	2.9 (SD 2.4)	3.3 (SD 2.4)	p=0.006
Control (n=132)	3.4 (SD 2.3)	3.3 (SD 2.3)	p=0.833

Difference from baseline between groups p=0.045
*Mean difference 0.0 (95%CI -0.55, 0.55), p=1.00

Foot care (0 to 7)

	Baseline	6 months	Mean change
Intervention (n=148)	2.2 (SD 1.7)	3.2 (SD 2.1)	p<0.001

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<td></td>
<td>There was deviation from inclusion criteria (age: n=2 for control, n=4 for intervention; BMI: n=4 for control, n=5 for intervention) but these participants were still included in all statistical analyses.</td>
<td>
<table>
<tr><td>Control (n=132)</td><td>2.6 (SD 2.0)</td><td>2.6 (SD 2.1)</td><td>p=0.639</td></tr>
</table>
Difference from baseline between groups p<0.001
*Mean difference 0.60 (95%CI 0.11, 1.09), p=0.02

Smoking (% of smokers)
<table>
<tr><td></td><td>Baseline</td><td>6 months</td><td>Mean change</td></tr>
<tr><td>Intervention (n=148)</td><td>18.4%</td><td>26 (17.5%)</td><td>Not reported</td></tr>
<tr><td>Control (n=132)</td><td>21.8%</td><td>28 (21.1%)</td><td>Not reported</td></tr>
</table>
Difference from baseline between groups p=0.466
*RR= 0.83 (95%CI 0.51, 1.34), p=0.44

*Calculated by NICE technical team using RevMAN 5.3
</td>
</tr>
<tr>
<td colspan="5">Limitations identified by authors
May have underestimated effect of intervention as excluded newly diagnosed, treatment-naïve people with diabetes (who have higher education need). Hawthorne effect may also have contributed to underestimating effect.
Participants voluntarily recruited, so may not be representative of the general diabetes population. Did not collect data on refusal rate and reasons for refusal.
Only recruited regular pharmacy users to ensure sufficient follow up – may reflect stronger interest in self-management, possible positive selection bias.

Limitations identified by review team
Unclear if baseline outcome measurements were similar, how missing data were addressed and whether outcomes were assessed blindly.

Other comments
Results for fasting blood plasma glucose and HbA1c are reported in the paper but are not presented here as participants were also receiving pharmacotherapeutic changes and advice on medication adherence in addition to intervention of interest. Sustainability of observed effects was only reported for fasting blood plasma glucose and HbA1c and is therefore not presented here.</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
Petkova 2006
Quality score -
Study type
Before-After study

Location and setting
Bulgaria, community pharmacy setting
Aims
To assess the applicability of a diabetes educational programme in a community pharmacy setting.</td>
<td>Health area
Type -2 Diabetes

Number of participants
24 individuals with type 2 diabetes

Participant characteristics
<table>
<tr><td></td><td></td></tr>
<tr><td>Female</td><td>71%</td></tr>
<tr><td>Mean age (SD)</td><td>65.0 (10.2)</td></tr>
<tr><td>Mean (SD) Duration of diabetes since diagnosis in years</td><td>8.7 (5.1)</td></tr>
<tr><td colspan="2">Drug consumption, Mean (SD)</td></tr>
<tr><td>Sulphonylurea agents</td><td>72%</td></tr>
<tr><td>Biguanides</td><td>25%</td></tr>
<tr><td>Prandial glucose regulators</td><td>4%</td></tr>
<tr><td>Alpha glucosidase inhibitors</td><td>4%</td></tr>
<tr><td>Thiazolidinediones</td><td>4%</td></tr>
<tr><td>Blood glucose levels (mmol/l), Mean (SD)</td><td>8 (2.0)</td></tr>
</table>
Inclusion criteria</td>
<td>Intervention
Intervention delivered by pharmacy students in their last course of study. Participants given 5 teaching units over one month
<u>Unit 1</u>: Acquainted each patient with aim of educational program, provided general concepts about diabetes and self-monitoring. At the end of this session each patient provided written materials on hypo/ hyper glycaemia and asked to monitor glucosuria twice daily.
<u>Unit 2:</u> Effect of obesity on insulin sensitivity and advantages of weight reduction discussed. Participants also provided written materials on proper nourishment for diabetic patients and physical activity</td>
<td>Recruitment:
Individuals who met inclusion criteria and agreed to participate included in the study. No further information provided about recruitment strategy. Patient satisfaction questionnaire administered at baseline and 6 months to assess quality of life.

Analysis:
Not reported. Assume simple descriptive analysis for continuous and categorical variables.</td>
<td>Primary outcomes (n=24):
<table>
<tr><th></th><th>Baseline</th><th>1 month</th><th>3 month</th><th>6 month</th></tr>
<tr><td>Blood glucose levels, mmol/l, Mean (SD)</td><td>8 (1.95)</td><td>7.91* (1.44)</td><td>7.52 (1.19)</td><td>7.2 (0.99)</td></tr>
<tr><td>Frequency of hypo/hyperglycaemic incidents (%)</td><td>14 (58%)</td><td>6 (25%)</td><td>3 (12%)</td><td>0</td></tr>
<tr><td>QoL-positive mood (%)</td><td>3 (12.5%)</td><td>NR</td><td>NR</td><td>5 (19.2%)</td></tr>
<tr><td>QoL-Feel days “being easy” (%)</td><td>4 (18.4%)</td><td>NR</td><td>NR</td><td>6 (25.3%)</td></tr>
<tr><td>QoL Increase in social activity (%)</td><td>3 (10.8%)</td><td>NR</td><td>NR</td><td>3 (14%)</td></tr>
<tr><td>QoL-Feel “Rested” (%)</td><td>4 (15%)</td><td>NR</td><td>NR</td><td>4 (17.4%)</td></tr>
<tr><td>QoL increase in physical activity (%)</td><td>3 (13.4%)</td><td>NR</td><td>NR</td><td>5 (19.2%)</td></tr>
</table>
QoL- Quality of Life, NR- Not reported
<u>BLOOD GLUCOSE*</u>
Mean Diff at 1 month- -0.09 (95%CI -1.06, 0.88), p=0.86
Mean Diff at 3 months -0.48 (95%CI -1.39, 0.43), p=0.30
Mean Diff at 6 months -0.80 95%CI (-1.67, 0.07), p=0.07

<u>QoL*</u>
Positive Mood at 6 months OR=1.84 (95%CI 0.39, 8.77), p=0.44</td>
</tr>
</table>

Length of follow up 6 months Source of funding NovoNordisk provided help and support in the preparation of the educational materials and for the planning of the research	Type 2 diabetes without severe complications such as retinopathy or nephropathy. Patients on monotherapy and those not using insulin in addition to per-oral antidiabetics preferred. Exclusion criteria Severe life limiting illness and inability or unwillingness to participate in diabetes education.	Unit 3: Educator performed foot examinations and explained potential seriousness of foot sores and lesions. Patients taught about what neuropathy was. Unit 4: Pharmacist discussed diabetic eye disease, including diabetic retinopathy, cataract and glaucoma. Unit 5: Adverse drug reactions that can arise during drug treatment discussed. Patients informed that diabetics may develop weakness, sweating, nausea and palpitations if oral antidiabetic drug reduces blood sugar levels too much. Patients told to strictly follow prescribed dose and seek pharmacist or GP adverse events occurred. Written materials on AEs provided at the end of the session. Comparator None		Days being easy at 6 months OR= 1.67 (95%CI 0.40, 6.87), p=0.48 Social activity at 6 months OR= 1.0 (95%CI 0.18, 5.53), p=1.0 Feel rested at 6 months OR = 1.0 (95%CI 0.22, 4.56), p=1.0 Physical activity at 6 months OR= 1.84 (95%CI 0.39, 8.77), p=0.44 *Summary measures calculated by NICE technical team using RevMan 5.3 Secondary outcomes (costs converted from euros to UK pounds sterling as at 01/07/2003 [bankofengland.co.uk]): The total cost for the 6 month education was €6 (£4.19), that is the minimal possible cost and the whole project cost was €143 (£99.77). Cost-effectiveness ratio calculated on the basis of the decrease in blood glucose level per patient was €7.5 (£5.23) for achieving one intermediate clinical outcome (€6 [£4.19]: 0.8 mmol/l). The long term clinical outcomes could not be calculated during the six month project but the steady decrease of blood glucose level, decrease in hypogylcemic incidents and increase in overall QoL are prerequisites for achieving such improvements. At the end of the program no incidents were matched that €10/patient (£6.98), which is the cost paid by the Bulgarian health insurance fund for the consultation of a patient with specialists. For 58% of the observed patients that report having such incidents at the beginning such savings were €140 (£97.68) and thus benefit to cost ratio is at least about 1:1 (€140 to €142.80) [£97.68 to £99.63) if there are no other expenses.
Limitations identified by authors Author did not report any limitations Limitations identified by review team Unclear how study population obtained. Study was supported by pharmaceutical company (Novo Nordisk). This appears to be quite an intensive intervention. No information provided on time/per patients and its applicability in other community pharmacy settings. Other comments				

<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
Saini 2004

Quality score
-

Study type
RCT

Location and setting
Community pharmacies in Australia

Aims
To develop, implement and evaluate an asthma care model for use in community pharmacy settings

Length of follow up
6 months

Source of funding
Pharmacy Research Trust and the Pharmacy Board of New South Wales</td>
<td>Health area
Asthma

Number of participants
Intervention pharmacists: 12
Intervention participants: 52 recruited; 39 completed until end-point

Baseline data:
Control pharmacists: 7
Control participants: 20

Follow up data:
Control pharmacists: 6
Control participants: 28

The rate of recruitment and retention of control patients was very low, and so a second group of control participants was recruited at the time point that coincided with the post-service data collection in the intervention group

Participant characteristics
<u>Intervention participants:</u>
Age (SD): 43 (+/- 10)
Gender: 39% male
Severity score (SD): 2.6 +/- 0.5

<u>Control group 1:</u>
Age (SD): 52 (+/-15)
Gender: 27% male</td>
<td>Intervention
Asthma care model is a 6 step plan containing a training element using the principles of adult learning and a service element.

The plan consisted of the following factors:
Assessment of patients asthma severity
Achievement of best lung function
Maintenance of best lung function through avoidance of triggers
Maintenance of best lung function through optimal medications
Provision of written action plan
Education and regular review
Self-study manuals addressing these 6 steps were provided for pharmacists, and pharmacists were invited to attend a 2 day training course.

The service element of the model consisted of pharmacists:
Seeing patients on an appointment basis
Conducting individual needs analysis framed around the 6 steps
Conducting interventions to address needs assessed through individual analysis
Documenting interventions and outcomes
Collaboratively setting goals with the patient for the next visit
Monitoring patients at 1 month, 3 month and 6 months after the initial intervention</td>
<td>Recruitment:
Pharmacy recruitment:
Intervention pharmacies were recruited by approaching the local pharmacist's association. In the control area, pharmacist recruitment utilised cold calling and personal contacts.

Marketing tools were used to recruit patients, as well as professional networking within the Division of General Practice, asthma educators at the local hospital, the local asthma working group and schools.</td>
<td>Primary outcomes:

Asthma knowledge scores:
There was a statistical significant improvement in perceived control of asthma and asthma-related knowledge scores in the intervention group compared with the control group between baseline and final visit

<table>
<tr><td></td><td colspan="2">Control</td><td colspan="2">Intervention</td><td>p*</td></tr>
<tr><td></td><td>Group 1</td><td>Group 2</td><td>Baseline</td><td>Follow up</td><td></td></tr>
<tr><td>Participant number</td><td>22</td><td>28</td><td>52</td><td>39</td><td></td></tr>
<tr><td>Asthma knowledge mean score (SD)</td><td>20.3 (5.7)</td><td>20.3 (5.6)</td><td>19.7 (4.8)</td><td>23.1 (5.0)</td><td>0.04</td></tr>
<tr><td colspan="6">**Mean difference for Intervention vs Control 2.80 (95%CI 0.59 to 5.01), p=0.01</td></tr>
</table>
* p value compares change in control groups 1 and 2 and follow up intervention group scores
** Effect estimate calculated by NICE technical team Cochrane formula for pooled mean and standard deviation for control group and RevMan and
[a] asthma knowledge scored between 0-31

Asthma severity score
Final mean severity scores were lower in the intervention group at final visit (1.6 SD 0.7) compared with control groups 2.4 (sd-0.5), p<0.001.</td>
</tr>
</table>

	Severity score (SD): 2.7 (+/- 0.7) <u>Control group 2:</u> Age (SD): 42 (+/- 18) Gender: 21% male Severity score (SD): 2.4 (+/- 0.5) **Inclusion criteria** Patients with a previous diagnosis of asthma who used bronchodilator medications >3 times/week; those with frequent acute attacks or those with general concerns about their asthma **Exclusion criteria** <12 years of age; patients with other major disease (e.g. lung cancer, COPD, AIDS) or terminally ill patients.	Collaborating with other healthcare practitioners involved in the asthma care of the patient. An average of 14 interventions/patient were administered, over a mean total time of 96.4 minutes per patient An average of 56.4 minutes was spent at the 1st visit, 18.8 minutes at the 2nd visit and 21.1 minutes at the third visit. **Comparator** Pharmacists in the control area were not offered any training and did not perform any interventions. Baseline data was collected and end point data was collected from recruited control participants. **Primary Outcome** Asthma severity- Score obtained from patient report on frequency symptoms, score range 1-3 (Lower number is less severe) Asthma knowledge- Validated questionnaire 31 true/false responses, scored 0-31 QoL- 20 items scaled 0-80 (o best, 80 worst)	**Data collection:** Pre- and post-intervention questionnaires at 3 months (data not reported) & 6 months **Analysis**: The Student's t-test for independent samples or a one-way ANOVA was carried out. Proportional data were analysed using the chi-squared test, 5% level of significance was used for all statistical procedures.	
Limitations identified by authors The sample sizes were small The same control group could not be followed through the study, and a different control group was recruited for comparison Pharmacy numbers were quite small, thus effect size based on pharmacy or pharmacist type could not be demonstrated **Limitations identified by review team** No attempt to blind participants to their allocation **Other comments** Medication services were included in the intervention, and therefore all outcomes which may have been influenced by this have been excluded from this review and not reported here				

<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
Saini 2011

Quality score
-

Study type
Before and after

Location and setting
Regional and metropolitan areas in New South Wales, Queensland, Victoria and the Australian Capital Territory, Australia.

