TITLE OF THE STUDY

Personalised Primary care for Patients with Multimorbidity (PP4M) – a primary care service improvement initiative

SHORT STUDY TITLE

PP4M

PROTOCOL VERSION NUMBER AND DATE

Version	Date	Change
0.1	01/06/2021	First draft
0.2	2021-12-01	Second draft, for RED submission
0.3	2021-12-06	Minor update, for RED Submission
0.4	2021-12-15	Minor changes to itemise Maxwell intervention, and to indicate that participants in patient questionnaire will give consent
1.0	2021-12-16	Final version for ethics and governance review
1.1	2022-01-26	Revisions requested by REC. (1) Changes to inclusion/exclusion criteria for participants lacking capacity. (2) Clarification that companions will be off-camera in recorded consultations. (3) Note that a £10 voucher will be offered to patients who participate in interviews or observations.
2.0	2022-02-07	New version accepting the changes that have been approved by the REC.
2.1	2022-02-10	Change to how 'multimorbidity' is operationalised, replacing 2+ conditions with 3+ conditions, and slight changes to how conditions are grouped. Collection of fully anonymised routine data about the number of adult patients in whom the template was used, whether or not they were in the cohort with multimorbidity. Approved by REC 2022-04-12
3.0	2022-08-25	Addition of a second study arm of control practices to provide anonymised data, providing a stronger basis for comparison than the original plan to compare the study practices before and after the intervention. Provided greater flexibility in the number of patients recruited per practice, given difficulties in recruiting practices but some recruited practices having large numbers of eligible patients. Approved by REC 2022-09-26

This protocol has regard for the HRA guidance. It is based on the HRA qualitative research template but also includes elements of the HRA clinical trial template where appropriate for the quantitative elements of this mixed methods study.

RESEARCH REFERENCE NUMBERS

IRAS Number:	303831
SPONSORS Number:	Case number 2021 - 5588
FUNDERS Number:	Generated by the funder. Enter if applicable

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KEY STUDY CONTACTS

Insert full details of the key study contacts including the following

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Sponsor	University of Bristol. Adam Taylor adam.taylor@bristol.ac.uk (0117) 394 0177
Funder(s)	**Funders:** (1) NIHR ARC Multiple Long-Term Conditions Implementation Programme via ARC East Midlands – ARC East Midland Assistant Director: Donna Richardson. dr16@leicester.ac.uk. (2) NIHR School for Primary Care Research (funding evaluation of training in subset of 3 Bristol practices). Dr Georgina Fletcher. Assistant Director. E.g.fletcher@keele.ac.uk **In kind funding:** ARC West – ARC West Chief Operating Officer: Pippa Craggs. Pippa.craggs@bristol.ac.uk ARC West Midlands – ARC West Midlands Programme Manager: Anne-Marie Brennan. A-M.Brennan@warwick.ac.uk ARC Wessex – ARC Wessex Chief Operating Officer: Richard Trowbridge. R.M.Trowbridge@soton.ac.uk
Key Protocol Contributors	R Johnson and C Salisbury, as above

STUDY SUMMARY

It may be useful to include a brief synopsis of the study for quick reference. Complete information and, if required, add additional rows.

Study Title	Personalised Primary care for Patients with Multimorbidity (PP4M) – a primary care service improvement initiative
Internal ref. no. (or short title)	PP4M
Study Design	General practices regularly review patients with long-term health conditions included in the Quality & Outcomes Framework (QOF) using computerised templates (checklists).

	This approach can lead to fragmented care for people with multiple health problems (multimorbidity) and can ignore conditions that are not included in QOF. These are sometimes the problems that bother patients most. In the NHS Plan it is a priority to make care more personalised, as described in the NHS Comprehensive Model for Personalised Care. Some practices have replaced separate disease-focused reviews with a combined annual review consultation for people with multimorbidity. A promising way to improve personalised care is to use a 'smart' template focused on what matters most to patients, which supports self-management and shared decision-making. It includes links to social prescribing and pharmacist review of complicated medication, and involves agreeing a care and support plan, while also meeting QOF requirements. This approach has been shown to improve personalised care in several research trials. In this project we will adapt a template already developed for multimorbidity and make it more personalised. We will make it widely available to general practices, supported with training and other tools e.g. to identify patients with multimorbidity, and to incorporate use of patient reported outcome measures. With CCGs, AHSNs and primary care networks in three areas we will support implementation of this approach (whole-person review, template, training, tools). To reduce health inequalities, we will prioritise practices in deprived areas and patients with multiple long term conditions that include at least one cardiovascular disease. Implementation will be evaluated in a study using mixed qualitative and quantitative methods. The aim is to evaluate implementation and effectiveness of the intervention using a realist approach (how does it work, for whom, in what circumstances). The evaluation of the implementation will be examined using Normalisation Process Theory (NPT) as a theoretical evaluation framework. Participating CCGs will encourage implementation amongst all practices in their area but we will collect data in about 24 'beacon' practices (8 in each area). In a nested sub-study, three practices in deprived areas of Bristol will receive additional support and training to change the way they manage patients with multimorbidity, including the template. This will make it possible to examine the impact of the template alone or as part of a wider practice change. The evaluation will use concurrent mixed-methods to obtain evidence about intervention acceptability, feasibility, adoption, fidelity, cost, reach and sustainability. Data collected in the first few practices will be used formatively to improve future roll-out.

	Data sources will include the following, collected in about 24 'intervention' practices (arm 1) from patients with two or more long term health conditions and eligible for an annual review: • Interviews with patients • Video-recorded observations of consultations • Interviews with staff • NPT NOMAD questionnaire for clinical staff • Anonymised routinely collected data about numbers of patients receiving each intervention component • Patient reported outcome measures based on survey before and after review Routinely collected data will be collected in about 24 'control' practices (arm 2) who have not been actively encouraged to use the template, for comparison purposes. In both intervention and control practices, data will be collected from 1 April 2021 to 31 March 2023, including periods before and after introduction of the template. This project will provide evidence to inform wide-spread implementation of a 'whole-person' review for patients with multimorbidity in line with the NHS Comprehensive Model for Personalised Care.
Study Participants	Patients aged 18 or over with two or more long term health conditions eligible for an annual review of their conditions
Planned Size of Sample (if applicable)	The following sample sizes are approximate estimates: • Interviews with patients n= 55 • Video-recorded observations of consultations n= 39 • Interviews with staff n=55 • NPT NOMAD questionnaire for clinical staff n=168 • Anonymised routinely collected data about numbers of patients potentially receiving each intervention component n= 7200 in intervention practices and 7200 in control practices • Patient reported outcome measures based on survey before and after review n= 1440
Follow up duration (if applicable)	Patients will receive reviews over a 12 month cycle; each patient will be only invited to participate once, and survey follow-up of each patient is 2 months
Planned Study Period	26 months
Research Question/Aim(s)	The research aims are: • To explore the most effective strategies to implement a template to promote personalised care in patients with multimorbidity.

	• To examine under what circumstances, for which patients and in what ways the template leads to benefits for patients and/or practice staff.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
NIHR via ARC East Midlands – ARC East Midland Assistant Director: Donna Richardson. dr16@leicester.ac.uk.	Funding for main study
SPCR	
ARC West - ARC West Chief Operating Officer: Pippa Craggs. Pippa.craggs@bristol.ac.uk	Matched funding for staff and other resources
ARC Wessex – ARC Wessex Chief Operating Officer: Richard Trowbridge. R.M.Trowbridge@soton.ac.uk.	Matched funding for staff and other resources
ARC West Midlands – ARC West Midlands Programme Manager: Anne-Marie Brennan. A-M.Brennan@warwick.ac.uk.	Matched funding for staff and other resources

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor is the University of Bristol.

The main funder is NIHR via a contract with East Midlands ARC managed by Nottinghamshire Healthcare NHS Foundation Trust. A secondary funder is the NIHR School for Primary Care Research who have funded more detailed research in a sub-set of three practices in deprived areas of Bristol which will receive additional training and support.

The funders will have no role in study design, conduct, data analysis and interpretation, manuscript writing, or dissemination of results. The intention is to publish all results from this study and decisions to publish will be the responsibility of the research team, not the funder.

STUDY MANAGEMENT COMMITTEES/GROUPS

We have established a research group, a regional stakeholder group and a PPIE group in each of the three study areas: ARC West, ARC West Midlands, ARC Wessex. See Figure 1.

In each study area:

- The research group is the team of local researchers leading the evaluation in the relevant area.
- The stakeholder group consists of representatives of the regional AHSN, NHS England Office, ICS or STP, CCGs, and general practices.

- The PPIE group advises the above two groups.

These regional groups report to the cross-site research team (orange in centre of Figure 1), within which there is a small Executive team with at least one representative from each area. The Executive team co-ordinates and leads the research.

A PPIE lead and the PPIE co-applicant co-ordinate the work of the local area PPIE groups (orange, to right hand side of Figure 1).

In addition to these groups there are a number of collaborators from other organisations, specifically the West of England AHSN, West Midlands AHSN, Ardens (supplier of the template), the Year of Care Partnerships, NHS England and NHS Improvement, NHS Hampshire and Isle of Wight STP.

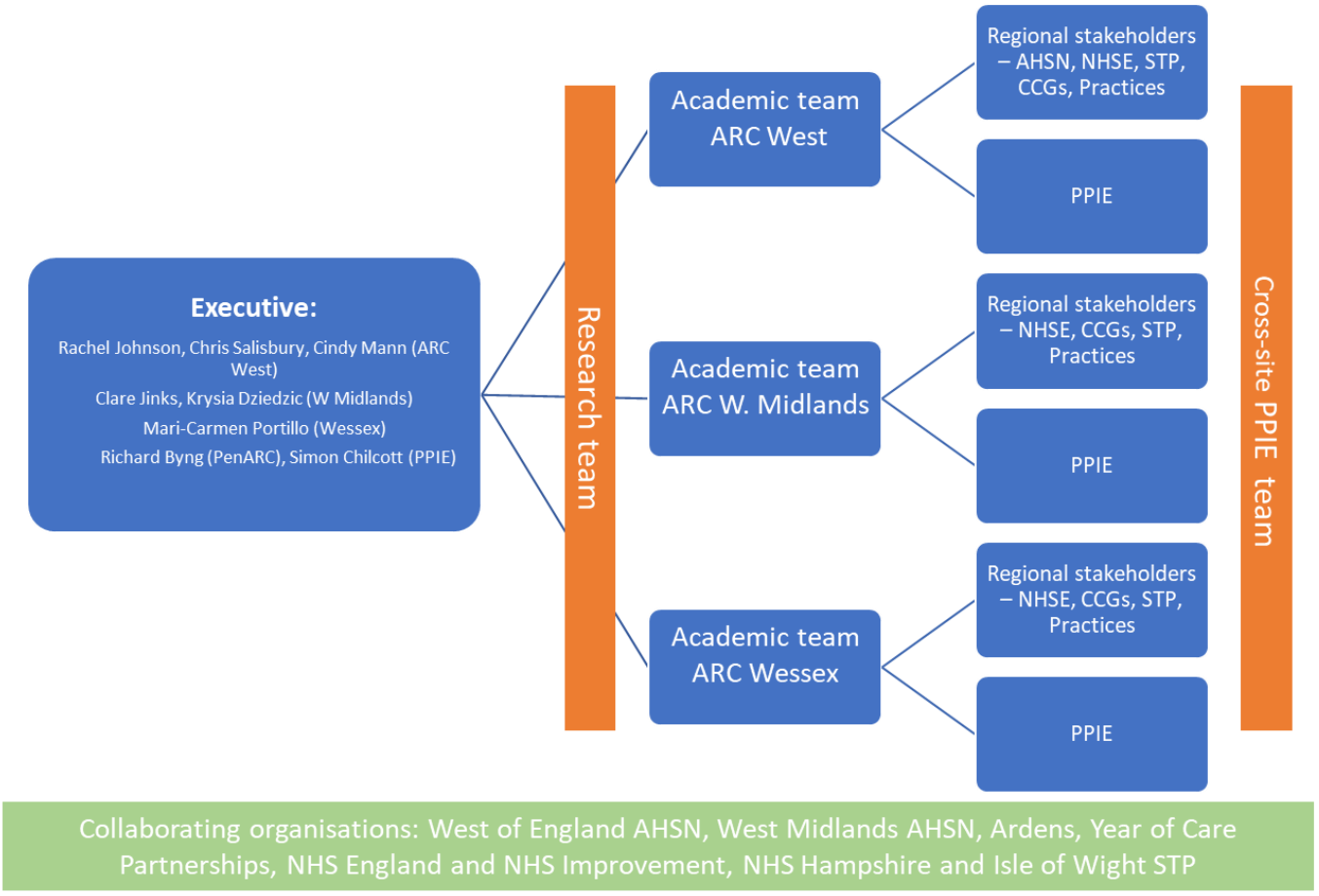


Figure 1. Study management

PATIENT & PUBLIC INVOLVEMENT AND ENGAGEMENT (PPIE)

