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Highlighting alcohol use in medication appointments with clinical pharmacists: the CHAMP-1 mixed methods research programme

Duncan Stewart, Mary Madden, Andrew Bartlett, Ranjita Dhital, Brendan Gough, Shona Haining, Ronan O'Carroll, Margaret Ogden, Cate Whittlesea and Jim McCambridge





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Extended Research Article

Highlighting alcohol use in medication appointments with clinical pharmacists: the CHAMP-1 mixed methods research programme

Duncan Stewart[®],^{1,2*} Mary Madden[®],¹ Andrew Bartlett[®],¹ Ranjita Dhital[®],³ Brendan Gough[®],⁴ Shona Haining[®],⁵ Ronan O'Carroll[®],⁶ Margaret Ogden[®],¹ Cate Whittlesea[®]⁷ and Jim McCambridge[®]¹

*Corresponding author d.stewart@londonmet.ac.uk

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¹Department of Health Sciences, University of York, York, UK

²School of Social Sciences and Professions, London Metropolitan University, London, UK

³UCL Arts and Sciences Department, University College London, London, UK

⁴School of Humanities and Social Sciences, Leeds Beckett University, Leeds, UK

⁵North of England Commissioning Support (NECS), Newcastle, UK

⁶Department of Psychology, University of Stirling, Stirling, UK

⁷UCL School of Pharmacy, University College London, London, UK

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Abstract

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Background: Brief interventions have been the cornerstone of alcohol prevention in the National Health Service, but there are important limitations to the underpinning evidence base, and implementation has been problematic. We completed the first community pharmacy brief intervention trial and found no effect. A different approach was needed. This programme proposed to integrate attention to alcohol clinically within existing pharmacy service delivery, supporting pharmacists to discuss alcohol as a toxic psychoactive drug in the contexts of potential impacts on treatments, conditions and health.

Aims: The aims were to: (1) work with pharmacists and patients to design and evaluate an intervention that develops the health and well-being role of pharmacists in relation to alcohol consumption, specifically within the context of an existing medication review service; (2) engage with policy-makers throughout the duration of the programme about the intervention and wider systemic and workforce development needs for the pharmacy profession.

Design and methods: Methods incorporated reviews, qualitative observational and interview studies, coproduced intervention development and process studies, and a cluster pilot randomised controlled trial. During the programme, national policy decisions moved National Health Service-commissioned medication reviews from community pharmacy into newly created Primary Care Networks of general practices, in the form of a new service, the Structured Medication Review. With funder approval, we adapted the programme and the intervention to the general practice setting. This included early studies of Structured Medication Review implementation and feasibility study of using primary care data sets for evaluation purposes.

Setting: Community pharmacies initially, and subsequently general practice.

Participants: Pharmacists and medication review patients.

Interventions: The Medicines and Alcohol Consultation was developed to support pharmacists to integrate attention to alcohol within routine medication reviews.

Results: The programme comprised three phases, reflecting major, unanticipated changes in the organisation of National Health Service medication review services, and thus to the research plan. Phase 1 developed the intervention with patients and community pharmacists, informed by the conceptual work, reviews, observational and interview studies. Feasibility studies established the planned trial methods, and the external cluster pilot trial met main trial progression criteria for rates of recruitment and follow-up. In phase 2, now in general practice, we studied how national policy was being translated into practice, in order to understand contextual factors influencing the early implementation of Primary Care Networks and the Structured Medication Review, including substantial COVID-19-related delays. Interviews with senior staff, clinical pharmacists and patients indicated that Structured Medication Review practice had fallen short of the original person-centred policy vision for the service, and clinical pharmacist role development in Primary Care Networks was limited. The quality of national Structured Medication Review data was uncertain. In such circumstances, it was decided that it was not possible to undertake a definitive trial. In phase 3, the Medicines and Alcohol Consultation programme was delivered to a cohort of 10 clinical pharmacists in general practice, with data from pharmacists, patients, practice development coaches and audio-recordings triangulated. Progress towards more skilful, person-centred practice was observed for the pharmacists who completed the programme, with acknowledged limitations. This was particularly the case for alcohol itself. The local policy and service contexts were examined in an integrated care system stakeholder interview study that laid bare major challenges to be faced in addressing alcohol.

Limitations: The programme has comprised predominantly qualitative studies within the North East and Yorkshire region, so transferability to other regions is not known.

Conclusions: Pharmacists can be supported to increase skilfulness in working clinically on alcohol with patients. Workforce development and systemic pressures make this more difficult than it needs to be. The idea that alcohol should be regarded as a drug, to be discussed alongside prescribed medications, is foundational for clinical pharmacists. The new thinking about how healthcare professionals more broadly talk about alcohol with patients has been articulated as a new paradigm, brief interventions 2.0, for advancing future research.

Future work: Implications for future work on alcohol are far-reaching. Advancing brief interventions 2.0 requires interventions to focus on personal health and social contextual factors, entailing much broader discussions of the place of alcohol in peoples' lives. This means avoiding the pitfalls of focusing on stereotyped notions of problem drinking. It requires a systemic, strategic approach to prevention. The Medicines and Alcohol Consultation is a starting point for this agenda, which we will advance in debate and new research.

Study registration: This study is registered as Current Controlled Trials ISRCTN57447996 (pilot trial).

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Report Supplementary Material 1 The MAC programme

Report Supplementary Material 2 Clinical pharmacist interactional analysis

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/GJJM1624).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

The supplementary materials (which include but are not limited to related publications, patient information leaflets and questionnaires) are provided to support and contextualise the publication. Every effort has been made to obtain the necessary permissions for reproduction, to credit original sources appropriately, and to respect copyright requirements. However, despite our diligence, we acknowledge the possibility of unintentional omissions or errors and we welcome notifications of any concerns regarding copyright or permissions.

List of abbreviations

ARRS	Additional Roles Reimbursement Scheme	NMS PI	New Medicine Service principal investigator
AUDIT-C	Alcohol Use Disorders Identification Test-Consumption	PPI PPPG	patient and public involvement Pharmacy Professional Practice Group
BI CHAMP-1	brief interventions Clinical pharmacy: Highlighting Alcohol	PAG	Policy Advisory Group
CHAMI	use in Medication aPpointments	PCN	Primary Care Network
СР	clinical pharmacist	PCPEP	Primary Care Pharmacy Education Pathway
DES	Directed Enhanced Service	PMG	Programme Management Group
GP	general practitioner	PSC	
ICS	integrated care system		Programme Steering Committee
MAC	Medicines and Alcohol Consultation	RCT	randomised controlled trial
MRC	Medical Research Council	SMR	Structured Medication Review
MUR	medication use review	VTC	variation to contract

Plain language summary

A lcohol causes harms to individual drinkers and to other people, but it is not well dealt with in healthcare services. This is partly because alcohol is a difficult subject for practitioners and patients to talk about. To address this problem, we developed a new way for pharmacists to include alcohol when discussing medications with their patients. This aims to help people make more informed decisions about their drinking, because even small amounts of alcohol can have important adverse effects on treatments and on health.

We first worked closely with patients and pharmacists in community pharmacies on how and when alcohol should be discussed during medication reviews. Using findings from interviews and workshops, we developed the new approach, conducted a successful pilot study and prepared to do a large study to test if this approach worked. Then the main National Health Service medication review service delivered by pharmacists was moved to general practice. We had to change our research plans. We studied local National Health Service leader, patient and pharmacist perspectives of the organisational changes. We then adapted the ways we prepared pharmacists to discuss alcohol with patients, after further major delays caused by the COVID-19 pandemic. In the final year of our programme, we trained 10 pharmacists to discuss the effects of alcohol on medications and health with patients. With permission, we audio-recorded some discussions and spoke with pharmacists and patients to help us better understand how they felt about these discussions. We learnt that the new approach was well received by patients. Pharmacists also valued the changes to their practice and told us they need ongoing support to discuss alcohol with their patients.

We concluded that new ways of thinking and talking about alcohol are needed across the National Health Service. We now have a better understanding of how this can work with pharmacists. Discussions of alcohol should not just be about how much someone drinks. Other aspects of alcohol consumption, how it affects treatments and conditions and its role in people's lives are meaningful topics that can be discussed. Thinking about alcohol as a drug, alongside the drugs prescribed for treatments, is a useful place to start.

Scientific summary

Background

Alcohol harm is an important public health problem which widens health inequalities. Reducing alcohol consumption to reduce harmful impacts requires public health policies to increase price, and reduce the accessibility of alcohol and the social acceptability of heavy drinking. These policies are challenging to implement, and individual-level, brief interventions (BI) in routine health service contacts are recommended. BIs target drinking directly and have been the cornerstone of alcohol prevention. Yet, the underpinning evidence has important limitations: primary care trials demonstrating efficacy do not translate well into conditions of routine clinical practice, and recent large NHS pragmatic trials show no benefit. Our previous randomised controlled trial (RCT) of an alcohol intervention within the community pharmacy setting also found no effect. We concluded that a different approach was needed, moving away from targeting alcohol as a standalone topic, and paying attention to the reasons why people attend community pharmacies in the first place. We sought to optimise the alcohol contribution to health and well-being within the core pharmaceutical care role itself. Integrating attention to alcohol within existing pharmacy service delivery focuses discussion on the properties of the drug itself, implications for specific conditions and related prescribed medication interaction and adherence issues.

Aims and objectives

The aims of this research programme were to:

- Coproduce with the pharmacy profession and with patients, and evaluate in a definitive trial, an intervention that develops the health and well-being role of community pharmacies in relation to alcohol consumption, specifically within the context of established pharmaceutical services.
- To engage with policy-makers to help implement this intervention if shown to be effective, and/or to contribute
 to decision-making about the wider systemic and workforce development needs involved in extending the health
 improvement role of community pharmacies.

Description of methods and findings are organised into three phases, reflecting changes to the programme detailed below.

Phase 1: intervention development in community pharmacy

Methods

Phase 1 comprised six studies, as originally planned for the programme:

- 1. a scoping review of the NHS community pharmacy medicine review service literature
- 2. ethnographic observation of medicine review practice
- 3. semistructured interviews with people taking medication for long-term conditions
- 4. intervention co-design workshops with patients and pharmacists
- 5. an exploratory intervention delivery study and
- 6. an external cluster pilot RCT with an embedded process study.

Key findings

The review identified consultations to be short, with limited engagement with patients and their health problems. Observations and interviews confirmed current practice to be a checklist style of delivery, with alcohol only briefly mentioned if not avoided altogether. The intervention, the Medicines and Alcohol Consultation (MAC), was developed iteratively from component study findings. Conceptualising alcohol as a drug, the MAC explores possible connections

with the conditions for which medicines are prescribed and issues of adherence and medicines optimisation. Proficiency in core consultation skills was identified as needed to enable pharmacists to introduce and discuss alcohol confidently and in a non-judgemental fashion. Preparing pharmacists to deliver the MAC incorporated audio-recorded consultations used to facilitate in-depth reflection and discussion of pharmacists' actual practice.

The pilot trial investigated planned study procedures to inform progression to a definitive trial. Intervention pharmacists (n = 5) received the programme to deliver the MAC in medicine reviews, with the control pharmacists (n = 5) providing medicine review services as usual. Almost all of the 54 eligible patients (94%; n = 51) consented to participate, and 92% (n = 47) of these patients were followed up at 2 months. The process study explored the challenges involved for the participating pharmacists. They found engagement in the programme to be rewarding and the trial procedures acceptable.

Changes to the original research plan

Several major changes to the programme were required due to circumstances beyond the control of the research team. During the pilot trial, the main NHS medication review service in community pharmacy was decommissioned and replaced with a new service model, the Structured Medication Review (SMR). This was to be delivered by a largely new clinical pharmacist (CP) workforce in Primary Care Networks (PCNs). The original programme aims remained intact, as we adapted the MAC to the new setting with a view to a definitive trial.

Phase 2: transfer to general practice

Methods

Phase 2 comprised five studies:

- a review and analysis of national policy documentation associated with the introduction of PCNs and the SMR
- 2. semistructured interviews (n = 12) with senior PCN staff to explore the issues for primary care
- 3. a longitudinal study of emerging CP roles (10 new CPs interviewed three times and 10 existing CPs interviewed once)
- 4. recruitment feasibility and semistructured interviews with SMR patients (n = 10) and
- 5. a prescribing and SMR policy evaluation feasibility study.

Key findings

Primary Care Networks and SMRs were implemented at speed and based on limited evidence. The COVID pandemic placed practitioners and services under additional pressure. This raised questions about CPs' preparedness for practice development and emphasised that support for pharmacists in developing their roles and acquiring more well-developed person-centred skills were key for the intended benefits of SMRs to be realised. Factors moderating implementation locally included: the presence of pre-existing collaborative structures, 'pro-pharmacy' PCN leadership and senior pharmacist input into PCN decision-making. PCNs required time to fully form and develop the new clinical pharmacy roles while integrating the new workforce.

Clinical pharmacists were developing SMR practice in this challenging context. Patient-facing skill acquisition competed with organisational pressures and remote working during the COVID pandemic. Templates used to structure SMRs undermined the intended shared decision-making nature of the new service. Pharmacists established in general practice were clear about the clinical practice requirements of the new medication reviews. Alcohol was either avoided in consultations or introduced only in units of consumption terms, without further exploration. Pharmacists had typically not considered alcohol as a drug within their clinical practice, but were interested in the MAC approach, with some recognising the linked need to enhance their consultation skills.

At that time of the recruitment feasibility study, most SMRs were delivered by telephone, necessitating revisions to the ethical approval to incorporate approaches to patients, ascertainment of eligibility and informed consent in person and by phone. The study confirmed that our approach was appropriate. Patients reported that their experiences of what were called SMRs were in fact brief ad hoc medication reviews. The idea of the SMR, as described in the policy

specification, was highly attractive to patients, as was the possibility of including alcohol in the ways developed in our intervention. The feasibility of using OpenPrescribing data to construct linked PCN data sets for modelling purposes was broadly confirmed. However, the utility of national SMR data were problematic, as other types of medication reviews were coded as SMRs.

Further changes to the research plan

As SMR implementation had been delayed substantially by the COVID-19 pandemic, and in light of study findings on SMR delivery, after careful consideration it was judged by the funder to be not feasible to conduct a definitive trial. As we had adapted the intervention to this setting through the conduct of these studies, we extended the programme for 12 months. We studied MAC delivery in the general practice contexts instead, while also examining the broader primary care, NHS, policy and scientific contexts.

Phase 3: programme extension into the final year

Methods

Two studies were conducted in this final year of the programme:

- 1. we delivered the MAC programme for the first time in primary care to 10 CPs. Data sources included observations of the two MAC training workshops, peer support groups, coaching records and coach interviews, audio-recordings of SMR consultations (n = 19), interviews with pharmacists pre and post the programme, and interviews with patients (n = 10)
- 2. semistructured interviews with senior integrated care system (ICS) stakeholders (n = 14) within the North East and Yorkshire NHS region.

Key findings

Medicines and Alcohol Consultation delivery study

All pharmacist participants enjoyed and found value in the individually tailored coaching and face-to-face workshops, even though the content challenged their ideas about their own practice, and about alcohol. A range of external factors impacted engagement with the programme, such as holidays, illness and other workplace demands that required prioritisation. SMR numbers were lower than expected, in part because contractual changes in the NHS removed financial incentives for practices to conduct SMRs. Three pharmacists did not compete the programme. Those who did complete were highly positive about it and said they would recommend it to others.

All started the programme with abstract concepts of person-centred practice, without previously having the opportunity to work on practice development using audio-recordings of actual clinical practice. This entailed a very different experience to previous training, involving simulated practice scenarios in workshops without feedback from coaches, the limitations of which were clear to the pharmacists. All participants found some benefit in the programme, including the non-completers.

Informed by exposure in workshops to a range of underpinning microskills required for person-centred communication, the pharmacists worked with coaches on refining skills to allow patients more space and time to raise their own concerns. This generally meant the pharmacist learning to talk less and listen more. After progressing from initial self-consciousness, use of audio-recordings enabled the pharmacist to focus on how exactly what they were doing influenced patients' responses in consultations. All who listened to their recordings found them highly illuminating. Changes to clinical practice were observed closely, and progress occurred in highly individualised ways, with those starting the programme with greater foundational skills more able to make most progress.

Confidence in talking about alcohol was low initially and improved but remained a challenge throughout. Lack of role clarity was an issue; pharmacists found it hard to avoid direct advice-giving and to think about how to be helpful otherwise. There was evidence of progress, and also of limitations, in recognising and seizing upon opportunities to discuss alcohol in meaningful ways during consultations, linked to medications, conditions and patient concerns.

Crucially, framing alcohol as a drug gave the pharmacists legitimacy and increased confidence to raise alcohol, and they recognised the value to patients of linking this particular drug to others prescribed. Continued practice development is anticipated, for example, with one peer group meeting after the programme ended, though not for all participants.

Integrated care system stakeholder study

We examined alcohol in NHS contexts in two contrasting ICSs, one of which had strategically prioritised alcohol. Interviews also included views on current primary care practice relating to alcohol, and the MAC approach. Financial constraints, pressure on services and evolving organisational structures generated enormous demands on the system, particularly in primary care, and in these circumstances, alcohol was not a priority on the ground.

All interviewees recognised that this was unsatisfactory, and leaders from both ICSs wanted more upstream, prevention-orientated interventions. For the ICS with an alcohol strategy, workforce engagement was key to raising the profile of alcohol harm as an issue, as part of concerted efforts to 'win hearts and minds' of health professionals. Reframing alcohol as a drug of relevance to clinical care resonated with stakeholders. They recognised that alcohol needed to be regarded differently if progress was to be made. National policy shortcomings left public health leaders feeling hampered in implementing evidence-informed prevention ideas.

Conclusions

The contemporary NHS is a challenging environment in which to develop and scientifically evaluate innovations in new service delivery based on training CPs in patient-centred skills. Alcohol has long been a difficult issue for health services to address, and that is why the enhancement of clinical skills is a key focus. The programme has demonstrated that working with practitioners to integrate attention to alcohol in everyday clinical work, by developing clinical skills and reframing alcohol as a drug, are promising for pharmacists, and likely also for other professions. This involves exploring alcohol and health more deeply and widely, even at seemingly low levels of consumption. It also entails not having as a primary orientation the identification of some people as problem drinkers, and by implication, others as non-problematic, for whom discussions are not warranted. CHAMP-1 originated in the BI literature. The original paradigm is no longer fit for purpose, and we have proposed BI 2.0 as an alternative. This suggests that much broader content is needed to help people to think differently about, and to discuss, the place of alcohol in their lives and in wider society, in ways that are congruent with the work of health services. Programme findings will inform NHS decision-making on pharmacist roles, the future of medication reviews and the emerging agenda for system-wide perspectives on alcohol as a clinical and population health challenge and how it may be addressed.

Study registration

This study is registered as Current Controlled Trials ISRCTN57447996 (pilot trial).

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research programme (NIHR award ref.: RP-PG-0216-20002) and is published in full in *Programme Grants for Applied Research*; Vol. 13, No. 12. See the NIHR Funding and Awards website for further award information.

Synopsis

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Background to the programme

Alcohol is an important public health problem which widens health inequalities.¹ Reducing alcohol consumption requires public health policies to increase price, limit accessibility and marketing and challenge the social acceptability of heavy drinking.² While effective, these policies are challenging to implement, and the World Health Organization has also recommended individual-level interventions in routine health service contacts to help people who drink in a hazardous and/or harmful manner to reduce their alcohol intake.³ Attention has recently been drawn in the UK to the need to develop interventions for older adults who are hazardous or harmful drinkers.⁴-6 This need exists alongside wider policy imperatives to better manage multiple long-term conditions in the context of an ageing population.⁵-9 Alcohol consumption, even at modest levels, complicates existing health problems, so effective interventions that reduce drinking may generate wider health benefits.6

Brief advice and counselling interventions to reduce alcohol consumption have been conceptualised as 'brief interventions' (BI).^{3,10} These target drinking directly and, when delivered in primary care, have been the cornerstone of the alcohol prevention paradigm for 40–50 years.¹¹ Important limitations to the large BI literature have not been addressed.^{10,12} Findings of randomised trials demonstrating efficacy do not translate well into conditions of routine clinical practice; more recent large trials conducted in naturalistic conditions in the NHS show no benefit.¹⁰ We completed the only previous trial of a BIs within the community pharmacy setting worldwide, which produced a convincing null finding.¹³ Like us, other leaders in the field have also concluded that a new paradigm for BI is needed for research, policy and practice.^{14,15} This was the starting point for the programme, originally titled Community pharmacy: Highlighting Alcohol use in Medication aPpointments (CHAMP-1).

