

**Protocol for a Realist Evaluation Developing detailed 'how to' guidance for integrated palliative care and heart failure services across the NHS**

**Acronym: PalliatHeartSynthesis II**

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## **1. Summary of Research (abstract)**

### Background

Inequity of palliative care provision is an ongoing problem for underserved groups, such as those with heart failure (HF) who are mostly older age with multi-morbidities. This puts considerable burden on patients, their caregivers and health services with frequent avoidable hospitalisations. Recognising the importance of this topic, the NIHR HS&DR funded our research team to complete a realist synthesis of the integrated palliative care (PC) and HF literature (PalliatHeartSynthesis – under review). The aim was to understand what kind of integrated PC and HF services work, why, how and for whom. The synthesis found that integrated PC and HF services work when service providers are motivated to integrate services and have the right opportunities and capabilities to support behaviour change. However, our synthesis also identified significant knowledge gaps. Most documents were from America: few focused on the UK NHS setting. While acknowledging these limitations, we developed a series of implications based on our programme theory of what strategies can help when integrating palliative care and heart failure services.

### Research question

How do we set up, sustain, and embed integrated PC and HF services across the NHS?

### Objectives

1. Use a realist approach to evaluate existing integrated PC and HF services in NHS organisations to understand how they have been set up, sustained, and embedded in routine practice.
2. Use these data to confirm, refute or refine our existing programme theory regarding this process to co-produce a detailed 'how to' guidance for setting up, sustaining, and embedding integrated PC and HF services across the NHS.
3. Develop a community of practice to support those who wish to set up, sustain and embed integrated HF and PC services.

### Methods

This project will use co-design and realist evaluation approaches to generate primary data across five NHS Sites (England x 2, Scotland, Wales, and Northern Ireland (NI)). The five sites were purposively sampled for geographic and integrated PC and HF service variation. The research will be delivered via three work packages (WP). WP1 will involve a realist evaluation at each site using documentary analysis, observations, and semi-structured interviews. WP2 will involve co-design of a detailed 'how to' guide for setting up and improving integrated HF and PC services in the NHS. WP3 will involve development of a community of practice to support those who wish to set up, sustain and embed integrated HF and PC services.

### Timelines for delivery

36 months starting in January 2025.

### Anticipated impact and dissemination

This research will enable us to create the knowledge, and knowledge translation needed for better tailoring and implementation of NHS integrated PC and HF services and provide timely evidence for Integrated Care Boards and service providers to inform and optimise the integration of these services across the NHS.

## **2. Background and Rationale**

HF is a modern-day global epidemic, increasingly common in an aging population with multi-morbidities, where this debilitating disease is estimated to reach 64 million people by 2050

[1]. The absolute number of people with HF in the United Kingdom (UK) during 2014 was 920 616 (1.4% of the overall population), outnumbering patients with the four leading forms of cancer combined [2]. Patients and their informal caregivers (carers) have debilitating physical, psychological, and social symptoms with high dependency on healthcare services where costs are driven by repeated hospital admissions during the patient's last year of life, costing the NHS £2bn per annum [3].

The provision of appropriate, early access to palliative care (PC), integrated into HF management, offers an effective and cost-effective intervention for many of these issues, relieving suffering, improving the quality of life for patients and their carers, and reducing days in hospital [4-5]. Integration of PC is enshrined in HF clinical guidelines globally [6-8]. Yet, two decades after the first calls to redress the lack of support, planning and holistic care for those living with, and dying from HF, and despite the growing evidence base to support the use of multidisciplinary integrated PC, people with HF remain more likely to receive PC much later than people with cancer, or not at all [9-11].

Integrated PC aims to achieve continuity of care by integrating administrative, organizational, and clinical services that make up the care network (12). Integrated PC and HF Interventions should involve cohesive working across all care settings. Additionally, such interventions are underpinned by unified and consistent communication approaches, which should run parallel to active HF management to support quality of life and end of life person centred care outcomes [6-8]. There are examples of good practice [9-10], but they are not routinely implemented. Therefore, it is imperative to understand why the pace of integration of PC into HF management is so slow.

This proposal directly addresses the James Lind Alliance priorities for advanced HF, in particular priorities 6 (enabling conversations about end-of-life care), and 12 (the long-term care needs of people with advanced HF be better met by closer co-operation between HF and PC teams) [13].

The UK population is living longer than ever before. This increased life expectancy comes with significant challenges for the NHS now and in the future; it is estimated that by 2040, up to 47% more people will have PC needs from several chronic conditions including HF [14]. Older people have a high prevalence of HF, have complex health needs and multiple long-term conditions (on average 4.5 comorbidities). HF often dominates due to its range of physical and psychological symptoms that the syndrome includes (15), along with it being the costliest aspect of patient care due to: high rates of hospitalisation; pharmacology; device; and surgical treatments as their HF progresses [3]. Inequity of access to PC is evident; the PC needs of people with HF have often been overlooked, with calls for more attention to, and research for, this vulnerable group to ensure they receive appropriate, effective treatment and care (6-9, 13, 15).

Integration of PC and HF services is an ethical and financial imperative for mitigating both the human and health service costs through improved patient and carer experience, reduced ambulance callouts, emergency department visits and hospital admissions [3-5]. This is consistent with the prioritisation of integrated services in NHS England's Long-Term Plan [16] to address "increasing inequalities and pressures from a growing and ageing population". Our proposed research will directly affect healthcare service delivery through an improved understanding of why integration of PC into HF management remains so difficult and finding solutions to improve accessibility to PC for people with HF who need it. By doing so, we will improve the health and wellbeing of a large proportion (1.4%) of NHS service users with HF and provide findings applicable to other patient cohorts with non-cancer conditions who remain disadvantaged in their access to PC. It is consistent with the aim of

HSDR to produce rigorous and relevant evidence to improve the quality, accessibility and organisation of health and social care services. The study will have a direct impact in shaping integrated PC and HF services by further developing and refining the programme theory (PT) developed by our realist review (NIHR HSDR NIHR131800). We will conduct a realist evaluation of integrated multidisciplinary PC and HF teams across all relevant settings (primary, secondary, third sector organisations (TSOs) and social care) to identify how barriers to implementation have been overcome (or not).

#### Literature review of published evidence

McIlvennan and Allen (17) published a literature review summarising the evolving role of PC for patients with HF, along with the barriers and opportunities for its integration into routine practice. The review included a search of PubMed and clinicaltrials.gov registry between January 2010 to September 2015, with an additional search for publications prior to 2010 which were only included if they demonstrated impact on the current state of evidence. Findings from the review highlighted the need for evidence on how best to integrate PC and HF given the cultural and environmental differences in how PC services are delivered.

