**THE CLINICAL PATHWAY OF PATIENTS WITH HEART FAILURE IN PRIMARY CARE**

**by**

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# ABSTRACT

**Background:** Heart failure is a common clinical syndrome associated with major adverse symptoms and poor outlook for patients, and high costs for healthcare systems globally. This thesis examines four aspects of the clinical pathway of patients with heart failure in primary care.

**Methods:** Routinely collected GP records are used to estimate the number of newly diagnosed heart failure cases by year. A qualitative interview study explores the patient experience of the diagnostic pathway. Survival analysis is used to determine prognosis of patients following a first diagnostic label. Finally, a screening study examines who develops heart failure over time.

**Results:** The incidence of heart failure has been static at 2.3 cases per 1,000 person-years since 2006. Patients initially normalise their symptoms so delay seeking help, GP access is challenging and communication in secondary care, particularly delivery of diagnosis, could be improved. Survival rates are 81.5%, 51.6% and 29.5% at 1, 5 and 10 years, respectively, and have not changed over time. Screening provides an alternative pathway to identify patients with heart failure.

**Conclusions:** Strategies to reduce the number of new cases of heart failure, enhance patient experience, improve survival and explore new diagnostic pathways should be important priorities for the NHS.

## DEDICATION

To my parents for their love and support, always

# ACKNOWLEDGEMENTS

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# ABBREVIATIONS

ACE: Angiotensin converting enzyme

AF: Atrial fibrillation

BMI: Body mass index

BSE: British Society of Echocardiography

CI: Confidence intervals

CPRD: Clinical Practice Research Datalink

ECG: Electrocardiogram

ECHOES: Echocardiographic Heart of England Screening Study

E:E': Ratio of mitral peak velocity of early filling (E) to early diastolic mitral annular velocity (E')

ESC: European Society of Cardiology

GP: General Practitioner

HES: Hospital episode statistics

HFPEF: Heart failure with preserved ejection fraction

HFREF: Heart failure with reduced ejection fraction

LVSD: Left ventricular systolic dysfunction

MI: Myocardial infarction

MRI: Magnetic resonance imaging

NHS: National Health Service

NICE: National Institute for Health and Care Excellence

NIHR: National Institute for Health Research

NP: Natriuretic peptide

NT-proBNP: N-terminal pro-B type natriuretic peptide

ONS: Office for National Statistics

QEHB: Queen Elizabeth Hospital Birmingham

QOF: Quality and Outcomes Framework

R&D: Research and Development

RCGP: Royal College of General Practitioners

THIN: The Health Improvement Network

UK: United Kingdom

US: United States

# 1. BACKGROUND AND AIMS OF THESIS

## 1.1 Chapter Overview

This chapter starts with an overview of this thesis, including the purpose and aims, to explain why examining the clinical pathway of patients with heart failure in primary care is important and justified. The rest of the chapter explores the relevant heart failure literature. First, the importance of heart failure, how it develops and how the definition has changed over time are explored. Next, the epidemiology of heart failure, in terms of incidence and the potential of general practice records as a source of epidemiological data are described. Then the experience of undergoing a diagnostic process from the patient's perspective is examined. Evidence from heart failure prognosis research with a discussion of survival rate estimates is presented. Finally the role of screening in identifying patients with heart failure is considered. The chapter concludes with a detailed summary of the aims and objectives of this thesis.

## 1.2 Overview of Thesis

The overall aim of this thesis is to explore the clinical pathway for patients diagnosed with heart failure in primary care. The thesis comprises four elements, which are described in detail below but first, to set the scene, there is a brief description of my background and the circumstances that led to, and ultimately justify, this thesis.

**1.2.1 My Background and Justification for this Thesis**

I am an academic GP in Birmingham practising in a deprived inner city surgery and conducting research and teaching at the university situated a mile away. The research questions in this thesis arose from encounters in both clinical and teaching situations where I realised that I did not have an evidence-based answer for either my patient or my student. The questions were relevant to different parts of the clinical pathway for patients with heart failure and, as in my clinical practice; I wanted my doctoral research to be 'patient-centred'.

From my perspective as a GP, heart failure is a common problem. Patients present with symptoms such as breathlessness along with a myriad of other, both physical and mental, health conditions and working out what is the main problem, and then a sensible investigation and management plan, is part of the challenge of being a generalist. I have always had an interest in cardiovascular disease and so I see a disproportionate number of patients with heart problems at the practice. I carry out the Quality and Outcomes Framework (QOF) coronary heart disease annual reviews and I am often the doctor who our respiratory nurse sends patients to if, despite optimisation of inhaler therapy, the patient with lung disease remains breathless.

Perhaps due to my background, I consider heart failure as a differential diagnosis in any breathless patient, or those who have had previous cardiac events, so I've identified many cases over the years. But how many new cases of heart failure should we, as a practice,

expect to be diagnosing each year? And what is that initial part of the diagnostic pathway – starting to get symptoms and then deciding to see the doctor – like for the patient?

I teach a Masters module on heart failure and in one of my teaching sessions I ask students to find a patient with heart failure and look back in their notes to see what happened leading up to, and following, a code of heart failure being entered into the record. The pathway my students describe is never uniform, as some guidelines might suggest it would be. Patients were seeing their doctor for several reasons, often having multiple health conditions and medications to manage. They had a variety of initial tests, sometimes, but not always, including investigations for heart failure, and were ultimately seen by the secondary care team to confirm the diagnosis. But what was that diagnostic process like from the patient's perspective?

In the practice, I regularly review patients with heart failure and I had one patient who, new to the area, attended to have his medication prescribed; however during the consultation, it became clear he did not realise that he had heart failure. Patients are seen and diagnosed in secondary care but often return to primary care afterwards. What are patients told about, and what do they understand by, a diagnosis of heart failure and what impact does it have on their lives?

I also teach medical students and I keep a record of the heart failure patients I see. I invite these patients to the surgery to speak to my students, or send the students out to see housebound patients. I noticed that, sadly, patients were dying and therefore dropping off my list after a year or two.  I started to wonder, what is the outlook for patients in general practice following their initial diagnosis of heart failure? The survival rates in the literature are from cohort studies in other countries or hospital populations where the patients are much more unwell than the people that I see with heart failure in general practice. If a patient wanted to discuss their prognosis following a diagnosis of heart failure, what survival figures are available that are relevant to them? And has the outlook improved in recent years, as it has for patients with cancer?

Finally, I have been part of the Heart Failure team in my research department for several years and I have worked on a large heart failure screening study. I noticed that participants in the study who we found to have heart failure were then entering the healthcare system through an entirely different route, which did not rely on them presenting to their GP with symptoms. Also most of the patients we were screening were healthy volunteers and when assessed they did not have heart failure. I wondered if we were picking up sufficient heart failure cases as a result of screening a cohort of the general population and if this was something that may or may not be worthwhile on a larger scale.

So I started to plan my doctoral work based on these areas of uncertainty. The aim was to provide answers to these fairly simple questions which were important to me as a practising

GP, the patients that I look after and the students that I teach. How many new cases of heart failure does the average GP practice see in a year and has this number gone up or down? What is it like for the patient going through the diagnostic process, from when they first notice some breathlessness or ankle swelling, through having tests, to receiving a diagnosis of heart failure? For the patient who is diagnosed through this route, rather than being diagnosed acutely in hospital, what is their outlook? And does screening actually pick up cases of heart failure in an otherwise healthy general population? In this thesis, I seek answers to all of these questions using four different methods which are described in more detail below; my contribution is detailed fully in Appendix 9.1.

### 1.2.2 Aims of this Thesis

The overall aim of this thesis is to examine four aspects of the clinical pathway for patients with heart failure in primary care as shown in Figure 1.
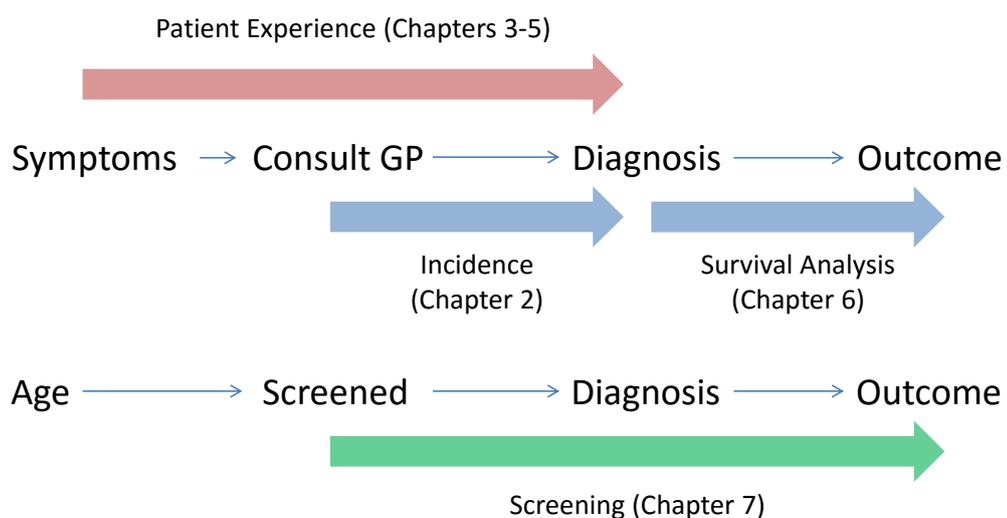
Figure 1: Diagram of components of PhD thesis

Firstly, the burden of disease will be determined by calculating the number of cases of heart failure recorded per year (incidence) in a general practice dataset. Heart failure is an important and costly condition so knowing how many patients are affected in a given population, how many new cases are emerging and if incidence is changing over time are all import considerations for clinicians and commissioners. Epidemiological data on the trends of heart failure in the population are available from a number of cohort studies from the United States and Europe but determining incidence of heart failure from routinely collected general practice data is a novel approach.[1]

Secondly, the patient experience of the diagnostic pathway will be explored. Patients with heart failure may start to experience symptoms such as breathlessness, ankle swelling or fatigue and then consult their GP and undergo an investigative process to arrive at a definitive diagnosis. The patient experience of this process has not previously been researched.

Thirdly, the outlook of patients diagnosed with heart failure will be explored also using data from general practice. Prognosis data for heart failure is usually derived from epidemiological studies or secondary care populations. The survival rates of patients in general practice using data from routinely collected records has not previously been determined.

Finally, the role of screening in identifying patients with heart failure will be explored using data from a heart failure screening study. Screening provides an alternative diagnostic pathway where individuals are invited for assessment to determine whether they have a diagnosis of heart failure.

The thesis concludes with a summary of the key findings from the four studies above, areas identified as requiring further research and recommendations for how the care of patients with heart failure in primary care could be changed or improved.

Four different methodological approaches are used to accomplish each of the four aims above. **The thesis is therefore presented in an 'Alternative Format' model according to the guidelines set out by the University of Birmingham.**[2] Chapter 1 describes the literature around the four areas of the clinical pathway for heart failure in detail. Then chapters 2, 6 and 7 start with an abstract, introduction, methods, results and conclusion. Due to the volume of qualitative data from the interview study, the methods, findings and discussion have been presented in three chapters (Chapters 3-5), rather than one. The final discussion section (Chapter 8) summarises and synthesises the key findings and recommendations from each of the four studies.

## 1.3 Background on Heart Failure

### 1.3.1 Why is Heart Failure Important?

Heart failure is an important public health problem associated with significant morbidity and mortality for patients and high costs for healthcare systems.[3] It occurs mainly in older people so may be predicted to increase as the population ages and more patients survive myocardial infarction but with a damaged heart.[4] Accurate estimates of heart failure incidence and prognosis are vital to healthcare commissioners to allow appropriate allocation of resources for treatment and palliative care, to physicians in making management decisions and, perhaps most importantly, to patients to allow informed decisions about treatments and end of life care.[5][6]

### 1.3.2 What is Heart Failure?

Heart failure is a clinical syndrome characterised by an inability of the heart to pump blood effectively enough to meet the metabolic needs of the rest of the body. Patients experience symptoms such as breathlessness, fatigue and swollen ankles. Clinical signs including lung crepitations, a raised jugular venous pressure and pitting oedema of the ankles and calves may be found on examination. Investigations include blood tests and imaging with echocardiography or cardiac magnetic resonance imaging (MRI). According to the European Society of Cardiology, symptoms/signs and objective evidence are required in order to confirm a diagnosis of heart failure.[7]

Heart failure is often an end result of considerable insult to the structure and function of the heart. Cardiovascular risk factors such as hypertension, high cholesterol, diabetes and subsequent coronary artery disease often predate the development of heart failure.[8] Treatments for coronary artery disease and heart failure may overlap but some may be contradictory, and novel therapies are emerging for both conditions.

### 1.3.3 Types of Heart Failure

In recent years the terms 'heart failure with reduced ejection fraction' (HFREF) and 'heart failure with preserved ejection fraction' (HFPEF) have evolved which recognise two distinct entities.[9] HFREF occurs when there is left ventricular systolic dysfunction (LVSD) resulting in a reduction in ejection fraction. In developed economies, this is most commonly linked to coronary artery disease, particularly myocardial infarction, and is due to cell death followed by scarring and remodelling resulting in a reduction in the ability of the left ventricle to eject blood efficiently through the aortic valve and to the rest of the body.[10] In developing economies, cardiomyopathies linked to aetiologies such as metabolic insult or infections, may be a more important driver of HFREF than coronary artery disease.[11]

HFPEF appears to be a different clinical and pathological entity and is associated with left ventricular stiffness and reduced filling but a preserved ejection fraction.[12] In HFPEF, the association with preceding coronary artery disease is less clear although risk factors such as hypertension or diabetes are often present.[13] Other causes of heart failure include cardiac

arrhythmias and significant valvular disease which may be correctable with intervention. Angiography is usually performed prior to valve surgery to check for concomitant coronary disease which may be managed with bypass grafting during the procedure.

### 1.3.4 How Does Heart Failure Develop Over Time?

Heart failure is the end result of considerable pathological insult to the heart resulting in an inability to pump sufficient blood to meet the physiological needs of the body.[7] The risk factors for, and precursors to, heart failure, such as hypertension, diabetes and high cholesterol, should be optimally managed as part of holistic primary prevention of cardiovascular disease.[14] Where damage has occurred, such as following myocardial infarction or prolonged high blood pressure, patients may develop heart failure but have mild symptoms of shortness of breath, swollen ankles and fatigue for some time before presenting to their GP or being admitted to hospital. Detecting patients at an early stage may provide a valuable window of opportunity to intervene to slow further decline and improve prognosis.[15]

### 1.3.5 Progression to Heart Failure

The outcomes for patients with established coronary artery disease initially improved with the advent of thrombolysis in patients with ST elevation myocardial infarction (STEMI) and optimal secondary prevention strategies. Primary percutaneous coronary intervention (PCI) has further improved outcomes for patients with STEMI over and above the benefit derived

from thrombolysis.[16] Timely access to a primary PCI service is now crucial in healthcare service planning in the developed world. As patients with coronary artery disease are living longer, the number with heart failure has increased. Hence, the prevalence of heart failure increases with age from around 1 to 1.5% in the general population overall to 10% in those over the age of 75.[17] Patients may develop heart failure symptoms many years after the identification of risk factors.[18] This provides a window of opportunity both for therapy to minimise the risk of progression to heart failure and early detection and treatment initiation if heart failure should develop. The prognosis of patients with heart failure is poor with survival rates for patients diagnosed after an acute admission for heart failure worse than most cancers [19] but early diagnosis and implementation of evidence based therapies could help to improve the outlook for patients.

The risk factors for coronary artery disease and most types of heart failure are similar. Cardiovascular risk factors such as hypertension and diabetes promote the development of atherosclerosis which leads to coronary artery disease. Heart failure can occur as the result of coronary artery disease or as a direct result of a particular cardiovascular risk factor (e.g. hypertension leading to HFPEF) as shown in Figure 2.[20]

