BHF Healthcare Innovation Fund Awards Confirmed March 2024

British Heart Foundation

A total of £818,479 was awarded in March 2024 to five projects as part of the funding call from September 2023 to November 2023.

The standard of applications received was high and the successful projects were identified as part of a competitive process subject to expert peer review. The Innovation Fund Committee assessed the applications on the following criteria:

- Novelty
- Feasibility of proposed design
- Potential for scalability
- Intended patient impact and
- Value for money.

Project Title	Lead Applicant	Institution	Amount Awarded
Modernising heart failure service provision in the UK: a '4x4' model of care delivery	Louise Clayton	Leicester University Hospitals	£202,716
West of Scotland Cardiac Device Psychology Service	John Sharp	Golden Jubilee Hospital, Glasgow	£99,446
Real-time ambulance to GP notification of atrial fibrillation: A digital solution to prevent stroke	Chris Wilkinson	Hull York Medical School	£99,969
Piloting a biopsychosocial service to enhance engagement in physical activity in people living with adult congenital heart disease (ACHD).	Helen Wallis	University Hospital Wales	£99,034
Triple Cardiovascular Disease Detection with an Artificial Intelligence-enabled Stethoscope – Primary Care Clinician Use for Screening	Nicholas Peters	Imperial College, London	£317,313.48

A high-level summary of each application listed above is provided overleaf.

Title: Modernising heart failure service provision in the UK: a '4x4' model of care delivery

Lead Applicant: Louise Clayton – Leicester University Hospitals

Award: £202,716	**Duration**: 17 Months

Summary of the application:
This project aims to test the scalability of a novel framework for implementation of heart failure drug therapy for patients.

Unmet need
The burden of HF in the UK is high and increasing. In a population-based study, involving 4 million individuals within the UK, the estimated number of individuals with newly diagnosed HF increased by 12% between 2002-2014, in the context of an ageing population and improved survival from acute and chronic cardiovascular disease. The estimated number of prevalent HF cases in the UK over this period has also increased dramatically by 23%. As a result, the volume of work and caseload size of our HF workforce have increased markedly over the past decade. Many services are struggling to manage the additional demand of an ageing population and provide quality care for our HF patients. A survey performed by the BSH HF nurse forum in 2017 reported that the majority of HF services across the UK were unable to provide timely post-discharge follow up of patients admitted with HF. In this setting, the current care model, proposed and initiated 20 years ago, may no longer be fit for purpose. In order to provide high-quality care to the increasing number of patients with complex, comorbidities, we must look to modernise existing models of care to improve HF care delivery.

Pharmacological therapies such as renin-angiotensin system inhibitors, beta blockers (BB), mineralocorticoid receptor antagonists (MRA) and sodium glucose co-transporter 2 inhibitors (SGLT2i) now form the 4 pillars of treatment for patients with HFrEF.. Although the benefits of comprehensive pharmacological therapy is clear, real-world attainment of target doses and the utilisation of novel agents such as Angiotensin receptor neprilysin inhibitor (ARNI) and SGLT2i remain low. Suboptimal HF treatment may be a key contributor to poor outcomes in HF patients. Increasing effort has been put on identifying to optimise initiation and up titration of evidence-based HF medications. A recent multinational randomised controlled trial showed that most patients admitted for acute HF and not treated with optimal doses of HF therapies can be rapidly and safely up-titrated to recommended doses of drugs (ARNI/BB/MRA) within a few weeks after discharge with regular clinical and laboratory assessments. This approach was associated with a 34% reduction in HF readmission or all-cause death up to day 180.

As already described, standard delivery of the 4 pillars of drug treatment heart failure with reduced ejection fraction (HFrEF) has a “start low, go slow” format; initiation of one medicine at low dose, followed thereafter by up-titration of that agent and sequential introduction of the other agents. Until earlier this year, current guidelines, for example the European Society of Cardiology Heart Failure guidelines recommend initiation of beta-blocker at the lowest dose available, and doubling the dose at “not less than two week intervals”. For Mineralocorticoid Receptor Antagonist treatment, the recommendation is for initiation at low dose and to “Consider dose up-titration after 4-8 weeks”. This approach remains standard across the UK and other countries. Based on the results from a single trial, STRONG-HF, a focused update of ESC

guidelines in 2023 states “high-intensity care for initiation and rapid up-titration of oral HF therapies and close follow-up in the first 6 weeks after discharge for an acute HF hospitalization is recommended to reduce HF readmission or all-cause death. During the follow-up visits, particular attention should be paid to symptoms and signs of congestion, blood pressure, heart rate, NT-pro BNP values, potassium concentrations, and eGFR”. The focused update acknowledges the limitations in STRONG-HF, such as patient selection and low rates of evidence-based therapy in the usual care arm.