Aims
To assess if pharmacists can deliver improvements in asthma knowledge if they tailor the education program to the patients' needs

Length of follow up
6 months

Source of funding</td>
<td>Health area
Asthma

Number of participants
<u>Total:</u>
Baseline: 570 (from 96 pharmacies)
Follow up: 398

(The total number receiving the relevant interventions over 6 month intervention period is unknown, but at least 524 received the intervention 'counselling on trigger factors' and at least 457 received the intervention 'provision of trigger factor information')

Participant characteristics
402 (70%) from urban areas
Mean age 50.6 years (+/- 16.8)
62% female; 38% male

Inclusion criteria
None specifically reported

Exclusion criteria
Patients with a terminal illness, those who did not speak English well enough to communicate with the pharmacist and complete the study questionnaires independently, anyone enrolled in another study, or those who did not self-administer their medicines/inhalers.</td>
<td>Intervention
Pharmacists were trained in advanced asthma care, over 2 days and incorporated pathophysiology of asthma, recruitment and motivation of patients and how to use the protocol effectively.

6 month intensive asthma service: Patients attended either 3 or 4 visits at their pharmacy over a 6 month period, where educational needs were assessed by the pharmacists so that educational interventions delivered were targeted to individual needs.

Interventions included the provision of trigger factor information, such as quit smoking information and</td>
<td>Recruitment:
Pharmacist recruitment was by invitation through a web interface established by a pharmacy body.

Patients were recruited through their regular community pharmacy based on their risk of poor asthma control, using a risk assessment tool

Data collection:
Consumer Asthma Knowledge Questionnaire (CQ) was used. This was a 12-item questionnaire comprising true/false questions.

Analysis:
McNemar's test was used to calculate the significance between knowledge score at baseline and at the end of the service</td>
<td>Primary outcomes:
Asthma knowledge change before and after the intervention period:
<table>
<tr><th>Group</th><th>N</th><th>V1 Mean (SD)</th><th>FV Mean (SD)</th><th>V1 vs FV p-value</th></tr>
<tr><td>3-visits</td><td>212</td><td>7.51 (2.39)</td><td>8.60 (2.25)</td><td><0.001</td></tr>
<tr><td>4 visits</td><td>179</td><td>7.80 (2.33)</td><td>8.98 (1.99)</td><td><0.001</td></tr>
<tr><td></td><td>391</td><td></td><td></td><td></td></tr>
</table>
Overall pooled result: Overall mean difference from baseline to 6 month follow-up for both groups combined is 1.14 (95%CI 0.83 to 1.45)
Asthma knowledge significantly improved as a result of service (7.65 sd2.36, n=561 to 8.78 sd 2.14, n=393). This improvement was retained for at least 12 months

*Mean Difference (95%CI)
3 visits: 1.09 (95%CI 0.65 to 1.53), p<0.001
4 visits: 1.18 (95%CI 0.73 to 1.63), p<0.001
4 vs. 3 visits: 0.38 (95%CI -0.04 to 0.80)p>0.05
*Mean difference (95%CI) and p-values calculated by NICE technical team using Rev Man.

Number of patients answering correctly the question "Going from a cold to a hot environment can trigger asthma, but going from a hot to a cold environment does not trigger asthma"
<table>
<tr><th>Baseline, n=570 (%)</th><th>Follow-up, n=398 (%)</th><th>% change</th><th>p (difference in proportion correct)</th></tr>
<tr><td>370 (65%)</td><td>290 (73%)</td><td>8%</td><td>0.014</td></tr>
</table>
</td>
</tr>
</table>

Australian Government Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement		counselling patients on trigger factors **Comparator** Baseline knowledge		
Limitations identified by authors The intervention was complex and thus it is difficult to relate improvement in knowledge of the patients to any specific intervention. There is no direct measure that this change in knowledge has been translated into behaviour. Cannot necessarily be linked that the increase in knowledge is due to pharmacist counselling **Limitations identified by review team** Not reported how many participants received the specific interventions overall, only how many received the interventions at each visit The proportion of participants within each intervention group having a change in knowledge score for specific questions is unknown, thus no comparison of each intervention type can be made for this review **Other comments** Other aims, methods to achieve these aims and outcomes are reported but are not within the scope of this review and thus not reported here				

<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
Sarkadi 2004

Quality score
-

Study type
RCT

Location and setting
Sweden; Pharmacies

Aims
To investigate the effectiveness of an experience-based group educational program to identify mediators that might pay a role in achieving desired metabolic outcomes.

Length of follow up
2 years from baseline (One-year post intervention)

Source of funding
Swedish Foundation for Health care Sciences and Allergy Research Grant. First author received funding from the</td>
<td>Health area
Type 2 Diabetes

Number of participants
<u>Participant flow:</u>
-84 Eligible (7 not randomised)
-77 Randomized (39 intervention; 38 control)
-33 (85%) Completed trial (intervention group)
-31 (82%) completed trial (Control group)

Participant characteristics
<table>
<tr><th></th><th>Intervention N=33</th><th>Control N=31</th></tr>
<tr><td>Age; Mean (SD)</td><td>66.4 yrs (7.9)</td><td>66.5 yrs (10.7)</td></tr>
<tr><td>BMI at baseline</td><td>27.2 (3.6)</td><td>28.6 (5.8)</td></tr>
<tr><td>Duration of disease; Mean (SD)</td><td>5.9 yrs (5.8)</td><td>2.6 yrs (2.2)*</td></tr>
</table>
*p<0.05 difference between groups
Inclusion criteria
Diagnosed with Type 2 diabetes and if treated with insulin, only for 2 years or less
Exclusion criteria</td>
<td>Intervention
12 month group education program led by specially trained pharmacists, assisted by a diabetes nurse specialist on the first two occasions. Pharmacists received 3-day intensive training to become facilitators for a program where the main objective was to convey the pedagogical principle of the program, experience based learning. Throughout their training pharmacists monitored their blood glucose levels, did the shopping for lunch and snacks, prepared meals and went on walks after meals to test the effects of exercise on blood glucose levels. The materials used to train pharmacists were identical to those the program participants would use which included a video on how to “live well” with diabetes; a dice game where questions had to be answered but no set answers were available; a booklet on “how to manage your diabetes”. The booklet also contained logs of imaginary people who had some typical faults in diet or treatment and were used to simulate discussion of more appropriate routines.
Goal of the educational program was to reinforce participant’s experiences and use these experiences as a basis for the acquisition of practical</td>
<td>Recruitment:
Participants self-referred, responding to ad in newspapers and flyers. In order to be randomised participants had to leave an initial HbA1c measurement, complete a questionnaire and provide consent.

Analysis:
Power calculations resulted in 18 participants per group necessary to detect a decrease of 1% unit in HbA1c (7.2-6.2%) with alpha=0.05 and Beta=0.1 using two tailed testing. One way ANOVA used to calculate difference in Blood glucose levels at 6,12 and 24 months from baseline.</td>
<td>Primary outcomes:
HbA1c Blood Glucose Level, measured at 6, 12 and 24 months

<u>Intervention vs. control</u>
6 months: p=0.047
12 months: p=0.240
24 months: p=0.008

Mean HbA1c levels significantly lower in intervention group relative to control at 6 and 24 months post-baseline but not at 12 months. Participating in intervention decreased HbA1c by 0.4% at 24 months after baseline.

Secondary outcomes:</td>
</tr>
</table>

Knut and Alice Wallenberg Foundation in Stockholm	Long-term insulin treatment was determined based on reports from the study circle leaders who felt that dietary and exercise interventions did not lead to immediately demonstrable effects for this group.	skills needed for self-management of diabetes. Participants encouraged to experiment with different nutritional components and exercise and monitor blood glucose reactions as a means to promote experience based learning. Groups met once a month and self-monitoring diaries shared. The educational program also geared to provide participants with support for dealing with the emotional aspects of diabetes. Comparator No intervention		
Limitations identified by authors Selection procedure introduced a systematic bias, presumably resulting in persons motivated to improve diabetes self-management. Hence 52% of participants found to be under the WHO HbA1c target value but as randomisation occurred after recruitment the bias was equally present for both groups. Limitations identified by review team Selective outcome reporting in that there appears to be a range of exploratory analyses but only those with significant findings mentioned in paper with p-values only and the direction of effect and groups of reference not always clear. Other comments This intervention is very intensive and it's applicability to the English health service is unclear.				

Study details	Population	Intervention and comparator	Methods and analysis	Results
Reference	Health area	Intervention	Recruitment:	Primary outcomes:

Skowron 2011
Quality score
+

Study type
RCT
Location and setting
Krakow, Poland
Aims To assess if pharmaceutical care as defined by Hepler and Strand may improve effectiveness of hypertensive therapy
Length of follow up
November 2004 to Jan 2006
Source of funding
No specific grant from any funding agency in the public, commercial or not for profit sectors

Hypertension

Number of participants
55 TOTAL Pharmacies enrolled
Intervention Group
28 Pharmacies (44 pharmacists) randomized
70 patients enrolled
Control group
27 pharmacies (51 pharmacists)
123 patients enrolled

Patient Participant characteristics

	ITT Population	
	Intervention (n=28) N (%)	Control (n=56) N(%)
Women	17 (61)	33 (60)
Education		
Elementary	2 (7.1)	2 (4)
Vocational	10 (36)	13 (23)
Secondary	6 (21)	20 (36)
Higher	10 (36)	21 (38)
Age		
31-45	1 (4)	6 (11)
46-60	12 (43)	24 (43)
61-75	11 (40)	22 (39)
>75	4 (14)	4 (7)
Mean BP (SD)		
Systolic	144 (10)	147(20)
Diastolic	85 (10)	90 (11)
Avg # of medications used (SD)		
TOTAL	3.9 (1.9)	3.7
CVD	2.9 (1.5)	(2.2)
Arterial hypertension	2.0 (0.8)	3.1 (1.7)

Pharmacists received three 5 hour trainings in Oct and Nov 2004 which included detection, classification and monitoring of drug related problems, pathophysiology of hypertension, risk factors and life style factors influencing disease and rules of pharmacotherapy of hypertension. At least 12 meetings between pharmacist and patients that included measuring blood pressure using sphygmomanometer, detecting and solving drug related problems, and EDUCATING patients about pathophysiology, risk factors, treatment and lifestyle in relation to hypertension.

Comparator
Pharmacists met their patients included in the study only two times between November 2004 and January 2006, with at least 14 months interval between these 2 meetings.

Study just mentions random study with pharmacists from Krakow Poland and surrounding area.
Recruitment not described
Analysis: Unpaired t-test and Mann-Whitney U test for between group comparisons. Categorical data compared using chi-square test with continuity correction of Fisher's exact test. Significance of p<0.05 deemed to be significant.