Atherosclerosis

```
┌─────────────────┐          ┌─────────────────┐
│  Cardiovascular │   ────►  │    Coronary     │
│   Risk Factors  │          │  Artery Disease │
└─────────────────┘          └─────────────────┘
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Diastolic                              Myocardial
dysfunction                              injury

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                    ┌─────────────────┐
                    │  HEART FAILURE  │
                    └─────────────────┘
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┌─────────────────┐          ┌─────────────────┐
│ Heart failure with│        │ Heart failure with│
│ preserved ejection│        │ reduced ejection │
│ fraction (HFPEF) │         │ fraction (HFREF) │
└─────────────────┘          └─────────────────┘
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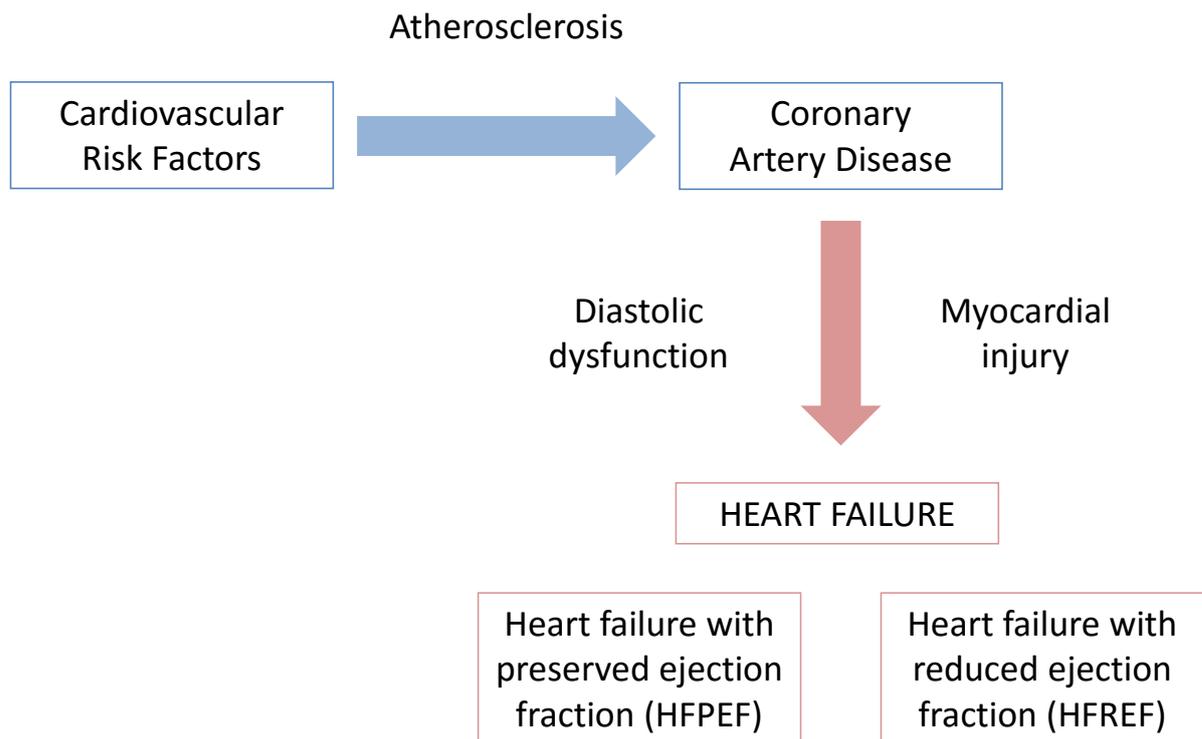
Figure 2: Relationship between risk factors, coronary artery disease and heart failure

## 1.3.6 Multimorbidity

Atherosclerosis usually affects most major blood vessels so although coronary lesions may present acutely as a heart attack, blockage of other arteries can also lead to catastrophic events - cerebral vessel blockage causing stroke and limb vessel occlusion resulting in critical ischaemia. The renal vasculature is often also involved and can be a limitation in optimising heart failure treatments which act via the kidneys.

Heart failure often occurs in the presence of other co-morbidities which share a common risk factor profile. For example smoking predisposes to coronary artery disease and chronic

obstructive pulmonary disease (COPD). The symptoms of heart failure can often overlap with those of COPD,[21] resulting in heart failure being unrecognised, and therefore untreated, in patients with COPD. In a study of elderly patients with stable COPD, heart failure was not recognised in 80% of those with both conditions in routine healthcare.[22] Similarly, chronic kidney disease is associated with common cardiovascular risk factors and may complicate and limit heart failure management options.

Heart failure is largely a disease of the elderly and multimorbidity - the presence of more than one physical or mental health problem - is common in this particular age group; furthermore, as the number of physical health conditions increases, so does the risk of a concomitant mental health problem.[23] Optimisation of both physical and mental wellbeing is therefore needed in these patients and primary care is well placed to offer holistic, person-centred care in this way.

### 1.3.7 Making a Diagnosis of Heart Failure

There is significant evidence to support heart failure treatments but making the diagnosis can be challenging.[24] Echocardiography is the most commonly used modality to identify objective evidence of cardiac dysfunction but resources are limited by cost and the number of trained echocardiographers. The symptoms and signs of heart failure are non-specific and the presence of co-morbidities and polypharmacy can complicate the diagnosis further. A recent systematic review showed that patients with symptoms such as shortness of breath,

fatigue and ankle swelling are significantly more likely to have heart failure if they have a history of myocardial infarction.[25] As a result, some guidelines recommend referral directly for echocardiography in these patients.[26]

Natriuretic peptides (NPs) are also increasingly being used to identify those patients with symptoms who have an increased likelihood of heart failure.[27] NPs are released from the chambers of the heart in response to pressure or fluid overload, acting on the kidneys to induce a diuresis and on the vasculature to cause both arterial and venous dilatation, thereby reducing preload and afterload. Heart failure is associated with an increased NP level. A rising NP level can be an early sign of heart failure however other factors such as renal impairment and ACE inhibitors can influence the NP level so results need to be interpreted in light of these other factors.

### 1.3.8 An Evolving Definition of Heart Failure

Over time the definition of heart failure has changed leading to dysynchrony between epidemiological studies making comparison difficult and meaning a code of heart failure in the medical record may be based on different criteria depending on the accepted definition at the time of diagnosis. The original heart failure definition derived from the Framingham Heart study and this has been updated since the original publications in the 1970s.[28] The European Society of Cardiology has also updated its definition of heart failure multiple times in the last two decades.[7 29 30] The criteria used in the Framingham definition rely on the

presence of symptoms and signs to determine a diagnosis of heart failure as shown in Table 1. A definitive diagnosis of heart failure requires the presence of two major or one major and two minor criteria concurrently.[31]

| Major Criteria | Minor Criteria |
|---|---|
| Paroxysmal nocturnal dyspnoea or orthopnoea | Bilateral ankle oedema |
| Distended neck veins | Night cough |
| Rales | Dyspnoea on ordinary exertion |
| Increased heart size by x-ray | Hepatomegaly |
| Acute pulmonary oedema on x-ray | Pleural effusion on x-ray |
| Ventricular (S3) gallop rhythm | Decrease in vital capacity by one third from maximum record |
| Increased venous pressure | Tachycardia (120 beats per minute or more) |
| Hepatojugular reflex | Pulmonary vascular engorgement on chest x-ray |
| Pulmonary oedema, visceral congestion, cardiomegaly shown on autopsy | |
| Weight loss on heart failure treatment (10lbs in 5 days) | |

Table 1: Framingham criteria for diagnosis of heart failure

The European Society of Cardiology definition of heart failure 2008 [30] required the presence of objective evidence in addition to symptoms and signs as shown in Table 2.

Heart failure is a clinical syndrome in which patients have the following features:

Symptoms typical of heart failure (breathlessness at rest or on exercise, tiredness, fatigue, ankle swelling).

*and*

Signs typical of heart failure (tachycardia, tachypnoea, pulmonary rales, pleural effusion, raised jugular venous pressure, hepatomegaly, peripheral oedema).

*and*

Objective evidence of a structural or functional abnormality of the heart at rest (cardiomegaly, third heart sound, cardiac murmurs, abnormality on echocardiogram, raised b type natriuretic peptides).

Table 2: European Society of Cardiology heart failure definition 2008

A more recent update of the guideline has recognised that signs may not always be present and has also delineated between two distinct heart failure types: HFREF and HFPEF as shown in Table 3.[7] The emergence of this new type of heart failure has meant that the clinical picture of heart failure has changed over time.[32]

The diagnosis of HF-REF requires three conditions to be satisfied:

1. Symptoms typical of heart failure

2. Signs typical of heart failure*

3. Reduced left ventricular ejection fraction

The diagnosis of HF-PEF requires four conditions to be satisfied:

1. Symptoms typical of heart failure

2. Signs typical of heart failure*

3. Normal or only mildly reduced left ventricular ejection fraction and left ventricle not dilated

4. Relevant structural heart disease (left ventricular hypertrophy/left atrial

enlargement) and/or diastolic dysfunction.

*Signs may not be present in the early stages of heart failure (especially in HF-PEF) and in patients treated with diuretics.

Table 3: European Society of Cardiology guideline 2012: Diagnosis of heart failure

## 1.4 Epidemiology of Heart Failure

Most epidemiological data about heart failure comes from cohort studies or secondary care populations. This section provides a summary of the key data on incidence and prevalence from around the world.

### 1.4.1 Incidence and Prevalence of Heart Failure in United States Cohorts

The trend in incidence of heart failure over time was examined by Barker et al in a cohort of United States (US) patients over the age of 65 using the medical records of a large US healthcare provider. Framingham criteria were used to determine presence or absence of

heart failure.  The incidence of heart failure was found to have increased over time between the period of 1970-1974 and 1990-1994 from 11.7 to 12.7 per 1000 person-years in men and 8.6 to 11.8 per 1000 person-years in women, respectively.[4]

The Rochester Epidemiology Project in Olmsted County, Minnesota links patient records from the Mayo clinic, Olmsted Community Hospital and Olmsted Medical Centre allowing analysis of complete medical records for a defined geographical population.[33] Roger et al examined the trends in the number of new cases of heart failure in this population to establish whether incidence was changing over time.[34] 4537 Olmsted County residents, average age of 74 years and 57% women, with a diagnosis of heart failure validated using Framingham criteria were included in the study. The incidence of heart failure in men was 3.60, 3.90, 3.75 and 3.83 per 1000 person-years in the five year periods 1979-1984, 1985-1990, 1991-1995 and 1996-2000 respectively. Incidence for women over the same time intervals was 2.84, 2.92, 2.60 and 3.15 per 1000 person-years. No statistically significant difference was found in incidence over time for either sex.

Prevalence of heart failure has also been examined in the Olmsted County population. Redfield et al conducted a cross-sectional survey of 2042 Olmsted County residents over the age of 45.[35] Framingham criteria were used to confirm a diagnosis of heart failure and Doppler echocardiography was also carried out to assess systolic and diastolic function. The overall prevalence of heart failure was 2.2% (95% CI 1.6% to 2.8%). Forty four per cent of participants with heart failure had an ejection fraction above 50%. Prevalence increased with

age from 0.7%, 1.3%, 1.5% and 8.4% in the age groups 45-54, 55-64, 65-74 and 75+ years, respectively.

## 1.4.2 Incidence and Prevalence of Heart Failure in European Cohorts

The Rotterdam study is a prospective population-based cohort study in the Netherlands recruiting 7983 patients over the age of 55.[17] In a study of the cohort by Bleumink et al, baseline assessment was carried out from 1989 to 1993 and participants were followed up until 2000 through linkage of their general practice records and health authority data. Heart failure was defined according to the European Society of Cardiology 1995 definition. Point prevalence in 1999 was 7.0% (95%CI 6.4 to 7.7) with a mean age of 74.5 years in the study population. Incidence of heart failure was 14.4 per 1000 person-years (95%CI 13.4 to 15.5) overall with higher incidence in men (17.6 per 1000 person years, 95%CI 15.8 to 19.5) than women (12.5 per 1000 person-years, 95%CI 11.3 to 13.8). Incidence increased with age from 1.4, 3.1, 5.4, 11.7, 17.0, 30.1, 41.9 and 47.4 in the 5 year age bands from 55-59 years through to 90+ years.

The Echocardiographic Heart of England Screening (ECHOES) study in the UK screened 6162 participants in the period 1995-1999 and found a heart failure prevalence of 2.3% in the general population group over the age of 45.[18] The ECHOES-X study re-screened participants from the original cohort a decade later and found a prevalence of 5.5% in the now 55 years and over general population group who did not have heart failure or LVSD on assessment in

the original ECHOES study. Overall, 176 cases of heart failure were found in a total of 1618 participants re-screened; 103 (58%) had an ejection fraction below 50% and were classified as HFREF and 73 (42%) had HFPEF. Multiple echocardiographic abnormalities were seen in participants with heart failure suggesting a complex and multifactorial disease. The full results of the ECHOES-X study are described in Chapter 7.

### 1.4.3 Incidence and Prevalence of Heart Failure with Preserved Ejection Fraction

Our understanding of the epidemiology of heart failure may be changing as HFPEF becomes increasingly recognised. Trends in prevalence of HFPEF were examined in the Olmsted County population over a 15 year period from 1987-2001 and reported in 2006.[36] Patients discharged from the Mayo Clinic Hospitals with a diagnosis of heart failure were classified as HFPEF if they had an ejection fraction of 50% or higher on echocardiogram. 6076 patients were discharged with a code of heart failure over the time period and 4596 (76%) had an ejection fraction recorded, of which 53% had an ejection fraction above 50%. Over time the proportion of heart failure cases classified as HFPEF increased from 38% to 47% to 54% in the time periods 1987-1991, 1992-1996 and 1997-2001, respectively.

## 1.5 General Practice Records as Sources of Epidemiological Data

Most general practices in the UK have been computerised since the 1990s.[37] Several providers have come into the market with software packages which allow GPs to record information in an electronic medical record. There has been considerable interest in using

routinely collected GP data since the start of computerisation but initially the quality of data was of concern to researchers.[38] Sustained improvements in the way data are recorded by GPs and the implementation of quality assurance processes over the past two decades has made general practice records an increasingly attractive source of data.[39] Several organisations have developed technology which can extract and store data anonymously in large databases and this has led to a significant and growing number of academic publications demonstrating the potential of record linkage to ultimately improve health outcomes.[40 41]

### 1.5.1 General Practice Databases

Routinely collected GP records provide a powerful source of data to answer important clinical questions.[42 43] There are four large databases which collect data from NHS general practice records and store them securely for research purposes: Clinical Practice Research Datalink (CPRD), QResearch, ResearchOne and The Health Improvement Network (THIN).

CPRD is owned and funded by the UK government through the National Institute for Health Research (NIHR) and the Medicine and Healthcare products Regulatory Agency (MHRA).[44] Currently, CPRD contains 11.3 million patient records; 4.4 million are active patients from 674 practices contributing data.[45] CPRD data are linked across the NHS from primary care, secondary care – through Hospital Episode Statistics (HES) – and to other organisations such as the Office for National Statistics (ONS) mortality database. CPRD is also developing

systems to allow clinical trial data to be extracted directly from the electronic health record and is pioneering innovative products including collection of patient reported outcomes and biosamples directly from patients.

QResearch is a collaboration between the University of Nottingham and Egton Medical Information Systems (EMIS).[46] The database holds data from 18 million electronic health records. There are currently 1,000 contributing practices through EMIS software systems. The QResearch database has been used to generate risk prediction tools including QRisk2 which is recommended by NICE for estimation of cardiovascular risk in patients over the age of 35.[47]

ResearchOne is also a database increasingly used for research purposes.[48] Data are collected from over 4,500 healthcare settings using SystmOne including general practice, community care, acute hospitals, accident and emergency and out of hours services. Where providers are all using SystmOne the clinical data merges into one patient record avoiding the need for additional linkage.

THIN is a database of anonymised patient records which has been widely used for epidemiological and drug safety research.[49] It currently collects data from 570 practices, representing 6.05% of the UK population, and has a total of 11.7 million patients (3.7 million of these are currently active records).[50]

The data stored in these databases includes demographic details, diagnoses, prescribing data, additional health information such as test results, free text comments and socioeconomic status. Databases are also able to link patient records to other information sources such as HES which holds secondary care data. The data are anonymised to ensure individual patients cannot be identified. The demographics section includes general information such as year of birth, gender and dates the patient joined and left the practice but does not contain any identifiable information such as name, date of birth, postcode or NHS number.

In this thesis, THIN database is used to explore the incidence of a first diagnostic code of heart failure in the GP record (Chapter 2) and the survival rates of people with a heart failure diagnosis (Chapter 6). The choice of THIN was, above all, a pragmatic one. For all databases, researchers must pay a fee to access the data. These charges may be one off payments or in the form of a license fee where institutions are granted access to the whole database for a fixed annual rate. For the duration of my PhD, the University of Birmingham had access to THIN through an annual license. The strengths and limitations of THIN database will now be considered.

*Strengths*

THIN provides a window into the day to day activity of general practice in the UK. Practices using Vision software provide data through a programme called 'In Practice Systems' which

runs in the background and does not disrupt routine recording of patient care. All patient identifiers are completely removed. Researchers can access the data by request through the THIN central registry. The database therefore provides a true reflection of what is happening every day in the NHS.

THIN collects data from 570 practices which represents 6.05% of the UK population. Studies using THIN datasets are therefore likely to be generalizable to the general population.[51] Research using other methods, such as cohort studies, is unable to achieve this degree of representativeness.

THIN contains a large volume of data with a total of over 80 million patient years of computerised data. Data are longitudinal, and continually updated, so changes in disease patterns and the effects of new treatments can be monitored over time. This provides an incredibly powerful dataset for researchers.

*Weaknesses*

Research databases rely on the quality of data input at the time of the clinical consultation. The application and consistency of clinical coding is crucial for researchers to be able to reliably identify patterns in disease. The limitations of the use of clinical data for research are considered in the next section of this chapter.

Data may also be missing. For example, blood pressure or cholesterol measurements may not have been entered in a format where the data can be extracted. This can be dealt with by using the data which is present in the database to impute missing values for individuals. In addition, some data may simply not be captured. For example, over the counter medicines are not recorded in the electronic medical record and some fields, such as occupation, are often left incomplete.

THIN is the smallest of the main database providers but the number of patient records is still very large. Cohort studies using THIN, such as the heart failure cohort used to examine incidence over time in Chapter 2, still have far greater numbers than any prospective cohort study might achieve.

Linkage in THIN is less advanced than CPRD; while some practices in THIN link to HES data this is not universal. In addition, information such as cause of death from ONS mortality data has only recently been accessible. Innovative practice including integration of clinical trials, patient reported outcome measures and the possibility of biosamples from individual patients has been pioneered by CPRD rather than THIN.[52] For the observational studies in this thesis, this functionality was not required and would therefore have been of no benefit.

For all GP databases, to provide a reliable picture of activity in the NHS, particularly for observational studies, a database which includes all NHS records, in both primary and

secondary care, is needed but at present remains only an aspiration. Controversy around

patient confidentiality and data security has stalled progress in this area.[53]

## 1.5.2 Using Clinical Data for Research

General practice databases have a wealth of data for use in research but, as for any study,

the data collected and used to answer the research question must be of high quality.

Research databases have evolved over the past two to three decades and there is increasing

recognition of the need to assess the 'readiness' of data sources before embarking on

research projects.[54] De Lusignan et al argue that six key concepts should be considered, and

reported, for all research studies involving routinely collected datasets so both the

researchers themselves and the readers of the final paper are clear about the data source.[55]

Firstly, they describe data quality as the overarching principle asking the fundamental

question of 'are these data fit for purpose? Secondly, the issue of data provenance - how the

data were created – should be considered. In the case of the THIN database, this is

dependent on clinical coding during routine consultations (considered in more detail in

subsequent sections). Then data extraction and data processing must also be assessed. To

extract data from THIN a list of clinical codes is used and the process of generating this list is

described in Chapter 2. Finally, traceability – the degree to which reported results can be

traced back to the original dataset – and curation which considers the importance of data

storage to allow future researchers to replicate results or use the data source for new

projects. To achieve this level of data quality requires expertise in terms of clinical coding, data extraction and data analysis. Skills in some of these areas, particularly data extraction, are limited in the research community and, as a result, NHS data are currently underused for research purposes.[56]

### 1.5.3 Clinical Coding in General Practice Records

The information contained in GP clinical systems is a combination of free text and 'coded' data. During consultations, GPs input the clinical details of the encounter under a heading which broadly describes the problem. This may be a diagnosis or a symptom. Patients may consult with several different problems during one consultation and these are usually entered under separate problem headings. Each of the problem headings is a clinical code. The system of clinical coding used in practice is often referred to as 'Read codes' after their inventor Dr James Read. In the early 1980s, Dr Read, a practising GP, identified the need for a consistent set of clinical codes which were both intuitive and easy to use.[57] He worked with a software manufacturer to develop a comprehensive thesaurus of clinical codes which were integrated into clinical systems. GPs have been using computerised record systems, and inputting coded data, since the early 1990s resulting in a large volume of clinical information, dating back over two decades, which can be used to analyse disease pattern and healthcare delivery over time.[58]

**1.5.4 The Impact of the Quality and Outcomes Framework on Clinical Coding**

There are a wide range of Read codes which can be used for a particular disease and GPs often vary in their choice of code.[59] In 2004, the Quality and Outcomes Framework (QOF) was introduced as a payment incentive scheme in the NHS in England. The points-based system assesses clinical performance, particularly chronic disease management. Specific Read codes, recognised by QOF, are required for computer searches to allocate points. Multiple conditions such as diabetes mellitus, coronary artery disease, hypertension and heart failure are included in the QOF schemes with a limited range of Read codes. More broadly, the link to payment means that GPs have become much more aware of the need to accurately code diagnoses, investigations and treatments.

**1.5.5 Coding of Heart Failure in Primary Care Records**

The accuracy of clinical coding is a crucial consideration for researchers using primary care databases.[60] The clinical codes extracted from the database for use in the research dataset should ideally be both valid and complete but in the real world of primary care data input this is rarely fully achieved. The concepts of validity and completeness, in the context of heart failure coding, are explored below.

*Validity*

For a heart failure code to be valid, the patient with that code in their medical record should have heart failure in real life. Heart failure is a clinical syndrome i.e. a collection of symptoms

and signs. The GP may initially code the symptoms with which the patient presents such as ankle swelling, breathlessness or lethargy, prior to a formal diagnosis being made. The diagnosis should be confirmed through further investigation, usually echocardiography. Once the severity and type of heart failure has been established, evidence-based treatments can be commenced and optimised to both relieve symptoms and improve outcomes for patients.

Since 2006, the QOF has included a heart failure indicator, requiring practices to have a register of all patients with heart failure and ensure that the diagnosis of heart failure is validated either by the presence of an echocardiogram report or a letter from a consultant cardiologist confirming the diagnosis. Due to the requirement for objective testing, a diagnosis of heart failure in high performing QOF practices is likely to be validated.[61] A clinical code of heart failure prior to this date may still though be valid. Heart failure is above all a clinical diagnosis and earlier definitions of heart failure did not require formal objective testing as described in the previous section.

*Completeness*

Researchers aspire to a complete data set to be confident in their research results and the conclusions they draw. Primary care research databases are reliant on the extent of coding at the time of consultation to ensure completeness. For example, if a diagnosis of heart failure is not coded according to a recognised system, this data cannot be extracted for

research purposes. This could result in an underestimation of prevalence or incidence of a particular disease.

Recording in general practice databases may not be 100% accurate and the definition may have changed over time, but the data in GP records does reflect the real life situation of the healthcare system in which patients are managed each day in the UK. To provide clinicians with epidemiological information for patients in general practice it may be more appropriate to use data from general practice to calculate incidence and survival rates. If, for example, the prognosis of heart failure in epidemiological studies is different to the prognosis of 'diagnosed heart failure' in general practice it implies that there may still be significant misclassification. A better understanding of the epidemiology of the condition within the general practice setting will be helpful in determining the healthcare burden posed by heart failure now and in the future.

## 1.6 Patient Experiences of Heart Failure Diagnosis

The evidence above illustrates that heart failure is a common, treatable and possibly preventable condition so making a diagnosis is important. Heart failure is a major cause of morbidity and mortality in our ageing population where survival from myocardial infarction has improved and effective treatments for cardiovascular disease have become available.[4][18] Healthcare costs in terms of hospital admissions and long term care remain high.[3][19][62] Heart failure is a syndrome characterised by symptoms of shortness of breath, oedema and fatigue

but can overlap with other medical conditions making accurate diagnosis challenging.[63] But if heart failure is diagnosed correctly and in a timely manner, evidence-based treatments exist to improve prognosis and quality of life.[26] [30] [64] The patient experience of the diagnostic process and what the term 'heart failure' means to them is currently unknown.

The diagnostic pathway for patients with heart failure in primary care is under-researched. The National Institute for Health and Care Excellence (NICE) guidance on Chronic Heart Failure 2010 provides an investigation algorithm (natriuretic peptide test or direct referral for echocardiogram) for patients once the diagnosis of heart failure is suspected but the patient experience and clinical decision-making prior to initiating investigation to confirm the diagnosis is unclear.[26] The NICE guidance, and the evidence upon which it is based, does not address the grey area from when the patient first experiences symptoms to the time they seek medical attention and the diagnostic process prior to the GP considering heart failure and referring for an investigation to confirm the diagnosis. There has been some qualitative research around end of life care for patients with heart failure[65] [66] but the patient experience of the diagnostic pathway has not been critically evaluated. It is unclear what prompts patients to first seek medical attention, which symptoms are most common in primary care in patients who subsequently have a diagnosis of heart failure, and what patients understand by the diagnostic label of 'heart failure'.

**1.6.1 Symptoms Onset and Seeking Medical Attention**

Symptom onset can vary according to disease. For example, patients with stroke may experience a sudden onset of symptoms with one-sided weakness, speech disturbance or facial asymmetry. Early intervention can lead to life-saving treatment yet there is often a delay in patients seeking emergency medical attention. Mackintosh et al conducted a qualitative interview study to understand what factors might be involved in the delay and found that help-seeking decisions by patients experiencing symptoms of stroke were complex.[67] Some patients did not know the symptoms of stroke and others did not appreciate the importance of seeking medical help urgently. The role of primary care services in responding quickly in patients presenting with stroke symptoms was also variable. In addition to lack of knowledge, patients described fear of stroke or hospital admission and a subsequent denial which prevented them from seeking help immediately. Witnesses also played a key role in recognising stroke symptoms and taking action to access medical services.[68]

Similarly, patients with acute myocardial infarction, or heart attack, often experience a sudden onset of symptoms namely crushing central chest pain. Henriksson et al conducted focus groups with patients and their relatives to explore their thought processes when symptoms of acute myocardial infarction occurred.[69] Patients felt uncertain about the cause of their symptoms, often assuming they were caused by something less serious, and tried various methods to alleviate symptoms prior to seeking help. Relatives played a vital role

and were usually more concerned than the patient themselves, encouraging them to take further action such as calling for an ambulance.

Unlike stroke or acute myocardial infarction, heart failure symptoms are often insidious in onset.[7] Patients may experience a gradual onset of breathlessness on exertion over several months, mild ankle swelling or general tiredness. The patient experience of early symptoms and decision-making around seeking medical attention prior to a diagnosis of heart failure has not been evaluated. The first part of the qualitative study presented in Chapters 3-5 explores the patient perspective from when they first noticed something wrong and what prompted them to seek medical help.

**1.6.2 Diagnostic Process from the Patient Perspective**

The process of heart failure diagnosis is complex and guidelines differ in the tests they suggest clinicians should use to assess the likelihood of the condition. For example, the NICE guidelines in England state that patients with symptoms suggestive of heart failure should be assessed using a natriuretic peptide test, unless they have a history of myocardial infarction where they should then be referred directly for echocardiogram.[26] However the European Society of Cardiology still advocate the use of ECG and chest x-ray, as well as natriuretic peptide testing, in the diagnostic process.[7] Echocardiogram is the most commonly used investigation to confirm the diagnosis but availability of echo machines and appropriately trained echo technicians, as well as cost, limits the availability to primary care.

Some studies have looked at the role of the clinician in the diagnostic process for heart failure. Fuat et al carried out focus groups with general practitioners to explore the barriers to accurate diagnosis, and management, of heart failure in primary care.[70] Clinical knowledge, GP understanding of the investigative process, availability of local resources and a mistrust of the relevance of the evidence base to primary care were all factors affecting timely diagnosis and management. However, the process of visiting the GP, attending for diagnostic tests, waiting for results, and in some cases initiation of treatment, prior to receiving a formal diagnosis has not been explored from the patient perspective. Part of the qualitative study in Chapters 3-5 aims to find out what patients experienced in the pathway between first seeing their GP with symptoms to the point where they received a formal diagnosis of heart failure.

### 1.6.3 Understanding of Heart Failure by Patients and Carers

According to international guidelines, at the end of the diagnostic pathway in primary care, patients should receive a formal diagnosis of heart failure which is confirmed by echocardiogram and explained to them.[7] However, some studies have identified that patients are not necessarily told, or do not retain, the diagnostic label of heart failure or may not understand what it means. Andersson et al interviewed patients with a label of heart failure in their medical records. Patients did not recall being given a diagnosis of heart failure and many put their symptoms down to advancing age rather than any underlying disease.[71]

For those who are aware of their diagnosis of heart failure, understanding the term and adapting to living with the condition can be challenging and involve several stages. Stull et al

interviewed patients in Ohio to explore their experiences of being told they have heart failure and living with the disease.[72] They found that the diagnosis was often made following a crisis event, rather than after a timely diagnostic process, and that patients and their families went through a process of role adaptation before finally coming to terms with the diagnosis and finding ways of moving on with their lives.

## 1.7 Prognosis of Heart Failure

Prognostic data are a vital part of the epidemiological information used by clinicians, public health experts and healthcare commissioners to inform the way care is provided at an individual and population level. Patients may want to discuss their outlook with their doctor and use this information to make informed decisions about their treatment options. Public health specialists monitor trends to see if the patterns of disease are changing and whether efforts to improve survival rates have been successful. In addition, commissioners need to understand the treatment and end of life care needs of the population for which they provide healthcare. Therefore accurate and contemporary epidemiological data from a directly relevant source is vital.

The large epidemiological studies described above such as Framingham, Olmsted County, Rochester, ECHOES and other studies have examined survival rates in addition to incidence and prevalence rates. The study by Barker et al reported 30 day, 1 year and 5 year mortality rates in men and women in the Framingham Heart Study for the periods 1970-74 and 1990-

94.[4] In men, mortality rates fell from 14.2% (95%CI 9.1 to 19.3) to 9.8% (95%CI 7.6 to 12.0), 46.8% (95%CI 39.7 to 53.0) to 32.5% (29.0 to 36.0) and 82.7% (95%CI 77.4 to 88.0) to 68.8% (95%CI 65.3 to 72.3) at 30 days, 1 year and 5 years, respectively between the two time periods. Mortality rates were less in women but did not reduce significantly between the two time periods (hazard ratio for mortality 1.01, 95%CI 0.77 to 1.30).

Roger et al also reported mortality rates in those diagnosed with heart failure in the Olmsted County population between 1979 and 2000.[34] In the 1996 to 2000 group, 30 day, 1 year and 5 year mortality was 6% (95%CI 5 to 7), 21% (95%CI 18 to 24) and 50% (95%CI 45 to 54), respectively in men and 4% (95%CI 3 to 4), 17% (95%CI 14 to 19) and 46% (95%CI 42 to 51), respectively in women. Overall age-adjusted 5 year mortality declined over time from 57% in the 1979-1984 cohort to 48% in the 1996-2000 cohort. Survival gains were greatest for men and younger participants (below 75 years at time of heart failure diagnosis). A study by Redfield et al also in the Olmsted County population but looking at the burden of systolic and diastolic dysfunction found after controlling for age, sex and ejection fraction, the presence of moderate or severe diastolic dysfunction was predictive of all-cause mortality.[35]

The Rotterdam study, which recruited participants over the age of 55 between 1989 and 1993 and followed them up to the year 2000, reported survival, rather than mortality, rates. The median survival time following a diagnosis of heart failure was 2.1 years (range 1 day – 9.0 years). Overall survival was 86% (95%CI 83 to 88) at 30 days, 63% (95% CI 59 to 66) at 1

year and 35% (95%CI 31 to 39) at 5 years. There was no statistically significant difference in survival between men and women (log rank test, p=0.15).

The ECHOES study is one of the few studies to report 10 year, as well as 5 year, survival rates. All deaths in the cohort were collated from routinely collected mortality data. Five-year survival rate was 53% in patients with heart failure and LVSD and 62% in patients with heart failure and no LVSD compared to 93% for the general population over the age of 45. Overall the mortality rate for all-cause heart failure was 9% per year.[73] At ten years, survival was 27% for those with heart failure and LVSD and 27% for those with heart failure and no LVSD compared to 75% in those without heart failure.[78]

## 1.8 The Role of Screening

Currently in the UK there is no widespread screening programme to identify patients with heart failure. Instead, patients present with symptoms and undergo the diagnostic process outlined above. This may mean that patients have symptoms for some time and present later in the disease trajectory, although there is currently little evidence to suggest screening for heart failure in primary care is warranted. This final section explores the definition of screening and the existing evidence on screening for heart failure in the community.

**1.8.1 Definition of Screening**

The aim of any screening intervention is to identify disease early to allow treatment which will improve outcome. The criteria used to determine if screening is a worthwhile process were developed by Wilson and Jungner.[74] The UK National Screening Committee assesses any screening programme against a comprehensive set of criteria[75], shown in Table 4.

The NHS in England currently has three widespread screening programmes in operation: cervical cancer, breast cancer and bowel cancer screening.[76] These programmes use screening tests to identify patients who require further investigation to confirm or rule out a diagnosis. Those found to have the disease are managed according to national guidelines. The aim of each programme is to diagnose and treat cancer sooner to improve the likelihood of cure but there is some controversy about whether screening on such a large scale may contribute significant harm in terms of over diagnosis and psychological stress.[77]

**Criteria for appraising the viability, effectiveness and appropriateness of a screening programme**

Ideally all the following criteria should be met before screening for a condition is initiated:

**The Condition**

1. The condition should be an important health problem

2. The epidemiology and natural history of the condition should be adequately understood.

3. All the cost-effective primary prevention interventions should have been implemented.

**The Test**

4. There should be a simple, safe, precise and validated screening test.

5. The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.

6. The test should be acceptable to the population.

7. There should be an agreed policy on the further diagnostic investigation.

**The Treatment**

8. There should be an effective treatment or intervention for patients identified through early detection, with evidence of early treatment leading to better outcomes.

9. There should be agreed evidence based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.

10. Clinical management of the condition and patient outcomes should be optimised.

**The Screening Programme**

11. There should be high quality evidence that the screening programme is effective in reducing mortality or morbidity.

12. There should be evidence that the complete screening programme is clinically, socially and ethically acceptable to health professionals and the public.

13. The benefit from the screening programme should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment).

14. The opportunity cost of the screening programme should be economically balanced in relation to expenditure on medical care as a whole (i.e. value for money).

15. Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be available.

16. Evidence-based information, explaining the consequences of testing, investigation and treatment, should be made available to potential participants.

Table 4: Adapted from the UK National Screening Committee criteria[75]

**1.8.2 Heart Failure Screening Studies**

The Echocardiographic Heart of England Screening Study (ECHOES) recruited 16 general practices from the West Midlands region and invited over 10,000 patients to attend for screening. Patients were assessed by medical history-taking, clinical examination, ECG and echocardiogram. A cardiologist determined the diagnosis of heart failure. In the screened cohort, the overall prevalence of definite heart failure was 2.3% in the general population over the age of 45.[18]

The mortality rates of all-cause, all-stage heart failure found at screening in the ECHOES population were around half those reported for patients diagnosed for the first time with heart failure during a hospital admission.[78] Patients admitted to hospital present at a later stage in the disease process and have more severe heart failure with a consequently worse prognosis.[79] However, these findings are subject to lead time bias where patients diagnosed earlier in the disease process show an increased survival simply because they had a label applied sooner than those presenting with symptoms to routine health services.

The role of screening has also been examined for other chronic diseases, such as COPD, which are insidious in onset and are often diagnosed once symptoms become significant. Van Mourik et al examined the detection of heart failure and COPD in the frail elderly through a targeted screening method.[80] Frail patients over the age of 65 years were sent a questionnaire asking about breathlessness and reduced exercise tolerance. Those with

either symptom were invited to attend a clinic appointment for further assessment which included clinical history and examination, blood test, spirometry, ECG and echocardiogram. Of 570 participants who responded to the questionnaire, 395 (69% of respondents) had reduced exercise tolerance and/or shortness of breath. 389 participants attended for screening and in this group, 127 patients (33.5% of the screened cohort) received a new diagnosis of heart failure and 65 patients (16.8% of the screened cohort) had a new diagnosis of COPD. The authors concluded that this was a simple and effective method of identifying patients with undiagnosed heart failure and/or COPD but the impact of detection on quality of life and survival is yet to be explored.

In a follow-up of the COPD cohort, the authors examined the electronic medical records of patients with a new diagnosis of COPD at 6 and 12 months following the screening visit to identify any change in treatments, hospitalisations and survival.[81] The management strategies seemed to change little despite a new diagnosis of COPD. However 32% of patients with a new diagnosis of COPD were hospitalised within a year of screening representing a significant healthcare burden. The reasons for lack of management changes were not explored but the authors speculate that the patients may not have complained about their symptoms if they were not severe compared to their other co-morbid conditions. Alternatively the clinician may have been reluctant to alter medications in patients with extensive polypharmacy for fear of adverse events although the inhaled nature of most COPD medications makes drug interactions less likely than with oral therapies.

Definitive evidence for widespread echo screening to detect heart failure is currently lacking and a large randomised controlled trial would be required to determine the clinical and cost-effectiveness of screening prior to implementation of a population-wide programme. While screening programmes are still debated, all practitioners need to have a low index of suspicion for heart failure in patients with a history of coronary artery disease. Early referral for investigation is important to ensure optimal management and improve patient prognosis.

## 1.9 Overview and Aims of Thesis

### 1.9.1 Thesis Overview

The overall aim of this thesis is to explore the clinical pathway for patients diagnosed with heart failure in primary care as illustrated in Figure 1.

Firstly, the burden of disease will be determined by calculating the number of recorded cases of heart failure in a general practice dataset. Heart failure is an important and costly condition so knowing how many patients are affected in a given population, how many new cases are emerging and if survival rates are changing are all import considerations for healthcare providers. Epidemiological data on the trends of heart failure in the population are available from a number of cohort studies from the United States and Europe but determining incidence of heart failure from routinely collected general practice data is a novel approach.[1]

