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Can point-of-care ultrasound improve the current community diagnostic pathway for acute dyspnoea and suspected heart failure in older people? A feasibility study of comparative accuracy and implementation

Submitted to Swansea University in fulfilment of the requirements for the Degree of Doctor of Philosophy

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Abstract

Diagnosing heart failure (HF) is challenging in elderly, acutely dyspnoeic community patients with high frailty and multiple comorbidities. Current readily accessible diagnostic tools prevent a definitive diagnosis of HF at the point-of-care. There is growing evidence that novices can learn focused point-of-care ultrasound (POCUS) to increase diagnostic accuracy of clinical examinations and improve immediate clinical management.

Despite the abundance of data supporting POCUS by different users in different settings, there is a notable absence of attention to contextual complexities that influence implementation. This limits generalisability and leaves uncertainty regarding how and where POCUS should be placed to maximise clinical- and cost-effectiveness.

This thesis examines whether nurse-led POCUS serves as a useful triage tool when added to the clinical examination of elderly patients with acute dyspnoea at risk of HF. It details a comprehensive approach to intervention development. An explanatory-sequential mixed-methods approach provided preliminary data regarding feasibility, acceptability, accuracy, and clinical impact of POCUS in the proposed context.

It concludes that, following bespoke training, community nurses can accurately and reliably detect left ventricular systolic dysfunction and signs of pulmonary congestion using POCUS in elderly acutely dyspnoeic community patients with suspected HF. Adding POCUS improved the diagnostic accuracy of the assessment, reduced time-to-diagnosis, and could improve triaging of echocardiography referrals, without missing significant dysfunction. Despite contextual challenges of the home-setting, nurse-led POCUS was feasible in most patients and welcomed by nurses. Training and support were perceived as key determinants in implementation success while training interruption was seen as a major barrier.

Preliminary findings suggest nurse-led POCUS as a triage tool has the potential to improve the current diagnostic pathway for elderly patients with suspected HF. It provides valuable data to support further larger-scale research and proposes refinements to research methods. POCUS has potential for more widespread clinical use, but exploration of contextual influences is pivotal in ensuring effective implementation in new contexts.

Declarations and Statements

DECLARATION

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

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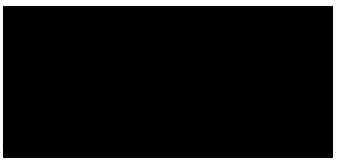
STATEMENT 1

This thesis is the result of my own investigations, except where otherwise stated. Where correction services have been used, the extent and nature of the correction is clearly marked in a footnote(s).

Other sources are acknowledged by footnotes giving explicit references. A bibliography is appended.

Signed……  (candidate) Date: 22nd July 2023

STATEMENT 2

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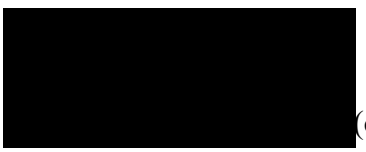
Signed……  (candidate) Date: 22nd July 2023

Dedication

This thesis is dedicated to my dad.

Thank you for always being a positive role model and teaching me the importance of hard work and determination.

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List of Publications/Conferences

Due to Covid-19 related delays and subsequent thesis-completion time pressures, I am yet to have submitted any manuscripts for publication. However, I have almost completed an opinion piece and am working on publications relating to training and clinical feasibility results based upon my thesis findings.

I have submitted, and had accepted, aspects of this research project for presentation at conferences. These include:

Health Research Wales Conference 2020

- Title: Should we be training community nurses to perform focused heart scans as part of the physical examination
- Virtual presentation. Presented nurse training programme and results (Chap 4).

Health Technology Assessment International (HTAi) Annual Meeting 2021

- Title: Could training community nurses to detect heart failure using hand-held ultrasound devices improve the accuracy of their assessment
- Abstract accepted but had to withdraw as delays in data collection.

Swansea University Postgraduate Research Conference 2021

- Title: Can the current community-based diagnostic pathway for older people with shortness of breath be improved by adding POCUS?
- Virtual presentation. Overview of research project.

British Society of Echocardiography Conference 2022

- Title: Could community nurses add POCUS to their assessment tool kit in those with suspected heart failure?
- Poster presentation. Provided overview of the non-clinical single-blind diagnostic accuracy and reproducibility study (Chap 4).
- Abstract published: Meeting Abstracts from the British Society of Echocardiography Annual Meeting: BSEcho 2022. (2023) *Echo Research Practi*ce **10** (Suppl 1), 18. https://doi.org/10.1186/s44156-023-00030-z

-Moosavi, S, Adenwalla, A., Davis, A, Ionescu, A. Rees, E. (2023) Could community nurses add point-of-care ultrasound to their assessment tool kit in those with suspected heart failure? *Echo Research & Practice* , 10 (Suppl 1):ABS016

Association of Cardiovascular Nursing & Allied Professional (ACNAP) Conference 2023

- Title: Does nurse-led point-of-care ultrasound (POCUS) improve the triage of elderly community patients with suspected heart failure? A feasibility study
- In person presentation (by Dr Rees as I had unavoidable personal commitments). Presented clinical data (Chap 5).
- Abstract published: Moosavi, S., Ionescu, A., Griffiths, E., Adenwalla, F., Davies, A., Rees, E. (2023) Does nurse-led point-of-care ultrasound (POCUS) improve the triage of elderly community patients with suspected heart failure? A feasibility study. *European Journal of Cardiovascular Nursing*, 22 (1). https://doi.org/10.1093/eurjcn/zvad064.061

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Lastly, I would be remiss in not mentioning my friends and family. I could not have got through this process without their enduring support and patience. Their encouragement and positivity have helped to keep me sane and given me the push I needed during difficult times along the way. In particular, I would like to thank Simone for her calmness during my computer issues, and for keeping me fed and watered throughout the write-up process. It has been a long journey for all of them too, and I look forward to spending quality time together now that this work is complete.

List of Abbreviations

Abbreviation	Definition
2D	Two Dimensional
A2C	Apical Two Chamber
A3C	Apical Three Chamber
A4C	Apical Four Chamber
ACE	Angiotensin-Converting Enzyme
AR	Aortic Regurgitation
AS	Aortic Stenosis
ASE	American Society of Echocardiography
BLUE	Bedside Lung Ultrasound in Emergency
BMI	Body Mass Index
BNP	Brain Natriuretic Peptide
BSE	British Society of Echocardiography
CFIR	Consolidated Framework for Implementation Research
CLUE	Cardiopulmonary Limited Ultrasound Examination
COPD	Chronic Obstructive Pulmonary Disease
CRF	Case Report Form
EACVI	European Association of Cardiovascular Imaging
ECG	Electrocardiogram
ESC	European Society of Cardiology
FATE	Focus-Assessed Transthoracic Echocardiography
FoCUS	Focus Cardiac Ultrasound
GE	General Electrics
GP	General Practitioner
HF	Heart Failure
HFmrEF	Heart Failure mildly reduced Ejection Fraction
HFpEF	Heat Failure preserved Ejection Fraction
HFrEF	Heart Failure reduced Ejection Fraction
IFEM	International Federation for Emergency Medicine
ISCU	International Society of Cardiovascular Ultrasound
IVC	Inferior Vena Cava

LA	Left Atrium
LCI	Lung-Cardiac-Inferior vena cava
LuCUS	Lung and Cardiac Ultrasound
LUS	Lung Ultrasound
LV	Left Ventricle
LVH	Left Ventricle Hypertrophy
LVSD	Left Ventricular Systolic Dysfunction
MCQ	Multiple-Choice Question
MR	Mitral Regurgitation
MRC	Medical Research Council
MS	Mitral Stenosis
NHS	National Health Service
NICE	National Institute of Clinical Excellence
NIHR	National Institute for Health and Care Research
NPV	Negative Predictive Value
NT-proBNP	N-Terminal Pro B-type Natriuretic Peptide
OSCE	Objective Structured Clinical Examination
PEER	Patient Experience and Evaluation in Research
PLAPS	PosteroLateral Alveolar and/or Pleural Syndrome
PLAX	Parasternal Long Axis
PLE	Pleural Effusion
POCUS	Point-Of-Care Ultrasound
PPV	Positive Predictive Value
PROM	Patient Reported Outcome Measures
PROMIS	Patient Reported Outcomes Measurement Information System
PSAX	Parasternal Short Axis
PSSRU	Personal Social Services Research Unit
RV	Right Ventricle
S4C	Subcostal Four Chamber
S.IVC	Subcostal Inferior Vena Cava
TTE	Transthoracic Echocardiogram
UK	United Kingdom

Chapter 1: General Introduction

Chapter Overview

This initial chapter provides a critical discussion of the current context surrounding acute dyspnoea and suspected heart failure (HF) in elderly community patients. This is a vital first step in understanding the development of the intervention which aims to overcome some of the existing challenges.

The ageing population is a major contributor to the rise in HF prevalence. The needs of an ageing population demand transformation of existing pathways. Diagnostic inaccuracies in current readily available point-of-care tests are leading to ineffective and inefficient care. This is adding to the echocardiography workforce crisis and contributing to untimely diagnosis.

Given the inadequacies of the current patient pathway for elderly community patients with acute dyspnoea and suspected HF, this research looks to explore whether adding point-of-care ultrasound (POCUS) to the initial point-of-care assessments adds clinical value. The chapter ends by providing an overview of the thesis structure.

It should be noted that this research was significantly impacted by the COVID-19 pandemic. The influence of the pandemic upon study methodology and conduct is explained within the relevant chapters.

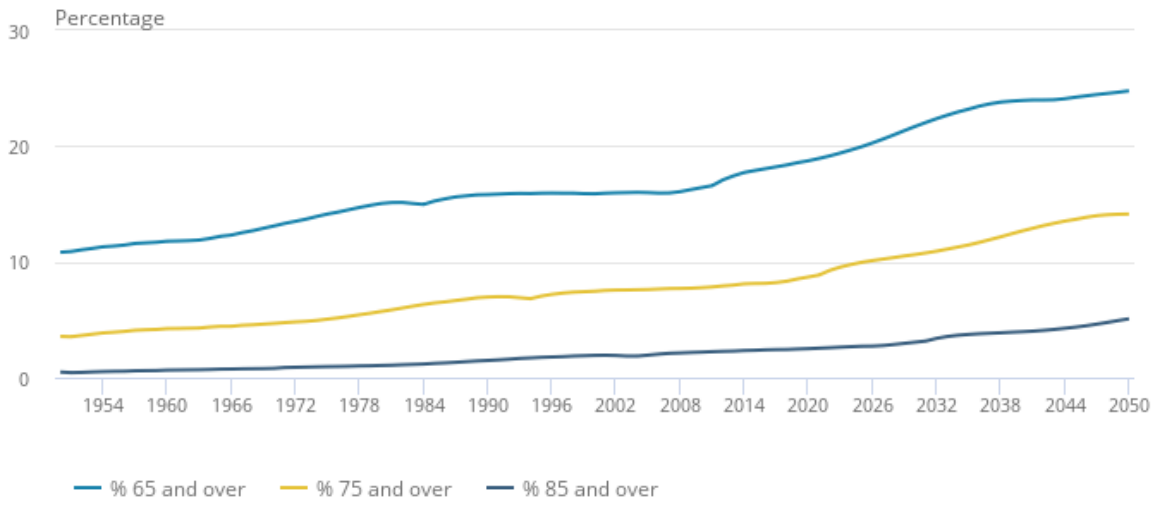
Context of Research

An ageing population places greater demand on healthcare services

Globally, the proportion of older people is growing faster than any other age group. Projections suggest that by the middle of this century, 25% of the United Kingdom (UK) population will be aged ≥65years (Figure 1.0). In Wales, national population projections (2020-based) estimate that the number of people aged ≥65years will increase by 16.1% to 776,300 between mid-2020 and mid-2030 (Welsh Government, 2022)

Figure 1.0

Percentage of older people in Great Britain, 1950 to 2050 (Office for National Statistics, 2019b)



It is generally considered that treating an elderly, rather than a younger, population is more costly because with increasing age comes increasing prevalence of disability and chronic illnesses (Age UK, 2019; Office for National Statistics, 2019a). Acute exacerbations of chronic illnesses, multiple co-morbidities (diagnosed and undiagnosed), complex profiles, and frailty are more common amongst the elderly (Barnett et al., 2012). Just over half of those aged 65-74years live with at least one long term health condition, increasing to nearly two thirds in those aged ≥85years (Age UK, 2019). Compared to those with one or no long-

term conditions, people with multimorbidity have an increased risk of functional decline, poorer quality of life, greater healthcare use, and increased mortality (Yarnall et al., 2017). In the UK, the elderly population receives approximately two thirds of care provided, or arranged by, a local authority, and accounts for around half of total public spending on adult social care (Age UK, 2019). In England, the mean hospital expenditure for an average 89-year-old male is three times greater than that for an average 70-year-old, and nine times that for an average 50-year-old (Kelly et al., 2016).

Healthcare services need to adapt to meet changing demands

The multiple economic, public service, and societal impacts of treating an ageing population mean adaptation of current healthcare services is required to meet changing demands. In an elderly population with complex healthcare needs, the original disease-orientated medical approach is no longer appropriate. Instead, a more integrated, multidisciplinary, holistic, person-orientated approach is needed (Dammacco, 2012). Care of the elderly can no longer be neatly compartmentalised into in-patient and out-patient phases; there is an increasing need for improved out-of-hospital diagnosis and treatment (Andersen et al., 2014).

Growing healthcare demands, worsened by the COVID-19 pandemic, mean services are under increasing pressure to deliver more clinical- and cost-effective interventions. It is well recognised by UK government and local health boards that the crucial factor to relieving healthcare pressure is placing a greater emphasis on out-of-hospital community services and avoiding unnecessary hospital admissions. The 2014 National Health Service (NHS) "5yr Forward View" promotes the delivery of more care closer to patients' homes and encourages multidisciplinary collaborations to provide integrated out-of-hospital care (National Health Service England, 2014). It encourages changing healthcare delivery by utilising digital technologies and developing new skills and roles to provide more convenient care for patients. The Welsh governments prudent healthcare initiative identifies the need to reduce unnecessary and inappropriate tests, change the outpatient model to make it easier to access specialist advice in primary care, and ensure public services work together to deliver the right care, at the right place, at the right time. NHS Wales have recognised that focusing on prudent innovation can help improve services and offer better care to patients (Welsh Health Circular, 2014).

Dyspnoea is a common medical complaint, more prevalent in the elderly

Dyspnoea (breathlessness) is one of the most common presenting medical complaints and approximately 60% of those presenting with dyspnoea are aged ≥65years (Charles et al., 2005). A large national primary care study found that breathlessness as a reason for consultation increased with age; reporting 37% of people seen by their family practitioner with breathlessness were aged over 75 years (Currow et al., 2013). A cross-sectional population-based study conducted in South Wales reported the prevalence of dyspnoea in older people (≥70years) at home to be 32% (Ho et al., 2001; Remme et al., 2008). However a systematic review assessing the prevalence of dyspnoea in the elderly reported that (across twenty study populations of older persons) the prevalence of moderate-to-severe dyspnoea ranged from 17% to 62% (van Mourik et al., 2014). Inconsistencies in age boundaries, methods of assessment, and subjective reporting contribute to variability in reported prevalence of dyspnoea in the elderly.

A consensus paper by the American Thoracic Society states that dyspnoea can originate from interactions among multiple physiological, psychological, social, and environmental factors, and can produce secondary physiological and behavioural responses (Parshall et al., 2012). This highlights the complexity of predicting dyspnoea rates in populations, particularly elderly cohorts.

Recognising and, where possible, managing dyspnoea is important due to its potential impact upon physical and mental health. In older adults, dyspnoea is associated with impaired daily function; reduced quality of life (Ho et al., 2001); increased use of hospital services; and increased risk of death (Fragoso et al., 2014; Hegendorfer et al., 2017; Ho et al., 2001; Mentz et al., 2015; Parshall et al., 2012; Santos et al., 2016; van Mourik et al., 2014).

Dyspnoea can be multifactorial making diagnosis challenging

The importance of managing dyspnoea is widely agreed however difficulties exist in managing this non-specific, complex symptom. As mentioned, the subjective nature of dyspnoea adds to the difficulty in determining a diagnosis (Berliner et al., 2016) with assessments often relying upon individual's perceived recognition of their feelings (Parshall

et al., 2012). The numerous potential causes of dyspnoea further challenges management. These include (but are not limited to) acute HF, pneumonia/bronchitis, exacerbation of chronic obstructive pulmonary disease (COPD) or asthma, pulmonary embolus, and renal and hepatic causes (Mebazaa et al., 2015; Weintraub et al., 2010). A systematic review of the underlying cause of dyspnoea in older people reported that the origin was considered cardiac in 19%, pulmonary in 42%, cardiac and pulmonary in 9%, other in 18%, and had no explanation in 12% (van Mourik et al., 2014).

Despite the multiple potential causes of dyspnoea, evaluation in the elderly is traditionally focused on cardiorespiratory diseases (Enright et al., 1994; van Mourik et al., 2014) rather than systematically evaluating the multiple impairments that frequently occur with advancing age and may be contributing to dyspnoea (Fragoso et al., 2014; Freid et al., 2012; Miner et al., 2016). The predominant focus on identifying/excluding cardiorespiratory causes is likely attributable to the clinical significance of these pathologies and the importance of immediate appropriate management if present.

The assessment of dyspnoea in an older population is challenged further because overlapping clinical presentations and multiple chronic comorbidities (diagnosed and undiagnosed) are prevalent, subjective awareness of dyspnoea may be reduced, and dyspnoea may be attributed to normal ageing and deconditioning (Berliner et al., 2016; Parshall et al., 2012; Petersen et al., 2014; Ramalho et al., 2019; van Mourik et al., 2014). In the elderly, the prevalence of multiple chronic comorbidities is increased, with half of those aged ≥65years having three or more chronic conditions requiring medical attention (Boyd et al., 2005). Therefore, in the elderly patient with acute worsening of chronic dyspnoea, a new condition in the presence of an existing chronic condition, or an exacerbation of an existing condition should be considered (Parshall et al., 2012).

Despite the difficulties with diagnosis, early identification of the cause of dyspnoea is important to allow effective patient management and improve patient outcomes. Some underlying conditions can occur acutely and be life-threatening, meaning rapid evaluation and targeted diagnostic studies are paramount (Berliner et al., 2016). However, current healthcare services are not designed for the complexities of diagnosis in older people with multiple long-term conditions (Leidi et al., 2016).

The initial workup for those presenting with dyspnoea

For those presenting with dyspnoea, work-up typically includes a clinical history, physical examination, electrocardiogram (ECG), chest x-ray and biochemical assays, such as brain natriuretic peptide (BNP) and N-terminal pro-B-type natriuretic peptide (NT-pro BNP) (Parshall et al., 2012). There is no diagnostic test or biomarker that correlates closely with changes in dyspnoea across all conditions or settings. Specific tests, such as spirometry or peak flow, D-dimer, BNP, and arterial blood gases, have diagnostic utility in specific, but not all, clinical settings. If routine initial work-up fails to confirm a cause for the dyspnoea, specialist referral is often required to help identify the underlying cause (Flaherty et al., 2001; Hekier & Mandel, 2009; Parshall et al., 2012).

HF may not be, as mentioned, the most likely cause of acute dyspnoea. However, confirming or excluding the presence of HF in those with acute dyspnoea is clinically important given the clinical significance of leaving HF untreated and recognising that the incidence of HF is higher in the elderly.

Heart failure is more common in the elderly and prevalence is set to rise

The prevalence of HF increases with age. Age has been independently associated with the presence of HF (Oudejans et al., 2011) and the growing number of older people has been identified as the principle cause for the rise in incidence and prevalence of HF (Conrad et al., 2018; National Institute for Health and Care Excellence, 2018). In the UK, prevalence of HF is estimated to be 1 in 35 people aged 65-74yrs, 1 in 15 aged 75-84yrs, and just over 1 in 7 in those ≥85yrs (National Institute for Health and Care Excellence, 2018).

The increasing prevalence of chronic HF makes it a growing public health concern. HF imposes a direct economic burden to healthcare systems caused by frequent hospitalisations and long-term treatment needs. Indirect costs exist through morbidity, premature mortality, and lost productivity (Cook et al., 2014; Mosterd et al., 1999; Redfield et al., 2003; Stewart et al., 2003). In England and Wales acute HF is the leading cause of hospital admission in people aged ≥65yrs (Public Health Wales, 2019). Acute HF is responsible for approximately 2% of all NHS hospitalised bed-days and 5% of all NHS emergency admissions (Dworzynski

et al., 2014; National Institute for Clinical Excellence, 2014; National Institute for Health and Care Excellence, 2018). HF accounts for approximately 2% of the total NHS budget (Cook et al., 2014). The largest contributor to HF costs (60-70%) are those related to hospitalisation (Braunschweig et al., 2011). According to European data, approximately 50% of those admitted with HF will be readmitted within twelve-months (Ponikowski et al., 2016). This emphasises the importance of early diagnosis and effective treatment to improve patient outcomes and help reduce emergency hospital admissions where possible.

HF is the leading cause of morbidity and mortality in older adults (Butrous & Hummel, 2016). The UK 2019 National HF audit reported in hospital mortality at 10%, with higher (12%) mortality rates in those aged >75years (National Institute for Cardiovascular Outcomes Research, 2019). For those discharged, one-year mortality was 32%. Mortality rates for those with established HF requiring hospital admission due to an acute decompensation are high. Up to one in six dies during admission, or within thirty-days after discharge (Dharmarajan et al., 2015; Parenica et al., 2013). Survival rates are far more favourable for HF detected during screening (Levy et al., 2002; Redfield et al., 2003). Primary care data (between 2000-2017) for 55,959 HF patients (aged ≥45years) showed survival rates were better for patients not requiring admission to hospital around the time of their HF diagnosis (median difference 2.4years; 5.3years versus 2.9years, $P<0.001$) (Taylor, 2019). These results support the need for earlier diagnosis to improve survival and highlight the importance of research into new strategies to achieve timely diagnosis and early initiation of appropriate treatments in primary care. It is well recognised that early initiation of the correct HF medication (such as angiotensin-converting enzyme inhibitors and beta blockers) is linked to better patient prognosis and outcomes (Komajda et al., 2018; Spencer et al., 2013).

Defining heart failure for the purpose of this research

Before beginning discussions regarding suspected HF, it is important to define what is meant by the term HF.

HF is a progressive, complex clinical syndrome characterised by signs and symptoms that suggest impaired heart function caused by functional or structural heart abnormalities (National Institute for Health and Care Excellence, 2018). Signs and symptoms typical of HF

include elevated jugular venous pressure, third heart sound, lateral displaced apical impulse, dyspnoea, orthopnoea, paroxysmal nocturnal dyspnoea, reduce exercise tolerance, and fatigue (McDonagh et al., 2022). A structural and/or functional abnormality of the heart causes increased intracardiac pressures and/or insufficient cardiac output at rest and/or during exercise (McDonagh et al., 2022). There are multiple potential causes of HF, including (but not limited to) coronary heart disease, primary cardiomyopathy, hypertension, and valvular heart disease (Berliner et al., 2016), most of which are more prevalent in the elderly. It is important to identify the cause of the cardiac dysfunction to ensure appropriate treatment.

HF has commonly been classified based upon left ventricular (LV) ejection fraction. The rationale being that original treatment trials in HF demonstrated substantially improved outcomes in patients with LV ejection fraction ≤40% (McDonagh et al., 2022). Failure of the LV to pump sufficient blood into the circulation is commonly termed LV systolic dysfunction (LVSD). LVSD refers to a form of HF where the ejection fraction is reduced. This is termed HF with reduced ejection fraction (HFrEF). An alternative form of HF exists where systolic function (and ejection fraction) is preserved but LV relaxation is impaired (diastolic dysfunction) (National Institute for Health and Care Excellence, 2018). This is commonly termed HF with preserved ejection fraction (HFpEF). It is characterized by reduced LV relaxation, increased LV stiffness, increased interstitial deposition of collagen, and modified extracellular matrix proteins (Maeder & Kaye, 2009; Paulus et al., 2007). Consistent with LVSD, stroke volume and cardiac output are reduced in HFpEF, and outcomes are similarly comparable (Jasinska-Piadlo & Campbell, 2023).

The European Society of Cardiology (ESC) 2021 guidelines for the diagnosis and treatment of acute and chronic HF classify HF into three categories: HF reduced ejection fraction (HFrEF); HF mildly reduced ejection fraction (HFmrEF); and HF preserved ejection fraction (HFpEF) (McDonagh et al., 2021). Definitions are provided in Table 1.0.

Table 1.0

ESC definitions of HF (McDonagh et al., 2021)

Type of HF		HFrEF	HFmrEF	HFpEF
Criteria	**1**	Symptoms ± Signs[a]	Symptoms ± Signs[a]	Symptoms ± Signs[a]
	2	LVEF ≤40%	LVEF 41–49%[b]	LVEF ≥50%
	3	-	-	Objective evidence of cardiac structural &/or functional abnormalities consistent with presence of LV diastolic dysfunction/raised LV filling pressures, including raised natriuretic peptides[c]

Note,

a - signs may not be present in early stages of HF (especially HFpEF) & in optimally treated patients.

b - for diagnosis of HFmrEF, presence of other evidence of structural heart disease (e.g., increased left atrial size, LV hypertrophy or echocardiographic measures of impaired LV filling) makes diagnosis more likely.

c - for diagnosis of HFpEF, the greater the number of abnormalities, the higher the likelihood of HFpEF.

It is estimated that 50% of those with HF have preserved ejection fraction and HFpEF is the most common type of HF in the elderly (Dunlay et al., 2017). The British Society of Echocardiography (BSE) provide a guideline protocol for the echocardiographic assessment of diastolic dysfunction which includes pulsed wave Doppler, Tissue Doppler imaging, Colour M-mode and LA volume evaluation (Matthew et al., 2013). Due to the advanced imaging modalities required to accurately assess diastolic function, comprehensive evaluation by trained personnel using a high-end ultrasound machine is required. HFpEF cannot be diagnosed using a low-end specification hand-held ultrasound device due to the absence of advanced imaging modalities (Nieminen et al., 2006).

For this research, the focus is on reduced LV systolic function (LVSD). While ejection fraction is not specifically measured or estimated via POCUS, the proposed threshold for LVSD is a visually estimated ejection fraction <50%. Therefore, in relation to the ESC definitions, the term LVSD (in this research) covers both HFrEF and HFmrEF categories. In the context of acute dyspnoea, the primary focus is on confirming/excluding cardiogenic causes. This would include insufficient forward flow from the ventricles or pulmonary congestion, both of which are detectable by focused ultrasound imaging of the heart and lungs. While it is recognised that HFpEF is more common in the elderly and cannot be accurately assessed using handheld ultrasound devices, the inclusion of lung ultrasound

allows assessment for signs of pulmonary congestion, and it is unlikely that diastolic dysfunction (HFpEF) in the absence of pulmonary congestion is the cause of acute dyspnoea.

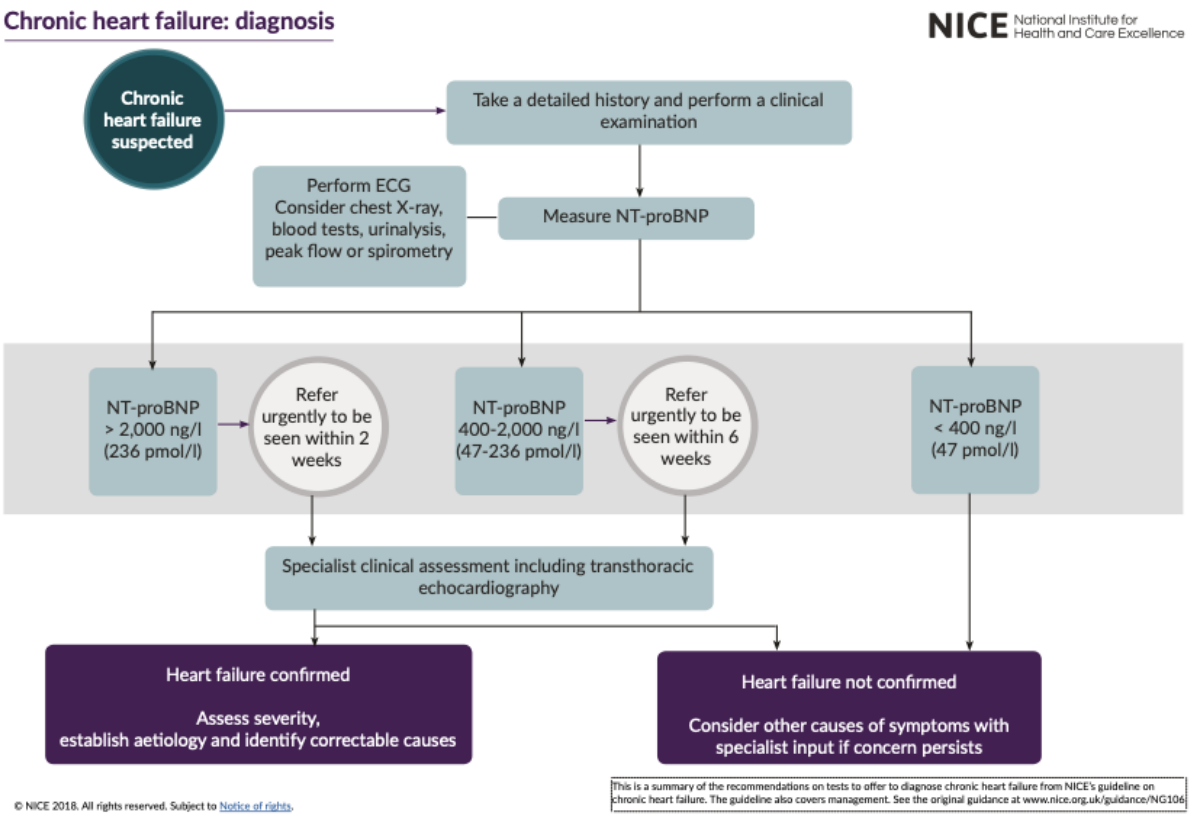
It is also worth noting that since the proposed clinical presentation is acute dyspnoea, the focus (in terms of HF) is on acute rather than chronic HF. Acute HF refers to rapid or gradual onset of symptoms and/or signs of HF, severe enough for the patient to seek urgent medical attention. Acute HF may be the first manifestation of HF (new onset) or, more frequently, an acute decompensation of chronic HF (McDonagh et al., 2022).

The current diagnostic pathway for suspected HF

In the UK, the National Institute for Health and Care Excellence (NICE) provide guidelines regarding the diagnostic work-up for those with suspected acute and chronic HF. The current NICE chronic HF diagnosis guidelines (NG106) (Figure 1.1) recommend a detailed history, clinical examination, natriuretic peptide measurement, and ECG (National Institute for Health and Care Excellence, 2018). Due to the poor prognosis associated with very high levels of NT-proBNP, NICE recommend those with suspected HF and a NT-proBNP level >2,000ng/litre are referred urgently for specialist assessment and transthoracic echocardiography (TTE) within two-weeks. For those with levels between 400-2,000ng/litre they suggest specialist assessment and TTE within six-weeks.

Figure 1.1

NICE chronic HF diagnosis guidelines (NG106) (National Institute for Health and Care Excellence, 2018)



This is a summary of the recommendations on tests to offer to diagnose chronic HF from NICE's guidance on chronic HF. See the original guidance at www.nice.org.uk/guidance/NG106

[Taken from: National Institute for Health and Care Excellence (2018) Chronic heart failure in adults: diagnosis and management (NG106)]

For those presenting with new suspected acute HF, NICE guidelines (CG187) similarly recommend a history, clinical examination, and standard investigations (in line with chronic HF guidelines) but recommend a single measurement of serum natriuretic peptides with a threshold value for excluding HF of <300 ng/litre for NT-proBNP or <100 ng/litre for BNP (National Institute for Health and Care Excellence, 2014). If levels are raised, TTE is indicated to establish the presence or absence of cardiac abnormalities and guidelines propose that this should ideally be within 48hrs post-admission to guide early specialist management. The ESC similarly recommends that the diagnostic work-up for those with acute HF includes clinical signs and symptoms, ECG and echocardiography (McDonagh et al., 2022). If the

diagnosis is uncertain, they also recommend measuring plasma natriuretic peptide levels with BNP and NT-pro-BNP cut-offs for acute HF being consistent with NICE (but also include midregional pro-atrial natriuretic peptide with a cut-off <120 pg/mL).

While NICE provide recommendations for the diagnostic work-up in those with suspected acute HF, access to testing (primarily TTE) in the UK is variable across different areas of healthcare meaning not all patients follow a pathway aligned with NICE guidelines (Bottle et al., 2018).

The successful management of any acute condition involves early diagnosis, the identification of underlying reversible causes, and the timely implementation of effective therapies (Ray et al., 2006). However, the current readily available routine tests lack sufficient diagnostic accuracy to confirm reduced heart function and demand-supply issues associated with TTE mean there are frequently delays in HF diagnosis. This subsequently delays initiation of evidence-based medication which impacts negatively upon prognosis.

Issues with insufficient accuracy and timely availability

Although well established and widely utilised, there are important limitations associated with the current diagnostic patient pathway for HF. The guidelines recommend a diagnosis based upon a collection of signs and symptoms, supported by imaging and laboratory testing (McMurray et al., 2012). However, each step in the pathway has its own issues regarding sensitivity, specificity, and/or availability which prevents, or delays, a definitive diagnosis of HF.

Clinical history and physical examination are undoubtedly useful for gaining an initial impression to alert to the possibility of HF. While there are numerous symptoms that can suggest HF, such as dyspnoea, fatigue, reduced exercise tolerance, and fluid retention (Ponikowski et al., 2016), there is no definitive sign or symptom that is both sensitive and specific for HF. Therefore, HF cannot be diagnosed based on the history and physical examination alone. The clinical examination is challenged further in the elderly because cardinal HF symptoms of fatigue, dyspnoea, and reduced exercise tolerance are frequently attributed to advanced age (Butrous & Hummel, 2016), less often present in older people, and

may be more difficult to detect due to the increased prevalence of pre-existing comorbidities which can mimic or mask signs and symptoms of HF (Lien et al., 2002; Oudejans et al., 2011; Rich, 2005; van der Wel et al., 2007).

In the context of dyspnoea and suspected HF, an ECG is useful for ruling out HF. A normal ECG reliably excludes the probability of HF and should prompt investigation for an alternative cause for the presenting symptom(s). While an abnormal ECG is consistently found in those with HF, an abnormal ECG (in isolation) does not confirm HF (low specificity). Commonly reported ECG abnormalities suggestive of HF include evidence of previous myocardial infarction, left ventricular hypertrophy (LVH), atrial fibrillation, and left bundle branch block (Gillespie, 2005). However, there is variability in types of abnormalities and their corresponding sensitivity and specificity for HF. There is no single ECG abnormality that is specific (exclusively) for HF. Therefore, an abnormal ECG highlights the need for further cardiac assessment (Gillespie, 2005) but cannot confirm a diagnosis of HF.