We decided that an entirely different intervention design, more firmly rooted in the pharmacy setting itself, was needed, giving attention to the reasons why people attend particular healthcare settings in the first place. Rather than asking pharmacists to take on a new public health role, and delivering the same intervention as delivered in other contexts, we located the new intervention approach within the core pharmaceutical care role itself. This was achieved by integrating attention to alcohol clinically within existing pharmacy service delivery, avoiding targeting only the self-regulation of hazardous and harmful alcohol consumption, such as was evaluated in our trial. A core concept for this approach is that alcohol should be regarded as a toxic and addictive drug, causing direct harms to health and making existing health problems worse, thereby broadening the context for raising alcohol in clinical consultations. This entails that it be discussed alongside prescribed medications, for reasons of medication safety, effectiveness and adherence. Thus, it not only legitimises pharmacists raising the subject with patients but also recognises as good clinical practice with anyone who consumes alcohol. This is particularly so for older people who are prescribed multiple medications for chronic conditions.

Our culture does not support honest conversations about alcohol. Stereotypical ideas and misconceptions abound, so pharmacists are wary of raising alcohol.¹⁷ To do so requires skill. Person-centred consultation skills can be used to appropriately manage clinical enquiry, and to create a safe discussion climate in which both participants feel more comfortable with this subject being raised and explored. The use of such skills should also enhance the quality and effectiveness of medication reviews more broadly.

The programme research plan

CHAMP-1 commenced in January 2018 and was initially funded for 5 years. The aims of the programme were to: (1) coproduce with the pharmacy profession and with patients, and evaluate in a definitive randomised controlled trial (RCT), an intervention discussing alcohol within medication appointments and (2) engage with policy-makers to support implementation and contribute to decision-making on extending the health improvement role of community pharmacies [and later, clinical pharmacists (CPs); see below]. All fieldwork was conducted in Yorkshire and the Humber and the North East of England. Details of the original objectives, workstreams and governance arrangements are provided in *Appendix 1*.

Changes to the original research plan

Circumstances beyond the control of the research team necessitated several changes to the programme (see diagram below). A detailed account of the revisions is provided in *Appendix 2*. This report is organised to reflect the three phases of the programme, as it was delivered and summarised in *Figure 1*: (1) intervention development in community pharmacy, (2) transfer of medicine review services to general practice and (3) programme extension to deliver the intervention to new NHS structures.

During the conduct of the phase 1 pilot trial, a national policy decision was made to move NHS-commissioned medication use reviews (MURs) from community pharmacy. A new service model was introduced, the structured medication review (SMR), to be delivered in Primary Care Networks (PCNs) by a greatly expanded workforce of CPs based in general practice. This decision, while favourable to our vision for alcohol, created major challenges to our intended programme of work. We moved the research programme into the entirely new setting of general practice and undertook a series of studies to adapt our evolving intervention accordingly in phase 2. Implementation of the new SMR service was delayed by the COVID-19 pandemic, then largely delivered by phone after it was rolled out. These changes meant that it was not possible to conduct the planned definitive trial of the Medicines and Alcohol Consultation (MAC) intervention we developed within this award. Instead, we extended the programme for 12 months (phase 3) in order to study closely the implementation of the MAC with CPs, while also examining the broader primary care practice, NHS, policy and scientific contexts.

Phase 1: intervention development in community pharmacy

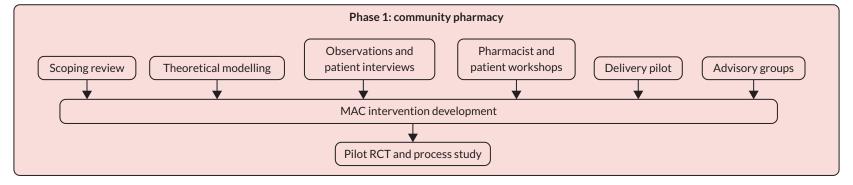
Community pharmacy medicine review services

At the time of the grant award, all community pharmacies in the UK were contracted by the NHS to deliver a range of 'advanced' services, including MURs and the New Medicine Service (NMS).²¹ MURs were intended to improve patients' understanding of their medicines and adherence, particularly among those with chronic conditions, and to reduce medicine wastage.²¹ The NMS is still provided and supports people with long-term conditions, and newly prescribed medication improve their medicines' adherence as well as support patients make decisions about their treatment and self-management.²² These services were the original target for our intervention, as incorporating alcohol appeared in line with the services remit.

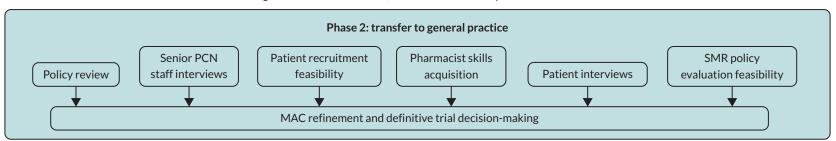
Intervention development study methods

The starting point in the grant application was to coproduce an intervention that provided pharmacists with information, and the skills to discuss the effects of alcohol on medications, adherence and the management of long conditions. This was to be located within the existing Medication-Related Consultation Framework.²³ Existing pharmacist training, consultation skills models and guidelines were to be drawn on for this new purpose. We have published accounts of the subsequent iterative development of the MAC intervention as a four-stage process, up to the point of preliminary evaluation in a pilot RCT, informed by early study findings, conceptual discussion within the team and consultations with practitioner and advisory groups.^{24,25} We draw upon these reports and other published outputs to summarise the intervention development process here, with more detail provided in *Appendix 3*. Component studies were:

- A scoping review of the MUR and NMS literature.
- An ethnographic observational study of medicine review practice (nine pharmacists at five community pharmacies).
- Semistructured interview study with 24 people taking medication for long-term conditions who drank alcohol regularly.
- Workshops with patients (n = 14) and pharmacists (n = 7) seeking to explore the acceptability and feasibility of the evolving intervention and how it could be improved.
- A pilot intervention delivery study with seven pharmacists in order to examine intervention implementation, research procedures and the experience of the intervention for both pharmacists and patients.



NHS changes: MUR decommissioned, new SMRs delivered by new CPs in new PCNs



No definitive trial: Covid impacts on implementation of SMRs and new pharmacist roles. New ICSs context

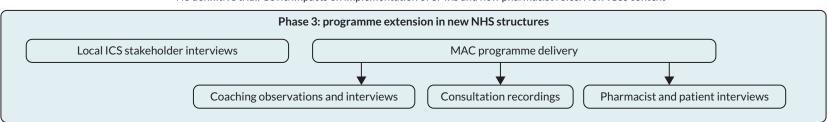


FIGURE 1 The CHAMP-1 programme structure.

Results overview

The CHAMP-1 research programme completed the planned formative pre-trial developmental work in the community pharmacy setting to schedule. We had developed a novel intervention, the MAC, which was coproduced with patients and with pharmacists, ²⁵ also drawing on the findings of the review, observational and interview studies. ^{24,26-31} These had revealed MUR and NMS practice to be far from the person-centred ideal: the services delivered were brief and structured in a checklist fashion. Discussions were often avoided. The first version of the MAC focused on existing consultation skills and practice, information on interactions between alcohol and medications, enhanced consultation skills exercises, clinical scenario case studies and support for continued professional development. Most content was planned to be delivered online, supported by a paper-based MAC guide, one-to-one support calls and opportunities for peer support. Co-design workshops with patients and pharmacists provided enthusiastic support for the alcohol as a drug idea, but pharmacists were concerned about finding time to access all of the online materials and expressed preferences for more substantial in-person delivery of training and support.

We revised the content accordingly, introducing two in-person training days to underpin the other programme elements, and weekly individual practice support site visits and telephone calls, to include discussion of audio-recordings of MAC consultations. We undertook initial feasibility testing of an abbreviated version of the MAC (version 2) and piloted the research methods (see *Appendix 3*). Our experiences echoed the earlier observational studies that medicine review consultations were almost entirely pharmacist-led and adopted a checklist style of delivery. We also observed that intervention pharmacists had unexpected levels of unmet need in becoming proficient in the core consultation skills underpinning MAC delivery. These included asking open questions, making affirmative statements, reflective listening and summarising as the key microskills. The clear conclusion was that greater attention to the process of person-centred consultation skill acquisition was needed before pharmacists would be able to introduce and discuss alcohol confidently and proficiently in the way we had envisaged.

After subsequent revisions (version 3), and input from patient and pharmacist advisory groups, version 4 of the MAC was designed as programme of practice development support. This placed greater emphasis on training pharmacists in the fundamentals of *how* to skilfully raise the subject of alcohol within MURs or the NMS, and explore carefully in a person-centred way, possible connections between alcohol consumption, the conditions for which medicines are prescribed and issues of medicine use and adherence.²⁴ To this end, and throughout the programme, the audio-recorded consultations have proven to be invaluable in facilitating in-depth reflection and discussion of pharmacists' actual practice rather than their subsequent accounts of it. The detailed data therein afforded close attention to the development of technical mastery of the microskills and how patients were responding to pharmacists during consultations.

External cluster pilot randomised controlled trial

This phase of the programme concluded with an external cluster pilot RCT to investigate planned study procedures to inform progression to a definitive trial, including refinements of the intervention. Three published outputs are summarised here. $^{32-34}$ Ten community pharmacies in Yorkshire and Humber were recruited, with a pharmacist from each who regularly conducted MURs and NMSs. Randomisation and outcome data collection were undertaken by the University of York Trials Unit. Intervention pharmacists (n = 5) received the programme to deliver the MAC in MUR/NMS consultations, with the control pharmacists (n = 5) providing these services as usual.

The target population was patients aged 18 and over attending routine MUR/NMS consultations, who reported consuming alcohol at least twice per week during screening. Patients were not eligible if they had received treatment for alcohol in the past 12 months.

Pharmacists in both arms asked consecutive MUR or NMS patients (in the pharmacy private consultation room) about taking part in a study of about how pharmacists discuss patients' health and well-being in medicine reviews. If interested, patients completed a brief screening form, which included a single-item alcohol screening question embedded in other health and service utilisation questions. Those eligible were provided with a study information statement and completed an informed consent form. Existing alcohol service referral pathways were available for patients.

Participants were followed up at 2 months by telephone interview. The candidates' primary outcomes for the definitive trial were: total weekly UK units (8 g of ethanol per unit) of alcohol consumption in the week prior to follow-up; patient confidence in medications management using the Patient-Reported Outcomes Measurement Information System Self-Efficacy for Managing Medications and Treatment scale (six-item version). We also assessed recruitment, attrition and follow-up rates as progression criteria for the definitive trial. We found that almost all eligible patients (94%) consented to participate, and 92% of these patients were followed up at 2 months. We published a summary of actions undertaken to achieve this high response rate.³⁵ Although not powered to examine intervention effects, we did find between-group differences on both primary clinical outcomes of alcohol consumption and confidence in medication management that may be expected to be statistically significant in a full trial. We thus concluded that it would have been feasible to conduct a definitive trial of the MAC in community pharmacy, had decommissioning of MURs during the pilot trial not occurred.

Process study

An embedded qualitative process evaluation involved interviews with the MAC pharmacists, patient interviews, observations of training days and audio-recordings of consultations (with patient consent).³² Paying detailed attention to actual consultation practice was new to the pharmacists, and they found it challenging at first. However, those who engaged most actively with the programme valued the feedback during the training days from facilitators and patients, as well as the discussions of developing practice with the MAC support staff. Both components were valued as having influenced consultation practice positively. We observed improved use of person-centred consultation skills within workshops, without being able to study their use in time pressured and transactional practice environments.

We also found the trial procedures to be acceptable to the participating pharmacists.³⁴ Few had previous experience of involvement in research and so found the research training and support provided helpful. Instances where pharmacists deviated from the recruitment protocol were identified early, but there were some useful adaptions made to usual routines and interactions with patients to accommodate the research.

Conclusion

The research programme made good progress, generating outputs and a novel intervention ready to trial. We also took opportunities in phase 1 to develop and promote understanding of the nature of the problem being addressed in high-profile editorials and other short papers, with consideration of the prospects for the general practice setting a prominent part of the thinking that developed at that time. 10-12,16,36-41

Phase 2: transfer to general practice

Early preparations for the CHAMP-1 main trial were underway when a major NHS policy decision was made independently of the programme to move commissioned MURs from community pharmacy into newly created PCNs (see above and *Appendix 4* for key dates and documents). This meant ending MURs in community pharmacy, which we had concluded was to be the primary service targeted for intervention delivery, as the NMS yielded too few patients at a particular moment on the patient care pathway at which there were other priorities. The new SMR service to be introduced was to be delivered by a largely newly recruited workforce of CPs working in general practice. These pharmacists, many of whom were recruited from community pharmacy, were funded by the Additional Roles Reimbursement Scheme (ARRS). Introduced in 2019, ARRS enabled PCNs to claim reimbursement for the salaries (and some related costs) of new roles within the multidisciplinary general practice team.

National Health Service England published an SMR specification, which identified target groups of people to be prioritised: in care homes; with complex and problematic polypharmacy, specifically those on 10 or more medications; on medicines commonly associated with medication errors; with severe frailty; who are particularly isolated or housebound or who have had recent hospital admissions and/or falls; using potentially addictive pain management medication. Longer consultations of 30 minutes' duration were specified, underpinned by shared decision-making principles. The risk of alcohol interactions with medicines was recognised explicitly. These developments thus enhanced the potential for contribution of this research programme to this new NHS service, and more broadly on knowledge of how alcohol prevention can be integrated with medicine-focused work.

Despite such significant changes to the pharmacy, general practice and medicine review landscapes, the original programme aims remained intact because the long-term contribution envisaged by this research remained to be fulfilled; the 'C' preceding pharmacy in the CHAMP acronym title was simply changed from 'Community' to 'Clinical'. At that time, prior to COVID, we still believed it would be possible to conduct a definitive RCT, and agreed with NIHR a further formal trial progression checkpoint. Before getting there, however, in this new phase of the programme, we first needed to investigate how national PCN and clinical pharmacy policy were being translated into local practice, to develop understanding of the contextual factors that influenced the early implementation of the SMR and other patient-facing pharmacy services in primary care. In short, we needed to do the preparatory studies that situated the evolving MAC intervention within this new NHS context.

Phase 2 methods

Details of methods and findings of the phase 2 studies are available in *Appendix 5*. In summary, the component studies of this phase of research were:

- A review and analysis of national policy documentation associated with the introduction of PCNs and the SMR.
- Semistructured interview study with senior PCN staff to explore perceptions of the policy changes in primary care relevant to the introduction of the new SMR service.
- A longitudinal study of the emerging pharmacist roles, SMR practice, views on alcohol, professional development and person-centred skills acquisition.
- A SMR patient recruitment feasibility study.
- Semistructured interview study with SMR patients to explore views and experiences of receiving the new service.
- A prescribing and SMR data availability and policy evaluation feasibility study.

The COVID pandemic meant that we were unable to conduct two originally planned preliminary ethnographic studies of SMR practice and instead we conducted two review studies, 43,44 with NIHR agreement. These were of qualitative research on perceptions of one's own alcohol use, and validation studies of instruments measuring individual practitioner person-centred consultation skills and behaviour. Both are described in *Appendix 5*.

Results overview

Policy developments and senior Primary Care Network staff perspectives

We first reviewed the development and implementation of PCN and SMR policy; ¹⁸ it was already clear that delivering SMRs to the original policy specification was going to be challenging. PCNs and SMRs had been introduced quickly, with limited opportunities for consultation, alongside rapid recruitment of CPs under ARRS. The pandemic delayed SMR implementation by 6 months, but when it was eventually started in October 2020, pressures on recruitment and service delivery were still pronounced, raising important questions about the readiness of pharmacists to deliver the new service and develop their roles in newly formed multidisciplinary primary care teams. ¹⁸ These concerns were reinforced by interviews with senior PCN staff, ⁴⁵ who described considerable variations in PCN policy implementation. More time and support to fully form the new PCN clinical pharmacy roles was needed, with much resting on existing collaborative structures and the involvement of pharmacists in decision-making processes. In part, reflecting the delays to implementation, we concluded that the feasibility of using national SMR data for evaluation purposes was doubtful at that point in time.

Pharmacist and patient perspectives

We investigated the experiences of training, skills, role and organisational development of a cohort of new CPs (n = 10), with three interviews each between September 2020 and February 2022 and compared these experiences with pharmacists already working in general practice (n = 10, one interview each).^{20,46,47} SMRs were not yet a priority in PCNs, and provision was ad hoc. The new CPs had yet to adapt their practice to the broader clinical scope of SMRs in general practice, with many struggling with the intended holistic person-centred approach, resulting in the adoption of generic templates to guide SMR delivery. Pharmacists already working in general practice were more prepared for, and comfortable with, the greater complexity of SMRs compared to other types of medication reviews, and compared to their less-experienced counterparts.

The new workforce of CPs recruited via the ARRS were enrolled on the 18-month Primary Care Pharmacy Education Pathway (PCPEP). Although the PCPEP training provided a basic knowledge base, remote working during the pandemic had limited opportunities for patient-facing contact, and so development of the skills needed for person-centred medication reviews had not advanced as it might have done otherwise. Alcohol was either not raised at all, or addressed solely in terms of calculating units of consumption, sometimes with advice to reduce drinking. Thinking about alcohol as a drug was a new idea to most of the pharmacists, but they responded favourably to this concept and, of particular importance to the programme, its clear relevance to SMR practice.

We explored patient (*n* = 10) experiences of SMR consultations who reported them to be brief medication enquiries that paid scant attention to alcohol.⁴⁸ However, considering alcohol as a drug impacting on their medications and conditions changed the way in which some patients thought about their own drinking, and they welcomed the possibility of including alcohol in SMRs in the ways developed in our intervention.

Adapting the Medicines and Alcohol Consultation for clinical pharmacists in primary care

These findings informed refinements to the MAC, adapting content and delivery to the primary care setting (version 5). Importantly, practice development was now conceptualised as a coaching process rather than an enhancement with an alcohol focus of existing training on person-centred skills. This meant that practice development work was explicitly tailored to meet the needs of individual pharmacists as far as possible, to accommodate their varying experiences, skills, learning needs and organisational contexts. We prepared a coaching manual (see *Report Supplementary Material 1*) to guide practice in building supportive working relationships with pharmacists necessary for the acquisition, development and application of key consultation microskills. This required a working alliance that centred on discussion of the complexities of discussing alcohol in SMRs, including the challenges being faced. The manual provided a framework for flexibly structuring coaching calls with individual pharmacists during the programme. After the early weeks, the key focus was on discussions of audio-recorded SMR consultations (with patient consent). The process allowed for the flexibility to discuss newly arising practice issues by inviting pharmacists to set the agenda for each call. Weekly coaching team meetings were designed to share individual pharmacists' progress. The emerging practice development issues across the group as a whole were to be reviewed, informing refinements to workshop planning, now integrated with the coaching programme content.

The range of MAC resource materials developed for the phase 1 pilot trial was also revisited and adapted to the SMR and primary care contexts, alongside the strengthening of the coaching component. Three notable changes were made. Most of the additional resources were to be provided by e-mail in bundles at strategic points during the programme (including at the start), rather than being distributed in one block as a hard copy pack. We also extended the programme to 10 weeks, scheduling the second workshop for week 7, and introducing audio-recording of consultations earlier, to allow more time for pharmacists to embed the MAC into SMR practice before tackling more advanced consultation skills in the second workshop. Finally, we directly facilitated arrangements for peer groups in the second workshop, but the actual content of the peer sessions was then left to pharmacists to decide and organise themselves. An overview of the 10-week programme is provided in *Report Supplementary Material 1*, and each MAC component and links to detailed content, where available, are shown in *Table 1*.

