

## Heart Failure Test Bed Project (104657)

Listening to the messages from Heart Failure patients – ‘Smart with Your Heart’

# FINAL EVALUATION REPORT

September 2020



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## Executive Summary

Our project – Listening to the messages from heart failure patients – Smart with your Heart is part of the NHS Test Beds wave 2 programme. Its aims were to use a combination of market ready digital tools to improve patient care. It is a collaboration of 2 NHS organisations, 2 University departments, 3 digital partners and a patient led patient charity – Pumping Marvellous Foundation.

We planned to use: Flo (interactive text messaging), Recap Health (a bespoke patient education system) and I-Navigator (a digital platform to refer to third sector and voluntary organisations).

We aimed to use these products in a heart failure pathway. We chose patients admitted or recently admitted to hospital with heart failure as we believed they had a 50% readmission rate to hospital at 6 months.

### **Aims and Objectives**

Our aim was to try and reduce this ‘revolving door’ readmission rate to hospital using digital tools within our heart failure pathway.

Our project has 5 main objectives:

1. Earlier detection of patients with deteriorating health in the community – and help to facilitate appropriate sources of help outside of the hospital – to reduce readmission rates after an index admission with heart failure
2. Educate and empower patients through personal education material delivered via Recap Health
3. Engagement with third sector and voluntary organisations to help in a timely way with problems that the NHS is less well equipped to help with e.g. financial and anxiety issues, loneliness etc. – to reduce readmissions prompted by the impact of psychosocial issues on physical health
4. Enhance access to care using a Tele Health Co-ordinator(THC) to facilitate access to care
5. Experience – provide a good or better health care experience than patients expected or were used to

## **Project in context of NHS and local Priorities**

Locally priorities were to:

- Improve patient experience
- Deliver better or equivalent care for reduced costs
- Reduce hospital utilisation

We aimed to review 230 heart failure patients and enrol 200 of them in this service evaluation.

We used multiple data sources to evaluate the project including: routinely collected service data in hospital, in GP surgeries, in the community heart failure nurse service, quality of life measures, patient activation measures, patient satisfaction surveys, health economic modelling.

The data was analysed by collaborators from:

- Staffordshire University
- University of East Anglia
- An independent experienced qualitative researcher

## **Project**

We enrolled 103 patients in a 9 month period due to a number of delays and challenges.

90 of these patients used at least Flo, 76 patients used at least Recap Health (61 used both), 17 patients used I Navigator (8 patients used all 3).

## **Evaluation**

NHS improvement recommends using the Donabedin model (2005) as a means to evaluate the quality of care that 'underpins measurements of improvement'.

The 4 components of the model are:

1. Outcomes – what did the project demonstrate?
2. Process – did we do what we said we would do to make the outcomes happen?
3. Structure – was there a structure in place to ensure the process occurred?
4. Balance – what are the unintended consequences or limitations of our project?

## 1. Outcomes

### All Cause Readmissions

In comparison to a usual care hospitalised group (and a usual care < 75 yr. age group):

- Our project significantly reduces readmissions to hospital at 3 and 6 months post discharge.
- Our project significantly reduces readmissions to A and E at 30 days, 3 and 6 months following hospital discharge.

These results are significant in the whole groups or if comparisons are for patients who have survived to the end of the time periods of interest.

The table below demonstrates the actual and relative risk reduction for patients who potentially had 6 months of follow up. The Usual Care group are all patients leaving hospital with a discharge coding for heart failure as the primary diagnosis. The < 75 years old portion of this group are the Usual care < 75 years group.

Hospital admissions	All cause readmissions at 6 months as a percentage of index readmission numbers %	Relative risk reduction of Project active in comparison to other groups
Project active n 58	52	
Usual Care n 537	90	-42%
Usual care <75 yrs. n 127	94	-45%

A and E admissions	Actual all cause readmissions at 6 months as a percentage of index readmission numbers	Relative risk reduction of Project active in comparison to other groups reduction
Project active n 58	34%	
Usual Care n 537	99%	-66%
Usual care <75 yrs. n 127	100%	-66%

There is a 52% and 56% relative risk reduction in hospitalisations at 6 months if all, or only patients living for at least 6 months from discharge are considered respectively . Similar results are seen in A and E admissions

### **Cost savings – approached in 2 ways**

#### **1. Readmission reduction and crude cost savings**

We have assumed that 1 hospital readmission (including preceding A and E attendance) costs approximately £3000.

If the relative risk reductions are extrapolated to each of the following groups then savings would be:

- All the < 75 years usual care group – saving £342,000 per year
- All usual care group – saving £1,500,000 per year
- To the NHS 80,000 patients hospitalised with heart failure - £50,000,000 per year

The cost of the intervention for a single service is approximately £54,000 for digital licences and 1 Tele Health Co-ordinator per 200 patients. Increased uptake by more clinical groups in the health economy would add to costs of scale savings.

Locally reducing readmissions by approximately 88 less than our current total in 1 year (or 44 admissions for each 6 months) would mean a relative risk reduction at 6 months in the usual care group of just 13% in comparison to our current 42-56% reductions.

#### **2. Health Economic Modelling, cost efficiency, cost effectiveness and return on investment**

The Smart with your heart independent health economic evaluation project was cost-efficient and cost-effective. It shows a return on investment of £1.20 to £3 for each £1 invested in it. If these figures were more generalised and applied to the 1 tenth of the £900,000,000 invested nationally in acute heart failure yearly then this would equate to a net £ 108,000,000 to £270,000,000 ‘saving’ with a £90,000,000 investment.

Interestingly the model was more dependent on the cost of GP services to remain cost-effective than readmissions. Some of the costs ‘saved’ from readmissions could therefore be invested in community services to maintain cost-effectiveness/efficiency in the future.

### **Patient Experience**

Our data demonstrates positive experiences in project patients. It demonstrates improved experiences of the heart failure pathway in patients previously known to the heart failure service (and now on our project). There is a positive patient response to the digital products and to Tele Health Co-ordinators.

## **Education and self-empowerment of patients**

Our data demonstrates that patients are more confident with their heart failure management with our project

## **Earlier detection of deterioration**

Patients who texted 'red' or 'worse' were more likely to be readmitted into hospital especially at 6 months.

### **2. Structure**

We employed 2 Tele health Co-ordinators. There was additional training for the Community Heart Failure team and an additional Community HF nurse was recruited on the basis of patients scoring 'RED/Feeling Worse' and needing access to clinic. GPs and community teams knew of the projects aims.

### **3. Process**

Of the 103 patients – 90 were at least using Flo, 76 were at least using Recap Health (61 on both), 17 on I Navigator (8 on all 3 products).

We can demonstrate improved patient knowledge and motivation in managing their own health.

We can demonstrate that patients answering 'red' or 'worse' are at greater risk of readmission. This is reflected when they no longer have access to the Tele health Co-ordinator to facilitate their care.

### **4. Balance**

#### **Patient population**

#### **Demographics and Digital products**

Patients were referred into the project by the hospital Heart Failure Nurses. Patients in our project have a mean age of 66 compared to the usual care group at 78 years old. We have used patients in the usual care group who are < 75 years old as a convenience comparator group (as this group have a similar mean age and sex distribution to the project active group). It is unclear whether there was any referral bias into the project, but the project patients referred to us were all approached to be on the project.

The reasons for 103 out of a total of 232 patients approached were eventually enrolled on the project reflects the fact that patients had to have access to both an email account and a mobile phone with texting capabilities or live in the locality served by the hospital (excluding 58% of ineligible patients). Additionally a change in registration process for the project

meant that there was a significant reduction in 'drop out' rate once patients were home. Lessons learned would mean that the initial 'drop out' rate would be less in future iterations of the project.

We accept that our project active group is smaller than we would have wished for – but it remains a relatively large size for a telehealth initiative aiming to reduce all cause readmissions.

### **Baseline outcomes and processes for Usual Care**

The admissions and readmission rates for the usual care group have worsened in the life time of the project (admissions greater than proportional increases in general medical admissions readmissions at 6 months of 90% rather than 50%). It is not clear how these unexpected increases in background rates contributed to the project's success. It was equally surprising that only 30% of hospitalised patients with a primary diagnosis of heart failure were referred to the community heart failure nurses.

These issues are not able to be dealt with within the project, but are opportunities to improve the heart failure pathway in other ways.

GP surgeries review patients discharged from hospital 15 times more than the recommended review frequency for chronic stable heart failure patients. It is unclear whether the numerical increase in the frequency that project patients are seen is clinically (although not statistically) significant.

### **Digital Products**

It is unfortunate that we did not get to test social prescribing starting within secondary care for heart failure patients.

We will be able to test out the impact of social prescribing as it is a national priority that it is set up and active in our communities. We still feel that access to social prescribing for patients leaving the hospital may reduce anxiety, depression and financial issues sooner than by referring into community services.

### **Conclusions**

Our project reduces all cause readmissions at reduced costs. It is cost effective and cost efficient and has an increased return on investment of £1.20 for every £1 spent within 3 months of hospital discharge. Similar relative risk reductions could save NHS between £50-100,000,000

It would be useful to hone the model further in our area and to use our results to set up a multi-platform, multi-centre research trial to see whether our success locally can be replicated nationally.

## Introduction

NHS England and the Office for Life Sciences launched their Phase 2 Test Bed Programme in March 2018 for NHS Organisations and industry to bid for funding to tackle some of the biggest challenges by introducing innovative approaches.

University Hospital North Midlands (UHNM), Midlands Partnership Foundation Trust (MPFT), and 3 SMEs – Health2Works; Simple Health and Signum Health and a heart failure patient charity – Pumping Marvellous Foundation - were successful with their application for a £1.1m grant. The following shows the grant allocation was split across 5 partners against a range of industry costs.

### Grant Allocation – April 2019

File reference: 104657

Date: Tuesday, 16 April 2019

Competition: NHS Test beds wave 2

Project Title: Listening to the messages from heart failure patients - Amendment 1

I write with reference to the grant offer letter dated 17 December 2018. The offer letter is hereby amended as follows:

Change in participant(s):

DELETE "Stoke-on-Trent CCG"

Appendix 1: Eligible costs and funding entitlement

New Appendix –

Industry Costs	Royal Stoke University Hospital	Signum Health Ltd	Simple Shared Healthcare Limited	Health2Works Limited	Midlands Partnership NHS Foundation Trust	Total (industry)
Labour	£597,516	£85,566	£0	£23,064	£57,850	£763,996
Overheads	£0	£17,113	£0	£4,613	£0	£21,726
Materials	£2,000	£0	£0	£0	£0	£2,000
Capital Usage	£0	£1,880	£0	£0	£0	£1,880
Subcontract	£0	£146,720	£75,000	£150,250	£0	£371,970
Travel and subsistence	£16,500	£37,890	£0	£6,336	£4,290	£65,016
Other Costs1	£0	£1,500	£17,360	£0	£33,675	£52,535
Other Costs2	£0	£0	£0	£0	£0	£0
Other Costs3	£0	£0	£0	£0	£0	£0
Other Costs4	£0	£0	£0	£0	£0	£0
Other Costs5	£0	£0	£0	£0	£0	£0
Other Costs WBBA	£0	£0	£0	£0	£0	£0
<b>Total Eligible Costs</b>	<b>£616,016</b>	<b>£290,669</b>	<b>£92,360</b>	<b>£184,263</b>	<b>£95,815</b>	<b>£1,279,123</b>
<b>Rate of Grant (%)</b>	<b>100.00%</b>	<b>70.00%</b>	<b>70.00%</b>	<b>70.00%</b>	<b>100.00%</b>	<b>86.70%</b>
<b>Total Grant</b>	<b>£616,016</b>	<b>£203,469</b>	<b>£64,652</b>	<b>£128,984</b>	<b>£95,815</b>	<b>£1,108,936</b>

### Grant Allocation – June 2020 (amendment) – latest approved allocation which sees a shift in grant to digital partners

File reference: 104657

Application number: 16249

Date: Thursday, 25 June 2020

Competition: NHS Test Beds: testing innovations to address health and care challenges -Full stage

Project title: Listening to the messages from heart failure

Industry costs	Royal Stoke University Hospital	Simple Shared Healthcare Limited	Health 2 Works Limited	Signum Health Limited	Midlands Partnership NHS Foundation Trust	Total (industry)
Labour	£424,516	£6,371	£79,219	£97,074	£82,848	£690,028
Overheads	£0	£0	£15,844	£19,415	£0	£35,259
Materials	£9,000	£0	£3,360	£0	£8,542	£20,902
Capital usage	£0	£0	£1,500	£1,592	£0	£3,092
Subcontract	£103,000	£107,227	£120,775	£168,197	£0	£499,199
Travel and subsistence	£9,500	£0	£3,003	£13,215	£2,000	£27,718
Other Costs1	£0	£0	£0	£500	£2,425	£2,925
Other Costs2	£0	£0	£0	£0	£0	£0
Other Costs3	£0	£0	£0	£0	£0	£0
Other Costs4	£0	£0	£0	£0	£0	£0
Other Costs5	£0	£0	£0	£0	£0	£0
Other Costs WBBA	£0	£0	£0	£0	£0	£0
<b>Total eligible costs</b>	<b>£546,016</b>	<b>£113,598</b>	<b>£223,701</b>	<b>£299,993</b>	<b>£95,815</b>	<b>£1,279,123</b>
<b>Rate of grant (%)</b>	<b>100.00%</b>	<b>70.00%</b>	<b>70.00%</b>	<b>70.00%</b>	<b>100.00%</b>	<b>85.05%</b>
<b>Total grant</b>	<b>£546,016</b>	<b>£79,519</b>	<b>£156,591</b>	<b>£209,995</b>	<b>£95,815</b>	<b>£1,087,936</b>

### **Total Spend across partners (estimated at July 2020)**

The expected spend by 30 September would be £1,123,423 of which the estimated cost for the analysis works of the evaluation is £36,000

### **Programme Management**

The Programme was managed on behalf of NHSE and OLS by Innovate UK who provided the governance and financial structures to which the Test Bed reported on a quarterly basis.

### **Local Project Delivery**

A Project Team, Steering Group and Project Board provided local governance to the delivery of the Smart with your Heart project which had relevant supporting working groups to help with delivering the aims and objectives of the project. The Evaluation Working Group was responsible for the evaluation plan, data management and validation pathway and a glossary of terms to ensure consistency across partners.

## Chapter 1. Background

### Reason for choosing inpatient enrolment

Patients admitted to hospital with heart failure have increased risk of both repeated hospitalisations and death compared to patients who have not been hospitalised.

[1]Enrolment of patients admitted to hospital was therefore chosen for their high risk of readmission once discharged. This meant that there may be greater readmissions to compare our project group with the usual care group – especially as the project is a service evaluation rather than a case control research study.

The Royal Stoke University Hospital is a District General and Tertiary Centre hospital serving a district general population of 750,000 people and a tertiary care population of over 2 million people.

A PFI new build meant the loss of over 400 beds in 2012 and the loss of some community bed capacity subsequently.

Usual care is delivered by the primary care and secondary care heart failure teams. They are both under different organisations, but both work closely together.

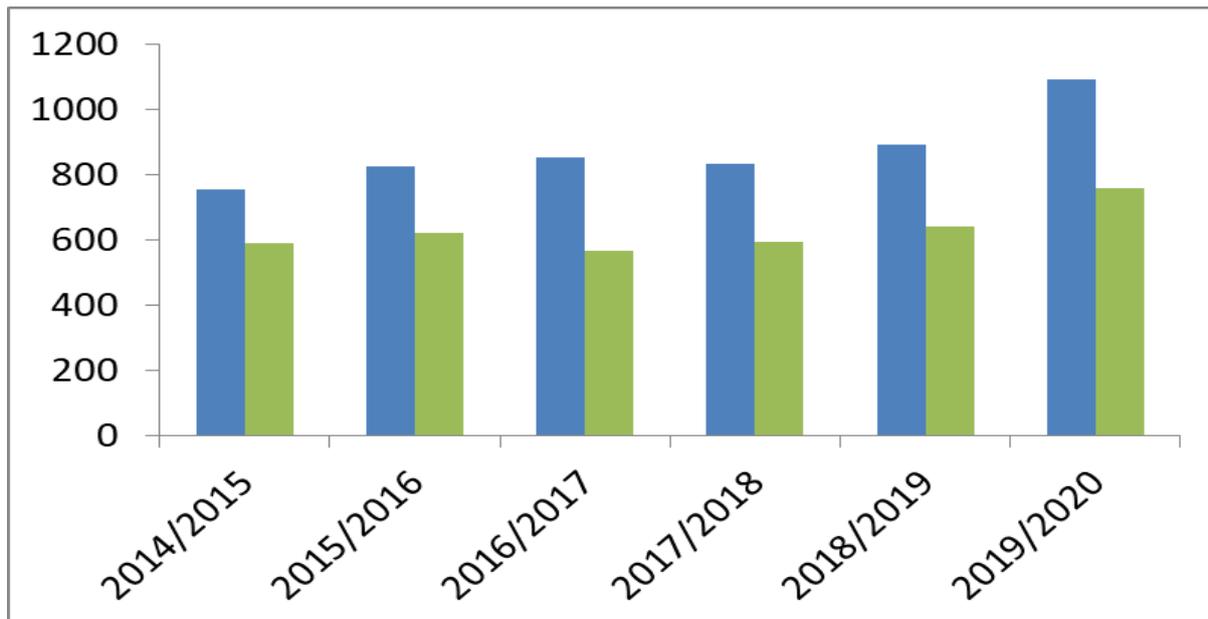
The secondary care team consist of 6 Consultant Cardiologists with interests in heart failure and 9 Specialist Heart Failure nurses within the hospital.

The primary care service consists of 7 Community Heart Failure Nurses.

### **Local Secondary care utilisation in the lifetime of the project A and E attendances and primary reason for hospitalisation from 2018-2020 in context of prior years**

The year on year increase in the number of A and E admissions and hospital discharges with heart failure is without precedent within the last 5 years. Continued increases in secondary care heart failure admissions / readmissions and A and E attendances are expensive and will potentially further strain the limited bed base at the Royal Stoke University Hospital. See Fig.1

COVID 19 changed the behaviour of patients with non-COVID 19 related illnesses as there was a national reduction in emergency hospital admissions and A and E attendances during January – June 2020.[2] To exclude the impact of COVID 19 on our heart failure data, we have considered A&E attendances and hospitalisations due to heart failure during the dates 1<sup>st</sup> April – 31<sup>st</sup> Jan for each year.



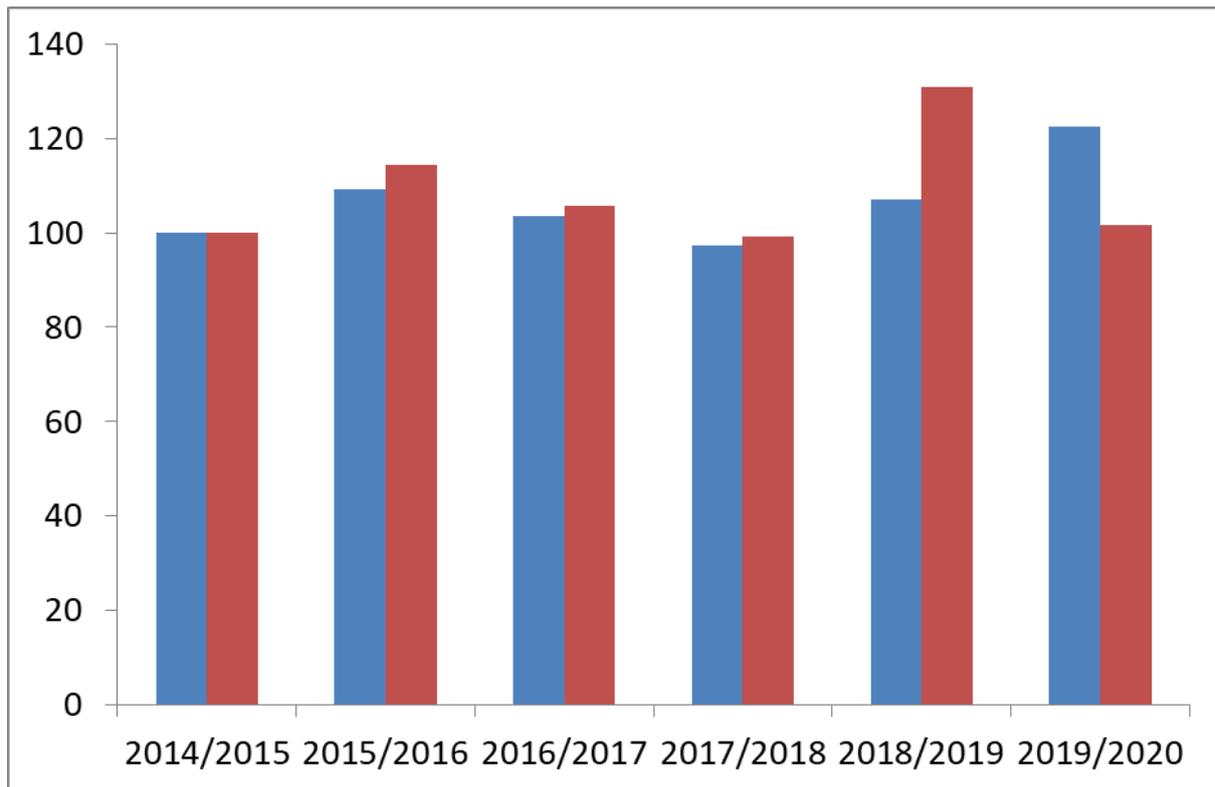
**Figure 1. Heart failure admissions (HF- in blue) and A&E attendances due to heart failure (A&E – in green) to the Royal Stoke University Hospital, from April to January, by year. The figure demonstrates an upward trend in heart failure admissions and A and E attendances within the last 3 years.**

The increase in HF admissions over the preceding 3 years is also demonstrated by the total overall admissions in heart failure over the whole financial year – i.e. this trend would be evident even without the COVID pandemic. The total admissions to the Royal Stoke University Hospital in the financial year 2019/2020 was approximately 300 more than in 2017/18.

### **Relative rise in heart failure admissions in comparison to general medicine**

Heart failure is a commonly encountered general medical problem. Hospitalisations from heart failure are set to rise. We arbitrarily used the data from 1<sup>st</sup> April 2014-Jan 2015 as the reference data – and ascribed a value of 100% to the heart failure and general medicine admissions during that year. Each subsequent year is then compared to the 2014/15 data to allow yearly comparisons of cardiology and general medicine admissions and to allow comparisons between any relative changes between them – Figure 2

We have demonstrated in the figure below that the admissions with heart failure have been on par with the increases in general medical admissions (indexed against 2014/15 values) just prior to the project starting. In the 2 years of the project there has been an increase in heart failure admissions and in the past year that increase is greater than expected for the rise in general medical admissions alone.



**Figure 2. Percentage change in UHNM heart failure hospital admissions (blue) and general medical admissions (red) relative to 2014/5 data (April-Jan each year).** Increases in admissions relative increase being > 100% and reduction < 100%. This data suggests a relative increase in heart failure admissions overall in 2018/19 - although greater than 2014/15 levels it is less than the increase in general medical admissions. However in 2019/20 for the first time not only is there an increase in heart failure admissions, it proportionately exceeds that of general medial admissions.

### **6 month hospital readmissions following a primary discharge code of heart failure - comparison between 2014/2015 and 2018/2019**

2014/15 – number of patients discharged alive with primary coding of heart failure = 596

2018/19 – number discharged alive with primary coding of heart failure = 841

In this time period there are more overall discharges with heart failure. Figure 3 below demonstrates the changes in readmissions between 2014/15 and 2019/20 where the readmission rate uses the total number of readmissions in this 6 month period rather than the number of individual patients readmitted.

**Figure 3 This graph demonstrates the proportion of readmissions within 6 months as a proportion of the index discharge with heart failure between the years 2014/5 and 2018/9.**

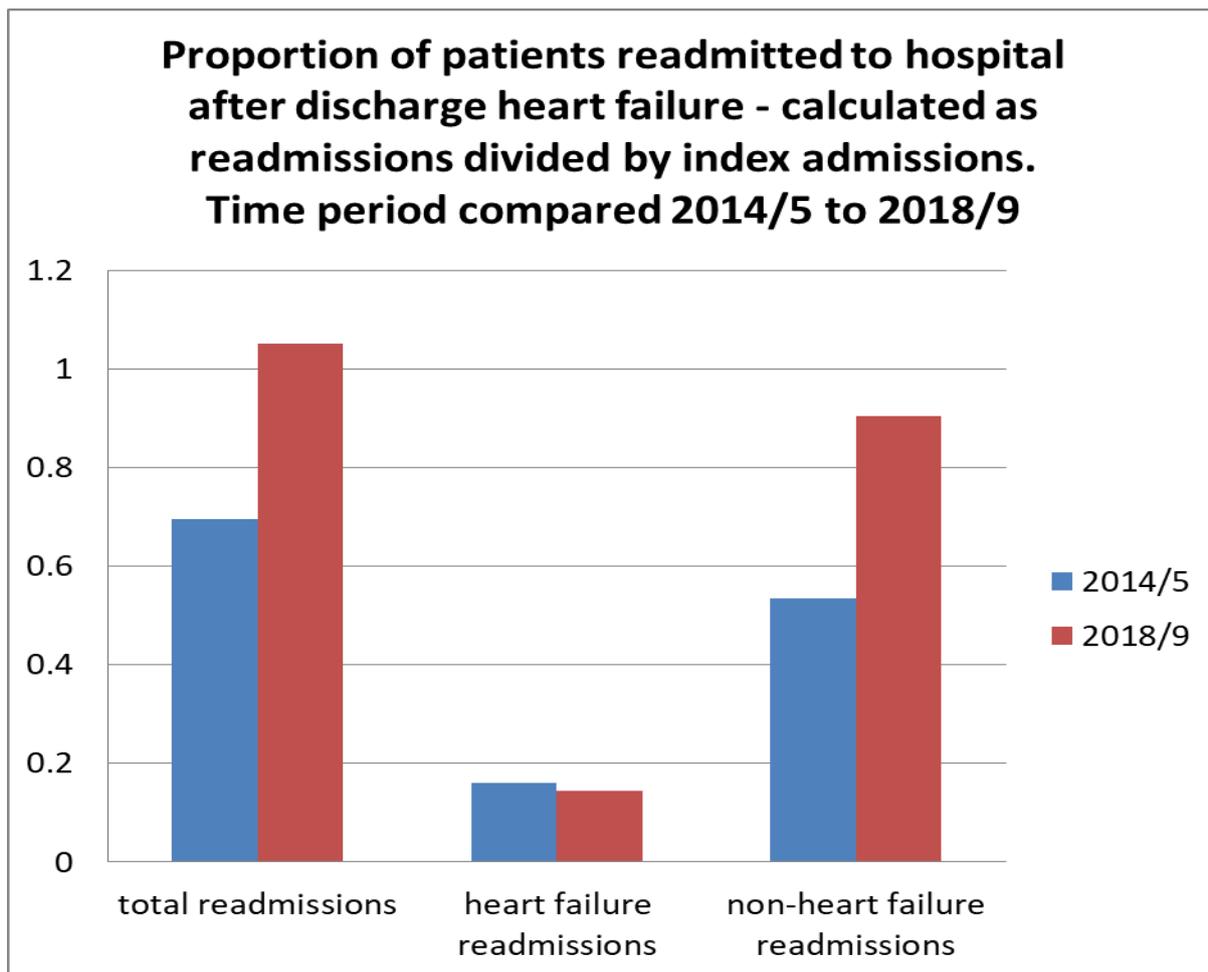


Figure 3 demonstrates that there has been a 1.5% reduction in heart failure readmissions between 2014/15 and 2019/20. There has been an increase in non-heart failure readmissions by 37% i.e. in 2018/9 there was a reduction in heart failure admissions by 12 patients in comparison to 2014/15 figures and a corresponding increase in non-heart failure admissions by 311 patients (i.e. for every 1 reduction in heart failure readmissions in 6 months there are 26 patients readmitted with a non-heart failure readmission).

In the 2 years of the project this has meant a total increase in patients attending A and E and admitted to hospital between 01 April 2018 01 Jan 2020. There were 543 more patients who attended A and E or were hospitalised with heart failure in comparison to 2014/15. The increase in admissions and readmissions is unaffordable for the health economy and disruptive to patient's lives. Additionally hospitalisation contributes to increased patient risk.

Our project among other aims will endeavour to reduce aims to readmissions to hospital after an index admission with heart failure.

## References

### References

1 The health services burden of heart failure: an analysis using linked population health data-sets [BMC Health Serv Res.](#) 2012; 12: 103. doi: [10.1186/1472-6963-12-103](#) accessed 19/09/2020

2 Rapid cardiovascular data: We need it now (and in the future)  
<https://www.nicor.org.uk/wp-content/uploads/2020/09/NICOR-COVID-2020-Report-FINAL.pdf> accessed 19/09/2020

## Chapter 2      Methodology

### Rationale for Project aims, Digital partner use and Tele-health Co-ordinator protocol

#### Introduction

Heart Failure (HF) accounts for 80,000 admissions in the UK annually – approximately 1000 of these are at the Royal Stoke University Hospital.

Patients discharged from hospital following a HF admission have an approximately 25% risk of readmission within 30 days, 50% at 6 months and 70% at 1 year respectively.[1] The presentation rates to the emergency department are similar. [2]

Our aim is to try and reduce this ‘revolving door’ readmission rate to hospital using digital tools within our heart failure pathway.

Our project has 5 main objectives:

1. Earlier detection of patients with deteriorating health in the community – and help to facilitate appropriate sources of help outside of the hospital – to reduce readmission rates after an index admission with heart failure
2. Education and self –empowerment of patients to help them manage their heart failure and other co-morbidities
3. Engagement with third sector and voluntary organisations to help in a timely way with problems that the NHS is less well equipped to help with e.g. financial and anxiety issues, loneliness etc. – to reduce readmissions prompted by the impact of psychosocial issues on physical health
4. Enhance access to care using a Tele Health Co-ordinator(THC) to facilitate access to care
5. Experience – provide a good or better health care experience than patients expected or were used to

#### Project in context of NHS and local Priorities

Locally priorities are to:

- Improve patient experience
- Deliver better or equivalent care for reduced costs
- Reduce hospital utilisation

Our project also supports the intentions of the NHS long term plan [3]:

- More care out of hospitals
- Reduce the burden on emergency services
- People getting more control of their own health
- Technology to help with care
- Improving cardiovascular care
- Prevention of ill health
- Investing in the workforce

Early adoption of innovation is part of the ethos of the Cardiology Department at Stoke, given the introduction of: TAVI, Mitraclip, Atrial appendage occlusion, PFO closure, leadless pacemakers, the Cardiac Assessment Nurse service, HIS bundle pacing, remote pacemaker monitoring, Cardiomems, the SHINE ambulatory heart failure clinic etc.

For the current project, we sought to achieve our project objectives through:

- Using interactive texting with the Flo telehealth system
- Using a bespoke digital library service – Recap Health - into which patients could recommend content of specific interest to them or their clinicians felt would benefit their understanding of a particular problem- coupled with a feedback mechanism to demonstrate use of the library by patients to clinicians and allowed comments on content usefulness by the patient
- Using I Navigator – a social prescribing platform – that allowed referral into third sector organisations coupled with a feedback loop of informing the GP of the referral and whether the patient attended for their referral
- Using a Tele Health Co-ordinator to pro-actively respond to patients texted responses suggesting deteriorating health and, based on-patient response, steer them to an available and suitable health resource outside of the hospital environment.

### **Telehealth/Telemonitoring**

Telehealth/Telemonitoring refers to numerous mechanisms of remote interactive monitoring for patients using a variety of different technologies. Information gathered in this way can then be used to:

- improve healthcare behaviours
- help identify populations at greater risk of events
- inform treatment choices

Sir Bruce Keogh<sup>1</sup> said of technology enabled care (TECS) ‘TECS are the future’. This is exemplified by the position statement on telehealth from the ESC, the inaugural British

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<sup>1</sup> Sir Bruce Keogh, Medical Director of the National Health Service in England from 2007 and National Medical Director of the NHS Commissioning Board from 2013 until his retirement early in 2018

Cardiac Society Social Media, Digital Health and technology symposium in 2018, and the favourable Cochrane report on telemedicine in heart failure.[4,5]

We have had similar roles to Tele health Co-ordinators at Stoke since 2014, but monitoring is limited to the approximately 15-20% of the total HF population implanted with complex devices or Cardiomems for treatment and monitoring of their HF.

## **Project methodology – Digital tools**

### **Flo – Simple Telehealth**

Flo is an interactive texting service used as part of standard care in over 20 countries nationwide.

Flo is used as part of a long term management strategy in cardiovascular disease, COPD and diabetes amongst others e.g.[6]

Flo is also part of the NHS test beds 1 site service evaluation and is therefore a technology familiar to Innovate UK.

We used Flo for pre-hospital identification of symptomatic deterioration inpatient's self-assessment of their own health subjectively and against a 'traffic light' (red/amber or green) symptom checker – see below

### **Interactive texting with Flo**

#### **a) Better , the same, worse**

The Flo telehealth system is an interactive system accessible to all ages. It is a system of automated interactive text messaging whose responses can be used to monitor pre-set outcomes.

Patients' own subjective assessments of their health in terms of a 'wellness' rating will be obtained by:

- A perception of their recent pre-admission (their 'baseline wellness state')
- Their post-discharge feelings of 'wellness' in comparison to their baseline (beginning at discharge and then updated every 48 hours depending upon their last response).

Patients' subjective assessments will act as the comparator to daily subjective assessments of 'wellness' in comparison to the prior 48 hrs. This time frame is the same as in the McGill palliative care quality of life questionnaire.

Improved symptoms and self-reported health status are linked to patient outcomes – the better you feel the better your outcome. [7] It has also been shown that health related quality of life is reflected in symptom burden in HF and that outcomes are worse as symptom burden worsens. [8,9]

We used the Flo system on an alternate day basis to simply ask (patients discharged following HF hospitalisation) whether they feel: better, worse or the same as 2 days before. Phone contact and sign posting to the appropriate community service will be made by a central team member (the telehealth co-ordinator) for patients demonstrating:

- No improvement in subjective health since discharge (if worse than normal on discharge)
- Worsening subjective assessment of health (irrespective of discharge self-reported health status)

Examples of sequential responses from patients discharged from hospital are shown in table 1.

**Table 1** demonstrates post-discharge self-assessment on alternate days by patients discharged from hospital with acute decompensated heart failure (day 0). The red bars are a graphical representation of patient ‘wellness’; the bars moving upwards representing improvement in self-assessed health, downwards as a decline in health and unchanged as the same health status. Graphical trends are analysed by the Co-ordinator and patients who are feeling ‘worse’ or failing to improve from a ‘worse’ baseline after 2 days will be contacted.

All patients at baseline, in this example, feel worse than the best health they have experienced in the 3 months prior to hospitalisation. Patient 1 improves after discharge. They do not need to be contacted by the Tele health Co-ordinator.

Patients 2 and 3 are both contacted on day 2 for failing to improve from a ‘worse’ baseline and are getting worse respectively.

**TABLE 1**

Patient	Response of Tele Health Co ordinator	Wellness Comparison Response in patient discharged not feeling as well as their baseline state	Days post discharge							
			0	2	4	6	8	10	12	
1	Usual Care – no contact	Better								
		Same								
		Worse								
2	Intervention With phone call	Better								
		Same								
		Worse								
3	Intervention With phone call	Better								
		Same								
		Worse								

**b) Are you red amber or green?**

We developed a patient symptom checker / joint management sheet in 2012/3 as part of a CQUIN to reduce heart failure readmissions at RSUH. The documentation for our strategy was approved by Trust Governance meetings.

The contents of the symptom checker were based around the most common reasons for 30 day readmission following a HF index admission to RSUH. Data for over 3000 HF hospitalisations and causes for subsequent readmissions were determined.

Potential cardiac causes for readmission accounted for approximately 50% of readmissions with a third due to HF causes.

Our symptom checker / joint management sheet was developed such that green is for the lowest risk of 30 day readmissions and red is the highest risk.

The contents of the heart failure specific sections of the symptom checker / joint management sheet are similar to many around the country including the AHA symptom checker.[10]

The symptom checker / joint management sheet is unusual in that it not only includes standard HF advice, but it also considers:

- Co-morbidity health – as suggested in NICE multi-morbidity guidelines and HF guidelines such as ESC (in which 17 different co-morbidities affecting HF patients are discussed).[11,12]
- Carer health – as suggest in NICE HF guidelines 2018 [13]
- Sick day rules – as per local protocols
- Medicine reconciliation – as suggested in NICE HF2018 guidelines and others [13]

Our UHNM symptom checker has been adopted and produced in written and pictorial forms by the Pumping Marvellous Foundation, a patient led Heart Failure Charity.

It has been approved by their non-executive clinical board of the Pumping Marvellous Foundation – whose chair is Prof Martin Cowie from Imperial College (past president of the British Society of Heart Failure).

It is used by the North West Ambulance service as its heart failure triage tool.

Pumping Marvellous has distributed 40,000 across the UK with no report of adverse outcomes or complaints. It is distributed by the 80% of UK heart failure services that use Pumping Marvellous literature.

The contents of the Pumping Marvellous Foundation website are endorsed by NICE for patient education in their current HF guidelines 2018 (page 417).[13]

The actions taken in response to symptom deterioration are in keeping with standard local and national practice.

Patients received alternate day texts for the first 30 days asking whether they were in the 'green, amber, or red' sections of their symptom checker. The texts became more infrequent over time.

The Tele Health Co-ordinator contacted patients who text 'red' and facilitated the patient's own understanding of the actions suggested within the symptom checker / joint management plan.

## **Recap Health – Health2Works**

### **Education and patient self-management in heart failure using a digital, bespoke, patient library**

Only 1% of a HF patient's time is spent with clinicians. Our project aimed to encourage patients to use time away from clinicians to improve their own self-care behaviours.

A recent systematic review – Strategies to modify the risks of heart failure readmissions: a systematic review and meta-analysis *'The independent and combined effects of education and assessment are the most beneficial strategies to yield a positive benefit to avoid or reduce readmissions of HF patients'*[14]

The White Paper on heart failure 2014 from the World Heart failure alliance states that "any programme aimed at improving long term management should recognise that patients with HF have a key role to play in their own care, self-care comprises maintenance, monitoring ... Education programmes are a priority." [15]

Education and health literacy for patients are key priorities within the current NICE guidelines in HF and is part of the position statements of benefit from the AHA.[16,17].

Improving a patient's health literacy can improve their ability and willingness to manage their long term condition – this is called patient activation. Patient activation additionally improves patient satisfaction and can reduce health care utilisation including readmission rates. Improving patient activation is supported by the Kings Fund (Supporting people to manage their health – an introduction to patient activation 2014) and NHS England.[18]

Multi-media health education is key. We currently provide patients with English language health care booklets for all aspects of their care. These booklets may not be available at time of greatest need. Additionally the most important information that is needed may be lost within a whole sheaf of provided literature.

Recap Health allows the clinician to 'prescribe' relevant information i.e. send material directly to an individualised patient portal on the Recap Health platform.

The process of accessing Recap Health started with the patient being emailed a link to the site by their clinician with the patient's permission to do so.

The patient then enters a unique code contained in their 'welcome' email, which once they have entered the portal it allows them to access, in their own time, health literature pertinent to them and selected for them by their clinician.

The site provided a feedback loop to the clinician concerning how often the patient looked at the literature and patient feedback about the usefulness of the content.

### **Site governance for Recap Health**

The library contained within the Recap Health platform is entirely governed by the UHNM Cardiology Department. Initially the content would be a digital form of what is already given to patients from NICE recommended sites such as the British Heart Foundation and the Pumping Marvellous Foundation.

Other clinical teams were encouraged to add literature of value to patients either from their own approved patient resources or bespoke literature to benefit the Trust and the project equally.

Patients are aware that their data can be removed from the site at any stage in keeping with GDPR.

### **Risks and limitations**

While we are mindful of the risks of unwanted or distressing information to patients, we do not believe a digital platform to provide patients with information (that they specifically request, which is accessible to them at a time of their choosing and displayed on a screen with the potential to alter font sizes) would contribute to any more adverse health care preoccupations or behaviours than the access patients currently have to the same literature in a printed format or from unfiltered information available on the internet.

The limitations of our current literature are also reflected in the limitations of the digital platform i.e. content only in English at present.

### **iNavigator – Signum Health**

#### **Improving access to third sector organisations –social prescribing**

It is thought that approximately 20% of GP consultations are about psychosocial issues. Equally, poor environment and mood can lead to deteriorating physical health[19].

Social (or community) prescribing is the referral of patients to trusted third sector or voluntary local organisations to intervene in some of these psychosocial issues, and to offer

opportunities to engage in activities likely to improve the patients' overall wellbeing, e.g. dance classes, allotment working, walking groups.

Social prescribing is promoted by NHS England and by the DOH as one of the top 10 priorities for GP practices in the NHS Forward View. [20] Of course these kinds of activities have been around as long as third sector organisations have been around, but the wellbeing outcomes from commissioning of these services is now becoming apparent.

An evaluation of over 1000 patients referred to a social prescribing service demonstrated an improvement in quality of life scores and financial wellbeing in the recipients. The NHS cost effectiveness is £20-30,000 per QALY (Quality adjusted life year). The cost per QALY for this intervention was less than £2000. This suggests that the health benefits accrued from investing £1 in social prescribing would usually only be achieved by the health economy spending £10 [21]

A review of over 300 patients referred to the South Merton social prescribing programme not only demonstrated an improvement in quality of life, but also a reduction in GP attendances by 30% and in A+E attendances of 50% over a 1 year period. [22]

GP practices in Stoke and North Staffordshire have been using social prescribing at small scale in the community for approximately 3 years.

A more formalised and commissioned approach to social prescribing started locally from October 2017 with the creation of 6-9 sites across Stoke and North Staffordshire to have their own 'link support worker' to implement patient's social prescribing needs.[23]

The charity 'VAST' is an example of an organisation that links third sector organisations locally with social prescribers. It's Voluntary and Community centre Hub is a service commissioned by Stoke and North Staffs CCGs to provide this service. [24] Our strategy was to explore the options of utilising VAST as a link into all third sector organisations.

Signum Health developed iNavigator as a secure platform to facilitate the electronic referral of patients to accredited third sector organisations. It is hosted behind the NHS N3 firewall, and the company is compliant with IGT2 and is an accredited NHS digital supplier. Signum works with client NHS organisations to identify approved third sector organisations and the required accreditation credentials which will be checked by the Tele Health Coordinator.

Approved third sector organisations received direct referrals from the Tele Health Coordinator as actioned by the clinical team who have identified a social prescribing need for individual patients.

Agreed and relevant patient data was entered onto the referral forms in the same way that demographics are required for all referrals.

The third sector organisation and patient would feed back about whether the patient attended (from a referral perspective) and whether the patient found the process and the outcome satisfactory.

An example of a third sector organisation who already received sign-posted referrals from the HF team currently is the Dove Bereavement Service.