Natriuretic peptide testing (BNP or NT-proBNP) similarly has rule-out utility but cannot confirm HF. While a normal natriuretic peptide has negative predictive values of 94-98% (Ponikowski et al., 2016), much like the ECG, the diagnostic utility of natriuretic peptide testing is reduced because elevated levels are not specific to HF. Aside from HF, there are numerous cardiovascular and non-cardiovascular conditions that can cause elevations in natriuretic peptide levels including acute coronary syndromes, valvular heart disease, arrhythmia, pulmonary emboli, renal failure, sepsis, anaemia, respiratory disease (such as COPD), diabetes, cirrhosis of the liver, and advanced age (Gaggin & Januzzi, 2013; Krauser et al., 2005; Luchner et al., 2005; Maisel et al., 2002; Medina et al., 2011; National Institute for Health and Care Excellence, 2018; Schwam, 2004).

Other considerations regarding BNP testing include inaccuracies of natriuretic testing in those with known HF and a suspected exacerbation because levels can be chronically elevated thereby making the test inconclusive (Kajimoto et al., 2012). Conditions exist, such as high body mass index, African or African–Caribbean ethnicity, acute pulmonary oedema, acute mitral regurgitation, atrial myoma, mitral stenosis, and stable New York Heart Association I with low ejection fraction, where natriuretic peptide levels are reduced and caution is needed when interpreting results in these settings (Maisel et al., 2002). Those undergoing treatment with diuretics, angiotensin-converting enzyme (ACE) inhibitors,

beta-blockers, angiotensin II receptor blockers, or mineralocorticoid receptor antagonists can also have reduced natriuretic peptide levels (Madamanchi et al., 2014; National Institute for Health and Care Excellence, 2018).

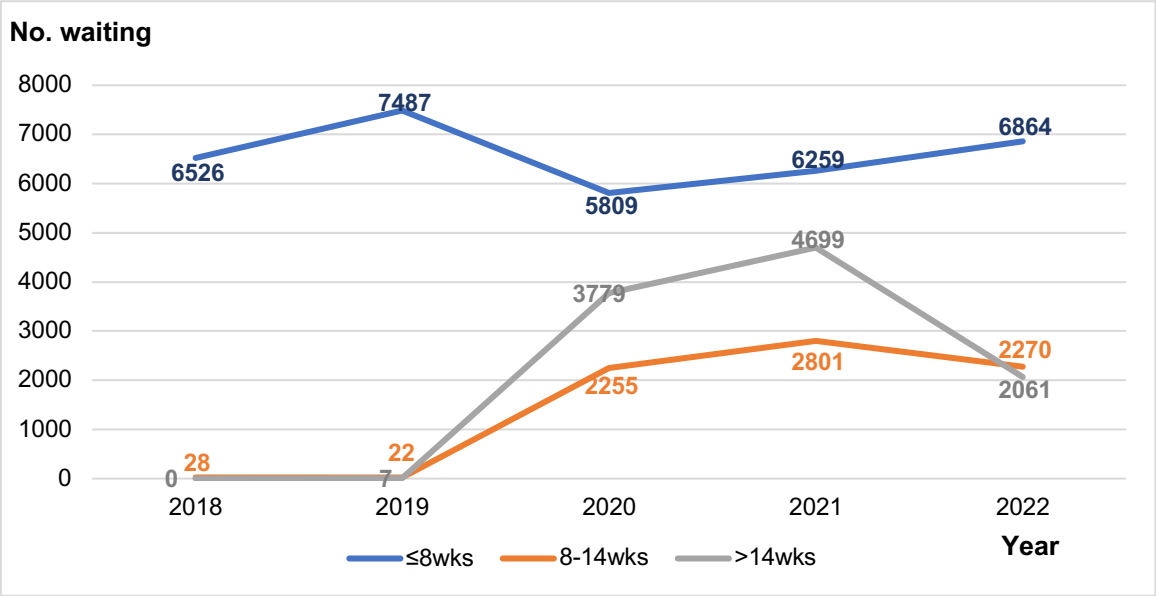
There is evidence that the diagnostic performance of natriuretic peptide testing for suspected HF is less robust in the elderly because plasma natriuretic peptide levels increase with age (Yousaf, 2012). In a case-control study of elderly participants aged ≥75years (n=260), an NT-proBNP >300ng/l was found in 34% of patients without LVSD (and 95% with LVSD) (Olesen & Andersen, 2016). This effect of age is independent of the age associated increase in prevalence of diastolic dysfunction and renal impairment (Cleland, 1998).

At present, TTE is the most useful, well established, cost-effective diagnostic imaging tool in patients with suspected HF (Cowie, 2017; Ponikowski et al., 2016; Senior & Galasko, 2005). Unlike ECG and BNP testing, TTE has proven sensitivity and specificity for cardiac dysfunction (Dickstein et al., 2008; McMurray et al., 2012; Nagueh et al., 2011; Spencer et al., 2013) but there are issues with timely access to TTE, particularly in the community setting. In the UK, most echocardiography machines are located in hospitals and operated by a limited number of highly trained personnel (Mjolstad, Snare, et al., 2012). The study group on HF Awareness and Perception in Europe reported only 50% of primary care physicians could obtain TTEs directly (16%) or via specialists (34%) within a month (Remme et al., 2008).

The lack of timely access to TTE, caused by a demand-supply mismatch, means waiting times for TTE are frequently longer than recommended by NICE (All Party Parliamentary Group, 2016). According to the National Echocardiography Survey, demand for TTE has increased (on average) by 3-4% annually in the UK (All Party Parliamentary Group, 2016). The national shortage of those trained in echocardiography within the UK has also added to the echocardiography demand-supply mismatch. This has resulted in more people having to wait longer for TTE. In Wales, those waiting over the Welsh eight-week referral to treatment target for diagnostic tests is higher than pre-COVID-19 figures (Figure 1.2).

Figure 1.2

Waiting times for TTE across Welsh hospitals for the month of October 2018-2022 (StatsWales, 2023)



It is expected that demand for echocardiography will continue to grow significantly over time due to increasing indications and the aging population. Many conditions, once diagnosed, require echocardiography surveillance which places further demands on echocardiography services. In broadening and expanding echocardiography services, the workforce shortages become even more apparent (Fox, 2007) and threaten the ability to meet increasing demand (British Cardiovascular Society & Society for Cardiological Science and Technology, 2015). This further emphasises the importance of rethinking existing service provision and reducing unnecessary referrals.

Time to HF diagnosis often remains poor, particularly in primary care (Bottle et al., 2018). Diagnosing HF is particularly challenging in out-of-hospital settings due to the absence of direct (or limited) access to echocardiography (Oudejans et al., 2011; Rich, 2005). Therefore, most HF diagnoses are made in hospital despite numerous patients presenting to primary care with symptoms that should have triggered earlier assessment (Bottle et al., 2018; Vijayakrishnan et al., 2014). The development of new models of primary care echocardiography services could be beneficial by providing earlier access to echocardiography and subsequently earlier diagnosis of HF . Primary care led research is

needed to understand the complexity of HF diagnosis and management in the community, and to develop and test new strategies to achieve better outcomes for patients (Taylor, 2019).

A potential solution proposed by an acute clinical team

This body of research arose from a current clinical shortcoming identified by nurses working with older people in community services. A group of nurses from a community acute clinical team approached the Faculty of Medicine Health and Life Science at Swansea University seeking advice regarding the use of POCUS as an adjunct to the physical examination to help confirm or exclude systolic HF in those with new or worsening dyspnoea.

The acute clinical team run an advanced nurse practitioner-led 'hospital at home' community service. They provide rapid assessment and clinical intervention for a growing number of mainly frail, older people with multiple co-morbidities. Sources of patient referral include general practitioners (GPs), the Welsh Ambulance Service, and inpatient and outpatient services from hospitals within their local Health Board. Patients spend varying durations under the care of the acute clinical team and, depending on outcomes, they may be discharged into the community, or admitted to hospital. The service enables several treatments, such as medication changes and intravenous fluids, to be given at home rather than in hospital. The aim of the service is to provide optimal clinical care at patients' homes in the hope of keeping patients out of hospital wherever possible.

The home visits are typically performed by qualified nurses who use clinical examination skills and routine tests (in line with NICE guidance) to determine clinical status. However, under the current care model, the nurses communicated difficulties in managing elderly dyspnoeic patients. They expressed challenges in deciding if or how these patients should be treated when a definitive cause for the dyspnoea could not be identified and therefore reliance upon referral to secondary care for additional diagnostic testing to confirm a diagnosis. This presents additional logistical challenges in a predominantly elderly, frail cohort.

There are increasing UK and Welsh government strategies to promote improvements in community-based care and avoid unnecessary hospital admissions. The ambitions include moving care closer to patients' homes, using technology to support better care, and providing

diagnostic testing out of hospital. The Welsh Government Heart Conditions Delivery Plan outlines the need for quick and effective diagnosis and treatment of heart conditions, as close to home as possible (Welsh Government, 2017). The current COVID-19 pandemic has increased the urgency to reconfigure diagnostic pathways with increased healthcare provision in community settings aimed at keeping people out of hospital where possible.

The nurses believe that adding a limited type of ultrasound scan to their standard assessment process could improve their ability to identify, or exclude, one of the important causes of acute dyspnoea, systolic HF (LVSD). They hope POCUS could facilitate them in making more accurate decisions about which patients need to go to hospital, which can be treated at home, what tests are required (and how quickly), and the appropriate immediate therapeutic management.

Is point-of-care ultrasound one way of potentially improving the current diagnostic pathway?

In recent years, the use of focused, clinically driven POCUS has emerged as a safe and rapidly evolving diagnostic modality (Bhagra et al., 2016). Technological advancements have led to the development of smaller, cheaper, fully portable hand-held ultrasound devices making point-of-care scanning more accessible to non-traditional ultrasound users across a range of settings. Numerous studies support the use of POCUS to improve the diagnostic accuracy of the physical examination and there is evidence that non-traditional ultrasound users can be taught POCUS in relatively short timeframes (detailed in Chapter 3).

While it may seem logical that adding a focused point-of-care ultrasound scan to the current diagnostic patient pathway for elderly, dyspnoeic community patients would improve the diagnostic accuracy of the patient assessment and the effectiveness of patient management, the complexity of implementing a new intervention into an existing pathway must be considered.

POCUS has the potential to improve the nurses' ability to identify or exclude pathology at the initial point-of-care. An earlier, accurate diagnosis of HF (specifically HF with reduced ejection fraction) offers the potential to start evidence-based treatments sooner which is

linked to improved quality of life and patient outcomes. It also has the potential to reduce healthcare costs associated with emergency admissions and unnecessary referrals. The possible reduction in appointments, patient travel and hospital admissions align with societal aims of reducing carbon footprint. However, while this strategy appears sensible, there is a risk that re-organising healthcare away from specialist services may lead to an unintended reduction in the quality of care. Inadequate training poses the potential risk of misuse resulting in misdiagnosis, duplication of tests, increased care costs and worse outcomes (Blanco & Volpicelli, 2016). Decisions regarding re-organising healthcare away from specialist hospital services need to be evidence-based to ensure avoidance of unintended reduction in the quality of care and/or added costs.

Although not the only option for improving the current diagnostic pathway, this body of research seeks to explore the potential implementation of nurse-led POCUS (as an extension of the physical examination) within the current pathway for elderly, acutely dyspnoeic patients with suspected HF in the domiciliary environment.

It should be noted that the proposed definition and application of POCUS (for the purpose of this research) is detailed within Chapter 3.

Initial Research Aims

The initial aim of this research is to explore the potential clinical impact of adding POCUS to the existing diagnostic pathway for elderly community patients with new or worsening dyspnoea and suspected HF. Given the complexities of potentially implementing a new intervention into an existing pathway, the Medical Research Council (MRC) framework for developing and evaluating complex interventions was used to guide intervention development.

Original Contribution of the Research

This research is the first to explore the use of nurse-led POCUS in the context of elderly acutely dyspnoeic patients with suspected HF in the domiciliary setting. It considers the complexities of POCUS (intervention) implementation in a new setting and uses theory to guide intervention adaptation. Through staged feasibility testing, it assesses the acceptability, feasibility, diagnostic accuracy, reproducibility, and clinical impact of adding POCUS by non-specialist community nurses to the current assessment process as a triage tool in elderly, acutely dyspnoeic patients with suspected HF. It provides novel insight into contextual implementation considerations regarding POCUS use in the domiciliary setting and provides preliminary evidence to inform, and guide the methodology, of a larger multi-centre trial.

Structure of the Thesis

This general introductory chapter is followed by the following chapters:

- **Theoretical frameworks underpinning research design (Chapter 2)**
  Detail of the established complex intervention guidance used to inform research design.

- **Developing (adapting) the intervention (Chapter 3)**
  In line with MRC complex intervention development and evaluation guidance, an outline of the intervention adaptation process (based upon a review of the existing literature).

- **Pre-clinical feasibility study (Chapter 4)**
  Detail of the devised, delivered, and assessed bespoke nurse-tailored POCUS training programme.

- **Clinical feasibility study (Chapter 5)**
  Detail of the clinical feasibility study focused at gaining initial insight into the feasibility, acceptability, accuracy, and impact of adding nurse-led POCUS to the existing patient pathway.

- **General discussion (Chapter 6)**
  A summary of the key findings and the original contribution of this research to the existing literature, along with recommendations for future research.

Chapter Summary

This chapter gives an overview of the relevant background information in relation to the clinical context of this research. It provides justification for the proposed clinical context, describing the current challenges associated with caring for elderly, acutely dyspnoeic patients with suspected HF in the community under the current diagnostic patient pathway and the clinical significance of these challenges. It introduces POCUS as one potential option for improving some of the inadequacies in the current diagnostic pathway. The chapter details the initial research aims and concludes by providing an outline of the thesis structure.

Key take home points:

- *The population is ageing.*
- *Dyspnoea is one of the most common medical complaints and over half of those that present are aged ≥65years.*
- *Dyspnoea is a non-specific, complex symptom which makes deciphering a cause challenging, particularly in elderly patients with multiple comorbidities.*
- *While HF is not the most common cause, it is important to confirm/exclude its presence in the patient work-up given the clinical significance of untreated acute HF.*
- *The current diagnostic pathway for those with suspected HF prevents a definitive diagnosis due to inadequacies in accuracy and/or availability of the current tests at the initial point-of-care resulting in referral for further diagnostic testing.*
- *Delays in diagnosis are associated with unscheduled hospital admissions and worse prognosis.*
- *The development of smaller, cheaper, easier to use hand-held devices has made them accessible diagnostic tools for non-traditional ultrasound users. There is growing evidence supporting the use of POCUS to improve the diagnostic yield of the physical examination and the potential to improve patient triage.*

Chapter 2: Theoretical frameworks underpinning research design

Chapter Overview

Having defined the clinical problem (insufficient specificity of the current diagnostic pathway for suspected HF), detailed the selected population/context (elderly acutely dyspnoeic patients with suspected HF in the community), and proposed one potential solution (nurse-led POCUS), attention moved to research design. Given the complexities associated with implementing a user-dependent technology within an area of clinical practice not previously examined, established frameworks and guidance regarding complex intervention implementation were considered.

This chapter provides an overview of how the research was designed based upon MRC guidance. It describes the complexity of potential POCUS implementation and outlines the methodology used to develop the intervention within the proposed context. It details the proposed preliminary research needed as part of the intervention development and feasibility phases and details evaluation and implementation considerations.

Introduction

Healthcare delivery is changing within the UK and there is an increasing drive to implement more clinically- and cost-effective interventions to help improve the quality and efficiency of healthcare. Despite the widespread support for implementation of evidence-based interventions, it is well recognised that implementation is often slow. This is commonly termed the "evidence-to-practice gap." The complexity of intervention implementation is a likely contributor to this.

Implementing a new intervention and altering the current care pathway is often challenging. Nurse-led POCUS, like so many interventions within healthcare, should be considered a complex intervention due to the multiple interacting components that could influence intervention success and patient outcomes (Damschroder et al., 2009; May et al., 2016; May et al., 2009; Murray et al., 2011). In addition to organisational and contextual challenges,

POCUS imaging itself is complex, relying upon acquisition of diagnostic quality images (user and subject dependent) that must be interpreted and applied to the clinical context.

The complexities of intervention implementation should be considered from the offset. There are well-established frameworks and guidance for developing and evaluating complex interventions which have been designed to aid researchers. However, it is widely reported that intervention development and piloting before implementation is often poor; facilitators and barriers to implementation are often inadequately examined. Failure to sufficiently capture and consider context has been identified as a major barrier to evaluating the generalisability and transferability of study findings (Waters et al., 2011). Despite the multiple established frameworks and guidance regarding complex intervention implementation, this has failed to translate to the POCUS literature which is dominated by assessments of diagnostic accuracy (detailed in Chapter 3).

The absence of data regarding POCUS use by nurses in elderly patients with suspected HF in the domiciliary setting means it is unclear if, or how, POCUS should be implemented within this context, and whether it adds clinical value. Prior to implementation, the MRC framework recommends thorough intervention development and initial piloting focused at addressing the main uncertainties, followed by an exploratory, and then definitive, evaluation (Craig et al., 2008).

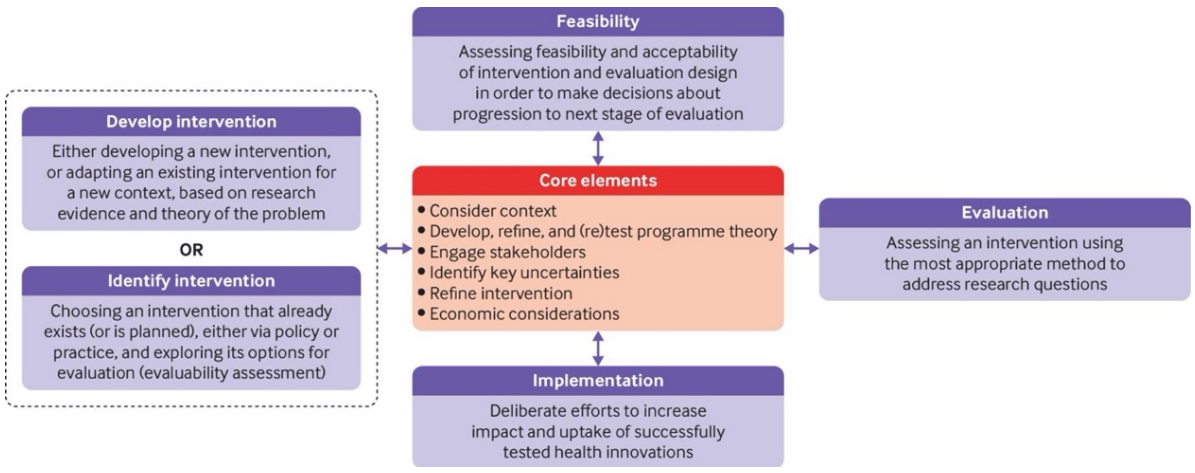
This research seeks to adopt a rigorous, systematic, phased approach to complex intervention implementation using appropriate evidence and theory (Craig et al., 2008). It plans to comprehensively describe the development and piloting of nurse-led POCUS for elderly patients with suspected HF in the domiciliary setting. Through preliminary feasibility testing, the intention is to better understand POCUS use within the proposed context, gaining an insight into accuracy, acceptability, feasibility, recruitment/retention, potential implementation facilitators and barriers, and the potential impact of POCUS on immediate medical decision making. The research seeks to provide initial guidance to inform a potential future trial assessing comparative diagnostic accuracy and a formal evaluation of implementation constructs.

Using A Framework for Intervention Implementation

Multiple theories and frameworks exist to support the design and evaluation of a complex intervention. Focus was placed on the MRC framework because it has been widely used across disciplines with proven flexibility and adaptability for various clinical contexts. Important conceptual, methodological, and theoretical developments have taken place which have resulted in updates of the MRC framework, the most recent of which was published in 2021 (Skivington et al., 2021a). The new framework still divides complex intervention research into four phases but proposes six 'core elements' to guide all phases of complex intervention research. An overview of the framework is provided in Figure 2.0.

Figure 2.0

Updated MRC framework for developing and evaluating complex interventions (Skivington et al., 2021a)



[Taken from: Skivington at al. (2021) A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance, BMJ 2021;374: n2061]

Compared with previous guidance, the update places greater emphasis upon economic considerations and the importance of context; recognising that interventions should be viewed as events that cause effects through interactions with features within the context in which they are implemented (Skivington et al., 2021b). Context includes the wider socio-economic background, the healthcare system, the people involved, the prevalence of the condition studied, and how these factors vary (Campbell et al., 2007; O'Cathain et al., 2019). While different phases are identified, the intent is for a dynamic, iterative process.

Echoing my earlier statement regarding the POCUS literature being dominated by diagnostic accuracy studies and lacking data regarding wider impact and implementation consideration, the updated MRC framework recognises that a shift in the approach to complex intervention research is needed. It recognises that real-world successful implementation relies upon more than whether the intervention works (intervention effectiveness). Consideration should be given to how it is implemented, its acceptability, cost-effectiveness, scalability, and transferability across contexts (Skivington et al., 2021a). It recommends a pluralistic approach and identifies four perspectives, (Table 2.0).

Table 2.0

Four perspectives for guiding complex intervention design and conduct (Skivington et al., 2021a)

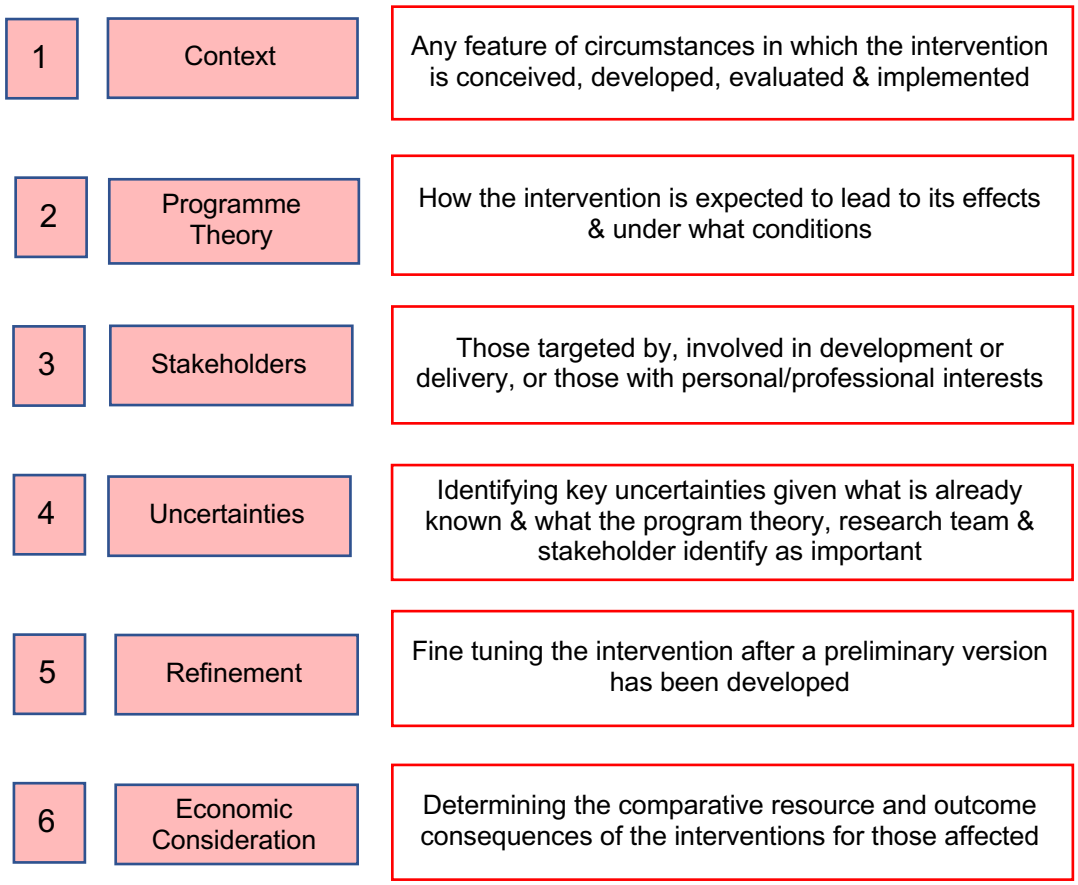
	Perspective	Considerations
1	**Efficacy** *(extent to which intervention produces intended outcomes in ideal setting)*	Maximises internal validity to provide precise, unbiased estimate of efficacy.
2	**Effectiveness** *(extent to which intervention produces intended outcomes in real world setting)*	Intervention and standard care compared with results informing which one better supports obtainment of the desired outcome
3	**Theory based** *(what works in which circumstances & how)*	Understand how change happens, recognising context and guiding potential refinement
4	**Systems** *(how the system & intervention adapt to each other)*	Considers the intervention to be a disruption to a complex system

This research project was not limited to a single perspective approach. All perspectives were considered to help guide research design and conduct, and help provide meaningful preliminary insight.

The six 'core elements' (detailed in Figure 2.1) were considered throughout the research process and used to guide all phases of complex intervention research (Skivington et al., 2021a). At this initial stage of research, economic consideration is limited to the resource costs associated with adding POCUS but with the suggestion to include cost-evaluation in the subsequent exploratory trial.

Figure 2.1

The six-core MRC components (Skivington et al., 2021a)



Developing (Adapting) an Intervention

Rather than developing a new intervention, this research is concerned with adapting an existing intervention (POCUS) for a new context. There is an abundance of data supporting the addition of POCUS to the physical examination to improve diagnostic yield in various clinical settings. However, adding community nurse led POCUS to the assessment process of elderly patients with suspected HF in the domiciliary setting has not been studied previously.

Based upon a study funded by the MRC and National Institute for Health and Care Research (NIHR), O'Cathain et al. (2019) identified eleven key principles and actions to consider when developing healthcare interventions. While each should be considered for relevance and importance, it is recognised that it is often impractical (or unnecessary) to address all actions and instead development approaches should be tailored to the capacity of the team, context, and resources (Skivington et al., 2021a). Based upon this guidance, Table 2.1 provides an overview of development process used for this research. Context specific adaptations were deployed. For example, research context and resource availability limited the breadth of the research team and limited stakeholder involvement to include the clinical team (providers) and representatives from the university's Patient Experience and Evaluation in Research group (PEER) (users).

Table 2.1

Key actions to consider during intervention development based upon guidance by O'Cathain et al. (2019)

Action	Description
Plan development process	Problem identified. Refine understanding of it & whether it is a priority. Consider aspects amenable to change. Consider whether the potential benefit justifies the cost of development. Determine time needed for intervention development. Obtain sufficient resources/funding for study development. Draw on published intervention development approaches.
Involve users & providers	Work closely with users/providers throughout development. Academic & clinical team discussions. Integrate public & patient involvement into development process via University PEER group. Include provider/user opinions in piloting phase.
Form a team & establish decision-making process	Team formed including clinical and academic representatives & two PEER representatives. Agreed decision-making process (academic team).
Review published research	Review existing literature (before & throughout development process). Identify existing evidence base (supporting evidence & evidence intervention may/may not work as intended).
Draw on existing theories	Identify existing theory/frameworks to inform the intervention (MRC & Consolidated Framework for Implementation Research)
Articulate programme Theory	Programme theory relates to how the intervention works & under what conditions. Develop, test, & refine programme theory throughout the development process.
Undertake primary data collection	Preliminary feasibility research to identify unknowns/gaps in the literature. Mixed-methods approach to help understand context & quantitative outcome measures.
Understand context	Understand context- the intended population, setting, social, economic, cultural & political influences & factors affecting implementation (for example, organisation, funding, and policy). Qualitative component to help enrich understanding
Consider future real-world implementation	Understand facilitators & barriers, future use, scalability, & sustainability. Mixed methods approach.
Design & refine intervention	Generate ideas about format & delivery. Refine based on results of preliminary feasibility testing & inform further studies.
End development phase	No established criteria for stopping the intensive development phase. Write-up intervention development process to allow judgements regarding the quality of the process & to guide the need for/direction of future research.

To help prevent a narrow perspective, stakeholder engagement was considered from the offset. A research team was formed comprising of clinical and research representatives. This included an associate professor and healthcare scientist with BSE accreditation; cardiac physiologist with BSE accreditation; consultant cardiologist specialising in echocardiography; acute clinical team advanced nurse practitioners; acute clinical team consultant; and university professor specialising in health outcomes research and health economics) . In addition, two members of the university's patient experience evaluation in research group. There was also access to university services such as value-based health care team, clinical trials unit, and statisticians. There was team engagement throughout the research process to help ensure the research addressed relevant questions. A thorough review of the literature (Chapter 3) was undertaken to establish the existing knowns and unknowns, and to identify key measurable uncertainties that the research aimed to address (Skivington et al., 2021a).

An economic evaluation, including comparative analysis of alternative courses of action (costs and consequences) (Skivington et al., 2021a), is outside the scope of this preliminary research. However, initial identification of the potential costs of implementing POCUS in the proposed context was considered and clinical outcomes reported to help guide future economic evaluations where economists input would be required.

The intervention developmental phase is more comprehensively described in Chapter 3.

Feasibility

This phase is designed to explore the uncertainties that have been identified at the development phase and ascertain whether it is appropriate to move onto the evaluation phase and optimise study design (Skivington et al., 2021a). A series of pilot studies is often needed to ensure the intervention can be delivered as intended and to progressively refine study design prior to embarking upon a full-scale evaluation (Craig et al., 2008).

Progression criteria should be used to guide the decision on whether to proceed to the next stage of evaluation or to undertake further feasibility work, or to return to the development phase and/or terminate the research (Skivington et al., 2021a). Progression criteria (target outcome thresholds) was determined following discussion with the research team, which included service user representation.

The intention of feasibility testing at this initial stage of research was to assess the accuracy, feasibility, recruitment and retention, acceptability, and clinical impact of adding the intervention in the proposed setting and evaluate design to help determine the need for, and guide the design of, subsequent larger exploratory research. Qualitative and quantitative methods were considered to help explore and address uncertainties.

The first phase of feasibility testing, focused on exploring training requirements and whether nurses could accurately and reliably perform POCUS in a controlled, pre-clinical setting (efficacy). This is described in Chapter 4. The subsequent clinical feasibility study, sought to assess accuracy, acceptability, clinical impact, and associated costs, of adding nurse-led POCUS in the domiciliary setting (effectiveness). This study is described in Chapter 5.

Evaluation

The evaluation phase involves assessing the intervention in the most appropriate ways to address the research questions; it is concerned with selecting appropriate outcome measures against which the intervention will be assessed (Skivington et al., 2021a). Evaluations should consider the suitability, integration, and effectiveness of the intervention in the intended clinical setting (Flottorp et al., 2003; Haynes, 1999; Oakley et al., 2006).

The key uncertainties identified as needing exploration included whether the nurses could accurately and reliably use POCUS in a controlled environment (efficacy); whether they could do the same in the clinical setting (effectiveness); the feasibility and acceptability (including recruitment and retention) of adding nurse-led POCUS in the domiciliary setting (systems); and understanding how and why it had the outcomes it did in the proposed context (theory-based). Process evaluations include qualitative and/or quantitative process data to provide insight in to the how and why.

Implementation

The implementation phase is concerned with deliberate effort to increase impact and uptake of the intervention (Skivington et al., 2021a). Implementation was considered from the offset and throughout the research process, considering what uncertainties needed to be addressed to maximise impact. Different stakeholder perspectives were considered to try and increase impact and while comprehensive cost evaluations were outside the scope of this work, resource costs were included to inform future evaluations.

It is well reported that a good theoretical understanding of how the intervention causes change is needed to identify (and then strengthen) weaknesses within the process (Craig et al., 2008). Consideration should be given to ease of implementation, how, where, when, and by whom (Glasgow et al., 2003; Tunis et al., 2003). Potential barriers can include cognitive, behavioural, organisational, sociocultural, or financial factors (Campbell et al., 2007). In terms of behaviours, it is important to understand the factors that facilitate and hinder change

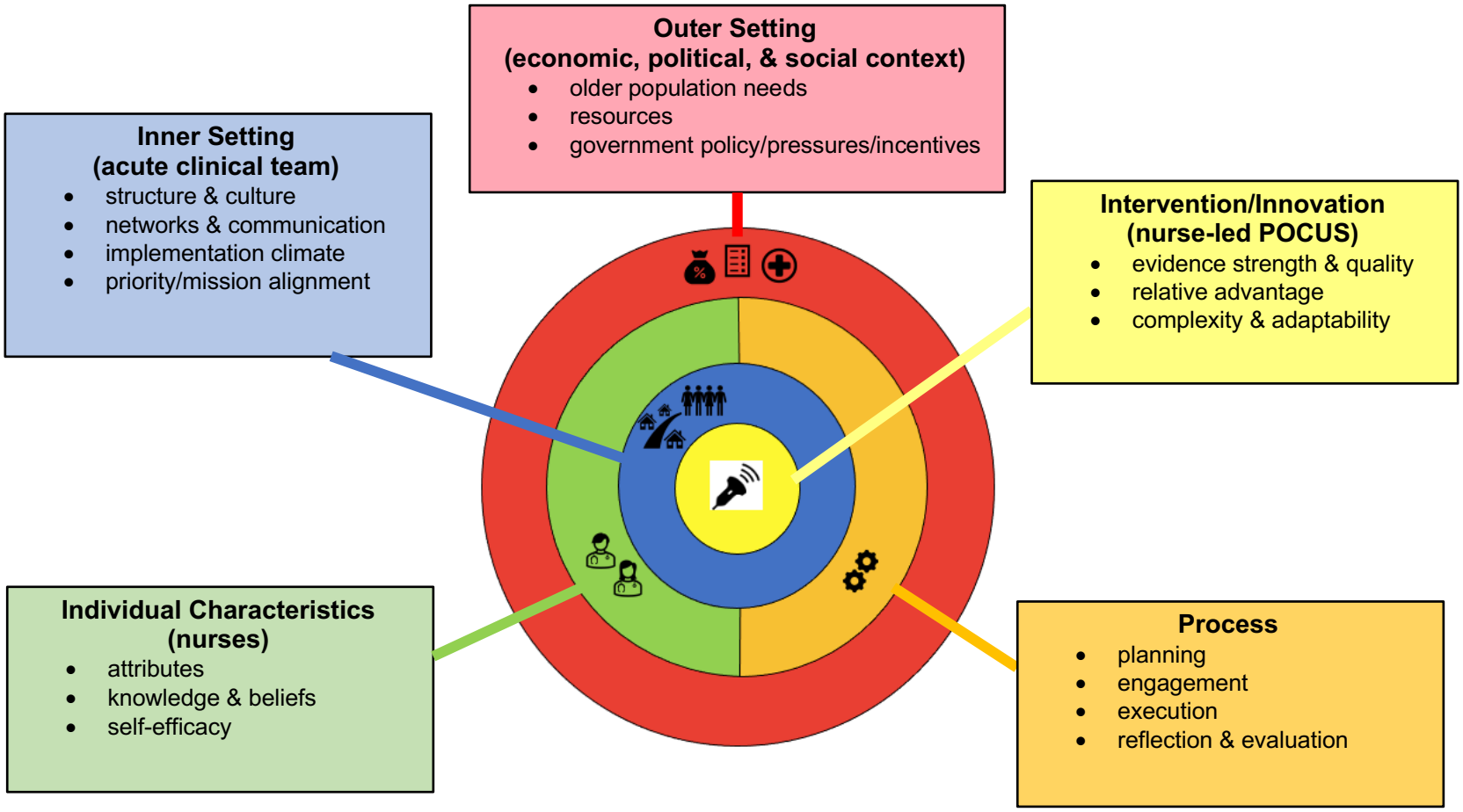
and maintain current behaviour (Eccles et al., 2007; Michie et al., 2005; Rowlands et al., 2005). Recognising this, feasibility study design included qualitative data to help gain initial insight into nurse-perceived service user (patient) and provider (nurse) opinions of adding nurse-led POCUS in the community and to help identify potential facilitators and barriers to implementation.