Conclusions

Overall, these studies demonstrated just how profound the policy and COVID-19-related influences on general practice were for the process of intervention development. At the time of writing, SMR implementation has yet to match the original policy vision of an invited, holistic, shared decision-making service. The anticipated CP role development has left practitioners more conscious of their need for support, including of person-centred consultation skills. Many had struggled to adapt their community pharmacy style of practice to the complexities of medicine management in the general practice context. In parallel, and as a result of the careful development work, our ideas and intervention content resonated with practitioners. For example, framing alcohol as a drug could help shift the focus of consultations from notions of 'patients with alcohol problems' to problems caused for many patients by alcohol, that the pharmacist had an important role in addressing.

TABLE 1 The MAC intervention components

Component	Description
Practice development training days	Day 1 to focus on core person-centred consultation skills acquisition (e.g. asking open questions), using the MAC in consultations, and preparing a practice development plan. Day 2 explored key issues identified in using the MAC in practice, more advanced person-centred skills and case studies
Guide to the MAC approach	A paper-based summary of the structure of the MAC and approach to planning the conduct of consultations. Six steps to flexibly organise the consultation to be responsive to patients and explore possible connections between alcohol consumption, use of medicines and health
Learning support resources	Case studies, information about alcohol and specific medications, and practice development exercises
Coaching calls	Individually tailored weekly practice development support by the MAC support team. Audio- recording of consultations (with patient consent) was used to facilitate discussions of practice development and experiences of using the MAC
Peer support	Voluntary invitation to engage in peer support [buddying in pairs and group discussions over WhatsApp (WhatsApp LLC, Menlo Park, CA, USA)]

We sought the variation to the contract required to conduct a main trial. We were explicit about the risks and challenges involved in this situation. This was declined by NIHR, and with the benefit of hindsight, this decision has proven to have been correct.

We were also mindful of ongoing NHS policy developments and their potential impacts on services and the CHAMP-1 programme during this period. Integrated care systems (ICSs) had been developing in preparation to becoming formal legal entities (under the Health and Care Act 2022). By providing collaborative and localised health service planning and commissioning, ICSs aim to improve population health, tackle inequalities, enhance productivity and support social and economic development. At the same time, PCNs had already been reporting pressures to minimise the duration of SMRs in order to manage backlogs, when new funding incentives were introduced to the Network Direct Enhanced Service (DES) contract in 2022.⁴⁹ This had raised fears that striving to achieve SMR targets would hasten a tendency to prioritise quantity over quality.⁵⁰ Significant changes to the contractual framework for general practice have become regular occurrences, and can be expected to continue in the future. Only 1 year later, financial incentives for SMRs were removed.⁵¹

Phase 3: programme extension in new National Health Service structures

Although the MAC coaching programme is well suited to integration with the intended national SMR service specification, there is substantial variation in how this is delivered in practice locally, and there are also other patient-facing services for which the MAC is also useful. Phase 2 of the programme demonstrated how the contexts of service delivery in primary care are complex, dynamic and challenging. This impacts on how these consultations occur in routine practice and SMR service delivery that departs considerably from the national vision is widespread.

With a trial no longer possible, and with a no-cost 1-year extension to the programme (see *Appendix 2*), we followed updated Medical Research Council (MRC) complex interventions guidance⁵² to implement the MAC in general practice for the first time, while investigating the local NHS and policy contexts which might be expected to influence intervention delivery. Specific objectives were to:

- Explore multistakeholder views on clinical pharmacy roles and practice relating to alcohol within the emerging context of the ICS infrastructure.
- Deliver the MAC programme and study in depth how CPs engage and acquire person-centred skills in practice, including alcohol-specific and other challenges faced, and how practice changes or does not.
- Examine how patients participate in and respond to alcohol discussions within SMRs.

Medicines and Alcohol Consultation programme delivery study

Introduction

This was our first opportunity to deliver the MAC in general practice. The aim was to examine the delivery of the MAC intervention from the perspectives of participating CPs, patients receiving SMRs, and the MAC coaching team. The programme provided individually tailored practice development coaching to enable pharmacists to skilfully engage with patients, to help them think through whether drinking affects their medication use, conditions and health, in a person-centred manner. The 10-week programme began on 27 February 2023, following the weekly schedule (described in *Report Supplementary Material 1*). The two in-person training workshops were conducted in York on March 9 and April 27. Telephone calls with the coaching team were scheduled each week, to discuss evolving practice and issues raised.

Ten CPs from the Yorkshire and North East regions were recruited to the study, selected from an existing pool of PCNs/pharmacists previously contacted by the research team and who were relatively advanced in the implementation of SMRs. All potential participants completed an online survey about their SMR practice and were called by the research team to elaborate on the nature of the study and to confirm commitment to full involvement in practice development and research activities, including attendance at training workshops on specific dates. All selected pharmacists were provided with written information about the study and provided written consent to participate. Various sources of data were collected and are summarised below.

Data collection

Pharmacist interviews

Audio-recoded interviews were conducted immediately pre and post the MAC programme on pharmacists' views about their own alcohol-specific and wider SMR practice within their particular general practitioner (GP) practice and PCN context. The pre-programme interview explored perceived gaps in alcohol knowledge and skills and their expectations of the programme. Shortly after completing the programme, they were asked about the extent to which they were making changes to their SMR practice, reasons for this and whether they are feeling more confident in discussing alcohol as a drug with their patients.

Medicines and Alcohol Consultation programme engagement

Pharmacist engagement during the programme was investigated through analysis of observation data on pharmacists at practice development workshops, peer support groups and weekly coaching records kept by the coaches for each pharmacist. These summarised the content of coaching calls and were shared in advance of coaching team meetings, where practice development issues across the group as a whole were discussed.

Structured Medication Review audio-recordings

The MAC programme used audio-recording of SMR consultations (with full patient consent) as the key mechanism for self-assessment of developing practice, supported by feedback from coaches. Nineteen recordings were obtained from six pharmacists. This was lower than anticipated due to: (1) low number of SMRs; (2) some pharmacists being slow to get started and not recognising the value at first, until done; (3) technical difficulties with recorders and (4) losing momentum over the Easter break.

Patient participation

The pharmacists introduced the study to consecutive SMR patients, explained that their eligibility needed to be checked and asked if they were willing to complete a brief screening form. The screening form included a single-item question about alcohol consumption [frequency of drinking question from Alcohol Use Disorders Identification Test-Consumption (AUDIT-C)] and other brief health questions. Patients drinking weekly or more frequently were eligible for the study. Existing alcohol service referral pathways were available for patients. The pharmacists then gained consent to take part, for audio-recording of the consultation and to be interviewed. Ten patients were interviewed. A further three refused to be interviewed when first contacted, one agreed but did not make further contact, and five could not be contacted at all to arrange the interview. How the patients participated in and responded to alcohol discussions was assessed in the audio-recordings alongside semistructured interviews to explore the experience of discussing alcohol during the SMR, and their wider views on discussing alcohol as a drug linked to their medicines and conditions.

Analysis

Adopting a case study design, this study utilised triangulation of these multiple sources of data to provide a rich and in-depth account of the practice development journey for each of the 10 pharmacists, in real-world, complex clinical contexts.⁵³ As well as providing a detailed description of each pharmacist 'case', we also used cross-case comparisons to examine similarities and differences in experiences of the MAC programme and practice development outcomes. A modified framework was used to organise and present data, supporting a constructionist thematic approach to analysis. Minimal case descriptors are reported in this report (see *Appendix 6*, *Tables 3* and 4) to protect participant confidentiality.

Results overview

Engagement with the Medicines and Alcohol Consultation programme and connections to practice

The programme sought to recruit CPs who actively wanted to develop their practice. In their exit interviews, most said the programme was not what they expected, 'but not in a bad way'. They expected a more familiar didactic learning model rather than the participatory person-centred programme, tailored to their own evolving self-identified practice development needs. Some were able to engage with this quite different approach more fully than others. All participants enjoyed and found value in the coaching and face-to-face workshops, even when this challenged their pre-existing views of their own practice and competence. Each of the ten pharmacists was asked about their experience of the MAC programme in their exit interview; a summary of individual responses is provided in *Appendix 7*.

Engagement with the programme was impacted by interrupted momentum from holidays, illness and participants being required to meet the demands of their workplaces, including prioritising other tasks, or covering for other staff on leave or ill. All participants struggled to recruit patients, and three participants left early because they were not doing any SMRs. Interviews revealed that practices stopped the drive for SMRs when funding under the Investment and Impact Fund incentive scheme stopped at financial year end.⁵¹ There was wide variation in types of medication review services delivered, with few conforming closely to the SMR policy documents. It was clear across the interviews that pharmacists and their practices did not distinguish between SMRs and any other review:

I'm not sure it's massively different to stuff I've always done ... If you look at four different pharmacists, SMRs will mean four different things ...

Usual practice was to deliver reviews by telephone. There was no routine SMR invitation process which would allow patients to prepare, though ad hoc arrangements were made for patients to attend for study purposes. Patient expectations of the appointment were shaped by prior experience of a 'pill review' (PMAC4) or an 'MOT' (a general check-up; PMAC 8). Some arrived under the impression that they had been brought in to discuss one specific thing: a condition, or a change in medication, and in some cases, they had. Pharmacist interviews show that during the study, some left SMR recruitment to other colleagues, while others attempted their own recruitment process targeting alcohol. Study eligibility questions meant that all reviews started with questions about 'lifestyle' topics (including alcohol) which were not audio-recorded.

Those who completed the programme attended an observed online peer support session in small groups. In their interviews, pharmacists said they enjoyed exchanging workplace experiences of alcohol skills development in practice. Some said they picked up small tips listening to others. A group intending to continue to meet after the programme ended had cross-cutting discussions about the frustrations of attempting to change the habits of patients resistant to advice, recognising their shared professional 'fix it' orientation, as well as regarding their thinking about their practice as having altered.

Person-centred consultation skills development

There was a high degree of congruence between the coach and participant perspectives on progress made in developing consultation skills (*Table 2*). All participants realised there was still work to be done. Those who engaged least, or struggled most, cited time constraints as the key reason inhibiting them offering a more person-centred approach to patients. Ironically, given the holistic aims of SMRs, the more complex the review, the less time they felt able to give patients to speak. Those who engaged most with the programme saw the approach as a means of maximising patient benefit in the time they had. Patients commented in their interviews on how much time they

TABLE 2 Pharmacist and coach perspectives of individual progress

Case	Pharmacist	Coach
A	Previously felt pressure to perform talk on alcohol even when not appropriate. Also, not allowing any silence, filling gaps to avoid awkwardness. Thinks their patients might now feel a bit more heard because letting them talk more at the start. Then 'towards the end you have to take over and summarise and wrap it up in a time-productive way'. Feels less 'ignorant' about alcohol and less likely to shy away from raising it. Understands alcohol should not be a tick box exercise left to the end	Lack of confidence apparent early on, leading to closed didactic style with patients Bombarded patients with unsought alcohol advice, not well related to clinical contexts. Identified listening as main practice challenge. Was at an early stage of developing microskills, and giving patients opportunities to raise concerns
В	Felt they were already involving patients in reviews but now letting them talk first is, 'a permanent change', because this allows patients to, 'give more to the consultation'. Still a 'long way to go for it to become more natural'. Finds talking about alcohol in a different way is, 'the hardest bit'. Finds it difficult not tell people what they should be doing, and is unclear about role when there is no obvious problem	Has a friendly, open style, and values the personal dimension with patients. They worked on restructuring their consultations to introduce alcohol and cede more space to the patient. Made progress here, but less on linking alcohol to medicines and health issues. The practitioner was becoming more responsive to what the patient said and letting them dictate pace. Less advanced in strategic use of microskills
С	Saw self as empathetic and non-judgemental and in need of skills acquisition. By the end of the programme was doing things differently and, 'definitely speaking less, listening more'. Found it less frustrating and more satisfying taking a gentler approach. Still on a learning curve connecting alcohol to medication and includes alcohol in a lifestyle discussion (bundled with other subjects) whereas it would have been left out before	Thoughtful and articulate in talking about own practice. Very unconfident about alcohol initially. Made good advances in consultation skills, building on existing person-centred foundation to extend repertoire. The programme demystified alcohol and made it available for discussion, but still struggling with restraining the impulse to jump in with advice
D	Started uncertain of consultation skills and aware of gaps in clinical knowledge. Conscious was lacking 'natural confidence'. Using the MAC approach felt better; 'I feel like I got more out of patients, more of what they wanted to talk about, and resolved issues that I feel might not have necessarily been addressed without that approach'. Confidence enhanced and they felt better able to manage their 'tone of voice' in consultations. Now they, 'wouldn't say very confident [discussing alcohol], but not worried about it. I'll happily address it with them'	Had confidence issues, approaching the programme as if a daunting prospect. Took a conscientious, thoughtful approach, identifying what they wanted from it on structuring clinical consultations. Coaching relationship began with addressing confidence before direct engagement with practice issues. Recognised widespread clinical relevance of alcohol and were working on consultation flow, reducing hesitations and finding ways to invite the patient to reflect on their drinking
E	Appreciated the chance to make changes they 'probably wouldn't have done off my own bat'. Identified changing the start to of the consultation, trying to 'give people a chance to set their own agenda' as the key insight. Says has incorporated approach and, 'I'm definitely using all of the lovely little micro-skills that either plant little seeds or get people to just stop and think' I've found it really works, and it can be as efficient, if not more efficient than the rigid, tell me about your breathing, tell me about this'. Feels more confident about introducing 'normal drinking' as a topic without hectoring or feeling they have to, '' fix it. Not tell people what to do but think about it'	Relished opportunity to create space to look at own practice and think about the idea of listening more to patients. Took some time to apply abstract thinking to own consultation practice. By the end describing inverting prior practice by listening and giving more time to people. Challenge identified to sustain changed practice in face of managerial pressures to achieve SMR numbers as efficiently as possible
F	Was encouraged to hear, with coach feedback, better use of summarising and reflections. By the end, could see the connection between allowing the patient to raise their own issues and making reflections to focus subsequent exploration. Believes the development of skills has made their consultations shorter; 'if you reiterate to a patient that you understand what they've said quite early on then you can move on to something else that might be on their mind'. Continues to find it harder to talk about alcohol with heavier drinkers who 'don't think it's a problem'	Had a good foundation on which to build. A motivated learner. Thought about things deeply and responded to feedback. Understood benefit of listening back to their own consultations. Had previously avoided talking about alcohol; did not know what to say and was anxious about conflict with patients. Missed opportunities to connect alcohol to medicines and health issues. Struggled to go beyond a 'lifestyle' framework and the idea that they should tell patients what to do when it came to their drinking
G	Found it useful to try out different styles of questioning but 'it didn't feel that natural'. Realises that they rush things when feeling time pressured. Is 'trying to take out the more closed and dead-end type questions' and ask more open questions, letting patients do more talking: 'more consultations have been partnership consultations rather than didactic type'. Has always been 'a bit antialcohol'. Rarely raised it before but thinks this is a less judgmental approach	Some prior exposure to person centred concepts and working with alcohol. Enjoyed talking abstractly about issues but struggled to engage with own practice issues. Spoke about practice as if wider forces limited any agency to change how things could be done within consultations. Took something of an all or nothing approach, either you control what happens or the patient does. Struggled to see that focusing on how the interaction could happen in ways that were to the best

interests of the patient was not the same as simply giving

people what they wanted

were afforded in these interactions by pharmacists, with 'more time to listen to you' (PMAC 9) in explicit or implicit comparisons to GP appointments.

Being articulate in person-centred concepts did not readily translate into pharmacists being able to identify and discuss consultation skills issues in practice on joining the programme. As part of their required training, pharmacists universally and abstractly applied these concepts to their own consultation practice (it is professionally unacceptable to not describe one's practice as person-centred). This was described in terms of, 'start[ing] consultations with their agenda ... shared decision-making'; 'putting the patient's needs first'; 'listening'; 'partnership' and balancing what matters to patients while achieving targets. At the beginning, most said that the consultation format presented in the MAC guide was 'more or less' what they were doing anyway, except for the attention paid to alcohol.

The MAC focus on communication skills entailed that familiar concepts were given substantive meaning, largely through new understanding of how this differs from current practice. Participation in the programme thus resulted in participants beginning to understand how person-centred concepts might be applied. They gained new and deeper insights into the rationale for person-centred practice and the challenges involved in changing what they do in their consultations to achieve it. Interviews show that this was considered important learning.

Through workshops and audio-recordings, participants recognised that their practice with patients at the beginning of the programme largely took the form of a pharmacist-led question-and-answer dialogue. From interviews and workshop discussions, it was clear that a checklist task fulfilment approach provided a sense of safety in alleviating concerns about missing things and keeping the focus on matters that the pharmacist felt able to address in short interactions. Changing this to a more open, person-centred conversational flow was not straightforward. In workshop exercises, they observed the difference between the way they listened to each other about sensitive issues compared to their approach with patients. There was recognition throughout the programme that inducing change in a somewhat abstract way, rather than fully discussing what was involved, got in the way of understanding the needs of the person in front of them, and the actual prospects for change and issues to be navigated.

Participants increasingly recognised and sought to apply some of the underpinning microskills required for person-centred communication. By the end of the programme, all were asking more open questions (something they thought they were doing on entry but discovered they often struggled to do). As anticipated, those with some foundational skills were more able to focus on how people responded to their communicative style and made most progress in becoming more skilful. Interviews showed all pharmacists struggled with the concept and practice of making affirmations, often confusing recognising strengths with giving praise which might sound patronising. The audio-recordings were largely regarded as key to practice development by those who made them, alongside the coaching and workshop sessions.

Left early cohort (*n* **= 3)** Three participants did not make any audio-recordings of their practice and left the programme early. Through the workshops, these pharmacists recognised that they were asking lots of closed questions that gave little space to the patient, and that this could get in the way of the information they sought to acquire. A compliance-focused and information-giving frame meant little attention was paid to how the patient was understanding or feeling about the information being transmitted. These pharmacists began to recognise that interrupting to ask another question, and information giving as the first and predominant strategy could come at the expense of understanding an important issue for the patient.

Although sometimes critical in interviews of workplace practices and policies in ways common across the whole cohort, these pharmacists largely presented their core role as enacting reviews on behalf of their practices and securing patient compliance:

I don't agree with certain things but I comply, because that's how it is, so come to terms with it ...

This was accompanied by a presumption that patients should, and will, listen to instruction from GPs and pharmacists. This didactic approach to practice operates not (only) at the level of individual pharmacist but for the profession as a whole. Our observational and interview studies amply demonstrated that pharmacists generally expected the provision of information to be sufficient for behaviour change. Sharing the agenda with patients who may not want a

proposed change initiated by the practice was perceived as problematic in this group. On leaving the programme, these pharmacists all said they were asking more open questions as a means of eliciting more information at the start of a consultation and retaining the pre-existing format thereafter.

Completed programme cohort (n = 7) Each pharmacist encountered practice development challenges fundamentally shaped by prior professional experience of, and in some cases by personal experience with, alcohol. Summaries are provided in this section, with more detailed analysis of how individuals (cases A–F) progressed in the programme, from audio-recordings and patient interviews, provided in *Report Supplementary Material 2*. Case G was not able to obtain consent for audio-recordings but remained committed to the programme.

Two pharmacists who completed the programme, notwithstanding gaps in engagement, continued to enact a didactic approach (cases A and G). Interviews and observations showed they shared the assumption that information giving led to behaviour change and that this was more difficult with complex patient groups, especially involving addictive or other medications where people might be defensive against de-prescribing. Coaching was focused on practice recognition and listening skills.

The other five pharmacists who completed the programme also shared ideas such as identifying their role as 'fixers' and concerns about patients 'not doing what is best for them' which shifted somewhat over time. They also came in with a more skilful and open communicative styles on which to build (cases B–F inclusive). They worked with coaches on how to cede more space to patients and respond more effectively by reflecting on their interactions in consultation recordings and how they could do things differently. All were working to develop confidence in what they could offer patients and to reconcile tensions between workplace requirements for short interactions with the idea that something could be done differently within those constraints, or might take longer but was worth doing.