Interventions group: 42/70 (60%) Lost to follow-up
Control group: 67/123 (54%) lost to follow-up

Clinical Outcomes

	Intervention (n=28)	Control (n=56)	p-value
Number medications used on last visit, Mean (SD)			
Total	5.4 (2.2)	4.1 (2.5)	0.02
CVD related	4.4 (1.8)	3.0 (1.4)	0.00
Hypertension	2.6 (1.3)	2.2 (0.9)	0.05
Level of arterial blood pressure (mmHg) on last visit, Mean (SD)			
Systolic	138 (12.5)	142 (19.6)	0.5
Diastolic	83 (9.9)	88 (9.2)	0.4

*Mean Diff (total Meds) 1.30 (95%CI 0.25, 2.35); p=0.01
*Mean Diff (CVD meds) 1.40 (95%CI 0.64, 2.16); p<0.001
*Mean Diff (Hypertension Meds) 0.40 (95%CI -0.14, 0.94); p=0.14
*Mean Diff (Systolic BP) -4.0(95%CI -10.91, 2.91); p=0.26
*Mean Diff (Diastolic BP) -5.00(95%CI -9.39, -0.61); p=0.03

22/28 (79%) in intervention group vs 31/56 (55%) in the control group had normal BP at the end of study p<0.05
Similar trends observed in per protocol population analysis

Knowledge (No information provided on minimum and maximum range of score or scale used to assess knowledge). NICE technical team assumed that a positive change score was more favourable.

	Intervention (n=28)	Control (n=56)	p-value	Mean diff of the change*
Knowledge progress (Mean difference, SD)				
Total	3.2 (3.0)	1.3 (5.3)	0.1	1.9 (0.11, 3.69), p=0.04
About disease	1.5 (2.4)	-0.2 (2.7)	0.006	1.7 (0.56, 2.84), p=0.03
About diet	-1.1 (3.5)	1.1 (3.1)	0.92	-2.2 (-3.73,-0.67),p=0.005
About medications	0.5 (1.5)	-0.1 (2.0)	0.37	0.6 (-0.17, 1.37),p=0.12

		2.2 (0.9)			
Mean # of visits (sd)	11.8 (3.5)	2 (0)			
Length (in days) of pharmaceutical care (sd)	359 (81.2)	439 (20)			

Inclusion criteria
Mean And women age 18 years or older with hypertension, pharmacologically treated for at least 6 months who were able to keep moving independently
Exclusion criteria
Patients with CVD incident within the last 6 months or a history of diabetes, asthma, COPD, depression, schizophrenia, or unable to independently maintain contact with pharmacists.

About health attitude	0.11 (1.2)	0.1 (1.3)	0.91	0.01 (-0.55, 0.57), p=0.97

*Calculated by NICE technical team using RevMan
Similar trends observed in per protocol population analysis
Analysis of health related QoL done by filling out the SF-36 found the intervention had no effect on improvement of Qol in either the ITT or per protocol analysis. No statistical analysis reported

Limitations identified by authors
Randomization of community pharmacies to study and control group done to avoid unintended increase in quality of standard of pharmaceutical care but may have influenced the number and characteristics of patients enrolled in the study. Assignment to the intervention arm could be a reason for drop-out.
Limitations identified by review team
Large number of patients enrolled lost to follow-up (~60%). Additionally 6/28 (21%) of pharmacies in the intervention arm and 3/27 (11%) of pharmacies in the control group dropped out. Overall the information reported in this paper is unclear making it difficult to understand what was actually done and the results.
Other comments

<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 2013

Quality score
+

Study type
Cluster RCT

Location and setting</td>
<td>Health area
Orthopaedic – lower back pain
Number of participants
317 pharmacy users from 35 pharmacies
Pamphlet plus education= 102 users from 11 pharmacies
Pamphlet only= 111 users from 11 pharmacies
Control group= 104 users from 13 pharmacies

Participant characteristics:
<table>
<tr><th></th><th>Intervention 1, n (%)</th><th>Intervention 2, n (%)</th><th>Control n (%)</th></tr>
</table>
</td>
<td>All participants given a questionnaire at baseline (prior to intervention and prior to leaving pharmacy). Sealed in a pre-paid envelope and</td>
<td>Recruitment:
35 community pharmacies between May 2011 and August 2011

Participants recruited by approach from pharmacist, if requesting</td>
<td>Back beliefs (score range 9 to 45, higher score indicates more positive beliefs, n=206)
<table>
<tr><th>Time</th><th>Intervention 1</th><th>Intervention 2</th><th>Control</th></tr>
<tr><td>2 weeks</td><td>27.0 (7.4)</td><td>27.1 (6.3)</td><td>24.9 (6.6)</td></tr>
<tr><td>8 weeks</td><td>26.7 (8.1)</td><td>26.1 (7.0)</td><td>25.8 (6.8)</td></tr>
<tr><td colspan="4">Mean Difference (95%CI)*
Int 1 vs. Control at 2 wks: 2.10 (95%CI -0.34 to 4.54), p=0.09
Int 1 vs. Int 2 at 2 wks: -0.10 (95% CI -2.57 to 2.37), p=0.94
Int 1 vs. Control at 8 wks: 0.90 (95% CI -1.80 to 3.60), p=0.51
Int 1 vs. Int 2 at8 wks: 0.60 (95% CI -2.19 to 3.39), p=0.67</td></tr>
</table>
Physical activity related fear (higher score indicates higher fear avoidance beliefs, n=206)</td>
</tr>
</table>

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, and to deliver a pamphlet with and without additional verbal reinforcement of the pamphlet key messages by community pharmacy staff.

Length of follow up
8 weeks

Source of funding

female	57 (55.9%)	72 (64.9%)	63 (61%)
Duration of current LBP episode <3 months	20 (19.6%)	15 (13.5%)	24 (23.1%)
Duration of current LBP episode ≥3 months intermittently	32 (31.4%)	34 (30.6%)	23 (22.1%)
Duration of current LBP episode ≥3 months continuously	50 (49.0%)	61 (55.0%)	57 (54.8%)
	Intervention 1, Mean (SD), range	Intervention 2, Mean (SD), range	Control Mean (SD), range
24 hour pain severity-	5.2 (2.4), 0 to 10	5.0 (2.3), 0 to 10	5.7 (2.0), 2 to 10
24 hour activity impairment-	4.2 (2.3), 0 to 10	4.3 (2.7), 0 to 10	4.9 (2.7), 0 to 10
Back beliefs-	25.8 (7.3), 9 to 45	25.7 (7.5), 9 to 42	25.0 (6.6), 12 to 38
Physical activity-related fear believes	15.1 (5.3), 1 to 24	15.7 (5.3), 2 to 24	15.7 (6.1), 0 to 24
Work-related fear believes	17.2 (12.0), 0 to 42	17.9 (11.9), 0 to 42	17.5 (12.5), 0 to 42

Inclusion criteria

posted to research team.

Intervention 1
Usual care and pamphlet with evidence-based information on low back pain, e.g. need to stay active, stay positive and stay engaged

Participants also received verbal reinforcement on pamphlet content from a trained member of pharmacy staff.
Intervention 2
Usual care and same pamphlet as intervention 1 but no reinforcement from pharmacy staff.

Comparator
Usual care alone.

medicine for LBP or self-inquiry after seeing poster:

Cluster allocation by pharmacy. All users in one pharmacy were assigned to the same intervention.

Pharmacy allocation concealed from pharmacy & researcher. But not users.

Analysis: Questionnaires completed at baseline, and 2 & 8 weeks post intervention

78% power 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

Time	Intervention 1	Intervention 2	Control
2 weeks	15.1 (5.8)	13.7 (5.5)	15.0 (5.5)
8 weeks	13.8 (6.4)	13.4 (5.8)	14.8 (4.9)
Mean Difference (95%CI)*			
Int 1 vs. Control at 2 wks: 0.10 (95%CI -1.86 to 2.06), p=0.92			
Int 1 vs. Int 2 at 2 wks: 1.40 (95%CI -0.82 to 3.62), p=0.18			
Int 1 vs. Control at 8 wks: -1.00 (95% CI -3.06 to 1.06), p=0.34			
Int 1 vs. Int 2 at8 wks: 0.40 (95% CI -1.99 to 2.79), p=0.73			

Work-related fear (higher score indicates higher fear avoidance beliefs, n=203)

Time	Intervention 1	Intervention 2	Control
2 weeks	15.9 (12.4)	17.6 (11.07)	18.6 (12.2)
8 weeks	15.4 (10.9)	15.6 (11.3)	17.7 (12.8)
Mean Difference (95%CI)*			
Int 1 vs. Control at 2 wks: -2.70 (95%CI -6.97 to 4.57), p=0.22			
Int 1 vs. Int 2 at 2 wks: -1.70 (95% CI -5.92 to 2.52), p=0.43			
Int 1 vs. Control at 8 wks: -2.30 (95% CI -6.41 to 1.81), p=0.29			
Int 1 vs. Int 2 at8 wks: -0.20 (95% CI -4.05 to 3.65), p=0.92			

Pain severity (0=no pain, 10=worst pain, n=210)

Time	Intervention 1	Intervention 2	Control
2 weeks	4.3 (2.3)	4.7 (2.1)	4.3 (2.4)
8 weeks	3.7 (2.6)	4.3 (2.5)	4.4 (2.5)
Mean Difference (95%CI)*			
Int 1 vs. Control at 2 wks: 0 (95%CI -0.81 to +0.81), p=1.00			
Int 1 vs. Int 2 at 2 wks: -0.40 (95% CI -1.19 to +0.39), p=0.32			
Int 1 vs. Control at 8 wks: -0.70 (95% CI -1.62 to +0.22), p=0.14			
Int 1 vs. Int 2 at8 wks: -0.60 (95% CI -1.54 to +0.34), p=0.21			

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

Time	Intervention 1	Intervention 2	Control
2 weeks	3.4 (2.5)	3.7 (2.1)	3.6 (2.8)
8 weeks	3.1 (2.7)	3.5 (2.5)	3.7 (2.7)
Mean Difference (95%CI)*			
Int 1 vs. Control at 2 wks: -0.20 (95% CI -1.12 to 0.72), p=.67			
Int 1 vs. Int 2 at 2 wks: -0.30 (95% CI -1.13 to +0.53), p=0.48			
Int 1 vs. Control at 8 wks: -0.60 (95% CI -1.57 to +0.37), p=0.23			
Int 1 vs. Int 2 at8 wks: -0.40 (95% CI -1.36 to +0.56), p=0.41			

Perceived usefulness of pamphlet (GIPU score)

	Intervention 1	Intervention 2	Between group difference

Department of Health, Government of Western Australia, Curtin University preparation of the manuscript.	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 to 65 years Read and comprehend English **Exclusion criteria** Pharmacies: proprietor did not agree to be involved in the study Users: none	Users received the pamphlet at completion of the study.	in each pharmacy	<table><tr><td>2 weeks</td><td>6.2 (SD 2.5)</td><td>5.3 (SD 2.1)</td><td>0.9 (-0.1 to 1.9)</td></tr><tr><td>8 weeks</td><td>5.7 (SD 2.7)</td><td>4.9 (SD 2.5)</td><td>0.9 (-0.1 to 1.9)</td></tr></table>Difference between groups pooled over time= 0.9 (95% CI 0 to 1.8) * Mean difference (95% CI) and p-values calculated by NICE technical team using Review Manager

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.
Other comments
Competing interests: one of the authors is a proprietor of a community pharmacy what 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]).

Study details	Population	Intervention and comparator	Methods and analysis	Results
Reference Watman 2002 **Quality score** + **Study type** Before and after **Location and setting**	**Health area** Cardiovascular disease **Number of participants** n=449 patients **Participant characteristics** 66% white 28% south Asian 6% Afro-Caribbean **Inclusion criteria**	**Intervention** Health screening interview with emphasis on good nutrition in maintaining well-being. Emphasis was placed on importance of an integrated diet in CHD prevention, reinforced by literature from the British Heart	**Recruitment:** 560 patients were randomly selected (method of randomisation not reported) from the practice computer and invited for a	<table><tr><td></td><td>Mean number of cigarettes/cigars per day at baseline</td><td>Mean number of cigarettes/cigars per day at 2 years</td><td>P value for baseline vs. 2 years</td></tr><tr><td>All smokers (n=110)</td><td>10.66 (SD 9.30)</td><td>7.16 (SD 8.51)</td><td>p<0.001</td></tr><tr><td>High risk patients (n=71)</td><td>8.93 (SD 11.06)</td><td>5.80 (SD 9.18)</td><td>p<0.005</td></tr><tr><td colspan="4">*Mean Difference -3.5 (95%CI -5.58 to -1.42), p<.001 * Mean difference (95% CI) and p-values calculated by NICE technical team using Review Manager</td></tr></table>

GP practice in London, UK **Aims** To evaluate the contribution made by a community pharmacist to a cardiovascular health screening programme aimed at improving the health status of patients in primary care. **Length of follow up** 2 years **Source of funding** None reported	15 to 65 years No other criteria reported **Exclusion criteria** None reported	Foundation distributed at the end of the review. All patients were given relevant advice which followed a standardised protocol. Style of communication of information was modified to be sensitive to and reflect the understanding of the individual. Patients were split into high risk (n=71), intermediate risk (n=153) and low risk (n=225) groups. High risk patients saw the pharmacist every 6 months, intermediate risk every 12 months and low risk just attended a final health screen. At these follow ups, health message was reinforced.	health screen consultation with the pharmacist. 449 (80%) patients responded. 398 (89%) attended consistently throughout the study (68 high risk, 138 intermediate risk, 192 low risk). **Analysis**: An 'internal and external quality assurance scheme' was used to ensure the accuracy and reliability of the data collected (no further details provided). T-test were used to estimate variance.	The mean number of or mean change in cigarettes/cigars per day was not reported for intermediate and low risk patients. Of the 110 smokers at the start of the study, 29 had stopped at some time during the 2 years (p value not reported). No-one, to the pharmacist's knowledge, had started smoking during the study.
Limitations identified by authors None reported. **Limitations identified by review team**				

The outcome assessor was aware of the intervention exposure of participants.
The intervention was delivered by a single pharmacist but it is not clear if the intervention was delivered consistently over the 2 years.
Possibility of selective outcome reporting – statistical significance of smoking status in medium and low risk groups is not reported separately as it is for the high risk group.