Conceptual frameworks can be used to help explore the implementation process and help understand why an intervention has the effect it does within a particular context (implementation science). They can increase the efficiency of research and improve scalability and interpretability of research findings (Keith et al., 2017). Following reading and discussion with implementation science researchers at my institution, the framework that resonated was the Consolidated Framework for Implementation Research (CFIR) which has been widely used within healthcare research to assess contextual factors (Damschroder et al., 2009). It provides a practical guide for systematically assessing context in terms of potential barriers and facilitators and can be used in preliminary research prior to intervention implementation (Damschroder et al., 2009).

The CFIR provides a menu of thirty-nine constructs, arranged across five domains (innovation/intervention characteristics; outer setting; inner setting; characteristics of individuals; and process), that have been associated with effective implementation. The framework was reviewed to help provide direction for quantitative and qualitative data collection. It is often impractical to assess all constructs and domains in a single study. Therefore, considering the research questions, each construct was reviewed for relevance. The intention was to try and address those that were deemed relevant (and assessable at this initial preliminary stage) during quantitative and/or qualitative data collection. Figure 2.2 provides an overview of the CFIR framework applied to this research context and the proposed intervention (nurse-led POCUS). The template of the diagram has been adapted from that published in an article by Best et al. (2021).

Figure 2.2

Addressing the CFIR domains for this context based upon the format used by Best et al.(2021)



Given this is an initial feasibility study assessing potential intervention use by a cohort and setting not previously explored, the principal focus was to increase understanding of the 'inner setting' (the acute clinical team) and the 'characteristics of the individuals' (predominantly the nurses) because, at this stage, they are the main drivers in determining intervention success.

'Inner' and 'outer' settings can change depending on the area of study. For this research, the 'inner setting' relates to the acute clinical team operating within community care. The intention was to seek information relating to its infrastructure; culture; communication; engagement; implementation climate; and readiness for implementation within this setting. At this stage, the focus was on the acute clinical team and their patients rather than wider stakeholder engagement. For the individuals (principally the nurses), the hope was to gain insight into their knowledge and beliefs about POCUS, as well as their professional beliefs/motivations; self-efficacy; personal attributes, and stage of change.

In terms of the implementation 'process,' the research sought to explore planning, engagement, and execution, and to reflect upon findings and suggest potential refinements to methodology. It intended to identify potential facilitators and barriers to implementation to inform future larger-scale implementation research.

In general, the clinical advantage and adaptability of POCUS (the 'intervention') is well reported. However, its adaptability to the domiciliary setting in elderly acutely dyspnoeic patients is not reported. Therefore, information regarding its suitability (adaptability) and advantage (nurse perceived) was sought.

While relevant, the 'outer setting' was not the predominant focus at this stage. The growing elderly population and their complex healthcare needs is widely recognised within healthcare. Increasing government pressure to deliver prudent healthcare, and improve diagnostic services within primary care, is well publicised and more context-specific guidance reports, such as recommendations from Health Technology Wales regarding the use of hand-held ultrasound for diagnosing systolic HF in the community (Health Technology Wales, 2019a), have also been published. Awareness of such policies and pressures can introduce potential bias towards implementation and while this is important, this is outside the scope of this initial feasibility work.

In terms of maximising impact, it is widely recognised that research findings must be accessible and actively disseminated. Although this research does not extend to implementation, preliminary study findings will be actively disseminated and reported in an accessible format to help support (and guide) larger scale studies and possible definitive trials.

Chapter Summary

Recognising the complexities of implementing nurse-led POCUS in the domiciliary setting, this brief chapter provides an overview of theoretical frameworks underpinning research design. Subsequent chapters provide detailed accounts of intervention development and feasibility testing.

Key take home points:

- *The proposed intervention is complex given that POCUS is a user-dependent technology requiring application of findings to the clinical context, and the multiple interacting components of use within the community setting.*
- *It is well reported that interventional research frequently fails to explore implementation challenges and contextual influences.*
- *The updated 2021 MRC framework, which places a greater emphasis on context, was used to guide research design.*
- *The CFIR framework was considered to help improve understanding of contextual influences and improve scalability and interpretability of findings.*

Chapter 3: Development of the Intervention

Chapter Overview

This chapter examines whether POCUS is a clinically useful intervention to improve diagnostic accuracy in the proposed context. If so, can POCUS be applied as described in the literature or is a degree of adaptation needed? The work began with a critical discussion of the existing diagnostic pathway (that allows the problem to exist and persist), and then explored how this could be changed, how improvements might be quantified, and whether potential benefits justify associated costs (Campbell et al., 2007; O'Cathain et al., 2019).

Research was conducted in two phases; Phase I was a comprehensive literature review of the current evidence-base. The scope of the review was limited to POCUS performed by novices and included consideration of HF diagnosis and out-of-hospital settings. Phase II extended the development process, engaging patient representatives and stakeholders in discussion of the proposed intervention in the context of a community acute clinical service for elderly people with acute dyspnoea.

The chapter ends with discussion of the key knowns and areas of uncertainty, detailing how these were used to drive design of the subsequent feasibility studies and research objectives.

Introduction

There is growing evidence that POCUS can improve the diagnostic accuracy of the physical examination and help guide early clinical management decisions (Ahn et al., 2017; DeCara et al., 2005; Kobal et al., 2005; Nelson & Sanghvi, 2016; Price & Kricka, 2007; Spencer et al., 2013). The portability, affordability, and simplicity of hand-held ultrasound devices has facilitated POCUS use by non-traditional ultrasound users who have been trained to diagnose certain pathology, including left ventricular systolic dysfunction and associated venous congestion (Price & Kricka, 2007; Spencer et al., 2013). A position statement from the European Association of Cardiovascular Imaging (EACVI) supports the use of hand-held

ultrasound for accurate qualitative assessment of ventricular function in hospitals and recommended its use in extending the physical examination to obtain a tentative diagnosis and support patient management in out-of-hospital settings (Cardim et al., 2019).

However, evidence to date is predominantly from small studies, in hospital or outpatient clinic settings, with significant variation in methodology and results (Albaroudi et al., 2022; Galusko et al., 2018; Jenkins et al., 2021) making it difficult to draw any definitive conclusions that can be applied to new contexts. Potential cost savings have been proposed by reducing referrals for TTE based upon normal POCUS examinations but there is little evidence about the cost-effectiveness and clinical impact of changing service models. In 2019, a Health Technology Wales evidence appraisal of hand-held ultrasound devices for cardiac assessment and diagnosis of systolic HF in the community or primary care setting found insufficient evidence to recommend use (Health Technology Wales, 2019b). They suggested the need for a pilot study undertaken by community nurses, GPs, or other healthcare professionals, to assess clinical and system outcomes, financial consequences, and logistics of introducing POCUS into a primary or community care setting.

While the addition of POCUS to the existing diagnostic pathway appears sensible, there is a risk that re-organising healthcare away from specialist services could lead to an unintended reduction in the quality and effectiveness of care. This is because novices and non-specialists can lack confidence in using new tests and are prone to over-testing and over-diagnosis. There is some evidence that adding expert-interpretation of novice-acquired images may improve clinical utility (Evangelista et al., 2016), however the literature is inconclusive regarding the optimal method of POCUS implementation.

Given that POCUS by non-specialist nurses in the domiciliary setting in elderly patients with suspected HF has not been previously tested, we cannot assume the same outcomes previously reported in other contexts. While the adaptability of POCUS is well reported, existing POCUS studies fail to describe the complexities of implementing POCUS and the contextual influences upon implementation success. Care pathways are complex processes comprising of multiple interacting and interdependent components and outcomes. Therefore, an understanding of the logistical organisation of care is needed as the multiple interacting components (including service user and provider behaviours) and outcomes vary depending

on clinical context (Campbell-Scherer & Saitz, 2016; Luig et al., 2018; May et al., 2016; Petticrew, 2011).

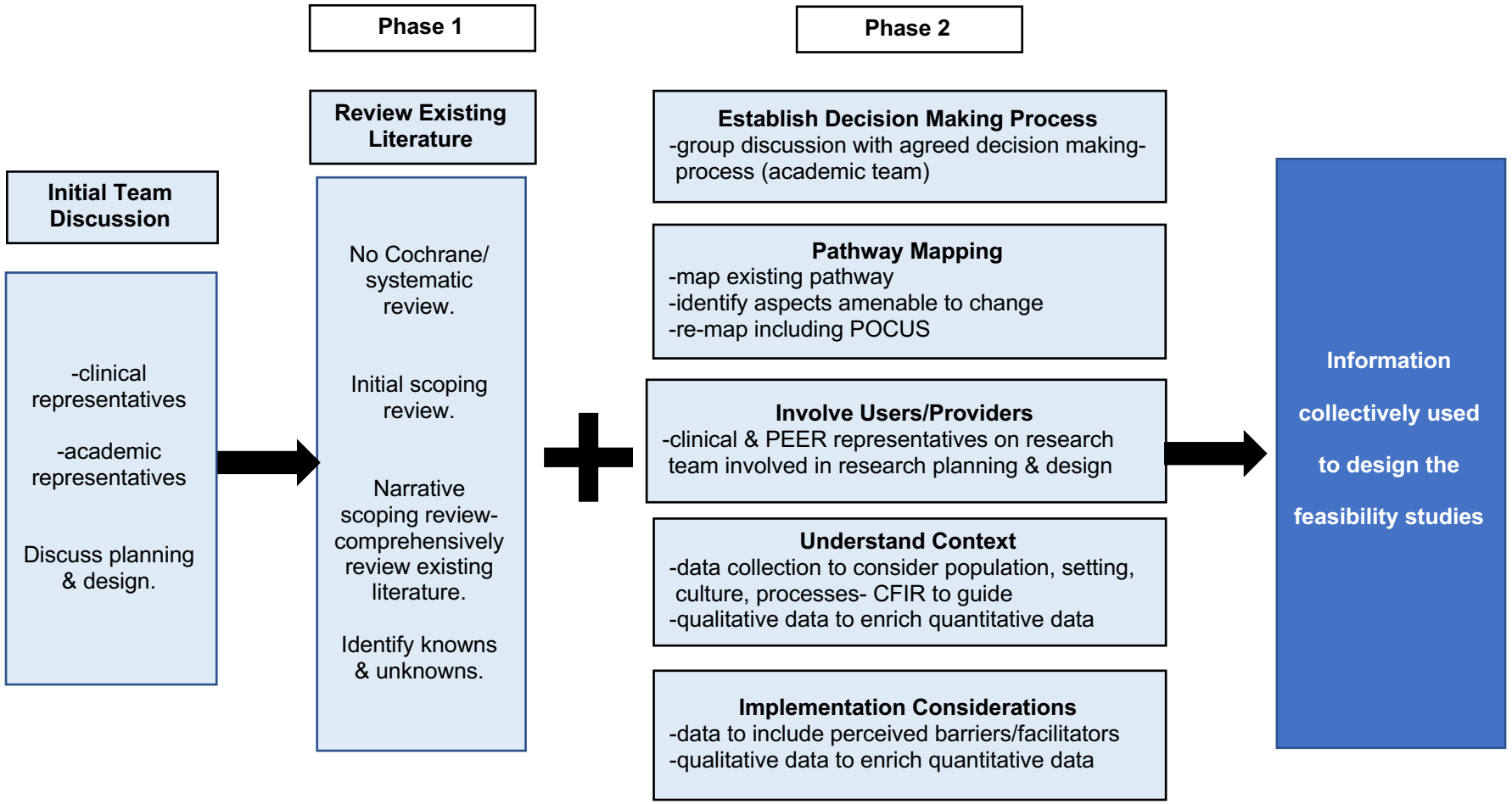
A systematic review has not been conducted on this specific topic. Therefore information has been drawn from the Health Technology Wales evidence appraisal (Health Technology Wales, 2019b) and my own review of the literature. The aim was for results to guide adaptation of the intervention for the new proposed context.

Method

An initial meeting took place, whereby the acute clinical team presented the clinical problem and their proposed solution to the university team. The clinical team comprised of cardiology clinical lead (consultant cardiologist), community medical lead (consultant geriatrician), and two advanced nurse practitioners (acute clinical team lead and university-based lecturer and nurse practitioner). The university team comprised of a clinical scientist/associate professor (BSE accredited), a health economist (university professor), and I, a PhD student/cardiac physiologist (BSE-accredited). From this meeting, the planning process began. An overview of the approach to intervention adaption/development is provided in Figure 3.0.

Figure 3.0

Adapting the intervention process



Phase I method: review of the literature

At the early stage of project planning, an initial brief scoping review was performed to gain a broad insight into the current literature regarding POCUS use by non-specialist nurses. It sought to provide a narrative integration of the relevant evidence to aid early discussions concerning research development.

Methods of literature searching

In this research setting, the focus of the literature review was research synthesis. Given the broad research question and intention to explore the current evidence-base, it was felt that a more narrative scoping review would be preferential (Armstrong et al., 2011).

The intention of the scoping review was to ask broad questions, search for relevant evidence, and describe what was found. It sought to form the narrative of the thesis; to provide insight into the extent, range, and nature of the existing literature relating to POCUS use by nurses in elderly community patients with acute dyspnoea and suspected HF. An iterative process was adopted to understand the existing literature and highlight gaps which could be used to inform and guide research design and help develop specific research questions. The steps within the review process included: identifying the research questions/objectives; defining inclusion/exclusion criteria; searching for evidence; selecting evidence; extracting evidence; recording/ tabulating results; and presenting results.

The literature review methodology was based upon the foundations of the Arksey and O'Malley six-stage methodological framework for conducting a scoping study (Arksey & O'Malley, 2005). The stages of the literature review process are outlined in Table 3.0. For the optional sixth 'consultation' stage of the Arksey and O'Malley framework, stakeholder involvement was not included in the literature review process (Phase I) however insight was sought in terms of research design (Phase II).

Table 3.0

Stages of the scoping review

	Stage	Description
1	**Define the research question** Defining the relevant aspects of the question	Main question: Is adding nurse-led POCUS to the assessment process of elderly patients in the community with suspected HF feasible and what is the clinical impact? • Hand-held POCUS as an adjunct to physical examination • Using hand-held POCUS in suspected HF • Hand-held POCUS by nurses/novices • Hand-held POCUS training for nurses/novices • Using hand-held POCUS in community/primary care • Clinical impact of adding hand-held POCUS
2	**Identifying relevant studies** Sources, search terms, limits	**Sources:** electronic databases (Web of science, CINAHL, Swansea University "iFind"), review of reference list of selected papers **Keywords** for each aspect (alternative combinations of search terms used): ▪ *Intervention:* POCUS; hand-held ultrasound; hand-carried echocardiography; focused cardiac ultrasound ▪ *Operators:* nurses; nurse practitioners; non-expert users; novice users; non-physicians ▪ *Clinical Setting:* primary; community; home visits ▪ *Outcomes*: training; diagnostic accuracy; feasibility; acceptability; reliability; clinical utility; clinical impact; cost-effectiveness; cost benefits N.B. see Table 3.2 for keyword alternatives **Filters:** title (to focus search); 10yrs (initially)- shorter could exclude key studies & longer unsuitable due to technological advancements in ultrasound); English-only (absence of translation facilities) **Boolean operators:** "AND" to narrow search in terms of themes; "OR" to broaden in terms of alternative words for the same term **Quotation marks**: for terms (e.g., POCUS) to ensure that the individual words appeared immediately next to each other
3	**Study selection**	Study selection based on the specifics of the research questions and whether the study provided relevant information relating to any of the topics/themes identified in stage 1. If the title suggests relevance, abstract reviewed for further information to decide whether full study should be reviewed.
4	**Recording the data**	Data-recording spreadsheet created and used to record relevant information from each study and group relevant studies together in themes/topics. Table headings: author/year; article type; aims; setting and study population; methods; key results; comments regarding limitations/quality.
5	**Collating, summarising, & reporting results**	Data recording spreadsheet consulted and studies within each group/theme compared/contrasted. Findings for each topic discussed, establishing what is known and identifying gaps.

To structure the research question and facilitate a focused search, the patient/population, intervention, comparison, outcomes (PICO) question format, commonly used in evidence-based clinical practice, was used. This is outlined in Table 3.1.

Table 3.1

The patient/population, intervention, comparison, outcomes (PICO) question

Concept	Description
Patient/Population	Elderly community patients with acute dyspnoea and suspected HF
Intervention	Community nurse-led POCUS
Comparison	Standard patient assessment process (clinical history; physical examination; ECG; BNP testing; routine bloods)
Outcomes	Improve the diagnostic accuracy of the point-of-care assessment and immediate clinical decision making

An overview of the process used to find and select relevant studies is provided in Figure 3.1. The alternative terms/synonyms of the keywords are outlined in Table 3.2. Search terms were limited to the 'title.' Since this was a scoping review articles were not limited to primary data, and review articles and policy documents, for example, were included. The inconsistency in terminology used for 'POCUS' and 'small hand-held devices' within the literature meant that numerous phrases had to be used in the searches to try and ensure relevant papers were not missed (column one of Table 3.2).

Figure 3.1

Overview of scoping review process

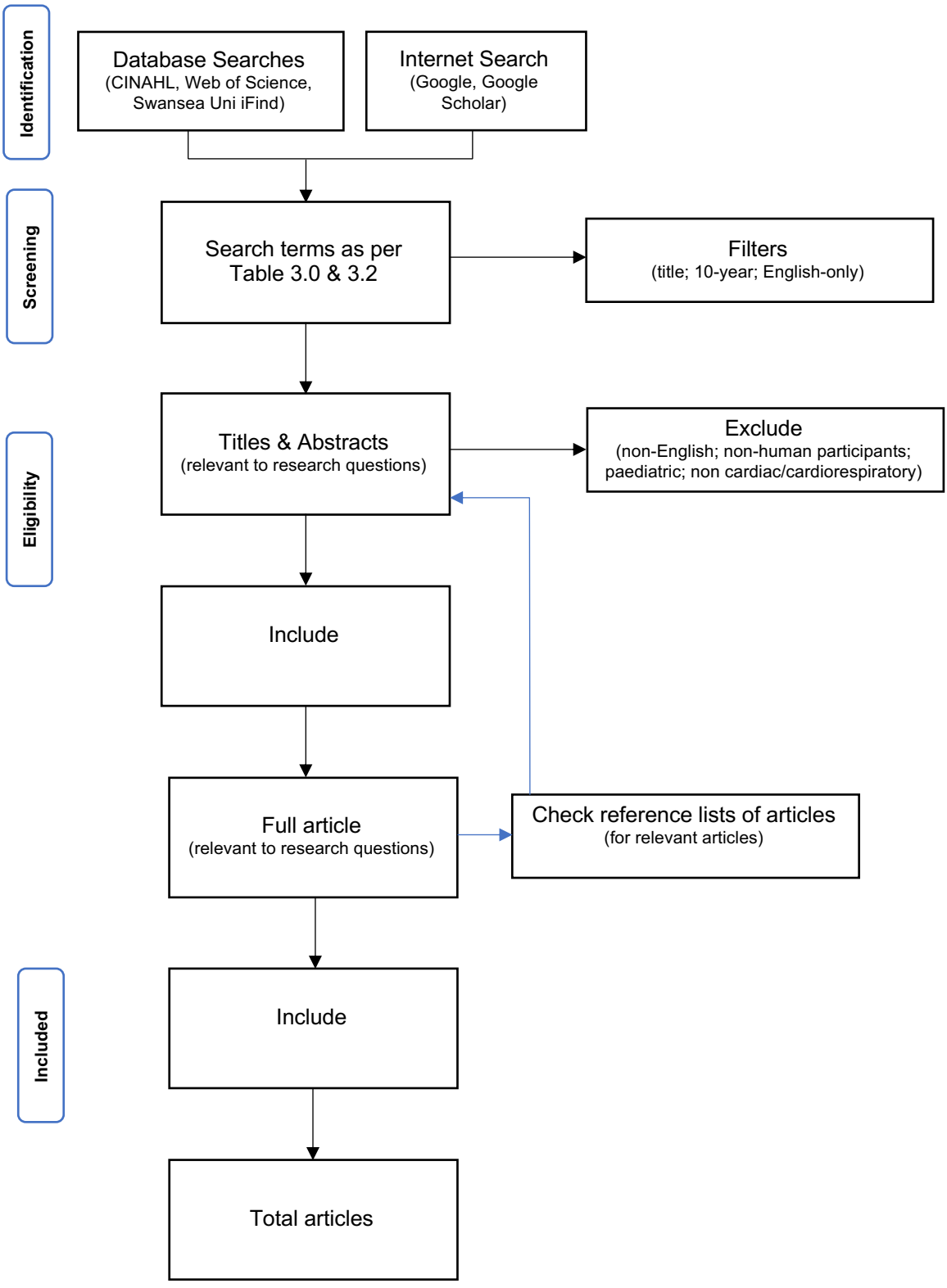


Table 3.2

Keywords used in literature search

POCUS	Novice-use	Use	Clinical Setting/ Context		Training	Accuracy	Clinical Impact	Implementation	
point-of-care ultrasound	Nurse	Examination	heart	home	training	diagnostic accuracy	cost-effectiveness	feasibility	telemedicine
point-of-care	advanced nurse practitioner	physical examination	cardiac	house	teaching	accuracy	cost	barriers	tele-mentored
hand-held ultrasound	novice	adjunct	heart failure	out of hospital	competence	diagnostic yield	clinical impact	challenges	remote
pocket-size ultrasound	non-experts	adding	left ventricular function	community	supervision	repeatability	clinical effectiveness	difficulties	tele-ultrasound
VScans	non-cardiologist	diagnosis	dyspnoea	primary care	education	reliability	outcomes	facilitators	remote expertise
focused ultrasound	non-specialist	extension	breathlessness	bedside	curriculum	reproducibility	clinical utility	acceptability	real-time
focused echocardiogram	non-physicians	screening	fluid imbalance		skills	usefulness	management	attitudes	
hand-held echocardiogram	non-medic		volume status		protocol		treatment	risks	
ultrasound	physicians		congestion				prognosis	benefits	
ultrasound device	residents		fluid status				economic		
hand-carried portable ultrasound	trainee		old						
portable echocardiography	student		elderly						
goal-directed ultrasound									
goal-orientated									

For the initial searches a ten-year limit was applied. The reasoning for this time frame was an attempt to exclude much older model devices (due to technological advancements in device functionality) but not to risk excluding important papers and foundation knowledge. When reference lists of selected studies were reviewed, older studies (>10yrs) were still reviewed if the title appeared appropriate and felt to contribute to foundation knowledge however device specification was considered.

Non-English articles were excluded due to absence of translation facilities. Keeping the clinical context in mind, studies included were limited to adult, human participants. Studies whereby POCUS was conducted outside the cardiorespiratory context were excluded.

Relevant studies were tabulated (stage 4 of Table 3.0) according to author/year; article type; aims; setting and study population; methods; key results; comments regarding limitations/quality). Study findings were then compared and collated (narrative approach) based upon the different aspects of the research questions (themes) to help identify patterns and look for convergence and divergence (and potential reasons why). This was used to establish the current evidence base.

While there was no formal quality assessment, the robustness of the studies/articles were considered. The purpose being to remove irrelevant and/or weak studies, assess validity, and assess usefulness and clinical application. Critical Appraisal Skills Programme (CASP) checklists are varied depending on study type and while these were not formally used the checklists were considered when reading retrieved articles. The following points were contemplated when reviewing articles: journal type (whether peer-reviewed); clarity and relevance of the research question; appropriateness of study design/methods (and level of detail provided); attempts to minimise bias; statistical analysis appropriateness and accuracy; validity of outcome measures; whether data justify conclusions; acknowledgment of limitations; and any conflicts of interest.

When considering the potential methodology for literature searching, practicalities had to be considered. Time, budget, and personnel resources are potential and acknowledged limiting factors of literature reviews. Ideally multiple experienced people would conduct the review however in this setting the conduct of the review was limited to a single individual (myself).

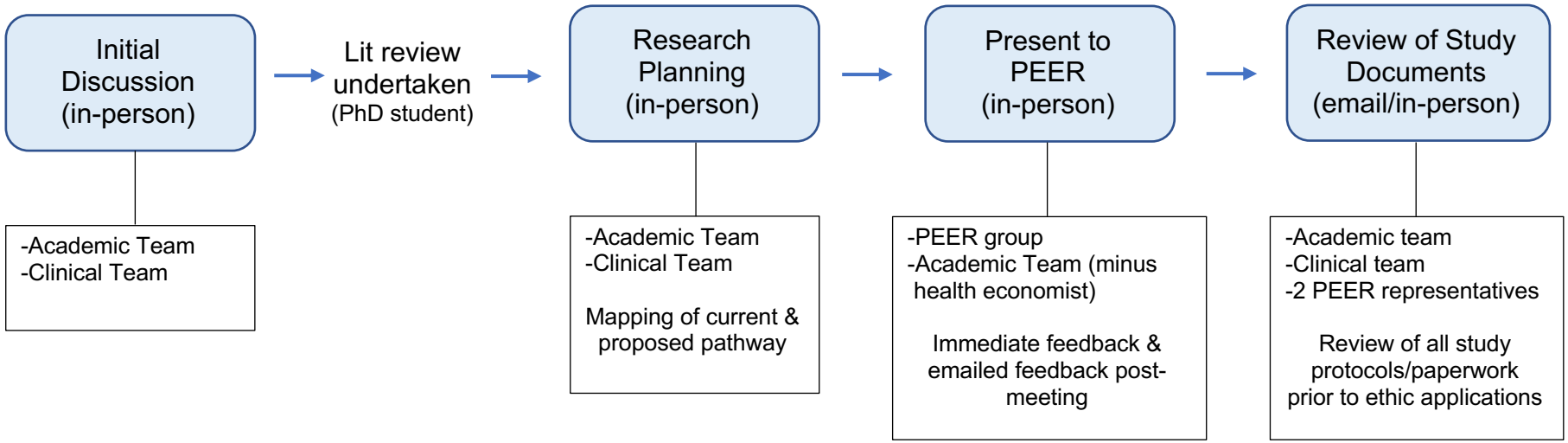
The main literature search as part of the development phase was conducted between July 2018 and December 2018 (refreshed search prior to submission to ensure recent relevant articles had not been missed).

Phase II method: stakeholder engagement and contextual adaptation of the intervention

The research meetings between clinical and academic staff did not draw on theory. The format of the initial meeting was dictated by the clinical organisation leading them and comprised of informal, unstructured discussion to outline ideas. Sessions thereafter focused on generating ideas and building relations, comprising of informal discussion and debate. These sessions were driven by the academic team. There was more structure to sessions in which study protocols and documents had to be reviewed and signed off. Members of the research team were given individual (via email) and group (in-person meetings) opportunity to review documents and provide feedback so that individual and collective opinions were heard. There was more structure to the PEER meeting (detailed below). Figure 3.2 provides an overview of the included team meetings/engagement.

Figure 3.2

Overview of team meetings



Initial academic and clinical team discussions centred on the need for the intervention (confirming scale of the problem/prevalence) and understanding the current pathway. The pathway used by the acute clinical team for patients with suspected HF was mapped, identifying current limitations, identifying aspects that were amenable to change, and considering whether potential benefits were justified. The pathway including POCUS was then mapped. Findings and generalisations from previous research were used to inform the initial assessment of how much improvement the intervention might achieve and potential barriers to implementation. The mapped pathways were discussed with the clinical team (acute clinical team doctor and nurses) and the academic team (clinical scientist/associate professor and I) to gain additional insight and ensure suitability.

To help ensure an adequate breadth in perspectives, the proposed research idea was then presented to the PEER group based at our university. The university PEER group have their own protocol and the panel comprise of public volunteers that have all undergone training. They are all briefed on (and had prior opportunity to review) research projects being presented to them. All PEER meetings have a structured format that is driven by the PEER lead. The PEER group were asked to give their opinions on the proposed intervention. Following this, two members of the group were asked to join the research team to provide input on design and refinement throughout the research project. The importance of including service user and provider perspectives, was discussed, and considered during the design of the pilot studies.

The CFIR (detailed previously in Chapter 2) was reviewed by the research team and discussed. Considering the research questions, each construct was reviewed for relevance so that the assessment of contextual factors could be planned into the feasibility testing.

Results and Discussion- Phase I

Data were collated into themes as follows:

1) Defining POCUS use in the context of this research
2) Impact of POCUS on the diagnostic accuracy of the physical examination
3) Novices use of POCUS
4) POCUS training
5) POCUS protocol for an elderly, dyspnoeic cohort with suspected HF
6) POCUS implementation in the community
7) Clinical- and cost-effectiveness of adding POCUS to the pathway

Theme 1: Defining POCUS use in the context of this research

Application of POCUS has grown rapidly over the last twenty-years (Filopei et al., 2014), particularly since the development of small, hand-held ultrasound devices. POCUS is used by various specialties, in diverse situations, and in numerous clinical scenarios. In general POCUS use can be broadly categorised into diagnostic, procedural and screening applications (Moore & Copel, 2011). The American Society of Echocardiography (ASE) consider the principal use of POCUS is to extend the accuracy of the bedside physical examination (Seward et al., 2002) which was the approach adopted for this research. There is increasing use of ultrasound examinations of the heart as a first-line diagnostic tool at the initial point-of-care in acute settings (Neskovic et al., 2018).

POCUS refers to focused portable ultrasound imaging performed and interpreted at the patient bedside (Tarique et al., 2018). It is a goal orientated, limited ultrasound examination, following a predefined limited protocol, used to answer a specific clinical question (Cardim et al., 2019; Soni et al., 2015). It is intended as an adjunct to, or an extension of, the physical examination providing early, additional information that helps narrow the list of potential diagnoses and guide appropriate management (Adhikari et al., 2014; Ahmed, 2009). Recognising that in the acute setting a comprehensive evaluation is not always necessary, the intention is to gain restricted information to help understand underlying pathophysiology,

narrow the list of potential differential diagnosis, and guide immediate decision-making and/or treatment (Neskovic et al., 2018).

POCUS is intended to extend the standard examination to provide early, additional preliminary information to help formulate the healthcare professional's initial impression (working diagnosis) (Spencer et al., 2013). It provides images of pathology rather than reliance upon clinical signs and symptoms as surrogate markers of disease (Galusko et al., 2018). Unlike the physical examination, POCUS provides digital images that can be stored and retrospectively reviewed and used for comparative and auditing purposes. There are no known adverse effects of ultrasound used at diagnostic imaging intensities, it allows safe, serial assessments (Spencer et al., 2013).

There are a variety of terms that have been used in the current literature to describe a focused ultrasound examination. These include but are not limited to POCUS, focus cardiac ultrasound (FoCUS), hand-carried cardiac ultrasound, and bedside cardiac ultrasound. In the literature (internationally), the terms 'POCUS' and 'FoCUS' are frequently used interchangeably. While FoCUS has been frequently used in the acute setting, I adopted the term 'POCUS' because I found it was the most widely used term in international studies, offering meaningful comparisons with my work. For that reason, the term POCUS is used consistently throughout the thesis and is defined as a pre-defined, abbreviated cardiac and lung ultrasound examination performed by a non-expert intended to enhance the clinical examination, reducing the list of differential diagnoses, and guiding early management decisions in the context of acutely dyspnoeic patients. On reflection, I appreciate that the term FoCUS would be equally valid in this context.

There is a perception that POCUS requires less training and expertise given the abbreviated nature of the scan (Spencer et al., 2001). This may be true if it is implemented using a strict algorithm but it important that the scope of use is clearly understood. POCUS is not a replacement for, nor equivalents to, comprehensive echocardiography. It is different in terms of scanning location, time-constraints, scope of the examination (restricted protocol), the experience of the operator, and the functional capabilities of the equipment (often a hand-held ultrasound device) (Andrus & Dean, 2013; Neskovic et al., 2018). There is the risk of missed or incorrect diagnosis which is why appropriate training is vital to ensure scope of

practice is understood, and potential benefits are maximised and potential risks minimised (Neskovic et al., 2014).

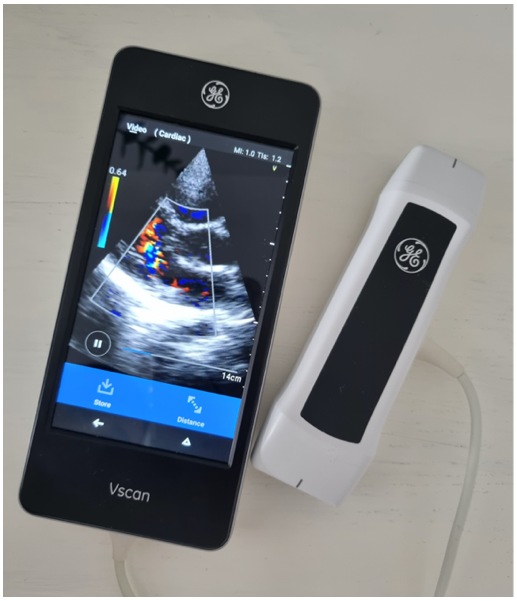
Given the limited scanning protocol and operator experience, TTE is recommended to accurately define and quantify any abnormalities seen on POCUS (Spencer et al., 2013) and if clinical suspicion of cardiovascular disease remains high, comprehensive TTE is still indicated despite a normal POCUS examination (Neskovic et al., 2014). Some pathologies are subtle, difficult to recognise, and may require multiple views and extensive experience to correctly identify and define. It is not only the user that influences results and outcomes but also the processes and support around the user. This does not appear to have been comprehensively considered in prior studies.

Over recent decades, technological advancements have led to the development of smaller, battery-operated hand-held ultrasound devices (Moore & Copel, 2011). The development of these smaller devices with limited imaging capabilities are characterised by simplicity, portability, and affordability (Kobayashi & Kato, 2016). They have generated a new genre in cardiac imaging (Spencer, 2008) and have been termed the biggest advancement in bedside diagnosis since the development of the stethoscope 200-years ago (American Academy of Family Physicians, 2018). The reduced cost and ease of use of handheld ultrasound devices have made them accessible tools to non-traditional ultrasound users.

There are a variety of hand-held ultrasound devices available. Current models typically consist of a probe/transducer and display unit. The transducer performs most of the beam forming, image acquisition, and reconstruction processing, and the smartphone-like display serves as the display screen, often connected to a cloud-based application (Chamsi-Pasha et al., 2017). Generally, hand-held ultrasound devices offer diagnostic quality grey-scale two-dimensional (2D) imaging, colour Doppler imaging in real-time with fixed colour box size and a fixed pulse repetition frequency, and measurements restricted to distances and areas. Images can be obtained via automatic autocycle without the need for an ECG trace and can be stored and transferred to a computer or USB (Sicari et al., 2011). The Vscan Extend from General Electric (GE) Healthcare (GE, Wauwatosa, WI, USA) has been widely used in previous POCUS studies. Figure 3.3 shows a GE Vscan Extend which was the device used for the clinical study detailed in Chapter 5.

Figure 3.3

GE Vscan Extend hand-held ultrasound device



The functional capabilities of hand-held devices are inferior to high-end echocardiography machines and reduced functionalities limit scope of use. Handheld ultrasound devices do not routinely contain spectral Doppler which prevents the assessment of diastolic function, pericardial constriction, pulmonary hypertension, outflow obstruction, and quantification of valvular regurgitation and stenosis severity (Spencer et al., 2013). However, models continue to develop and there are now more manufacturers producing hand-held ultrasound devices with evolving imaging capabilities.