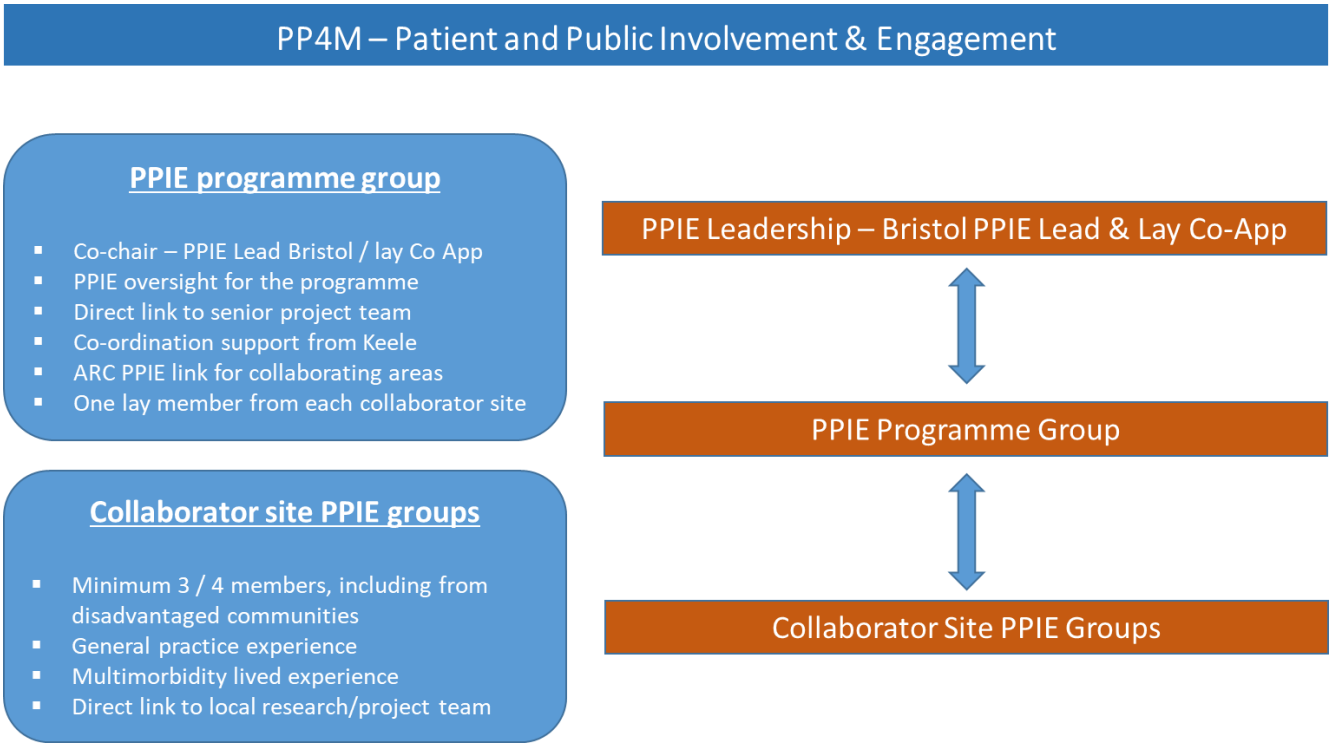
Our PPIE will build on active, diverse and established groups in each ARC area, that will continue into the project.

The Bristol group provided significant input into project design, including template wording, content of the patient preparation letter and evaluation measures that reflect what is most important to patients. Their recommendations include making an appointment with a known clinician, and providing choice in the way the practice communicates and provides consultations. Simon Chilcott, who previously contributed to the 3D study, is a co-applicant and will be a core team member.

For the project we will arrange sub-groups with public contributors from each of the three collaborating sites (see Figure 2) These groups will consider ways of encouraging patient engagement with the

reviews, implementation strategies and adaptive strategies for particularly deprived or under-served areas. We may also work through community groups in areas of health inequity to recruit additional public contributors to advise on barriers to care and inform local engagement strategy. A PPIE Programme Group will lead overall PPIE strategy, chaired by the PPIE lead from ARC West and the lay co-applicant (SC) and to include the PPIE lead and a lay representative from ARC Wessex and ARC W.Midlands. This Programme Group will collate feedback from the three local PPIE groups, and will have a direct link into the Executive (Figure 1).

Figure 2 Patient and public involvement and engagement



PROTOCOL CONTRIBUTORS

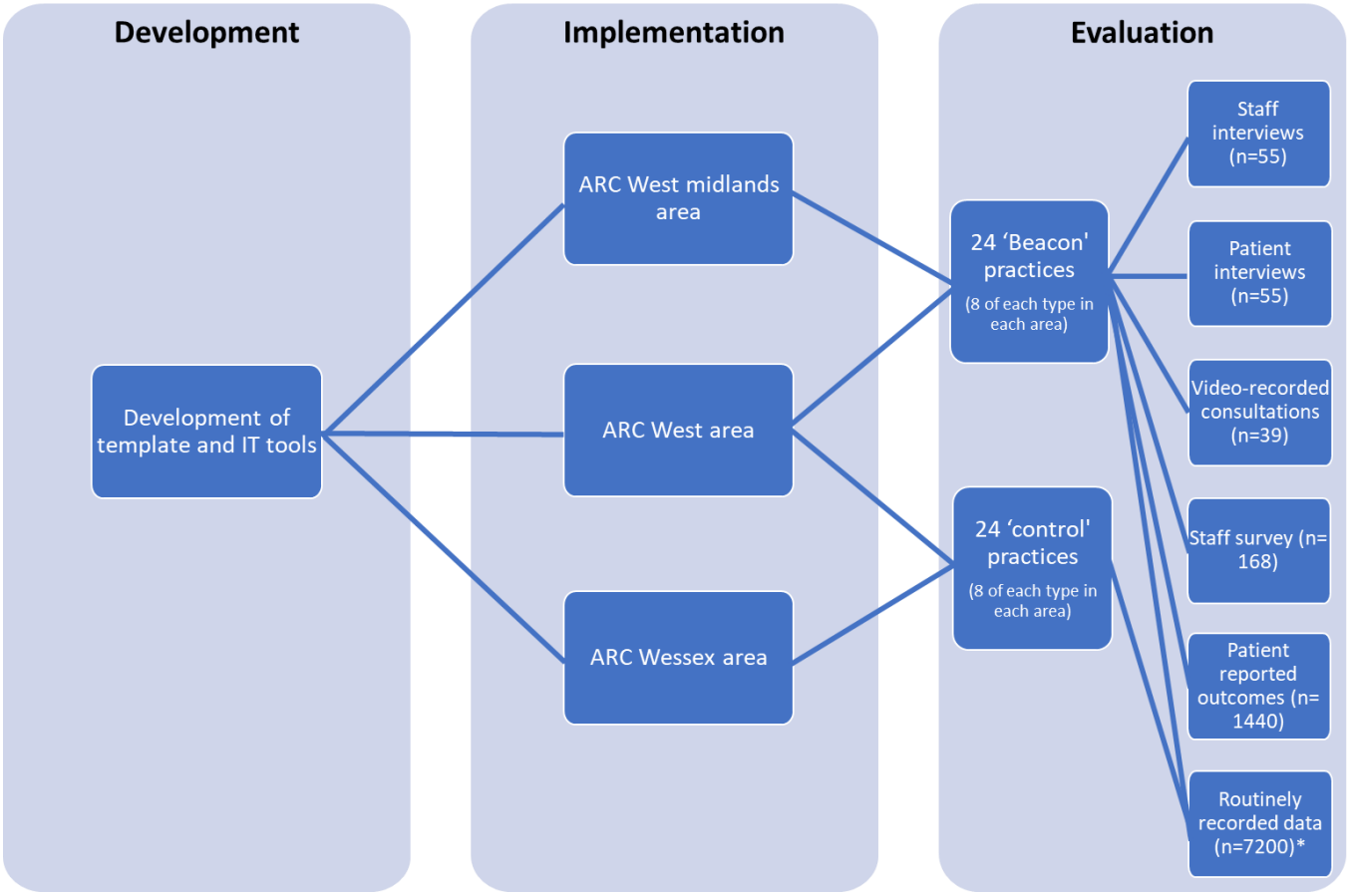
The protocol was designed by the co-PIs (Dr Rachel Johnson and Prof Chris Salisbury) in collaboration with the members of the core research team and specific methodological input from members of the extended research team (see Appendix 4).

KEY WORDS:

Multimorbidity; primary care; general practice; computers; patient-centred care

STUDY FLOW CHART

Figure 3 shows the flow of the study.



* NB in the control practices, only the routinely recorded data will be collected

See appendix 5 for a project GANTT chart.

STUDY PROTOCOL

Personalised Primary care for Patients with Multimorbidity (PP4M) – a primary care service improvement initiative.

1) BACKGROUND

General practices regularly review patients with long-term health conditions included in the Quality and Outcomes Framework (QOF), using different computerised templates (checklists) for each disease.[1] However, many patients have multiple long term health conditions (also known as multimorbidity). Reviewing each condition in isolation leads to fragmented care for patients and can ignore conditions that are not included in QOF, which are sometimes the problems that bother patients most.[1,2] Being invited to repeated reviews for each of their conditions is inconvenient for patients and undermines a 'whole-patient' perspective.[2] In the NHS Plan it is a priority to make care more personalised, based on the NHS Comprehensive Model for Personalised Care.[3] This model includes supported self-management, care and support planning, shared decision making, and links to social prescribing. Although the elements within the Comprehensive Model for Personalised Care (e.g. supported self-management) are evidence-based, how best to support implementation within general practice is unclear.[4,5]

As well as providing fragmented care to patients, the use of different templates to review each long-term condition is inefficient for general practices because there is a large element of duplication (for example, many templates include questions about smoking and blood measurement). Some practices have introduced combined annual reviews, at which they review all of the patient's conditions at once. This can mean that care is organised around the patient rather than by one disease at a time. In order to support this holistic type of care, practices have either used home-made or commercially produced templates. However, these combined templates are difficult to design and have almost always focused on meeting the requirements of the Quality and Outcomes Framework (QOF)[1] rather than promoting personalised care. There is evidence that the design and use of templates tend to shape the nature of consultations,[6] and could be used to encourage more personalised consultations.[7]

In this project we will implement and evaluate a highly functional integrated multimorbidity review template which, while fulfilling QOF, also supports practices to offer the key elements of the Personalised Care Model. This is a 'smart' template, which uses algorithms so that only questions relevant to the individual patient and their combination of conditions are included. The template supports the clinician to make care more personalised by guiding them to ask about what matters most to patients. By focusing on the patients' priorities and perceived needs the template can help to support self-management and shared decision-making. The template also includes links to social prescribing and pharmacist review of complicated medication, and involves agreeing a care and support plan, while also meeting QOF requirements. The template has been made widely available to general practices, and in this project we will support its implementation with training and other tools e.g. to identify patients with multimorbidity, and to incorporate use of patient-reported outcome measures. We will also work with CCGs, AHSNs and primary care networks in three areas to encourage use of the template. To reduce health inequalities, we will prioritise implementation in practices in deprived areas and our evaluation will focus on patients with multiple long-term conditions that include at least one cardiovascular disease.