On this background, the potential benefit of rapid introduction and titration of 4 pillars is gaining traction. However, establishing patients with LVSD on maximum tolerated doses of the 4 pillars often remains a protracted process, a situation exacerbated by limited specialist staff to deliver care.

Proposal
In our single-centre pilot study, we demonstrated feasibility of the 4x4 approach in a cohort of patients with HFrEF, the group for which treatment with the 4 pillars is indicated. The current application will assess the feasibility of the 4x4 approach in routine care across the UK. We will include centres in which delivery of the 4 pillars involves allied health care professionals, reflecting modern workforce expertise and utilisation. We will assess safety and tolerability of rapid titration to a real world population across multiple sites, and the generalisability of 4x4 as a standardised approach to medicines management in this patient group, reducing inequity of delivery and access to services with more efficient utilisation of specialist staff.

Aims:
To assess:

- 4x4 as a standard mechanism for delivery of medical treatments in patients with HFrEF
- Safety and tolerability of 4x4
- Barriers to success of the 4x4 approach; are there specific patient characteristics identifying patients as unlikely to succeed ?
- Variation among sites in proportion of patients established on 4 pillars of treatment Acceptability to patients of 4x4
- Health economics assessment of 4x4

Deliverables:
To demonstrate:

- 4x4 can be established in the UK healthcare system
- 4x4 can be delivered to scale in differing health care settings
- 4x4 facilitates establishment of 4 pillars of care in the majority of patients with HFrEF

We have agreement from 12 sites in the UK (and 1 in New Zealand) committed to delivery on the aims of this project. The sites are geographically and socioeconomically diverse. The general opinion from participants and patients is that this project is a 'must do' and should be addressed as a time critical project.

As highlighted earlier, outcomes for heart failure patients remain poor despite clear evidence for improvements if patients can gain access to treatment in a timely fashion. At each site, 4x4 will be delivered by one or more members of the usual care team, overseen by a local senior clinician, responsible for delivery of the project. For

each patient there will be a maximum of 4 visits at weekly intervals, in the home , community or virtual setting that requires an intervention to take place at each appointment. Patients will be informed on the proposed approach and potential benefits, as well as need for this to be a partnership.

All 4 pillars of treatment should be initiated, and where possible optimised, in the time frame of 4 visits in 4 weeks. Sequencing of medications will not be mandated, but at the discretion of the local health care team. Each site will recruit 40-50 patients to the innovative 4x4 project. Participant sites are geographically distributed across the UK, including sites in England, Wales, Northern Ireland and Scotland.

We propose to include a single site in Auckland New Zealand (Prof R Doughty/ Melinda Copley). By doing so we will assess the applicability of 4x4 out with the UK healthcare system. The Auckland site will recruit a similar number of patients to UK sites; initial analysis of the outcomes of our project will include data from the UK sites only; subsequently we will include data from Auckland, ensuring inclusion of an overseas site does not unduly influence interpretation of our findings.

Evaluation
The evaluation will be summative and focus on process, impact and health economics measures using a mixed methods approach.

Each site will collate data on:

- achieved doses of treatments; safety;
- tolerability; side effects;
- barriers to dose-optimisation.

We will assess quality of life impact, symptom improvement and survey patients' satisfaction of 4x4, and also guidance on future roll out. Data will be collated centrally and analysed alongside healthcare economic modelling. Each site will have funding to support clinician time for delivery of 4x4, data collection and administrative work as a consequence of clinical reviews. Each site will be governed by their local clinical audit processes.

Scalability
Should the project prove successful, it will show that our new approach to managing heart failure is feasible, safe and economically viable. The sample size of 400-500 patients across 12 sites in the UK is also a strength of the project as it will allow us to showcase a range of approaches by different clinicians.