A forward citation search of McIlvennan and Allen's (17) review, along with a PubMed search using the same search terms "heart failure", "palliative care", "quality of life", "symptom burden", and "end of life" identified three subsequent systematic reviews (18-20). Diop et al.'s (18) Systematic Review and Meta-Analysis of PC Interventions for patients with HF included fifteen studies, all of which varied in terms of methods, patient populations, interventions, settings, measurement tools, and outcomes. Although the authors suggest that findings support the use of home and team-based PC interventions for improving patient-centred outcomes, documentation of preferences and healthcare utilisation, these claims must be interpreted with caution as the authors did not conduct a quality appraisal of included studies.

Two years later, Datla et al (19), published a more robust systematic review and narrative synthesis of patients with HF, including a more comprehensive search of five electronic databases and grey literature. Twenty-three studies were included. Evaluation phase studies provided evidence for the effectiveness of multi-component, multidisciplinary PC interventions for improving patient-centred outcomes (symptom burden, depression, quality of life, functional status) and reducing healthcare resource utilisation and costs of care, with no impact on survival. The most recent systematic review of randomised controlled trials (n=9) conducted by Sahlollbey et al. in 2020 showed that compared to usual care (HF management only), the integration of multidisciplinary PC improved both symptom burden and QoL, substantially reduced hospitalizations and had no adverse effects on survival (20).

Research on integrating PC and HF has seen an exponential increase since the turn of the century, increasing from 10 publications on average in 2000 to over 100 publications per year in 2017. However, despite increasing evidence of benefit (19-20) and clinical guidelines (6-8) integration of PC and HF is still not part of routine practice.

Considering this, we completed a realist review of the literature (PalliatHeartSynthesis) to understand why the pace of PC integration into routine HF care has been so slow-moving across the NHS and subsequently developed implications for policy and practice. Our realist review represents the most up to date and current detailed understanding of the integrated palliative care and HF literature. We provide details on its findings below. The final report was submitted to the NIHR in June 2023 and is currently under review following a first round of revisions.

Our realist analysis developed 6 overarching context-mechanism-outcome configurations (CMOCs) with 30 sub CMOCs. The resulting programme theory was summarised in relation

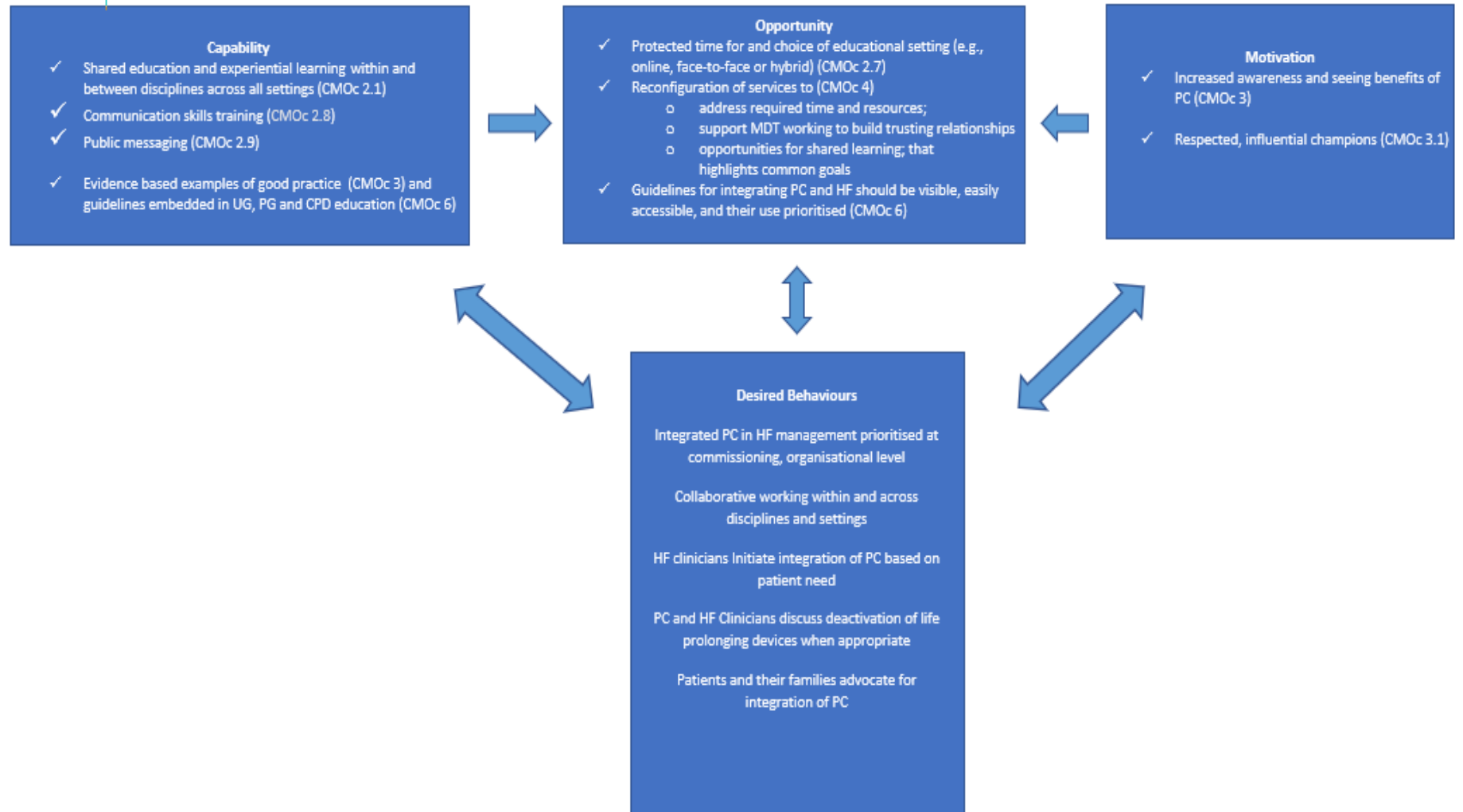
to the three core components of the COM-B model – capability, motivation and opportunity. We chose to discuss our findings this way as both the literature and stakeholder feedback indicated that the key barriers to integrating care largely involve human behaviour in response to underlying processes (motivation etc.) shaped by the contexts in which key players operate (see Figure 1). Although the COM-B model relates to individual behaviour change, it also considers team and organisational behaviour. For example, an individual's capacity to carry out a specific behaviour also depends on the organisational culture they work within, and the opportunities afforded to them within their team and organisation.

Integrated PC and HF services work when there is protected time for evidence-based education and choice of educational setting (e.g., online, face-to-face or hybrid), and the importance of increased awareness of and seeing benefits of PC are optimised as key intervention strategies, the emotive and intellectual need for integrating PC and HF is spread via credible champions, seeing direct patient benefit, and having visible guidelines. Based on our findings we developed a series of implications and strategies for those working to set up integrated PC and HF services (Figure 1). The programme theory in Figure 1 will form the basis of the initial programme theory of the realist evaluation and be developed and tested further (see section 4. Methods below for more details).

