

1. Project title: Community pharmacy interventions for public health priorities: systematic review of community pharmacy delivered smoking, alcohol and weight management interventions.

2. Background:

2.1 Existing Research

The government has set a clear agenda for the future of public health in the UK, focused on improving the healthy life expectancy of the population and, where possible, reducing or removing threats to this aim (DH, 2010). One strand within this is to create accessible, multi-disciplinary networks of public health professionals who work within communities and provide services to address key public health issues, health inequalities, and ultimately improve health and wellbeing.

Community pharmacies may be an important component of this agenda; there are over 10,500 community pharmacies in England, distributed across urban and rural areas (PSNC, 2010). The public can access healthcare via community pharmacy services very easily and without an appointment. Pharmacies are open at convenient times, including evenings and weekends allowing access for people who work a wide range of hours. This situation has consistently improved in recent years with policy drives to improve access to medicines, including the promotion of '100 hour pharmacies', which must open 100 hours per week for every week of the year (DH, 2008). Further to this, it has been estimated that 99% of the population can get to a pharmacy from home within 20 minutes either by car, by walking, or using public transport. Importantly, this includes those living in the 10% most deprived areas of the country (DH, 2008).

Estimates vary with regard to the reach of the community pharmacy network with some sources suggesting that 95% of the population make at least one visit during the year (NHS Scotland, 2008). In summary, the population has convenient access, at a time of their own choosing, to all services within community pharmacy. This includes individuals who cannot, or choose not to, access conventional healthcare providers. Community pharmacists are also able to deliver healthcare advice at an opportunistic level, related to prescription or non-prescription medicines and as part of focused services designed to reduce specific risks to health (Andersen *et al.*, 2009).

Given the wide availability and accessibility of community pharmacies, they have the potential to play a significant role in delivering public health interventions. Indeed, one recent success story, which also illustrates the opportunity for community pharmacy to have a positive impact on patient-related public health outcomes, is the healthy living pharmacy (HLP) programme (NPA, 2011). This concept was initially developed by NHS Portsmouth but now – supported by the Department of Health – is being rolled out across a number of other areas, as part of a HLP pathfinder programme. The HLP framework is a tiered commissioning system aimed at achieving consistent delivery of a broad range of high quality services through community pharmacies to meet local need, improving the health and wellbeing of the local population, and helping to reduce health inequalities.

Interventions which aim to reduce obesity, smoking rates and alcohol misuse – led by community pharmacists – have been identified by the government as public health priorities (DH, 2008; DH, 2010). In view of this, many pharmacists now offer, through locally enhanced services, alcohol, smoking cessation and weight management schemes (PSNC, 2005). At present, these services are commissioned by the local authority according to local need; all services are delivered to an agreed framework specification that allows for variations in the delivery of the service at a local level.

References

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2.2 Risks and benefits:

A potential risk of this research is that we will not identify sufficient studies for inclusion in our review, and hence we will not be able to make any useful recommendations about the effectiveness of community pharmacy interventions which aim to tackle obesity, smoking, and excessive alcohol intake. As part of the preparation for this full application bid, we conducted a scoping search and are confident that we will find sufficient studies of relevance with respect to community pharmacy interventions which aim to tackle obesity and smoking, but not excessive

alcohol intake. We have designed the methods for our review as to allow lower level (evaluations) of community pharmacy interventions which aim to tackle excessive alcohol intake so that we can provide recommendations based on the best available evidence for community pharmacy interventions which aim to tackle obesity and smoking, and excessive alcohol intake.

2.3 Rationale for current study:

Obesity, smoking and excessive alcohol intake are three of the most significant modifiable risk factors for morbidity and mortality in the UK (Bambra et al, 2009; Marmot, 2010). Conditions which are caused or exacerbated by these risk factors include cardiovascular disease, liver disease, and lung cancer. The way in which society is organised causes inequalities in these conditions, and inequalities in these conditions are major contributors to overall inequalities in health, morbidity and mortality.

The prevalence of obesity in both children and adults remains relatively high in the UK, compared with most other European countries, particularly in areas of social deprivation. Obesity is known to be a risk factor for coronary heart disease, type 2 diabetes, and some cancers, and it is also associated with various other health issues, such as muscular-skeletal and psychosocial problems. The prevalence of obesity in women is highest amongst those living in areas of social deprivation, but the association in men is less clear.