Title: West of Scotland Cardiac Device Psychology Service	
Lead Applicant: John Sharp - Golden Jubilee National Hospital	
Value: £99,446	**Duration**: 12 Months

Summary:
This project aims to test a model of using digital technology to provide a regional psychological service to support to patients who have an implanted cardiac device in Scotland.

Unmet need:
Up to 40% of people with cardiac devices can experience related psychological distress which can be tackled with appropriate expert support. There is a clear unmet need though as access to such services can vary significantly.

The regional heart failure service is a tertiary referral service for patients with advanced heart failure from the West of Scotland, a population of approximately three million people, providing complex device therapy, such as implantable cardioverter defibrillators (ICDs) and cardiac resynchronisation therapy (CRT). A significant proportion (~40%) of people in receipt cardiac devices experience notable psychological distress. Currently, there is substantial variation in access to psychocardiology for people in Scotland following device implantation as there is no psychology resource attached to the regional heart failure service and only three of NHS Scotland's 14 regional health boards have any dedicated psychocardiology resource. There is a longstanding and hitherto unmet need to improve recognition and response to emotional and behavioural sequelae associated with cardiac devices.

The provision of psychological support for people with cardiac disease is an area of significant unmet need, despite its recommendations in a number of guidelines and strong evidence of its value. It is often identified as a key gap in the patient journey, and this has been a key finding from the Scottish Heart Disease Lived Experience Network.

Proposal
The proposed test will establish a new regional psychological service for those in receipt of a cardiac device. The project will test the provision, effectiveness and adoption of evidence based treatment delivered remotely from a central location utilising the use of video enabled therapies. This use of an innovative model of service delivery will work across regional borders with treatment being delivered as part of routine practice in 1 to 1 and group settings as appropriate.

Individuals will be able to access the new service from across multiple regional health boards with treatment being delivered in patients own home regardless of geographical location. Clinical staff will be situated in a "central hub" hosted within the regional heart failure service in the Golden Jubilee University National Hospital.

The test will focus its learning on how to maximise the use of video enabled technologies and assess the impact of the service model to reduced inequalities of service provision and its ability to increase access to vital treatment and support to

those currently excluded from service due to lack of service availability, geographical location, or mobility/health issues.

Number of patients to be included in the test period

The West of Scotland Regional Heart Failure service implants approximately 450 devices per year with approximately 180 of these patients requiring some level of psychological intervention. Within the test period we will seek to establish and offer a programme of psychological prehabilitation for all prospective device recipients, provide direct psychological intervention to a minimum of 50 patients through 1 to 1 therapy and deliver an additional 30 patients therapies via group settings.

Evaluation methodology

Data for evaluation will be collected using a number of different approaches and methodologies including: data collated from within the Near Me platform (uptake, satisfaction and reach), information gathered through routine clinical practice (clinical outcomes and referral numbers), semi-structured interviews of organisational and patient perspectives (acceptance, training and satisfaction).

Route to adoption and general implementation in the Health Service

The initial test will be within the WoS Regional Heart Failure Service. This comprises:

- NHS Greater Glasgow & Clyde
- NHS Ayrshire & Arran
- NHS Lanarkshire
- NHS Highland
- NHS Dumfries & Galloway
- NHS Western Isles

Participating regions will be invited to adopt clinical pathways and service models developed within the project. Delivery will be supported through the current Near Me service infrastructure. Support for the scale up and implementation has been secured through the existing Near Me service infrastructure this is already operational and fully established nationally with the national Near Me team providing ongoing technical implementation advice and support. Service implementation support and expertise will be provided through the national Digital Mental Health Programme and the Clinical Priorities Unit within Scottish Government. The Heads of Psychological Services group will provide the appropriate regional support for the expansion process, psychological clinical governance and strategic alignment to national policy and priorities while the Heart Disease Task Force will provide support for engagement, and clinical input from cardiology services.

The growth in digital solutions including video enabled therapies and computerised cognitive behaviour therapy (cCBT), can reduce the barriers to accessing evidence-based psychological therapies. This project aims to use digital platforms to test a cross regional psychological service to support to patients in with an implanted cardiac device. This model proposes to use digital and video enabled therapy to allow experts in psychological therapies to reach patients outside of the geographical boundaries and therefore increase access.