The programme was well received and acted upon, operating as a process of enrichment and fulfilment of a commitment to practise development. All were used to writing reflective pieces on their practice; listening to recordings made plain the limitations of recall of consultation interactions. They got over initial self-consciousness about making audio-recordings and began to focus on how patients responded to their use of technical skills (rather than the correctness of their own performative style). All found it highly illuminating, and made efforts to apply material on microskills and consultation management from the workshops.

Two pharmacists were clear that pushing things when patients were not ready was counterproductive (cases B and C):

it doesn't matter how much you know that will benefit the patient, if that's not on their agenda, then it's impossible ...

Others shared this approach to different degrees. All saw the challenge of working towards a freer flowing structure at odds with current practice which was, 'already imprinted in your head ... because you do it all the time ... I do think I'm better ... but I still think there's a long way to go for it to become more natural'. These five pharmacists began to see value in allowing patients more time to talk and a more relational interaction produced a sense of professional satisfaction:

you see the difference in the consultation ... you get so much more satisfaction. You feel like you've made more of a difference. And you go into these professions to make a difference.

One of the pharmacists, who had been making efforts to use reflections to show their understanding of what the patient was saying and structure the session, said counter to their own expectations, they found their consultations were becoming shorter and better focused as a result (case F).

Comparison with previous training in consultation skills

On entry, most said they considered themselves well trained and some considered themselves advanced in consultation skills. At exit, all said the MAC programme was very different from prior training which, 'talked a lot about personcentred practice but less about how to achieve it'. Some described the pharmacy training model as more focused on watching examples and recognising behaviour, 'it's a bit like learning to play football by watching it'. Support and

feedback from coaches based on listening to consultations was new to all participants. They valued the tailored, interactive, actual practice focus compared to prior training approaches:

you talk about it [person-centred practice] a lot, but ... no one listens to you back, no one gives you feedback ... you don't then go off [and] practise ... This was very tailored ... this is the skills ...

although we've talked about person-centred care in the past ... open questions and the golden minute, we perhaps haven't talked about the reflections ... summaries and ... affirmations ... if you're reflecting and summarising, they know that they've been heard ...

we all practice differently. We all learn differently ... I didn't realise how many closed questions I was asking ... you really limit yourself in a consultation, you really limit the patient as well ... it was so positive to get ... feedback ...

this is more real ...

All of those who completed the programme said they would recommend it to others as, 'a rare and invaluable opportunity' to focus on consultation skills. One said that much in the emerging clinical pharmacy role was based on a patient's history, 'and if you can't listen to people and talk to people, then I don't know how you get that right'.

Changing perceptions of person-centred practice

All except one of those who completed the programme said their understanding of person-centred practice had changed. They valued this more as something to be done in practice (rather than something to be), recognising the gap between it and their usual practice:

That's what I've learnt ... what I thought was patient-centred actually was ...a lot more closed-ended questions that ... weren't as patient-centred as I thought.

it's always been about the patient. But just in a tick boxy kind of way ...not where my consultation and communication [is] as open as it is now ...I see the value of it more...

[The difference is knowing it means] changing the way I've done the consultation ... I just got stuck in a rut of doing something a certain way ... this allowed me to reflect on that and change things.

[The pharmacy] version of person-centred is about how many different metrics are you ticking for each person ... can you deliver all of your important objectives ... [now I'm thinking] in terms of helping people with whatever health needs they've got by offering people a chance to set their own agenda ... [which] can be as efficient, if not more efficient than the rigid, tell me about your breathing, tell me about this...

One participant who completed the programme while engaging with it at a more abstract than applied level maintained their entry view that being person-centred risked 'giving in' to patients who might not know what is best for them (case G).

Helping patients make decisions about alcohol and medications; the ultimate intervention target

Pharmacists started with little confidence in talking about alcohol (see *Table 2* for perspectives on individual pharmacist progress). Their direct experience was limited to asking about and recording units and advising reduction if consumption was perceived to be very high. The focus in such interactions was on identifying those drinking too much rather than helping people see the problems alcohol causes for health. When raised, alcohol was usually bundled with other 'lifestyle' issues at the end of a consultation in a 'tick box' exercise leading to minimal or 'tiptoeing' conversations. All were conscientious practitioners who recognised that they lacked knowledge underpinned by evidence about alcohol. Some of the pharmacists who had never consumed any alcohol said they were very unconfident because of their lack of personal experience. One recounted in their entry interview being flustered when a patient asked why units recommendations had changed from 21 to 14:

I thought, oh god ... I really don't know enough about this to comment ... I didn't even know where that came from.

Programme participation meant more exposure to the complexities of the roles that alcohol plays in people lives and in the ways in which people talk about their own drinking. Some, who anticipated reluctance to talk about alcohol among religious groups for whom alcohol was forbidden, were surprised to find it such a sensitive subject across the board.

Most came to the programme largely wanting to find ways to achieve alcohol behaviour change in patients. One explicitly framed this as getting people who refused advice to, 'take responsibility for their actions'. There was a particular disjunction between conceptualising a consultation as inducing change in patients through information and advice-giving and the creation of discomfort when attempting to raise a sensitive issue some regarded as more personal or 'social' rather than medicine related. Some initially felt that asking a question about drinking might be seen as implicitly accusing someone of having a 'problem', faulty 'lifestyle' decision-making or being irresponsible. Alcohol was not understood by any as a public health issue in which they had a clear clinical role. This precluded opening conversations and reduced interactions to a quick exchange which did not embarrass either party.

A shared presupposition that people need to be told things many times before they will do it was challenged at the workshops. During the programme, participants found it hard to shake the feeling that they were going to have to tell patients what to do when it came to their drinking, and this continued to make them reluctant to talk about alcohol in more meaningful ways. Some worked at curbing a habit of quickly telling people to reduce their drinking. Consultations show pharmacists informing patients that alcohol is a drug without checking how the person understood the relevance to them of a phrase that patient interviews show can be interpreted narrowly to mean alcohol is addictive:

everybody knows that it's a drug ... Anything that there is a possibility that you could get addicted to could be classed as a drug.

PMAC08

Although the programme focus was on the problems any alcohol consumption can cause for any patient taking medication, some pharmacists maintained a focus on 'problem' or heavy drinkers. A pharmacist who assumed the programme was targeting 'alcoholics' retained that narrow focus with a new legitimising focus:

I certainly wasn't thinking of alcohol as a drug, I was looking at it as a problem. [This] will just let me ... approach it in a less judgmental way ... so it's an encompassing part of the review ... as opposed to attacking someone's ... personal habits ... People can be quite defensive about lifestyle ...

All shared an early fear of opening a 'can of worms'. One pharmacist was particularly concerned about getting embroiled in time-consuming conversations about why people were drinking without being able to offer anything. By the end of the programme, this pharmacist started to recognise offering the chance to talk about something as a useful offer in itself, rather than only as a means to get and give information for specific actions. This and acknowledging the limitations of what they could or should 'fix', 'save' or 'change' in people made pharmacists less fearful of letting patients talk. Others said they realised that 'planting a seed' to be revisited was important, and immediate change, however professionally desired, was unlikely.

Framing alcohol as a drug gave pharmacists a clear sense of legitimacy to raise alcohol in medication reviews, though the prospect of a well-developed clinical role remained distant for most. It made raising it less 'taboo', and all were struck by the current lack of attention paid to alcohol as a potent drug in the mix with other medications. Many of the pharmacists for whom we have audio-recordings were able to get details of how people drink, though the depth of the information was variable. Once alcohol was raised, most of the pharmacists remained unsure how to respond and missed opportunities to discuss drinking in a way that connected to a particular person's concerns about their medicines and health. Some recognised and discussed such missed opportunities, and the coaches regarded these practitioners as in many ways still in the early stage of a journey. The pharmacists agreed:

I do now more look at ... if they are drinking, what medication are they on and what effect might it be having on them? And ... are they not taking their medication if they are drinking? ... I still feel a little bit nervous about [talking about alcohol] ... I still feel like I need to get more confidence ...

I'd always kind of known that alcohol does affect medication but because ... not enough has been made of it [in training] ... I didn't give it that same importance ... I don't know how good patients are at connecting [medicines and alcohol] and I feel as though I can't really blame them, because a few months ago, I wouldn't have been as good as I am now and I'm health professional trained ...

These two pharmacists, who previously avoided talk about alcohol, developed a more open consultation style in which they continued to include alcohol in a 'lifestyle' bundle with subjects with which they were more comfortable. This usually set people up to give short responses. Both, nevertheless, coped well in consultations with heavy drinkers, one with a particularly challenging conversation style, managing to deal with a pharmacy issue by not being overshadowed by the alcohol issue (cases C and F). Other pharmacists also began to see the importance of, and were able to allow, more space for a person to talk without feeling rushed or judged:

allowing patients to open up a bit more, seeing us as a clinician, [building] better rapport [and a] more trusted environment ... making those links with patients ... those really subtle links, and just seeing that flick[er] for them, rather than it being, 'alcohol, no, don't do that'.

After the programme, this initially unconfident pharmacist was comfortable being sent referrals of heavy drinkers when that was not the MAC population focus, and they had not gone that far with alcohol (case D). Another saw this approach as 'bigger than alcohol' (case E):

What I'm taking away from this is that I'm more skilled, I think ... to discuss alcohol, but [also] ... it's a better model for agenda setting and allowing patients to discuss problems.

Against their initial expectations, they saw this approach as a potentially more effective means of working, which promised better outcomes from letting patients 'tell their story', rather than the current 'algorithmic' practice which engaged patients in lots of small, fragmented and possibly less-effective encounters.

In keeping with our earlier work, patients interviewed who had been in these interactions said a conversation about alcohol was appropriate but had poor recall of discussions. More abstractly, they thought it would be more useful for other people who are 'heavy drinkers' or because they said it was 'too late' for them. Recordings and patient interviews show attempts to make connections but also missed opportunities for relevant conversations about alcohol, medications and conditions.

Discussion

The professional socialisation of pharmacists involves giving accounts of practice which conflate the work they do with the work described in training and policy documents. Commitments to person-centred practice as experienced previously were thus rather abstract, and early acquaintance with the MAC programme was both challenging and positive for all pharmacists. The extent of the challenge varied, and appeared insurmountable for some when SMRs were no longer being prioritised, and other workplace pressures combined to encroach on or remove the space for practice development opportunities.

Even among those who completed the programme, all had to work hard to secure advances in practice. The completers as a group found it rewarding, and most but not all moved to some extent from addressing and advising a generalised 'type' of patient to becoming committed to finding out about particular patients, and inviting and being more open to their points of views and the ways in which the SMR could be helpful. The coaches, as well as the pharmacists themselves, saw both progress, and limitations to how far they had reached. There was some evidence of commitment to taking practice development forward after the programme ended in at least one peer group session having taken place.

This cohort of pharmacists have taken different things from the MAC programme, just as they began it from different starting points. For all, it been based on exposing their interactions with patients to careful and detailed self and coach scrutiny, reflection and dialogue. Unsurprisingly, there is more convincing evidence of progress in promoting

person-centred consultation skills than their application to alcohol. Thinking about how to handle alcohol clinically was less well developed, as was shedding stereotyped ideas about alcohol problems.

Progress in practice development was shaped by contexts in other ways. Most pharmacists worked extra hours to develop their practice and undertake this study, juggling other professional and personal roles. There was evidence of small gains across the cohort as a whole, including those who did not complete the programme, becoming more adept at asking open questions to gather information, without in many cases having acquired more advanced skills to use it in a person-centred manner. This may or may not follow in time. There were indications that any future appointments with the same patients would be informed importantly by the consultations examined, if these occur. Precarities in the wider system in which patients are trying to navigate encounters in what seems an increasingly fragmented system without continuity of care were reflected in this study. The idea of the SMR incorporating alcohol is a good one, valued both by patients and pharmacists, because pharmacists can do this work, and do it better if they are given more ongoing support than was offered in the MAC programme. Developments in the NHS system must be examined first, however, in order to consider how far clinical practice with potential for prevention may be translated into population health improvement.

Integrated care systems: a new context for National Health Service innovations on alcohol

Introduction and method

Integrated care systems had been introduced to develop local, place-based integrated health and social care services to improve population health in England. To examine how the MAC intervention may work in this new context, we examined decision-making and progress on alcohol in two contrasting ICSs, one of which had strategically prioritised alcohol. This study was undertaken prior to the delivery study. We conducted in-depth semistructured interviews with 14 senior ICS stakeholders (interviewees numbered in brackets below) in total. The topic guide covered the ICS itself and handling of alcohol therein, as well as views on current primary care practice relating to alcohol. We also discussed the broader MAC approach, the reframing of alcohol and the implications for clinical practice.

Results overview

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Stakeholders reported working in stretched and underfunded circumstances, trying to map resources and develop priorities across diverse organisational units, seeking to align these with ideas forming at a system level. Systems thinking on alcohol harm prevention was absent in one ICS and nascent in the other. The latter had long-standing recognition of the harm alcohol does regionally and hoped to link to prevention and health inequalities agendas.

Key system levers or mechanisms for progress on alcohol identified by one interviewee were 'an enormous shift in what our workforce culturally think of as their role, and [are] capable of delivering, and [are] confident and enthused by' (S11). All interviewees identified the importance of getting the workforce engaged with this broader perspective and able to contribute. For the ICS-led alcohol strategy, this meant, 'winning hearts and minds', that is, getting NHS staff to recognise and acknowledge alcohol harm as an issue, and gain a sense of the implications for their own roles (S1).

The other ICS was still focusing on interventions promoted in existing national guidance. A public health team offered free, one-off, alcohol identification and brief advice training to non-alcohol specialists and found take-up to be low. The leader of this team, however, wanted more upstream intervention and aspired to introduce local-level minimum unit pricing but was struggling with feasibility issues: '[in terms of] the things that we know work around alcohol on a population level, you feel very helpless' (S6). Primary care leaders in both ICSs explained that work on alcohol was not a practice priority given that this was not financially incentivised and because, 'when there's an overwhelming demand on the system and you're firefighting', the focus is on the most acute and immediate problems (S4).

Reframing alcohol as a clinically important drug resonated with all the stakeholders. They recognised that despite alcohol use being an important consideration for treatment effectiveness at a clinical level, it was not currently considered in these terms. According to one interviewee,

tagging it in as part of polypharmacy and as a drug within that to be optimised ... strength, dose, timing ... like we would do any drug, is actually probably a very good tack to go from, from a clinician point of view.

S3

Some stakeholders identified examples where alcohol had been overlooked in their own work, for example, in producing antidepressant de-prescribing guidance. This interviewee stated:

alcohol is not mentioned anywhere in that ... it should be, because ... you don't want somebody to attempt to self-medicate with alcohol, as a replacement, because, clearly, that's not going to work and will cause all sorts of other health problems.

S10

While framing alcohol as a drug made sense to these key stakeholders, interviewees recognised that many health professionals were not confident with the subject, and thus need support to talk to people about such a sensitive issue (S2, S5, S7, S9). This would mean moving away from template-driven lifestyle questions (S1, S8) and generic stock information-giving (S9, S10). Giving more meaningful attention to alcohol carries obvious risks for clinicians of not being able to offer more as things stand. As one said:

I know full well that's [current practice] meaningless and it has a very poor outcome, they need structured support and ... monitoring ... if you haven't got the resource to make that happen as a clinician, that's probably the bit that makes you shy away.

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Seeing alcohol as a drug entails not just reconceptualising targets for clinical attention but also taking stock of the ways in which alcohol is relevant to the broader endeavours of improving population health by better integrating services. A focus only on a minority of heavy drinkers was something that leaders in public health identified as in need of change. No NHS strategic direction on alcohol outside of the Long Term Plan⁹ left public health leaders feeling limited in their powers to implement evidence-informed upstream interventions. This, therefore, risks repeating the failures of the past in a vicious circle, with alcohol doing untold damage over time, increasing NHS workload and leaving staff, as one interviewee put it, 'in survival mode, just doing the basics' (S2).

Conclusions

Integrated care system formation occurred when services had been under sustained pressures and lines of communication and accountability were emergent and unclear. Stakeholders identified fundamental disconnects between prevention and treatment and a clear sense that alcohol was not currently well dealt with. ICS strategic prioritisation of alcohol engendered new perspectives and novel actions. While the MAC approach was congruent with the vision of how the new system should be working, there were doubts about capacity in current circumstances. There remains much to do to create a joined-up, system-wide approach to alcohol and thus a need for a national NHS alcohol strategy to guide ICS decision-making, addressing links between NHS work and public health.

Medicines and Alcohol Consultation programme logic model

We built upon logic models produced during earlier phases of the programme, ^{32,45} and key component studies which informed them, ^{18,20,24,26,28,30,31,46,47,55} to arrive at a finalised logic model that summarises our understanding of the forces at work in developing CP practice on alcohol, and in medications reviews, with the MAC. As seen in *Figure 2*, the health system, environmental, cultural and historical contexts operate as macro-level influences or moderators of MAC effectiveness. ^{11,18,24,43,46} These interact with meso-level factors, including adaptations resulting from the COVID pandemic, ^{18,20,45-47} to define the parameters of the space for practice development at this time, as targeted by the MAC. These apply to the studied practitioners, and thus the CP workforce more broadly, as a whole, while acknowledging local variability in SMR implementation.

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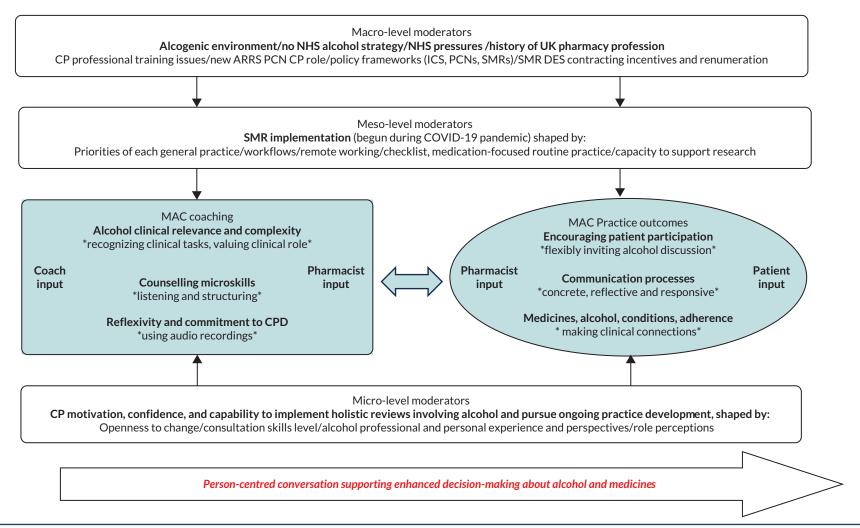


FIGURE 2 Logic model for using the MAC programme to develop alcohol and related practice with CPs.

Progress in coaching and individual practice-level change is also shaped by micro-level moderators of effectiveness acting at the level of the individual CP.^{29,30,32,34,46} These are both contemporaneous and historical in nature, based on prior professional and personal experience. This presentation emphasises the heterogeneity of experience and progress with the MAC approach within the group, and topics appropriate for consideration of wider dissemination of the MAC within the general practice setting.

At the centre of the model (in blue) are the MAC programme and practice development outcomes. The sought clinical outcomes are presented at the end of the figure. MAC coaching inputs are distilled into three principal components, reflecting how the programme was designed to operationalise attention to these targets in pharmacists' everyday SMR practice.

Firstly, the more widespread clinical relevance of alcohol and how it complicates treatment and patient health, entailing pharmacists recognise the tasks involved in raising and discussing alcohol sensitively and appropriately in the context of prescribed medications, and how these challenges may be overcome. Regarding alcohol as a drug must be foundational to the CP role. It is difficult to imagine how alcohol can otherwise be incorporated into routine clinical practice, and we found repeatedly that this gives both legitimacy and understanding of importance to both pharmacists and patients. Within the 10-week programme delivery, limited progress was made in appreciation of the complexities posed by alcohol, and how they may be handled clinically (see above).