The template builds on the positively-evaluated 'Year of Care' approach[8] and findings from the 3D trial.[5] Randomised trials of 3D and similar interventions have shown that a combined patient-centred review achieves the aims of the Personalised Care model to support people with long-term health conditions to build knowledge, skills and confidence and to self-manage their health conditions, (e.g. evidenced using the Patient Assessment of Care for Chronic Conditions (PACIC)).[5,9] Although there is little evidence that any multimorbidity intervention improves clinical outcomes or quality of life,[9] improving the personalisation of care (which includes patients' experience of care, their ability to self-manage, and their sense of agency in their care) is an important and worthwhile aim in itself.[10]

The multimorbidity template has been adapted from one already developed and provided by Ardens, the leading supplier of general practice templates in England. It has been made available at no additional cost to practices subscribing to Ardens (about 50% of all practices in England).

This project is relevant to any patient with multimorbidity. This is a more appropriate model for delivering primary care than attempting to design different interventions for every combination of diseases, which would increase segmentation of services and reduce person-centred care. The template designed here to support care for patients with multimorbidity can also be used with patients with many single long term health conditions that require regular review, so one 'smart template' can be used with a wide range of patients which aids implementation. Although practices may choose to use the template with patients with single conditions, this study will only include its use in patients with multimorbidity.

In this project we will support and encourage implementation of the multimorbidity template across multiple primary care networks, investigate facilitators and barriers to implementation, and provide evidence of impact in meeting the aims of the Comprehensive Model for Personalised Care. In a small sub-set of practices, we will explore the benefit of a wider service change (labelled 'Maxwell', to reflect maximising well-being), by facilitating community engagement in implementation, together with support and in-depth training from Year of Care Partnerships, in addition to provision of the template and associated tools.

2) RATIONALE

This intervention is designed to balance a number of considerations:

- Improving personalised care is one of the main priorities in the NHS Long Term Plan. This requires attention to each patient's context, needs and priorities in order to individualise care. Meaningful support for self-management requires time in consultations to understand these issues and to discuss alternative treatment strategies.
- This individualisation needs to be balanced against the increasingly protocolised nature of modern health care in order to standardise care, illustrated by pay for performance schemes such as QOF and the use of computerised templates, The aim of this standardisation is to improve the technical quality of care but there is a risk that personalisation and patient choice are neglected.
- Against a background of increasing demands on primary care, but a static or declining GP workforce, primary care teams are increasingly delegating care to less highly trained staff, and seeking ways to maximise productivity.

The use of 'smart' templates is one way to balance these competing priorities. Smart templates use algorithms to ensure that questions that are relevant to the individual patient are included, but questions are excluded if they are not relevant to the patient because of their age, sex, health conditions, medication or previous care. Our approach of introducing personalised care by means of a template recognises the benefits of standardising care and the way in which templates can provide structure and support for less experienced staff so that important aspects of care are not overlooked. However, by including topics such as screening for mental health problems, exploring medication adherence, and identifying patient goals within the template, these aspects of care which are also important but not included within the QOF (and therefore often overlooked) can be prioritised. There is evidence (see above) that the template approach is both feasible and effective. However, the templates and strategies developed for research studies such as the 3D trial have not been widely introduced, partly because of problems with implementation. This implementation study seeks to work with an experienced commercial provider of templates for primary care to overcome these implementation difficulties.

We have had discussions with key individuals in three areas of England (Bristol/Gloucester/Somerset in the ARC West area; Stoke-on-Trent/Staffordshire in ARC west Midlands; Hampshire in Wessex ARC), including STP/ICS leaders responsible for Personalised Care strategy, CCG medical directors

and representatives of primary care networks. These discussions highlighted that many general practices support the personalised care concept, but feel overwhelmed by rising workload. They focus on QOF as the essential review activity, while recognising this is insufficient for patients with multimorbidity.[1] Any move towards personalised care for multimorbidity needs to build incrementally on how care is provided currently, without generating excessive new workload, and to make good use of the skills of the multi-disciplinary team. Using a template to support personalised care, building on templates designed to meet QOF requirements, and supporting clinicians from different backgrounds to contribute to care in a standardised way, meets these needs.

This study will provide lessons and evidence about the benefits of a patient-centred template for multimorbidity which can then be rolled out nationally, beginning with the existing Ardens subscription base.

We recognise that a template is just one element needed to support a wider whole system change to improve care for patients with multimorbidity in primary care. Meaningful change in patient outcomes will also require additional training for practice staff, organisational change to improve continuity of care, and incentive structures to encourage personalised care. The long-term aim of the research team is to develop a new model of care which incorporates these elements, labelled 'Maxwell'. The Maxwell approach includes the following elements:

- Offer whole person longer reviews designed around the person, not the diseases
- Provide information so the person can prepare for their review
- Elicit the person's agenda, priorities and preferences
- Promote continuity of care to support the patient/clinician relationship
- Include all aspects of health in reviews: physical, mental and quality of life
- Personalise treatment to take account of all conditions and optimise clinical care
- Reduce unnecessary tests, prescriptions and appointments
- Support self-management through use of non-medical resources, including social prescribing, local community provision and digital resources
- Arrive at decisions and plans in collaboration and share them in writing

The template which is the main subject of this protocol is an important and necessary step to support this system change. However, we also have the opportunity to explore the feasibility and potential benefits of other aspects of the Maxwell approach in a small subset of practices in the Bristol area. Within the 24 practices included in this study, Bristol, North Somerset and South Gloucester (BNSSG) have provided funding for three practices in deprived areas to receive additional support and training from Year of Care Partnerships. Year of Care have considerable experience of helping practices re-organise their systems for supporting patients to self-manage their long-term conditions, and in particular offer training in consultation skills to encourage a more collaborative and patient-centred conversation with patients.

The extent of training available to the other 21 participating practices will be more limited and variable, and will depend on the resources made available by CCGs, primary care networks and AHSNs in local areas. One focus of interest in this research will be how the type and depth of training provided to practices affects the successful implementation of the template.

THEORETICAL FRAMEWORK

Normalisation Process Theory (NPT)[11] will inform the strategies used to promote implementation of the template, as used in another recent study.[12] NPT provides a framework for understanding how new practices become accepted, embedded and integrated into normal working life within complex organisations. In the context of this study, it will include a focus on examining how practitioners make sense of the template by considering its relevance, appropriateness, workability and added value to their existing practice. NPT posits that working practices become normalised (or not) through a process of sense making (coherence), active engagement (cognitive participation), working together to

enact the change (collective action) and informal reflection and formal evaluation (reflexive monitoring).

As well as informing strategies for implementation, the NPT framework will also be used to structure the evaluation. We will combine use of NPT as a substantive theory with a realist approach which seeks to understand causal processes through elucidating context-mechanism-outcome configurations (commonly described as 'what works, for whom, and in what circumstances?').[13] There is increasing interest in combining these approaches, although there has been limited discussion of the theoretical implications of combining these two different methods.[13] We will add to the literature by reflecting on our experience of these methods in combination in this evaluation.

NPT is based on an implementation science paradigm, but this project also includes some strategies drawn from quality improvement methodology.[14] For example, implementation and evaluation will be iterative, with repeated cycles of collecting data, feeding back findings to practice teams and making changes to the intervention in order to improve implementation.

3) RESEARCH QUESTION/AIM(S)

Aims

The research aims are:

1. To explore the most effective strategies to implement a template to promote personalised care in patients with multimorbidity.
2. To examine under what circumstances, for which patients and in what ways the template leads to benefits for patients and/or practice staff.

Objectives

1. To optimise an existing multimorbidity template already provided by Ardens and include more patient-centred elements in line with the NHS Comprehensive model of Personalised Care
2. To implement this template in general practices in three areas of England, supported by West of England AHSN, Keele Impact Accelerator Unit and local CCGs.
3. Through interviews with general practice staff to understand factors that lead to, or impede, implementation of the multimorbidity template in general practices in these three areas. This includes how training influences implementation.
4. Using the NOMAD questionnaire based on an NPT framework, to understand the extent to which the template becomes normalised within general practices
5. Through analysis of quantitative data from practice records, to explore the extent of implementation and factors influencing uptake of the multimorbidity template.
6. Through consultation observations and interviews to examine the different ways in which staff use the template
7. Through qualitative research based on interviews, analysis of patient reported outcome measures and direct observation of consultations, to examine under what circumstances, for which patients and in what ways the template leads to benefits for patients and/or practice staff.
8. Through interviews with patients and staff, to explore how the template and its implementation could be improved to ensure wider adoption and reach.
9. To explore the feasibility of the Maxwell approach to broader system change to support patients with multimorbidity in a sub-set of practices which receive training from Year of Care Partnerships in addition to the template.

Deliverables

The deliverable benefits from this study will be:

- Evidence about the feasibility and potential impact of a personalised template to support review and self-management in patients with multimorbidity.
- Understanding of factors which determine the implementation of the template and the way it is used, with recommendations on how to ensure effective implementation.

4) STUDY DESIGN

This is a concurrent mixed methods study,[15] in which qualitative and quantitative data collection is inter-woven in order to meet the overall study aims.

5) SETTING

General practices and their local commissioning organisations in three areas of England: Bristol/Gloucester/Somerset within ARC West; Stoke-on-Trent/Staffordshire (ARC West Midlands); Hampshire (Wessex ARC).

Bristol, North Somerset and South Gloucestershire CCG covers a diverse population of 1 million people living in a range of urban and rural areas. The CCG commissions care from 81 GP practices as well as hospital and community services. BNSSG CCG and its partners in the BNSSG Integrated Care System (ICS), are committed to supporting personalised care.

Staffordshire and Stoke-on-Trent STP includes practices in the following 6 CCGs: North Staffordshire; Stoke on Trent; South East Staffs & Seisdon; East Staffordshire; Cannock Chase and, Stafford & Surrounds. These CCGs are part of the 2 Integrated Care Partnerships (ICPs) in Staffordshire, both of whom have identified long term conditions/multi-morbidity as a priority in the restoration and transformation plans moving forward.

Hampshire and Isle of Wight Sustainability and Transformation Partnership STP) comprises NHS and local authority organisations, serving a population of >1 million people. A key priority in the STP is the development and implementation of personalised care strategies (https://personalisedcare.hiowhealthandcare.org/) across the CCGs connected to the partnership. The STP includes four CCGS; in this project we will be mainly working with North Hampshire CCG.

The prevalence of multimorbidity is strongly linked to deprivation. There are areas of deprivation in all of these CCGs, particularly around Stoke-on-Trent/Staffordshire, and with further examples in Bristol (including 3 areas amongst the 1% most deprived in England) and areas of deprivation around Portsmouth and Southampton in Hampshire. We will prioritise implementation in practices with above average deprivation (in the top five deciles for deprivation measured using Index of Multiple Deprivation), ensuring that the majority of the 'beacon' practices we select for detailed research are from these areas. The template and patient materials will be designed to ensure they are suitable for use with patients in deprived areas, for example being easy to understand by patients with limited education or without English as a first language. In the three practices testing the Maxwell approach we will also undertake community engagement and co-production involving community representatives, to optimise access to, and uptake of the reviews, as well as providing training from Year of Care.