Secondly, the patient experience of the diagnostic pathway will be explored. Patients with heart failure may start to experience symptoms such as breathlessness, ankle swelling or fatigue and then consult their GP and undergo an investigative process to arrive at a definitive diagnosis. The patient experience of this process has not been previously researched.

Thirdly, the outlook of patients diagnosed with heart failure will be explored also using data from general practice. Prognosis data for heart failure is usually derived from epidemiological studies or secondary care populations. The survival rates of patients in general practice using data from routinely collected records has not previously been determined.

Finally, the role of screening in identifying patients with heart failure will be explored using data from a heart failure screening study. Screening provides an alternative diagnostic pathway where individuals are invited for assessment to determine whether they have a diagnosis of heart failure.

### 1.9.2 Aims of Chapter 2 – Incidence of Heart Failure

The aim of Chapter 2 is to determine the incidence of heart failure in the general practice population using routinely collected data. A cohort of patients with a diagnosis of heart failure was extracted from the THIN database to explore the number of new cases. The

clinical codes used to record a diagnosis were used to identify a first diagnostic label of heart failure. The objectives of Chapter 2 are:

- To calculate the incidence of a first diagnostic label of heart failure in a general practice population by sex and age band.

- To determine if the incidence of heart failure has changed over time.

This epidemiological information is important to allow healthcare providers to plan services based on the number of patients with heart failure. It is also important to clinicians to understand if the pattern of the disease is changing, particularly whether new heart failure cases are being prevented by better primary and secondary prevention strategies for cardiovascular disease.

### 1.9.3 Aims of Chapters 3, 4 and 5 – Patient Experience of Diagnosis

The aim of Chapters 3-5 is to explore patient experiences of a diagnosis of heart failure, to develop an understanding of heart failure diagnosis from the perspective of the patient and to use this data to highlight behaviours and processes which could be modified to improve the patient experience and outcome. These aims are achieved by using semi-structured interviewing to gather data on participants experiences of heart failure diagnosis from when they first noticed symptoms to receiving a formal diagnosis of heart failure, and asking participants to reflect back on the experience to identify anything that could have been improved. Then a framework analysis of the data is carried out to describe key behaviours and processes in the participants' journeys. The objectives of this study are:

- To explore how patients describe the onset of heart failure symptoms and the explanations they have for the symptoms initially.

- To determine what prompts patients to seek medical attention for their symptoms.

- To explore how patients describe the experience of seeing the GP and having tests carried out.

- To examine what patients understand by a diagnosis of heart failure, what the term means to them and what impact the diagnosis has on their lives.

- To gather patient's views on their experience of the heart failure diagnostic pathway in hindsight and how they feel things might have been improved.

The findings of the study provide a rich description of the patient experience of heart failure diagnosis from first symptoms to impact of the diagnosis on their everyday life. The data are used to identify what factors are important at key points in the diagnostic pathway (in particular, decision to initially consult, investigative processes and receiving a formal diagnosis) which could be modified to optimise patient experience.

### 1.9.4 Aims of Chapter 6 – Survival of Patients with Heart Failure

The aim of Chapter 6 is to explore the survival rates of patients with heart failure in the community. Routinely collected general practice data are used to determine the outlook for patients following a first diagnostic label of heart failure. The objectives of Chapter 6 are:

- To determine the one, five and ten year survival rates of patients following a diagnosis of heart failure.

- To explore whether survival of patients with heart failure has improved over time.

Up to date and relevant survival rates from a community population are important if patients wish to discuss outlook following a diagnosis of heart failure. Examination of trends in survival rates over time is also useful to determine if prognosis has improved with modern treatments and interventions.

### 1.9.5 Aims of Chapter 7 – Role of Screening

The aim of Chapter 7 is to explore the role of screening in diagnosing heart failure in the community. The ECHOES-X study procedure and findings are presented along with a discussion on the use of screening to identify heart failure patients in primary care. The original ECHOES study screened over 6,000 people to identify patients with heart failure. The aim of the follow-up study - ECHOES-X - was to estimate progression to heart failure within the previously screened cohort. Participants who were still alive from the original cohort were invited for re-screening. The objectives of Chapter 7 are:

- To determine how many participants in a previously screened cohort have evidence of heart failure or left ventricular systolic dysfunction (LVSD) at re-screening.

- To explore the outcome of those with heart failure or LVSD from the original ECHOES cohort.

- To examine the role of natriuretic peptide testing in screening for heart failure in a community population.

Screening can detect disease before symptoms become apparent. For some diseases, an earlier diagnosis can allow effective treatments to be started sooner and improve the subsequent outlook for patients, although the role of screening remains controversial.

Identifying patients with heart failure at re-screening from a previously screened cohort can provide vital insight into the natural history of heart failure. The role of natriuretic peptides in identifying those most likely to have a diagnosis of heart failure is also important.

## 1.10 Summary of the Chapter

This chapter started with an overview of this thesis which explores the clinical pathway for patients with heart failure in primary care. The background section began with a description of heart failure, including the definitions and classifications, the progression of disease, the importance and challenge of making the diagnosis and the role of multimorbidity. The literature related to the four aspects of the thesis was then explored. First, the epidemiology of heart failure, in terms of incidence and the potential of general practice records as a source of epidemiological data were described. Then what is known about the experience of undergoing a diagnostic process from the patient's perspective was examined. Evidence from heart failure prognosis research with a discussion of survival rates estimates was presented. Finally the role of screening in identifying patients with heart failure was considered. The overall plan, and aims and objectives of the thesis, was set out in detail.

In this thesis, by investigating the epidemiology of heart failure using general practice records, exploring the patient experience of the diagnostic process and considering the role of screening in identifying patients with heart failure earlier, the aim is to provide a better understanding of the clinical pathway for patients with heart failure in primary care.

## 2. INCIDENCE OF HEART FAILURE DIAGNOSIS IN GENERAL PRACTICE

## 2.1 Chapter Overview

This chapter aims to explore the incidence of heart failure in the community by examining a large database of general practice records. The background and aims of the study are described then the methodological approach to using general practice records for research purposes is explained. The results are presented then a discussion of the strengths and limitations of the study and the findings in relation to existing literature are explored.

## 2.2 Abstract

**Background and Aims:** Accurate and relevant epidemiological data are vital to monitor trends in chronic diseases to both inform clinical practice and plan healthcare services. The aim of this study was to determine the incidence of a first diagnostic label of heart failure in general practice records.

**Methods:** This retrospective cohort study examined UK general practice records from The Health Improvement Network (THIN) between 1st January 1995 and 31st December 2012. All individuals over the age of 45 in the THIN dataset were included. Outcome was a label of heart failure by age, sex and year of diagnosis.

**Results:** Of 2,730,738 patients in the cohort, 55,248 had a first diagnostic code of heart failure. Incidence fell from 5.36 (95%CI 5.17 to 5.55) per 1,000 person-years in year 2000 to

2.41 (95%CI 2.33 to 2.49) per 1,000 person-years in 2007 and remained around 2.3 per 1,000

person-years until 2012. Overall, incidence of heart failure increased with age, and was more

common in men than women in all age groups.

**Conclusions:** The number of new cases of heart failure in general practice declined before

2007 then remained stable. Further research is needed to explain these trends and to find

strategies to reduce incidence.

## 2.3 Background and Aims

As set out in Chapter 1, heart failure is an important public health problem associated with

significant morbidity and mortality for patients and high costs for healthcare systems.[3] It is

defined as a clinical syndrome requiring symptoms and objective evidence of a structural or

functional cardiac abnormality to confirm the diagnosis.[7] Accurate estimates of heart failure

incidence are vital to healthcare commissioners to allow appropriate allocation of resources

and to doctors and researchers to explore and understand patterns in the disease.[5 6]


The incidence of heart failure has been well described by screening studies such as

Framingham and Olmsted County in the United States[82] and the Rotterdam and ECHOES

studies in Europe.[18 78] These populations represent well-phenotyped and distinct cohorts of

patients who voluntarily took part in research and may not therefore be fully representative

of the general community population.[83] In recent years there has been increasing use of

routinely collected datasets from general practice databases. This chapter explores the use

of one of these datasets to determine the incidence of heart failure in a primary care population.

Hospital records and billing data can also be used to monitor trends in disease patterns but this approach has limitations. A Canadian study examined the incidence of heart failure in an administrative health dataset.[84] The incidence varied according to the definition of heart failure used; when heart failure was defined as a record of one hospitalisation with a heart failure code in the billing record in a year, the incidence was 33% lower than if the definition was broadened to include hospitalisation or 2 physicians' claims for heart failure in a year. This reflects the reality that most patients with heart failure will be managed within the community without necessarily requiring hospital admission.

In many countries around the world, electronic primary care records are providing a valuable source of data directly relevant to community populations.[39 85 86 87 88] Most general practices in the UK have been computerised since the 1990s thanks to software packages which allowed general practitioners (GPs) to record information in an electronic medical record.[37] [38] Patient records contain diagnostic codes as well as demographic and treatment information.[89 90] Large datasets of anonymised patient records have become an increasingly attractive source of data for researchers.[40]

In the UK, at birth every individual is assigned an NHS number. Healthcare delivery throughout their lifetime is linked to this number which is unique to each patient. The NHS provides universal healthcare free at the point of access to all. General practice is the foundation of the NHS and almost the entire population of the UK are registered with a general practitioner; this structure for healthcare delivery provides a unique environment for research. THIN is one of the largest databases of general practice records in the world. It currently includes data from 587 practices in the UK, approximately 6% of the whole UK general practice population.[50]

Heart failure can affect all age groups including children. The types of heart failure affecting children and younger people are pathologically distinct from heart failure found in older adults.[91] The randomised controlled trials conducted in the 1990s to examine the effectiveness of drug treatment in patients with heart failure recruited participants who were from middle-age onwards.[92] [93] [94] The ECHOES study recruited patients over the age of 45 for this reason. To allow comparison with the ECHOES findings, an age group of 45 or older was also used for this cohort study.

The aim of this study was to determine the incidence of heart failure in the general practice population using routinely collected data. A cohort of patients with a diagnosis of heart failure was extracted from the THIN database to explore the number of new cases. The clinical codes used to record a diagnosis were used to identify a first diagnostic label of heart failure. The objectives of the study were:

- To calculate the incidence of a first diagnostic label of heart failure in a general practice population by sex and age band.

- To determine if the incidence of heart failure has changed over time.

This epidemiological information is important to allow healthcare providers to plan services based on the number of patients with heart failure. It is also important to clinicians to understand if the pattern of disease is changing - particularly whether new heart failure cases are being prevented by better primary and secondary prevention strategies for cardiovascular disease.

## 2.4 Methods

### 2.4.1 Design

An open matched retrospective cohort study was carried out using data from THIN database for the period between 1st January 1995 and 31st December 2012.

### 2.4.2 Setting

THIN is a primary care database containing electronic patient records from 587 general practices in the UK. At each consultation, the GP records details of the medical encounter. Symptoms or diagnoses are entered using a clinical coding system. Prescriptions and laboratory results/observations (e.g. blood pressure) are recorded electronically. Demographic details such as age, sex and linked deprivation scores also form part of the

record. Practices that contributed at least one year of clinical data were included in the study.[95]

## 2.4.3 Study Population

To determine incidence, a cohort was extracted from the database including all persons aged 45 years and over, registered at the practice for at least 12 months during the study period. Patients with a previous diagnosis of HF were excluded. Eligible cases were defined according to the following criteria:

- A clinical code of heart failure from a list generated using the NHS terminology browser and the Quality and Outcomes Framework coding list.

- Age 45 and over at the time of code recording. There was no upper age limit.

- Confirmed cases were those with a hospital letter stating the diagnosis or abnormal echocardiogram recorded in the notes.

- Unconfirmed cases were those with a clinical code of heart failure alone.

- Index date was the first recorded heart failure diagnosis.

- First diagnostic code was entered between 1st January 1995 and 31st December 2012.

## 2.4.4 Clinical Codes

Participants with a diagnosis of heart failure were identified using the clinical codes used by GPs to record new diagnoses in the medical record. The NHS Clinical Terminology Browser

and Quality and Outcomes Framework guidelines were used to generate a comprehensive list of terms used to code for a diagnosis of heart failure:

| | |
|---|---|
| 1O1..00 | Heart failure confirmed |
| G1yz100 | Rheumatic left ventricular failure |
| G232.00 | Hyperten heart&renal dis with (congestive) heart fail |
| G234.00 | Hyperten heart&renal dis+both (congestive)heart fail |
| G58..00 | Heart failure |
| G58..11 | Cardiac failure |
| G580.00 | Congestive heart failure |
| G580.11 | Congestive cardiac failure |
| G580.14 | Biventricular failure |
| G580000 | Acute congestive heart failure |
| G580100 | Chronic congestive heart failure |
| G580200 | Decompensated cardiac failure |
| G580300 | Compensated cardiac failure |
| G580400 | Congestive heart failure due to valvular disease |
| G581.00 | Left ventricular failure |
| G581.12 | Pulmonary oedema – acute |
| G581000 | Acute left ventricular failure |
| G582.00 | Acute heart failure |
| G583.00 | Heart failure with normal ejection fraction |
| G583.11 | HFNEF - heart failure with normal ejection fraction |
| G58z.00 | Heart failure NOS |

Heart failure is a clinical syndrome and the diagnosis requires the presence of symptoms and objective evidence of a structural or functional abnormality of the heart.[7] Patients with a clinical code of heart failure and either an echocardiograph report or a hospital letter were

classified as being a confirmed case of heart failure and those with just a clinical code alone as unconfirmed cases.

### 2.4.5 Baseline Variables

Demographic variables including age, sex, ethnicity, area deprivation quintile (Townsend [96]), cardiovascular risk factors and co-morbidities were extracted. The latest deprivation quintile prior to the index date was used or, if unavailable, the most recently recorded after the index date. Cardiovascular risk factors (smoking, blood pressure, cholesterol, body mass index (BMI)) were the most recent recorded prior to index date. Cardiovascular co-morbidities (angina, myocardial infarction (MI), ischaemic heart disease, diabetes, hypertension, stroke, atrial fibrillation, valve disease), were defined by the presence of a clinical code at any time prior to the index date.

### 2.4.6 Outcome Measures

For the incidence calculations, outcome was presence of a first diagnostic code of heart failure.

### 2.4.7 Statistical Analyses

Data were extracted directly from THIN database using the list of clinical codes. Analysis was carried out using Stata versions 10 and 11. The number of practices, absolute numbers of

confirmed and unconfirmed heart failure cases and proportion of heart failure cases classified as confirmed was calculated. Age distribution of heart failure cases and participants characteristics for confirmed, unconfirmed and all heart failure cases were also summarised.

Overall incidence of heart failure was calculated using the total number of new diagnoses of heart failure cases and the total number of patient years of observation in the THIN database between 1st January 1995 and 31st December 2012. Incidence was also calculated by sex and 10 year age bands from 45 years onwards. Incidence, by year of first diagnostic label of heart failure, was also calculated and adjusted for age using the mid-year population estimates from the Office for National Statistics for 2012 (the last year of the study).

## 2.5 Results

### 2.5.1 Practices

A total of 564 practices contributed at least one year of data between 1st January 1995 and 31st December 2012. The number of contributing practices increased significantly over time from just 9 in 1995 to over 500 by 2008 as shown in Figure 3.
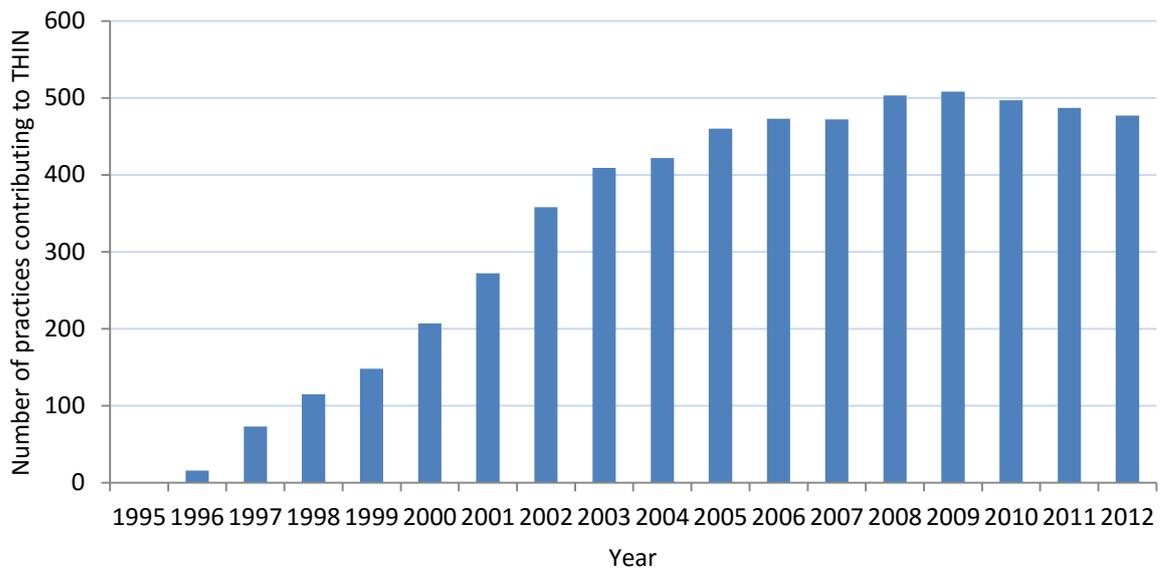
Figure 3: Number of practices contributing to THIN dataset by year

A total of 2,730,738 patient records were included in the incidence dataset. 55,248 participants had a new clinical code of heart failure during the study period; 40,615 with a code of heart failure alone (unconfirmed case) and 14,633 with additional evidence to support the diagnosis such as hospital letter or echocardiogram result (confirmed case).

The total number of new cases of heart failure per year in the dataset increased to nearly 5,000 in 2003 then declined to around 3,500 in 2007 which remained stable until 2012 as shown in Figure 4. The number of confirmed cases increased during the first years of the study period then peaked in 2007 at 34% then declined year by year to just over 20% in the last year of the study.
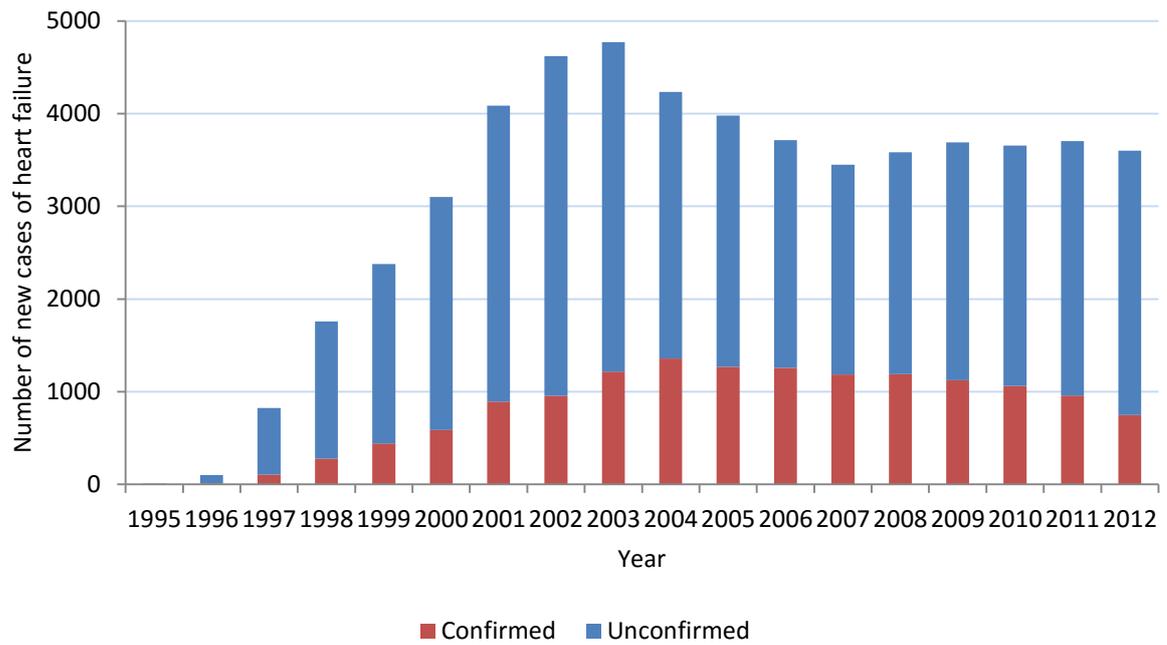
Figure 4: Number of new cases of heart failure by year

## 2.5.2 Study Population

The age distribution of all heart failure patients is shown in Figure 5. It remains a disease largely of the elderly with the majority of cases occurring between the ages of 70 and 90 years.
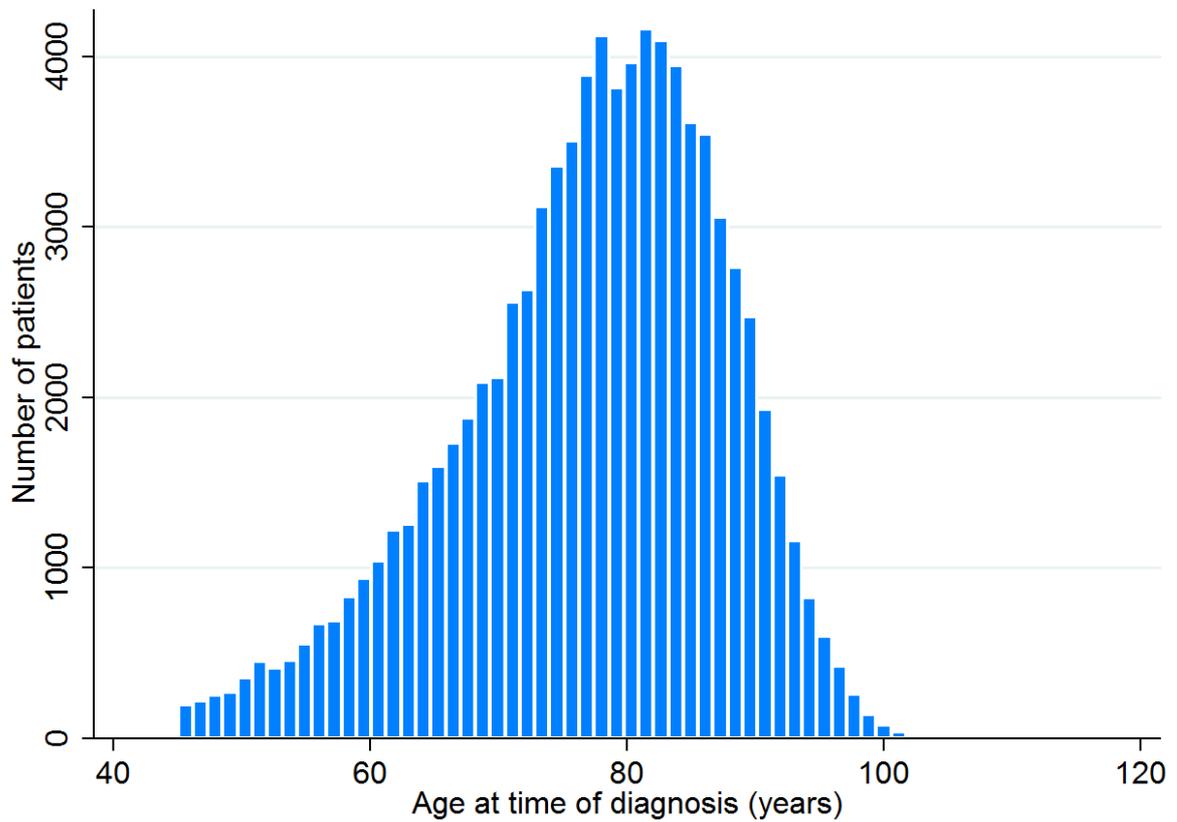
Figure 5: Age distribution of patients with a first diagnostic code of heart failure

The characteristics of cases with confirmed and unconfirmed heart failure are shown in Table 5. Cases with confirmed heart failure were younger and 56% were male compared with 50% in the unconfirmed group. All five Townsend deprivation quintiles were similarly represented except for the most deprived group which had around one third fewer cases than the other four groups. The proportion of participants in each Townsend score group was similar for confirmed and unconfirmed cases. BMI was similar and there were 2% more smokers in the confirmed compared to the unconfirmed heart failure group. Ischaemic heart disease, angina and MI were all more common in the confirmed group. Cardiovascular co-morbidities such as AF and stroke were common in both heart failure groups.

| Characteristic | HF: confirmed (n=14,633) | HF: unconfirmed (n=40,615) | HF: all (n=55,248) |
|---|---|---|---|
| Age (years) | | | |
| 45-54 | 585 (4.0%) | 1,182 (2.9%) | 1,767 (3.2%) |
| 55-64 | 1,745 (11.9%) | 3,598 (8.9%) | 5,343 (9.7%) |
| 65-74 | 3,571 (24.4%) | 8.807 (21.7%) | 12,378 (22.4%) |
| 75-84 | 5,558 (38.0%) | 15,750 (38.8%) | 21,308 (38.6%) |
| 85-94 | 2,983 (20.4%) | 10,238 (25.2%) | 13,221 (23.9%) |
| >=95 | 191 (1.3%) | 1,040 (2.6%) | 1,231 (2.2%) |
| Male | 8,204 (56.1%) | 20,206 (49.7%) | 28,410 (51.4%) |
| Townsend score | | | |
| 1 | 2,877 (19.7%) | 8,233 (20.3%) | 11,110 (20.1%) |
| 2 | 2,905 (19.9%) | 8,449 (20.8%) | 11,354 (20.6%) |
| 3 | 2,952 (20.2%) | 8,346 (20.6%) | 11,298 (20.5%) |
| 4 | 3,008 (20.6%) | 8,068 (19.9%) | 11,076 (20.1%) |
| 5 | 2,314 (15.8%) | 5,733 (14.1%) | 8,047 (14.6%) |
| Not known | 577 (3.9%) | 1,786 (4.4%) | 2,363 (4.3%) |
| BMI | | | |
| Mean (SD) | 27.9 (5.8) | 27.8 (5.9) | 27.9 (5.9) |
| Missing | 1,862 (12.7%) | 7,181 (17.7%) | 9,043 (16.4%) |
| Smoking status | | | |
| Smoker | 2,290 (17.7%) | 5,502 (13.6%) | 7,792 (14.1%) |
| Not current smoker | 11,731 (80.2%) | 32,051 (78.9%) | 43,782 (79.3%) |
| Missing | 612 (4.1%) | 3062 (7.5%) | 3674 (6.7%) |
| Diabetes | 2,971 (20.3% | 7,878 (19.4%) | 10,849 (19.6%) |
| Hypertension | 7,922 (54.1%) | 21,247 (52.3%) | 29,169 (52.8%) |
| Angina | 3,575 (24.4%) | 9,201 (22.7%) | 12,776 (23.1%) |
| Myocardial infarction | 3,919 (26.8%) | 8,528 (21.0%) | 12,447 (22.5%) |
| Ischaemic heart disease | 6,985 (47.7%) | 16,694 (41.1%) | 23,679 (42.9%) |
| Stroke | 1,270 (8.7%) | 3,761 (9.3%) | 5,031 (9.1%) |
| Atrial fibrillation | 4,732 (32.3%) | 10,894 (26.8%) | 15,626 (28.3%) |
| Valvular disease | 1,727 (11.8%) | 3,841 (9.5%) | 5,568 (10.1%) |

Table 5: Characteristics of patients with heart failure

### 2.5.3 Incidence of Heart Failure

The incidence of heart failure overall for the entire study period was 3.02 (95%CI 2.99 to 3.05) per 1,000 person-years and was higher amongst older individuals increasing from 0.29 (95%CI 0.28 to 0.31) per 1,000 person-years in the 45-54 year age group to 18.60 (95%CI 17.59 to 19.67) per 1,000 person-years in those aged over 95 (Table 6). The incidence of heart failure was higher in men than women in every age band. Overall incidence in the age group 65 and older was 6.83 (95% CI 6.77 to 6.89) per 1,000 person-years and in the age group 75 years and older was 10.93 (95%CI 10.82 to 11.04) per 1,000 person-years.

| Age (yrs) | Men | | | Women | | | Total |
|---|---|---|---|---|---|---|---|
| | No. with HF | Person years at risk | Incidence per 1,000 person-years (95%CI) | No. with HF | Person years at risk | Incidence per 1,000 person-years (95%CI) | Incidence per 1,000 person-years (95%CI) |
| 45-54 | 1,230 | 3,050,852 | 0.40 (0.38-0.43) | 537 | 2,965,141 | 0.18 (0.17-0.20) | 0.29 (0.28-0.31) |
| 55-64 | 3,754 | 2,602,456 | 1.44 (1.40-1.49) | 1,589 | 2,604,100 | 0.61 (0.58-0.64) | 1.03 (1.00-1.05) |
| 65-74 | 7,419 | 1,802,119 | 4.11 (4.02-4.21) | 4,959 | 1,973,082 | 2.51 (2.44-2.58) | 3.28 (3.22-3.34) |
| 75-84 | 10,728 | 1,007,799 | 10.64 (10.45-10.85) | 10,580 | 1,397,598 | 7.57 (7.43-7.72) | 8.86 (8.74-8.98) |
| 85-94 | 4,992 | 254,472 | 19.62 (19.08-20.17) | 8,229 | 545,587 | 15.08 (14.76-15.41) | 16.53 (16.25-16.81) |
| >=95 | 287 | 13,620 | 21.07 (18.77-23.66) | 944 | 52,577 | 17.95 (16.85-19.14) | 18.60 (17.59-19.67) |
| All ages | 28,410 | 8,731,318 | 3.25 (3.21-3.29) | 26,838 | 9,538,085 | 2.81 (2.78-2.84) | 3.02 (2.99-3.05) |

Table 6: Incidence of heart failure by age and sex (per 1000 person-years at risk)

The overall age-adjusted incidence of heart failure from 1995 to 2012 is shown in Figure 6. The incidence in 1995 was 7.44 per 1,000 person-years (95%CI 2.59 to 12.29) but just one practice contributed data in the first year of the study. The number of contributing practices increased rapidly in the first two years of the study period (Table 7). Incidence from 1997 onwards is therefore likely to be most accurate. Incidence declined from 5.36 per 1,000 person-years (95%CI 5.17 to 5.55) in 2000 to 2.41 per 1,000 person-years (95%CI 2.33 to 2.49) in 2007, after which the rate stabilised at around 2.3 cases per 1,000 person-years.
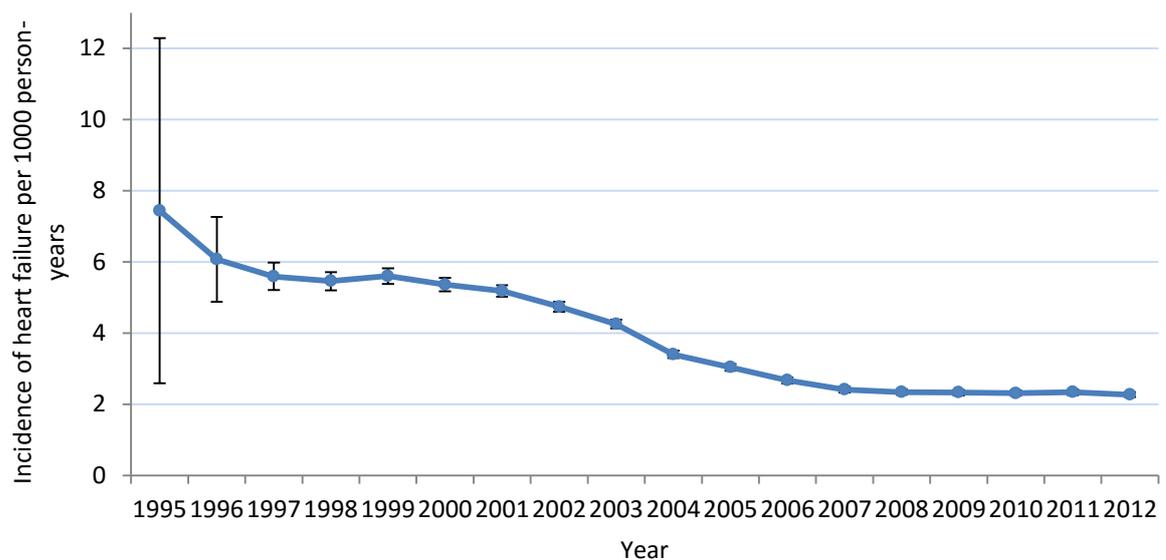
Figure 6: Age-adjusted incidence of heart failure per 1000 person-years by year

| Year of diagnosis | Number of contributing practices | Crude incidence per 1,000 person-years (95%CI) | Age-adjusted incidence per 1,000 person-years (95%CI) |
|---|---|---|---|
| 1995 | 1 | 6.15 (3.20-11.82) | 7.44 (2.59-12.29) |
| 1996 | 16 | 5.68 (4.68-6.91) | 6.07 (4.88-7.26) |
| 1997 | 73 | 5.18 (4.84-5.54) | 5.59 (5.21-5.98) |
| 1998 | 115 | 5.23 (4.99-5.48) | 5.46 (5.20-5.71) |
| 1999 | 148 | 5.36 (5.15-5.58) | 5.60 (5.38-5.82) |
| 2000 | 207 | 5.12 (4.94-5.30) | 5.36 (5.17-5.55) |
| 2001 | 272 | 4.97 (4.82-5.12) | 5.18 (5.02-5.34) |
| 2002 | 358 | 4.55 (4.42-4.69) | 4.74 (4.60-4.88) |
| 2003 | 409 | 4.05 (3.94-4.17) | 4.25 (4.13-4.37) |
| 2004 | 422 | 3.27 (3.17-3.37) | 3.40 (3.30-3.50) |
| 2005 | 460 | 2.91 (2.82-3.00) | 3.04 (2.94-3.13) |
| 2006 | 473 | 2.56 (2.48-2.64) | 2.67 (2.58-2.75) |
| 2007 | 472 | 2.32 (2.25-2.40) | 2.41 (2.33-2.49) |
| 2008 | 503 | 2.26 (2.19-2.33) | 2.34 (2.27-2.42) |
| 2009 | 508 | 2.24 (2.17-2.32) | 2.33 (2.25-2.40) |
| 2010 | 497 | 2.24 (2.17-2.32) | 2.31 (2.24-2.39) |
| 2011 | 487 | 2.28 (2.21-2.35) | 2.34 (2.26-2.41) |
| 2012 | 477 | 2.23 (2.15-2.30) | 2.27 (2.20-2.34) |

Table 7: Numbers of practices, crude and age-adjusted incidence of heart failure by year

## 2.6 Discussion

### 2.6.1 Summary of Results

This study confirmed the incidence of a first diagnostic label of heart failure is higher amongst older individuals and is more common in men than women. Incidence of a heart failure clinical code fell by more than half from 5.36 to 2.41 per 1,000 person-years between 2000 and 2007. Since then incidence has remained stable at around 2.3 heart failure cases per 1,000 person-years.

### 2.6.2 Strengths and Limitations

This study reports incidence of heart failure from a large representative set of general practices and is therefore likely to be generalizable to the community population as a whole.[97] The cohort included in this analysis is much larger than those used in epidemiological studies of heart failure. The large number of patients in each age and sex category improves the accuracy of the incidence estimates.

The NHS has a strong primary care base and provides healthcare to the entire population, free at the point of access. This means nearly everyone in the population is registered at a general practice allowing a denominator – the number of people in the population – to be generated. General practice datasets like THIN are therefore able to generate a rich dataset which provides detailed information about routine care across a large number of participants from the general population. Unlike screening cohort studies, general practice

databases do not rely on participants volunteering to take part in the study rather they represent a cross-section of the entire population.

The main limitation of the study is the reliability of GP coding. Heart failure is a chronic condition which is often insidious in onset and can masquerade as other conditions making early and accurate diagnosis difficult.[21] The first recorded heart failure diagnosis in this dataset was in July 1995. Clinical coding improved significantly following the introduction of widespread computerisation and the use of Read codes. Previous authors have reported significant improvements in coding prior to the formal introduction of a QOF indicator.[98] The heart failure QOF indicator, introduced in 2006, required robust evidence of heart failure. The number of heart failure cases fell prior to the introduction of QOF and has remained stable since then at around 2.3 cases per 1,000 person-years. so the fall between 2000 and 2007 may partly reflect more robust clinical coding methods rather than a true fall in incidence.

The number of confirmed heart failure cases – i.e. those without objective evidence - may reflect a lack of coding of echocardiogram or hospital letter rather than these elements being missing in the general practice record. This is another limitation of routinely collected datasets which rely on detailed coding of every piece of information for it to be retrievable for analysis. However, THIN provides a snap shot of real-life general practice which is complementary to detailed phenotyping by screening studies.

Over time the definition of heart failure has changed leading to dysynchrony between epidemiological studies, making comparison difficult, and the meaning of a code for heart failure in an individual's medical record may be based on different criteria depending on the accepted definition at the time of diagnosis.[7 29 30] A more recent update of the European Society of Cardiology guideline has also recognised two distinct heart failure types: heart failure with reduced ejection fraction (HFREF) and heart failure with preserved ejection fraction (HFPEF).[7] The emergence of this new classification has meant that the clinical picture of heart failure is changing and, from a recent search we undertook for these codes in THIN database, coding in the general practice record has not, until very recently, started to capture this.

All data extracted from the THIN dataset have been presented here for the purposes of this thesis, however, the first three years (1995-1997) of the dataset included data from less than 100 practices. As shown in Figure 6, the confidence intervals for incidence are therefore wider than estimates for subsequent years. Previous research has suggested that THIN is similar to the UK general population[51] but this may not be the case for the first three years of the study when the number of participants in the population was low.

### 2.6.3 Comparison with Existing Literature

There is a paucity of contemporary epidemiological information on heart failure from a primary care setting. In England, the QOF (a payment incentive scheme for general practice) report annual prevalence figures for heart failure which have been 0.8-0.9% per year since the introduction of the heart failure indicator in 2006.[99] However the number of new cases

per year is not recorded. National heart statistics include heart failure incidence and mortality within an umbrella term of 'cardiovascular disease' so estimates for heart failure alone are lacking.[100]

Incidence has therefore come from epidemiological studies such as the Framingham Heart study in the US or the ECHOES studies in the UK. The Framingham Heart study began in 1948 and followed up the original cohort every 2 years.[28] A study of the Framingham cohort examining the trends in incidence of heart failure between 1950 and 1999 found incidence was 5.54 per 1,000 person-years for men in 1999 and had remained unchanged in 50 years, however the incidence in women had fallen from 4.20 (95%CI 3.36 to 5.04) to 3.27 (95%CI 2.66 to 3.88) per 1,000 person-years at risk over the same period.[101] This is similar to the incidence in the THIN dataset pre-2006. However, the Framingham participants are largely white, middle class and voluntarily took part in research so are unlikely to be fully representative of the UK primary care population. The original criteria used in the Framingham definition also relied on the presence of symptoms and signs to determine a diagnosis of heart failure but more recent definitions emphasise the importance of objective evidence of a structural or functional abnormality of the heart, usually from imaging.[31]

The Framingham Offspring Study follows up the children of the original Framingham participants and continues to explore cardiovascular disease patterns. Participants in the Offspring cohort were originally screened between 1995 and 1999 and are followed up every 4 years. In a study to identify markers of new onset heart failure, Velagaleti et al examined

the cumulative incidence of heart failure following the original screening visit. There were 2754 participants included in the sample with a mean age of 58 years and 54% female. Over a mean follow-up period of 9.4 years (maximum 12.8 years), there were 95 new cases of heart failure, providing a cumulative incidence of 3.4%. However the authors did not calculate the incidence by year or by person-years at risk so it is not possible to determine trends in incidence over time.[102]

A screening study in the Netherlands also recently reported incidence of new onset heart failure in a screened cohort. The Prevention of Renal and Vascular End-stage Disease (PREVEND) study screened 8592 participants in 1997 and 1998. Age at recruitment was 28-75 years and most participants were Caucasian. After 11.4 years follow-up, 374 participants had developed heart failure – a cumulative incidence of 4.4%. Participants were recruited due to a mildly raised urinary albumin excretion at baseline, a marker of possible cardiovascular risk, so the cohort is unlikely to be representative of the general population.[103]

Sweden has well-developed, high-quality health registries which allow more detailed examination of the epidemiology of diseases. A cross-sectional study of 2.1 million residents of the Stockholm region was carried out by Zarrinkoub et al using an administrative health data register.[104] The register contains records of both primary and secondary care consultations, as well as hospitalisations. Between 2006 and 2010, the overall prevalence of heart failure was estimated to be 2.2% and incidence was 3.8 per 1,000 person-years. During

the study period there was a reduction in incidence of 0.9 per 1,000 person-years (a relative 24% decrease, P<0.002) between 2006 and 2010 which was the same for both men and women. A similar decrease was not seen in the THIN dataset during this time period.

## 2.6.4 Implications for Practice

The data in GP records reflects the real life situation of the UK healthcare system in which a million patients are managed each day.[105] In order to provide doctors and commissioners with accurate epidemiological information to inform patient care and plan health services, it is perhaps most appropriate to use data from general practice to calculate incidence. From our findings, a moderately sized GP practice with, for example, 5,000 patients over the age of 45 will have around 10 patients receiving a new heart failure diagnosis per year. This information is important when planning heart failure services at a local and regional level but also to individual GPs when considering the number of patients they are likely to see and treat within a year.

The incidence of heart failure in this study has remained stable since 2007. The reasons for this are complex and require further research. Heart failure is a disease of the elderly and as the population ages the incidence would be likely to increase. However, awareness of the causes of heart disease, and more proactive treatment of risk factors at a population as well as individual patient level, are likely to improve cardiac health and push down incidence. Furthermore, improved survival for patients following acute myocardial infarction (MI) but with a damaged heart may be expected to increase incidence of heart failure however, prompt, more effective treatments at the time of MI may reduce the amount of muscle

damage and therefore the likelihood of developing heart failure in the future.[106] The diagnostic criteria applied to determine a heart failure label can also influence the observed incidence. Further studies are required to examine the relative roles of risk factor management, MI treatment and the diagnostic pathway to highlight areas where intervention could ultimately help to reduce the incidence of heart failure over time.

## 2.7 Summary of the Chapter

This chapter presented a study using data from a general practice records database to determine the incidence of heart failure in the community population of the UK. The study included over 2.7 million patient records and found 55,248 patients with a first diagnostic label of heart failure in their GP record. The results were consistent with other studies which reported that the incidence of heart failure increases with age and is more common in men than women. The study found a reduction in heart failure incidence between 1995 and 2007, which may partly be explained by changes in clinical coding, but then a stable incidence of 2.3 per 1,000 person-years since 2007 which coincides with more robust recording since the introduction of the heart failure QOF indicator in 2006. The literature on heart failure incidence was then presented which varies in methodology, quality and findings but with some studies reporting a reduction in incidence over time which differs from the results of this study. Possible reasons for the stable incidence were considered, along with the importance of this data for physicians and healthcare providers.

# 3. PATIENT EXPERIENCE OF HEART FAILURE DIAGNOSIS: METHODS

## 3.1 Chapter Overview

This chapter presents the methods of a qualitative study which explores the process of heart failure diagnosis in primary care from the patient's perspective. Patients with a new diagnosis of heart failure were asked to describe key points in their journey from the time they first noticed symptoms to when they received a formal diagnosis. The methods and justification are presented here and the findings and discussion are presented in subsequent chapters.

## 3.2 Abstract

**Background and Aims:** Heart failure is a common and important disease which causes troublesome symptoms for patients. International guidelines suggest a simple diagnostic algorithm for patients presenting with symptoms suggestive of heart failure in primary care but it is unclear what the process entails from the patient's viewpoint. The aim of this study was to explore the journey through the diagnostic process from the patient perspective and to highlight areas where care might be improved.

**Method:** Qualitative interview study. Patients with a recent (<1 year) diagnosis of heart failure were invited for interview. Participants were asked to describe key points in their journey from the time they first noticed symptoms to when they received a formal diagnosis

of heart failure. Interviews were recorded and transcribed verbatim. Data were analysed using the Framework method.

**Results:** Sixteen participants were interviewed. The findings are grouped into three key themes.

*Heart Failure Onset*: Participants experienced shortness of breath, ankle swelling and fatigue but initially normalised their symptoms, attributing them to ageing, other co-morbidities, lack of physical fitness or a side effect of medications. Participants only sought medical help once symptoms affected their activities of daily living.

*Interactions with Healthcare*: Participants entered the healthcare system through primary care and were referred for further testing in secondary care. Participants who were acutely unwell were admitted directly from their GP surgery. Participants valued the longitudinal relationship they had with their GP and practice. Interactions with secondary care professionals were less personal and felt rushed at times. Logistical frustrations such as GP access and hospital waiting times added to patient burden.

*Diagnosis and Impact*: Participants' understanding of the term 'heart failure' varied and the term itself caused anxiety. Delivery of the diagnosis by clinicians, and provision of information about the disease, could be improved in some cases. The impact of a heart failure diagnosis depended on participants' adaptability and the presence of other conditions, which could cause more debilitating symptoms than heart failure itself.

**Discussion:** The findings of this study on the diagnostic pathway for heart failure highlighted areas where the patient experience could be improved. Greater public awareness of heart

failure symptoms, improved access to primary care, a generalist patient-centred approach, better communication in secondary care and adequate explanation of 'heart failure' as a term are potential areas of service improvement.

## 3.3 Background and Aims

Heart failure is a common and important disease which causes troublesome symptoms and reduces life expectancy for patients.[4] There are many treatments which improve quality of life, and survival, but making a diagnosis can be complex.[26 30 63 64] Heart failure symptoms include shortness of breath, ankle swelling and fatigue but these can be present in many other conditions, or just a normal part of life.[107] National and international guidelines provide investigation algorithms which lead the clinician through the appropriate testing and formal diagnostic criteria once the possibility of heart failure has been considered. However the patient experience and decision making prior to initiating investigation to confirm a diagnosis of heart failure is unclear.

Guidelines do not address the grey area from when the patient first experiences symptoms to the time they seek medical attention and the subsequent diagnostic process from their perspective. It is unclear what prompts patients to first seek help, what patients experience at key points during the diagnostic pathway and what patients understand by the diagnostic label of 'heart failure'. The existing literature in these areas was discussed in detail in Section 1.6 of Chapter 1.

The aim of this study was to explore participant experiences of a diagnosis of heart failure to develop an understanding of the diagnostic pathway from the perspective of the patient and to use this data to highlight behaviours and processes which could be modified to improve both experience and outcome. The objectives of the study were:

- To explore how patients describe the onset of heart failure symptoms and the explanations they have for the symptoms initially.

- To determine what prompts patients to seek medical attention for their symptoms.

- To explore how patients describe the experience of seeing the GP and having tests carried out.

- To examine what patients understand by a diagnosis of heart failure, what the term means to them and what impact the diagnosis has on their lives.

- To gather patient's views on their experience of the heart failure diagnostic pathway in hindsight and how they feel things might have been improved.

The findings of the study provide a rich description of the patient experience of heart failure diagnosis from first symptoms to impact of the diagnosis on their everyday life. The data are used to identify what factors are important at key points in the diagnostic pathway (in particular, decision to initially consult, investigative processes and receiving a formal diagnosis) which could be modified to optimise patient experience. The methods are described in detail in this chapter, the findings are presented in Chapter 4 and the discussion, in relation to the sociological and medical literature, follows in Chapter 5.

## 3.4 Methods

### 3.4.1 Study Design

A qualitative study, using semi-structured interviews with patients diagnosed with heart failure, was carried out between August 2014 and May 2015. Interviews were recorded, transcribed and analysed using the Framework method.[108] Justification for the methodological approach is now briefly considered.

The choice of research methodology depends on the phenomena being studied and question which needs to be addressed. The other three studies included in this PhD thesis use quantitative methods to answer the questions posed. The research paradigm – the beliefs and set of practices within which research is conducted – determines the approach to any study.[109] Quantitative methods are usually associated with a positivist view of the world. Positivism assumes the nature of reality (or ontology) is fixed and discoverable.[110] In epistemological terms, positivists believe knowledge exists to be found through methodologies which objectively measure phenomena and test hypotheses.[111] This is important to explore numerically-based questions like how common is heart failure, how long do patients survive and how many new cases are found through screening?[112]

The positivist approach, however, fails to effectively answer questions such as 'what is it like to be a patient going through the heart failure diagnostic process' or 'what do patients understand by the term heart failure and how does it affect their lives'?[113] These represent

issues particularly important to the patient and a better understanding of their experience is fundamental to improving healthcare services.[114] To answer the questions of why and how, the alternative research paradigm of interpretivism, or social constructivism, is often used which rejects the existence of 'one reality' and instead argues that human beings are an integral part of the construction of their own reality and they are also a fundamental part of the knowledge about that reality. Qualitative methods used to gather data to support this ontological and epistemological viewpoint include interviewing, observation and document reviews.[115]