It is important to note that handheld ultrasound devices differ from hand-carried and smaller platform echocardiography machines. Various types of smaller ultrasound devices exist, and various terms have been used to describe these devices. Therefore, when comparing study findings, it is important to note the type of ultrasound device used and its specifications.

Theme 2: Impact of POCUS on the diagnostic accuracy of the physical examination

The decline in physical examination skills (Oliver et al., 2013; Roelandt, 2014), coupled with the evidence that basic POCUS skills can be readily learnt, has resulted in hand-held POCUS being termed 'the advanced stethoscope;' augmenting the physical examination skills of expert and novice operators (Marwick et al., 2014). Rapid image acquisition and interpretation allows healthcare professionals to develop a shorter, more accurate list of differential diagnosis more quickly at the point-of-care assessment (Cardim et al., 2019; Shokoohi et al., 2015; Volpicelli et al., 2013). There was initial concern that introducing technology at the bedside could diminish the rich tradition of examination and further decline physical examination skills (Narula et al., 2018). However, POCUS is not intended as a replacement for physical examination but rather an adjunct. The two should be viewed as providing complementary sets of information that, in combination, support a quicker, more accurate diagnosis (Chamsi-Pasha et al., 2017).

There is an abundance of data showing improved diagnostic accuracy when POCUS is added to the physical examination. Numerous comparative studies have shown superior diagnostic accuracy based on assessment findings using focused hand-held ultrasound compared with physical examination (DeCara et al., 2005; Filipiak-Strzecka et al., 2013; Galderisi et al., 2010; Mehta et al., 2014; Panoulas et al., 2013; Stokke et al., 2014). POCUS, as an adjunct to the physical examination, has been shown to increase diagnostic yield by more than 50% and highlight unsuspected (but clinically relevant) diagnoses in approximately 20% of patients (DeCara et al., 2005; Fukuda et al., 2009; Galderisi et al., 2010; Mjolstad, Snare, et al., 2012; Prinz & Voigt, 2011; Roelandt, 2014; Spencer et al., 2001; Vourvouri et al., 2005). It has been reported that diagnostic influence of adding POCUS may be greater in the elderly (Andersen et al., 2015; Mjolstad, Dalen, et al., 2012), this is likely the result of higher disease prevalence.

In the case of suspected HF, there is widespread support for the inclusion of POCUS in the initial point-of-care assessment. By providing visualisation of the heart, POCUS offers objective information beyond the indirect information obtained by physical examination alone (Roelandt, 2014) thereby increasing the diagnostic yield (Fukuda et al., 2009; Roelandt, 2014). A position statement from the EACVI supports use of hand-held ultrasound for accurate qualitative assessment of ventricular function in hospitals and recommended its use

in extending the physical examination to obtain a tentative diagnosis and support patient management in out-of-hospital settings (Cardim et al., 2019). ASE recommendations similarly support the use of focused scanning to extend the concept of the 'complete physical examination' and allow more rapid assessment of cardiovascular anatomy, function, and physiology (Seward et al., 2002).

While it is clear from the literature that adding POCUS to the physical examination has the potential to improve the diagnostic accuracy of the initial clinical examination, the added diagnostic yield is dependent upon the quality of the images obtained, which is operator, patient, and setting dependent, and the analytical skills of the operator. It is important that these factors are recognised as they will influence the outcome of intervention (POCUS) implementation. While there is some reference to rates of obtainment of diagnostic quality images, contextual influences are not clearly reported in existing clinical POCUS studies.

Theme 3: Novice use of POCUS

The portability, affordability, and ease of use of hand-held ultrasound devices have made them accessible tools for non-traditional ultrasound users (Spencer et al., 2013). While there is now a growing pool of evidence supporting hand-held POCUS use by a wide range of non-traditional ultrasound operators, the marked variability in novices' background experience, POCUS protocols, study settings, and outcome measures makes it difficult to compare training efficacy or draw inferences regarding training requirements for different users.

Numerous studies have reported that POCUS by non-traditional ultrasound operators, such as medical residents, intensivists, GPs, nurses, junior doctors, and medical students, is feasible and diagnostically accurate for a range of pathologies (Andersen et al., 2014; Brennan et al., 2007; Evangelista et al., 2016; Frederiksen et al., 2013; Gustafsson et al., 2015; Henderson et al., 2010; Kobal et al., 2005; Martin et al., 2009; Mjolstad, Snare, et al., 2012; Panoulas et al., 2013; Russell et al., 2015). Training durations have generally ranged from a couple of hours to several days (40hrs) with some including additional image acquisition practice periods (Andersen et al., 2014; Brennan et al., 2007; Croft et al., 2006; DeCara et al., 2005; Kobal et al., 2005; Lucas et al., 2009; López-Palmero et al., 2015; Manasia et al., 2005; Panoulas et al., 2013; Razi et al., 2011).

Given that this research is based upon nurse-led POCUS, the literature search focused on (but was not limited to) studies in that context. Compared with other healthcare professions, far fewer studies have assessed POCUS by nurses. Existing nurse-led POCUS studies have tended to be relatively small and set in either emergency settings with broad scanning protocols, or outpatient settings with narrow focused scanning protocols.

There are well established accreditation processes in emergency medicine and studies have shown assessments by nurses to be accurate following formal accreditation (Bowra et al., 2010; Henderson et al., 2010). However, these centre upon emergency care and are not tailored at using POCUS to determine whether acute dyspnoea is the result of reduced cardiac systolic function. There is limited evidence of LV systolic function assessment by nurses using POCUS in the setting of suspected HF. One small early study showed that following four-hours didactic training, performance of twenty-five supervised scans, and provision of fifty sample cases (to review as desired), nurses (n=3) could accurately detect LVSD in high-risk patients (n=63) in an outpatient diabetic clinic using hand-held ultrasound (Kirkpatrick et al., 2005). Using a threshold of <40% to indicate LVSD, the nurses detected all three cases of LVSD (100% sensitivity) and over-reported LVSD in ten patients (specificity 0.83 and positive predictive value 0.23). While this provides promising data that after relatively brief training nurses can be taught to accurately detect LVSD, the small sample size and low prevalence of confirmed pathology must be recognised when considering the generalisability of the findings.

A larger number of predominantly small, single-centre studies have assessed use of nurse-led POCUS to assess for signs of congestion. This is relevant in those presenting with acute dyspnoea, and potentially decompensated HF, as it indicates that HF may be causing pulmonary congestion. There is substantial evidence that the assessment of volume status via POCUS is significantly more accurate, with less inter-observer variability, than other tools such as medical history, physical examination, and laboratory testing and can be used to guide therapy (Gundersen et al., 2016).

With training ranging from thirty-minutes to eight-hours, studies have shown substantial nurse agreement with reference interpretation and high accuracy to detect ultrasound signs of congestion (Brunhoeber et al., 2018; De Lorenzo & Holbrook-Emmons, 2014; Graven et al., 2015; Gundersen et al., 2016; Gustafsson et al., 2015; Steinwandel et al., 2018). However,

the contexts of use are variable (HF clinics, post-cardiac surgery, emergency care, renal clinics) with differences in scanning protocols. The assessment of volume status in some studies were limited to inferior vena cava (IVC) size and/or collapsibility while others included and/or pericardial effusion, pleural effusion (PLE), and pulmonary congestion (B-lines). Focusing on nurse studies in the context of HF, there is evidence that HF nurses in outpatient settings can achieve substantial agreement with reference test and high accuracy measures (sensitivity and specificity ≥0.8) for PLE and pulmonary congestion (B-lines) using hand-held ultrasound (Gundersen et al., 2016; Gustafsson et al., 2015). However, given differences in POCUS protocols, the nurses' prior ultrasound experience, and the training (four hours to a month) it is difficult to directly compare outcomes.

To summarise, numerous studies have shown nurse-led POCUS to be feasible and accurate in certain contexts and for assessments of certain pathology. However, there is marked heterogenicity in study context, nurse experience, scanning and reporting protocols, and the nature and duration of POCUS training. This makes it difficult to draw any definitive conclusions or generalise findings to new contexts. To the best of my knowledge, there are no data available relating to the use of POCUS by non-specialist community nurses to assess LV systolic function and volume status in those with acute dyspnoea and suspected HF in the domiciliary setting.

Theme 4: POCUS training

It is widely accepted that adequate POCUS training is essential to ensure safe and effective use of POCUS. The easier operation of hand-held ultrasound devices does not remove the need for adequate training to acquire and interpret images (Spencer et al., 2013). Inadequate training poses the potential risk of misuse, resulting in misdiagnosis, duplication of tests, increased care costs and worse outcomes (Blanco & Volpicelli, 2016). Competence in POCUS requires image acquisition and interpretative skills, as well as application of findings to the clinical context (Cartier et al., 2014; Todsen et al., 2016). Trainees must understand clinical applications of POCUS relevant to their scope of practice, and the potential benefits and limitations of POCUS use (Tarique et al., 2018)

With the expansion of POCUS use in different settings and by different users, comes the issue of differing training needs. The current literature is inconclusive regarding training and competence requirements for non-experts. It is unclear if, and how, training needs vary for different types of healthcare professionals and for different clinical purposes. This has resulted in the literature being highly heterogenous in terms of the training methods adopted.

Since this research seeks to assess POCUS use by nurses, Table 3.3 provides examples of previous POCUS training programmes utilised in nurse POCUS studies. Given the heterogenicity in the nurses' clinical background and imaging goals, the accuracy measures are variable. This prevents use of the measures to compare training adequacy. I was unable to find any evidence relating to POCUS training for non-specialist community nurses.

Table 3.3

Example POCUS training programmes for ultrasound novice users

Study	User	Prior Training	Training	Imaging Goals	Accuracy
Tulleken et al. (2019)	ICU Nurse (n=8)	No	8hrs didactic & hands-on (two 4hr sessions)	Lung (BLUE protocol) & cardiac (LVOT VTI)	123 scans. 100% full proficiency with median 13 exams in 21wks for LUS & median 13 exams in 26wks for cardiac
Brunhoeber et al. (2018)	ICU nurse (n=8)	Variable	30min project information session	Fluid status: IVC	50 patients. 86% diagnostic images. 81% interpretation accuracy.
Gustafsson et al. (2015)	HF nurse (n=4)	No	4hrs didactic & hands-on	Fluid status: B-lines, PLE, IVC diameter	104 patients. B-lines (n=29): sensitivity 0.79 & specificity 0.91. PLE (n=9): sensitivity 0.88 & specificity 0.93. IVC (n=71): sensitivity 0.64 & specificity 0.51. Cardiologist agreement: B-lines κ=0.71; PLE κ=0.66; IVC κ=0.39.
Graven et al. (2015)	Cardiac Nurse (n=2)	No	3mth at bedside (education & hands-on) & independent scan (mean 60)	Pericardial effusion & PLE	59 patients. ≥Moderate pericardial effusion (n=36): sensitivity 0.91 & specificity 0.56. ≥Moderate PLE (n=96): sensitivity 0.98 & specificity 0.70.
Dalen et al. (2015)	HF nurse (n=2)	Yes	1mth, performed 15-20 exams	Fluid status: PLE & IVC	62 patients. 100% diagnostic images. Correlation with reference all r ≥0.79. Any PLE (39 of 124): sensitivity 0.92 & specificity 0.99. High RAP (n=18): sensitivity 0.72 & specificity 0.98. Low RAP (n=22): sensitivity 0.64 & specificity 0.95.
Henderson et al. (2010)	Emergency nurse (n=5)	None specified	16hr didactic & hands on plus 1yr supervised practice	Cardiac function & pericardial fluid (& abdominal, pelvic, renal, aortic, biliary, obstetric)	229 ultrasound exams. 86% diagnostic images. Correctly identified disease pathology in 93% & absence of pathology in 98%.
Kirkpatrick et al. (2005)	Diabetic nurse (n=3)	None specified	4hrs, 25 scans, & CD with 50 video cases	LVSD	63 patients. LVSD (n=3) sensitivity 1.0 (negative predictive value 1.0) & specificity 0.83 (positive predictive value 0.23). Excluding AF cases, specificity 0.87.

Note BLUE= Bedside Lung Ultrasound in Emergency; LVOT VTI= LV outflow tract velocity time integral; LUS= lung ultrasound; κ= kappa (Cohen); r= correlation coefficient; RAP= right atrial pressure; AF= atrial fibrillation

Several professional organisations and societies recommend standardised training (American College of Emergency Physicians, 2009; Labovitz et al., 2010; Physicians, 2009; Sicari et al., 2011). Guidance recommends training in common point-of-care echocardiography applications; competence assessment as part of the credentialing process; and continued education and quality improvement initiatives (including didactic training performance assessment) (American College of Emergency Physicians, 2009; Labovitz et al., 2010). However, these guidance statements lack specific details.

Over the last decade, national and professional societies have developed POCUS training programmes and there are specialty specific accreditation processes, such as in emergency care. In 2016, the Society for Acute Medicine published the first POCUS curriculum within the UK designed for physicians called Focused Acute Medicine Ultrasound (FAMUS). In the UK, the Intensive Care Society developed Focused Intensive Care Echocardiography (FICE) and Core Ultrasound in Intensive Care (CUSIC) covering focused echocardiography and POCUS, respectively. However, these are focused on emergency and critical care and assessments are not limited to assessing heart function (and volume status) which is the goal for this research. There is no established consensus statement on POCUS training, competency, and accreditation requirements for non-traditional ultrasound users that is applicable across specialties.

It is widely agreed that competence should be formally assessed after completion of training to determine the effectiveness of training (Moore & Copel, 2011; Pelliccia et al., 2012; Tarique et al., 2018) and that the aims of any POCUS training programme should be clearly defined so that the attainment of competence can be assessed against these. However, competence requirements, much like training, vary depending on the application and setting of clinical use (Roelandt, 2014). There are currently no objective metrics or validated tools to determine competence in POCUS (Neskovic et al., 2014; Spencer et al., 2013). There is a lack of high-quality studies looking at determining competence thresholds for users to practise independently (Galusko et al., 2018).

When novice-user experience, and clinical context are highly variable it appears logical to assume that learning needs will similarly be variable. Therefore, it is unlikely that a strictly predefined training programme would be appropriate for all novice-users. Current EACVI and International Society of Cardiovascular Ultrasound (ISCU) recommendations recognise

this variation in trainees' learning needs and the need for individualising training accordingly (Neskovic et al., 2014; Pelliccia et al., 2012). However, how this should be executed and managed is less clear.

In summary, the need for POCUS training is well reported however how training should be delivered in a new context is less clear. Despite multiple studies demonstrating acceptable novice-user accuracy from which one could surmise that the training protocol used was adequate, the marked heterogeneity amongst studies, in terms of trainees' background experience, study settings, scanning and analysis protocols, and competence requirements, makes direct comparison of their success challenging. Given the absence of prior studies focusing on training non-specialist nurses to use POCUS in the context of elderly community patients with acute dyspnoea and suspected HF, there does not appear to be an existing training programme that is suitable for adoption for this research. Instead, it appears more appropriate to use the existing literature to adapt a context-specific bespoke training programme.

Theme 5: POCUS protocol for an elderly, dyspnoeic cohort with suspected HF

Having established the potential for POCUS to improve the diagnostic yield of the physical examination, there was a need to examine the scope of the POCUS protocol given the proposed clinical context, functionalities of hand-held ultrasound devices, and the proposed users (community nurses) experience. It is widely agreed that the scope of POCUS examination should reflect the clinical question; scanning what is necessary to allow confirmation or exclusion of the disease in question (Spencer et al., 2013). In the proposed setting, POCUS primarily seeks to confirm/exclude LVSD and/or pulmonary congestion as the cause of the patients' new/worsening dyspnoea at the initial point-of-care. If confirmed, these are the patients who are most likely to benefit from early introduction of HF medication, such as ACE inhibitors, beta blockers, and intravenous diuretics (pulmonary congestion).

Cardiac imaging is the most widely used modality and provides direct visualisation of systolic function (and ejection fraction) (Jones et al., 2003; Labovitz et al., 2010; Manasia et

al., 2005). Assessment of LV systolic function is the most established use of cardiac POCUS. It allows direct visual assessment of the LV enabling LVSD to be readily confirmed or excluded. LVSD is often missed by physical examination but is reliably detectable with POCUS (Galusko et al., 2018; Spencer et al., 2013). In acutely dyspnoeic patients, POCUS can also provide information relating to valve regurgitation and volume overload thereby aiding a diagnosis of acute decompensated HF and guiding optimal initial treatment (Labovitz et al., 2010; Vourvouri et al., 2003).

In those with dyspnoea and suspected LVSD, knowledge of volume status and whether pulmonary congestion is present is clinically important in terms of patient management. Timely knowledge of loading conditions is essential to help guide appropriate medical therapy (Blehar et al., 2009; Goonewardena et al., 2008; Mirabel et al., 2015; Tchernodrinski et al., 2015; Yavaşi et al., 2014). Ultrasound imaging of the IVC and lungs allows estimation of intravascular volume status (Blehar et al., 2009; Nagdev et al., 2010; Stawicki et al., 2009) and detection of interstitial oedema and pleural effusions (Agricola et al., 2005; Jambrik et al., 2004; Lichtenstein & Meziere, 1998; Lichtenstein et al., 1997; Picano et al., 2006).

Knowledge of right atrial pressure is critical to confirm haemodynamic congestion (De Vecchis et al., 2016) and ultrasound imaging of IVC size and collapsibility offers a simple, non-invasive, sensitive, and accurate estimate (Agricola et al., 2005; Blehar et al., 2009; Kataoka & Takada, 2000; Nagdev et al., 2010). IVC dilation and reduced respiratory collapse of the distal tract of the IVC have been identified as reliable indicators of haemodynamic congestion (De Vecchis et al., 2016). Reduced respiratory variation in IVC size reflects elevated central venous pressure which has a high sensitivity for detecting acute decompensated HF. However, this finding is not specific for HF. In a study seeking to test the screening potential of a hand-caried ultrasound for the detection of LVSD (n=88), IVC collapse <50% had low sensitivity (26%) and positive predictive value (38%) for the detection of LVSD (Vourvouri et al., 2003). Elevated central venous pressure can be seen in other conditions, such as cardiac tamponade, pulmonary embolism, valvular heart disease, obesity, and renal failure (Blehar et al., 2009), therefore the finding must be interpreted within the clinical context.

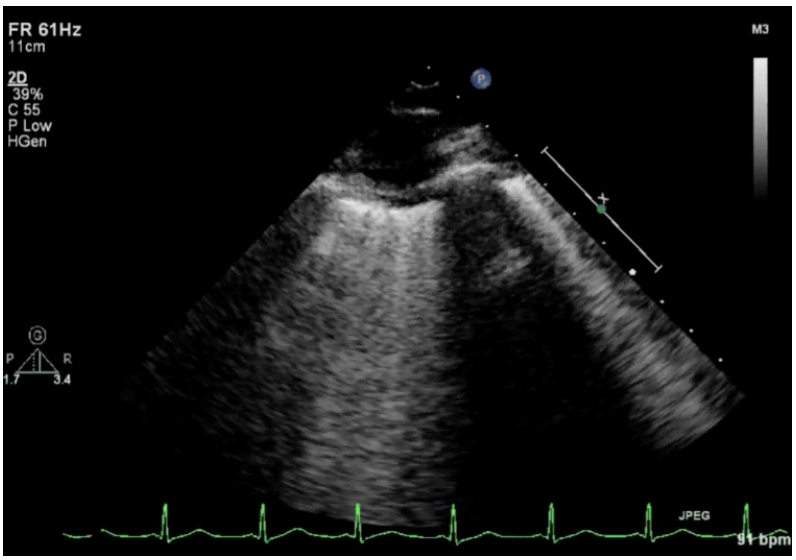
Lung ultrasound (LUS), while a newer and less widely used technique than cardiac ultrasound, is rapidly becoming established as a useful tool in distinguishing cardiac and

pulmonary causes of dyspnoea (Gargani, 2011; Gargani & Volpicelli, 2014; Lichtenstein & Meziere, 2008). Multiple large, observational studies have shown that LUS improves diagnostic accuracy over clinical assessment and chest x-ray (Pivetta et al., 2015; Russell et al., 2015). A large, multicentre, prospective cohort study (n=1005) in seven Italian emergency departments found a LUS-based approach was more accurate (sensitivity 0.97, specificity 0.97) than the initial clinical workup (sensitivity 0.85, specificity 0.90); chest x-ray (sensitivity 0.70, specificity 0.82); and natriuretic peptides (sensitivity 0.85, specificity 0.62) in differentiating acute decompensated HF from noncardiogenic dyspnoea (Pivetta et al., 2015). Several imaging societies now recognise the role of LUS alongside echocardiography in the setting of suspected acute HF (Lancellotti et al., 2015; Mebazaa et al., 2015; Price et al., 2017).

On LUS, extravascular lung water and pulmonary oedema may be suggested by the presence of multiple, diffuse B-lines (Agricola et al., 2005; Cibinel et al., 2012; Lichtenstein & Meziere, 1998; Liteplo et al., 2009; Volpicelli, Cararnello, et al., 2008; Xirouchaki et al., 2011). B-lines are discrete laser-like vertical hyperechoic reverberation artefacts that arise from the pleural line, extend to the bottom of the screen without fading, and move synchronously with lung sliding (Volpicelli et al., 2012) (Figure 3.4).

Figure 3.4

Still image of a clip showing B-line artefacts on ultrasound



Identification of B-lines allows immediate differentiation between COPD and congestive HF, enabling more accurate and efficient treatment at the initial point-of-care (Lichtenstein, 2009; Liteplo et al., 2009; Picano et al., 2010; Volpicelli, Caramello, et al., 2008; Volpicelli et al., 2012). Compared with other forms of ultrasound, LUS is associated with high intra- and inter-operator reproducibility, ease of learning, and short exam duration (less than five-minutes) making it an advantageous point-of-care tool (Frederiksen et al., 2013; Platz & Solomon, 2012). In the setting of suspected HF, LUS is useful to examine for evidence of elevated left atrium (LA) pressure from cardiac decompensation presenting as pulmonary oedema or pleural effusions (Kimura et al., 2015).

B-lines can be detected early in the decompensated state, before symptoms develop, and therefore can be an early indicator of significant deterioration (Bedetti et al., 2006). In patients with impending acute HF syndrome, there is often a relatively long incubation period, of days and weeks, during which there is a gradual accumulation of water within the lungs but outside the pulmonary vasculature (extravascular lung water) (Picano & Pellikka, 2016). In patients with acute HF, pulmonary congestion is an almost universal finding and detection and treatment of this before it is clinically evident can prevent hospitalisations and HF progression (Picano & Pellikka, 2016).

However, like many diagnostic tools, LUS suffers from a lack of specificity (Gargani & Volpicelli, 2014). Multiple diffuse bilateral B-lines have a high sensitivity for cardiogenic pulmonary oedema, but this finding is non-specific (Copetti et al., 2008; Gargani, 2011; Gargani & Volpicelli, 2014; Picano et al., 2010; Russell et al., 2015). Bilateral B-lines are also associated, but not limited to, noncardiogenic pulmonary oedema, bilateral pneumonia, pulmonary fibrosis, acute lung injury, and acute respiratory disease syndrome (Copetti et al., 2008; Gargani, 2011; Picano et al., 2010). Oedematous (wet) B-lines cannot be readily distinguished from fibrotic (dry) B-lines (Lichtenstein et al., 1997; Picano et al., 2006; Volpicelli et al., 2012). To improve specificity, B-line assessment should be interpreted within the clinical context and integrated with other findings, such as cardiac ultrasound; it has been proposed that the clinical condition of the patient is the most important feature that aids LUS findings and patient management (Gargani & Volpicelli, 2014).

To summarise, cardiac, IVC, and lung ultrasound are readily available and widely validated ultrasound modalities. Collectively they allow identification of reduced cardiac

function (LVSD) and venous congestion. Unlike other biomarkers, POCUS can allow direct visualisation of the underlying cause of symptoms, allowing immediate initiation of appropriate interventions and avoidance of contraindicated therapies (Price et al., 2006). In a prospective observational cohort study, Anderson et al. assessed the diagnostic accuracy of cardiac, IVC and lung ultrasound (in isolation and combined) in diagnosing acute decompensated HF among acutely dyspnoeic patients (n=101) in the emergency department (2013). In isolation each modality lacked sufficient specificity for a definitive diagnosis but combining the three modalities gave a specificity of 1.0. They found no significant difference between using two (of the three) modalities and the three different combinations (specificity range 0.93-0.98) and proposed that in cases of, for example difficult cardiac windows, B-lines and IVC could be used as an alternative because the pleura is a superficial structure that is easier to visualise than the heart. This multi-modality POCUS approach is supported by several European and American imaging recommendations (Gheorghiade et al., 2010; Lancellotti et al., 2015; Mebazaa et al., 2015; Neskovic et al., 2018; Sicari et al., 2011).

Could an existing POCUS protocol be applied to the proposed context?

Multiple point-of-care, focused scanning protocols exist, many of which are specific to trainees and/or clinical settings. Two widely used, standardised focused echocardiography protocols include the Focus Assessed Transthoracic Echo (FATE) and Focus Cardiac Ultrasound (FoCUS). These are widely utilised and have recognised training and competency requirements. FoCUS includes parasternal long axis (PLAX), parasternal short axis (PSAX), apical four chamber (A4C), subcostal four chamber (S4C) and subcostal IVC (S.IVC) views and is focused at assessing global LV systolic function and size; global right ventricular systolic function and size; pericardial effusion; and intravascular volume assessment (Neskovic et al., 2018). However, the clinical questions are broader than are required in the proposed setting. While LUS is not included in the list of views, EACVI guidance recognises that cardiovascular diseases are often associated with pulmonary abnormalities/manifestations and suggests that LUS (limited to the recognition of pleural effusions and interstitial syndrome) should be performed in each case as an integral part of the FoCUS examination (Neskovic et al., 2018). The FATE protocol suggests a four-point approach including the S4C; A4C; PLAX and PSAX; and pleural scanning. It has been

shown to provide a systematic, focused approach that can be easily learnt (Holm et al., 2012). It intends to assess cardiac function (contractility, chamber size, and hypertrophy); valvular dysfunction; cardiac tamponade; and pericardial and pleural effusions (Nagre, 2019). However, scanning does not include B-line assessment for pulmonary oedema.

In April 2018, the British Society of Echocardiography (BSE) launched Level I accreditation for the rapid bedside assessment to support early identification of critical cardiac pathology that may require emergency treatment. It comprises seventeen images and includes the standard PLAX, PSAX (all levels), A4C, apical five chamber, and subcostal views (four chamber and IVC) (Hindocha et al., 2020). While this provides an established, standardised protocol (with a formalised accreditation process), it is more comprehensive (and therefore requires greater user experience) than that required for our targeted setting whereby POCUS is intended to confirm or exclude LVSD (and/or pulmonary congestion) as the cause of acute dyspnoea. While it includes assessment of global function and detection of gross pathology, its focus is not limited to suspected LVSD. It includes additional views, such as multiple level PSAX views, and measures which are not necessary in our acute setting. The protocol is not intended for use with a hand-held device as it includes M-mode assessments (tricuspid annular plane systolic excursion and IVC variation), and guidance includes use of ECG monitoring. LUS is also not included in the BSE Level 1 minimum dataset.

Within the POCUS research literature, combined cardiac and lung scanning protocols have been examined; those which include cardiac function and/or signs of congestion are outlined in Table 3.4.

Table 3.4

Current POCUS heart and lung scanning protocols

Protocol	Type	Views included	Purpose/Use	Reported Accuracy	Comments
BLUE (Lichtenstein & Meziere, 2008)	LUS	6- bilateral upper point; lower point; PLAPS.	Diagnosing acute respiratory failure. Assess: artifacts (A- & B-lines); lung sliding; alveolar consolidation &/or PLE.	N= 260. 91% correct diagnosis. Pulmonary oedema (in 62) sensitivity 0.97 & specificity 0.95	No cardiac views.
CLUE (Kimura et al., 2011)	Cardiac LUS	4 points.	Screening for LVSD; LA enlargement; IVC plethora; B-lines.	N=1016. LVSD (in 23%) sensitivity 0.69, specificity 0.91, accuracy 0.89. LA dilation (in 91%) sensitivity 0.75, specificity 0.72, accuracy 0.73.	Cardiac & lung. No PLE. LV function PLAX only. Accuracy measures for IVC & B-lines not given (just prognostic value).
LCI (Kajimoto et al., 2012)	Cardiac LUS	Standard cardiac & 8 lung (bilateral- upper anterior, lower anterior, lateral)	Differentiating acute HF from primary pulmonary disease in acute dyspnoea. Assess**:** B-lines; LV systolic function; mitral & tricuspid regurgitation; IVC.	N= 90. Differentiating acute HF (n=53) from pulmonary disease, sensitivity 0.94 & specificity 0.92	Cardiac & lung. Cardiac views- more extensive than required.
LuCUS (Russell et al., 2015)	Cardiac LUS	12 points- 4 anterior/lateral lung; PLAX; PSAX; S.IVC; A4C; midaxillary extended FAST (bilat).	Diagnosing ADHF in dyspnoeic patient in emergency department. Assess B-lines, ejection fraction, IVC, PLE, diastolic function	N= 99. 93% agreement. ADHF (in 36%) sensitivity & specificity 0.83	Cardiac & lung. Not limited to hand-held devices- includes diastolic function.
SEARCH8Es (Ahn et al., 2017)	Cardiac LUS	11 (or 13) points- bilateral upper & lower anterior; bilateral PLAPS; IVC; abdominal aorta; PLAX; A4C; S4C (if chest pain, PSAX & suprasternal).	Use in dyspnoea, chest pain, or symptomatic hypotension. Assess pulmonary embolism; airway disease; pneumothorax; PLE; pneumonia; acute pulmonary oedema (LVSD); ARDS or pulmonary oedema (diastolic HF); pericardial effusion; ACS; AA/AD; hypovolaemic shock; septic shock.	N= 308. 89% overall concordance. Overall sensitivity 0.91 & specificity 0.99. Acute pulmonary oedema (n=70) sensitivity 0.94, specificity 0.98. Significant PLE (n=14) sensitivity 1.0, specificity 0.99. Pericardial effusion or tamponade (n=2) sensitivity, specificity 1.0.	Cardiac & lung. Not limited to dyspnoea (also chest pain & hypotension)

Note: BLUE= Bedside Lung Ultrasound in Emergency; PLAPS= PosteroLateral Alveolar &/or Pleural Syndrome; CLUE= Cardiopulmonary Limited Ultrasound Examination; LCI= Lung-Cardiac-IVC; SEARCH8Es= Sonographic Evaluation of Aetiology for Respiratory difficulty, Chest pain, and/or Hypotension; ADHF= Acute decompensated HF; ARDS= Acute Respiratory Distress Syndrome; ACS= Acute coronary syndrome; AA= Aortic aneurysm; AD= Aortic dissection

In the setting of dyspnoea and suspected HF, the two most relevant protocols appear to be the Cardiac Limited Ultrasound Examination (CLUE) (Kimura et al., 2015) and the Lung-Cardiac-IVC (LCI) protocol (Kajimoto et al., 2012). The CLUE protocol focuses on heart function and volume status and includes assessing for LVSD; LA dilation; B-lines; pericardial and pleural effusions; right ventricle (RV) enlargement; and IVC plethora (Kimura et al., 2015). It was created to comply with practical requirements; needing to be completed within a few minutes, routinely applied, and requiring only basic skills and equipment to enable training that could be broadly incorporated into physical examination training.

A potential limitation of the CLUE protocol for this context is that it fails to include assessments of gross valve (aortic and mitral) disease or pleural effusions which is relevant in our proposed context. However, I believe the main limitation is that it proposes assessing global LV systolic function from the PLAX view only. Despite reasonable accuracy (89%) for detecting LVSD, this method of assessing global LV systolic function relies on the visualisation of the basal-to-mid segments of only two LV walls (anterior septum and inferolateral). To provide an accurate estimation of global systolic function visualisation of all LV walls is preferential because significantly reduced function of any wall segment(s) will impact upon global systolic function. In elderly populations, where prevalence of coronary artery disease is higher (and therefore regional wall motion abnormalities more likely), I believe scanning from multiple views is even more pertinent to ensure accurate assessments of global systolic function.

A previous nurse POCUS study validated the assessment of LV systolic function from the parasternal window only (PLAX and PSAX) by having a level 2 trained echocardiographer assess function in 100 randomly chosen echocardiograms from only the parasternal views and then, several weeks later, using all views (Kirkpatrick et al., 2005). Overall accuracy of assessing function from the parasternal window was reported at 88% compared with analyses using all views. Therefore, in the hands of an experienced operator 12% of interpretations were inaccurate even for a present/absent interpretation using an ejection fraction <40% as the threshold for LVSD. In terms of the nurses' results, significant LVSD (using only the parasternal view) was missed in 1% of patients and overreported in 16%. Overinterpretation is common in novices and having only one imaging window on which to base their analyses

may heighten this. However, low prevalence of pathology (n=3) makes it difficult to assess the accuracy of pathology detection.

The Lung-Cardiac-IVC (LCI) protocol includes lung, cardiac, and IVC ultrasound and is intended to differentiate acute HF syndromes from primary pulmonary disease in those presenting with acute dyspnoea (Kajimoto et al., 2012). This protocol has been found to be highly sensitive and specific (0.94 and 0.92 respectively) for diagnosing acute decompensated HF when performed by cardiologists and more accurate than LUS alone. Anderson et al. later adopted a similar protocol but with limited cardiac views (four) and found a specificity of 1.0 for diagnosing acute decompensated HF (2013). However, the LCI protocol includes standard cardiac views and eight lung zones. In the POCUS setting where experience, machine functionalities, and time are often limited, use of all standard cardiac views is often impractical.

Despite the acceptable results found in several of the protocols outlined, none of the existing protocols (in my opinion) specifically seek to assess cardiac function and volume status in a suitably focused, yet adequately comprehensive way that is suitable for novice operators using a hand-held ultrasound device at the initial point-of-care. Therefore, rather than adopt one of these protocols for this research it would appear more appropriate to adopt parts of different protocols to inform and guide the design of a study-specific scanning protocol that considers: the limited functional capabilities of the hand-held GE Vscan Extend ultrasound device; the image acquisition and interpretive skills of the nurses; and the abnormalities that require assessment given the proposed clinical context. Scanning time is also a consideration. POCUS is intended to be timely; providing a brief targeted scan used as an adjunct to the physical examination to assess cardiac function and volume status. The intention is not to provide a comprehensive evaluation.

Theme 6: POCUS implementation in the community

The clinical utility of POCUS implementation depends heavily on operator competence. However, contextual factors should also be considered as these can influence clinical implementation success. The current POCUS literature lacks recognition of contextual influences. Despite MRC guidelines advocating comprehensive approaches to intervention

development, evaluation and implementation, the POCUS literature is dominated by diagnostic accuracy studies. Some show reductions in TTE referrals when the POCUS examination is negative (and propose potential cost savings associated with this). However, they fail to report upon the complexities of potential implementation and contextual influences. There is a lack of evidence about ease or acceptability of implementation and potential barriers/facilitators to implementation.

Implementation science recognises the importance of context, and implementation frameworks, such as CFIR (Chapter 2), are intended to help researchers explore the implementation process and understand why an intervention has the effect it does within a particular context.

