Perspectives from a successful NIHR application

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(March 2019 – Feb 2022)

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UNIVERSITY OF LIVERPOOL

BRITISH SOCIETY FOR HEART FAILURE

CardiomyopathyUK
the heart muscle charity

Overview

- Introduction to RENAL-HF
- What we think went well
- Experiences as a public co-applicant
- What we would improve in the future

RENAL-HF: Personalising renal function monitoring and interventions for people living with heart failure

WP1
Predict which people living with heart failure are at risk of kidney problems using electronic health records

WP2
Co-creation of a clinical pathway for implementing model-guided kidney test frequencies

WP3

A cluster randomized controlled trial to test clinical effectiveness of the new renal health primary care pathway

WP4

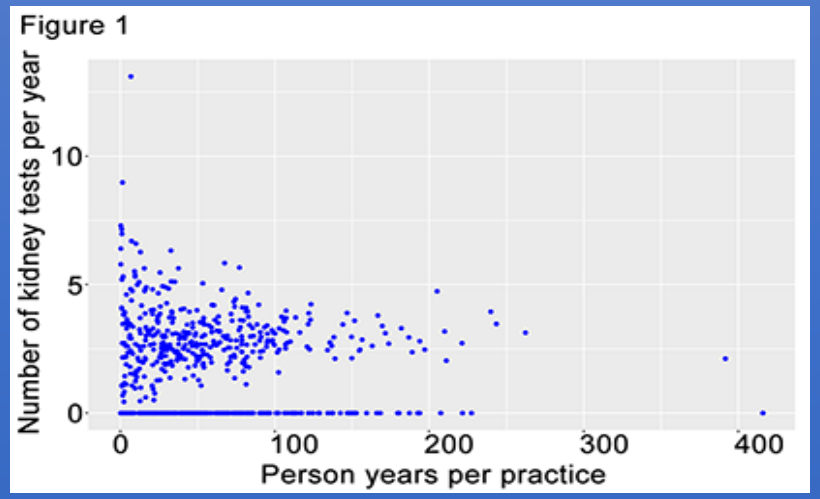
Cost effectiveness analysis of the renal health primary care pathway from an NHS perspective

WP5

PPI: Drawing on lived experience to co-create a renal health primary care pathway for people living with heart failure

What worked: right project, right scheme

Proof of need and concept



- Funding from NIHR Applied Research Collaboration North-west Coast
- Alignment with NHS long term plan

Fit for Scheme

Programme Grants for Applied Research fund "collaborative, multidisciplinary research that's solving health and social care challenges"

- Heart failure affects ~15% of those aged over 75 years
- By 2050 there are expected to be an extra 3 million people over 75 years

What worked: team leadership and expertise

- Professor Sir Munir Pirmohamed – Chief Investigator
  - 15 co-applicants
  - Six partner institutions: NHS, government, and university

- Including the Clinical Research Practice Datalink team was critical for delivering the work and for future implementation

UNIVERSITY OF LIVERPOOL

MANCHESTER 1824
The University of Manchester

PRIFYSGOL BANGOR UNIVERSITY

CPRD

NHS
Liverpool University Hospitals
NHS Foundation Trust

NHS
Liverpool Heart and Chest Hospital
NHS Foundation Trust

What worked: project design

- Input from multiple statisticians
- Statistician co-applicant
- Prof Mark Gabbay reviewed for RDS

- Clearly separated design and evaluation phases.
- For each phase we highlighted:
  - Impact
  - Cost
  - Risk

What worked: response to reviews

What Worked: response to reviews

The endpoint to be used in the trial will be discussed and evaluated by the expert panel and the PPI group based on the evidence generated.

We would be happy to convene a separate data monitoring and safety committee.

Response balanced change in light of criticism with rebuttal

Appropriate patients with heart failure, some with serious heart failure and kidney disease and who are no longer with us, have been included throughout the preliminary work conducted prior to this application.

In response to the reviews, we propose that guidance developed with our PPI groups and expert panel be placed under public consultation prior to the clinical trial.