### **Site governance for I-Navigator**

All third sector organisations for the i Navigator system were approved within the Trusts standard governance arrangements.

### **Risks and limitations**

Multiple service evaluations of now over 2000 patients have shown that there is no obvious harm from social prescribing.[25] Any harm to patients that occurred during the project were noted in our risk registers.

### **Tele Health Co-ordinator**

A non-clinical administrator i.e. not a nurse or doctors were responsible for:

- Explaining project nature to patients
- Educating patients on the use of the appropriate digital platforms
- Ensuring patients understand their on-going responsibility for managing their own health
- Ensuring patients understand the frequency of texted responses
- Ensuring patients agree to the use of their e mail details for the digital platforms and their pseudoanonymised data to be held on the digital platforms as part of the information governance needed for GDPR and mandated by the trusts IG guardian
- Explaining the repeated quality of life questionnaires and patient activation measures that will be collected throughout the project
- Ensuring patients understand the role of the Tele health Co-ordinator:
  - is not a medically qualified member of the Heart Failure Team;
  - will help to facilitate care choices from the patient's own understanding of their symptom checker / joint management sheet
  - will help patients engage with the digital platforms used – i.e. an 'IT' support role
- Responding to appropriate 'alerts' arising from texted responses
- Providing technical support, encouragement and education about interacting with Flo or the other digital partners
- Facilitating access to pre-specified community services as outlined in the symptom checker / joint management sheet

- Seeking Clinical help when there are any patient related issues not covered within the symptom checker / joint management sheet
- Facilitating the use of the social prescribing digital platform (see below) to refer patients identified with specific identified and qualified third sector needs by the HF team to those specific providers
- Collating data about their interactions and any onward referrals – to feed into the project meetings
- Removing patients from monitoring at their request from one or all digital platforms
- Inviting all patients and carers to patient focus group meetings at the start of and at the end of their 3 month use of Flo interactive texting and to complete a post 3 month patient experience questionnaire

Any patient responses falling outside of the initial protocol were discussed with the Heart Failure Consultants.

### **Tele Health Co-ordinator responses to patient self-reported deterioration in health**

The Tele Health Co-ordinator used 4 themed questions to interact with patients (see specific questions below). The themes were:

1. Heart failure - worsening of your heart failure symptoms and signs – if so the co-ordinator will contact the community heart failure nurses or shine clinic for earlier review of the patient by phone or in person
2. A known co-morbidity worsening – in which case the co-ordinator will contact the community Hub or designated community matron responsible for the patient
3. A medical problem unrelated to known co-morbidities – patient signposted to community hub or to GP
4. A non-medical problem –the co-ordinator will discuss this with the available senior clinician and signpost the patient appropriately – using the social prescribing platform as appropriate

The questions and Co-ordinator responses are expanded below:

**Question 1:** “Is the reason you are not improving the same as the reason that you came into hospital (breathlessness, oedema etc.)?”

- If yes –
  - Co-ordinator asked “What does it say to do on your self-management chart?” Action: patient to activate planned action from chart. (If the patient does not have the self-management chart to hand, the co-ordinator will run through the sections with them).

- Tele Health Co-ordinator to facilitate contact with the secondary care heart failure nurses for earlier review of the patient by phone or in person
- If no – go to Question 2

**Question 2** “Is it one of the other medical conditions you are known to have that is worse?”  
(Patient should have co-morbidities noted on initial database)

- If yes –
  - If so which one does the patient feel is worse?
  - What does the self-management tool advice in this situation? Do you have it to hand? If not I will run through it with you.
  - the co-ordinator will contact the secondary care nurses or designated community matron responsible for the patient or GP surgery as suggested by patient interpretation of the symptom checker / self-management sheet as appropriate
- If no – go to Question 3

If patient worse again then needed to highlight to secondary care heart failure nurses / community team or GP (repeat questions to see whether worsening due to heart failure / other known co-morbidity / new medical problem or psycho social issue).

**Question 3** “Do you feel unwell because of a new medical problem that has arisen?”

- If yes –
  - Patient signposted to secondary care heart failure nurses / community matron or to GP on behalf of the patient – patient advised to discuss with their GP or community matron responsible for co-ordinating their care. If they wish to discuss with the community matron, the Tele Health Co-ordinator asks ‘Do you want me to contact the community matron for you?’ (need to have co-ordinating nurse’s contact details on the data base or accessible via the community co-ordinating hub)
- If no – go to Question 4

**Question 4** “Do you feel unwell because of a non-medical problem?”

- If yes –
  - Is it to do with your home circumstances or difficulty in physically managing your usual daily activities (that is not caused by a medical problem)?
  - What does the self-management tool advice in this situation? Do you have it to hand? If not I will run through it with you.
  - Free text details will be elicited by the co-ordinator and the patient signposted to secondary care nurses / community hub / social services / citizen’s advice bureau etc. once discussed with clinician

- If no –
  - Is the problem to do with your mood? Is there a particular problem that is worrying or upsetting you?
  - Who would you normally contact in this situation? Would you like me to contact the hub on your behalf?
- Even if no contact with other health professionals required currently by patient – please note in data base and discuss with key community worker

If the patient answered no to all of these questions then the Tele Health Co-ordinator asked the secondary care Heart Failure Nurses or Cardiology Consultant to contact the patient for a telephone triage of their symptoms.

Secondary care nurses in the ambulatory heart failure clinic were the first port of call for all enquiries as it was decided that this would replicate access to community services by patients in the SHINE clinic (the heart failure ambulatory care unit) and therefore the only difference in the heart failure pathway would be the use of the digital tools and Tele Health Co-ordinator intervention.

### **The Patient**

Patients in the project understood that the project:

- Was not a replacement for self-care or for their usual HF care
- Would not change their usual HF care
- Was not an emergency service

Patient's acknowledged that:

- they remained responsible for their health, and understood that their text message responses are sent to an inanimate machine
- they agreed to respond to messages from Flo
- they allowed their data to be used by the 3 digital platforms to enable patient access to those digital services
- they may be contacted by the Tele health Co-coordinator
- they needed to respond to daily questions about improvements in symptoms and status on the symptom checker / self-management sheet
- standard post-discharge care would continue unaffected by their involvement in the project.
- they could withdraw from one or any of the digital platforms at any stage
- they signed a consent form to allow their data to be used in keeping with GDPR (see Appendix 1 – 'Methodology Patient Agreement Leaflet')

The project process map is included as Appendix 2 ('Methodology – Process Map').

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## Patient Enrolment

### Patient Enrolment

#### Patient ward location

Patients with decompensated heart failure were chosen as the population for enrolment due to their higher rates of readmission than patients with heart failure diagnosed in an outpatient setting.

Over 60% of all in patients with heart failure are based on non-cardiology wards.

Heart failure can be a difficult diagnosis to make by clinicians outside of the heart failure team e.g. 40% of notes of patients who died in hospital with heart failure were felt not to have heart failure in the recent NCEPOD national enquiry into in hospital heart failure deaths .[1]

We wanted to ensure that all patients on our project definitively had the heart failure syndrome.

We used the secondary care heart failure nurses as the 'gold standard' to verify that patients referred to the Tele Health Co-ordinators had decompensated heart failure as a clinically active problem – rather than just a stable co-morbidity.

The Best practice tariff is an additional fee paid to the hospital if 60% of patients in hospital with final discharge code of heart failure are seen by the heart failure team (nurses and / or doctors).

Of the 834 patients discharged from hospital between 01/07/2019 and 13/03/2020 - 306 were seen by a heart failure nurse and 329 by a doctor.

The 306 patients seen by the heart failure specialist nurses were the maximum pool of patients available for enrolment into our project – see Figure 1

### Patient criteria for participation and exclusion

#### Initial criteria

##### Inclusion

- Heart failure syndrome
- Likely to survive to discharge from hospital
- Has access to a mobile phone with texting capabilities (either their own or carers)
- Has access to an email address and computer / tablet / phone that can access the internet (either their own or a carers)
- Can read and respond in English (or has a carer who will do this with them)

- Live in the area supported by Stoke and North Staffordshire community heart failure nurses – as other areas do not take all types of heart failure

### **Exclusion criteria**

- Patient does not wish to be involved
- Does not meet the inclusion criteria

### **Expanded inclusion criteria**

We expanded the enrolment routes for patients with decompensated heart failure, as we realised that not all hospitalised heart failure patients were seen by the secondary care heart failure nurses while in hospital.

The 2 new enrolment routes were:

1. Post discharge 2 week follow up review

Patients who are hospitalised with heart failure are seen within 2 weeks of hospital discharge. Any patients not enrolled while in a hospital bed was then approached at their 2 week follow up.

2. Patients in the ambulatory heart failure clinic requiring intravenous diuretics

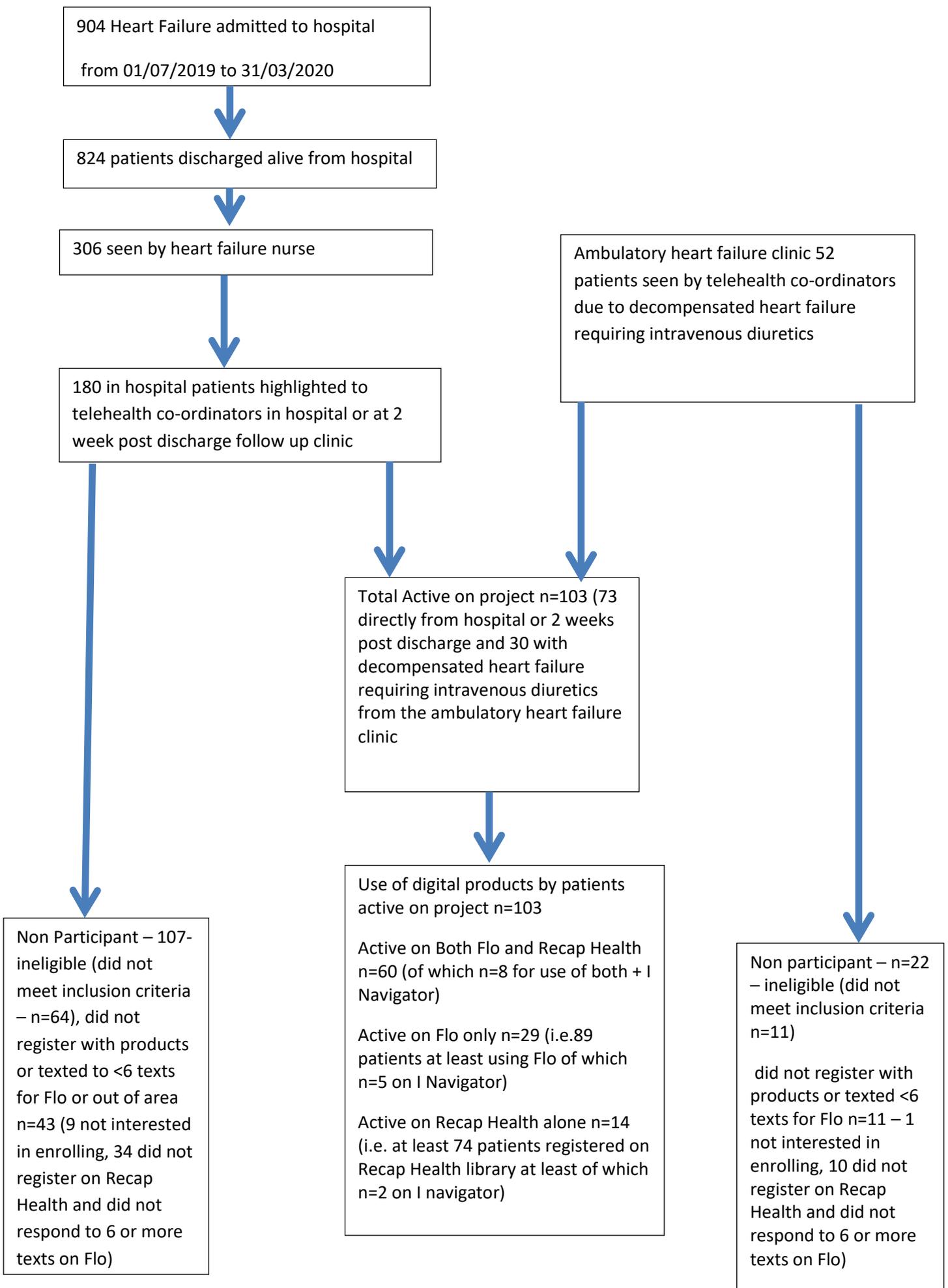
Patients who have worsening or decompensated heart failure are usually admitted to hospital for intravenous diuretics. We have an ambulatory setting where some patients can attend for intravenous diuretic to avoid occupying a hospital bed. These patients were also approached to be on our project.

Of the 103 patients on our project 70% were hospitalised with heart failure and 30% required intravenous diuretics in the ambulatory clinic.

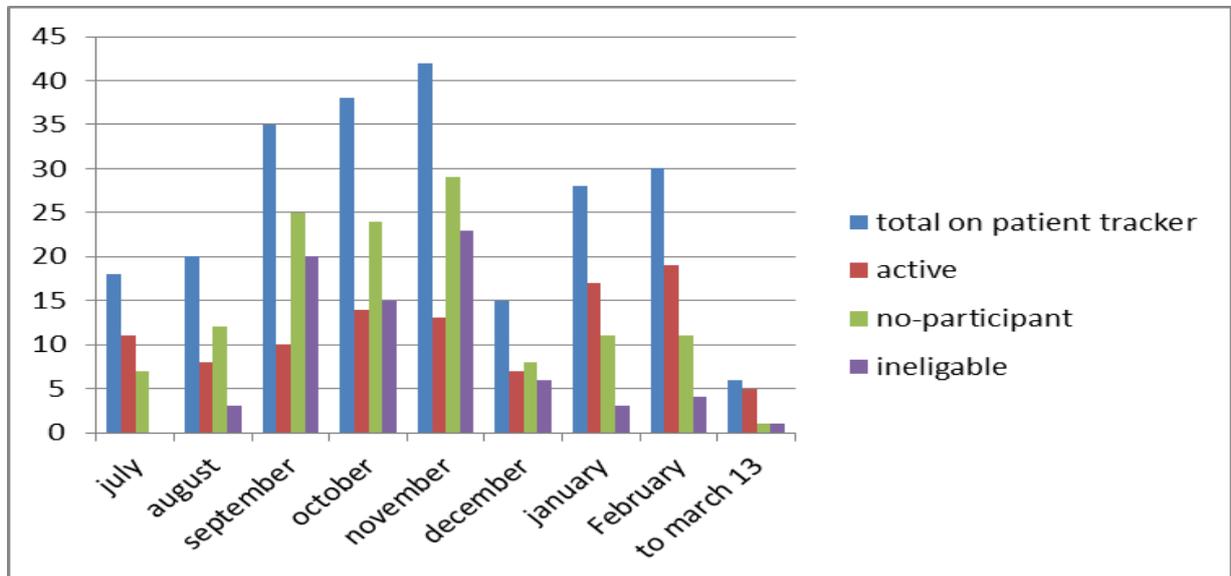
### **Patient Participation**

The patient flow chart below demonstrates the outcomes of patients approached to take part in our project – Figure 1.

**Figure 1. Demonstrating patient enrolment numbers from total heart failure admissions to the Roval Stoke University Hospital**



**Figure 2. The distribution of total patients seen per month of the active portion of the clinical project.** The total number is broken down into: active patients (patients actively engaged with the project), patients ineligible for the project (due to failure to meet the inclusion criteria), patients who were non-participant (patients who did not register with the digital products once they got home and failed to text to more than 6 interactive texts)



This figure reflects the reduction in ineligible patients referred to the Tele Health Co-ordinators over the lifetime of the clinical part of the project. The lower than expected figures for February and the cessation of clinical enrolment on 13/03/2020 reflects the impact of COVID 19 on the country but also the need for shielding of at least one of the Tele Health Co-ordinators.

### Expected patient enrolment vs. actual

The initial grant proposal had suggested that we would be referred 230 patients by the heart failure team of which 200 would be enrolled.

We had increased the number of referrals to 300 in the second stage.

However, the reasons for not achieving this initial target may well have been because:

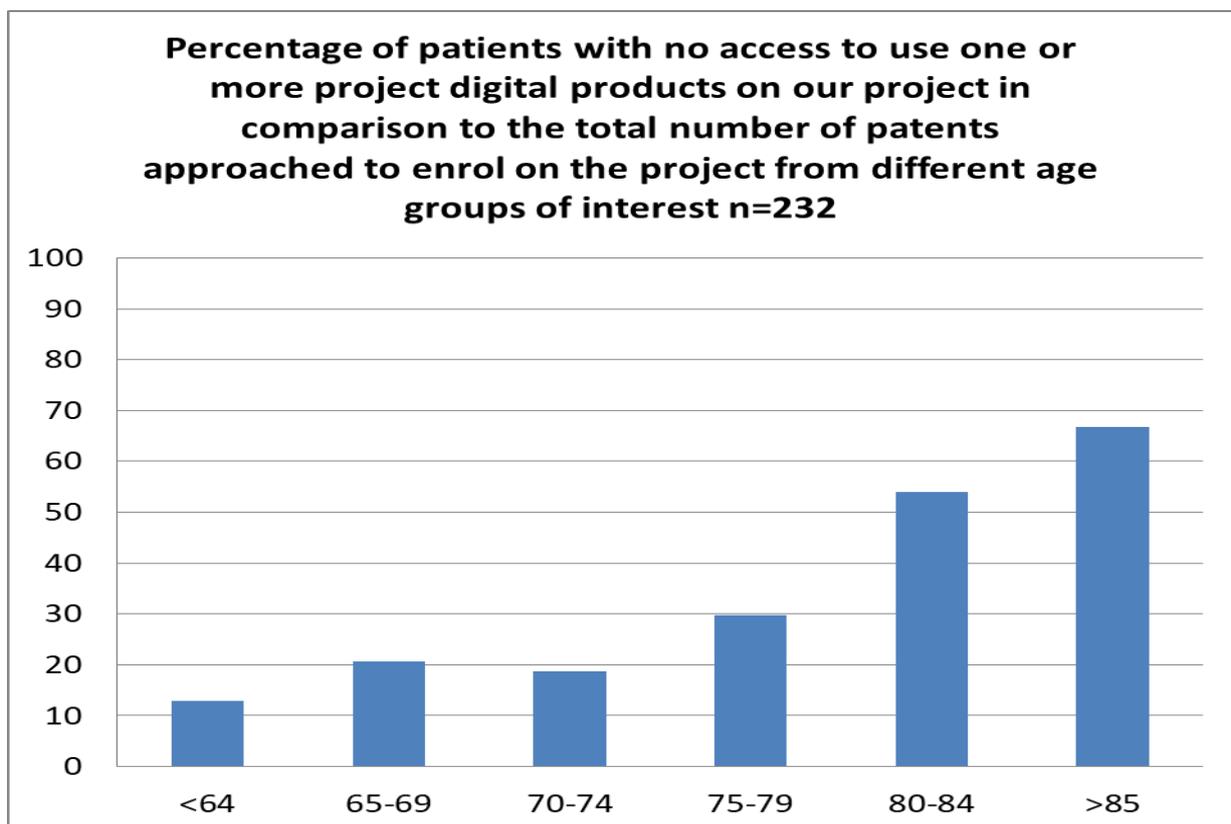
- We had overestimated the number of patients seen by the heart failure nurses in real life – this may relate to increase in heart failure workload, the nursing contingent being depleted due to nurses leaving the service or for periods of sickness – actual number seen 306
- We were referred the amount of patients we thought we would initially have referred, but the proportion of excluded patents was higher than the 15% predicted.

129 of 232 patients were non-participants in our project – actual non participant rate of 56%. The reasons for non-participation were

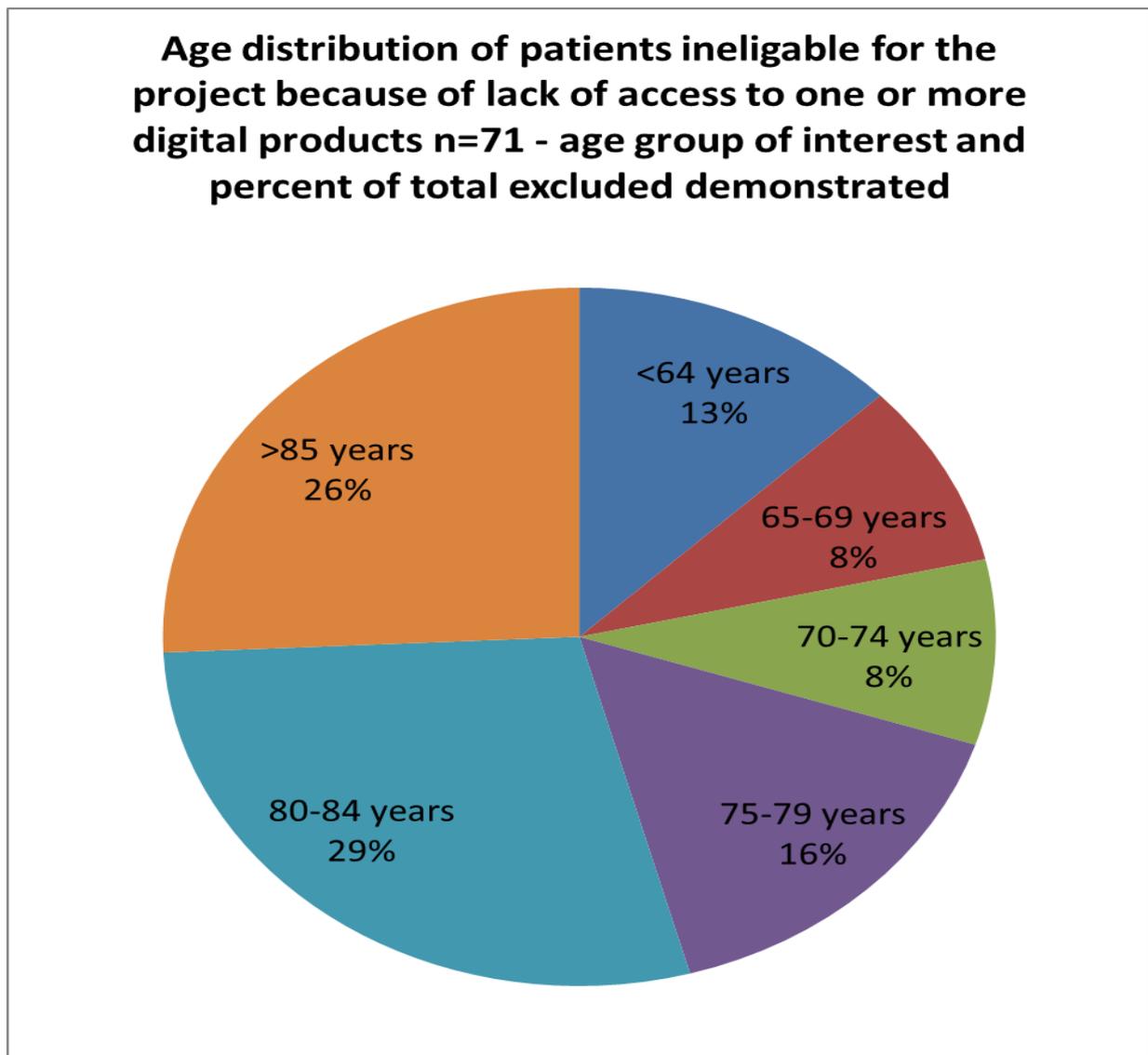
- **Ineligible** - 75/129 were ineligible usually because patients would not be able to access one or more the digital products themselves or through a carer and 4 because they were out of area– male 43, female n=32, mean age76.2 (youngest patient 20 yrs. old) SD 12.5 years. Remember this means that 71 had no access to phones that could receive and transmit texts or to an email account or both –individually or from carers. The percentage of patients with no access to resources to use one or other digital product in our project is represented as a percentage of the total number of patients in that age group approached to enrol in our project is demonstrated in Figure 3 below. It demonstrates a decrease in access to our digital products by age with 2/3 > 85 year old patients approached having neither access themselves or through a carer.

Figure 3 demonstrates the proportion of the different age ranges of interest that comprise the 70 patients ineligible for the project due to lack of access to our digital products

**Figure 3 demonstrates the percentage of patients in each age group who do not have access to one or more of our digital products based on the total number of patients in that age group approached to enrol in our project.**



**Figure 4 Age distribution of patients ineligible for the project due inability to access digital products themselves or through a relative as a percentage of total ineligible patients n=71. More than 50% of ineligible patents were > 80 years old.**



32/71 (45%) of in-eligible patients were from the Stoke-on-Trent area which is an area with a high deprivation index. Patients from this area have lower incomes and poorer health literacy overall than other patients from more affluent areas served by our hospital.

- **Not-interested** - 10 patients were not interested in enrolling in the project – interestingly these 10 were seen between January and February 2020 – the latter stages of the project. This is 4% of the 232 patients approached by the Tele Health Co-ordinators.
- **Did not register on recap health and texted only 6 or fewer interactive texts – did not engage** - 44 patients did not register with Recap Health and responded to 6 or

fewer texts from Flo. Only 6 of these patients were approached and enrolled after 13/12/2019. This may reflect the change in the simplicity of registration for the digital products which occurred as a development to the starting minimal viable product. This is 19% of the total number of patients approached to be part of the project and 28% of patients who were eligible for the project.

### **Reflection on enrolment**

180 of the 306 patients who were hospitalised with a primary diagnosis of heart failure were seen by the Tele Health Co-ordinators – 59%. This is a rate as predicted in our initial grant bid. What we had not anticipated was the number of ineligible patients.

Figure 2 reflects the improvement in enrolment and numbers of patients seen with a full project team. The fall in enrolment over December and January reflect staff holidays and sickness within the project team. There was additionally an increasing 'conversion rate' of people seen by the Tele Health Co-ordinators who then agreed to be part of the project. This reflected the secondary care teams understanding of the project over time and their engagement with the project. It also reflected the developments in the 3 digital products to make registration for the patient simpler and easier to complete – potentially even during the first Tele Health Co-ordinator visit.

We felt confident that had COVID 19 not stalled the enrolment seen prior to December then we would have been able to enrol close to our initially planned 200 patients.

It should be remembered that agreed referral criteria from the heart failure nurses to the Tele Health Co-ordinators was merely:

- Patients likely to survive to discharge from the hospital
- Patients who could read or write in English – or had a carer who could read or write in English for the patient
- A patient who would agree to be approached by the Tele Health Co-ordinator to discuss the project. The ineligible proportion is higher than expected and is one of the reasons for fewer active patients than predicted.

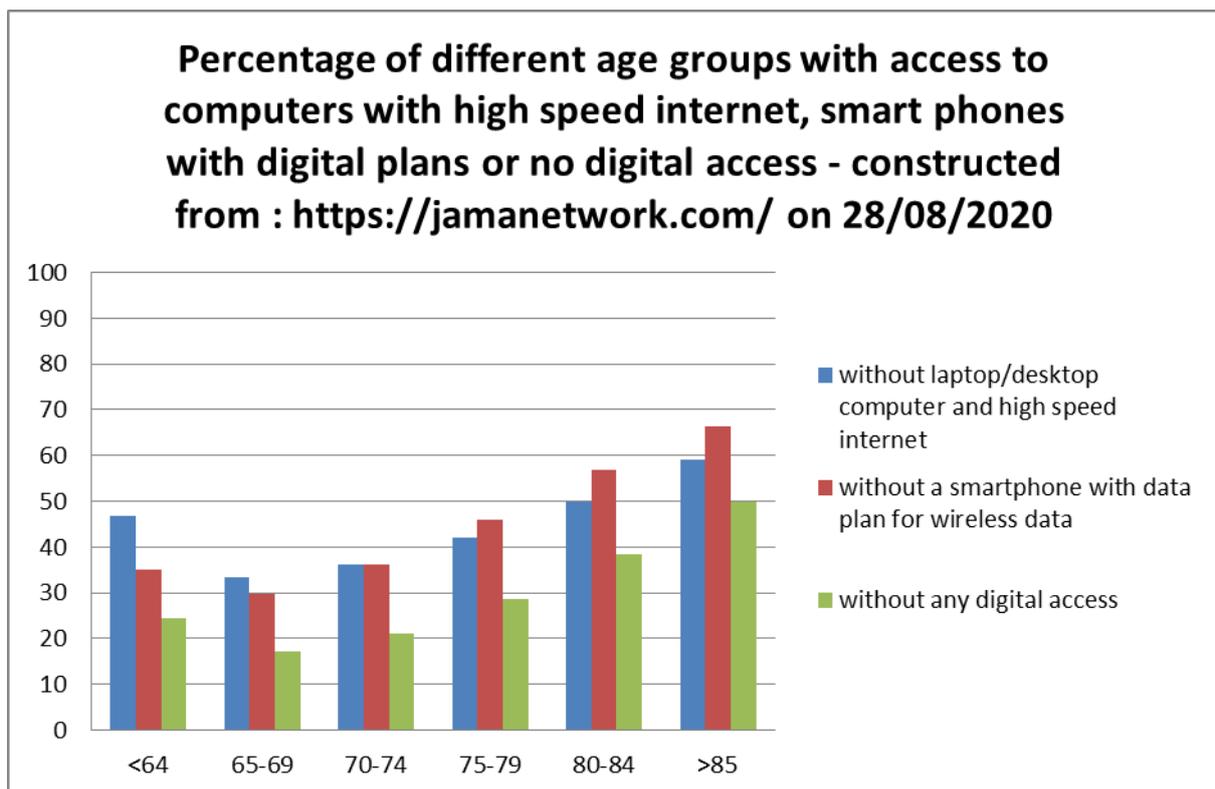
The predominant ineligibility criteria were lack of access to one or more of the digital products. This was only determined once the patient was reviewed by the Tele Health Co-ordinator.

In hindsight this should have been a pre-requisite in the screening performed by the secondary care heart failure team. At the time the heart failure team were stretched in their clinical duties and felt that this was an additional task they were unlikely to be able to consistently address.

The COVID pandemic rapidly facilitated the use of digital products in just a few months. This also led others to determine whether patients are ready for this new era of telemedicine.

A recent article from JAMA has suggested that, unsurprisingly, that access to digital tools declines with age. Their data is reconstructed into the graph below – Figure 5.

**Figure 5 demonstrating the different age groups and access to computers AND high speed broadband, smart phones WITH data plans for wireless data and no digital access.**



Our data mirrors that above. The older you are the less ready you may be to accept digital technologies. However this may be the one positive impact of the COVID pandemic in that it may encourage more elderly patients to access simple digital platforms using interactive texting or obtaining an email account and or smart phones/ laptops.

Nearly 50% of patients ineligible for our project because of inability to access our digital products were from an area with a high deprivation index.

Government /charity or third sector initiatives to subsidise:

- Digital education for elderly patients
- digital products
- modification of digital products to render them usable in this age group

may help to improve this inequity of access.

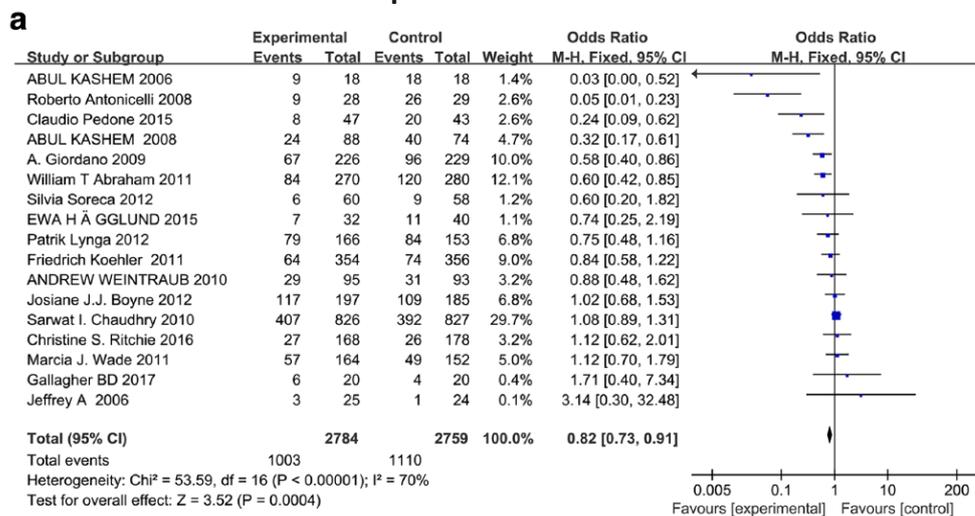
## Context of enrolment in published literature

Since the start of the project a recent meta-analysis of randomised control trials in telehealth initiatives to reduce *all* cause admissions has been published. This is demonstrated in Figure 6 below. This analysis does not include recent large telehealth trials such as: TIM-HF2 trial 2018, the TELEREH-HF trial 2019, the OSICAT TRIAL 2020 or the SUPPORT- HF trial 2020 – as the aims of these trials were not to reduce all cause readmissions. Only the TIM-HF2 trial of all of these recent studies reduced time spent out of hospital.[2-6]

In the positive trials from the 2020 meta-analysis below the majority have fewer patients in the active arm than in our project. One study uses an implantable device and is therefore unsuitable for comparison with our project. One 2009 study had a mean age of patients in the active arm of 58 (10) years. Although this was also a study that enrolled patients with decompensated / hospitalised heart failure the usual care arm did not receive any routine cardiology specialist care input until 12 months post discharge. This is therefore not a truly comparable study given that our usual care patients should have been referred to the specialist heart failure teams in the community and in secondary care.

The number of ‘active’ patients in our study in comparison to the meta-analysis below suggests that 103 active patients is not an insubstantial number. It is identical to the numbers in the most recent SUPPORT-HF trial and would be the third largest ‘active group’ cohort in comparison to other studies in the 2020 meta-analysis below.[6]

**Figure 6. Table from meta-analysis of randomised controlled trials demonstrating the impact of the trial on all cause hospital readmission**



Heart Failure Reviews (2020) 25:231–243

## Non-participants in other studies (representative examples below)

In the BEAT HF trial 30 844 were assessed for eligibility and 92% of these patients were ineligible, Of the 2368 patients left 23% did not wish to participate in the trial when approached. The median age of patients was 73 (IQR 62-84).

In the TIM-HF2 trial 35% declined to participate in the trial when approached. The mean age of participants in the active arm were 70 (11) years old.

In the most recent telehealth trial – SUPPORT HF – the active patient numbers were identical to our project– n=103. They screened 363 patients of whom 12% were ineligible and 29% declined. The final patient numbers were split into 2 arms. The mean age in this project was 72.8 (11.1)

All of these studies were predominantly male patients.

The withdrawal rate or discontinuation rate for patients in the active arm is not available for all trials. Representative data from studies are:

- In BEAT-HF 43% of patients did not engage / withdrew from the active arm of the study.[7]
- In TIM-HF2 4% of these patients did not engage / withdrew from the active arm.[3]
- In OSICAT 17% of their 482 patients did not engage / withdrew from the active arm of their study.[5]

The withdrawal rate in our study was unpredicted at 28% but improved over time as the registration process to access the digital products improved.

Our problems with enrolment mirror larger studies. Our patient groups in terms of age and sex distribution are similar to those participating in the active arms of randomised controlled studies of telehealth interventions.

### **Project Duration**

#### **Planned**

We had planned for the clinical part of the project to enrol patients from 01/02/2019 until 01/12/2019 which was 10 months of enrolment with:

All patients from 01/02/2019 to 01/12/2019 – having 30 day follow up – 10 months of patients

All patients from 01/02/2019 – 30/09/2019 having up to 3 months of follow up – 8 months worth of patients

All patients from 01/02/2019 -30/06/2019 having up to 6 months of follow up – 5 months worth of patients

#### **Actual**

The project was delayed in starting and the start date for clinical enrolment was from 01/07/2019. The project was extended past the initial date of completion (from 31/04/2020 to the new date of 30/09/2020).

COVID 19 curtailed and then finally stopped patient recruitment on 13/03/2020.

Patients were followed up by the Tele Health Co-ordinators for the 3 month protocol while on Flo and with ongoing ad hoc patient support for alerts or patient contact until the clinical project end on 13/06/2020.

The actual duration of the clinical enrolment part of the project is 9 rather than 10 months.

The number of months for patient enrolment for 30 day follow up is therefore 9 rather than 10 months.

The number of months for patient enrolment for 3 month follow up is longer at 9 rather than 8 months.

The actual number of months for patient enrolment for 6 months follow up is equivalent at just over 5 months.

The actual number of months for enrolment and follow up are demonstrated in Figure 7 below.

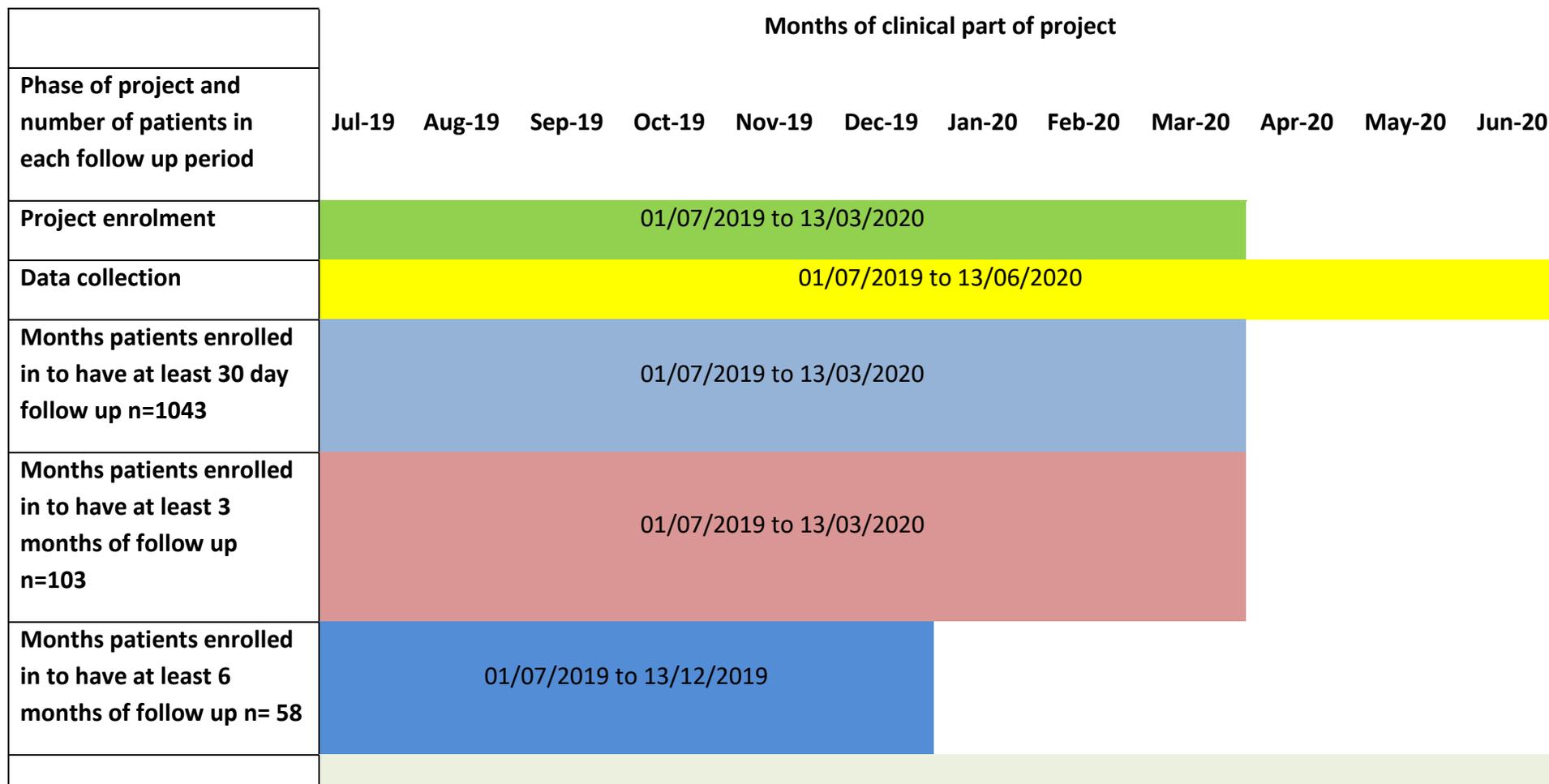
### **Follow up in the context of other studies**

Our follow up reflects the short duration of the test beds programme. The follow up studies in the meta-analysis are predominantly between 6-12 months.

### **Summary**

Our patient active group is a large in comparison to other telehealth studies that aim to reduce all cause readmission. The demographics of our project active group is reflective of patients in published trials. The patients who were ineligible for the project were ineligible predominantly because they did not have access to 2 digital products. The initial 'drop out' rate once patients went home had diminished with time and reflects a change in our patient registration protocols.

Figure 7 below demonstrates the actual number of months for enrolment of patients. Patients were enrolled from 01/07/2019 till 13/03/2020 and data collected till 13/06/2020



## References

- 1 Failure to Function A review of the care received by patients who died in hospital following an admission with acute heart failure  
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- 2 Effectiveness of telemedicine systems for adults with heart failure:a meta-analysis of randomized controlled trials. *Heart Failure Reviews* (2020) 25:231–243.  
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- 3 Efficacy of telemedical interventional management in patients with heart failure (TIM-HF2): a randomised, controlled, parallel-group, unmasked trial. *Doi.org/10.1016/s0140-6736(18)31880-4*. Accessed 19/09/2020
- 4 Effects of a 9-Week Hybrid Comprehensive Telerehabilitation Program on Long-term Outcomes in Patients With Heart Failure. *JAMA Cardiol.* 2020;5(3):300-308.  
Doi:10.1001/jamacardio.2019.5006 accessed 19/09/2020
- 5 Telemonitoring versus standard care in heart failure: a randomised multicentre trial. *Eur J Heart Fail.* 2020 Jun;22(6):985-994. doi: 10.1002/ejhf.1906. Epub 2020 Jun 15. Accessed 19/09/2020
- 6 Home monitoring with technology-supported management in chronic heart failure: a randomised trial. ([http:// dx. doi. org/ 10. 1136/heartjnl- 2020- 316773](http://dx.doi.org/10.1136/heartjnl-2020-316773)). Accessed 19/09/2020
- 7 Effectiveness of Remote Patient Monitoring After Discharge of Hospitalized Patients With Heart Failure: The Better Effectiveness After Transition–Heart Failure (BEAT-HF) Randomized Clinical Trial. [JAMA Intern Med. 2016 Mar 1; 176\(3\): 310–318.](#)  
doi: [10.1001/jamainternmed.2015.7712](#) accessed 19/09/2020

## Data collection

### **Hospital admission and all cause readmission data**

Routinely collected Hospital Episode Statistics (HES) data and data such as an index admission with heart failure and hospital and A and E admissions / readmissions following discharge was used. Data was provided by Steve Dunne, Information Lead, Information Services, from the University Hospital North Midlands and Sean Davies Heart Failure Data Analyst.