The experiences of patients with heart failure are not only associated with how many tests are performed, where the tests are carried out or what drugs are started. Each person undergoing the process is unique with their own background and previous life events, current view of the world and influence from their wider social circumstance. Their view of the diagnostic pathway is likely to be different to the next patient with heart failure. For this reason, an interpretivist, or constructionist, view point was taken. I wanted to capture the 'story' of each participant from the start of symptoms to the impact of diagnosis and this was most achievable using semi-structured interviews.

Each patient story was unique but I wanted to explore the similarities and differences between each story to gain a better understanding of the heart failure diagnostic pathway as a whole. The Framework method, a type of thematic analysis, adopts a pragmatic approach

to analysing real world data using a clearly defined technique, described in more detail in Section 3.4.9 below, and so was chosen as the analysis method for this study.

### 3.4.2 Recruitment

To investigate the whole clinical pathway, participants needed to have a confirmed diagnosis of heart failure and be able to recall events easily. In addition, to capture the primary care part of the clinical pathway, participants needed to have presented to their GP and subsequently been referred to secondary care for objective testing and confirmation of a diagnosis of heart failure for the first time, rather than being admitted as an emergency or having a prior heart failure diagnosis.

Participants were recruited from the heart failure clinic at the Queen Elizabeth Hospital Birmingham (QEHB). The clinical administrative team identified patients with a recent diagnosis (<1 year) of heart failure who had been referred from primary care. Patients with a heart failure diagnosis more than 12 months previously, who had not been diagnosed following referral to primary care, were not able to give written informed consent or who were too unwell to take part, were excluded.

### 3.4.3 Setting

Birmingham is a large, socioeconomically diverse city in central England. The QEHB is part of the University Hospitals Birmingham NHS Foundation Trust and is located in the suburb of Edgbaston, close to the centre of the City. QEHB is the largest single site hospital in the UK.[116] Local GPs can refer patients to QEHB through a primary care referral process. Patients with symptoms and signs suggestive of heart failure require a natriuretic peptide test to be performed by their GP. If the natriuretic peptide level is raised, patients can be referred to the heart failure clinic directly. The service is run by a consultant cardiologist at QEHB and the team includes heart failure specialist nurses, cardiology registrars, echocardiographers and administrative support staff.

In the diagnostic heart failure clinic, patients are assessed through clinical history taking and physical examination. They have investigations which usually include an electrocardiogram (ECG) and echocardiogram (echo). Some patients may require more specialised tests such as cardiac magnetic resonance imaging (MRI). Patients are seen by a consultant cardiologist at the end of the assessment to explain whether they have a diagnosis of heart failure or not. Subsequently, the heart failure nursing team give the patient further information and provide follow-up at local community clinics to monitor physiological parameters such as pulse rate, blood pressure and weight and optimise heart failure medications. There are five heart failure community clinics located around the Birmingham area.

The European Society of Cardiology definition of heart failure requires both symptoms and objective evidence to confirm the diagnosis. Participants were recruited from the QEHB heart failure clinic to ensure they had undergone a thorough diagnostic assessment so only those with a reliable diagnosis of heart failure were interviewed.

This study aimed to explore the primary care aspect of the heart failure diagnostic pathway from when the patient first experienced symptoms to receiving a formal diagnosis. To ensure experiences were recent, and could be recalled easily, only patients who had received a diagnosis of heart failure within the last 12 months were invited to take part.

### 3.4.4 Sampling

Qualitative research aims to explore the experiences of individuals within their own context by collecting, analysing and interpreting data from interviews or observations.[117] Unlike quantitative research, the aim is to achieve a depth of understanding of the experiences of a group of people in a particular time and place. The number of participants included in qualitative studies cannot therefore be determined by a power calculation – the method used in quantitative studies such as clinical trials to ensure the number of participants in the study is large enough to detect a difference between two groups.[118] Instead, the number of participants required for a study is determined by the aims of the study, the quality of data collected from the interviews and the findings at the analysis stage, including the concept of saturation. [119]

At the planning stage of the study, my supervisor (an experienced qualitative researcher) and I discussed the number of participants required. The concept of 'sample specificity' as described by Malterud et al [120], examines the extent to which the participants to be recruited to a study are similar and how this related to the overall study aims. In studies where 'sample specificity' is high, participants are recruited from a narrow group of individuals often with several criteria in place. The aim of this study, set out above, was to explore participant experiences of a diagnosis of heart failure to develop an understanding of the diagnostic pathway from the perspective of the patient. The study was to recruit patients over the age of 55 from a single outpatient heart failure clinic at the local hospital who had been diagnosed with heart failure within the last year following referral from primary care. While variation of experience within this group was expected, and necessary for the study, these detailed criteria meant the number of participants required to achieve saturation would be less than if the sample specificity was broader. From my supervisor's experience, interviews with between 12 and 20 participants were usually adequate to achieve the study aims in this context. We agreed an initial aim of 20 participants, but to review this in light of the interview data and subsequent analysis.

Heart failure usually occurs in older age groups, typically over the age of 55, and can affect men and women of different ethnic groups. Purposive sampling was planned in order to achieve demographic variation. The aim was to recruit a total of 20 patients over the age of 55 years with at least 2 participants from each age group of 55-65, 65-75, 75-85 and 85+ years old to be included. A mix of men and women in each age group and patients of White,

Asian and Black ethnicity were also sought. Arrangements for an interpreter to be used where needed were put in place to prevent exclusion of non-English speaking patients. Unfortunately, due to challenges in the recruitment process, detailed below, purposive sampling according to the criteria above was difficult to achieve fully. Participants were a range of ages and a mix of gender but ethnic mix was not achieved. All but one participant was White and all participants spoke English as their first language. This has implications for the application of the findings and is discussed in detail in Chapter 5.

During the interviews, participants provided rich and detailed descriptions of their experiences of the diagnostic process. After each interview, audio data were transcribed and coded. The Framework method, described in more detail below, was used to analyse data. This method requires systematic coding and sorting of data into an analytical framework which allows data from each participant to be compared easily. Following 12 interviews, no new themes were emerging. We agreed to carry out the remaining 4 scheduled interviews and once all 16 interviews had been completed we found no new or emerging themes and felt saturation had been achieved.

### 3.4.5 Recruitment Process

The study aim was to recruit 20 participants within a four month period between September and December 2013. Prior to the start of the recruitment phase, a meeting was held with the QEHB heart failure clinic team, which included the heart failure nurse specialists and

consultant cardiologist, to discuss the logistics of the recruitment process. The clinical team were enthusiastic about the project and, after discussion, felt that handing out patient information leaflets in the clinic would be acceptable to patients and minimally disruptive to the usual running of the clinic.

The research documents (Appendices 2-3) received ethical approval on 28th August 2013 from the Hampshire A Research Ethics Committee (reference 13/SC/0475). The Head of Research and Development (R&D) at QEHB gave authorisation for the Heart Failure clinic to be a Participant Identification Centre. The patient information sheet (Appendix 9.2) was given to all patients receiving a new diagnosis of heart failure between November 2013 and January 2014.

Ethics and R&D requirements meant that as a researcher I was unable to approach patients directly for the study because I was outside of their usual clinical team. The patient information sheet, handed out by the heart failure specialist nurses, contained details of the research project and contact information for those who wished to take part in the study. Unfortunately this prospective recruitment strategy did not yield *any* participants. The reasons why recruitment was unsuccessful were not entirely clear but may have included factors such as time pressures within the clinic meaning heart failure nurse specialists did not have the opportunity to discuss the study in detail or that patients who had just received a diagnosis of heart failure were too overwhelmed to consider being part of a research study.

Following consultation with my PhD supervisors, the heart failure clinical team and the head of R&D at QEHB, a new recruitment strategy was agreed which involved letters being sent directly to patients who had received a diagnosis of heart failure in the last 12 months. A substantial amendment was sought from the ethics committee and the revised protocol was approved on 16th June 2014. The conditions of the ethics and R&D approval meant that the clinical team needed to identify patients who met the eligibility criteria: 55 years and over with a recent (<1 year) diagnosis of heart failure following referral from primary care. Initially this was challenging as clinical time was very limited and this cost had not been factored in to my original PhD Fellowship application. Following further discussions, it was agreed that the clinic administrative staff would identify patients for the study and send out the invitation letters and patient information sheets.

Letters were sent out to a total of 100 eligible participants in August and September 2014. Patients were invited to contact me by phone to discuss any aspect of the study and to volunteer to take part if they wished by returning the reply slip which was enclosed along with a prepaid envelope addressed to the clinical team. The clinical administrators collated reply slips and sent a spreadsheet with the name, address and phone number of all those who had responded and were willing to take part. In total, 21 participants responded to the invitation letter and were contacted by phone to arrange a time and location to carry out the interview. The location of interview was decided by the patient. I offered to travel to the patient's own home or to arrange another quiet and private location that was convenient to

them. A convenient date and time was also agreed. No payment was available for participants taking part in the study but travel expenses were offered.

From the list of 21 participants who returned the reply slip, 16 participants agreed to take part. One participant had changed her mind when contacted, one participant had recently been admitted to hospital so was no longer available to be interviewed and three participants were not contactable through the details given on the reply slip.

### 3.4.6 Data Collection

Interviews took place between October and December 2014. Fifteen interviews took place in the participants' home and one interview was conducted by telephone. I conducted all interviews myself. All 16 interviews were recorded using a digital voice recorder. For each participant, I explained the aims of the study, as outlined in the patient information sheet, and invited questions. Once all questions had been addressed, written informed consent was obtained using the consent form (Appendix 9.3).

Semi-structured interviews were carried out with an originally estimated duration of between 30 - 60 minutes. An interview topic guide (Appendix 9.4) was used to ensure key areas were covered to achieve the aims and objectives of the study. The topic guide included questions on symptom onset and seeking medical attention, the investigative process and understanding a diagnosis of heart failure.

I carried out all of the interviews and the subsequent analysis. I therefore was integral to the research process and could not be truly independent so I needed to be aware of how I might influence and inform the research, a process known as reflexivity. This process is vital to reduce researcher bias and ensure results are credible.[121]

The behaviour of study participants can be influenced by the researcher – the 'observer effect' – and the professional role of the interviewer can influence interview interactions.[122] I am a female general practitioner and researcher. I have worked in the NHS for 12 years and subspecialised in academic general practice 8 years ago. I work in a busy inner city practice which serves a largely socially-deprived population. Several steps were taken during the research process to reduce the effect of researcher bias and observer effect.

Firstly, I introduced myself by my first name and emphasised to participants that I was interviewing them as a researcher from the university rather than as a GP to reduce the observer effect of participants feeling they could not perhaps be open and honest about their experiences when talking to a doctor.

I had not carried out any qualitative interviewing before but I have had extensive training in interview technique through my medical and particularly general practice training. This included the importance of asking open questions (rather than closed or leading questions), listening and encouraging participant contribution. However, I am aware that qualitative

interviewing requires a technique dissimilar from the doctor-patient consultation.[123] Qualitative interviewing aims to encourage participants to share their experiences, meanings they attach to events and views of the world with the interviewer in an uninhibited way. In the doctor-patient relationship, listening is key to a successful consultation but the outcome is often to arrive at a diagnosis or treatment choice with the patient.

I had no previous experience of analysing qualitative data so I attended a Health Experiences Research Group course in Oxford on Qualitative Data Analysis. To ensure the style of interviewing and data analysis was appropriate, I conducted and transcribed my first two interviews under the close supervision of my PhD supervisor (NG), an experienced qualitative researcher. We met and discussed my interview technique and repeated this process for the next 2 interviews. NG was happy with my technique and the quality of the interview data so the remaining interviews were carried out independently.

Finally, I have considerable experience of diagnosing and managing patients in primary care so had some ideas of what the study may find but tried to suspend these expectations during the interview process. I used well-recognised qualitative methods for producing novel results that could ultimately inform practice and used triangulation to ensure data analysis was consistent.

### 3.4.7 Data Management

Digital audio recording equipment was used during the interviews to collect data. The digital files were downloaded to a designated folder on the University of Birmingham secure network. I transcribed the first two interviews which helped me to become familiar with the data and also to reflect on my interview technique. I transcribed the words only and did not include details about conversational style, tone or interruptions. I met with my supervisor (NG) to discuss the interview method, transcription technique and to consider refining the topic guide. In the first two interviews, the participant descriptions of their understanding of a heart failure diagnosis, and the meaning they associated with the term, was not explored in great detail. To achieve a depth of understanding of the patient experience, my supervisor suggested I spend more time on this part of their diagnostic journey before terminating the interview. The structure of the topic guide remained unchanged but I ensured that during subsequent interviews I allowed more time and space for patients to talk about the term heart failure and what it meant to them in the context of their individual circumstances. I carried out two further interviews which I also transcribed and discussed with my supervisor. Both interviewees gave an insightful and detailed account of heart failure as a term, the mechanisms they felt underpinned the condition, the impact on their lives and subsequent adaptation they and their family had experienced. The interview technique, and topic guide, was therefore not adjusted further. I then completed the remaining 12 interviews. A professional transcription service was used for these interviews so I read and re-read the transcripts to familiarise myself with the data. Audio-recordings and transcripts will continue to be stored on the secure network at the University of Birmingham for 5 years.

**3.4.8 Ethics**

Formal ethical approval for the study was sought from the National Research Ethics Service (NRES) using their online application system and the University of Birmingham Ethics Committee. The first ethics application was approved through a process called 'Proportionate review'. This is a new fast-track process which aims to deal with simple studies where the patient is exposed to minimal risk. The next available ethics committee reviews the application without the need for the researcher to attend. The study received a favourable ethical opinion from the Hampshire A Research Ethics Committee (13/SC/0475) in August 2013. As described above, due to problems with recruitment a substantial ethical amendment was required which was approved in June 2014. Confirmation of full ethical approval was received prior to commencement of the study which was sponsored by the University of Birmingham.

**3.4.9 Data Analysis**

Data were analysed using the Framework method.[124] This is a systematic approach carried out in 7 stages: transcription, familiarisation with the interview, coding, developing an analytical framework, applying the analytical framework, charting data into the framework matrix and interpreting the data.

*Transcription*

All interviews were digitally recorded and transcribed verbatim. Data were anonymised by removing any information which would make the patient identifiable. I carried out the transcription for the first four interviews then the remaining 12 interviews were transcribed by a professional transcription service. All participants available for and willing to take part were interviewed.

*Familiarisation and initial coding*

I read and re-read all transcripts to ensure I was familiar with the data. The first two transcripts were then coded by hand to generate a list of codes. The coding was reviewed by my supervisor (NG) to ensure the types and range of codes applied was appropriate. A further three transcripts were coded by hand which generated further coding lists. An iterative process, with constant comparison, was used during the interviews and analysis to ensure that the key areas identified in the objectives were addressed along with any new and emerging themes.[125]

*Developing and applying the analytical framework*

The coding lists were used to develop an analytical framework which finally contained 150 codes organised into 17 categories (Appendix 9.5). The framework was reviewed by two of my supervisors (NG and TM). An experienced qualitative researcher (SS), independent of the project team, also coded an interview and commented on the analytical framework leading

to further modifications. I then coded all of the interview transcripts, according to the agreed codes and categories, using the software package NVivo10. I attended a course on using qualitative data analysis software packages to ensure I was able to use NVivo effectively to code, categorise and export the data.

*Charting data into the Framework matrix*

Coded data were exported from NVivo according to individual code and saved as separate documents. The data for each code was read, re-read then summarised for each of the 16 participants in the study. Microsoft Excel was used to manage the summarised data. A new worksheet was used for each of the 17 categories. The name of the relevant code was inserted at the top of a column and the participants 1 to 16 were numbered down the left hand side. This process was repeated for each of the 17 categories (including all 150 codes). An example of charted data is presented in Appendix 9.6.

*Interpreting data*

Each category was then interpreted using an analytical memo (Appendix 9.7) to explore emerging themes and concepts. At this stage the key findings of the study began to surface and my supervisor (NG) and I had several meetings to discuss the main themes in detail. As part of this process, 'deviant cases', also called 'disconfirming cases', were considered. For example, as in Appendix 9.7, one participant had been to the heart failure clinic and had volunteered to be part of the research study but the participant, and his wife, did not appear

to realise or acknowledge he had heart failure. This was an isolated case and all of the other participants were aware they had the condition and were willing to discuss it openly. As part of the Framework Analysis this type of disconfirming case was acknowledged and described in the findings section (Chapter 4) but, as only observed in a single participant, did not contribute to an emerging theme. The literature, both sociological and clinical, was also explored to further examine the place and importance of the findings, and to consider implications for policy and practice.

## 3.5 Summary of the Chapter

This chapter summarised the background and aims of this qualitative study to explore the experiences of patients who have recently received a diagnosis of heart failure. The methods including sampling, recruitment strategy, interview technique and analysis using the Framework method were described in detail. The next chapter presents the findings of the study.

# 4. PATIENT EXPERIENCE OF HEART FAILURE DIAGNOSIS: FINDINGS

## 4.1 Chapter Overview

This chapter presents the findings of the qualitative study described in Chapter 3. The interviews were transcribed and analysed, using the Framework method, to develop a better understanding of the heart failure diagnostic process from the patients' point of view. The key characteristics of participants are summarised then the three key themes which emerged from the data are presented along with illustrative quotes. A discussion of the findings in relation to the literature, and key recommendations, follows in Chapter 5.

## 4.2 Participants

Sixteen participants identified by the heart failure clinic to have a diagnosis of heart failure within the previous 12 months were interviewed. Interview duration was an average of 42 minutes with a range of between 21 minutes and 74 minutes.

The demographic characteristics of the study participants are shown in Table 8. Five women and 11 men agreed to take part. Participants were in their 50s, 60s, 70s and 80s with a median age of 78.5 years; the youngest participant was 52 years old and the oldest was 87 years old. The final ethnic make-up of the sample was not as diverse as originally intended with all but one participant being White British. Ten of the 16 interviewees were

accompanied by a relative during the interview. The interviews were primarily with study participants but the contribution of relatives present was welcomed throughout.

| Participant | Age | Sex | Ethnicity | Relative present |
|---|---|---|---|---|
| P1 | 76 | Male | White British | Spouse |
| P2 | 75 | Female | White British | |
| P3 | 79 | Female | Black | |
| P4 | 80 | Male | White British | Spouse |
| P5 | 84 | Male | White British | Spouse |
| P6 | 87 | Male | White British | Spouse |
| P7 | 81 | Male | White British | Spouse |
| P8 | 71 | Male | White British | |
| P9 | 78 | Male | White British | Spouse |
| P10 | 70 | Male | White British | Spouse |
| P11 | 80 | Female | White British | Spouse |
| P12 | 67 | Male | White British | |
| P13 | 52 | Female | White British | Daughter |
| P14 | 67 | Female | White British | Spouse |
| P15 | 85 | Male | White British | |
| P16 | 87 | Male | White British | |

Table 8: Demographic characteristics of study participants

## 4.3 Overview of Themes

Three key themes emerged from the data. The first theme was Heart Failure Onset which included symptom onset, progression and the decision to seek medical attention. The second theme was 'Interacting with Healthcare' which included contact with both primary

and secondary care during the diagnostic process. The third theme was Heart Failure Diagnosis - Delivery and Impact which included both the delivery of the diagnosis and the subsequent impact and adaptation process which followed. Each theme, and associated categories, will now be discussed along with illustrative quotes.

## 4.4 Heart Failure Onset Theme

The Heart Failure Onset theme incorporated participants' recollections of the time prior to developing heart failure, the symptoms they first noticed, when these occurred and the explanations they initially used, the role of time and what prompted them to seek medical advice.

### 4.4.1 Symptoms

This category included the symptoms participants experienced during the onset and progression of their disease.

- Shortness of breath

Shortness of breath featured in all participant stories. It was often gradual in onset and was only noticed as a problem when it interfered with usual daily activities such as going for the bus, gardening or going to the toilet. Initially shortness of breath was put down to being a normal part of ageing, trying to 'do too much', going up a steep incline, weather, bringing it on self by 'panicking' or due to another co-morbidity. Participants initially coped with symptoms by resting or 'calming down' to resolve the breathlessness.

*"I used to panic and I just couldn't get any breath…When I sat up, it was okay after a short time. I just have to calm myself down because I felt like, am I bringing this on myself by getting in a state?" (P5)*

Respiratory disorders were blamed for shortness of breath but increases in treatment for these conditions didn't improve symptoms. The degree of breathlessness could be significant before the participant thought it was a problem e.g. shortness of breath on walking to the toilet a few yards down the hallway or waking up gasping for breath. Participants carried on with usual activities despite significant limiting symptoms.

*"I was going up the hill at the golf course and I can't breathe. I couldn't breathe. It was really bad. I should have stopped, but no. I stood there for a while and got myself up again, hit the ball again. Out of breath again. I should have stopped, but I didn't. I kept on going all the way around, but I was really getting out of breath." (P7)*

- Swollen ankles

Some participants had swollen ankles while others did not. For those with swollen ankles it was or still is a visible persistent reminder that something is wrong.

*"...swelling of the feet. Which is still going on as you can see there, I end up like a hobbit by the evening." (P4)*

Ankle swelling caused significant discomfort and morbidity for some while others did not have these symptoms and wonder why they were always asked about it.

*"I'm suffering badly with very, very swollen feet. If I don't put them up here all day long, they are just horrendous. I can't get shoes on in the evening." (P11)*

For some participants, the swelling was initially put down to vein problems and remained untreated while for others medication was used to 'get rid of fluid' which meant the ankles became less swollen. For those on treatment, slim ankles as an effect of the medication became a marker of health.

- Tiredness

Four participants described tiredness, lethargy or a decrease in energy levels which could result in the need for an afternoon nap. For one participant, tiredness was the main symptom but was initially put down to being busy.

*"I kept feeling really tired and my feet kept swelling an awful lot throughout the day." (P13)*

- Lack of symptoms

Two participants reported a lack of any initial symptoms – one participant had an arrhythmia picked up incidentally on ECG while in hospital for another condition and another participant

had evidence of a previous heart attack also found on ECG. Cough or mild shortness of breath was noticed in retrospect but not thought to be a significant symptom initially.

- Other symptoms

Two participants recalled episodes of severe chest pain due to heart attack or angina and dizziness, occurring in warm weather on holiday or being related to blood pressure medication. Pain elsewhere was not a reported feature.

- Symptom improvement

Several participants reported improvement or resolution of symptoms following diagnosis and treatment – this was not a direct part of the interview remit but came up as participants told their story.

*"They say to me, "Do you sit up in bed at night? Or do you wake up gasping?" I don't. I'm really well, really well; I think they've done a marvellous job on me." (P11)*

### 4.4.2 Explanation of Symptoms

Participants had a variety of explanations for their symptoms including that they were just a normal part of life rather than indicative of underlying disease. Participants who normalised

their symptoms often put them down to being a normal part of ageing or blamed themselves for over-exertion or 'doing too much'.

*"I just put it down to the fact that [er] I over stretched myself you know. Yeah I was trying to do too much. Simple simple as that." (P4)*

*"I just thought it was probably my age. I don't think I thought it was the heart to start with, no. I just thought that it was because I was walking a long distance and I needed to stop." (P6)*

Participants also thought symptom onset had occurred, or was perhaps noticed more, when they were outside of their usual environment such as away from home staying with family or on holiday and this was used as an explanation for the symptoms. Others thought that symptoms could be due to their other medications or that they were bringing the symptoms on themselves. A stoical approach sometimes prevented participants from taking action to deal with their symptoms.

*"I thought that's what it was. I was telling myself, "Well I've got to put up with this. It's the medication and I've got to put up with it." So I wasn't doing anything about it." (P7)*

One participant just felt ill and didn't have a particular explanation for why they felt that way but assumed that the symptoms would probably resolve with time.

"I didn't know really, I was mystified, I thought that's unusual and why is this and it probably went on for a couple of months before I went to see the doctor. I thought it would probably pass." (P16)

Participant background influenced the explanation and conclusions they came to. One participant had a nursing background. Being a retired nurse she thought swollen ankles were due to problems with the heart or kidney – if the swelling could be pressed in with a finger then it was due to the heart. She did not know exactly what heart problem it was but went to the GP several times as she was worried. Her professional background drove her to feel there was something wrong.

Participants had comorbidities and sometimes thought their symptoms were due to their other medical conditions. One participant with chronic obstructive pulmonary disease (COPD) thought his breathlessness was because he needed stronger inhalers.

"I think perhaps my lungs, COPD. I mean this is what I attach to myself, to thinking, I suppose, for decades now...So I think I must have concentrated and focused on the COPD when it could have been the heart otherwise." (P8)

Most participants had retired but many maintained active social lives which were disrupted by the symptoms. One younger participant was working age and thought that tiredness was a normal part of her busy lifestyle and job.

*"Just tiredness, just my job which is physical really running round wards and stuff." (P13)*

### 4.4.3 Multimorbidity

Multimorbidity is the presence of more than one chronic disease.[23] Heart failure is a disease of the elderly and patients often have several medical conditions. The presence, type and impact of multimorbidity influenced the participant's perception of 'heart failure onset'.

- Cardiovascular co-morbidities

The presence of other cardiovascular diseases, such as heart attacks and arrhythmias, pre-dating heart failure onset, was found in some participant stories. Cardiovascular problems often spanned decades – for example, P4 (male, age 80) had high blood pressure in the 1980s, a stroke in 2004 then severe chest pain more recently which was diagnosed as angina. Some participants were found to have pre-existing heart problems during investigations for heart failure e.g. evidence of a previous heart attack found on ECG of which they had been unaware.

- Arthritis

The age of participants in the study meant arthritis was common and one participant felt arthritis was 'blamed for everything'. For three participants their main limitation was arthritis not heart failure e.g. painful walking, difficulty getting dressed.

*"Yeah, maybe slower because of your knees, but not because of your heart." (P14 spouse)*

The pain of arthritis was so severe it dominated life for these participants and the resulting disability limited daily activities more than any other disease.

*"Oh God, I'd never have believed what arthritis is like. You have to have it, to know it. I never paid any attention to things like this until now." (P11)*

*"I mean, my hand, I don't know what will happen when… I hope I'm gone before that hand goes like this one because… I mean even when my grandkids were little, opening a bottle of pop, they'd say, "I'll do it granddad," I couldn't, absolutely no strength at all." (P16)*

For these participants, the presence of arthritis limited their ability to self-manage their multiple conditions. For example, one participant needed to lose weight in order to have a knee operation, to help with her arthritis, but could not exercise due to pain in her knee. The treatment of heart failure also limited the use of arthritis medications.

*"I suffer from arthritis, but because of this medication they've put me on, I can't have my arthritis tablets." (P7)*

Participants were also reluctant to push for arthritis treatment due to heart problems.

*"No cartilage in this shoulder at all, that's a bone rubbing job. And I'm taking paracetamol for that. And my left hip is a a little bit dodgy. Can't sleep on it occasionally. I haven't pressed the issue because of [erm] the heart condition." (P3)*

Arthritis is a painful and debilitating condition but many participants took a stoical approach to their symptoms and had a real determination to 'get on with it'.

*"I mean the arthritis comes and goes and I get a lot of back ache, but you learn to accommodate pain. I think you really do, I mean I know it's going to be painful when I walk, and I just try not to think about it and think of other things."(P16)*

- Mental Health

The presence of cardiovascular disease was perceived to have a direct effect on the mental health of some participants. One participant described being irritable and short tempered following his heart attack but that this gradually improved. There was a determination to stay mentally strong despite the physical symptoms and disability caused by heart failure

and other medical conditions. But for one participant, his mental health problems were more difficult to cope with than his physical health conditions.

*"I had my other doctor, before I left to come up to this area, she was, she said, "Oh, I'm really impressed how you've got over that testicular cancer, you're marvellous"… I said, "Love, it's nothing compared with mental illness.""* (P8)

He was also concerned that his mental health problems could have impacted on his physical health e.g. chronic alcohol use affecting the heart.

- Other conditions

Chest infections often complicated heart problems and were a source of significant suffering for two participants. Amongst those interviewed, many had also experienced multiple other conditions from cataracts to testicular cancer, anaemia, oesophageal tear, diverticulitis, restless leg syndrome, prostate problems and macular degeneration. Some co-morbidities had been unmasked by starting heart medications, for example one participant had an upper gastrointestinal bleed after starting anti-platelet therapy for her heart condition. In addition, co-existing diseases were sometimes found incidentally during tests for heart problems.

The presence of previously diagnosed conditions sometimes limited treatment options for heart problems. One participant (P2) had a significant cerebral haemorrhage in 2002 which

led to concerns over the safety of prescribing warfarin following diagnosis of an arrhythmia for which anticoagulation was otherwise indicated.

*"They were thinning my blood down and they didn't know whether it was a good thing to do, to do that or not but the blood specialist eventually said yes you know, there's no reason why she shouldn't, shouldn't have it so that was the deciding factor. Yeah. But I'm awkward aren't I. It's not just one thing wrong, its several things wrong." (P2*)

Some participants experienced severe and life-threatening illness which was not related to their cardiovascular disease.

*"I still survived having had two brushes with death, I had two years ago pancreatitis which was a very close run thing I'm told, I was unconscious at the time and I was in hospital six months…" (P15)*

### 4.4.4 Time

The Time category explored participants' descriptions of the onset of symptoms and how they progressed over time, when participants sought medical advice and what prompted them to do so. Participants varied in their ability to recall events and the temporal sequence of events often involved a back story of previous illnesses over many years.

- Symptom onset and progression

Symptom onset timing ranged from gradual onset over a number of years to a sudden event which required immediate action. Shortness of breath, ankle swelling and tiredness were often described. Participants took symptoms seriously only once they started to affect activities of daily living e.g. getting shortness of breath when going for the bus. Symptoms were initially put down to other conditions as described above.

*"Anyway we lived on a hill and of course I was starting getting breathless, going up this hill to the shops or whatever, I started getting breathless and I thought, well this is never right, so it went on for a few weeks, and I just went and seen the doctor and he said, "Well I'm going to send you for a test..." (P10)*

Symptoms often progressed over time. For example, participants noticed their shortness of breath gradually impinging on activities of daily living up to quite severe levels where they were 'gasping for breath' and unable to sleep. One participant called an ambulance after realising he had become so unwell.

*"I was getting more and more ill...I hadn't realised it because you have a steady decline...You don't feel well one day and not the next ..." (P15)*

- Decision to seek medical advice

Most participants were quick to seek medical advice from their GP as soon as they realised something was wrong. Initially some did not realise there was anything wrong and hoped symptoms would pass, whilst others, with the benefit of hindsight, wished they had gone to their doctor sooner and reflected that they had known something was wrong but had not sought medical advice, instead wanting to carry on as normal.

*"I should have gone to see him. I should have stopped straight away. Knowing what I know now, what I've been told, I should have stopped and gone straight to see the doctor, but I didn't". (P7)*

The prompt to seek medical advice was either symptom severity and/or when there was a direct impact on daily life e.g. breathless walking to the bathroom or around the golf course, or unable to sleep at night. Others waited until they were seeing their doctor for another complaint to raise the issue of their recent symptoms.

- Recall and temporal sequence of events

In recalling events, participants used time of year – particularly seasons and Christmas – to place when things happened. The exact dates of sudden, serious events were recalled most easily. Some participants could not recall events particularly when lots of appointments and tests occurred over a short time period. The participant's spouse or partner was often helpful in recalling events that they could not remember.

Some participants had a complex temporal sequence of events and experienced multiple pathologies e.g. heart attack, stroke then developed heart failure. Multiple events often occurred over years or even decades and there was usually a significant time lag between an initial cardiac event and development of heart failure, with participants experiencing a good quality of life in the intervening period.

*"I had about another two heart attacks while I was in hospital… I came back and I went to see the heart specialist whatever they said 'Righto [P1], you can go back to work provided you have a light job' which was no problem and going back to work and within two days I'd had another heart attack. So I was off again then for another few months. And that was different, only a mild one. I had another couple of months off and then after that I went back. I don't think I had another day off from work from 1982 right up until 1998"* (P1)

Family played an important role within the sequence of events including in decision-making such as taking patients to the GP practice or calling an ambulance, as described in the next section.

## 4.5 Interacting with Healthcare Theme

The second theme of Interacting with Healthcare explores the patient experience from their first contact with the health system through the investigative process to the point of receiving a diagnosis.

**4.5.1 Logistics**

The logistics category considers the logistical arrangements in the patient journey through the diagnostic pathway, including medical interactions in both primary and secondary care.

- Access to General Practice

GP access was an issue raised by several participants; some had positive experiences of accessing healthcare whilst others found access difficult.

*"Our surgery is excellent, he really is up there, like we've been up here 30 odd years and only once have I ever failed to get an appointment on the day I wanted one and they really are good. And now you can phone and talk to them if you have a problem. The doctor will talk to you…They're brilliant up there. When my wife was ill, they were absolutely fantastic. I could ring up any time and they would be down and I couldn't have had better service if we were paying. They were really fantastic." (P16)*

There was an awareness of 'how the system worked', e.g. one spouse knew to call just before 8.30am to get a same day GP appointment, however this sometimes led to disappointment and frustration when, despite calling early, they were still unable to get an appointment.

Participants were keen to see the same GP. Some identified with a doctor that was 'their' GP. There was an idea that seeing the same GP meant they did not have to 'start from the beginning'. Many participants spoke favourably of their GP, despite not always being able to see them.

*"She's supposed to be my doctor but I can never get to see her because she's always booked up months in advance literally. She's, she's always booked up. You never get to see her so [er] that's, that's disheartening to think that she can't see, and and I mean she is very good." (P2)*

However, in some cases seeing a different GP led to the diagnosis of heart failure being considered when it hadn't been previously. One participant (P3) saw three doctors and only on the third occasion was she examined thoroughly and referred for further investigations. Another participant was frustrated when treatment was initiated by one GP but she was unable to get an appointment to see the same GP for follow-up.

In circumstances where an urgent appointment was needed, participants had usually been 'fitted in' but often with a GP they didn't know. In one case, the GP queried why the patient hadn't come sooner as they were acutely unwell and the patient said 'not my fault' as she had been unable to get an appointment.

- Assessment in primary care

GPs were quick to spot the possibility of heart failure for most participants and arranged for further tests (e.g. ECG or blood test) or direct referral to cardiology at the first appointment. Two participants were admitted directly from the GP surgery. Delays occurred in two cases where the patient was initially treated for an alternative diagnosis e.g. chest infection with antibiotics and ankle swelling put down to venous insufficiency. In retrospect both these patients felt the diagnosis could have been quicker.

*"Well, I mean I could be treated earlier. They had noticed, they had taken notice what I was showing them. You know I, I could be treated earlier. Then I think I could have gone into cardiac arrest and nearly die because they take so long." (P3)*

- Emergency care

Many participants praised the speed of response of ambulance services to emergencies in the past – heart attack or stroke – and to more recent acute onset symptoms of heart failure. The spouse or partner, rather than the patient themselves, often called the ambulance and were comforted by their response. Most participants had needed to use an ambulance at some point in their medical past.