Crucially, our review identified significant knowledge gaps. Most included documents were from the United States of America. Only 30 of the 130 documents included in the review were specific to the UK, thus few focused on NHS settings. Most documents considered the experiences of nurses and physicians only, with few including perspectives from the wider multidisciplinary team involved in integration of PC into HF management. This limited understanding of what works, for whom in this situation. While the findings of the realist review are still informative for the NHS, a realist evaluation collecting and using primary data would enable us to further develop, confirm, refute, or refine our 'implications' specifically for NHS settings. This proposal aims to fill the knowledge gaps by addressing the following research question: 'What can we learn from existing NHS integrated PC and HF services to develop a detailed 'how to' guide for setting up, sustaining, and embedding integrated HF and PC services across the NHS'?

An important aspect of the study is that we will focus on providing 'how to' guidance applicable across the NHS, achievable within current NHS constraints, rather than asking the NHS to create unaffordable new services. We will learn from existing services how they have been able to offer an integrated service to people with HF within current NHS constraints. Our research will enable us to create the knowledge needed for setting up, sustaining and embedding NHS integrated PC and HF services and provide evidence for Integrated Care Boards (ICBs) and service providers to inform and optimise the integration of these services across the NHS. This work is especially timely, given the recent amended Health and Social Care Bill giving ICBs responsibility to provide PC to all who need it within the population they serve, and also timely given the recent NHSE document for ICBs on this subject (<https://www.england.nhs.uk/publication/addressing-palliative-and-end-of-life-care-needs-for-people-living-with-heart-failure/>)

Figure 1: PalliatHeartSynthesis Programme Theory



## 1. Aims and objectives

### Aim

Learn from existing successful NHS integrated PC and HF services to develop detailed 'how to' guidance for setting up, sustaining, and embedding integrated PC and HF services across the NHS?

### Objectives:

1. Use a realist approach to evaluate existing integrated PC and HF services in NHS organisations to understand how they have been set up, sustained, and embedded in routine practice.
2. Use these data to confirm, refute or refine our existing PT regarding this process.
3. Develop a community of practice to support those who wish to set up, sustain and embed integrated HF and PC services.

### Concise statement of proposed research

This project will use co-design and realist evaluation approaches to generate primary data across five NHS Sites. The five sites were purposively sampled to involve specific groups of multidisciplinary integrated PC and HF service providers including primary care, secondary care. The sites are based in England, Scotland, Wales and Northern Ireland (NI). The research will be delivered via three work packages (WP) at each site. WP1 will involve a realist evaluation of existing integrated PC and HF services using documentary analysis, routinely collected audit data e.g., improvements in patient reported outcomes (symptoms and quality of life), patient and caregiver satisfaction with care), and semi-structured interviews. WP2 will involve co-design of a detailed 'how to' guide for setting up and improving integrated HF and PC services in the NHS. WP3 will involve development of a community of practice to support those who wish to set up, sustain and embed integrated HF and PC services. This research will enable us to create the knowledge, and knowledge translation needed for better tailoring of NHS integrated PC and HF services and provide timely evidence for Integrated Care Boards and service providers to inform and optimise the integration of these services across the NHS.

## 4. Methods

### 4.1 Primary Research: Realist Evaluation and Co-Design

We propose a three-stage project using realist evaluation (21) and co-design (22) approaches (more details about each work package can be found below). Primary data will be generated at five sites to further develop our PalliatHeartSynthesis 1 programme theory of how best to set up and run integrated PC and HF services in the NHS. This in turn will produce NHS specific recommendations and consider issues relating to the implementation of these recommendations via the co-designed 'how to' guide. This research design is underpinned by MRC guidance for the development, evaluation, and implementation of complex interventions to improve health (23).

Co-design methods are based on a philosophy and ethic of equity. Taking a pragmatic approach, co-design methods enable the researcher to be responsive and bridge the gap between theory, research and practice enabling researchers and stakeholders to drive the research forward and refine the approach to answer the research question (23). This partnership approach challenges hierarchy within the team and across stakeholders (24) and fits well with realist methods.

Realist approaches assume that few (if any) programmes or interventions work everywhere for everyone: context makes a considerable difference to programme outcomes (25). We have adopted a realist approach because it was clear from our realist review (PalliatHeartSynthesis I) that integrated PC and HF services are complex and how well they work (or not) depends on context, who delivers them and how. Furthermore, integrated PC and HF services typically do not really pre-exist as an 'off the shelf', ready to go entity. NHS services vary greatly depending on differences in geographical patterns of

disease, clinicians' behaviour, incentives in health care financing etc. This makes theory - driven realist approaches particularly apt for this problem area.

Realist research (e.g. realist reviews or realist evaluations) identifies causal processes (mechanisms) for outcomes of interest (intended and unintended). Findings are potentially transferable because in realist research the assumption is that most mechanisms are widely occurring in different settings, situations and/or people, but may not be activated unless the right contexts exist (26). Using a realist evaluation approach will also enable us to focus on the mechanisms (causal processes) for desired and undesired outcomes from integrating PC and HF services. Our realist review has identified important mechanisms that are likely transferable across settings but need to be better understood in the NHS. Our specific focus on the transferable causal mechanisms will enable us to make 'recommendations' for integrated PC and HF services that are relevant and applicable across different settings in the NHS.

#### 4.2 Sites and Sampling

The study will involve five integrated PC and HF services in the NHS. The sites were purposively sampled to involve the specific groups of multidisciplinary integrated PC and HF service providers across all care settings (e.g., primary care and secondary care) ensuring diversity of the populations they serve, and varied service models (see Table 1. Study Sites).

Both sites in England (South London and Northumbria) were identified through MJ who has worked with site leads on successful integrated PC and HF projects and were chosen for their differences (large urban vs town/rural; north vs south; ethnic minority representations; model of PC-HF service delivery). We also included devolved nation sites (Scotland, Wales, and NI) to ensure UK-wide applicability. We chose the specific three sites in Scotland, Wales and NI because of existing relationships with the service leads via the PalliatHeartSynthesis 1 Stakeholder group. These service leads (including co-applicants YM and CA) were keen to continue collaboration to improve their existing integrated PC and HF services and generate learning for those setting up integrated services. We are confident that these sites will be sufficiently varied in terms of their degree of integration and the paths they have taken to integration to provide an in-depth understanding of the integrated PC and HF process across primary and secondary care in the NHS.

To increase engagement, particularly in NI where integration was least established, we secured funding from the NI Public Health Agency to hold a HF and PC conference to share learning from PalliatHeartSynthesis 1 and share plans for PalliatHeartSynthesis II. YM also shared learning from the well-established integrated PC and HF service in Scotland, and our PPI partners spoke on why this project is so important to them from a patient and carer perspective. The chosen sites not only have what we judge to have the diversity needed for this study to be a success, but we have also developed deep-rooted relationships with stakeholders in the sites, who have been very proactive in their interest and participation to date, reflected in their willingness to be co-applicants. This preparatory work is vitally important in ensuring the success of this study.