### **Use of GP and community heart failure services**

We collected this data from GP surgeries and Midlands Partnership Foundation Trust – MPFT - (who employ the community heart failure nurses). The data from MPFT was produced by Ian Porter, Information and Performance Lead, MPFT. Individual GP surgeries provided the information on their patients with heart failure.

### **All patients approached to be on the project**

A database of routinely collected data on all patients approached for the project was made to allow us to determine the reasons for non-participation in the project – ineligibility vs. patient non-participation.

### **Digital Product Utilisation**

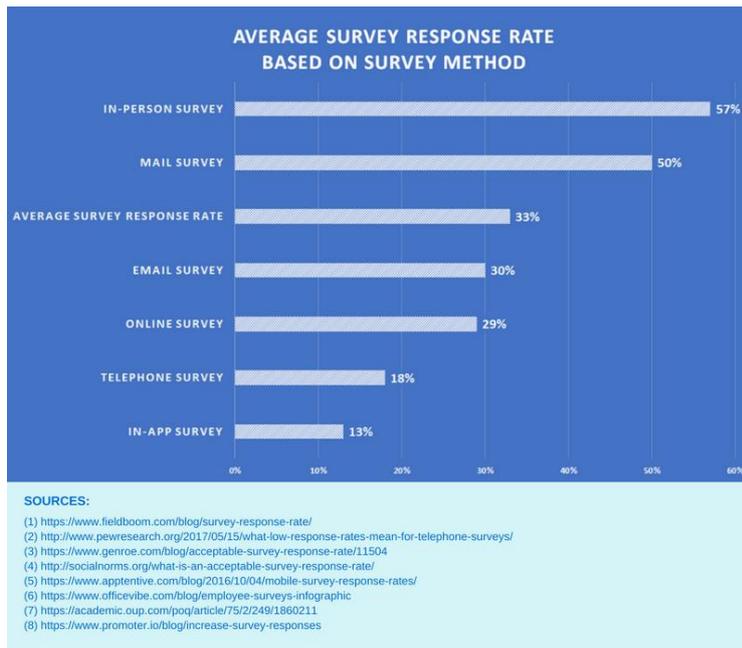
Data was collected from each of the products used to demonstrate service utilisation

### **Patient related outcomes measures**

We used a multi-faceted approach to this:

- Automated surveys from digital product utilisation
- Quality of life scores and patient activation measures tools routinely collected for all hospitalised heart failure patients – i.e.:EQ5D, KCCQ, PHQ4, PAM13
- End of 3 months patient survey conducted by the Tele health Co-ordinators
- Patient focus groups

**Figure 1 demonstrating average response rate based on type of survey [1]**



The actual response rates to the surveys for the project active group were:

- Quality of life at discharge postal (and Tele health Co-ordinator telephone help during the COVID pandemic) – 61/103 (59%)
- Repeat Quality of life at 3 months postal (and Tele health Co-ordinator telephone help during the COVID pandemic) – 39/61 (64%)
- Patient 3 month telephone survey – 66/103 (64%)
- Flo automated ‘in app’ surveys – 31-39/90 (34-43%)
- Recap Health automated ‘in app’ survey – 15-24/74 (20-32%)

### Data Linkage

Patients were cross linked between the data bases with their own unique pseudo identification number – which was assigned by Steve Dunne or Sean Davies.

### Methodology

Delay to the project occurred between October and 11/12/2019 while internal and external reviews confirmed that the project was service evaluation.

### Evaluation

Data collection, co-ordination and cleansing were supervised by the Royal Stoke Research and Innovation Team led by Dr Simon Lea and their Data Analyst Andrew Nicholson. They were supported by the Tele Health Co-ordinators.

Statistical analysis was performed by Dr M Asaduzzaman, Staffordshire University.

A qualitative report of patient responses was performed by Dr K Kinmond.

The Health Economic Team from the University of East Anglia produced a health economic evaluation of the intervention.

The lessons learned report was written by Ms S Piggott, Project Manager.

The other reports were written by Dr Satchithananda and verified by the Project Evaluation Working Group and overall Project Steering Group.

The evaluation plan framework is based on the Donabedian Model to demonstrate quality of care 2005 accessed from the NHS Improvement website.[2]

In brief this uses multiple methods to demonstrate that project outcomes are feasible based on project structure, processes and unintended consequences (balance). This model is expanded in the Evaluation report.

### **Quality of life (QOL) questionnaires and Patient related outcome measures**

Before and after comparators for QOL and patient activation were collected as patient related outcome measures (PROM).

The use of PROMs is standard in a variety of different surgical procedures within the NHS since 2008.

Disease specific PROMS for heart failure (e.g., Kansas City Cardiomyopathy questionnaires – (KCCQ)), generic quality of life questionnaires (e.g. EQ5D) and PAMs (patient activation measures) are supported for collection as part of service evaluation by the RSUH clinical audit team.

North Staffs and Stoke CCG have suggested a HF related PROM as part of the routine assessment of the HF service within the commissioning document produced in 2015/6. The HF team have decided that the preferred routine PROM for service evaluation of the SHINE clinic should be the KCCQ tool in January 2018.

The routine collection of QOL has also been reported in the evaluation of heart failure and cardiac surgical patients in other centres. [3-5]

### **Patient Focus groups**

Patient and carer focus groups were aimed to be convened to determine patient experience of the project at the start and end of their 3 month interaction with the project and in terms of their overall heart failure care. The focus groups were to be facilitated by the Pumping Marvellous Foundation and Dr K Kinmond – who has similarly evaluated the experience of COPD patients.

Patient focus group did not produce the number of patient experience stories that we would have hoped for. This is further explained in the qualitative evaluation report.

## **Patient Groups**

We compared the experiences of patients newly diagnosed with HF patients in comparison to patients with pre-existing experience of the HF services prior to their current admission as part of our project.

## **Data Storage**

Data was stored securely within N3 compliant systems and in keeping with GDPR guidelines. Information sharing agreements were ratified and implemented by the Royal Stoke University Hospital information governance lead Leah Carlisle and her deputy Jean Lehnert.

Hospital based data was stored on trust computers.

## **Lessons Learned**

The lessons that have been learnt cover the duration of the 18month journey and have enabled those directly involved to provide reflection and comparison to what was planned to actual delivery. This forms a separate report.

For our project, the distinctions between service evaluation and research can sometimes be difficult to differentiate between individuals, departments and institutions.

It is therefore important that Innovate UK / NHS England include methodological reviewers and members from Research Ethics Committees to review methodology to prevent these issues arising for other projects.

## **References**

1 [from <https://surveyanyplace.com/wp-content/uploads/average-survey-response-rate.png> – accessed 09/11/2020]

2 Model for measuring quality care (structure, process, outcome and balancing measures. <https://improvement.nhs.uk/resources/measuring-quality-care/> accessed 19/09/2020]

3 file:///C:/Users/satchd91/Downloads/Gallagher\_et\_al-2018-ESC\_Heart\_Failure.pdf accessed 19/09/2020

4 (BMC Health service research 2017:17:536) accessed 19/09/2020 accessed 19/09/2020

5 Open heart 2016;3:e000315.doi:10.1136/openhrt-2015-000315). Accessed 19/09/2020

## The Statistical Approach

### **Statistical methodology:**

To evaluate the success of the project, we have applied a wide variety of statistical techniques on different aspects of the project. Measurement scales are used to categorise and quantify variables. We dealt with the four scales of measurement- nominal, ordinal, interval, and ratio scales commonly used in statistical analysis. With the vast amount of data measured in different scales provided a great opportunity to evaluate the success of the project accurately. The statistical techniques used for the data analysis can be broadly categorised as: descriptive statistics and inferential statistics. We applied a wide variety of descriptive statistical measures and graphical techniques including:

- percentage and rates
- frequency table, cross-table
- pie chart, bar chart, histogram, scatter-diagram.

We also applied many inferential statistical techniques/significance tests to measure the effectiveness of an intervention. The key inferential statistical techniques we used are—

- t-test or Mann-Whitney if the parametric assumptions are not met (to test the equality of two means),
- paired t-test or Wilcoxon signed-rank test if the parametric assumptions are not met (to test the equality of two means for pair samples),
- chi-square test or Fisher's exact test for 2-by-2 table with expected cell frequencies less than 5 (to test the association between two categorical variables)
- rate ratio test (to test the equality of rates for two groups)
- correlation analysis (to measure the strength of linear relationship between two numerically measured variables).

### **P-value and Bonferroni correction:**

We reported the significance test results by p-values. The p-value is defined in statistics as the probability of obtaining results at least as extreme as the observed results of a statistical hypothesis test, assuming that the null hypothesis is correct. Therefore, a p-value is the minimum level of significance at which a null hypothesis can be rejected. Throughout our analysis, we used a 5% level of significance to decide whether or not a null hypothesis can be rejected. However, due to multiple comparison/testing problem (performing a set of interdependent statistical tests simultaneously), we applied Bonferroni correction, which

sets the significance cut-off at the level of significance divided by the number of interdependent statistical tests.

## Chapter 3 Outcome Results

Primary Outcome Analysis – impact on A and E and Hospital all cause readmission after an index episode of decompensated heart failure

### Patient Groups and Data sources

#### Usual care

- **Usual care - Historic group**

Patients discharged alive from hospital in the same time period as the project but from the year before (01/07/2018 to 13/03/2019). Follow up data was till 13/06/2019. This data was from Hospital episode statistics. Some of the clinical interventions of the project were to increase heart failure specialist nurse education and access to care of the palliative care and elderly care services. We wanted to ensure that there was no change to the usual care outcomes because of this intervention.

- **Usual care group**

This group were patients discharged alive from hospital in the same date range as patient enrolment for the project – 01/07/2019 to 13/03/2020 with follow up till 13/06/2020.

- **Patients Active on the project**

These were patients who were active on the project in terms of registering on Recap Health and/ or replying to more than 6 interactive text messages from Flo.

#### Potential Comparator groups

As this was a service evaluation project there were no 'control' groups for comparison.

We initially thought of 2 pragmatic comparator groups:

- 1. Non-participants**

These were patients who were either ineligible for the project or were eligible BUT did not engage with the project by completing a registration process once they got home or did not respond to 6 or more texts from Flo (the equivalent of one week's texts).

The majority of patients were ineligible for the project (70/75 as they did not have access to 1 or more of an accessible texting phone or email address, 5/75 as they lived in an area outside that serviced by the community heart failure teams of Stoke and North Staffordshire).

What was not initially appreciated was that the patients who failed to register with the project once they were home or who failed to respond to 6 or more interactive texts were also contacted by the telehealth team during their first month post discharge. This was to try and help patients overcome any technological barriers to participating with the project. There were initially 64 patients in this group, but after phone support 10 patients became active with the project.

The utilisation of digital products and access to the Tele health Co-ordinators is demonstrated below in Figure 1. The interaction of the Tele health Co-ordinator with some of the non-participants and failure to fulfil the ineligibility criteria made this group an inappropriate choice for a comparator group.

**Figure 1 demonstrating the interaction of active on project and the 2 non-participant groups with digital products and with the Tele health Co-ordinator.**

Patient access to Tele health Co-ordinators and to digital products	Project timeline and potential time frames of digital product use and involvement with Tele health Co-ordinators				
<b>Active on project n=103</b>					
	interactive texting protocol	till end of project 30/09/2020			
Flo protocol of interactive texting for 3 months	3 month automatic Flo protocol				
Tele health Co-ordinator	weekly contact for first month then ad hoc for alerts	ad hoc for enquiries, patient satisfaction survey, to arrange patient focus groups			
Recap Health	from registration till the end of project				
I Navigator				available from December 2019 to end of project	
<b>non-participant failed to register and texted &lt; 6 interactive texts n=54</b>					
Flo protocol of interactive texting for 3 months	Not applicable				
Tele health Co-ordinator	Weekly for first month to try and engage patients onto digital platforms	Not applicable			
Recap Health	Not applicable				
I Navigator	Not applicable				
<b>Non-participant ineligible as do not meet inclusion criteria n=75</b>					
Flo protocol of interactive texting for 3 months	Not applicable				
Flo protocol of interactive texting for 3 months					
Tele health Co-ordinator					
Recap Health					
I Navigator					

## **2. Usual care group < 75 yrs. old.**

We used this group as a pragmatic younger age group to compare to our active project group. This group serendipitously had a mean age and sex difference comparable to the project active group.

### **Time periods of interest**

- Within 30 days of discharge - When patients are discharged there already exists a national benchmark for all cause readmission at 30 days following discharge.
- Within 3 months of discharge - Patients are involved in the Flo and Recap protocols together for a maximum of 3 months. After which patients are longer sent interactive texts, but continue to have access to their Recap Health library.
- Within 6 months of discharge – This was pre-specified as the longest period of follow up data of interest in the initial grant application bid. Patients who could potentially have 6 months of follow up data had to have been enrolled between 01/07/2019 and 13/12/2019 as the last data collection was on 13/06/2020.

### **Definition of All cause readmissions and Calculations of all cause readmission rates for different time points**

At our hospital most hospital admissions are directly preceded by an A and E admission. Our 'hospital all cause readmission' are therefore a composite of an A and E admission in >90% of cases followed by hospitalisation.

An A and E all cause readmission is one in which the patient attends A and E and is discharged without a hospitalisation within 24 hrs of their A and E attendance i.e. an attendance that was not felt to be serious enough to warrant hospitalisation

We have represented the denominator for at risk patients/ admissions in 2 ways:

- **Deaths not censored**

This assumes that all patients who potentially had sufficient follow up for the time period of interest (i.e. follow up for 30 days, or 3 months or 6 months post discharge) formed the denominator irrespective of whether they died within the time period of interest. The denominator represents not just the number of index admissions, but also individual patients.

- **Deaths Censored**

We wanted to know whether the impact of the digital intervention for all patients who **survived** for the whole time period of interest i.e. if you died then you would not be able to contribute to all cause readmissions.

The denominator was therefore all of the patients who survived to the end of the time periods of interest. Therefore the denominator again was both the total number of individual patients and the total number of index admissions.

Patients who fulfil the entry criteria for a time point of interest act as the denominator. These are also individual patients when acting as denominator.

The numerator – the number of all cause readmissions is then divided by the denominator to give the all cause readmission rate for a particular time period.

The number of patients involved in those all cause readmissions is also included in our results. However cost of all cause readmissions is based on the number of overall all cause readmissions and not on the number of individual patients readmitted.

### **Descriptors of the Project Active group n=103**

The mean age of the group was 66 years (SD 13), and 66 (64%) were male.

The NT-proBNP result was available in 92 patients at the time of admission or enrolment.

The median NT – proBNP was 3618ng/l (IQR 1579 – 9318)

The mean number of co-morbidities in this group was 6.2 (SD 1.4). In terms of specific co-morbidities:

- 51% had hypertension
- 35% Ischaemic heart disease
- 29% diabetes
- 22% COPD
- 6% CVA

### **New vs. existing diagnosis of the heart failure syndrome**

New patients are patients who have a new diagnosis of heart failure and their admission or need for intravenous diuretics are part of this early diagnosis of heart failure. They have not been exposed to the heart failure pathway before requiring hospitalisation or intravenous diuretics.

There were 61 patients with newly diagnosed heart failure and 42 had pre-existing heart failure

The distribution of new and existing heart failure diagnoses in the active group and the mechanism of their heart failure as determined by the teams supervising their overall care is demonstrated in the table 1 below:

**Table 1. Distribution of new and existing and hefref and hefpef patients within the project active group.**

	New	Existing	Total
Hefpef	16	17	33
Hefref	45	25	70

Hefpef = heart failure with preserved ejection fraction

Hefref = heart failure with reduced ejection fraction

61.2% of patients in the Project Active group lived in the Stoke-on-Trent area which is the area of greatest social deprivation within the population served by the Royal Stoke University Hospital.

### Groups for Comparison and outcomes – Primary end points

Patients in each of the above groups are described below in terms of age and sex distribution in Table 2 below

**Table 2. Age and sex distribution for each group**

Group	Total number of patients	Number by sex (Male, Female)	Age (Mean, St Dev)	Age by sex	
				Male (Mean, St Dev)	Female (Mean, St Dev)
Project Active	103	(66, 37)	(66, 13)	(66, 12)	(66, 14)
Usual Care	824	(435, 389)*	(80, 10)*	(79, 10)	(82, 10)
Usual Care (Age < 75)	192	(125, 67)	(66, 8)	(66, 8)	(66, 10)
Usual care Historic (HES)	691	(348, 343)*	(78, 11)*	(76, 12)	(81, 11)

\*= significant difference when compared to Project Active group

15/103 of the project active group (15%) were 80 years or older.

The entire Usual care and Usual care - Historic groups were older and were more likely to be men than the Project Active group. There was no age or sex difference between the Project Active and the less than 75 age group of the Usual care patients.

### Number of Deaths in each time period

The number of total deaths in each time period is demonstrated below in Table 3

The number of patients with the potential for at least 3 months of follow up are given. Additionally the numbers of patients in the project active and usual care group from 01/07/2019-13/12-2019 are demonstrated to reflect the number of patients who have the potential for at least 6 months of follow up data. The date range is for exactly one year prior to the project for the Usual care – Historic group.

**Table 3. The number of deaths in each time period of interest for the different groups of interest.**

Date to death	Total Deaths per time period not cumulative			
	0 30 days	31 90 days	91 180 days	Over 180 days
Project Active (n=103) and n=58 for patients with at least 6 months follow up	0	4	6	2
Usual care Historic total (n=691) and n=439 for patients with at least 6 months follow up	47	58	49	140
Usual care (n=824) and n=537 for patients with at least 6 months follow up	52	71	60	34
Usual care < 75 (n=192) and n 127 for patients with at least 6 months follow up	8	10	8	7

There was no difference in death rates at 6 months between the project active group and the usual care and the usual care <75 years groups.

### Hospital all cause readmissions

Table 4 demonstrates the outcomes for all cause readmissions in each group when all patients who could have potentially survived to the end of the time period of interest form the denominator

**Table 4 Patient all cause readmission rates for time points of interest for all patients with the data of patient’s who died not censored. There is a significant reduction in the all**

cause readmission rates at 3 and 6 months for the Project Active group in comparison to all usual care groups.

Groups	Hospital all cause readmission	No. of patients	No. of patients	Hospital all cause readmission	No. of patients	No. of patients	Hospital all cause readmission	No. of patients	No. of patients
	% (30 days)	(30 days)	Died (30 days)	% (3 mths)	(3 mths)	Died (3 mths)	% (6 mths)	(6 mths)	Died (6 mths)
Project Active	16% (16)	103	0	30% (31)	103	4	52% (30)	58	6
Usual care	27% (226) *	824	52	55% (456) *++	824	71	90% (482) *++	537	60
Usual care (Age < 75)	27% (52)	192	8	57% (109) *++	192	10	94% (119) *++	127	8
Historic (HES)	30% (206) *++	691	47	64% (442) *++	691	58	105% (463) *++	439	49

\*= P<0.05 on univariate testing compared to Project Active group

++= significant after Bonferroni correction for multiple comparisons compared to Project Active Group

The number of patients in each time period responsible for the admissions recorded in those time periods and the mean number of all cause readmissions per patient who was readmitted are shown in Table 5

**Table 5 All cause readmissions to hospital with patients survived to the end of the time period of interest i.e. all cause readmission rate per time period for patients surviving to the end of the time period i.e. deaths in the time period of interest are censored**

Groups	Hospital all cause readmission	No. of patients	No. of patients Died	Hospital all cause readmission	No. of patients	No. of patients Died	Hospital all cause readmission	No. of patients	No. of patients Died
	% (30 days)	(30 days)	(0 30 days)	% (3 mths)	(3 mths)	(31 60 days)	% (6 mths)	(6 mths)	(61 180 days)
Project Active	16% (16)	103	0	28% (28)	99	4	41% (20)	49	6
Usual care	27% (207)*	772	52	51% (356)*++	701	71	86% (349)*++	405	60
Usual care (Age < 75)	27% (50)*	184	8	52% (90)*++	174	10	93% (101)*++	109	8
Usual care Historic (HES)	27% (177)*	644	47	60% (353)*++	586	58	101% (340)*++	337	49

**\*all deaths are cumulative**

\*= P<0.05 on univariate testing compared to Project Active group

++= significant after Bonferroni correction for multiple comparisons compared to Project Active Group

Table 6 demonstrates the number of individual patients responsible for the number of hospital all cause readmissions in the time periods of interests and demonstrates the mean number of all cause readmissions per patient for those time periods. There was no statistically significant difference between the mean number of all cause readmissions per patient for any of the Usual care groups in comparison to the project active group at 6 months.

**Table 6 Number of individual patients within each group responsible for the total number of hospital all cause readmissions in the time period of interest. There was no significant difference between the numbers of all cause readmissions per patient at 6 months in comparison to the Project Active group at 6 months.**

	Number of 30 days all cause readmission	Number of patients for 30 days all cause readmission	30 days all cause readmission per patient	Number of 3 mths all cause readmission	Number of patients for 3 mths all cause readmission	3 mths all cause readmission per patient	Number of 6 mths all cause readmission	Number of patients for 6 mths all cause readmission	6 mths all cause readmission per patient
Project Active n=103 and 58 for 6 months of follow up data	16	14	1.14	28	21	1.33	20	14	1.43
Usual care	207	170	1.22	356	240	1.48	349	190	1.84
Usual care < 75	50	41	1.22	90	58	1.55	101	47	2.15
Usual care Historic	177	147	1.21	353	224	1.58	340	171	1.99

## A and E all cause readmissions

Table 7 demonstrates the outcomes for all cause readmissions in each group when all patients who could have potentially survived to the end of the time period of interest form the denominator – no deaths are censored – for all cause readmissions to A and E

**Table 7 Patient all cause readmission rates to A and E for time points of interest for all patients with the data of patient’s who died not censored. There is a significant reduction in the all cause readmission rates at 3 and 6 months for the Project Active group in comparison to all usual care groups**

Groups	A&E all cause readmission % (30 days)	No. of patients (30 days)	No. of patients Died (30 days)	A&E all cause readmission % (3 mths)	No. of patients (3 mths)	No. of patients Died (3 mths)	A&E all cause readmission % (6 mths)	No. of patients (6 mths)	No. of patients Died (6 mths)
Project Active	8% (8)	103	0	18% (19)	103	4	34% (20)	58	6
Usual care	27% (220)*++	824	52	57% (471)*++	824	71	99% (530)*++	537	60
Usual care (Age < 75)	27% (51)*++	192	8	61% (117)*++	192	10	100% (127)*++	127	8
Usual care Historic (HES)	28% (191)*++	691	47	61% (420)*++	691	58	102% (448)*++	439	49

\*= P<0.05 on univariate testing compared to Project Active group

++= significant after Bonferroni correction for multiple comparisons compared to Project Active Group

Table 8 demonstrates the outcomes for all cause readmissions in each group when all patients who survived to the end of the time period of interest form the denominator – i.e. deaths are censored – for all cause readmissions to A and E.

**Table 8 All cause readmissions to A and E with patients who survived to the end of the time period of interest i.e. all cause readmission rate per time period for patients surviving to the end of the time period of interest with deceased patient data censored**

Groups	A&E all cause readmission % (30 days)	No. of patients (30 days)	No. of patients Died (0 30 days)	A&E all cause readmission % (3 mths)	No. of patients (3 mths)	No. of patients Died (31 60 days)	A&E all cause readmission % (6 mths)	No. of patients (6 mths)	No. of patients Died (61 180 days)
Project Active	8% (8)	103	0	18% (18)	99	4	39% (19)	49	6
Usual care	26% (197)*++	772	52	50% (352)*++	701	71	92% (372)*++	405	60
Usual care (Age < 75)	26% (48)*++	184	8	52% (91)*++	174	10	96% (105)*++	109	8
Usual care Historic (HES)	25% (159)*++	644	47	56% (328)*++	586	58	95% (321)*++	337	49

\*all deaths are non-cumulative

\*= P<0.05 on univariate testing compared to Project Active group

++= significant after Bonferroni correction for multiple comparisons compared to Project Active Group

**Table 9 demonstrates the number of individual patients responsible for the A and E admissions at each time period of interest and the all cause readmissions per patient readmitted in that time period.**

There was no significant difference between the all cause readmissions per patient at 6 months for the Active Project group in comparison to the other groups.

	Number of 30 days all cause readmission	Number of patients for 30 days all cause readmission	30 days all cause readmission per patient	Number of 3 mths all cause readmission	Number of patients for 3 mths all cause readmission	3 mths all cause readmission per patient	Number of 6 mths all cause readmission	Number of patients for 6 mths all cause readmission
Project Active	8	8	1	18	14	1.29	19	12
Usual care	197	155	1.27	352	233	1.51	372	194
Usual care < 75	48	35	1.37	91	55	1.65	105	44
Usual care Historic	159	129	1.23	328	204	1.61	321	166

## Discussion

Our data demonstrates that there is a significant reduction in A and E all cause readmissions not warranting hospitalisation and also in hospital all cause readmissions in patients active on our project in comparison to usual care groups. This is also the case when we compare the project group to a convenience comparator group of ‘younger’ heart failure patients admitted to hospital. The relative risk reduction for hospital all cause readmissions is 42% at 6 months post discharge and 66% relative risk reduction for A and E attendance( without subsequent hospitalisation). This larger scale pilot intervention mirrors the outcomes of an initial smaller pilot.

It is possible that referral bias has led to the selection of the project active group. However this would mean that this bias arose initially outside of the project team as suitable patients were referred to the Tele health Co-ordinator by secondary care nurses. The Tele health Co-ordinators then determined whether patients were eligible or ineligible for the project. The large number of ineligible patents initially suggests that this referral bias is less likely.

### Potential reasons for the project being successful and some potential limitations of the project

#### Patient population

Our project active group has multiple co-morbidities and a high median NT-proBNP. Although younger than the whole hospitalised heart failure population, they do not appear to be a significantly lower risk group apart from their age.

We have tried to diminish the impact of any age or sex referral bias by comparing the project active group with the usual care < 75 group. We accept that differences between the

project active group and the usual care < 75 years group may be more complex than age and sex differences alone, however reducing all cause readmissions even in lower risk groups is of value to our patients, our health economy and the wider NHS.

### **Change in expected baseline readmission data**

Our results may also be because the all cause readmission rates at 6 months for the usual care group are nearly double what we predicted using 2014 figures and those included in the initial grant application. This is an issue that can only be resolved by the collaboration outside of this project.

There appears to be no difference in the frequency of all cause readmission for individual patients who were readmitted to A and E or hospitalised in the project group in comparison to the usual care groups.

This suggests that if people are readmitted then their readmission behaviour / need may not be impacted by our digital products with our current protocols. It is not clear whether these individuals have modifiable health care behaviours or have needs that cannot be met outside of hospital.

However it is also possible that these patients may benefit from even closer remote monitoring (with telehealth), more personalised self-management education greater than that provided within the Recap Library currently (i.e. content on the Recap Health platform may need to expand to include co-morbidity and refractory symptom self-management) and more focused input from community services i.e. aim to help their pre-existing health care choice and intervene earlier to offer them suitable alternatives out of hospital.

### **Change due to positive involvement with the project**

The difference in all cause readmission rates could also be from patients in the project group who benefitted from:

- Early detection of worsening health
- Education sufficient to manage their condition or seek help outside of hospital
- Facilitated support through the Tele health Co-ordinators

The widespread use of social prescribing may help reduce all cause readmissions further.

### **Rationale of the project interventions**

The holy grail of telehealth predictive interventions to prevent hospitalisation are to detect an abnormality that will lead to hospitalisations before they cause debilitating symptoms e.g. the mean duration between symptom deterioration and heart failure admission is 30 days. [2] Our telehealth intervention like other studies that have reduced hospitalisation rely on a patient self- assessment of health and a patient educational component. [3].

Physiological parameters such as blood pressure and pulse are important in the acutely unwell patient in hospital, but appear not to be useful in reducing hospitalisations.

Our intervention is also a multi-parameter intervention as with the complex device therapy algorithms that have reduced all cause readmissions in heart failure patients.[4]

Our educational component not only includes a patient's bespoke digital library – with content added as requested by the patient – but also an initially alternate day reminder to review a 'symptom checker' that includes components on co-morbidity and carer health. We are able to demonstrate improvement in patient's knowledge and management of their own health (see section on Digital Partners, Tele Health Co-ordinator and Special groups from page 96).

Our intervention also has a responsive Tele health Co-ordinator phone review to facilitate more rapid resolution of patient concerns. This may allay their concerns sufficiently to not require a review in A and E or a subsequent admission – as 80% of patients attending A and E with heart failure symptoms or signs are likely to be admitted to hospital.[5] (see section on Tele-Health Co-ordinator role page 126-134 and Quantitative evaluation of the intervention pages 157-180).

Heart failure is a homogeneous term that reflects heterogeneous population in terms of different risk profiles.[6] Our project does not allow us to determine which risk profile would benefit most from the principles of our project. Reductions of all cause readmissions in any or all risk profiles in acutely decompensated heart failure is a worthwhile outcome for patients and the health economy alike.

The impact of this multi-platform approach on larger populations would be warranted in a large multi-centre trial of all aspects of our intervention.

### **Summary and Financial Implications**

Our multifaceted digital intervention reduces absolute hospitalisations by 45% compared to the usual care group and a relative risk reduction of 52%.

- If we applied our project results to a 52% relative risk reduction for the 482 all cause readmissions at 6 months = 250 reduced admissions. In a year this would be 500 reduced readmissions = £1500000 saved from a hospital spend in a year. Some of these 'savings' could potentially be re-invested in services outside hospital to maintain a lower all cause readmission rate. We have assumed the cost of an all cause readmission is approximately £3000.
- If our project results were only applied to the < 75 year old hospitalised patients, then this would be a reduction in all cause readmissions of 57 patients in 6 months to give a cost saving / redistribution of £171 K in 6 months or £342,000 per year.

- If our project were applied to half of the 80,000 patients admitted with heart failure annually – to reflect 6 months of admissions, then we would reduce all cause readmissions  $(0.86 \times 40,000) - (0.86 \times 40,000 \times 0.52) =$  approximately 16500 all cause readmissions saved.
- If an estimated all cause readmission costs are estimated at a conservative £3000 then in 6 months we would save the NHS £50,000,000.

## References

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6. Predictive Value of the Get With The Guidelines Heart Failure Risk Score in Unselected Cardiac Intensive Care Unit Patients, *J Am Heart Assoc*. 2020;9:e012439. DOI: 10.1161/JAHA.119.012439. – accessed 19/09/2020

## Health Economy results - Summary

### Difficulties in determining cost irrespective of modelling used

NICE [1] suggest that:

‘It is estimated that heart failure accounts for a total of 1 million inpatient bed days (2% of all NHS inpatient bed days), 5% of all emergency medical admissions to hospital, and costs around £2bn (2% of the total NHS budget) (All Party Parliamentary Group on Heart Disease Inquiry into Living with Heart Failure 2016). Heart failure was the cause of over 81,000 emergency admissions in 2016/17 (Hospital admitted patient care activity, 2016-17) and is the most common cause of admission in people over 65. The average length of stay is 6—9 days depending on the requirement for additional specialist cardiology management (National institute for Cardiovascular Outcomes Research (NICOR), National heart failure audit 2017). Readmissions are common: about 1 in 4 patients are readmitted in 3 months. On average, a GP will look after 30 patients with heart failure and suspect a new diagnosis of heart failure in 10 patients annually. Those who work in more deprived areas are likely to have more patients with suspected heart failure. The cost of GP consultations for heart failure has been estimated at £50 million per year, with an additional £50 million for GP referrals to outpatient clinics. In addition, community-based drug therapy for heart failure costs £150 million per year.’

However these heart failure specific metric do not take account of multi-morbidity of the heart failure patient and the health care utilisation of the whole patient rather than the pathophysiology of heart failure – patient costs rather than ‘disease’ costs.

Studies in the literature account for a variety of different costs, which vary between studies – see figure 1

**Figure 1** Figure taken from reference [2]. This figure demonstrates different studies and different costs that they use to determine the total cost per patient. The different costings taken into consideration are shown on the left and the reference numbers of the studies within reference [2] are shown on the top of the table.

**Table 3** Summary of the cost components (studies with an incident and mixed approach are underlined)

Cost components	(37)	(29)	(36)	(35)	(28)	(23)	(24)	(30)	(38)	(31)	(32)	(27)	(34)	(33)	(26)	(25)
Direct costs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Inpatient care	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Medication				✓			✓	✓	✓	✓	✓	✓	✓			
Laboratory									✓		✓		✓			
Physicians				✓					✓							
Intensive care units			✓		✓											
Nursing home	✓	✓		✓	✓											
Outpatient care	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
Hospital Outpatient care				✓	✓						✓					
Physicians	✓	✓	✓	✓	✓				✓			✓	✓			
Specialist	✓															
Home care	✓			✓												
Medication	✓	✓	✓	✓	✓			✓	✓	✓	✓			✓	✓	✓
Laboratory /Procedures					✓				✓		✓		✓	✓		
Paramedical staff		✓		✓	✓											
Medical transport	✓	✓								✓	✓					
Indirect costs				✓						✓	✓					
Informal care costs	✓									✓						

**Figure 2** demonstrates the differences in costs in local currency for the studies included in reference [2].

Figure 2 Demonstrating the wide variation in cost for heart failure per patient with a wide variation in cost and expenditure per capita.

**Table 4** Summary of cost estimates (studies with an incident and mixed approach are underlined)

Reference	Year of cost data	Country	Reported annual costs in local currency (costs per patient)	Local currency in 2016	\$US (2016 PPP)	% of inpatient costs of all direct costs	Expenditure on health, per capita, US\$ (2016 PPP)
Voigt, 2014 [35]	2012	USA	\$60.2 - \$115.4b <sup>a</sup> (direct costs) \$70.8 - \$127.0b <sup>a</sup> (total costs)	\$62.9 - \$120.7b <sup>a</sup> \$74.0 - \$133.0b <sup>a</sup>	62.9-120.7b <sup>a</sup> 74.0-133.0b <sup>a</sup>	66	9892
Czech, 2013 [36]	2010	Poland	7739 PLN	8312 PLN	4755	92 <sup>e</sup>	1798
Delgado, 2013	2010	Spain	4860€ (healthcare costs)	5166€	7792	58 <sup>e</sup>	3248
Bogner, 2010 [24]	2009	USA	22,230\$ <sup>b</sup>	24,873\$ <sup>b</sup>	24,873 <sup>b</sup>	84	9892
Zugck, 2010 [30]	2002	Germany	11,794-16,303 € <sup>c</sup>	14,297-19,762 € <sup>c</sup>	18,472-25,532 <sup>e</sup>	72	5551
Neumann, 2009 [29]	2006	Germany	2,879b € <sup>a</sup>	3,293b € <sup>a</sup>	4,255b <sup>a</sup>	60	5551
Liao, 2007 [23]	2006	USA	\$10,832	12,907\$	12,907	65 <sup>e</sup>	9892
Agvall, 2005 [28]	2000	Sweden	37,060 SEK	44,971 SEK	5044	47	5488
Stafylas, 2016	2014	Greece	4411 €	4295 €	7053	73 <sup>e</sup>	2223
Ogah, 2014 [33]	2010	Nigeria	2128\$	2343\$	2343	44	NA
Lee, 2016 [31]	2016	South Korea	868\$ (perspective of third party payer) 1414\$ (perspective of society)	868\$ 1414\$	868 1414	53	NA
Dunlay, 2011 [34]	2007	USA	109,541\$ (lifetime costs from HF diagnosis until death)	126,819\$	126,819	77	9892
Corrao, 2014 [33]	2011	Italy	11,100 €	11,597 €	15,952	92 <sup>e</sup>	3391
Liao, 2006 [25]	2000	USA	32,580-33,023\$ (prevalent group) <sup>d</sup> 45,604-49,128\$ (incident group) <sup>d</sup>	45,406-46,023\$ <sup>d</sup> 63,557-68,468\$ <sup>d</sup>	45,406-46,023\$ <sup>d</sup> 63,557-68,468\$ <sup>d</sup>	65-67 70-72	9892
Ory, 2005 [26]	2000	USA	14,465\$ (prevalent group) 17,744\$ (incident group)	20,159\$ 24,729\$	20,159 24,729	NA	9892
Murphy, 2016	2013	Ireland	12,206 € (patients with preserved EF) 13,011 € (patients with reduced EF)	12,194 € 12,999 €	15,334 16,330	92 <sup>e</sup> 98 <sup>e</sup>	5528

<sup>a</sup>Aggregated costs for all HF patients  
<sup>b</sup>Costs aggregated for two years  
<sup>c</sup>Costs depend on number of visits to doctors  
<sup>d</sup>Cumulated costs for 5 years  
<sup>e</sup>Not clearly stated in the study  
SEK Swedish kronas, PLN Polish Zloty, b Billions, EF ejection fraction

Other studies suggest that the cost of heart failure is dependent on the time from diagnosis. [2,3] There appears to be a 'U' shaped curve of expenditure with greatest costs around the time of diagnosis and within a year of death.

Therefore exact costings are based on a multitude of considerations including patient effects (duration of heart failure, recent hospitalisation, whether in end stage heart failure or not, carer costs and indirect costs etc.), health economy considerations (expenditure per capita on health, type of health system etc.).

### UEA Model

Modelling includes hospital, GP and community heart failure nurses utilisation costs based on the selection of data from each source. Some guidance for the model is obtained from the expected use of services but this is for chronic heart failure and is not specifically for patients discharged from hospital.

The change in individual EQ5D 'crosswalk' scores are used to calculate QALYs also. These numbers may be small, but the numerical values in these groups is similar to those published for other heart failure groups (see section on Quality of Life results pages 142-156).

The UEA model tries to mitigate these variations by being based on the model analysed with a 1000 different permutations of all variables.

**Outcomes (see full University of East Anglia Health Economics Report page xxx)**

In summary the cost per patient for heart failure for our patients are £5,000 per patient 6 months. This is not dissimilar to the costs above, but less than a recent Danish telehealth cost analysis paper of £16,241 per patient per year.

Our intervention saves £42 per patient at 3-6 months, with costs included for the provision of the digital products and the telehealth co-ordinator. Other costs for use of the 'heart failure pathway' are already available and accounted for in the routine pathway such as the cost of a community heart failure nurse, the cost of a cardiologist etc.

The total cost of the 3 digital products (Flo, Recap Health and I Navigator) are £54000 for the Heart Failure Service. The total cost of 1 Tele Health Co-ordinator to supervise the care of 200 patients is £39,000.

The fixed costs re £54,000 for the digital products for the Heart Failure Service

The costs for the Tele Health Co-ordinator are: 13 readmissions reduced for 1 telehealth co-ordinator

From our readmissions analysis and assuming 1 readmission costs £3000 (with one readmission cost being the A and E admission cost + the subsequent hospital cost), (see Section on the Results – Impact on A&E and Hospital all cause readmission pages 52-66) would need to save:

18 readmissions to continue the licences for the Heart Failure Service

13 readmissions for 1 Tele Health Co-ordinator per 200 patients

In our analysis there were 405 patients with 6 months of follow up in the Usual care group and 349 readmissions in that 6 month period.

- **This means we would have to reduce the all cause readmissions by 44 from those 349 admissions to make our intervention cost neutral (readmission reduction of approximately 13% every 6 months)**

If the project were used ONLY in the usual care < 75 age group – in whom there were 109 patents with 6 months follow up data and 101 readmissions:-

- **We would have to reduce the number of all cause readmissions by 11 every 6 months to make our intervention cost neutral (readmission reduction of approximately 11%)**

- **That means for 1000 patients we would have to reduce readmissions at 6 months by approximately 44 to make our intervention cost neutral at 6 months (a 13% admission reduction every 6 months)**

The UEA analysis suggests a return of £1.20 on every £1 spent, so if the project spend were £100,000 then the return on investment would be an additional £120,000.

### **Limitations**

Our sample is a pragmatic sample. The patients referred to the project are from the heart failure team. The patients who enrol have to have access to 2 digital products. The number of returned quality of life questionnaires is as expected, but still reflects <50% of potential patients. The values of the quality of life are similar to those of other heart failure populations. The model used has been repeated with a 1000 different permutations

The usual care quality of life questionnaires are taken from patients who were ineligible for the project because of lack of access to a texting phone, an e mail address, lived in the wrong geographical area or did not wish to engage with the project once they returned home.

Our sample size is what we have at the end of the day and we have done all we can to demonstrate that they are truly representative of hospitalised heart failure patients albeit at a younger mean age.

### **Discussion**

Our project is cost effective, cost efficient and produces better outcomes for less cost with improved

Very few reductions in readmission will make the whole project cost neutral. Additional cost savings to be re-invested in community services would be expected from the additional readmissions reduced by the principles of our project – over and above the break even all cause readmission reductions.

The model developed by the University of East Anglia includes hospital admission costs and GP and community heart failure nurse costs.

Values for usual care in the literature range from

### **Reference**

1 Resource impact report: Chronic heart failure in adults: diagnosis and management (NG106) <https://www.nice.org.uk/guidance/ng106/resources/resource-impact-report-pdf-6537494413>. accessed 19/09/2020

2 Cost-of-illness studies in heart failure: a systematic review 2004–2016. *BMC Cardiovascular Disorders* (2018) 18:74. doi.org/10.1186/s12872-018-0815-3 accessed 19/09/2020

3 **The economic burden of heart failure in Denmark from 1998 to 2016.** *European Journal of Heart Failure* (2019) doi:10.1002/ejhf.1577 accessed 19/09/2020

## Health Economy – Full Report

### Introduction

Heart failure (HF) conditions affect more than 900,000 individuals in the United Kingdom (National Institute for Health and Care Excellence, 2018), which results in substantial mortality and morbidity, as well as reduced quality of life (Kim *et al.*, 2020). Patients with HF are usually older individuals with comorbidities, who may have extremely dissimilar medical and social needs (National Institute for Health and Care Excellence, 2018). A multidisciplinary team (MDT) is considered the current gold standard practice for HF management (Morton, Masters and Cowburn, 2018) and is endorsed for high-risk patients in the Health and Social Care Act of 2012 (Legislation.gov.uk, 2012), including other national (Department of Health, 2013; National Collaboration for Integrated Care and Support, 2013; NHS, 2014) and international guideline (Yancy CW *et al.*, 2013; Ponikowski *et al.*, 2016)

“*Smart with your heart*” is an Innovate UK project at the University Hospital of North Midlands (UHNM) which aims to evaluate the impact of early detection of pre-hospital deteriorating health, in patients who were previously admitted with heart failure, and to ascertain the impact on secondary care utilization. This was facilitated by integrating the commercially available digital health technologies, merged with a more efficient and responsive heart failure pathway.

For the purpose of the health economics assessment of the “*Smart with your heart*” intervention, a cost-effectiveness analysis was implemented aiming to compare HF Proposed Self-Management Approach’s cost-effectiveness against the current pathway which includes GP appointments and Community HF Management after the first discharge from the hospital. A cost-effectiveness analysis is a type of economic analysis that aims to compare the relative costs and effects of different interventions or pathways. It is typically expressed in terms of a ratio where the denominator is a gain in health and the numerator is the cost associated with that health gain (Gold *et al.*, 1996). One of the most commonly used outcome measures is the quality-adjusted life years (QALYs) (Bleichrodt and Quiggin, 1999).