Smoking is associated with the highest number of preventable deaths in the UK with, on average, half of all life-long smokers dying prematurely, losing on average about 10 years of life. It is estimated that up to 86,500 preventable deaths each year can be attributed to smoking. Up until 2007 the rates of smoking declined in the UK population to around 21%, but since then this figure has remained unchanged. In the UK, the rates of smoking are greatest in low socio-economic groups.

The number of alcohol-related deaths in the UK is increasing and, since 1991, has almost doubled. As with smoking and obesity rates, higher rates of excessive alcohol intake and alcohol-related deaths are reported in those living in areas of social deprivation. In addition, for men in unskilled low paid occupations, the rate of alcohol-related mortality is around 3.5 times greater than those in managerial and professional occupations. For women, this figure is even higher, with those in unskilled low paid occupations at around 5.7 times greater risk of alcohol-related mortality than those in managerial and professional occupations.

In almost all regions of the UK, community pharmacies are often the most accessible and available healthcare provider to the community, and higher numbers of community pharmacies are found in areas of high social deprivation. Because of this, community pharmacies have been identified as potentially ideal settings to deliver public health interventions. However, the existing reviews relevant to community pharmacy weight management, smoking and alcohol interventions were not able to make a judgement about the efficacy of these interventions, primarily because the evidence base they included in their reviews was limited or of poor quality, or both. Of note, many more trials of good quality have been published since these reviews were published, and many more are on-going or about to start. In 2008, the

Department of Health stated that *'a sound evidence base that demonstrates how pharmacy delivers effective, high quality and value for money services is needed'*. Indeed, this application proposes to contribute to that evidence base by identifying and reviewing, systematically, all of the relevant evidence on this topic (DH, 2008).

References

Bambra C, Joyce K, Maryon-Davies A: Strategic Review of Health Inequalities in England Post-2010 London: University College London, Institute of Health Equity; 2009, (Marmot Review) (Task Group 8: Priority public health conditions: final report). Available at: <http://www.instituteofhealthequity.org/projects/priority-public-health-conditions-task-group-report>

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3. Research objectives:

Primary objective:

To assess the effects of community pharmacy interventions on health and health behaviours in relation to weight management, smoking cessation and alcohol misuse.

Secondary objectives:

To explore if (and how) socio-economic status, gender, ethnicity and age moderate the effect of the interventions; and,

To describe how the interventions included in the review have been organised, implemented and delivered, since context is an important factor governing the success of public health interventions.

4. Research design:

The review will be carried out following established criteria for the good conduct and reporting of systematic reviews (Higgins & Green, 2011). A Review Steering Group comprising of key stakeholders will guide the research. The review will be registered with PROSPERO (International Prospective Register of Systematic Reviews), and reported to the PRISMA recommendations.

Interventions

The review will examine community pharmacy interventions which focus on weight management, smoking cessation and alcohol misuse in people of all ages, in any setting (including NHS settings), and in any country.

The 44 studies identified from our scoping search were predominantly from middle and high income countries (9 UK; 22 USA; 3 Australia; 2 Japan; 2 Jordan; and 1 each from Canada, Chile, New Zealand, Spain, Switzerland and Thailand). Although the healthcare system differs between these countries, we are of the view that the evidence from these different countries will be of use in informing policy and practice in the UK. Therefore, we are not proposing to limit the inclusion of interventions in our reviews by country of origin.

Study designs

A rigorous and inclusive international literature search will be conducted for all randomised controlled trials (RCTs) and non-randomised controlled trials (NRCTs). We will also include controlled before-after studies (CBAs) and interrupted time series (ITS) and repeated measures studies.

Given the results of our scoping search, it is apparent that there is a dearth of trial evidence on community pharmacy-based alcohol misuse interventions. Therefore, we propose to contact local councils in the UK, and a range of other organisations and people, to ask for any (independent) relevant evaluations which they have commissioned or are aware of. We are aware of a recent evaluation on this topic which has been conducted by Dr Sally Brown (who works in our Department at Durham University) which was commissioned by NHS Durham and Darlington (personal communication, report not yet in public domain), and know of 10 PCTs which have commissioned alcohol screening and brief intervention services from community pharmacies (PSNC database). We understand that this type of evidence is not as strong as that from trials, but have designed the research project so that we can provide recommendations based on the best available evidence.