To ensure research inclusion, we will work closely with our site leads and PPI co-applicant to ensure our service user sample is representative of HF populations, such as younger working age adults that are not suitable for transplant, older people living with multimorbidity, those living in deprived areas, those with HF with preserved ejection fraction, those with complex devices, non-English speaking etc., (see Table 1. Study Sites). Site leads will review the demographics of their current service users including age, ethnicity, diagnoses (cardiac phenotype and multimorbidity), functional status, to enable them to sequentially approach patients/carers representative of different characteristics to facilitate recruitment of a diverse sample of patients/carers. Our patient/carers sample will be monitored via fortnightly team meetings with site leads, so we can refocus recruitment efforts on those who are underrepresented. Plans to support inclusion of those who are isolated or lack support structures include the option for online interviews, or telephone interviews for those who do not have Wi-Fi access. We have also costed back-fill for informal carers to enable them to be involved, and we have a sign language interpreter list for each site for those with hearing needs.

Interviews with people living with HF and focus groups will be conducted by the research fellow (RF), with support from the research assistant (RA), who will have experience of interviewing people from underserved groups, and those with life limiting conditions where consideration around cultural sensitivity and patient fatigue is paramount. The person with HF will have the opportunity to stop the interview if they become fatigued, and a distress protocol will be put in place setting out guidance that the RF and RA should observe and apply (according to circumstances) during interviews and focus groups with patients (27). All patient and public facing study documents will be designed by our PPI partners, and the findings will be shared with study participants, along with £25 vouchers for each interview and/or focus group that they take part in. Taxis have been costed in for patient and/or caregivers who have no access to transport to enable their participation at the in-person focus group workshops. We have also provided more detail on the diversity of patients seen by the included sites in Table 1: Study sites.

Table 1: Study sites

Location	Participant Sample (inpatient & outpatient)	Population diversity
England site 1	<ul style="list-style-type: none"> <li>- Cardiologist</li> <li>- PC Consultant</li> <li>- PC and HF nurses</li> <li>- District nurse</li> <li>- GP</li> <li>- Pharmacist</li> <li>- Admin support</li> <li>- Spiritual care / Chaplaincy</li> <li>- Social worker</li> <li>- Complementary Therapist</li> <li>- Pacing clinic health care provider (deactivation of ICDs)</li> <li>- Commissioner</li> <li>- Patient</li> <li>- Informal carer</li> </ul>	<p>St Christopher's Hospice serves a diverse population of 1.5 million in the London boroughs of Bromley, Croydon, Lambeth, Lewisham and Southwark reaching some of England's most deprived areas.</p> <p>Bromley has largest frail older population of London Boroughs. The CCG and St Christophers jointly funded and evaluated a pilot heart failure/ palliative care service working across the hospital/community in Bromley and linked closely with local GPs. This includes all HF phenotypes; 1/3 of patients with preserved ejection fraction.</p> <p>The success of this venture supported successful application for external funding to extend and adapt/test a similar service in Croydon, which has a more ethnic diverse population and sits within a neighbouring ICS. Currently 25% of service users live alone.</p>
England site 2	<ul style="list-style-type: none"> <li>• Cardiologist</li> <li>• HF specialist nurse (secondary care)</li> <li>• Community HF specialist nurse</li> <li>• District nurse</li> <li>• Cardiac physiologist (pacing/ICD clinic care provider)</li> <li>• PC nurse</li> <li>• PC doctors</li> <li>• District nurse</li> <li>• Spiritual care / Chaplaincy</li> <li>• GP</li> <li>• Patients and carers</li> </ul>	<p>Serving one of the largest geographical areas of any NHS trust in England, Northumbria Healthcare provides a wide range of services to more than half a million people living in Northumberland and North Tyneside. The Trust provides services to people that live in urban areas (North Tyneside and southeast Northumberland) and to those that live in some of the most rural parts of England. Both areas have industrial histories ranging from ship building to coal mining, with limited population movement out of area (creating an older age profile) and as such the local population has some of biggest health challenges nationally. There are high rates or cardiovascular disease and lower life expectancy than national averages.</p>
Scotland	<ul style="list-style-type: none"> <li>- Patient</li> <li>- Informal carer</li> <li>- Cardiologist</li> <li>- PC Consultant</li> <li>- COE Consultant</li> <li>- HFPC Nurse Consultant</li> <li>- PC/HF/ANP &amp; DN nurses</li> <li>- GP</li> <li>- Pharmacist</li> <li>- Pharmacist Assistant</li> <li>- Admin support</li> <li>- Hospice Services</li> <li>- Cardiac Physiologist Department (Pacing/Echo/ECG/ deactivation of ICDs)</li> <li>- Long Term Conditions Benefits Services</li> </ul>	<p>Diverse &amp; predominantly deprived geographical population. Inclusive of all HF phenotypes (HF<sub>r</sub>EF &amp; HF<sub>p</sub>EF, Valvular patients not suitable for corrective intervention &amp; Amyloidosis patients). Patients with CRT-D or ICD cardiac devices that requires timely deactivation. The service approach consists of clinic, telephone and/or home visiting to suit individual person focused needs. Care Home Patients are also included as these patients are predominantly excluded from the HF service across Glasgow. Patient referrals from the advanced transplant centre who reside within the North East Glasgow area will also be included although the numbers are low.</p>

	<ul style="list-style-type: none"> <li>- Spiritual care / Chaplaincy</li> <li>- Health &amp; Social Care</li> <li>- OT/Physio/Dietician/Psychologist/</li> <li>- Access to other services as appropriate.</li> </ul>	
Wales	<ul style="list-style-type: none"> <li>- Cardiologist</li> <li>- PC Consultant</li> <li>- Junior Doctors</li> <li>- PC and HF nurses</li> <li>- District nurse</li> <li>- Occupational therapist</li> <li>- Physio</li> <li>- Psychologist</li> <li>- Dietician</li> <li>- Aseptic Unit Team</li> <li>- Pharmacy Team</li> <li>- GP</li> <li>- Admin support</li> <li>- Spiritual care / Chaplaincy</li> <li>- Value based project manager</li> <li>- Finance Team</li> <li>- Pacing clinic health care provider (deactivation of ICDs)</li> <li>- Commissioner</li> <li>- Patient</li> <li>- Informal carer</li> </ul>	<p>Cardiff and Vale UHB serves a population of 600 000 with a multi-cultural/multi-sociodemographic, and is both a secondary and tertiary centre including patients from a wide area across South West, East and Mid Wales with significant ethnic population mix and deprivation within the urban areas and wider reach to areas with significant rurality. C&amp;VUHB is also the cardiothoracic surgical centre. Patient groups include: younger patients not suitable for transplant, patients with preserved and reduced ejection fraction, patients with valvular disease, patients with amyloidosis, patients with complex devices. Services are adapted for patients who can't afford/unable to travel (e.g. clinics: including hot review, online appointments, phone support, home visits, hospital review (a cross-boundary model), access to ambulances, multidisciplinary team including occupational therapy, physiotherapy, dietetics and psychology as well as clinical nurse specialists and medics. The integrated PC and HF model in Wales covers urban and rural areas, with a community of practice forum. Referrals include patients from tertiary adult congenital heart disease services. The Welsh government have invested Value-Based recurrent funding for expansion of the integrated model to other chronic disease pilot areas.</p>
Northern Ireland	<ul style="list-style-type: none"> <li>-Consultant Cardiologist</li> <li>-PC Consultant</li> <li>- Cardiology Specialty Doctor</li> <li>- HF Specialist Nurse</li> <li>- PC Specialist Nurse</li> <li>- Community PC nurse</li> <li>- Spiritual care / Chaplaincy</li> <li>- Admin Support</li> </ul>	<p>Lagan Valley Hospital is a local acute hospital with an urgent care centre which is part of the South Eastern Health and Social care Trust. It is an integrated Trust, incorporating acute hospital services, community health and social services. The newly established integrated service is inclusive of all heart failure phenotypes including HF<sub>r</sub>EF and HF<sub>p</sub>EF, patients with CRT-D or ICD in situ requiring device deactivation discussions and patients with frailty</p>