Optimal model of implementation

The application of POCUS will vary depending upon the clinical situation. As mentioned previously, there is limited evidence on the use of hand-held POCUS by novices in community care. Of those identified, POCUS use is limited to primary care, GP settings, rather than the domiciliary setting. For this body of research, POCUS is intended to be implemented in the domiciliary setting by non-specialist community nurses. From reviewing the current literature, I cannot find evidence of prior studies that explore the use of POCUS in the proposed setting.

Methods of optimal POCUS implementation remain unclear. The evidence is mixed regarding whether fully-novice led POCUS is appropriate or whether expert analytical support is required and, if so, when, and how this should be provided. Advances in telemedicine offer access to remote expertise for image review and real-time guidance. Remote expertise could significantly improve access to expert healthcare providers and reduce the time needed to train novices.

In the large primary care study by Evangelista et al. (2016) ultrasound-novice GP (n=14) interpretation, following four days training (twenty-eight hours), was compared with remote expert interpretation to assess the best model of implementation. Focusing on LVSD (n=51) (target pathology for this research project), the GPs were unable to achieve adequate

diagnostic accuracy to reliably detect LVSD (sensitivity 0.50, specificity 0.93, agreement with expert Kappa =0.51) and remote expert review significantly improved sensitivity (0.90) and reliability (inter-rater agreement of K= 0.72). They proposed that expert analytical input was required to ensure adequate accuracy (and potential cost savings by reducing down-stream testing). However, in numerous other studies, novice-led POCUS image acquisition and interpretation has been accurate and reliable (Andersen et al., 2014; Dalen et al., 2015; Filopei et al., 2014; López-Palmero et al., 2015; Razi et al., 2011). Between study variability in accuracy may be dependent on the extent of POCUS protocol (visual, normal–mild or moderate–severe assessment of LVSD, LVH, LA dilation; valve abnormalities; aortic root size; and pericardial effusion), and training delivery, duration, and assessment. When considering potential models of implementation, the time to train needs to be considered alongside the feasibility and timing of remote expert-analysis (and associated costs).

There is some evidence, albeit in different contexts and small studies, that adding real-time remote expert guidance during novice-acquisition and analysis provides diagnostic quality images, high diagnostic accuracy for LVSD, and shortens novice training time (≤1-hour device orientation) (Mai et al., 2013; Olivieri et al., 2020). However, the focus of these studies is on comparing concordance between remote tele-mentored ultrasound performed by novices and POCUS performed by experts. They do not assess fully novice-led POCUS examinations to those in which expert guidance was given.

In a recent systematic review aimed at summarising the current uses of real-time remote tele-mentored echocardiography to diagnose and manage cardiovascular dysfunction, twelve of fifteen relevant articles demonstrated the feasibility of tele-mentoring novice sonographers to obtain clinically useful images (Salerno et al., 2020). However, there was substantial heterogeneity amongst studies in terms of the types of experts and novices, the type of training (range 20-60mins), the type of telemedicine technology, and the outcomes of interest. The review acknowledged that most articles were small studies or case reports and highlighted the need for large scale studies to establish the use of real-time remote tele-mentored echocardiography in different clinical settings and to assess trade-offs between time and cost, and superior data transfer. In out-of-hospital settings the infrastructure and resources required to implement telemedicine-based models must be considered.

While studies compare the accuracy of different models, they do not discuss expert availability or comprehensively evaluate and compare the clinical- and cost-effectiveness of alternative models. There is currently insufficient comparative information comparing methods of POCUS implementation and a lack of information regarding the large-scale integration of remote expert support in primary care (Singh et al., 2013). Therefore, it remains unclear what the most effective model of POCUS implementation may be in community care and whether remote expertise is necessary and if so, in what format.

Where should POCUS be implemented in the pathway?

There is no evidence examining the optimal timing of POCUS within the existing community pathway for patients with suspected HF, or whether its addition removes the need for any other current tests. Given the evidence from acute care settings, it seems logical that POCUS should be placed as early in the pathway as possible and as an adjunct to the physical examination. It has the potential to influence first-line management decisions, and (in the right hands) is more specific for detecting LVSD than the other tests included in the standard assessment for HF (physical examination, ECG, and BNP testing).

A large community-based study sought to assess the screening characteristics and cost-effectiveness of incorporating POCUS for the purpose of screening for LVSD in community subjects (Galasko et al., 2006). The study population was not focused on those with suspected HF, instead it included general public participants and higher risk participants (defined as any of the following: ischaemic heart disease, hypertension, diabetes, peripheral vascular disease, cerebrovascular disease, and alcohol usage ≥40units/week). All screening strategies gave excellent negative predictive value, and screening high-risk participants, was naturally more cost-effective than screening low-risk participants. However, a model where POCUS was used after NT-proBNP or ECG pre-screening, provided the greatest cost-savings (although a model where POCUS occurred before was not included). These data suggest that when POCUS is added to the pathway to screen high-risk individuals in the general population, it may be possible to remove one of the other tests from the pathway without losing effectiveness. This would need to be examined in further prospective trials.

Adaptability

While there is evidence that novice-led POCUS is feasible and accurate in other settings, there is no published evidence of feasibility, accuracy, and effectiveness when it is performed by community nurses in elderly patients with suspected HF. It is well recognised that patient factors, such as obesity (due to the thickness of the ribcage and soft tissues), reduced patient mobility (limiting optimal patient positioning), and presence of subcutaneous emphysema (preventing the propagation of the ultrasound beam to the subpleural lung parenchyma), can heavily impact upon image quality (Gargani & Volpicelli, 2014). In addition, 2D imaging and image processing is (generally) inferior in hand-held ultrasound devices compared with high-end TTE machines. Hand-held ultrasound devices have reduced image resolution; limited processing; a small screen; a narrow sector; and simplified transducer technology (Chamsi-Pasha et al., 2017; Spencer et al., 2013; Via et al., 2014). Therefore, the ability to assess LV systolic function in the proposed setting is unknown.

Compatibility with the current assessment process and workload must be considered. While the limited nature of POCUS examinations means that they are quicker to perform than comprehensive scans, imaging time depends on the scanning protocol and user experience (Andersen et al., 2019).

If POCUS is to be adapted to a community setting with isolated working in home-settings, access to expertise needs to be considered. Multiple studies present findings from a hospital setting in which expert advice is readily available. However, in our proposed setting, where live guidance is not available, consideration should be given to resources needed for image upload and remote expert review. The importance of retrievable image archiving has been previously reported by imaging societies so that cases can be reviewed (and compared) and for quality assurance (Labovitz et al., 2010; Neskovic et al., 2014; Spencer et al., 2013). This is particularly important in the proposed context where novice users are performing POCUS independently and remote expert advice may be required.

Acceptability

There is some evidence of patient acceptance of POCUS predominantly in hospital settings and GP surgeries. However, nurse and patient acceptability of adding nurse-led POCUS in our proposed clinical setting is unknown.

In the early stages of POCUS, concerns were expressed amongst healthcare professionals regarding patient perception of POCUS compared with TTE. However, there is evidence of consistent patient satisfaction. In emergency settings, patient satisfaction is reported to be higher in those who received bedside scans compared with those who did not (Claret et al., 2016; Howard et al., 2014). Patients that had bedside POCUS had statistically significant higher satisfaction scores for overall care, diagnostic testing, and patient confidence in emergency physicians (Claret et al., 2016). The additional time and engagement with the patient during scanning and the real-time demonstration of the operator's technical skills have been proposed as potential causes for higher scores. It has also been suggested that patients are frequently interested in being able to see inside their own bodies, which can increase patient satisfaction, and that technologically advised treatments can increase patient reassurance (Claret et al., 2016; Rudkin et al., 2006). Therefore, it must be recognised that the POCUS intervention itself may not be responsible for increases in patient confidence scores but rather that the added interaction with the patient may be the critical variable. When interpreting measures of patient experience the subjectivity of patient reported measures must be considered.

In the primary care setting, there is evidence of improved patient satisfaction when POCUS is included. In a systematic review of the training and use of POCUS by GPs, five articles were identified that addressed patient perspective (Andersen et al., 2019). Of these, patient experiences were generally reported as positive with patients seeing value in POCUS (Hussain et al., 1999) and gaining a sense of security about their health (Rosenthal et al., 1994). There was evidence that patients preferred having the scan locally rather than travelling to a specialist (Eggebø et al., 1990; Pertierra-Galindo et al., 2019; Wordsworth & Scott, 2002). Despite the general patient positivity towards POCUS, one study in the review reported that ultrasound examinations had led to unnecessary worry, and 29% of patients said that doctors generally emphasized technology too much (Glasø et al., 2007). A recent cross-sectional survey of patients experiences of POCUS across eighteen GP surgeries (n=564)

found POCUS improved patient satisfaction (Andersen et al., 2021). Results of the survey showed that high percentages (>80%) reported that the POCUS exam integrated naturally into the consultation; they felt more thoroughly examined; POCUS provided them with a better understanding of their health problem; POCUS made them feel more secure; and POCUS improved the level of service and the quality of care. The POCUS examinations were not limited to cardiac ultrasound and included focused and full exams as well as diagnostic, screening, and procedure-related studies, and the methods of assessing patient perspective were variable.

Despite evidence of patient positivity towards POCUS in the settings described, our proposed context (providing tests in the homes of very elderly individuals) is quite different therefore an exploration of patient views and acceptability is needed.

Potential barriers –training and resource availability

Most existing POCUS studies fail to comprehensively report contextual challenges associated with POCUS implementation and impact upon outcomes.

In different contexts, studies have revealed that barriers to POCUS adoption include insufficient training and time to train; equipment (machine) availability (Bhagra et al., 2016; Olson et al., 2015; Spencer et al., 2001); a lack of templates for documentation and electronic image archiving; and procedures for quality assurance (Bhagra et al., 2016; Micks et al., 2016; Wong et al., 2020).

The lack of suitable POCUS training programmes and available trainers have been recognised as major barriers to the widespread uptake of POCUS in the UK (Jaques et al., 2017; Smallwood et al., 2015). Cardiologists and accredited sonographers are the 'gold standard' for teaching hand-held ultrasound of the heart but they are not easily released from their clinical duties to provide training (Galusko et al., 2017). Alternatives have been studied, such as specifically trained students, however they still require initial training and assessment before they are competent to teach (Fox et al., 2014). In a small study of eight intensive care nurses, survey results revealed that trainer enthusiasm and availability ranked first among factors impacting implementation of nurse-led POCUS (Tulleken et al., 2019).

Similarly, a multi-centre survey of practicing hospital-based internists (n=170) reported three of the top five barriers to learning and using POCUS related to training (Wong et al., 2020). The top five comprised lack of training (79%), lack of hand-held ultrasound devices (78%), lack of direct supervision (65%), lack of time to perform POCUS (65%), and lack of quality assurance processes (53%). This was consistent with a United States national survey of family medicine educators on the current practice of POCUS within family medicine residencies training which revealed a lack of appropriately trained staff (reported by over 95%), limited access to ultrasound equipment (reported by 48%), and a lack of comfort in interpreting images without radiologist review as the three leading barriers (Hall et al., 2015).

Within the primary care setting, consistent barriers to POCUS implementation have been identified. Results of a web-based questionnaire, completed by key stakeholders (n=15) with knowledge about the use of ultrasound in general practice across twelve European countries, cited financial aspects, lack of time to scan, and lack of training as important barriers to GPs use of POCUS by 92%, 100%, and 100% respectively (Mengel-Jørgensen & Jensen, 2016). Other barriers considered important by 58% included lack of evidence regarding patient care; healthcare costs; scepticism in the medical community and resistance from radiologists; lack of training and integration in the curriculum for GPs; and support from the regional health authorities. While there is some debate amongst healthcare professionals' acceptability of POCUS in different contexts, the multi-centre survey by Wong et al. (2020) revealed participants' attitudes towards POCUS were favourable, including high interest in learning POCUS and positive belief about the utility of POCUS. However, generalizability of the findings to other settings must be considered as the centres approached for the survey all had a designated internal medicine POCUS champion.

In a systematic review of hand-held ultrasound in medical education, Galusko et al. (2017) reported poor quality data to guide policy; lack of consensus on desirable competence; limited qualified trainer availability; and uncertainty about skill retention as barriers to the widespread adoption of hand-held ultrasound in undergraduate medical education. Although based in medical education, the barriers identified have potential relevance to clinical practice and are in keeping with the studies described previously.

It is clear from the existing literature that training is a recognised barrier to POCUS implementation, yet the literature is unclear regarding the necessary infrastructure to educate

and train those providing initial point-of-care POCUS within primary care. The absence of established curricula to standardise training and define competence is a widely recognised contributor to the limited, inconsistent uptake.

Theme 7: Clinical- and cost-effectiveness of adding POCUS to the pathway

POCUS literature is dominated by studies showing the added diagnostic yield of POCUS compared with physical examination alone. While diagnostic accuracy is important for any diagnostic tool, it is not the only important consideration. There is a lack of comparative accuracy of outcomes from the current pathway versus a new pathway that includes POCUS.

POCUS can provide relevant clinical information at the first point-of-care (Cardim et al., 2019), thereby enabling immediate initiation of appropriate, individualised interventions and management (Price et al., 2006). In the context of suspected HF, bedside use of limited cardiac ultrasound can provide earlier knowledge of LV systolic function, enabling initiation of appropriate therapies and avoidance of contraindicated therapies before comprehensive TTE is requested, performed, and reported (Spencer et al., 2013). A United States National survey of family medicine educators on the current practice of POCUS within family medicine residencies reported that the three leading perceived benefits of POCUS included facilitating a quicker diagnosis (identified by 80% of programs), potential saving in healthcare costs (noted by 60%), and the potential to improve patient outcomes (listed by 45%) (Hall et al., 2015). Despite the widespread reporting of potential benefits, there is less substantiative evidence of improved or quantified clinical impact.

This review could not find any evidence of the use of non-specialist nurse-led POCUS in the domiciliary setting. There is limited evidence on the use of community non-expert healthcare professional (GP) led POCUS (Bornemann et al., 2015; Evangelista et al., 2016; Mjolstad, Snare, et al., 2012) and/or expert-led POCUS within community care (Fabich et al., 2016; Williams et al., 2019) and a lack of evidence of the clinical- and cost-effectiveness of adding POCUS to the current pathway of community patients with suspected HF.

When the review centred on evidence for novice users in an out-of-hospital setting, a small number of studies were identified with GPs, rather than nurses, performing POCUS. One

such study of GPs used septal mitral annular excursion as a surrogate marker of LVSD in patients (n=92) at risk of developing or who had established HF and reported adequate GP accuracy (sensitivity 0.83 and specificity 0.78) (Mjolstad, Snare, et al., 2012). However, results were limited to accuracy and did not assess impact upon decision making. This is a common approach in the literature. In a large (n=1312) prospective observational community based-study, the accuracy of GP-led POCUS interpretation (following twenty-eight hours training) was compared with the accuracy of remote expert interpretation of GP acquired images (Evangelista et al., 2016). GP sensitivity and specificity for detecting LVSD was lower (0.5 and 0.93 respectively) than remote expert analysis (0.9 and 0.97 respectively). The small number of studies, variable training, and varied POCUS protocols prevents pooled analysis of diagnostic accuracy.

There is limited evidence regarding the influence of POCUS findings on medication decisions. It is widely agreed that the early initiation of appropriate medication in the setting of LVSD is linked to better patient outcome. While the potential for improved medication decisions based on earlier knowledge of LV status is widely reported, I failed to find detailed evidence of changes in medication choices post novice-led POCUS in the context of community patients with suspected HF. In other contexts, hospital-based studies have shown that POCUS can influence treatment decisions compared with standard patient history, physical examination, ECG, and chart data, and facilitate earlier initiation of appropriate medication (Gorcsan et al., 2004; Lucas et al., 2011; Razi et al., 2011). While there is promising short-term data proposing the potential for POCUS to improve immediate treatment decisions, there is an absence of comprehensive evaluation of comparative treatment decisions, with and without POCUS.

Amongst the POCUS literature, a reported benefit is improved triaging. It is widely recognised that expediting triage and time to diagnosis are crucial in decreasing morbidity and mortality in critically ill patients (Rooney & Schilling, 2014). Of the few community-based novice POCUS user studies, one referred to clinical impact (Evangelista et al., 2016). Evangelista et al. reported referrals for TTE post-remote expert review of GP acquired images were 21% compared to 66% before POCUS (post-history and examination) (2016). In hospital and outpatient cardiology settings, the addition of POCUS has been shown to reduce referrals for TTE by around 25-30% (range 26-31%) based upon the exclusion of

pathology on POCUS (Cardim et al., 2011; Di Bello et al., 2015; Greaves et al., 2005; Mehta et al., 2014; Trambaiolo et al., 2007).

While the potential for POCUS to guide the timing and need for expediting TTE referrals has been reported (Galusko et al., 2018; Khan, 2014; Kitada et al., 2013), I have not found data regarding how TTE referral 'speed' has been prioritised based upon POCUS findings (as most are reported on an absent/present format). It has also been proposed that POCUS can help reduce TTE department workload based upon reducing referrals if the POCUS exam is negative (Cardim et al., 2011; Greaves et al., 2005), however I have, again, not found any evidence other than 'anticipated' effects. Where an abnormality is detected on POCUS (suspected or incidental), comprehensive TTE should be indicated to accurately evaluate and grade pathology and detect a potential cause. Therefore, in some settings, POCUS could result in an increase in referrals and (to my knowledge) the clinical implications of this have not been comprehensively explored.

A negative POCUS examination does not necessarily exclude the need for comprehensive TTE. The abbreviated nature of POCUS by non-experts means important abnormalities may be missed or misinterpreted. Therefore, when clinical suspicion of cardiovascular disease remains high, comprehensive TTE is still indicated despite a normal POCUS examination (Neskovic et al., 2014). Some pathologies are subtle, difficult to recognise, and may require multiple views to correctly define. In addition, the diagnosis of many pathologies requires extensive training and experience which is outside the scope of knowledge of those with basic POCUS training. I have not found clinical data relating to the incidence or downstream consequences of missed, or misinterpreted pathology.

I failed to identify studies that reported the cost-effectiveness of POCUS in community care for cardiac assessments. However, in the Health Technology Wales evidence appraisal report (2019b) they developed a cost consequence analysis based on the reported change in clinical management pathway from the Evangelista et al. (2016) study data. They compared rates referred for conventional TTE, referral to cardiology, clinical hand-held ultrasound follow-up, and discharge based on assessments with GP-acquired and remote cardiologist-analysis POCUS and normal GP assessment (without POCUS). They estimated a £42 (Vscan £21, expert analysis £8, digital platform £1, and GP training £12) increase in cost per consultation when POCUS is added. Based upon the clinical management changes reported for the 1312

patients, they estimated a higher cost for the POCUS approach (cost-prohibitive) with a per patient increase to cost of £30. However, findings are highly sensitive to a range of assumptions within the modelling, particularly the proposed patient volume per device and number of trainees. The patient population (signs/symptoms suggestive of cardiovascular disease) was not limited to those with suspected HF. Context of intended use is highly influential on results and limits the generalisability of findings to different contexts.

Conversely, outside of the context of community care, there is growing evidence reporting estimated cost savings associated with adding POCUS. The high (>95%) negative predictive value of an integrated physical examination (including POCUS) suggests further testing (predominantly TTE) can be avoided in patients with a normal POCUS study (Greaves et al., 2005; Roelandt, 2014; Trambaiolo et al., 2007). Prior cost analyses are dominated by reported savings based upon reductions in TTE referrals in the setting of normal POCUS examinations (Greaves et al., 2005; Mehta et al., 2014; Trambaiolo et al., 2007; Vourvouri et al., 2003). Studies have similarly shown reported cost reductions (by reducing TTE referrals) when hand-held ultrasound is used as an initial screening tool prior to TTE (Galasko et al., 2006; Kitada et al., 2013). Given the marked variability in the context of use and estimated costs based on different costing models, the resulting reported cost savings are variable and study specific.

The current literature lacks comprehensive evaluations of the cost-effectiveness of adding POCUS. While several studies note a shorter time to diagnosis at a lower cost (Vourvouri et al., 2003), the impact of earlier diagnosis on earlier initiation of appropriate medication (and potential reduced hospital admissions) has not been explored. Some studies have acknowledged that potential misdiagnoses could have a significant negative impact upon cost-benefits accrued (Greaves et al., 2005). However, there is a lack of comprehensive examination of the potential costs associated with incorrect or missed diagnosis, and of the cost associated with the identification (and subsequent follow-up) of incidental findings (over-medicalisation). In a systematic review of training in and use of POCUS by GPs, misdiagnoses, in terms of false-positives and false-negatives, were described in 17% and 16% respectively, and incidental findings were described in 20% (Andersen et al., 2019). Data are lacking regarding the cost implications associated with these. Similarly, initial setup costs required to train, test, and certify users in POCUS is not comprehensively described in the current literature. One study comparing hand-held ultrasound and bedside TTE in

inpatients with focused clinical questions (n=92), involved a cost-effectiveness analysis based on the cost-minimization analysis (Gianstefani et al., 2013). Overall cost for both modalities was calculated and included staff cost, equipment cost and maintenance, hospital costs, time taken for a sonographer to travel between patients, plus mean scanning and reporting times. Hand-held ultrasound led to a cost saving per scan of 76%. While the methodology of costing can be recognised, calculated costs were specific to that context and would not be the same for a community setting, and reference to clinical outcomes was not included.

There are no longer term data regarding the impact of not referring for TTE, for example in terms of future presentations or admissions. The impact of misdiagnosis/inappropriate clinical decision making, and potential wasted resources (over-referral for false positives) has not been evaluated. Since a positive POCUS examination (pathology detected) should prompt referral for TTE to comprehensively evaluate and grade the severity of pathology, POCUS has the potential to increase referrals due to pathology detection (incidental and suspected). This should be considered alongside the potential impact of follow-up of incidental findings.

In summary, POCUS might support earlier diagnosis of LVSD and initiation of medication but the clinical impact, financial consequences, and logistics of introducing nurse-led hand-held ultrasound devices into the proposed community setting is currently unclear. The limited evidence on the diagnostic accuracy of novice-led POCUS in this context and an absence of evidence regarding clinical outcomes was similarly recognised by Health Technology Wales in their 2019 appraisal report (EAR009) examining the clinical and cost-effectiveness of hand held ultrasound devices for cardiac assessments and diagnosis of systolic HF in the community or primary care setting (Health Technology Wales, 2019b). They recommend further research to investigate the implementation of POCUS in the primary or community setting and recognised the need for considering clinical and system outcomes, such as the avoidance of hospital referral, the impact of earlier diagnosis, and earlier commencement of HF treatment (Health Technology Wales, 2019a).

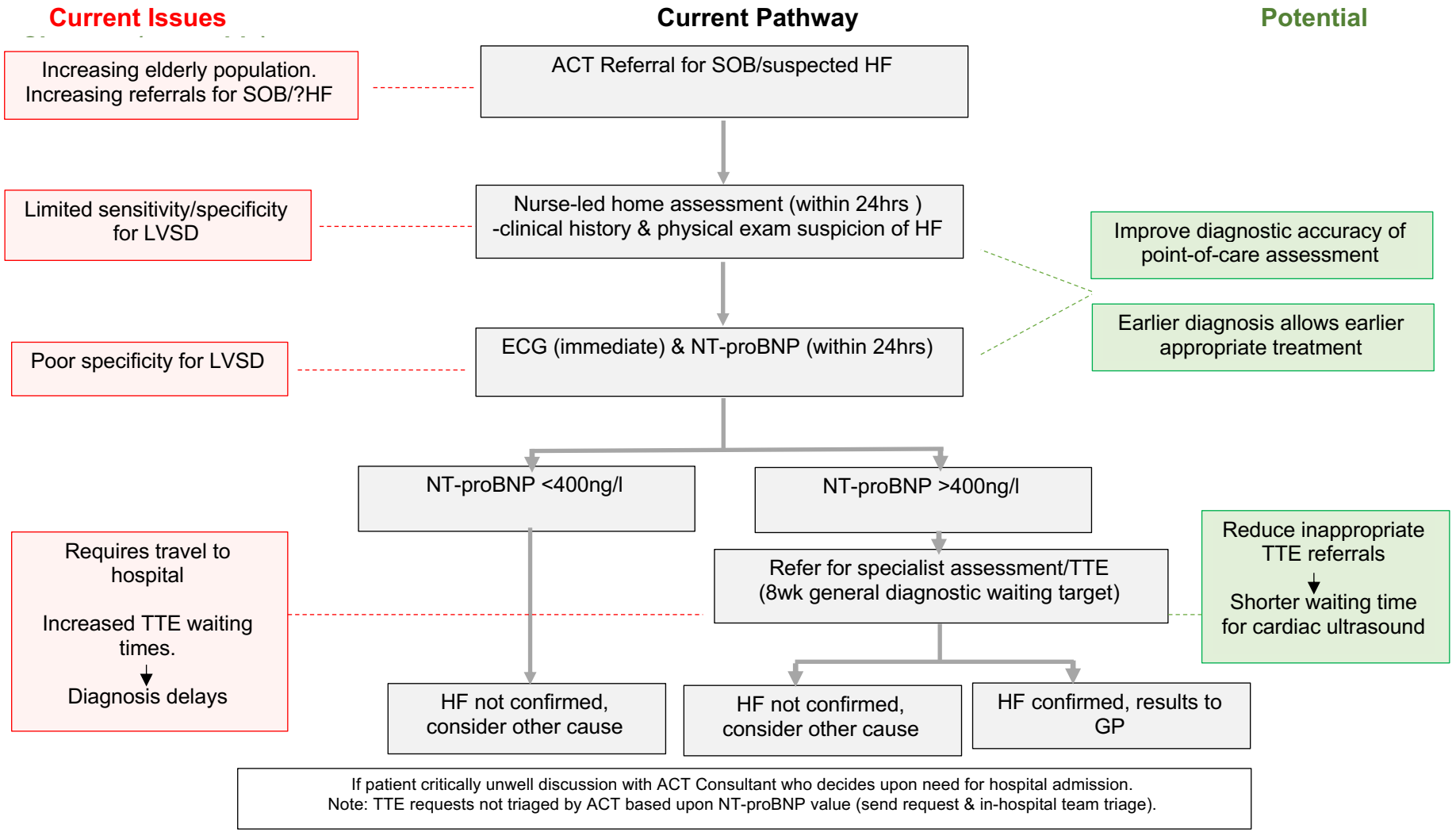
Results and Discussion- Phase II

The current acute clinical team pathway for patients with suspected HF was mapped (Figure 3.5). The current pathway is shown in grey, the current limitations are in red, and steps amenable to change (improvement) are in green.

NICE acute HF diagnosis guidance (CG187) proposes an NT-proBNP threshold <300ng/litre to rule out the diagnosis of acute HF and suggests consideration of echocardiography within 48hrs of admission. NICE chronic HF diagnosis guidance (NG106) suggests an NT-proBNP level <400 ng/l makes a diagnosis of HF less likely and recommends specialist assessment and TTE within two-weeks if NT-proBNP is >2000ng/l and within six-weeks if between 400-2000ng/l (Chapter 1, Figure 1.1). In their current clinical practice, the acute clinical team use a threshold value of 400ng/l to determine the need for echocardiography.

Figure 3.5

Current ACT patient pathway for those with suspected HF (new or worsening) with proposed improvements



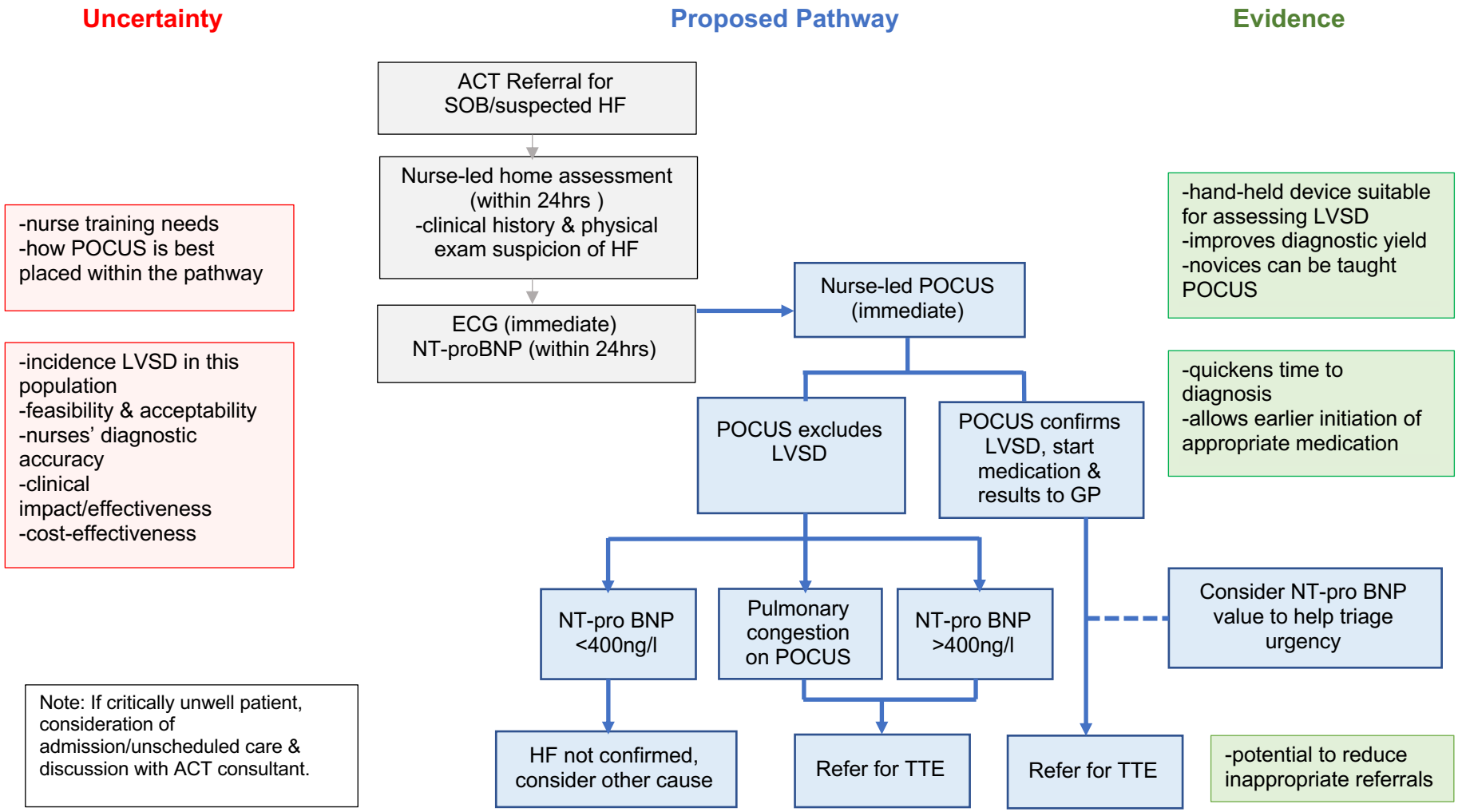
Certain steps within the process are not amenable (for us) to change, such as the number of referrals received, NT-proBNP thresholds, waiting times for TTE, sensitivity and specificity of the existing tests in the pathway. However, there are potential opportunities where improvements could be made (shown in green). Adding a more accurate triage step at the point of care could improve the initial assessment which would likely affect the number and appropriateness of referrals, as well as time to diagnosis and first-line treatment.

Under the current pathway, nurse assessment typically occurs within 24hrs of referral and NT-proBNP results are returned after a further 24hrs. Waiting times for TTE mean that this definitive diagnostic test may not be performed for several weeks. NICE acute HF guidance recommend TTE within 48-hours and chronic guidelines suggest TTE should be performed within two- or six-weeks depending upon NT-proBNP level. The general Welsh referral-to-treatment time targets for diagnostic testing is eight-weeks however post-Covid-19 waiting times for TTE have worsened. In October 2022, all Welsh health boards reported a significant number of patients waiting over the eight-week target (Chapter 1, Figure 1.2).

Having confirmed the intended intervention (nurse-led POCUS), the diagnostic pathway was re-mapped including POCUS (Figure 3.6). Grey indicates steps in the current pathway and blue shows the proposed pathway (where POCUS is added) and its potential impact upon the pathway. Evidence supporting POCUS use in this setting is highlighted in green and areas of uncertainty regarding POCUS use in the proposed context are shown in red.

Figure 3.6

Proposed patient pathway including POCUS



Adding POCUS to the initial assessment has the potential to confirm/exclude LVSD at the initial point-of-care. This could support immediate initiation of appropriate first-line evidence-based treatments for acute HF which are linked to better patient outcomes. Under the current pathway it takes approximately 48hrs to exclude LVSD and LVSD cannot be confirmed until a TTE has been performed, which typically takes several weeks.

Service users (the PEER group) showed collective support for the proposed intervention; they saw value in providing diagnostic testing in the home setting. Their only concern was that non-specialists would be interpreting scans and may be more likely to miss an important finding or misinterpret a diagnosis. This concern was acknowledged and used to guide the design of the pilot studies. A conservative staged approach to testing and confirming accuracy was planned and for the clinical study, all scans were reviewed by a BSE-accredited sonographer with the current care pathway driving clinical decision making (hypothetical influence of POCUS recorded but not acted upon by the nurses). Two service users with personal experience of chronic conditions, diagnostic investigations, and health service delivery across NHS organisations joined the research team to provide insight and guidance throughout the research process. Research group discussions included methods for exploring participant opinions. The preferred method would have been for the researcher to perform one-to-one interviews with a purposive sample of participants (patients). However, the clinicians felt that in the context of COVID-19, it would not be appropriate for a university researcher to conduct a face-to-face interview in home settings. Additionally, given the advanced age and frailty of the patient group, they felt online/telephone interviews would not be feasible. Therefore, for this feasibility research, any participant comments or feedback received by nurses would be recorded in case report forms or field-notes.

Considering future implementation and wider stakeholder engagement, discussion about implementation research resulted in a focus on certain CFIR domains (Chapter 2, Figure 2.2). These included the inner setting, to increase understanding of the acute clinical team; the characteristics of the POCUS operators (nurses) because, at this stage, they are the main drivers in determining intervention success; and the process, to test methods and help identify facilitators and barriers to implementation. The intention was to seek information relating to infrastructure; culture; communication; engagement; implementation climate; and readiness for implementation within this setting.

Integrated Summary of Intervention Adaptation

Having explored the current (relevant) literature and reviewed the current pathway, it appears reasonable to suggest that adding nurse-led POCUS to the assessment of elderly patients with suspected HF in the community has the potential to improve aspects of patient care. However, it is equally evident that there are numerous uncertainties regarding optimal POCUS implementation in the proposed setting which require exploration prior to clinical implementation.

There is an abundance of data supporting the added diagnostic value of including POCUS in the initial point-of-care assessment and evidence that specialist nurses can use focused POCUS in the emergency care setting and in outpatient HF clinics to assess volume status (Brunhoeber et al., 2018; Dalen et al., 2015; Gustafsson et al., 2015). However, information is absent regarding whether nurses, who do not specialise in cardiology, can accurately and reliably learn to perform, and interpret, POCUS examinations aimed at assessing LV systolic function and volume status in those with suspected HF.