*"I phoned the paramedics. I said he couldn't breathe, he couldn't get his breath properly and they said, "We'll come along." This was on a Sunday morning and they were extremely good...they were so kind". (P6 spouse)*

- Assessment in secondary care

Participants in the study were all under the care of one heart failure service. Initial diagnostic appointments took place in the main hospital heart failure clinic and follow-up was at community heart failure clinics located either at the main hospital or at peripheral sites.

Some participants felt that outpatient appointments in secondary care were rushed and impersonal. Specialists did not introduce themselves and their directness was difficult to manage for some patients.

*"I think appointments telling you more about your particular problem. I realise their hurry and it seems like they want to get you out because the next person's waiting to come in..." (P2)*

*"Just how impersonal the personnel were when I went in for my heart examination. That could be improved immensely. It wouldn't have hurt them to have become a little human and thought a little bit about the... just the diagnosis and "There you are.". There's a better way of dealing with somebody than that. Not difficult to do." (P6)*

The systems in secondary care also seemed illogical to participants at times e.g. long waits for x-ray due to inpatients taking priority. The burden of the number of appointments participants needed to attend and different locations was confusing and meant it was difficult to plan life. There were also some good experiences with one example where the participant had been seen, had a heart scan done and was then reviewed by the specialist all within one appointment.

- Waiting and consequences

Two participants with ischaemic heart disease and valve disease had long waits for operations. One of these participants had become more acutely unwell and was advised to call an ambulance but he did not want to be seen as 'jumping the queue'. He was admitted as an emergency and subsequently had surgery at a different hospital with a successful outcome.

The other participant (P10) had a coronary artery bypass graft (CABG) operation cancelled four times, with no cardiac medications commenced in the interim, then the surgeon said he was unable to do the procedure as the patient had developed heart failure and become too unwell. This was an unusual case with poor patient experience throughout. The participant's wife was concerned about the perceived poor care her husband had received and felt there should be other options and had heard about 'stenting the artery' being a possibility when bypass surgery was not feasible. She spoke to the surgeon's secretary to ask if this was an option and the secretary arranged an appointment for a second opinion from a cardiologist.

The patient subsequently had 5 stents inserted by the cardiologist and made a good recovery.

*"Now this took 12 months for all this to come out. Why didn't they pick that up straight away? Why didn't they treat him on some sort of medication to stop anything happening? I mean, his heart is damaged..." (P10)*

For some participants, once they were in hospital and the surgery had been performed, there was a further delay in discharge. One participant suggested a possible solution for his own discharge was a step-down bed in the local community hospital where he had been previously and this was subsequently arranged by the ward.

- Follow-up

Participants were often followed up in heart failure clinics after receiving a diagnosis of heart failure or a hospital admission and found locations of the clinics were closer to home which made appointments easier to attend. Participants described the process during the clinic, including pulse and blood pressure checks, but the purpose of the clinic visits wasn't always clear. Many patients remain under cardiology follow-up.

**4.5.2 Decision-making**

This category considered decision-making along the diagnostic pathway, including the decision to seek help and medical interactions in both primary and secondary care.

- Decision by patient to see GP

As described in the Heart Failure Onset theme, participants often had symptoms that had been present for weeks, months or longer, and had sometimes become severe before they made the decision to see their GP. Patients sometimes found it difficult to recall the exact timeframe between symptom onset and seeking help. The decision to seek help was often based on symptoms having an impact on activities of daily living. Once participants realised there was a problem, most made contact with the GP as soon as possible.

- Initial GP appointment

Two participants were on holiday or staying with family when symptoms first occurred. One participant got in touch with the GP as soon as they got back home. The other participant became suddenly breathless while staying with his daughter in Australia. His daughter took him to her own GP the same day and, following an ECG at the practice, he was admitted directly to hospital.

Participants perceived that GPs realised there was something wrong, including the possibility of heart failure, in the first consultation in most cases and arranged tests or admitted the patient directly to hospital. For one participant, the GP expressed concern that she had not sought medical help sooner.

*"We're going back two and a half years. I had a bad coughing fit, so I went to the doctor. She put me onto the hospital and everything started from there...Yes, I went for the cough. She was a new doctor then. She'd just come into general practice...Yeah, she looked at me, listened to me, sounded me out and said, "You're going to hospital.""* (P9)

Two participants were initially treated for other conditions before heart failure was considered a possibility. Both of these participants felt they should have been assessed more thoroughly and diagnosed sooner, and felt let down by the first doctors they had seen.

*"The lady that, at my own practice, the lady she was very thorough. She, she sort of, she did blood tests and so on [erm] but she [erm] as I say she examined me you know with a stethoscope for a long time and she must have noticed that there was something wrong. But other doctors had, had, had, had examined me on, on very few occasions 'cause they don't bother to examine you really. They just fob you off. (P2)*

- Referral to Secondary Care

Participants were referred promptly to secondary care by their GP in most cases. Some patients were admitted directly to hospital but in less acute cases, tests such as ECG or blood tests were done at the GP surgery prior to referral. This process was usually carried out quickly, for one participant in less than a week. Even in cases where the patient felt there had been a delay, referral to a cardiologist was usually done by the third or fourth appointment for those who could recall the consultations in detail, and often followed a blood test. Delays did not occur over months for any of the participants in this study.

One GP diagnosed heart failure based on the blood test result alone and informed the patient of the diagnosis at the time of referral. Other GPs did not offer a possible diagnosis but used more vague language of 'sending to a cardiologist' or 'I think we'll get some cardiology checks'.

*"It came back, I mean it came back didn't it and then he told us that he had got heart failure. I'll refer you to heart failure clinic at Hospital X. Then you had an appointment come through then quite quickly." (P1 spouse)*

GPs generally stayed within their competence and remit and did not offer a definitive diagnosis or prognosis estimates until the patient had been seen by a specialist and the diagnosis of heart failure had been confirmed.

*"You wonder how long you've got to live really. You know, and like I said to the GP who came, I said, "Is it very severe?" "Well, all heart problems are severe," he said, "To a lesser or greater degree, but I'll refer you to the hospital and see your heart specialist in the hospital," and that's when I met Dr X (cardiologist)." (P16)*

- Experience of secondary care

The patient experience of secondary care was a mix of positive and negative accounts. Some participants had a very positive experience of having an appointment and scan done quickly and the process explained. There was particular affection and admiration for consultants involved in key events such as performing heart bypass operations. However, some participants felt appointments were rushed and their expectation was that this would always be the case. One participant was surprised when the consultant listened and answered her queries.

*"…because sometimes with Dr X he is a bit quick too… because he's so busy to get you out the door and then I'll come out and think, oh I wish I had asked that…*

*…No but I thought he was just going to sort of laugh me out the door almost but he really did take a lot of time to go through everything with me which was really nice I thought. I thought well he's not going to pay any attention to me…" (P13)*

Several participants described an impersonal approach in cardiology clinic with no-one introducing themselves and a general lack of empathy.

*"He didn't give a name. He didn't say, "I'm a so and so". All he said was that I've got a weak heart. I said, "What would happen if something... I needed to come in, what treatments?" He said none. There'd be no treatment if I came in. So I thought "Well, what a happy day!" (P6)*

Some participants expressed a desire for more information, tailored to their particular case and often felt they did not receive adequate information during the consultation. Participants also felt they were not involved in clinical decision-making and there was a lack of time to ask questions. There were also examples of good patient experience where a direct approach to risk had helped informed decision making.

*"I said, "Well my attitude is if it's wrong, fix it if it's at all possible"...I saw Mr X early in February and he said he would do it, warned me I could die but that's standard practice but he said 90% survive so I thought it was worth going ahead so did he." (P15)*

- The Role of Heart Failure Nurses

Heart failure nurses played an important ongoing role in the care of heart failure patients. One participant was seen prior to discharge and given an explanation of ongoing care arrangements. Some appointments with the heart failure nurse were for initiation or

uptitration of heart failure medications whereas others were for monitoring of pulse, weight and blood pressure only. A blood test was often taken for monitoring the effect of medication e.g. the impact of ACE inhibitors on renal function.

*"I have seen a heart failure nurse, I was under the heart failure nurses till all my medication was sorted out and I can ring them at any point I want as well, chat to them." (P13)*

Some participants seemed less clear on the purpose of these routine appointments, one participant questioning why this could not be done at their local surgery.

*"…they've monitored my weight. That was about it really. It was [er] one way [pause] just my pure thoughts here, it was a bit of a waste of time going there when I could have gone to my own doctor just to check my blood pressure sort of thing but they were only doing their best for me so I take it as it comes in that situation." (P4)*

The heart failure clinics are situated in different geographical locations around the area and participants generally preferred those closer to home for convenience.

- Ongoing GP relationship

Participants identified with their GP and described a familiarity with their doctor and the practice, often over a period of time. Their main frustration was being able to get an

appointment with their 'usual doctor' as they were often booked up for months in advance although some participants were pleasantly surprised by the performance of the doctor they knew less well.

GPs played a role in co-ordinating care and providing a stable longitudinal relationship with the participants who often went in and out of the secondary care system. GPs had a role in prescribing and adjusting heart failure medications, on the advice of the cardiologists. In one case, target medication doses suggested by the specialist were not achievable in reality as the patient could not tolerate the higher dose which led to low blood pressure. His GP wrote back to the cardiologist as part of an ongoing dialogue to ensure coordinated care.

*"So that's where I've been going backwards and forwards from the GP to Dr X and that's when they started talking about having something because it was getting dangerous with the low blood pressure." (P13)*

The GP had knowledge of the patients overall health and their past medical history. The cardiologist suggested addition of an ACE inhibitor for one participant (P15) but his GP reviewed his notes first and found cough on ramipril in the past so initiated an alternative drug following further consultation.

## 4.6 Heart Failure Diagnosis – Delivery and Impact Theme

### 4.6.1 Explanation of Diagnosis and Cause

This category examined the explanation of heart failure diagnosis from the participant's own perspective and what they recall being told by their GP and specialists. It also explores the causes of heart failure.

- Patient own explanation

Patient explanations were varied in complexity and depth. Some simply described having a 'weak heart' or 'not getting enough oxygen in my blood to have the energy to push myself' while others had a detailed description in their mind. Participant education and background influenced their understanding and sense-making of the diagnosis.

One participant had seen a cardiologist, attended the nurse-led heart failure clinic and had responded to take part in the heart failure study but, even on direct questioning during the interview, did not realise that he had heart failure. Conversely, two participants were engineers by background and appeared to have a detailed understanding of the disease process by thinking of heart failure in mechanical terms.

*"…it's a pump system isn't it that's all it is, it's a pump system. You've got the power of the pump, you've got the pipework going round, and the various sizes of the pipework. And if you*

*increase the size of the pipework, the pump will bang it round very easily but if the pipework gets constricted in any way then the pressure will go up. There [is] an easy hydraulic relationship with that…" (P4)*

Some participants actively sought extra knowledge about the diagnosis by looking online or in textbooks whilst others preferred to avoid knowing too much.

*"I didn't bother to go too deeply into it, you know knowledge can kill you, the wrong kind of knowledge, or half knowledge" (P8)*

One participant was still working and found she needed an explanation for her condition which she could tell work colleagues to account for why she gets so tired.

*"I just tell them it's a heredity thing, I've got a bit of heart failure and I get more tired than what you do. As I said it's probably being twice as tired and working twice as hard as what they do". (P13)*

There was considerable fear associated with the term heart failure for many participants. An understanding of the problem in the heart led to a greater awareness of symptoms for one participant.

*"Well I mean heart failure means, when they [say] heart failure it means your heart's going to, it's wearing out or whatever, it's going to stop. It could stop. It's failing. And I know you've only got one so I mean let's face it that's not a good thing." (P2)*

*"I'd been told that the valves were not operating properly and they told me the result was a reflux and I was… I would often wake up very conscious of this going on in my chest. Knowing what it was I could imagine blood not just going through and then shutting off but coming back again and sort of regurgitating inside the heart." (P15)*

- Medical professional explanation

Secondary care specialists, usually cardiologists, were responsible for giving the diagnosis to most participants. GPs were involved in initial investigation of the problem and referral for a definitive diagnosis but did not explain in detail what heart failure was as the diagnosis was not confirmed. Breaking bad news was not handled well in some cases with a lack of ascertainment of what they already knew, signposting or empathic delivery described by several participants. There were examples of participants being left shocked by the mode of delivery of the bad news as well as the diagnosis itself. There was a need for more time and space to explore and understand the problem.

*"Just how impersonal the personnel were when I went in for my heart examination. That could be improved immensely. It wouldn't have hurt them to have become a little human and*

*thought a little bit about the... just the diagnosis and "There you are".  There's a better way of dealing with somebody than that. Not difficult to do." (P6)*

For some participants the explanation was proportionate and appropriate, delivering the news of heart failure gradually and initially avoiding use of the term.

*P13: "It was very good, I mean he says, it's just a degree of heart failure. They actually didn't use those words for a long time to me, he just said… he told me it was a left valve that wasn't pumping properly. It should pump at so much percentage and it was pumping at a lesser percentage and that's why you're feeling tired because it's having to work harder. You're working twice as hard as you should be, he says, that's why you feel tired. He explained to me quite well..." (P13)*

*"No it was all explained to me very well and I had visions of valves going like this so I got a clear picture of what was going on inside my heart". (P15)*

The explanations of the term 'heart failure' offered by medical professionals were sometimes clear as described above but in some cases medical jargon led to a lack of understanding although some participants preferred to take a stance of 'not wanting to know too much'.

*"They tried, but they used so much jargon, I didn't understand. I didn't want to know too much, anyway. But I saw what was written down and was able to translate that...They say my left ventricle is not working fully. They don't say why...The last thing I do is worry. There's a hospital full of doctors. Let them do it." (P9)*

- Causation

None of the participants had thought that previous cardiac events had led to heart failure prior to receiving their diagnosis. However, when they were told they had heart failure some participants suggested their own reasons for why they had developed the condition whilst others recalled being given a particular explanation by the specialists.

*"But a part of my heart is damaged, he says, which is caused by a heart attack I suppose". (P10)*

One participant blamed himself for 'over doing it' and was convinced his heart failure had been brought on by his own behaviour.

*"I think this is one of the reasons I've, over the years, probably just wore myself out...I'm just like an engine, just blowing up, you know." (P7)*

- Heart failure terminology

Many different ways to describe heart failure were used by participants and specialists. The term itself was often associated with fear and a concern that the heart may stop or that outlook was poor. Participants developed strategies to cope with this as time went on.

*"It was worrying I mean you know when they tell you that your heart's not working properly and they call it 'heart failure', whatever's wrong with your heart they call it heart failure don't they which I think is horrible because failure means it could stop you know. That's worrying but the longer you live with it, the more you get used to it". (P2)*

There was some confusion over ejection fraction terminology and what that meant – if ejection fraction was 20%, for example, one participant assumed that meant only 20% of their heart was working and were not aware that a normal ejection fraction is 50% or above.

### 4.6.2 Impact on Life and Current Health State

These categories captured participant views of the impact that a heart failure diagnosis had on their lives.

- Activities of daily living/physical activity

Symptoms which affected activities of daily living were often the reason participants first sought medical advice. Until then, symptoms had often been ignored until they had a significant impact on day to day life such as shortness of breath on walking to the bathroom or being unable to mow the whole lawn as usual. Once the diagnosis had been confirmed, participants adapted to cope with the limitations of their illness e.g. wife cuts the grass or have carer to help. Some participants and their spouses reflected on the comparative difference in activity levels between themselves since the participant had become unwell.

*"So you do some exercise because we're out shopping. But you're not out and about all the time like I am. You go so far, and then as I say, by lunchtime, that's it. It's enough, really." (P9 spouse)*

For some participants, the limitation of their symptoms meant they had to stop and rest when necessary. Although others found diagnosis and treatment had meant they were able to 'get back to normal' and were sometimes fitter than their peers.

*"All my mates say the same. They go play golf this morning, they go home and they won't do nothing. But I do. I'm doing the fence at the moment, putting all the new fence all the way up there." (P7)*

Some participants described remarkable recoveries following episodes of severe or life-threatening illness.

*"I was able to tell him [surgeon] that the weekend before I'd walked a couple of miles again. He expressed surprise...so he said I don't need to see you again which was music to my ears." (P15)*

The provision of cardiac rehabilitation at the hospital following surgery helped some participants in their recovery.

*"the [hospital] do a good thing they invited me to go for exercises for a period of eight sessions and I've got my last one next week." (P15)*

- Patient adaptability

At the time of recruitment, participants had been diagnosed with heart failure within the past 12 months. During interview participants talked about how they were coping and adapting to their new diagnosis.

*"I've been all right. I've been coping quite well. You know, you take one day. Sometimes you're better than others. You feel more spritely some days than others. Oh, well, we are all right. We're survivors, aren't we?" (P6)*

Participants had generally learnt to cope with their new circumstances. But doing activities at the edge of their limits could be a reminder that they were not completely back to their previous self e.g. one participant planned to start line dancing classes run by the hospital, but recently walked up a steep hill in town and needed to sit down when he got to the top so acknowledged he was 'still not 100%'. The determination to 'get out every day', despite some limitation, was important to one participant.

*"The bus is… we go through a gully we call it there, but I just get through that gully and turn the corner and then I start… my breath starts to go…I just keep taking the medication and, as I say, it enables me to get out every day…" (P16)*

Participants described the 'work' and routine of attending frequent hospital appointments became 'the norm' after a while.

*"It's a strange sort of thing, you almost get used to this way of life, as you say, going from nothing, from no tablets and nothing really, to all of a sudden this took off. You hit this wall, don't you, of medication and tablets and everything." (P9)*

Some patients found knowing and understanding the diagnosis helped them to adapt and cope.

*"I think since I've realised what it was you see I can address it more because I think it was there before for a few years but I didn't know what it was, I didn't know what was happening really." (P13)*

Adaptations were physical as well as psychological and included physical alterations to the home, stopping driving, getting help from a carer or limiting travel.

### 4.6.3 Outlook

This category explored participant views on outlook following their diagnosis of heart failure. Participants were very aware of their own mortality and many described episodes of acute illness where they had 'brushes with death'. There were also amazing stories of recovery, sometimes following major surgery or a long hospital stay, with participants able to get back to a good quality of life.

*"How I survived that heaven knows. I didn't realise at the time but my wife stayed overnight because mostly it was touch and go whether I would make it through the night." (P12)*

Participants reflected on the death of peers and the age that other family members passed away. Operative risk meant some participants were refused surgery and risk of death had been discussed in detail. A fear of death was often present when participants were acutely unwell or didn't know what was causing their symptoms. Prognosis, in terms of survival

rates, was not discussed in any great detail. Some participants questioned the value of knowing information of this type.

*"I mean how bad does it get before you, is it a good thing to know [laughs] is it a good thing to know that that your heart is getting worse or, you know, or improving a bit, I don't know. [pause] I really don't know." (P2)*

Discussions about survival rates, long term planning and Do Not Attempt Resuscitation (DNAR) were overall lacking and had not been addressed during medical interactions.

*"I think it's always in the back of your mind that you worrying that you're going to get worse as well...I just think well there's no cure, there's no actual cure for heart failure, there's no cure. It's one of those things but there's a lot of preventions and stuff but is that going to be [my] downfall? You do think that but there you go." (P13)*

## 4.7 Summary of the Chapter

This chapter presented the key findings of the qualitative study of patient experiences of the diagnostic pathway for heart failure in primary care. Three key themes emerged – Heart Failure Onset, Interacting with Healthcare and Diagnosis Delivery and Impact – and were explored along with verbatim quotes from interviews. The next chapter summarises the findings, discusses them in relation to the literature and makes some key recommendations.

# 5. PATIENT EXPERIENCE OF HEART FAILURE DIAGNOSIS: DISCUSSION

## 5.1 Chapter Overview

The findings of the study in Chapter 4 highlight important behaviours and processes which could be modified to improve the experience of patients with heart failure. This chapter explores emerging concepts from the key findings, compares with the existing literature and gives key recommendations, policy implications and suggestions for further research.

## 5.2 Heart Failure Onset Theme

### 5.2.1 Emerging Concepts and Comparison with Existing Literature

The emerging concepts from the Heart Failure Onset theme include symptom explanation and normalisation, symptom type and onset, symptom awareness, complexity and multimorbidity and facilitators of help-seeking. These concepts are discussed in relation to the existing literature and theories.

*Symptom explanation and normalisation*

Participants in the study did not realise initially that the symptoms of breathlessness, ankle swelling or tiredness were due to heart failure. Instead they thought their symptoms were due to normal ageing, 'doing too much', other medical conditions and medications or just

assumed that they would pass. Studies looking into decision-making at the onset of other chronic medical conditions have also found a similar phenomenon. McCabe et al interviewed patients with a recent diagnosis of atrial fibrillation (AF) to explore their experience of symptom onset; most participants had initially 'misinterpreted' their AF symptoms and had attributed them to ageing, excess work demands, physical deconditioning or stress and had dismissed them as 'not important'.[126]

Normalisation of symptoms is a common sociological phenomenon and a barrier to diagnosis in other medical conditions, such as dementia where 'forgetfulness' is initially seen as a normal part of ageing.[127] The presence of symptoms in the general population is common which might explain why 'normalising' prevalent symptoms such as fatigue or breathlessness is so widespread. A study by Petrie et al examined the prevalence of symptoms in a randomly selected sample of 1,000 participants from the general population.[107] Researchers asked participants if they had experienced any of a list of 46 symptoms in the previous 7 days. Thirteen percent had experienced shortness of breath and 36% had experienced fatigue. The challenge therefore is to enable patients to identify symptoms which are significant and associated with a pathological disease process rather than within normal limits.

*Symptom type and onset*

Participants experienced symptoms including shortness of breath, ankle swelling, fatigue and dizziness which were gradual in onset. Symptoms were often severe, and had an impact on activities of daily living, before participants sought medical help.

A narrative review by Gravely-Witte et al explored the length of delay in seeking medical care for heart failure patients - admitted to hospital rather than presenting to primary care - according to symptom type and onset.[128] Participants who suddenly developed shortness of breath were less likely to delay seeking help than those with symptoms of more gradual onset such as ankle swelling or fatigue. In this review most patients already had a diagnosis of heart failure and the delay was the time between symptom onset and admission to hospital which ranged from 2 hours to 7 days. This differs from the current study which examined the diagnostic pathway for patients referred from primary care. The community population with new onset chronic heart failure is likely to differ from the population with existing heart failure experiencing an exacerbation which requires hospital admission, however the impact of symptom type on delay in seeking medical help within primary care is worthy of further consideration in future research.

The concept of 'biographical disruption' was first described by Bury in the 1980s. He interviewed patients with a new diagnosis of rheumatoid arthritis and found that the symptoms, and ultimately label of disease, had a profound effect on the patient's social

world and their sense of self.[129] In the interviews with heart failure patients, participants reflected that their whole world changed at the point where they realised something was wrong and sought medical help.

*Symptom awareness*

A delay in seeking help has also been found for other cardiovascular conditions like stroke and heart attack. Patients with an acute stroke most commonly experience a sudden onset of symptoms with one-sided weakness, speech disturbance or facial asymmetry; early intervention can be lifesaving but patients do not always seek immediate medical attention. Mackintosh et al conducted a qualitative interview study to try to understand what factors might be involved in the delay and found that some patients did not know the symptoms of stroke and others did not appreciate the importance of seeking medical help urgently.[67] In addition to lack of knowledge, patients described a fear of stroke or hospital admission and a subsequent denial which prevented them from seeking help immediately. Witnesses, who were most often family, played a key role in recognising stroke symptoms and taking action to access medical services.[68]

Similarly, patients with acute myocardial infarction, or heart attack, often experience a sudden onset of symptoms - usually crushing central chest pain - but may delay getting help. Henriksson et al conducted focus groups with patients and their relatives to explore their thought processes when symptoms of acute myocardial infarction occurred.[69] Patients felt

uncertain about the cause of their symptoms, often assuming they were due to something less serious, and tried various methods to alleviate symptoms prior to seeking help. Relatives played a vital role and were usually more concerned than the patient themselves, encouraging them to take further action such as calling an ambulance.

*Complexity and multimorbidity*

Many participants in this heart failure study had a history of previous cardiovascular disease and had multiple past contacts with healthcare. Epidemiological evidence shows that patients who have had a previous myocardial infarction are more likely to develop heart failure than those who have not had a previous event.[25] Yet participants were initially unaware that their symptoms could be due to heart failure.

Multimorbidity increases with age and the participants in this study were in the older age group (median age 78.5 years). Conditions such as arthritis were common and contributed to poor quality of life; indeed symptoms from other diseases in some cases overshadowed those due to heart failure. Participants also attributed their symptoms to side effects of medications which added to complexity and influenced their help-seeking behaviour. The management of chronic conditions, often according to single disease guidelines, can result in older patients taking a large number of medicines, but with a lower likelihood of receiving optimal therapy for specific conditions such as heart failure.[130] More research is required to examine the impact on patient outcomes including those with a heart failure diagnosis.[131]

Symptom worsening, effect on activities of daily living and family concern were all reasons for participants in the study to see their GP. A qualitative synthesis by Smith et al, exploring patients' help-seeking experiences and delay in cancer presentation, found remarkable similarities in their list of triggers to recognition of illness which included "symptoms worsen or do not go away", "symptoms affect everyday life" and "discussion of symptoms with friends and family".[132] Other triggers which were not found in the current study were "specific well-known symptoms (e.g. lump)" and "knowledge of cancer symptoms and awareness of risk". These concepts were notably absent from all of the interviews in the heart failure study suggesting awareness of heart failure symptoms is much less than for cancer symptoms in the general population.

## 5.2.2 Recommendations, Policy Implications and Further Research

Participants developed plausible explanations for their symptoms which delayed their presentation to primary care. Increased awareness of heart failure symptoms is vital for patients, carers and the public to recognise the condition. Campaigns by government and charities have raised awareness of the symptoms of several different cancers with the prospect of earlier diagnosis leading to better outcomes.[133] A similar campaign at a national level, or a more targeted campaign aimed at those with a previous history of myocardial infarction, may help encourage patients with possible heart failure to access healthcare earlier.

Participants who had previous cardiac events were unaware of the possibility of developing heart failure and therefore did not recognise the onset of symptoms yet they interacted with medical services frequently through cardiac rehabilitation and primary care follow-up. Tailored education, perhaps during cardiac rehabilitation following a heart attack, could help to raise awareness in this particularly at risk population.[134] In addition, patients with a history of coronary artery disease are reviewed annually as part of the QOF. This provides an opportunity to assess these at risk patients for evidence of heart failure by asking a screening question such as 'do you feel breathless, tired or do your ankles swell?' and/or carry out a blood test for elevated natriuretic peptides. Further research is required to determine if these approaches would be cost-effective.

Alternatively, as participants did not recognise their symptoms as important, so did not present to medical services for some time after symptom onset, screening may help to identify heart failure in the non-presenting community population; this potential approach is considered in more detail in Chapter 7.

Heart failure is a syndrome that results from acute and/or sustained insults to the heart. Primary and secondary prevention strategies are important to stop or slow progression to heart failure. Increasing patient awareness of cardiovascular risk factors and prompt action in the event of a myocardial infarction could help limit cardiac damage and prevent the development of heart failure.[135]

## 5.3 Interactions with Healthcare Theme

### 5.3.1 Emerging Concepts and Comparison with Existing Literature

The emerging concepts in the healthcare interactions theme included access to healthcare, diagnostic uncertainty, continuity of care in general practice, communication in secondary care and the role of generalism.

*Access to Healthcare*

GP access and continuity was a source of frustration for patients in the study, although examples of good access arrangements were also described. The difficulties in GP access have been documented for some years and have been more widely recognised recently.[136] The Royal College of General Practitioners (RCGP) has described general practice as underfunded and overstretched meaning patients can struggle to get a GP appointment.[137] General practice undertakes 90% of healthcare interactions but has less than 10% of the NHS budget.[138] Some patients in the study were affected by lack of GP appointments and this represented a delay in their diagnostic pathway.

The first contact with the GP often initiated a cascade of tests, appointments and treatments. Realising something was wrong and attending the GP surgery, then hospital clinics, participants adopted the 'sick role' originally identified by Talcott Parsons.[139] Participants were often off work and spouse and family became more involved in daily activities. There were several examples where a close relative was instrumental in initially

accessing healthcare – in one case, for example, the spouse of the participant had called an ambulance after realising he had become so unwell.

*Diagnostic uncertainty*

When seen by the GP, care was usually thorough and prompt with further tests or referral arranged within 1-2 appointments. In cases where the diagnosis of heart failure was 'delayed', a differential diagnosis (e.g. chest infection) was considered first. All patients in this study who could recall their diagnostic pathway in detail were usually referred by their third or fourth GP appointment and delays did not occur over months.

The symptoms of heart failure can overlap with other medical conditions which can make the diagnosis challenging.[140] Symptoms such as shortness of breath may be caused by a wide range of conditions other than heart failure such as COPD, chest infection, anxiety and muscle disorders.[21] Point of care testing can help to differentiate the causes of shortness of breath. Natriuretic peptides are significantly elevated in patients with heart failure and can be measured through a blood test to support clinicians in deciding which patients require referral for further diagnostic testing.[141]

*Continuity of care in general practice*

Patients wanted to see the same GP, ideally the person they identified as 'their GP', over time. The value of continuity of care has been previously described; seeing the same doctor and forming a 'therapeutic relationship' can improve both patient safety and outcomes.[142] However, in two cases, being seen by a different GP led to the alternative diagnosis of heart failure being considered, tests arranged and referral to secondary care.

Whilst the literature strongly supports the ideology that continuity of care remains valuable in the care of patients with chronic conditions, some recent evidence has suggested that seeing a different doctor during the early stages of the disease can be beneficial in some circumstances. The effect of continuity of care in the diagnostic pathway for cancer was investigated by Ridd et al using electronic medical records.[143] Continuity – seeing the same doctor at each consultation – in the 12 months prior to the index consultation was found to be associated with later diagnosis for colorectal and lung cancer. The authors suggest that familiarity could mean that symptoms are put down to pre-existing diagnoses rather than a new disease process.

*Communication in secondary care*

Participants tended to spend more time in, and have more contact with, secondary care during the diagnostic process and their experiences were mixed. The approach of some secondary care staff was impersonal and led to poor patient satisfaction. Participants felt

less connection with the secondary care team compared with their general practice. The role of heart failure nurses was unclear to some patients.

Secondary care interventions were also associated with long waiting times. Some patients required cardiac surgery or interventional cardiology procedures and in one case, the surgery was cancelled four times, with little communication in the interim; and the patient subsequently became too unwell to have the procedure. The issue of safe and compassionate care was highlighted in the public enquiry into the Mid Staffordshire NHS Foundation Trust where hundreds of patients died unnecessarily due to poor quality care. The report found failings in communication and compassion in all areas and made recommendations to prevent this situation reoccurring within the NHS.[144] The importance of communication skills remains a priority in NHS Trusts and specialty training programmes.

*The role of generalism*

The place of generalism was explored by the Commission on Generalism in their report 'Guiding Patients Through Complexity: Modern Medical Generalism' which was published in October 2011.[145] The Commission reflected on the rise of specialisation within healthcare services whilst the population they serve is becoming older with multiple co-existing conditions. The report highlighted the need for generalists – clinicians who deal with the whole person, including multiple conditions and within their social context, presenting with often undifferentiated illness.

**5.3.2 Recommendations, Policy Implications and Further Research**

The healthcare system is under considerable strain and general practice was a key entry point to the diagnostic pathway for most patients. Improved access to general practice through increasing the number of GP appointments would facilitate patients being seen more easily and quickly but would require recruitment and retention of more GPs. The RCGP have estimated that 8,000 more GPs are needed in England by 2020[146] to meet the current patient demand and in response, the government have committed to work towards increasing GP numbers through increasing training numbers, recruitment campaigns and initiatives to improve retention of the existing workforce.[147]

When the participant was able to see the GP, the care was usually good but in two cases, a different diagnosis was considered before heart failure. Availability of point of care testing to measure natriuretic peptide level within the practice may help differentiate the cause of symptoms for some patients. Further research is required to prove the cost-effectiveness of this option.[148]

There is a need for a compassionate, patient-centred approach in secondary care. The 'Hellomynameis…' campaign in hospitals is helping to improve communication skills of secondary care staff and help patients feel more at ease by knowing the name of the person responsible for their care.[149] Clinicians should explain key parts of the diagnostic pathway, including what tests are required and why, and patients should have time and opportunity to

ask questions. The need for generalist care within general practice and hospitals is crucial for patients with multiple co-morbidities including heart failure. More emphasis on generalism, and training in generalist skills, within secondary care would improve the holistic care of these complex patients.

## 5.4 Heart Failure Diagnosis - Delivery and Impact Theme

### 5.4.1 Emerging Concepts and Comparison with Existing Literature

The emerging concepts in the Heart Failure Diagnosis theme included 'heart failure' as a term, diagnostic delivery and understanding, and adaptation and optimising function.

*'Heart Failure' as a term*

Participants understanding of 'heart failure' as a term varied. Some participants could describe the mechanisms of heart failure, in terms of a failing pump system, and relate this to previous heart damage whereas other participants chose not to consider the diagnosis in considerable detail. One participant in the study did not even know that he had heart failure.

The nomenclature used around heart failure is complex and does not perhaps accurately describe the pathological processes involved in deterioration of cardiac function.[150] In recent years the emergence of a new type of heart failure where the ejection fraction is within normal limits – heart failure with preserved ejection (HFPEF) – has led to debate about the

classification which should be used by specialists for consistency.[151] In guidelines, there has

been an emphasis on publishing precise definitions required for heart failure diagnosis and

there has also been a suggestion by some authors to 'stage' the disease in a similar way to

cancer.[152] But for patients the term 'heart failure' itself is associated with fear and

uncertainty. There is little research on the impact of the terminology used in heart failure

and a change in the name to a less frightening and better descriptive term may be helpful for

patients and clinicians.

*Diagnostic delivery and understanding*

In this study, 15 out of the 16 participants were told they had a diagnosis of heart failure

within secondary care. Across Europe the place of diagnosis varies between countries. Hobbs

et al interviewed 1363 primary care physicians from 14 European countries and reviewed

11,062 patient notes and found that overall 50% of heart failure diagnoses were made in

primary care.[153]

Some participants were satisfied with the explanations they had received but for others the

appointment where they had been told they had a diagnosis of heart failure had felt rushed

and uncaring. Breaking bad news is a key communication skill for clinicians delivering any life

changing diagnosis.[154] Discussions need to be tailored to the individual and based on pre-

existing knowledge and understanding as well as their wishes for what they want to be told

about their diagnosis. The current evidence base focuses on interventions for practitioners