**Work package 1: Realist Evaluation of existing integrated PC and HF services (Months 7-25)**

The output of WP1 is a detailed understanding of existing NHS services that manage to deliver integrated PC and HF services. We will use a realist evaluation (21) approach to understand what is working/not working, for whom, to what extent, in what contexts, how and why. The primary data we collect will enable us to confirm, refute or refine parts of our PalliatHeartSynthesis 1 programme theory (see Figure 1). We will use the improved programme theory to update our original ‘policy and practice implications’ on how integrated PC and HF providers support reconfiguration of their existing services. Where relevant, we will draw on existing frameworks (e.g., behaviour change research by Michie (28-29)) to help us to develop our ‘how to’ guidance.

A summary of data collection activities at each site is presented in Table 2. Our evaluation will involve semi-structured interviews with up to 20 stakeholders, identified via co-designed purposive sampling (to ensure inclusion of participants who have insight into how integrated PC and HF services have been set up, sustained and embedded in routine practice – e.g., healthcare professionals (HCPs) n = 15, patients and informal carers n=5) at each of the five sites. Steps to ensure service users’ research inclusion have been outlined under 4.2 Sites and Sampling. The final sample size will be determined when we have enough data for theoretical saturation (21)). Sampling for realist interviews is theory based, i.e. participants are selected because they are in a position to cast light on a hypothesis or a particular aspect of the programme theory (21). Because the unit of analysis is not the person but the events and processes around them, every respondent can uncover a collection of micro events and processes, each

of which can be explored in multiple ways to test theories. This means that a relatively small number of participants with detailed knowledge of the integrated service can be interviewed multiple times to confirm, refute or refine the initial PalliatHeartSynthesis I PT (21).

One-to-one face-to-face interviews will be conducted at a place / time convenient to participants. If necessary (e.g. Covid restrictions, or for participants convenience), interviews may also be carried out over the telephone or by video-call (Zoom, Microsoft Teams). If service users (patients and/or carers) choose to be interviewed at home, a lone worker policy will be put in place for the RF/RA's safety, where they will share the time and location of each interview with a member of the research team before and immediately after an interview takes place. An interview schedule will be developed, guided by PalliatHeartSynthesis I programme theory and piloted, evolving as the programme theory is refined. [19] With consent, interviews will be audio recorded and transcribed verbatim. Each participant will be asked if they would like to take part in subsequent focus groups, and if they agree, they will be contacted again for formal consent prior to each focus group. Transcription will be carried out by professional transcribers who specialise in health service interviews.

We will also seek out any site-specific routine data from each site (e.g. reports, case summaries, audit data, and patient reported outcome measures (PROMs)) to shed light on what facilitated or hindered set up, sustaining and embedding of integrated PC and HF services. There will be variation in what is collected at each site, but where relevant and feasible, we will endeavour to collect comparable data. This will be supplemented with focused observations (n=1-3 per site) of the integrated PC and HF services, and how teams and systems operate on the ground and taking field notes of the same. A participatory ethnographic approach (30) will guide the observations. Ethnography seeks to understand the culture of a particular setting or environment. It is inherently a co-constructed process of research practice that emerges and evolves over a period of sustained co-inquiry, rather than inquiry driven by the researcher's interests. Observation and field notes are corner stones of the approach, which allow the development of relationships with research participants providing an insight into the context, with a focus on the culture and social interaction of the subject of study. Ethnography is particularly valuable in understanding the influence of social and cultural norms on the effectiveness of health interventions and understanding how complex interventions work (31). The RF and RA will undergo Unconscious Bias training via the university prior to carrying out the observations of the integrated PC and HF services at each site and will take field notes. These ethnographic activities will enable us to 'see' if what we are told plays out as expected in practice.

Table 2: Summary of data collection at each site

Location	Documents (WP1)	Audit Data (WP1)	No. of Interviews (WP1)	Observations of integrated PC and HF services (WP1)	No. of Focus Groups (WP2)
England site 1	Site specific	Site specific	20	1-3	2
England site 2	Site specific	Site specific	20	1-3	2
Scotland	Site specific	Site specific	20	1-3	2
Wales	Site specific	Site specific	20	1-3	2
Northern Ireland	Site specific	Site specific	20	1-3	2
Totals			100	5-15	10

### Data analysis of observations, site specific data, and interviews

All field notes from the observations, site specific data and interview transcripts will be entered into NVivo 12 computer-aided qualitative data analysis software to aid analysis. Where possible and relevant other variables (e.g. the characteristics of the individuals in multidisciplinary teams and the settings they work in) will also be entered into NVivo.

Data will be analysed using the same realist logic of analysis that we used in PalliatHeartSynthesis 1 (32). A realist logic of analysis is a way of interrogating theory with data and of using theory to understand patterns in data to further refine the programme theory. A realist analysis of data follows a generative explanation for causation that is, an outcome (O) of interest was generated by relevant mechanism(s) (M) being triggered in context (C) (33). Data analysis is iterative over the course of the evaluation, with earlier stages of analysis being used to refine programme theory and/or refine evaluation design for subsequent stages. Following each data collection period, the analysis will involve reading and rereading the transcripts and other data sources before moving on to coding. In this sense the data is purposely mined for information that would help us test (confirm, refute or refine) the CMOcs that we found in our realist review from PalliatHeartSynthesis 1. Where indicated by our interpretations of the data we will develop and refine new CMOcs based on the primary data collected in this study. This process is not linear, and will involve much iteration, discussion and deliberation between and across phases.