Title: Real-time ambulance to GP notification of atrial fibrillation: A digital solution to prevent stroke

Lead Applicant: Chris Wilkinson – Hull York Medical School

Value: £99,969	**Duration**: 24 Months

Summary:
Many people with Atrial Fibrillation (AF) remain undiagnosed and untreated, due to the lack of obvious symptoms, leaving them at risk of experiencing a stroke. This proposal aims to test a novel method of identifying new AF patients via the ambulance service for follow up within primary care.

Unmet need:
Atrial fibrillation and atrial flutter (collectively known as AF) are the most common sustained cardiac arrhythmias and are associated with an increased risk of stroke and systemic embolism. Although this risk is substantially reduced by the use of oral anticoagulant (OAC) medications, approximately one third of patients with AF in England are currently undiagnosed, and so are untreated - and therefore remain at elevated risk of stroke. Stroke affects up to 100,000 people per year in the UK with an associated care cost of £26 billion.

Improving AF identification is an important component of prevention as the linked activity of increasing OAC prescription uptake over time for people with AF is associated with a significant reduction in stroke admissions. The move away from face to face visits, is leading to a decline in opportunistic pulse checks requires alternative approaches

Ambulance services often attend calls to patients for various issues who they do not need to take to hospital. Their routine use of ECGs often identify patients with AF, but this is not automatically notified to the GP and the patient therefore remains at risk

Previous scoping work undertaken by the applicant team comprising interviews in 13 ambulance services and 'deep dive' activity within 2 of them. Their findings included an absence of formal pathways for ensuring ongoing care for people identified with an incidental finding of new AF amongst those not conveyed to hospital.

Proposal

Hull York Medical School and North East Ambulance Service (NEAS) propose to develop and test a technology led pathway on patients attended by paramedics who are noticed to have undiagnosed AF, but do not require transfer to hospital. The aim is to test the pathway on approximately 700 patients with potential undiagnosed AF who are estimated to be seen by the service during the project lifetime.

The BHF grant will enable the following activities within the project:

Technology Development: The development and coding of a software solution that will link the NEAS Cleric system, with GP systems and to include a bespoke data field enabling paramedics to flag the discovery of new AF. The two systems will be linked so that it will allow the attending paramedic to record the newly observed AF which in turn will create an alert and generate an automated notification to the GP electronic system, incorporating a letter and the ECG carried out. The letter and the

ECG will support patients to be followed up by the GP to arrange an appointment in relevant cases begin appropriate drug treatment to reduce their risk of stroke.

Training: An AF Champion Paramedic will lead the development and delivery of a multi format training programme to support paramedics to understand the importance of AF identification and oral anticoagulation. The training will support paramedics in accurate ECG interpretation for AF identification. They will also be trained on how to effectively use the technological solution. This training will be delivered in multiple formats including, face to face, online and supported by the development of written resources to support consistent application of the pathway the ECG to the patients GP via the NEAS and GP existing electronic record systems, highlighting their need to be followed up.

Expansion: The team will also explore how the pathway can be adopted nationally in the event of a successful pilot by forming a community of practice across other ambulance service as well as feeding back findings into nationally recognised bodies such as National Association of Ambulance Service Medical Directors (NASMED)

Evaluation methodology

Their evaluation will comprise of two key areas:

1) A quantitative outcome evaluation will use EMS data linked with primary care data. The team will quantify uptake rates of the intervention amongst potentially eligible patients, and compare new entry to the primary care 'AF register' and OAC prescription rates by pathway use, and compare with the preceding year.
2) A process evaluation consisting of semi-structured interviews with EMS clinicians, GPs, and general practice managers to understand the ways in which notification is actioned or not in clinical practice, and identify ways in which the intervention could be improved.

The team will engage an experienced qualitative researcher with previous experience of the proposal to lead an 'end-to-end' rapid qualitative service evaluation with selected key stakeholders.

Scalability
The team delivering the project have already assessed the potential for scalability noting that electronic patient care records are in use in 13 Ambulance services and can be achieved if the project evaluation is positive.

Several services are also using the same platform as NEAS and through sharing of the software changes rapid upscaling can be implemented to reach a population of up to 21 million people.

Broad support for the idea has already been identified across ambulance services during the scoping stage.

