Health Research Authority

FULL/LONG TITLE OF THE STUDY

Health care moments of opportunity: a review of evidence and community dialogue to explore responsive health care for refugees and people seeking asylum in the UK.

SHORT STUDY TITLE / ACRONYM

MORRA Study (Health care **M**oments of **O**pportunity: a review of evidence and community dialogue to explore **R**esponsive health care for **R**efugees and people seeking **A**sylum in the UK)

PROTOCOL VERSION NUMBER AND DATE

V 1.1 Date: 26.11.21

RESEARCH REFERENCE NUMBERS

IRAS Number:	
SPONSORS Number:	Not applicable
FUNDERS Number:	NIHR132961

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: .....

Date: 1 July 2021

Name (please print): Margaret Cooper

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Position: Associate Director of Research & Development

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Chief Investigator:

Signature: Andrew F. Smith

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Date: 1 July 2021

Name: (please print): Professor Andy Smith

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STUDY SUMMARY

Study Title	Health care moments of opportunity: a review of evidence and community dialogue to explore responsive health care for refugees and people seeking asylum in the UK.
Internal ref. no. (or short title)	MORRA Study
Study Design	Evidence synthesis: comprehensive literature search, case study analysis of exemplar practice, dialogic synthesis.

Study Participants	Refugees and people seeking asylum (UK); service users and staff within community/NHS services.
Planned Size of Sample (if applicable)	We anticipate including six services in our *evidence in practice* stream. In each of these sites we hope to engage three service user and two/three staff participants.
Follow up duration (if applicable)	Not applicable
Planned Study Period	01.07.21 to 31.12.22 (18 months)
Research Question/Aim(s)	This project aims to integrate evidence and knowledge on interventions and practices that support responsive health care and improved health agency for forced migrants across different health care moments of opportunity. We will begin by considering what moments, opportunities, contexts, and relationships exist to improve the health care journeys of forced migrants and who the important actors are in these spaces. We will then integrate existing evidence, and the contextualised experience of both practitioners and forced migrant communities (ensuring we consider, for example, how the experience of forced migrant communities may differ between groups such as lone males, families, women and unaccompanied children as well as those with different immigration status), in current practice and contexts, setting this knowledge into a unique synthesis process of action-orientated dialogue between health, care and other public sectors, forced migrant-related support services and forced migrant communities.

FUNDING AND SUPPORT IN KIND

FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute of Health Research Evaluation, Trials and Studies Coordinating Centre University of Southampton 023 8059 5586	**£225,189.60**

ROLE OF STUDY SPONSOR AND FUNDER

The Sponsor will be responsible for the regulatory management of the study and will not play any role in study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

The Funder will not play any role in study design, conduct, data analysis and interpretation, manuscript writing, and dissemination.

DISCLAIMER

This study/project is funded by the National Institute for Health Research (NIHR), for the Health Services and Delivery Research Programme (HS&DR) (NIHR132961). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Advisory Group
The project Advisory Group will complement our methodological expertise and clinical content, ensuring that we keep consideration of the patient and public agenda to the fore, and maintain links with the public health and forced migration community as well as representatives from other relevant professions and disciplines. They will also be able to advise us on 'target-specific' engagement and dissemination activities.

The Group will meet via videoconference 2-3 times during the project. Additional meetings will be arranged during the project if necessary, but we expect that most contact will take place by email and telephone.

Study Steering Committee
As there is an element of primary research within this project we have established a Study Steering Group to provide overall supervision for the study and to ensure we are operating within the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice.

All permanent members of The Study Steering Committee are independent from the Sponsor, the Investigators and our study, achieving the 75% independence required by the National Institute for Health Research (NIHR).

Positions including Chair will be designated by the NIHR Health Services & Delivery Research Programme Director. The Study Steering Committee will meet at least annually; it is predicted that it will meet no more than three times for the duration of the study. A minimum of two-thirds attendance is required to be quorate. Attendance by non-members will be at the Study Steering Committee's discretion though it is anticipated that the Chief Investigator or a member of the Project Team, and a representative of the Sponsor, as appropriate, will attend.

PROTOCOL CONTRIBUTORS

The following members of the study team contributed to the initial project idea and approved the final protocol:

Amy Robinson, Research Associate, Lancaster Patient Safety Research Unit, University Hospitals of Morecambe Bay NHS Trust

Sharon Lewis, Senior Research Associate, Lancaster Patient Safety Research Unit, University Hospitals of Morecambe Bay NHS Trust

Professor Andy Smith, Lancaster Patient Safety Research Unit, University Hospitals of Morecambe Bay NHS Trust

Dr Laura Nellums, Associate Professor in Global Health, University of Nottingham.

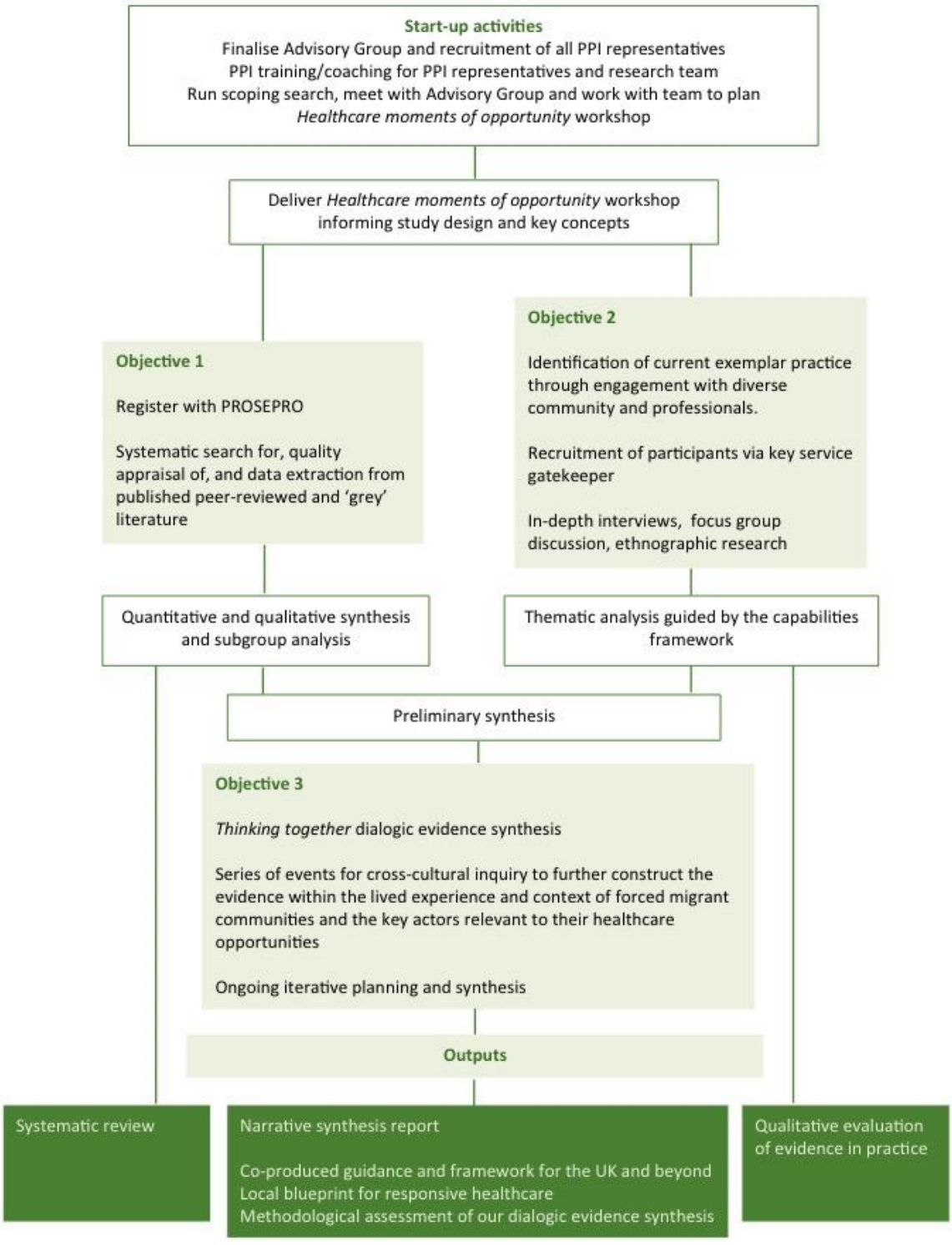
Gisela Renolds, Director of Global Link, Lancaster.

Michael Pritchard, Research Associate, Lancaster Patient Safety Research Unit, University Hospitals of Morecambe Bay NHS Trust

The proposal for this study evolved primarily in response to experiences and observations by members of the study team through involvement with grassroots refugee support organisations in the north of England, including conversations with asylum seekers and refugees in the area, with GPs locally and other health practitioners and specialist services across the UK. The study design has been discussed with our lead patient representative.