Other comments
Other outcomes are reported in the study (such as blood pressure, BMI, cholesterol), but 26 patients were prescribed new or replacement medication or had their medication altered, and so the results for these outcomes are not presented here.

Appendix Dii – Acceptability evidence tables

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
Author name and year Chauhan, 2012 **Quality score** - **Study type** Qualitative **Aim of the study** To explore experiences of pharmacists who provide and customers who received pharmacy based health checks. **Location and setting** Leicester, UK Inner city pharmacies, local faith groups and community-based health promotion events **Source of funding** Leicester City Primary Care Trust commissioned the University of Leicester	**Intervention** 2007 pilot program providing health checks, which included one-to one consultation with pharmacist. Demographic info and measurements of blood glucose and weight recorded to calculate client absolute and relative risk scores based on Framingham risk score. Lifestyle advice offered and "high-risk" individuals referred to GP. No follow-up consultations were provided by pharmacists. **Sampling Frame** 467 Service users and 39 pharmacists sent questionnaires asking for their views and willingness to participate (34 service users, 19 pharmacists). **Data collection** Semi-structured telephone interviews using topic guide (Year not specified, assume post-2007). Purposive sample selected until saturation reached. Interviews audio recorded and transcribed verbatim **Method of analysis** Interviews individually free coded; discussion of emerging themes and development of coding framework. Computer software used to assist with organisation and management of data during the analysis.	**Inclusion:** Service Users -Age 40-70 years -No previous diagnosis of diabetes or CVD Pharmacists participating in pilot program	Pharmacists N=12 - Number of checks conducted ranged from 7 to 231 Service Users N=14 - 5 (35%) male - Age range 41-66 yrs (mean 54 yrs) - 7 (50%) White European - 6 (43%) South Asian - 1 (7%) Mixed white/African - Range of deprivation scores represented in the sample	Pharmacists Views (Not extracted as outside scope) Service users views Experience and Acceptability POSITIVE ASPECTS - Some reported that the length and person-centred delivery of consultation exceeded their expectations - Appreciation of pharmacists providing the checks - Users liked the convenience of the location and lack of waiting time - Generally comfortable about checks being conducted by pharmacists who were perceived as professional and competent. - Most felt information provided about lifestyle was adequate and enabled those who perceived change to be necessary to consider modification of diet, exercise and smoking habits especially as information was specific to cultural needs (e.g. differences in South Asian cooking practices) NEGATIVE ASPECTS - Minority felt nurse or GP would be more appropriate intervention provider

Notes
Limitations identified by author
Findings may not be generalizable to all pharmacies or service users in UK. Interviews conducted only in English despite intervention being provided in area with high non-English speaking population. Unable to confirm any lifestyle changes that service users reported making in response to health checks

Limitations identified by review team
Consent not sought for reporting direct quotations from respondents so they were not included in the study paper. Unable to determine how long after intervention delivered interviews took place. General lack of richness in data reporting. Information presented is very high level and superficial.

Author name and year
Dhital, 2010

Quality score
-

Study type
Qualitative

Aim of the study
To investigate the potential uptake by pharmacy customers of alcohol Screening and Brief Intervention (SBI) in community pharmacies with a view to developing and trialling such an intervention

Location and setting
Westminster PCT (London), Community Pharmacies

Source of funding
- Pharmacy Practice Research Trust

Intervention
Participant leaflets left at pharmacy 2 weeks before the study. Over 3 months (Sept-Nov 2008) time sampling approach used to collect equivalent data across pharmacies. Recruited participants asked about their views of a POTENTIAL Pharmacy based SBI. Interviews took place in private consultation rooms and respondents assured anonymity.
The following questions were asked (Interview schedule):

A. SERVICE NEED. Advantages and disadvantages of the potential service
B. TAKING PART: Willingness to discuss alcohol use with the pharmacist and receive feedback
C. UPTAKE OF THE SERVICE- Reasons that may or may not lead to participation
D. Demographics
E. AUDIT-C items:
    a. How often do you have a drink containing alcohol?
    b. How many drinks containing alcohol do you have on a typical day when you are drinking?
    c. How often do you have six or more drinks in one occasion?

* *Those identified as risk drinkers (via AUCIT-C score ≥3 for women, ≥4 for men) advised by research to reduce alcohol consumption and

Inclusion
Adults who approached pharmacy counter to make health enquiries, present prescriptions or purchase medications.

*Protocol required researcher on completion of the previous interview to consecutively sample the first customer to leave the pharmacy counter following termination of their interaction with pharmacy staff

Pharmacies
4 Pharmacies (2 independent, 2 chain multiples)

Pharmacy users
-237 adults approached, n=102 (43%) agree to interview

Respondent characteristics (n=102)

	%
Female	62
Age range (yrs)	
18-39	34
40-59	38
60+	28
Ethnicity	
White	85
Black	11
Asian	2
Other	2
High-risk drinker	52
#v visits to pharmacy	
2+ times/ week	16
Once a week	16
Fortnightly	19
Once a month	31

HYPOTHETICAL ACCEPTABILITY

1.Pharmacist as information source

The majority of respondents supported the role of pharmacists as an information source
Pharmacists were perceived as able to provide advice on alcohol use, practical information on reducing consumption and on pharmacological interactions of alcohol with medicines.

"Would like to receive information on how to give up, how to cut down and how to do it"

2.Appropriateness of role for pharmacists
Pharmacists thought of as being more accessible to public than GPs; however concerns expressed on if pharmacists were knowledgeable or had suitable training to conduct SBI
Positive responses
"It's hard to get a GP appointment therefore service is a good idea"
"Pharmacist has training and is used to talking to the general public"

Negative responses
"Prefer to discuss alcohol use with GP"
"Not sure how much pharmacists will know about alcohol, not sure about their alcohol training"

3. Communicating with pharmacist

- Harold & Marjorie Moss Charitable Trust Fund	provided the NHS booklet on alcohol misuse atUnits and You' provided to all participants **Data collection** Purposive sample to select 2 independent and 2 branch pharmacy multiple chains. Data collected by one researcher continuously for 4 hour periods between 9AM and 6PM depending on availability of consultation room. Information cards with AUDIT-C items and an illustration of a 7 day retrospective drinking diary used to describe potential pharmacy SBI to participants. Researcher summarised responses from 10 minute interview on written form. Interviews not audio-taped **Method of analysis** Responses analysed inductively to derive categories. Analysis done by one researcher and checked by two others. Disagreements resolved through discussion.		<table><tr><td>>once a month</td><td>18</td></tr><tr><td>Type of pharmacy</td><td></td></tr><tr><td>Independent</td><td>58</td></tr><tr><td>Multiple</td><td>42</td></tr><tr><td>Occupation</td><td></td></tr><tr><td>Professional</td><td>32</td></tr><tr><td>Non-paid</td><td>28</td></tr><tr><td>Retired</td><td>26</td></tr><tr><td>Non-professional</td><td>14</td></tr><tr><td>Qualification</td><td></td></tr><tr><td>None</td><td>20</td></tr><tr><td>GCSEs</td><td>10</td></tr><tr><td>A Levels</td><td>21</td></tr><tr><td>Degree</td><td>28</td></tr><tr><td>Post degree</td><td>20</td></tr></table>	Positive responses "Easier to talk to a pharmacist than doctor" "Pharmacist talks to you like a normal human being" Negative responses "Would depend on the personality of the pharmacist, how approachable they were" "May feel got at, wagging a finger at them" 4. Pharmacy environment Some concerned about delivery of the service in a new setting. Fears of feeling patronised or labelled as having an alcohol problem also expressed. Concerns about privacy in the pharmacy and records may not be completely anonymous. Positive responses *"Good first port of call if people don't know where to go or what to do"* *"Capture a wide range of people who don't normally visit their GP*" Negative responses *"It's a bit public here, even doing it her in this consultation room"* *"Untrained people are at the front, customers would have to deal with non-professional staff who are less trained; this would put people off"* " *need to know if the service is totally anonymous or not"*

Notes
Limitations identified by author
Interviews only lasted for ~10 mins in pharmacy consultation room and interviewers were not recorded hence yielding "less rich" data. Were SBI to be commissioned nationally a decision to require personal details to be collected could pose a barrier to service uptake. Not possible to generalise findings as community pharmacies and participants not a representative sample.

Limitations identified by review team
Responses represent hypothetical acceptability of an alcohol screening service that could be created.

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
Author name and year Fuller 2011 **Quality score** - **Study type** Before-after study with a Qualitative survey component **Aim of the study** To develop, implement and evaluate a pharmacist led sleep health awareness, education and evaluation program for patients at risk for a sleep disorder. **Location and setting** Australia, Community pharmacies **Source of funding** Australian Government Department of Health through the Pharmacy Guild of	**Intervention** Health Action Process Approach (HAPA) based pharmacy sleep program, which applies a two-phased approach to behaviour change. Phase 1: (Motivational Phase) Used to implement structures and processes to create awareness and form intentions in patients. - Pharmacists received 2 day sleep training; - Information about project shared with physicians - Signage with project materials in pharmacy to prompt patients - Screening for sleep disorders by pharmacists - Referral of those at risk of sleep disorder - Information provision - Counselling - Follow-up date suggested Phase 2: Volitional Phase (Measuring changes made by patients) Closeout questionnaire used to measure changes in Sleep health behaviour, referral uptake and impact of service on confidence in sleep health (as a surrogate measure of self-efficacy)	**Inclusion** -18 years or older -Responded to the sleep health promotion material/ or had pharmacist identifiable risk factors -Reasonable proficiency in English -No terminal/major current illness **Exclusion** -People diagnosed sleep disorder or taking prescription meds for sleep problems	**Health Area** Sleep disorders 325 patients recruited 143 (44%) identified as being at risk for one or more sleep disorders Mean Age 55 yrs (sd15.9) 53% Female European 35% Caucasian (52%) Asian (2%) Indigenous (2%) Mean BMI 29.9 (SD 6.4) Mean pack-years 10.5 (SD 17.3)	<u>Patient experience/ Acceptability</u> The majority of patients felt positively about the program and indicated they would recommend the service to a friend. The following comments about the main outcome of the service are reported below *"I found it helpful to sit down and talk to the pharmacist and [to] discover small changes that I would make that have improved the number of hours I sleep…the written information was wonderful"* *"I am far more aware of things which affect my sleep patterns e.g. TV in room, radio, suduko, reading, getting up and using toilet (often unnecessarily) each time I wake up. Following the service I average 30-50 minutes extra sleep per night"* *"The main outcomes are that I am getting blocks of quality sleep. I've taken the advice of my pharmacist and changed my sleep hygiene around and so far it's worked wonders. I am also less worried and anxious about not sleeping"* *These are the only comments reported in paper No negative comments were reported by patients

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
Australia's Fourth Community and Ageing	**Data collection** Recruitment between January-April 2009 either by self-selection in response to sleep health awareness materials displayed in pharmacy or through pharmacist approach. **Method of analysis** Quantitative descriptive analysis. The survey asked a few open-ended questions where respondents could provide their opinions. Some of these were reported in the results section, but no description of analysis methods is provided.			
Notes **Limitations identified by author** **Limitations identified by review team**				

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
Author name and year Gray, 2012 **Quality score** **Study type** UCLAN IBA report – only qualitative data extracted	**Intervention** Blackpool and Knowsley PCTs had based their service on the Wirral PCT model: Wirral (33 pharmacies') – Alcohol screening using AUDIT tool then Brief Intervention (IB) if score was 8-15: A) Explain daily amounts and what a unit is B) Category pf drinker C) Leaflet content	**Inclusion** Adults who approached pharmacy counter to make health enquiries, present prescriptions or purchase medications.	**Pharmacies** 68 Pharmacies (across 3 PCT's) **Pharmacy users** -semi structured interviews conducted with 16 service users at 2 weeks and 3 months follow up of the IBA services. Interviews lasted 5-10 minutes	<u>*User experience from Market researchers*</u> In some pharmacies Market researchers reported that the layout did not provide sufficient privacy, even where quiet areas were utilised. *"It did not feel very private or confidential as I was speaking in front of the other customers. [Speaking] about my results in a public setting deterred me from speaking openly about my drinking."*

<table>
<tr><th>Study details</th><th>Research Parameters</th><th>Inclusion/ Exclusion criteria</th><th>Population</th><th>Results</th></tr>
<tr>
<td>Aim of the study
To characterise, consolidate and optimise both the constant and variable elements of the pharmacy alcohol identification/brief advice (IBA) service in NHS northwest

Location and setting
Northwest – community pharmacies in 3 PCT’s: Wirral, Knowsley and Blackpool.