Finally, the team will create a network (community of practice) of people in ambulance services interested in this area to share learning and opportunities. This will support future collaborations and wider adoption as other services will already be engaged with the project. Updates and information will also be fed into national

bodies such as the National Ambulance Research Steering Group (NARSG), the lead paramedics group and the National Association of Ambulance Service Medical Directors (NASMED) who are key decision makers.

The findings will be shared at relevant conferences such as the EMS999 Forum and College of Paramedics annual research events, and published in journals that are widely read by practitioners such as the British Paramedic Journal and British Journal of General Practice.

Title: Piloting a biopsychosocial service to enhance engagement in physical activity in people living with adult congenital heart disease (ACHD).

Lead Applicant: Helen Wallis – University Hospital Wales

Value: £99,034.70	**Duration**: 12-15 Months

Summary:
This proposal is for an exercise programme for adults with congenital heart disease (ACHD) in South Wales. Patients will receive individualized support from physiotherapy, nursing and psychology to help them overcome the barriers and concerns about exercising, with the aim of improving health and wellbeing.

Unmet need:
ACHD patients are born with their condition. Many have already undergone previous surgery and may face further surgery or interventions. Additionally, they face further risk of acquired heart disease. Research suggests that patients living with adult congenital heart disease (ACHD) are at increased risk of developing cardiovascular (CV) risk factors, and compared to the general population, ACHD patients are more likely to be sedentary. Local data from the applicant showed that 58% of patients were either overweight or obese.

These patients will benefit from a programme of physical activity to improve their health and prevent development of further heart disease. Despite patients being encouraged to exercise, many reported a reluctance to increase their activity levels. There were many barriers to people with ACHD engaging in exercise. These included:

- Biological factors: (i.e. health status, mobility, breathlessness, fatigue)
- Psychological factors (i.e., beliefs about exercise, motivation, confidence, anxiety)
- Social factors (i.e., opportunity and access)

As well as the biopsychosocial barriers cited. Many patients were cautioned against exercise in childhood. They have limited experience of exercise and express anxiety about the risk of exercise on their cardiovascular (CV) status. Many private gyms report a reluctance to accept patients with ACHD.

Proposal

The project aims to implement a biopsychosocial approach to address the barriers and improve health outcomes for ACHD patients, by increasing physical activity, optimise medical treatments and enhance positive health behaviours in the ACHD population, through access to a 12 week programme.

Patients will receive individualized support from physiotherapy, nursing and psychology to help them overcome the barriers and concerns about exercising, with the aim of improving health and wellbeing. The programme will utilise a virtual platform for remote access to the team as well as the Giraffe Exercise app to allow patients to exercise at home. The programme will also provide opportunity to attend face to face sessions for exercise and to access psychosocial support and guidance.

Number of patients to be included in the test period
This proposal and funding is to pilot for an exercise programme for adults with congenital heart disease (ACHD) in South Wales. The pilot is for approximately 125 patients.

Evaluation methodology

Evaluation will be focussed on a range of validated patient measures for tracking progress and sharing outcomes. Baseline measures will be established be reassessed during and at completion of the 12-week programme.

Physical Measure: The team plan to assess quantitative changes in cardio-respiratory fitness and qualitative data will also be captured about patients' perceived level of fitness and ability. Validated questionnaires will be used to measure quality of life and psychology measures (e.g PHQ9 depression questionnaire). In addition, the team will gather qualitative feedback on patient experience / reported outcomes of the project (PREMs). This will be co-developed with the local patient experience team.

Regular meetings will take place within the team to assess the progress of the project and the evaluation measures.

Scalability
If the pilot proves that this approach is both viable and effective, the team propose to support early stage scaling through satellite ACHD clinics across South Wales.

Findings and outcomes will be shared with the South Wales and South West Congenital Heart Disease Network through the Governance Meetings and also present project finding a at national conferences.

Title: TRICORDER-PLUS: Triple Cardiovascular Disease Detection with an Artificial Intelligence-enabled Stethoscope – Primary Care Clinician Use for Screening

Lead Applicant: Nicholas Peters - Imperial College London

Value: £317,313.48	**Duration**: 18 Months

Summary:
This project aims to test a pathway in which Artificial Intelligence enabled digital Stethoscopes are used to improve rapid identification testing and earlier treatment of patients with undiagnosed Heart Failure (HF), Atrial Fibrillation (AF) and Valvular Heart Disease (VHD)

Unmet need
The most common and deadly forms of heart disease are usually diagnosed late, when patients are very unwell, causing poor quality of life, premature death and substantial costs for the NHS. HF alone is considered to cost the NHS is over £6 Billion per year – 4% of its annual budget.