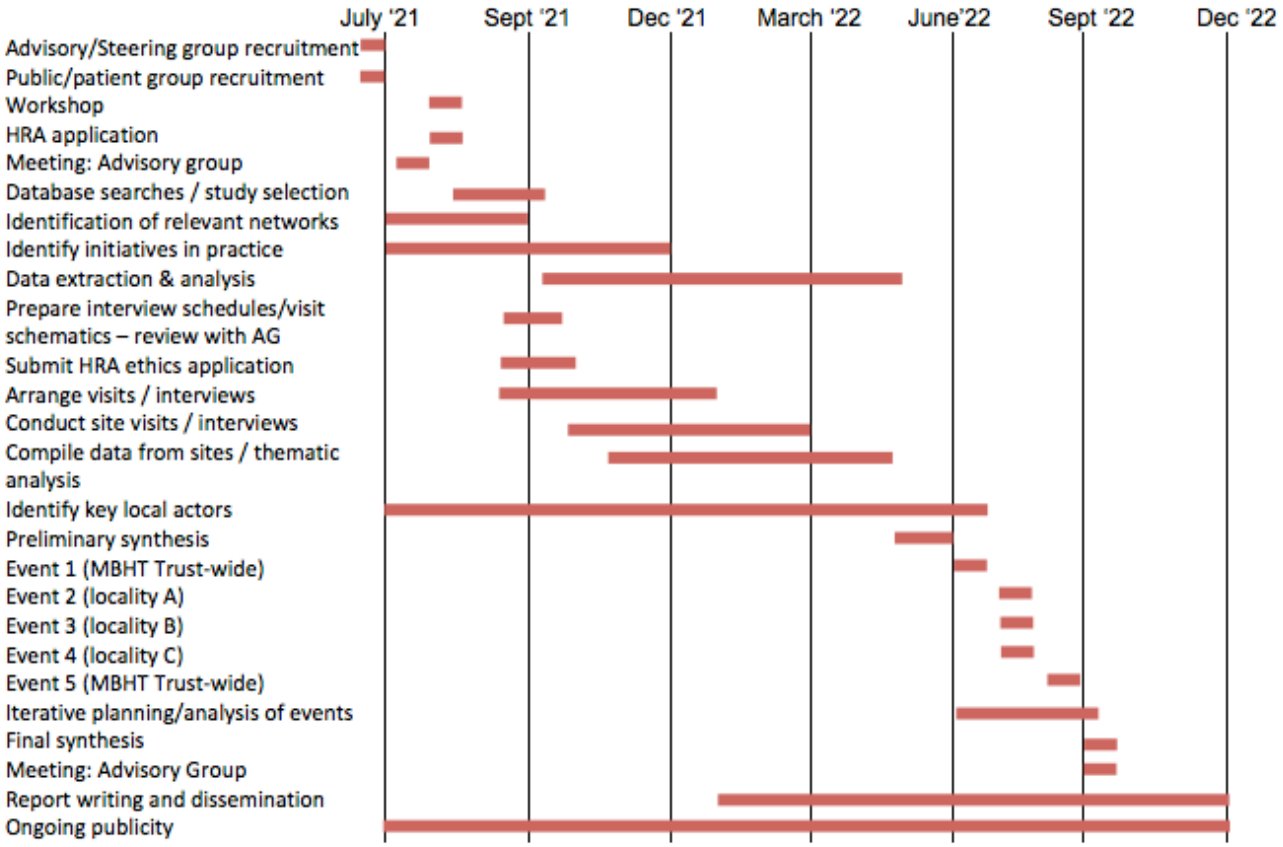
KEY WORDS: Refugee; asylum seeker; healthcare; access; diversity; public health

STUDY FLOW CHART



Flow diagram: Health care moments of opportunity for forced migrant communities: a review of evidence and dialogic synthesis to promote responsive healthcare and health agency for asylum seeking and refugee communities in the UK

Study Gantt chart (key milestones/tasks)



STUDY PROTOCOL

Health care moments of opportunity: a review of evidence and community dialogue to explore responsive health care for refugees and people seeking asylum in the UK.

1 BACKGROUND

The right to health, including the determinants of health applies to all. The health of forced migrants, individuals who have been forcibly displaced from their countries of origin including people seeking or refused asylum, refugees, and undocumented migrants, has shown to be precarious and vulnerable [1] and compared to those born in the UK they are at much greater risk of experiencing diverse and comorbid conditions (including infectious, cardiovascular and chronic respiratory diseases, cancers, and diabetes) [2,3]. Forced migrants are also more likely to experience poor mental health [4] yet much less likely to engage with psychological services than native-born populations in receiving countries [5]. They are also more likely to present at acute services than other population groups [6], and their health care encounters commonly result in misdiagnosis, leading to unmet needs or inappropriate treatment [7].

An increasing body of evidence identifies the experiences and substantial barriers for forced migrants in accessing primary and secondary care [7-11]. These include interconnecting factors from experiences throughout the displacement journey - from country of origin to beyond the seeking of protection and settlement - and include the prevailing attitude and structures in the receiving country [12, 13]. There are, for example, challenges in adapting to a new dominant culture [14], and in making sense of structures and systems, expectations and new knowledge. There is overt and more nuanced marginality associated with language, cultural literacy, gender, race, citizenship; and there is recognition that in the UK, health and care practices are too often neither responsive nor equipped to ensure equality of care for this population [7, 15].

Studies, primarily with a focus on primary care, emphasise evidence of services that are difficult to navigate and negotiate, the avoidance of services – with its resulting long-term impacts on care systems [7], issues with prescriptions and capacity to reach provision [10], short appointments or a lack of GP awareness of the complexity of forced migration, difficulties with communication, poor doctor–patient relationships, and culturally inappropriate care [8, 16]. The significance of first encounters in health care and how crucial they are to later events [17], as well as what it means to be left feeling dismissed by professionals [18] is also well documented and stresses the value of *getting it right first time*.

The context for the ‘care-giver’ has been identified as complex too. A review [15] focussed on high-income states has highlighted the challenges faced by primary care workers operating in cross-cultural interactions, often in systems not structurally configured or politically favourable to facilitate the provision of quality care. The review offers recommendations for additional resources, better interpreter services with face-to-face options, and the development of specific clinical guidelines for provision of care to forced migrant groups, drawing on the best available evidence. The WHO [2] and others [10, 19, 20] stress the repercussions of knowledge limitations amongst providers in recognising the formal protections owed to forced migrants, including fundamental rights to access health services,

with many incorrectly being refused primary care [21]. There is also encouragement for greater professional support for those working with patients who present with complex psychological difficulties [15], with evidence cultural competency training may be a facilitator [22] in improving understanding and in recognising the interconnections of culture, experiences and context. The provision of up-to-date information for health professionals about the needs of current influxes of refugees and asylum seekers, as well as greater flexibility and collaboration between agencies and clear referral pathways are all further suggestions for improvement [15].

The United Nations [23] 2030 Agenda for Sustainable Development promotes the inclusion of migrants' health in the development of regional and national health strategies; and the mental health of those displaced by war and violent conflict has long been described a pressing area [24, 25] with The British Psychological Society [26] encouraging the focus to extend into educational settings, the workplace and within communities. A 2018 (p.11) report published by the Equality and Human Rights Commission [22] describe a 'clear need for good practice examples to demonstrate solutions to some of the barriers posed' in access to health care for people seeking and refused asylum. While the WHO [13] conducted a rapid scoping review on the health of refugees and migrants within Europe, and have provided some details and signposting on public health interventions across the region, there remains limited clarity on what works and how recommendations could or should be integrated into different contexts.

A number of current studies are seeking to address these questions. In Australia, for example, authors [27] are looking at improvements in general practice delivered to patients with a refugee background, focussing on the use of accredited interpreters, health assessments, and referral pathways. The STRENGTHS project [28] is exploring whether the use of Syrian refugees to deliver mental health care to other Syrian refugees is a scalable model, with a focus on how it can be implemented in different contexts across Europe, the Middle East and North Africa. Authors in a just-published review of experiences of palliative care for forced migrant families identify characteristics of compassion from health care professionals, a philosophy of individualised collaborative care, and cultural humility, where the acknowledgement of a lack of knowledge for example, for both parties is seen to support trusting relationships between patients, their families and health care workers [29]. Authors in the UK have conducted a systematic review, including identifying facilitators in accessing health care for forcibly displaced migrants within Western European countries, which follow a review of evidence for people seeking and refused asylum in the UK which highlighted the key roles of primary care and third-sector organisations for facilitating access to care and information sharing in forced migrant groups [10].

In addition to the more traditional avenues by which we might typically see the delivery of health care, Brady [9] encourages a focus on the work that patients do beyond the health care encounter to help us consider where resources are best placed, and who might be better placed to negotiate the health care journey with a migrant patient. Similarly, a general critique of access to health care [30] encourages focus on the conditions that influence a patient's capacity to engage in their health care experience, such as hostile public discourse or in overcoming initial difficulties seeking a service [31]. While Juárez et al [6], in their review looking at the effects of non-health-targeted policies on migrant health (including forced migrants), suggest that policies should actively work to improve the

maintenance of generous rather than restrictive policies to prevent the exacerbation of health inequalities.