### Methodology

In order to conduct a health economics assessment of the Proposed Self-Management Approach intervention, a cost-effectiveness analysis methodology was implemented aiming to compare the Proposed Self-Management Approach cost-effectiveness against the current

pathway followed after the hospital discharge due to an HF incident. Cost-effectiveness analysis is a type of economic analysis that compared the relative costs and effects (outcome) of different courses of actions.

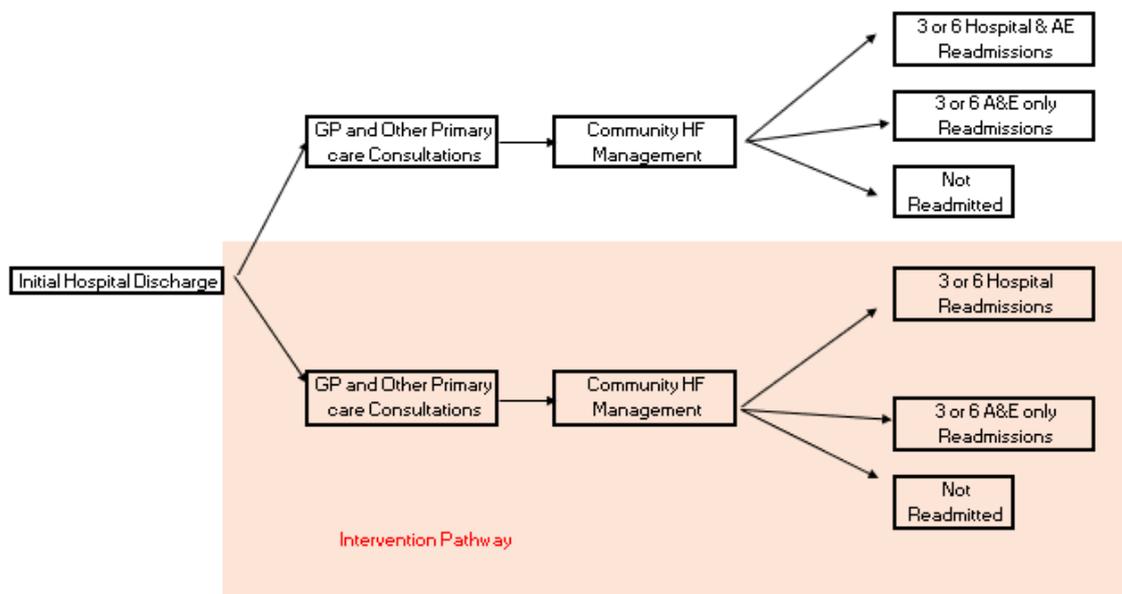
Apart from the deterministic outcome, a Bayesian stochastic approach was implemented to account for potential variance in the dataset collected from published sources in different UK areas and NHS averages.

### Model

A cost-effectiveness analysis was implemented in this study through a decision-tree model with a time horizon of 1-year, built-in Microsoft Excel program. Cost-effectiveness is usually expressed as an incremental cost-effectiveness ratio (ICER), which reflects the difference in costs and the difference in benefits of two interventions/pathways (Arlandis-Guzman *et al.*, 2011)

The health economics model developed aimed to assess the Proposed Self-Management Approach intervention by comparing its cost-effectiveness against the current pathway.

**Figure 1: Decision Tree Model**



All adult individuals admitted to UHNM (Royal Stoke Site) were heart failure patients and lived within the North Staffordshire and Stoke-on-Trent Clinical Commissioning Groups (CCG) catchment area. Patients with heart failure were identified by the heart failure team and referred for the project. Some admitted patients were not seen by the heart failure team. For the purpose of the evaluation, two cohorts were formed based on the participating patients:

1. **Project patients' group:** formed by the new and existing heart failure patients.

- a. Patients who are newly diagnosed with heart failure for the first time, have never been treated previously and have no history of heart failure.
  - b. Existing heart failure patients who have been treated by the heart failure team before.
2. **Usual care patient group:** This group was formed by the new and existing heart failure patients, who either did not want to participate in the project or they were not eligible due to the exclusion criteria of the project, patients who were not referred to the heart failure team, and patients who were not referred to the project team by the heart failure service

The participating patients were subject to inclusion and exclusion criteria. In order to take part in the project:

- Patients must have access to a mobile phone and be able to receive and respond to text messages.
- Patients must be able to use and navigate internet-based systems
- Patient must give explicit informed consent to participate in the digital services, in keeping with GDPR regulations.
- Patients must be new to the 'Smart with your heart' service, i.e. patients will only participate through the service once.
- Patients or a carer must be able to speak and/or understand English and be able to respond to text messages and understand patient information presented in the health library.

Patients were excluded from the project if they had a lack of mobile phone/internet access, were previously registered with the "*Smart with your heart*" service, or declined to give explicit consent to participate in the project.

The current suggested pathway for managing heart failure consists of (NICE, 2010):

- a GP session within one week after hospital discharge.
- a visit to the hospital within 2 weeks after hospital discharge.
- Contact with an NHS community team (usually nurse by consultant support) and further appointments as required.
- Prescription of angiotensin-converting enzyme (ACE) inhibitor or beta-blocker licensed drugs.
- Insertion of a pacemaker or implantable cardioverter-defibrillator (ICD).

The proposed pathway consists of the utilization of conventional health status questionnaires and a new telehealth application (mobile phone symptom log) to manage more efficiently patients discharged from hospital after heart failure is diagnosed.

Recent studies have shown that telehealth applications for self-management of Heart Failure while was not consistently superior to usual care, can present fewer negative effects and are a safe option for delivery of self-management support (Hanlon *et al.*, 2017).

The main aim of this new pathway is to reduce the readmissions to the hospital after initial discharge and thus reducing the costs of managing heart failure whilst offering the same

### **Parameters**

Due to the rise of health care costs, policymakers and taxpayers expect a clear framework for decision-making regarding the allocation of scarce economic resources (Wickwire 2016). So, a health economic standpoint must take into consideration not only the clinical efficacy of disease-specific interventions but also their global value comparative to other disease and treatment options. In order to perform these contrasts, there has to be a common metric to compare unrelated treatments.

To conduct a cost-effectiveness analysis, it is necessary to use appropriate measures. This usually depends on the aims and objectives of the interventions being evaluated. Some of the most common measures used in previous cost-effectiveness studies have been “lives saved” and “life-years gained” (Robinson, 1993).

One of the most common metrics is the quality-adjusted life-year (QALY), which is a homogeneous unit of measurement that accounts for both time, as well as quality of life in a specific state (Wickwire, Shaya and Scharf, 2016)

The EQ-5D-5L was launched by the EuroQoL Group in 2009 in order to improve the instruments’ sensitivity (EuroQoL Group, 2017). The system comprises of five dimensions: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression (EuroQoL Group, 2017). Each dimension has five levels: no problems, slight problems, moderate problems, severe problems, and extreme problems (EuroQoL Group, 2017). The patient should select the most approach state for each of the dimensions and this results in a 5-digit number that describes the patient’s health state. The EuroQoL Group organized a study that administered both the 3- and 5- level versions of the EQ-5D so that a “crosswalk” between the EQ-5D-3L value sets and the new 5L descriptive system, which results in a crosswalk value set for the EQ-5D (EuroQoL Group, 2019a). The crosswalk was based on the response mapping approach that estimated the relationship between responses to the 3L and the 5L systems which established a link to the 3L value sets (Van Hout *et al.*, 2012). In the EuroQoL website is possible to download an Excel file containing the 5L value sets for multiple countries. In the file there are three sheets available: “transition probabilities” which present the transition probabilities when going from a 5L to a 3L level for each dimension; “probability matrix” gives the transition probabilities for all 5L to 3L health states and finally the “EQ-5D-5L value sets” which gives the EQ-5D-5L index values based on the crosswalk for the different countries (EuroQoL Group, 2019b). In the file, there is also a tool available that transforms the EQ-5D-5L value's index into utility values.

Patient-level QALYs are usually estimated by applying the area under the curve (AUC) approach (Matthews *et al.*, 1990), that is implemented summing the areas of the geometrical shaped found by linear interpolating between utility scores other the study period (Manca, Hawkins and Sculpher, 2005).

All the costs related to the intervention and standard of care were either provided by project leaders or taken from the PSSRU Report 2019 (Curtis and Burns, 2019) and well-established bodies of literature.

### **Probabilistic Sensitivity Analysis**

In most studies, there is a good deal of uncertainty about costs and outcomes of the different procedures (Robinson, 1993). One solution to deal with this issue is to implement a risk-averse strategy. This is most appropriate when comparing a new technology with an already established one and which entails making assumptions against the new technology whenever uncertainty arises (Robinson, 1993). If the new technology appears to be the preferred option, even after assumptions have been made, then the results can be assumed to have some confidence.

To include uncertainty in the simulated cost-effectiveness analysis, we conducted a probabilistic sensitivity analysis using Monte Carlo simulation.

Probabilistic Sensitivity Analysis (PSA) validates the parameter uncertainty in a decision problem. The technique involves sampling parameters from their respective distributions (instead of simply using mean/median parameter values). A key output of a PSA is the proportion of results that fall favourably, i.e. that are considered cost-effective, concerning a given cost-effectiveness threshold. This can be represented graphically by using a cost-effectiveness acceptability curve (CEAC).

Costs usually display positive skewness, so the gamma distribution is usually used to accommodate these (Mantopoulos *et al.*, 2016). Effects expressed in terms of QALYs usually have data truncated at both ends of the distribution (ranging between 0 and 1 when the time horizon is one year) (Mantopoulos *et al.*, 2016). QALYs can also exhibit negative skewness with most of the values lying around the upper end of the scale (Mantopoulos *et al.*, 2016). The beta distribution is normally used to model ranges, while still supporting both negative and positive skewed distributions (Mantopoulos *et al.*, 2016)

In this economic evaluation, a gamma distribution was used for the costs, and beta distribution was used for QALYs and other measurements between 0 and 1.

### **CEAC, ICER and Cost-effectiveness Plane**

A standard cost-effectiveness analysis was performed (Drummond *et al.*, 2005) and the cost-effectiveness ratio, expressed in British pounds per year of life saved, was calculated. An incremental analysis was conducted to assess the cost-effectiveness of the “*Smart with your*

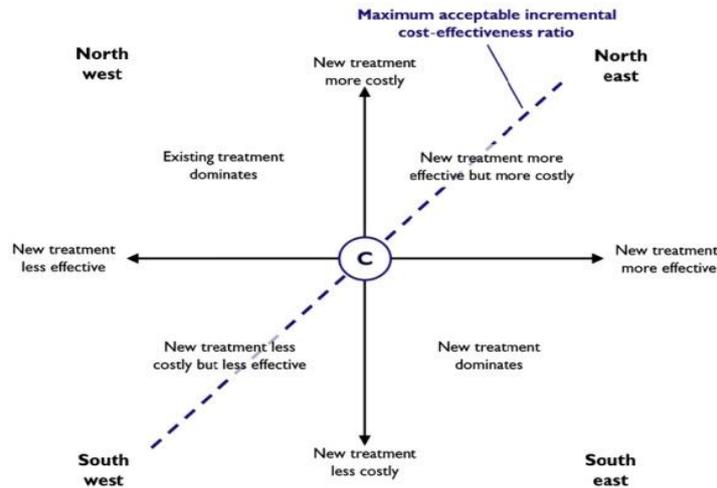
*heart*” program. Assuming that costs will occur in one year, the costs were not discounted (Georgiou *et al.*, 2001).

The cost-effectiveness acceptability curve (CEAC) is a graph summarising the impact of uncertainty on the outcomes of economic evaluation and is frequently expressed as an incremental cost-effectiveness ratio (ICER) in relation to the possible value of the cost-effectiveness threshold (York Health Economics Consortium, 2020)

The graph plots a range of cost-effectiveness thresholds on the horizontal axis against the probability that the intervention will be cost-effective at a specific threshold on the vertical axis. It can usually be drawn directly from the results of a PSA.

The cost-effectiveness plane is used to represent visually the differences in costs and effects between two interventions, and it is usually done by plotting the costs against outcomes on a graph. The effects are usually plotted on the x-axis and costs on the y-axis. The graph is divided into four quadrants most cost-effectiveness analyses deliver results in the north-east (NE) quadrant, in which new interventions generate more health gains but are more expensive. Other quadrants are relevant when a new intervention generates poorer health outcomes (NW or SW) or lower costs (SW or SE) (York Health Economics Consortium, 2016). The plane is also useful to show the uncertainty around cost-effectiveness outcomes, often represented as a cloud of points on the plane corresponding to different iterations of an economic model in a (probabilistic) sensitivity analysis (York Health Economics Consortium, 2016).

## **Figure 2: Cost-effectiveness Plane**



### Return on Investment

Return on Investment (**ROI**) is a performance measure used to evaluate the efficiency of an investment comparing the ratio of the net value of the investment against the cost of the investment.

$$\text{ROI} = \frac{(\text{Current Value of Investment} - \text{Cost of Investment})}{\text{Cost of Investment}}$$

As the value of the investment HEC used the perceived value of the intervention as it arises from the difference of the cost between the usual care and intervention cohorts.

ROI of less than 1 indicates that the programme cost more to deliver than was saved in terms of treatment costs. ROI greater than 1 indicates that the programme saved enough in terms of treatment costs to more than cover its own costs. An ROI of less than 1 does not necessarily mean the programme is not worthwhile, as by adding in the benefits of the programme you could make a more comprehensive case for investment.

### Results

We used published sources and PSSRU to represent the costs of the usual care pathway. The estimated costs associated with the Proposed Self-Management Approach (**Table 1**).

Changes in utility scores are shown in **Tables 2** and **3**. Patients in the project active group had a higher mean utility score (mean 0.607, SD 0.318) than the usual care group (mean 0.505, SD 0.328). The utility scores for the patients in the project active group can be seen to gradually increase at 3-months and 6-months. The same does not happen for the patients in the usual care group. The patients in this group lose quality of life at 3- and 6-months. However, this could be due to the fact that there are significantly fewer patients in these groups than in the project active group.

**Table 1: Component Costs used in the Economic Evaluation**

	<b>Cost (Unit)</b>
GP Visit (per minute)	£4.30
Outpatient	£125
A&E visit	£160
Community Management per appointment	£18.73
Readmission Outpatient Visit	£125
Readmission to A&E	£160
Proposed Self-Management Approach Cost	£34.82

**Table 2: Utility scores and change from baseline for the usual care group**

NP	Utility Score		
	Mean	SD	95% CI
<b>Baseline</b>	0.505	0.328	0.376-0.882
<b>3-month</b>	0.403	0.302	0.284-0.687
<b>6-month</b>	0.294	0.267	0.190-0.484

**Table 3: Utility scores and change from baseline for the project active**

P	Utility Score		
	Mean	SD	95% CI
<b>Baseline</b>	0.607	0.318	0.527-0.687
<b>3-month</b>	0.694	0.274	0.625-0.763
<b>6-month</b>	0.949	0.184	0.903-0.995

The incremental cost saving was approximately £42 per patient, while the incremental effectiveness showed a gain of 0.06 QALYs per patient. We calculated the ICER to be approximately £ 851.49 (based on 3 months' outcomes, Single Unit implementation) and approximately £ 1,026.84 (6 months' outcomes, Single Unit implementation) per QALY gained indicating that the intervention was more cost-effective than the usual care.

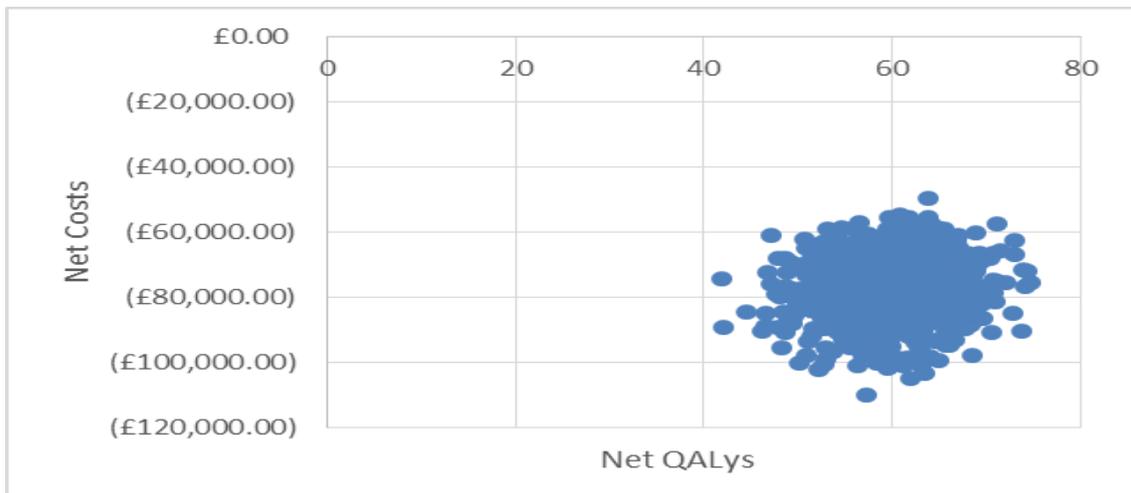
The initial calculation of the QALMs was converted to QALYs and all the costs were referring to a year.

The probabilistic analysis resulting from the 1000-time Monte Carlo simulations demonstrated efficacy and plotting the incremental costs and incremental benefits on the cost-effectiveness plane it is confirmed that the intervention is less costly and more

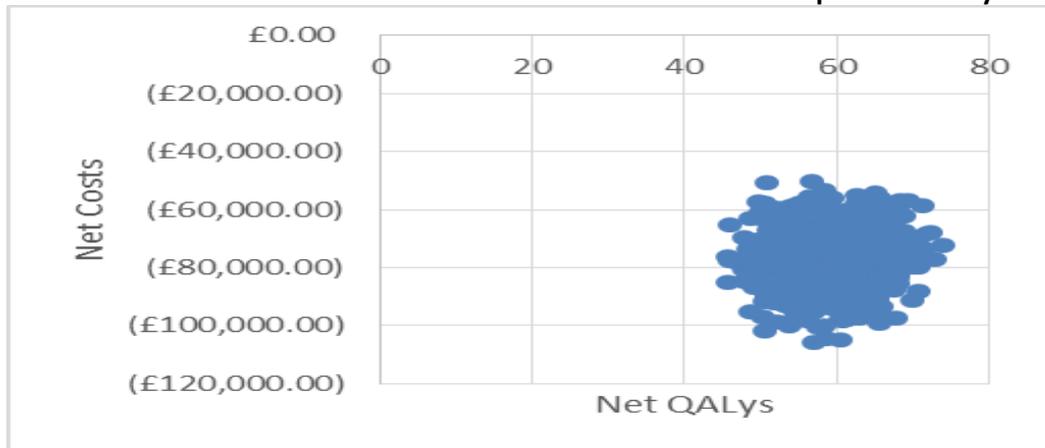
effective than the usual care group taking into account the 3 and 6 months' outcomes, extrapolated for a year.

The cost-effectiveness plane (Figures 3 and 4) shows that the intervention generates more quality of life and requires fewer costs, at both 3- and 6-months.

**Figure 3: Cost Effectiveness Plane - based on 3-Month outcomes extrapolated for a year**



**Figure 4: Cost Effectiveness Plane - based on 6-Month outcomes extrapolated for a year**



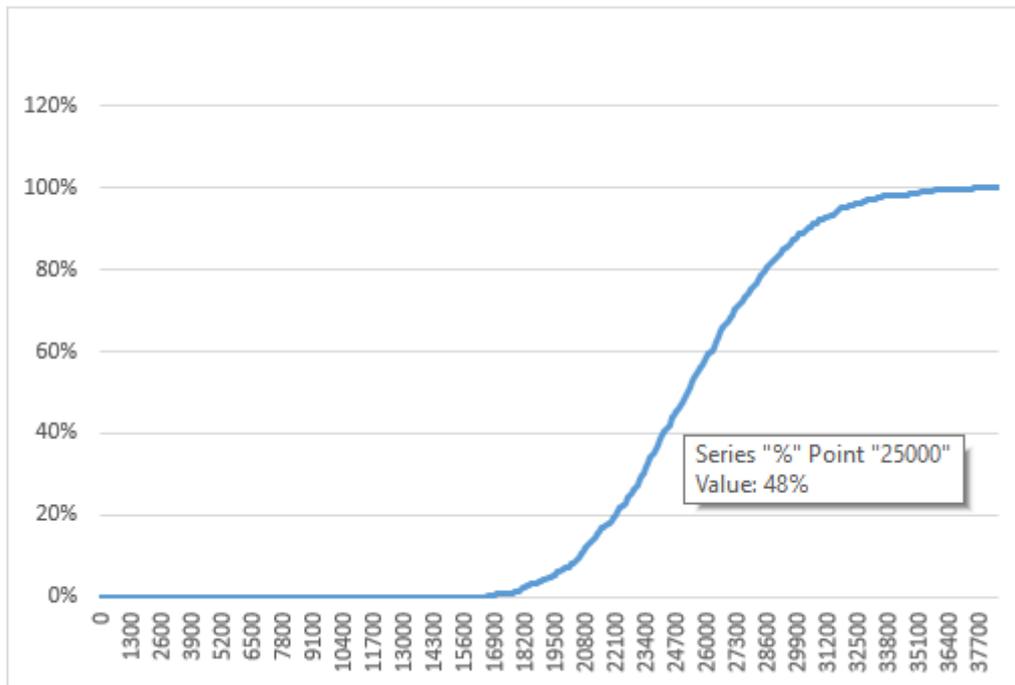
The ROI results for the current project were also positive showing that the intervention has a significant ROI of  $\approx$  £1.2 - £3 per patient for each 1£ invested depending on the systems' implementation and the scale of implementation.

### Discussion and Concluding Remarks

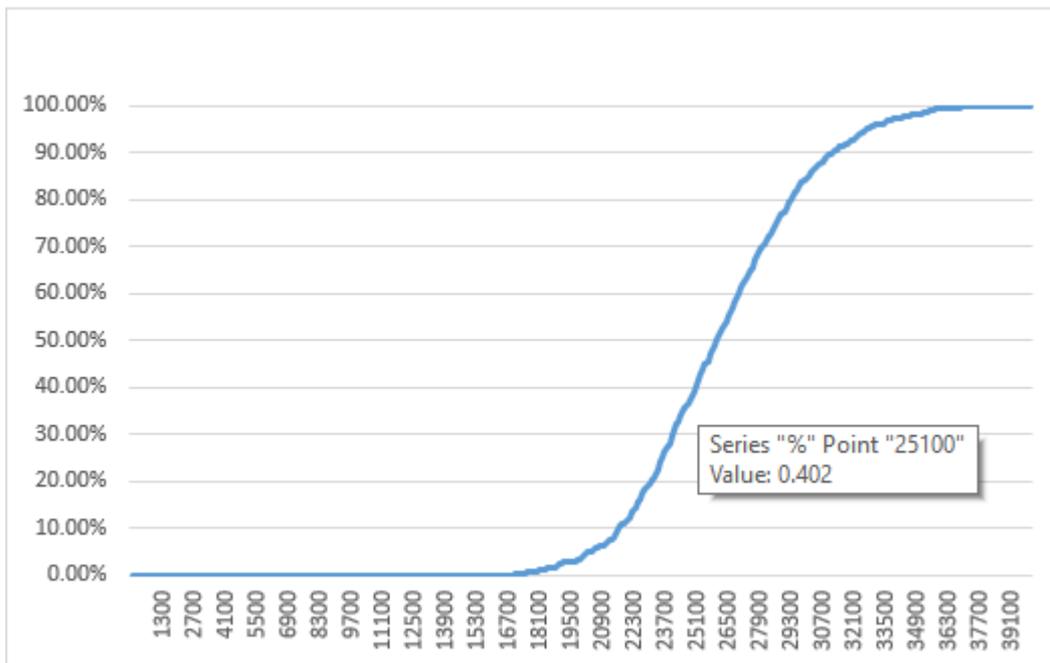
The outcomes of health economics modelling were significantly positive for the intervention. Since there was quite a variance in the sources and the coding of the variables and we will refer to those in more details in the description of the limitations of the study, apart from the PSA we performed also a deterministic sensitivity analysis by increasing various service utilization variables assuming that the intervention will increase the flow

towards those services and aiming to identify a break-even point after which the intervention stops cost-efficient and adoptable by NICE. Our findings suggest that utilization rates for GP and other primary care changes affect the project cost efficiency negatively until reaching an increase of 75% were the project is not cost-efficient (Cost-effectiveness probability <50% at the threshold of £25,000 per QALY gained) based on the 3 months outcomes extrapolated for a year, and until reaching an increase of 90% were the project is not cost-efficient based on the 6 months outcomes extrapolated for a year

**Figure 5: Graph showing Cost-Effectiveness at 3 Months**



**Figure 6: Graph showing Cost-Effectiveness at 6 Months**



Variables like the utilization of Community Care Services and the probability of readmission at the hospital did not affect the cost-efficiency of the project. These outcomes although positive should be taken with caution due to the limitations of the study described in the section below.

However, some limitations should be noted. First, there was no appropriate control group recruited. There should have been patients with HF recruited who did not have the intervention to make an appropriate comparison between the current and proposed pathways and were matched for age and sex and co-morbidities with the intervention group. The pragmatic comparison cohort had the same mean age and sex distribution as the project active group. They were not co-morbidity matched. There was however a statistically significant reduction in both A and E and hospital utilization between these comparative groups.

The comparison cohort consisted of patients who did not have access to a mobile phone with texting capabilities or have access to email. They were otherwise no different clinically or in terms of the other project inclusion criteria. The usual care group were not matched to the project active group and therefore were not a true control group.

We accept that patients who do not have access to commonplace digital products or email may be different in an unqualifiable way to the project's active group and represent a convenience comparator group.

The generalizability of this data should therefore be treated with caution.

One second limitation is the fact that the EQ-5D-5L was used to derive utility values. NICE does not recommend using the EQ-5D-5L value set for England, published by Devlin *et al.*, 2017. It is recommended that companies and academic groups planning evidence submissions for NICE use of the 3L value set for reference-case analysis (National Institute for Health and Care Excellence, 2019). Although the 'crosswalk' score to calculate country-specific conversions from the EQ5D to the 3L value set was used and ratified by NICE. The mortality rates provided by the project leads were also not used since this included other death reasons besides HF.

We accept that this is a service evaluation project, but for future research, it is recommended that if data were to be gathered using the EQ-5D-5L descriptive system, the utility values should be calculated by mapping the 5L descriptive system data onto the 3L set. On the other hand, if analyses use data that was gathered using both 3L and 5L systems, the 3L value set should be preferred to derive all utility values, and the 5L system is mapped into the 3L is needed (National Institute for Health and Care Excellence, 2019). It is also recommended the use of the (Van Hout *et al.*, 2012). It is also recommended that the design of the study is reconsidered in future iterations to recruit a control group so that an appropriate comparison can be made between the current and proposed pathways. A larger future group with more long term follow-up will allow for more robust evaluation and may help tease out individual parts of the intervention of greatest value.

### **Summary Outcomes**

The Smart with your heart project was cost-efficient and cost-effective. It shows a return on investment of £1.2 to £3 for each £1 invested in it. If these figures were more generalizable and applied to the 1 tenth of the £900,000,000 invested in acute heart failure yearly then this would equate to a net £ 108,000,000 to £270,000,000 'saving' with a £90,000,000 investment.

Interestingly the model was more dependent on the cost of GP services to remain cost-effective than readmissions. Some of the costs 'saved' from readmissions could therefore be invested in community services to maintain cost-effectiveness/efficiency in the future.

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## Community services utilisation – GP and community Heart failure nurse service utilisation data

### **GP datasets**

There are 85 different GP practices in Stoke and North Staffordshire. Awareness of the test beds project was raised at multiple protected learning events and other educational events. GP's were informed about the project and the hope that patients with early deterioration could be prioritised for early review if the GP surgeries were contacted by the Tele Health Co-ordinators, the Community Heart Failure Nurses or the secondary care Heart Failure Nurses.

All GP practices had repeated information sheets about the project and additionally a request to share service utilisation data on GP face to face service use by patients discharged from hospital following an admission with decompensated heart failure and with patients enrolled on the test beds project. This contact could be with GPs themselves or with any of the multitude of other professional services within the GP practice.

Only 6 GPs replied.

We then targeted the GP surgeries in the top 10 in terms of numbers of patients from that practice discharged from hospital with a diagnosis of heart failure and those in the top 10 for patients enrolled in the test beds project.

All GP surgeries contacted were recorded as the patient's GP on our hospital patient information system.

18 GP practices were identified in this way – some being in the top 10 in both lists.

Of these 3 practices failed to reply or complete a Data Sharing Agreement.

The data therefore represents the return from 15 GP practices with regard to service utilisation.

GP surgeries provided no data on 36 patients they did not recognise in their practice list OR who had moved from their practice.

GPs did not provide service utilisation data on 15 patients who died following hospital discharge. None were active on the project.

### **Project Active patients on GP dataset**

This represents service utilisation data on 35/104 (34%) patients active on the project overall – data is included in 2 patients who died after enrolment. The total number of months of data collection while patients were/ are alive is 595.2 months (mean 5.5, SD 2.3 months).

### Usual Care Group in GP dataset

This data represents 79 of 824 (9.5%) patients discharged from hospital with heart failure coded in the first position at discharge – data is included on 11 patients who died after discharge. The total number of months of data collection while patients were / are alive is 460.1 months (mean 5.8, SD 2.2 months)

The age and sex distribution of the total GP dataset, the project active and usual care groups are demonstrated in Table 1 below.

**Table 1 shows the age and sex distribution of total, project active and usual care groups in the GP dataset.**

Group	Total number of patients	Number by sex (Male, Female)	Age (Mean, St Dev)	Age by sex	
				Male (Mean, St Dev)	Female (Mean, St Dev)
Total	113	(66, 47)	(74, 13)	(73, 11)	(75, 14)
Project Active	35	(17, 18)	(66, 11)	(64, 11)	(67, 11)
Usual Care	78	(49, 29)	(78, 11)	(77, 14)	(80, 9)

In the GP data set 23/35 patients used both Flo and Recap Health.

### GP utilisation after discharge / enrolment

This is demonstrated in Table 2 below.

**Table 2: Demonstrating GP surgery utilisation by patients in the usual care and project active groups. The figures are represented as totals and means per patient in each group after discharge. There was no significant difference between the groups for GP surgery face to face utilisation between project active and usual care for any category of GP utilisation.**

The clinicians who saw patients in the GP surgeries ( primary care consults') were: Pharmacist, Practice Nurse, ST1, Physician Associate, HC Support Worker, Nurse Practitioner, Elderly Care Facilitator, Diabetic Nurse, Nurse Practitioner, Paramedic Prescriber, Medical Student, Social Prescriber, UCP. 1 person from the usual care group was referred to a social prescriber.

**Table 2**

	<b>Project active n=35</b>	<b>Usual care n=79</b>
<b>Total number of all primary care visits</b>	218	569
<b>Mean (SD)</b>	6.4 (3.3)	7.2 (4.6)
<b>Total number of GP visits per month alive after discharge / enrolment</b>	60.7	62.5
<b>Mean (SD) per patient per month</b>	1.8 (3.7)	0.8 (0.8)
<b>Total number of other primary care consults per month alive after discharge / enrolment</b>	27.7	55.6
<b>Mean (SD) per patient per month</b>	0.8 (1.4)	0.7 (0.8)
<b>Total number of all primary care visits per month alive after discharge / enrolment</b>	88.4	118.1
<b>Mean (SD) per patient per month</b>	2.6 (4.5)	1.5 (1.4)

We additionally examined the utilisation of GP services by patients on the project who were newly diagnosed or already known to the heart failure team (existing) or whether they had hefref or hefpef as the mechanism for their heart failure – Table 3

Table 3 GP utilisation data as (mean, SD) for total number of visits to GPs, other clinician reviews in GP surgeries and patients in the project active group split into new vs. existing heart failure diagnosis and hefref vs. hefpef. The data is represented as mean number of clinician reviews per patient per month of data collection.

**Table 3.**

	<b>Mean number of total GP visits per patient (mean, SD)</b>	<b>Mean number of total other GP surgery visits per patient (mean, SD)</b>	<b>Mean total all GP surgery visits per patient (mean, SD)</b>
<b>Existing n=20</b>	(4.88, 3.14) n = 17	(2.53, 2.45) n = 17	(7.41, 3.52) n = 17
<b>New n=15</b>	(3.22, 1.96) n = 18	(2.11, 1.94) n = 18	(5.33, 2.79) n = 18
<b>Hefref n=23</b>	(4.04, 2.75) n = 23	(2.83, 2.44) n = 23	(6.87, 3.52) n = 23
<b>Hefpef n=12</b>	(4, 2.7) n = 12	(1.33, 1.07) n = 12	(5.33, 2.64) n = 12

**Discussion**

It is surprising that Hospital coding systems appear to have the incorrect GP data in 36/140 patients = 26%. The electronic patient record may improve the accuracy of recorded GP data.

It is estimated that 60% of all patients with heart failure will see their GP at some time in a year.[1] NICE chronic heart failure guidelines suggest that it costs general practice £50 million a year to review heart failure patients – with a minimum of 2 reviews per year by their GP.[2] This would equate to a minimum of 0.17 visits per patient per month. Stewart et al suggested that in 1995 that men and women with heart failure visited their GPs between 2.3-2.5 times per year.[3] This data emanates from a time of more inaccurate heart failure diagnosis and when hefref was the only mechanism for heart failure that was recognised.

Our data suggests that patients on our project are seen 10 times as often by GPs themselves or seen by any clinician within a GP practice 15 times more in comparison to the minimum suggested by NICE in stable chronic heart failure patients.

Usual care patients were seen at a GP surgery 1.5 times per patient per month in comparison to 2.6 for the project active group.

It is possible that this 60% increase in frequency of reviews at the GP surgery for the project active group may have been clinically but not statistically significant in terms of improving their health care and reducing all cause readmissions.

Our data reflects the fact that patients discharged from hospital following a heart failure admission consume GP resources far more than suggested for chronic heart failure patients and greater than that recognised historically. [1,2]

## References

1 Health service use by patients with heart failure living in a community setting: a cross-sectional analysis in North West London. Kim D, Hayhoe B, Aylin P, Cowie M, Bottle B. *British Journal of General Practice* 2020; 70 (697): e563-e572. DOI: <https://doi.org/10.3399/bjgp20X711749>

2 <https://www.nice.org.uk/guidance/ng106/resources/resource-impact-report-pdf-6537494413> NICE resource implications of Chronic Heart Failure Guideline 2018 – accessed 19/09/2019

3 The current cost of heart failure to the National Health Service in the UK. [Stewart S](#), [Jenkins A](#), [Buchan S](#), [McGuire A](#), [Capewell S](#), [McMurray J](#). 19 January 2012. [https://doi.org/10.1016/S1388-9842\(01\)00198-2](https://doi.org/10.1016/S1388-9842(01)00198-2) accessed 19/09/2020

## Midlands Partnership Foundation trust (MPFT) data review – community heart failure nurse utilisation

The MPFT dataset comprises all patients on the community heart failure nurses database from 01/07/2018 to 13/03/2020 with cumulative visits per patient at 30 days, 3 months and 6 months from referral into that service.

The referrals to the community heart failure service arise from:

- Community – referrals from primary care (GPs and other community nurses ) and from patients seen in secondary care out-patient clinics
- Hospitalised patients – patients admitted to hospital can be referred by the team responsible for the patient's care. This may also be from the secondary care heart failure team.

### Project Intervention

In addition to the digital products used for the project active patients, there were additional training sessions for the specialist heart failure nurses in palliative and elderly care. The heart failure nurses were also given direct access to an elderly care helpline.

GP practices were also informed of our project and encouraged to consider a deteriorating heart failure patient as someone warranting rapid review. GPs were also informed of the patient self-assessment interactive texting and the prospect of red or worse alerts being referred to community nurses – and subsequently may be referred by community nurses to GPs themselves.

The data set is divided into 2 time periods :-

- from 01/07/2018 to 13/03/2019 – a time period corresponding to enrolment on the test beds project, but one year prior to the project starting
- from 01/07/2019 to 13/03/2020 to correspond to the time period for enrolment into the test beds project.

The defined groups of interest are:

- Usual care – historic (n=191) – patients with a primary discharge diagnosis of heart failure from a hospital admission who were reviewed by the community heart failure nurses one year before the project started
- Usual Care (251)– Patients who were discharged from hospital with a primary diagnosis of heart failure in the time period for enrolment to the test beds project.

- Usual care < 75 years – these were patients who were under the age of 75 and discharged from hospital with a primary diagnosis of heart failure in the time period of enrolment to the test beds project
- Project Active (40) – Patients who were enrolled and active on the test beds project

All patients in the project active group had at least 3 months of potential follow up data available. Only patients enrolled on the project by 13/12/2019 had at least 6 months of follow up data.

### **Demographic Data**

There were 695 patients on the community heart failure nurse database from 01/07/2018 to 13/03/2019 and 966 patients on the community heart failure nurse database from 01/07/2019 to 13/03/2020 – an increase in workload of approximately 40%.

The proportion of patients with a primary hospital discharge with heart failure (from 01/07/2018 – 13/03/2019) referred to the community heart failure service was 29.7%, which accounted for 27.5% of the caseload.

The proportion of patients with a primary hospital discharge with heart failure (from 01/07/2019 – 13/03/2020) referred to the community heart failure service was 30.5%, which accounted for 27.5% of the caseload. These values were 23.5 and 6% respectively for patients under the age of 75 within this time period.

Only 38.4% of patients active on the test beds project were also in the community heart failure nurse database. This accounted for 4% of the community heart failure caseload in the time period for enrolment of the test beds project.

The age and sex distribution to each patient group is demonstrated in Table 1.

The mean age and sex distributions between both the entire usual care groups are similar numerically between the time periods.

The Project active and usual care < 75 groups have no statistically significant differences between the mean ages and sex distributions between the groups.

### **Table 1 demonstrating age and sex distribution of groups of interest in the time periods of interest**

Group	Total number of patients	Number by sex (Male, Female)	Age (Mean, SD)	Age by sex	
				Male (Mean, SD)	Female (Mean, SD)
<b>Usual care - Historic patients (Pre 30 June 2019)</b>	191	(92, 88)	(80, 12)	(76, 12)	(83, 11)
<b>Project Active (Post 30 June 2019)</b>	40	(24, 16)	(68, 12)	(68, 12)	(68, 13)
<b>Usual care (Post 30 June 2019)</b>	251	(142, 109)	(80, 9)	(80, 9)	(81, 9)
<b>Usual care (&lt;75) (Post 30 June 2019)</b>	59	(38, 21)	(67, 7)	(67, 7)	(67, 9)

### Utilisation of Community Heart Failure Nurse Service

Table 2 below demonstrates the mean number of cumulative visits per time period of interest to the heart failure nurse service in the different time periods of data collection. The patients with 6 months of potential follow up were referred to the heart failure nurse service between 01/07 – 13/12 2018 and 2019 respectively.

The table demonstrates that there was a significant fewer community heart failure nurse reviews of patients in the project active group in comparison to the usual care groups for both time periods of data collection at 30 days and 3 months post discharge. There was a trend to a difference between the usual care 2019 patients and project active group at 6 months which did not achieve significance once corrected for multiple comparisons.

**Table 2 Mean number of reviews by community heart failure nurses at 30 days, 3 months and 6 months following referral for different groups and during different time points for data collection ( see above for definitions). Any differences in the reviews per patient did not remain significant when patients with at least 6 months follow up were considered.**

Groups	Mean Number of Reviews (30 days)	No. of patients (30 days)	Mean Number of Reviews (3 months)	No. of patients (3 months)	Mean Number of Reviews (6 months)	No. of patients (6 months)
<b>Historic patients (Pre 30 June 2019)</b>	1.22 (233)*++	191	2.53 (483) *++	191	3.63 (345)	95
<b>Project Active (Post 30 June 2019)</b>	0.62 (25)	40	1.85 (74)	40	3.40 (68)	20
<b>Usual Care (Post 30 June 2019)</b>	1.14 (286)*++	251	2.77 (695) *++	251	4.46 (678) *	152
<b>Usual care (&lt;75) (Post 30 June 2019)</b>	0.69 (41)	59	1.88 (111)	59	3.47 (125)	36

- \*P<0.05 univariate analysis in comparison to project active group
- ++ P significant after Bonferroni correction in comparison to project active group

## Community Heart Failure Nurse Utilisation based on New vs. Existing and Hefref vs. Hefpef for patients in the project active group

In the project active group there were 17 new patients and 30 patients with hefref. Table 3 below demonstrates the frequency of community heart failure nurse review for each of the categories

**Table 3. Community nurse utilisation in new vs. existing and hefref vs. hefpef patients from the 40 of the project active patients.** It is unsurprising that there were greater number of visits for the heart failure with reduced ejection fraction patients to facilitate titration of guideline directed medical treatments.

	Cumulative community heart failure nurse review per patient		
	30 days	3 months	6 months
Existing n 23	0.43	0.71	1.12
New n=17	0.20	0.87	1.23
Hefref n 30	0.36	1.07**	1.59**
Hefpef n=10	0.15	0.24	0.33

\*\* statistically significant after Bonferroni correction for multiple comparisons

### Discussions

The data provided suggests that it is only a minority of patients discharged from hospital – the highest group for readmissions and death – who are referred to the community specialist heart failure nurses. This may in general explain the high readmission rates in the all groups. This is a finding that will need further evaluation outside of this project.

There seems little difference between the historic usual care and usual care groups.

The frequency of heart failure nurse clinic reviews are surprisingly greater for the usual care group in comparison to the project active group up to 3 months after hospital discharge. However there is no difference between the usual care group < 75 and the project active patients. This suggests that older patients may have greater heart failure nurse need and are therefore prioritised for review over the 6 month period.

Equally younger patients may respond better to telephone triage and therefore may have been contacted by other means apart from a face to face interaction.

The restrictions on the community heart failure service during the peak of the COVID pandemic do not appear to have reduced the numerical mean number of visits per patient

at any time period of interest when comparing the usual care groups from 2017/18 and 2019/20 respectively.

Project active patients with hefef are seen more frequently than project active patients with hefpef which is unsurprising given the need to titrate medical managements to improve symptoms and prognosis and which are demonstrated in trials to reduce hospitalisation.[1]

The relatively low mean number of community heart failure face to face reviews do not explain the reductions in readmissions seen in the project active group in comparison to the usual care or usual care < 75 years old groups.

#### References

1 Nice Chronic Heart Failure Guideline 2018.

<https://www.nice.org.uk/guidance/ng106/resources/chronic-heart-failure-in-adults-diagnosis-and-management-pdf-66141541311685> accessed 19/09/2020

## Digital Partners and Telehealth Co-ordinator and groups of special interest

### Recap Health

Recap Health is a digital library accessed via patient or their carer's email address. Patients are invited to register on the website. They then activate their registration and agree to receive content.