Throughout the analysis we will move iteratively between the analysis of examples, refinement of programme theory, and further iterative primary data collection to test specific parts of the programme theory (32). As mechanisms are often hidden or not articulated very well, we will use retroductive reasoning to infer and elaborate on the mechanisms. Retroductive analyses are analytical processes that seek to identify the hidden causal processes that lie beneath identified patterns or changes in those patterns (34). Thus, our approach will involve repeatedly going from data to theory, to refine explanations about the occurrence of certain behaviours. We will endeavour to construct these explanations at a level of abstraction that would encompass a range of phenomena or patterns of behaviour. Where relevant we will draw on substantive theories to help us develop and test our emerging programme theory. An example of one such theory that we anticipate may be relevant is Normalisation Process Theory (35).

We will identify relationships between contexts, mechanisms and outcomes from within and across different data sources (e.g., inferred mechanisms from one interview/documentary analysis) could help explain the way contexts influenced outcomes in another interview). We will use these analytic processes:

- a) Juxtaposition of sources of evidence e.g., where evidence about behaviour change in one source allows insights into evidence about outcomes in another source.
- b) Reconciling of sources of evidence – where results differ in similar situations, these will be further examined to find explanations for these differences.
- c) Consolidation of sources of evidence – where different outcomes occur in similar contexts, a reason will be developed as to how and why these outcomes happen differently.

We will use any relevant quantitative data (e.g., audit data) that is available at each site to help us test our programme theory. For example, if a site has collected PROMS data that shows HF patients are unhappy with the PC service, but service providers claim their service is excellent, then the PROMS data is useful for informing our interview guides in relation to asking patients what it is about the service that is not working for them, and similarly ask service providers why they think the service is excellent. The refined programme theory and our findings will feed into Work package 2) and form the basis of our NHS specific 'how to' guide. The guide will detail our key findings on how the integration of PC and HF services produce their effects in NHS settings, along with a series of recommendations on how to tailor and implement integrated PC and HF services relating to each specific finding.

## **Work package 2: Co-design of a detailed 'how to' guide for setting up and improving integrated HF and PC services in the NHS (Months 27-31)**

We will use the programme theory from WP1 to co-design our detailed 'how to' guidance for setting up, sustaining and embedding the delivery of integrated HF and PC services in the NHS. We will draw on behaviour change research by Michie (28-29) to underpin the design of the 'how to' guidance. The behaviour change wheel (BCW) outlines nine intervention functions aimed at addressing deficits in a particular 'behaviour system'. Our findings from WP1 will enable us to understand what behavioural changes are needed from integrated PC and HF service providers to optimise the delivery of their service. We will then use these findings to select the appropriate blend of interventions suggested by the BCW. The 'how to' guidance will include detailed information on how to use the 'recommendations' in different contexts and populations (i.e. different integrated PC and HF services). Such a 'how to' guide is needed as integrated PC and HF services are not only delivered differently in different locations, but also that because trying to 'force' each service to make one-size-fits-all changes is not only unlikely to work but would also be unacceptable to local integrated PC and HF services. Our 'how to' guidance will enable NHS integrated PC and HF services to deliver better services themselves.

Using a co-design approach (22,36) the 'how to' guidance will be developed through a series of focus groups with each of the five site teams (n=2 per site, 10 in total). Approximately 6-8 stakeholders will participate in the focus groups at each site e.g., the integrated PC and HF service leads, PC and HF multidisciplinary teams n=4-6, patients and informal carers n=2) The first focus group will involve an in-depth discussion of each recommendation in detail. This will include:

- Practical advice from their experience of the integrated service at their site
- Common contextual factors and behaviours that affect the success of each recommendation including examples

The focus groups will be held in a private room at each site and will be led by the RF. The focus groups will be digitally audio-recorded and transcribed verbatim by a professional transcriber bound by a confidentiality agreement. Participants will be anonymised prior to transcription and will be referred to by a reference number. The transcripts will be uploaded into NVivo 12. The data generated at each site on each individual recommendation will be subjected to a realist logic of analysis by the RF, RA, and the wider research team. This analysis will inform the contents of the 'how to' guide. A draft of the 'how to' document will then be co-produced by the research team and the stakeholder group and shared with each site.

Each site will review the 'how to' guide and then discuss and provide feedback on its usability via a second focus group. Details on how the 'toolkits' will be disseminated are outlined in the dissemination, outputs and anticipated impact section.

### **Work package 3: Develop a community of practice to support those who wish to set up, sustain and embed integrated HF and PC services (month 27 to 31)**

The Community of Practice is not considered to be research. Communities of practice are defined as groups of people with a common goal who regularly meet to provide support to each other, share and create knowledge together, and explore innovative ways to reach their goal (37-38). Communities of practice are encouraged within the NHS and are well established in quality improvement efforts. In this study, work packages 1 and 2 support the development of a co-designed 'how to guide' to help existing services deliver an integrated palliative care and heart failure approach. The community of practice in work package 3 will help us to disseminate findings among heart failure specialist clinics and provide support to those services which are interested in implementing an integrated model of care. The community of practice will allow us to assess if the 'how to guide' meets the needs of service providers and identify if there are facilitators or barriers to its implementation. In this way, the content of the community of practice meetings will help the research team to amend the 'how to' guide and ensure that it best meets the the information and support needs of service providers. Although the community of practice is not considered research, we will treat participants with the same consideration as research participants, be transparent in our purpose, ensure informed consent is taken where appropriate and, will maintain confidentiality of any personal information collected to facilitate the community of practice. A community of practice is especially important for this project given its interdisciplinary and cross organisational boundary nature, which helps reduce fragmented practice across services, through a

shared focus on problems such as integrating PC and HF services; that are too complex for any one individual, profession, or organisation. Within the NHS, “a community of practice differs from a delivery network because membership is optional, and the ways of working are informal...it’s a conversational relationship of peers who want to share and learn from each other. They will also help... develop cross boundary relationships with leaders in other parts of the organisation or community.” (NHS Improvement Leaders’ Guide: Institute for Improvement and Innovation <https://www.england.nhs.uk/improvement-hub/wp-content/uploads/sites/44/2017/11/ILG-3.4-Leading-Improvement.pdf>)

We will not be collecting research data for this work package, as the community of practice will be self-sustaining after the research project has completed. We will set up a community of practice to enable support and cross-learning across services for others who want to set up or sustain their HF and PC services. Participants will be identified and contacted through our clinical partners who are co-applicants in the study and have established contacts with heart failure specialists and clinics across the UK. We will follow Wenger-Traynor’s model (39) which has three key characteristics for success; 1) The domain (every group member must be invested in the shared domain of interest); 2) The community (interaction and collaboration are absolutely essential as the community is established, to ensure knowledge sharing and dissemination through organising joint activities to apply their acquired knowledge; 3) The practice (practical application of acquired knowledge is the key goal and outcome of a community of practice, through allocating and dispersing resources and sharing their lived experience of the domain of interest). We will apply this model by

- 1) Setting The Objective; we will ask our stakeholders who should be invited to the group and how best to invite them.
2. Create A Plan; Once identified, we will set up an initial meeting of those interested and collect each member's goals and learning objectives. The plan will include a list of key resources required to facilitate learning outcomes within the group and other individuals/teams wanting to integrate their services.
3. Schedule Regular Meetings; we will organise up to three meetings (one per month) during WP3 using online platforms such as MS Teams or Zoom to facilitate a community of practice across the UK. WhatsApp will also be used to facilitate cross-site sharing.
4. Document the Process; we will video record the meetings (with attendees’ consent) and record the minutes so that shared knowledge is not lost. Documenting the meeting processes, personal lived experiences of integrating PC and HF, and subsequent discussions will help us accumulate shared learning and knowledge so we can keep track of progress and share learning with new members.