Furthermore, there is a growing focus on intersectionality as a theoretical framework [32] to democratise public health, and engage *head-on* with discussions that bring to surface racism and oppressions that potentially damage health care interactions [18]. Indeed, recent work from Phillimore [33] in considering refugee integration encourages a shift of attention to 'the ways in which receiving society contexts shape refugee-integration opportunities'. This echoes Nussbaum's [34] recognition that in order for services to be responsive to the individual, we must first recognise that the normative design of our public (and private) space is determined by (and for) the dominant majority. This design is therefore in tension with a care system that hopes to be responsive and equitable because it starts from a structure that is formed for the dominant/normative population and not a diverse one. As such efforts risk accommodating rather than acknowledging and designing for, cross-cultural variations in how we might present, interpret or consider health and health care.

Taking a broad approach to considering the health care opportunities that occur both within and beyond the traditional health practitioner exchange, as well as the interconnected and interdependent factors and characteristics of good health and of the forced migrant experience, could help improve responsive health care for forced migrant communities. Understandings of the initiatives, behaviours and practices, which recognise these opportunities however, are largely unexplored; it is around these opportunities that we propose to focus.

2 RATIONALE

Around 40,000 people seek asylum or are granted refugee status in the UK each year contributing to a population of more than 172,000 people of concern (refugees and people with pending asylum system claims) and an estimate of more than half a million undocumented migrants [35-37]. It is important to acknowledge too, that this is a moment in which the planet is in flux, in which the movement of people and cultures, and where protracted displacement as a repercussion of climate breakdown, can only increase.

Throughout the precarity of seeking protection and even in the settlement context, the socio-political and economic marginality of displacement experiences can compound existing health vulnerabilities. Studies indicate these experiences are part-shaped by the fluid interconnection of social, linguistic and cultural barriers, and discrimination (both intended and unintended) [14]. Reduced protective and supportive factors such as broader family and social networks can further exacerbate health needs and health anxieties, and reduce capabilities around help seeking and managing conditions.

Good health allows us to play an active part in society; it supports the capacity to engage in everyday activities, social relationships and be economically active [38]. Conversely, poor health has consequences for individuals and for society, including lower social cohesion, discrimination, and barriers to accessing and sustaining good employment [39]. For refugees in particular, who do not face policy barriers to labour market participation, unmet or undiagnosed health care needs can have substantial impact on their capacity for successful employment [40].

Comorbid health problems and delayed treatment increase demand on medical and social services and present a substantial public health and civil society challenge [7, 8]. Minimising misdiagnosis, repeated presentations, and the exacerbation of acute conditions help an NHS under substantial deficit. Reducing demand, for example on *urgent and emergency care*, *delivering services more efficiently, early diagnosis of mental health and cancer,* and *diabetes prevention, proactively helping people to prevent ill-health* and maximising opportunities to *Get it Right First Time* are all key areas of focus set out in the NHS *Long Term Plan* [41]. Investment in General Practice and communities is a further avenue in reducing population impacts on NHS hospitals [42] and improving the patient experience has long been an aim of the NHS.

Despite WHO [2] encouragement for European regions to adopt refugee- and migrant-sensitive health systems and interventions, including 'equitable access to universal health coverage', there is no framework relating to forced migrant health care across the UK. In addition, there are no recommended practices or training opportunities supporting health systems to get this right. Equally, there is a limited body of evidence from which practitioners or actors can engage that demonstrate the practical approaches that could address the limitations described.

This absence of a guiding framework and understanding of *what works* in responsive health care for forced migrant communities, as well as the creation of the right conditions for forced migrants to have greater agency over their health, is a space this study wishes to address. In addition, the study seeks to explore how the health encounter, including the organisation of localised health care systems, could more readily respond, not in a way that accommodates forced migrants within the normative approach on which it has long evolved [9], but as an inclusive space that is acutely conscious of the different dimensions of oppression and their intersections at play in contemporary UK society. Indeed, in this new COVID-19 era there is increasing cognisance of the intersecting inequities impacting the health of black and minority ethnic groups in the UK, including unprecedented attention on the implicit biases, cultural and structural racism, and interpersonal discrimination shaping the health of this population [30, 43, 44].

These considerations are central to the aims of our research and to our analytical approach, and through our Patient and Public Involvement (PPI) strategy and study design, we will aim for participatory parity, that allows forced migrants and the forced migrant experience to be an equal 'partner' in 'negotiating' and considering the actions and behaviours needed for a responsive model of health care in the post-displacement context.

3 THEORETICAL FRAMEWORK

This project involves a mixed-methods approach. We will deliver a cross-community workshop, with representation from different forced migrant communities, health, social, and civil society actors (both within and beyond the traditional health care context, including in policy and practice roles) to explore and articulate the moments, opportunities, contexts, relationships and actors involved in health care journeys of forced migrants. Outputs from this workshop will help to refine our criteria and focus for a comprehensive review of relevant literature and study of evidence in practice.

We will conduct a systematic review to enable us to identify and appraise available peer-reviewed and 'grey' literature on interventions and practices that support responsive health care and/or improved health agency for forced migrants. We will seek evidence on outcomes defined during the workshop, conduct a thematic synthesis of intervention and practice designs, and where study designs are appropriately homogenous we will undertake meta-analysis following standard Cochrane principles [45].

Taking a broad view of 'evidence [46], we will, in tandem, identify examples of relevant interventions and models of care in current practice. We will use case study methods to consider the network of intersubjective experiences and cultural and organisational factors which shape the delivery of services, and the experiences of those engaging in services, as well as the structural and institutional practices shaping these contexts. We will conduct in-depth interviews with health (or other professionals) face-to-face or remotely; focus groups with patient/forced migrant groups face-to-face or remotely, and where appropriate (and only in the UK) ethnographic research to observe the settings [47] in which provision or interactions take place. We will also collect documents such as service information and evaluations where available, and establish the local context as it relates to the organisation, policy, forced migrant populations and their needs.

Thematic synthesis of qualitative data will be guided by established methodologies [48]. We will also be guided by Nussbaum [34] and Sen's [49] capabilities framework in considering how far approaches go in addressing or mediating the structural/institutional/social conditions influencing someone's capacity to access and engage in health care opportunities.

Finally, we will deliver a series of dialogic events as a form of evidence synthesis that will also act as the third stage in our data collection process. With the expert help of a facilitator, we aim to create and sustain a space for the open exchange of ideas and the consideration of possibilities (free of judgement [50,51]) between relevant 'stakeholders'. These dialogic events will aim to provide a transformative opportunity [52] in which the exchange of those ideas, insights, and evidence are rooted within the social, cultural, and structural realities in which they exist [53]. We see it therefore providing a tangible learning and reflective experience (for everyone involved) and helping to better determine how the evidence gathered throughout the project can be constructed and fostered in practice.

We will include an assessment of the robustness of our overall evidence, using decision-making tools to report the confidence in our findings [54]. We will also explore and report any limitations to our research [55].

4 RESEARCH QUESTION/AIM(S)

This project aims to integrate evidence and knowledge on interventions and practices that support responsive health care and improved health agency for forced migrants across different health care moments of opportunity.

We will integrate existing evidence, and the contextualised experience of both practitioners and forced migrant communities (ensuring we consider, for example, how the experience of forced migrant communities may differ between groups such as lone males, families, women and unaccompanied children and young people as well as those with different immigration status), in current practice and contexts, setting this knowledge into a unique synthesis process of action-orientated dialogue between health, care and other public sectors, forced migrant-related support services and forced migrant communities.

Throughout this process we will consider three key questions:

1. What are the health care *moments of opportunity* for forced migrant communities?
2. What practices and models could be used in these *moments of opportunity* to support responsive health care and improved health for forced migrant communities?
3. How can these practices and models be integrated into UK health and civil society systems?

4.1 Objectives

Our research plan incorporates the following objectives:

1. Comprehensively examine existing evidence of relevant interventions through a systematic review
2. Identify current exemplar practice through engagement with diverse community and professional groups in the UK and internationally
3. Synthesise evidence and knowledge (of relevant stakeholders) through a process of action-orientated dialogue between health, social, other public sector and civil society actors, and forced migrant communities.

In addition to these objectives, we will carry out two patient and public engagement processes, which will form key components of the proposed work. We will:

1. Bring together forced migrant communities, health, social care and civil society actors to identify a pathway that captures the different health care moments of opportunity for forced migrant communities, and to identify the critical outcomes that measure the effectiveness of interventions. This will inform the study design, key concepts, interpretation of the data, and dissemination.
2. Conduct five participatory and dialogic events (using Bohm's *Thinking together* approach) [56] to produce recommendations and a framework for the participatory evolution of improved responsive health care for forced migrants in the UK and beyond.

Through this engagement with patient and provider groups, we will then produce a guiding framework that sets this understanding in the context of traditional and more nuanced health and community interactions as well as a blueprint for what a responsive system of care could look like for forced migrants in a North West region of England.