Secondly, we understood early that because alcohol was challenging to discuss for both pharmacists and patients, counselling microskills need to be learnt and applied with some sophistication in consultations. ^{10,25,26,31} This was in order to open up discussions of alcohol and medications and wider patient-initiated health contexts and concerns, and to proactively structure the consultation to explore their inter-relationships. ^{24,32,34,37} This really lay at the heart of the MAC coaching input and required the activation of the two other principal components to help patients think through and make better decisions about alcohol and medicines.

Thirdly, none of this was straightforward for practitioners to accomplish, and so required commitment to ongoing practice development on the part of the pharmacist.^{20,29,45-47} In many cases, unlearning habits established over many years was at issue, and this challenge was relished by some, and rejected by others, among other micro-level moderators of effectiveness. This involved exposing practice to critical self-reflection, via audio-recordings of consultations, and guided by coaching interactions. The pharmacists we worked with were typically not well supported in their participation in this research by their practices.^{32,33,35,45,46}

The MAC coaching components correspond to the three practice development outcomes. First, the subject of alcohol must be raised widely, and for many patients a brief discussion will suffice. For others, where there are medication issues raised and/or patient concerns, the active participation of the patient in consultations is essential to discussing alcohol consumption flexibly, and exploring the implications.^{25,27,31} This is facilitated by a communication style that focuses on understanding the needs of the patient first, and the creation of an environment that facilitates a supportive exploration of concrete issues.^{27,32,46} Checking out possible connections between alcohol use and medicines, conditions and adherence, can be accommodated while respecting the lead role of the patient in agenda setting. In the most basic terms, it is a conversation that is led by the person, because it is the enhancement of their decision-making powers that is sought, with the pharmacist having a clinical role akin to that of the coach in the MAC (see intervention materials in appendices).

The double-sided arrow between the MAC coaching and practice development outcomes is important. It indicates a dynamic process, grounded in the realities of clinical practice with patients, and mirrored in the coaching process. This involves both pharmacist agenda setting and coaching feedback and other inputs, ultimately tailored to the needs of individual pharmacists as they progress through the programme. Topics for coaching sessions are discussed and negotiated between coach and pharmacist to highlight practice development issues, including both progress and challenges, with CP self-identified goal setting key (see *Report Supplementary Material 1*).

Giving attention to the professional and policy moderators of programme effectiveness at different levels^{16,29,30,37,39,40} provides indications of where and how practice development and clinical outcomes may be enhanced. CPs discussing

alcohol with patients in general practice is more difficult than it needs to be. The wider environment normalises heavy drinking, promotes stereotypical ideas of alcohol problems and is underpinned by few restrictions on marketing. 11,36,39 These provide constraints on professional practice development, and may also serve as opportunities for discussions of patient concerns, albeit constrained in turn by pressures on the NHS. 46 There appears a real risk of the NHS being stuck in a vicious circle of using under-prepared CPs, and perhaps other professionals, to cope with the consequences of the lack of a strategic response on alcohol (see *Integrated care system stakeholder study*).

The impacts of changes to the organisation of primary care and medication review services have been far-reaching, not just for our research programme, but to the experiences of practitioners who struggled to develop practice and deliver SMRs in the manner envisaged by the policy guidance. Perhaps it is unsurprising that there is variability in how far individual pharmacists progressed towards person-centred conversations on alcohol in SMRs. That does not mean this is not an important finding, and there may be merit in considering advanced clinical practice roles for alcohol. On the basis of this programme of research, this would be unwise without substantial investment in selection and training of this workforce, and giving appropriate attention to making progress on the macro-, meso- and micro-level moderators identified here.

Patient and public involvement

The programme patient and public involvement (PPI) group was initiated at the time of the CHAMP-1 funding application. Co-chaired by a lay co-investigator (recruited at the start of the application process) and the programme manager, the original group comprised 10 active members who regularly attended meetings. Members were recruited from local support groups for people with long-term conditions (i.e. the target population for medicine review services) and through advertising on the NIHR People in Research website. We operated a rolling process of recruitment, as members withdrew over time due to illness and other commitments. As well as some downsides, this meant that the group benefited from fresh perspectives during the programme. Three meetings were scheduled per year, with additional contributions to the programme organised on an ad hoc basis as necessary. All members were remunerated for their time and travel in line with NIHR INVOLVE guidelines. In addition to the lay co-investigator, another PPI group member represented the group on the Programme Management Group (PMG). PPI members were made aware of, and were consulted about the changes to the NHS, with discussions focusing on the corresponding revisions required of the programme to make it relevant and as part of our sign-off process for reporting to NIHR. Adaptions were made to remote working during the COVID-19 pandemic and subsequently.

Further details of the PPI group composition, working methods, contributions and impacts have been published in *Health Expectations*.²⁵ This paper, co-authored with two PPI group members, provides a critical overview of the development of the group and how PPI and coproduction with patients have been interpreted and applied within the programme. In summary, PPI contributions were integral to intervention development and related research activities throughout. We consulted the group on patient facing components of the intervention, study recruitment and consent materials, and design of a patient recruitment pitch for pharmacists to use. Two members provided hosting and facilitation support at the phase 1 workshop, and two different members were involved in patient simulation activities in the pilot trial pharmacists training. Research training was provided to members to support their participation in these activities. This was usually organised at group meetings in the context of the studies being conducted at the time; for example, we provided a session on RCTs before discussing plans for the pilot and definitive trials. We have received consistent positive feedback from NHS ethics committees on the planning and management of PPI.

Equality, diversity and inclusion

Given the design of the research and the intervention, we strove to capture medicine review service delivery in routine clinical conditions, even when planning the pilot and definitive trials. We thus aimed to recruit successive eligible patients who were attending the pharmacy or general practice during the fieldwork periods, rather than targeting specific patient groups. In the case of SMRs, national policy proposed a range of prescribing categories for the service,

to be prioritised at a local level. This meant considerable variation between practices, PCNs and ICSs in the types of patients who were being invited to an SMR.

All recruitment materials were coproduced with pharmacists and patients, seeking to optimise the appeal of the research. The emphasis for patient participants was on inclusivity, with very few exclusion criteria for the component studies; adults drinking at least twice per week were the principal selection criteria. We were more selective when recruiting pharmacists for the intervention delivery studies. We advertised the opportunity widely through local clinical, professional and research networks but stipulated from the outset the expectations we had for those taking part. This was to ensure transparency and full understanding of the time commitment involved, but also because we were seeking pharmacists conducting enough medicine reviews to make patient recruitment feasible, and to be motivated to develop their practice to some degree. This should be borne in mind when interpreting study findings. We achieved a reasonable range of equality, diversity and inclusion characteristics among pharmacists in terms of age and relatedly professional experience, gender, ethnicity and relationships with alcohol. All pharmacist and patient participants were remunerated for their time.

Much of the research was observational and qualitative, and thus conducted with relatively small sample sizes. While limiting representativeness in numerical terms, these studies provided in-depth insights into experiences and behaviours concerning alcohol and medication that are seldom found in the literature, not least because for patients, practitioners and researchers, alcohol remains a difficult topic to discuss. The programme was located in Yorkshire and Humber and the North East of England. Reflecting the population characteristics of these regions, we recruited pharmacists and patients from diverse ethnic groups and from some of the most socio-economically deprived communities in the country. It is in such places that the individual and social harms from alcohol are likely to be greatest. For example, Office for Health Improvement and Disparities data show the North East to have the highest standardised rates per 100,000 of alcohol related mortality, admission episodes for alcohol related conditions (broad), and a range of other alcohol harm indicators. Our phase 2 analyses of OpenPrescribing data showed this region to also have the highest level of opioid analgesics prescribing; these drugs pose risks for interactions with alcohol and are one of the target categories for the SMR. The Yorkshire and Humber region is also above the England average for these metrics.

Conclusions from the whole programme

Pharmacists are a good example of a candidate workforce who could contribute to prevention through integrating Bls on alcohol within core roles in the NHS and beyond. CHAMP-1 has examined carefully the process of embedding attention to alcohol within the clinical practice of pharmacists in medication reviews by supporting practice development through a dedicated intervention, the MAC programme based on coaching structured around audio-recorded consultations. Throughout, patients have been receptive to the prospect of discussing alcohol with a pharmacist if introduced and explained appropriately within a medication review. Numerous organisational and situational pressures, policy decisions, prior readiness and skills enhancement issues have been encountered, that warrant four principal conclusions from this research programme.

- 1. Workforce development, from initial pharmacy professional training onwards, needs to give more substantial attention to person-centred consultation skills, as they are applied to alcohol, than has previously been the case.
- The effects of systemic pressures on primary care need to be managed to support rather than inhibit innovations in practice that contribute towards prevention, or the person-centred ambitions espoused in policy documents will not be realised.
- 3. Practitioners can be supported towards enhanced skilfulness in working clinically on alcohol with the MAC, with more intensive support for those wishing to further develop their practice likely to produce further benefit.
- 4. Seeing alcohol as a drug resonates strongly in primary care as it has multiple clinical and population-level implications. This idea could be particularly useful to developing thinking about how the NHS may better address the major public health challenges with which alcohol is implicated, albeit currently not well recognised as such.

These conclusions apply directly to CPs in primary care, and likely also with caveats to pharmacists in other settings, and are also relevant to other professions in both health and non-health settings.

Reflections on what was and what was not successful in the programme

The research programme had to contend with a series of major national policy decisions that impacted directly upon the research aims and conduct, and the interruption of routine NHS services caused by COVID. It was not possible to undertake our planned RCT in these circumstances. This research programme has nonetheless identified major implications for BIs and NHS and primary care management of alcohol's harm to health. This has been based on rigorous and intimate study of the process of practice development among pharmacists, alongside studies conducted, of and with, patients, managers and other stakeholders. The contributions made to the research literature will inform NHS decision-making on the roles of pharmacists, the potential of medication reviews, and more broadly on alcohol as a clinical and population health challenge and how it may be addressed.

Limitations relating to the method or execution of the research

Due to external circumstances, we were not able to test the efficacy of the MAC as originally planned. In phase 1, changes to the NHS community pharmacy contractual framework removed the planned service to host the MAC (MUR) from the contract altogether. This impacted patient recruitment during the pilot trial when it was announced. This meant the extensive intervention development work conducted in community pharmacy would need to be supplemented with further developmental studies adapting the intervention for delivery by CPs in primary care through a new service (SMR), arguably better fitting programme aims.

In phase 2, in the general practice setting, we explored pharmacist and patient perspectives in the context of the significant challenges arising from SMR implementation during the COVID-19 pandemic. Implementation was slower than originally envisaged, which we studied and published on. Initially delivered entirely remotely in ways that departed from the vision for the SMR, this impacted on planned research, particularly our ability to recruit SMR patients for interviews.

Evaluation of MAC delivery in phase 3 was undertaken in depth. Intensive coaching with audio-recordings of practice among participating pharmacists yielded rich data on their engagement and practice development journey. The small volunteer sample is not likely to be representative of the broader CP workforce, though the evaluation does show what is possible and delivers important lessons for future interventions.

Overall, the programme has comprised predominantly qualitative studies within the North East and Yorkshire NHS. This has yielded insights informing research contributions that have been well received. The contribution to NHS decision-making may be appreciated within the contexts of the evolving research literatures on alcohol, person-centred skills enhancement and pharmacist training, and dissemination work is ongoing.

Recommendations for future research

The four principal conclusions entail needs for further research on pharmacists, primary care and the NHS/health system management of alcohol. In this section, a global perspective on this field of alcohol research is adopted. The 1980s screening and BI paradigm is no longer fit for the purpose of informing how conversations about alcohol should take place within healthcare services. We need a new paradigm that guides how we conceptualise and study BIs. This need has also been recognised by others.

14,15,59 The CHAMP-1 programme shows how this research agenda may be advanced. Alcohol is currently largely avoided in routine practice consultations, and where addressed is dealt with by pharmacists in ways which are judged unlikely to be beneficial. This is likely to be true also for other healthcare professions. We make four recommendations, for advancing research that we refer to as BI 2.0:

- 1. the focus should not be only on self-regulation of alcohol consumption, in isolation from personal health and social contextual factors
- 2. much broader intervention content is needed to help people to think differently about, and to discuss, the place of alcohol in their lives and in wider society
- 3. BI programmes should support a candid public conversation about how alcohol and alcohol problems interfere with the lives that people want to live, reframing existing ideas about what constitutes an alcohol problem
- 4. BI programmes should form a key part of more comprehensive alcohol strategies, as important synergistic effects are anticipated.

Implications for practice and any lessons learnt

The principal conclusions and research recommendations embody lessons learnt and carry important implications for practice. Pharmacists (and other NHS professions) have important roles to play in contributing towards a prevention agenda for alcohol, that has not yet been articulated by the NHS. Practice-based research is needed to optimise this contribution. Progress in research on the costs to the NHS and society, as well as on new intervention approaches needs to be accelerated. Regardless of whether non-NHS public health policies are implemented, alcohol should feature more strongly in high-level NHS workforce planning, training, prioritisation and other strategic decision-making. It is suggested that if we do not make progress on alcohol and primary care pharmacy research in these directions, then it seems likely that what we do not know will continue to interfere unnecessarily with the work of the NHS, at great cost to health. 16,37,60 The same is true if we do not act on what we already do know now, even if we need to know it better.

Additional information

CRediT contribution statement

Duncan Stewart (https://orcid.org/0000-0001-7355-4280): Conceptualisation, Funding acquisition, Methodology, Investigation, Project administration, Supervision, Writing – original draft, Writing – reviewing and editing.

Mary Madden (https://orcid.org/0000-0001-5749-2665): Conceptualisation, Funding acquisition, Methodology, Investigation, Formal analysis, Writing – original draft, Writing – reviewing and editing.

Andrew Bartlett (https://orcid.org/0000-0002-6927-0899): Investigation, Formal analysis, Writing – reviewing and editing.

Ranjita Dhital (https://orcid.org/0000-0002-4504-7318): Conceptualisation, Funding acquisition, Methodology, Writing – reviewing and editing.

Brendan Gough (https://orcid.org/0000-0001-7438-0139): Conceptualisation, Funding acquisition, Methodology, Formal analysis, Writing – reviewing and editing.

Shona Haining (https://orcid.org/0009-0005-9211-6119): Funding acquisition, Project administration.

Ronan O'Carroll (https://orcid.org/0000-0002-5130-291X): Conceptualisation, Funding acquisition, Methodology, Writing – reviewing and editing.

Margaret Ogden (https://orcid.org/0000-0002-7644-2310): Conceptualisation, Funding acquisition, Writing – reviewing and editing.

Cate Whittlesea (https://orcid.org/0000-0002-4951-2272): Conceptualisation, Funding acquisition, Methodology, Writing – reviewing and editing.

Jim McCambridge (https://orcid.org/0000-0002-5461-7001): Conceptualisation, Funding acquisition, Methodology, Investigation, Formal analysis, Project administration, Supervision, Writing – original draft, Writing – reviewing and editing.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

Research undertaken in this programme received NHS ethics committee/HRA approval as detailed below.

Phase 1 intervention development studies: Yorkshire and The Humber - South Yorkshire.

Research Ethics Committee (17/YH/0406); December 2017.

Phase 1 pilot trial: South West - Frenchay Research Ethics Committee (19/SW/0082); June 2019.

Phase 2 practitioner interviews: HRA (20/HRA/1482); June 2020.

Phase 2 patient perspectives: South West - Frenchay Research Ethics Committee (20/SW/0194); January 2021.

Phase 3 ICS stakeholder interviews: HRA (22/HRA/3638); September 2022.

Phase 3 MAC delivery study: North East – Newcastle and North Tyneside 2 Research Ethics Committee (22/NE/0237); February 2023.

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Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/GJJM1624.

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Publications

This list includes links to institution repositories where publications are not open access via the journal.

Kypri K, McCambridge J. Alcohol must be recognised as a drug. BMJ 2018;362:k3944. https://doi.org/10.1136/bmj.k3944

Madden M, Morris S, Stewart D, Atkin K, Gough B, McCambridge J. Conceptualising alcohol consumption in relation to long-term health conditions: Exploring risk in interviewee accounts of drinking and taking medications. *PLOS ONE* 2019;**14**:e0224706. https://doi.org/10.1371/journal.pone.0224706

McCambridge J, Morris S. Comparing alcohol with tobacco indicates that it is time to move beyond tobacco exceptionalism. *Eur J Public Health* 2019;**29**:200–1. https://doi.org/10.1093/eurpub/cky227

McCambridge J, Saitz R. Rethinking brief interventions for alcohol in general practice. *BMJ* 2017;**356**:j116. https://eprints.whiterose.ac.uk/111206/

Morris S, Madden M, Gough B, Atkin K, Mccambridge J. Missing in action: Insights from an exploratory ethnographic observation study of alcohol in everyday UK community pharmacy practice. *Drug Alcohol Rev* 2019;**38**:561–8. https://eprints.whiterose.ac.uk/146471/

Stewart D, McCambridge J. Alcohol complicates multimorbidity in older adults. *BMJ* 2019;**365**:l4304. https://eprints.whiterose.ac.uk/148108/

Stewart D, McCambridge J. Authors' reply to Rao. BMJ 2019;366:I5151. https://doi.org/10.1136/bmj.I5151

Gough B, Madden M, Morris S, Atkin K, McCambridge J. How do older people normalise their drinking?: An analysis of interviewee accounts. *Appetite* 2020;**146**:104513. https://doi.org/10.1016/j.appet.2019.104513

Madden M, Morris S, Atkin K, Gough B, McCambridge J. Patient perspectives on discussing alcohol as part of medicines review in community pharmacies. *Res Social Adm Pharm* 2020;**16**:96–101. https://eprints.whiterose.ac.uk/144441/

Madden M, Morris S, Ogden M, Lewis D, Stewart D, McCambridge J. Producing co-production: Reflections on the development of a complex intervention. *Health Expectations* 2020;**23**:659–69. https://doi.org/10.1111/hex.13046

McCambridge J, Stewart D. Managing alcohol use in primary care. *BMJ* 2020;**371**:m4129. https://repository.londonmet.ac.uk/6201/1/Managing-alcohol-use-in-primary-care.pdf

Stewart D, van Dongen A, Watson M, Mandefield L, Atkin K, Dhital R, *et al.* A pilot cluster randomised trial of the Medicines and Alcohol Consultation (MAC): an intervention to discuss alcohol use in community pharmacy medicine review services. *BMC Health Serv Res* 2020;**20**:943. https://doi.org/10.1186/s12913-020-05797-z

Stewart D, Whittlesea C, Dhital R, Newbould L, McCambridge J. Community pharmacist led medication reviews in the UK: a scoping review of the medicines use review and the New Medicine Service literatures. *Res Social Adm Pharm* 2020;**16**:111–22. https://eprints.whiterose.ac.uk/145387/

Watson M, van Dongen A, Hewitt C, Mandefield L, Stewart D, Watson J, *et al.* Optimising retention success: a research team's experience of following-up participants recruited to a pilot trial through community pharmacies in England. *F1000Res* 2020;**9**:1042. https://doi.org/10.12688/f1000research.25372.2

Atkin K, Madden M, Morris S, Gough B, McCambridge J. Community pharmacy and public health: preserving professionalism by extending the pharmacy gaze? *Sociol Health Illn* 2021;**43**:336–52. https://doi.org/10.1111/1467-9566.13221

Madden M, McCambridge J. Alcohol marketing versus public health: David and Goliath? *Global Health* 2021;**17**:45. https://doi.org/10.1186/s12992-021-00696-2

Madden M, Morris S, Ogden M, Lewis D, Stewart D, O'Carroll RE, *et al.* Introducing alcohol as a drug in medicine reviews with pharmacists: Findings from a co-design workshop with patients. *Drug Alcohol Rev* 2021;**40**:1028–36. https://doi.org/10.1111/dar.13255