There is a lack of clarity regarding POCUS training requirements for ultrasound novice non-specialist nurses. With limited training, various types of novice users, including nurses, have been shown to accurately and reliably use POCUS to improve the diagnostic accuracy of the patient examination but studies are markedly heterogenous in terms of the contexts of POCUS use, background experience, and POCUS scanning and reporting protocols. This makes it difficult to draw any definitive conclusions regarding training that can be applied to new contexts. While the importance of individualising training based on user experience and POCUS application is well reported, there is no formal training requirement for POCUS use in the proposed context. Given the unique study setting, it seems inappropriate to adopt a previously utilised training programme or existing scanning protocol that had been intended for different contexts. Instead, it appears more appropriate to develop a bespoke nurse-tailored POCUS training programme and POCUS protocol that is user (non-specialist nurses) and context (acute dyspnoea and suspected HF in the elderly) specific.

Discussions of the development of previous training programmes and feasibility of execution are lacking. The absence of previous data in this context meant that it was important to consider how the nurses should be trained, and how learning would be assessed to ensure sufficient POCUS competence prior to clinical implementation.

The importance of adequate training and evidence of competence was reiterated by the service users (PEER representatives) who expressed concern about novices interpreting scans. Therefore, an emphasis was placed upon training and ensuring competence, reproducibility, and accuracy prior to clinical testing (Chapter 4). Design of the clinical study (Chapter 5) ensured all patient management decisions were driven by the existing care model and only the hypothetical impact of nurse-led POCUS recorded. Expert review of all nurse scans was included with comparison of nurse and expert interpretation used to determine the optimal method of implementation.

Whilst the project arose from the clinical team approaching the academic team about the use of POCUS, different options for intervention implementation were still debated. The clinical context of this study (community care); the age of the population; the growing desire to improve community care and deliver care closer to home; and the current literature base supporting the use of hand-held POCUS to provide immediate knowledge of gross LV systolic functional status were all considered. In the context of an elderly, often frail cohort, the possibility of reducing the need for patient transfer by improving the accuracy of the home-based point-of-care-assessment is preferential. Therefore, the research team collectively felt that the most appropriate option for altering the current patient pathway, would be to add POCUS by a non-traditional ultrasound user (in this case nurse), or to have nurse-acquired images that were subsequently analysed remotely by an expert. Other models, such as expert-led POCUS in the domiciliary setting or expert-led community TTE clinics, may be feasible but we wanted to explore the possibility of reducing the need to travel to clinic appointments or additional visits. There is evidence of using remote expert acquisition guidance to aid image acquisition by novices. This model is associated with the greatest cost and was not possible for this research. Several hand-held ultrasound devices now have artificial intelligence applications which can be used to assist users. For example, GE Vscan applications such as 'LVivo EF' can automatically measure ejection fraction and 'Scan Coach FATE' guides the user on protocol views. At this stage of research, we chose not to use these, but they could be considered for future research projects.

Current reported POCUS studies lack comprehensive recognition, or at least reporting, of implementation considerations and contextual influences. The need to recognise context is well reported in the implementation literature but this has failed to translate to cardiac POCUS studies. This limits the generalisability of findings to new contexts and wide-spread

changes in practice. The feasibility, acceptability (user and provider), and accuracy of adding novice nurse-led POCUS in an elderly population with high prevalence of multiple comorbidities and restricted mobility is unknown.

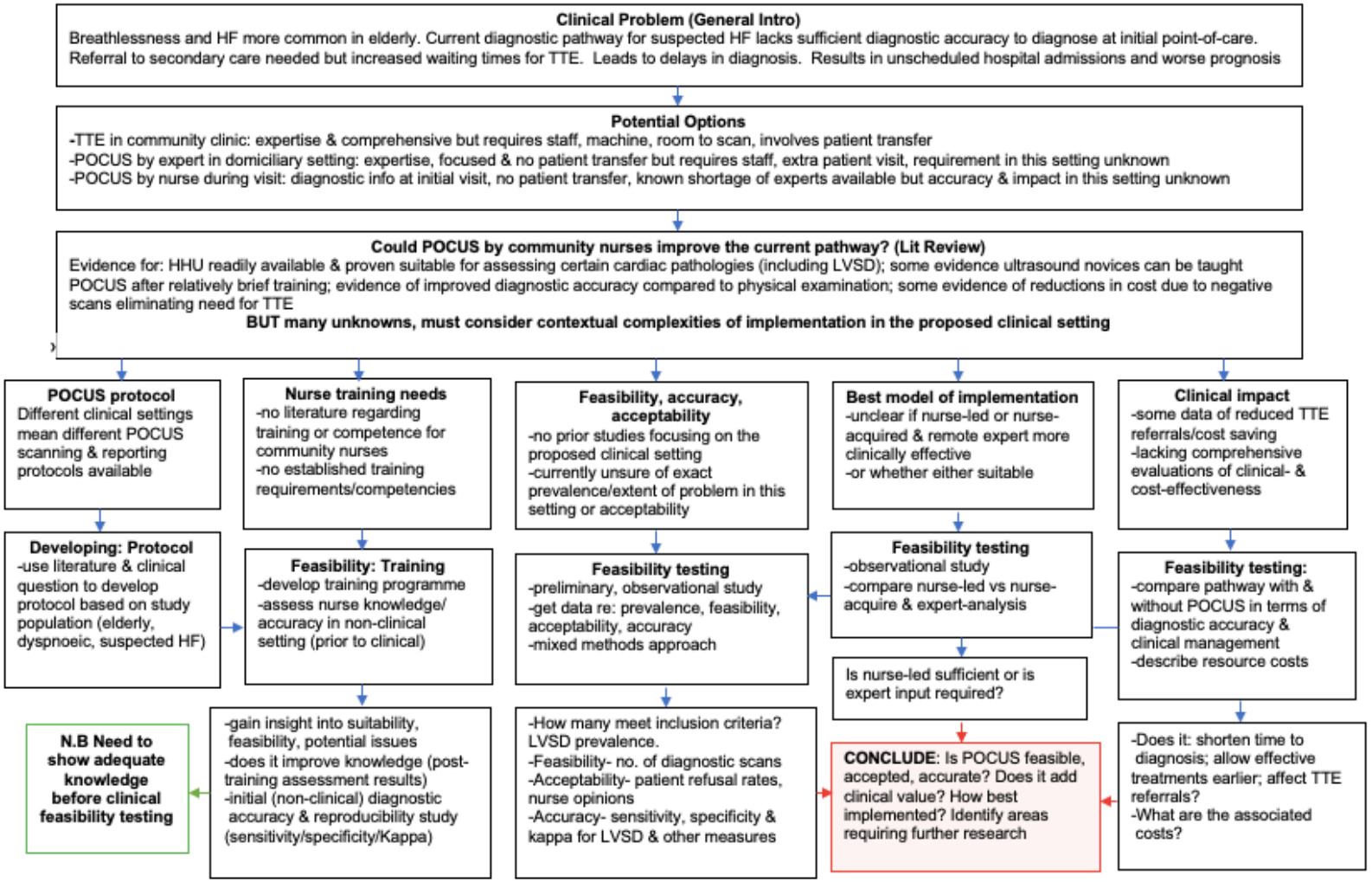
There was a collective decision to use a mixed-methods research design to examine how and why intervention outcomes were reached. Nurses felt face-to-face patient interviews would be inappropriate in the context of COVID-19 and that online/telephone interviews would be unsuitable for the proposed elderly population. Qualitative data collection regarding opinions of POCUS would therefore be limited to fieldnotes regarding patient/carer views and the nurses' personal opinions vocalised during the proposed focus group meeting post-clinical study (Chapter 5).

When considering a change in healthcare delivery, it is imperative that the change has a positive clinical impact. There is some evidence that adding POCUS to the physical examination has the potential to reduce TTE referrals, and with that decrease costs, (Galasko et al., 2006; Greaves et al., 2005; Trambaiolo et al., 2007). However potential costs associated with misdiagnosis (and subsequent downstream testing) and clinical and resource implications associated with the follow-up of incidental findings have not been described. Based on existing literature, the clinical impact of adding nurse-led POCUS in the proposed context is unclear. There is also uncertainty regarding the cost of adding POCUS in the proposed context given that previous cost estimates have been based on context specific estimations.

An overview of the development (adaptation) phase of this research, leading to the proposed feasibility studies, is provided in Figure 3.7. The outcomes of this chapter led to refined research objectives (Pg 93-94) and informed methodology of the pre-clinical phase of work and clinical feasibility testing.

Figure 3.7

Overview of the intervention development (adapting) phase and proposed areas of feasibility testing



Chapter Summary

This chapter provides an overview of the intervention development (adaptation) phase. It details how the current literature was reviewed and provides an overview of the information yielded and how the current knowns and unknows were used to guide feasibility testing. It concludes by providing the key research aims.

Key take home points:

- *While there is evidence of acceptable novice competence from which one could surmise that the training programmes were appropriate, the marked variability in contexts of use, user experience, and scanning protocols makes it is difficult to draw any definitive conclusions.*
- *Given the unique study setting, the appropriate training and POCUS protocol remains unclear. Therefore, it appears more appropriate to formulate a context-tailored training programme and POCUS protocol.*
- *Prior clinical studies fail to comprehensively describe intervention development and do not describe the impact of context upon potential implementation.*
- *There is evidence in other contexts that adding POCUS can provide quicker, more accurate diagnoses at the initial point-of-care, help decide who needs referral for TTE, and allows earlier initiation of appropriate treatment associated with improved patient outcomes. However, this has not been tested in the proposed context.*
- *Initial feasibility research is required to gain an insight into the diagnostic accuracy, reproducibility, feasibility, and acceptability of adding nurse-led POCUS in the domiciliary setting and to explore potential implementation challenges within this setting.*

Research aims and objectives

Aim

Given that POCUS has not been previously tested in the proposed setting, adaptation of the intervention to the new context was required. This research sought to, for the first time, provide preliminary data on the addition of nurse-led POCUS to the current patient pathway for elderly acutely dyspnoeic patients in the domiciliary setting.

Objectives

The main research objectives:

1) Design and assess a POCUS scanning and reporting protocol focused on confirming the presence/absence of LVSD and ultrasound signs of congestion and other significant common cardiac pathology

2) Develop and assess the suitability of a bespoke POCUS training programme aimed at teaching non-specialist community nurses to acquire and interpret focused POCUS to determine the presence/absence of LVSD and ultrasound signs of congestion

3) Assess the feasibility and acceptability of adding nurse-led hand-held POCUS in the domiciliary setting in elderly patients with suspected HF

4) Assess the diagnostic accuracy and reproducibility of nurse-led POCUS to detect/exclude significant LVSD (target pathology), plus ultrasound signs of volume overload, in older people with new or worsening dyspnoea

5) Determine whether remote specialist interpretation offers a significantly better model than nurse acquired and analysed POCUS

6) Estimate the clinical impact of adding POCUS to the existing pathway by:
    a) Measuring the change in diagnostic accuracy associated with adding POCUS
    b) Recording the potential (hypothetical) impact on immediate patient management decisions
    c) Describing resource use and implementation costs associated with adding POCUS to the existing pathway

Chapter 4: Pre-Clinical Feasibility Testing

Chapter Overview

A key determinant in the success of POCUS implementation is nurse competence. This involves not only image acquisition and analytical skills, but also evidence-based decision making which integrates POCUS findings with the clinical context. The proposed intervention will only have clinical utility if the nurses can learn to use POCUS to detect specified pathology (target pathology LVSD) accurately and reliably.

Due to the absence of data regarding community nurse led POCUS, and the hesitance of the service users for non-experts to perform POCUS (presented in Chapter 3, Phase II results), the first phase of feasibility testing sought to assess whether the nurses could learn POCUS and to test their accuracy and reliability in a controlled, non-clinical setting prior to clinical testing.

This chapter begins with an overview of the relevant literature pertaining to POCUS training. The chapter provides comprehensive detail of the bespoke training programme I designed, delivered, and assessed. Given the absence of comprehensive detail regarding training in previous studies, the intention was to provide a detailed 'training manual' and sufficient evaluation so that others could determine which elements of the training programme were core and which could be adapted to new contexts.

Introduction

The abbreviated nature of POCUS and functional limitations of hand-held ultrasound devices do not remove the need for adequate training. POCUS is a user-dependent technology that requires understanding of the relevant information, technical acquisition, interpretive skills, and application of findings to the clinical context (Cartier et al., 2014; Todsen et al., 2016). The importance of adequate POCUS training to ensure safe, effective implementation is well reported. While some context specific accreditation processes exist, primarily within

emergency care, there is no universal agreement for POCUS training, competence and accreditation requirements for non-traditional ultrasound users that is applicable across specialties.

The existing POCUS literature shows marked variability in training durations and delivery. Some studies have described training programmes in terms of set time frames (minutes to months) (Brunhoeber et al., 2018; Galusko et al., 2018; Henderson et al., 2010), others have specified volumes of scans (ranges of 10-150) (Hellmann et al., 2005; Razi et al., 2011; Royse et al., 2006), and some have used both (Dalen et al., 2015; DeCara et al., 2005; Kimura, Gilcrease, et al., 2012). It is difficult to draw inferences regarding training efficacy given the variability in trainee experience, intended contexts of use, and study endpoints (outcome measures). A systematic review of the diagnostic utility of POCUS and training requirements similarly reported the inability to draw definitive conclusions regarding how much training is required for inexperienced users due to study variability (Galusko et al., 2018). Recognising variability in individual trainee needs, there has been a more recent movement towards use of competency-based training to ensure all learners reach the same performance standard before advancing to clinical practice (Jensen et al., 2018; McGaghie, 2015; Motola et al., 2013). However, what constitutes 'competence' is variable in different contexts.

Recommendations from imaging bodies suggest a formal, structured approach to training to ensure development of the necessary knowledge and skills to perform POCUS (Spencer et al., 2013). Existing training programmes frequently include an initial introduction (to provide core knowledge and skill development); opportunity to gain experience (supporting acquisition and interpretive practice and application of findings); and assessment of competence (Hayward et al., 2015; International Federation for Emergency Medicine, 2014). The International Federation for Emergency Medicine (IFEM) also suggest dividing the basic components of a training programme into two: curriculum content and delivery. Educational studies have shown didactic education, hands-on practice, and interpretative experience to be effective and well received by trainees (Bhagra et al., 2016; Shokoohi et al., 2016). However, the content and delivery of training in prior studies is highly variable.

Several imaging societies have recognised core components of POCUS training programmes which include (International Federation for Emergency Medicine, 2014; Pelliccia et al., 2012; Spencer et al., 2013):

- ultrasound physics
- anatomy, physiology, and pathophysiology
- image acquisition and optimisation
- normal structure and function
- pathology for scope of practice
- POCUS indications, limitations, and good POCUS governance (including when comprehensive TTE is indicated)

The importance of trainees understanding the scope and limitations of POCUS given the specific equipment, situation, and user experience is widely reported. Inappropriate use may result in patient harm through incidental findings, inaccurate diagnosis, and unnecessary further investigations (Moore & Copel, 2011; Neskovic et al., 2014; Pelliccia et al., 2012; Spencer et al., 2013). Opportunity to review normal and abnormal cases is recommended given that the breadth of pathology seen during hands-on practice in training is likely to be far less diverse than that seen in clinical practice (Pelliccia et al., 2012; Spencer et al., 2013).

The literature conclusively regards hands-on practice an integral component of POCUS training but there is ambiguity amongst the literature in terms of how much and how hands-on practice should be gained and supervised. There is marked variability in the amount of hands-on practice varying from minutes to months (Brennan et al., 2007; Croft et al., 2006; Evangelista et al., 2016; Henderson et al., 2010; Kobal et al., 2005; Mjolstad, Snare, et al., 2012; Panoulas et al., 2013). After completion of initial training (didactic and hands-on scanning), several studies have found benefits from including an extended practice period to develop acquisition skills (Engelman et al., 2015; Filopei et al., 2014; Henderson et al., 2010; López-Palmero et al., 2015; Mjolstad, Snare, et al., 2012; Ojeda et al., 2015; Tulleken et al., 2019). In the early stages of learning, use of imaging aids (such as three-dimensional cardiac models and simulation mannequins) have been reported to be beneficial in expediting understanding of imaging planes and their corresponding anatomy, as well as transducer

placement and orientation (Ogilvie et al., 2015; Spencer et al., 2013). While the literature supports initial practice on simulators, it suggests most hands-on practice should be performed on human subjects so that trainees gain experience regarding variations in body habitus, chest wall structure, heart orientation, movement with respiration, patient cooperation, and image optimisation (Chamsi-Pasha et al., 2017; Spencer et al., 2013). Opportunity to have supervised practice (with immediate feedback) and independent image acquisition opportunity is reportedly beneficial for trainees (American Academy of Family Physicians, 2018; Spencer et al., 2013).

The existing literature is generally limited to brief overviews of the POCUS training, highlighting the amount of didactic teaching and hands-on practice, with some including an overview of the topics covered during didactic sessions, and examination of diagnostic accuracy to assess learning (Andersen et al., 2014; Dalen et al., 2015; Evangelista et al., 2016; Graven et al., 2015; Gustafsson et al., 2015; Kirkpatrick et al., 2005; Lucas et al., 2009; Mjolstad, Snare, et al., 2012; Panoulas et al., 2013). However, previous clinical studies fail to discuss how training programmes were developed, methodology choices for design and delivery, or ease of delivery.

In educational research, there has been some reference to training design and delivery, and the need for acquisition practice to develop acquisition skills is well-reported. Hayward et al. (2015) used Ericsson's model of deliberate practice to create a POCUS curriculum for emergency department residents encouraging deliberate practice with feedback (Bordage, 2009; Ericsson, 2004; Ericsson et al., 1993). It suggests that the learning task should:

- motivate the learner through performance improvement
- consider learner's pre-existing knowledge (learning curve)
- allow skill repetition
- provide immediate feedback
- provide variation

Key recommendations for delivering didactic information include small group format, case-based didactic presentations that are less than twenty minutes with up to five key messages, and video clip examples (Cartier et al., 2014; Hempel et al., 2014). Alternating between theory and hands-on sessions has been shown to help prevent fatigue and enhance knowledge retention (Hempel et al., 2014). Several programs advocate involving trainees in the design and subsequent modification of the POCUS curriculum; starting with a few sessions and expanding this depending on trainee feedback, resources, and time (Griksaitis et al., 2014; Hoppmann et al., 2011).

An important part of training programme design is defining competence. Competence in POCUS requires acquisition and interpretative skills; understanding of the relevant information; performance of the technical skill; and application of findings to the clinical context (Cartier et al., 2014; Todsen et al., 2016). It is widely agreed that competence should be formally assessed after completion of training to determine the effectiveness of training (Moore & Copel, 2011; Pelliccia et al., 2012; Tarique et al., 2018). The POCUS literature is dominated by diagnostic accuracy studies meaning that most clinical studies assess competence in terms of diagnostic accuracy (chiefly sensitivity and specificity for pathology). In undergraduate education, a scoping review found the most frequent methods of evaluating competence were (Tarique et al., 2018):

- self-assessments of knowledge, attitudes, and perceptions via surveys, questionnaires, and interviews
- technical skill evaluation via observed structured clinical examination (OSCE)
- knowledge assessments via multiple-choice and written questions, pictorial, or case-based questions, and skill assessment on simulators

Existing data suggests multiple choice questions (MCQs) that include images and video clips are preferential (Bornemann, 2017; Flick, 2016) with an OSCE-type assessment to assess practical skills. However, there are currently no objective metrics or validated tools to determine competence in POCUS (Neskovic et al., 2014; Spencer et al., 2013) and there is a lack of high-quality studies looking at determining thresholds for users to practise independently (Galusko et al., 2018).

Several studies have demonstrated acceptable novice accuracy with relatively brief training from which one could surmise that the training protocol used was adequate (DeCara et al., 2005; Galderisi et al., 2010; Kimura et al., 2005; Lucas et al., 2009; Martin et al., 2009). However, there is marked heterogenicity amongst studies, in terms of trainees' background experience; study settings; types and durations of training; scanning and analysis protocols; and competence requirements. In studies where the trainee was a nurse, or a GP in the community setting, there was considerable variation in the length of training (ranging from thirty minutes to a year), the scope of POCUS (several focusing on assessments of volume status only), and prior user experience (Brunhoeber et al., 2018; Dalen et al., 2015; Evangelista et al., 2016; Graven et al., 2015; Gustafsson et al., 2015; Henderson et al., 2010; Kirkpatrick et al., 2005; Mjolstad, Snare, et al., 2012; Tulleken et al., 2019). This makes it difficult to compare the adequacy of training.

The diversity of applications and healthcare professionals using POCUS mean that a 'one size fits all' definitive POCUS training programme will be unsuitable for all novice ultrasound users and intended context of use must be considered. Community nurse-led POCUS in the context of acute dyspnoea and suspected HF has not been previously explored. Therefore, I believe that adoption of a previously utilised POCUS training programme that yielded positive results in a different context would be unsuitable for the proposed context. Unlike many previous POCUS studies, the training programme for this study is not intended to be a simplified, easily executed program that is delivered to high volumes of healthcare professionals in the shortest possible timeframe. Instead, the aim was to provide a training program that allows a specific cohort of nurses to accurately perform and interpret limited cardiac and lung POCUS during home visits to improve patient management. Therefore, I decided to draw upon my knowledge of the existing evidence base to design a bespoke training programme tailored to the contextual needs of this research project.

The intended clinical context drove training programme design; the focus was on teaching community nurses, without previous POCUS experience, how (and why) to acquire and interpret specific ultrasound images to determine (predominantly) LV systolic functional status and whether signs of pulmonary congestion exist. The devised POCUS training programme (detailed further in the methodology section) included a five-day introductory course followed by a subsequent period of practice. Learning was assessed via MCQs, video

case reviews, and evaluation forms at the end of the workshop and practice period. A nurse triggered OSCE was performed to assess practical skills towards the end of the practice period. Analytical accuracy was subsequently formally assessed in a small non-clinical reproducibility study to ensure competence prior to progression to a clinical feasibility phase.

Given that the POCUS literature fails to detail methods used to design curricula, I chose the Arena Blended Connected (ABC) curriculum design method which is a well-used education training tool that promotes variability in methods of delivering information (Young & Perovic, 2016). The purpose of the tool is to consider the ways different learning methods can be combined to achieve learning outcomes.

Aims and Objectives

The aim was to design and deliver a bespoke POCUS training programme that provided adequate didactic information and practical opportunity to enable ultrasound-novice community nurses to (accurately and reliably) acquire and interpret focused POCUS images of the heart and lungs and apply their findings clinically.

Training aims included the nurses being able to:

- identify in which patients POCUS has the potential to impact upon the diagnosis and management plan
- understand the advantages and disadvantages of the physical examination and how POCUS, in conjunction with the physical examination, can aid management
- provide reproducible, standardised ultrasound views (in line with the developed focused POCUS scanning protocol)
- understand the importance of image quality and recognise diagnostic and non-diagnostic images
- accurately and reliably recognise normal images
- accurately and reliably recognise LVSD (and other common significant cardiac pathology) and relate findings to the clinical context
- understand and adopt good POCUS governance.

The specific objectives were to assess the nurses':

1) theoretical POCUS knowledge after training
2) acquisition skills after training
3) perception of training programme effectiveness
4) diagnostic accuracy (sensitivity and specificity) for detecting LVSD
5) LVSD reliability (Cohen's kappa)
6) Ability to detect other significant common cardiac pathology (in line with the scanning protocol and scope of practice)

Methodology

The trainees (nurses)

Four qualified senior community nurses working within an acute clinical team enrolled on the training programme. The nurses included were chosen by the acute clinical team based upon their seniority. The clinical team decided upon the number of nurses considering the training demands of enrolling in this body of research and the need to maintain clinical service provision. All four nurses were female, age range (at time of recruitment) 40-53 years. They all had prior basic ultrasound experience relating to scanning the bladder and vein visualisation but did not have any previous cardiac or lung ultrasound experience.

Nurse eligibility criteria included:

- qualified senior nurse
- currently working for the local acute clinical team
- no previous POCUS experience prior to the POCUS training programme associated with this research project

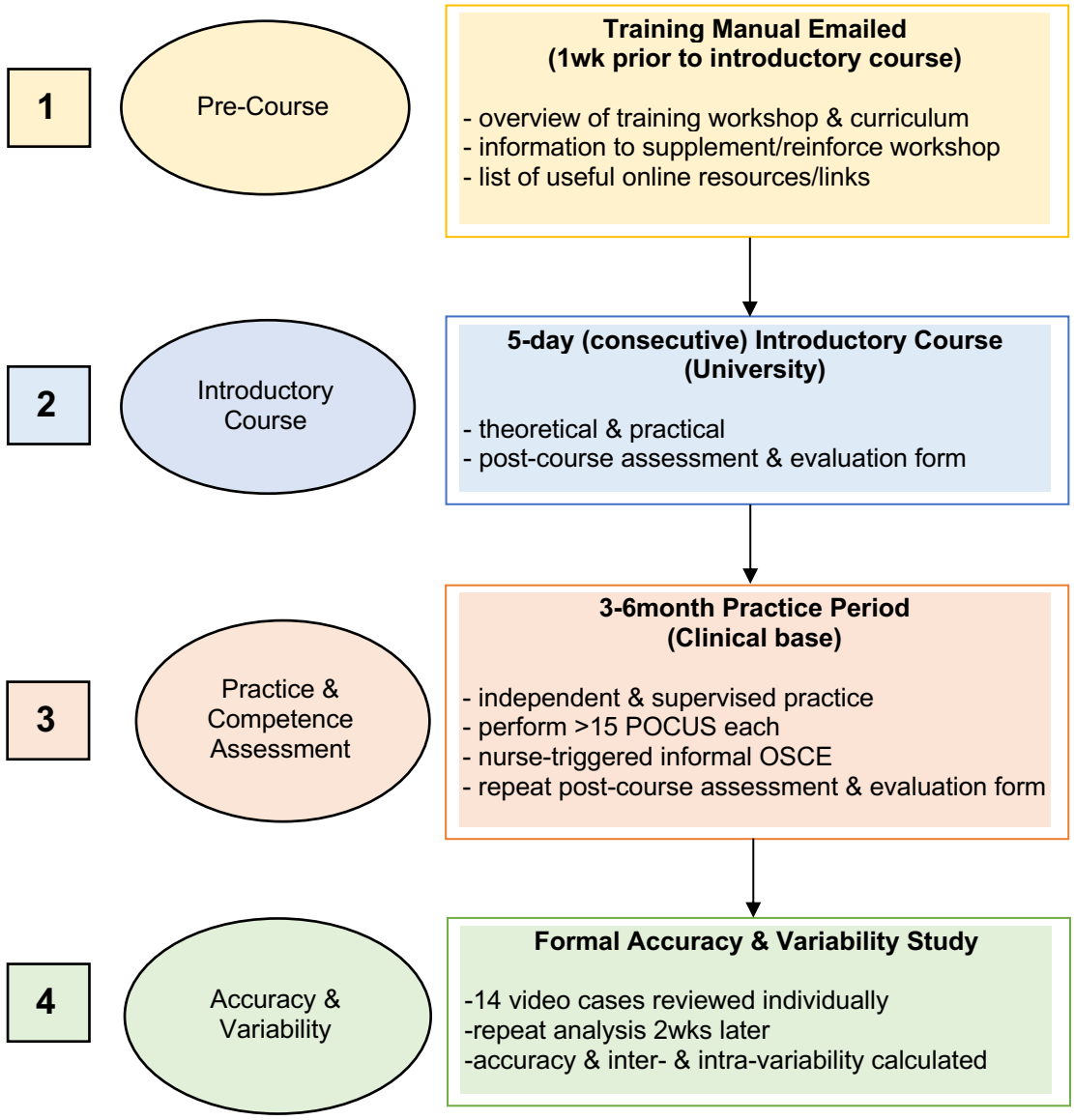
Four-stage training programme

Although I am a PhD student, I am also a highly specialised cardiac physiologist with BSE TTE accreditation and considerable clinical experience in performing TTEs and training others. Considering the existing literature (detailed in introduction section and previously in Chapter 3, Theme 4 of Phase I results and discussion), I designed the POCUS training programme with support from my primary supervisor, Dr Emma Rees, who is an experienced Clinical Scientist and Associate Professor specialising in echocardiography with twenty-years of academic experience.

Training programme design focused on the content of the curriculum and the methods of delivery. The devised training programme comprised of four stages including pre-training material; initial introductory course; practice period; and achieving competence (Figure 4.0).

Figure 4.0

Diagrammatic overview of nurse POCUS training programme



Curriculum content

The curriculum was designed based upon widely accepted core components of POCUS training programmes and the contextual specific needs of this research (trainees and intended clinical setting). An overview of the curriculum is provided in Table 4.0.

Table 4.0

Overview of the POCUS training curriculum

Topics	Brief Detail
Background	
POCUS Overview	Definition; purpose; technological advancements; application; advantages; limitations; current knowns & unknowns
Research Study Overview	Rationale; aims; methodology; outcome measures
The Physical Examination	Recap of physical examination/history (in the setting of HF). POCUS as an adjunct to physical examination- why, how, & when it can be useful to add POCUS
Anatomy & Physiology	Overview of basic heart and lung anatomy & physiology
Pathophysiology	Pathophysiology of HF
Ultrasound Physics	Basic ultrasound physics overview- ultrasound- definition, interactions in the body, principles relating to image acquisition, & optimisation
POCUS Scan	
POCUS Views	Cardiac & lung views- how to get them, & what to assess
GE Vscan Device	Features & functions; limitations; maintenance
Image Quality	Assessing image quality; image optimisation; recognising non-diagnostic images
Data Storage	Storing images; importance of documentation
Scope of Practice	Being accountable; knowing limits; seeking help/advice
Normal Findings & Pathology	
Ventricular Assessment	Assessing size & function; relevant signs/symptoms; recognising normal/abnormal images
Volume Overload	Relevant signs/symptoms; recognising normal/abnormal images (pericardial and pleural effusions, B-line positivity, abnormal IVC)
Valve Assessment	Relevant signs/symptoms; recognising normal/abnormal images
'Other' Abnormalities	Focused on scope of practice. Recognising significant valve disease, hypertrophy, masses, features of pulmonary embolus, prosthetic valves.

The POCUS protocol

Given the unique study context, I devised a context-tailored (elderly patients with acute dyspnoea and suspected HF) bespoke POCUS protocol. The protocol sought to:

- balance the clinically driven, focused nature of POCUS scanning and ensure provision of sufficient clinically relevant information to support accurate assessment
- recognise the nurses' novice status
- recognise the functional limitations of hand-held ultrasound devices (specifically GE Vscan).

The existing POCUS protocol literature (Chapter 3) was used to guide protocol design. All hands-on practice and analytical practice were underpinned by the proposed POCUS protocol. The protocol included heart and lung ultrasound. The scanning views, including transducer positioning and the images to be recorded in each view, are detailed in Table 4.1 and a copy of the scanning guidance is provided in Figure 4.1.

Table 4.1

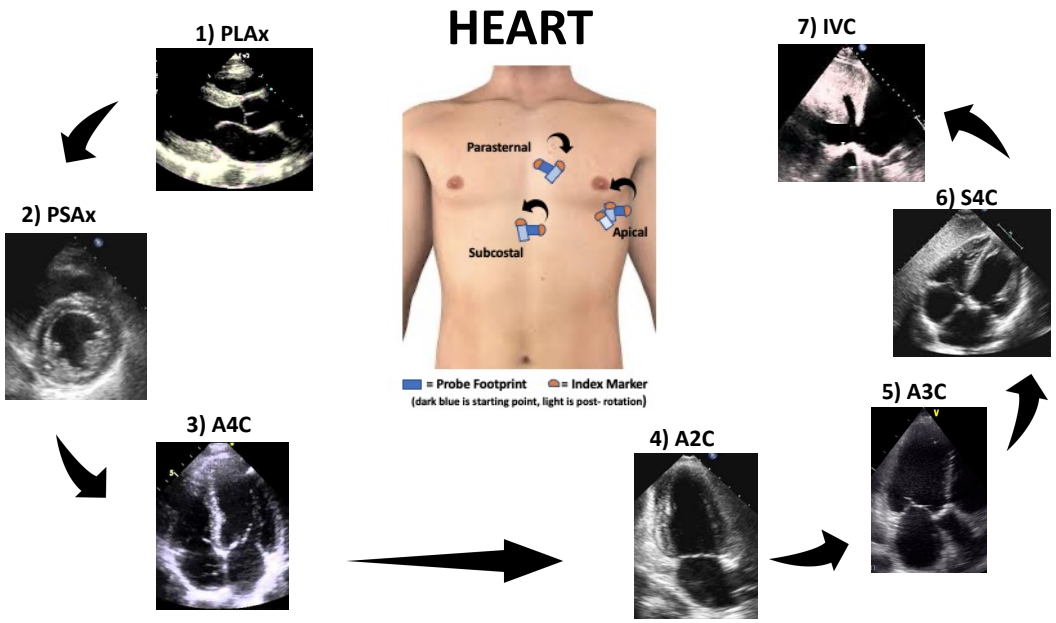
POCUS views, transducer placement, and what to record in each view

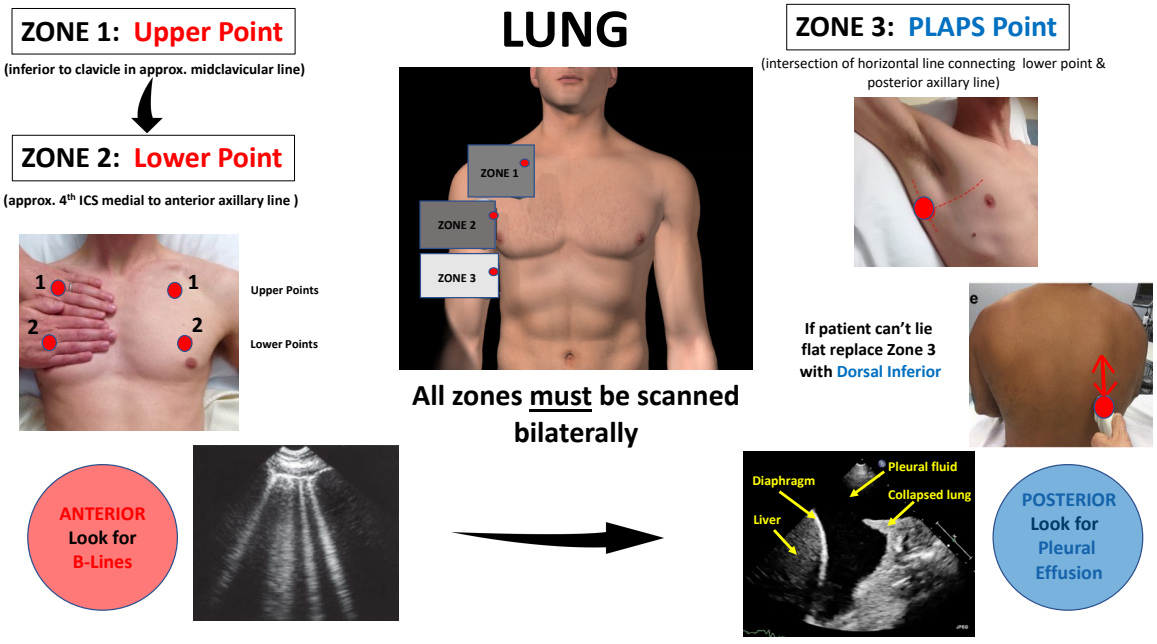
	View	Transducer Position	What to Record
Cardiac *Probe: Phased Array. Pre-set: Cardiac. Orientation: Start transverse*			
1	PLAX	- ~3rd intercostal space - index marker to patient's right side (~11 o'clock)	2D Colour over AV Colour over MV
2	PSAX	-from PLAX, rotate probe ~90° clockwise (~1 o'clock) -tilt down towards patient's left leg for LV at papillary muscle level	2D
3	A4C	-probe over apex beat -index marker towards patient's left side (~3 o'clock) -tilt probe up towards the patients' head	2D Colour over MV
4	A2C	-from A4C, rotate probe ~60° anticlockwise -index marker at ~12 o'clock	2D
5	A3C	-from A2C, rotate a little further & tilt anteriorly	2D
6	S4C	-probe below xiphisternum -index marker to patient's left (~ 3 o'clock) -tilt into the body towards the heart, angle towards patient's left	2D
7	S.IVC	-from S4C, rotate probe so the index marker at ~12 o'clock -angle towards patient's right a little	2D- assess absence/presence respiratory collapse
Lung *Probe: Linear 8-11, Phased Array 12-15. Pre-set: Lung. Orientation: Longitudinal. Marker: To Head*			
8	Left UPA	-left 2nd/3rd intercostal space, mid clavicular line	2D
9	Right UPA	-right 2nd/3rd intercostal space, mid clavicular line	2D
10	Left LPA	-left 4th/5th intercostal space, anterior axillary line	2D
11	Right LPA	-right 4th/5th ICS, anterior axillary line	2D
12	Left PLAPS Point	-left posterior axillary line at base of lungs (~9-11th intercostal space) -intersection of horizonal line at level of lower point & vertical line at posterior axillary line	2D
13	Right PLAPS Point	-right posterior axillary line at base of lungs (~9-11th intercostal space)	2D
14	Left DP	-left mid-scapular line at the lung base	2D
15	Right DP	-right mid-scapular line at the lung base	2D

Note AV = aortic valve; MV= mitral valve; A2C= apical two chamber; A3C= apical three chamber; UPA= upper point anterior; LPA= lower point anterior; PLAPS= PosteroLateral Alveolar and/or Pleural Syndromes; DP= dorsal posterior

Figure 4.1

The POCUS scanning views (heart and lung)





POCUS reporting was concerned with confirming or excluding the presence of significant pathology since this has the greatest clinical use in immediate point-of-care decision making and management. The principal parameters requiring assessment included LV size; global LV systolic function; and volume status (IVC size and collapsibility; pericardial effusion +/- haemodynamic compromise; pleural effusion; and B-lines). Analysis was qualitative and interpretations recorded using tick box options. The analysis guidance and reporting form are shown in Table 4.2 and Figure 4.2 respectively. For all parameters requiring assessment, an 'uncertain' option was included; this was intended for cases of novice uncertainty and if the parameter was not assessable (non-diagnostic) from the images obtained.