4.2 Outcome

There will be five outputs from this proposed work:

1. We will publish the systematic review as the first output of this project.
2. We will produce a report presented as a narrative synthesis of approaches to addressing barriers to health care and health agency for forced migrant communities.
3. We will disseminate co-produced recommendations and a guiding framework for improving responsive health care and health agency for forced migrants. This will be the key output of the series of dialogic events and the collective coming together of everyone's contributions throughout the project. The content will evolve throughout the synthesis of the research evidence and the diverse perspectives, experiences and contexts of event contributors. The production and presentation will be carefully framed for different stakeholders including health and care practitioners, and other public sector authorities, civil society groups, and for forced migrant communities. To support this framing we will utilise the support of a creative consultant to support the translation of key findings and recommendations into resources appropriate for a culturally diverse forced migrant audience.
4. A blueprint for what a responsive system of care could look like for forced migrants in a North West region of England will be a further output and result from the discussions and reflections during the *Thinking together* events. This blueprint will effectively test the recommendations and guiding framework produced above. It will be locality specific, identifying appropriate approaches, collaborative pathways and the supports necessary to address the challenges around responsive health care across the area. It will identify where shifts and interventions may be required, and where further investment to implement or develop provision in response to identified gaps may be necessary.
5. We will also aim to produce peer-reviewed publications of the qualitative evaluation of evidence in practice and the methodological approach to participatory dialogic synthesis that we take throughout the *Thinking together* events.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

The study design for our mixed-methods approach includes four streams:

1) Cross-community and inter-professional workshop
2) Comprehensive systematic review
3) Evidence in practice
4) Dialogic synthesis

5.1 Cross-community and inter-professional workshop – *what are the health care moments of opportunity for forced migrant communities?*

Health care opportunities occur both within and beyond the traditional health practitioner exchange. Considering this, as well as the intersectionality of good health and of the forced migrant experience, we will deliver a workshop, with representation from different forced migrant communities, health, social, and civil society actors (both within and beyond the traditional health care context e.g. with housing providers, education and employment services), to explore and articulate the moments, opportunities, contexts, relationships and actors involved in health care journeys of forced migrants.

We will consider these the *health care moments of opportunity* for forced migrant communities. Recognition of these moments of opportunity will enable us to refine our systematic review criteria and our identification of evidence in practice. It will also ensure that as we move into the dialogic synthesis that we include representatives from all relevant sectors and communities. This will be an opportunity to work with patients, potential patients and the public in a way that can inform the study design, key study concepts, and help us to identify the key measures of effectiveness (i.e., outcomes) of interventions that support or indicate responsive health care and improved health agency.

We will work with our Advisory Group and patient and public representatives to plan and to consolidate the outputs, of this workshop. We will use a WhatsApp group and/or other media, as requested by groups, to inform participants of these outputs.

5.2 Comprehensive systematic review

We set out below a proposed framework for our systematic review. However, we see the discussions in our cross-community workshop as crucial to defining what we mean by those health care moments of opportunity for forced migrant communities and who might be the critical people involved, or relevant, in those interactions, as well as the important outcomes to both forced migrant communities and to those who might better support their health. As such the following is indicative of our focus but precise details are dependent on the above.

Types of study: we propose to include a wide range of study designs which report either qualitative or quantitative data, as well as those that have used mixed methods approaches. Whilst randomised controlled trials (RCTs) contribute the most robust study design for data synthesis, and controlled before-after studies would similarly provide efficacy of interventions, we anticipate finding few studies with these designs. We will therefore expand our search to include non-randomised study designs, and observational study designs. We will exclude comparative studies (where a study compares outcomes between a ‘host’ and forced migrant population) that do not evaluate an intervention. We will also exclude retrospective studies that report only quantitative data (for example, relating to the utility of a service), unless the study reports how a service may have changed in order to increase the number of people using the service. We will include studies conducted in any country and in any language.

Types of participants: we will include studies evaluating two types of participants. We will include adults or children who are forced migrants. We define a forced migrant as an international migrant who has been forcibly displaced (for example due to conflict, persecution, natural disaster, or climate change). This will include: asylum seekers, refused asylum seekers, refugees, unaccompanied minors, undocumented migrants (but not where a person is defined as an economic migrant or migrant having entered a country for the purpose of education), and forcibly displaced persons (but not internally displaced persons). If participants are mixed, i.e., defined for example as ‘migrants’ of whom some are assumed/defined as being forced migrants, we will include these studies. We acknowledge the risk of arbitrary categorisation and the absence of agreement on where the line between ‘voluntary’ and ‘forced’ migration may be drawn [49]. We will attempt to consider how these terms differ within the language adopted by study authors noting the variation in terminology across

countries. We will include forced migrant participants where they are in contact with or in need of (future or current) contact with health care services.

We will also include participants who are critical or relevant to a health care moment of opportunity for a forced migrant (as defined by our cross-community workshop). This could, for example, be a health care professional or receptionist who has been provided with training to support their ability to care for or respond to forced migrant patients, or an employment advisor trained to recognise symptoms in forced migrants that are associated with PTSD.

Types of intervention: we will include interventions or practices that aim to address the health care needs of forced migrants. These might be interventions supporting forced migrants to understand the local health system (for example, written information, a workshop, event, or technology), or it could be a specialist health service for forced migrant communities. The intervention could support practitioners, such as training or education relating to forced migrants' health, or the creation of more equitable institutional practices that address the disadvantages or barriers experienced by forced migrants in these or broader contexts. We will only include interventions designed to meet a health need (such as trauma), if it also includes interventions or change in practice that address barriers to receiving that care, such as the provision of information in different languages or the use of additional support or interpreters. We will also include interventions which focus on facilitating greater agency amongst forced migrant communities, either where health agency is made explicit or implicit, such as in respect of social impact or wellbeing.

We will include interventions in any setting, for example, in a domestic or residential setting, in the community, an education or other public service setting, or in a health care setting.

Types of outcomes: we will look at studies with interventions directed both at forced migrant communities themselves and at interventions directed at those who might support better health outcomes in this group. Outcomes will therefore differ between groups. There is no established core outcome set for this topic. We include here a preliminary indication of outcomes of interest; we will establish a final list of outcomes during our cross-community and inter-professional workshop and may group outcomes into themes. We will aim to limit the number of outcomes to only those that are likely to be meaningful to intended users and recipients of the reviewed evidence. During the process of consultation, we will seek to prioritise the outcomes into those that are 'critical', 'important, and 'not important' for decision making, and we will seek to consider adverse effects of interventions as well as benefits.

For forced migrant participants, we are interested in outcomes related to:

- Capabilities (using measures such as ICECAP or Adult Social Care Outcomes Toolkit (ASCOT), or qualitative tools).
- Self-efficacy for health (either for general health or a more specific health component, such as breastfeeding self-efficacy).
- Resilience (using measures such as The Recovery Star)
- Realised access to healthcare:

    - People accessing services;
    - Actual knowledge of healthcare systems;
    - Acculturation.
- Early-stage detection, diagnosis, or treatment of any condition
- Psychosocial outcomes:
    - Depression and anxiety (using measures such as the Generalised Anxiety Scale (GAD-7), Hospital Anxiety and Depression Scale (HADS), Edinburgh Postnatal Depression Scale);
    - Psychological trauma (using measures such as Children's Impact of Event Scale (13) (CRIES 13), Child Trauma Screening Questionnaire (CTSQ), the Crisis Support Scale (CSS));
    - Grief and fear (using measures such as the Inventory of Prolonged Grief, Screen for Child Anxiety Related Disorders (SCARED)).
- Quality of life or wellbeing (using measures such as SF-36, EQ-5D, WHOQOL).
- Experiences (using qualitative data describing the experiences of seeking, receiving or needing health care).

For health care workers or others important to health care opportunities, we are interested in outcomes related to:

- Knowledge of, or experiences or attitudes relating to forced migrant patients/communities;
- Cost (economic or social returns).

We will collect outcome data reported at any time point within the study. We will include only studies that report one of our outcomes of interest; however, we will record details of all excluded studies that meet the review criteria for study design, population, and interventions but report different outcomes.

Search methods: We will develop a search strategy in MEDLINE, which we will then adapt to suit different interfaces for other databases. We will search MEDLINE, Embase, CENTRAL, CINAHL, PsycINFO, Web of Science, and the NIHR Journals Library. We will search databases from inception and pose no restriction on language of publication. In order to identify ongoing studies, we will conduct searches of clinical trials registers ClinicalTrials.gov and the WHO trials register search portal (apps.who.int/trialsearch/). We will conduct forward citation of studies which meet our inclusion criteria, and backward citation of reviews using Web of Science citation index. We will also contact authors and experts in the clinical and organisational area of interest.

In order to identify relevant unpublished studies, we will also conduct grey literature searches using opengrey.eu (www.opengrey.eu/) and ProQuest Dissertations and Theses (via ProQuest Nursing & Allied Health and Health & Medical). We will also search the websites and make contact with relevant agencies, for example, the WHO, UNHCR, Open Society Foundation, Amnesty International, Council of Europe, Refugee Studies Centre, International Organisation for Migration, UK Refugee Council, Norwegian Refugee Council, and the International Committee of the Red Cross.

A draft search strategy is included in Figure 2.