When the community of practice is up and running, we will identify, with the group, ways that we can sustain the group long term. This will involve identifying suitable leadership and also considerations of whether additional resources might be needed and how these might be obtained. Our co-applicant (GW) has experience of developing a highly successful community of practice via an email listserv for realist methods, which has been sustained for over 10 years and grown to its current 1300+ members. We also have another co-applicant (CA) who had established a PC and HF community of practice forum with 20 members running for one year. CA will share experiences regarding set up and spread of the model.

### **4.3 Participants and eligibility criteria**

*Patients with heart failure, their family caregivers and members of the direct care team who are providing an integrates palliative and heart failure services.*

The study population will consist of people with heart failure who are receiving a service from an integrated palliative care and heart failure service, their primary family caregiver and healthcare professionals who are delivering an integrated palliative and heart failure service (see Table 3).

Table 3. Inclusion criteria for participants	
<i>Inclusion criteria</i>	<i>Screened by</i>
<u>Patient</u>	
Has received a diagnosis of heart failure and is receiving a service from the integrated palliative care and heart failure service.	Treating clinician or member of direct care team.
Over 18 years of age	Research Team
Written informed consent	Research Team
<u>Family caregiver</u>	
<i>Primary informal caregiver as identified by the HF patient</i>	<i>Patient</i>
Patient has consented to carer being approached	Research Team
Over 18 years of age	Research Team
Written informed consent	Research Team
<u>Healthcare Professional</u>	
A member of the Palliative and Heart Failure Team or other knowledgeable professional	Member of direct care team and Research Team
Written informed consent	Research Team

## 5. Dissemination, outputs and anticipated impact

There will be one substantial output from the study, namely a detailed 'how to' guide for setting up and sustaining the delivery of integrated HF and PC services in the NHS.

Our dissemination strategy will build on the co-design approach of our research, with input from the site teams and PPI representatives to ensure that the project outputs will be used by the NHS. We will also leverage our pre-existing relationships with stakeholders from PalliatHeartSynthesis 1. Our stakeholders include members from key organisations that are well placed to disseminate and implement our project output (see Table 4). We have existing, strong links with Marie Curie UK who have helped increase the policy impact of PalliatHeartSynthesis 1. TM shared the findings at the DHSC meeting April 12th, 2023. Subsequently, our PPI partner was invited to speak at the Major Conditions Strategy UK Roundtable Discussion on Palliative and End of Life Care. This was instrumental in helping to get palliative care recognised within the Major Conditions Strategy (MSC) consultation questions, which cited our research.

At our Month 18 stakeholder group meeting, we will consult with them on the formats and content that would be most suited to their colleagues. We anticipate at present (pending feedback and advice from our stakeholders) that the findings will be disseminated via:

1. publication in peer-reviewed journals
2. user-friendly summaries of the findings and recommendations tailored to the needs of interested audiences including patients
3. relevant conferences e.g. HF and the European Association for Palliative Care (EAPC)

4. Relevant PC and HF associations/charities such as All Ireland Institute of Hospice and Palliative Care (AIHPC), Marie Curie, British Heart Foundation, National HF nurse networks (British Society for HF Nurse Forum and Scottish HF Nurse forum) and the HF Association of the European Society of Cardiology (ESC).

6. providing the 'toolkit' in an open access format online so that it is available for use by any integrated PC and HF service in the NHS.

The expected impacts of this study are three-fold:

Firstly, direct improvement for delivery of five integrated PC and HF services in the UK. Secondly it will test and refine the programme theory of how integrated PC and HF services work, thereby providing more in-depth understanding of what works to set up, sustain and embed the delivery of integrated PC and HF services across the NHS. This understanding informs the co-design work to produce a 'how to' guide that will be able to help any NHS provider set up and sustain an integrated PC and HF service. Thus, filling a current knowledge gap identified by PPI and providers. Thirdly, this study will result in tangibly improved integrated PC and HF services, with a network of experts (including the five sites) well-positioned to further advance knowledge and application of successful integrated services.

Findings may also be relevant to those beyond the HF end-of-life community of practice. People with HF have multiple long-term conditions including HF with preserved ejection fraction (HFpEF), and their PC need might arise from any one or a number of these. There is a need to break down silos across specialities and settings (including geriatrics, primary and secondary and tertiary care settings). This work has already started at our Welsh site where we plan for broader impact by sharing the findings with colleagues who are actively expanding the integrated model of care for people with HF to three other chronic life limiting conditions including chronic liver, renal and interstitial lung disease. Plans for broader impact also include dissemination of the findings to other chronic life limiting condition charities and clinical leads.

Given the practical and moral imperatives of improving integrated care in a way that will improve access to PC for patients with HF, the outcomes of this project will be central to the NHS's long term plan objective of more integrated services to address "increasing inequalities and pressures from a growing and ageing population" (16)

## **6. Project Timetable**

The proposed project timetable is outlined in table 5. The study end date is 31<sup>st</sup> March 2028.

## **7. Project Management**

The project will be managed via three groups:

1. the research team
2. the steering group
3. the stakeholder group.

The projects organisational structure is depicted in Figure 2.

## **Figure 2: Project's organisational structure**



**Research Team**

The day-to-day running of the project will be managed by the research team. The research team will consist of all co-applicants, the RF, and RA employed to carry out the research. This team will plan and monitor day to day progress, ensure ongoing communication among team members, study quality and timeliness of outputs, and manage day-to-day risks and issues. The research team will be responsible for undertaking the research, producing the project outputs and dissemination. We will use online software as needed to enable us to conduct high-quality remote interaction and file sharing. The research team will meet bi-monthly. In between these meetings the research team will be in regular contact as needed (e.g. via email, telephone and video-call). The meetings will be chaired by TM who will also line manage the RF. This infrastructure will support (but not replace) regular meetings between different members of the research team, as needed, to execute the study, plan data collection, conduct analyses, discuss emerging findings and prepare outputs. TM will use her experience to mentor the RF to ensure they complete first-author publications. TM will also support them to line manage the RA, facilitate their attendance to present at the international European Society of Cardiology conference and avail of the training provided by the Queen’s Postdoctoral Centre. This will ensure that the RF is competitive for fellowships. Research & Development at Queen’s University will provide one-to-one support to the RF for applications for an NIHR early career or advanced fellowship).