Source of funding</td>
<td>Blackpool (18 pharmacies) – AUDIT + information leaflet + BI if score is 7-15 (same content as Wirral)
BI provided in consultation room

Knowlsey (17 pharmacies) – AUDIT + information leaflet + IBA. BI if AUDIRT score is 7-15

AUDIT test – detects alcohol problems experienced within the last year. The test contains 10 multiple choice questions on quantity and frequency of alcohol consumption. Answers are scored on a 5 point scale. A sore of >8 indicates an alcohol use problem.
AUDIT C tool – short 3 item screen developed from the AUDIT instrument. Score on a 5 point scale from 0 to 4, with scores of 4 or higher for men and 3 or higher for women indicative of positive and harmful drinking.

All PCTs required pharmacists and staff delivering the service to attend at least a half-day training session, run by an outside organisation (most often by specialist alcohol services).

Data collection and analysis
Pharmacies in each of the three PCTs providing an alcohol IBA service in the North West during the fieldwork period, January to April 2012 were involved in the service user engagement and feedback part of the study. Participating pharmacies within NHS Wirral, Knowsley and Blackpool were purposively selected to</td>
<td></td>
<td>Respondent characteristics of those screened:

Wirral (n=10907)
<table><tr><td></td><td>%</td></tr><tr><td>Male</td><td>41</td></tr><tr><td>Female</td><td>59</td></tr><tr><td>Age range (yrs)</td><td></td></tr><tr><td>15-19</td><td>2.6</td></tr><tr><td>20-24</td><td>8</td></tr><tr><td>25-29</td><td>8.2</td></tr><tr><td>30-34</td><td>7.6</td></tr><tr><td>35-39</td><td>8.4</td></tr><tr><td>40-44</td><td>9.5</td></tr><tr><td>45-59</td><td>9.6</td></tr><tr><td>50-54</td><td>9</td></tr><tr><td>55-59</td><td>7.9</td></tr><tr><td>60+</td><td>29.2</td></tr></table>
Blackpool (n=511)
<table><tr><td></td><td>%</td></tr><tr><td>Age range (yrs)</td><td></td></tr><tr><td>16-19</td><td>1.4</td></tr><tr><td>20-24</td><td>8</td></tr><tr><td>25-29</td><td>10.4</td></tr><tr><td>30-34</td><td>9.6</td></tr><tr><td>35-39</td><td>13.1</td></tr><tr><td>40-44</td><td>10</td></tr><tr><td>45-59</td><td>12.1</td></tr><tr><td>50-54</td><td>9</td></tr><tr><td>55-59</td><td>7.8</td></tr><tr><td>60+</td><td>18.6</td></tr></table></td>
<td>All 5 occasions in which Market researchers received a full IBA consultation I the consultation room were positively evaluated regarding the private space and this provided for an open discussion of their drinking habits

“The separate room gave total privacy. I felt I could open up and answer honestly.”

<u>Interviews with Service users:</u>

1.Usefulness of the service

Interviews with 16 service users revealed that the service was positively received, with the most prominent theme being perceived useful of the services to individuals considered ‘at risk’. Respondents readily subscribed to the view that the services was a good idea – in particular for other/younger people and that they would recommend it to family and friends if appropriate.

“If it helps someone to, you know, if they’ve got a drinking problem, if you can stop it going further, it’s going to save money for the NHS and it’s going to save their life”

2.Appropriateness of role for pharmacists
Service users were generally happy with the manner in which the service was delivered, however a minority of respondents felt that GPs might be more appropriate for discussion regarding personal alcohol consumption. One respondent felt like the service was a bit pointless and primarily applicable to other people

“I don’t think it’d change anyone’s life. I don’t think it would change the way they drink cos of doing that.”</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></td>
<td>represent a range of settings and because of their high alcohol IBA service activity levels.

Data collected by:
• Structured observation of pharmacy engagement with customers (field notes from market researchers acting as service users who visited 11 CP's - concerning the pharmacy environment and promotion and experience of the alcohol IBA service)

• Qualitative analysis of telephone interviews with service users (semi-structured 5-10 minute interviews with 16 service users around 2 weeks and then 3 months following the IBA service. Interviews at 2 weeks focused on the perceptions of the service and interviews at 3 months focused on the impact on alcohol consumption. Audio recordings were transcribed verbatim. Transcripts were thematically analysed)

• Qualitative analysis of telephone interviews with pharmacy staff (3 pharmacists and 4 pharmacy staff in 5 different pharmacies across the North west region volunteered to take part in a short telephone interview in order to gain a deeper understanding about their experience of delivering the services. Interviews took between 5-20 minutes and were digitally recorded and transcribed verbatim. They were conducted in May/June 2012

Only data from pharmacy customers was used</td>
<td></td>
<td>Knowsley (n= 2462)

<table>
<tr><td></td><td>%</td></tr>
<tr><td>Age range (yrs)</td><td></td></tr>
<tr><td>16-19</td><td>2.2</td></tr>
<tr><td>20-24</td><td>7.6</td></tr>
<tr><td>25-29</td><td>7.5</td></tr>
<tr><td>30-34</td><td>4.9</td></tr>
<tr><td>35-39</td><td>8.1</td></tr>
<tr><td>40-44</td><td>11.9</td></tr>
<tr><td>45-59</td><td>12.1</td></tr>
<tr><td>50-54</td><td>10.9</td></tr>
<tr><td>55-59</td><td>9.4</td></tr>
<tr><td>60+</td><td>25.4</td></tr>
</table>
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<td></td>
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</table>

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
Notes **Limitations identified by author** There was inevitable self-selection bias within the respondents to surveys and Interviews. There was a smaller number of service users engaged with the project than initially envisaged and desired. Some of the measures were based on self-report. **Limitations identified by review team** Only demographics of the screened population reported. Not all characteristics of participants who were interviewed about the service reported.				

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
Author name and year Krska, 2014 **Quality score** - **Study type** Qualitative	**Intervention** Pilot service included key elements agreed by research working group: • Staff designed and used their own pharmacy specific promotional materials and methods to	**Inclusion** 6 community pharmacies recruited known to PCT commissioner	5 community pharmacies participated (4 independent and one multiple), all in areas of high deprivation. 164 users screened in two months - 113 (69%) low risk AUDIT score 0-7) - 24 (15%) increased risk (8-15) - 19 (12%) high risk (16-19) - 9 (5%) dependent (20 or more)	***Experience / Acceptability*** - All interviewees had positive views of the service and reported professional staff attitudes with no sense of being pressurized *"There were very sincere and very friendly, they don't look down on people like ourselves… it should be available in every pharmacy so that people are aware about what alcohol actually does" (Male service user 10)*

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
Aim of the study To evaluate a pilot pharmacy-based alcohol screening and advisory service from multiple perspectives **Location and setting** Sefton PCT(North West England), Community pharmacies **Source of funding** Liverpool John Moores University and Sefton PCT	supplement standard materials; • No specific group to be targeted, with selection left to individual pharmacy teams; • Involvement of pharmacy support staff, using AUDIT-C as a prescreen; • Discussion of full AUDIT score to take place in private area, with pharmacists; • Direct referral to local alcohol treatment services **Data collection** Pharmacy staff collected data on number of customers offered screening, screening scores and interventions offered. After screening user sent letter inviting them to participate in phone interview **Method of analysis** Interviews digitally recorded and transcribed verbatim. Thematic analysis using NVivo. Field notes taken during direct observations also analysed thematically. Data from interviews and		- *10 service users interviewed* • 5 (50%) males • 8 targeted by pharmacy staff, 2 requested screening on seeing pharmacies promotional material	*"The girl she offered me a leaflet or something to fill out… they were fine it wasn't forceful or anything like, no, they were just all friendly- it went quite well" (Female service user 6)* - None of the interviewees raised confidentiality as a concern, but most mentioned privacy. Several viewed screening at the counter as acceptable, but only when no other customers were present, most feeling that they would wish to use the consultation room if the pharmacy was busy *"There were no customers in so it wasn't too bad busy I wouldn't have done it… Just like err may be a private screened area just like you know like a photo booth style curtain or something just at the end of the counter- nothing more than that- I'm not talking about a private room or anything"- (Male service user 2)* There were 10 hours of on-site researcher observation. The following observations were noted: 1. There was clear information about the service displayed in the window and inside 3 pharmacies: One promoted the service intermittently on a display screen, one had a display board and one a large home-produced poster on "Alcohol Awareness Week". The remaining 2 pharmacies had unit calculators/ leaflet displays on the counter, but posters were displayed only in the consultation room, in compliance with company policies 2. Sometimes there were insufficient staff to provide alcohol screening but a variety of methods were used to approach customers. Size and layout of pharmacies considered suitable for providing services, each having a good sized private consultation room but one was not audibly discrete. Divider screens/ booths were present in three pharmacies but the areas afforded were not audibly discrete.

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
	surveys triangulated to compare and contract different perspectives.			

Notes
Limitations identified by author
A variety of promotional methods used but some were limited in some cases by company policies despite their obvious effectiveness. Recruitment of the general public proved difficult in affluent areas and participants from these areas had less positive views on pharmacy staff broaching the subject of alcohol (**No data to this effect reported in results**). No pharmacy located in affluent area was recruited. Pharmacies invited to join study based on the personal knowledge of PCT commissioners, with no intention to be representative of different types of pharmacies. Very small scale study
Limitations identified by review team

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
Author name and year Mackridge 2016 **Quality score** + **Study type** Mixed-methods study **Aim of the study** To develop and apply a model for in-depth scrutiny of community pharmacy screening and intervention services with feedback to service providers to support development of best practice. **Location and setting** 3 former Primary Care Trusts in North West England **Source of funding** NHS Liverpool via an unrestricted educational grant from Lundbeck UK	**Intervention** Brief screening using the Alcohol Identification and Brief Advice (IBA) services **Data collection & Analysis** Ethnographic observation and interviews conducted. Comprised 4 phases: 1) Observation of interactions at the pharmacy counter by 2 trained researchers for at least 30 hours at each participating pharmacy. Standardized data collection forms used with pre-determined coding framework, 2) Audio recordings of consultations that were provided in a private area. Recordings transcribed verbatim my 2 researchers and analysed independently using constant comparative technique with emergent codes subsequently reviewed and combined to reach the final framework 3) Follow-up semi-structured interviews incorporating critical	**Inclusion** Pharmacies: None stated, researchers used a purposive sample Staff gave written consent prior to observations. During observation phase, posters were displayed in the pharmacy stating that a study was taking place and interactions at the counter may be observed and customer consent was assumed unless they asked not to be observed. Pharmacy customer scoring >5 on AUDIT-C offered in-depth consultation	Pharmacies 13 initially approached, n=5 participated in study Pharmacy customers: Phase 1: Female 1949/3299 (59%) *Age Groups** -Under 25 n=253 (8%) -25-34 yrs, n=424 (13%) -35-44 yrs, n=650 (20%) -45-54 yrs, n=660 (20%) -55-64 yrs, n=580 (18%) -65+yrs n=723 (12%) *Age estimated by study researchers	<u>Phase 1:</u> 3299 counter interactions during 171 hours of observation. Including 112 (3.3%) offers of alcohol screening, of which 74 (66%) accepted. Common reason for refusal was “not drinking alcohol” and “not having enough time”. About 76% of observed interactions related to prescriptions. Other reasons for visits were non-medicine purchases (14%), over the counter medicine purchases (9%) advice (5%) and accessing services (4%). Multiple reasons for visiting were recorded for some visits. Tendency for those <65 years to be offered screening more often, and there were inconsistent availability of trained staff owing to other work activities or shift patterns, restrictions on numbers of service episodes per week/ month and eligibility criteria for customers as factors that might impact on service provision. <u>Phase 2</u>: 9 consultations. 6 (67%) with male customers. Estimated age below 25 years for 4 (44%) of customers with the remaining customers estimated as being aged 55 or over. Six (67%) visited for a prescription, 2 (22%) for a non-medicine purchase and 1 911%) had pre-booked consultation. Five (55) scored lower risk (AUDIT 0-7), three (33%) as increasing risk (score 8-15) and 1 (11%) as high risk (score 16-19). Staff displayed discomfort in questioning service users’ personal lives via the consultation and two were observed to employ strategies to minimize this in conversations. <u>Phase 3 (Customer interviews)</u> 16 customers completed follow-up interview at 2 weeks and 14 participated in a further interview at 3 months. 7 were male Most described the service positively reporting that the delivery was acceptable and highlighted that their existing rapport with pharmacy staff encouraged them to use the service, however a minority felt that GP surgeries were more appropriate for alcohol discussions. “*This is our regular pharmacy that we go to so it wasn’t a problem you know*” Participants considered the service could raise awareness of risks around alcohol consumption but many emphasized that it would predominantly