Figure 2: **Draft search strategy – MEDLINE (Ovid SP)** 1 refugees/ 2 "transients and migrants"/ 3 "emigrants and immigrants"/ 4 (undocumented immigrant* or migrant*).ti,ab. 5 human migration.ti,ab. 6 "emigration and immigration"/ 7 asylum.ti,ab. 8 refugee*.ti,ab. 9 (migrant* or immigrant* or emigrant*).ti,ab. 10 (forc* adj2 (migran* or migrat* or immigra* or emigra*)).ti,ab. 11 (displac* adj1 (forced or mass or person* or people* or population* or child* or young*)).ti,ab. 12 resettl*.ti,ab. 13 or/1-12	14 health/ 15 health care/ 16 primary care/ 17 secondary care/ 18 maternal health services/ 19 patient/ 20 patient care/ 21 “GP”.ti,ab. 22 care prov*.ti,ab. 23 (wellbeing or well-being or well being).ti,ab. 24 dentis*.ti,ab. 25 (mental* or psychiatr*).ti,kf. 26 prescri*.ti,ab,kf. 27 psychoso*.ti,ab,kf. 28 (mental* adj1 (health* or ill* or well* or disease* or disorder*)).ti,ab,kf. 29 28 adj2 (promot* or prevent*).ti,ab,kf. 30 or/14-29 31 13 and 30

Identification of studies: we will use reference management software (Endnote) to manage and remove duplicates from search results. We will use software designed to manage systematic review

organisation (Covidence www.covidence.org) to screen references according to inclusion and exclusion criteria based on title and abstract. We will then perform a full-text review of possible studies, and identify a final selection of studies that meet our review criteria. Two review authors will independently carry out screening and selection of studies for the review. Any discrepancies will be resolved via discussion with a third reviewer in order to achieve consensus.

Data collection: we will extract data from studies using electronic data collection forms in Covidence which we will adapt and then pilot to meet the needs of the review. We will review this pilot with our lead patient representative and Advisory Group and make changes where necessary. We will collect information on:

Study design:

- *Participants:*
    - *Forced migrants* (where available gender, age, health care need, time in 'resettlement' context; immigration status, country of origin, first language and languages spoken),
    - *Practitioner/community actor* (role, type of organisation, relationship with forced migrant group, experience delivering intervention, collaborators);
- *Intervention* (timing of intervention, type of intervention – where it is delivered and by who, how it is delivered, context in which it is delivered, barriers it seeks to address);
- *Commissioners and funders of the intervention and/or study;*
- *Outcomes collected* (including measurement tool, scales, and time point of measure).

We will attempt contact with study authors if important data appear to be missing or unclearly reported.

Assessment of study quality: We anticipate identification of a variety of study designs. We expect there will be a limited number of RCTs due to the nature of the interventions and practices of interest. Where these do exist, we will conduct risk of bias assessment using the Cochrane risk of bias tool in Higgins 2011 [8]. For other study designs, we will seek the appropriate recognised tool to assess risk of bias according to the type of study designs that we encounter (for example, we will use ROBINS-I for non-randomised controlled trials).

At least two reviewers will independently assess the methodological quality of included studies.

Quantitative and qualitative synthesis and subgroup analysis: Thematic synthesis of qualitative data will be guided by established methodologies [48]. We will also be guided by Nussbaum [34] and Sen's [49] capabilities framework in considering how far approaches go in addressing or mediating the structural/institutional/social conditions influencing someone's capacity to access and engage in health care opportunities.

For quantitative data, we will undertake meta-analysis only where this is meaningful, i.e. if the study includes a comparison group, and if the interventions and participants are comparable. We will not combine RCTs in meta-analysis with other non-randomised study designs. Any meta-analyses performed will follow standard Cochrane principles [45]. Where possible, we will calculate effect estimates for our outcomes, using risk ratios for dichotomous data and mean differences (or standardised mean differences) for continuous data and report these summary statistics using 95% confidence intervals. We will use a random effects model in these calculations to account for the expected variation between participants in studies. In the event that insufficient data have been reported by study authors to calculate summary statistics, we will report the data as presented by study authors (for example, using median values, or P values); and if appropriate we will use narrative summaries of the data as suggested by Campbell [57].

We will examine separately, where appropriate, particular groups whose displacement typically differ, for example, those with different citizenship status i.e., asylum seekers and those granted formal refugee protection, population groups, such as lone males. Where we are able to, because data are reported quantitatively and we identify sufficient studies, we will perform formal statistical subgroup

analysis for these particular groups. Otherwise, we will examine the findings according to these particular groups and use a narrative approach to reporting these findings.

Using the GRADE approach, we will appraise the certainty of the body of evidence associated with the review outcomes, and we will report our findings based on the extent to which we can be confident in any associations that are reflected in our results. Evaluation of the certainty of a body of evidence considers risk of bias, indirectness, impression, inconsistency, and risk of publications bias; we will use the information collected during the data extraction process, the assessment of study quality (or risk of bias process), and the collection of outcome data and its synthesis. We will construct summary findings tables according to the separate comparisons in the review; we will distinguish therefore between interventions aimed at health care providers (or actors who are relevant to health care opportunities for forced migrants), and interventions targeting forced migrants directly.

5.3 *Evidence in practice*

Within the complex world of public services and their intricate interactions with civil society, there is a network of interpersonal relationships, intersubjective understanding, and cultural and organisational factors which shape the delivery of services and the experiences of those engaging in or in need of that provision. Recognising these nuances as well as the structural and institutional practices shaping these contexts and interactions will be essential for understanding how interventions and practices can become embedded in practice [58].

We will utilise the expertise and networks of our Advisory Group as well as web-based searches, contact with primary refugee agencies and initiatives identified during our literature search, to identify and document practical initiatives. While our primary focus is specifically for the benefit of the UK, we will take an outward focus, recognising there is learning to gain from responses and practices in other countries. While we may visit locations in the UK to improve our understanding of the context of different practices (for example, we have identified specialist staff delivering health care to refugees and asylum seekers as part of an inclusion team within Guys' and St Thomas' NHS Foundation Trust in London), there is no intention to visit sites abroad; we do not think this would be appropriate in view of Covid-19, from an environmental/climate perspective nor in terms of financial resources. We believe that we can gain adequate understanding through remote contact with international sites.

We will focus on initiatives where active steps have been taken to support health and health care for forced migrant groups. These could be initiatives situated in any context and delivered by any means as long as the aim or outcome is the improvement of health, responsive health care, or health agency for forced migrants. Should we discover attempted but unsuccessful innovations, we will consider including them, as valuable lessons could still be learned. In the absence of relevant interventions for forced migrant groups, we will look to relevant interventions working with minority ethnic populations that may be transferrable to the forced migrant population of interest.

Practical schemata: We will develop a template for site visits/contact, with support from our PPI representatives, specifying practical details such as identification of key stakeholders/informants, data collection activities, interpreter/translation support required, sources to be consulted/documented etc.

Data collection: We will identify up to six primary practices of interest in the UK, Europe or further afield. We will use our networks, including those of our expert Advisory Group and our PPI representatives, contact with key UK refugee agencies, refugee agencies based in other countries, and international refugee organisations, and web searches to help us to identify these practices. We will also note practices of interest as we conduct our systematic review and use social media (such as Twitter) to 'advertise' what we are looking for. We will compile this information and review it in collaboration with the full study team, including PPI representatives, and our expert Advisory Group. In selecting practices, we will aim for a varied representation of models: we will consider the design of initiatives, the contexts in which they are delivered, the moments of opportunity to which they respond or fit, and the different forced migrant populations to which they are aimed.

We will build a relationship with a primary contact/'gatekeeper' situated within the organisation of interest and secure their support in organising further contact with colleagues and the forced migrant communities with whom they interact. We will conduct in-depth interviews with health (or other professionals) face-to-face or remotely; focus groups with patient/forced migrant groups face-to-face or remotely, and where appropriate (and only in the UK) ethnographic research to observe the settings [54] in which provision or interactions take place. We will encourage 'gatekeepers' to support us to reach a representative sample of colleagues (for example, across roles and responsibilities) and forced migrants (for example, migration status, capacity for English language, time in the UK, health needs, gender, lone individuals/family). We will follow saturation methodologies to determine this [59]. We will ensure the provision of professional translation where necessary and the provision of appropriate vouchers to ensure transport and subsistence costs are covered and to thank participants for their contribution. We will do this both where we visit a service and where we conduct remote interviews/discussions. An interview/discussion guide will be developed collaboratively with the research team including PPI representatives, and clinical and community practitioners and patient information sheets and consent forms will be developed with support from our PPI representatives. Interviews may be conducted privately or as small group discussions. These will always be in familiar locations for participants.

We will establish the local context as it relates to policy, forced migrant populations and needs. We will aim to gain understanding of the historical background, physical setting, and other institutional and organisational factors relating to services or initiatives [60]. This may include gathering information on service design, on those who use, or for whom, the service is aimed, staffing, resources, the political and institutional context in which the service or its users are situated, as well as experiences of those using or delivering, or essential, to those services. We will ask services to share service operating procedures, frameworks, written guidance or information including those for the public and patients, and any evaluations or reports about a service already produced.