Content consists of packs of patient education or information under a global heading.

Each bundle consists of multi-media content – reading material, links to other useful website information etc. The content was curated by The Pumping Marvellous Foundation and approved by the UHNM cardiothoracic directorate governance meeting.

Once the Recap Health site is accessed patients have a baseline content package of education and information. New content is 'pushed' to the patient's individualised library by:

- patients requesting more information from their clinicians
- clinicians' feeling that a certain topic within a bundle or a whole bundle of content may benefit the patient at this particular time.

The patient content packs were titled:

Packs = 12

1. HF: New Diagnosis
2. Rehabilitation
3. Medications
4. Tests and Investigations
5. Reasons for HF
6. Cardiac Devices
7. Living with HF
8. Coping with the Emotional Impact of HF
9. Breathing Techniques
10. Power of Attorney
11. Palliative Care

## 12. Newly Diagnosed

Items of content = 129 entries- composed of:

- Videos = 49
- Webpages = 43
- Leaflets / Booklets = 44
- Audio = 4
- App = 1

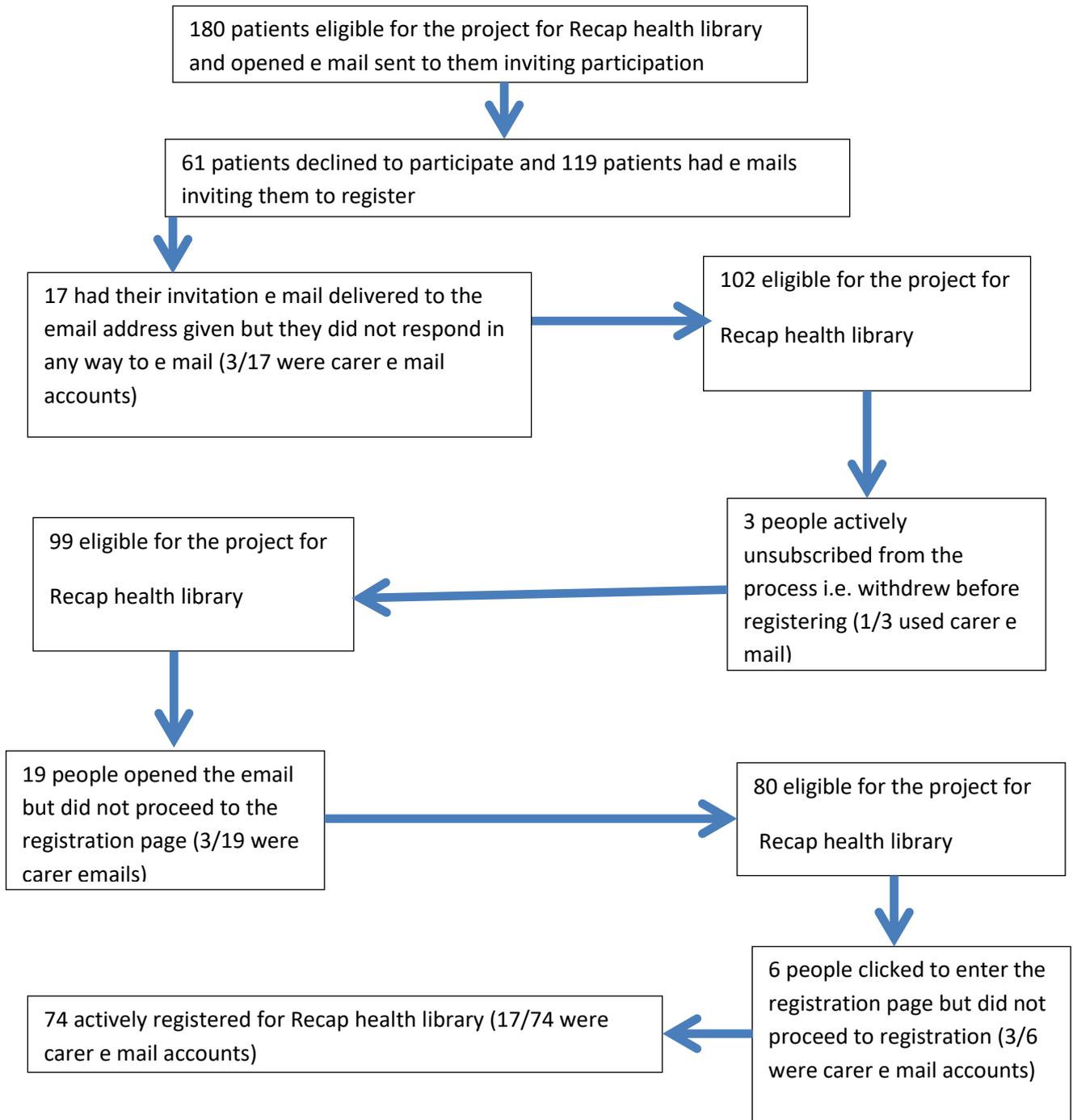
\* some content includes video and webpage or webpage and leaflet

The initial registration process required the patient to be at home when registering which led to some patients not registering with the system. This registration process was changed so that patients could also be registered at the same time as the Tele health Co-ordinator enrolled the patient. This led to an improvement in the numbers of eligible patients that enrolled.

### **Patient Enrolment**

Figure 1 below demonstrates a flow chart of patient enrolment that led to the final number of patients enrolled on the project using Recap Health library.

**Figure 1 Recap Health flow chart of outcomes from the 119 patients who agreed to share their (or their carers) e mail addresses to register for use of the Recap Health Library.**



- 86% of patients registered within 7 days of invitation being issued
- 51% of patients registered within 1 day or less of the invitation being issued.

## Patient Utilisation

### Demographics

61/74 patients were active in the project using both the Recap Health library and Flo interactive texting. Their mean age and sex distribution are shown below in Table 1.

Table 1 age and sex distribution of all patients using the Recap Health Library

Group	Total number of patients	Number by sex (Male, Female)	Age (Mean, St Dev)
<b>Total Patients using Recap Health Library</b>	74	(48, 26)	(66, 13)
<b>Patients using only Recap Health Library</b>	13	(11, 2)	(65, 15)
<b>Patients using Recap Health Library and Flo</b>	61	(37, 24)	(67, 13)

The mean number of days patients had access to the Recap Health library – up to end of data collection on 13/06/2020 was 193.1 days (SD 73.9).

The age group distribution of patients using the Recap Health Library is shown in Table 2.

Table 2 The mean age and sex distribution of patients using Recap Health in the under and over 75 years old groups.

Group	Total number of patients	Number by sex (Male, Female)	Age (Mean, St Dev)
<b>Total Patients using Recap Health Library with age &gt; 75</b>	19	(12, 7)	(82, 4)
<b>Total Patients using Recap Health Library with age &lt;= 75</b>	55	(36, 19)	(61, 11)

## Content viewed by patient

Only 6 of the 74 patients who actively registered on Recap health did not look at any content.

The mean number of times patients accessed content over the duration of the project was 20 (SD 37.2)

The graphs below demonstrate:

Figure 1 – total number of content views over time. Of the 74 patients

- 43 patients looked at 8 or fewer pieces of content
- 31 patients looked at 9 or more pieces of content

Figure 2- average number of views of content per month. Of the 74 patients:

- 6 viewed no content
- 42 only viewed content in the first month
- 26 viewed content for 2 months or more

Figure 1 – Total number of patient content views per month

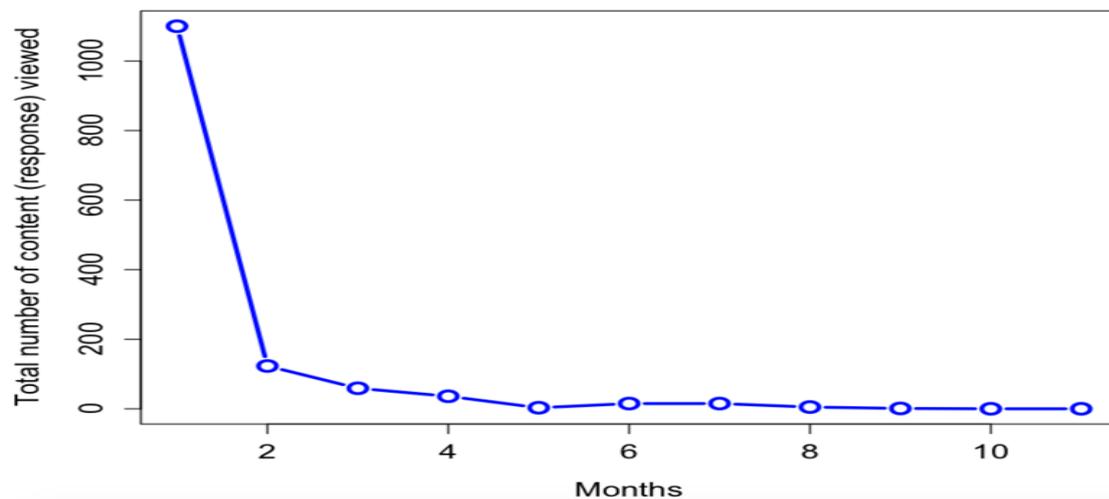


Figure 2 – Average number of patient content views per month

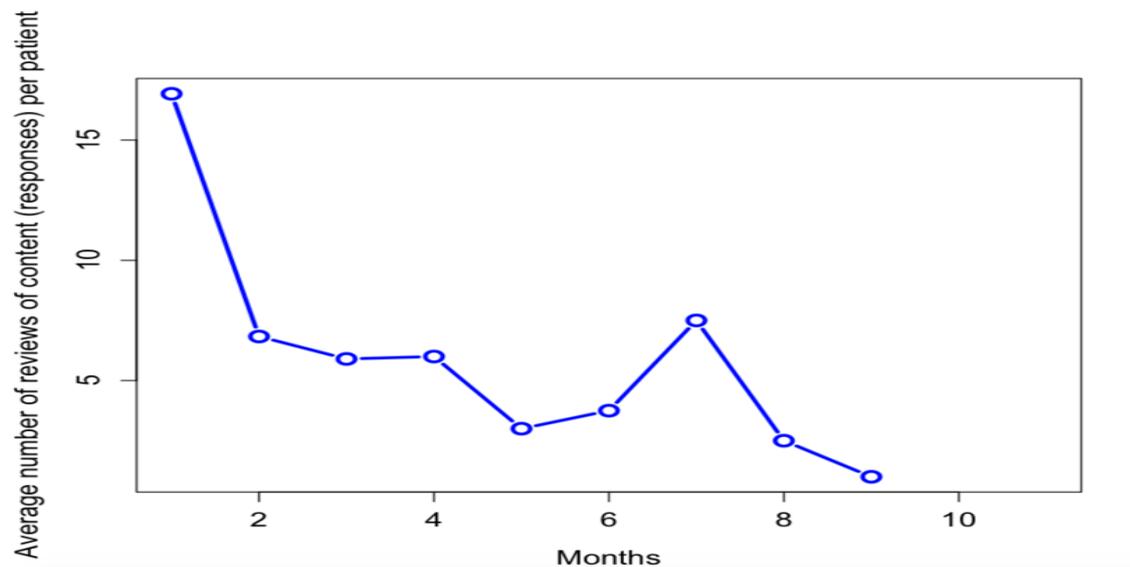
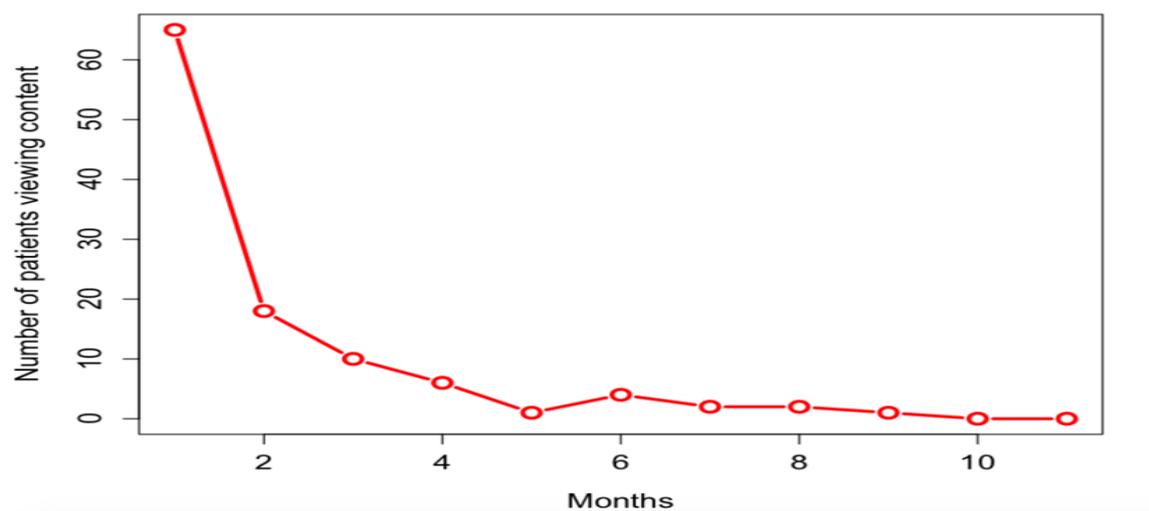


Figure 3 Number of patients viewing content each month



**Content accessed via own email or content accessed via carer**

There was no difference to content access if it was achieved through the patient’s own email address or that of their carer – see Table 3a+ b

**Table 3 a- Mean content reviewed based on whether the email address used to access Recap Health was the patient’s own or their carer’s.** There was no statistically significant difference between the 2 groups

	Average number of views of content per patient (mean, SD)
Patients who used their own email	(11, 30)
Patients who used carer email	(12, 30)

Table 3 b – Mean content accessed based on patients age or sex. There was no difference of content views based on age or sex

	Average number of views of content per patient (mean, SD)
Age > 75 n=	(18, 34)
Age < 75 n=	(20, 39)
Male	(30, 54)
Female	(14, 23)

### Outcomes and Recap Health

The patients on both digital products far outnumber those on Recap Health alone. Therefore there is likely to be greater effect of both products in any statistically meaningful comparison. We therefore demonstrated the change in the KCCQ self-efficacy score over time as a potential impact of Recap Health (and Flo) Table 4 on a patients education and self-management off their heart failure.

**Table 4 The effects of the amount of content views and the duration of content views on changes in the KCCQ self-efficacy score from discharge / enrolment to 3 months post discharge** (a marker of a patient’s understanding of whether they understand the symptoms and signs of heart failure deterioration and what they can do about it). All groups (whether they looked at > 8 pieces of content or whether they looked at content for 1 month or less) improved their KCCQ scores.

Category Change in 3 month qol scores i.e. 3 month discharge score)	All users of recap n 74 (mean, SD)	Recap users looking at > 8 pieces of content n 31 (mean, SD)	Recap users looking at 8 or fewer content n 43 (mean, SD)	Recap users looking at content for 2 months or more n 26 (mean, SD)	Recap users only looking at content in first month or no content n 48 (mean, SD)
KCCQ Self efficacy score	(25, 23) n = 32	(30, 22) n = 13	(21, 24) n = 19	(24, 22) n = 29	(29, 36) n = 3

**Content Comments and Usefulness Survey of interaction with Recap Health**

24 patients provided comments on content 15 of which also expressed their views about the usefulness Recap Health. There were 115 comments on content - mean number of comments per patient on content was 5 (SD 8)

The pie chart – Figure 4 - below demonstrates the responses as a proportion of the total.

**Figure 4 Pie chart demonstrating comments to the content in Recap Health library. 91% of returned responses suggested that content was either very useful or useful.**

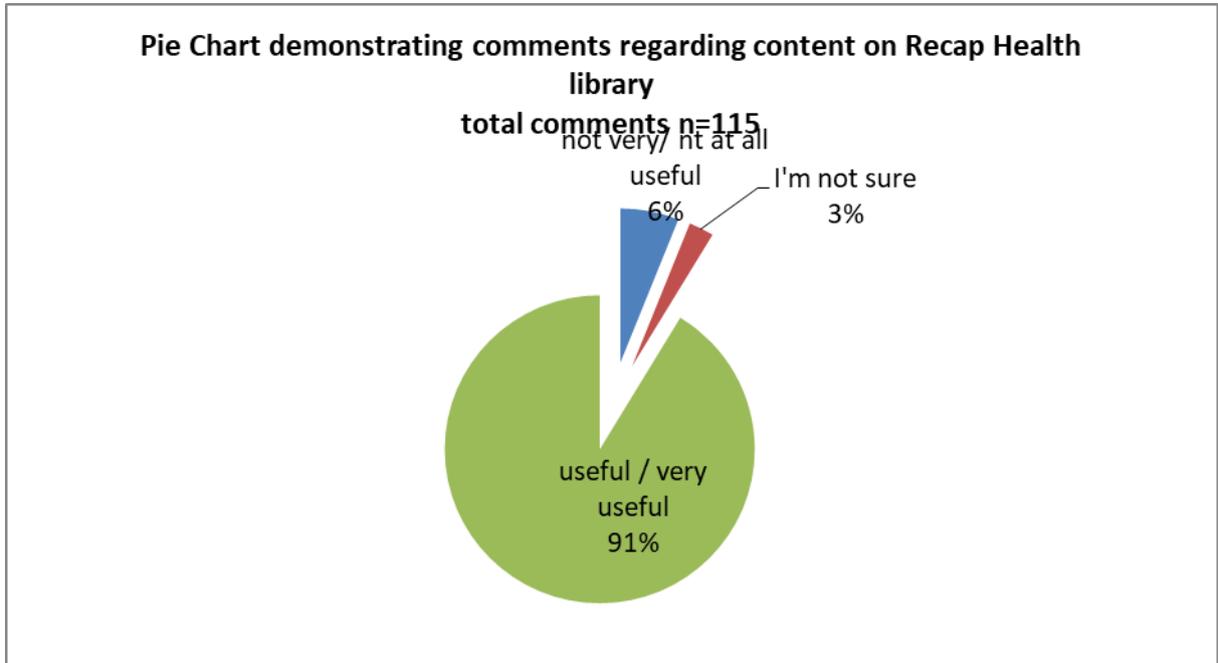
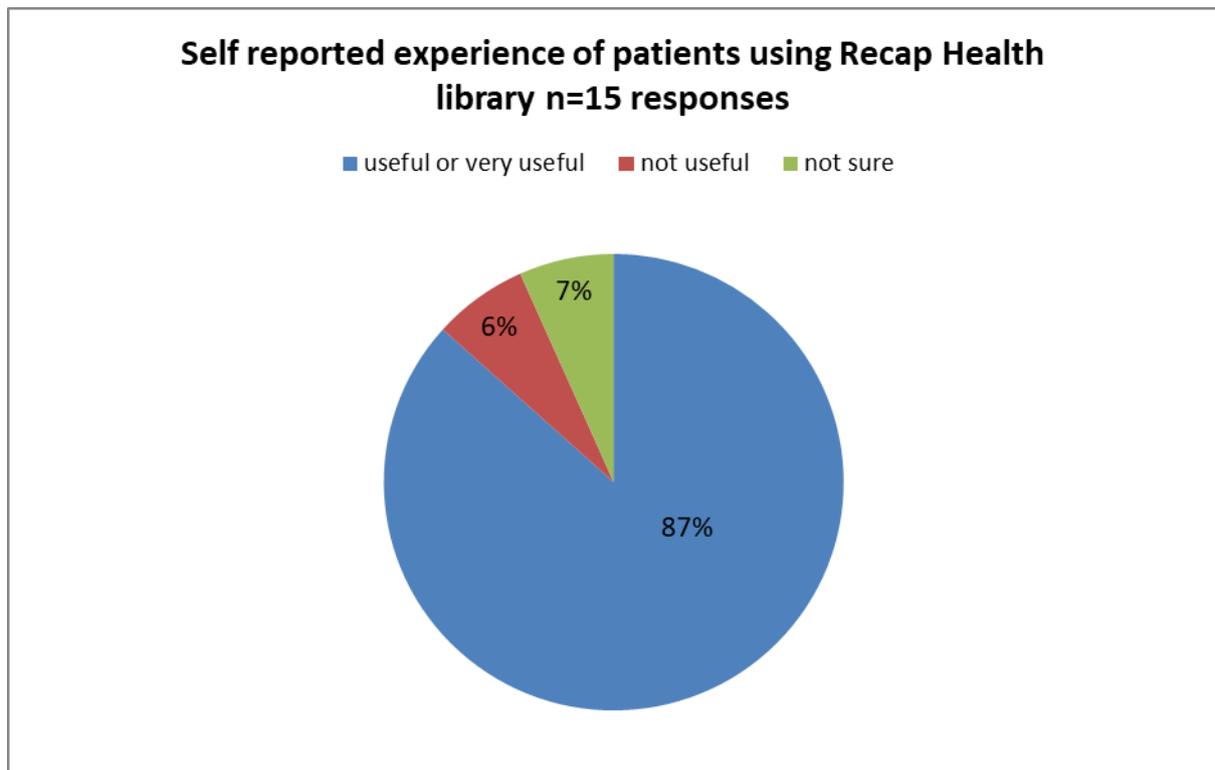


Figure 5 demonstrates the patient’s experience of using the Recap Health library

**Figure 5 Patient self-reported experience of using Recap Health library. The response was useful or very useful in 87% of respondents (n=15)**



## **Discussion**

The improvement in registration process has improved the number of patients active on Recap Health over time and demonstrates the responsiveness of the product to need within the project.

### **Access to content**

Patients access content on their Recap Health library as often through their own individual emails as when they use their carers email.

There is no difference between the use of Recap Health based on age or sex either.

The majority of patients view content within the first 3 months. A greater number of prompts or new content may help stimulate content view over a greater period of time. Equally patients may have all of the information they need after their first month of concentrated product views. It is also hoped that using digital products in this way encourages patients to explore other heart failure educational and support sites such as Pumping Marvellous Foundation, British Heart Foundation, Cardiomyopathy UK etc.

Patients KCCQ self-efficacy scores improve whether they access 8 or fewer content or whether they view their library in the first month only.

## **Content**

Although only 32% of patients commented on content, the comments were positive in 91% of cases. This is unsurprising as the Pumping Marvellous Foundation is one of the 3 trusted sources of patient data in the NICE Chronic Heart Failure guideline 2018.

Although only 20% of Recap Health Users commented on their experience of using Recap Health, the comments were positive about their experience in 87% of cases.

Other supportive data on the patient experience with Recap Health are available in the Qualitative evaluation section. That chapter reports on the experience of nearly 65% of our total active patient group. – (see Section Qualitative evaluation of the Intervention pages 157-180)

The patient experience with Recap Health was positive for most patients. There was also evidence that patients used their Recap Health library. Patient need for their library content was predominantly within the first 2 months after discharge / enrolment into the product.

Improvements to the product may include more varied content to account for patients co-morbidities – to help reduce non-heart failure morbidity in the heart failure population.

## Actual comments about experience with Recap spelling as entered by patient

Very good guide just the job
Good tips all round
Very simple and positive
You can see what you been told
Simple easy to understand language
Although I knew some of the things mentioned it helped me to understand this is not necessary the beginning of the end of my life and I can get help and reassurance. It helped me to stop panicking.
Already practise first and third but didn't know about the fan.  Will try it when I think I it will help me.
Had not tried this before, certainly felt more relaxed. Will use this again.
Gives a hope that life can get back to normal or somewhere near.
Mum is quite infirm, unsteady on her feet and gets out of breath. I think she needed this earlier in her illness. I would love my mum to be able to take some exercise.
Taking part in this project on behalf of my mum who is 84 and living with heart failure dementia and old age, I wish she was able mentally to access the information both mentally and physically. Thank you.
helped me to understand more by watching and listening to videos
Helps to understand.
Shows what help there can be.
It was good to actually see what happens on the day and how the device is fitted.
I found listening to different peoples stories useful. I picked out information suitable to my personal condition.
It's good to be positive

Maybe give information on how to start exercising and building up as I am frightened of overdoing it.
Reassuring.
This has given me good information.
I found this most informative and I do a fair amount of travelling.
It was good to know how the heart works.
The film reassured me about going for an echocardiogram.
Good for Information.
I just keep going back to this site to read the booklet over again as there is a lot of Information to take in.
Another booklet with lots of information.
This information is very reassuring.
It was very good to see this technique as it takes your mind off of the problem and helps you to relax.
Very soothing and relaxing.
It's good to listen to someone who has actually experienced breathlessness.
Seeing the actual video of an operation keeps me informed of what could happen.
I think a carer needs this kind of support.
This video gives me the confidence that I can still exercise and that it shouldn't do me any harm.
I like this because it is all in the one place and I don't have to search for the information. Thank you
I am breathless and tired do I have heart failure? So what should I do? I was breathless and tired and I had iron deficient anaemia and HF so a double whammy treated for anaemia showed Dr swollen ankles, he said nothing you'll be better in a month after the iron tablets. Had to go back to Dr's 2 weeks later with very swollen legs referred straight to AEC and the rest is history.
It explains all the symptoms I should be looking for

## Florence Simple telehealth 'Flo'

Florence, better known as Flo is a smart text messaging service which has been used with over 100,000 patients in 60 different health conditions.

Flo is part of the NHS Test Bed Programme 1 site service evaluation and is therefore a technology familiar to Innovate UK. We had previously completed a very small scale pilot with Flo in heart failure that led to this larger scale pilot.

In the current project, once a patient has agreed to take part in the project, the patient is then signed up to Flo and is required to opt in to enable further communications from Flo.

Alternate texts requiring responses were sent to the patients asking whether they are:

- Better, worse or the same as when they last responded to Flo
- Red, amber or green on their symptom checker – appendix 1

Messages were sent at the scheduling days at 11am and if no response to the message was received then a reminder question was sent to the patient to remind them that they hadn't responded to the first initial request.

Patients could opt out of receiving further messages at any time by replying to Flo with STOP.

The baseline question asks patients (at the time of discharge or enrolment into the project), whether they felt better, worse or the same in comparison to their best health in the last 3 months.

Patients were contacted by the Tele Health Co-ordinator if the response was 'worse' , 'amber' or 'red'. The Tele Health Co-ordinator would then direct the patient to the most appropriate source for resolution of the reason for their response.

In addition to the interactive messages there were supportive messages requiring no text response. These were:

- Messages asking patients whether they had looked at their Recap Health library
- Whether patients required any other content for the library
- Whether patients needed any additional information from the heart failure team
- Messages to support patients who felt anxious or depressed and advised them to discuss this with the heart failure team

A patient satisfaction survey was sent to the patient when they had completed their period on the protocol. 11 patients withdrew/opted out from participation before they received their surveys.

## **Frequency of monitoring**

Monitoring through Flo was due to be for 6 months and so protocols were developed for: the first 2 months and then 1 month thereafter for a maximum of 6 months.

The delay to starting the project meant that the protocols were changed to 3 months. A separate 3 month protocol was subsequently produced (All protocols in appendix 2).

The minimum number of questions requiring a response for the 3 and 2 month protocols were:

- 3 month protocol minimum number of questions = 65 (including baseline question)
- 2 month protocol minimum number of questions = 41 (including baseline question)

The most total number of questions sent to any patient was 115 in a 3 month protocol to a patient that did not opt out.

77 patients were added to the 3 month protocol and 13 patients were added to the 2 month protocol.

Each protocol had:

- an initial phase of intense interactive texting (alternate day questions for 6 out of 7 days for 2 months of the 3 month protocol and 1 out of 2 months for the 2 month protocol) – minimum 48 questions over 2 months
- a 1 month second part of the protocol of interactive texts for 4 out of 7 days – minimum 24 questions in a month

## **Summated responses to better worse or the same**

An arbitrary health score was created to reflect the total numbers of better / worse/ the same responses over the entire protocol.

Each response was weighted as below:

1. Total number of worse responses X (-1)
2. Total number of 'same' responses X (0)
3. Total number of 'better' responses X (1)

The baseline score (if available) was noted and the scores were summed to the end of the patients protocol n=76. There were no baseline scores in 12 patients. These patients had their scores for their responses to the 2 parts of their protocol only. An overall positive score meant that patients had answered 'better' more often. An overall negative score meant patients had answered 'worse' more often. A zero score meant a combination of better /

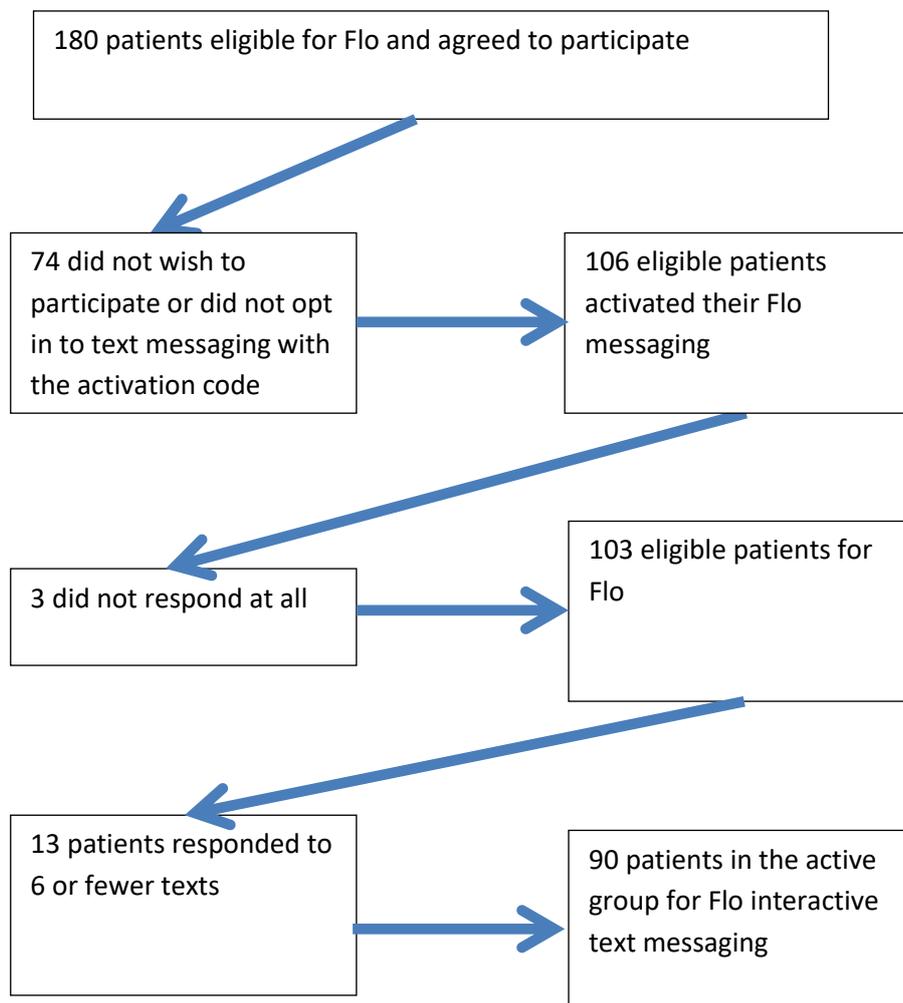
worse and or the same – but overall any ‘worse’ texts would have been cancelled out by any ‘better’ texts.

### Numbers using Flo

There were 90 patients using Flo – 29 patients were active on Flo alone and 61 were active on both Flo and Recap Health.

The chart below demonstrates how the numbers for active use of Flo arose.

Flo patient ‘waterfall’ – demonstrates the reasons for 90 active patients from the 180 initially approached



The active patients form 56% of patients approached. This reflects in part:-

- the registration process – which initially was activated only once the patient had left hospital, but was changed so that registration could be activated at the same time as their review by the telehealth co-ordinator.

- The timing of enrolment – as it may be more appropriate to enrol patients outside of the high anxiety setting of a hospital visit with acute decompensated heart failure

## Demographics

The age and sex distribution is demonstrated below in Table 1

**Table 1 Age and sex distribution between all patients using Flo, patients using both Flo and Recap Health and patients only using Flo.**

Group	Total number of patients	Number by sex (Male, Female)	Age (Mean, St Dev)
<b>Total Flo Active</b>	90	(55, 35)	(66, 13)
<b>Using Flo only</b>	29	(18, 11)	(65, 12)
<b>Using Flo and recap Health</b>	61	(37, 24)	(67, 13)

Of the 90 patients using Flo:

- 54 were newly diagnosed with heart failure (36 had an established diagnosis)
- 61 had heart failure with reduced ejection fraction (29 had heart failure with preserved ejection fraction).

## Use of Flo

There were 90 patients who answered the 'red/amber/green' questions in the first part of the protocol and 72 who answered the same question in the second part of the protocol – a 20% 'drop out' rate.

There were 90 patients who answered the 'better / worse / the same' question in the first part of the protocol and 76 in the second part – a 16% 'drop out' rate.

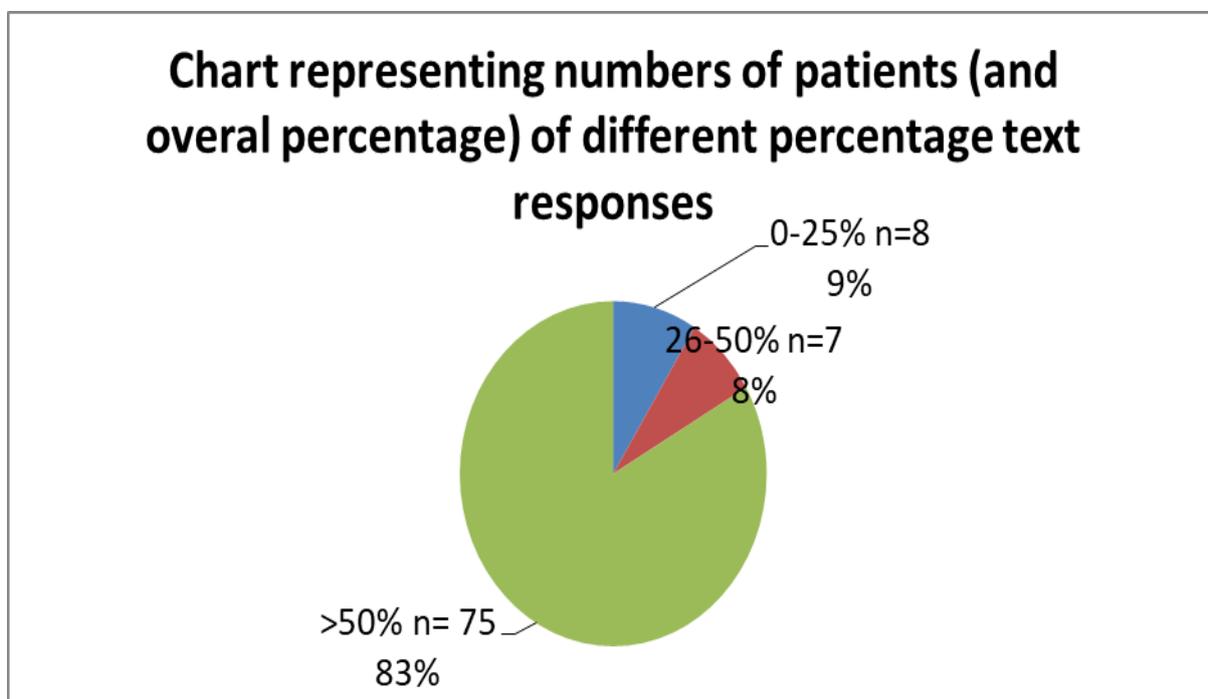
## Responses to Flo

### Overall

The maximum number of texted questions should be 5538, but there were 5128 texted questions overall. This reflects the number of patients that opted out of the project. The mean percentage response rate was 77% (SD 27.2).

The chart below (Figure 1) demonstrates that 83% of patients responded to more than 50% of texted questions

**Figure 1 Percentage response rate to questions from Flo: 0-25%, 26-50% and 51% and above response rates. The majority of patients respond to more than 51% of possible questions from Flo. This reflects good patient engagement with Flo.**



### Change in summative responses to better/ worse/ the same

At the time of enrolment / discharge patients overall summed responses when compared to the best they had felt in the last 3 months were:

- 15 felt worse (19% of all scored)
- 35 felt the same (45% of all scored)
- 28 felt better (36% of all scored)
- 12 did not provide scores

Of the 76 patient's texting to 'better / worse / the same' questions in the second part of their protocol:

- 53 had an overall positive count – ‘better’
- 19\* were neutral – ‘the same as their baseline text – if available’
- 4 were negative – ‘worse’.

\*The discharge / enrolment answers of the 19 who were ‘neutral’ at the end of their second part of the protocol were:

- better than their best health in the last 3 months– n=2
- Same as the best health they had felt in the last 3 months n=11
- Worse than their best health they had felt in their last 3 months n=3
- No response n=3

We suggest that demonstrates an improvement in health (or maintenance of the best health patients had felt 3 months prior to admission/ enrolment) in 66 of the 76 patients (87%).

### Responses to Red amber Green and better same worse

There were surprisingly few patients who responded red or worse – and the majority of these were in the first part of the protocol as shown in table 2 below.

**Table 2** The number of each potential response in both Flo Protocols. The majority of either red or worse responses were during the first part of the protocol. The total percentage of red answers was 1% of the total.. The total percentage of worse answers was 2% of the total. Thirty three patients (33/90 = 37%) responded red or worse at some stage of their interaction with Flo.

Protocol	Responses as( %) total and n=) number of individual patients responding			
	Red(% total)	Amber	Green	Total
Protocol 1 n 90	16 (1) n=10	325	1057	1398
Protocol 2 n 72	2 (0.1) n=2	139	362	503
	Worse (% total)	Same	Better	Total
Protocol1 n=90	40 (3) n=22	1059	367	1466
Protocol 2 n 76	7 (1) n=6	398	121	526

### Red / worse vs. no red/worse responses and readmissions

Anyone answered Red or Worse	3 month	6 month
Hospital readmission	36% (12) n = 33	76% (13) n = 17 p=0.04 <b>(significant)</b>
A&E readmission	15% (5) n = 33	47% (8) n = 17
Non Red/Worse Group		
Hospital readmission	21% (12) n = 57	32% (10) n = 31
A&E readmission	19% (11) n = 57	26% (8) n = 31

These are small numbers and we therefore compared the 6 month all cause readmissions to hospital between patients answering 'red' or 'worse' at any stage with patients who did not. The hospital readmission is usually inclusive of an A and E attendance also. Patients who answered 'red' or 'worse' only accounted for 56% of all readmissions to hospital for all users of Flo. However they had a 76% all cause readmission rate to the 32% of other users of Flo at 6 months – a relative increase of approximately 140%.

### Frequency of response and Readmissions

We determined whether there was a correlation between the response rate to Flo interactive texts during the predominantly 3 month protocol and to see whether there was any longer term effect of using Flo and having on-going access to the Recap Health library. This is demonstrated in the correlation table 3 below.

Table 3 Correlation between response rate to Flo compared to readmissions at different time points. Frequency of Flo did not impact on A and E readmissions. However there was a significant negative correlation (more you interact with Flo the less you were readmitted) at 3 months. It is also significant when patients were no longer active on Flo at 6 months.

Correlation analysis	0 month	3 month	6 month
Hospital readmission VS response rate	-0.34 (p-value: 0.001, significant)	-0.30 (p-value: 0.003, significant)	-0.26 (p-value: 0.014, significant)
A&E readmission VS response rate	-0.13 (p-value: 0.221, insignificant)	-0.25 (p-value: 0.018, insignificant, due to Bonferroni)	-0.23 (p-value: 0.028, insignificant, due to Bonferroni)

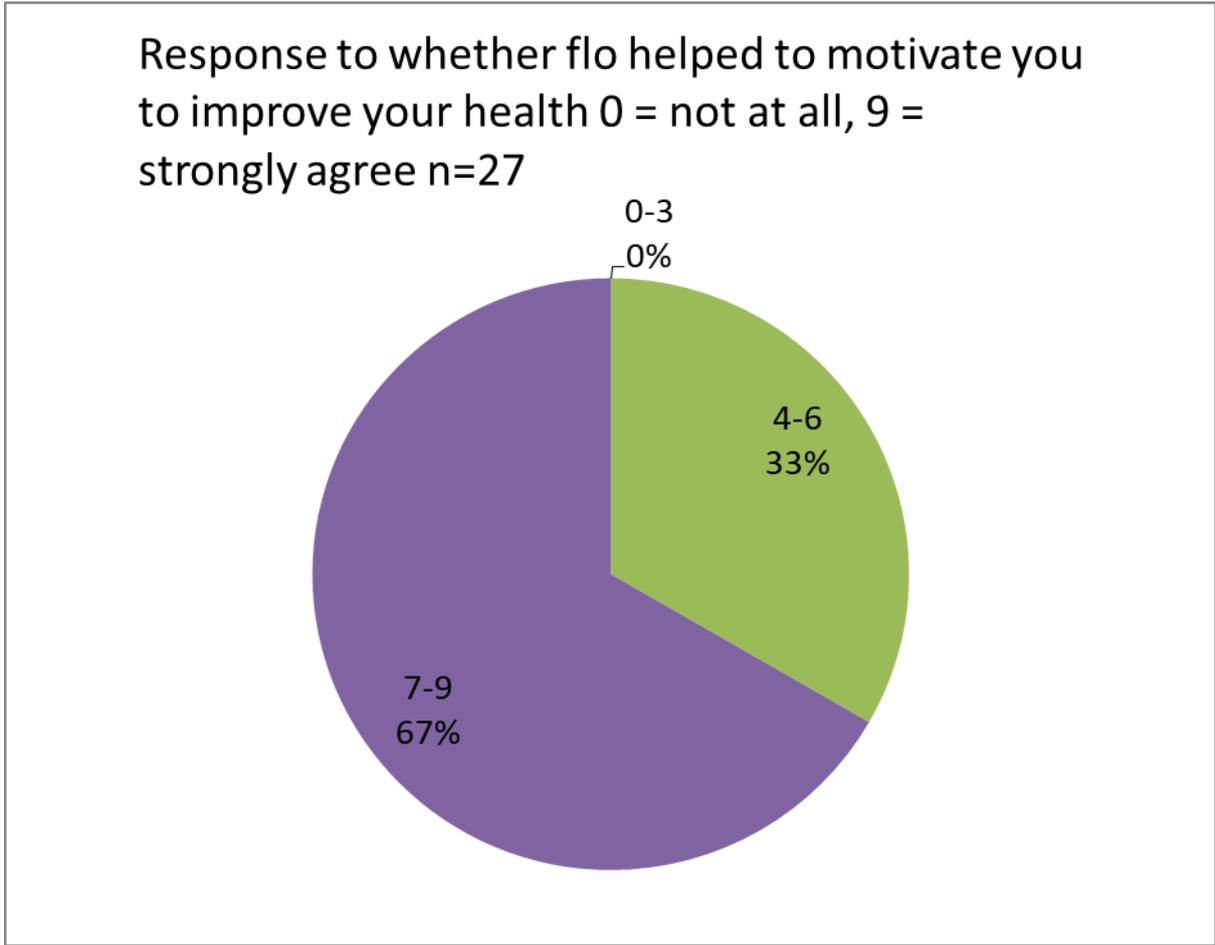
### Patient satisfaction

Of the 41 patients who responded:

- 39 would recommend Flo to Family and Friends (95%)
- Of the 37 patients who responded 33 felt that being on Flo had improved their understanding of heart failure (89%)
- Of the 31 patients who responded 27 felt Flo had helped them manage their heart failure better (87%)

Patients were also asked whether they were motivated to improve their health following their interaction with Flo (n=27).