**Steering Group**

The project will also involve a steering group to provide project oversight, monitor progress against milestones and oversee research governance and financial management. The steering group will consist of the research team (including Linda our PPI co-applicant) plus members of finance and research and governance teams from Queen’s University Belfast. We will hold six steering group meetings throughout the study as set out in the project timetable below. The group will also provide advice, promote the project, communicate with stakeholders and help maximise dissemination and impact of findings.

**Stakeholder Group**

We had a very successful and engaged stakeholder group for PalliatHeartSynthesis 1, who have remained involved in this next phase of planned work. The stakeholder group consists of two groups of participants i.e. lay members as well as a variety of key professional stakeholders in integrated PC and HF process e.g. patient/carers, local, national, content experts, multidisciplinary practitioners and policy makers. The stakeholder group will: help us to sense check emerging findings; provide additional feedback and advice that will enable us to optimise our outputs and dissemination plans and; co-produce feasible and practical recommendations for relevant wider stakeholders. The stakeholder group will also have members from key organisations such as the NHS, palliative care and HF charitable organisations and PPI groups, having people/bodies who will use the end product, or be in a position to promote its use, and will be involved in at least four meetings throughout the study.

Table 4 List of stakeholders

Organisation	Role
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British Heart Foundation Patient and Public Involvement Network member	PPI Partners
Marie Curie Senior Research Manager: Research Management & Impact	Implementation Science and impact
Cardiac Palliative Care at NHS National Services Scotland	Cardiology Consultant and Clinical Lead
Health and Social Care Trust Northern Ireland	Speciality Doctor Cardiology
NHS Scotland	GP
Texas Heart Institute, Houston, USA	CEO, internationally recognized thought leader in HF, heart transplantation, and mechanically assisted circulation.
Queensland University of Technology (QUT)	Academic chronic HF and PC
NHS Trust Northern Ireland	Consultant in Palliative Medicine
Nexus Health Group/London based GP partnership	HF clinical nurse specialist
NHS Trust Northern Ireland	HF Nurse Specialist
Marie Curie	Policy Manager Northern Ireland
Marie Curie	Senior Research & Policy Manager (Health & Wellbeing)
British Heart Foundation	Policy Northern Ireland
Marie Curie	Research Development/expertise in recruiting underserved groups to research

## 8. Data collection and management

This study will comply with data protection procedures and will comply with relevant legislation. Data collected throughout the study will be coded and stored in a safe data environment. Our policy regarding the storage and use of data has been informed by the Caldicott Principles (2013), Data Protection Act legislation (2018) and the General Data Protection Regulation (EU, 2016/679). Participants will provide informed consent and will receive an indication of what type of data is being captured, why it is being captured and how it will be stored and used. Furthermore, the informed consent and participant information sheets will describe the location of the data servers (within the QUB cloud storage system). From a data storage perspective, the principle of Protection by Design has informed our procedures and we will separate identifiable information from the data at the earliest timepoint possible so that participants cannot be linked to their data by anyone other than approved members of the research team.

All hard copies of study information will be stored in a locked filing cabinet within a secure building on the Queen's University Belfast site. These buildings are closed to the public and accessed via a keypad. Access to the study data will be restricted to research team members who will adhere to a clear desk policy.

The recordings of qualitative interviews with patients, informal family carers and health care professionals will be transcribed by a third party who has completed a Confidentiality and Data-Processing Agreement. Upon doing so, a member of the research team will check the transcriptions for

accuracy before removing all personal data from the transcriptions; for example, names of individuals and place names will be replaced by aliases. Interview transcripts will receive a code. The key to the code will be kept in such a way that identification of the participant will only be possible for authorised members of the research team.

If face-to-face interviews cannot be undertaken for example in the event of unforeseen circumstances such as the COVID-19 pandemic or, if participants do not want to meet in person, a GDPR-approved online platform (e.g. MS Teams, Zoom) will be used to complete interviews or focus groups. Again, these interviews or focus groups will be audio recorded and transcribed using the procedure set out above.

Electronic copies of study information will be kept in secure cloud-based storage within Queen's University Belfast and will only be accessible by approved members of the research team.

All participants in the study will complete an informed consent form, clarifying all implications in terms of the privacy and protection of their personal data.

In line with the purpose limitation information provided to participants, we will delete all personal data within 5 years of the study end-date.

## **9. Ethics**

Given the nature of the research, particularly service users with advanced HF and/or their carers will require sensitive and flexible approaches. PC and HF healthcare and social care providers are also operating under stressful circumstances which will require recognition and sensitivity in the research. Approval to conduct the research will be sought from NHS/HSC REC and governance permission from each recruitment site. In the ethics application we will identify how we will manage and secure service user participant distress and support; follow relevant safeguarding policies and practices, obtain informed consent, ensure confidentiality, anonymity and undertake appropriate storage and management of data, particularly when working across sites.

## **10. Success criteria and barriers to proposed work**

The main success criteria are site engagement so that we can learn from each site, and work together to develop the 'how to' guide and establish a community of practice. Therefore, measures of success will include:

- Access to routinely collected data and documents that provide insight into what is working/not working at each site in relation to integration of PC and HF;
- Hitting our target recruitment of up to 15 HCPs and 5 patient/carers across all 5 sites;
- Hitting our target for between 4-6 HCPs and up to 2 patients/carers for focus groups at each site;
- Support from our site leads to establish a community of practice

Barriers to this proposed work include recruitment of patients/carers. However, we will do everything possible to make this project accessible to patients as outlined in 4.2 Sites and Sampling. We will work with charities such as Marie Curie and The Centre for Ethnic Health Research, local site leads, make documents accessible in other languages, and have a list of sign language interpreters for those with hearing needs. We have costed back-fill for carers, taxi fares for those with no transport to attend interviews and/or focus groups and interpreters for non-English speaking service users.

Another barrier to proposed work relates to the ongoing impact of the Covid 19 pandemic on staff resourcing and subsequent workloads. PalliatHeartSynthesis 1 findings also highlighted staff time and resources as historical barriers to integration of PC and HF prior to the pandemic, and these barriers may also impact on our ability to recruit to this study. We have discussed these concerns with our site leads who have advised that they will do all in their power to support and encourage staff to attend

interviews and focus groups and were confident that recruitment would be successful. We have costed for staff time to attend interviews and focus groups, and £25 vouchers are available to all participants.

### 11. Who is the study sponsor?

This study is sponsored by Queen's University Belfast. Any reference to 'we' means the study sponsor and not the local sites directly involved in this research.

### 12. Indemnity statement

The study sponsor, Queen's University Belfast has arranged appropriate insurance and indemnity cover for any liabilities which may arise from the design, management and conduct of this study.

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