Madden M, Morris S, Stewart D, Atkin K, Gough B, Mills T, *et al.* Using qualitative process evaluation in the development of a complex intervention to advance person-centred practice by pharmacists: The Medicines and Alcohol Consultation (MAC). *SSM Qual Res Health* 2021;**1**:100012. https://doi.org/10.1016/j.ssmqr.2021.100012

McCambridge J. Reimagining brief interventions for alcohol: towards a paradigm fit for the twenty first century?: INEBRIA Nick Heather Lecture 2019: This lecture celebrates the work of Nick Heather in leading thinking in respect of both brief interventions and wider alcohol sciences. *Addict Sci Clin Pract* 2021;**16**:41. https://doi.org/10.1186/s13722-021-00250-w

McCambridge J, Atkin K, Dhital R, Foster B, Gough B, Madden M, *et al.* Addressing complex pharmacy consultations: methods used to develop a person-centred intervention to highlight alcohol within pharmacist reviews of medications. *Addict Sci Clin Pract* 2021;**16**:63. https://doi.org/10.1186/s13722-021-00271-5

McCambridge J, Madden M. Think big about developing the science. *Addiction* 2021;**116**:2947–8. https://doi.org/10.1111/add.15568

Morris S, Stewart D, Madden M, McCambridge J. A scoping review of qualitative research on perceptions of one's own alcohol use. *Eur J Public Health* 2021;**31**:432–6. https://doi.org/10.1093/eurpub/ckaa211

Stewart D, Hewitt C, McCambridge J. Exploratory Validation Study of the Individual AUDIT-C Items among Older People. *Alcohol Alcohol* 2021;**56**:258–65. https://doi.org/10.1093/alcalc/agaa080

Stewart D, Madden M, Davies P, Whittlesea C, McCambridge J. Structured medication reviews: origins, implementation, evidence, and prospects. *Br J Gen Pract* 2021;**71**:340–1. https://doi.org/10.3399/bjgp21X716465

Stewart D, Madden M, Van Dongen A, Watson M, Morris S, Whittlesea C, *et al.* Process study within a pilot cluster randomised trial in community pharmacy: An exploration of pharmacist readiness for research. *Res Social Adm Pharm* 2021;**17**:1750–7. https://eprints.whiterose.ac.uk/170755/

Madden M, Mills T, Atkin K, Stewart D, McCambridge J. Early implementation of the structured medication review in England: a qualitative study. *Br J Gen Pract* 2022;**72**:e641–8. https://doi.org/10.3399/BJGP.2022.0014

Mills T, Madden M, Stewart D, Gough B, McCambridge J. Integration of a clinical pharmacist workforce into newly forming primary care networks: a qualitatively driven, complex systems analysis. *BMJ Open* 2022;**12**:e066025. https://doi.org/10.1136/bmjopen-2022-066025

Madden M, Stewart D, Mills T, McCambridge J. Alcohol, the overlooked drug: clinical pharmacist perspectives on addressing alcohol in primary care. *Addict Sci Clin Pract* 2023;**18**:22. https://doi.org/10.1186/s13722-023-00378-x

Madden M, Stewart D, Mills T, McCambridge J. Consultation skills development in general practice: findings from a qualitative study of newly recruited and more experienced clinical pharmacists during the COVID-19 pandemic. *BMJ Open* 2023;**13**:e069017. https://doi.org/10.1136/bmjopen-2022-069017

Madden M, Stewart D, McCambridge J. 'Really putting a different slant on my use of a glass of wine': patient perspectives on integrating alcohol into Structured Medication Reviews in general practice. *Addict Res Theory* 2023;**31**:459–7. https://doi.org/10.1080/16066359.2023.2207017

van Dongen A, Stewart D, Garry J, McCambridge J. Measurement of person-centred consultation skills among healthcare practitioners: a systematic review of reviews of validation studies. *BMC Med Educ* 2023;**23**:211. https://doi.org/10.1186/s12909-023-04184-6

Madden M, Stewart D, McCambridge J. Barriers and leverage points for seeing alcohol differently in integrated care systems in England: a senior stakeholder interview study: *BMJ Public Health* 2024;**2**:e000829. https://doi.org/10.1136/bmjph-2023-000829

Stewart D, Madden M, McCambridge J. Brief interventions 2.0: a new agenda for alcohol policy, practice and research. *Global Health* 2024;**20**:34. https://doi.org/10.1186/s12992-024-01031-1

References

- Mackenbach JP, Kulhanova I, Bopp M, Borrell C, Deboosere P, Kovacs K, et al. Inequalities in alcoholrelated mortality in 17 European countries: a retrospective analysis of mortality registers. PLOS Med 2015;12:e1001909. https://doi.org/10.1371/journal.pmed.1001909
- 2. World Health Organisation. *Draft Action Plan* (2022–2030) to Effectively Implement the Global Strategy to Reduce the Harmful Use of Alcohol as a Public Health Priority. Geneva: World Health Organisation; 2022. URL: https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_7Add1-en.pdf (accessed 28 November 2023).
- 3. World Health Organisation. *The SAFER Technical Package: Five Areas of Intervention at National and Subnational Levels.* Geneva: World Health Organisation; 2019. URL: www.who.int/publications/i/item/9789241516419 (accessed 28 November 2023).
- Royal College of Psychiatrists. Our Invisible Addicts, 2nd edition. College Report CR211. London: Royal College of Psychiatrists; 2018. URL: www.rcpsych.ac.uk/improving-care/campaigning-for-better-mental-health-policy/ college-reports/2018-college-reports/our-invisible-addicts-2nd-edition-cr211-mar-2018 (accessed 9 January 2024).
- 5. Rao R, Schofield P, Ashworth M. Alcohol use, socioeconomic deprivation and ethnicity in older people. *BMJ Open* 2015;**5**:e007525. https://doi.org/10.1136/bmjopen-2014-007525
- 6. Rao R, Crome IB, Crome P. Managing older people's alcohol misuse in primary care. *Br J Gen Pract* 2015;**66**:6–7. https://doi.org/10.3399/bjgp16X683041
- 7. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. *Lancet* 2012;**380**:37–43. https://doi.org/10.1016/S0140-6736(12)60240-2
- 8. House of Commons Health Committee. *Managing the Care of People with Long-term Conditions*. London: The Stationery Office Limited; 2014. URL: https://publications.parliament.uk/pa/cm201415/cmselect/cmhealth/401/401.pdf (accessed 28 November 2023).
- 9. NHS. *The NHS Long Term Plan*; 2019. URL: www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf (accessed 28 November 2023).
- 10. McCambridge J, Saitz R. Rethinking brief interventions for alcohol in general practice. *BMJ* 2017;**356**:j116. https://doi.org/10.1136/bmj.j116
- 11. McCambridge J. Reimagining brief interventions for alcohol: towards a paradigm fit for the twenty first century?: INEBRIA Nick Heather Lecture 2019: this lecture celebrates the work of Nick Heather in leading thinking in respect of both brief interventions and wider alcohol sciences. *Addict Sci Clin Pract* 2021;**16**:41. https://doi.org/10.1186/s13722-021-00250-w
- 12. McCambridge J, Madden M. Think big about developing the science. *Addiction* 2021;**116**:2947–8. https://doi.org/10.1111/add.15568
- Dhital R, Norman I, Whittlesea C, Murrells T, McCambridge J. The effectiveness of brief alcohol interventions delivered by community pharmacists: randomized controlled trial. Addiction 2015;110:1586–94. https://doi. org/10.1111/add.12994
- 14. Glass JE, Andréasson S, Bradley KA, Finn SW, Williams EC, Bakshi AS, *et al.* Rethinking alcohol interventions in health care: a thematic meeting of the International Network on Brief Interventions for Alcohol & Other Drugs (INEBRIA). *Addict Sci Clin Pract* 2017;**12**:14. https://doi.org/10.1186/s13722-017-0079-8
- 15. Rehm J, Anderson P, Manthey J, Shield KD, Struzzo P, Wojnar M, Gual A. Alcohol use disorders in primary health care: what do we know and where do we go? *Alcohol Alcohol* 2016;**51**:422–7. https://doi.org/10.1093/alcalc/agv127

- 16. McCambridge J, Stewart D. Managing alcohol use in primary care. *BMJ* 2020;**371**:m4129. https://doi.org/10.1136/bmj.m4129
- 17. McCaig D, Fitzgerald N, Stewart D. Provision of advice on alcohol use in community pharmacy: a cross-sectional survey of pharmacists' practice, knowledge, views and confidence. *Int J Pharm Pract* 2010;**19**:171–8. https://doi.org/10.1111/j.2042-7174.2011.00111.x
- 18. Stewart D, Madden M, Davies P, Whittlesea C, McCambridge J. Structured medication reviews: origins, implementation, evidence, and prospects. *Br J Gen Pract* 2021;**71**:340–1. https://doi.org/10.3399/bjgp21X716465
- 19. NHS England and Improvement. *Primary Care Networks: Revised Network Contract Directed Enhanced Service for 2020/21. Explanatory Note.* NHS England and Improvement; 2020. URL: www.england.nhs.uk/wp-content/uploads/2020/03/cover-note-gps-commissioners-revised-network-contract-des.pdf (accessed 28 November 2023).
- 20. Madden M, Mills T, Atkin K, Stewart D, McCambridge J. Early implementation of the structured medication review in England: a qualitative study. *Br J Gen Pract* 2022;**72**:e641–8. https://doi.org/10.3399/BJGP.2022.0014
- 21. Department of Health and Social Care. *Pharmaceutical Services* (Advanced and Enhanced Services) (England) Directions 2013. Department of Health and Social Care; 2013. URL: https://assets.publishing.service.gov.uk/media/5a7ae6d6ed915d670dd7f64c/2013-03-12_-_Advanced_and_Enhanced_Directions_2013_e-sig.pdf (accessed 28 November 2023).
- 22. Community Pharmacy England. *New Medicine Service (NMS)*. Community Pharmacy England; 2013. URL: https://psnc.org.uk/services-commissioning/advanced-services/nms/ (accessed 9 January 2024).
- 23. Abdel-Tawab R, James DH, Fichtinger A, Clatworthy J, Horne R, Davies G. Development and validation of the medication-related consultation framework (MRCF). *Patient Educ Couns* 2011;83:451–7. https://doi.org/10.1016/j.pec.2011.05.005
- 24. McCambridge J, Atkin K, Dhital R, Foster B, Gough B, Madden M, *et al.* Addressing complex pharmacy consultations: methods used to develop a person-centred intervention to highlight alcohol within pharmacist reviews of medications. *Addict Sci Clin Pract* 2021;**16**:63. https://doi.org/10.1186/s13722-021-00271-5
- 25. Madden M, Morris S, Ogden M, Lewis D, Stewart D, McCambridge J. Producing co-production: reflections on the development of a complex intervention. *Health Expect* 2020;**23**:659–69. https://doi.org/10.1111/hex.13046
- Madden M, Morris S, Atkin K, Gough B, McCambridge J. Patient perspectives on discussing alcohol as part of medicines review in community pharmacies. Res Social Adm Pharm 2019;16:96–101. https://doi.org/10.1016/j. sapharm.2019.03.145
- 27. Madden M, Morris S, Stewart D, Atkin K, Gough B, McCambridge J. Conceptualising alcohol consumption in relation to long-term health conditions: exploring risk in interviewee accounts of drinking and taking medications. *PLOS ONE* 2019;14:e0224706. https://doi.org/10.1371/journal.pone.0224706
- 28. Morris S, Madden M, Gough B, Atkin K, McCambridge J. Missing in action: insights from an exploratory ethnographic observation study of alcohol in everyday UK community pharmacy practice. *Drug Alcohol Rev* 2019;**38**:561–8. https://doi.org/10.1111/dar.12960
- 29. Atkin K, Madden M, Morris S, Gough B, McCambridge J. Community pharmacy and public health: preserving professionalism by extending the pharmacy gaze? *Sociol Health Illn* 2021;43:336–52. https://doi.org/10.1111/1467-9566.13221
- 30. Stewart D, Whittlesea C, Dhital R, Newbould L, McCambridge J. Community pharmacist led medication reviews in the UK: a scoping review of the medicines use review and the New Medicine Service literatures. *Res Social Adm Pharm* 2019;**16**:111–22. https://doi.org/10.1016/j.sapharm.2019.04.010
- 31. Gough B, Madden M, Morris S, Atkin K, McCambridge J. How do older people normalise their drinking?: An analysis of interviewee accounts. *Appetite* 2020;**146**:104513. https://doi.org/10.1016/j.appet.2019.104513

- 32. Madden M, Morris S, Stewart D, Atkin K, Gough B, Mills T, McCambridge J. Using qualitative process evaluation in the development of a complex intervention to advance person-centred practice by pharmacists: The Medicines and Alcohol Consultation (MAC). SSM Qual Res Health 2021;1:100012. https://doi.org/10.1016/j.ssmqr.2021.100012
- 33. Stewart D, van Dongen A, Watson M, Mandefield L, Atkin K, Dhital R, et al. A pilot cluster randomised trial of the medicines and alcohol consultation (MAC): an intervention to discuss alcohol use in community pharmacy medicine review services. BMC Health Serv Res 2020;20:943. https://doi.org/10.1186/s12913-020-05797-z
- 34. Stewart D, Madden M, Van Dongen A, Watson M, Morris S, Whittlesea C, McCambridge J. Process study within a pilot cluster randomised trial in community pharmacy: an exploration of pharmacist readiness for research. *Res Social Adm Pharm* 2021;17:1750–7. https://doi.org/10.1016/j.sapharm.2021.01.005
- 35. Watson M, van Dongen A, Hewitt C, Mandefield L, Stewart D, Watson J, McCambridge J. Optimising retention success: a research team's experience of following-up participants recruited to a pilot trial through community pharmacies in England. F1000Res 2020;9:1042. https://doi.org/10.12688/f1000research.25372.2
- 36. Kypri K, McCambridge J. Alcohol must be recognised as a drug. *BMJ* 2018;**362**:k3944. https://doi.org/10.1136/bmj.k3944
- 37. Stewart D, McCambridge J. Alcohol complicates multimorbidity in older adults. *BMJ* 2019;**365**:l4304. https://doi.org/10.1136/bmj.l4304
- 38. Stewart D, McCambridge J. Authors' reply to Rao. BMJ 2019;366:I5151. https://doi.org/10.1136/bmj.I5151
- 39. Madden M, McCambridge J. Alcohol marketing versus public health: David and Goliath? *Global Health* 2021;**17**:45. https://doi.org/10.1186/s12992-021-00696-2
- 40. McCambridge J, Morris S. Comparing alcohol with tobacco indicates that it is time to move beyond tobacco exceptionalism. *Eur J Public Health* 2019;**29**:200–1. https://doi.org/10.1093/eurpub/cky227
- 41. Gaume J, Heather N, Tober G, McCambridge J. A mediation analysis of treatment processes in the UK Alcohol Treatment Trial. *J Consult Clin Psychol* 2018;86:321–9. https://doi.org/10.1037/ccp0000287
- 42. NHS England. *Network Contract Directed Enhanced Service. Structured Medication Reviews and Medicines Optimisation: Guidance*; 2021. URL: www.england.nhs.uk/wp-content/uploads/2021/03/B0431-network-contract-des-smr-and-mo-guidance-21-22.pdf (accessed 9 January 2024).
- 43. Morris S, Stewart D, Madden M, McCambridge J. A scoping review of qualitative research on perceptions of one's own alcohol use. *Eur J Public Health* 2021;**31**:432–6. https://doi.org/10.1093/eurpub/ckaa211
- 44. van Dongen A, Stewart D, Garry J, McCambridge J. Measurement of person-centred consultation skills among healthcare practitioners: a systematic review of reviews of validation studies. *BMC Med Educ* 2023;**23**:211. https://doi.org/10.1186/s12909-023-04184-6
- 45. Mills T, Madden M, Stewart D, Gough B, McCambridge J. Integration of a clinical pharmacist workforce into newly forming primary care networks: a qualitatively driven, complex systems analysis. *BMJ Open* 2022;**12**:e066025. https://doi.org/10.1136/bmjopen-2022-066025
- 46. Madden M, Stewart D, Mills T, McCambridge J. Consultation skills development in general practice: findings from a qualitative study of newly recruited and more experienced clinical pharmacists during the COVID-19 pandemic. *BMJ Open* 2023;**13**:e069017. https://doi.org/10.1136/bmjopen-2022-069017
- 47. Madden M, Stewart D, Mills T, McCambridge J. Alcohol, the overlooked drug: clinical pharmacist perspectives on addressing alcohol in primary care. *Addict Sci Clin Pract* 2023;**18**:22. https://doi.org/10.1186/s13722-023-00378-x
- 48. Madden M, Stewart D, McCambridge J. Really putting a different slant on my use of a glass of wine': patient perspectives on integrating alcohol into Structured Medication Reviews in general practice. *Addict Res Theory* 2023;**31**:459–67. https://doi.org/10.1080/16066359.2023.2207017

- 49. NHS England. *Network Contract Directed Enhanced Service Investment and Impact Fund 2022/23: Updated Guidance*; 2022. URL: www.england.nhs.uk/publication/network-contract-directed-enhanced-service-investment-and-impact-fund-2022-23-updated-guidance/ (accessed 28 November 2023).
- 50. Robinson J. NHS lead to investigate pharmacists being given just ten minutes for medication reviews. *Pharm J* 2022;**308**. https://doi.org/10.1211/PJ.2022.1.143562
- 51. NHS England. *Network Contract Directed Enhanced Service Investment and Impact Fund* 2023/24: Guidance. NHS England; 2023. URL: www.england.nhs.uk/wp-content/uploads/2023/03/PRN00157-ncdes-investment-and-impact-fund-2023-24-guidance.pdf (accessed 28 November 2023).
- 52. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, *et al.* A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ* 2021;**374**:n2061. https://doi.org/10.1136/bmj.n2061
- 53. Crowe S, Cresswell K, Robertson A, Huby G, Avery A, Sheikh A. The case study approach. *BMC Med Res Methodol* 2011;**11**:100. https://doi.org/10.1186/1471-2288-11-100
- 54. Madden M, Stewart D, McCambridge J. Barriers and leverage points for seeing alcohol differently in integrated care systems in England: a senior stakeholder interview study. *BMJ Public Health* 2024;**2**:e000829. https://doi.org/10.1136/bmjph-2023-000829
- 55. Madden M, Morris S, Ogden M, Lewis D, Stewart D, O'Carroll RE, McCambridge J. Introducing alcohol as a drug in medicine reviews with pharmacists: findings from a co-design workshop with patients. *Drug Alcohol Rev* 2021;**40**:1028–36. https://doi.org/10.1111/dar.13255
- 56. INVOLVE. Payment for Involvement: A Guide for Making Payments to Members of the Public Actively Involved in NHS, Public Health and Social Care Research. Eastleigh: INVOLVE; 2010. URL: www.invo.org.uk/wp-content/uploads/documents/INVOLVEPayment%20Guiderev2012.pdf (accessed 28 November 2023).
- 57. Bellis MA, Hughes K, Nicholls J, Sheron N, Gilmore I, Jones L. The alcohol harm paradox: using a national survey to explore how alcohol may disproportionately impact health in deprived individuals. *BMC Public Health* 2016;**16**:111. https://doi.org/10.1186/s12889-016-2766-x
- 58. Office for Health Improvement and Disparities. Fingertips Public Health Profile. 2023. URL: https://fingertips.phe.org.uk/profile/local-alcohol-profiles/data#page/3/gid/1938132984/pat/15/par/E92000001/ati/6/are/E12000001/iid/93763/age/1/sex/4/cat/-1/ctp/-1/yrr/1/cid/4/tbm/1 (accessed 7 November 2023).
- 59. Heather N. Can screening and brief intervention lead to population-level reductions in alcohol-related harm? *Addict Sci Clin Pract* 2012;7:15. https://doi.org/10.1186/1940-0640-7-15
- 60. Holton AE, Gallagher P, Fahey T, Cousins G. Concurrent use of alcohol interactive medications and alcohol in older adults: a systematic review of prevalence and associated adverse outcomes. *BMC Geriatr* 2017;**17**:148. https://doi.org/10.1186/s12877-017-0532-2
- 61. NHS England. Investment and Evolution: A Five-Year Framework for GP Contract Reform to Implement The NHS Long Term Plan; 2019. URL: www.england.nhs.uk/wp-content/uploads/2019/01/gp-contract-2019.pdf (accessed 28 November 2023).
- 62. Department of Health and Social Care. Good for You, Good for Us, Good for Everybody: A Plan to Reduce Overprescribing to Make Patient Care Better and Safer, Support the NHS, and Reduce Carbon Emissions. London: Department of Health and Social Care; 2021. URL: www.gov.uk/government/publications/national-overprescribing-review-report (accessed 28 November 2023).
- 63. Madden M, Morris S, Atkin K, Gough B, McCambridge J. Patient perspectives on discussing alcohol as part of medicines review in community pharmacies. *Res Social Adm Pharm* 2020;**16**:96–101. https://doi.org/10.1016/j.sapharm.2019.03.145
- 64. Stewart D, Whittlesea C, Dhital R, Newbould L, McCambridge J. Community pharmacist led medication reviews in the UK: a scoping review of the medicines use review and the New Medicine Service literatures. *Res Social Adm Pharm* 2020;**16**:111–22. https://doi.org/10.1016/j.sapharm.2019.04.010