6) METHODS

The methods are described under three headings:

- Development of the template
- Implementation
- Evaluation

7) THE INTERVENTION: DEVELOPMENT OF TEMPLATE (OBJECTIVE 1)

Content of template

Ardens produces templates on a wide range of topics, and these are made available to practices that subscribe to their services. About half of all general practices in England subscribe to Ardens. Ardens have previously developed a pair of templates ('initial assessment' and 'annual review' templates) which seek to enable a review to cover all of the requirements of the QOF for patients with multimorbidity. Throughout this application we will refer to these as the multimorbidity template (singular) since they are the first and second part of the same template. The original Ardens multimorbidity template was effectively a concatenation of existing disease specific templates. It was therefore very long and included a large element of duplication. It focused almost entirely on meeting QOF requirements and did not include some other elements of good clinical practice for these conditions. The original template only included diseases which are included in the QOF framework therefore other common and important conditions (e.g. hypothyroidism, dementia, epilepsy) were not included. The original template did not include elements which are considered important priorities for personalised care, such as promoting self-management and care and support planning.

The research team have worked with Ardens to improve their existing template. This builds on the experience of the research team in developing a template for the intervention evaluated in the 3D trial, which itself was informed by extensive patient and public involvement. Plans for the template also involved the Year of Care partnerships, an organisation with considerable experience of training general practices to implement care and support planning for patients with long term conditions. The key changes to the template include:

- Meeting the requirements of the main groups of patients that require regular review in general practice, whether or not these conditions are included in the QOF framework
- This includes patients identified as frail, irrespective of specific diagnoses
- Inclusion of all essential items of good practice, whether or not incentivised by QOF
- Starting the annual review by asking patients about 'what matters to you?'
- Questions about mental health, memory, well-being and quality of life
- Questions about difficulties with medication and about medication adherence
- Links to relevant good practice guidance e.g. from NICE and to online tools (e.g. QRISK for cardiovascular risk assessment; PHQ9 for screening for depression).
- Prompts to consider social prescribing to encourage involvement with local community organisations.
- Patient preparation: encouraging patients to reflect on and write down their main aspirations for improving their health in advance of the appointment
- Care and support planning: supporting a conversation at which goals and actions are discussed, agreed and recorded, as a way of supporting patients' sense of engagement and responsibility for their health
- Sharing test results and treatment plans in writing with patients, to reinforce their involvement

The revised and personalised template has been made available to all Ardens subscribers, following a 'soft launch' in November 2021. In this project we will encourage implementation of the template, study factors associated with facilitators and barriers to implementation, and identify ways in which the template could be further improved.

Use of the template

Patients will be invited for annual review in their birthday month. In most cases, the review includes an initial appointment with a health care assistant to collect information and take blood tests, guided by

the initial assessment template. Following the initial assessment, patients will be sent a letter that includes their test results and prompts to think about how they would like to improve their health, in preparation for their clinician review. At this consultation a nurse or GP, guided by the annual review template, will review the information and agree a care and support plan with the patient. Patients will make their own plan during the consultation, with summary details entered by the clinician in the medical record. The template will prompt clinicians to review patient's medication, and in some practices patients will have their medication reviewed in detail by a practice pharmacist before the consultation. Problems identified during the annual review will be followed up through normal primary care appointments or referrals as necessary.

Supporting tools

In addition to the template, we are using or developing a number of tools to enable implementation. Some of these tools are based on those already provided by Ardens or developed for the 3D trial:

- A tool to identify patients with multiple long-term conditions covered by the template
- A recall system to enable the identification and recall of patients needing an annual review
- Training to use the recall system and to use the template, through webinars. In three practices in Bristol we will provide more extensive training from Year of Care Partnerships.
- Technical support, from Ardens
- Standardised mail-merge formats for personalised letters and reports for patients, which summarise their test results and prompt them to consider their health goals. These letters have been developed by Year of Care partnerships.
- A mechanism for patients to be sent questionnaires before and after their annual reviews. These questionnaires will consist of a brief patient reported outcome measure, and it will be possible to complete it online or on paper.

8) IMPLEMENTATION (OBJECTIVE 2)

The implementation strategy is intended for use by each study site to guide the implementation process and provide iterative feedback between the research and implementation teams and general practices to ensure that key learnings are actioned in real time. The process is 'non-linear' and will be co-ordinated by the implementation steering group. The implementation strategy will be delivered in partnership by NHS commissioners and the research team, guided by the Keele Impact Accelerator Unit whose experience includes implementing NICE quality standards in primary care using electronic templates. [16]

Working groups will be established in each of the three regions, including representatives from the ARCs (including multi-morbidity leads CS, MC, KD, AF), the core research team, local Integrated Care System multi-morbidity groups and Primary Care Networks, leads for personalised care from the local ICS or STP, and with regional AHSN support. These working groups will co-ordinate the process of advertisement and roll-out to local practices, and the selection of 8 'beacon' practices in each region who will participate in the evaluation. They will also co-ordinate training, on-going support and local data collection.

The implementation strategy has been informed by implementation theory (Normalisation Process Theory, NPT),[11] a Knowledge Mobilisation Toolkit for Primary Care,[17] and an established track record in researching and delivering implementation in primary care.[18] Using a whole practice approach, we will identify and map barriers and facilitators to implementation of the intervention, develop and describe the strategies to mitigate the impact of barriers and reinforce facilitating factors, and explore the effectiveness of these strategies. Our understanding of barriers and facilitators to implementation will evolve during the study, based on feedback, lessons learnt, findings from the NoMAD questionnaire (an instrument aligned with NPT, used to understand stakeholder views about how the

intervention impacts on their work, and their expectations about whether it could become a routine part of their work) with staff, and the interviews with staff and patients.

Table 1 illustrates the implementation strategy, providing an overview of the four constructs of NPT, the relevant implementation strategies, and the key stakeholders involved.

NPT Construct	Implementation Strategies to consider	Key stakeholders involved
Coherence – the sense making work that people do individually and collectively to understand the intervention purpose and value. GPs have to be convinced of patient need in relation to the problems they encounter in everyday consultations, particularly with regard to their own perceptions of being able to offer patients effective care. PP4M needs to be believable and promise real benefit to either facilitating GPs' work or to patients. The symbolic significance of the template is crucial because its 'fit' with clinical routines will determine uptake. To ensure that GPs understand the purpose of the intervention and what they are expected to do, sufficient time for training and ongoing support has to be agreed. Finally, the research team should demonstrate sensitivity to the local context, especially the unique characteristics of each general practice.	• Preparation of resources (including patient and/or practitioner stories) to demonstrate case of need/benefits of intervention • Identify nominated implementation lead/champion for each region • Prepare a video pitch for the concrete proposal for change, with the CI and PPIE, year of care, Ardens • Engage and establish credible practice teams – to include research champion, clinical champion (discipline specific) and patient champion (from practice PPG or LINK group) • Identify two early adopting sites in each region and confirm eligibility and consent • Arrange the initial 'Practice sell', identifying the appropriate person with a strong understanding of current practice pressures; introductory meeting with short presentation from research team (Chief Investigator video, in Video, Ardens, YoC) (then, short weekly practice meeting slots advised to discuss and understand ongoing usage and implementation issues) to better understand practice context and how the template will fit with existing processes, meet key decision makers, understand potential barriers to usage and implementation, drivers, and motivators, help practices to identify the relevance, appropriateness, and added value of the intervention, and identify where support or adaptation may be required at an individual and organisational level • Launch event with a focussed topic	Research team Practice staff (GPs, nurses, practice managers) Patients and the public (from local PPG, charity or LINK group) Regional working groups CRN, AHSN
Cognitive Participation – the relational work that people do to build and sustain a community of practice around the new intervention, to contribute to the work involved in getting sustained buy in/ engagement with the intervention	• Establish and host a local Community of Practice around multimorbidity and draw upon outputs to further inform the local implementation plan (further opportunity to hear about local contextual issues and identify how the template will fit with existing processes) • Training on the template by Ardens will be delivered to show stakeholders how it supports their professional identity of caring for individuals rather than diseases (consider use of patient simulation to test the template at part of the training).	Practice staff (GPs, nurses, practice managers) CCGs, local Primary Care Networks, West of England ANSN Regional working groups

	• Promotion of the template and Q&A opportunity, using message-boards to share ideas. • Practice discussion of how best to operate their recall system and use the template to meet their local needs. This should include discussion and clarification of roles and responsibilities and nomination of a personalised care lead for each practice. • Consider fit with existing MM reviews	Patient and Public voice
Collective Action - the work of putting the intervention into operation, enacting the new approach in practice In identifying and defining roles and responsibilities, decide a nominated lead (and responsibilities of lead); ensure protected time for training; engage whole practice in implementation ensuring all staff are aware of the project	• Adopt a whole practice approach (all practice staff should be aware of the new approach being adopted so encourage sessions where all staff can be present), taking local contextual issues (identified at practice sell/launch event/Community of Practice) into consideration • Training for practice staff via webinars and online training materials to address individual and operational considerations e.g. recall systems. • Allow sufficient time for training and ongoing support, working with practice leads to allow sufficient time for training which is targeted at all staff - a light touch training for other staff less involved. • Further training will be available from the NHS Personalised Care Institute https://www.personalisedcareinstitute.org.uk/ • Understand integration – if staff already complete MM reviews, how will the template fit with existing processes? Are staff able to operationalise the template components in practice? • Analysis of target group and setting with the first early adopters • Develop and collect a set of strategies and measures to change practice	Practice staff (GPs, nurses) Ardens Research team
Reflexive Monitoring – the appraisal work that people do to assess and understand the way that the intervention affects them/their team The Implementation Steering group will meet monthly to act on emerging feedback and results. Monthly meetings with qualitative researchers to understand emerging insights from evaluation	• Identify challenges at a practice level and during consultations, and explore barriers and facilitators to continued use • Identify any adaptations required to optimise implementation from staff and patient perspectives • Local data collection • Consider early use of NOMAD to diagnose implementation problems. • Findings from ongoing qualitative and quantitative evaluation will be fed back to the practices concerned and publicised locally to encourage wider adoption, and through peer-reviewed reports to encourage national spread. • Further development, testing and execution of implementation plan	Implementation steering group Research team Practice staff (beacon practices)

9) EVALUATION OF IMPLEMENTATION (OBJECTIVES 3 TO 8)

Evaluation will be based on synthesis of findings from qualitative and quantitative data collected from patients, staff and routine records, as described below. Since this is a pragmatic implementation project it is important that evaluation has minimal impact on patients and staff to ensure that it reflects 'real-world' care. As far as possible, evaluation will be conducted using pseudonymised routinely collected data, apart from a small number of patients and staff invited to take part in interviews or video-recorded consultations.

Qualitative data collection

Given the recent Covid-19 pandemic we will offer maximum flexibility in how we conduct interviews, depending on the purpose of the interview, the preference of the interviewee, and guidance about social distancing in operation at the time. As far as possible we will offer the choice of face-to-face, telephone or video (e.g. Zoom) interview.[19] For the same reasons, we will offer maximum flexibility in how we record consultations. We will include options to video-record in-person consultations, and, if annual reviews are not being conducted face to face, to audio-record phone reviews and video-record video consultations as appropriate and feasible. Patients participating in interviews or recorded consultations will be offered as £10 voucher as a thank you for taking part. Patients participating in both components will be offered two vouchers. Qualitative data will be collected in three purposively sampled general practices in each of the three regions, and in the additional three general practices in areas of socio-economic deprivation in BNSSG who receive additional training from Year of Care partnerships as described above.

Patient interviews: We will invite a purposive sample of patients to participate in interviews about their experience of care in general practice for their long-term health conditions, and about their experience of their consultations after the template has been introduced. The interviews will be based on a topic guide and explore the extent to which the template altered the nature of their consultation, whether it increased their sense of personalisation, choice and control in their care, and whether it will lead to any change in their self-management behaviours. The topic guides will be refined iteratively as interviews and preliminary analysis progress. These interviews will be recorded and fully transcribed for analysis. The inclusion criteria, sampling, sample size, recruitment and analysis are described later. It is possible that we may interview some patients in a focus group rather than individually, but the approach to patient recruitment and the topic guide will be the same.