Table 4.2

Methods of POCUS assessment and thresholds for abnormal

Assess	Method	View	Abnormal Appearance	Reporting Options	Threshold for Abnormal
Global LV systolic function	Visual	PLAX, PSAX, A4C, A2C, A3C	Reduced: wall thickening; inward endocardial movement; reduction in LV cavity size; MV annulus movement towards apex.	Grossly normal; Abnormal; Severely abnormal; Uncertain	Visual EF: Normal ≥50%; Abnormal 36-49%; Severely abnormal ≤35%
LV dilation	Visual	PLAX & A4C	Visually large, often globular/spherical.	Absent; Present; Uncertain	Moderate-severely dilated
IVC size & collapsibility	Visual	S.IVC (~2cm RA entrance)	Dilated/engorged &/or reduced respiratory change in diameter.	Absent; Present; Uncertain	≥21mm &/or <50% collapse
Pericardial effusion	Visual	PLAX, S4C (plus A4C, A3C, A2C)	Fluid in pericardial sac/space. Tracks above descending aorta (PLAX).	Absent; Present; Uncertain	>5mm
Pleural effusion	Visual	PLAPS/DP, PLAX (+A4C)	Fluid in pleural space. Tracks below descending aorta (PLAX). Fluid (black space) posteriorly above the diaphragm (PLAPS)	Absent; Present; Uncertain	>5mm
B-line Positive	Visual	UPA & LPA	B-line (vertical hyperechoic artefact extending from pleura to bottom of screen without fading)	Absent; Present; Uncertain	≥3 B-lines/zone = positive
LV wall thickness	Visual	PLAX	Wall thickness appears increased, may make LV cavity look small	Absent; Present; Uncertain	Moderate-severe LVH
LA dilation	Visual	PLAX	LA dimension >Aortic root dimension (PLAX)	Absent; Present; Uncertain	LA size > Aortic root dimension (PLAX)
RV dilation/ dysfunction	Visual	A4C	RV equal to/bigger than LV (A4C). Reduced: wall thickening, inward endocardial movement, reduction in RV cavity size, reduced TV annulus movement towards apex.	Absent; Present; Uncertain	RV size ≥ LV size Moderate-severe dysfunction
Stenosis (AV or MV)	Visual	PLAX, A3C	Increased leaflet thickness; reduced excursion; turbulent colour flow.	Absent; Present; Uncertain	Moderate-severe stenosis
Regurgitation (AV or MV)	Visual	PLAX, A4C	Backward colour flow jet (size/width); flow disturbance downstream from valve; receiving chamber dilation.	Absent; Present; Red flag; Uncertain	Moderate-severe regurgitation

Note A2C= apical two chamber; A3C= apical three chamber; RA= right atrium; PLAPS= PosteroLateral Alveolar &/or Pleural Syndrome; DP= dorsal posterior; AV= aortic valve; MV= mitral valve; UPA= upper point anterior; LPA= lower point anterior; TV= tricuspid valve

Figure 4.2

Overview of the POCUS reporting format

FINDINGS

1) What was the left ventricular systolic function? *(tick the appropriate box):*

	Grossly Normal	Abnormal	Severely Abnormal	Uncertain
LV Systolic Function			*	

What was the LV size?

	Normal	Abnormal	Uncertain
LV Size			

2) Were there signs of congestion? *(tick appropriate boxes):*

2a)	Normal	Abnormal	Uncertain
IVC Size & Collapsibility		*	

2b)	Absent	Present	Uncertain
Pericardial Effusion			
-If present, any haemodynamic compromise? (e.g., RV/RA collapse, heart 'swinging', septal bounce)		*	

2c)	Absent	Present	Uncertain
Pleural Effusion		*	

2d)	Absent	Present	Uncertain
B-Lines (present i.e., abnormal= ≥3 per zone) N.B. ≥2 positive zones (bilaterally) suggests pulmonary oedema		*	

3) Were any other abnormalities seen? *(tick appropriate boxes):*

	Absent	Present	Uncertain
Significant LV hypertrophy			
Significant left atrial (LA) dilation			
Significant RV dilation &/or impaired function		*	
Significant aortic valve stenosis		*	
Significant mitral valve stenosis		*	

	Absent	Present	Red Flag *
Aortic regurgitation			
Mitral regurgitation			

Other findings e.g., mass (please specify)	*

The intention of POCUS analysis was to provide qualitative gross assessment and, consistent with most prior POCUS studies (detailed in Chapter 3), interpretation was based upon a "present/absent" or "yes/no" analysis format using a predefined specific imaging protocol (Neskovic et al., 2014). POCUS is intended to answer the clinical question, not to provide a comprehensive analysis, and the ability to accurately grade more precise severity requires greater experience and expertise and is outside the scope of practice of novice POCUS users. In addition, learning how to make even basic measurements adds to the duration of didactic and practical training and pausing to quantify the size of a cardiac structure requires additional time and ECG absence hinders the accuracy of several measurements (Spencer et al., 2013).

For LV systolic function assessment only, broad categorisation options of normal, reduced, or severely reduced were included. The protocol did not specifically differentiate between HFrEF and HFmEF. However, a 'severely reduced' option was included because knowledge of whether LV systolic function is severely reduced allows immediate therapeutic decisions to be made in a patient presenting with acute decompensated HF (Spencer et al., 2013), as well as triaging the need (and speed) for comprehensive TTE (relevant in the subsequent clinical study). Exposure to numerous case examples of different grades of LV systolic dysfunction (and normal LV systolic function) during training intended to support the development of an ability to categorise LV systolic function according to the broad categories. Reporting of ejection fraction was not included however the threshold for LVSD presence was a visually estimated ejection fraction <50% and ≤35% for severely reduced LV systolic function (in line with BSE guidelines).

The only quantitative measure was counting the number of B-lines as there is evidence supporting speed and ease of learning (Bedetti et al., 2006.). After an hour teaching session, novice ultrasound users have been able to reach the same accuracy in counting B-lines as a highly experienced cardiologist (Chiem et al., 2015).

The second part of analysis involved assessing for the absence/presence of significant: RV dilation and/or dysfunction; aortic and/or mitral regurgitation and/or stenosis; LV hypertrophy (LVH); and left atrial (LA) dilation. The rationale for including these was that they may be clinically significant findings that are more prevalent in the elderly. Therefore, it is useful to assess whether they can be reliably identified by the nurses to

help guide the analysis protocol for the subsequent clinical study. Significant LVH and LA dilatation were included because they can be suggestive of diastolic HF. Although diastolic HF cannot be quantitatively assessed by novice-POCUS users this could (in the subsequent study) be considered as a potential prompt for TTE if clinical suspicion remains high. Assessment of these additional parameters was visual and involved determining whether present, absent or uncertain. The nurses were not expected to grade these abnormalities due to their novice status and machine limitations. However, numerous video examples of different degrees of severity were provided during training to support the development of an ability to recognise significant abnormalities. In terms of regurgitation (aortic and mitral) a "red flag" option was provided (in addition to present/absent options) because although the colour flow on hand-held devices permits an accurate assessment of regurgitation severity and severity grading requires additional training, we felt it important (clinically) that suspected severe/torrential regurgitation was highlighted to facilitate an urgent review.

Pre-course material (training manual)

I designed a dedicated POCUS training manual (Microsoft Word document) (freely available on request). It included the training curriculum and additional theoretical information to supplement and expand upon the introductory course lectures. It recommended open access online learning resources. I also produced a workshop booklet containing the logistical information; learning objectives; curriculum overview; workshop timetable; the scanning and reporting protocols; and links to online self-directed material and recommended texts. Both were sent (electronically) to the nurses included in the training programme one week prior to the introductory workshop and paper copies provided on day one of the introductory course.

Introductory course design

The intention of the introductory course was to provide didactic information and initial hands-on practice opportunity. The clinical team and academic team collectively agreed upon a timeframe of five consecutive days for the initial introductory course. We considered the importance of providing sufficient training opportunity and the ability to maintain clinical service demands whilst the nurses were undertaking the course. Consecutive days were

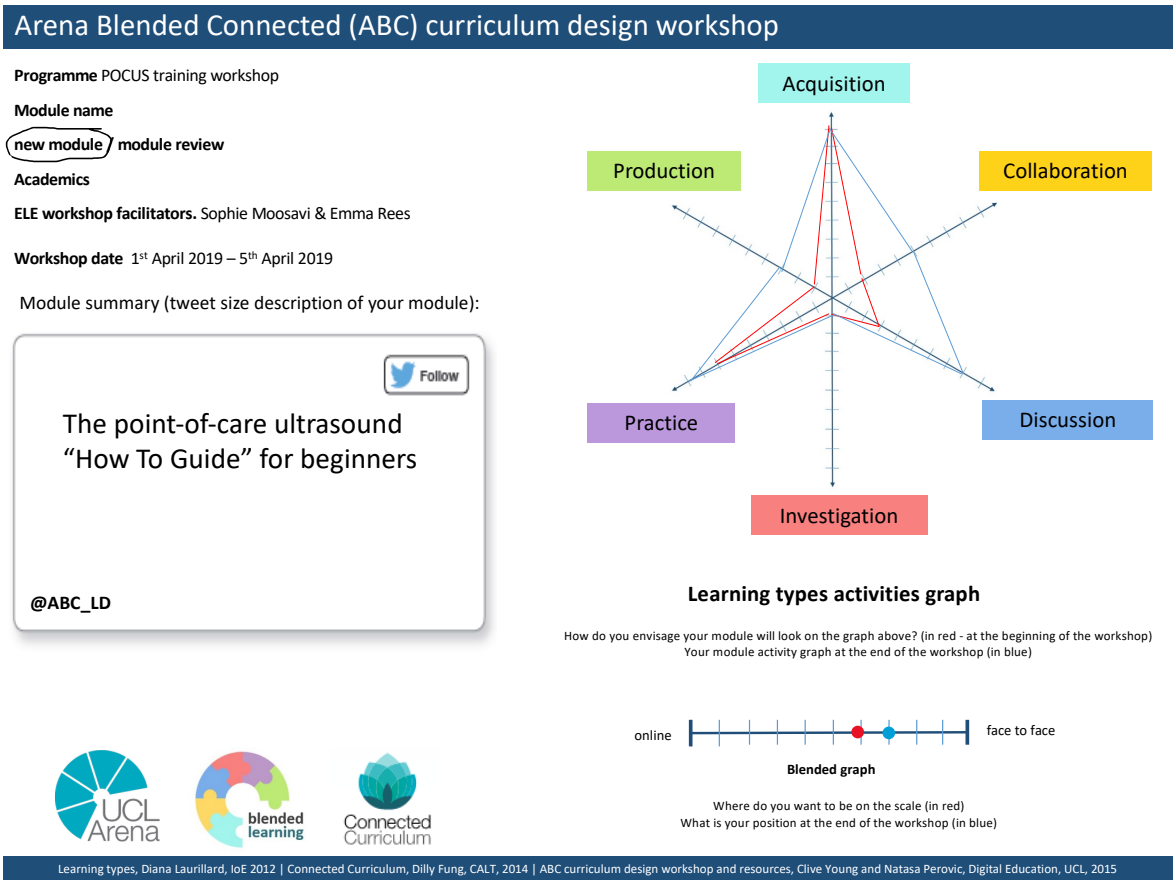
selected to enable repetition and reinforcement of information and practical skills. I chose face-to-face delivery to ensure any questions could be answered immediately and to allow opportunity for hands-on practical support throughout.

The course was intended to be learner-centred, including case-based scenarios and hands-on sessions, drawing on existing knowledge and skills and application to clinical practice**.** While facilitated learning through lectures did occur, the focus was on a collaborative pedagogical approach to help support group learning; providing opportunity for learners to contribute, interact, and share experience and knowledge. A reflective approach was adopted, during and after, to assess effectiveness and potential ways of improving training delivery.

To provide structure to the training methodology, I used the Arena Blended Connected (ABC) curriculum design (Young & Perovic, 2016) (Figure 4.3). This is recommended to teaching staff at my university as a validated approach to curriculum design.

Figure 4.3

The Arena Blended Connected workshop curriculum design tweet and graph (Young & Perovic, 2016)



I compiled a draft storyboard for the introductory course by sequencing and stacking six 'learning types' cards (including acquisition; investigation; collaboration; discussion; practice; and production). A scaled down version of the storyboard is outlined in Table 4.3. I chose learning activities and identified opportunities for assessment (starred in Table 4.3).

Table 4.3

The Arena Blended Connected storyboard workshop design

Timeline	Learning Types				
Pre-Entry	**Acquisition** -Websites/digital resources -Digital training manual				
Day 1	**Acquisition** -Listen to in-person presentations -Watch demonstrations -Links to video guides	**Collaboration** -Group work-POCUS -Group work-A&P	**Discussion** -Class discussion -Group discussion	**Practice** -Hands-on with Vscan -Heart & lung models	
Day 2	**Acquisition** -Listen to in-person presentations -Watching demonstrations -Links to video guides	**Collaboration** -Group work-image quality -Group case reviews	**Discussion** -Class discussion -Group discussion	**Practice** -Hands-on practice (simulator)	
Day 3	**Acquisition** -Listen to in-person presentations -Watch demonstrations	**Investigation** -Compare current POCUS guidelines	**Collaboration** -Group case reviews	**Discussion** -Class discussion -Group discussion	**Practice** -Hands-on practice (simulator)
Day 4	**Acquisition** -Listen to in-person presentations -Watch demonstrations	**Collaboration** -Group case reviews	**Discussion** -Class discussion -Group discussion -Group email/WhatsApp	**Practice** -Hands-on practice (volunteers)	**Production** -Perform scans -Report example cases
Day 5	**Discussion** -Class discussion -Group discussion -Group email/WhatsApp	**Practice** -Hands-on practice (volunteers)	**Production** Perform scans Report example cases Evaluation form		

I planned lectures to be as brief as possible and didactic information to be broken up with discussions, breaks, and practical sessions. The course was designed to alternate between theory and hands-on session and for didactic information to be delivered in a classroom setting.

To facilitate practical training, use of three-dimensional cardiac models and ultrasound simulation mannequins were included. Simulator use was planned at the early stages of the course to aid understanding regarding anatomy and imaging planes. The second half of the course provided opportunity to scan human volunteers. Exposure to normal and abnormal findings and pathologies comprised POCUS video case examples and normal/abnormal case examples on the simulator. The case mix covered the breadth of pathology that the nurses would be expected to recognise in clinical practice (LVSD, significant valve disease, pericardial and pleural effusions, B-line positivity; thrombus/mass).

I created a flexible course timetable to provide structure while allowing session formats and content to be adapted to trainee needs.

Introductory course delivery

The introductory course was delivered by two trainers, an Associate Professor at the university and I (detailed previously), both of whom are BSE-accredited in TTE. Additional input, in terms of guiding LUS teaching content, was provided by the Consultant Cardiologist (Imaging Specialist) associated with this research project.

The five-day (thirty-hour) POCUS introductory course was delivered at Swansea University. Content and methods of delivery were consistent with those planned. The theoretical information was delivered using Microsoft PowerPoint presentations. In addition to text, these included images and case examples/video clips. Case study examples were used to help support knowledge development. Where relevant, didactic information was complemented with the use of three-dimensional models and demonstrations on the simulator to support teaching. As intended, theoretical sessions were broken up with discussions, breaks, and practical sessions.

The flexible timetable was followed with alterations based upon the nurses training needs. It became clear at the start of the workshop that the nurses required additional teaching regarding the pathophysiology of HF and clinical signs, symptoms, and murmur explanation. Therefore, they were provided with additional lectures on these topics to review at home and any questions encouraged. On day two the nurses (collectively) noted that they found it useful to keep revisiting the scanning views and the structures seen in each view therefore a recap of this was included at the start of all subsequent morning and afternoon sessions.

Hands-on experience was initially gained using the HeartWorks simulator which allows simulation in cardiac anatomy, TTE, and LUS. It has an integrated anatomy textbook with content covering 160 cardiac structures and a fully interactive three-dimensional heart model. The simulator contains numerous heart and lung pathology models which were used to ensure exposure to an adequate breadth of pathology. Real-time imaging on the screen allowed users to identify probe placement in relation to the captured ultrasound plane and corresponding cardiac structures and surrounding organs. Split screen views showed the ultrasound image in relation to the three-dimensional heart anatomy.

For the second half of the course, trainees had opportunity to scan human volunteers using the GE Vscan with Dual Probe (phased array and linear array). The volunteers (six) were recruited by the Associate Professor and comprised of university staff who had previously volunteered for other university echocardiography teaching courses (previous screening). They were all clinically stable (asymptomatic) and without cardiac pathology.

On the final day of the course, all four nurses completed the post-course assessments (MCQs, case reviews, and evaluation form) under university exam-like conditions (supervised by the two trainers).

Practice period design

The practice period was designed to provide opportunities for additional image acquisition and interpretation experience independently and in the presence of an expert with immediate feedback.

Weekly supervised practice sessions with a qualified sonographer (myself) were planned with the intention of providing immediate feedback and guidance during image acquisition followed by analysis discussion post-scan. Three to five case reviews (relevant to the nurses' scope of practice) were to be shown at the start of each session (prior to hands on practice) to support adequate development of analytical skills and provide exposure to pathology.

Nurses were instructed to keep records of independently performed and analysed cases which could be reviewed by the expert at the subsequent supervised session with the intention that any discrepancies and feedback would be communicated to the trainee as part of the learning process. A USB containing a range of clinical cases (thirty) relevant to the nurses' scope of practice (dominance on LV systolic function) was created and given to the nurses. It included the correct interpretation (to facilitate learning).

A broad time frame was proposed (three-six months) during which each nurse was required to perform and interpret more than fifteen scans and trigger an OSCE when they felt competent.

Despite the poor correlation between volume and competence, a minimum number of scans was provided to ensure that each nurse undertook at least that. Several studies have reported "acceptable" levels of acquisition and interpretive skills by novices within 20 to 40 studies, depending upon the scope of acquisition and interpretation (Hellmann et al., 2005; Kimura, Amundson, et al., 2012; Royse et al., 2006). Since hands-on practice is included in the prior introductory workshop before scanning "real" patients in their clinical environment each nurse will have performed in excess of 20 scans. It should be noted that I am not proposing that completion of a set number of scans equates to adequate training, instead a suggested minimum case load (which is anticipated to be exceeded) is given prior to accuracy testing.

Practice period delivery

I provided support for the extended practice period (all theoretical and practical in-person and virtual sessions). There was opportunity for additional support from the other trainer and the Consultant Cardiologist, but this was not required. Towards the beginning of the practice period, due to receipt of funding, two GE Vscan Extends were purchased and used for the remainder of the practice period.

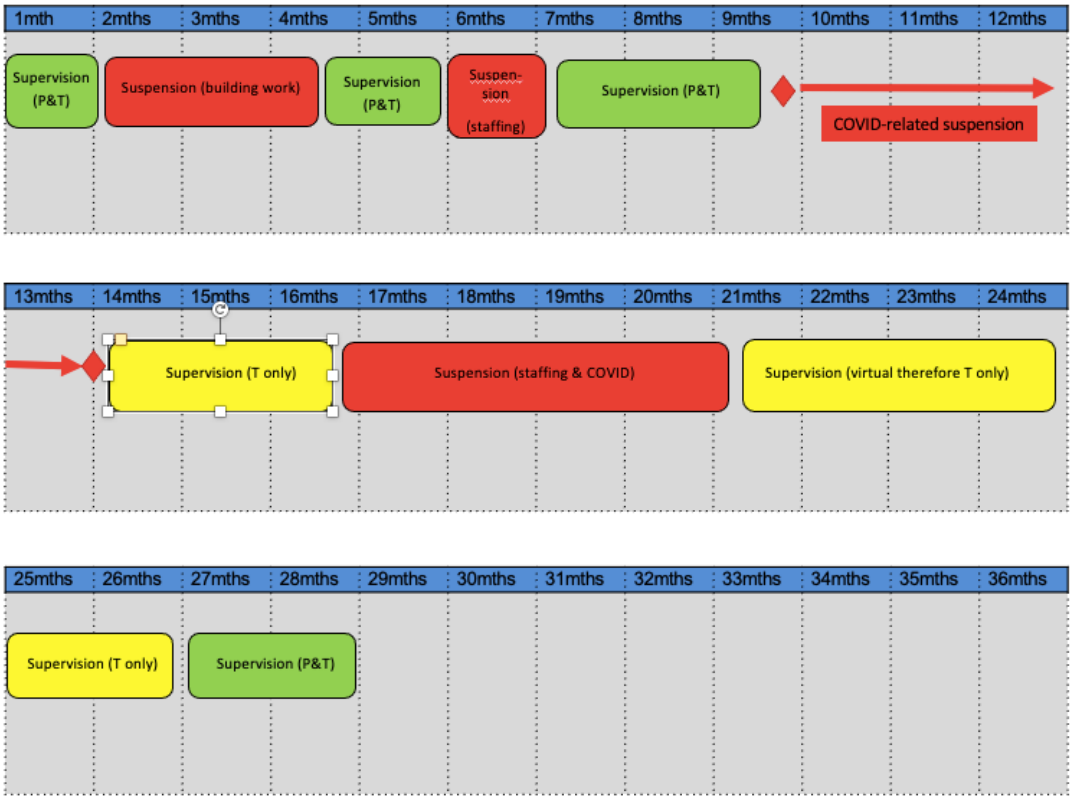
As planned, the beginning of every supervised session included reviewing video case examples of normal and abnormal scans. For most sessions, the nurses completed POCUS analysis forms independently and then collectively discussed the findings because feedback from the introductory course revealed that the nurses found this useful. The nurses all accessed the USB containing the case examples sporadically (depending on time). Hands-on scanning opportunity during the practice period was performed on clinically stable staff volunteers working at the nurses' clinical base.

The planned practice period included weekly supervised sessions however this was disrupted by external factors outside of our control. Early in the practice period, training was suspended for just over two months due to building work at the nurses' clinical base and staff shortages. Training was subsequently interrupted twice due to the COVID-19 pandemic. The pandemic significantly impacted the service. In the early stages, the nurses were heavily relied upon for COVID screening and then later, for providing field hospital support. Training was suspended due to increased clinical demands and staff shortages. As pressures eased slightly, theory-only training sessions were allowed (adhering to social distancing recommendations). The second wave of the pandemic caused another halt in all training. Once pressures eased slightly, theory-only virtual training sessions were caried out via a video conferencing app (Microsoft Teams). Due to the prolonged break in training, it was necessary to provide a recap of theoretical knowledge (including case reviews) during these sessions. COVID-19 restrictions meant that hands-on practice was prevented for prolonged periods. Extensive delays meant nurse confidence and competence was markedly reduced, and training had to return to the basics.

A timeline for the training during the practice period is provided in Figure 4.4 where "P" relates to practical, hands-on practice, and "T" relates to theory. However, within the blocks shown, sessions were not always possible weekly due to COVID-19 related pressures on the service.

Figure 4.4

Overview of the practice period timeline



Note P= practical; T= theory

In terms of training sessions that included practical and theoretical components (green in Figure 4.4), the nurses received approximately six to seven months of discontinuous training. This equated to approximately twenty sessions of training where each training averaged approximately two-and-a-half hours (range two to three hours). The total duration of theory sessions (yellow in Figure 4.4) was approximately eight to nine months, again discontinuous, and consisted of approximately twenty-six sessions (each session approximately two-hours).

Due to the prolonged periods where hands-on practice was prevented, during the last two months of the practice period each nurse was allocated two one-day sessions (approximately six-hours/day) of hands-on practice at the University. During these sessions, each nurse scanned approximately eight healthy volunteers (variable age/gender/body mass index). The volunteers were recruited from the university via an email invitation for volunteers (screened by qualified sonographer). The nurse scanning sessions were supervised by a qualified sonographer who provided guidance and feedback throughout.

The nurses were told to trigger an OSCE assessment when they felt competent. Due to the disruption in hands-on training practice this did not occur until late on in the practice period. All nurses performed the OSCE in the same month. The OSCE was assessed by a BSE-accredited qualified cardiac physiologist (myself) against the pre-defined criterion (Appendix A). Each nurse independently performed a POCUS scan (using the GE Vscan Extend hand-held ultrasound device) on a clinically stable volunteer unknown to them and completed a POCUS analysis form in line with the study scanning and reporting protocol. All nurses then completed the same MCQs and evaluation forms that they had completed after the introductory course.

Assessments of learning- Part I

Assessment of competence comprised of two parts (I and II).

Part I involved knowledge-based assessments (metric and trainee perceived knowledge) and evidence of practical ability (via OSCE examination). Table 4.4 provides detail of the initial assessments.

Table 4.4

Initial methods of assessing competence

	Written Examination	Case Views	Evaluation Form	OSCE
Testing:	-Theoretical knowledge	-Analytical knowledge	-Perceived knowledge -Opinion of training	-Practical skills
Format:	-MCQs -Annotations	-Video case views	-Likert scale -Open Questions	-OSCE
Detail:	Ten MCQs & four annotation questions. Total marks 29 where 1 mark for correct, 0 for incorrect. Topics included POCUS use & limitations; presentation of common cardiac pathology; anatomy; basic ultrasound physics & image optimisation; principles of LUS; colour flow mapping; normal and abnormal pathology; & labelling scanning views & structures.	5 video cases. Review & identify absence/presence of pathology. Cases included LVSD & mitral regurgitation; PLE; pericardial effusion & echo signs of tamponade; normal; and aortic stenosis.	Grade perceived knowledge (1-5) pre- & post-training for each aspect of the POCUS curriculum. Rate, from 1 (strongly agree) to 4 (strongly disagree), how much agree/disagree with statements relating to training appropriateness. Open questions relating to what was most useful; least useful; how to improve; & what/if any additional training needs.	Total marks 68. 34 different points (7 general; 9 cardiac views; 3 lung views; 15 reporting). 2 points awarded for excellent, 1 for satisfactory, & 0 for poor/absent. Perform & report protocol driven POCUS examination on a clinically stable, healthy volunteer selected by the BSE-accredited assessor.
When:	Post-introductory course & post-practice period.	Post-introductory course & post-practice period.	Post-introductory course & post-practice period.	Nurse-triggered (during practice period).

The MCQs and video cases were created by the Associate Professor who is experienced in writing assessments. The evaluation form (including perceived knowledge) was collectively designed by both trainers (Appendix B). An OCSE was included to assess acquisition skills. Each nurse was required to perform an OSCE on a clinically stable, healthy volunteer whom they had not scanned previously. At this stage the intention of the OSCE was to provide general guidance of competence to help direct additional training and to provide the nurses with experience of what would be required of them in clinical practice, The criterion (Appendix A) was adapted and expanded from the OCSE used by Bornemann et al. (2017) in

their assessment of a POCUS curriculum's effect on competency measures in family medicine graduate medical education.

Training programme design included assessments of learning at the end of the introductory course and at the end of the practice period (repeated). The intention being that post-introductory results could be used to guide additional training needs for the subsequent practice period, and the impact of the additional period of practice on knowledge could be assessed.

Assessments of learning- Part II (accuracy & reproducibility study)

Part II of the assessment process involved formally assessing the diagnostic accuracy and reproducibility of community nurse-led POCUS for confirming/excluding LVSD. This was conducted after the practice period and OSCE.

Originally a double-blind diagnostic accuracy and reproducibility study was planned to assess the diagnostic accuracy of POCUS by community nurses for the detection of LVSD in older adults (n=100) with and without LVSD in a controlled (non-clinical) environment (study overview provided in Appendix C). The study gained Health Research Authority and Health Care Research Wales approval (Research Ethics Committee ref: 20/WA/0119) and was due to begin in April 2020. However due to the COVID-19 pandemic and government restrictions, the study could not be conducted. The lasting COVID-19-related restrictions, and PhD time pressures, meant that study methodology was no longer feasible and therefore I redesigned the proposal to comply with COVID-19-restrictions. The modified design did not include assessment of acquisition skills (thereby removing patient contact).

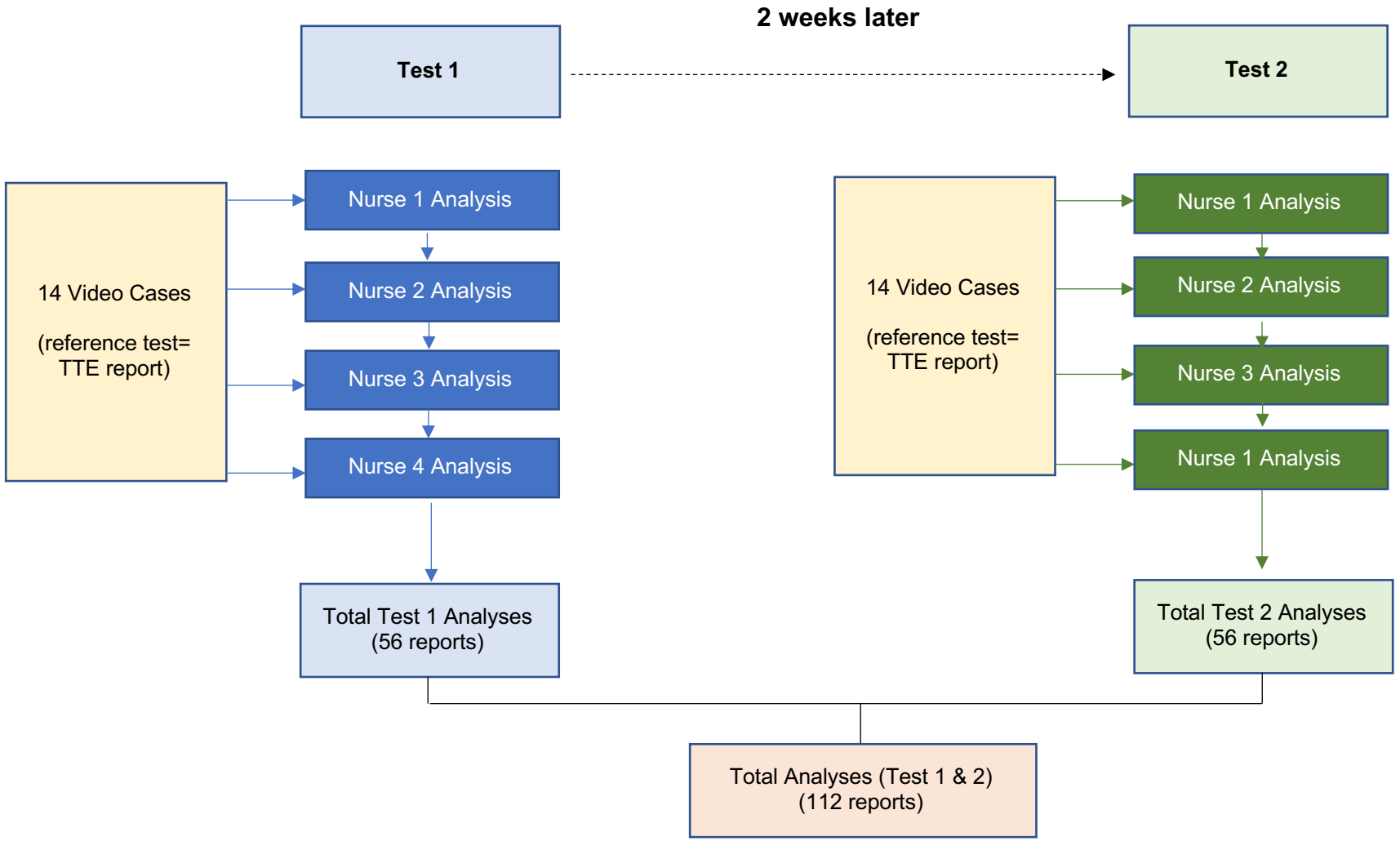
Instead, a single-blind, diagnostic accuracy and variability study was designed (Research Ethics Committee reference: 21/HCRW/0027, IRAS 304785) to assess the analytical accuracy (sensitivity and specificity), inter-operator variability (reproducibility), and intra-operator variability (repeatability**)**. The reference test was a comprehensive TTE report by a BSE-accredited echocardiographer. The study involved the nurses reviewing and interpreting fourteen video cases (blind to clinical information) twice (two-weeks apart).

Prior to undertaking a reliability study, a sample size calculation is recommended to provide a stated probability of detecting a statistically significant kappa coefficient or of providing a confidence interval of a desired width (Donner & Eliasziw, 1992; Flack et al., 1988). Sample size is a function of alpha (type I error), power (1 – type II error) and effect size. To simplify all calculations, alpha and power are usually set at 0.05 and 80.0% respectively and was the case in this study (Bujang & Baharum, 2017). Sim and Wright provide tabulated guidance regarding the minimum number of participants required to detect a kappa coefficient as statistically significant, with various values of the proportion of positive ratings made on a dichotomous variable by two-raters (Sim & Wright, 2005). They specify that if the kappa to detect is 0.7, in a two-rater study to detect a statistically significant kappa ($P \geq 0.05$) on a dichotomous variable (80% power and null hypothesis value of kappa 0.00) the proposed number of subjects for a 1-tailed and two-tailed test null hypothesis is thirteen and seventeen respectively. It should be noted that the proposed sample sizes assume no bias between raters. Bujang and Baharum similarly provide tabulated sample size calculations intended to assist researchers in determining the minimum sample sizes required for conducting Cohen's kappa agreement test (Bujang & Baharum, 2017). If the expected minimum kappa value is 0.7 for every item (K2=0.7) and assuming no agreement for the test-retest at the first place (K1=0), they suggest that when the power and alpha are pre-specified at 80.0% and 0.05 respectively a minimum sample of fourteen is required, while holding an assumption that the proportion of ratings in agreement by both operators in each category is assumed to be directly proportional to one another. Based upon this, a sample size of fourteen was used for this study.