- 65. Elliott RA, Boyd MJ, Salema NE, Davies J, Barber N, Mehta RL, *et al.* Supporting adherence for people starting a new medication for a long-term condition through community pharmacies: a pragmatic randomised controlled trial of the New Medicine Service. *BMJ Qual Saf* 2016;25:747–58. https://doi.org/10.1136/bmjqs-2015-004400
- Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, Tyrer P. Framework for design and evaluation of complex interventions to improve health. BMJ 2000;321:694–6. https://doi. org/10.1136%2Fbmj.321.7262.694
- 67. Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;**337**:a1655. https://doi.org/10.1136/bmj. a1655
- 68. Petticrew M. When are complex interventions 'complex'? When are simple interventions 'simple?'. *Eur J Public Health* 2011;**21**:397–8. https://doi.org/10.1093/eurpub/ckr084
- 69. Leventhal H, Brissette I, Leventhal EA. The Common-Sense Model of Self-Regulation of Health and Illness. In Cameron LD, Leventhal H, editors. *The Self-Regulation of Health and Illness Behaviour*. London: Routledge; 2003.
- 70. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci* 2012;7:37. https://doi.org/10.1186/1748-5908-7-37
- 71. NHS England. *Network Contract Directed Enhanced Service Contract Specification* 2019/20; 2019. URL: www. england.nhs.uk/wp-content/uploads/2019/03/network-contract-des-specification-2019-20-v1.pdf (accessed 28 November 2023).
- 72. NHS England. *Network Contract Direct Enhanced Service Draft Outline Service Specifications*; 2019. URL: www. engage.england.nhs.uk/survey/primary-care-networks-service-specifications/supporting_documents/ Draft%20PCN%20Service%20Specifications%20December%202019.pdf (accessed 28 November 2023).
- 73. NHS England. *Update to the GP Contract Agreement* 2020/21–2023/24; 2020. URL: www.england.nhs.uk/wp-content/uploads/2020/03/update-to-the-gp-contract-agreement-v2-updated.pdf (accessed 28 November 2023).
- 74. NHS England. *Network Contract Directed Enhanced Service Contract Specification 2020/21-PCN Requirements and Entitlements*; 2020. Updated SMR patient groups and clinical pharmacist role requirements. URL: www. england.nhs.uk/wp-content/uploads/2020/03/network-contract-des-specification-pcn-requirements-entitlements-2020-21.pdf (accessed 28 November 2023).
- 75. NHS England. *Network Contract Directed Enhanced Service Guidance for 2020/21 in England*; 2020. Guidance for commissioners and practices, including clinical pharmacist training and supervision and SMR metrics. URL: www.england.nhs.uk/wp-content/uploads/2020/03/network-contract-des-guidance-2020-21.pdf (accessed 28 November 2023).
- 76. NHS England. *Explanatory Note*; 2020. URL: www.england.nhs.uk/wp-content/uploads/2020/03/cover-note-gps-commissioners-revised-network-contract-des.pdf (accessed 28 November 2023).
- 77. NHS England. Structured Medication Reviews and Medicines Optimisation: Guidance; 2020. URL: www.england. nhs.uk/wp-content/uploads/2020/09/SMR-Spec-Guidance-2020-21-FINAL-.pdf (accessed 28 November 2023).

Appendix 1 Original CHAMP-1 objectives, workstreams and programme governance

The original objectives were to undertake:

- 1. Intervention development, feasibility and acceptability studies to prepare the intervention and trial design for a definitive evaluation study.
- 2. A pilot trial in advance of the main trial.
- 3. A definitive RCT evaluating the clinical and economic effects of the intervention.
- 4. Four participant-centred qualitative process studies which explore the complexities of medication appointments and their effects on patients and pharmacists.
- 5. A long-term health economics modelling study to estimate future costs and outcomes.
- 6. Policy engagement throughout the duration of the programme to assist post-trial decision-making regardless of the result.

Six workstreams corresponded to the study objectives as follows:

- 1. Intervention development, feasibility and acceptability studies (months 0–15).
- 2. Pilot RCT (months 13-23).
- 3. Definitive RCT (months 24-48).
- 4. Participant-centred qualitative process studies (months 20–47).
- 5. Long-term health economics modelling study (months 43-60).
- 6. Policy engagement and implementation (months 49-60).

Programme governance

Programme Management Group

Progress in research and co-ordination of co-investigator inputs were overseen by the PMG. This was chaired by the principal investigator (PI) and included all co-investigators, key research staff and one additional member from the PPI group. The group initially meet every 2 months in the first year, and then three times per year, with additional meetings arranged as needed at key points in the research process, and to address issues that arose outside the control of the research team.

Patient, Practice and Policy Advisory Groups

The development of the research plans was supported throughout by a Pharmacy Professional Practice Group (PPPG), a Policy Advisory Group (PAG) and a patient and public involvement (PPI) Group. Membership of the former two evolved to reflect changes in the programme. The groups were consulted during the development of the MAC intervention, trial planning and on changes to the programme. We also reconfigured PPPG and PAG membership to reflect the transfer of the programme to the general practice setting. Advisory group membership and functions were as follows:

Pharmacy Professional Practice Group

Purpose: lead professional input into development and testing of the intervention.

- Support pharmacies/pharmacists to undertake the research.
- Advise on intervention development and manual.
- Assist dissemination via education materials, professional groups and forums.

Membership:

- Pharmacy research champions.
- Centre for Pharmacy Postgraduate Education (CPPE) representatives.
- Local Authority Public Health.
- Local Pharmaceutical Committees, Practice Forums, and Professional Networks (pharmacy).

Meet: 3 times in year 1, twice in years 2–4, twice in final year.

Policy Advisory Group

Purpose: co-lead dissemination strategy with the research team.

- · Communicating results.
- Implementation of alcohol in MURs (or NMS) in line with trial results.
- Workforce development planning.
- Education and support for pharmacists.
- Contribution to wider policy agendas.

Membership (reps):

- NHS England.
- · Service commissioners.
- · Royal pharmaceutical society.
- CPPE.

Meet: annually in years 1-4, twice in final year.

Patient and public involvement

Purpose: support all aspects of the programme, including:

- Intervention content issues.
- Design of qualitative studies.
- Reviewing all patient materials.
- · Leading PPI dissemination activities.

Membership: 10-12 members

Meet: 3 times each in years 1-2, two in years 3-5.

Programme Steering Committee

The Programme Steering Committee (PSC) comprised an independent Chair, three independent members one of whom was a statistician and one of whom represented the interests of patients and the public:

Claire Anderson (Chair), School of Pharmacy, Nottingham University.

Alan Montgomery, Director of Nottingham Clinical Trials Unit, University of Nottingham.

Niamh Fitzgerald, Institute for Social Marketing, University of Stirling.

Ms Lynn Laidlaw, lay representative.

The PSC meetings were all attended by the PI and Programme Manager, and an additional research team member as necessitated by the principal issues to be discussed (e.g. pharmacy, trials, qualitative findings). The PSC advised on progress issues and proposed changes to the programme's plans and approved all requests to NIHR.

Appendix 2 Summary of changes to the original research plan, their rationales and key formal decision-making processes involved

National medicine review service and primary care policy

See the main report for content on the decommissioning of the MUR. Announced in 2019,⁶¹ the SMR was a central component of the Primary Care Network (PCN) Network Contract DES, and identified in the Department of Health and Social Care National Overprescribing Review⁶² as the 'ideal tool to help people with problematic polypharmacy' (p. 31). CHAMP-1 originally selected pharmacists for an enhanced prevention role, and in our view the introduction of SMRs in general practice made this service the natural home of this work within the NHS (see also main report phase 2 text for other conducive features).

Up to that point in June 2019, we had made good progress in the research and were conducting the planned pilot RCT in community pharmacy to schedule. A stakeholder meeting was subsequently held with NIHR in November 2019 to discuss the implications of the major policy decision for the programme. We discussed a number of different options and requested a 12-month funded extension in order to proceed with the programme with a significant delay to enable the team to move the programme into general practice. This required undertaking additional studies to explore the setting, the recruitment and training needs of a greatly expanded pharmacy workforce, and the introduction of the new SMR service, in order to adapt the intervention. The PGfAR panel agreed with the research team's plans and proposed further studies but deferred decision-making specifically on a 12-month funded extension until it became clearer whether a definitive trial was still possible within the award. The new plans included a revised checkpoint in June 2021 at which point a decision could be made on a definitive trial. In the event of not proceeding to a trial, the panel requested that the checkpoint review contain a proposal about the how the team could best use the time and remaining resource within the programme to carry out research which can clearly demonstrate benefit to patients, public and/or the health and social care system. A variation to contract (VTC) was thus agreed thus.

COVID pandemic impacts

We agreed a second VTC in September 2020 to revise the checkpoint date from June to December 2021 due to the impact of the pandemic on primary care services and research. The introduction of the SMR had been delayed by 6 months until October 2020, meaning the planned studies would be conducted at a time when most SMRs continued to be undertaken by telephone and implementation was uneven. We deferred the conduct of two preliminary observational studies as they were not possible to undertake and embarked on two review studies as replacements for the observational fieldwork, following discussion with the Programme Manager, and as noted in the additional information section of the second VTC.

Progression to a definitive randomised controlled trial

Although we had managed to adapt the programme to the primary care setting in challenging circumstances, the accumulated impacts of national policy and COVID-related factors had implications for the feasibility and timing of a definitive trial. The process for our decision-making about whether a definitive trial was possible, and what would follow if a trial was not judged to be possible, proceeded as follows:

1. Key trial feasibility discussion points shared with the PMG in December 2020. At that time, the PMG members agreed that, broadly, our analysis of the risks and the basis for decision-making were correct and that by virtue of

- the timing (trial fieldwork not having started) we were actually well placed to navigate the research through the uncertainties being faced by the NHS during the COVID pandemic.
- 2. The research team then mapped out more completely the decisions to be made for each stage of the programme (for current studies; feasibility work; and definitive trial) and identified the major issues relevant to these activities. These were then distilled into questions that it was essential to answer, focused on what would prevent us from proceeding to a trial, what information would be needed to inform such a decision, and various options for trial design.
- 3. In February 2021, the PMG agreed that the criteria for progression to the trial could be reduced to the following key questions: whether sufficient numbers of SMRs were being done for the purposes of patient recruitment (from NHS Digital data), and whether we could recruit sufficient numbers of PCNs and CPs.
- 4. In June 2021, we consulted the PPI group and the PSC, both of which endorsed our approach to trial decision-making and the progression criteria, which involved the commencement of PCN and CP recruitment from that point onwards. The PSC recommended that specific thresholds for trial progression were not required, and that engagement with other regions be initiated in the event of difficulties identifying PCNs and/or pharmacists delivering sufficient numbers of SMRs in Yorkshire and Humber and the North East regions.
- 5. A detailed timetable for the final decision-making, leading up to the December checkpoint, was approved by the PMG in September 2021.
- 6. We proceeded with recruitment of CPs, involving an 'in principle' agreement with the PCN, because it was premature to formalise the arrangement in advance of the funding agreement for a costed extension.
- 7. Provisional recruitment was undertaken in anticipation of the trial beginning in the spring/summer of 2022. However, various delays to the implementation of the SMR service and outstanding issues in the organisation of PCNs indicated that it would be risky to attempt to proceed with the trial during 2022, and instead that it was necessary to acquire a more secure understanding of SMR practice from the perspectives of both practitioners and patients. At the checkpoint, we thus proposed that the trial would be less risky to undertake if the timing was delayed until 2023.
- 8. We submitted the checkpoint review in December 2021 with a recommendation to proceed with the trial with a delay. The feedback indicated there were too many risks with recommending the planned trial, because of uncertainty with SMR roll-out nationally and whether the team would be able to recruit the desired sample size.
- 9. We were invited to elaborate on our preliminary plans for a no trial scenario that we had provided in the check-point review. This was for a no cost extension of the programme with studies focusing on the pharmacist role and skills development in the context of a multidisciplinary team in general practice, with a particular focus on alcohol. Without a trial, we also dropped the economic modelling and extensive policy engagement work we had planned for the end of the programme. Instead, we adopted a complex systems perspective on how the delivery of the intervention could impact on alcohol practice in the PCNs and ICSs in which it was delivered, requesting a 2-year no-cost extension.
- 10. These plans were felt to depart too far from the original research aims. We agreed instead a 1 year no cost extension that comprised a stakeholder interview study of ICSs as they were being introduced, and an implementation study drawing on audio-recording, coach, patient and pharmacist data sets.

Appendix 3 Phase 1 intervention development, feasibility and acceptability studies

he intervention development process was organised into four stages as described below.

Stage 1: preliminary observational, patient interview and scoping review studies

Medicine review practice observation study²⁸

We conducted an ethnographic observation study in five community pharmacies featuring nine pharmacists. The aim was to understand how alcohol does or does not fit into routine service provision of MURs and the NMS, and pharmacists' everyday practices in community pharmacies. A total of 31 consultations (16 MUR and 15 NMS) were observed along with informal interviews with pharmacists conducted during the observations. The reality of routine medicine review practice was that alcohol was raised, if at all, as part of a brief lifestyle check which came at the end of the consultation and framed solely in terms of quantity of consumption. Pharmacists found the topic of alcohol challenging to discuss with patients and were concerned that discussions about alcohol might alienate them.

Patient interviews^{27,31,63}

Semistructured interviews were conducted with 25 people eligible for medication reviews whose AUDIT-C screening scores identified they were risky drinkers. The study aimed to explore their views on the appropriateness of alcohol as a subject for discussion in the community pharmacy context. Most patients said they were open to the idea of a discussion that linked alcohol to their medications if this was well-conducted and confidential.⁶³ While reporting being concerned about the felt effects of concurrent alcohol and medicine use,²⁷ they had limited awareness of, or regard for, potential future harms to their health from alcohol use. Their ideas about the nature of alcohol problems made it more difficult to reflect on possible impacts on their health.^{27,63} Being perceived as in control of their consumption underpinned efforts to convey drinking in moderation and rationalisations of their drinking.³¹ Interventions were regarded as necessary for obviously problematic drinkers, and prevention and early intervention ideas had little resonance.

Scoping review⁶⁴

We conducted a scoping review of the MUR and NMS literature to map the nature of the published evidence for these services. In particular, we sought data on barriers and facilitators to conducting MUR or NMS consultations, the perceptions of pharmacists and patients, how these consultations are conducted and patient outcomes. We did not publish or register our study protocol. Systematic searches identified 41 papers (from 37 studies). Evaluation of clinical outcomes was limited to a single RCT of the NMS. Most were observational studies focusing on the introduction and implementation of MURs and the NMS. The experiences of pharmacists and patients was generally positive for both services, despite substantial implementation challenges. Importantly for the CHAMP-1 programme, the review indicated that MUR and NMS consultations were short, such that opportunities for meaningful engagement with patients (on any topic) were limited. There was also very little information in the literature about the extent and nature of advice on health behaviours offered during consultations.

Theoretical and modelling work to inform intervention design decision-making

The intervention was developed following MRC complex interventions guidance, 66,67 but our perspective was pragmatic, recognising that 'there are no "simple" or "complex" interventions, and that simplicity and complexity are instead pragmatic perspectives adopted by researchers to help describe and understand the interventions in question'.68 We thus adopted a 'bottom-up' data-led approach to coproduction. We conceptualised alcohol as a toxic psychoactive drug, posing a potential problem directly via its impact on health and well-being, and indirectly by potentially reducing adherence to, or the effectiveness and safety of prescribed medications. In seeking to enable patients to better regulate their own alcohol consumption, we drew on Leventhal's common-sense model of self-regulation, 69 but also other conceptual material that fitted emerging qualitative data and to inform our approach to intervention design.

Stage 2: co-design workshops

A co-design workshop was held with 14 people recruited from community pharmacies who regularly drank alcohol and took medications for long-term conditions. This was co-facilitated by patient advisory group leads.⁵⁵ Overall, patients welcomed the idea of conceptualising alcohol as a drug to be discussed alongside prescribed medicines' use, safety and effectiveness. This was new to them and gave legitimacy to pharmacists to raise alcohol in medicine reviews. The workshop also involved consultation on the design of MAC materials, including preferences for ways of asking about alcohol.

Two workshops were held for pharmacists: one in Yorkshire (n = 3) and one in the North East (n = 4). These explored the acceptability and feasibility of the MAC Programme and how it could be improved in term of: compatibility with existing practice; perceived benefits for patients; changes or additions to MAC content; and potential barriers to implementation and means of overcoming them. The premise of viewing alcohol as a drug, and the implications for how integrating alcohol into medicine reviews, was fully supported. Pharmacists' concerns focused on finding time to engage with the online materials and they recommended incorporating some in person delivery. Feedback for the basic concept was overwhelmingly positive.

Stage 3: Medicines and Alcohol Consultation delivery study

The aims of this study were to examine: (1) the implementation of the intervention and research procedures, including screening and recruitment procedures and (2) the experience of the intervention for pharmacists and patients. The study was conducted with five intervention pharmacists and two others to act as controls. The former received an abbreviated version (a single training day) of the MAC programme. All participating pharmacists administered a screening protocol to successive MUR and NMS patients. Patients were eligible if they consumed alcohol twice a week or more frequently, and informed consent was obtained by the pharmacist. The consent form enabled participants to indicate their consent separately for study participation and consultations to be audio-recorded and, for patients at intervention sites only, for telephone interviews to take place after the consultation. Semistructured interviews were conducted with pharmacists from intervention sites to explore their experiences of the MAC programme and putting it into practice.

The study demonstrated the feasibility of delivering the MAC programme and of our approach to recruiting patients to a trial. The recruitment and consent procedures were acceptable to both pharmacists and patients. Some of the pharmacists experienced some initial confusion over eligibility criteria that was quickly rectified. The greatest challenges lay in the additional time required in the consultation for the screening and consent process, and in delivery of the intervention (see main report). Intervention pharmacists preferred the interactive nature of the training to online provision.

Stage 4: revisiting programme theory, and pharmacist patient advisory groups

The final stage involved further theoretical and modelling work, aiming to refine the description of the MAC intervention components and their rationales. We used the theoretical domains framework⁷⁰ to construct a complete programme theory. No major omissions of relevant theoretical constructs were identified. A final version of the MAC was then agreed with the patient and pharmacy advisory groups for the pilot trial, which was the next stage of the research.