Recorded consultations: We will invite a purposive sample of patients to participate in recorded observation of their review consultations at which the new template is used to understand the part it plays in the review and the interaction with the patient. For in-person reviews we will set up a camera with a wide-angle lens to capture both the patient and the clinician, ensuring that there is a clear view of the clinician and how they use the computer. The camera will be positioned so that the examination couch is not visible. Healthcare practitioners will switch on the camera when the patient comes into the consulting room and switch if off when the patient leaves. Patients and healthcare practitioners will give fully informed written consent and their consent will be re-confirmed after the consultation. For reviews taking part by telephone or video-consultation, the healthcare practitioner will, with the patient's agreement, record the consultation audio or video as appropriate and feasible. The healthcare professional will begin recording at the start of the consultation and stop recording at the end of the consultation. The patients taking part in recorded observations will also be invited to be interviewed and form part of the sample described above.

Staff interviews: Practice staff involved in using the template, and administrative staff involved in organising the reviews, will be invited to take part in an interview. The interviews will be based on a topic guide that focuses on staff attitudes to personalised care, the contribution of the template to promoting personalised care, its functionality and clarity, and staff perceptions of the usefulness of different aspects of the template (e.g. questions about patients' goals, medication adherence, mental health etc). The interviews will also explore difficulties with the template and ways in which it could be improved. The extent of training for managing review consultations will vary between practices and

staff within practices, and in particular the staff in the three Maxwell practices will receive additional training from Year of Care partnerships. The usefulness of training received will be an additional focus for the interviews. The topic guide will be informed by the NPT framework and will be refined iteratively as interviews and preliminary analysis progress. Some of the staff interviewed will be those who have been involved in video-recorded consultations, and in these cases the recorded consultation may be used as a prompt to aid discussion.

Quantitative data collection

Descriptive data about practice characteristics at baseline

We will collect details of practice list size, staffing, deprivation and CCG from routinely available NHS Digital datasets.

Patient reported outcome measures

There is increasingly interest within the NHS in using patient-reported outcome measures in the context of routine care, to inform clinicians about the needs of individual patients and as a quality improvement method, rather than as research tools. We will seek to implement this principle by asking patients to complete a brief patient-reported outcome measure before and 2 months after their annual review consultation. We view this as part of the intervention rather than as a research tool. We will send practices regular reports about aggregate results from their patients' responses, so they can identify problems and/or improvements over time in, for example, whether patients thought their care was well co-ordinated. We will ask patients to complete the Person-Centred Coordinated Care Experience Questionnaire (P3CEQ).[20] Practice administrative staff will send patients the initial questionnaire when they send their appointment for their multimorbidity review. Patients will be asked to return their questionnaire to the research team for analysis. The questionnaire will invite patients to give their consent to the research team sending them a follow-up questionnaire 2 months after the consultation.

Routinely collected data

These data will be used in three ways.

Cohort details: First, details will be extracted from the computerised record system within each participating general practice. Full anonymous data will be provided about the total number of patients in the practice, and the number meeting the eligibility criteria by age-group. The eligible patients form the cohort for the study. We will collect pseudonymised data about the characteristics of the cohort, including the number with each of the chronic diseases which define the eligibility criteria (see page 23), their age-group, month of birth, sex, ethnicity and deprivation (Index of Multiple Deprivation decile). Month of birth is necessary for the difference in difference analysis described later.

Process and outcome measures: Patient-level data will be extracted about the process and outcomes of care for the eligible cohort of patients before and after implementation of the template. This will include details of whether patients were invited for a long-term conditions review, whether they attended, the level of completion of different aspects of the review, number of drugs prescribed, number and duration of consultations in primary care, and indicators of clinical control eg BP, HBA1C). All of this data will be extracted in pseudonymised form from the computer system and only identified by a pseudonymised ID from which the research staff cannot identify individual patients. This pseudonymised ID is a long alphanumeric code generated automatically by the EMIS software, and not the same as the patient's EMIS number which is the standard identifier used within EMIS practices. We will ensure that no features are included which raise a risk of identification e.g. we will use age-group and month of birth rather than date of birth, deprivation decile rather than post code, and will only include details of common long-term conditions so that patients cannot be identified through having a particular rare condition. Details will be collected for the period from 1 April 2021 to 31 March 2023.

We will collect fully anonymised data about the number of adult patients with whom the template was used, and the age and long term conditions of those patients, whether or not they are included in the

cohort of patients with multimorbidity. This is to explore the extent to which practices use the template in patients with long-term conditions who are not included in the multimorbidity cohort, including, for example, those with single conditions.

Resource utilisation: Third, we will collect data necessary to assess resource utilisation from an NHS perspective. In addition to the variables listed above, we will collect details of the number and types of hospital admissions, outpatient referrals and emergency department attendances. We may collect these data from general practices as above, but we have experience of extracting this information from routine primary care records and recognise that it is not always reliable. We will therefore explore the feasibility of obtaining Secondary Uses Service (SUS) data in linked anonymous form from an NHS Commissioning Resource Unit or from a CCG level system wide dataset. Resource utilisation will be calculated based on the number and types of consultations in primary care (and secondary care, subject to data availability) and the number, type and quantities of drugs prescribed.

All of the above data listed under the heading or 'Routinely collected data' will also be collected in about 24 control practices, for comparison with the intervention practices in which the template has been actively promoted and implemented.

Staff questionnaires

All members of staff who are involved in using the template in the 24 beacon practices will be asked to complete a NOMAD questionnaire, which explores the extent of coherence, cognitive participation, collective action and reflexive monitoring (the key constructs from the NPT framework). These questionnaires will be sent after staff have had at least 3 months experience of using the new multimorbidity template. Practice managers will distribute these questionnaires which will be returned to the research team in pseudonymised form, using staff code numbers not identifiable by the research team. We will offer completion of the questionnaire either online or on paper. The research team will inform the practice manager about the ID numbers of people who have responded and s/he will send up to two reminders to non-participants.

Eligibility criteria

Practice eligibility

To be eligible, intervention practices will need to:

- Use the EMIS practice computer system. The template is currently only available for EMIS. However, if this study shows it to be a valuable resource we envisage that a similar template will be developed for other computer systems.
- Have a subscription to Ardens templates. Ardens have developed the template to the specification of the research team, free of charge, by modifying one of their existing templates. We have made suitable arrangements for intellectual property so that if the template proves to be a valuable resource the research team can use their foreground IP to work with other suppliers to develop their own templates which fulfil similar purposes and design principles.
- A practice list size of at least 5000 patients. Very small practices will not have sufficient patients fulfilling the eligibility criteria to meet the sample size requirements.

Control practices will need to have >=5000 patients and use Emis, but not necessarily a subscription to Ardens.

Within the area covered by BNSSG CCG, we will invite 3 practices to implement the full Maxwell approach, including more in-depth training from Year of Care Partnerships, funded by the CCG. These practices will all be in areas of above average deprivation.

Patient eligibility:

Patients are eligible for inclusion if they are:

- registered with a practice that agrees to take part in the evaluation
- aged 18 or over
- have at least three of the types of chronic health condition listed below, including at least one of those asterisked (these are conditions which are already subject to annual review).
- are due to be invited by their practice for an annual review of their chronic conditions at the practice within the next 12 months

Note that the final inclusion criterion above will automatically exclude some patients who would not be invited for annual review under normal circumstances, for example if they have a terminal illness. It also excludes some patients who are housebound or in a nursing home if it is not possible to conduct the same type of 'template-based' review away from the surgery. In some cases, practices offer 'virtual' reviews for these patients, and in such cases the practice will be encouraged to use the multimorbidity template. The usefulness of a virtual review will be dependent on the patient's combination of conditions and this will be left to the discretion of the practice and clinician.

The following chronic conditions are included because they benefit from regular review in general practice. Some conditions (e.g. the first group listed) are grouped so that two or more diagnoses within the group just count as one for the purpose of defining multimorbidity.

- Cardiovascular disease: Coronary heart disease*, hypertension*, heart failure*, peripheral arterial disease or chronic kidney disease (stage 3 to 5), Atrial fibrillation
- Stroke/TIA*
- Diabetes*
- Chronic Obstructive Pulmonary Disease* or Asthma*
- Epilepsy
- Depression OR Severe mental health problems (schizophrenia or psychotic illness)*
- Learning disability
- Rheumatoid arthritis*
- Dementia* or Frailty (severe)*: although not a single diagnosis, if a patient is on the frailty register it makes sense to do their annual review as part of this annual multimorbidity review, rather than calling the patient back again.

To be eligible for this study, patients must have at least one of the conditions asterisked, since these conditions already lead to annual recall in most general practices to meet the requirements of the QOF. Given the current pressures on general practice, it would not be feasible to create additional work in practices by asking them to recall patients that they do not recall already. However, when a patient is recalled on the basis of having one of the asterisked conditions, the multimorbidity template encourages review of all of the conditions listed above.

For the purposes of this implementation project we will prioritise and focus evaluation on patients with cardiovascular conditions and other co-morbid long-term health conditions. First, because cardiovascular conditions are more prevalent in deprived areas; second, because these common conditions account for the highest proportion of preventable deaths and; third, because starting with a specific patient group facilitates evaluation of clinical impacts. However, the multimorbidity template will be applicable and used with any patient with multimorbidity.

For the qualitative research where we need to approach patients for individual patient consent, patients' GPs will screen the list of potential participants and exclude any they feel should not be invited, for any reason. We will record the number and reasons for these exclusions. Patients lacking capacity to consent will not be eligible to take part in the interviews, recorded consultations, or the

questionnaires, but will be included in the collection of anonymised routine data (which does not require consent).

Sampling

Practice sampling

We will purposively sample general practices within the 3 study areas, seeking to recruit practices so that across the study as a whole there is wide variation in practice size and urban/rural location and in the characteristics of their patient populations in terms of deprivation and ethnicity. In particular, we will seek to ensure that more than half of the recruited practices are from areas of above average deprivation.

The new multimorbidity template will be available to all general practices in each area that subscribe to Ardens templates, but we will only conduct the evaluation in 8 purposively selected practices in each area, described as 'beacon' practices. Of these, 3 purposively sampled practices in each area will take part in the qualitative evaluation, and all 8 will take part in the quantitative evaluation. In addition all three of the Maxwell practices in BNSSG will take part in further qualitative evaluation focused on the impact of training on implementation and use of the template (see next paragraph) i.e. 6 of the 8 practices in BNSSG will take part in qualitative evaluation. We will initially recruit and conduct evaluation in 2 practices in each area in order to optimise implementation and evaluation processes before wider roll-out.

Within BNSSG, all practices in areas of deprivation will be invited to participate and to receive training from Year of Care funded by the CCG in order to explore the feasibility of the Maxwell approach. The first three practices which agree to receive the training and to use the template and to participate in the evaluation, will be accepted. These 3 practices will be included within the 8 practices recruited in the BNSSG area.

All staff contributing to annual reviews of patients with multimorbidity will be eligible to complete a NOMAD questionnaire, and a purposive sample of staff will be selected for interview to ensure variation in terms of experience, gender, ethnicity, type of general practice and professional type (including GPs, nurses, health care assistants, pharmacists, receptionists and administrative staff).

We will recruit the same number of control practices as the number of intervention practices, and will seek to ensure that the overall profile of control practices is as similar as possible to the intervention practices in terms of practice size, deprivation and region.

Patient and staff sampling

The aim is that healthcare practitioners in the participating practices will use the new template with any patient with multimorbidity having an annual review. Some practices may also choose to use it with patients having a review for a single condition, but these patients will not be included in this study. Some practices may decide not to use the template with all eligible patients, but will choose to start with a particular group of patients. We will be flexible in working with practices and the decisions about how they choose to use the template are one item of interest in the qualitative evaluation.

Practices will use their usual procedures to invite people for review. In many practices this is done using the patient's month of birth (so that patients with a birthday in June are invited for review each June) and we will encourage this approach.