The results are presented in the pie chart below.



**Discussion**

Only 56% of patients eligible to participate with Flo were in the active part of the project.

We feel this number would be improved if enrolment occurred outside of hospital as our patients interacted well with Flo and responded to a mean of 77% of texted questions and would recommend Flo to friends and family.

Being a user of Flo reduces your risk of all cause hospital readmissions even at 6 months. It is interesting that the effects of interacting with Flo persisted outside of patients’ direct involvement with Flo i.e. after the majority of patents had stopped using Flo at 3 months. It is therefore possible that the education and self-management underpinning the use of Flo and Recap Health persists. This is reflected in the Flo survey responses, which suggests that patients also learned about and improved their understanding of their health.

The ‘red’ or ‘worse’ responses appear to highlight a group who remain at risk of readmission. But they do not uniquely identify all patients who are likely to readmit. It is interesting that once patients no longer have access to the Tele Health Co-ordinator routinely there is a difference to all cause hospital readmissions at 6 months. We will

consider user focus groups to add additional criteria to the symptom checker that captures more of the nuanced symptoms or signs of deterioration.

We would additionally consider altering the protocol such that patients who texted 'red' or 'worse' in future would automatically receive unprompted Tele Health Co-ordinator supporter for a period of time:

- Corresponding to the date of the text e.g. phone contact 2 times per week for the next 4 weeks – to detect any deterioration in mood or symptoms that may warrant intervention to reduce readmissions further
- Extending the Flo protocol to 6 months for that individual

The majority of patients (87%) feel the same or better than the best health they felt before admission / enrolment to hospital which is a testament to their in-hospital treatment.

Nearly a quarter of patients feel worse at some stage of the first part of their protocol. Further protocol and pathway amendments may reduce readmissions in this group further.



**GREEN - KEEP WATCH**

Your weight has not increased/has increased by 4lb/2kg over 3 days but you agree with the statements below;



You are no more breathless than usual.



Your ankles are no more swollen than usual.



All of your other medical conditions are OK.



You are as active and mobile as you normally are.



Your main carer's health is unchanged.

**WHAT SHOULD YOU DO?**

There is no need for a review by the heart failure specialist team/GP/Practice Nurse apart from your regular reviews. However, you should be reviewed at least twice a year.



**AMBER - STAY ALERT**

Your weight has increased/had increased by 4lb/2kg over 3 days and/or one of the statements below is true;



You are feeling more breathless than usual.



Your legs are more swollen than before.



You are breathless at night or need more pillows to sleep on.



You are unable to be as active as usual/you are a bit more muddled than usual.



Any of your other conditions are worsening.



Your main carer is becoming more ill and unable to help look after you as much as before.

**WHAT SHOULD YOU DO?**

Try simple measures to improve your symptoms and/or consider a sooner appointment with the heart failure specialist team/GP/Practice Nurse if you feel it is necessary.



**RED - TAKE ACTION**

If your symptoms continue to worsen over 3 days, or you have any of the problems below;



You have symptoms of an infection and/or you feel very unwell.



Any of your other medical conditions are continuing to worsen.



You have blacked out.



You have become confused about your medications.



You have had diarrhoea or vomiting for more than 24 hours.



Your carer becomes very ill/has been admitted to hospital and is unable to take care of you.



You have worsening breathlessness or leg swelling or are unable to be as active as usual.



You have worsening or new angina.

**WHAT SHOULD YOU DO?**

Consider urgent advice from GP, or heart failure service. If you feel very unwell, call 999.

This Marvellous Symptom Checker has been put together by the Pumping Marvellous Foundation and developed with NHS heart failure teams and patients from Staffordshire. Sponsored by an unrestricted grant by Novartis. For details of any terms you don't understand please visit the patient academy on the Pumping Marvellous website.

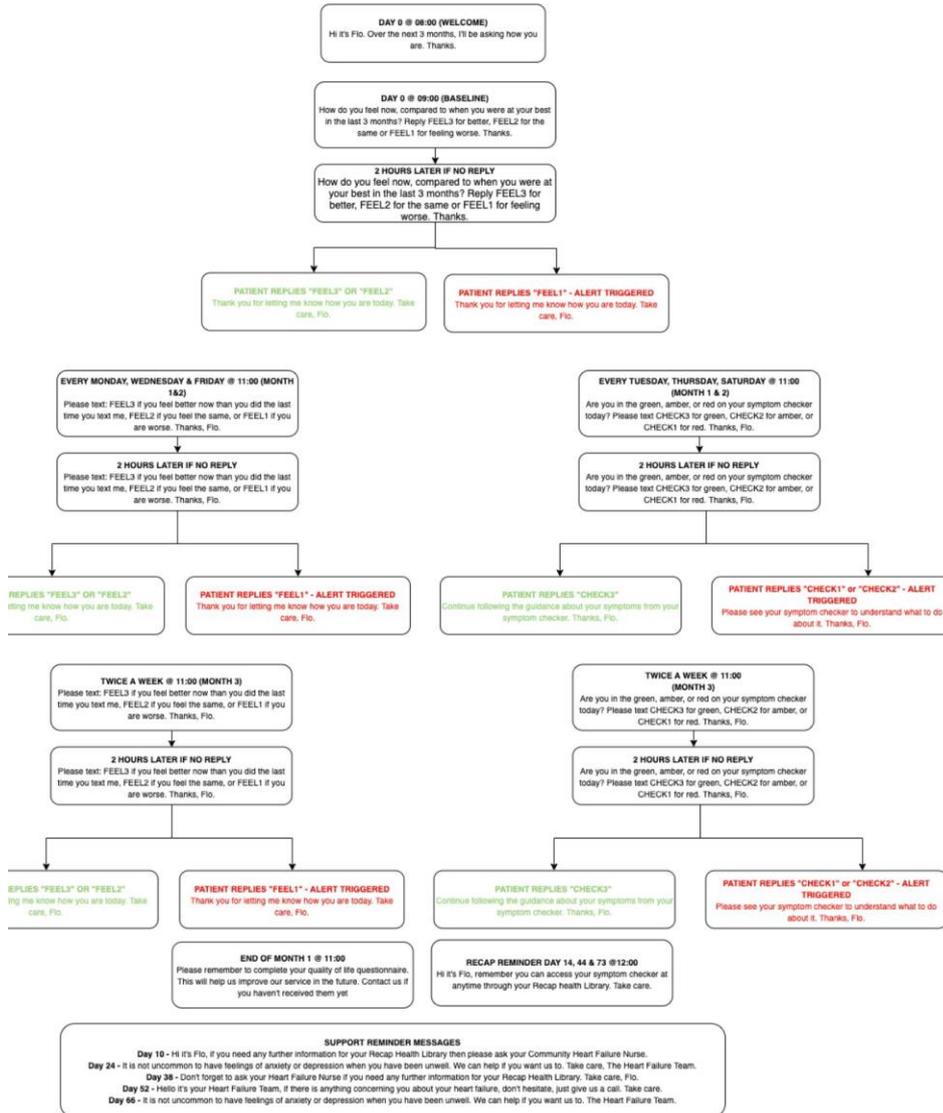


**Appendix 2 – Flo protocols**

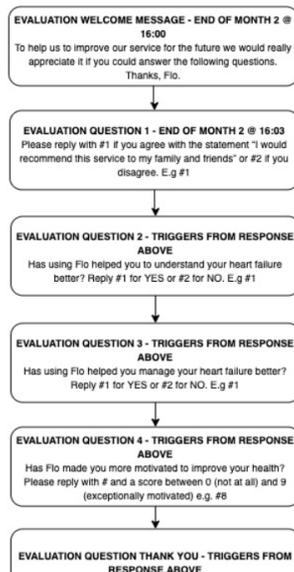
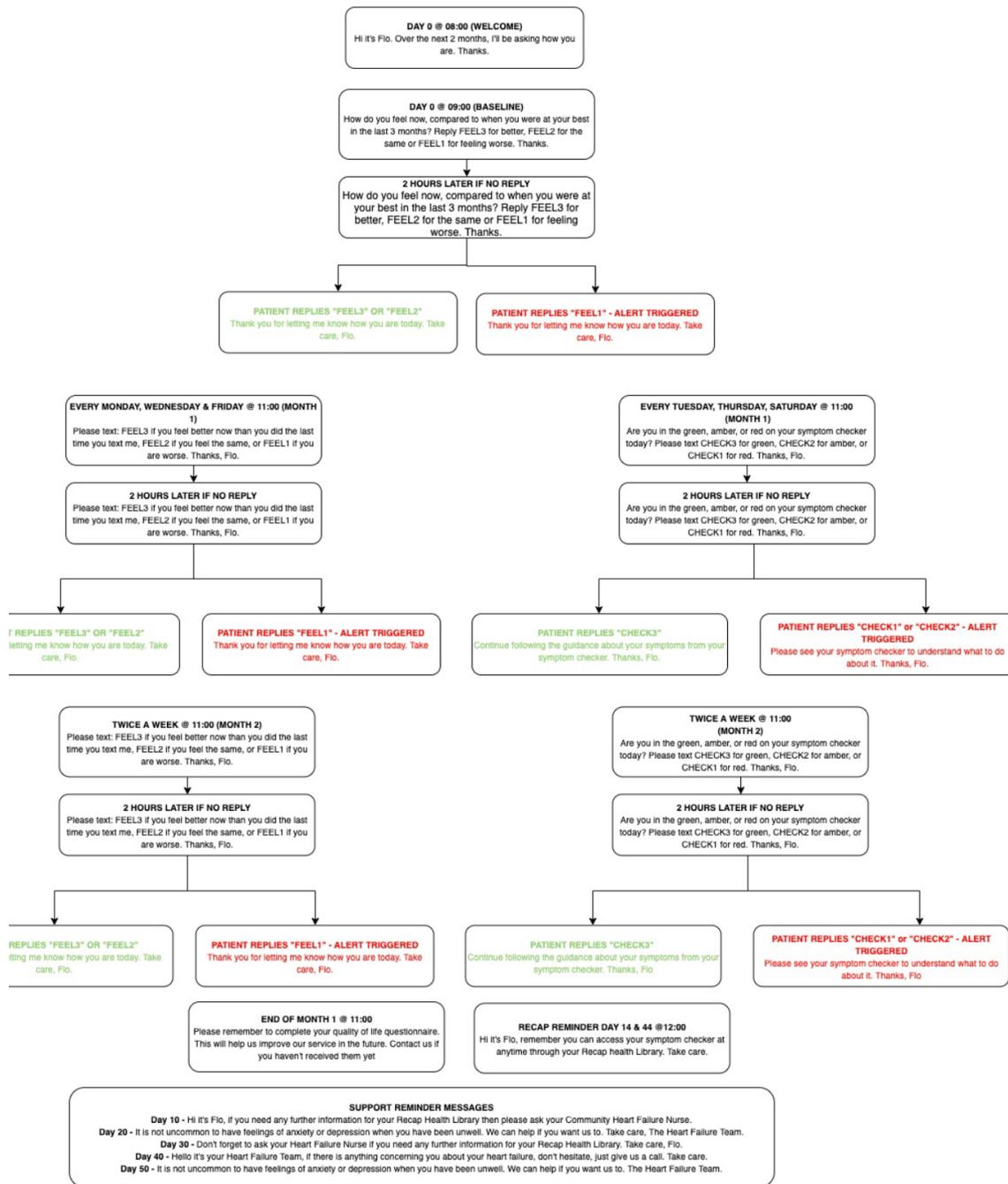
**3 MONTHS**

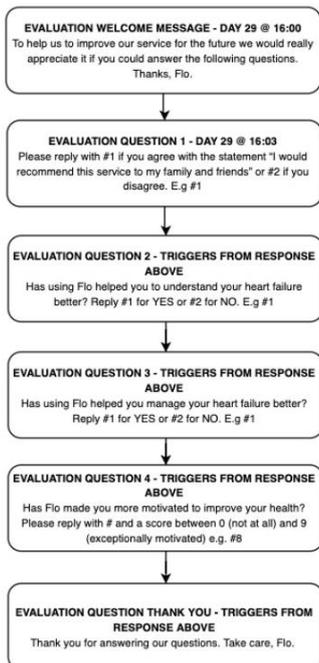
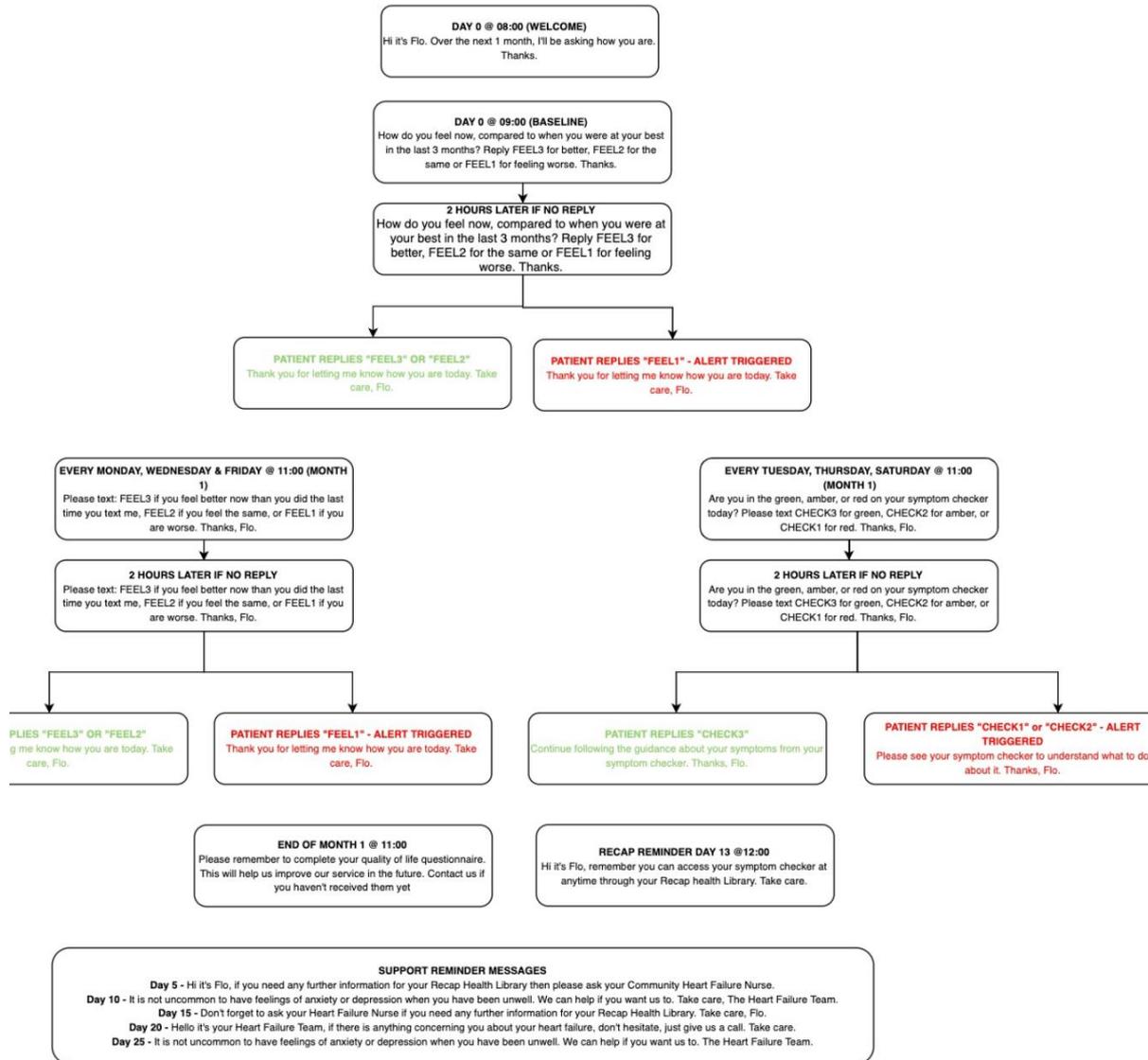
**2 MONTHS**

**1 month**



Approved May 2019





## iNavigator – Signum Health

### **Evaluation of I Navigator**

Social prescribing is a method of using community services outside of the NHS to provide psychosocial support for patients. It deals with problems that the NHS may be less equipped to deal with in a timely fashion such as loneliness, financial worries, anxiety and depression. It is accessed by patients after an assessment by link workers. The link worker then 'links' the patient with community services that may be able to help them

It is a national priority with the government investing in 1 link worker per 50,000 population in England.

We wanted to consider referral to community resources via social prescription of heart failure patients from within the hospital rather than waiting for this to be arranged via primary care.

There is already a small use of community services by the heart failure team with referrals to organisations such as Dove bereavement service and Healthy minds for patients from Stoke on Trent.

### **Aims**

Our aim had been to use the I Navigator platform to use the Tele Health Co-ordinator to refer patients directly to community services or via a central referral hub.

When our project started the local CCGs had not determined the details for setting up a social prescribing network. We did not want to develop a social prescribing network independently of the planned CCG social prescribing pathway.

One of the main issues for setting up a social prescribing network with our project was that the information governance requirements for organisations working with secondary care are comprehensive and unlikely to be fulfilled by small support groups such as 'knit and natter' or walking groups etc. This issue was not appreciated by the CCGs and the solutions were not available through NHS England. Other groups who had published their experiences with social prescribing also had information governance issues that they felt required a minimum of 12 months to 'iron out'.

NHS England suggested in Feb 2020 that we consider a hybrid model where we referred through the CCGs preferred 'hub'.

We had many preliminary talks with the CCG's preferred 'hub' – an organisation called VAST. However this organisation lost its funding for this role during 2019.

This eventually led to the project seeking information governance agreements with 5 larger community organisations: VAST, Aspire Housing, Revival, Beat the Cold, Healthy Minds, and

### Experience with patients

17 patents were referred through I Navigator

- 10 patients were referred to Healthy Minds (for mood related problems) of which there were =- 3 positive comments, 2, neutral comments, 2 uncontactable patients, and 3 patients who were from the wrong CCG for this particular organisation BUT were directed to other websites and materials that could help with their psychological issues.
- 7 patients were referred to an organisation called Revival Housing (3 with financial problems, 2 with housing issues and 2 with mood related problems). There were 3 neutral responses, 2 negative responses and 2 patents could not be contacted for their experience

### Limitations

It is unfortunate that national and CCG and information governance issues did not allow us to evaluate the technology and also the potential for using social prescribing in a secondary care setting.

However we still feel that this is a worthwhile goal to pursue.

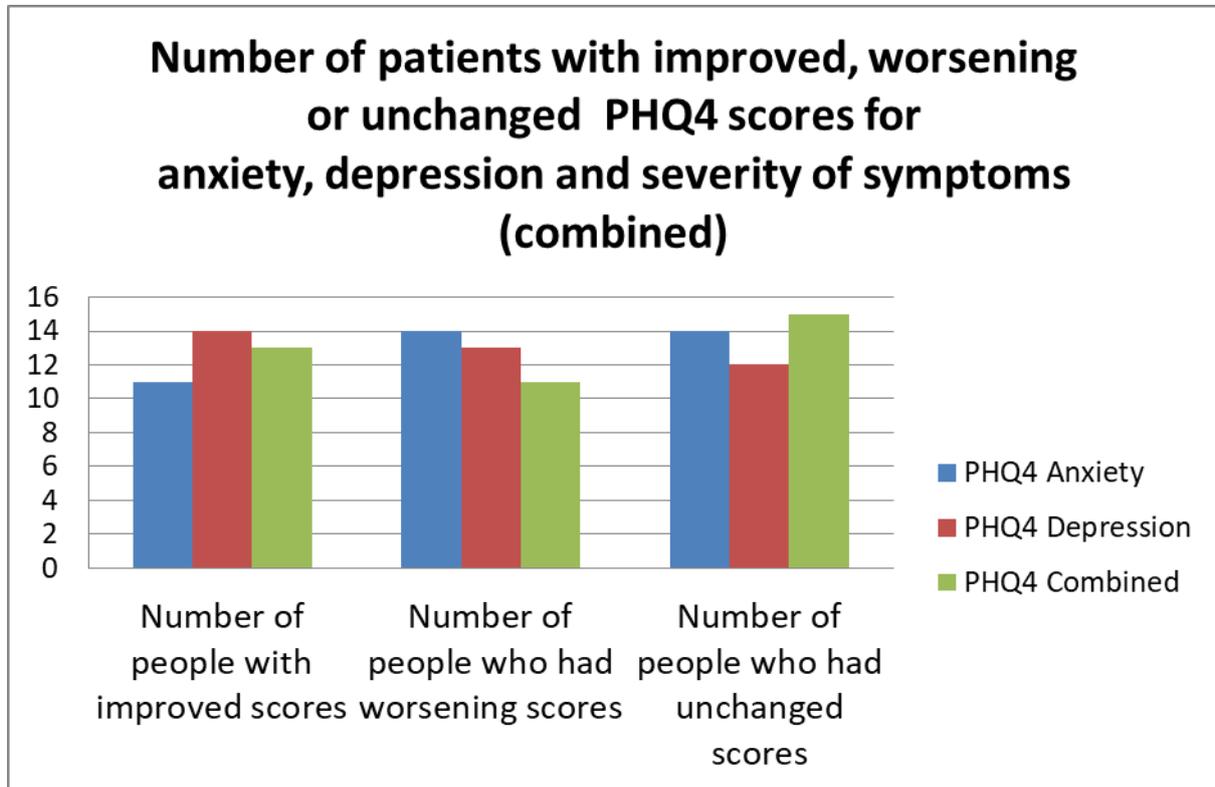
A survey by the Pumping Marvellous Foundation of their closed Facebook patient group is demonstrated below in Figure 1

**Figure 1 Patient responses to a survey on what patients worried about one discharged home**



Figure 2 demonstrates the changes in patients PHQ4 scores between discharge and 3 months post discharge.

**Figure 2 Changes in PHQ4 from discharge to 3 months post discharge in the project active group. This graph demonstrates that there is a significant minority of patients with worsening anxiety, depression and combined scores. The combined score reflects severity of mood problems.**



## Discussion

It is difficult to fully evaluate the benefits of social prescribing from our project. However we have demonstrated an ongoing need for our patients.

Social prescribing will be accessed by heart failure patients in 2020 due to wider initiatives outside of our project. We hope that local co-ordination for referring and evaluating the impact of social prescribing will through the I Navigator platform.

## Tele Health Co-ordinator Role

Recruitment to the role was time consuming due to the recruitment process within UHNM as an organisation in special measures.

During the lifetime of the project there were 6 Tele health Co-ordinators.

The Tele health Co-ordinators were previously:

- Working in R and D consenting patients for the 100,000 genome project
- Data Analyst with Staffordshire University
- Discharge facilitator from the Gastroenterology ward
- PA in Child Health
- Ward bed management / flow co-ordinator.
- Management trainee

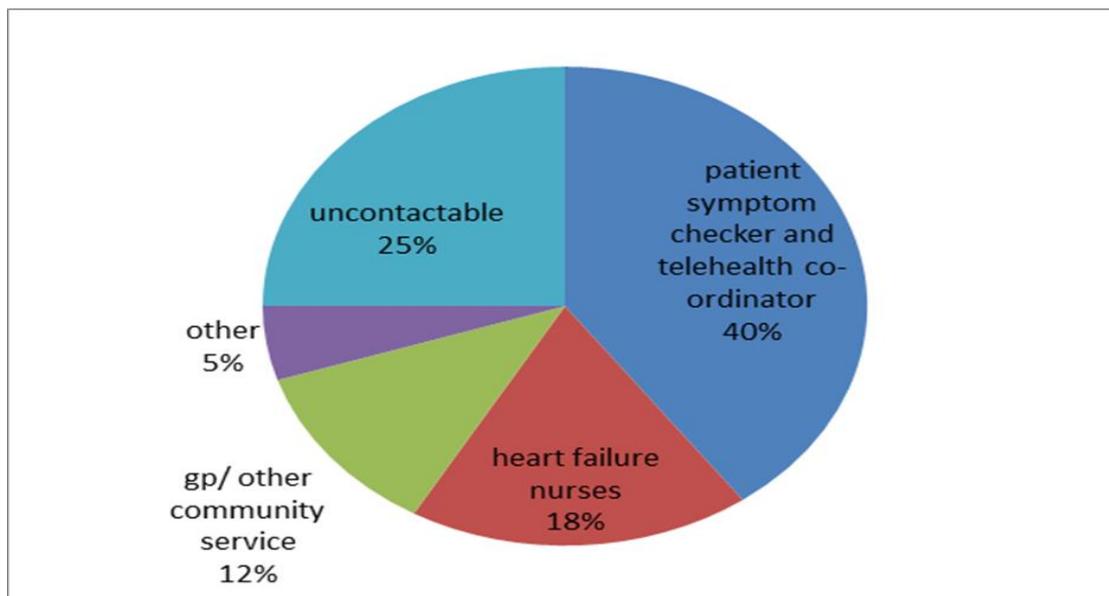
Actions of Tele Health Co-ordinators to texts with replies of 'worse' or 'red'

There were 65 patient responses during their 3 month protocols for 'worse' or 'red'. We have data on the outcomes of the first contact with patients and what the Tele health Co-ordinators were able to facilitate for patients within their scripted options (see Chapter Methodology pages 18-51).

Figure 1 below demonstrates the actions Tele Health Co-ordinators were able to take.

**Figure 1 actions of Tele Health Co-ordinators to 'red' or 'worse' text responses based on initial phone call to patient n=60 text responses ( 5 missing responses i.e. 65 actual 'red' or 'worse' texts from 33 patients). Of the 16 un-contactable patients 3 were subsequently contacted the next day.**

THC = Tele Health Co-ordinator.



There were 12 all cause hospital readmissions for patients answering 'red' or 'worse' within 3 months of discharge. Three patients texted while as an inpatient that they were 'red' or 'worse'. They had no 'red' or 'worse' texts shortly preceding their hospitalisation. This demonstrates that 'red' or 'worse' are markers of high risk, but not uniformly discriminatory for the Tele health Co-ordinator.

Of the remaining 9 readmissions: 4 patients were un-contactable, 3 were resolved by the patient with their symptom checker and 2 had pre-existing community appointments.

Table 1 The responses of the Tele Health Co-ordinators to the 9 patients who responded 'red' or 'worse' and were hospitalised. When the patient used their symptom checker there were 17 and 62 days before admission. It is not clear whether the heart failure pathway response was insufficiently timely to prevent admission in these 2 patients. It is difficult to know whether the 1 to 5 days from text response to admission could have been prevented. It is unclear whether further patient education for earlier signs of symptom deterioration and earlier use of community resources may have helped. This is also true for patients who were un-contactable. It is equally possible that rapid deterioration of the patient overwhelmed any of the potential services that could have kept a patient out of hospital.

**Table 1 demonstrates the number of days (from the Tele Health Co-ordinator responding to the patients who texted 'red' or 'worse') to the patient being admitted.**

Action following red or worse text for hospitalised patients	Number of days from alert to all cause hospital readmission
Un-contactable n=4	5,2,4,4
Patient symptom checker and Tele health Co-ordinator n=3	17,62,1
Community heart failure nurses n=1	1
Community nurse follow up appointment n=1	1

### **Any markers of harm of the Tele health Co-ordinators**

There is no marker that all patients with care facilitated by the Tele Health Co-ordinator came to harm. The death rates in the project were no greater than for the Usual care group – (see Section Results- Impact on A&E and Hospital all cause readmission after an index episode pages 52-66).

There were no Patient Liaison service (PALS) complaints about the project.

It is interesting that in the 3 months of using the protocol there were 23 all cause readmissions to A and E and hospital in patients who didn't answer 'red' or 'worse' at any time.

All patients have access to usual care. It is possible that alterations to the symptom checker with focus groups from these admitted patients may help us design a more nuanced symptom checker to help with readmission reduction at 3 months.

Patient behaviour may reflect why patients visit A and E despite having community appointments already arranged i.e. patients may put up with symptoms for a long time, not wish their care expedited by the Tele health Co-ordinators ( as they don't want to bother anyone) and then attend hospital in extremis ( even 1 day later) because they can no longer cope. This is unfortunately not an unusual occurrence.

### **Any markers of benefit from the involvement of the Tele health Co-ordinators**

The Tele health Co-ordinator role is intrinsic to the project and therefore difficult to separate from the positive project results themselves. A care co-ordinator role has already been demonstrated to be important in many other telehealth initiatives. [1-3]

### **To Patients**

We can reflect that out of 65 texts for 'red' or 'worse' there were only 12 all cause hospital readmissions at 3 months and 13 at 6 months. There is a doubling of admissions at 6 months

when patients no longer have routine access to the Tele health Co-ordinator team. This may reflect that 'red' and 'worse' texts are less discriminatory while the Tele health Co-ordinator is accessible, but more so when they are no longer part of the routine protocol. This reflects the importance of care co-ordination and additionally the human path of digital pathways which may help reduce anxiety and increase the feeling of 'someone being there for you' – (see Section Qualitative Evaluation of the Intervention pages 157-180). This is reflected in some patient comments about their experience of the project.

### **To the health economy**

The Tele health Co-ordinator takes a patient through their symptom checker to understand their choices for self-management. Only 35% of interactions required facilitated care to services such as GPs, Community Teams or Heart Failure nurses. It is possible that the telehealth team helped patients resolve the issues that led them to text 'red' or 'worse' requiring no further action. Only 3 of these 19 interactions preceded a hospitalisation. Helping patients to self-manage their condition in this way may help reduce the hidden costs of heart failure patients.

### **To the telehealth staff**

Direct interaction with patients brings its own rewards to clinicians and they require, among other qualities, compassion, empathy and resilience.

The experience of direct patient contact with people in a very unwell and vulnerable stage of their lives brought back similar memories of life experiences in the past of 2 of the Tele Health Co-ordinators. They felt they had to leave the role early.

The other 4 had nothing but positive comments about it. The experiences of the 2 Tele health Co-ordinators in post at the completion of the project are in Appendix 1.

### **Discussion**

There does not appear to be any obvious signal of harm from the Tele health Co-ordinator role. This may reflect the individuals concerned, but equally the close clinical relationships they have access to in order to facilitate patient care in a timely manner.

There is much evidence of Tele health Co-ordinator benefit in the project.

One role to consider for expansion is the Tele health Co-ordinators contribution to improved patient self-care, education and health care seeking behaviour. These roles have the potential to be expanded.

It is a limitation of the project that we were not able to evolve:

- the symptom checker to be more discriminatory for symptoms and signs likely to lead to deterioration;
- the protocol to allow for more targeted telephone support from the Tele health Co-ordinators for patients texting 'red' or 'worse';

This may improve both patient and Tele health Co-ordinator experience in the future.

#### References

1 Structured telephone support or non-invasive telemonitoring for patients with heart failure. Cochrane Database Syst Rev 2015;(10):CD007228 – accessed 19/09/2020

2 A home telehealth heart failure management program for veterans through care transitions, DOI: [10.1097/DCC.0b013e318299f834](https://doi.org/10.1097/DCC.0b013e318299f834). Accessed 19/09/2020

3 Early outcomes of a care coordination-enhanced telehome care program for elderly veterans with chronic heart failure 2005 Feb;11(1):20-7. doi: 10.1089/tmj.2005.11.20 accessed 19/09/2020

## **Day in the Life of Ricky O’Leary a Telehealth Co-ordinator.**

### **What is the role .....**

*The role entails working with the Heart Failure Nurses in identifying newly diagnosed or existing patients that are being discharged from hospital or those patients attending a Shine Clinic for IV infusions or a 2-week follow-up appointment. We would discuss and guide through the digital platforms that are required for the patient to use. Flo we would explain that this is a monitoring texting service which send daily message alternating between, Feel 1,2 and 3 and also checking their symptom checker and inputting check 1,2 and 3,if any alert were raised i.e. feel 1 (worse) or check 1 or 2 (red and amber) would be sent to ourselves which then we would contact them to find out the problem to which we would be able to direct/aid in either contacting their Heart failure team or Consultant.*

*The second technology we discuss is the online library (Recap) which has been accepted by clinicians (Consultant cardiologists) that this is safe and correct to educate others using the content.*

*This basically gives the support for patients who don’t know how to cope at home/or if it will change the life if so how much, some people are interested to find out about medications, some people would like to know of other people with the same experience which can be shown as videos on Recap.*

*It’s another tool alongside Flo to help manage their health better.*

*Some people we approached would be struggling mentally some with depression or on the verge of it, we offered a third digital partner called iNavigator which is an online referral process which we could refer patient to Healthy Minds for support, and also other issues which could be supported i.e. home adaptations, benefit help, housing issues which Revival or Staffordshire Housing would be able to assist with.*

*We would put the patients on a 3 month protocol in which we would monitor daily and once a week would contact them to see how they are getting on and if we could help in anyway.*

*All patients we approached need to be tracked so we created a tracker with all information that we would require for then and for later purposes for data validation, analysis and evaluation.*

### **Was it what you expected?**

*The role has changed a lot from the start as it is a Test-bed project so changes were to be expected as the role evolved into a more complex job from patient recruitment and monitoring/evaluation support/steering groups/commercialisation. Was it what I expected no but for the better as it required more involvement into the project and felt like a valued asset of the project.*

*This has also given me the opportunity to acquire new skills that I can use for future jobs*

### **What do you love about the role?**

*I loved everything with the project from the interaction with patients getting to know and understand their situations and how the digital platforms we have to offer can help them. It's nice to catch up with the patients to see how well they have coped/self-managed their health thanks to using the digital technology.*

*To the data analysis/evaluation and validation of data for the reports to be presented to the respected partnerships/ and Innovate UK. Meeting new people from patients to different specialities and business partners which through time has helped me be more diverse.*

*That's a bit hard to say really with this being an Innovative Test Bed Project so things were constantly changing for the better. The role in its self I would not change as it has evolved so well, but from a project point of view I would have wanted to branch out patient recruitment wise covering more areas (GPs) or community at the beginning of the project to gain bigger numbers and results.*

### **What were the main challenges and how did you overcome them?**

*One of the main challenges was approaching the patients and not coming across as some 'sale pitch', with this in mind it helped to ensure the patients that it was a project to benefit their health (potentially) by giving confidence managing their own wellbeing. The other main challenge was patients that weren't very confident using technology. We had a few different approaches either to ask if they had a relative who would be able to assist navigating through Recap and Flo and the other would be to give them a demonstration of how the technologies work; then guide them through it when they do it themselves.*

### **How do you think patients have benefited from the project?**

*Since recruiting patients on to the project specially patients who are not aware of how to manage their conditions or any other co morbidities I found that these patient through sticking to the 3 months protocol gained a lot of confidence on how to manage their health using Recap, their symptom checker(flo) and also help them understand that there are other alternatives to preventions / aid towards their health other than A&E/Hospitalisation.*

*Also been educated/guidance using Recap which gave patient re-assurance and help to cope with everyday matters. I.e.: share your concerns to relatives, medication understanding, where to get assistance for benefits, mental health contents which also partners with iNavigator for referrals.*

### **Do you think the role/project is sustainable in future?**

*Yes with the results, evidence and experience while being on the project patients felt very re-assured once chatting to THC they felt like they had good support and in some cases they could speak to us of other issues concerning them that they didn't want to be open about to their families as they didn't want to worry them e.g. not coping mentally struggling physically with day to day activities.*

*To be evaluated/analysed and validated in order to support the results of the project so for this to roll out into the community or hospital environment itself then this would ideally require 1 if not 2 THC.*

## **Day in the Life of Nicola Antrobus a Telehealth Co-ordinator.**

### **What is the role?**

*For me the key roles were engaging with heart failure patients, explaining how the project worked, the benefits of using digital technology and the support that the project could offer. Communication I feel is one of my key strengths, so had no problems with the daily visits to the SHINE clinic and Cardiology wards, speaking to the MPFT (community HF team) to chat to patients, nurse etc. re “SMART WITH YOUR HEART”. Another key role for me is my involvement with all three digital partners but particularly Health2Works, who set up the Recap Health library. This is an online health library, especially for heart failure patients.*

*My role involved inviting our project patients to participate and sign up to receiving the information especially for heart failure patients and their families. The library of information is a mix of slides, patient’s stories, videos, audio files, leaflets to download and links to a large selection of relating websites. My Recap role was to ensure all of these links were still live to access and to encourage our project patients to view this information.*

*I am also actively checking the alerts on Flo from patients to ensure I act on the responses that ‘FEEL WORSE’ or there is a change in responses. Flo is the text messaging service, used daily to ask HF patients how they are feeling and in conjunction with their “symptom checker” provide a text reply. The replies are followed up with a call from the Telehealth Coordinators and my comments from the conversation then added to a patient tracker*

### **Was it what you expected?**

*Yes and more. I love the variety and interactions of the post. Every day brings a new challenge*

### **What do you love about the role?**

*I love the patient interaction part of the role and have felt that the services that have been available have been very well received. Our project patients have enjoyed the calls to ask how they are today, the idea there is someone at the end of a phone and the extra support this project has offered*

*Feedback from CC “LOVE MY CALLS, IT’S A LIFE LINE, SOMEBODY CARE AND ITS WONDERFUL”*

*I also have an input in the third digital, partner INavigator , which is a social prescribing platform. This has received positive feedback too, especially when the COVID 19 virus took hold and extra resources came in very useful and the Tele Health Co-ordinator can refer our project patients to external services , which include Revival and Beat the Cold. Our patients can be referred for extra support in a number of areas*

### **What were the main challenges and how did you overcome them?**

*Some of the main challenges have been trying to continually get clinicians to become engaged and enthusiastic about the project and work with us, have more of an active role with the project. At times a lack of patient engagement, signing up for the project but then don’t reply or complete the process to access the Recap library. Also getting patients to engage with focus groups .*

*Issues with I Navigator a long and slow process to get this service up and running, once up and running not all of the initial providers were on board. A lot of the issues were down to IG issues. It is a shame really as there were originally 6 providers to take part and we had 3 in the end*

**How do you think patients have benefited from the project?**

*This project can only be a positive benefit for our patients, providing extra support for their HF, the communication if an alert was raised and general calls to see how they have found all the various aspects of this project, an added bonus to the clinical elements of this condition. The majority of patients who have taken part on the project have nothing but praise and thanks*

**Do you think the role/project is sustainable in future?**

*Yes I think with a THC overseeing the role is can be a useful and proactive role with in any healthcare setting.*

## Project active special groups

The special groups concerned are:

- those who are newly diagnosed with heart failure in comparison to patients with pre-existing heart failure (and therefore patients who would have experienced the heart failure service before our project started and are also at risk of greater hospitalisation)
- patient's with hefpef (heart failure with preserved ejection fraction) and hefref (heart failure with reduced ejection fraction) as patients with hefref theoretically have treatments that will reduce hospitalisations.[1]

### Context

It is estimated that 70% of all newly diagnosed heart failure patients are diagnosed in hospital. [2]

It is estimated that nearly 70% of echocardiograms performed for heart failure while patients are hospitalised demonstrate reduced ejection fraction i.e. hefref. [3]

### Distribution of hefref / hefpef and new/ existing in project active group

Table 1 demonstrates the number of patients in these groups out of the total project active group.

**Table 1 Distribution of new/ existing and hefref / hefpef in all 103 project active patients**

	New	Existing
Hefref	45	25
Hefpef	16	17

### Demographics in special groups

This is demonstrated in table 2 below

**Table 2 Age and sex distribution of the groups of interest – existing / new and hefref / hefpef**

	Age (mean, SD)	Sex (male, female)
Existing n 42	(67, 13)	(26, 16)
New n=61	(66, 13)	(40, 21)
Hefref n 70	(64, 12)	(49, 21)
Hefpef n=33	(71, 12)	(17, 16)

### Use of digital products by special groups

This is demonstrated in table 3.

**Table 3 Use of the digital products (Both = Recap Health and Flo, Flo only, Recap Health only) by the special groups new/ existing and hefref / hefpef. The majority of patients in each special group are on both Flo and Recap Health**

	Both n	Flo only n	Recap Health only n
Existing n 42	26	10	6
New n=61	35	19	7
Hefref n 70	42	19	9
Hefpef n=33	19	10	4

### Experience of special groups with the project

Patients were asked about their experiences with the project at the end of their second Flo protocol. 66 patients responded out of 103. The questions were phrased slightly differently to existing patients to reflect their comparative experience of the heart failure services before and after their involvement with the project.

Table 4 demonstrates the response of the hefref and hefpef groups,

**Table 4 Patients with hefref or hefpef as the mechanism of their heart failure diagnoses at the time of enrolment into the project and their per cent positive, neutral or negative responses to a patient survey at the end of their second Flo protocol. There were negative responses to survey questions in 10% or fewer of responders.**

Total answering satisfaction survey n=66		Q1 How have you found being on the Project? %	Q2 How has Flo and Recap Health helped you to manage your Heart Failure? %	Q3 How has your confidence in managing your own health changed? %	Q6 Did you feel supported on the project %
hefref n=50 (49 for q 6)	positive	60	70	72.00	93.9
	neutral	32	20	24.00	4.1
	negative	8	10	4.00	2
hefpef n=16	positive	80	80	66.66	100
	neutral	13.3	13.3	26.67	0
	negative	6.7	6.7	6.67	0

### Experience of New and Existing heart failure patients

The questions asked to new and existing patients were phrased slightly differently to reflect the fact that existing patients could compare their prior experience to the heart failure services with their current experience while on the project.

The table below demonstrates that even patients known to the heart failure service had a positive experience of the project. All existing heart failure patients improved their confidence in managing their heart failure. 84% of them felt better able to manage their heart failure. All of them also felt supported on the project. Only 10% or fewer patients had negative comments about their experience on the project in comparison to their experience with the heart failure service prior to the project.

Although only approximately 52% of newly diagnosed patients had a positive response to using Flo and Recap Health, more than 70% felt able to manage their heart failure better and more than 90% felt more confident in managing their heart failure better and supported in the project.

Our project produces an improved patient experience for patients who have benefitted from heart failure services in terms of their confidence and ability to manage their heart failure.

**Table 5. Patients with newly diagnosed or existing heart failure diagnoses at the time of enrolment into the project and their per cent positive, neutral or negative responses to a patient survey at the end of their second Flo protocol. The difference in the questions asked is demonstrated by the red highlight of the text.**

	Responses	Q1 How have you found being on the Project? %	Q2 How has Flo and Recap Health helped you to manage your Heart Failure? %	Q3 How has your confidence in managing your own health changed? %	Q6 Did you feel supported on the Project? %
Newly diagnosed heart failure patient n=40 (39 for q6)	Positive	52.5	72.5	92.31	92
	neutral	35	17.5	5.13	5
	Negative	12.5	10	2.56	2
	Responses	Q1 How have you found being on the Project? %	Q2 How have Flo and Recap Health helped you to manage your Heart Failure? How is this different to before %	Q3 Has your confidence in managing your own health improved? %	Q6 Did you feel supported on the Project? %
Existing heart failure diagnosis n=26	Positive	84.6	73.1	100.00	100
	neutral	15.4	19.2	0.00	0
	Negative	0	7.7	0.00	0

**Impact of special groups on all cause readmissions**

Table 6 below demonstrates A and E and hospital all cause readmissions based on the special groups described above.