We aim to talk to study participants and observe relevant interactions where appropriate/sites are visited; our intention is not to change the course of patients' care or treatment during these observations. We will rely on the support of key 'gatekeepers' to support the recruitment and initial explaining of the study to potential participants, including introducing of the consent process. We will also ensure that there is a mechanism in place that enables participants (both service users and staff) to participate anonymously, for example by providing contact details for the research team. Explaining

of the study and the consent process will be repeated once we are in direct contact with participants (whether in-person or remotely). Due to the nature of the study, some participants will have experienced traumatic events; therefore, avoiding distress and re-traumatisation will be prioritised. Where accredited interpreters are required to undertake interviews, we will ensure that interpreters sign a confidentiality clause. Interviews and group discussions will be recorded. Recordings will be transcribed by the research team. During transcribing, participants will be anonymised and any identifiable details excluded. Once transcribed, recordings will be deleted.

Given the Covid-19 context, we will make assessments as to the risks posed by face-to-face contact, in-line with Government and organisational advice at the time and take any necessary precautions. If our approach, as planned, is not practical we will adapt our methods in order to ensure we are working in a Covid-secure way be that through outdoor interaction, the use of video conferencing or other approaches.

Analysis: The descriptions of initiatives in practice and interview transcripts will be categorised through an inductive process into broad areas of focus after which we would use an inductive thematic analysis approach aimed at identifying less directly observable content. We will consider how closely data collected align with the objectives of our research proposal and we will make an assessment of the initiative's effectiveness, efficiency, and acceptability. We will be guided by the capabilities framework [34, 49] which supports a systematic focus on multidimensional aspects of quality of life including relationships, participation, notions of freedoms and a focus on agency and empowerment. We will use this to continually consider how far approaches go, or what contributions they make, in addressing or mediating the structural/institutional/social conditions influencing someone's capacity to access and engage in health care opportunities.

Narrative synthesis: Again, guided by the capabilities framework we will take our evidence both from the literature and within practice, and bring this together as a narrative synthesis of preliminary evidence. We will consider different initiatives and their effectiveness relative to context [61, 62], to their location or potential location across the health care moments of opportunity we have previously identified and how they might be integrated across different disciplines, for the greatest possible benefit. We will conduct this analysis in conjunction with our Advisory Group and PPI representatives producing a synthesis report as well as a simplified set of summary documents to be used as part of the dialogic synthesis to follow.

The multiple data collection sources used for the study of initiatives in practice will allow triangulation, improving the accuracy and completeness of the account built up of the interventions studied [63]. We will however include an assessment of the robustness of our overall evidence, using decision-making tools to report the confidence in our findings [54]. For transparency, we will also explore and report any limitations to our research [55].

Reporting: We will follow recommendations in reporting. In particular, the NIHR-funded work of Rodgers et al [64] who used a Delphi-type process to define a set of standards for organisational case study research, including consistency, rigour and reporting, will be useful. We would anticipate that this will help us achieve our aim of making our work more accessible to different audiences.

5.4 Thinking together - dialogic evidence synthesis

Dialogic practice relies on an openness to engage and be informed by others and rests on the idea that what can be shared (knowledge, understanding and perspectives), is reciprocal and valuable to the practice, knowledge and experience of all [65]. Dialogic approaches have been honed across a range of learning contexts: in the classroom [66], in broader spaces of educational disadvantage [65], and in healthcare as an enabler of compassion [67], a practice for fostering inter-professional working, quality improvement, and the emergence of productive action [68, 69], and as a systemic approach to working cross-community with hard-to-reach young people [70]. In common, these models describe as mutually dependent the learning dialogue between colleagues and the dialogue with their public (students, parents, young people, patients, community) with the emphasis on learning, the expert value of all contributors, and localised relevance.

Discussing dialogue, physicist David Bohm [56] suggests it should be centered on the idea of "thinking together… in the spirit of the whole…" and it is in this *spirit* that we will approach a series of dialogic events. These events will act as the third stage in our data collection providing a further opportunity for knowledge creation in which we are able to overlay the findings of our empirical research and systematic review, with the diverse perspectives, experiences and ideas of the expert group of people involved. Dialogue has a number of conceptions that set it aside from, say a focus group. The attempt is to allow the "the actual words of subjects (here, forced migrant communities and essential actors in those 'health care moments of opportunity') [to] share space with those of the author" [71]. It demands that we, with the expert help of a facilitator create and sustain a space for the open exchange of ideas, and the consideration of possibilities, free of judgement [50, 51]. In doing so it provides, what Gadamer discussed as the transformative quality of dialogue [52], an opportunity in which the exchange of those ideas, insights, and evidence are rooted within the social, cultural, and structural realities in which they exist [53]. We see it therefore providing a tangible learning and reflective experience (for everyone involved) and helping to better determine how the evidence gathered throughout the project can be constructed and fostered in practice.

We will invite a broad range of 'stakeholders', using the *health care moments of opportunity* framework we will have already identified, including forced migrant communities as well as structural 'gatekeepers' (such as commissioners, service managers, and strategic membership). We will aim for comprehensive representation from across the three localities/districts within University Hospitals of Morecambe Bay NHS Health Trust footprint in the North West of England. We, as researchers, will contribute our learning (from the findings of the systematic review and from the evidence we have gathered from practice). Key representatives will contribute their lived experience either of health and health care as a forced migrant in the UK, or as a practitioner on the frontline of an encounter that could support health for forced migrants, or a manager or a commissioner of that frontline 'encounter'. This might, for example include a social worker, foster carer, officers working in resettlement, housing, the police, employment and benefit services, a pharmacist, a teacher or other school or nursery education worker, a language tutor, nurse, midwife, health visitor, GP or other 'traditional' healthcare professional, the receptionist of any relevant office or service, an advocacy officer, faith leaders, members of civil society groups and support networks including services for refugees and people seeking asylum. Together, we will consider and synthesise the evidence (*Thinking together*) through

dialogue to produce actionable guidance and plans to facilitate better encounters and better health for this group.

In bringing together the literature, the evidence from practice, and diverse and perhaps unlikely conversationalists, we hope to minimise the risk of idealising 'a solution'. We hope the approach will also help to bring to the surface intersectional aspects, and consideration of the wider structures and interconnecting factors that might present stumbling blocks to adoption, or impact the capacity for responsive health care or health agency for this population.

The events will take an iterative approach. We anticipate five and we would aim for each participant to attend at least three of these events. This inclusive and repeated process will support the production of engaged practice as well as support the conditions for participatory parity, as advocated by Fraser [72]. The first event will bring representatives from across the whole Trust footprint, the subsequent three 'sandwich' events, will focus in turn on each of the three locality / districts within that footprint, and the final event will again bring everyone together. The locality/district focus will aim to recognise that each area presents its unique context, population and existing provision and/or capacity of services and practices.

We acknowledge and will continually consider critiques of dialogue in contexts of cultural difference (Ellsworth, for example [73]) and will actively seek to address the inherent hegemony of the 'dominant worldview' [74] and will approach these events with a responsibility not to privilege the dominant view/participants or 'way' of communication. We anticipate that the prior workshop, PPI engagement, and fieldwork alongside the expertise of our facilitator, will have helped us to consider the best framework with which to do this, and while the philosophy of 'dialogue' will be central, we will likely take a number of approaches including non-verbal, small group and break out workshops.

The events will be guided by a highly experienced facilitator with support from the study team and will be situated within the lived space of the group whose health this work seeks to support. This process will enable the constructive synthesis of evidence into actionable recommendations and a guiding framework for adoption by other localities across the UK and beyond. In addition, this will be a blueprint to support change locally as well as a critique of our synthesis methodology, that if proves practical, could support responsive health care development for other populations.

6 STUDY SETTING

The core project team will be based within Lancaster Patient Safety Research Unit, at the Royal Lancaster Infirmary, part of University Hospitals of Morecambe Bay NHS Trust. Project team colleagues will be located at the University of Nottingham, Global Link (Lancaster, UK), and Captain French Surgery, The Gillinggate Centre (Kendal, UK).

The cross-community, inter-professional workshop will take place in a community space identified by the project community partner, Global Link, as a space familiar and/or appropriate to the local forced migrant population.

For our evidence in practice, we will identify up to six sites in the UK, Europe or further afield. We will identify these sites, as described above, and will liaise directly with a key 'gatekeeper' at each site to support the identification and recruitment of staff and 'clients' who will act as participants in interviews. We will aim to visit in person, sites identified in the UK but for any international sites we will rely on video-conferencing to engage with participants.

Dialogic events will take place in community spaces identified with support of the project community partner, Global Link and other local community organisations working with the local forced migrant community.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

For our evidence in practice (section 5.3), we will require participants to:

- Provide consent to participate in a recorded interview or group discussion.
- Have lived experience of forced migration and are attending, have attended or are considering attending a service supporting improved access to health care, responsive health care, or health agency.
- Or, be a member of staff/volunteer in an organisation working to improve access to health care, responsive heath care or health agency for forced migrant populations.

7.1.2 Exclusion criteria

- Where informed consent is not provided or consent is retracted during the interview or in the period prior to data analysis. We acknowledge that some of the conversations we may have during discussion groups could prompt anxieties around confidentiality (such as criticisms of UK provision or individuals' needs or experiences). Though we will seek to ensure our approach to anonymity is understood, we acknowledge that there may be withdrawals of consent during the study.