to enhance their communication skills but more research is required to establish how breaking bad news impacts on patient reported outcomes, and how this can be improved.[155]

Rodriquez et al interviewed American patients about their knowledge and understanding of a heart failure diagnosis.[156] Patients reported a need for more information about heart failure and greater opportunity to discuss their condition in detail with their physician. Patients also expressed a desire to discuss prognosis but reported this was lacking during medical consultations.

Most participants in the current study had not been given any written information so some went online to find out more about their condition. However, participants would have preferred information tailored to their own particular condition and circumstance and would have welcomed more time to discuss the diagnosis with the secondary care team, perhaps at a further appointment. In a review by Davidson examining tools for conversations about treatment decisions and outlook in patients with heart failure, the 'receptivity' of the patient to information about their conditions was not uniform.[157] Patients valued honesty in general but the depth and type of information they required was highly variable. An individualised approach to delivering the diagnosis and providing further information is therefore required.

*Adaptation and optimising function*

The impact of the diagnosis was different for each participant. A heart failure diagnosis had led to effective treatment for some which had meant they were able to get back to a good quality of life. For others, adjusting to the diagnosis was difficult and took time. Some participants worried about the future although few spoke explicitly about prognosis or advanced care planning.

As described previously, Bury introduced the concept of biographical disruption which accompanied a new diagnosis of rheumatoid arthritis but the concept has been found to apply to many chronic illnesses including COPD and cancer.[158] Heart failure has a poorer prognosis than many cancers. A recent study exploring the 'disruption' of a cancer diagnosis with a poor outlook found that participants acknowledged that a full recovery was impossible, with their self-identity and social world already changed forever, and instead aimed to achieve a 'new normal' within the limits of what their disease allowed.[159]

Previous qualitative studies have examined the impact of a heart failure diagnosis on patients' everyday lives. Jeon et al undertook a systematic narrative review of qualitative studies examining the experiences of patients living with heart failure.[160] The main impact was living in fear, a sense of loss of control and social isolation. Knowledge and understanding of their disease trajectory, along with easy access and continuity of care

within healthcare services which were high quality, enabled patients to adapt and improve their quality of life through regaining control and self-management.

Pihl et al examined the impact of heart failure on daily physical activities in a phenomenographic analysis. Patients were limited by their heart failure symptoms but found ways of adapting and changing their daily activities to accommodate this. They felt it was important to maintain a degree of physical activity for as long as possible to maintain independence and prevent social isolation. However, interviewees described a fear of increasing physical activities as they associated this with possibly putting their cardiac health at risk.[161]

Many participants in the current study described multiple medical conditions which impacted on their life, sometimes more than their heart failure symptoms. The presence of more than one chronic disease, including mental illness, is common in patients with heart failure due to their age and common risk factors. Murad et al examined the prevalence of comorbidities in a subgroup of the Cardiovascular Health Study cohort with incident heart failure.[162] Sixty percent of participants with incident heart failure had three or more comorbidities, and 17% had cognitive impairment. It is therefore vital that patients are managed in a holistic way by practitioners who are able to consider the whole person with all of their diseases, within their social context. As discussed previously, the role of generalists therefore is crucial in heart failure management.

### 5.4.2 Recommendations, Policy Implications and Further Research

The term 'heart failure' may be unhelpful but there is little research of the impact this has on patients. Further work is required to establish what terminology patients might find helpful and the feasibility of changing the terms routinely used in healthcare. Any change in terminology would require a global consensus. Further consideration of this important area could occur through discussion with international organisations such as the European Society of Cardiology and American Heart Association, perhaps at their annual conferences.

Delivery of the diagnosis is important and patients remember if this is not done well. Clinicians delivering a heart failure diagnosis should be appropriately trained in 'breaking bad news' and this should include regular updates to ensure their technique and knowledge remains adequate throughout their career. Further research is required to understand the impact of diagnostic delivery on the long term outcome of patients with heart failure.

Appropriate written information should be available to all patients following a diagnosis of heart failure. Further opportunities to discuss the diagnosis, its implications, and to ask any questions, should be agreed for a future date a short time after the initial diagnosis is given. Facilitating physical and psychological adaptation following the diagnosis should be an important part of any heart failure management plan.

Multimorbidity is common in patients with heart failure and can mean it is not always their main problem. A generalist approach in both primary and secondary care should be used to optimally manage patients with multiple diseases and polypharmacy. Complex decisions on the balance of benefit versus harm of treatments may be required rather than following single disease guidelines. There is also a need to consider what is most important to patients through patient-centred care and shared decision-making.

The issue of prognosis was not covered in detail by this study. There may be risks and benefits of discussing survival rates and outlook at the time of diagnosis. Further research into patient wishes for prognostic information and the way in which this could be delivered is needed.

## 5.5 Limitations of the Study

This study examined the experiences of a group of 16 people with a recent diagnosis of heart failure recruited from a single centre. Throughout the research process every effort was made to minimise bias to ensure the results were both valid and trustworthy. There are however some limitations which will now be discussed in detail.

*Sampling bias*

Qualitative research in general does not attempt to be representative of the whole population but seeks to explore the experiences of a particular group of people to gain a deeper understanding of the complex thoughts, actions and underlying sociological processes in a particular time and context.[163] In this study, the original intention was to use purposive sampling to ensure participants were from a range of ages, gender and ethnic groups. The challenges in recruitment described in Chapter 3 limited the number of participants available for the study. There were participants from each decile from 50 years to 90 years and a mix of men and women however only one of the 16 participants was from a minority ethnic group. All participants also spoke English as their primary language. The experiences of patients from different ethnic groups and non-English speakers were not captured in this study. The findings are therefore less likely to be relevant to this group.

Participants were recruited from a single outpatient clinic at a large tertiary referral hospital close to the centre of Birmingham. This means that the findings are particularly relevant to this centre however some of the emerging themes may be relevant to other heart failure units.

*Researcher bias*

The researcher is an integral part of the qualitative research process but can introduce bias if their influence and pre-existing ideas are not recognised and acknowledged throughout the

conduct of any study.[164] As an academic GP, I encounter patients with heart failure during my clinical work in general practice and I have also worked within acute hospital settings within a cardiology team. I therefore had my own preconceived ideas of where there may be issues within the patient diagnostic pathway. However, I have not worked in the hospital in Birmingham and fortunately, do not have any personal or family experience of undergoing the diagnostic process for heart failure.

At the start of the study I clearly described the sampling, data collection and analysis techniques in the study protocol which received ethical approval. I also explored the issue of reflexivity in detail in Chapter 3 to highlight and therefore attempt to minimise any bias I may unintentionally introduce.

*Data Collection - Interviews*

Participants were aware that I was a GP from the participant information leaflet but during interviews, I emphasised that my role in the study was as a researcher (rather than a GP) and my intention was to understand the experience of the diagnostic pathway for heart failure from the patients' perspective. I also made sure participants were aware that I was not part of their clinical team and no identifiable information would be available to their own cardiologist or GP. Interviews were conducted in participants own homes, at a time convenient to them. Participants spoke openly about their experiences, both positive and negative, and did not appear to be holding back or tailoring their story for my benefit

although it is difficult to say for certain that this did not occur at all.[122] Interviews were recorded and transcribed verbatim to ensure all data were included in the final analysis.

*Data analysis and interpretation*

Several researchers were involved during the analysis and interpretation process to offer specialist expertise in qualitative methods and highlight any areas where my perspective as the main researcher appeared biased. Data were analysed using the Framework method. A detailed coding framework was generated then reviewed by an experienced qualitative researcher (NG). A sample transcript was then coded using the draft framework by another experienced researcher (SS), who was independent of the research team, and further modifications were made to the framework as a result of her feedback. During the interpretation phase, findings were discussed with NG and another researcher (TM) to explore emerging themes and consider how these fitted within existing sociological theories and literature. This thorough approach ensured findings were credible and trustworthy as well as relevant to the original research question.[165]

*Generalisability and transferability of findings*

Generalisability describes the extent to which research findings can be applied to the non-study population and is a common goal of quantitative research.[166] This study recruited 11 male and 5 female participants age 52 years to 87 years, all white British except one Black female participant, from a single heart failure clinic based at a large teaching hospital in

inner city Birmingham. Qualitative research aims to understand both the experiences of a defined group of people and explore the meaning they attach to these events.[167]

The findings of this study are therefore relevant to the group of participants interviewed but the emerging themes and concepts are likely to be relevant and transferable to the wider NHS. It is unlikely that the interviewees are unique in not recognising their symptoms as heart failure until a late stage as this has been described for other disease processes. The interactions with healthcare may be more specific to the clinic from which participants were recruited and engagement with the leading clinician to agree and implement changes to improve the patient experience is planned. Primary and secondary care doctors are trained according to national standards so the issues of communication and compassion highlighted in the analysis are likely to be of national significance. Further research is required to explore how the points of delay or poor patient experience in the heart failure diagnostic pathway identified by this study can be improved for future patients.

## 5.6 Summary of the Chapter

This chapter provided a summary of emerging concepts for the key emerging themes: Heart Failure Onset, Interacting with Healthcare and Heart Failure Diagnosis – Delivery and Impact and integrated these with the existing literature. For each theme, recommendations were presented which, if implemented, could impact on policy and improve the experience of the diagnostic pathway for patients with heart failure. Areas for further research were also

highlighted. Finally the limitations of the study, including biases and transferability of the findings, were considered.

# 6. SURVIVAL OF PATIENTS WITH A HEART FAILURE DIAGNOSIS IN GENERAL PRACTICE

## 6.1 Chapter Overview

This chapter explores the survival of patients with heart failure in the community population. The prognosis of patients with heart failure has previously been estimating in secondary care populations following discharge from hospital with a heart failure related problem, or from longitudinal cohort studies where patients were followed up over time.[18] [78] These populations do not represent the general practice population so survival data relevant to this group is currently lacking.[83] General practice records collated in routinely collected datasets can be used to explore disease patterns, including prognosis, for patients in the community.

The study in this chapter uses THIN dataset to describe the prognosis of patients with heart failure in a primary care population. The background and aims of the study are described then the methodological approach to using general practice records for prognostic research is explained. The results are presented, the strengths and limitations of the study are discussed and the findings in relation to existing literature are explored.

## 6.2 Abstract

**Background and Aims:** Survival estimates are useful to monitor the outlook of patients with chronic diseases and to understand the impact of treatments and plan healthcare services. The aim of this study was to determine the overall survival rates for patients with heart failure from the time of diagnosis.

**Methods:** Retrospective cohort study of UK general practice records from The Health Improvement Network (THIN) database between 1st January 1995 and 31st December 2012. For the survival analysis, patients aged 45 or over with a first diagnostic label of heart failure, were matched by age, sex and practice to people without heart failure. Outcome was death in the heart failure and non-heart failure comparator cohorts.

**Results:** Overall survival rates for cases with a first diagnostic label of heart failure were 81.5%, 51.6% and 29.5% at one, five and ten years respectively. Survival has changed little between 2000 and the most recently available data.

**Conclusions:** The survival rates for patients diagnosed with heart failure have not improved over time. Further research is needed to explain these trends and to find strategies to improve prognosis.

## 6.3 Background and Aims

Heart failure is a common condition with an estimated 1-2 in every 100 people (of all ages) in Western populations living with heart failure.[168] The costs of heart failure to the NHS in

the UK are second highest for any disease after stroke.[3] Accurate estimates of heart failure prognosis are vital to healthcare commissioners to allow appropriate allocation of resources, to physicians in making management decisions and, perhaps most importantly, to patients to allow informed choices about treatments and end of life care.[5][6]

The prognosis of patients with heart failure has been established from hospital data and from following up participants of screening studies. Recent analysis of Medicare billing data in the US found that following an admission with heart failure, 67.4% of patients were readmitted to hospital within a year and 35.8% died within the same period.[169] Heart failure requiring hospital admission therefore has a poor outcome for patients and is also associated with significant healthcare costs arising from multiple admissions.

The outlook for participants in community screening studies is less bleak. In the Olmstead County population, 1 year mortality was 21% for men and 17% for women and at 5 years was 50% and 46% for men and women, respectively.[35] The ECHOES study, which screened a general population cohort over the age of 45, found a 5 year survival rate of 53% in participants with heart failure due to LVSD, compared with 93% in the group without heart failure.[73]

Hospital data and screening studies however fail to explore the survival rates of patients who are diagnosed in a community setting and are not admitted to hospital nor actively

involved with screening for research purposes. As described in Chapter 2, electronic primary care records provide a valuable source of data directly relevant to community populations.[39] [85] [86] [87] [88] The computerisation of general practice in the UK and increasingly robust coding of medical information has led to large datasets which, following anonymization, can be used to explore epidemiological trends, including survival rates. [37] [38] [39] [89] [90] THIN is one of the largest databases of general practice records in the world; it currently includes data from 587 practices in the UK, approximately 6% of the whole general practice population.[50]

The aim of this survival analysis was to determine the one, five and ten year survival rates of patients with heart failure in a general practice population and examine whether prognosis has improved over time.

## 6.4 Methods

### 6.4.1 Design

An open matched retrospective cohort study was carried out using data from THIN database for the period between 1[st] January 1995 and 31[st] December 2012.

### 6.4.2 Setting

THIN is a primary care database containing electronic patient records from 587 general practices in the UK. At each consultation, the GP records details of the medical encounter

and symptoms or diagnoses are entered using a clinical coding system. Prescriptions and laboratory results/observations (e.g. blood pressure) are also recorded electronically. Demographic details such as age, sex and linked deprivation scores also form part of the record.

Practices that contributed at least one year of clinical data were included in the study.[95] Only data after the practice acceptable mortality reporting date (the date on which the practice reported mortality was consistent with predicted all-cause mortality[95]) were included in the survival analysis.

### 6.4.3 Population

The incidence cohort, described in Chapter 2, was also used for the survival analysis. The incidence cohort was extracted from THIN database and included all persons aged 45 years and over, registered at the practice for at least 12 months between 1st January 1995 and 31st December 2012 and after the date of acceptable mortality reporting. Patients with a previous diagnosis of HF were excluded.

To determine survival, a matched cohort was extracted from the incidence cohort. Cases had a clinical code indicating heart failure. The index date was the first date of a recorded heart failure code. Cases were matched with up to five comparators who were registered in the

same practice on the index date but did not have a diagnosis of heart failure on that date (but could become a case later). Comparators were also matched on sex and age +/- 5 years.

To allow comparison with the ECHOES findings, an age group of 45 or older was also used for this survival analysis. The types of heart failure affecting children and younger people are pathologically distinct from heart failure found in older adults[91] and the randomised controlled trials conducted in the 1990s to examine the effectiveness of drug treatment in patients with heart failure recruited participants who were from middle-age onwards.[92 93 94] The ECHOES study recruited patients over the age of 45 for this reason.

### 6.4.4 Clinical Codes

Participants with a diagnosis of heart failure were identified using clinical codes, also known as Read codes, diagnostic codes used by GPs to record new diagnoses in the medical record. The NHS Clinical Terminology Browser and Quality and Outcomes Framework guidelines were used to generate a comprehensive list of terms used to code for a diagnosis of heart failure. Heart failure is a clinical syndrome and the diagnosis requires the presence of symptoms and objective evidence of a structural or functional abnormality of the heart.[7] Patients with a clinical code of heart failure and either an echocardiograph report or a hospital letter were classified as being a confirmed case of heart failure and those with just a clinical code alone as unconfirmed cases.

### 6.4.5 Baseline Variables

Demographic variables including age, sex, ethnicity, area deprivation quintile (Townsend[96]), cardiovascular risk factors and co-morbidities were extracted for each case and control. The earliest deprivation quintile prior to the index date was used or, if unavailable, the most recently recorded after the index date. Cardiovascular risk factors (smoking, blood pressure, cholesterol, body mass index (BMI)) were the most recent recorded prior to index date. Cardiovascular co-morbidities (angina, myocardial infarction (MI), ischaemic heart disease, diabetes, hypertension, stroke, atrial fibrillation, valve disease), were defined by the presence of a clinical code at any time prior to the index date.

### 6.4.6 Outcome Measure

The outcome measure was time to death (all-cause mortality).

### 6.4.7 Statistical Analyses

Data were extracted directly from THIN database using the list of clinical codes. Analysis was carried out using Stata versions 10 and 11. The number of practices, absolute numbers of confirmed and unconfirmed heart failure cases and proportion of heart failure cases classified as confirmed was calculated. Age distribution of heart failure cases and participants characteristics for confirmed, unconfirmed, all heart failure cases and comparators without heart failure were also summarised.

Practice patients included in the survival analyses were followed until the earliest of the following dates: patient died, patient left (de-registered from) their practice, the practice ceased contributing data to THIN, or the study ended.

Kaplan-Meier curves were used to compare survival in participants with and without heart failure and by age group and Townsend quintile. Log rank tests were used to compare survival between groups. One, five and ten year survival rates for cases were calculated for each 10 year age band over the age of 45. For comparison, survival rates of patients over the age of 45 without a diagnosis of heart failure were also determined. Survival rates were calculated by year of diagnosis to examine trends over time. Survival within the confirmed and unconfirmed heart failure groups was determined separately.

## 6.5 Results

### 6.5.1 Practices

A total of 564 practices contributed at least one year of data between 1st January 1995 and 31st December 2012. The number of contributing practices increased significantly over time from just 9 in 1995 to over 500 by 2008. A total of 55,248 participants had a new clinical code of heart failure during the study period; 40,615 with a code of heart failure alone (unconfirmed case) and 14,633 with additional evidence to support the diagnosis such as hospital letter or echocardiogram result (confirmed case).

### 6.5.2 Population – Confirmed and Unconfirmed Heart Failure

The characteristics of people with confirmed and unconfirmed heart failure, and comparators without heart failure, are shown in Table 9. Cases with confirmed heart failure were younger and 56% were male compared to 50% in the unconfirmed group. All five Townsend deprivation quintiles were similarly represented except for the most deprived group which had around one third less cases than the other four groups. The proportion of participants in each Townsend score group was similar for confirmed and unconfirmed cases. BMI was similar and there were 2% more smokers in the confirmed compared to the unconfirmed heart failure group. Ischaemic heart disease, angina and MI were all more common in the confirmed group. Cardiovascular co-morbidities such as AF and stroke were common in both heart failure groups.

### 6.5.3 Population – Heart Failure and Comparator Cohorts

A total of 55,248 participants had a first-ever clinical code of heart failure during the study period and were matched with up to 5 comparators by age, sex and practice. The characteristics of cases and comparators are shown in Table 9. All five Townsend deprivation quintiles were similarly represented except for the most deprived group which had around one third less cases than the other four groups. BMI was similar in cases and comparators, but there were 1.2% more smokers in the heart failure group. Cardiovascular co-morbidities, particularly ischaemic heart disease, AF and valvular disease were more common in cases than comparators.

| Characteristic | HF: confirmed (n=14,633) | HF: unconfirmed (n=40,615) | HF: all (n=55,248) | Non-HF (n=259,322) |
|---|---|---|---|---|
| Age (years) | | | | |
| 45-54 | 585 (4.0%) | 1,182 (2.9%) | 1,767 (3.2%) | 8,830 (3.4%) |
| 55-64 | 1,745 (11.9%) | 3,598 (8.9%) | 5,343 (9.7%) | 26,693 (10.2%) |
| 65-74 | 3,571 (24.4%) | 8.807 (21.7%) | 12,378 (22.4%) | 61,554 (23.7%) |
| 75-84 | 5,558 (38.0%) | 15,750 (38.8%) | 21,308 (38.6%) | 101.955 (39.3%) |
| 85-94 | 2,983 (20.4%) | 10,238 (25.2%) | 13,221 (23.9%) | 56,250 (21.7%) |
| >=95 | 191 (1.3%) | 1,040 (2.6%) | 1,231 (2.2%) | 4,040 (1.6%) |
| Male | 8,204 (56.1%) | 20,206 (49.7%) | 28,410 (51.4%) | 132,478 (51.1%) |
| Townsend score | | | | |
| 1 | 2,877 (19.7%) | 8,233 (20.3%) | 11,110 (20.1%) | 59,941 (23.1%) |
| 2 | 2,905 (19.9%) | 8,449 (20.8%) | 11,354 (20.6%) | 57,030 (22.0%) |
| 3 | 2,952 (20.2%) | 8,346 (20.6%) | 11,298 (20.5%) | 51,777 (20.0%) |
| 4 | 3,008 (20.6%) | 8,068 (19.9%) | 11,076 (20.1%) | 46,827 (18.1%) |
| 5 | 2,314 (15.8%) | 5,733 (14.1%) | 8,047 (14.6%) | 32,531 (12.5%) |
| Not known | 577 (3.9%) | 1,786 (4.4%) | 2,363 (4.3%) | 11,216 (4.3%) |
| BMI | | | | |
| Mean (SD) | 27.9 (5.8) | 27.8 (5.9) | 27.9 (5.9) | 26.4 (4.7) |
| Missing | 1,862 (12.7%) | 7,181 (17.7%) | 9,043 (16.4%) | 53,694 (20.7%) |
| Smoking status | | | | |
| Smoker | 2,290 (17.7%) | 5,502 (13.6%) | 7,792 (14.1%) | 33,414 (12.9%) |
| Not current smoker | 11,731 (80.2%) | 32,051 (78.9%) | 43,782 (79.3%) | 199,001 (76.7%) |
| Missing | 612 (4.1%) | 3062 (7.5%) | 3674 (6.7%) | 26,907 (10.4%) |
| Diabetes | 2,971 (20.3%) | 7,878 (19.4%) | 10,849 (19.6%) | 27,790 (10.7%) |
| Hypertension | 7,922 (54.1%) | 21,247 (52.3%) | 29,169 (52.8%) | 107,878 (41.6%) |
| Angina | 3,575 (24.4%) | 9,201 (22.7%) | 12,776 (23.1%) | 29,151 (11.2%) |
| Myocardial infarction | 3,919 (26.8%) | 8,528 (21.0%) | 12,447 (22.5%) | 16,579 (6.4%) |
| Ischaemic heart disease | 6,985 (47.7%) | 16,694 (41.1%) | 23,679 (42.9%) | 44,508 (17.2%) |
| Stroke | 1,270 (8.7%) | 3,761 (9.3%) | 5,031 (9.1%) | 15,183 (5.9%) |
| Atrial fibrillation | 4,732 (32.3%) | 10,894 (26.8%) | 15,626 (28.3%) | 18,149 (7.0%) |
| Valvular disease | 1,727 (11.8%) | 3,841 (9.5%) | 5,568 (10.1%) | 6,326 (2.4%) |

Table 9: Characteristics of confirmed, unconfirmed heart failure cohorts and non-heart

failure comparator cohort

## 6.5.4 Survival in the Cohort

The pattern of survival of patients with and without a diagnostic label of heart failure in their medical record is shown in Figure 7. Patients with heart failure had a significantly worse prognosis than those without heart failure (log rank test, $\chi^2$ (1) 12,817.30, 1, P<0.0001).
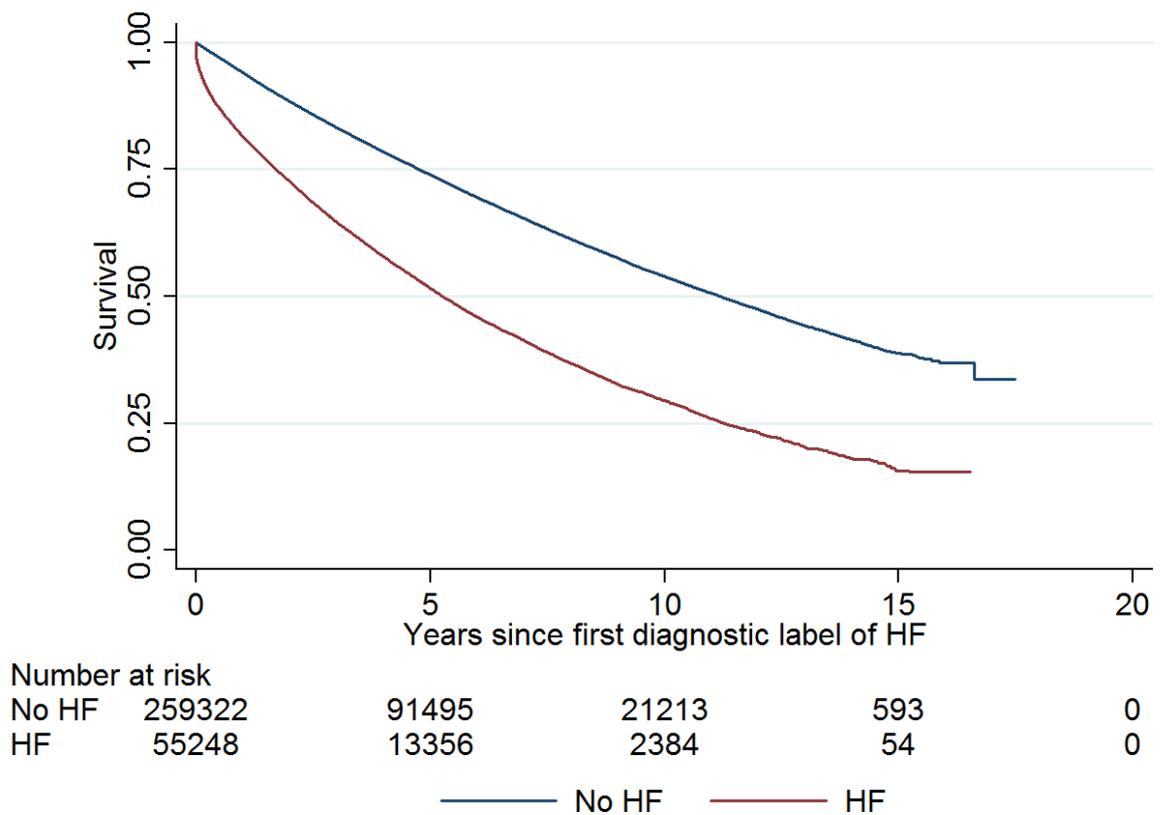


Figure 7: Kaplan-Meier curve showing survival of people with and without heart failure

Survival of heart failure cases was also related to age group with risk of death increasing with each 10 year age band (Figure 8).
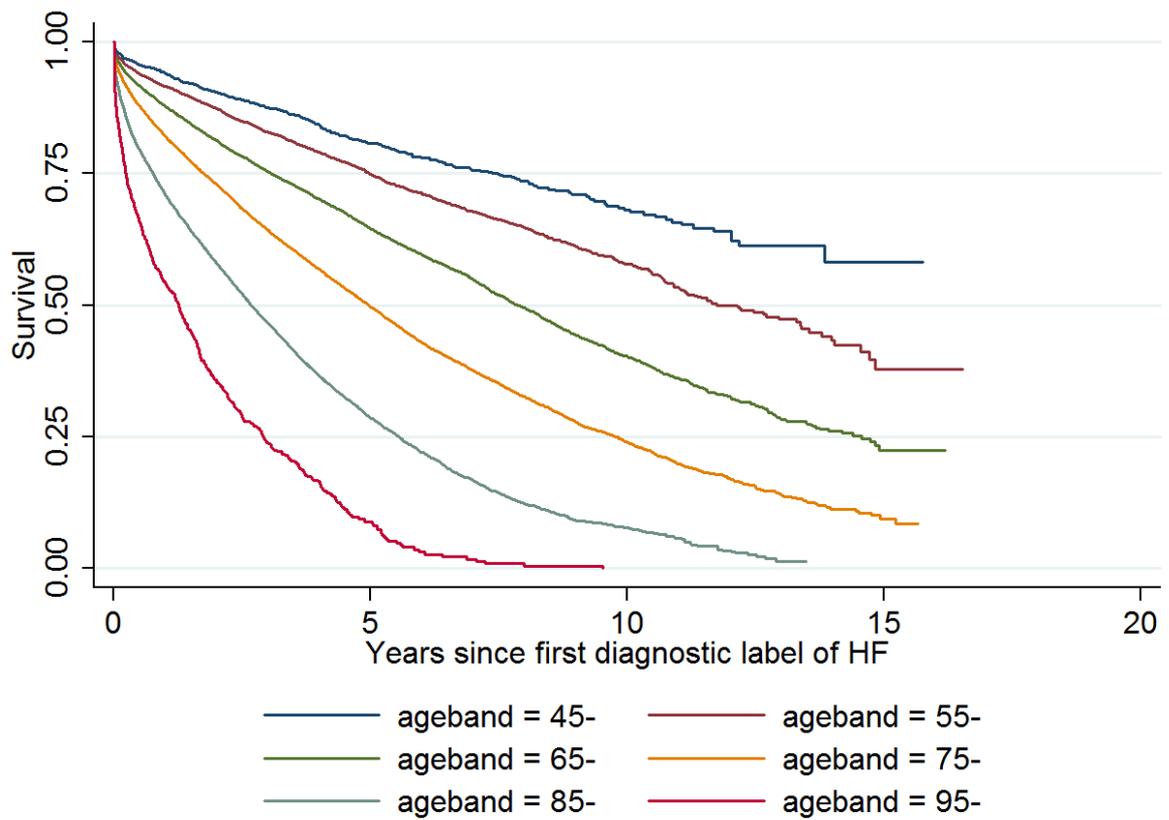
Figure 8: Kaplan-Meier curve showing survival of people with heart failure by age band

The survival of patients with heart failure by Townsend Score is shown in Figure 9. There was significant overlap between each group with no clear pattern in survival difference between groups.
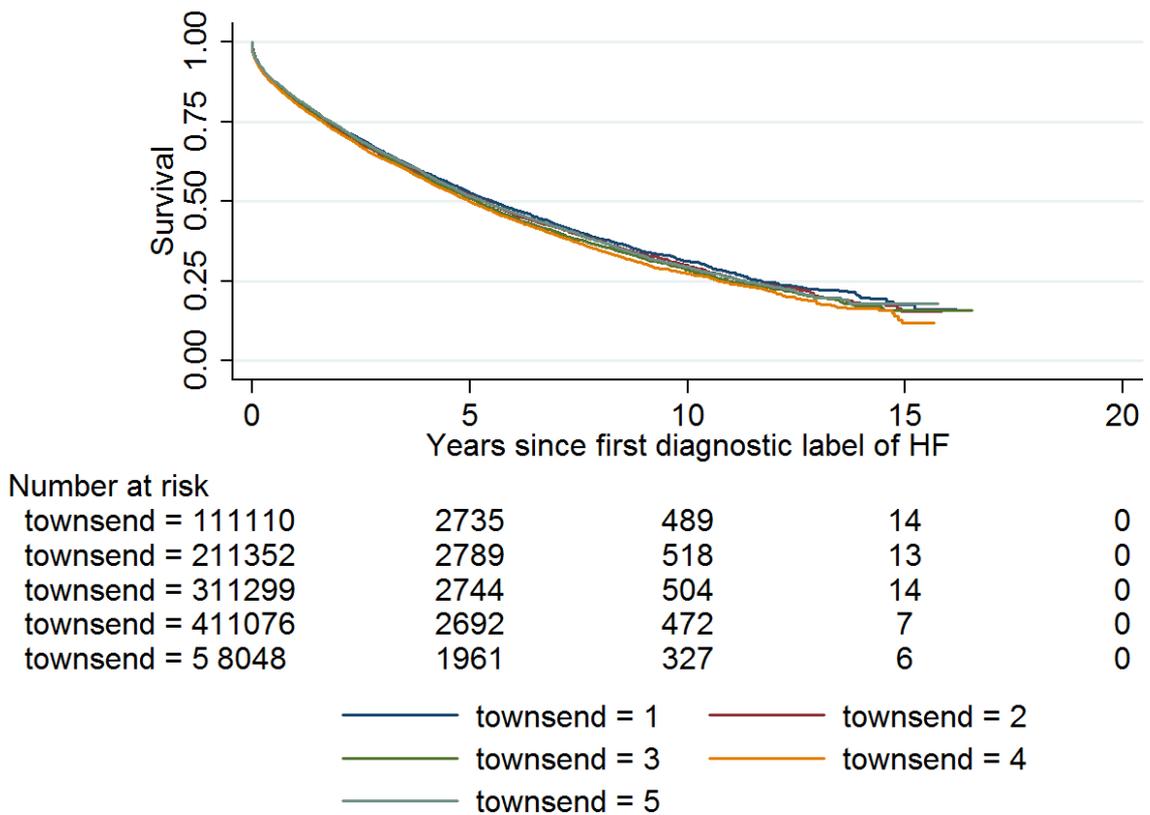
Figure 9: Kaplan-Meier curve showing survival of people with heart failure by Townsend

Score quintile

The survival rates for all patients diagnosed with heart failure during the study period are shown in Table 10. Overall survival rates were 81.5% at one year from date of diagnosis, 51.6% at five years and 29.5% at ten years. The survival rates of age, sex and practice matched comparators are shown in Table 11 for comparison.

| Age (years) | Survival (%) | | |
| --- | --- | --- | --- |
| | 1 year (95% CI) | 5 year (95% CI) | 10 year (95% CI) |
| 45-54 | 94.0 (92.8-95.0) | 80.8 (78.5-82.9) | 68.1 (64.4-71.4) |
| 55-64 | 91.6 (90.8-92.3) | 74.9 (73.5-76.3) | 57.9 (55.7-0.60) |
| 65-74 | 87.7 (87.1-88.3) | 64.5 (63.5-65.5) | 40.2 (38.8-41.6) |
| 75-84 | 82.1 (81.5-82.6) | 49.6 (48.8-50.5) | 23.9 (22.9-24.9) |
| 85-94 | 70.9 (70.1-71.7) | 28.6 (27.6-29.7) | 7.77 (6.7-8.8) |
| >=95 | 54.2 (51.2-57.1) | 8.8 (6.3-11.6) | 0 - |
| Overall | 81.5 (81.1-81.8) | 51.6 (51.1-52.1) | 29.5 (28.8-30.1) |

Table 10: One, five and ten year survival rates of people with heart failure by age

| Age (years) | Survival (%) | | |
| --- | --- | --- | --- |
| | 1 year (95% CI) | 5 year (95% CI) | 10 year (95% CI) |
| 45-54 | 100.0 (99.5-99.8) | 97.9 (97.4-98.2) | 95.3 (94.5-95.9) |
| 55-64 | 99.2 (99.0-99.3) | 94.7 (94.3-95.0) | 87.6 (86.9-88.2) |
| 65-74 | 97.5 (97.4-97.7) | 86.5 (86.1-86.8) | 71.1 (70.5-71.6) |
| 75-84 | 94.2 (94.0-94.3) | 71.8 (71.5-72.2) | 45.9 (45.3-46.4) |
| 85-94 | 87.6 (87.3-87.9) | 49.6 (49.0-50.1) | 19.2 (18.5-19.9) |
| >=95 | 77.6 (76.2-78.9) | 24.3 (22.4-26.3) | 0 - |
| Overall | 94.1 (94.0-94.1) | 74.0 (73.8-74.2) | 53.9 (53.6-54.3) |

Table 11: One, five and ten year survival rates of people without heart failure by age

**6.5.5 Survival Over Time**

The survival rates of all people with heart failure by year of diagnosis are shown in Figure 10. One and five year survival rates have remained stable since 2000 at around 80% and 50% respectively. Ten year survival rates from 1997 to 2002 were stable at 28%.
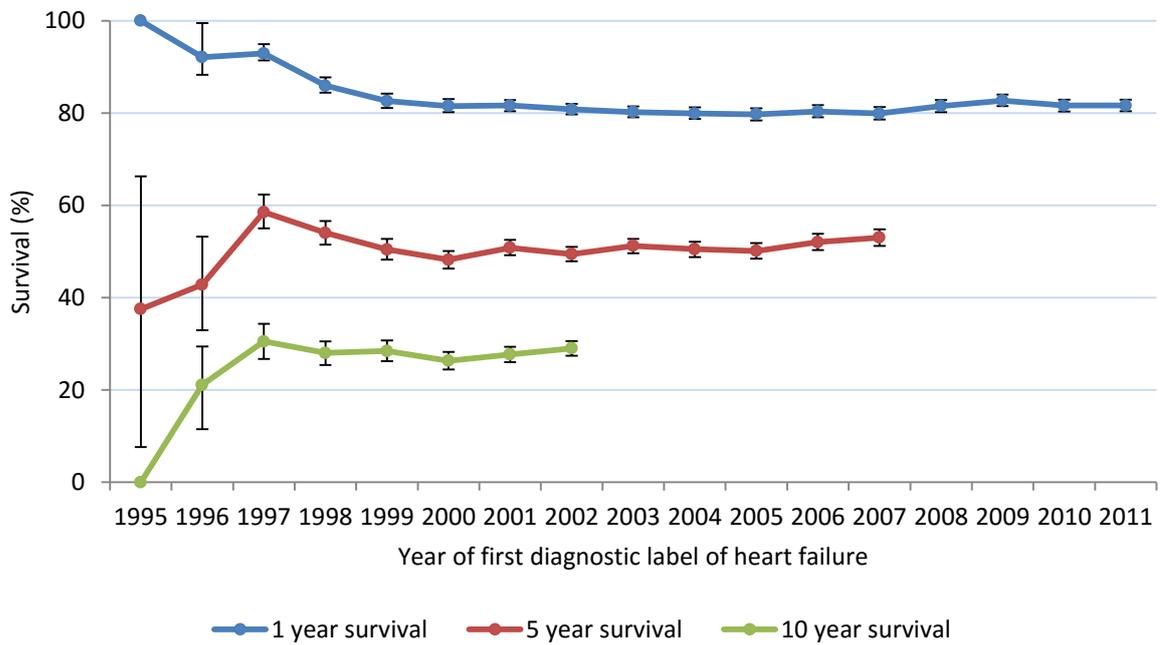


Figure 10: One, five and ten year survival rates for all people with heart failure by year of diagnosis

**6.5.6 Survival by Case Definition**

The number of confirmed cases (14,663) made up just over a quarter (26.5%) of the total number of heart failure cases (55,248) in the dataset. The overall survival rates were worse for those with unconfirmed heart failure than those with confirmed heart failure (log rank

test, $\chi^2$ (1) 170.37, 1, P<0.0001) as shown in Figure 11. Table 12 shows overall around a 5% difference in one, five and ten year survival rates between the confirmed and unconfirmed heart failure groups.



| Number at risk | | | | |
|---|---|---|---|---|
| Unconfirmed HF | 40615 | 9539 | 1882 | 49 | 0 |
| Confirmed HF | 14633 | 3817 | 502 | 5 | 0 |
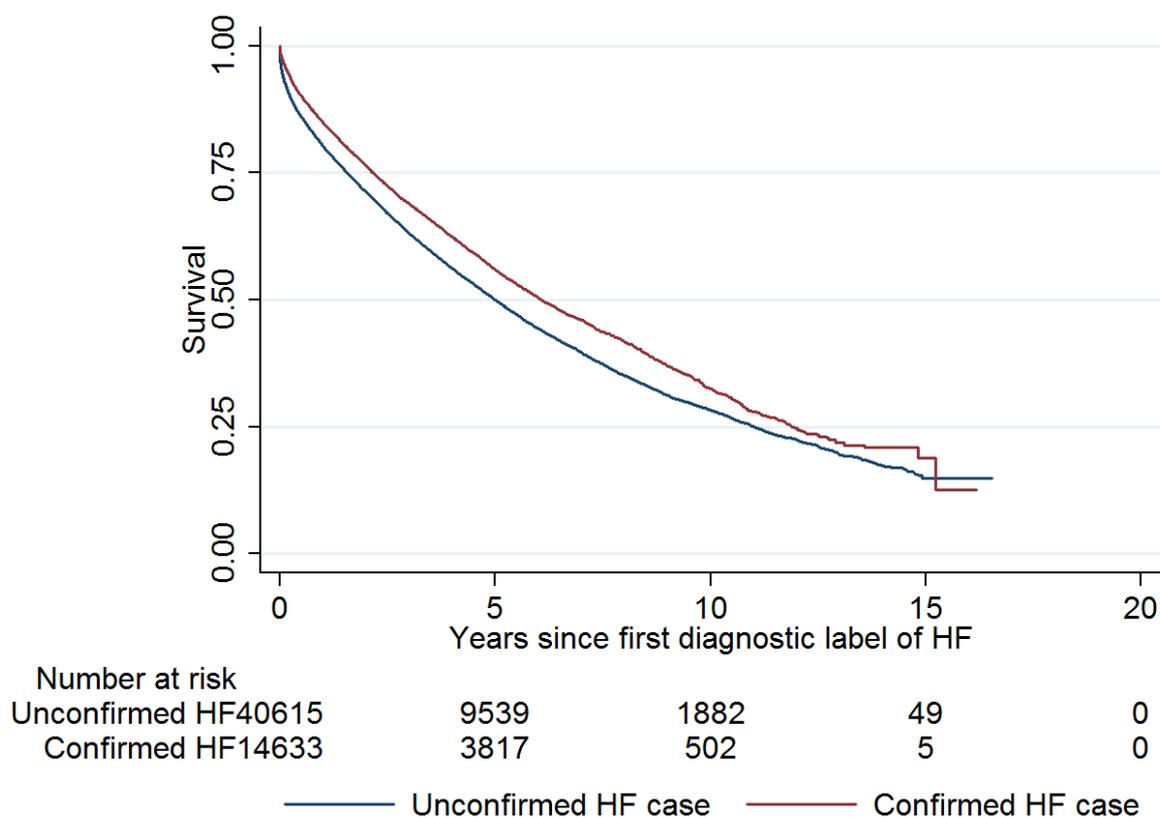
Figure 11: Kaplan-Meier curve showing survival of people with confirmed and unconfirmed heart failure

| Years since first diagnostic label of HF | Survival (%) | |
|---|---|---|
| | Confirmed HF Case (95% CI) | Unconfirmed HF Case (95% CI) |
| One year | 84.9 (84.2-85.6) | 80.2 (79.8-80.6) |
| Five years | 55.9 (54.9-56.9) | 50.0 (49.4-50.5) |
| Ten years | 32.5 (31.1-34.0) | 28.3 (27.6-29.0) |

Table 12: One, five and ten year survival rates of people with confirmed and unconfirmed heart failure

The number of confirmed and unconfirmed cases with a recording of a first diagnostic label of heart failure by year is shown in Table 13. The number of contributing practices rose sharply in the first five years of the study period meaning the number of patients with a first diagnostic label of heart failure also increased. The number of contributing practices, and therefore heart failure cases stabilised from 2000 onwards to between 3,000 and 4,000 per year. The proportion of confirmed cases in this time varied between 20 and 30% with an increase that coincided with the introduction of the Quality and Outcomes Framework in 2004.

| Year | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total cases (n=55,248) | 9 | 101 | 825 | 1758 | 2378 | 3102 | 4085 | 4619 | 4771 | 4233 | 3979 | 3712 | 3449 | 3582 | 3689 | 3654 | 3705 | 3597 |
| Confirmed cases (n=14,633) | 0 | 11 | 104 | 277 | 441 | 588 | 894 | 955 | 1216 | 1359 | 1268 | 1258 | 1185 | 1188 | 1123 | 1062 | 959 | 747 |
| Unconfirmed cases (n=40,615) | 9 | 90 | 721 | 1481 | 1937 | 2514 | 3191 | 3664 | 3555 | 2874 | 2711 | 2455 | 2265 | 2395 | 2567 | 2592 | 2746 | 2853 |
| Percentage of cases confirmed (%) | 0 | 10.1 | 12.6 | 15.8 | 18.5 | 19.0 | 21.9 | 20.1 | 25.5 | 32.1 | 31.9 | 33.9 | 34.4 | 33.2 | 30.4 | 29.0 | 25.9 | 20.8 |
| Total comparators (n=259,335) | 45 | 477 | 3991 | 8501 | 11346 | 14591 | 19105 | 21671 | 22353 | 19880 | 18642 | 17341 | 16044 | 16720 | 17094 | 17084 | 17452 | 16998 |
| Number of practices | 1 | 16 | 73 | 115 | 148 | 207 | 272 | 358 | 409 | 422 | 460 | 473 | 472 | 503 | 508 | 497 | 487 | 477 |

Table 13: Number of people in confirmed and unconfirmed heart failure cohorts, and non-heart failure comparator cohort, by year

Survival rates for people with confirmed and unconfirmed heart failure by year of diagnosis are illustrated in Figure 12 and the absolute numbers are shown in Table 14. The one year survival rates for those diagnosed from 1995 to 2011 were around 85%. The five year for those diagnosed from 1995 to 2007 were around 50% and ten year survival rates, for those diagnosed 1995 to 2002 were around 30%. There was a difference in survival rates between confirmed and confirmed cases; the unconfirmed heart failure group had worse survival rates with on average 5% worse survival at one, five and ten years as summarised in Table 14.
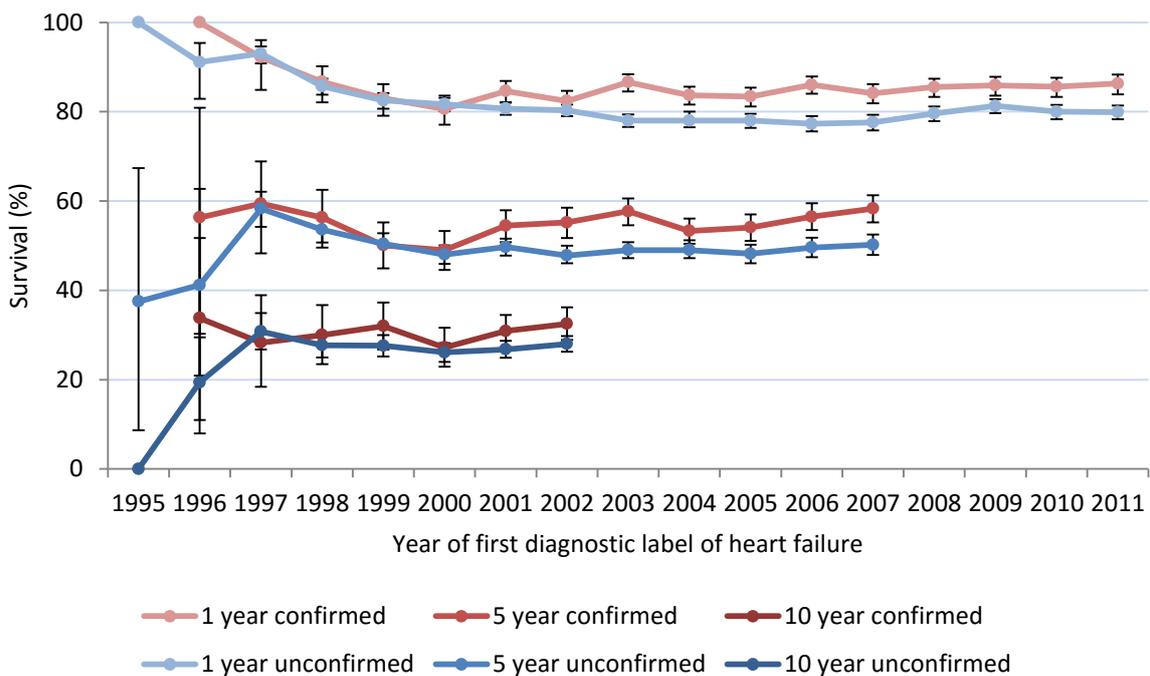


Figure 12: One, five and ten year survival rates of people with confirmed and unconfirmed heart failure

| | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total cases (n=55,248) | 9 | 101 | 825 | 1758 | 2378 | 3102 | 4085 | 4619 | 4771 | 4233 | 3979 | 3712 | 3449 | 3582 | 3689 | 3654 | 3705 | 3597 |
| One year survival (%) | 100 | 92.1 | 92.9 | 85.9 | 82.6 | 81.5 | 81.6 | 80.8 | 80.2 | 79.9 | 79.7 | 80.3 | 79.9 | 81.5 | 82.7 | 81.6 | 81.6 | - |
| Five year survival (%) | 37.5 | 42.8 | 58.5 | 54.0 | 50.4 | 48.2 | 50.8 | 49.4 | 51.2 | 50.5 | 50.1 | 52.0 | 53.0 | - | - | - | - | - |
| Ten year survival (%) | 0 | 21.1 | 30.5 | 28.0 | 28.4 | 26.3 | 27.7 | 29.0 | - | - | - | - | - | - | - | - | - | - |
| Confirmed cases (n=14,633) | 0 | 11 | 104 | 277 | 441 | 588 | 894 | 955 | 1216 | 1359 | 1268 | 1258 | 1185 | 1188 | 1123 | 1062 | 959 | 747 |
| One year survival (%) | - | 100 | 92.2 | 86.7 | 83.0 | 80.6 | 84.6 | 82.4 | 86.6 | 83.7 | 83.4 | 86.0 | 77.6 | 79.6 | 85.9 | 85.6 | 86.3 | - |
| Five year survival (%) | - | 56.3 | 59.4 | 56.3 | 50.1 | 49.0 | 54.5 | 55.2 | 57.7 | 53.3 | 54.1 | 56.5 | 50.2 | - | - | - | - | - |
| Ten year survival (%) | - | 33.8 | 28.3 | 30.0 | 32.0 | 27.2 | 30.9 | 32.5 | - | - | - | - | - | - | - | - | - | - |

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Unconfirmed cases (n=40,615) | 9 | 90 | 721 | 1481 | 1937 | 2514 | 3191 | 3664 | 3555 | 2874 | 2711 | 2455 | 2265 | 2395 | 2567 | 2592 | 2746 | 2853 |
| One year survival (%) | 100 | 91.1 | 93.0 | 85.7 | 82.5 | 81.7 | 80.7 | 80.3 | 78.0 | 78.0 | 78.0 | 77.3 | 77.6 | 79.6 | 81.3 | 80.0 | 79.9 | 86.3 |
| Five year survival (%) | 37.5 | 41.2 | 58.3 | 53.6 | 50.4 | 48.0 | 49.7 | 47.8 | 49.0 | 49.0 | 48.2 | 49.6 | 50.2 | - | - | - | - | - |
| Ten year survival (%) | 0 | 19.4 | 30.8 | 27.7 | 27.6 | 26.1 | 26.8 | 28.0 | - | - | - | - | - | - | - | - | - | - |
| Percentage of cases confirmed (%) | 0 | 10.1 | 12.6 | 15.8 | 18.5 | 19.0 | 21.9 | 20.1 | 25.5 | 32.1 | 31.9 | 33.9 | 34.4 | 33.2 | 30.4 | 29.0 | 25.9 | 20.8 |
| Total non-HF comparators (n=259,335) | 45 | 477 | 3991 | 8501 | 11346 | 14591 | 19105 | 21671 | 22353 | 19880 | 18642 | 17341 | 16044 | 16720 | 17094 | 17084 | 17452 | 16998 |

Table 14: Survival rates of people with un/confirmed heart failure, and without heart failure at one, five and ten years

## 6.6 Discussion

This study found overall survival rates for cases with a first diagnostic label of heart failure were 81.5%, 51.6% and 29.5% at one, five and ten years, respectively. Survival changed little between 2000 and the most recently available data. Confirmed evidence of heart failure was associated with improved survival.

### 6.6.1 Strengths and Limitations

The results provide survival rates for heart failure patients from a large representative set of general practices and are therefore likely to be generalizable to the community population as a whole.[97] Unlike screening cohort studies, general practice databases do not rely on participants volunteering to take part in the study rather they represent a cross-section of the entire population. The cohort included in this analysis is much larger than those used in epidemiological studies of heart failure and the follow-up was over 15 years for some patients. The large number of patients in each age and sex category also improves the accuracy of the survival rate estimates.

Research using general practice databases is reliant on the accuracy of clinical coding input by GPs during the consultation and this can be a limitation of this type of study.[21] The first recorded heart failure diagnosis in THIN was in July 1995 and clinical coding has improved significantly since then. The introduction of the heart failure QOF indicator in 2006 required robust evidence of heart failure and evidence of significant improvements in coding prior to

the formal introduction of a QOF indicator have previously been observed.[98] The benefit of THIN and similar general practice databases are that they provide an insight into real-life general practice and the survival rates of patients with a clinical code of heart failure in their record is likely to be an important statistic for practising GPs.

There have also been changes to the definition of heart failure with the emergence of two distinct heart failure types: heart failure with reduced ejection fraction (HFREF) and heart failure with preserved ejection fraction (HFPEF) which have only been coded very recently in GP records so estimates of survival by heart failure type was not possible in this study. [7 29 30 32]

### 6.6.2 Comparison with Existing Literature

The ECHOES study is one of the few studies to report 10 year survival rates. All deaths in the cohort were collated from routinely collected mortality data. In ECHOES, the five-year survival rate was 53% in patients with heart failure due to left ventricular systolic dysfunction compared to 93% for the general population over the age of 45. Overall the mortality rate for all-cause heart failure was 9% per year.[73] At ten years, survival was 27% for those with heart failure due to LVSD compared to 75% in those without heart failure.

The overall 10 year survival rate of 29.5% for the heart failure group in the present study is therefore remarkably similar to the screened population in ECHOES. However, the survival

rates for the general population were significantly less in the THIN cohort than ECHOES. This may reflect selection bias which affects most prospective epidemiological studies in that those likely to participate in research are often more healthy from the start. The participants of ECHOES without heart failure were younger and had less cardiovascular co-morbidities then the non-heart failure comparator cohort in this study. The comparators derived from the THIN dataset are more likely to represent the full spectrum of patients found in community populations.

The Framingham Heart study began in 1948 and followed up the original cohort every 2 years.[28] A study of the Framingham cohort examining the trends in survival rates for heart failure between 1950 and 1999 found an overall improvement in survival of 12% per decade between 1950 and 2000.[101] However, the Framingham participants were largely white, middle class and voluntarily took part in research so are unlikely to be fully representative of the UK primary care population. The original criteria used in the Framingham definition also relied on the presence of symptoms and signs to determine a diagnosis of heart failure but more recent definitions emphasise the importance of objective evidence of a structural or functional abnormality of the heart, usually from imaging.[31] Therefore patients diagnosed with heart failure in the earlier decades of the study may have had more advanced heart failure at the time of diagnosis.

The Rotterdam study, which recruited participants over the age of 55 between 1989 and 1993 and followed them up to the year 2000, reported overall survival was 86% (95%CI 83-

88) at 30 days, 63% (95% CI 59-66) at 1 year and 35% (95%CI 31-39) at 5 years. There was no statistically significant difference in survival between men and women (log rank test, p=0.15).

A cross-sectional study using an administrative health data register in Sweden which included 2.1 million people examined survival rates for patients with heart failure over the age of 40. The overall 5 year survival rate was 48%, similar to the THIN study results, however between 2006 and 2010 there was a 19% decrease in mortality in both men and women (P<0.001).[104]

Previous epidemiological research has shown a strong correlation between socioeconomic status and longevity; people in lower socioeconomic groups live shorter, and less healthy, lives than those from more privileged parts of society.[170] The Kaplan-Meier curve comparing survival of patients with heart failure from all Townsend quintiles (Figure 9) however showed no difference in mortality between socioeconomic groups. This may be due to immortal time bias which occurs when participants do not have an opportunity to be exposed to the disease, or drug, of interest.[171] In this case, people from the lowest socioeconomic groups may have died before having an opportunity to enter the cohort and the number of people in the THIN dataset from the lowest Townsend quintile was one third less than in the other Townsend groups. However, there is evidence to suggest that the mortality gradient related to socioeconomic status is diminishing for people with heart failure. A study by Hawkins et al, using a primary care dataset found that outcomes of patients with heart failure were

similar regardless of socioeconomic status. In particular, the use of evidence based medicines known to improve prognosis in patients with heart failure was equitable across socioeconomic groups.[172] Further research is required to explore the relationship between the socioeconomic status and prognosis of patients with heart failure in more detail.

### 6.6.3 Implications for Practice and Further Research

From our findings in Chapter 2, a moderately sized GP practice with, for example, 5,000 patients over the age of 45 will have around 10 patients receiving a new heart failure diagnosis per year. From the results presented in this chapter, at least two of these patients are likely to die within a year, half will still be alive at 5 years but perhaps only two of these patients will still be alive at 10 years. This information is important for practising GPs if patients want to discuss their outlook following a diagnosis of heart failure.

The overall one, five and ten year survival rates for patients with a first diagnostic label of heart failure have not improved over time which differs from the findings in other European and North American populations. More research is needed into the disease trajectory and management of heart failure in order to explain the lack of improvement in survival over time found in this study despite the availability of evidence-based therapies shown to improve outcomes in clinical trials.

The results of this study are estimates at a population level but discussions with the individual patient require tailored statistics and information in a form that they can

understand. Prognostic estimates will vary depending on age and sex but also other co-morbidities, treatments and variables such as blood pressure and ejection fraction. An analysis by Pocock et al pooled 30 prognostic studies to derive a survival risk calculator which is available online at www.heartfailurerisk.org and calculates predicted one and three year survival.[173] [174] Prognostic modelling to include other variables from the THIN database to more accurately predict survival for individual patients is an area where further research is planned.

## 6.7 Summary of the Chapter

This chapter presented a study examining survival of 55,248 patients with heart failure in a general practice population. One, five and ten years survival rates were presented along with survival rates by year which do not appear to have improved over time. The reasons for this are not clear and require further research to explore trends and identify strategies which can improve outlook for heart failure patients following diagnosis. More individualised prognostic risk scoring is also an area for further work.

# 7. THE ROLE OF SCREENING FOR HEART FAILURE IN THE COMMUNITY

## 7.1 Chapter Overview

This chapter explores the role of screening in identifying patients with heart failure. In Chapters 3 to 5, interviews with participants revealed that they did not seek help for some time following symptom onset only when symptoms were severe enough to significantly affect their daily activities did participants seek medical help. In Chapter 6, a survival analysis of over 55,000 patients with heart failure found prognosis had not improved over time. Strategies to identify and treat patients earlier in their disease process may be a method to improve outcomes. The effectiveness of screening patients for heart failure remains uncertain, but theoretically has the potential to identify those patients who do not present to medical services prior to the onset of severe symptoms.