Search strategy

We will run just one overarching search to identify studies of relevance for all three topics, and we will include the following electronic database searches (host sites given in parentheses): MEDLINE (Ovid), Embase (Ovid), CINAHL (NHS Evidence Health Information Resources), PsycINFO (NHS Evidence Health Information Resources), Social Science Citation Index (Thomson Reuters Web of Science), ASSIA (CSA), IBSS (EBSCO Publishing, Barnet, UK), Sociological Abstracts (CSA) and the NHS Economic Evaluation Database (NHS CRD). The skills of a trained information scientist (HJM) will be used to develop and implement the searches.

All databases will be searched from start date to the present. We will not exclude papers on the basis of language, country of origin or publication date. We will supplement the electronic database searches with website and grey literature searches, and we will search trial registers and websites of funding organisations for ongoing studies. We will include an online search of The Pharmaceutical Journal and also hand search relevant conference abstracts (such as the Royal Pharmaceutical Society conferences). We will hand search the bibliographies of all included studies and request relevant information on unpublished and in-progress research from key experts in the field. We will also contact study authors for unpublished data on health inequalities.

As mentioned above, we also propose to seek information from a range of organisations and people in the UK (local councils in the UK; pharmacy local practice forums, an advert in the Pharmaceutical Journal; Google searches) to ask for any

(independent) evaluations on community pharmacy-led interventions related to alcohol which they are aware of.

Outcomes

We will only include studies of relevance if they include at least one behavioural outcome which fits into one of the four categories listed below. The review will utilise the causal modelling framework proposed by Hardeman et al (2005) to conceptualise behavioural outcome measures, where we will use four categories of behavior outcomes (Table 1), which will allow the modelling of effects.

Table 1

Intervention	The four categories of behaviour outcomes			
	Determinant of Behaviour	Behaviour outcomes	Physiology and biochemical outcomes	Hardeman outcomes
Community Pharmacy smoking cessation	Usual care and advice/other non-pharmacy delivered interventions	Cessation of smoking, reduction in carbon monoxide levels, improvements in lung capacity	General physical or mental health (e.g. SF8, GHQ-12) Health-related quality of life (e.g. EQ5D) Health service use (e.g. GP visits) Costs of intervention	Incidence rates for lung cancer
Community Pharmacy alcohol screening and intervention	Usual care and advice/other non-pharmacy delivered interventions	Reduced score on the FAST ALCOHOL SCREENING TEST (FAST) demonstrating a reduction in alcohol intake	General physical or mental health (e.g. SF8, GHQ-12) Health-related quality of life (e.g. EQ5D) Health service use (e.g. GP visits) Costs of intervention	Incidence rates for liver disease.
Community Pharmacy weight management	Usual care and advice/other weight management services such as Weight Watchers	Weight loss, reduction of BMI, reduction in waist circumference, self-reported physical activity	General physical or mental health (e.g. SF8, GHQ-12) Health-related quality of life (e.g. EQ5D) Health service use (e.g. GP visits) Costs of intervention	Cardiovascular risk score Incidence rates for CVD

Classifying behavioural outcomes might be further complicated by studies focussing on incorporating implementation effect. For example, we might have a range of trials where Pharmacies are randomised to conditions in which the Pharmacy staff are trained to deliver the intervention.

Data on the organisation, implementation and delivery of interventions will be extracted using existing methodological tools which assess the implementation of complex public health interventions (using Egan et al, 2009; Cochrane PH and EPOC Review Group resources) adapted and refined for the purposes of this review.

Examples of the implementation components that will be examined include theoretical underpinning, implementation context, experience level of the intervention team (planners and implementers), consultation and/or collaboration processes (planning and delivery stages) and resources (for example, time, money, staff and equipment).

Data extraction and quality appraisal

The initial screening of titles and abstracts will be conducted by two reviewers (PDRA and AT), with a random 10% of the sample checked by a third reviewer (CS). Full-paper study inclusion and data extraction will be conducted by two reviewers (PDRA and AT) independently using established data extraction forms (using Cochrane PH and EPOC Review Group resources) adapted and refined for the purposes of this review. Any discrepancies will be resolved through discussion between the PDRA and AT, and if consensus is not reached then with CS. The methodological quality of the included studies will also be appraised independently by two reviewers (PDRA and AT) using a recommended Quality Assessment Tool (using Cochrane PH and EPOC Review Group resources), adapted and refined for the purposes of this review. Information recorded will include, amongst other things, an examination of sampling strategy, response and follow-up rates, intervention integrity, statistical analyses and assessment of adjustment for confounders. Again, any discrepancies will be resolved through discussion between the PDRA and AT, and if consensus is not reached then with CS. We will use the quality appraisal criteria for descriptive purposes and to highlight variations between studies.