7.2 Sampling

7.2.1 Size of sample

We anticipate including six services in our *evidence in practice* stream of work. Due to the nature of the services we anticipate engaging with and the variability in their provision, it is not possible to state at the outset how many participants we will recruit from each service. However, we will be guided by saturation and expect this to be at least three service users and two/three members of staff from each service.

7.2.2 Sampling technique

We will use a purposive sampling technique to select both the evidence in practice sites and study participants associated with these sites.

7.3 Recruitment

7.3.1 Sample identification

Evidence in practice: we aim to identify a broad range of potential services/initiatives following different approaches and working with people with different displacement experiences and statuses.

Within each service/initiative, we will identify a key 'gatekeeper' to support the identification of participants. We will provide 'gatekeepers' with a brief information sheet/leaflet explaining the study to support participant identification/recruitment.

Travel/subsistence expenses of £15 each have been budgeted for forced migrant participants.

7.3.2 Consent

We will obtain informed consent prior to conducting interviews and group discussions. We will produce a Participant Information Sheet (PIS) for each 'group' of participants with our lead PPI representative supporting us to produce an appropriate document for forced migrant participants.

We will have the PIS and Consent Form translated into any relevant languages, such as Farsi or Arabic, where appropriate. We will seek the support of the key 'gatekeeper' at each site to discuss the study, the PIS and the Consent Form, with potential study participants. Translators will be provided where appropriate. Provisional agreement will be sought from potential participants to take part in the study.

Following provisional agreement to participate but prior to any interviews/discussions, the researchers, with translators where appropriate, will provide a further opportunity to discuss the purpose of the study and the consent process, and answer any questions, including relating to how participants' information will be stored and what it will be used for. At this point, participants will be asked to provide written (in-person) or verbal (remote) consent.

The capacity of the potential participant to understand, and therefore consent to involvement, will be assessed prior to researcher contact with participants by the service 'gatekeeper'. Participants will be encouraged to retain a copy of the PIS and consent form for their information. We will make available, on request, copies of our HRA Approval, ethical approval, this protocol and copies of the researchers' CVs and training records, as well as evidence of funding for the study, for examination by potential participants.

It is commonplace for the period of time between sight of the PIS and requesting/receiving consent to be a minimum of 24 hours. Our two-stage process which will take place across the course of at least one week will ensure that this is the case.

An indicative Participant Information Sheet and Consent Form is provided in the Appendix. These should be seen as drafts and have not yet been worked on with the PPI group. These will be developed with their support prior to ethics submissions.

We will seek formal consent only from those who agree to participate in an interview or group discussion. As such, there may be other individuals who are observed during a site visit and ethnographic observations from whom we have not gained consent. Our intention is not to change the course of patients' care or treatment during these observations and we will not observe clinical interactions unless invited to do so. No recording (visual or audio) will be made. However, notes may be made during observation and the researcher may interact verbally with individuals. All the data that we gather during a visit/observations will be anonymised and any potentially identifiable characteristics changed. The data will be managed as per interview data, and although initially it may be handwritten, it will be stored in an encrypted file at the end of each day and the original notes destroyed. The key 'gatekeeper' will make individuals within a site aware of the study and why the researchers are there. However, it is possible that some individuals may enter and exit the site without being aware of the study.

8 ETHICAL AND REGULATORY CONSIDERATIONS

Use of the Health Research Authority's (HRA) screening tool indicates that the study approach requires Research Ethics Committee approval. An application will be made to the HRA for ethics approval once we begin to identify services we would like to include in our *evidence in practice* stream of work.

We will utilise our networks and those of our Advisory Group to negotiate access for visits or remote video discussions. We aim to talk to study participants and observe relevant interactions where appropriate; our intention is not to change the course of patients' care or treatment during these observations. We will rely on the support of key 'gatekeepers' to support the recruitment and initial explaining of the study to potential participants, including introducing of the consent process. This will be repeated once we are in direct contact with participants. Interviews/discussions will take place in spaces familiar to participants and will include where appropriate the use of accredited interpreters. We also aim to include, where feasible our lead PPI representative or Global Link colleague (both with displacement experiences) in discussions alongside our researcher. Due to the nature of the study, some participants will have experienced traumatic events; therefore, avoiding distress and re-traumatisation will be prioritised. Where accredited interpreters are required to undertake interviews, we will ensure that interpreters sign a confidentiality clause.

While we will identify the services/initiatives which we study, personnel and service users will be anonymised and for service users, any potentially identifiable characteristics, will be changed.

8.1 Assessment and management of risk

The systematic review does not include participants and is not subject to management of risk.

During our *evidence in practice* work we will have contact with participants in the context of group discussions (forced migrants) and group or one-to-one interviews (staff/volunteers). There may also be some contact during observations of services. We do not anticipate a risk to participants though acknowledge that due to the nature of the study, some participants will have experienced traumatic events; therefore, avoiding distress and re-traumatisation will be prioritised. In the unlikely event that we encounter the disclosure of any sensitive information or issues of harm to self or others, we will bring these to the attention of local staff for referral to the appropriate safeguarding mechanisms within the host organisation.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

This study will be submitted to the HRA Research Ethics Committee for ethical review. This protocol, Participant Information Sheets, consent forms and other relevant documents and processes will be examined and a favourable opinion sought before any research activity with participants is commenced.

The Chief Investigator will produce the annual reports as required.

Regulatory Review & Compliance

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

For any amendment to the study, the Chief Investigator, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment.

Amendments

If an amendment to the study is required we will be bring it to the Advisory Group in the first instance. This will allow for discussion regarding the necessity of amendment, whether the amendment is substantial or non-substantial; and to set in action the process for submitting the amendment. We will make the Study Steering Committee aware if an amendment is deemed necessary and we will seek their agreement to the proposed amendment. We will advise the Sponsor and Funder to their actions.

We will use the Integrated Research Application System (IRAS), which will instruct us to whether we need to notify any specific review bodies and in what capacity; and to receive further information regarding the submission of amendments.

Ultimately, the Sponsor will determine if an amendment is substantial or non-substantial. If an amendment is deemed to be substantial, the Sponsor will submit a Notice of Substantial Amendment form to the REC for consideration; and we will receive a response within 35 days of receipt of the notice.

At this stage, we will also notify of the amendment, whether substantial or non-substantial, to the study sites; the research team; the local Research & Development office; and the local Clinical Research Network. This will be undertaken by the Chief Investigator. Any amendment history will be recorded and will be accessible if required.

8.3 Peer review

The project proposal has been extensively peer reviewed during the application process by reviewers from the NIHR's pool of experts.

8.4 Patient & Public Involvement

We have considered the NIHR INVOLVE framework and all of our PPI representatives have been costed into the project to include time and travel. Where monetary 'reward' is prohibited under Immigration Law we will make reimbursements of travel, subsistence and mobile data costs only. We will keep a log of all PPI activity and PPI comments. As well as providing transparency, this will allow us to evaluate effectiveness of PPI activities throughout the project.

The proposal for this study evolved primarily in response to experiences and observations by members of the study team through involvement with grassroots refugee support organisations in the north of England, including conversations with asylum seekers and refugees in the area, with GPs locally and other health practitioners and specialist services across the UK. The study design has been discussed with our lead patient representative.

We will include three PPI representatives. One lead PPI representative will be involved on a regular basis throughout the duration of the project. Two further PPI representatives will provide additional support and perspectives to particular parts of the study (such as events and advisory group meetings). In addition, we will have the benefit of an experienced patient representative who will provide initial training/coaching to the three PPI representatives who do not have experience of working with a research team, and on-going mentoring support.

We aim for our PPI representatives to be individuals with different forced migration experiences and histories. This will support variability in contributions and perspectives.

Our Patient and Public Involvement strategy sees patient/public representation and contribution across the following areas:

1) Our lead PPI representative will be involved in all of the following activities, in addition, one or both additional PPI representatives will support some of these areas of the project:
    a. Initial review of the search strategy and planning including review and/or production of materials for the cross-community workshop
    b. Joining Advisory Group meetings
    c. Supporting the recruitment and support of representatives from the local forced migrant

community to participate in the workshop and later 'Thinking Together' events
   d. Review and selection of initiatives in practice
   e. Review of pilot data extraction template
   f. Development of interview guides and data collection template for site visits
   g. Joining one or more site visits
   h. Planning and delivery of dialogic events
   i. Assistance with dissemination materials
2) Cross-community and inter-professional workshop: we will deliver a patient and public engagement workshop, early in the study which will bring together representatives of forced migrant communities and health, social, and civil society actors to support identification of health care moments of opportunity for forced migrants. This will inform the study design and key study concepts.
3) Thinking Together – dialogic events: these will take place across five events as a form of participatory evidence synthesis. We will aim for comprehensive representation of local forced migrant communities, frontline practitioners and managers and those who commission services. We will share our findings from the literature and from the evidence we have gathered from practice, and together with the diverse perspectives of each event 'participant', consider and synthesise the evidence in order to produce actionable guidance and plans to facilitate better encounters and better health for forced migrants.

8.5 Protocol compliance

Accidental protocol deviations can happen at any time. We will document any such deviations on the relevant forms and report to the Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

We will bring all breaches of protocol compliance whether accidental, minor, significant or recurring to the attention of the Study Steering Committee in case further action is required and to decide on that action.