The Echocardiographic Heart of England Screening Extension (ECHOES-X) study was a longitudinal cohort study to examine progression to heart failure in a screened population. This chapter describes the background and aims of the study, detailed methods and results and a discussion of the findings in the wider context of heart failure screening. The results of this study have been published (Taylor et al, BMJ Open 2014) and my contribution to this work is detailed in Appendix 9.1.

## 7.2 Abstract

**Background and Aims:** Heart failure is a clinical syndrome which develops over time as a result of deterioration in cardiac function. The aim of the Echocardiographic Heart of England Screening Extension (ECHOES-X) study was to determine progression to heart failure in a screened community population.

**Methods:** Observational longitudinal cohort study to re-screen a large community population to assess progression to heart failure over time and the role of natriuretic peptide testing in screening. The setting was 16 socioeconomically diverse practices in central England. Participants from the original Echocardiographic Heart of England Screening (ECHOES) study were invited to attend for re-screening. Outcome was prevalence of heart failure at re-screening (overall and for each original ECHOES subgroup) and test performance of N-Terminal pro-B type natriuretic peptide (NT-proBNP) levels at different thresholds for screening.

**Results:** 1618 of 3408 participants underwent screening which represented 47% of survivors and 26% of the original ECHOES cohort. A total of 176 (11%, 95% CI 9.4% to 12.5%) participants were classified as having heart failure at re-screening; 103 had heart failure with reduced ejection fraction (HFREF) and 73 had heart failure with preserved ejection fraction (HFPEF). 68 out of 1232 (5.5%, 95% CI 4.3% to 6.9%) participants who were recruited from the general population over the age of 45 did not have heart failure in the original study, but had developed heart failure on re-screening. An NT-proBNP cut-off of 400pg/ml had sensitivity of 79.5% (95% CI 72.4% to 85.5%) and specificity of 87% (95% CI 85.1% to 88.8%) for the diagnosis of heart failure.

**Conclusions:** Re-screening identified new cases of both HFREF and HFPEF. Progression to heart failure poses a significant threat over time. The natriuretic peptide cut-off level for ruling out heart failure must be low enough to ensure that cases are not missed at screening.

## 7.3 Background and Aims

Chronic heart failure is a clinical syndrome which occurs following significant pathological insult to the heart over a period of time and is associated with poor outcomes for patients.[79] Symptoms are often insidious in onset and overlap with other conditions meaning diagnosis can be difficult.[21] Epidemiological studies have focused on the point prevalence of heart failure, which is around 1 - 1.5% in the general population rising with age to 10% in those over 75 years in some studies[17], and in particular on the development of heart failure following myocardial infarction[8], yet the progression to heart failure in the general population over time is less well understood. Natriuretic peptides can be used both in the diagnosis of heart failure and in determining disease trajectory although debate about diagnostic and prognostic threshold levels remains.[175 176]

The Echocardiographic Heart of England Screening (ECHOES) study was one of the largest and most well-phenotyped community cohorts for heart failure in the world and identified an overall prevalence of 2.3% in participants over the age of 45 in the general population. The ECHOES-X study started 10 years after the ECHOES study completed and aimed to re-screen participants still alive and contactable from the original cohort.

**7.3.1 The Original ECHOES Study**

The original ECHOES study screened 6162 participants from 16 general practices in central England between March 1995 and February 1999.[18] A full clinical assessment, combined with echocardiography and electrocardiogram, was used to determine the presence of heart failure or left ventricular systolic dysfunction (LVSD), defined as an ejection fraction less than 40%. The European Society of Cardiology (ESC) criteria published in 1995, shown in Table 15, were used to determine a diagnosis of heart failure.[29] A subgroup of the study population also had a natriuretic peptide level recorded.

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1. Symptoms of heart failure (at rest or during exercise)

   and

2. Objective evidence of cardiac dysfunction (at rest)

   and

3. Response to treatment directed towards heart failure (in cases where the diagnosis is in doubt)

   *Criteria 1 and 2 should be fulfilled in all cases*

---

Table 15: European Society of Cardiology criteria for diagnosis of heart failure 1995

The ECHOES study comprised four subgroups; general population over age 45, participants with risk factors (hypertension, history of myocardial infarction, angina and diabetes), participants with a prior diagnosis of heart failure, and a group prescribed diuretics. The

results of the ECHOES study provided a contemporary estimate of the prevalence of heart failure in these four groups as shown in Table 16.[18]

| Original ECHOES subgroup | No. in group | Heart Failure (%) | LVSD (%) |
|---|---|---|---|
| General population >age 45 | 3960 | 92 (2.3%) | 72 (1.8%) |
| Risk factors (hypertension, history of myocardial infarction, angina, diabetes) | 1062 | 86 (8.1%) | 87 (8.2%) |
| Prior diagnosis of heart failure | 782 | 256 (32.7%) | 174 (22.3%) |
| Prescribed diuretics | 928 | 123 (13.3%) | 81 (8.7%) |
| Total | 6162 | 449 | 328 |

Table 16: Prevalence of heart failure and LVSD in the original ECHOES cohort by subgroup[18]

## 7.3.2 The ECHOES-X Study

The ECHOES-X study aimed to follow up the ECHOES cohort to determine the rate of progression to heart failure or LVSD, calculate an estimate of incidence of heart failure and LVSD and determine the fate of those with heart failure or LVSD from the original cohort. The aim was also to examine the role of NP testing in screening for heart failure and LVSD in a community population. The study started in 2008 and received funding from the National Institute for Health Research School of Primary Care, the NHS Research and Development Support for Science and Roche Diagnostics. Full ethical approval was gained from the South Birmingham Research Ethics Committee.

## 7.4 Methods in the ECHOES-X Study

### 7.4.1 ECHOES-X Study Population

All participants involved in the original ECHOES study had their medical record 'flagged' to enable the Office for National Statistics to report all deaths to the study team. 2754 participants of the original ECHOES study had died prior to recruitment to the ECHOES-X study. All 3408 surviving participants were eligible to take part in the ECHOES-X study. The 16 practices included in the original ECHOES study were all invited, and agreed, to take part in the follow-up study.

### 7.4.2 Screening Assessment

All participants underwent clinical assessment by a general practitioner with an interest in cardiovascular disease, or a trained research nurse. ECG and echocardiography was carried out and reported by an echocardiographer accredited by the British Society of Echocardiography (BSE). In addition, participants had blood tested for natriuretic peptide using a near patient testing device (NT-proBNP point of care system, Roche Diagnostics, UK). All participants were also invited to complete a quality of life questionnaire. Data collection was carried out between October 2008 and June 2011.

### 7.4.3 European Heart Failure Diagnostic Criteria

The ECHOES-X protocol was written in 2007-8, however the diagnostic criteria for heart failure, according to the ESC, changed twice between the study start date and final

reporting. In 2008, the ESC guideline on chronic heart failure suggested that the presence of symptoms, signs and objective evidence were all required at assessment to confirm a diagnosis of heart failure as shown in Table 2 in Chapter 1. However in the revised 2012 ESC chronic heart failure management guideline, the society recognised that signs may not always be present, and that two distinct diagnostic categories of heart failure are now in use as shown in Table 17.[7] In light of this revised position, the data analysis plan needed to be re-written to ensure that the latest definition of heart failure was used.

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The diagnosis of HF-REF requires three conditions to be satisfied:

1. Symptoms typical of heart failure

2. Signs typical of heart failure*

3. Reduced left ventricular ejection fraction

The diagnosis of HF-PEF requires four conditions to be satisfied:

1. Symptoms typical of heart failure

2. Signs typical of heart failure*

3. Normal or only mildly reduced left ventricular ejection fraction and left ventricle not dilated

4. Relevant structural heart disease (left ventricular hypertrophy/left atrial

enlargement) and/or diastolic dysfunction.

*Signs may not be present in the early stages of heart failure (especially in HF-PEF) and in patients treated with diuretics.

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Table 17: European Society of Cardiology guideline 2012: Diagnosis of heart failure

Heart failure with reduced ejection fraction (HFREF) has been the most prevalent and well-researched type of heart failure to date. Traditionally a normal ejection fraction was

associated with a presumption that cardiac function was adequate and many of the early heart failure treatment studies only recruited patients with a reduced ejection fraction.[92] However in recent years, heart failure with preserved ejection fraction (HFPEF) has emerged as an important diagnostic concept and now may account for up to half of all heart failure cases.[177] It appears to be pathologically distinct from HFREF and is associated with left ventricular stiffness and reduced diastolic filling but an overall preserved ejection fraction.[12] The treatments known to be beneficial in HFREF have largely failed to improve outcome for patients with HFPEF in studies to date.[32]

The original ECHOES study required a reduced ejection fraction, or other structural or functional abnormality such as valve disease or arrhythmia, for a diagnosis of heart failure. Participants with heart failure due to atrial fibrillation (AF) may have partly captured the HFPEF group but it is likely that the original ECHOES study under-reported the incidence of heart failure overall according to the definitions in use today.[18]

### 7.4.4 ECHOES-X Heart Failure Diagnostic Criteria

Given the changes to the European definitions for heart failure, the diagnostic criteria for the ECHOES-X study were reviewed and revised. Proposals were circulated to the clinicians and the BSE accredited echocardiographer on the study team for agreement. The final criteria for objective evidence, and corresponding type of heart failure, are shown in Table 18.

| Abnormality | Criteria | Type of Heart Failure |
|---|---|---|
| Left ventricular systolic dysfunction | Ejection fraction 40% or below | **HFREF** |
| Borderline left ventricular systolic dysfunction | Ejection fraction 41-50% | **HFREF** |
| Diastolic dysfunction | Diastolic dysfunction defined as E:E' >13 or E:E' 8 to13 with LV hypertrophy (IVS >1.2cm) or LA enlargement (>4cm (males); >3.8cm (females)). | **HFPEF** |
| Significant valvular disease | Moderate to severe (grade 2-3) | **HFPEF** |
| Atrial fibrillation | Diagnosed on ECG | **HFPEF** |

LA=left atrium, IVS=interventricular septum, ECG=electrocardiogram

Table 18: ECHOES-X criteria for objective evidence of heart failure

All data from the clinical record form were input to the study database. An algorithm was designed which allowed the database to be interrogated to classify participants with heart failure to be consistent with the ESC definition 2012. In the algorithm, the presence of symptoms was vital for a diagnosis of heart failure, absence of signs did not exclude a diagnosis of heart failure and one or more objective evidence from the agreed list was required. Of note, we did not include the natriuretic peptide (NP) level in the diagnostic algorithm to allow subsequent calculation of sensitivity and specificity of NP testing. The algorithm is shown in Table 19.

**ECHOES-X Criteria:**

**Symptoms = Shortness of breath alone or with tiredness and/or ankle swelling**

Shortness of breath: 'Do you get short of breath when you walk?' or 'Do you get shortness of breath'.

AND/OR

Tiredness: 'Do you get tired easily'

AND/OR

Ankle swelling: 'Do your ankles/feet swell'


**Signs = May be no signs if early or treated HF as per ESC definition 2012 so removed from search criteria.**


**Objective evidence:**

| Abnormality | Criteria |
|---|---|
| Left ventricular systolic dysfunction | Ejection fraction 40% or below |
| Borderline left ventricular systolic dysfunction | Ejection fraction 41-50% |
| Diastolic dysfunction | Diastolic dysfunction defined as E:E' >13 or E:E' 8 to13 with LV hypertrophy (IVS >1.2cm) or LA enlargement (>4cm (males); >3.8cm (females)). |
| Significant valvular disease | Moderate to severe (grade 2-3) |
| Atrial fibrillation | Diagnosed on ECG |

NT-proBNP not included in diagnosis at this stage to allow for calculation of PPV and NPV

Table 19: Diagnostic algorithm to classify ECHOES-X participants

### 7.4.5 ECHOES-X Consensus Panel

The consensus panel comprised three clinicians: Dr Russell Davis (a Consultant Cardiologist and previous research fellow on the original ECHOES study), Professor Richard Hobbs (a General Practitioner and Professor with a research interest in heart failure) and I. Three meetings took place between December 2012 and February 2013. The panel reviewed the clinical notes and echocardiograms or reports of the following groups:

- Symptoms and no echo abnormality but objective evidence based on abnormal ECG.

- Symptoms, ejection fraction >50% and report of subjective left ventricular impairment recorded by echocardiographer, diastolic dysfunction or significant valve disease.

- All cases with a recorded ejection fraction of 50% but subjective record of left ventricular impairment by echocardiographer.

A total of 210 participant notes were reviewed. The result of the consensus panel was agreed to supersede the diagnosis assigned by the algorithm if this was different. The panel agreed that HFREF was given as a primary diagnosis in cases where ejection fraction was less than 50% in the presence of diastolic dysfunction, valve disease or AF.

### 7.4.6 Final Classification of Heart Failure Diagnosis

Following this process, a summary table was generated to allow analysis. The key headings are shown in Table 20. Each participant was assigned a case definition (heart failure or not heart failure). For each case, the type and cause of heart failure was recorded. Objective abnormalities and NT-proBNP levels were recorded for both groups.

| Pt ID | HF (yes/no) | Type (HFREF/ HFPEF) | Objective abnormality | | | | | NT-proBNP |
|---|---|---|---|---|---|---|---|---|
| | | | LVSD | Border-line LVSD | Diast dysfunc | Valve dis | AF | |
| | | | | | | | | |

Table 20: ECHOES-X classification summary table headings

### 7.4.7 Analysis Plan and Statistical Methods

There were several ways to analyse and present the data in order to answer the original research questions. The two ECHOES studies are similar in format and both had recruitment and diagnostic groups which made the analysis complex. It was important to draw out clinically relevant data and present the results in a useful, understandable way which would address the main research questions.

The overall prevalence rate of heart failure, subdivided into HFREF and HFPEF, was calculated for the ECHOES-X cohort. Prevalence of objective abnormalities for participants with and without heart failure was also calculated. The prevalence of heart failure by original diagnostic group was also determined. The general population subgroup was considered alone to determine the progress to new heart failure at re-screening. Finally, the median values of NT-proBNP were calculated for participants with and without heart failure, and performance characteristics for diagnosing heart failure, including sensitivity, specificity, positive and negative predictive values, were calculated for NT-proBNP thresholds of 150

and 400pg/ml. No data were available for those who did not attend for re-screening. Confidence intervals were calculated using the binomial exact method. Statistical analyses were undertaken using SAS V.9.2 and Stata V.10 and 12.

## 7.5 Results of the ECHOES-X Study

1618 of 3408 participants who were still alive at the start of the study underwent screening which represented 47% of survivors and 26% of the original ECHOES cohort. Figure 13 provides a summary showing flow and numbers of participants in the ECHOES and ECHOES-X studies.

The baseline characteristics of the ECHOES and ECHOES-X cohort are given in Table 21. Average age was 64 years in ECHOES and 71 years in ECHOES-X with an equal gender mix in both studies. The mean time between screenings was 13.4 years (SD 1.3, range 10.2-15.5 years).

The numbers of participants who were re-screened, did not respond or had died are shown in Table 22, grouped according to their original ECHOES recruitment subgroup. 80% of those in the 'previous label of heart failure' group in the original study had died. Those in the 'on diuretics' group also had a higher proportion of deaths (59%) than the general population group (36%).

**ECHOES STUDY RECRUITMENT GROUP**

| | |
|---|---|
| Gen population >45 yrs | 3960 |
| Previous label of HF | 782 |
| On diuretics | 928 |
| Risk factors | 1062 |
| Total | 6162 |

**ECHOES STUDY DIAGNOSTIC GROUP**

| | |
|---|---|
| No HF, no LVSD | 5604 |
| No HF, LVSD | 109 |
| HF, no LVSD | 230 |
| HF, LVSD | 219 |
| Total | 6162 |

**DIED**

| | |
|---|---|
| No HF, no LVSD | 2296 |
| No HF, LVSD | 80 |
| HF, no LVSD | 194 |
| HF, LVSD | 184 |
| Total | 2754 |

**ATTENDED RESCREENING IN ECHOES-X**

| | |
|---|---|
| No HF, no LVSD | 1579 |
| No HF, LVSD | 13 |
| HF, no LVSD | 13 |
| HF, LVSD | 13 |
| Total | 1618 |

**DID NOT ATTEND RESCREENING**

| | |
|---|---|
| No HF, no LVSD | 1729 |
| No HF, LVSD | 16 |
| HF, no LVSD | 23 |
| HF, LVSD | 22 |
| Total | 1790 |

Figure 13: Summary of participant numbers in ECHOES and ECHOES-X studies

| Characteristic | ECHOES (%) | ECHOES-X (%) |
|---|---|---|
| Age (yrs) | 64 | 71 |
| Gender male | 3083 (50.3%) | 803 (49.7%) |
| Ethnicity<br>White<br>Asian<br>Chinese<br>Black<br>Other<br>Not known | 5972 (96.9%)<br>34 (0.5%)<br>3 (0.1%)<br>126 (2.1%)<br>13 (0.2%)<br>14 (0.2%) | 1579 (97.8%)<br>6(0.5%)<br>1 (0.1%)<br>23 (1.5%)<br>6 (0.4%)<br>1 (<0.1%) |

Table 21: Baseline characteristics of ECHOES and ECHOES-X cohort

| Original ECHOES Cohort | Original sample | No. Re-screened | No. non-responders | No. Died |
|---|---|---|---|---|
| | | (% of original ECHOES cohort) | | |
| General popn age 45+ | 3960 | 1242 (31%) | 1299 (33%) | 1419 (36%) |
| Previous label HF | 782 | 59 (8%) | 97 (12%) | 626 (80%) |
| On Diuretics | 928 | 162 (17%) | 222 (24%) | 544 (59%) |
| High risk | 1062 | 214 (20%) | 297 (28%) | 551 (52%) |
| Total | 6162* | 1618* (26%) | 1790* (29%) | 2754* (44%) |

*some participants are in more than one cohort

Table 22: Number of participants in ECHOES-X by original ECHOES recruitment group

### 7.5.1 Prevalence of Heart Failure in ECHOES-X

A total of 176 (11%) participants from all four original recruitment groups were classified as having heart failure at re-screening; 103 (58.5%) participants had symptoms and an ejection fraction less than 50% and could therefore be classified as HFREF. The remaining 73 (41.4%) participants with heart failure had an ejection fraction above 50% with evidence of diastolic dysfunction, atrial fibrillation or significant valve disease and were classified as HFPEF. 84 of 176 (47.7%) participants with heart failure had more than one objective abnormality. Significant valve disease or atrial fibrillation was present in over 33% of heart failure cases and diastolic dysfunction was found in over 30%. In the general population group alone, there were 73 cases of heart failure out of 1242 participants re-screened giving a prevalence of 5.9% (95% CI 4.6% to 7.3%) in this group.

1442 participants did not have a diagnosis of heart failure according to the ESC definition but a significant number of this group had one or more objective abnormality of cardiac function. 105 (7%) participants had significant valvular disease and 37 (2.6%) participants had an ejection fraction of 41 to 50%, without heart failure. Diastolic dysfunction was present in 30 (2%) participants in the no heart failure group. 62 of 176 (35%) participants in the heart failure group had atrial fibrillation compared to 36 of 1442 (2.5%) in the comparator group without heart failure. Overall the prevalence of atrial fibrillation in the ECHOES-X cohort was 6.0%.

**7.5.2 Outcome of Participants from the Original ECHOES Cohort**

Participants in the original ECHOES study were categorised into 4 diagnostic groups following screening; no heart failure and no LVSD, heart failure and no LVSD, no heart failure and LVSD, and heart failure and LVSD. Table 23 shows the ECHOES-X outcome for each group. 184 of 219 (84%) participants with heart failure and LVSD, 194 of 230 (84%) participants with heart failure and no LVSD and 80 of 109 (73%) participants with no heart failure and LVSD had died. The largest group from the original ECHOES study was participants with no heart failure and no LVSD and of these, 144 of 1579 (9.1%) participants re-screened now had a label of heart failure.

| Original ECHOES diagnostic group | Original sample | Died | HF on re-screen | No HF on re-screen | Non-responders |
|---|---|---|---|---|---|
| No HF + no LVSD | 5604 | 2296 | 144 | 1435 | 1729 |
| HF + no LVSD | 230 | 194 | 12 | 1 | 23 |
| No HF + LVSD | 109 | 80 | 7 | 6 | 16 |
| HF + LVSD | 219 | 184 | 13 | 0 | 22 |
| Total | 6162 | 2754 | 176 | 1442 | 1790 |

Table 23: Outcome for ECHOES cohort by original diagnostic group

**7.5.3 Progression to Heart Failure**

When the original ECHOES study was reported, 5604 participants were assessed and found not to have heart failure or LVSD however ECHOES-X included some participants particularly at high risk of heart failure so to have a true baseline group to calculate heart failure progression, the general population group should be considered alone (Table 24). Data collection for the original ECHOES study took place between 1995 and 1999 and for the ECHOES-X study between 2008 and 2011. On completion of the ECHOES-X study, of the 3834 participants from the general population cohort in the no heart failure, no LVSD group in the original study, 1323 participants had died, 1279 did not respond and 1232 attended for re-screening; of those re-screened, 68 (5.5%, 95% CI 4.3% to 6.9%) were found to have developed heart failure.

| Original ECHOES diagnostic group | Original sample size | Died | HF on re-screen | No HF on re-screen | Non-responders |
|---|---|---|---|---|---|
| No HF + no LVSD | 3834 | 1323 | 68 | 1164 | 1279 |
| HF + no LVSD | 54 | 43 | 2 | 1 | 8 |
| No HF + LVSD | 34 | 19 | 2 | 4 | 9 |
| HF + LVSD | 38 | 34 | 1 | 0 | 3 |
| Total | 3960 | 1419 | 73 | 1169 | 1299 |

Table 24: Outcome for general population ECHOES cohort by original diagnostic group

A breakdown of progression to heart failure (including cause) according to original ECHOES recruitment subgroup is shown in Table 25. Of those recruited to the original study from the general population over the age of 45, 73 of 1242 (5.9%, 95% CI 4.6% to 7.3%) re-screened participants had a diagnosis of heart failure in ECHOES-X. Forty seven of 214 (22%, 85% CI 16.6% to 28.1%) participants with risk factors at the time of the original study (hypertension, diabetes, angina or history of myocardial infarction) had heart failure at re-screening. Heart failure was more common still in patients on diuretics or with a previous label of heart failure.

| Original ECHOES Cohort | Original sample | No. re-screened | Heart failure (% of re-screened group) | | |
|---|---|---|---|---|---|
| | | | HFREF | HFPEF | Total |
| Gen pop age 45+ | 3960 | 1242 | 39 (3.1%) | 34 (2.7%) | 73 (5.9%) |
| Previous label HF | 782 | 59 | 24 (40.7%) | 11 (18.6%) | 35 (59.3%) |
| On diuretics | 928 | 162 | 24 (14.8%) | 17 (10.5%) | 41 (25.3%) |
| Risk factors | 1062 | 214 | 28 (13.1%) | 19 (8.9%) | 47 (22.0%) |
| Total | 6162 | 1618 | 103 (6.4%) | 73 (4.5%) | 176 (10.9%) |

Percentages are proportion of total number in subgroup

Table 25: Progression to heart failure according to original ECHOES recruitment subgroup

**7.5.4 NT-proBNP levels in those with heart failure**

All participants in ECHOES-X were invited to have a blood test to assess NT-proBNP. Two attempts were made to take blood in those who provided consent. NT-proBNP level was available for 1511 (93%) participants. The median NT-proBNP level was 772pg/ml (IQR 454pg/ml to 1338pg/ml) in those with heart failure and 135pg/ml (IQR 72pg/ml to 255pg/ml) in those without heart failure.

The receiver operator characteristic (ROC) curve for NT-proBNP is shown in Figure 14. The area under the ROC curve was 0.90.
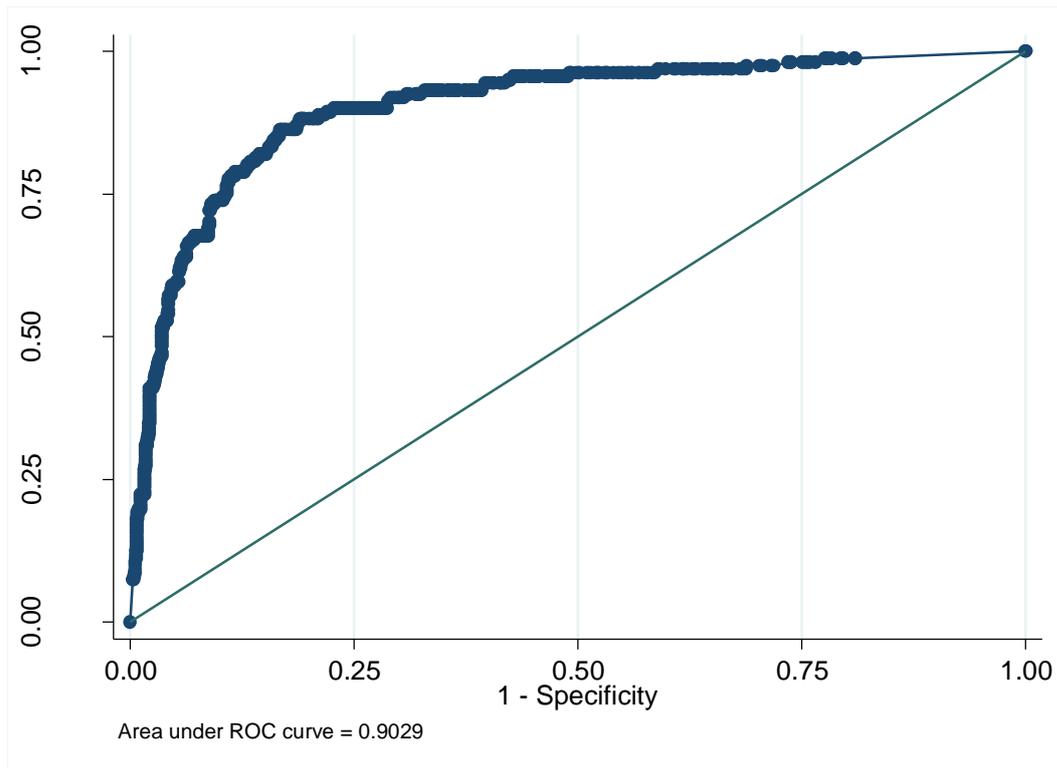
Figure 14: Receiver operating characteristics curve to show effectiveness of NT-proBNP in predicting a diagnosis of heart failure at screening

Thirty three of 176 (18.8%) participants with heart failure had an NT-proBNP level less than 400pg/ml, the current threshold suggested by the National Institute for Health and Care Excellence (NICE) in England for ruling out a diagnosis of heart failure. A cut-off of 400pg/ml had sensitivity for the diagnosis of heart failure of 79.5% (95% CI 72.4% to 85.5%), specificity of 87% (95% CI 85.1% to 88.8%), positive predictive value of 42.2% (95% CI 36.6% to 48.0%) and negative predictive value of 97.3% (95% CI 96.2% to 98.1%). A lower cut off of NT-proBNP less than 150pg/ml had a sensitivity of 95.7% (95% CI 91.2% to 98.2%), specificity of 54.4% (95% CI 51.7% to 57.1%), positive predictive value of 20% (95% CI 17.2% to 23.0%) and negative predictive value of 99.1% (95% CI 98.1% to 99.6%).

## 7.6 Discussion of the ECHOES-X Study Findings

Most patients with heart failure and/or LVSD in the original ECHOES cohort had died in the decade before re-screening commenced. At re-screening, those with cardiovascular risk factors in the original cohort were more likely to have heart failure on re-screening than those from the general population group. HFPEF was not recorded at the time of the original ECHOES study but accounted for 47% of heart failure cases in the ECHOES-X cohort. This would be expected to have been partially captured in the heart failure, no LVSD group of ECHOES. Multiple objective abnormalities were found in patients with heart failure in ECHOES-X suggesting a complex and multifactorial disease. NT-proBNP levels were generally higher in patients with heart failure yet almost 20% had levels below a 400pg/ml cut-off for heart failure, suggesting that this cut-off may be inappropriate for screening in a community setting.

### 7.6.1 Strengths and Limitations

The ECHOES study provided one of the largest community heart failure screening cohorts in the world. The ECHOES-X study followed up those still alive with a comprehensive clinical assessment to establish or rule out a diagnosis of heart failure of the time of re-screening. Progression to heart failure according to baseline group and the prevalence of HFREF vs HFPEF within the cohort are important epidemiological findings which advance our understanding of heart failure in community populations. The presence of multiple echocardiographic abnormalities and the performance of natriuretic peptide testing are important considerations for future studies screening for heart failure in the community.

Diagnosis was determined according to the latest guidance from the European Society of Cardiology which was agreed by a large expert panel of specialists in the field.[7] However, the definition requires symptoms to be present for a diagnosis of heart failure to be made yet patients on known effective treatments such as angiotensin converting enzyme inhibitors, beta-blockers or diuretics may have been rendered asymptomatic by therapy. The estimate of heart failure prevalence is therefore likely to be a conservative one in both the ECHOES and ECHOES-X studies.

The ECHOES and ECHOES-X studies were carried out a decade apart during which time there are likely to have been incident cases of heart failure who subsequently died or did not attend for re-screening. These results therefore give an estimate only for those who survived and attended for re-screening. Screening in itself requires high attendance rates to confer benefit and this is a consideration for any future screening programme.

A range of ethnic groups and social classes were represented in the ECHOES cohort to ensure that the study was generalisable to community populations in Europe.[18] The proportion of White participants in ECHOES-X was greater than the UK average and Black participants were under-represented; however the E-ECHOES study, which specifically included South Asian and Black participants, found that rates of heart failure were similar to that in the White population.[178]

The original ECHOES study required a reduced ejection fraction, or other structural or functional abnormality such as valve disease or arrhythmia, for a diagnosis of heart failure to be made and did not attempt to phenotype HFPEF.[177] Including participants with heart failure due to AF may have partly captured the HFPEF group but it is likely that the original ECHOES study under-reported the prevalence of heart failure overall according to today's definitions. Echocardiography technology has also improved significantly since the original study, for example tissue Doppler, which is used to diagnose diastolic dysfunction, was not available in 1995 when the original ECHOES study began.

### 7.6.2 Comparison with Existing Literature

Several registries document the characteristics of patients admitted to hospital with heart failure[179] and community-based studies, such as the Framingham and Olmsted County studies in the US or the Rotterdam study in the Netherlands, have followed up patients over a number of decades to describe the epidemiology of cardiovascular diseases, including heart failure.[1] [34] [180] However, the ECHOES-X study represents the first follow-up study of a large UK cohort previously screened for heart failure. In particular, patients selected from the general population and found not to have heart failure a decade ago were re-screened to ascertain how many had developed the disease.

At the time of the original ECHOES study, HFPEF was not identified as a separate diagnostic category[12] but the follow-up study used the latest echocardiographic definition to identify

participants with HFPEF. In ECHOES-X, 73 of 176 (41%) participants found to have heart failure were classified as HFPEF. Pooled estimates from international community-based studies found an average HFPEF prevalence of 54% (range 40-71%) amongst those with heart failure.[181] The presence of multiple echocardiographic abnormalities was also found in ECHOES-X and in previous screening studies has been shown to be associated with a significant increase in all-cause mortality.[35]

Both HFREF and HFPEF were found to be more common in participants with cardiovascular risk factors at baseline, compared to the general population, which is consistent with recent findings from Framingham.[4] However, the onset of heart failure timing in Framingham was determined according to outpatient and hospital records. In ECHOES-X, patients were fully screened, including echocardiography and NT-proBNP testing, to actively seek out new heart failure cases. The ECHOES-X results therefore represent findings from an actively screened community population.

### 7.6.3 Implications for Practice and Further Research

Screening identified a significant number of patients with previously undiagnosed heart failure in a population age 55 and over and therefore may provide a window of opportunity to intervene early and prevent heart failure progression, ultimately improving quality of life and survival. Screening of high-risk groups, in whom the prevalence of heart failure is highest, would seem the most effective strategy. Indeed data from the high-risk groups in

the original ECHOES study helped inform the UK Cardiovascular Disease National Service Framework[182] and other guidelines[183] recommending that echocardiography be undertaken in all patients following myocardial infarction; how frequently these patients should be re-screened remains unknown.

Other structural and functional abnormalities can also be discovered in asymptomatic patients which may provide further opportunities to provide timely treatment. For example, operating on patients with significant valvular disease who are well at the time of surgery substantially reduces their perioperative risk.[184] Further investigation into the clinical and cost-effectiveness of optimal intervention for LVSD is also warranted. The level of natriuretic peptide currently used to rule out heart failure may be too high for a screened population. Nearly 20% of participants in the heart failure group had an NT-proBNP level less than the current threshold used in national guidelines.[26]

Prospective studies are required to formally assess the value of screening - in particular to assess if and when patients with heart failure may benefit from earlier diagnosis and intervention. Patients at high risk of developing heart failure, such as those with a history of myocardial infarction, may benefit most from a targeted screening programme.

## 7.7 Summary of the Chapter

This chapter presented the findings of the ECHOES-X study which re-screened patients from the original ECHOES cohort. Progression to heart failure was more common in high-risk

groups but even in the general population was significant over time and screening provided an opportunity to identify new cases. The results of the natriuretic peptide sub-study showed that the cut-off level for ruling out heart failure must be low enough to ensure that a significant number of cases are not missed in a screened population.

# 8. DISCUSSION

## 8.1 Chapter Overview

This chapter gives a summary of the key findings in this thesis. The strengths and limitations of the methodologies used are considered then the implications for practice, key recommendations and areas for further research are considered.

## 8.2 Summary of Key Results

Heart failure is an important disease associated with troublesome symptoms and reduced life expectancy for patients and high costs for healthcare systems.[1,3] This thesis examined the clinical pathway for patients diagnosed with heart failure in primary care as illustrated in Figure 1. In Chapter 2, trends in the incidence of heart failure in the community were explored using records from a large general practice database. In Chapters 3-5, the patient experience from the development of symptoms to receiving a diagnosis of heart failure was considered and in Chapter 6, the survival rates of patients following a diagnosis of heart failure were determined from the same dataset. Finally in Chapter 7, the role of screening a community population to identify patients with heart failure was explored.

In Chapter 2, The Health Improvement Network (THIN) database was used to examine patterns of a first diagnostic label of heart failure within general practice records. Overall,

incidence of heart failure increased with age and was more common in men than women. The incidence of a first diagnostic label of heart failure fell from 5.36 (95%CI 5.17 to 5.55) per 1,000 person-years in year 2000 to 2.41 (95%CI 2.33 to 2.49) per 1,000 person-years in 2007 and remained around 2.3 per 1,000 person-years until 2012. A moderate sized practice with, for example, 5,000 patients over the age of 45 years could therefore expect 10-12 new cases of heart failure per year.

The qualitative interview study in Chapters 3-5 explored the patient experience of the diagnostic pathway. Patients with heart failure were asked to describe key points in their journey from the time they first noticed symptoms to when they received a formal diagnosis. Analysis using the Framework Method found that three key themes emerged: Heart Failure Onset, Interactions with Healthcare and Heart Failure Diagnosis - Delivery and Impact.

In the Heart Failure Onset theme, participants experienced shortness of breath, ankle swelling and fatigue but initially 'normalised' their symptoms by putting them down to ageing, other co-morbidities, lack of physical fitness or a side effect of medications. Participants only sought medical help once their symptoms affected activities of daily living.

In the Interactions with Healthcare theme, participants entered the healthcare system through primary care and were referred for further testing in secondary care. Patients valued the longitudinal relationship they had with their GP and practice and GPs were

usually quick to consider a diagnosis of heart failure, although not in all cases; two participants had a 'delayed' diagnosis where treatment for a different condition was initiated but failed to improve symptoms. Most participants in the study who could recall the sequence of consultations in detail were usually referred by their third or fourth GP appointment. Some participants described interactions with healthcare professionals in secondary care as impersonal or rushed. Logistical frustrations such as GP access and hospital waiting times for procedures added to patient burden.

Finally, the Heart Failure Diagnosis - Delivery and Impact theme highlighted that the term 'heart failure' was unhelpful for participants as they found it confusing. The impact of a heart failure diagnosis depended on the presence of other conditions, which may have caused more debilitating symptoms than the heart failure itself. Patient adaptability - ability and willingness to adapt to new circumstances – was important in determining the impact that the diagnosis had on patients' lives.

The findings of this qualitative interview study on the diagnostic pathway for heart failure highlighted areas where the patient experience could be improved. Greater public awareness of heart failure symptoms, improved access to primary care, a generalist patient-centred approach in secondary care and adequate explanation of 'heart failure' as a term are potential areas of service improvement.

THIN was used again in Chapter 6 to determine the survival rates in patients following a first diagnostic label of heart failure. The study found overall survival rates for cases with heart failure were 81.5%, 51.6% and 29.5% at one, five and ten years, respectively although survival changed little between 2000 and 2012. Confirmed evidence of heart failure was associated with improved survival.

In Chapter 7, the results of the ECHOES-X study, which re-screened the participants of the original ECHOES study, were reported. 1618 of 3408 participants underwent screening which represented 47% of survivors and 26% of the original ECHOES cohort. A total of 176 (11%, 95% CI 9.4% to 12.5%) participants were classified as having heart failure at re-screening; 103 (58.5%) had heart failure with reduced ejection fraction (HFREF) and 73 (41.5%) had heart failure with preserved ejection fraction (HFPEF). 68 of 1232 (5.5%, 95% CI 4.3% to 6.9%) participants who had been recruited from the general population over the age of 45 and did not have heart failure in the original study, were found to have developed heart failure on re-screening. An NT-proBNP cut-off of 400pg/ml had sensitivity of 79.5% (95% CI 72.4% to 85.5%) and specificity of 87% (95% CI 85.1% to 88.8%) for the diagnosis of heart failure, so one in five of those with heart failure would be missed at this threshold. Re-screening provided an opportunity to identify new cases of heart failure and participants with cardiovascular risk factors, particularly a history of myocardial infarction, were most likely to have developed the condition.

## 8.3 Strengths and Limitations of Methodologies

This thesis used both quantitative and qualitative methods to answer the research questions posed at the beginning. The strengths and limitations of these methods were considered in the discussion of each study and are summarised here.

### 8.3.1 The Health Improvement Network – Incidence and Survival Analysis

General practice databases such as THIN provide a large amount of data taken directly from the records of patients presenting to their GP with a wide variety of symptoms.[86] The NHS is free at the point of access and nearly everyone in the population is registered at a general practice allowing a denominator – the number of people in the population – to be generated. The number of patients in the dataset is far greater than prospective studies and, unlike some research cohorts, provides a snapshot of the activity in 'real-life' general practice.[87] The results of the incidence and survival analyses are therefore likely to be generalizable to the community population of the UK.[97]

The main limitation of THIN database is the reliability on accurate clinical coding.[39] Heart failure is a chronic condition which is often insidious in onset and can masquerade as other conditions making early and accurate diagnosis difficult.[21] All records within the database are anonymised so researchers are unable to see individual patient records. The quality of the data therefore depends on the accuracy of the clinical codes input by clinicians, usually GPs, who use the system during routine consultations. Reliability of coding has improved

over time, particularly for some conditions where payment for performance through the Quality and Outcomes Framework (QOF) relies on the use of certain clinical codes to identify work which has an associated financial incentive; a QOF heart failure indicator was introduced in 2006. [90] [90] The observed fall in incidence between 2000 and 2007 may partly reflect more robust clinical coding methods, in addition to any true reduction in new heart failure cases.[98]

The definition of heart failure has also altered over time so a code for heart failure in an individual's medical record may be based on different criteria depending on the accepted definition at the time of diagnosis.[7] [29] [30] In addition, two distinct types of heart failure have recently been recognised: heart failure with reduced ejection fraction (HFREF) and heart failure with preserved ejection fraction (HFPEF).[7] The emergence of this new classification has meant that the clinical picture of heart failure is changing and, from a recent search we undertook for these codes in THIN database, coding in the general practice record has not, until very recently, started to capture this.

The survival analysis did not explore cause of death, or other factors associated with outcome. THIN database does not record death certificate information although this is being introduced. More broadly the cause of death on certificates may not always be accurate.[185] This may be particularly true for heart failure which is associated with symptoms such as breathlessness or fatigue, may be due to a variety of causes and often occurs in patients with multimorbidity.

### 8.3.2 Qualitative Study

The qualitative interview study examined the experience of the diagnostic pathway for 16 patients referred from primary care to a large heart failure clinic at a teaching hospital in central Birmingham. The findings suggest that there are areas at both an individual patient and system level where patient experience and healthcare processes could be improved. As well as improved access to primary care, increased provision of generalist services and improved communication, the study highlighted a need to raise awareness of heart failure symptoms amongst the community population, particularly amongst those most at risk.

The study recruited participants from a single outpatient clinic which may have introduced a selection bias and could limit the generalisability to other heart failure services; however the findings are unlikely to be isolated to patients attending this clinic, particularly the observation that participants normalise their heart failure symptoms until they have an impact on daily life, a phenomenon which has been well described for other chronic conditions.[126] [127] [128] There was also the potential for researcher bias, as a GP conducting the interviews and carrying out analysis myself, although attempts were made to minimise this effect, as described in detail in Chapter 5. The study was carried out according to a detailed protocol and robust analysis using the Framework method and crosschecked by experienced researchers, supporting both the credibility and validity of the findings.

### 8.3.3 Screening for Heart Failure

The ECHOES-X study re-screened those still alive and willing to participate from the original ECHOES study. Participants underwent detailed clinical assessment which ensured a reliable diagnosis of heart failure could be made. The ECHOES cohort represents one of the largest groups of participants screened for heart failure in the world. The epidemiological information from the original ECHOES study, and related work on the five and ten year prognosis of the cohort, has advanced knowledge in the area of heart failure epidemiology in the community population. ECHOES-X provides a further understanding of the progression to heart failure more than a decade after the original study, and also provides a new baseline for further prognostic research.

Prospective research studies rely on volunteers and so may not be as representative of the general population as databases of routinely collected GP records. The interval between the original and follow-up studies also meant that participants could have developed heart failure and subsequently died in the intervening period. The relatively low response rate may have introduced bias and the rates of progression to heart failure may have been different in the non-attenders.

## 8.4 Implications for Practice, Recommendations and Further Research

### 8.4.1 New Heart Failure Cases

The incidence study found that new cases of heart failure are occurring at a consistent rate (2.3 per 1,000 person-years). This figure, stratified for age, sex and ethnicity of the population, could be used by commissioners to predict the likely number of new heart failure cases that will occur in the community they serve in any given year. This has implications for both diagnostic services and also provision of heart failure management including heart failure nurses, general practitioners and other community services.