We will collect anonymous routine data for the variables previously described for all patients meeting the eligibility criteria, and we will invite up to 4800 patients (an average of 200 patients per practice) to provide patient reported outcome data. Depending on the number of practices recruited, the number of eligible patients, and the response rate, we may invite more than 200 patients to complete the survey in some practices in order to reach our overall recruitment target.

We will purposively sample patients to take part in interviews and observation of their consultations, seeking to ensure maximum variability in terms of age, gender, ethnicity, and number and type of long-term conditions. We will aim to observe and interview patients and healthcare practitioners after a

mix of initial consultation and annual review consultations, and include both in-person and virtual consultations. We will aim to observe and interview a range of healthcare practitioners (healthcare assistants, nurses, GPs), some who are newer to using the template, and some who are more familiar with it, to better understand processes of normalisation. We will regularly review the profile of patients already recruited and use this to inform decisions about which patients to recruit subsequently.

Size of sample

We anticipate collecting qualitative data from the following numbers of individuals. Please note that we are over-sampling the qualitative data collected in the three Maxwell practices receiving the Year of Care training in order to understand their experience of that training and its impact on the use of the template.

- Audio/video-recorded observations of consultations (n=39 in total [8 interviews in each of 3 areas plus an additional 15 in practices exploring the Maxwell approach])
- Interviews with patients (n= approx. 55 in total [10-15 in each area plus an additional 24 in practices exploring the Maxwell approach])
- Interviews with staff (n=approx. 55 in total [10-15 in each area plus an additional 24 in practices exploring the Maxwell approach])

These numbers are estimates. The concept of 'information power'[21] will inform analysis, sampling and participant recruitment, which will be conducted in parallel to allow sampling to be refined as the project develops. Information power is a guiding principle in qualitative research, suggesting that the more information power the sample provides, the smaller the sample size needs to be, and vice versa.[21] In this study, excluding the Maxwell practices, the relatively small sample size is anticipated to be sufficient because the data will be focused and the participants will have rich experiences relevant to the research question. In the Maxwell practices the sample is larger to allow for exploration of the additional feasibility questions

For the quantitative data, we anticipate:

- NPT NOMAD questionnaire[22] from about 168 clinical staff (About 7 per practice in 24 practices)
- Routinely collected data about patients meeting the eligibility criteria (about 300 patients with multimorbidity in an average sized practice based on the 3D study,[5] about 7200 patients in total). Data about a similar number of patients will also be collected in control practices.
- Assuming an average of 200 patients per practice are invited for multimorbidity review, and 30% of these complete baseline and follow up surveys, equals 1440 patients providing survey data in total.

These estimates are based on collecting data on all patients who are invited for review over a full 12-month cycle. The size of the sample is primarily driven by the size of the relevant patient population and the number of reviews that practices might be able to conduct, but is sufficiently large to ensure that all estimates will have narrow confidence limits.

Sample identification and recruitment

Patient interviews and recordings of consultations

For the qualitative elements of the research, patients will be identified as potentially suitable by the research team using the pseudonymised routine data, in line with the purposive sampling approach. The research team will provide the practice with the pseudonymised identifier so that the practice can link this to patient identifiers. Practice staff will invite patients to participate using materials provided by the research team. Some patients may be invited by healthcare assistants when they attend for their initial consultation, as this will offer an additional opportunity to purposively recruit patients with a wide range of experiences.

Staff interviews and recordings of consultations.

It will be assumed that if a practice has agreed to participate in this study, then all members of staff are potential participants in interviews. The research team will identify staff members they would like to interview (i.e. staff members who undertake annual reviews, and members of the administrative and managerial team who are involved in organising reviews) and will ask the practice manager to forward to them the relevant invitation, participant information and consent form. In addition, during study set up, the practice manager will ask eligible staff members to indicate if they would be unwilling to have their annual review appointments with consenting patients audio/video-recorded. As indicated above, patients who are willing to have their appointments audio/video-recorded will contact the research team. The research team will then liaise with the practice manager to determine whether the healthcare practitioner that the patient has an appointment with has opted out of audio/video-recording their consultations. If so, the patient will be contacted and thanked for their interest in the study but will not participate further. Otherwise, the practice manager will send information to the healthcare practitioner inviting them to contact the research team and provide their contact details to confirm they are willing to be audio/video-recorded. Some staff members may be recruited for interviews via the NOMAD questionnaire (see below).

Staff questionnaires

A designated staff member (e.g. a receptionist or administrator) will send each eligible member of staff a NOMAD questionnaire, identified by a code number. The receptionist/administrator will keep an index which lists the staff members name and their code number. The questionnaires (identified only by a code number) will be returned to the research team. The research team will tell the receptionist/administrator the code numbers of respondents so that s/he can send up to two reminders to non-respondents at 10 day intervals. Staff completing the NOMAD questionnaire will also be asked if they would be willing to be interviewed, and if so to provide their contact details, as this will offer an additional route to purposive recruitment of staff members with a range of views about the template.

Routinely collected data

The quantitative research will be conducted using pseudonymised routine data, without individual patient recruitment. The only element of the quantitative research for which patients will be individually identifiable will be participants in the patient questionnaire survey (see below).

As previously described, all patients in the eligible cohort will be included in this evaluation. Pseudonymised routine data about the variables of interest (described in ‘Routinely collected data’ on page 23) will be extracted from the practice computer records and provided to the research team. All of the pseudonymised patient data will be stored securely at the local research site in Bristol, Keele or Southampton and collated in Bristol. No individual patient consent will be necessary, apart from for patient reported outcome data via the patient questionnaire (see below).

Questionnaire - Patient reported outcome data.

All patients will be given a questionnaire by their practice at the same time as they receive the appointment for their annual review consultation. If possible, we will ask practices to send these by post with a link to complete the questionnaire online if the patient prefers this option, since our patient representatives recommend that most patients in our target group are likely to prefer paper questionnaires. If a practice prefers to send all appointments by text or email, this will include a link to an online questionnaire although the message will include an option to receive a paper questionnaire instead. The online and paper questionnaires will explain that the patient’s responses will be sent to the local University (Bristol, Keele or Southampton) for them to prepare a summary of their responses to share with the practice. Patients will be given a Freepost envelope to return the questionnaire to their local research team. Patients will be invited to give consent to being sent a follow-up questionnaire after 2 months. This will be sent by the local research team.

Details of the age, sex, and number of long-term conditions of patients will be obtained from general practices and used to compare the characteristics of respondents and non-respondents to the survey

using a different pseudonymous identifier from that used for the collection of pseudonymised routine data. In this way, no-one outside the general practice can link the name and address of patients completing questionnaires with their routine medical records.

We do not propose to pay participants for completing questionnaires. First, because we are seeking to replicate the recommended practice of using patient questionnaires to inform and improve routine consultations, and patients would not be paid in these circumstances. Second, because the questionnaire will be very short (13 questions) and not burdensome.

Returning the questionnaires to the local university has three important advantages over asking general practices to manage the process. First, because some patients may be concerned about giving any criticism directly to the practice. Second, because it removes an administrative burden from practices at a time when they are under great pressure. Third because the university can enter and analyse the results and give the aggregated results to the relevant local practice. The final two considerations are important because at the present time general practices are unlikely to be able to cope with being given additional work.

Consent

Patients and staff invited to participate in the qualitative research will provide fully informed consent.

They will be given information sheets which include details of the nature and objectives of the study, what their participation would involve, how their data will be used and stored, and the opportunity to ask questions. All potential participants will have at least 48 hours to decide whether or not to participate.

Consent may be recorded on paper consent forms, by email from a named email address, by telephone (subject to the telephone call being recorded), or by completion of an online form which the patient or staff member accessed in response to a link in a text, email or phone message sent to their phone number held by their general practice.

Clinicians responsible for patient care will review the lists of patients who are going to be approached to participate in the qualitative research and asked to exclude anyone who does not have capacity to consent for themselves.

For patients invited to participate in recorded observation of their consultations, patients will also be given the opportunity to retract their consent after the consultation, and can withdraw their consent to the use of the recorded consultation at any time. Similarly, the clinician conducting these consultations will be asked to provide written consent to recording and use of the data. The consultations will only be used in the research if both the patient and the clinician provide consent. If patients bring a companion to the consultation with them, the companion will not be a research participant. The recorder will be positioned so that the companion is off camera, or they may choose to leave the room while the consultation takes place.

Staff will be sent the NOMAD questionnaire with a covering letter that explains the nature of the evaluation and how their data will be used. Return of the questionnaire will indicate consent. The respondents will not be identifiable by the research team. Both the covering letter and the questionnaire may be administered electronically or on paper.

Patients sent a baseline questionnaire will be told that their responses will be shared with the research team. Although return of the questionnaire can be said to imply consent, participants will tick boxes to confirm this and to give consent to being sent a follow-up questionnaire. Patients will receive information with the questionnaires in a covering letter (paper questionnaires) or an initial screen (online questionnaires).

Data analysis

This is a concurrent mixed methods study and the qualitative and quantitative data will be considered together.[23-25] Normalisation Process Theory constructs will be used to interrogate the data and inform interpretations about implementation.[11] Integration of qualitative and quantitative data will be achieved

using a convergent design and side-by-side joint displays. This will follow the established technique of 'following a thread' in which key themes are traced through all datasets.[23] Anomalies or deviant cases in one data set can be further investigated in another. We will explore the extent of implementation and variation in its forms and factors influencing uptake; under what circumstances, for which patients and in what ways the intervention was effective; and how the intervention could be improved.

The primary quantitative outcome for analysis will be the number of people who have received a care and support plan (defined by completion of one of the following codes: 'Personalised Care and Support Plan agreed' or 'Review of Personalised Care and Support Plan').

The evaluation will use the mixed-methods data to provide evidence about intervention acceptability, feasibility, adoption, reach, fidelity, cost, and sustainability. We will obtain preliminary indications of impact on patient outcomes and practice workload. Data collected in the first few practices will be used formatively to improve future roll-out.

- *Acceptability* will be determined through the patient and staff interviews, and also the staff NOMAD questionnaires
- *Feasibility* will also be discussed in these interviews
- *Adoption* represents the extent to which the general practices have implemented the intervention, for example are all staff offering it to all eligible patients? This will be explored in both the qualitative and quantitative data.
- *Reach* describes the number, proportion and representativeness of eligible patients that actually receive the intervention, and this will be analysed using the routine data
- *Fidelity* will be assessed through analysis of the observed consultations and the analysis of routine data. This will include the extent to which key personalised care elements of the consultation take place, including discussion of:
    - mental health and memory
    - falls and frailty
    - medication concerns and adherence
    - social prescribing
    - patient's goals and priorities
    - making a care and support plan

Fidelity in observed consultations will be assessed using a checklist.

- *Cost* will be assessed using the routine data extracted from record systems
- *Sustainability* will be explored in the staff and patient interviews, and the NOMAD questionnaire, including the practice's intention to keep using the template after the study ends.
- *Impact on patient outcomes* will be assessed using the PROMs data.
- *Impact on practice workload* will be assessed using the routine data about consultation rates and duration.

The data from patient and staff interviews, and from the staff questionnaires, will be used to understand the factors that led to successful implementation of the framework and factors that impeded its implementation. For example, practices will receive varied training according to their preferences and the resources available in their locality. Training in use of the template will be provided to all practices but personalised care consultation skills training will only be provided in the three Maxwell practices receiving Year of Care training. This variation may affect how practice staff use the template, their experience of using it and patients' experience of reviews. The interview data will be fully transcribed and coded. Once a coding framework has been agreed between the qualitative

researchers and with input from the PPI contributors, each transcript will be coded by one researcher and a sample of these transcripts will be reviewed independently by a second researcher. The thematic analysis[26] will be conducted by the small team of three members of research staff who conducted the interviews. These researchers will initially identify themes, which will then be discussed with other members of the research team and the PPI groups. The audio/video-recorded consultations will also be fully transcribed and analysed thematically, as described above. An observation guide will support analysis of the fidelity of use of the template. In addition to assessing fidelity, we will analyse the recordings of consultations to look for evidence of having received training, considering the variation in training and how this may have affected the practices' experience of, and approach to, using the template and patients' experience of the reviews. We will also look for evidence of use of person-centred consultation skills.