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
	incident technique with service users 2 weeks and 3 months following consultation. First interview focussed on perceptions of the service and the second on perceived impact on alcohol related behaviour. Same method of analysis as described in phase 3 , 4) interactive feedback session with pharmacy staff			benefit at-risk individuals a group from whom participants were careful to distance themselves. *"We did find out some things that we didn't know about the consumption of alcohol and the units. It was very useful"* *"I think if someone's got a problem obviously, it's a good idea"* Participants were happy with the level of privacy offered but where consultations took place in a public area, satisfaction was contingent on no other customers entering this space during the consultation *"Very discrete, yeah. We were away from the actual counter. It was just like the other end of the counter where other people weren't standing [so felt had enough privacy]"* Some participants said the service had made them think differently about their alcohol consumption and may have an impact on behaviour "*Instead of drinking 3, 4 times a week, I'm down now to twice a week…I thought I don['t really need that and you know, I look back and think, well I'm in work tomorrow so I have water with my dinners if I go out with friends rather than having an alcoholic drink*" Phase 4- reported pharmacists views so not included
Notes **Limitations identified by author** Small study and participating pharmacies were self-selected. Pharmacy staff and patients were aware they were being observed/ recorded in Phases 1 and 2 and this may have impacted their behaviour. There was use of estimated age group from Phase 1 observations so those data should be interpreted with caution. **Limitations identified by review team**				

<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
Dr Rachel Urban 2015

Quality score

Study type
Service evaluation-
Study 1: Calderdale Alcohol IBA

Study 2: Kirklees Alcohol IBA

Questionnaires to service users and staff which had a qualitative aspect (open ended questions)

Aim of the study
Evaluate the IBA service which raises awareness of the personal health risk of alcohol consumption through an IBA consultation with a trained member of staff

Location and setting</td>
<td>Intervention
Based on the North West scheme which demonstrated community pharmacies ability to deliver brief intervention. The IBA was delivered as part of the Healthy Living Pharmacy initiative.

Pharmacy staff used a scratch card containing the AUDIT-C screening tool: short 3 item screen developed from the AUDIT instrument. Questions were scored to give a total between 0 and 12. For a score of 4 or less the member of pharmacy staff reaffirmed the benefits of drinking within lower-risk levels, offered a general alcohol information leaflet, and asked the individual if they would like any further information (for example on alcohol units). For a score of 5 or more the person was asked to complete the next seven questions. Appropriate action was taken depending on their overall score, ranging from brief advice (Simple Structured Advice) and information, to referral for treatment.

Pharmacy staff received training in delivering brief intervention and advice, how to claim and enter information using PharmOutcomes and approaching patients to make every contact count.

In Calderdale - 19 pharmacies delivered 2085 AUDIT-C assessments. ¾ of these went on to have the full AUDIT screen. The amount of interventions delivered per pharmacy varied (range 12 to 369 per pharmacy).

In Kirklees – 15 pharmacies delivered 1557 AUDIT-C assessments. Half of these went on to</td>
<td>Inclusion
Patients who attended the pharmacy were approached and asked to the consultation room to answer a series of three alcohol screening questions (AUDIT-C) to determine the individual’s drinking risk category.</td>
<td>Pharmacies
Calderdale: 19 Pharmacies (across 3 PCT’s)

Kirklees: 15 Pharmacies

Pharmacy users
Calderdale: 31 completed the feedback questionnaire.
Kirklees – 31 completed feedback the questionnaire

Calderdale Respondent characteristics
<table><tr><th>Age range yrs.</th><th>N</th></tr><tr><td>16-19</td><td>2</td></tr><tr><td>20-24</td><td>4</td></tr><tr><td>25-34</td><td>2</td></tr><tr><td>35-44</td><td>4</td></tr><tr><td>45-54</td><td>9</td></tr><tr><td>55-64</td><td>7</td></tr><tr><td>65-74</td><td>3</td></tr><tr><td>75+</td><td>0</td></tr></table>
Kirklees Respondent characteristics:
<table><tr><th>Age range yrs.</th><th>N</th></tr><tr><td>16-19</td><td>0</td></tr><tr><td>20-24</td><td>4</td></tr><tr><td>25-34</td><td>6</td></tr><tr><td>35-44</td><td>7</td></tr><tr><td>45-54</td><td>7</td></tr><tr><td>55-64</td><td>4</td></tr><tr><td>65-74</td><td>1</td></tr><tr><td>75+</td><td>0</td></tr></table></td>
<td><u>Qualitative data from questionnaire with Patients:</u>
What worked well
Quick, easy and informative approach
Great leaflets and info provided on calories and units was useful
Friendly, relaxed and informal approach
Helpful and personal
Friendly and kind, yet professional approach from staff
Private and anonymous, particularly the private room
Time with staff
Made me think about cutting down or current consumption

How service can be improved
The majority of subjects felt the service was fine and couldn’t be improved. However some subjects felt that more leaflets given with the advice would be good. One subject wanted visual aids to show the effects of increased alcohol consumption. One subject mentioned that it was not necessary for pharmacy staff to ask alcohol related questions and another said it was too personal and a waste of time.</td>
</tr>
</table>

Study details	Research Parameters	Inclusion/ Exclusion criteria	Population	Results
Calderdale November 2013- October 2014 Kirklees March 2013- October 2014 **Source of funding** Commissioned by Calderdale PCT and then Calderdale Council	have the full AUDIT as required by a score of 5 or more. The number of interventions delivered per pharmacy varied (range 2-368 interventions per pharmacy). The interventions delivered within Kirklees pharmacy identified a higher rate of 'increasing risk' drinkers and a lower rate of 'high risk' drinkers than those published for Kirklees by Alcohol Concern. **Data collection and analysis** Patient views were sought using a paper copy patient satisfaction questionnaire given to patients during September 2014 completed following the intervention. Responses were inputted into Excel® and analysed using descriptive statistics and thematic analysis. Pharmacy staff were given the option of completing an electronic questionnaire via Survey Monkey® or a paper version of the same questionnaire to ascertain their views (also during September 2014) (See appendix B). Responses were extracted into Excel® and analysed using descriptive statistics and thematic analysis.		Blank 2	
Notes **Limitations identified by author** The anonymous nature of open ended questionnaires does not allow follow up for points to be clarified or probed in more detail and the level of detail within responses on the questionnaire varied between respondents. Patients and staff were offered the opportunity to participate in follow-up interviews to provide further detail on their responses. The uptake of this was too low to conduct meaningful data collection Kirklees - At the time of evaluation the age and ethnicity of the patient was not available. **Limitations identified by review team** Limited demographic data in both reports				

Appendix E – Forest plots

No forest plots were created for this review.

Appendix F – GRADE tables

GRADE profile 1- Clinical measurements or health outcomes

Quality assessment										
No. of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No. of participants	Effect	Quality of evidence for outcome	Importance of outcome
Activity impairment (0=no effect on daily living, 10=unable to perform any activities of daily living)										
Baseline vs. 2 weeks (Pamphlet + Education vs. Standard care) [ES2.1]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	128	Mean Difference -0.20 (95% CI -1.12 to +0.72), p=0.67	Very low	Critical
Baseline vs. 2 weeks (Pamphlet + Education vs. Pamphlet only) [ES2.1]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	119	Mean Difference -0.30 (95% CI -1.13 to +0.53), p=0.48	Very low	Critical
Baseline vs. 8 weeks (Pamphlet + Education vs. Standard care) [ES2.1]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	118	Mean Difference -0.60 (95% CI -1.57 to +0.37), p=0.23	Very low	Critical
Baseline vs. 8 weeks (Pamphlet + Education vs. Pamphlet only) [ES2.1]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	113	Mean Difference -0.40 (95% CI -1.36 to +0.56), p=0.41	Very low	Critical
Asthma severity (Patient reported symptom frequency, score range 1-3)										
Baseline vs six months (Education and reviews vs. standard care) [ES2.2]										
1[2]	RCT	Very serious[d]	Not applicable	No Serious	Very serious[e]	No	72	Mean 1.6 (SD 0.7) in intervention group vs. 2.4 (SD 0.5) in control P<0.001	Very low	Critical
Pain severity (0=no pain, 10=worst pain)										
Baseline vs. 2 weeks (Pamphlet + Education vs. Standard care) [ES2.3]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	128	Mean Difference 0 (95%CI -0.81 to +0.81), p=1.00	Very low	Critical
Baseline vs. 2 weeks (Pamphlet + Education vs. Pamphlet only) [ES2.3]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	119	Mean Difference -0.40 (95% CI -1.19 to +0.39), p=0.32	Very low	Critical
Baseline vs. 8 weeks (Pamphlet + Education vs. Standard care) [ES2.3]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	118	Mean Difference -0.70 (95% CI -1.62 to +0.22), p=0.14	Very low	Critical
Baseline vs. 8 weeks (Pamphlet + Education vs. Pamphlet only) [ES2.3]										

1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	113	Mean Difference -0.60 (95% CI -1.54 to +0.34), p=0.21	Very low	Critical
Number of individuals with reduction in Fagerström smoking dependence score										
Baseline vs 6 months [ES2.4]										
1[3]	RCT	Serious[f]	Not applicable	No serious	Serious[g]	No	160	RR =3.73 (95% CI 2.07 to 6.72)	Low	Critical
Number of individuals with no change in Fagerström smoking dependence score										
Baseline vs 6 months [ES2.4]										
1[3]	RCT	Serious[f]	Not applicable	No serious	Serious[g]	No	160	RR =0.57 (95% CI 0.45 to 0.73)	Low	Critical
Number of individuals with increase in Fagerström smoking dependence score										
Baseline vs 6 months [ES2.4]										
1[3]	RCT	Serious[f]	Not applicable	No serious	Very serious[h]	No	160	RR =0.33 (95% CI 0.01 to 8.06)	Very low	Critical
Change in Fagerström smoking dependence score (score range 1-10 [low-high nicotine dependence])										
Control vs photo-aging intervention (1 month follow-up) [ES2.4]										
1[3]	RCT	Serious[f]	Not applicable	No serious	Very serious[b]	No	160	Mean difference -0.69 in score P value not reported	Very low	Critical
Control vs photo-aging intervention (3 months follow-up) [ES2.4]										
1[3]	RCT	Serious[f]	Not applicable	No serious	Very serious[b]	No	160	Mean difference -0.96 in score P value not reported	Very low	Critical
Control vs photo-aging intervention (6 months follow-up) [ES2.4]										
1[3]	RCT	Serious[f]	Not applicable	No serious	Very serious[b]	No	160	Mean difference -1.62 in score P<0.001	Very low	Critical
Older vs younger individuals [ES2.21]										
1[3]	RCT	Serious[f]	Not applicable	No serious	Very serious[b]	No	160	P =0.001 (a reduced score more likely in younger participants)	Very low	Critical
0-5 vs 6-10 vs >10 cigarettes per day [ES2.22]										
1[3]	RCT	Serious[f]	Not applicable	No serious	Very serious[b]	No	160	χ^2_2=26.2, p<0.001 (a reduced score more likely in participants with higher baseline consumption)	Very low	Critical

Male vs female [ES2.23]										
1[3]	RCT	Serious[f]	Not applicable	No serious	Very serious[b]	No	160	No significant difference in score associated with gender P =0.34	Very low	Critical
Blood glucose levels, mmol/l										
Baseline vs. 1 months (Diabetes education program) [ES2.5]										
1[4]	Before-after study	Very serious[i]	Not applicable	No serious	Very serious[b]	No	24	Mean difference -0.09 (95%CI -1.06, 0.88), p=0.86 after intervention	Very low	Critical
Baseline vs. 3 months (Diabetes education program) [ES2.5]										
1[4]	Before-after study	Very serious[i]	Not applicable	No serious	Very serious[b]	No	24	Mean difference -0.48 (95%CI -1.39, 0.43), p=0.30 after intervention	Very low	Critical
Baseline vs. 6 months (Diabetes education program) [ES2.5]										
1[4]	Before-after study	Very serious[i]	Not applicable	No serious	Very serious[b]	No	24	Mean difference -0.80 (95%CI -1.67, 0.07), p=0.07 after intervention	Very low	Critical
Baseline vs. 6 months (Group based education vs. no intervention) [ES2.5]										
1[5]	RCT	Very serious[j]	Not applicable	No serious	Very serious[b]	No	64	HbA1c Levels significantly lower in intervention group relative to control, p=0.047	Very low	Critical
Baseline vs. 12 months (Group based education vs. no intervention) [ES2.5]										
1[5]	RCT	Very serious[j]	Not applicable	No serious	Very serious[b]	No	64	HbA1c Levels no difference between groups, p=0.240	Very low	Critical
Baseline vs 24 months (Group based education vs. no intervention) [ES2.5]										
1[5]	RCT	Very serious[j]	Not applicable	No serious	Very serious[b]	No	64	HbA1c Levels significantly lower in intervention group relative to control, p=0.008	Very low	Critical
Frequency of hypo/ hyper glycaemic incidents (%)										
Baseline vs. 1 months (Diabetes education program) [ES2.6]										
1[4]	Before-after study	Very serious[i]	Not applicable	No serious	Very serious[b]	No	24	Mean difference -33% in percent reporting incidents, P value not reported	Very low	Critical
Baseline vs. 3 months (Diabetes education program) [ES2.6]										