Appendix 4 Key Structured Medication Review and Primary Care Network policy developments

January 2019

The NHS Long Term Plan. SMRs formally announced. www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf

Investment and Evolution: A Five-Year Framework for GP Contract Reform to Implement The NHS Long Term Plan. ⁶¹ Further details of SMRs and the role of clinical pharmacists. www.england.nhs.uk/wp-content/uploads/2019/01/gp-contract-2019.pdf

March 2019

Network Contract Directed Enhanced Service Contract Specification 2019/20.⁷¹ Funding and workforce requirement for clinical pharmacists and other new PCN roles. www.england.nhs.uk/wp-content/uploads/2019/03/network-contract-des-specification-2019-20-v1.pdf

December 2019

Network Contract Direct Enhanced Service Draft Outline Service Specifications.⁷² Proposed SMR service model and requirements. www.engage.england.nhs.uk/survey/primary-care-networks-service-specifications/supporting_documents/Draft%20PCN%20Service%20Specifications%20December%202019.pdf

February 2020

Update to the GP Contract Agreement 2020/21–2023/24.⁷³ Revisions to SMRs in response to the consultation. www. england.nhs.uk/wp-content/uploads/2020/03/update-to-the-gp-contract-agreement-v2-updated.pdf

March 2020

Network Contract Directed Enhanced Service Contract Specification 2020/21–PCN Requirements and Entitlements.⁷⁴ Updated SMR patient groups and clinical pharmacist role requirements. www.england.nhs.uk/wp-content/uploads/2020/03/network-contract-des-specification-pcn-requirements-entitlements-2020-21.pdf

Network Contract Directed Enhanced Service Guidance for 2020/21 in England.⁷⁵ Guidance for commissioners and practices, including clinical pharmacist training and supervision and SMR metrics. www.england.nhs.uk/wp-content/uploads/2020/03/network-contract-des-guidance-2020-21.pdf

Explanatory Note.⁷⁶ Response to the COVID-19 outbreak, including SMR postponement. www.england.nhs.uk/wp-content/uploads/2020/03/cover-note-gps-commissioners-revised-network-contract-des.pdf

September 2020

Structured Medication Reviews and Medicines Optimisation: Guidance.⁷⁷ SMR specification published. www.england.nhs. uk/wp-content/uploads/2020/09/SMR-Spec-Guidance-2020-21-FINAL-.pdf

Appendix 5 Phase 2 studies and findings

Study 1: from policy to practice: early Structured Medication Review implementation incorporating trial feasibility assessment

The aims of this study were to investigate how national PCN and clinical pharmacy policy was being translated into local practice, in order to develop understanding of contextual factors that influence the early implementation of the SMR and other patient-facing pharmacy services in primary care. These early experiences were judged highly likely to have implications for how these services would become embedded in routine practice, with relevance for understanding CP participation in, and outcomes of, the trial. The work was organised into substudies to investigate:

- National policy factors that influenced implementation of PCN pharmacist led services.
- The implementation of the new service provision by PCN pharmacists, including:
 - Recruitment of pharmacists and their developing roles and responsibilities in PCNs.
 - The early day-to-day practice and medicine related service delivery of pharmacists in the early months of SMR implementation and subsequently.
 - Pharmacist and senior PCN staff perspectives on implementation and possible future service provision innovations, including changes to SMRs, public health interventions and alcohol.
- Pharmacist perspectives on the PCN pharmacist role in relation to research.
- SMR patient recruitment feasibility.

Study 1a: policy review¹⁸

We conducted a comprehensive review and analysis of national policy documentation associated with the introduction of PCNs and the SMR. Key factors influencing implementation were identified and summarised in a *British Journal of General Practice* editorial. The roll-out of PCNs and SMRs was done at speed, to the extent of having likely implications for the quality of service delivery. The challenges became more acute when the COVID pandemic placed practitioners and services under increased pressure. This raised important questions about the preparedness of the newly expanded CP workforce for practice development (see also below). Despite compelling reasons for expanding the clinical pharmacy workforce in primary care, the evidence underpinning the decision to introduce SMRs was very limited. We concluded that support for pharmacists in developing their roles in multidisciplinary primary care teams and acquiring more well-developed person-centred skills would be key for the sought benefits of SMRs to be realised.

Study 1b: senior Primary Care Network staff interviews⁴⁵

Semistructured interviews with senior PCN staff were conducted to explore perceptions of the possible benefits and challenges that may arise from the new pharmacist workforce in primary care and the SMR service, issues arising from implementation, and how progress will be monitored and the service to be developed. A paper was published in *BMJ Open* that draws on data from studies 1b and 2.⁴⁵ An unplanned follow-up was added because COVID interfered with both access to interviewees and the value of the interviews, as SMR implementation was delayed (see above). Twelve semistructured interviews were conducted with seven senior PCN staff (three GP clinical directors and four senior PCN pharmacists) in six PCNs based in the Yorkshire and Humber and North East regions, purposefully sampled for diversity in terms of PCN size, patient population and operating model. The first round of interviews took place between March 2020 and October 2020, and two clinical directors and the four senior pharmacists did a follow-up interview between March 2021 and September 2021.

The process of forming a PCN involved uncertainties, trade-offs and risks which extended into the local design of the new CP roles. Senior pharmacists reported examples of the new CPs being over- *and* under-utilised, with implications for staff well-being, retention and patient safety. Key factors that moderated implementation locally included: the presence of pre-existing collaborative structures, 'pro-pharmacy' PCN leadership and senior pharmacist input into PCN decision-making. COVID-19 constrained progress, although the primary-care led vaccine programme presented opportunities for some PCN pharmacy teams. Overly optimistic expectations that saw GPs have to form PCNs at the

same time that they integrated a new workforce with diverse experience and skills risked undermining the potential of both PCNs and the new roles, especially as GP interests were not necessarily well aligned with PCN policy objectives. Struggling PCNs required more time to fully form and implement the new PCN clinical pharmacy roles. Sensitivity to the organisational issues arising at the local level was obviously needed, so that trial recruitment efforts were targeted at PCNs with capacity to support conduct of the proposed study.

Studies 1c and 1d: ethnographic studies

The NHS introduction of the SMR was delayed by 6 months until October 2020, with subsequent implementation uneven in quantity and quality. SMRs were mostly conducted by telephone and in many cases departed considerably from the vision of the policy. We were unable to conduct two planned preliminary ethnographic studies of SMR practice; these were to involve observations of SMRs and interviews with pharmacists early and later into SMR implementation. Therefore, we embarked on two review studies as replacements for the fieldwork, following discussion with the NIHR Programme Manager (see also *Phase 2 methods*).

Scoping review of qualitative research on perceptions of one's own alcohol use⁴³

The qualitative studies in the programme had highlighted a distinct need to assess what research is available on how people talk about and think about their own alcohol consumption. This scoping review study aimed to map the extent, range and nature of qualitative research on how people make sense of their own alcohol consumption. We did not publish or register our study protocol. Systematic searches identified 313 eligible papers published over approximately 30 years. The majority focused on people's 'experiences' of their own drinking behaviours, particularly when they were drinking in ways commonly understood as heavy, risky or problematic. Fewer studies focused on people whose drinking was moderate or was risky in less obvious ways, such as our target population: older adults prescribed medications for chronic health conditions. We concluded that there are opportunities for future qualitative studies, including our own, to contribute to improved understanding of people's perceptions of their own alcohol consumption.

Review of reviews of validation studies of instruments measuring individual practitioner person-centred consultation skills and behaviour⁴⁴

Person-centred care is integral to high-quality health service provision, and to our intervention approach, but measuring it within clinical consultations is complex. We aimed to provide a high-level synthesis of a diverse literature in a systematic review of existing reviews of validation studies of instruments that measure person-centred practitioner skills and behaviours in consultations. We did not publish or register our study protocol. This study was undertaken to inform decision-making on instrument selection for quantitative process study within the trial. Four reviews were eligible, which included 68 unique validation studies examining 42 instruments. These used diverse conceptualisations of person-centredness and targeted distinct, sometimes mutually exclusive, practitioners and settings. The study provides researchers with a guide to the instruments available. Based on the existing literature, we suggested that further validation studies of existing instruments are needed rather than the development of new measures.

Study 1e: patient recruitment feasibility

This study examined how SMR patients eligible for the trial could be identified and recruited. We had planned to recruit from in person SMRs, but at the time, the majority of SMRs were being delivered by telephone. Conduct of the study was impacted in these circumstances, necessitating revisions to fieldwork timing (see also *Study 3: the scope for integrating the Medicines and Alcohol Consultation into Structured Medication Review practice: patient perspectives*) and ethical approval. The main change was that pharmacists would undertake eligibility checks and recruit patients rather than the researchers as originally proposed. We undertook discussions with pharmacists and senior PCN staff to devise study procedures that facilitated approaches to patients, ascertainment of eligibility and completion of informed consent both in-person and by phone. The study was conducted by five pharmacists from one PCN over a 5-week period. Ten eligible patients were recruited. Pharmacists reported recruitment to be challenging reflecting the nature of SMR delivery at the time: brief, opportunistic consultations, with pharmacists reporting being under pressure to work through backlogs of patients. It had not been possible to provide face-to-face, group-based research procedures training for the pharmacists as we had done in our previous studies, and the pharmacists did not follow the recruitment protocol consistently. Despite the challenges, we concluded that we had a feasible albeit risky recruitment approach that could be appropriate for both remote and in-person delivery of SMRs.

Study 2: person-centred skills acquisition of Primary Care Network pharmacists and congruence with Medicines and Alcohol Consultation practice development^{20,46,47}

This longitudinal study investigated emerging roles, SMR practice, views on alcohol, professional development and person-centred skills acquisition among new CPs. The study was also designed to examine these experiences partly in comparison with pharmacists already working in general practice. Ten newly appointed CPs in 10 PCNs in Northern England were recruited and interviewed three times between September 2020 and January 2022. In addition, another group of 10 pharmacists working in 10 other PCNs across England already established in GP practices, were also interviewed once between February and May 2021. A compulsory PCPEP 2-day history-taking and consultation skills workshop conducted by video conference in 2020 was observed with permission from CPPE providers and the attending group of workshop participants.

Structured Medication Reviews undertaken in GP practices were compared favourably against MURs in community pharmacy.²⁰ Those more experienced in clinical reviews said that it took time to develop the necessary knowledge and skills to do them.²⁰ However, SMRs were not yet a priority and practice was not well organised in clinics, being provided as an ad hoc service in numerous ways. Pharmacists already in general practice appearing to be more ready for implementation and were clear that SMRs took more time and were more challenging to do than other medication reviews because they were more clinically complex, in-depth, and patient focused.²⁰ New pharmacists were on the primary care education pathway and drew on pre-existing practice frames, habits, and heuristics. Those lacking patient-facing expertise sought template-driven practice, thus compromising the distinct purposes of the SMR.²⁰

We further explored CP perspectives of consultation training provision and skills acquisition for the new SMR service, with a particular focus on person-centred consultation practice. Remote working during the COVID pandemic had limited opportunities for patient-facing contact. Pharmacists new to their role in general practice were predominantly concerned with improving clinical knowledge and competence. Most said they already practiced person-centred care, but referred to transactional medicine-focused practice. Direct feedback on consultation practice was rarely received. Their CPPE training provided knowledge but with limited opportunities for actual skills acquisition; the pharmacists had difficulty translating abstract consultation principles into specific consultation practices.

Finally, with data from the third follow-up interview available, we examined pharmacists' experiences of discussing alcohol with patients in general practice. This included views on confidence about the subject, alcohol as a drug directly linked to patient health, conditions and medicines, and integrating alcohol into routine medication reviews.⁴⁷ Alcohol was either not raised at all or addressed in terms of calculating dose and level of consumption, leading to crude advice to reduce drinking. Pharmacists did not currently consider alcohol as a drug in their practice and were interested in learning more about this concept and the approach it entailed, particularly in relation to managing polypharmacy.⁴⁷ Some recognised a linked need to enhance their consultation skills.

Study 3: the scope for integrating the Medicines and Alcohol Consultation into Structured Medication Review practice: patient perspectives⁴⁸

This study investigated patient views and experiences of SMR consultations. The lay co-investigator and the PPI subgroup worked with us to refine the interview guide. We were advised by our PPI group not to proceed with this study at times of heightened concern about the COVID pandemic. It would have been delayed anyway by the rate of implementation of the new SMRs. When we were in a position to do the study, we limited the target sample size to 10 mindful of the need to explore experience of SMR delivery, including mode in particular, given phone was the predominant way this service was being delivered.

Structured Medication Reviews received by these interviewees did not match the ideal presented in policy documents. Rather than being invited to take part in a consultation for which they could prepare, patient or practice-initiated routine medication enquiries and reviews were categorised as SMRs if patients receiving these fitted any SMR target group criteria. Patients reported that the SMRs received were brief and paid scant attention to alcohol, yet they welcomed the possibility of including alcohol in SMRs in the ways developed in our intervention. They viewed our

approach as congruent with the aims of a holistic medicine review linked to their medical history.⁴⁸ Considering alcohol as a drug impacting on their medications and the conditions changed the way in which some patients thought about their own drinking.

Study 4: data availability and policy evaluation feasibility study

The overarching aim of this study was to explore the potential to use NHS England primary care data sets to evaluate the macro-level effects of the introduction of SMRs on prescribing patterns. This was intended to inform decisions about a substantive policy evaluation study in the absence of a definitive trial, and to provide useful background in the event that we were able to proceed to trial. We undertook scoping of OpenPrescribing (https://openprescribing.net/) data to examine the prevalence of prescribing for *British National Formulary* sections and subsections per calendar year, informed by the patient populations or drugs targeted in the SMR specification, as well as prescribing for conditions known to be related to alcohol (e.g. hypertension, cardiomyopathy, atrial fibrillation and depression) and for medicines known to interact with alcohol (e.g. hypnotics and anxiolytics), as a basis for further selection of drugs for more detailed analysis.

We explored trends and tools for identifying outliers and variations between geographical regions. We downloaded prescribing data for more detailed descriptive analyses, and specifically to examine and quantify variations between PCNs in the number of items prescribed (per 1000 patients). Variation between PCNs was assessed by organising the data into deciles. For example, comparisons between the lowest and highest PCN deciles showed that total items prescribed varied by 3.95 times for hypnotics and anxiolytics, 2.61 times for diuretics and 4.43 times for opioids. The feasibility of constructing prescribing data sets with variables from linked data sets for modelling purposes, including age, gender and chronic condition and workforce profiles at the PCN level was broadly confirmed.

The feasibility of using national data for the number of SMRs being conducted was more uncertain. The variations in recorded SMRs within and between PCNs was substantial but difficult to explain from the limited data available. Evidence from the other studies undertaken at this time indicated that in some PCNs, medication reviews are being coded as SMRs when brief medicines use checks of 10 minutes' duration or quicker were being undertaken. The broader extent of this issue was unclear, and the prospects for ameliorations in data quality over time likely depended on progress in the implementation of the SMR as a new and distinct service from other kinds of medication reviews. Data coded as SMRs thus comprises a range of different types of medication review, without any capacity to distinguish between them. Further work undertaken within this programme indicates that the fate of the innovation represented by the SMR as a new distinct service comprising a patient-centred clinical medication review will depend on decisions yet to be taken about its future.

Appendix 6 Phase 3 clinical pharmacists and patient interviewee characteristics

TABLE 3 Clinical pharmacists characteristics

Identifier	Ethnicity (self-described)	Years qualified	IP	Age	Religion	Gender	ESL
MAC_CP_01	Indian	16	Yes	38	Hindu	Man	Yes
MAC_CP_02	Pakistani	15	Yes	43	Muslim	Woman	Yes
MAC_CP_03	White	05	Yes	27	None	Woman	
MAC_CP_04	White	26	Yes	50	None	Man	
MAC_CP_05	White	23	No	42	RC	Man	Yes
MAC_CP_06	Pakistani	04	No	26	Muslim	Woman	
MAC_CP_07	White	13	No	41	None	Woman	
MAC_CP_08	Pakistani	08	No	38	Muslim	Man	
MAC_CP_09	White	14	Yes	48	C of E	Woman	
MAC_CP_10	Pakistani	22	Yes	47	Muslim	Man	

IP, independent prescriber; ESL, English as a Second Language.

TABLE 4 Patient interviewee characteristics

Identifier	Ethnicity (self-described)	Employment status	Age	Religion	Gender
PMAC1	White	Retired armature winder	70	RC	Man
PMAC2	White	Unemployed	51	Unassigned	Man
PMAC3	White	Retired driver/labourer	77	C of E	Man
PMAC4	White	Retired train driver/footballer/fireman	73	C of E	Man
PMAC5	White	Retired car insurance customer service/border force	59	RC	Man
PMAC6	White	Retired	74	C of E	Man
PMAC7	White	Retired civil service	71	None	Man
PMAC8	White	Civil servant	60	C of E	Woman
PMAC9	White	Unemployed	55	None	Woman
PMAC10	White	Disabled roadie/taxi driver	65	None	Man

Appendix 7 Medicines and Alcohol Consultation programme experiences reported by participating clinical pharmacists

Those who left early

CP01

A 'medium learning curve'. Valued the coaching interaction and coach expertise. Biggest learning was that he came in confident about practice and realised he was not doing things wrong but there were ways he could do things differently. Open questions and tools for starting conversations were good, but he left early and feels he missed out on the alcohol specific intervention aspects. Did not want to exit but changes at work and indecision about SMRs meant he had no clinics. Would have extended if he could.

CP05

Is in a new PCN role and is focused on clinical knowledge rather than consultation skills. It was new to him to step back and think about how he said things rather than what to say. Found it good. 'It certainly made me realise certain bad habits'. Had worked for years in community pharmacy where he used to speak to people as much as he does now in primary care, but had not experienced any consultation skills coaching in that setting. The way he speaks to people now is different. Left because his role changed, SMRs were no longer a priority and he was asked to do other tasks. Wanted more clinical content on alcohol.

CP08

The setup, training, face-to-face sessions and 'mentoring' were good. Enjoyed meeting new people. Overall, quite a good experience, something new that he was looking forward to as; 'a new way of discussing an old topic'. 'Eye-opening'. Although he checks alcohol units, he now realises that a lot of people don't know what a unit is, or that alcohol is a drug. Includes himself in this because he did not think of it in that way in a medicine-review context.

Those who completed the programme

CP02

'A journey' from which she gained a lot of satisfaction and got much more than she expected. There have been struggles; recruitment, unplanned events, work/life balance and time pressures. Overall, a really positive experience: 'I've learnt so much ... the coaching has been great. I've picked up so many skills'. Enjoyed meeting the team and other pharmacists. Saw many angles and viewpoints that she had not come across before about patient behaviour (not only in relation to alcohol) and even basic things on how alcohol intervenes with medication.

CP03

Thought it was good, and enjoyed it. It was better than expected. 'I don't think I knew what I was really signing up for'. Thought it would have more in-depth focus on alcohol. 'But I do now understand that the idea behind it is to get those consultation skills behind us, to then enable us to talk about alcohol more easily'.

CP04

Very good, very positive. Only problem was trying to get recruits in, it took a bit more time than expected, and minor technical issues. He found the open style and the focus on agenda setting fitted really well with a new role involving more physical health examinations.

CP06

Really helpful. A good experience. Grateful she had chance to do it. Enjoyed meeting people and the chance to reflect on consultations once she got over initial worries about this. Made her reflect on previous practice of asking people about units of alcohol consumed without quite knowing what this meant for either herself or the patient because it was 'easier to talk about alcohol that way'. Now sees this as a 'very unproductive' and a 'restrictive' conversation which can close people down because they are anticipating they are going to be told they are drinking too much. Feels the programme should be longer or include follow-up 'because we all get complacent'.

CP08

Interesting and supportive. 'I really think it did develop my consultation style ... using the reflections [and other microskills, because] ... I don't think I was doing [these] particularly well before doing the study'. The alcohol side was difficult because she found it difficult to recruit patients who were drinking. Would have preferred it if it was over a longer period of time. Feels she now has a basis that can be developed in her consultations. Enjoyed the peer support sessions which are continuing.

CP09

Grown in confidence. Found it tricky in terms of patient recruitment. Has realised she has a tendency to want to 'fix' everybody and has not changed in this, though has heard the message that telling people they are drinking too much will not make them change unless they see its relevance to their medication and health. Thought she was involving patient already in consultations, but now involves them more.

CP10

Interesting and useful experience. Feels he was becoming closed and 'going through the motions'. It was good to stop and think about how he is communicating with patients.

EME HSDR HTA PGfAR PHR

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