**Table 6 This demonstrates the special groups (new/ existing and hefref/ hefpef and the hospital and A and E all cause readmission rates associated with them. The significance after Bonferroni correction for multiple comparisons is also outlined below.**

	Cumulative secondary care utilisation					
	30 days		3 months		6 months	
	Hospital all cause readmission % (count) n	A and E all cause readmission % (count) n	Hospital all cause readmission % (count) n	A and E all cause readmission % (count) n	Hospital all cause readmission % (count) n	A and E all cause readmission % (count) n
<b>Existing n=42</b>	19% (8) n = 42	5% (2) + n = 42	42% (17) n = 40	25% (10) n = 40	68% (15) n = 22	73% (16)! n = 22
<b>New n=61</b>	13% (8) n = 61	10% (6) n = 61	19% (11)&& n = 59	14% (8)&& n = 59	19% (5)&& n = 27	11% (3)&& n = 27
<b>Hefref n=70</b>	14% (10) n = 70	7% (5)** n = 70	26% (18)** n = 69	13% (9)** n = 69	30% (10)** n = 33	30% (10)** n = 33
<b>Hefpef n=33</b>	18% (6) n = 33	9% (3) n = 33	33% (10) n = 30	30% (9) n = 30	62% (10) n = 16	56% (9) n = 16
<b>Usual care n=824</b>	27% (207) n = 772	26% (197) n = 772	51% (356) n = 701	50% (352) n = 701	86% (349) n = 405	92% (372) n = 405
<b>Usual care &lt;75 n=192</b>	27% (50) n = 184	26% (48) n = 184	52% (90)++ n = 174	52% (91)++ n = 174	93% (101)++ n = 109	96% (105)++ n = 109

! significant after multiple comparisons using Bonferroni correction New vs. existing at 6 months for reduction in A and E admissions (caution as

+ significant after multiple comparisons using Bonferroni correction Usual care vs. existing at 30 days for reduction in A and E admissions

&& significant after multiple comparisons using Bonferroni correction Usual care (and Usual care<75) vs. new at 3 and 6 months for both hospital and A and E all cause readmissions

\*\* significant after multiple comparisons using Bonferroni correction Usual care vs. hehref at 30 days (for A and E admissions) and for 3 and 6 months for both A and E and hospital all cause readmissions

++ significant after multiple comparisons using Bonferroni correction Usual care < 75 vs. hehref at 3 and 6 months for reduction in hospitalisation and A and E all cause readmissions

The patients in the project new and hehref groups had fewer all cause readmissions to both A and E and hospital in comparison to the Usual care and Usual care < 75 years at 3 and 6 months after discharge and 30 days for the usual care group comparison alone.

The reason for this is not clear from the existing heart failure pathway - as only 30 out of 70 (43%) of the hehref patients in the project were seen by the specialist heart failure nurses. The percentage of patients seen by the community heart failure nurses in the usual care group was 251/824 = 30% of all patients with a discharge diagnosis of heart failure. The percentage of those patients with hehref in the usual care group is not known.

## Discussion

Patient experience of the project is positive irrespective of whether patients are hehref / hefpf / newly diagnosed with heart failure or have pre-existing heart disease. It is encouraging that patients with previous experience of the heart failure service have a better experience and more confidence in managing their heart failure with the use of Flo and Recap Health digital products. Equally it would be expected that the 60% of the existing patients who had hehref would already have been on optimal medical therapy.

Patients in the project who have newly diagnosed heart failure (of which 25% have hefpf) or patients with hehref) – 36% of whom have already experienced heart failure services - have lower A and E and hospitalisation all cause readmission rates than patients in the usual care groups.

We would hope that equivalent patients in the Usual care group may have benefitted from our intervention – i.e. newly diagnosed heart failure (irrespective of hehref or hefpf) and patients with hehref (irrespective of whether they are newly diagnosed or have pre-existing and treated heart failure)..[2,3]

## References

1 NICE chronic heart failure guidelines.

<https://www.nice.org.uk/guidance/ng106/resources/chronic-heart-failure-in-adults-diagnosis-and-management-pdf-66141541311685> accessed 19/09/2020

2 20-year trends in cause-specific heart failure outcomes by sex, socioeconomic status, and place of diagnosis: a population-based study. Lawson C, Zaccardi F, Squire I, Ling S, Davies M, Lam C, Mamas M, Khunti K, Kadam U. *Lancet Public Health* 2019;4: e406–20

3 NICOR National Heart Failure Audit 2019. <https://www.nicor.org.uk/wp-content/uploads/2019/09/Heart-Failure-2019-Report-final.pdf> accessed 19/09/2020

## Quality of Life Report

### Quality of life tools

There is a substantial risk of worsening morbidity and mortality in at least the first year following discharge from hospital with a diagnosis of heart failure.[1] The secondary care heart failure team decided to use the following validated tools in all hospitalised patients with heart failure at discharge, 3 months, 6 months and 12 months following discharge from hospital:

**EQ5D – generic quality of life questionnaire.** This includes 5 questions about various aspects of general health. The patient has 5 possible responses to each of these questions – 1 being best health and 5 being the worst i.e. the lower the better. NICE have suggested that the distribution of the 1-5 responses to the questions can be arranged for any individual and converted (using country specific conversion rates) to an overall score for the distribution of responses to each individual question – the crosswalk score. NICE has suggested that the changes to these scores can be used to demonstrate any changes to Quality Adjusted Life Years. These changes can then be used to determine the cost benefit for the intervention that led to that change. Failure to respond to one of the 5 questions means that this ‘crosswalk’ score cannot be calculated for the patient. The patient can also either note down or mark ( on a 10 cm line) a score for their overall assessment of their own health- the visual analogue (or overall health status) score.

**KCCQ- The Kansas City Cardiomyopathy Questionnaire (KCCQ)** consists of a 23 item questionnaire to which the patient can respond to the most appropriate phrase in response to an individual question. Each phrased response is attributed a value. These values are added to the responses of other questions and weighted formulae for each response then contributes to forming various scores to describe the patient’s health. There are 7 such summated scores which are:

- Symptom score – the frequency and burden of clinical symptoms in heart failure
- Physical function score – describes the functional limitation due to heart failure
- Quality of life score – quality of life with respect to their heart failure symptoms and signs
- Social limitation score – the impact of heart failure on their ability to perform certain activities
- Self-efficacy score – the knowledge patients feel they have to reduce heart failure exacerbations and to manage their symptoms should this occur
- Symptom stability score – describes the change to patient symptoms in comparison to their symptoms 2 weeks ago
- Clinical summary score – which includes the physical function and symptom scores

- Overall summary score – which combines the symptom, physical function, social limitation and quality of life scores.

The most important scores for the project within the KCCQ are highlighted in red. The clinical efficacy score is a marker of the ability of the patient to manage their own health.

Any change of > 5 points is felt to be clinically significant. Failure to answer individual can still allow composite scores to be calculated if sufficient other questions used to calculate a composite score are completed i.e. failure to respond to one domain does not render the patient's whole data invalid.

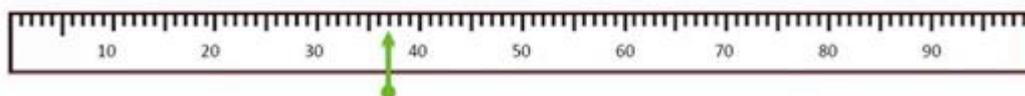
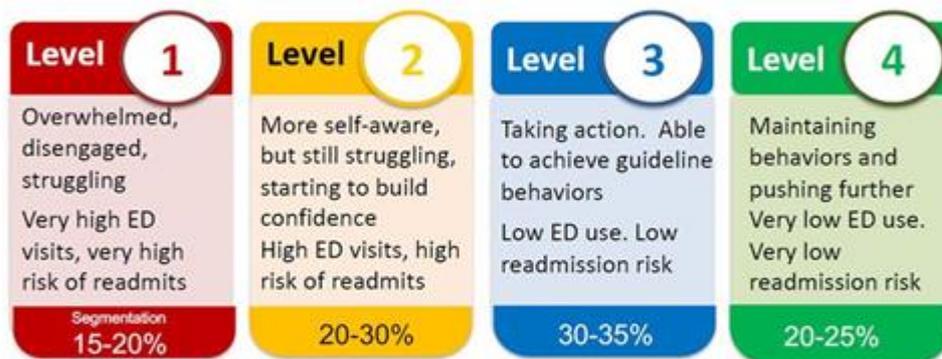
**PHQ4** –It is a 4 item anxiety and depression score. The patient has 2 questions about anxiety and 2 about depression. The responses are to the frequency of these symptoms outlined in each question – with 0 being not at all and 3 being nearly every day. The scores are summed and if the score is >3 for the sum of questions for anxiety and separately > 3 for depression then the patient is said to have anxiety and / or depression. The overall burden of symptoms is described by a total score for all questions with: 0-2 normal, 3-5 mild, 6-8 moderate and 9-12 severe.

**PAM 13** – this is a questionnaire with 13 questions that sum together to form 2 assessments of their overall engagement with their health:

PAM 13 Level. This is one of 4 levels. The higher the more engaged the patient. The levels are described as in Figure 1 below.

Figure 1 demonstrating the 4 different activation levels and what each level means in terms of self-care and potential hospital utilisation.

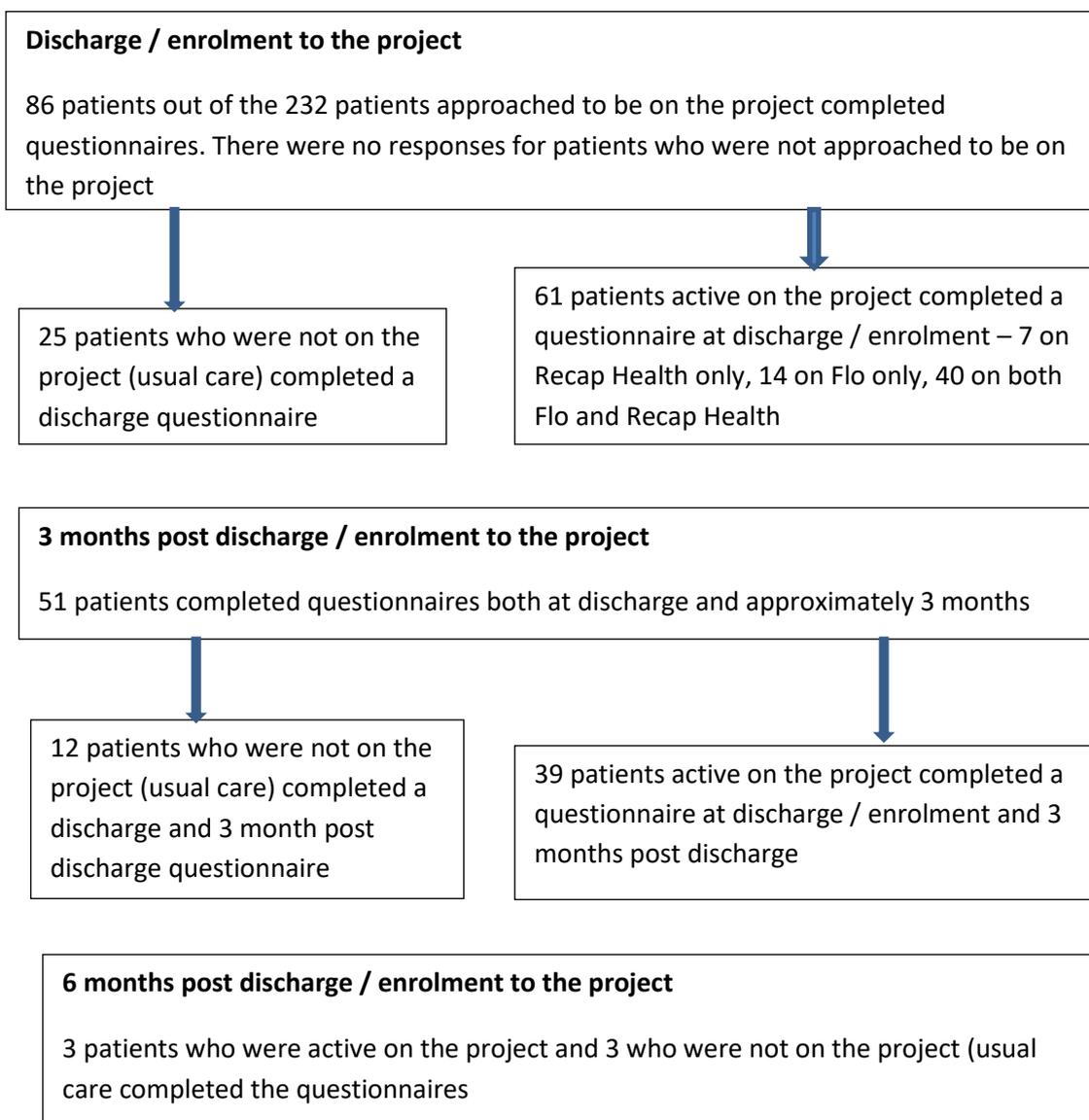
Four activation levels reside along an empirically derived, equal interval scale 100-point scale



The value of a single point change in PAM score is significant and well understood, as is the shift between PAM Levels

The wide margins of 'score' covered by each level means that comparisons between questionnaires at various time intervals may demonstrate changes in scores without corresponding changes in levels.

#### Completed Questionnaires at various time points



This means that in terms of the discharge / enrolment questionnaires:

61/103 = 59% of project active patients completed their discharge questionnaires

25/129 (the denominator is the number of people approached to be on the project who either declined, were ineligible or did not register for Recap Health or who replied to 6 or fewer texts from Flo) = 19.4%

The overall questionnaire return is less than expected – especially from our usual care hospitalised group. However in terms of the project active patients it is important to remember that the KCCQ development cohort was in 59 patients with decompensated heart failure of which there were 39 paired repeated questionnaires at 3 months post discharge. This is virtually equivalent to our data . [2]

### Age and sex distribution of patients returning discharge / enrolment questionnaires

Table 1 demonstrates the mean age and sex distributions for each of the groups of interest in terms of the groups of interest

**Table 1 Age and sex distribution within the Project active and usual care (non-project) groups**

Group	Total number of patients	Number by sex (Male, Female)	Age (Mean, St Dev)
Total	86	(58, 28)	(69, 10)
Project Active	61	(40, 21)	(69, 11)
Usual care	25	(18, 7)	(71,10)

### Missing data sufficient to discount single patients

Missing data fields sufficient to censor patients and exclude them from part of the evaluation occurred in the EQ5D only.

There were:

- 12 unfilled visual analogue scores by patients who completed discharge / enrolment questionnaires
- 2 unfilled question at discharge / enrolment – meaning 2 ‘crosswalk’ scores could not be calculated
- 1 unfilled question at 3 months by different patients – meaning 1 paired set of crosswalk scores were excluded from the analysis
- 7 visual analogue scores were not completed between paired data at either discharge / enrolment or at 3 months

Data sets were sufficient to complete the scores for the other questionnaires.

## Patient related Outcomes – Discharge/ enrolment

Table 2 demonstrates the scores at discharge / enrolment and 3 month and 6 month data for patient related outcome scores of interest for patients in the project – project active. The change in 3 month scores is for available paired data only. The significance between paired data between 3 month and discharge / enrolment questionnaires is demonstrated.

Category Project Active	Score at discharge mean SD n=61 (Mean, SD)	Score at 3 month Mean SD n=39	Change in score for group 3 month discharge score Mean SD n=39	Significance value 3 month paired <del>vs</del> vs. discharge paired Mean SD n=39	Score at 6 months n=3 Mean SD
<b>EQ5D</b>					
EQ5D Crosswalk Score	(0.61, 0.31) n = 60	(0.69, 0.22) n = 39	(0.09, 0.27) n = 38	0.057	(0.92, 0.14) n = 3
EQ5D VAS	(63.2, 20.35) n = 50	(66.18, 19.86) n = 39	(0.75, 23.56) n = 32	0.8585	(80, 17.32) n = 3
<b>PAM</b>					
PAM 13 score	(56.31, 12.58) n = 61	(54.93, 13.4) n = 39	(-1.16, 14.25) n = 39	0.615	(73.53, 13.83) n = 3
PAM 13 level	(2.38, 0.97) n = 61	(2.41, 0.94) n = 39	(0.03, 1.14) n = 39	0.889	(3.67, 0.58) n = 3
<b>PHQ4</b>					
PHQ4 anxiety	(2.44, 2.22) n = 61	(2, 1.92) n = 39	(-0.28, 1.86) n = 39	0.3504	(0.33, 0.58) n = 3
PHQ4 depression	(2.16, 1.85) n = 61	(1.82, 1.85) n = 39	(-0.18, 1.68) n = 39	0.510	(0, 0) n = 3
PHQ4 combined	(4.61, 3.82) n = 61	(3.82, 3.63) n = 39	(-0.18, 1.68) n = 39	0.364	(0.33, 0.58) n = 3
<b>KCCQ</b>					
KCCQ Self efficacy score	(61.89, 23.32) n = 61	(84.62, 20.77) n = 39	(24.68, 24.92) n = 39	<0.001++	(100, 0) n = 3
KCCQ Clinical summary score	(50.57, 27.29) n = 61	(64.39, 25.05) n = 39	(8.67, 25.8) n = 39	0.042++	(95.49, 4.7) n = 3
KCCQ Overall summary score	(45.05, 26.45) n = 61	(59.26, 23.62) n = 39	(10.66, 25.39) n = 39	0.013++	(95.83, 5.51) n = 3

++ significant to  $p < 0.05$  after Bonferroni correction for multiple comparisons

**Table 3 demonstrates the scores at discharge / enrolment and 3 month and 6 month data for patient related outcome scores of interest for patients not in the project – Usual care. The change in 3 month scores is for available paired data only. The significance between paired data between 3 month and discharge / enrolment questionnaires is demonstrated.**

Category Usual care	Score at discharge mean SD n=25	Score at 3 month Mean SD n=12	Change in score for group 3 month discharge score Mean SD n=12	P value 3 month paired <del>vs vs.</del> discharge paired Mean SD n=12	Score at 6 months n=3 Mean SD
<b>EQ5D</b>					
EQ5D Crosswalk Score	(0.51, 0.33) n = 25	(0.4, 0.43) n = 11	(-0.12, 0.41) n = 11	0.3416	(0.41, 0.52) n = 3
EQ5D VAS	(54.05, 24.06) n = 21	(56.55, 23.98) n = 11	(-6.3, 21.19) n = 10	0.3717	(71.67, 22.55) n = 3
<b>PAM</b>					
PAM 13 Score	(54.92, 13.12) n = 25	(51.13, 15.47) n = 12	(-8.41, 19.84) n = 12	0.1702	(54.53, 24.79) n = 3
PAM 13 Level	(2.32, 0.95) n = 25	(2, 0.95) n = 12	(-0.58, 1.38) n = 12	0.1708	(2.33, 1.53) n = 3
<b>PHQ4</b>					
PHQ4 Anxiety	(3.6, 2.31) n = 25	(1.17, 1.95) n = 12	(-2.08, 2.71) n = 12	0.02215*	(1.33, 2.31) n = 3
PHQ4 Depression	(3.2, 2.12) n = 25	(1.42, 1.83) n = 12	(-0.92, 2.15) n = 12	0.168	(1.33, 2.31) n = 3
PHQ4 Combined	(6.8, 4.11) n = 25	(2.58, 3.63) n = 12	(-0.92, 2.15) n = 12	0.0337*	(2.67, 4.62) n = 3
<b>KCCQ</b>					
KCCQ Self efficacy score	(60, 30.83) n = 25	(73.96, 31.29) n = 12	(9.38, 33.76) n = 12	0.3568	(75, 43.3) n = 3
KCCQ Clinical summary score	(36.16, 25.98) n = 25	(39.97, 31.34) n = 12	(1.56, 14.39) n = 12	0.714	(53.65, 46.62) n = 3
KCCQ Overall summary score	(31.62, 24.55) n = 25	(38.56, 33.87) n = 12	(6.42, 36.1) n = 12	0.5502	(54.6, 48.57) n = 3

- \*Significant for univariate analysis but NOT significant when corrected for multiple comparisons.

Our KCCQ data for the project active group demonstrates that there is a significant improvement in understanding of features of worsening heart failure and knowledge of what to do if they occur in our project group. There is also a non-significant trend to improvement seen in the EQ5D crosswalk score at 3 months in this group. The numerical values of all scores (apart from PAM13 level) appear to improve at 3 and 6 months.

The anxiety and total symptom frequency scores improve in the usual care group at 3 months – but this no longer becomes significant when corrected for multiple comparisons.

The numerical values of all scores (apart from PAM13 level) appear to improve at 3 and 6 months. It would be easy to dismiss the 6 patients that submitted their 6 month outcomes scores as only scores from patients with a polarised health status. However there is a surprising numeric difference between the project active patients – whose scores continue to show an improving trend over time – and the usual care group - who do not display the same magnitude of improvement. While this is an interesting observation no clear conclusions can be made from these very small groups.

### **Comparative Data**

**EQ5D** – We found 1 study on 6943 patients who completed EQ5D questionnaires at various time points on admission and up to 30 days post discharge from the USA.[3] Their crosswalk scores increased over time from  $0.56 \pm 0.23$  at baseline to  $0.67 \pm 0.26$  and  $0.79 \pm 0.20$ , respectively, at hour 24 and discharge and at  $0.78 \pm 0.20$  at day 30. Visual analogue scores also increased over time from  $45 \pm 22$  at baseline to  $58 \pm 22$  and  $68 \pm 22$ , respectively, at hour 24 and discharge and remained stable at  $67 \pm 22$  at day 30.

In our patients the mean discharge / enrolment scores for crosswalk and visual analogue scores are 0.51 (SD 0.33) and 54.05 (sd24.06).

Our patient's values are lower than the discharge scores for the American cohort. This is surprising as the American cohort had median NT-proBNP values ranging from 4110 – nearly 5000pg/ml – in comparison to our patients 3618ng/l. It is therefore a testament to the worse overall quality of life experienced by our patients on discharge / enrolment.

Our project active patients have a small but statistically insignificant improvements in their scores at 3 month, and at 6 months, but the mean 3 month scores remain lower than those of the American cohort at 30 days.

The usual care group predominantly had lower numerical changes in scores at 3 months or worse scores.

A study in younger chronic heart failure patients with diabetes demonstrated higher starting scores in the 'crosswalk' scores of 0.74 (control) and 0.75 (intervention). Both of these reduced to 0.61 (control) and 0.69 (intervention). The scores of our project group improved whereas the scores in our usual care group reduced. We feel that the positive trajectory of the crosswalk score demonstrated by project involvement is a real finding.[ 4]

KCCQ - Our KCCQ data for the project active group demonstrates that there is a significant improvement in understanding of features and management of worsening heart failure. There is also a non-significant trend to improvement seen in the EQ5D crosswalk score at 3 months in this group.

## Comparative data

**Table 3 demonstrates baseline / discharge KCCQ scores and either 3 month (African and USA) or 30 day repeated KCCQ scores against those recorded in our project.[5,6]**

Table 3 Data from 3 studies describing KCCQ scores of interest from Africa (2018), USA (2000 ), Greece (2014 publication date) against project active group. The values demonstrate scores at discharge and at 3 months – but at 30 days for the Greek study. Our project numbers for repeated questionnaires completed is similar to these other studies. Although there is a wide variation in repeated outcomes scores from these 3 studies, our project values appear consistent to these other studies. The magnitude of differences between baseline and the repeated questionnaire may reflect the post-discharge care available in different health economies.

KCCQ score	2018 n=195. Mean age 52  Africa [5]  Discharge	2018 n=45. Mean age 52  Africa [5]  3 months	N=39 age =68  USA [6]  discharge	N=39 Age 68  USA [6]  3 months	2014 n=52  Mean age =63  Discharge  Greece [7]	2014 n=52 Mean age 63 30 day  Greece [7]	Project ACTIVE N=39  Mean age =66  Discharge	Project active  N=35  Mean age 66  3 months
Self efficacy score mean (where available SD)	58.7 (21.7)	25 (24.4)	67.6	83	90	92	59.9 (21.8)	84.6 (20.8)
Clinical Summary Score(where available SD)	26 (18.6)	46.9 (24.9)	31.8	56.1	na	na	55,7(25.1)	64.4 (25.1)
Overall summary score (where available SD)	21.8 (15.8)	30.2 (21.4)	33	61.5	44	63.1	48.6 (25.2)	59.3 (23.6)

**PHQ4** – we can find no comparative data for hospitalised patients with PHQ4. In one study PHQ2 for depression was administered to 401 hospitalised heart failure patients - 79% of whom had had depression in comparison to 44% of our patients.[8]

In our study at 51 patients displayed mild or greater anxiety (84%) and 38 patients mild or greater depression (62%) with 43 patients (63%) having mild or greater frequency of symptoms.at discharge / enrolment.

A fall in the numerical score is a positive finding in the PHQ4 – a lower score suggests less anxiety and depression.

**PAM13** – 2 studies have PAM13 data on patients discharged from hospital with heart failure.[9] One excluded patients with depression scores > 3.[10]

Patients with depression scores > 3 were excluded from PAM 13 assessments of patients with decompensated heart failure. At discharge/ enrolment of all 61 responses from the project active patients depression score was > 3 in 38 patients. The mean PAM score on discharge were 57 and (( doi: 10.12688/f1000research.6557.1) and 53 ((J Cardiovasc Nurs. 2017) respectively.

Table 3 demonstrates that our patient populations for the project active group are broadly similar in distribution to those from the literature.

**Table 4 Comparative PAM 13 distributions at discharge between project active and PAM 13 levels from published comparators.**

PAM level	Percentage of study population with different PAM level at discharge		
	[10] n=100	[9] n= 302	Project active n=61
1	39	17	21
2	23	40	33
3	19	40	33
4	19	3	13

There was a greater numerical reduction in PAM scores at 3 months in the usual care more than the project active group. Interestingly there is a greater (and significant) rise in the KCCQ self-efficacy score in the project active compared to the usual care group. The self-efficacy score is an assessment is a marker of a patient’s knowledge of their deteriorating heart failure and what to do to help themselves.

These findings are interesting as the PAM score is about a patient’s engagement with their own overall health. It may well be that we have improved heart failure knowledge more in

the project active than usual care group, but have not helped patients engage as much with improving their knowledge and management of their other co-morbidities.

### Variations in individual patient scores within each overall quality of life domain of interest

Although we have displayed mean total scores and determined the differences between those means from discharge / enrolment to 3 months, we also demonstrate the variations seen within the scores of interest i.e. did individuals scores improve, worsen or stay the same.

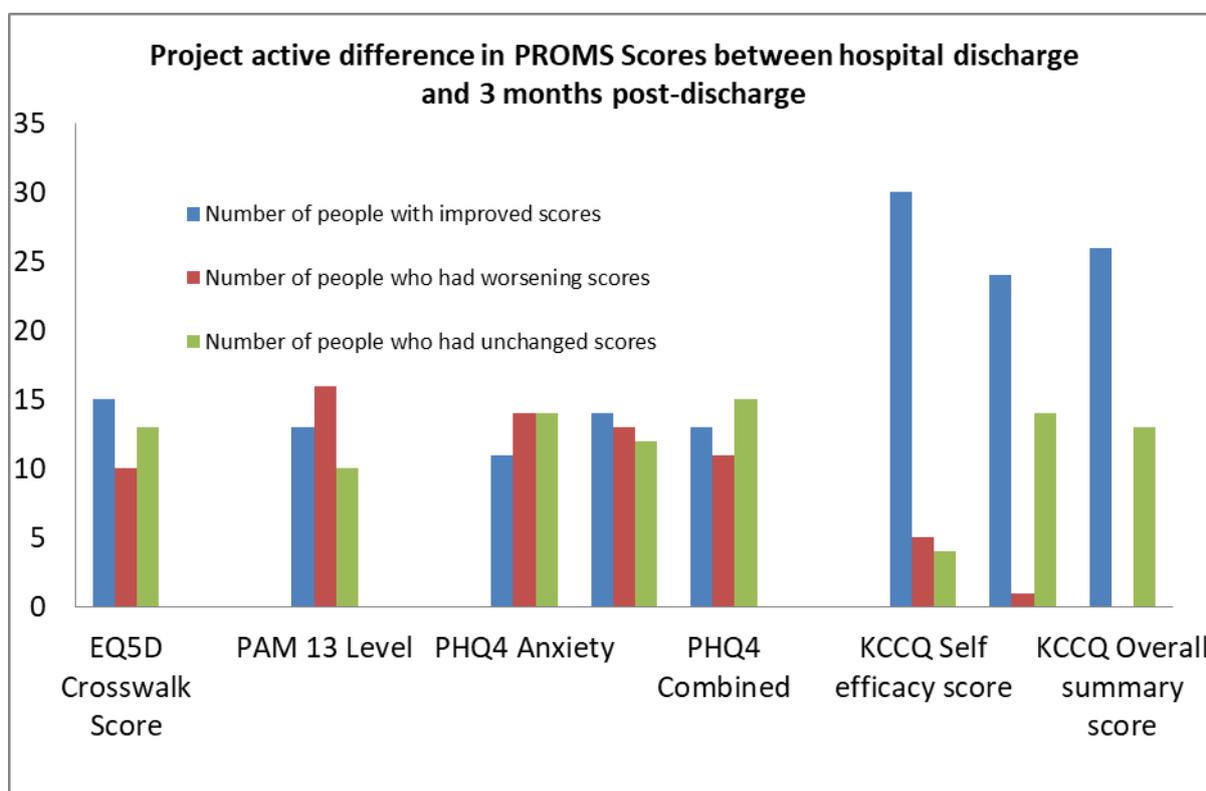
**Table 5 demonstrates these changes between scores for Project active and usual care patients and the difference in scores between the quality of life scores between 3 months and discharge / enrolment for project active and the usual care group**

	Difference in score between 3 month and discharge (39 for active and 12 for non participant)		
Category Project Active	Number of people with improved scores	Number of people who had unchanged scores	Number of people who had worsening scores
<b>EQ5D</b>			
EQ5D Crosswalk Score	15	10	13
EQ5D VAS	14	2	16
<b>PAM13</b>			
PAM 13 Score	18	5	16
PAM 13 Level	13	16	10
<b>PHQ4</b>			
PHQ4 Anxiety	14	14	11
PHQ4 Depression	12	13	14
PHQ4 Combined	15	11	13
<b>KCCQ</b>			
KCCQ Self efficacy score	30	5	4
KCCQ Clinical summary score	24	1	14
KCCQ Overall summary score	26	0	13
Category Non participant Usual care	Number of people with improved scores	Number of people who had unchanged scores	Number of people who had worsening scores
<b>EQ5D</b>			
EQ5D Crosswalk Score	4	2	5
EQ5D VAS	4	1	5
<b>PAM</b>			
PAM 13 Score	3	1	8
PAM 13 Level	2	4	6
<b>PHQ4</b>			
PHQ4 Anxiety	9	1	2
PHQ4 Depression	7	3	2
PHQ4 Combined	10	0	2
<b>KCCQ</b>			
KCCQ Self efficacy score	8	0	4

KCCQ Clinical summary score	7	0	5
KCCQ Overall summary score	7	0	5

The percentage variations in patients whose quality of life scores improve, stay the same or worsen is demonstrated for the project active group alone in Figure 1 below

Figure 1. Percentage of patients, whose quality of life scores improved, worsened or stayed the same. The numbers of patients with worsening scores were surprising given the overall numerical positive differences between the means for the different scores. The distribution for the worsening scores appears more prominent in the generic quality of life scores, the anxiety and depression scores and the patient’s activation in managing their overall health – in comparison to the heart failure specific quality of life score the KCCQ. Statistical analyses were not performed on whether there was a significant difference between these distributions between the different quality of life scores.



Our project suggests that there remains a significant amount of covert anxiety and depression even at 3 months post discharge – even if the average scores improve for the entire group.

### Can change in quality of life score reflect re-admissions

We determined whether patients with worsening or improving scores were potentially at risk of readmission. The percentage readmissions at 3 months in comparison to whether patient’s quality of life scores improved or worsened is demonstrated in Table 6 below.

**Table 6**

Category Project Active	Number of people with improved scores	Number of people who had worsening scores	Hospital Readmission rate at 3 months if improved quality of life scores % (n=)	Hospital Readmission rate at 3 months if worsened quality of life scores % (n=)	A and E Readmission rate at 3 months if improved quality of life scores % (n=)	A and e readmission rate at 3 months if worsening quality of life scores% (n=)
<b>EQ5D</b>						
EQ5D Crosswalk Score	15	13	7% (15)	15% (13)	20% (15)	15% (13)
EQ5D VAS	14	16	7% (14)	12% (16)	21% (14)	19% (16)
<b>PAM13</b>						
PAM 13 Score	18	16	0% (18)	19% (16)	0% (18)	25% (16)
PAM 13 Level	13	10	0% (13)	10% (10)	0% (13)	40% (10)
<b>PHQ4</b>						
PHQ4 Anxiety	14	11	7% (14)	18% (11)	7% (14)	27% (11)
PHQ4 Depression	12	14	0% (12)	14% (14)	0% (12)	21% (14)
PHQ4 Combined	15	13	7% (15)	15% (13)	0% (15)	31% (13)
<b>KCCQ</b>						
KCCQ Self efficacy score	30	4	10% (30)	0% (4)	10% (30)	75% (4)
KCCQ Clinical summary score	24	14	8% (24)	14% (14)	12% (24)	29% (14)
KCCQ Overall summary score	26	13	12% (26)	8% (13)	4% (26)	46% (13)
Category Usual care	Number of people with improved scores	Number of people who had worsening scores	Hospital Readmission rate at 3 months if improved quality of life scores % (n=)	Hospital Readmission rate at 3 months if worsened quality of life scores % (n=)	A and E Readmission rate at 3 months if improved quality of life scores % (n=)	A and E Readmission rate at 3 months if worsening quality of life scores% (n=)
<b>EQ5D</b>						
EQ5D Crosswalk Score	4	5	225% (4)	20% (5)	0% (4)	40% (5)
EQ5D VAS	4	5	150% (4)	20% (5)	25% (4)	40% (5)
<b>PAM</b>						
PAM 13 Score	3	8	0% (3)	125% (8)	0% (3)	25% (8)
PAM 13 Level	2	6	0% (2)	117% (6)	0% (2)	33% (6)

<b>PHQ4</b>						
PHQ4 Anxiety	9	2	150% (2)	78% (9)	0% (2)	33% (9)
PHQ4 Depression	7	2	0% (2)	100% (7)	0% (2)	14% (7)
PHQ4 Combined	10	2	150% (2)	70% (10)	0% (2)	30% (10)
<b>KCCQ</b>						
KCCQ Self efficacy score	8	4	12% (8)	225% (4)	12% (8)	50% (4)
KCCQ Clinical summary score	7	5	100% (7)	60% (5)	0% (7)	60% (5)
KCCQ Overall summary score	7	5	100% (7)	60% (5)	14% (7)	40% (5)

It is interesting that especially for the project active group worsening of generic scores appears on the whole associated with a numerical increase in readmissions. But each readmission represents very small numbers of patients so the table is merely to generate thought rather than suggest causal relationships.

## **Discussions**

The quality of life data from the published literature is similar numerically to our own data.

We demonstrate that there is an improvement in scores of interest within the disease specific quality of life in comparison to the generic scores. It is encouraging to see that the project improves patient's self-efficacy scores – suggesting that patients understand their heart failure more. It is also encouraging to see that these scores improved in 30/39 project active patients at 3 months.

This improvement is mirrored in the other disease specific scores in comparison to the generic scores. This may be because we have missed an opportunity to extend patient education to patient's wider health rather than their heart health alone. The symptom checker does contain reference to co-morbidity health, but there is little in the Recap Health library to re-enforce this.

It was also surprising to see that in 3 months there were a significant minority of patients whose anxiety and depression scores worsened.

It is possible that using quality of life tools may help us highlight patients who are becoming more anxious and depressed and who may benefit from psychosocial support through social prescribing. We know that patients who are anxious or depressed are less likely to engage with their own health care i.e. their PAM 13 levels may not increase.

Our Quality of life / patient engagement surveys have great potential to be routinely used patient related outcomes measures. They equally have the potential to help target psychosocial support to patients with worsening mental health that has not been detected during routine clinician reviews.

The next iteration of our project is likely to include targeted Tele Health Co-ordinator support for patients with worsening anxiety depression and crosswalk scores and consideration for social prescribing in this patient group.

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# Qualitative evaluation of the Intervention

## Introduction

### Aims

The main aims were

- To assess patients' experience of digital products to help in improving self-care management and understanding of their heart failure: looking specifically at their experience of using the digital products: FLO (an automated text service) and Recap Health (a digital library of online resources).
- To explore how far the digital products supported patients' self-management of their condition.

### Methods

A mixed methods approach was used for this project: This report details the qualitative evaluation.

Qualitative evaluation of the intervention employed the following methods:

- A short interview by Tele health Co-ordinators when patients exited the project exploring patient experience of using FLO and the Recap Health library; this included patient completion of a simple questionnaire.
- Patients' free text comments about their experience of resources within the Recap Health library when they had engaged with them.
- Focus groups (FG) with patients who had used the Interventions to explore in depth, their experiences of using them; specifically to see if the digital products had empowered patients to self-manage their condition more effectively.

It was also planned to hold focus groups with healthcare workers involved with patients who were on the Test beds project; no healthcare worker attended so no information is detailed in this report.

Information from all these sources were mapped onto the other data regarding patients' QoL, attendance at their GP/ admission to hospital to assess a complete picture of patient experience, and the usefulness of, the digital products – to the patients and to the NHS.

### FLO and the Recap Health library

FLO was available to patients from entry onto the project until 3 months. All patients were given access to an initial resource – 'Living with Heart Failure' - in the Recap Health library. Other resources were allocated to the patient by the Clinician, as deemed appropriate. This reflects the fact that patients had different health experiences pre-entry to the project. For example, some patients had been diagnosed with heart failure, had been living with it for

some time and had experience of being in hospital for treatment. For others heart failure was a new health experience. Therefore, different resources from the Recap Health library were appropriate; these were determined by the patient's clinician.

## **Patients**

103 patients were enrolled onto the study. 10 patients died before giving any interview, questionnaire or FG feedback, 1 patient was omitted from the list of patients to be contacted. Of 92 potential respondents, 2 patients were in hospital and 1 was being admitted when phoned and declined to give any feedback, 1 patient was being admitted to hospital when rung. We were unable to contact 23 patients.

66 patients gave feedback to the majority of questions (66%); however, uniformity of responses in terms of the number and frequency of responses varied. Not all 66 patients answered every question on the questionnaire or responded to evaluate their experience of Recap Health. Thus, the number of responses varies in data sets presented in this report. Only 4 patients attended/gave feedback to the FGs out of 24 invited patients (16.6%).

## **Focus Groups**

**Focus Group 1** was arranged to take place at University Hospital of North Midlands (UHNM) on Thursday 19/9/2019. 8 Patients were invited to attend by the Tele health Co-ordinator. 1 Patient attended (P1)

**Focus Group 2** was arranged to take place at University Hospital of North Midlands (UHNM) on Friday 20/9/2019. 8 Patients were invited to attend by the Tele health Co-ordinator. 1 Patient attended (P2)

1 other Patient (P 3) emailed responses to the Intervention (though the comments were not responses to the Focus Group questions)

Following a discussion/review of the challenges of Patient attendance at the Focus groups it was decided to present Focus Group 3 as a 'support group'. Taking account of shorter daylight hours in December this **Focus Group 3** was arranged for lunchtime on December 4<sup>th</sup>. 1 Patient attended with his wife (P4).

Due to only 1 Patient attending each Focus Group, the interaction between Patients which is a feature of Focus groups, did not happen. Instead, a 1-1 interview took place on each occasion.

## **Focus Groups: Patient Participants:**

P1. Female aged 55-60 - completed the 3 month project

P2. Female aged 45-50 - completed the 3 month project

P3 gender & age unknown to researcher – completed the 3 month project

P4 male aged 70 – had not fully engaged with the project or the digital products as he does not have a smart phone. FLO txt messages were being received on his mobile phone but he does not have access to other digital resources. P4 was enrolled to the study as an in-patient when he was very ill. He felt, in retrospect, that he was not fully aware of what he was consenting to as his main focus was on his illness.

## **Patient responses**

### **Patient responses to Telehealth Coordinators' questions**

The following section gives details of patients overall experiences of the project based on the results of the questionnaire and interview with Tele health Co-ordinators completed by patients on exiting the project.

Patients were asked the following questions by Tele health Co-ordinators:

1. How have you found being on the project? Response by n=66
2. How have Flo and Recap health helped you manage your heart failure? (if existing pt.-how is this different to before) Response by n=66
3. How has your confidence in managing your heart failure changed whilst being on the project ((Existing patient-? improved since using digital products: New patient-has this increased since discharge / enrolment)? Response by n=66
4. Did you attend A&E whilst on the project? Response by n=66
5. Did you attend your GP more whilst on the project? Response by n=65
6. Did you feel supported on the project? Response by n=65

Patients' responses were collected as free text rather than binary 'yes/no' responses. Comments were identified as positive, neutral or negative.

Results are presented in tables and charts with patients' comments also detailed.

## **Overall**

Responses to each Questions 1,2,3,6 –Actual comments are included in Appendix 1

	Questions with responses n (% of total)			
Responses	Q1 How have you found being on the Project ?	Q2 How has Flo and Recap Helped you to manage your Heart Failure?(if existing pt. how is this different to before)	Q3 How has your confidence in managing your own health changed? (Existing improved since using digital products: New has this increased)	Q6 Did you feel supported on the Project?
<b>Total</b>	66	66	66	65
<b>Helpful (% of total)</b>	43 (65)	48 (73)	47 (71)	62 (95)
<b>Neutral (% of total)</b>	18 (27)	12 (18)	16 (24)	2 (3)
<b>Negative (% of total)</b>	5 (8)	6 ( 8)	3 (5)	1 (2)

**Q1. Patient experience of being on the project (Tele health Co-ordinator – collected data)  
n=66**

**Summary**

Patient comments show that most patients experienced being part of the project as positive. Overall 43/66 (65%) patients commented that their overall experience of being on the project was positive with 18 patients (27%) commented that they had a neutral – neither good nor bad overall experience and 6 (8) No patient stated that they had had a negative experience.

There are no clear differences in the ages of patients who found the overall experience either positive or neutral; nor are there any marked gender differences.