1[4]	Before-after study	Very serious[i]	Not applicable	No serious	Very serious[b]	No	24	Mean difference -46% in percent reporting incidents, P value not reported	Very low	Critical
Baseline vs. 6 months (Diabetes education program) [ES2.6]										
1[4]	Before-after study	Very serious[i]	Not applicable	No serious	Very serious[b]	No	24	58% decrease after intervention (from 58% to 0%), p value not reported	Very low	Critical
Arterial Blood pressure (mmHg)										
Baseline vs 12 months; Systolic blood pressure (12 education sessions vs. 2 education sessions) [ES2.7]										
1[6]	RCT	Serious[k]	Not applicable	No serious	Serious[g]	No	84	Mean Difference -4.00 (95%CI -10.91, 2.91); p=0.26	Low	Critical
Baseline vs 12 months; Diastolic blood pressure (12 education sessions vs. 2 education sessions) [ES2.7]										
1[6]	RCT	Serious[k]	Not applicable	No serious	Serious[g]	No	84	Mean Difference -5.00 (95%CI -9.39, -0.61); p=0.03 in favour of the intervention group	Low	Critical

1. Slater et al 2013
2. Saini et al 2004
3. Burford 2013
4. Petkova 2006
5. Sarkadi 2004
6. Skrowron 2011

a. Downgraded 1 level as serious risk of detection bias as participants nor pharmacists blinded to intervention and high level of attrition.
b. Downgraded 2 levels as imprecision could not be calculated and total sample size is less than 400.
c. Available case analysis conducted with missing data.
d. Downgraded 2 levels as the original control group could not be followed through the study and a second control group was recruited midway for comparison, participants were not blinded to their allocation.
e. Downgraded 2 levels as insufficient data provided to calculate an effect size and only p-value reported, total sample size is less than 400.
f. Downgraded 1 level as scores for Fagerström smoking dependence were obtained from self-report which is likely prone to social desirability bias.
g. Downgraded 1 level as total sample size is less than 300.
h. Downgraded 2 levels as number of events is less than 300 and confidence intervals cross either 1 or both thresholds for determining a minimal important difference (0.75 and 1.25).
i. Downgraded 2 levels as unclear how study population obtained (selection bias), study funded by pharmaceutical company
j. Downgraded 2 levels for selective outcome reporting and selection bias
k. Downgraded 1 level as contamination may have occurred and large number of participants (60%) lost to follow-up

GRADE profile 2- Action

Quality assessment										
No. of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No. of participants	Effect	Quality of evidence for outcome	Importance of outcome
Cigarettes/cigars per day										
Baseline vs. 2 years (Health screening interview and nutrition and well being advice) [ES 2.8]										
1[1]	Before-after study	Serious[a]	Not applicable	No serious	Serious[b]	No	110	Mean Difference -3.50 (95% CI -5.58 to -1.42), p<0.001	Low	Critical
Diet (method of outcome assessment not provided)										
Baseline vs. 6 months (Diabetes, nutrition, exercise education vs. standard care) [ES2.9]										
1[2]	RCT	Very serious[c]	Not applicable	No serious	Serious[b]	No[d]	49	Mean Difference -0.04 (95% CI -0.32 to +0.24), p=0.78	Very low	Critical
General Diet, regards to a prescribed or generally helpful diet (Diabetes Self Care Activities questionnaire; score range 0 to 7) [ES2.9]										
Baseline vs 6 months (Diabetes education vs. standard care)										
1[3]	RCT	No serious	Not applicable	No serious	Serious[f]	No	280	Mean Difference 0.10 (95%CI -0.36, 0.56); p=0.67	Moderate	Critical
Specific Diet, assess the consumption of fruits and vegetables and high fat foods (Diabetes Self Care Activities questionnaire; score range 0 to 7) [ES2.9]										
Baseline vs. 6 months (Diabetes education vs. standard care)										
1[3]	RCT	No serious	Not applicable	No serious	Serious[f]	No	280	Mean Difference 0.60 (95%CI 0.24, 0.96); p=0..001 In favour of intervention group	Moderate	Critical
Exercise (method of outcome assessment not provided)										
Baseline vs. 6 months (Diabetes, nutrition, exercise education vs. standard care) [ES2.10]										
1[2]	RCT	Very serious[d]	Not applicable	No serious	Serious[b]	No[d]	49	Mean Difference +0.10 (95%CI -0.24 to +0.44), p=0.57	Very low	Critical
Physical exercise (Diabetes Self Care Activities questionnaire; score range 0 to 7)										
Baseline vs 6 months (Diabetes education vs. standard care) [ES2.10]										
1[3]	RCT	No serious	Not applicable	No serious	Serious[f]	No	280	Mean Difference 0.0 (95%CI -0.55, 0.55); p=1.0	Moderate	Critical
Smoking cessation										
Control vs photo-aging intervention (6 month follow-up; self-reported) [ES2.11]										
1[4]	RCT	Serious[e]	Not applicable	No serious	Serious[f]	No	160	RR =4.4 (95% CI 1.75 to 11.04), p <0.01	Low	Critical
Control vs photo-aging intervention (6 month follow-up; CO verified) [ES2.11]										
1[4]	RCT	No serious	Not applicable	No serious	Serious[f]	No	160	RR =11.0 (95% CI 1.45 to 83.21). p =0.003	Moderate	Critical
Baseline vs. 6 months (Diabetes education vs. standard care) [ES2.11]										

1[3]	RCT	No serious	Not applicable	No serious	Serious[f]	No	280	RR=0.83 (95%CI 0.51, 1.34); p=0.44	Moderate	Critical
Foot care (Diabetes Self Care Activities Questionnaire; score range 0 to 7)										
Baseline vs. 6 months (Diabetes education vs. standard care) [ES2.12]										
1[3]	RCT	No serious	Not applicable	No serious	Serious[f]	No	280	Mean Difference 0.60 (95%CI 0.11, 1.43); p=0.02	Moderate	Critical

1. Watman et al (2002)
2. Guirguis et al (2001)
3. Mehuys et al (2011)
4. Burford et al (2013)

a. Downgraded 1 level as outcome assessor aware of intervention exposure and selective outcome reporting as effect for medium and low risk groups not reported separately as was the case for high risk groups
b. Downgraded 1 level as imprecision could not be calculated and small sample size <400
c. Downgraded 2 levels as method of randomisation and allocation unclear and some data to suggest there were significant differences between intervention and control groups at baseline which were not controlled for during analysis. Unclear if participants in the control group received a higher level of care which was similar to the intervention group.
d. Available case analyses conducted and analyses were underpowered
e. Downgraded 1 levels as abstinence rates were obtained from self-report which is likely prone to social desirability bias
f. Downgraded 1 level as sample size less than 400

GRADE profile 3- Intention

Quality assessment										
No. of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No. of participants	Effect	Quality of evidence for outcome	Importance of outcome
Advice seeking occurrences (in one month)										
Leaflet display vs Leaflet and pharmacist offering to provide advice [ES2.13]										
1[1]	Non randomised controlled trial	Very serious[a]	Not applicable	Very serious[b]	Very serious[c]	No	210	19% difference (favouring intervention) (0% vs 19%)	Very low	Important
Leaflet (with instruction to seek advice vs Leaflet and pharmacist offering to provide advice [ES2.13]										
1[1]	Non randomised controlled trial	Very serious[a]	Not applicable	Very serious[b]	Very serious[c]	No	170	RR=0.96 (95%CI 0.57 to 1.64), p=0.89	Very low	Important
Leaflet with instruction to seek advice handed out by pharmacist vs. Leaflet and pharmacist offering to provide advice [ES2.13]										
1[1]	Non randomised controlled trial	Very serious[a]	Not applicable	Very serious[b]	Very serious[c]	No	213	RR=0.88 (95%CI 0.51 to 1.54), p=0.66	Very low	Important

1. Lloyd-Williams 2003

a. Downgrade 2 levels as allocation to interventions were not randomised
b. Downgrade 2 levels as outcome of interest is seek advice, no measure regarding association of seeking advice and health outcome. Also baseline health seeking behaviour not reported
c. Downgrade 2 level as imprecision due to small sample size <400 and confidence intervals cross the minimally important difference (0.75 and 1.25 for dichotomous outcomes, 0.5*SD of control group at baseline for continuous outcomes)

GRADE profile 4- Attitudes

No evidence was identified [ES 2.14]

GRADE profile 5- Knowledge

Quality assessment										
No. of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**No. of participants**	**Effect**	**Quality of evidence for outcome**	**Importance of outcome**
Asthma knowledge										
Baseline vs. immediately post intervention (Peer led asthma education) [ES2.15]										
1[1]	Before-after study	Very serious[a]	Not applicable	No serious	Very Serious[b]	No	92	Mean Difference 4.39 (95% CI 3.67 to 5.11), p<0.001	Very low	Important
Baseline vs 6 months (3 Education visits) [ES2.15]										
1[2]	Before-after study	Very serious[c]	Not applicable	No Serious	Very serious[d]	No	212	Mean difference 1.09 (95% CI 0.65 to 1.53), p<0.001	Very low	Important
Baseline vs 6 months (4 Education visits) [ES2.1]										
1[2]	Before after study	Very serious[c]	Not applicable	No serious	Very serious[d]	No	179	Mean difference 1.18 (95% CI 0.73 to 1.63), p<0.001	Very low	Important
Baseline vs 6 months (4 education visits vs. 3 education visits) [ES2.15]]										
1[2]	Before-after study	Very serious[c]	Not applicable	No Serious	Very serious[d]	No	391	Mean difference 0.38 (95% CI -0.04 to 0.80), p>0.05	Very low	Important
Baseline vs 6 months (Education and reviews vs. Standard care) [ES2.16]										
1[3]	RCT	Very serious[e]	Not applicable	No serious	Very Serious[b]	No[f]	89	Mean difference 2.80 (95%CI 0.59 to 5.01)[g] p<0.001	Very low	Important
Diabetes knowledge										
Baseline vs 6 months (Diabetes education vs. standard care); Diabetes Self-Care Activities questionnaire, score range 0 to 7 [ES2.17]										
1[4]	RCT	No serious	Not applicable	No serious	Serious[h]	No	280	Mean Difference 11.4 (95%CI 6.68, 16.12); p<0.001 in favour of intervention group	Moderate	Important
Baseline vs. 12 months (12 education sessions vs. 2 education sessions); No information provided on measure used to assess knowledge [ES2.17]										
1[5]	RCT	Serious[i]	Not applicable	No serious	Serious[j]	No	84	Mean Difference 1.7 (95%CI 0.56, 2.84); p=0.03 in favour of intervention group	Low	Important

1. Kritikos et al 2005
2. Saini et al 2011
3. Saini et al 2004
4. Mehuys et al 2011
5. Skowron et al 2011

a. Downgraded 2 levels as unclear how participants selected to participate and the sample frame used, unable to determine drop-out rate, unable to determine if all participants received intervention and likely variation in method of intervention delivery
b. Downgraded 2 levels as imprecision could not be calculated and small sample size <400
c. Downgraded 2 levels as serious risk of detection bias as participants nor pharmacists blinded to intervention, unclear how many participants received the specified intervention high level of attrition
d. Downgraded 2 levels as insufficient data provided to calculate an effect size and only p-value reported, total sample size is less than 400

e. Downgraded 2 levels as serious risk of detection bias as participants nor pharmacists blinded to intervention and high level of attrition
f. A second control group was recruited during the course of the study which resulted in different numbers of study participants being compared throughout the study
g. Downgraded 2 levels as confidence intervals cross the minimally important difference (0.5*SD of control group at baseline) and total sample size is less than 400.
h. Downgraded 1 level as sample size less than 400
i. Downgraded 1 level as contamination may have occurred and large number of participants (60%) lost to follow-up
j. Downgraded 1 level as total sample size is less than 300.