What worked: designing patient and public involvement

- Highly experienced public co-applicant brings lived experience and ‘added value’ of management expertise
- Dedicated patient and public involvement work package
- Evaluation built into patient and public involvement design, with dedicated researcher time

Personal perspectives on patient and public involvement

- My journey
- The public co-applicant role – one of leadership
- Patient – PLUS – Public Voice
- Critical to success – comprehensive work plan
- Remember – primary objective

We would improve: bid writing and management

- Engage finance teams at small, non research-intensive partners early

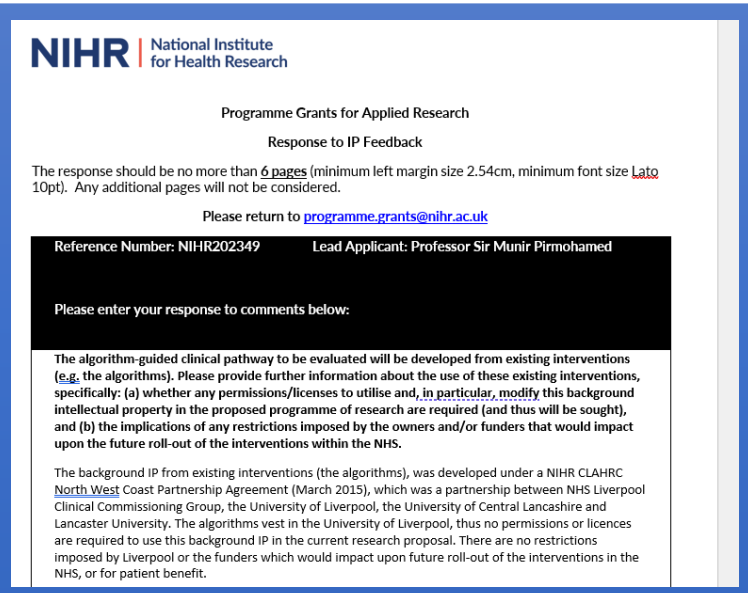
- Assign responsibility for each section of the application to a specific person
  - Ideally separate writing and administrative responsibilities
  - Do not underestimate the amount of time it takes to upload to the NIHR portal

- Agree a timeline for submission – including when last comments are welcome

- Write with the skim-reader in mind

We would improve: use of partner expertise

Intellectual property



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Programme Grants for Applied Research

Response to IP Feedback

The response should be no more than 6 pages (minimum left margin size 2.54cm, minimum font size Lato 10pt). Any additional pages will not be considered.

Please return to programme.grants@nihr.ac.uk

Reference Number: NIHR202349 Lead Applicant: Professor Sir Munir Pirmohamed

Please enter your response to comments below:

The algorithm-guided clinical pathway to be evaluated will be developed from existing interventions (e.g. the algorithms). Please provide further information about the use of these existing interventions, specifically: (a) whether any permissions/licenses to utilise and, in particular, modify this background intellectual property in the proposed programme of research are required (and thus will be sought), and (b) the implications of any restrictions imposed by the owners and/or funders that would impact upon the future roll-out of the interventions within the NHS.

The background IP from existing interventions (the algorithms), was developed under a NIHR CLAHRC North West Coast Partnership Agreement (March 2015), which was a partnership between NHS Liverpool Clinical Commissioning Group, the University of Liverpool, the University of Central Lancashire and Lancaster University. The algorithms vest in the University of Liverpool, thus no permissions or licences are required to use this background IP in the current research proposal. There are no restrictions imposed by Liverpool or the funders which would impact upon future roll-out of the interventions in the NHS, or for patient benefit.

- **Resolving IP issues after funding-in-principle was slow**

Peer review

Potential to do harm

Appropriate PPI not sought

Endpoint incorrect; potentially hazardous

- **Peer reviewers our team recruited were much less critical than the NIHR panel**

Summary

- Continually focus on the expected impact of the project
- Check alignment with funder goal, schemes and expected impact throughout bid preparation
- Partner institutions and design services have valuable expertise – don’t forget to use this!