8.6 Data protection and patient confidentiality

All project staff will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

- The majority of data that we collect from the study sites will be qualitative, however some sites may provide us with patient outcome data. This will not be cross-referenced to personal data or supplied with any personal identifying data and therefore there will be no need to code and depersonalise data; there are no means by which patient confidentiality can be breached.
- Audio recordings of focus group discussions/interviews will be transcribed by the research team. Any identifying data, such as names or identifiable characteristics will be omitted and the original

recordings destroyed. Any transmission of this data between researchers will be password protected.

- We will need to maintain some personal contact details for the participating staff members at the study sites. This will be located in password protected digital files and destroyed at the conclusion of the project. The purpose of keeping this information is to allow follow up/feedback with the participating sites as required.

8.7 Indemnity

For research within the NHS, NHS indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. Clinical Negligence Scheme for Trusts (CNST) provides indemnity that covers clinical negligence and harm caused.

8.8 Access to the final study dataset

The Chief Investigator and the Research Team alone will have access to the final study dataset.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

In our dissemination strategy:

- We will publish the systematic review as the first output of this project.
- We will produce a report presented as a narrative synthesis of approaches to addressing barriers to health care and health agency for forced migrant communities.
- We will disseminate co-produced recommendations and a guiding framework for improving responsive health care and health agency for forced migrants. This will be the key output of the series of dialogic events but the collective coming together of everyone's contributions throughout the project. The content will evolve throughout the synthesis of the research evidence and the diverse perspectives, experiences and contexts of event contributors. The production and presentation will be carefully framed for different stakeholders including health and care practitioners, and other public sector authorities, civil society groups, and for forced migrant communities. To support this framing we will utilise a creative consultant to support the translation of key findings and recommendations into resources appropriate for a culturally diverse forced migrant audience.
- A blueprint for what a responsive system of care could look like for forced migrants in a North West region will be a further output and result from the discussions and reflections during the dialogic events. This blueprint will effectively test the recommendations and guiding framework produced above. It will be locality specific, identifying appropriate approaches, collaborative pathways and the supports necessary to address the challenges around responsive health care across the area. It will identify where shifts and interventions may be required, and where further investment to implement or develop provision in response to identified gaps may be necessary.

- We anticipate publications in peer-reviewed journals, including the qualitative evaluation of evidence in practice and the methodological approach to participatory dialogic synthesis that we take throughout the dialogic events.

  In addition, we expect the project to network with relevant professional and research groups and civil society organisations from the start and we will utilise the networks and connections amongst the research team and our Advisory Group. We would anticipate active sharing of project updates and outputs to these networks and the public via online newsletters/blog posts as well as the individuals and organisations participating in the dialogic events. We will use the Lancaster Patient Safety Research Unit's website (www.lpsru.org) and our Twitter account (@LPSRU) to publicise the project throughout the period, as well as partner websites and Twitter accounts, including Global Link (globallink.org.uk). We will make use of mainstream news media as much as possible.

  We will encourage our PPI lead to share updates of the project with national forced migrant led networks and groups and all of our PPI representatives to engage with their own networks (be that social or professional) about the study; further encouraging them to bring any ideas or responses to the project as they see fit. We will set up a project WhatsApp group or similar to which we will invite workshop and event participants and use this to keep participants updated on outputs of events and work streams, and engaged in the project.

We aim to disseminate our approach and findings to public health policymakers at local, regional and national scale and we will encourage NICE, the Refugee Council and others to consider our recommendations and findings as part of their guidance production. With the support of our networks we will promote the outputs of our research to relevant national organisations, amongst others, the Royal College of General Practitioners, Royal College of Nursing, British Association of Social Workers, Serco, City of Sanctuary, International Committee of the Red Cross, and the Refugee Council.

We aim to reach frontline practitioners through our local NHS Trust and our local Advisory Group members, including local health care commissioners. The relationships developed throughout our dialogic events will aim to support reception of our recommendations.

Data arising from the study will be owned by the study Sponsor, the University Hospitals of Morecambe Bay NHS Trust. On completion of the study the data will be analysed and tabulated and a final study report will be prepared.

As per their guidelines, we will use the "Funded by NIHR" logo on all appropriate outputs. We will acknowledge NIHR as our funder, and a disclaimer regarding our findings/opinions will be on all written and oral output. The study protocol will be made available along with the abstract and plain English summary for the life of the study, on the NIHR website.

9.2 Authorship eligibility guidelines and any intended use of professional writers

We will adopt The International Committee of Medical Journal Editors' guidelines for authorship. These guidelines state that an author must meet four criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work.
- Drafting the work or revising it critically for important intellectual content.
- Final approval of the version to be published.
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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11. APPENDICIES

11.1 Appendix 1- Required documentation

Local documentation required prior to initiating a participating site:

- Participant Information Sheet (PIS) on headed paper, stating NIHR as funder, with detachable consent form.
- Regulatory applications and approvals: HRA/REC Approval; Organisation Information Document; NHS to NHS Confirmation of Pre-engagement Checks; Letters of Access, etc.
- Research team CVs and relevant training logs
- Data collection requirements e.g. interview and focus group discussion guides.

Draft Consent form

PARTICIPANT CONSENT FORM: Service users

Project Title: Health care moments of opportunity: a review of evidence and community dialogue to explore responsive health care for refugees and people seeking asylum in the UK.

What we are doing: Finding out about methods to help support better health care and better health outcomes for refugees and asylum seekers.

Researcher:

Please initial box

1. I confirm that I have read and understand the *Participant Information Sheet* dated XXX for the above study. ☐
2. I have had the opportunity to consider the information sheet, to ask the researchers any questions I had, and have received a helpful response. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my asylum status, health care, legal rights or access to services being affected. ☐
4. I am aware that I should retain a copy of the *Participant Information Sheet* and *Participant Consent Form* for future reference. ☐

5. I understand that while the information gained in this study will be published as explained, I will not be identified and individual information will not be published. ☐
6. I agree to group discussions being audio recorded and understand that any recordings will be destroyed once written down and no personal data will be recorded. ☐
7. I acknowledge that by joining a recorded focus group discussion that I agree to take part in the above study. ☐
8. I confirm that this consent form has been provided to me in a language that I can read and understand. ☐

Name of Participant:

…… **Date of verbal consent**…….....

I certify that I have explained the study to the individual above and consider that they understand what is involved and have freely consented to take part in the research.

Name of researcher:

Researcher's signature…… **Date**…….....

One copy will be retained by participant and one copy to be retained by researcher.

11.2 Appendix 2 – Schedule of Procedures

Phase		PHASE 1												PHASE 2				PHASE 3		
Milestones	Stream of work	Workshop Systematic review / Evidence in practice												Dialogic events				Final synthesis / Recommendations & framework Dissemination		
Project Month		-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Calendar Month		Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22
Advisory & Steering group recruitment	Study	x																		
Full study team meeting	Study		x																	
Public/patient group recruitment	PPI	x																		
Public/patient training/coaching	PPI		x																	
Scoping search for workshop (snap shot of outcomes, reported data etc)	Systematic review		x																	
Meeting: Prep workshop	Workshop/PPI		x																	
Workshop	Workshop/PPI			x																
HRA application	Evidence in practice			x																
Meeting: Advisory group	Study		x																	
Meeting: Steering group	Study		x																	
Database searches / study selection	Systematic review			x	x															
Identification of relevant networks	Study		x	x	x															
Identify initiatives in practice	Evidence in practice		x	x	x	x	x	x												
SR Data extraction	Systematic review					x	x	x												
SR Data analysis	Systematic review							x	x	x	x	x								
Prepare interview schedules/visit schematics – review with AG	Evidence in practice			x	x	x														
Submit HRA ethics application	Evidence in practice			x	x	x														
Arrange visits / interviews	Evidence in practice			x	x	x	x	x	x											
Conduct site visits / interviews	Evidence in practice					x	x	x	x	x	x									
Compile data from sites / thematic analysis	Evidence in practice					x	x	x	x	x	x	x	x							
Identify key local actors	Study / events		x	x	x	x	x	x	x	x	x	x	x	x	x					
Preliminary synthesis	Study											x	x							
Meeting: Prep events	Dialogue												x							
Event 1 (Trust-wide)	Dialogue													x						
Event 2 (locality A)	Dialogue														x					
Event 3 (locality B)	Dialogue														x					
Event 4 (locality C)	Dialogue														x					
Event 5 (Trust wide)	Dialogue																x			
Iterative plannin/synthesis of events	Study													x	x	x	x	x		
Updated database search, data extraction & analysis (SR)	Systematic review															x	x			
Final synthesis	Study																	x		
Meeting: Advisory Group	Study																	x		
Work with creative consultant	Dissemination																	x	x	
Report writing and dissemination	Dissemination								x	x	x	x	x	x	x	x	x	x	x	x
Ongoing publicity	Dissemination		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Team meetings	Study		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.1	26/11/21	Sharon Lewis / Amy Robinson	Re-ordering and more clearly defining (but not changing) outcomes for systematic review; minor re-wording of project title