The reasons why incidence has remained static need further exploration. Is it because more patients survive myocardial infarction but with a damaged heart and subsequently develop heart failure? Or is it that risk factor modification at a population level has been successful in some areas (e.g. reduced smoking rates) but not in others (e.g. rising obesity rates)? A better understanding of the trends in disease pattern could highlight areas where intervention may be best targeted. The effectiveness of any intervention could then be explored through prospective research particularly randomised controlled trials.

It is also important to explore the trends in incidence in other datasets so a similar analysis is planned in Clinical Practice Research Database (CPRD) to see if the number of new cases and pattern over time is similar. International comparison may also be valuable; Australia and

Canada have healthcare systems with a strong primary care base and so opportunities for epidemiological studies in these countries are being explored.

## 8.4.2 Awareness of Heart Failure Symptoms

The qualitative interview study revealed that patients developed plausible and complex explanations for their symptoms which delayed their presentation to primary care. Increased awareness of heart failure symptoms is vital for patients, carers and the public to recognise the condition. Campaigns by government and charities have raised awareness of the symptoms of several different cancers with the hope of earlier diagnosis leading to better outcomes. A similar campaign at a national level, or a more targeted campaign aimed at those with a previous history of myocardial infarction, may help encourage patients with possible heart failure to access healthcare earlier. This would have a large associated cost so further research in this area to consider effectiveness is warranted.

Patients who are at increased risk of heart failure such as those with a history of myocardial infarction, come into contact with the healthcare system frequently. Initially following a cardiac event, patients are invited to attend cardiac rehabilitation programmes. Yet none of the participants in the qualitative study with a history of MI had initially considered heart failure as a possible cause for their symptoms. Education about the symptoms of heart failure may be considered although further research would be required to assess the acceptability and usefulness of this approach. In addition, patients are seen annually by their

GP as part of the QOF coronary artery disease indicator. It should be feasible to include screening questions such as 'Do you get breathless, tired or swollen ankles' and/or arrange a natriuretic peptide test to effectively 'screen' for heart failure in this high-risk group.

### 8.4.3 Improving Patient Experience

Interviews with patients revealed some difficulty in accessing general practice which is a key entry point in the diagnostic pathway. Improved access to general practice through increasing the number of GP appointments would help to allow patients to be seen more easily and quickly. When the patient was able to see the GP, the care was good overall. In a small number of cases, a different diagnosis was considered before heart failure. Availability of point of care testing to measure natriuretic peptide level within the practice may have helped differentiate the cause of symptoms in those patients, although further research is required to assess the cost-effectiveness of this option.

There is a need for a compassionate, patient-centred approach in secondary care. The 'Hellomynameis…' campaign in hospitals is helping to improve communication skills of secondary care staff and help patients feel more at ease by knowing the name of the person responsible for their care.[149] Clinicians should explain key parts of the diagnostic pathway, including what tests are required and why, and patients should have the time and opportunity to ask questions.

The delivery of the diagnosis of heart failure needs to be done in an empathic way. Patients wanted more information about heart failure and often sought this out after being told about their condition. Appropriate written information should be given to all patients following a diagnosis of heart failure. Further opportunities to discuss the diagnosis and its implications and to ask any questions, should be agreed for a future date a short time after the initial diagnosis. Facilitating physical and psychological adaptation following the diagnosis should be an important part of any heart failure management plan; more research is required to establish how to achieve this in the most effective way.

Patients with heart failure are often managing multiple conditions and taking many medications so need generalist (managing the whole person rather than just one system) as well as specialist care. More emphasis on the benefits of generalism and training in generalist skills within secondary care are needed.

### 8.4.4 Outcome of Patients with Heart Failure

The survival rates presented in Chapter 6 provide estimates of prognosis by age and sex at a population level. Discussions with patients about their individual outlook should be done in a sensitive manner, if and when they wish to discuss the issue. More tailored and reliable prognostic information would be useful and this is an area of further research.

The outlook for patients with heart failure at one, five and ten years following diagnosis were better than reported for some hospital populations[169] but survival had not changed for more than a decade. More research is needed to examine this trend in greater detail and a similar analysis in a different UK dataset (CPRD) is planned. Has survival improved in some subgroups but declined in others resulting in no overall change in prognosis? What factors at an individual patient level are most important in determining prognosis? How can interventions at a population and individual patient level improve outlook for patients following a diagnosis of heart failure? International comparison is also planned to establish if this trend in survival rates is seen in other primary care settings, particularly Canada and Australia.

### 8.4.5 Could Screening for Heart Failure be a Solution?

Screening provides an alternative diagnostic pathway to identify patients with heart failure in primary care. The screening study in Chapter 7 identified participants with a new diagnosis of heart failure. Those with risk factors such as previous MI were particularly at risk of subsequently developing heart failure. However this thesis does not recommend screening as a diagnostic strategy and more research is required to evaluate the benefit. Table 4 sets out the criteria required by the UK National Screening Committee before recommending a screening programme and each of the four key criteria are considered below.

Firstly, the condition must be important and well understood, and primary prevention should have been implemented. Heart failure is often the end result of a sustained insult to the heart. Primary prevention of cardiovascular disease is a priority in the NHS but remains suboptimal.[186] Opportunities to modify risk factors associated with the development of heart disease are often missed. More emphasis on identifying and treating conditions which are the precursors to heart failure, such as hypertension and diabetes, could reduce the number of people diagnosed with the condition over time.[187]

Secondly, the screening test needs to be simple, precise and validated. Natriuretic peptide testing is a possible screening test for heart failure although the cut-off values remain controversial. As described in Chapter 7, the threshold level would need to be low enough to ensure cases of heart failure are not missed. In particular, in a screened population the levels of natriuretic peptide may be lower than in patients presenting with symptoms at a potentially more advanced stage of the disease. Further work on optimal cut-off levels in screening is planned.

Thirdly, effective interventions which improve outcomes need to be established for patients identified earlier in the disease process through screening. It is currently unclear if treatment for heart failure at an early, asymptomatic stage improves quality or quantity of life for patients. Further studies to investigate this area are planned.

Finally, the benefits, harms and opportunity cost of any screening programme need to be considered. Screening is expensive and can cause unnecessary psychological burden. More research is required to establish if screening for heart failure leads to improved outcomes for patients. Can an earlier diagnosis of heart failure improve patient outcomes such as quality of life and survival? Would a targeted screening programme, inviting those most at risk such as heart attack survivors, effectively identify patients with heart failure and be a cost-effective option to reduce morbidity, mortality and the high healthcare costs currently associated with the disease? Until all of the questions are addressed, the value of screening for heart failure remains uncertain.

## 8.5 Summary of the Chapter

This chapter summarised the key findings of the thesis, explored the strengths and limitations of the methodologies used and presented key recommendations and areas of further research.

## 8.6 Conclusion of the Thesis

The research questions in this thesis arose from real-life clinical and teaching scenarios in which I realised that there was not a current evidence-base to answer the questions posed by my patients and students. Through the four studies in this thesis, I have provided evidence to answer these questions and identified new areas in which further research is needed. Primary care remains an important part of the clinical pathway for patients with

heart failure and strategies to reduce the number of new cases, enhance patient experience

and improve long-term survival should be important priorities for the NHS in the next five

years.

# 9. APPENDICES

## 9.1 My Contribution

**GP Database Incidence and Survival Studies:** I conceived the idea, gained ethical approval through the Scientific Review Board at THIN, drafted the protocol, generated coding lists, carried out statistical analysis using Stata 10 and 11, interpreted the findings and presented the results at the NIHR School for Primary Care Research Showcase in Oxford, September 2014 as a plenary lecture (abstract ranked joint top).

Dr Ronan Ryan (research fellow) and Linda Nichols (data analyst) extracted the data from THIN and transferred into Stata. Linda Nichols provided statistical support at the early part of the study. Sayeed Haque (statistician) provided statistical advice at the end of the study. Professor Tom Marshall (supervisor) provided comment on data extraction, analysis plan and draft manuscripts throughout.

**Qualitative Interview Study:** I conceived the idea, drafted the protocol, obtained ethical approval through the National Research Ethics Service, conducted all 16 interviews, transcribed the first 4 transcripts, generated the coding framework, coded all transcripts, summarised the data into the analytical framework, developed the analytical memo for each category, identified emerging themes and concepts, reviewed the literature and presented the findings at the Society for Academic Primary Care conference in Oxford, July 2015.

Professor Francisco Leyva-Leon and team facilitated recruitment. Sonal Shah (research fellow) commented on the coding framework. Dr Nicola Gale (qualitative researcher and supervisor) oversaw each stage of data collection and analysis.

**ECHOES-X Study:** I have been part of the ECHOES-X study team since 2008. I carried out the data collection, along with a trained echocardiographer, for the first nine months of the study. I also trained research nurses to complete data collection. I provided clinical input and advice to the team throughout the study. Once data collection was completed, I worked with the study statistician to determine an analysis plan and I was one of three clinicians on the consensus panel to determine the diagnosis where it was equivocal.

The recognised definition of heart failure changed twice during the study so all cases of heart failure needed to be reclassified clinically based on the new criteria at the end of the study. I developed a diagnostic algorithm to allow a diagnosis to be allocated along with a plan for analysis and presented it to the team in 2012 and again, following further refinement, at a team meeting in February 2013. The study statistician calculated the final numbers according to this agreed analysis plan. I presented the final set of results at a team meeting in May 2013. I wrote the first draft of the manuscript and subsequent revisions prior to its publication in BMJ Open.

Professor FD Richard Hobbs was Principal Investigator for the study and Dr Russell Davis provided clinical cardiology expertise. Andrea Roalfe, senior lecturer and statistician for the heart failure team, undertook the statistical analysis using SAS. Dr Lynda Tait was project manager and Mrs Rachel Iles was research fellow.

The work submitted in this thesis has been presented at two national and one international

meeting and published in two peer-reviewed journals to date:

*Conference Abstracts*

- Taylor CJ, Ryan R, Nichols L, Gale G, Hobbs FDR, Marshall T. Incidence and Survival of Patients with a First Diagnostic Label of Heart Failure in General Practice. Plenary Presentation (top scoring abstract), NIHR School for Primary Care Research showcase, University of Oxford, September 2014.

- Hobbs FDR and Taylor CJ. Incidence and survival of patients with a first diagnostic label of heart failure in primary care. North American Primary Care Research Group Annual Meeting, New York, NY, November 2014.

- Taylor CJ. Heart Failure – A Primary Care Problem. Yvonne Carter Outstanding New Researcher Prize Presentation, Society for Academic Primary Care Annual Scientific Meeting, University of Oxford, July 2015.

- Taylor CJ, Hobbs FDR, Marshall T, Leyva-Leon F, Gale N. Patient experience of the clinical pathway for diagnosing heart failure in primary care. Society for Academic Primary Care Annual Scientific Meeting, University of Oxford, July 2015.

*Publications*

- Taylor CJ and Hobbs FDR. Heart failure therapy in patients with coronary artery disease. Curr Opin Pharmacol 2013; 13:205-209.

- Taylor CJ, Roalfe AK, Tait L, Davis RC, Iles R, Derit M, Hobbs FDR. Observational longitudinal cohort study to determine progression to heart failure in a screened community population: the Echocardiographic Heart of England Screening Extension (ECHOES-X) study. BMJ Open 2014; 4:e005256. doi:10.1136/bmjopen-2014-005256

Two further papers on the electronic database work and qualitative interview study are

being prepared:

Taylor CJ, Ryan R, Nichol L, Gale N, Marshall TP*, Hobbs FDR*. Incidence and survival of patients with a first diagnostic label of heart failure in general practice:  a UK retrospective cohort study (*joint senior author)

Taylor CJ, Marshall TP, Hobbs FDR, Leyva-Leon F and Gale N. Patient experience of heart failure diagnosis: a qualitative study.

## 9.2 Patient Information Sheet



**Patient Information Sheet**

**Patient Experiences of Diagnosis of Heart Failure in Primary Care**
**Principal investigator: Dr Clare J Taylor**

You are invited to take part in a study looking into heart failure diagnosis in primary care. This information sheet explains the reasons we are doing the study and what will be involved if you decide to take part. Please read the information in your own time and discuss with friends and family if you want to. Please contact us if you have any queries or would like to be involved. Thank you for taking the time to read this.

**What is the purpose of the study?**
The study is designed to find out about patients experience of seeing their doctor and being diagnosed with heart failure.

**Why have I been chosen?**
You have been invited to take part in the study because you have recently been diagnosed with heart failure.

**Do I have to take part?**
It is your choice whether to take part or not. If you do want to be part of the study, you will be asked to sign a consent form and you will be given a copy of this for your records. A letter will also be sent to your GP to let them know you are in the study. You can withdraw from the study at any time and you do not have to give a reason.

**What will happen to me if I take part?**
The study will involve being interviewed for approximately 1 hour by a training researcher. Interviews will take place in your own home or at an alternative location convenient to you. We will ask you to describe your experiences from when you first noticed symptoms to when you received the diagnosis of heart failure in the clinic. The interview will be recorded on a tape player and then analysed along with recording from interviews with other patients who have the same condition.

**Will my taking part in this study be kept confidential?**
The interview will be confidential and the data we gather will be recorded anonymously. The recordings will be transferred into a written document called a transcript. This will be securely stored at the University of Birmingham according to the university's 'Code of Conduct for Research'. According to this code, transcripts have to be kept securely for 10 years after the study has been reported. We may use some direct quotes in the final report but these will be anonymous so no one will know who said them.

**What will happen to the results of the study?**
The results will be published in a scientific journal which will allow doctors and other medical professionals to understand more about the patient experience of being diagnosed with heart failure.

**Who is organising and funding the study?**
The University of Birmingham is organising the study and it is funded by the National Institute for Health Research.

**What indemnity arrangements are in place?**
The University of Birmingham has an insurance policy which covers research studies.

**How can I get further information?**
Please contact Dr Clare Taylor ▮▮ ▮▮▮▮▮▮▮▮▮ if you would like to find out more about the study or would be willing to take part.

**Thank you for your help**

## 9.3 Consent Form

**UNIVERSITY OF BIRMINGHAM**

**Consent Form**

### Patient Experiences of Diagnosis of Heart Failure in Primary Care

|  | Please initial |
|---|---|
| I confirm that I have read and understood the patient information sheet for this study and have had the opportunity to ask questions. | |
| I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected. | |
| I agree to take part in the study. | |
| I agree to a letter to be sent to my GP to him/her know I am in the study. | |
| I confirm that I am happy to have my interview recorded and transcribed. | |
| I confirm that I give permission to use direct quotations. I understand that any quotations used will be anonymised. | |

Name of Interviewee [please print]_____

Signature _____    Date _____(day)/_____(month)/_____(year)

Name of Researcher [please print]_____

Signature _____    Date _____(day)/_____(month)/_____(year)

Version 1.1 – 7<sup>th</sup> August 2013

## 9.4 Interview Topic Guide

**Patient experiences of the clinical pathway for diagnosis of heart failure in primary care**

**Topic guide**

**Dr Clare J Taylor, GP and Clinical Research Fellow**


**Introduction (5 mins)**
Thank you for taking part in this research.

Introduce self – Clare Taylor doing PhD at University of Birmingham.

Duration – interview will last about an hour. Please let me know at any time if you would like to take a break.

Purpose of study – To get a better understanding of the experiences of patients affected by heart problems.

Confidentiality – As I mentioned before, I will be recording the interview using this tape machine if that's ok with you? All discussions are confidential and data will be safely stored.

Questions – We want to hear about your experience so there are no right answers. Please feel you can be open and tell us what you really think and feel.

**Respondent introduction (10 mins)**
Tell me a bit about yourself:
- Age
- Family
- Social situation

**Research topics (40 mins)**
Tell me about when you first noticed there might be something wrong?
- What symptoms did you experience?
- What did you think might be happening?

Tell me about your thinking around going to see the doctor for the first time.
- Was there anything that prompted you to go?
- Was there anything that stopped you from going?

Tell me what happened after that.
- Did you have any tests?
- Tell me about your symptoms during that time?
- How did you feel during this time?

Tell me about your diagnosis.
- What have you been told about your diagnosis?
- What does that mean to you?
- Is there anything you don't understand?

Are there are part of the process which you feel could be changed or improved?

**Close (5 mins)**
Summarise key topics discussed.
Are there any further questions?
Thank you for taking part.

## 9.5 Analytical Framework

| CODE | DESCRIPTION |
| --- | --- |
| **Patient Factors** | |
| Role of age | Influence of age in treatment decisions, lifestyle, outlook on life. As explanation for symptoms. |
| Retirement | Duration, daily activities, advantages. |
| Occupation | Influence on interpretation of symptoms, understanding of diagnosis. Manual or professional. |
| Social life | Sports, hobbies, going out, enjoyment. |
| Religion | Role in sense-making. Impact on decision-making. |
| Independence | Importance of maintaining independence. Independent thought and decision-making. Autonomy. |
| **Role of Family** | |
| Spouse/partner | Marriage. Co-dependence. Spouse fitness. Spouse illness. Bereavement. |
| Children | Jobs, location, offspring. No children. |
| Relationships | Generations, positive relationships, conflict. |
| Practical help | Support with daily activities, socialising. |
| Geographical location | Role of geography on relationship, help, involvement. |
| Interactions with healthcare professionals | Call ambulance. Speaking to doctor. Hospital appointments. |
| Role in decision-making | Support. Asking questions. Respect patients autonomy. |
| **Time** | |
| Symptom onset | Gradual. Sudden. |
| Delay in seeking medical advice | Reasons for delay. Lack of delay. |
| Progression of symptoms | Got worse. Got better. |
| Recall of events | Clear. Can't remember. Conflicting accounts. |
| Temporal sequence of events | What happened first, how did events link, emergency, planned. |
| Prompt to seek medical advice | Factors which influence help-seeking. Emergency. |
| Waiting | Length of wait. Consequences of wait. Cause of wait. |
| **Symptoms** | |
| Shortness of breath | Breathlessness, on exertion, at rest, in bed (orthopnoea). Onset. |

| | |
|---|---|
| Swollen ankles | When noticed. How often. Action. |
| Chest pain | Dizziness |
| Dizziness | When. Where. Severity. Cause. |
| Pain | Onset, duration, management, cause. |
| Lack of symptoms | Absence of expected symptoms. Symptoms resolved. |
| Patient understanding of symptoms | Put down to age, prior medical knowledge, media influence. |
| Symptom improvement | Following treatment, procedure, with time. |
| **Medical Interactions – logistical** | |
| GP appointments | Number of appts. Ease of obtaining appt. Same/different GP. |
| Telephone consultations | Role of telephone consultation. Acceptability to pt. |
| Home visits | Availability. HCP doing visit. Reason for visits. |
| Delay/prompt action in primary care | Were there delays, if so where and why? Was action prompt. |
| Ambulance | What prompted call. Who called ambulance. Speed of arrival. Role of ambulance crew. |
| Hospital appointments | Number. Where. Difficulties. |
| Hospital stay | Duration. Experience. Discharge. |
| Emergency or elective | Presentation, appropriateness of care. Speed of action. Effect of other emergencies. |
| Delay/prompt action in secondary care | Were there any delays or prompt action in secondary care. What caused delay/facilitated prompt action. Waiting lists. Cancellations. Consequences. |
| GP role in co-ordinating care | Request tests, referral. Expedite hospital appointments. Follow-up care. |
| Patient safety | Role of patient safety within primary and secondary care. Protocols and processes to ensure pt safety. |
| Patient empowerment | Knowledge of services. How to access care. Understanding of system. |
| Healthcare costs | Cost of care received. Amount in private sector. Foreign healthcare system costs. Value of health. |
| **Medical Interactions – decision-making** | |
| Initial GP appointment | When. Action agreed. Explanation. |
| Referral | To whom. When. Problems. |
| GP-patient relationship | Duration, positive, conflict, trust. |
| Primary/secondary care interface | Interaction between GP and specialists. |
| Consultant(s) | Actions – e.g. arrange tests. Explanation. Conflicting advice. Responsibilities. |

| Heart failure nurses | Actions. Role in care. Follow-up. Responsibilities. |
|---|---|
| Other healthcare professionals | Echo tech, nurses, porters. Effect on experience. |
| Shared decision making | Patient involvement in decisions. Patient ability to challenge medical opinion. |
| Alternative treatment options | Second opinion, all options, pros and cons. |
| Resources/rationing | Availability of expertise, beds. Role of waiting times. Equity, fairness. Competing pressures. |
| **Explanation of Symptoms** | |
| Patient explanation of symptoms | Patient's own explanation. Lack of explanation. |
| GP explanation of symptoms | Patient's recall and understanding of GP explanation. |
| Specialist (consultant/HF nurse) explanation of symptoms | Patient's recall and understanding of specialist explanation. |
| **Previous health state** | |
| Premorbid state | Prior to developing symptoms of HF. |
| Primary prevention | Strategies to keep well – done in past or wish had done. |
| Prior health beliefs | Ideas around cause of illness and protective factors. |
| **Multimorbidity/co-morbidities** | |
| Cardiovascular co-morbidities | Heart attack, stroke, arrhythmias. Contribution to heart failure. |
| Arthritis | When. Effect on life. Treatment. |
| Mental Health | Impact of mental health on physical health. Treatments. Quality of life. |
| Other conditions | Number of conditions. Treatment burden. |
| Ageing process | Role of the ageing process in symptoms and diagnosis. Impact of ageing on lifestyle. |
| **Diagnostic Tests** | |
| Electrocardiogram | When, how many, where, purpose of test. |
| Heart scan | When, how many, where, purpose of test. |
| Blood test | When, how many, where, purpose of test. |
| Specialised tests e.g. angiogram | Reason for the test, done by whom. |
| Patient understanding of tests | Reasons for tests, process involved, risks, what hope to find out. |
| **Explanation of Diagnosis (and Causes)** | |
| Patient's own explanation of HF | Patient's own understanding, meaning, theory about cause. |
| GP explanation | Patient's recall and understanding of GP explanation. |

| | |
|---|---|
| Specialist explanation | Patient's recall and understanding of specialist explanation. |
| HF nurse explanation | Patient's recall and understanding of HF nurse explanation. |
| Causation | Cause of heart failure. Relationship to symptoms. |
| Heart failure terminology | Meaning of the term 'heart failure'. Emotional response. Use of the term. |
| **Impact on Life** | |
| Activities of daily living | Limitations, what able to do, aids, support. |
| Physical activities | Limitations, adaptations, support. |
| Socialising | Events, relationships with friends, positives. |
| Driving | Role of driving. Limitations. Safety. |
| Travel | Concerns. Feasibility. Insurance. |
| Patient adaptability | Ability, willingness to adapt to new circumstances/limitations. Capacity to adapt – enablers and barriers. |
| **Treatment** | |
| Purpose of treatment | Why on tablets. What hope to achieve. |
| Initiation | When, by whom, any problems, timely, patient understanding. |
| Monitoring | What involved. Done by whom. Role of patient e.g. self-monitoring. Follow-up. |
| Side effects | What side effects. Explanation. Impact on lifestyle. |
| Polypharmacy | Multiple medications. Interactions. Treatment burden. |
| Delay in treatment | Cause of delay. Consequence of delay, avoidable/unavoidable factors. |
| Patient understanding and knowledge of treatments and side effects | What patient knows about medications. Ability to recognise causal link between medications and their side effects. |
| Cardiac surgery | When, where, duration, operative risks. |
| Cardiological intervention | Stents, angioplasty. Why, when, outcome. |
| Implantable cardiac defibrillator | Why needed, how inserted, what it does. |
| Effect of treatment on symptoms | Improve, worsen, no effect. How soon. |
| Treatment for other co-morbidities | Conflicting treatments, suboptimal treatment due to other conditions. |
| **Current health state** | |
| Wellness | Feeling well. Sense of wellbeing. |
| Age | Expectation for age. Comparison with age cohort. |
| Main limitation | What is main limitation, heart failure or other disease. |

| Psychological adaptation | Acceptance of diagnosis, coping with illness. |
|---|---|
| Uncertainty | Unanswered questions, worries. |
| Research and teaching | Assist in training doctors, medical students. 'Give something back'. |
| **Outlook** | |
| Death | Possibility of death during diagnostic pathway or treatment procedures. |
| Survival rates | Discussion with whom. Patient perception. Want/not want to know. Initiated by whom. |
| Long term planning | Residential care. Palliative care. End of life care. |
| Do Not Attempt Resuscitation (DNAR) | Had discussion? Outcome? |
| **Quality of Care** | |
| Failure in care | Breakdown of care. Failure to manage appropriately. Effect on patient. |
| Good experience | Positive experiences within care – who/what were these down to. |
| Continuity of care | GP, primary/secondary care interface, consultant, HF nurses, discharge. |
| Relationships with healthcare professionals (HCPs) | Patient relationship with GP, consultant, nurses, other HCPs. |
| General practice care | Overall quality of care provided by practice team |
| Hospital care | Overall quality of care provided by hospital |
| Communication skills | All HCPs. Listening, breaking bad news, dealing with conflict, checking understanding. |
| Patient satisfaction | Satisfied, frustrated, happy, recommend to others, dissatisfaction. |
| Complaints | Patients approach to raising concerns/complaint. Enablers and barriers. Reluctance to criticise. |
| Suggestions for change | Areas for improvement, complaints, conflict, unresolved issues. |
| Value of NHS | Importance of NHS in patient's lives. What it means to them. |
| **Patient's Emotions** | |
| Grateful | Gratitude, thankful to people and/or health services. |
| Relief | Sense of relief. Following period of worry. |
| Positive outlook | Feeling of happiness. Optimism about the future. |
| Fear | Scared, frightened, fearful during process or about the future. |

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|---|---|
| Anxiety | Anxious, worry before, during or after diagnosis. |
| Trust | Trust or lack of trust in individuals, healthcare service, spiritual figure. |
| Anger | Angry with medical care, disease process, hospital logistics. |
| Burden and guilt | 'Being a burden'. Feeling of over-reliance and dependence (e.g. on family) leading to feeling of guilt. |

## 9.6 An Example of Charted Data in Framework Matrix

Extract from Explanation of diagnosis (and causes) category

| | Patients own explanation of HF | GP explanation | Specialist explanation | HF nurse explanation | Causation | HF terminology |
|---|---|---|---|---|---|---|
| P1 | "I've got heart failure and [er] me heart is only [er] function, functioning at 20%. All the rest is [er] they say is dead you know soluble…" | | Breaking bad news: "...she was a registrar. She was good, no doubt about it, she knew her job. And [er] [pause] she came out with the [er] not very nice words, you realise you could drop down dead at any time and [er] it shook me to the core, and me wife, and me daughter." | | | |
| P2 | "Well I mean heart failure means, when they heart failure it means your heart's going to, it's wearing out or whatever, it's going to stop. It could stop. It's failing. And I know you've only got one so I mean let's face it that's not a good thing." | | "Well, they told me my heart's not working properly". Need for more detailed specialist explanation: "I've looked up on the computer...so I've I've a pretty good understanding I suppose of what happens but [erm] [pause] I don't know about me and that's | | | "It was worrying I mean you know when they tell you that your hearts not working properly and they call it 'heart failure', whatever's wrong with your heart they call it heart failure don't they which I think is horrible because failure means [laughs] it could stop you know. That's |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | what I want to know about me." Suggestion for more time and explanation as felt rushed: " I think appointments telling you more about your particular problem. I realise their hurry and it seems like they want to get you out because the next person's waiting to come in, I mean but [erm] I don't think age should, should, should be a factor in that. I think they should, you know, give you just as much time and explanation as they do with a young person [pause] but they don't." | | | worrying but [erm] the longer you live with it, the more you get used to it". |
| P3 | Pt seek out own information about diagnosis from textbook. | | "...he said to me that I could have, the heart wasn't pumping the blood, round the body sufficiently and I could have developed a cardiac arrest." Seen for tests at one stop clinic and cardiologist explanation at the end: "he says all this, that [um] me heart wasn't pumping the blood around the body but | | | |

| | | | [pause] that's what causes it." | | | |
|---|---|---|---|---|---|---|
| P4 | Engineer uses background to explain HF: "because [er] having been an engineer, it's a pump system isn't it that's all it is, it's a pump system. You've got the [er] power of the pump, you've got the pipework going round, and the various sizes of the pipework. And if you [er] increase the size of the pipework, the pump will bang it round very easily but if the pipework gets [er] constricted in any way then the pressure will go up. There's an easy hydraulic relationship with that, the viscosity of the blood is the other thing." | GP had provisionally diagnosed cause of swelling. "as my doctor had diagnosed, it was this [er] blood not getting circulated round." "the doctors described what [er] what he thought was going on with respect to the [erm] the swelling up. And really that was the only diagnosis I had 'cause I was satisfied that that was what was going on 'cause I understood the basics with regard to plumbing system shall we say." | Specialist did drawing to show damaged bit of heart at bottom, ", as my doctor had diagnosed, it was this [er] blood not getting circulated round. And it was then that [er] I was given the information that I could be having a development of heart failure. And that was it really they couldn't say what the heart failure was." | | Pt description (engineer): "as any other machine is, being static until it's asked to do something. It can't tell you what bits are are wearing out. They could tell you if you had a valve going or something like that. I know that the bottom end of my heart has been damaged slightly. So there really is not much other other that can be done. But they can't switch the power off and you can see the, your heart there. You only know what the physical effect of it is." | |
| P5 | Not aware has HF. | Only explanation pt has received was from GP: "Nobody mentioned anything about problems with my heart. It was only the one occasion when I was… Before I went to the hospital, I went to | Limited explanation from specialist: "But I've asked since, and they've said, at that particular time, my heart was like, you know, it's a bit iffy." | Not aware has heart failure, HF nurses not explained and reassured: "Of course I asked her that and she said, "We're perfectly happy. Your heart is giving no problems. Your blood is okay, and | | "Have they mentioned the diagnosis of heart failure to you specifically? Respondent: Sorry? Interviewer: Have they mentioned a diagnosis of heart failure to you specifically? |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | my GP and he gave me a good examination and he explained to me about this. I've got the leaflets in there." Use of humour: "So he knows all about it and all that. As a matter of fact, he's got a model of his heart on his desk. I said to him, "Can I have that? It looks a good one." (Laughter)" | | everything is okay." | | Respondent: No." |
| P6 | "I know I've got a weak heart." | | Poor explanation and communication: "I don't know what he was actually. He didn't give a name. He didn't say, "I'm a so and so". All he said was that I've got a weak heart. I said, "What would happen if something... I needed to come in, what treatments?" He said none. There'd be no treatment if I came in. So I thought "Well, what a happy day!" Lacking in feelings of any sorts. They were so impersonal." "Just how impersonal the personnel were when I went in for my heart examination. That could be improved | | No clear cause: "No. I just think I gradually got a weak heart." | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | immensely. It wouldn't have hurt them to have become a little human and thought a little bit about the... just the diagnosis and "There you are. [bump]". There's a better way of dealing with somebody than that. Not difficult to do." | | | |
| P7 | "I was having a job going up and down stairs and I was saying, because I'm not getting enough oxygen in my blood, to have the energy to push myself." | | "from what they tell me, the blood is coming in and the heart, the walls are weak and they're not squeezing it enough for it to go out as quick. So the heart goes into a wobble." | Faith in HF nurses: "They're clever, they are. They know all about it. They've got the little heart there and they explained to me how it all goes through and everything. They've been ever so good. They know what they're doing. They know all about everything." | "I think this is one of the reasons I've, over the years, probably just wore myself out...I'm just like an engine, just blowing up, you know." But also MI as reason: "They did find that my heart was scarred over from the previous heart attack 19 years ago". But overall is unclear on exact cause: "I don't know why I had that first heart attack, because I was fit when I had that. But I think, just like an idiot, I blew it up and went too fast. That's my theory. They never found out. I've got no heart disease of any sort, you see." | Ejection fraction causing confusion and worry: "25%. She worried me for a minute. We both looked at each other, because she said, "Your heart is only working at 25%. That's why you've got classed as serious heart failure." God, I thought, that's not very good, is it? But she said, "It's 25% of…" Basically she said, "It's 50, because the rest of it doesn't really come into it." So that would be what she said, wouldn't it? It's not really just 25% basically, it's 25% of a certain amount, like. It's bad, like, but not so bad as what it sounds." |

## 9.7 Example of Analytical Memo

**MEMO: 'Explanation of diagnosis and cause' category**

**Definition**

This category examines the explanation of HF diagnosis from patients own perspective and what they recall being told by GP and specialists. Also explores causes of HF.

**Codes**

Pt's own explanation of HF; GP explanation; specialist explanation; HF nurse explanation; causation; HF terminology.

**Summary of data**

**Pt own explanation**

Pt explanations were varied in complexity and depth. Some simply described having a 'weak heart' or 'not getting enough oxygen in my blood to have the energy to push myself' while others had a detailed description in their mind.

Pt education and background influenced their understanding and sense-making of the diagnosis. Several pts were engineers by background and thought of it in mechanical terms.

*P4: "…it's a pump system isn't it that's all it is, it's a pump system. You've got the [er] power of the pump, you've got the pipework going round, and the various sizes of the pipework. And if you [er] increase the size of the pipework, the pump will bang it round*

*very easily but if the pipework gets [er] constricted in any way then the pressure will go up. There an easy hydraulic relationship with that…"*

Some pts actively sought extra knowledge about the diagnosis by looking online or in textbooks whilst others preferred to avoid knowing too much.

*P8: "I didn't bother to go too deeply into it, you know knowledge can kill you, the wrong kind of knowledge, or half knowledge"*

One pt still working and finds needs an explanation to tell work colleagues to account for why she gets so tired.

*P13: I just tell them it's a heredity thing, I've got a bit of heart failure and I get more tired than what you do. As I said it's probably being twice as tired and working twice as hard as what they do".*

Fear associated with the term heart failure whilst for others an understanding of the problem in the heart led to a greater awareness of symptoms.

*P2: "Well I mean heart failure means, when they heart failure it means your heart's going to, it's wearing out or whatever, it's going to stop. It could stop. It's failing. And I know you've only got one so I mean let's face it that's not a good thing."*

*P15: "I'd been told that the valves were not operating properly and they told me the result was a reflux and I was… I would often wake up very conscious of this going on in my chest. Knowing what it was I could imagine blood not just going through and then shutting off but coming back again and sort of regurgitating inside the heart."*

**Medical professional explanation**

Secondary care specialists, usually cardiologists, were responsible for giving the diagnosis to most pts. GPs were involved in initial investigation of the problem and referral for a definitive diagnosis but did not explain in detail what HF was etc as diagnosis not confirmed.

Breaking bad news was not handled well in some cases. Lack of ascertainment of what pt knew already, signposting or empathic delivery. Several examples of pts left shocked by mode of delivery as well as diagnosis itself. Need for more time and space to explore and understand problem.

*P2: I think appointments telling you more about your particular problem. I realise their hurry and it seems like they want to get you out because the next person's waiting to come in…*

*P6: "Just how impersonal the personnel were when I went in for my heart examination. That could be improved immensely. It wouldn't have hurt them to have become a little human and thought a little bit about the... just the diagnosis and "There you are. [bump]". There's a better way of dealing with somebody than that. Not difficult to do."*

For others explanation was proportionate and appropriate, delivering the news of HF gradually and initially avoiding use of the term.

*P13: "It was very good, I mean he says, it's just a degree of heart failure. They actually didn't use those words for a long time to me, he just said… he told me it was a left valve that wasn't pumping properly. It should pump at so much percentage and it was pumping at a lesser percentage and that's why you're feeling tired because it's having to work*

*harder. You're working twice as hard as you should be, he says, that's why you feel tired. He explained to me quite well..."*

*P15: "No it was all explained to me very well and I had visions of valves going like this so I got a clear picture of what was going on inside my heart".*

Explanations clear for some 'heart not pumping blood around the body' or similar but for others medical jargon led to lack of understanding although some pts prefer to take stance of not wanting to know too much.

*P9: "They tried, but they used so much jargon, I didn't understand. I didn't want to know too much, anyway. But I saw what was written down and was able to translate that...They say my left ventricle is not working fully. They don't say why...The last thing I do is worry. There's a hospital full of doctors. Let them do it."*

**Causation**

Pts had developed their own, sometimes detailed, reasons why they had developed HF, for others they recalled being told by the specialists e.g. heart damaged due to heart attack.

*P10: "But a part of my heart is damaged, he says, which is caused by a heart attack I suppose".*

One pt blamed himself for 'over doing it'.

*P7: "I think this is one of the reasons I've, over the years, probably just wore myself out...I'm just like an engine, just blowing up, you know."*

**HF terminology**

As above. Many different ways to describe HF used by pts and specialists. The term itself was often associated with fear and a concern that heart may stop or that outlook was poor. Pts developed strategies to cope with this as time went on.

*P2: "It was worrying I mean you know when they tell you that your hearts not working properly and they call it 'heart failure', whatever's wrong with your heart they call it heart failure don't they which I think is horrible because failure means [laughs] it could stop you know. That's worrying but [erm] the longer you live with it, the more you get used to it".*

Some confusion over ejection fraction terminology and what that meant – if ejection fraction 20% pts assumed that meant only 20% of heart was working – not aware that normal ejection fraction is 50% or above.

**<u>Deviant cases</u>**

One pt (P5) had been to heart failure clinic and had volunteered to be part of the study which gave full details of what hoping to explore around HF but did not realise/acknowledge he had HF.

**<u>Points for further consideration</u>**

Delivery of diagnosis important. Breaking bad news needs to be improved in some cases. Provision of more information. Opportunity to ask questions. ?change in terminology of HF as frightening term.

## 9.8 Ethical Approval Letters

### 9.8.1 Scientific Research Committee at THIN Approval

## SRC Feedback
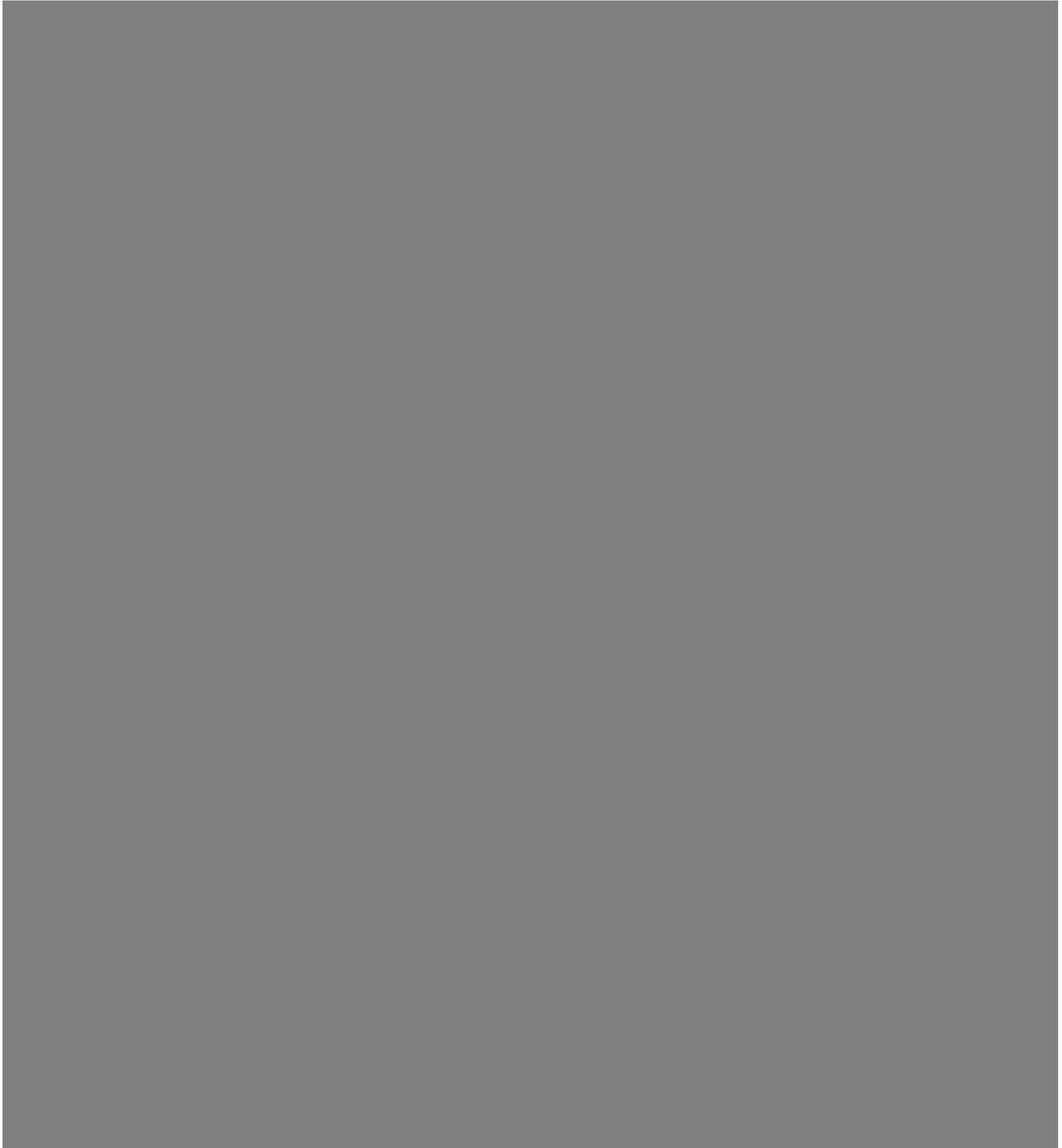
**9.8.2 Research Ethics Committee Letter – Favourable Opinion**
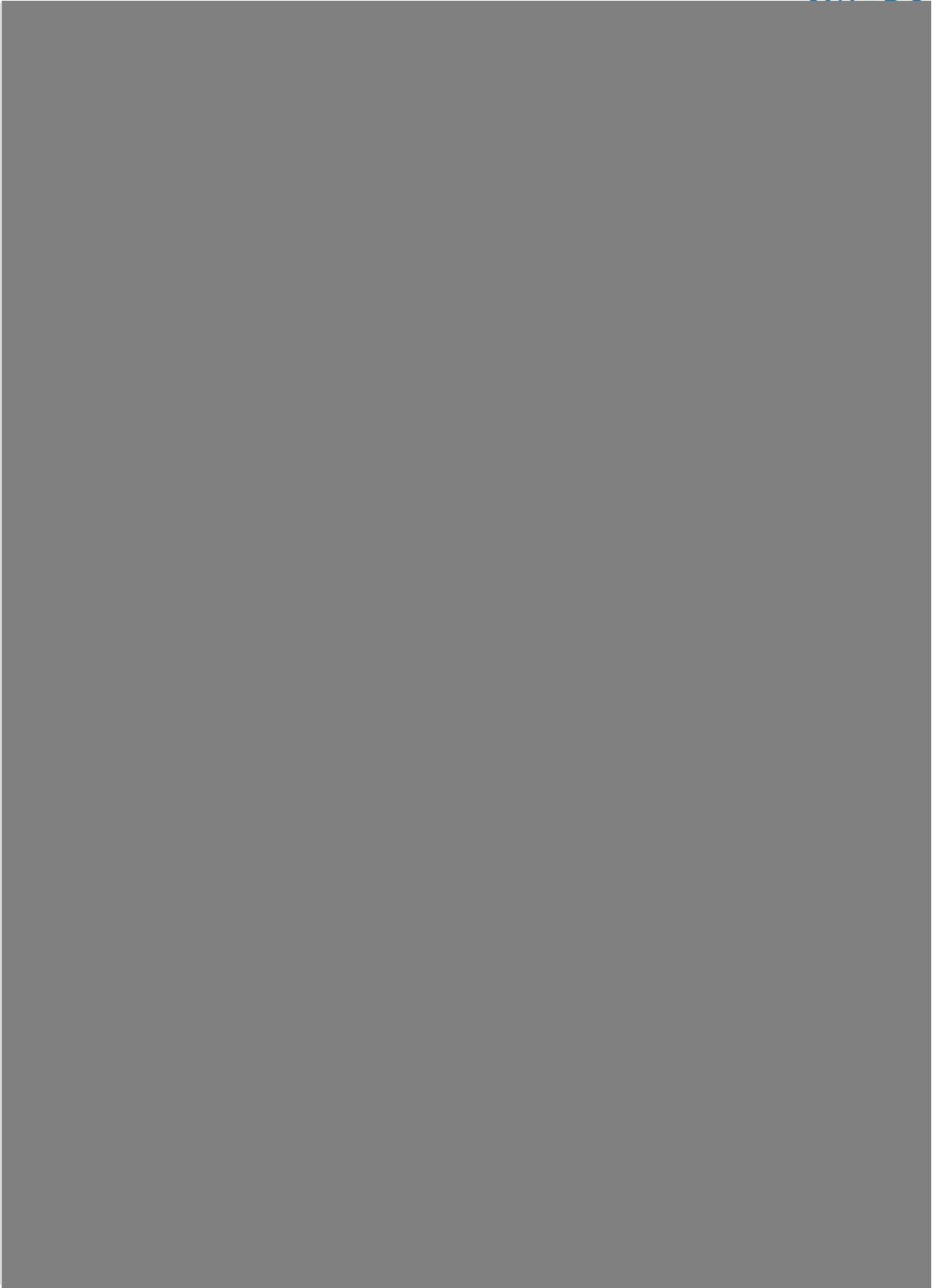
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