Of note is the emphasis in the positive comments on the importance of the psychosocial aspects of the project. The number of comments relating to the value of the contact afforded both by Flo and the Tele health Co-ordinators is marked. Unsurprisingly, this number is greatest in the patients who accessed only Flo; though it is evidenced also in patients who accessed both Flo and Recap Health.

Of the 6 patients accessing Recap Health only and giving feedback, overall feedback about being on the project is divided. 3 patients indicated positive responses – generally relating to the informative nature of Recap Health. However, 3 patients left neutral comments with one 58 year patient noting that he is ‘not good with apps’. This is an important point as the use of digital products is central to the project and it should not be assumed that it is only the very elderly that have difficulties accessing digital products.

The male patient aged 61 who stated that he found ‘not much benefit’ from being on the project appears to have had a mixed experience overall as his other responses indicate the digital product helped him manage his heart failure; but that his confidence did not improve whilst on the project; that he did not attend A&E or his GP whilst on the project but that he did not feel supported whilst on the project. The patient is colour coded in green on all tables.

## **Q2. Flo and Recap Health as a help to managing patients’ heart failure**

### **Summary**

48 patients (73%) who responded indicated that the digital products had helped them manage their heart failure; 12 patient’s responded neutrally and 6 patients responded negatively (total 27%).

Of the patients responding negatively, 2 left comments that it did ‘not really’ help; though they did not indicate any reason why they felt this. Many patients leaving positive comments gave reasons. Importantly, psychosocial communication support was the most common reason given. This is common whether or not patients accessed Flo or Recap Health only, or both digital products. The value of the Tele health Co-ordinators in providing vital support is part of this response.

## **Q3. Patients’ confidence whilst on the project**

Patients were asked whether their confidence had changed during their time on the project.

### **Summary**

47 patients (71%) across the three groups indicated that whilst using the digital products their confidence had increased. For some patients the increase was great and for others, ‘a little’. Several patients commented on their increased understanding of their personal condition and/or heart failure more generally, as being at the root of their increased confidence. 16 patients left neutral comments and 3 left negative comments about the impact of the digital products (total 29%). None of these patients provided detail about possible reasons for their comments. There is no evidence of patient age or gender impacting the patients’ experiences.

#### **Q4. Patients' attendance at A&E whilst on the project**

61 patients (n=66) said they had not attended A&E whilst on the project. Full data on the entire dataset for this is reported elsewhere. No patient comments were recorded for this.

#### **Q5. Patients' visits to GP whilst on the project n=65 (1not answered)**

No patient comments were recorded for this. Of the 65 patient responses:

45 had no GP visits = 69%,

13 had routine visits to the GP = 20%

5 urgent visits to the GP = 8%

2 patients continued going to the ambulatory heart failure clinic = 3%

#### **Q6. Patients experience of support whilst on the project**

##### **Summary**

62/65 patients responded positively to the question about whether they felt supported whilst on the project. The human contact provided by the Tele health Co-ordinators has been noted as positive. The importance of psychosocial factors to patient experience of managing their illness is clear in the comments.

Reviewing the neutral comments: the male patient aged 86 who commented that he didn't need much support had also responded to say that his confidence had increased whilst on the project. He did not attend A&E or his GP whilst on the project.

The Female patient aged 40 who commented that she felt 'sort of 'supported whilst on the project also stated that her confidence had increased whilst on the project. Perhaps some of her ambivalent response to her experience of support might relate to the fact that she did not have access to Flo; thus was only engaging with one of the digital tools.

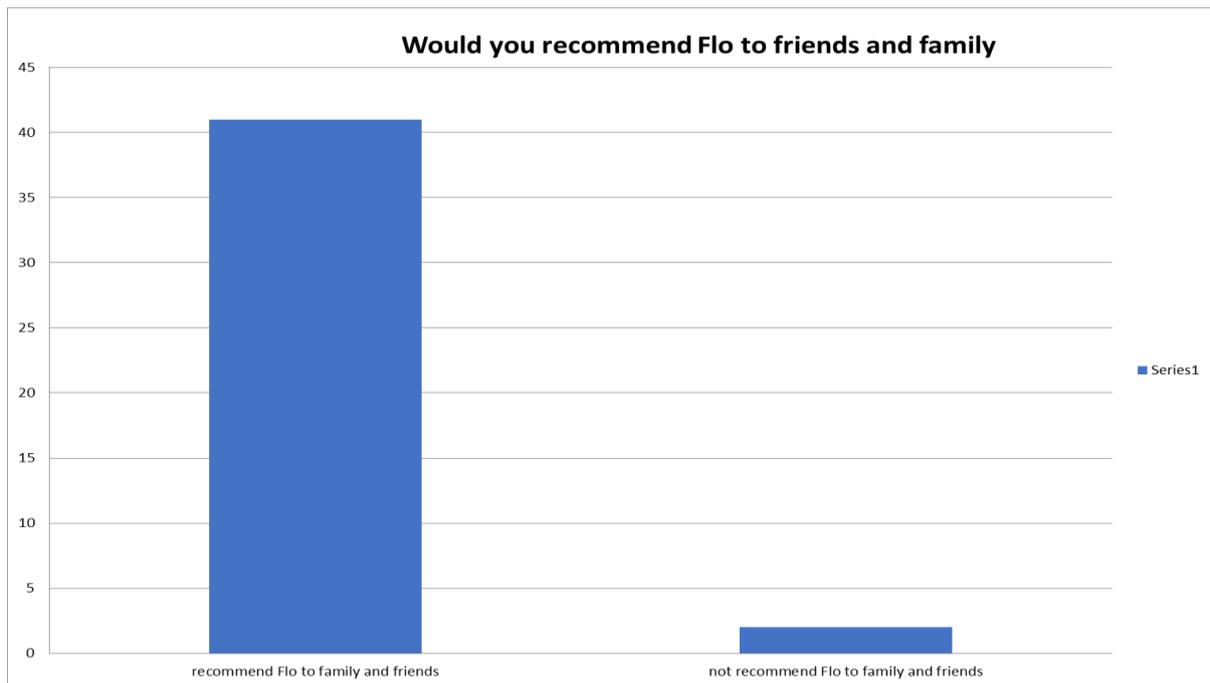
The single patient leaving a negative comment about the experience of support whilst on the project was a male patient aged 52 accessing both Flo and Recap Health. He said he did not really feel supported on the project and also commented that he struggled with Recap Health. Perhaps as a consequence of this he also commented that his confidence had not really improved whilst being on the project. It might be that if he had been able to use Recap Health more fully he would have found increased benefit from his time on the project. This patient's comments are highlighted in blue through all tables.

## Digital Products

Patients were asked specifically about their experience of using the different digital products.

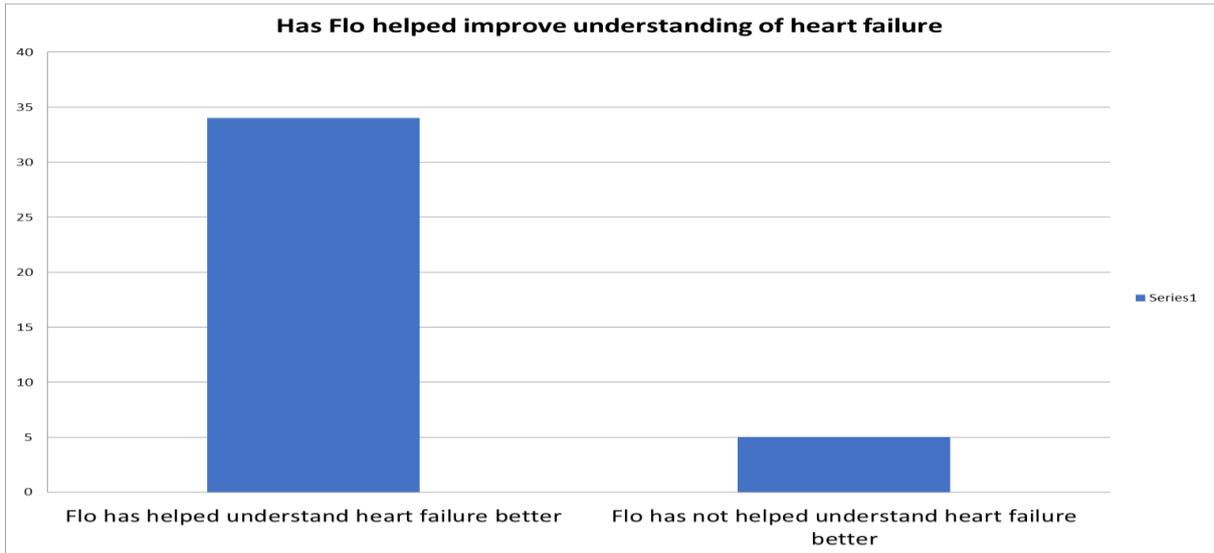
### Patient experience of using Flo

Patients were asked a series of questions about their experiences with Flo and its impact on their healthcare at the end of their Flo protocol. The bar charts below indicate responses. The number of patients responding to the questions varied.



41 patients (n=43) who responded said that they would recommend Flo to family and friends. 2 patients (n=43) said they would not.

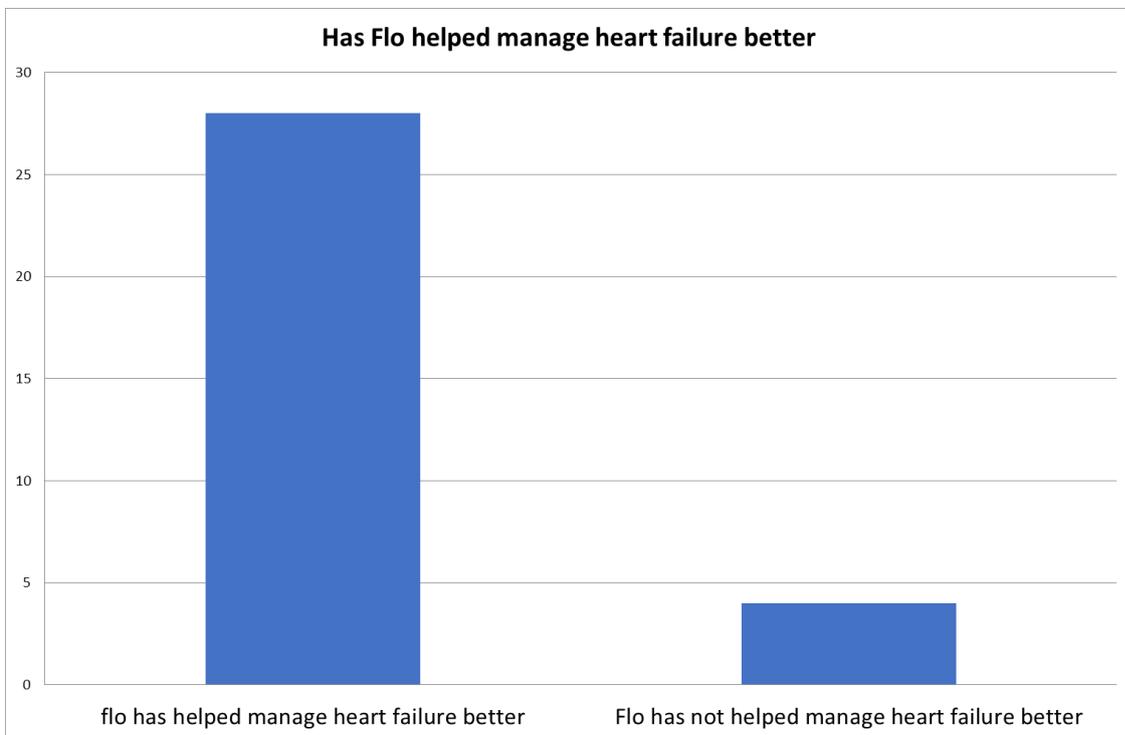
### FLO aiding understanding of Heart Failure



34 patients (n=39) said that FLO had helped them understand their heart failure condition better. 5 patients (n=39) said FLO had not helped them understand it better.

**Patients’ understanding of Heart failure**

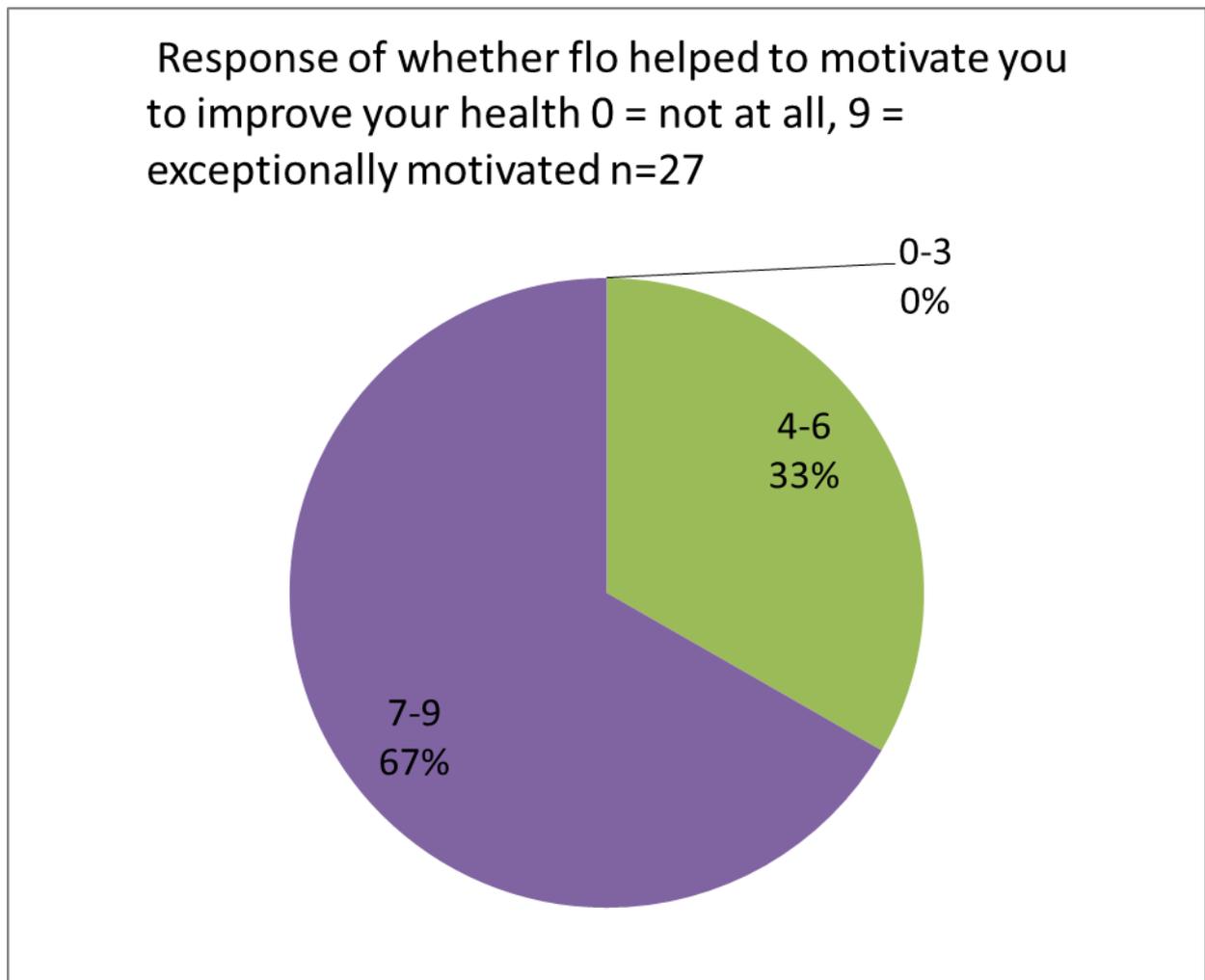
32 patients responded to the question about whether Flo had helped them understand heart failure better. 28 patients (n=32) said it had and 4 patients said it had not.



### FLO as motivating patients to look after their own health

Patients were also asked whether FLO had motivated them to look after their overall health more. The responses were recorded on a Likert scale scored between 0 and 9 where 0 was not at all and 9 was exceptionally motivated. Responses are shown in the figure below

Figure demonstrating that 67% felt that interacting with Flo had motivated them to look after their overall health.



### Summary

It is clear from the responses detailed above that patients experienced Flo as a helpful tool to manage their condition; also to help them to improve their health. Additionally, most patients would recommend it to their families and friends.

The ways in which Flo may help may be complex and multi-dimensional in terms of helping with confidence, management of heart failure and by helping with overall health too.

21 patients (n=30) said it had motivated them to improve their health with 5 stating that it had motivated them 'exceptionally'.

There is a clear emphasis within the free text responses on the psychosocial impact of Flo on patients' wellbeing. i.e. Flo was perceived positively as a psychosocial aid to patient wellbeing. FG responses are given below in patients' comments reported verbatim.

### **FG responses to using Flo**

Patients reported that Flo text messaging was a positive feature: (P2) "easy to respond to". (P1) "Very easy"

**Positive Psychological factors associated with Flo:** (P2) "Nice to know someone is monitoring"; "The call back when I was unwell was good....Validated my concerns"; (P1) "became a ray of sunshine"; "FLO was always on my shoulder, watching my back"; "when you come out of hospital you feel old and vulnerable. When FLO kicked in it gave me confidence"; "I looked forward to FLO, to having daily contact..."

**Personal nature of Flo:** (P2) "You get a txt from FLO, then you can txt back. Then Flo responds – it feels like a personal message" (P1) "It's very nice to get a txt every day" (P1) "I thought she was a real person, I did...! She felt like a friend". (wife of P4) I thought he was having an affair...all these messages from FLO...I said 'who's FLO??'"

**Empowerment:** (P2) "Made me more aware of how I should be feeling...helped increase my awareness of my condition and my self-monitoring" "I started from a fairly good base position – so not sure whether that came across (i.e. if it was a 0-10 scale I may have started on a 4, gone down to a 1 and then gone up to a 4 before and then up to a 7 - but without a scale, might not have known.." (P1) You know if its reporting a '2' you should go to your GP..." (P3) "The project that you helping to co-ordinate has empowered me to research, question and learn regarding issues of my heart. It also helps to point in the right direction if there are problems."

These verbal responses from patient participants in the FGs indicate quite clearly that they found Flo helpful not simply to monitor their condition but also they felt that it offered psychological support. At a time when many patients might feel 'vulnerable' the daily contact offered by FLO was experienced as very helpful. It also empowered patients to begin to self- manage their condition. It will be useful to assess how far the psychosocial aspects of Flo impacts patients' overall QoL and specifically how far it affects their anxiety and depression scores.

Patients in the FGs were also clear about the limitations and potential improvements to Flo. These are detailed below.

**Limitations: Information on the symptom checker:** (P2) “ Sometimes I felt worse, but the symptoms weren’t on the symptom checker, so said I was the same”; “It was good when I said I was worse and someone called me about it. However, it wasn’t worse on the NHA scale. I felt worse but didn’t know if the symptoms I had were or weren’t related to the drugs/condition”; “Some things are not on the scale...for example mood. I wanted to talk about this but Flo never asked”; “Maybe my scores were inflated because the scale didn’t ask about the significant uplift since starting different meds...” (P3) “I sometimes find it difficult to answer questions when asked how I feel compared to previous days, as from a written symptom point of view I may be good, where in reality am actually worse.”

**Txt message timing:** (P2) “Flo came in at 11 am every day...this is a good time because I am up and about and had my meds. Maybe if it asks at a different time it would be different?” (P3) “I realised it was coming in at the same time each day – 11.00 which is actually a good time of day. Keeping it static was good if you want consistent results, but if continuing it might be worth trying other times of the day to see if that alters results.”

**Interaction:** (P2) “It’s not a two-way conversation – which makes it easier to manage, but means I couldn’t get my questions answered...” “It needs to be a 2-way conversation with some space for free text too”; “Flo suggested accessing emotional support but didn’t say how”; (P1) “Flo messaged and said you can get psychological support, but didn’t say where from! I’m not sure what triggered that as Flo doesn’t ask about emotion...”

**Possible improvements:** (P1) need to tell me how to get help when I feel down” (P2) “Need links to emotional support” (P3) “ need to think how can this project be tailored to meet the needs of those who are frail/worse health than me and need the support of others to access information etc. “

The limitations and improvements suggested by patients centre around the psychological/psychosocial elements of Flo. This indicates a clear need for patients to receive support in this area. P2’s comments about Flo not recording changes in symptoms post a change in medication is interesting as the scale used asks about breathlessness – which is important to clinicians and symptom checker sheets. However, it might be helpful to add a further section or possibly, additional access to the telehealth team when patients feel something is wrong which is not covered by the symptom checker.

This emphasis on psychosocial aspects of the monitoring is further noted by patients request for “a two-way conversation”. Certainly, this is not something that is possible currently, but perhaps it is worth consideration for any future development of the service.

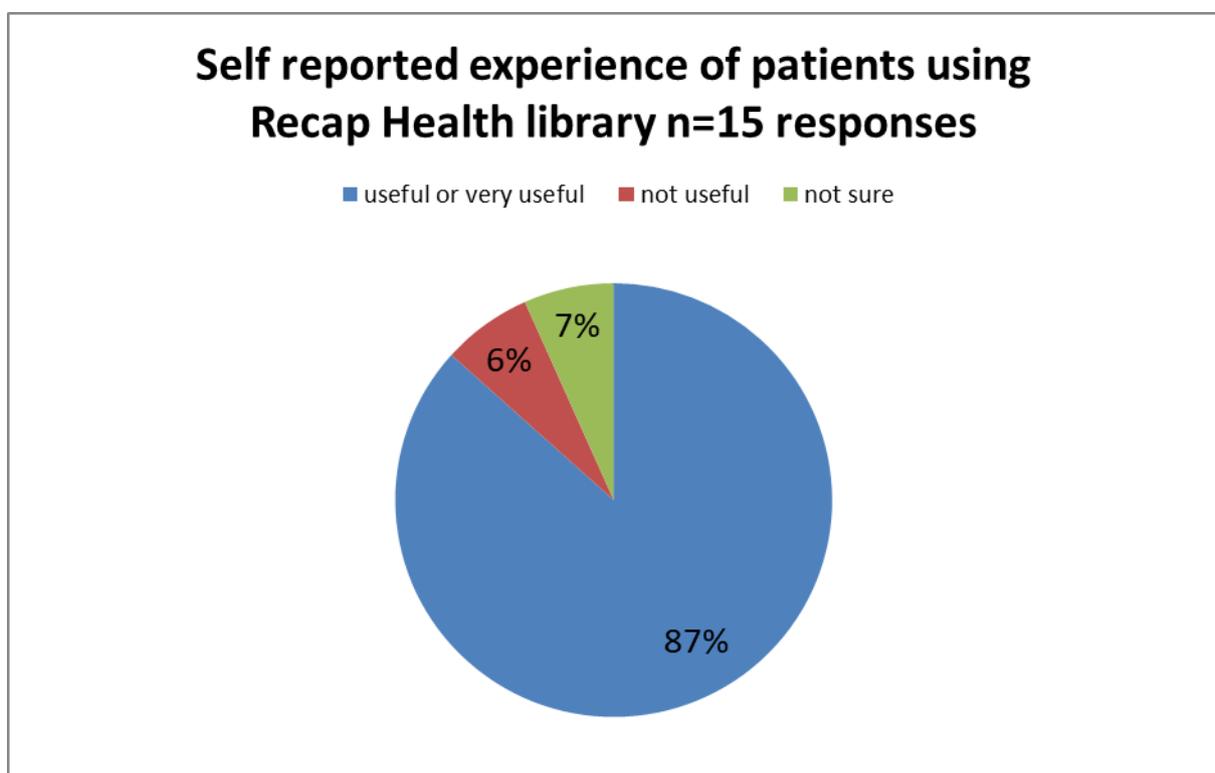
Additionally, the patient’s call for “emotional support” is important. Originally, an I Navigator social prescribing element was included in the project. Arguably, this tool would have responded to this suggested improvement.

## Recap Health

There were 74/103 of the project active group used Recap Health library. Upon completion of each element of Recap Health patients were invited to leave evaluative comments about their experience of the resource. Responses were limited. 15 patients left responses. The number of times each element of the different packs was accessed by participants is detailed below. Comments from the 15 patients are also detailed. The utilisation of the Recap Health Library is detailed in the section on Recap Health in the evaluation.

### Patients' comments

15 patients left comments about the usefulness of Recap Health.



### FG Patients' comments on RECAP HEALTH

(P2) "The practical information is useful. The videos – telling people's stories are really useful. The information about the device is really helpful" (P1) "RECAP HEALTH helped... The information was useful"

(P2)"it would have been helpful for my partner to have his own login with information about the issue and how I might be feeling, how they can support and how they can get support. "

(P2) "need to make sure the links are live"

(P2) "Some practical information about travel and things would help"

(P2) “There are links to ‘Pumping marvellous’ but need other local links too”

Other messages about the system and also patients’ illness are given below.

(P2) “The psychological impact of this illness was immense. I still have days when I could just walk out of the door....”

(P1) “You shouldn’t have to go home and do your own research. I felt like I’d come home without a diagnosis or prognosis. I felt so alone...like a ‘rolling cloud’. I felt really sorry for myself. I couldn’t do housework, or shower or drive or work or cook.... I was questioning everything - ; should I be doing this?’ Should I be feeling like this?’ Before if I felt down I would keep busy...but I couldn’t...”

### **Summary**

Patients’ responses show that they found Recap health a useful digital tool. Limiting definitive conclusion is the fact that only a small number of patients chose to leave comments about their experience of using the different digital tools.

### **Challenges and Limitations:**

Overall, patient comments indicate that patients had a positive experience of being on the project. 88% reported a positive experience. 12% stated they had either a neutral or negative experience.

Due to revised Governance (Clinical and Information Governance) stemming from GDPR requirements the qualitative researcher was unable to make contact directly with patients. This led to a more disconnected approach to collection of qualitative data; specifically via patient attendance at FGs. Initial patient enrolment was due to take place in Spring/Summer 2019. However, due to procedural issues this was unavoidably delayed. A consequence of this delay was that patients were not completing their 3 month time on the project until September and into early Winter. The weather is not as good at that time of year in the United Kingdom and the day-light becomes more limited. Additionally, Winter is not a goodtime for people with chronic illness (heart failure). Subsequently in Spring 2020 Covid-19 hit the UK (and the world). This had a further deleterious impact on patient engagement with the digital products and also patient evaluation of these.

The patients that chose to evaluate the different digital products and/or attend the FGs were very helpful and very motivated. It is interesting and concerning that more patients did not attend the FGs or respond to the evaluation of the specific digital products. There are many possible reasons for this.

- HF patients are very ill
- It is Autumn/Winter
- FGs were held at UHNM where it is very difficult to park
- Patients get little out of participating in research

- Patients may not want to be reminded of their illness/patient journey

### **Patient Interaction with Digital Products**

Overall, patients reported a positive response to FLO and Recap Health. All patients talked of the immense psychological impact of their condition. They commented that the digital products had helped with this as well as the physical impact of HF.

#### **Patient reported positive responses to FLO.**

FLO text messaging - which they found easy to respond to and the perceived personal nature of FLO. Patients reported that receiving and being able to respond to FLO messages made them feel more empowered and better able to manage their condition.

Several potential improvements were noted; patients noted that they were experiencing symptoms but had no way of recording or indicating these as the system did not ask about them; patients queried whether or not a different time of day to record symptoms might elicit a more complete view of their condition – rather than recording it at 11am daily; a desire for patient/clinician interaction (in real time); need a vehicle to report psychological symptoms.

#### **Patients reported positive responses to Recap Health**

The links & videos were found useful.

Potential improvements were noted: partner login with information about the issue and how the patient might be feeling, how they can support and how they can get support.; need to make sure the links are live; practical information about travel; local links to support groups/websites.

### **Conclusion**

The Aims of the qualitative part of this project were as follows:

1. To assess patients' experience of digital products to help in improving self-care management and understanding of their heart failure: FLO (an automated text service) and Recap Health (a digital library of online resources).
2. To explore how far the digital products supported patients' self-management of their condition.

It is clear that patients' experiences of the project and specifically their experience of the digital products have been positive even in the case of patients already known to the heart failure team.

All enrolled patients were given access to Flo and many engaged with the texting service. Flo was experienced by patients as a clear link to clinicians. The psychosocial benefits of having a daily text contact with 'somebody there' was reported by many patients as very positive.

Not all patients then engaged with Recap health. Of those who did, most found it beneficial and a positive experience. The resources provided were experienced as helpful and informative by patients.

It is clear from patient responses that age and gender have had little impact on engagement. All patients enrolled onto the project were required to possess and use a Smartphone; which might intuitively have suggested that older patients might not engage fully with the digital products. However, results show that patients of all ages engaged. Technology and its use was not a barrier to participation – regardless of age.

## **Future:**

### **Enrolment**

It is clear from some patients' comments that the timing of enrolment onto the project is important. Patients who are worried about their health probably will not be best placed to engage with a new intervention. So, it is possibly better to wait until a patient has left hospital to engage them in a new intervention/project.

### **Psychosocial issues**

An important message from this project seem to be that psychosocial issues are a very important element of patients' wellbeing following heart failure. Thus, emphasis might usefully be directed towards increased psychological support. Perhaps additional features on Flo might be useful to ask patients about psychological issues (e.g. anxiety) and then make available Tele Health Co-ordinator support. Also, directing patients to psychological resources on Recap health might be useful.

### **Telehealth coordinators**

Patients' comments clearly identified the benefit of Tele Health Co-ordinator contact. Patients requested more of this. So, arguably, it might be beneficial to patients' wellbeing to instigate this.

### **Attendance at A&E & GP**

Interestingly, some patients on the project stated that they did not feel they had a positive experience overall or that they were supported. However, statistics denote that patients' attendance at A&E and GP surgeries during the project were majorly reduced. In addition to increased patient well-being, this then would save the NHS money. This arguably is an important part of the potential future of this project.

**Appendix 1** – selected patient comments about their experiences on the project for Two patients are identified throughout the responses – one highlighted in green font and one in blue – as their comments are of specific interest.

Questions 1, 2, 3 and 6

Question 1 Patients giving feedback (N=66)	Examples of Positive comments	Examples of Neutral comments	Examples of Negative comments
<p><b>Active on Flo only and giving feedback (n=18)</b></p>	<p>‘reassuring’ (Male aged 64)</p> <p>‘good’ (Female aged 80)</p> <p>‘yes very useful the texting message very re-assuring knowing that some-one was on the other end of the phone’ (Female aged 64)</p> <p>‘found the texting service very useful’ (Female aged 61)</p> <p>‘excellent really helpful and wish it would continue’ (Female aged 36)</p> <p>“very helpful, someone to talk to” (Female aged 79)</p> <p>“yes very useful the texting message very re-assuring knowing that some-one was on the other end of the phone” (Female aged 64)</p>	<p>‘ok not much benefit’ (Male aged 61)</p>	

	<p>“good support to check on me if not feeling well” (Male aged 71)</p>		
<p><b>Active on Recap Health only and giving feedback (n=6)</b></p>	<p>‘ok helpful’ (Male aged 87)</p> <p>‘Good. It was comforting knowing someone was available to get in-touch’ (Female aged 58)</p>	<p>‘no problem’ (Male aged 82)</p> <p>‘ok’ (Male aged 49)</p> <p>“Good but not good with apps though” (Male aged 58).</p>	
<p><b>Active on both and giving feedback (n=42)</b></p>	<p>‘very good’ (Male aged 55)</p> <p>‘good, helpful’ (Male aged 66)</p> <p>‘good with brilliant information’ (Male aged 60)</p> <p>‘wonderful’ (Male aged 78)</p> <p>“Good. Helpful” (Male aged 64)</p> <p>“good with brilliant information” (Male aged 60)</p>	<p>‘ok, not intrusive’ (Female aged 40)</p> <p>‘ok not brilliant’ (Male aged 87)</p> <p>‘ok but needed help re texting’ (Male aged 73)</p> <p>‘ok but didn’t really understand, couldn’t send any comments back on Flo’ (Female aged 78)</p> <p>‘ok, but struggled re Recap Health’ (Male aged 52)</p>	

	<p>“Fantastic and very informative” (Female aged 58)</p> <p>“Thank you for your support I have found project helped me understand and recognise how my body feels and adapts each day with hf.” (Male aged 57)</p> <p>‘good support to check on me if not feeling well’ (Male aged 71)</p> <p>‘reassuring’ (Female aged 71)</p>		
<b>Question 2</b> <b>Patients giving feedback</b> <b>(N=66)</b>	<b>Examples of Positive comments</b>	<b>Examples of Neutral comments</b>	<b>Examples of Negative comments</b>
<b>Active on Flo only and giving feedback (n=21)</b>	<p>‘yeah Flo very helpful helped me manage a lot better than I would normally’ (Female aged 64)</p> <p>‘nice to have people at the end of the phone’ (Male aged 64)</p> <p>‘yeah was good’ (Male aged 66)</p> <p>‘yes’ (Male aged 61)</p>	<p>‘yes a little’ (Male aged 48)</p> <p>‘a little’ (Female aged 64)</p>	<p>‘not really’ (Male aged 76)</p>

<b>Active on Recap Health only and giving feedback (n=6)</b>	<p><b>(n=5)</b></p> <p>‘good info on Recap’ (Female aged 40)</p> <p>‘helpful to know someone there and info available if needed’ (Male aged 49)</p>		<p><b>(n=1)</b></p> <p>‘not really’ (Male aged 51)</p>
<b>Active on both and giving feedback (n=41)</b>	<p><b>(n= 34)</b></p> <p>‘Flo - ‘Smashing’ felt that there was somebody there Recap - not used as much’ (Male aged 66)</p> <p>‘Flo no issues easy to use, found recap information brilliant lots to read and videos helped me a lot’ (Male aged 60)</p> <p>‘yes loved the info and felt confident’ (Female aged 79)</p> <p>‘Flo - was like a best friend checking up on me. Recap - gave me the information I needed to feel reassured’ (Female aged 58)</p>	<p><b>(n=1)</b></p> <p>‘slightly’ (Female aged 77)</p> <p>‘yes, but struggled to access recap’ (Male aged 52)</p>	<p><b>(n=6)</b></p> <p>‘had issues sending messages. Kept responding back with cannot manage predictive text replies, even when they weren't using predictive text’ (Male aged 78)</p> <p>‘Flo - didn’t understand it , Recap - tried to access it but not very good with technology’ (Female aged 78)</p> <p>‘not much’ (Male aged 72)</p>

	<p>'Very useful and got immediate responses 'Flo' - was initially not confident with texting, but did answer the messages regularly. On occasion did 'Feel worse' and felt that the THC had their finger on the pulse and always tried their best to follow-up. Recap - Used and looked at some of the information. Liked the technical stuff and helped to start looking after yourself.' (Male aged 58)</p>		
<p><b>Question 3</b> <b>Patients active on Flo only and giving feedback (n=14)</b></p>	<p><b>(n=10)</b> 'more confidence in managing health' (Male aged 63)  'yes I do feel more confident and feel like I know what to do if anything happened to me' (Female aged 64)  'a little' (Male aged 76)  'yes a lot' (Female aged 58)</p>	<p><b>(n=3)</b> 'no change managed quite well' (Male aged 70)  'feel the same as I did before' (Male aged 66)</p>	<p><b>(n=1)</b> 'not really' (Male aged 61)</p>
<p><b>Patients active on Recap Health</b></p>	<p><b>(n=5)</b></p>	<p><b>(n=1)</b></p>	

<p><b>only giving feedback (n=6)</b></p>	<p>'improved confidence' (Male aged 83)</p> <p>'yes improved' (Male aged 49)</p>	<p>'a little' (Male aged 51)</p>	
<p><b>Patients active on both giving feedback (n=41)</b></p>	<p><b>(n=36)</b></p> <p>'YES, USEFUL' (Male aged 70)</p> <p>'yes helped me to cope better' (Male aged 66)</p> <p>'yes definitely' (Female aged 79)</p> <p>'yes-I am slowly getting used to what I can and struggle to do and start to understand the trigger points to avoid them.' (Male aged 57)</p> <p>'I definitely feel more confident in managing my own health' (female aged 58)</p> <p>'Confidence increased as far as understanding what you are dealing with. It gave reassurance between the Cardiology staff and THC' (Male aged 57)</p>	<p><b>(n=3)</b></p> <p>'a bit' (Female aged 77)</p> <p>'a little' (Female aged 76)</p> <p>'feel about the same as before. No changes' (Female aged 87)</p>	<p><b>(n=2)</b></p> <p>'not really, always need help' (Male aged 73)</p> <p>'no not really' (Male aged 52)</p>

Patients giving feedback (N=66)	Examples of Positive comments	Examples of Neutral comments	Examples of Negative comments
<p><b>Patients active on Flo only and giving feedback (n=14)</b></p>	<p><b>(n=14)</b></p> <p>‘yes, liked that there was someone checking I was ok’</p> <p>(Male aged 62)</p> <p>‘yes , so nice to have calls and texts’ (Male aged 64)</p> <p>‘I felt a lot of support from the project and the weekly phone calls to see how I was and how the project was for me was very nice.’ (Female aged 64)</p> <p>‘yes plenty of support from texting and telephone calls but was sorry did not have an email to obtain reading content’ (Female aged 71)</p> <p>‘yes good having someone there’ (Male aged 76)</p> <p>‘yes, knew where to call for help’ (Male aged 76)</p> <p>‘Felt completely supported by the THC and the use of Flo. It was helpful and felt</p>		

	<p>reassured.’ (Male aged 60)</p> <p>‘a lot of support from Flo and Telehealth coordinators’ (Female aged 36)</p> <p>‘yes’ (Male aged 61)</p>		
<p>Patients active on Recap Health only giving feedback (n=6)</p>	<p><b>(n=4)</b></p> <p>‘Yes good support’ (Male aged 59)</p> <p>‘yes , SHINE team very good &amp; rehab &amp; THC’ (Male aged 82)</p>	<p><b>(n=2)</b></p> <p>‘yes, but didn’t need much support’ (Male aged 86)</p> <p>‘sort of’ (Female aged 40)</p>	
<p>Patients active on both and giving feedback (n=41)</p>	<p><b>(n=39)</b></p> <p>‘Yes, nice to have the calls of support’ (Male aged 71)</p> <p>‘ Yes, nice to know someone’s there’’ (Male aged 70)</p> <p>‘yes, only a phone call away’ (Male aged 71)</p> <p>‘yes, liked having someone in the back’ (Male aged 66)</p> <p>‘yes definitely’ (Female aged 79)</p> <p>‘very well supported,</p>	<p><b>(n=1)</b></p> <p>‘Yes &amp; No , rang the Shine clinic for help’ (Female aged 78)</p>	<p><b>(n=1)</b></p> <p>No, not really’ (Male aged 52)</p>

	<p>miss it now it's finished' (Male aged 78)</p> <p>'Yes very supported. Received a couple of calls from the THC who helped. Being on the project helped so I didn't feel like I was sent home and forgotten about' (Female aged 58)</p> <p>'felt like there was a lot of support always somebody on the end of the phone' (Male aged 48)</p>		
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## Conclusions

Our aim was to try and reduce this 'revolving door' readmission rate to hospital using digital tools within our heart failure pathway. Did we do this?

Our service evaluation has demonstrated that patients who actively engage with our project have reduced all cause readmissions to A and E and as in-patients in hospital at 30 days (for A and E), and for 3 and 6 months post discharge for both. Our project is cost effective, cost efficient and has the potential to increase return on investment. It is affordable if readmissions in all admitted heart failure patients are reduced by approximately 20% of the actual readmission reductions achieved in our project.

It is interesting that the reduction in readmissions at 6 months in our project patients is at a time when patients are no longer on the Flo protocol (which ends at 3 months) and less likely to be avid readers of their Recap Health library (with most review of content before 3 months). This suggests that there may be a degree of improved self-management skills and potentially altered health care resource utilisation behaviour.

This 'hypothesis' is supported by the quality of life assessments that suggest an improvement in the self-efficacy metric from the KCCQ and additionally the patient surveys from Flo and conducted at the end of the 3 month Flo protocol by the telehealth co-ordinators.

It is interesting to note that there is no greater utilisation of the community heart failure nurse services by project patients in comparison to the usual care group. There is a numerical increase in GP utilisation by project patients in comparison to Usual care. The GP surgeries were selected by us as they represented more of our project patients. Although the number of visits per patient in the project vs. the usual care group were not statistically different, it is certainly possible that increased clinical input contributed to reduced readmissions.

We have demonstrated the high levels of patient satisfaction with project involvement. We have also demonstrated that patient experience is improved even for inpatients who have been cared for by the heart failure service before.

Patients also interacted well with (and made good use of) the Flo and Recap Health products.

It is pleasing to see an increase in relevant mean quality of life scores. Some of these increases did not reach significance, but it should be noted that some studies have suggested a worsening in quality of life scores in the early post-discharge period. Indeed this is what occurs as a non-statistically significant trend in paired EQ5D scores in the usual care group.

Care facilitation and telehealth co-ordinator contact was welcomed by patients and added to the job satisfaction for the co-ordinators themselves.

### **Limitations**

Patient numbers and age distribution of the project active group are not the same as all comers with heart failure. It must be remembered that the numbers of patients on our project are similar to those on other telehealth interventions. Equally the age of patients on trials that lead to guideline directed medical therapy in heart failure are in age groups similar to our project and extrapolated to the general heart failure population.

Only 15% of patients in our project group were over the age of 80 years. There may be many reasons for this. However failure to educate, engage and train our elderly patients to use either their text enabled phones or their e mails should not hamper the role out of digital enablers. Instead monies 'saved' from project implementation could be used to fund third sector organisations into helping create a new generation of 'silver' surfers and texters.

There was no intentional 'enrolment' bias on our part so any bias arose in patient referral bias by the heart failure team. However the initial frequency of ineligible patents suggests that there was no conscious referral bias.

The baseline admissions and readmissions to the Royal Stoke hospital have changed in the lifetime of the project. It is unclear whether the low referral numbers to the community nurses is a long standing or recent change in practice.

There is much unexpected data from the project to help improvements in the pre-existing heart failure services.

We were surprised by the not insignificant minority of patients whose quality of life, anxiety and depression and patient activation scores worsen at 3 months. This again may be an opportunity for the heart failure pathway to target extra resource to these patients to improve their lives further.

Future iterations of the project are likely to enrol patients in the community after discharge due to the significant anxiety experienced in the hospital.

### **Summary**

Our multi-faceted service evaluation - 'Listening to Messages from heart failure patients – Smart with your heart'- has exceeded our predicted relative risk reduction in all cause readmissions using predominantly 2 (out of 3) digital products in combination.

The lessons learned during our project have the potential to improve the heart failure pathway and patient engagement with these products in the future.

We have delivered a cost effective, cost efficient project with a return on investment likely to sustain a similar project at larger scale for all hospitalised heart failure patients. It is hoped that the cost savings to the health economy would be used to re-invest in community and third sector organisations that would ensure the projects results continue to improve.

The principles of our project may benefit other long term conditions and add to the overall predicted cost savings to the NHS of between £50-100,000,000 annually and locally an estimated £1.5m.