The routine data will be used to understand the adoption, reach and fidelity of implementation. This will include exploring the proportion of eligible patients who were invited to a review, the proportion that attended, and the extent to which key elements of the template were completed. We will also explore whether there are particular patient groups who were more or less likely to receive a complete review as intended. As far as possible, the quantitative analysis will include the items specified within the Finance, Commissioning and Contracting Handbook for Personalised Care (e.g. % eligible people receiving a personalised care plan, % referred to social prescribing link-workers).[27]

In the pre-intervention period, most patients will have been invited to an annual review consultation based on a pre-existing template, but this would rarely lead to provision of a care and support plan. The intervention consists of patients being invited for an annual review using the new template, which encourages provision of a care and support plan. Over the study time period, the number of eligible patients being invited for an annual review consultation based on the new template (the intervention) should increase. Some of these patients will receive a care and support plan (the primary outcome).

Comparative analyses using the routinely recorded data will explore whether the primary outcome of receipt of a personalised care and support plan differs between patients in intervention and control practices. Negative binomial regression will be used to assess the number of patients receiving a plan in each practice in each time period (2021/22 vs. 2022/23), in a difference-in-difference analysis framework. Intervention (a binary variable indicating intervention or control practices), period (2021/22 vs. 2022/23), and the interaction between the two will be fitted as fixed effects, with practice as a random effect. As the same patients will appear in both time points, no adjustment for age, sex, etc is required. Whether the effect of year differs within particular patient groups will be explored by fitting the patient group variable (e.g. sex) as well as additional interactions, in the model, all as fixed effects.

A second set of comparative analyses will look at the impact on practice workload, including frequency, duration, and type of consultation, as well as the staff group who performed the consultation. Further, the number of regular reviews for specific diseases, and the number of fidelity type measures (e.g. mood and memory) and drugs prescribed will be explored, among other indicators. We will explore whether use of the template has any impact on clinical indicators of high quality care, such as blood pressure control or diabetic control. Subgroup analyses (e.g. exploring telephone consultations only) will be analysed as separate models for each subgroup of interest.

For all methods outlined, underlying assumptions in statistical models will be checked using standard methods, e.g. residual plots, etc. If assumptions are not valid, alternative methods of analysis will be sought.

The patient questionnaire will be used to quantify patient-reported outcomes before and after receiving the patient-centred multimorbidity review. Simple descriptive statistics will illustrate the health difficulties that patients with multimorbidity report most commonly. We will also explore whether there is a change in patient experience after the review, using similar models as described above.

We will estimate implementation and delivery costs of the annual review intervention, and explore the wider impact on healthcare resources, from an NHS perspective. We will explore the possibility of including social care data as well, depending on the availability of linked data. The implementation

cost per GP practice will include administration and practice staff training to deliver the annual review intervention. The delivery cost per patient will include staff time, medication costs and investigations associated with delivering the annual review, and any further healthcare contacts instigated during the review.

Impact on wider healthcare resource use: in addition to the implementation and delivery costs, the intervention may lead to changes in healthcare use (e.g. (i) at an aggregate level, (ii) between primary and secondary care, or (iii) between elective and emergency care). We will use regression models to compare measures of healthcare cost during the postintervention period for patients who received the intervention and those who did not, in intervention and control practices. The post intervention period will be defined as the month of the patients' birthdate to the end of the data collection period. Models will account for baseline healthcare costs (those in the same period in the previous year) and patient and practice characteristics.

As described above, anonymised primary care data, including consultation duration, will be collected from practices' EMIS software (either directly by each practice, or via a system wide dataset), and we will seek to collect secondary care data from a system wide data set where available or the NHS Secondary Uses Service (SUS). Administration costs and time for practice staff training will be estimated from data collected by the research team. Staff time and medication costs will be based on national estimates,[29,30] and investigations will be costed using national estimates[29] or literature. Secondary care data will be costed using national tariffs.[31]

10) ETHICAL AND REGULATORY CONSIDERATIONS

This is an implementation project which seeks to explore how best to implement a computerised template, and to study the impact of implementing the template. The template itself is already in use and this project aims to improve the template and to study how to improve its implementation, with a view to supporting the ultimate aim which is to improve the personalisation of care. In most respects this can be considered a service improvement project, but we are seeking NHS ethics approval because the study is designed to produce generalisable or transferable findings beyond those practices included in the study.

The intervention itself does not raise any risks for patients beyond usual care. The decision to use the template, and clinical decisions which are connected with use of the template, are entirely at the discretion of the clinician consulting with the patient.

The routinely collected data will be pseudonymised (linked anonymous) and identifiable only by the patient's clinical team, not by the research team. We will ensure that we do not collect data that could in combination have a significant risk of making the patient identifiable.

The patient and staff interviews or questionnaire survey do not raise any ethical issues beyond the usual requirement to obtain fully informed consent.

The collection of recordings of general practice consultations raises ethical issues. We have considerable experience of collecting this type of data, for example in the 'one in a million' project http://www.bristol.ac.uk/primaryhealthcare/researchthemes/one-in-a-million/ .We will ensure that patients are fully aware of how their data will be stored and used and give fully informed consent as described under 'Consent' on page 22.

Assessment and management of risk

Potential risks from the study are described below. We will maintain a register which records details of any events of this type, how we responded and who we passed the information on to.

Risk	Mitigation

We identify patients who appear to have serious medical problems which have not been addressed.	We will draw this to the attention of the GP within the practice responsible for the patient's care
While undertaking an interview, or in a questionnaire response, we identify a patient or member of staff who appears to be at risk of suicide or of harming other people	If the risk relates to a patient, we will draw this to the attention of the GP within the practice responsible for the patient's care. If the risk relates to a member of staff we will draw this to the attention of the senior partner (or other partner if the senior partner is the person at risk).
While undertaking an interview, or in a questionnaire response, we identify a safeguarding concern eg in relation to child or adult abuse, domestic violence or other potential patient harms which the practice is not already responding to.	We will draw this to the attention of the GP within the practice responsible for the patient's care
We are given information which makes a patient identifiable, without their consent	We will immediately delete any information which makes the patient identifiable, and inform the practice's data protection officer for them to address this breach in line with their data protection policy.

Health Research Authority (HRA), Research Ethics Committee (REC) and other Regulatory approvals & reports

Before the start of the study, a favourable opinion will be sought from an NHS Research Ethics Committee and the HRA

All correspondence with the REC/HRA will be retained.

An annual progress report (APR) will be submitted to the REC/HRA within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.

The Chief Investigator will notify the REC/HRA of the end of the study.

If the study is ended prematurely, the Chief Investigator will notify the REC/HRA, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC/HRA.

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place.

Amendments

The sponsor (University of Bristol) is responsible for deciding whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the REC/HRA in order for them to issue approval for the amendment.

In case of the need for a substantial amendment to the protocol, we will submit a valid notice of amendment to the REC for consideration. Substantial amendments that require review by NHS REC/HRA will not be implemented until that review is in place and other mechanisms are in place to implement at sites.

Non-substantial amendments that require review by the Sponsor will not be implemented until that review is in place and other mechanisms are in place to implement at sites.

We will notify each participating general practice of approved substantial amendments, and non-substantial amendments where they affect research procedures within the practice. The Chief Investigator or designee will work with practices to implement the amendment and to confirm their support for the study as amended, as appropriate

Changes to the protocol as a result of amendments (both substantial and non-substantial) will be recorded at the beginning of this protocol.

Peer review

This study was funded as part of a competitive process under the NIHR ARC National Multiple Long-Term Conditions Implementation Programme. As part of this process the funding panel obtained 9 independent peer reviews, including from experts and from patient representatives. The additional funding from the NIHR School for Primary Care Research was also awarded via a competitive process and peer review.

Protocol compliance

This study involves exploring how to achieve wider implementation of a service improvement which is already in use in the NHS. The multimorbidity template encourages good practice in line with current NHS guidelines and the Quality and Outcomes Framework, therefore any risks to patients are very unlikely.

Given that the eligible cohort all have multiple long term conditions, and many of them will be elderly and frail, we expect a high rate of events such as hospitalisations and deaths which are not related to the implementation of the template. We will investigate any serious adverse events (SAEs) which anyone involved with the study reports could be related to the intervention or the research procedures, whether reported by patients, practice staff or researchers. Details will be collected using an adverse events form, and a register will be kept of all events investigated and how they were resolved. The Chief Investigator is responsible for defining each event in relation to its seriousness, relatedness and expectedness.

A Serious Adverse Events (SAEs) is defined as an event that:

- results in death;
- is life-threatening;
- requires hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability or incapacity; or
- consists of a congenital abnormality or birth defect; or
- is otherwise considered medically significant by the investigator.

SAE reporting is handled via a Service Level Agreement with University Hospitals Bristol and Weston NHS Foundation Trust. SAEs that are related to the study (ie they resulted from administration of any of the research procedures) and unexpected (ie not listed in the protocol as an expected occurrence) will be reported to the sponsor within 3 working days and emailed to the REC using the Non-CTIMP safety report to REC form within 15 days of the chief investigator becoming aware of the event.

Any urgent safety matters will be reported to the sponsor and REC immediately by telephone and email and confirmed in writing within 3 working days.

Data protection and patient confidentiality

All investigators and study site staff will be required to comply with the requirements of the Data Protection Act 1998 and GDPR with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

All research data collected in each region (ARC West, ARC West Midlands, ARC Wessex, relating to the universities in Bristol, Keele and Southampton respectively) will initially be stored in encrypted files in secure password protected servers at each of the three universities. It will then be copied for collation and storage onto a PP4M project folder on the University of Bristol server. The research teams in Keele and Southampton will copy data into this folder using a virtual private network under honorary contracts with the University of Bristol which cover issues of confidentiality and data protection. Only authorised members of the research team will have password protected access to this folder. The server at the University of Bristol is stored in a locked and alarmed building.

All routinely collected data will be pseudonymised, using an identifier which can only be linked to the patient by the practice and not by the research team.

Qualitative data will include identifiable information and will only be collected and stored with patient consent. Transcripts created from recorded interviews will be pseudonymised by removing any personally identifying information such as the names of patients or staff mentioned within interviews. The transcripts will be identified using coded study identifier (study IDs). The link between the study ID and the patient or staff details will be stored separately from the research data.

Baseline questionnaire data will be entered into a database using the Redcap system and will be identifiable only by the practice code and Emis number, which can only be linked to an individual patient by members of the local clinical team.

Identifiable personal data (names and addresses) used to send follow-up questionnaires will be kept separate from the dataset of questionnaire responses and will be destroyed at the end of the project. The pseudonymised data will be stored for 10 years at the University of Bristol.

Dr Rachel Johnson will be the data custodian.

Indemnity

Insurance will be provided by University of Bristol as project sponsor. This will meet the potential legal liability of the sponsor for harm to participants arising from the design of the research. The GP surgeries will also have their own professional indemnity for their activities connected with this research project.

Access to the final study dataset

The study investigators listed as members of the core or wider research teams, (see Appendix 4) and research staff specifically employed to work on this project in Bristol, Keele or Southampton will be the only people with access to the full study dataset.

11) DISSEMINATION POLICY

The data from this study will be owned by the University of Bristol.

On completion of the study, the data will be analysed and tabulated and a Final Study Report prepared. If appropriate this may be in the form of one or more research papers submitted for peer-reviewed publication, rather than a separate report.

The Final Study Report (and/or research papers) will be made openly and freely available via the University of Bristol Research Portal, and also on a project website.

All publications must include an acknowledgement of funding and disclaimers, as agreed with the funding body and ARC West, the lead organisation.

Participants in the study will be able to see the results of the study by following the study website. Information about this website will be included within participation information at the time of recruitment.