Analysis and synthesis

If we deem (guided by the methods set out in the Cochrane Handbook; Higgins & Green, 2011) that it is appropriate to conduct meta-analyses, then we will certainly do that. Whether or not we will conduct meta-analyses will depend on the volume of RCTs included in the reviews, and if there is enough relevant and valid data from comparable (or the same) outcome measures. The project statistician will take high level advice from Professor Julian Higgins regarding the conduct of meta-analyses. Stata will be used for regular meta-analyses (currently version 12), and for more complex analyses we will use WinBUGS. If such data are not available, the synthesis may have to be restricted to a narrative overview of individual studies looking at the same question. In such cases, a forest plot may be used to illustrate the results. We will also investigate publication bias by using funnel plot and Egger's test.

The first of our two secondary objectives is '*How do socio-economic status, gender, ethnicity and age moderate the effect of the interventions*'. Socioeconomic, gender and age inequalities in the effects of interventions are a secondary outcome for this review. As such, and following previous NIHR-funded systematic reviews of the effects of interventions on health inequalities (Bambra et al, 2011), those studies included under the primary outcome that also examine differential effects with regard to socio-economic status (education, income, occupation, social class, deprivation, poverty) or in which the intervention is targeted specifically at disadvantaged groups (e.g. unemployed, low SES, low income etc) or deprived areas, will be included in the health inequalities analysis. Such measures will thereby capture interventions that focus on reducing health gaps (between the most and least affluent), shifting health gradients (the health across the whole social hierarchy) or improving the

health of disadvantaged groups (Graham and Kelly, 2004). Similarly we will conduct sub-group analysis by gender and age where possible.

Looking at the trials identified through our scoping search, it is clear that we may struggle to find relevant data which could be used in the analyses suggested above. However, a number of the evaluations which we have identified do contain useful information in relation to health inequalities, and we will summarise the best available data in a way which is of most use to the users of this review.

The second of our two secondary objectives is '*How have the interventions included in the review been organised, implemented and delivered, since context is an important factor governing the success of public health interventions*', In keeping with our current NIHR-funded review of interventions to reduce inequalities in obesity (Bambra et al, 2011), contextual data on the organisation, implementation and delivery of interventions will be extracted using existing methodological tools which assess the implementation of complex public health interventions (using Egan et al, 2009; Cochrane PH and EPOC Review Group resources), adapted and refined for the purposes of this review. Examples of the implementation components that will be examined include: theoretical underpinning, implementation context, experience of intervention team (planners and implementers), consultation/collaboration processes (planning and delivery stages) and resources (e.g. time, money, staff, equipment). This information will help users of the review in translating the findings to their own policy or practice context.

Our analysis will emphasise explaining heterogeneity of effects, including a moderator analyses for population features such as socio-economic status and ethnicity. If there is sufficient data, we will also take features of the interventions delivered into consideration, as intervention content might be highly heterogeneous.

References

Bambra CL, Hillier FC, Moore HJ, Summerbell CD. Tackling inequalities in obesity: How effective are public health interventions at reducing socio-economic inequalities in obesity amongst children? *Systematic Reviews* 2012; 1:16

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Graham H, Kelly MP. Health inequalities: concepts, frameworks and policy. 2004, Health Development Agency: London.

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Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org

PSNC (Pharmaceutical Services Negotiating Committee) service database for alcohol screening and intervention. Available from: http://www.psnc.org.uk/services_db.php?service_type%5B%5D=35&funding_source=&commission_method=&location=&keyword=&search=Search [accessed 17/04/2013]

5. Study population: n/a

6. Socioeconomic position and inequalities (of population): n/a

7. Planned interventions: n/a

8. Give brief explanation of methods proposed: (described under point 4 above)

9. Proposed outcome measures: (described under point 4 above)

10. Assessment and follow up: n/a

11. Proposed sample size: n/a

12. Statistical analysis: (described under point 4 above)

13. Ethical arrangements: n/a

14. Research Governance:

The Project Lead (Summerbell) will be responsible for overall management of the project and will ensure that the systematic review runs to time, budget and specification. Summerbell will chair monthly project meetings (held between the research team) during the duration of the study.

Both organisations associated with this bid (Durham and Newcastle Universities) have a strong track record of efficient and effective project management. We will develop procedures to project manage, plan and coordinate effectively the delivery of the systematic review to time and quality.