GRADE profile 6- Beliefs

Quality assessment										
No. of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No. of participants	Effect	Quality of evidence for outcome	Importance of outcome
Back pain (possible score range 9 to 45, higher scores indicate more positive beliefs)										
Baseline vs. 2 weeks (Pamphlet + Education vs. Standard care) [ES2.18]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	128	Mean Difference 2.10 (95%CI -0.34 to 4.54), p=0.09	Very low	Important
Baseline vs. 2 weeks (Pamphlet + Education vs. Pamphlet only) [ES2.18]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	119	Mean Difference -0.10 (95% CI -2.57 to 2.37), p=0.94	Very low	Important
Baseline vs. 8 weeks (Pamphlet + Education vs. Standard care) [ES2.18]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	118	Mean Difference 0.90 (95% CI -1.80 to 3.60), p=0.51	Very low	Important
Baseline vs. 8 weeks (Pamphlet + Education vs. Pamphlet only) [ES2.18]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	113	Mean Difference 0.60 (95% CI -2.19 to 3.39), p=0.67	Very low	Important
Physical activity related fear on low back pain (Possible score range from 0 to 24, higher score indicates higher fear avoidance)										
Baseline vs. 2 weeks (Pamphlet + Education vs. Standard care) [ES2.19]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	128	Mean Difference 0.10 (95%CI -1.86 to 2.06), p=0.92	Very low	Important
Baseline vs. 2 weeks (Pamphlet + Education vs. Pamphlet only) [ES2.19]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	119	Mean Difference 1.40 (95%CI -0.82 to 3.62), p=0.18	Very low	Important
Baseline vs. 8 weeks (Pamphlet + Education vs. Standard care) [ES2.19]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	118	Mean Difference -1.00 (95% CI -3.06 to 1.06), p=0.34	Very low	Important
Baseline vs. 8 weeks (Pamphlet + Education vs. Pamphlet only) [ES2.19]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	113	Mean Difference 0.40 (95% CI -1.99 to 2.79), p=0.73	Very low	Important
Work related fears on low back pain (Possible score range from 0 to 42, higher score indicates higher fear avoidance)										
Baseline vs. 2 weeks (Pamphlet + Education vs. Standard care) [ES2.20]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	128	Mean Difference -2.70 (95%CI -6.97 to 4.57), p=0.22	Very low	Important
Baseline vs. 2 weeks (Pamphlet + Education vs. Pamphlet only) [ES2.20]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	119	Mean Difference -1.70 (95% CI -5.92 to 2.52), p=0.43	Very low	Important
Baseline vs. 8 weeks (Pamphlet + Education vs. Standard care) [ES2.20]										

1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	118	Mean Difference -2.30 (95% CI -6.41 to 1.81), p=0.29	Very low	Important
Baseline vs. 8 weeks (Pamphlet + Education vs. Pamphlet only) [ES2.20]										
1[1]	cRCT	Serious[a]	Not applicable	No Serious	Very serious[b]	No[c]	113	Mean Difference -0.20 (95% CI -4.05 to 3.65), p=0.92	Very low	Important

1. Slater et al 2013

a. Downgraded 1 levels as serious risk of detection bias as participants nor pharmacists blinded to intervention and high level of attrition
b. Downgraded 2 levels as imprecision as total sample size is less than 400 and confidence intervals cross the minimally important difference (0.75 and 1.25 for dichotomous outcomes, 0.5*SD of control group
c. Available case analysis conducted with missing data

GRADE profile 7- Awareness

No evidence was identified [ES 21]

GRADE profile 8- Health status

Quality assessment										
No. of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**No. of participants**	**Effect**	**Quality of evidence for outcome**	**Importance of outcome**
Physical function (Physical Composite Summary), range 0 to 100 where zero represents lowest level										
Baseline vs. 6 months (Diabetes, nutrition, exercise education vs. standard care) [ES2.22]										
1[1]	RCT	Very serious[a]	Not applicable	No serious	Very serious[b]	No[c]	49	Mean difference 2.20 (95%CI -2.66 to 7.06), p=0.38	Very low	Less important
Mental Well-being (Mental Composite Summary) range 0 to 100 where zero represents lowest level										
Baseline vs. 6 months (Diabetes, nutrition, exercise education vs. standard care) [ES2.23]										
1[1]	RCT	Very serious[a]	Not applicable	No serious	Very serious[b]	No[c]	49	Mean difference 6.60 (95%CI 1.49 to 11.71), p=0.01	Very low	Less important

1. Guirguis et al 2001

a. Downgraded 2 levels as method of randomisation and allocation unclear and some data to suggest there were significant differences between intervention and control groups at baseline which were not controlled for during analysis. Unclear if participants in the control group received a higher level of care which was similar to the intervention group.
b. Downgraded 2 levels as small sample size <400 and confidence intervals cross the minimally important difference (0.75 and 1.25 for dichotomous outcomes, 0.5*SD of control group
c. Available case analyses conducted and analyses were underpowered

GRADE profile 9- Wellbeing

Quality assessment										
No. of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**No. of participants**	**Effect**	**Quality of evidence for outcome**	**Importance of outcome**
Quality of Life (Measure used to assess not provided)										
Baseline vs. 6 months (%) –Positive mood [ES2.24]										
1[1]	Before after study	Very serious[a]	Not applicable	No serious	Serious[b]	No	24	OR=1.84 (95%CI 0.39, 8.77); p=0.44	Very low	Less important
Baseline vs. 6 months (%) –Days being easy [ES2.24]										
1[1]	Before after study	Very serious[a]	Not applicable	No serious	Serious[b]	No	24	OR=1.67 (95%CI 0.40, 6.87); p=0.48	Very low	Less important
Baseline vs. 6 months (%) –Social activity [ES2.24]										
1[1]	Before after study	Very serious[a]	Not applicable	No serious	Serious[b]	No	24	OR=1.0 (95%CI 0.18, 5.53); p=1.0	Very low	Less important
Baseline vs. 6 months (%) –Feeling rested [ES2.24]										
1[1]	Before after study	Very serious[a]	Not applicable	No serious	Serious[b]	No	24	OR=1.0 (95%CI 0.22, 4.56); p=1.0	Very low	Less important
Baseline vs. 6 months (%) –Feeling rested [ES2.24]										
1[1]	Before after study	Very serious[a]	Not applicable	No serious	Serious[b]	No	24	OR=1.84 (95%CI 0.39, 8.77); p=0.44	Very low	Less important

1. Petkova et al 2006

a. Downgraded 2 levels as unclear how study population obtained (selection bias), study funded by pharmaceutical company
b. Downgraded 1 levels as imprecision could not be calculated and total sample size is less than 400.

Appendix G – Economic evidence study selection

1. Burford O, Jiwa M, Carter O, Parsons R, Hendrie D. Internet-based photoaging within Australian pharmacies to promote smoking cessation: randomized controlled trial. Journal of medical Internet research. 2013; 15(3):e64.

Appendix H – Economic 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
New economic evaluation for this guideline

Quality score
++

Study type
Cost-utility analysis

Location and setting
NHS

Aims
To determine the costs and effects associated with a community pharmacy based photo-ageing intervention for smoking cessation identified in the evidence review.

Length of follow up
Lifetime model

Source of funding
N/A</td>
<td>Health area
Smoking cessation

Number of participants
N/A (modelling study)

Participant characteristics
From the effectiveness study for relative effects. Age-weighted to reflect UK population.

Inclusion criteria
As per evidence review

Exclusion criteria
As per evidence review</td>
<td><u>Photo-ageing vs. usual care (no intervention)</u>
(Burford et al .2013)</td>
<td>Lifetime cost–utility model developed composed of smoking status health states, 6 smoking-related comorbidities, and death. Model closely based on the model used for NICE GID-PH94 (itself based on PH10 & PH45).

Effectiveness was informed by incremental quit rate identified in the evidence review. Comorbidity and mortality risk dependent on smoking status. Quality of life dependent on smoking status and presence of comorbidity. Costs composed of intervention and management of comorbidities.

Results expressed in terms of discounted QALYs and costs (discount rate 3.5% per year), from the perspective of the NHS/PSS,</td>
<td>Photo-ageing software intervention:
<table>
<tr><th>Strategy</th><th>QALYs</th><th>Costs (£)</th></tr>
<tr><td>Intervention</td><td>16.61</td><td>10,345</td></tr>
<tr><td>Usual care</td><td>16.49</td><td>10,692</td></tr>
</table>
Sensitivity analysis:
Results determined to be highly robust to univariable sensitivity analysis. The intervention can cost significantly more than its base case level and still have an ICER under £20,000 per QALY gained. Probabilistic sensitivity analysis not undertaken.</td>
</tr>
</table>

			and the resulting ICER.	
Limitations identified by authors Substantial heterogeneity between studies precludes the development of a meaningful pooled analysis. Limited to separate comparisons for each study. Model does not capture secondary quit attempts or relapse. Probabilistic sensitivity analysis was not undertaken as this functionality was not possible using the original model (developed for NICE GID-PH94). **Other comments** Linked to Burford et al. (2013), Costello et al. (2011) Cramp et al. (2007) and Maguire et al. (2001)				

Also see evidence table for Burford et al. (2013) in Appendix Di.

Appendix I – Health economic evidence profiles

N/A

Appendix J – Health economic analysis

N/A

Appendix K – Excluded studies

See separate appendix K document.

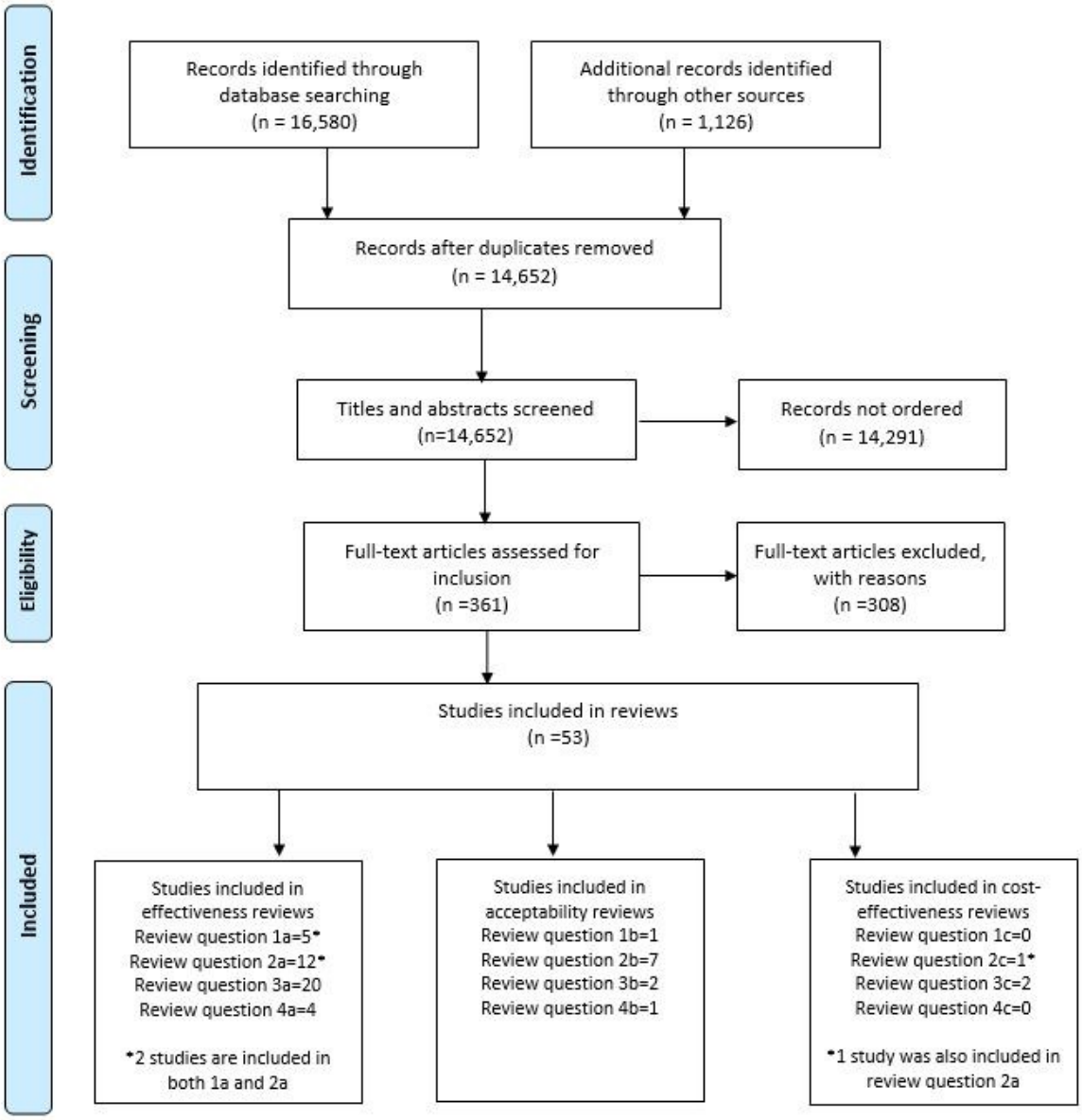
Appendix L – Research recommendations

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). *Preferred Reporting Items for Systematic Reviews and Meta-Analyses*: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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