Authorship eligibility guidelines and any intended use of professional writers

The core research team (see Appendix 4) will be responsible for drafting the final study report. The wider research team will also be listed as authors if they have contributed to the project for at least 12 months and fulfil International Committee of Medical Journal Editors (ICMJE) authorship criteria.

All participating investigators listed as members of the 'core' or 'wider' research team will be encouraged to contribute to at least one published research paper from this project, subject to conditions in the section below.

Researchers employed specifically to work on this study will also be entitled to contribute as authors to research papers.

Those listed as collaborators (see Appendix 4) will not be *entitled* to act as authors but may be *invited* to join as authors where appropriate.

All proposals for research papers must be submitted to the core research team for approval, in order to co-ordinate submissions and avoid duplication in publications.

Investigators will only have a right to publish research papers from this project if they contribute to the project for at least 12 months and if they fulfil ICMJE authorship criteria.

There is no intention to use professional writers.

12) REFERENCES

1. Chaplin K, Bower P, Man MS, et al. Understanding usual care for patients with multimorbidity: baseline data from a cluster-randomised trial of the 3D intervention in primary care. *Bmj Open* 2018; **8**(8): e019845.
2. Salisbury C. Multimorbidity: redesigning health care for people who use it. *Lancet* 2012; **380**(9836): 7-9.
3. Comprehensive model of personalised care. 2020.
4. Mann C, Shaw ARG, Guthrie B, et al. Can implementation failure or intervention failure explain the result of the 3D multimorbidity trial in general practice: mixed-methods process evaluation. *Bmj Open* 2019; **9**(11): e031438.
5. Salisbury C, Man MS, Bower P, et al. Management of multimorbidity using a patient-centred care model: a pragmatic cluster-randomised trial of the 3D approach. *Lancet* 2018; **392**(10141): 41-50.
6. Swinglehurst D, Greenhalgh T, Roberts C. Computer templates in chronic disease management: ethnographic case study in general practice. *Bmj Open* 2012; **2**(6).
7. Mann C, Shaw A, Wye L, Salisbury C, Guthrie B. A computer template to enhance patient-centredness in multimorbidity reviews: a qualitative evaluation in primary care. *Br J Gen Pract* 2018; **68**(672): e495-e504.
8. Young B, Roberts S. Year of Care: Report of findings from the pilot programme. June 2011 2011.
9. Smith SM, Wallace E, O'Dowd T, Fortin M. Interventions for improving outcomes in patients with multimorbidity in primary care and community settings. *Cochrane Database of Systematic Reviews* 2016; (3).
10. Dowrick C. Patient-centred care for multimorbidity: an end in itself? *The Lancet* 2018; **392**(10141): 4-5.
11. May C, Finch T. Implementing, Embedding, and Integrating Practices: An Outline of Normalization Process Theory. *Sociology* 2009; **43**(3): 535-54.

12. Knowles SE, Ercia A, Caskey F, Rees M, Farrington K, Van der Veer SN. Participatory co-design and normalisation process theory with staff and patients to implement digital ways of working into routine care: the example of electronic patient-reported outcomes in UK renal services. *BMC health services research* 2021; **21**(1): 706.
13. Dalkin SM, Hardwick RJL, Haighton CA, Finch TL. Combining Realist approaches and Normalization Process Theory to understand implementation: a systematic review. *Implement Sci Commun* 2021; **2**(1): 68.
14. Ogrinc G, Dolansky M, Berman AJ, Chambers DA, Davies L. Different approaches to making and testing change in healthcare. *BMJ* 2021; **374**: n1010.
15. Creswell JW, Plano Clark VL. Designing and Conducting Mixed Methods Research. 3rd ed: SAGE; 2017.
16. Jordan KP, Edwards JJ, Porcheret M, et al. Effect of a model consultation informed by guidelines on recorded quality of care of osteoarthritis (MOSAICS): a cluster randomised controlled trial in primary care. *Osteoarthritis Cartilage* 2017; **25**(10): 1588-97.
17. Swaithes L. From research to primary care: a knowledge mobilisation study in osteoarthritis.: Keele University; 2020.
18. Porcheret M, Main C, Croft P, McKinley R, Hassell A, Dziedzic K. Development of a behaviour change intervention: a case study on the practical application of theory. *Implement Sci* 2014; **9**(1): 42.
19. Lobe B, Morgan D, Hoffman KA. Qualitative Data Collection in an Era of Social Distancing. *International Journal of Qualitative Methods* 2020; **19**.
20. Lloyd H, Fosh B, Whalley B, Byng R, Close J. Validation of the person-centred coordinated care experience questionnaire (P3CEQ). *Int J Qual Health Care* 2018; **31**(7): 506-12.
21. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information Power. *Qual Health Res* 2016; **26**(13): 1753-60.
22. Finch TL, Girling M, May CR, et al. (2015). Nomad: Implementation measure based on Normalization Process Theory. . 2015.
23. Moran-Ellis J, Alexander VD, Cronin A, et al. Triangulation and integration: processes, claims and implications. *Qualitative Research* 2006; **6**(1): 45-59.
24. Noyes J, Booth A, Moore G, Flemming K, Tunçalp Ö, Shakibazadeh E. Synthesising quantitative and qualitative evidence to inform guidelines on complex interventions: clarifying the purposes, designs and outlining some methods. *BMJ Glob Health* 2019; **4**(Suppl 1): e000893.
25. Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs-principles and practices. *Health Serv Res* 2013; **48**(6 Pt 2): 2134-56.
26. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology* 2006; **3**(2): 77-101.
27. Finance, Commissioning and Contracting Handbook. 2019.
28. Dimick JB, Ryan AM. Methods for Evaluating Changes in Health Care Policy: The Difference-in-Differences Approach. *JAMA* 2014; **312**(22): 2401-2.
29. Curtis L, Burns A. Unit Costs of Health and Social Care 2020. 2020.
30. NICE. British National Formulary. 2021.
31. England N. National Tariff. 2021.

13) APPENDICES

Appendix 1- Required documentation

List here all the local documentation you require prior to initiating a participating site (e.g. CVs of the research team, Patient Information Sheet (PIS) on headed paper etc.).

Site specific documentation

- Research passport / honorary contracts / Letter of Access for researchers
- OID (Organisation information document)

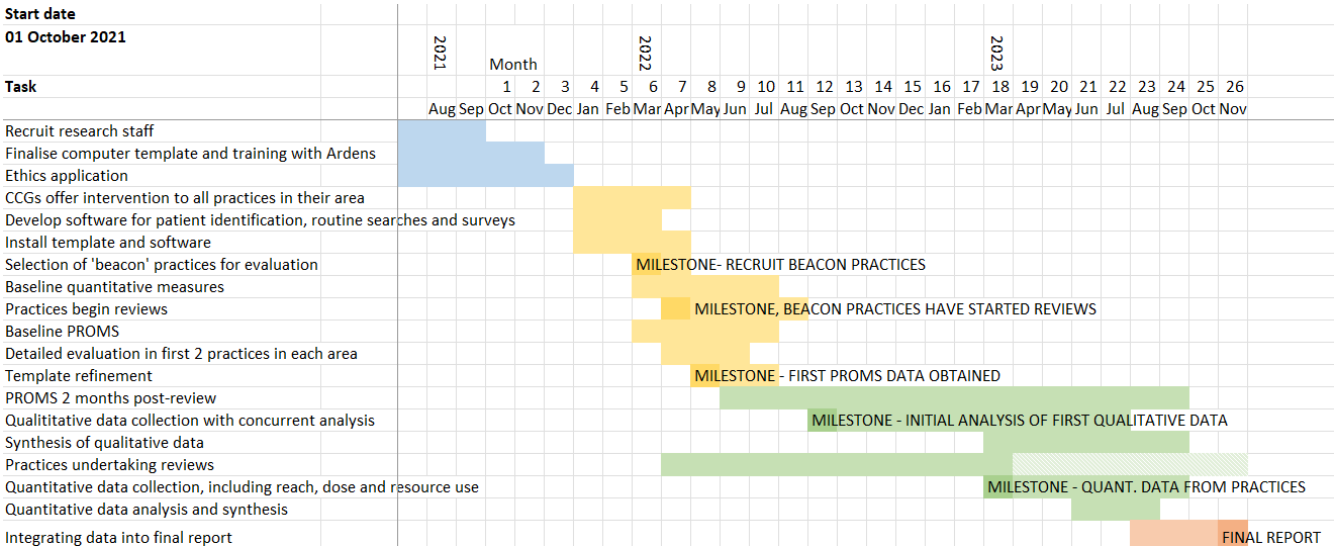
Questionnaires

- Patient questionnaire 1: Questionnaire
- Patient questionnaire 2: Questionnaire
- Staff questionnaire: Questionnaire

Interviews and observed consultations

- Patient interviews: Invitation letter
- Patient interviews: Participant information sheet
- Patient interviews: Consent form
- Patient interview: consent to contact reply slip
- Patient observations and interviews: Invitation letter
- Patient observations and interviews: Participant information sheet
- Patient observations and interviews: Consent form
- Staff interviews: Invitation letter
- Staff interviews: Participant information sheet
- Staff interviews: Consent form
- Staff observations: invitation letter
- Staff observations: Participant information sheet
- Staff observations: Consent form

Appendix 2 – Project GANTT chart



Appendix 3 –List of research team members and collaborators

Personalised care for People with Multimorbidity (PP4M)

Research team – core team and wider team		
Name, position	Organisation	Contact
Core research team		
Chris Salisbury co-lead	UOB / ARC West	c.salisbury@bristol.ac.uk
Rachel Johnson co-lead	UOB / ARC West	Rachel.johnson@bristol.ac.uk
Clare Jinks ARC West Midlands Multimorbidity Lead	ARC West Midlands / Keele University	c.jinks@keele.ac.uk
Krysia Dziedzic Implementation Advisor	ARC West Midlands / Keele University	k.s.dziedzic@keele.ac.uk
Mari Carmen Portillo ARC Wessex multimorbidity lead	ARC Wessex / University of Southampton	M.C.Portillo-Vega@soton.ac.uk
Richard Byng PenARC Complex Care Theme lead	PenARC / University of Plymouth	Richard.byng@plymouth.ac.uk
Cindy Mann Qualitative evaluation expertise / PPIE	University of Bristol	Cindy.mann@bristol.ac.uk
Wider research team - Bristol		

Matthew Ridd Support evaluation of implementation	UOB	mridd@bristol.ac.uk
Mairead Murphy PROMS expertise	UOB	Mairead.murphy@bristol.ac.uk
Frank De Vocht Evaluation and statistical expertise	UOB / ARC West	Frank.devocht@bristol.ac.uk
Jeremy Horwood Implementation, qualitative evaluation adviser	UOB / ARC West	J.Horwood@bristol.ac.uk
Hugh Mcleod ARC West Integrated and Optimal Care theme lead, health economic expertise	UOB / ARC West	Hugh.mcleod@bristol.ac.uk
Wider research team – outside Bristol		
Zoe Paskins Support evaluation of implementation	Keele University	z.paskins@keele.ac.uk
John Edwards Support evaluation of implementation	Keele University	j.j.edwards@keele.ac.uk
Andrew Finney Support evaluation of implementation, nursing expertise	Keele University	a.finney@keele.ac.uk
Simon Fraser Support evaluation of implementation	University of Southampton	s.fraser@soton.ac.uk
Year of Care		
Rebecca Haines Representing YOC	Year of Care Partnerships	rebeccahaines@nhs.net

Other collaborators

Name, position	Organisation	Contact
CCG and STP contacts		
Adwoa Webber Head of Clinical Effectiveness at BNSSG CCG	BNSSG CCG	Adwoa.webber@nhs.net

Rebecca Dunn Deputy Director of Transformation	BNSSG CCG	Rebecca.dunn8@nhs.net
Fran White Hampshire and Isle of Wight STP Programme Lead	NHS Hampshire and Isle of Wight STP	f.white1@nhs.net
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