70-80% of new HF diagnoses are made late, at emergency hospital admission. When compared to earlier diagnosis in primary care, this route to diagnosis results in poorer patient quality of life, clinical and health economic outcomes compared with earlier diagnosis, made by GPs. A key reason is that early initiation of inexpensive, guideline-directed, disease-modifying treatment – particularly for the most common form of HF, with reduced left ventricular ejection fraction (HFrEF) improves survival, quality of life, and reduces NHS costs. Critically, these therapies are effective in pre-symptomatic patients with reduced left ventricular ejection fraction (LVEF) ≤40%. Poor outcomes in AF and VHD – both treatable and associated with HF – are similarly driven by late diagnosis. These conditions could all be treated effectively if diagnosed early.

For HF, natriuretic peptide (NP) blood testing initiates the NICE recommended diagnostic pathway. Abnormal NP results trigger a referral for specialist review, diagnostic transthoracic echocardiography (TTE), and initiation of medical therapy.

However, the current evidence for extending NP testing to targeted screening is equivocal and without additional diagnostics, there is no viable, cost-effective solution. The absence of a quick, easy, point-of-care test that increases appropriate NP testing and use of the NICE diagnostic pathway is a clear unmet need which could improve outcomes for patients.

Proposal

The proposal is based on a two-phase implementation activity to assess the effectiveness of the AI stethoscopes as a method for early targeted testing for HF in primary care. In phase one, a validation exercise was undertaken on suspected HF patients in parallel with currently accepted gold standard diagnostic HF investigations. This demonstrated the stethoscope operated with a high degree of accuracy and sensitivity as a testing tool. In phase two the stethoscope was tested in a primary care setting on a targeted patient cohort to evaluate its effectiveness against the following aims:

- Determine feasibility and performance of AI-stethoscope for detection of NT-proBNP >400ng/mL in primary care
- Determine uptake of targeted screening for HF
- Identify undiagnosed patients with HF earlier than current practice

Following positive outcomes in both phases of early testing the team now intend to undertake early-stage scale testing against the following aims:

- Deliver an upscaled targeted screening programme for HF using the AI-stethoscope
- Measure the clinical and health economic impact of the programme, following National Screening Committee (NSC) criteria.
- Use implementation science methodology to establish a blueprint for deployment of this programme at the level of the NHS Integrated Care System – covering key clinical, information governance, financial and behavioural economic factors

The team will use data-informed targeting with 10 GP practices across London (urban) and Devon (rural) to invite patients for triple heart disease screening, with a particular focus on HF, in patients with no existing (coded) HF. Patients will be invited for a brief AI stethoscope examination and, where indicated, a confirmatory blood test. In patients where HF is detected, GPs will invite them to community HF clinics and undergo guideline approved treatment for their condition including appropriate drug therapy. The project will work with the National Steering Committee (NSC) to measure the patient-centred clinical, health economic, and wider holistic outcomes needed for the NHS to adopt this approach nationally.

Evaluation
The evaluation will examine the effectiveness of the model through analysis of data obtained from the AI Stethoscope, Electronic Patient Health Record Data and an ethics approved database of pseudonymized primary and secondary care clinical and health economic data.

This data will be used to evaluate performance against a primary outcome of incidence of HF from the targeted screening programme, following specialist review.

Additionally patient centric data will be captured and measured including healthy days at home and pre and post-screening anxiety. Clinical measures will also be examined, including unplanned emergency department attendance or hospitalisation, incidence of AF, or VHD, prescription of guideline-directed medical therapy for HF, AF and 12 month mortality. Health Economic data will also be captured and measured to support the development of commissioning focused blueprints

Scalability
If the project proves successful, the programme team will create a replicable 'blueprint' of the clinical, regulatory, financial and data governance for commissioning the screening services at the level of the NHS Integrated Care Board. This blueprint is being developed in collaboration with the National Screening Committee, with the ambition to submit to their annual call in July 2025.

The next round of the Healthcare Innovation Fund opens for applications early in April 2024. Please look at the website for further details. BHF Healthcare Innovation Fund