All projects will be managed using standard project management procedures which may be adapted to take account of any risks and control measures identified. Where appropriate, Durham University has a range of standard procedures, e.g. contracting with research consultants, budgeting and project management control, measuring client satisfaction, which are applied to all research projects. In addition, Durham University has clear research ethics procedures (www.dur.ac.uk/research.office/local/research_governance/research_ethics)

15. Project timetable and milestones

	2014-2015											
	M	A	M	J	J	A	S	O	N	D	J	F
Task	1	2	3	4	5	6	7	8	9	10	11	1 2
Protocol written (CS lead, involve all project team + RAG)		← 1										
Search strategy developed and piloted (HM lead)			← 2									
Screening and retrieval of studies (CS lead; PDRA, AT)						← 3						
Data extraction and quality appraisal (CS lead; PDRA, AT)									← 4			
Synthesis of results (CS lead; AK lead m-a, PDRA, AT)												← 5
Acquisition & synthesis of local evaluation reports (AT lead)												← 6
Write up journal paper (CS lead, involve all project team)												← 7
Dissemination, policy and practice (AH lead)												← 8
Review Advisory Group (RAG) meetings (AH lead)	☀										☀	
NIHR progress report (CS lead)												
NIHR final report (CS lead)												→

Milestone



Deliverable



Milestones:

1.	Protocol development	31/03/2014
2.	Search strategy developed and piloted	30/04/2014
3.	Screening of hits (titles and abstracts) and retrieval of papers	31/07/2014
4.	Data extraction and quality appraisal	31/10/2014
5.	Synthesis of results	31/01/2015
6.	Acquisition & synthesis of local evaluation reports	31/01/2015
7.	Draft paper for journal submission	28/02/2015
8.	Develop dissemination strategy for Policy & Practice	28/02/2015

Deliverables:

1.	Final report to NIHR	28/02/2015
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16. Expertise

This application brings together a project team of researchers from Durham and Newcastle Universities working in the UK CRC Public Health Centre of Excellence, the Centre for Translational Research (Fuse), and the NIHR School for Public Health Research. The application also brings together a range of key stakeholders, including users through an existing and dedicated pharmacy specific PPI which is a core component of the Pharmacy division at Durham University.

The project team bring expertise in systematic reviewing (CB, HM, FS, CS) and information science (HM), statistics (AK), pharmacy (AH, AT), behavior change (FS), and health inequalities (CB). In addition, members of the project team and or the Review Advisory Group provide expertise in the three specific topics of enquiry relevant to this project; obesity and weight management (HM, CS), smoking cessation (Elena Ratschen, Nottingham), and alcohol misuse (Eileen Kaner, Newcastle), and also Public Health (Peter Kelly, Stockton Local Authority).

17. Partner Collaboration

PPI is one of the key strengths of this application, both for the review process and the dissemination of findings, and we consider PPI members as partner collaborators on this project.

Review process

Nationally, AH has involvement with key stakeholders and networks relating to community pharmacy. AH has invited a number of key stakeholders to be a member of the Review Advisory group:

- o Prof. Claire Anderson, Professor of Pharmacy, Nottingham University (invited to Chair the Review Advisory Group);
- o Mr. Mark Burdon, from the Pharmaceutical Services Negotiating Committee (PSNC);
- o Prof. Peter Kelly, Director of Public Health for Stockton Local Authority;

Lead authors, who are also pharmacists, of key existing reviews on community pharmacy and obesity, smoking cessation or alcohol misuse:

- o Dr. Mags Watson, Senior Research Fellow, University of Aberdeen,
- o Prof. Christine Bond, Professor of General Practice & Primary Care, University of Aberdeen

Academic public health experts in alcohol and smoking (CS has expertise in obesity):

- o Prof. Eileen Kaner, Prof. of Public Health Research, Newcastle University;
- o Dr. Elena Ratschen, Lecturer in Epidemiology/ Tobacco Control, Nottingham University.

AH has also invited two representative members of the existing and dedicated pharmacy specific PPI, which is a core component of the Pharmacy division at Durham University, to be members of the Review Advisory Group

Dissemination

AH will ensure that the findings of the review are appropriately disseminated to key stakeholders, including the Department of Health, Local Councils, the Royal Pharmaceutical Society, the Pharmaceutical Services Negotiating Committee, the Local Government Association, the Faculty of Public Health, NICE, Alcoholics Anonymous, Weight Concern, and Action for Smoking and Health. In addition, contacts made with user, practitioner and policy groups through Bamba's involvement in the Strategic Review of Health Inequalities in England Post 2010 (Marmot Review) will be exploited as part of our dissemination strategy.