A diagrammatic overview of study methodology is provided in Figure 4.5.

Figure 4.5

Overview of the accuracy and reproducibility study



In a reliability study, participants (or in this setting video cases) should be representative of the study population. Video cases were drawn from the real world rather than simulated or perfect example cases. Cases (anonymised) were obtained from local NHS/university echocardiography reporting/storage system in terms of their reported conclusion. Cases were not randomly selected because specific pathologies (detailed in objectives) were required. Each case was allocated a unique, randomly generated, five-digit number. Cases were selected based on pathology relevant to the nurses' training including common pathologies and normal studies. LVSD was present in six of fourteen cases. Signs of congestion and significant valve disease were included. Collectively, the cases covered examples of normal studies (n=3); LVSD (regional and global) (n=6); pericardial effusion (n=6, one of which had echo signs of tamponade); pleural effusion (n=3); B-lines/pulmonary oedema (n=6); RV dilation/systolic dysfunction (n=3); aortic stenosis (n=2); mitral stenosis (n=1); aortic regurgitation (n=6); mitral regurgitation (n=12); and mass/thrombus (due to clinical significance and the association of thrombi and significant LV dysfunction) (n=1). The cases included sufficient images, selected from the bespoke POCUS scanning protocol, to allow accurate determination of the presence/absence of clinically significant abnormalities.

Each nurse independently reviewed (on a laptop) the fourteen focused ultrasound video examinations and completed a standardised protocol-driven POCUS reporting form (Figure 4.2) for each case (index test). The nurses were blind to demographic and clinical information. They were assigned a maximum of 10mins/case to complete analysis. I supervised the review sessions to ensure interpretation was performed individually without the use of aids. Results were compared with reference test result (echocardiography report). The same process was repeated two-weeks later with identical cases in the same conditions (Test 2) to gain insight into the repeatability of nurse analyses. The nurses were informed, and agreed, not to discuss the cases with other nurses involved in the study. The nurses were aware that they had to complete two review sessions (two-weeks apart) but unaware that the same cases were to be shown at each.

Other than the variable under assessment, study design aimed to keep all other variables constant. During inter-rater variability testing the cases shown, the reviewing system/setting, and the method of analysis (and analysis guidance) all remained constant with only the rater (nurse) changing. Due to clinical demands the time (day/date) of testing was not the same for each nurse. In terms of intra-rater variability testing, the cases shown, the reviewing system,

the method of analysis/analysis guidance and the rater all remained constant with only the time (two-week interval) and sequence of cases (to reduce potential bias) changing at testing session 2.

Diagnostic accuracy was determined by comparing index test results (nurse analyses) to reference test results (TTE report). The primary outcome measures were sensitivity and specificity for LVSD (target pathology) with target values set at ≥0.80. Analyses were made using a strict protocol based on qualitative assessment of ventricular systolic function. Ability to detect LUS findings of pulmonary venous congestion (PLE or pulmonary oedema), evidence of systemic venous congestion (dilated IVC ± reduced collapsibility), and additional significant cardiac pathology, were also assessed however the small sample size precluded the use of accuracy measures. Instead, numbers of identified/missed pathology were assessed.

The kappa statistic was used to measure the extent to which the nurses assigned the same score to the same variable (McHugh, 2012). This is in line with the Standards for Reporting Diagnostic Accuracy Studies (STARD) statement which is clear in its recommendations of the kappa statistic for the assessment of operator-variability for categorical variables (items 13 and 24) (Bossuyt et al., 2003). A kappa value of 1 indicates perfect agreement however in reality perfect agreement rarely exists (Bujang & Baharum, 2017). Landis and Koch proposed that the strength of agreement for kappa coefficients of 0.41–0.60 is moderate, 0.61–0.80 is substantial, and 0.81–1 is almost perfect (1977). Low levels of inter-rater reliability are not acceptable in clinical research because results can (hypothetically) influence clinical practice in a way that leads to poorer patient outcomes. Therefore, considering prevalence, bias, and the clinical context, a minimum kappa value of 0.7 (substantial agreement) was chosen as the target value.

Predetermined threshold values were selected to ensure sufficient accuracy and reproducibility before embarking on the subsequent clinical phase of feasibility testing.

Results

All four nurses completed all assessments as planned. Results of the MCQs (which included annotation questions) and video case reviews post-introductory course (blue) and post-practice period (orange), OSCE scores post-practice period (orange), and nurse accuracy and reproducibility of LV systolic function assessments (from accuracy and variability study) (green) are shown in Table 4.5.

For the formal accuracy and reproducibility assessment, each nurse completed the fourteen video case reviews twice (two-weeks apart). None required the full allotted time. Time taken to complete each analyses session (fourteen case reviews) ranged between 70-120mins. For accuracy measures, binary "absent/present" categories were used and, adopting a conservative trade-off, any ratings of 'uncertain' were considered positive. Therefore, for LV systolic function the broad categories were reduced to absent ("grossly normal") and abnormal (including 'abnormal,' 'severely abnormal,' and 'uncertain').

Table 4.5

Nurse assessment results at the different stages of testing

Nurse	MCQ (including annotations) Score (%)		Video Case Score (%)		OSCE Score (%) (Post-Practice Period)	Accuracy & Reproducibility Results for LVSD (based on Test 1 & 2 combined)					
	Post- Course	Post-Practice Period	Post- Course	Post-Practice Period		Sensitivity	Specificity	PPV	NPV	Accuracy	Kappa Value
1	83	83	40	100	90	1.0	0.88	0.86	1.0	0.93	1.0
2	86	97	60	100	88	0.83	1.0	1.0	0.89	0.93	1.0
3	83	59	40	80	88	1.0	0.75	0.75	1.0	0.86	0.72
4	93	86	40	100	85	0.92	0.94	0.92	0.94	0.93	0.71
Average	86	81	45	95	88	0.94	0.89	0.87	0.95	0.91	0.86

Note PPV= Positive Predictive Value; NPV= Negative Predictive Value

The nurses' individual results for the MCQs and video cases at the different stages were fairly consistent with each other. The exception was the MCQ score for nurse 3 post-practice period which was much lower than the other nurses at 59% (others ranged between 83-97%). Aside from nurse 3, MCQ scores were similar post-course and post-practice period. Results of the video case reviews were markedly higher (≥40% increase) post-practice period compared to post-course for all nurses with scores ≥80% post-practice period.

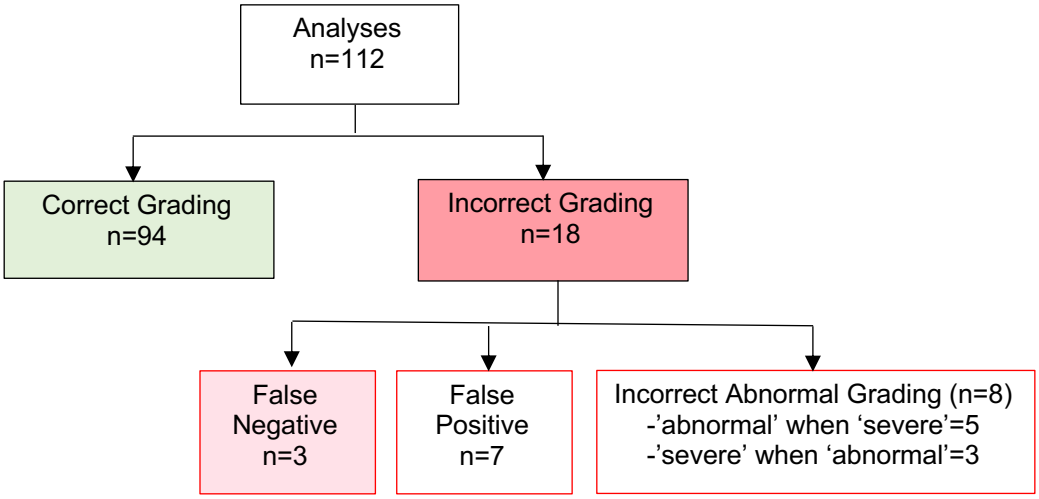
For the OSCE assessment, there were no non-diagnostic studies. Only one view (S.IVC) was unobtainable/non-diagnostic in one scan, and this was correctly recognised as a non-diagnostic scanning window by the nurse. All other views obtained were scored satisfactory (1 point) or excellent (2 points). OSCE scores ranged from 85-90% (mean 88%).

For the reproducibility study the nurses' sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy for detecting LVSD were calculated based on their analyses over the two testing sessions (twenty-eight analyses each) and the average results were calculated based upon the total analyses (n=112) (Table 4.5). All accuracy measures met the target value (≥0.8). The nurses' kappa values similarly exceeded the target of ≥0.7 (range 0.71-1.0).

In terms of grading LVSD, with options of grossly normal, abnormal, severely abnormal, and uncertain, gradings were correct in 84% (Figure 4.6). Three cases (3%) were graded normal when function was 'abnormal' (mild) on reference (false negative). The remaining cases with incorrect gradings related to false positives or incorrect choices regarding the degree of dysfunction (nurse graded 'abnormal' when reference 'severe' or vice versa).

Figure 4.6

Accuracy of grading LV systolic function status



The presence of other significant pathology (aside from LVSD) included in the POCUS report was correctly identified or excluded in most cases (Table 4.6). In terms of signs of ultrasound signs of congestion, the one case of significant pericardial effusion (with ultrasound signs of cardiac compromise) and four cases of pleural effusion were detected by all nurses at both testing sessions. Most cases of abnormal IVC (84%) and B-line positivity (81%) were collectively detected across the two testing sessions. For the other significant cardiac pathologies, all cases of significant aortic stenosis and mitral stenosis, and all but one case of aortic regurgitation, were detected by all nurses at both sessions. Most (93%) cases of significant mitral regurgitation were detected. There was more variability in assessments of the RV with 71% of cases of RV dilation ± RV dysfunction detected collectively.

Table 4.6

Nurse rates of detection of other significant pathology (aside from LVSD) across testing sessions 1 and 2 (accuracy and reproducibility study)

Nurse	Cases of Other Significant Pathology Detected (Testing session 1 & 2 combined)								
	Abnormal IVC (n=8)	**B-line positivity (n=8)**	**Pericardial effusion (n=2)**	**Pleural effusion (n=4)**	**Aortic stenosis (n=4)**	**Mitral stenosis (n=2)**	**Aortic regurgitation (n=8)**	**Mitral regurgitation (n=18)**	**RV dilation ± dysfunction (n=6)**
1	7	6	2	4	4	2	8	14	3
2	7	8	2	4	4	2	8	18	5
3	7	7	2	4	4	2	7	18	6
4	6	5	2	4	4	2	8	17	3
Total collectively detected	*27*	*26*	*8*	*32*	*16*	*8*	*31*	*67*	*17*
Total collectively missed	*5*	*6*	*0*	*0*	*0*	*0*	*1*	*5*	*7*

For the other additional pathologies there was greater variability with some under-reporting of LA dilation (ten false negatives and three false positives); over-report of LV dilation (ten false positives and two false negatives); and under- (and over-) reporting of LVH (three false positives and five false negatives). The consistency of the nurses' assessments of other pathology cannot be assessed via kappa due to low prevalence.

The evaluation form (Appendix B) assessed the nurses' self-rated knowledge level for different aspects of POCUS from 1-5 (1= no knowledge, 3= adequate, and 5= fully competent). Results for all nurses indicated no or little self-rated knowledge at baseline, with improvements post-course and highest perceived knowledge results post-practice period for all topics (Table 4.7). Average self-rated knowledge (across topics) at the three different time points showed higher self-rated scores post-practice period compared to baseline or post-introductory course. At the end of the practice period (post-training completion) all self-rated results indicated at least adequate-to-competent knowledge. Nurses 3 and 4 had lower average post-practice self-rated knowledge and nurse 3 had the lowest measured accuracy and post-practice period MCQ score.

Table 4.7

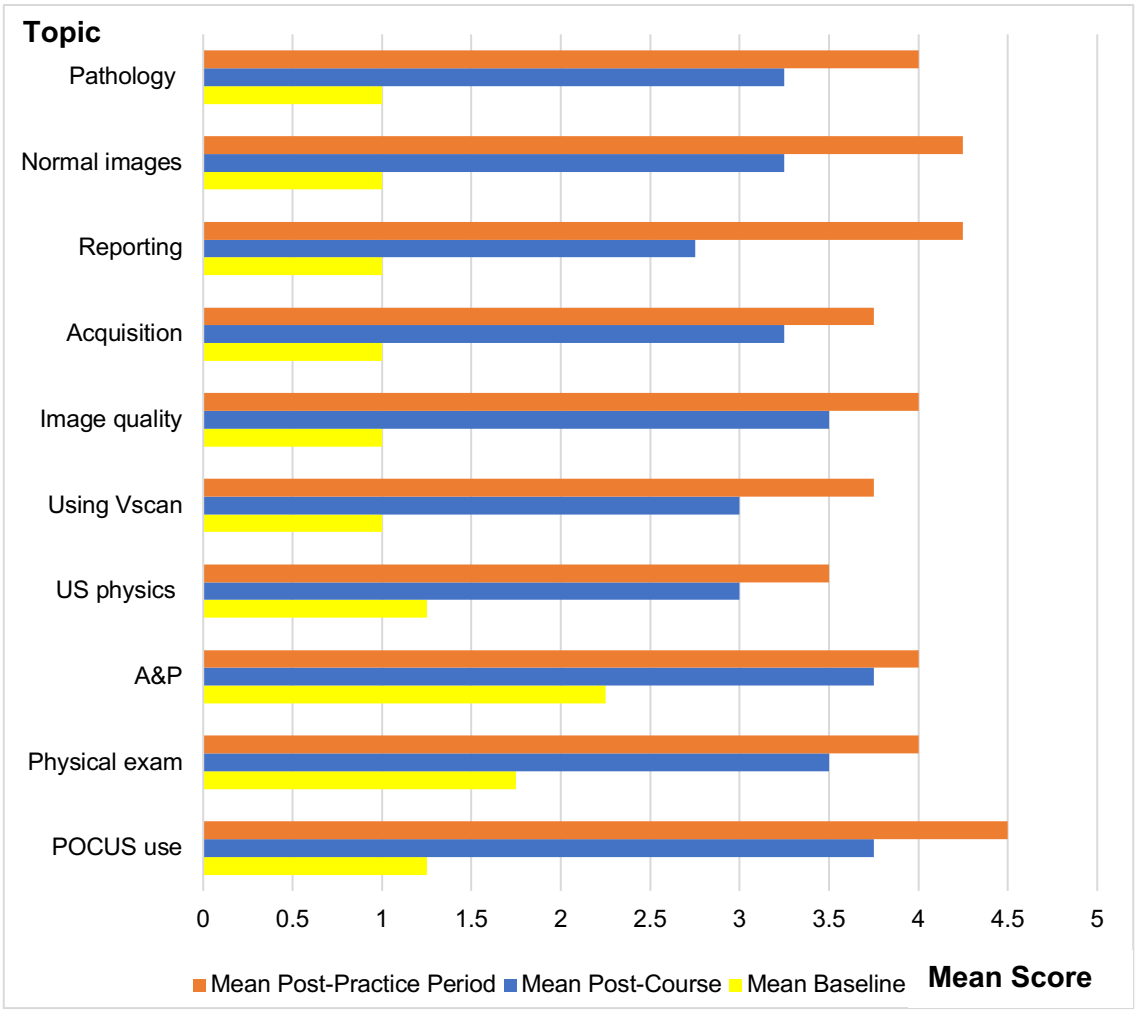
Nurses' average self-rated knowledge at baseline, post-course, and post-practice period

Nurse	Average Self-rated Knowledge (1=no knowledge; 3= adequate; 5= fully competent)		
	Baseline	**Post-Course**	**Post-Practice Period**
1	1.2	4	4.9
2	1.2	2.8	4
3	1.4	3.2	3.6
4	1.3	3.2	3.5
Nurse Average	1.25	3.3	4

To assess whether there were specific topics that impacted confidence, the mean self-rated knowledge for each topic was calculated at baseline, post-course, and post-practice period (Figure 4.7). At the end of training (post-practice period), self-rated knowledge was greatest for 'POCUS use,' followed by 'normal images' and 'reporting,' and lowest for 'ultrasound physics.' The smallest increase in self-rated knowledge across the stages of testing was for 'anatomy and physiology' which had the highest baseline score.

Figure 4.7

Mean self-rated knowledge scores per topic at baseline, post-introductory course, and post-practice period



Note Score: 1= No knowledge; 2= Some knowledge; 3= Adequate for POCUS; 4= Competent; 5= Fully competent

The nurses rated the adequacy of training by recording how much they agreed/disagreed with statements relating to the training with strongly agree; agree; disagree; and strongly disagree options. Table 4.8 shows the frequency of each response in relation to each statement post-introductory course and post-practice period.

Table 4.8

Collective number of each agreement response for the different aspects of training post-course and post-practice period

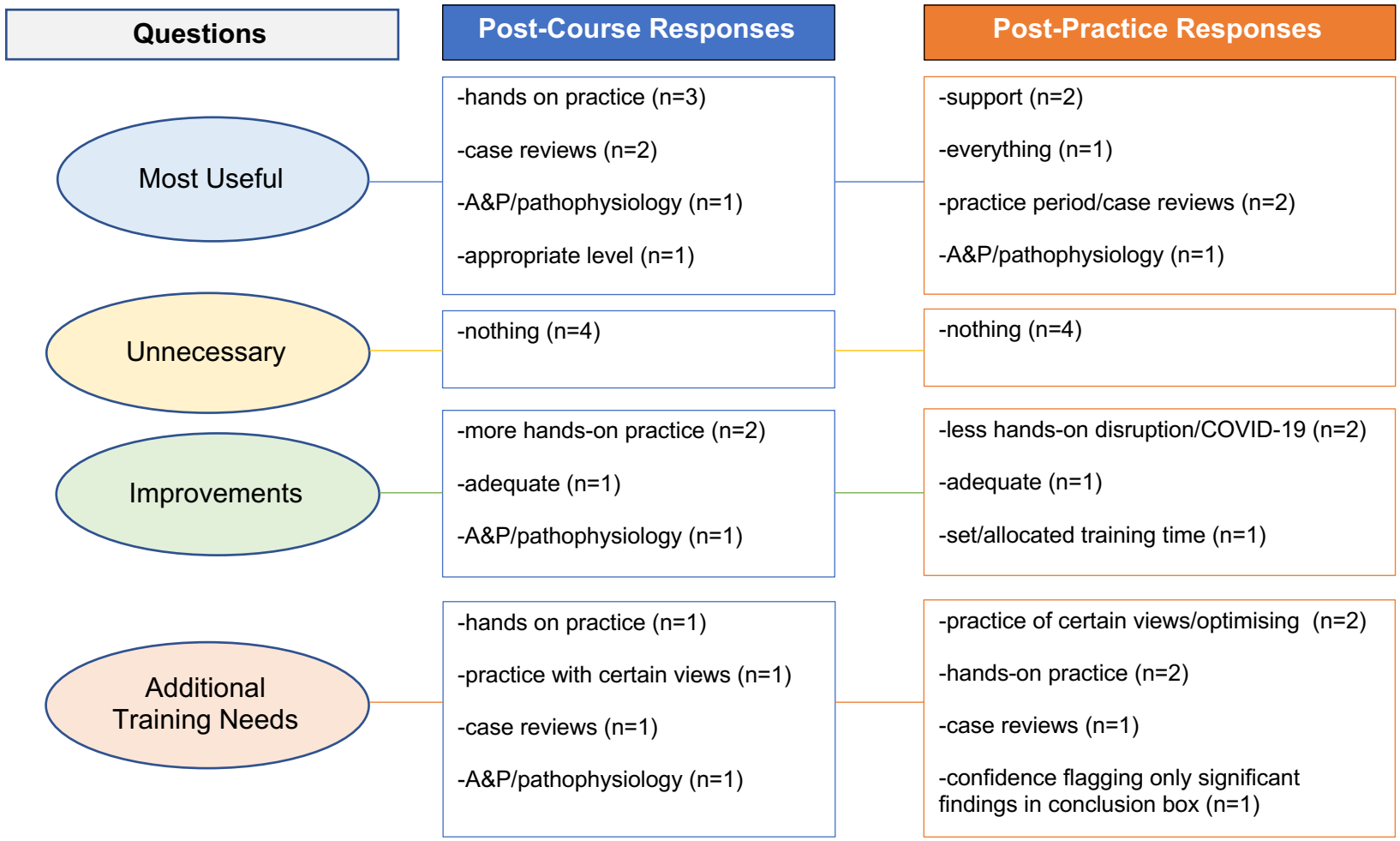
Statements regarding Workshop	No. of 'Strongly Agree'		No. of 'Agree'		No. of 'Disagree'		No. of 'Strongly Disagree'	
	Post-Course	Post-Practice	Post-Course	Post-Practice	Post-Course	Post-Practice	Post-Course	Post-Practice
Personal expectations met	3	4	1	0	0	0	0	0
Outlined training objectives met	3	4	1	0	0	0	0	0
Facilitators provided clear explanations of topics	3	4	1	0	0	0	0	0
Information delivered was relevant/appropriate	3	4	1	0	0	0	0	0
Methods of information delivery were appropriate	3	4	1	0	0	0	0	0
Facilitators welcomed questions and responded appropriately	4	4	0	0	0	0	0	0
Appropriate course length	2	4	1	0	1	0	0	0
Pace was appropriate for content & attendees	2	0	2	0	0	0	0	0
Activities included were helpful and relevant	3	4	1	0	0	0	0	0
Sufficient hands-on scanning practice	2	2	2	2	0	0	0	0
Sufficient exposure to 'normal' cases	2	4	2	0	0	0	0	0
Sufficient exposure to pathology relevant to patient cohort	2	4	2	0	0	0	0	0
Appropriate group size	3	4	1	0	0	0	0	0
Information delivered was relevant to my clinical practice	3	4	1	0	0	0	0	0
I would recommend the workshop to colleagues	4	4	0	0	0	0	0	0

The nurses collectively agreed ('strongly agree' or 'agree') with the appropriateness of all aspects post-course and post-practice period. There was one 'disagree' for 'appropriate course length' post-introductory course but none post-practice period. Comparing adequacy ratings, whereby a lower number is preferential (1= strongly agree; 2= agree; 3= disagree; 4= strongly disagree), all post-practice period scores were lower than, or equal to, post-course scores. There was one exception where nurse 3 scored a 2 (agree) to 'sufficient hands-on practice' post-practice period and had previously rated a 1 (strongly agree) post-course. The average post-introductory course ratings ranged from 1-1.75 (mean 1.32) and post-practice period ratings ranged from 1.0-1.5 (mean 1.03, mode 1.0).

The final part of the evaluation form consisted of the following four open questions: what was most useful; was anything included that you felt was unnecessary; how could delivery of information be improved; and do you require any additional training regarding any aspect of POCUS? An overview of the nurses' written responses to each open question post-introductory course and post practice period is provided in Figure 4.8. For some questions, responses exceed four as some nurses gave more than one response.

Figure 4.8

Nurse responses to the open questions



Note A&P= anatomy & physiology

In terms of what was found useful, practice (hands-on and case reviews) was noted by more than one nurse post-course and post-practice period. The same topics (hands-on practice, case reviews, anatomy and physiology, and support) were identified at each testing session but with hands-on being the most useful post-introductory course and support being identified as the most useful post-practice period. No part of the training was deemed unnecessary by any of the nurses. In terms of proposed improvements, hands-on practice, be that more or continuity, was recorded by more than one nurse at both assessment periods. More hands-on practice was also the most popular response to the question regarding additional training need post-course and post-practice period.

Discussion

Nurse competence

The primary focus of this initial phase of feasibility testing was to assess whether the bespoke POCUS training programme was sufficient to allow community nurses to accurately and reproducibly confirm or exclude LVSD from focused POCUS images in a controlled setting. Results obtained support its suitability.

For the first part of the assessment process, the thresholds for a 'pass' were set at a level consistent with university master modules (50% for MCQ and 70% for OSCE). After completing the four-phase training programme (i.e., post-practice period) scores exceeded these, with mean scores of 81% for the MCQs, 95% for the video cases, and 88% for the OSCE. These results suggest adequate background theoretical knowledge and development of sufficient POCUS acquisition (OSCE) and analytical (case reviews) skill.

The second phase of the assessment process formally assessed diagnostic accuracy and reliability with pre-defined thresholds which are widely considered acceptable for diagnostic testing. Diagnostic accuracy exceeded the target threshold (≥0.8) with a mean sensitivity and specificity of 0.94 (range 0.83-1.0) and 0.89 (0.75-1.0) respectively. This suggests that, following training, nurses can accurately (visually) assess whether LVSD is absent/present where the threshold for pathology is ejection fraction <50%. The Cohen's kappa measures of intra-operator variability exceeded the target value (≥0.7) with values ranging between 0.71-1.0 (mean 0.86) suggesting substantial inter-rater agreement and supporting the reliability of LV systolic functional assessments. The small sample size is recognised, and the measures are intended only to help determine whether progression to the next clinical phase is appropriate.

These findings support the growing literature showing that non-traditional ultrasound users can use hand-held POCUS to accurately assess LV systolic function. In a systematic review across studies of medical students, similarly high pooled sensitivities (0.88, 95% CI 0.83–0.92) and specificities (0.86, 95% CI 0.81–0.90) were achieved for detecting LVSD (Galusko et al., 2017). In a separate review article on the use of handheld echocardiography in focused

cardiac examinations (Chamsi-Pasha et al., 2017), high (>0.9) pooled sensitivities and specificities were reported for detecting LVSD, albeit not limited to novice users (Andersen et al., 2011; Galderisi et al., 2010; Liebo et al., 2011; Mjolstad, Dalen, et al., 2012; Panoulas et al., 2013; Prinz & Voigt, 2011; Razi et al., 2011).

The nurses correctly broadly categorised LV systolic function in most cases (84%). Considering the potential clinical impact, false negatives have the greatest impact because pathology is missed, and further testing may not be triggered. There were only three cases (collectively) of false negatives. For two of the false negatives (same case different analyses) the nurse had detected RV systolic dysfunction therefore the study was reported as abnormal which would have triggered referral for comprehensive testing. For the other false negative, the LVSD was mild and there were no signs of congestion (or other abnormalities) therefore although missed, the LVSD is unlikely to cause acute dyspnoea. For the five cases where function was graded abnormal when reference was severe, three had significant mitral regurgitation and two had signs of pulmonary congestion all of which were detected by the nurses therefore the cases were still reported as having a significant pathology. For cases where LVSD was graded severe when abnormal on reference, TTE would be indicated to accurately assess dysfunction. Urgency of referral for TTE is currently determined by BNP levels. For the seven false positives, four had significant pathology (pericardial effusion and tamponade, mitral stenosis) which was detected and would require TTE. Three cases classified as abnormal had no significant abnormalities, these would have resulted in inappropriate referral for TTE.

While the use of binary present/absent options would have given higher correct results (91%), given the clinical utility of knowing whether function is severely impaired and the nurses' high percentage of correct gradings (and low false positives) the continued use of the same broad categorisations for the next phase of research appears reasonable. The literature is mixed in terms of binary (Anderson et al., 2013; Galderisi et al., 2010; Razi et al., 2011) or categorical options (Andersen et al., 2011; Biais et al., 2012; Croft et al., 2006; Mjolstad, Dalen, et al., 2012; Panoulas et al., 2013) with evidence of high accuracy for both methods. The clinical advantage of using broad categorisations to guide immediate therapeutic decisions is recognised in the ASE consensus statement (Spencer et al., 2013). I have not found data directly comparing management decisions based on use of binary and categorical options. However, considering immediate management decisions, it appears reasonable to

suggest either the use of broad categorisations to differentiate significant dysfunction or the use of binary options with a threshold for abnormal at a level that is clinically significant in terms of management and clinical context (acute dyspnoea).

While LVSD was the target pathology, nurses could collectively recognise ultrasound signs of congestion which is clinically useful in the context of acute dyspnoea. No cases of pleural effusion were missed and few cases of B-line positivity and abnormal IVC were missed (six and five respectively). These missed cases were reported as 'uncertain' rather than 'absent' and occurred in the setting of LVSD which was detected. There was some under-reporting of small (non-significant) pericardial effusions but the case showing a significant pericardial effusion with ultrasound signs of tamponade was detected by all at both sessions. These data support existing literature that nurses can use ultrasound to assess volume status (Dalen et al., 2015; Graven et al., 2015; Gustafsson et al., 2015) however our findings need to be replicated in a larger study with higher prevalence of additional pathology. In terms of valve disease, all cases of significant valve disease (stenosis and regurgitation) were detected by all nurses. The few cases of missed regurgitation (one aortic and five mitral) were not 'red flag' (moderate +) cases.

Training suitability

Given that the intention of training is to develop competence, it appears reasonable to assess training suitability against obtainment of competence. Based upon the assessment results (which met target thresholds), the devised training programme appears appropriate. Evaluation forms imply that the training programme was valued by the nurses, with evidence of self-rated competence post-training. Successful development of measured competence and self-confidence are important given that both are essential for accurate decision making in the subsequent clinical study.

The pre-course material was not specifically assessed. On discussion with the nurses, they had only briefly reviewed the pre-course material prior to starting the introductory course. Unfortunately, we were unable to distribute it sooner due to timing constraints (delays with confirming trainee recruitment/availability and completion of the training manual material).

On reflection, distribution of this earlier would have given additional (potential) opportunity for the nurses to utilise the resource before the course.

The introductory course was intended to be followed by a dedicated period of practice to allow development of acquisition and analytical skills. Results of both the written assessments and evaluation forms suggest that a practice period is important in developing competence and confidence. The introductory course supported the development of adequate background theoretical knowledge (MCQ scores ≥83%) but provided insufficient opportunity to allow development of adequate analytical skills, with three of the four nurses' case review scores falling below 50% in the post-introductory course assessment.

Hands-on scanning opportunity is a widely accepted integral component of any POCUS training programme (Neskovic et al., 2014; Pelliccia et al., 2012; Spencer et al., 2013). We had anticipated that the opportunity given during the initial workshop would be insufficient, hence the inclusion of the practice period. This was reflected in the post-introductory course results where more hands-on scanning was identified as an area requiring further practice. It was also visible to both trainers that by the end of the five-day course additional analytical practice was needed.

Unfortunately, the delivery of hands-on practice was significantly impacted by the COVID-19 pandemic resulting in discontinuous and sporadic training with prolonged periods where the nurses were unable to gain any hands-on scanning practice. This was detrimental to their learning because, particularly in the early stages of learning a new skill, repetition is fundamental to the development of confidence and competence. After some continuity in training sessions, I observed visible improvements in scanning competence and confidence however after prolonged gaps in practice there was marked reductions in both. This resulted in needing to repeatedly return to the basics which negatively impacted upon the nurses' confidence. This was reflected in the nurses post-practice adequacy scores where all nurses strongly agreed with the adequacy of all topics except two lower scores for 'sufficient hands-on practice' (although still rated 'agree'). Hands-on practice also dominated answers to the open questions accounting for two-of-four responses to how training could be improved and the responses of all four nurses to the additional training needs question included points relating to additional hands-on practice.

Due to the unexpected interruptions in hands-on practice, each nurse was given two full days of scanning practice at the university. There was a visible increase in nurses' confidence and competence by the end of these and each nurse requesting their OSCE assessment following this. It is widely accepted that hands-on, deliberate practice is necessary to develop acquisition skills (Cawthorn et al., 2014; Florescu et al., 2015; Hayward et al., 2015).

Results of the OSCE assessments suggest that the additional practice period facilitated development of adequate POCUS acquisition skills. OSCE results revealed that, firstly, the nurses were able to recognise when they had developed sufficient acquisition skills (nurse-triggered), and secondly that the nurses had developed adequate POCUS acquisition and reporting skills (albeit in a normal subject). While study designs did not include an OSCE post-introductory course it was clearly visible to the trainers that the nurses had not developed the necessary skills to perform POCUS independently after the initial course alone and similarly more hand-on practice was identified by the nurses as an area of improvement and additional training need post-course.

One aspect of hands-on practice that was not executed as planned was independent scanning. Guidelines suggest that training should include independent and supervised acquisition practice (Spencer et al., 2013). While the nurses were repeatedly encouraged to gain independent scanning practice, this was poorly done with only a few scans being performed independently between supervised sessions. This, in part, is due to the increased clinical demands caused by the pandemic but for the delivery of future training programmes I would suggest placing more of an emphasis on this. Requesting a figure, such as one or two independent scans, prior to each supervised session may help encourage trainees to perform the scans independently which may help increase their scanning confidence and highlight more clearly, to the learner, their areas of strengths/weaknesses.

In addition to image acquisition, the practice period focused on analysis, providing exposure to normal/abnormal cases via clinical case reviews. Guidelines, such as those produced by the ASE and ISCU, recommend review of video images tailored to the pathologies relevant to the trainees' scope of practice to ensure sufficient exposure to pathology (Pelliccia et al., 2012; Spencer et al., 2013) and case reviews featured heavily in both the introductory course and practice period.

In addition to the case review practice at the start of the supervised sessions, a USB of example cases was provided to allow independent review in their own time. This is consistent with the study by Kirkpatrick et al. (2005) whereby nurses were given a CD with case examples of different LV systolic function as part of their training. The benefit of additional analytical practice was reflected in the marked increase in video case scores post-practice period compared to post-course. Self-rated knowledge scores for 'reporting' post-practice period also rose with all nurses rating their knowledge at least competent. Case reviews were well received by the nurses representing two of the responses to 'what was most useful' post-course and post-practice period. Despite case review sessions featuring heavily at each stage of the training programme, 'more case reviews' was indicated as an additional learning need post-practice period by one nurse. However, this nurse noted this was due to a personal period of absence (and wanting to refresh) rather than the training not including enough case review sessions.

The delivery of case reviews during the practice period was impacted by the COVID-19 pandemic. At the initial height of the pandemic training was stopped completely but by the second wave video conferencing services could be utilised to allow virtual case review sessions. In person case review sessions, whilst maintaining social distancing guidelines, were able to recommence earlier than practical hands-on sessions. This may account for why hands-on practice, which is generally considered to be easier than analysis, featured more frequently in the improvement/additional training responses.

Another purpose of the practice period was to address the additional training needs previously identified by the post-introductory course results. The post-introductory course results highlighted ultrasound physics, LVSD, and IVC as topics requiring additional training. The higher post-practice period results for these questions suggest that the added focus on these topics during the practice period supported knowledge development. However, there were some topics, such as POCUS use, anatomy and physiology, and LUS principles, where the scores were lower post-practice period compared to post-introductory course. We must appreciate that with time information may be forgotten, particularly theoretical concepts that are not regularly utilised. The time between workshop delivery and completion of the practice period was far longer than planned (COVID-19 related interruptions) and although theoretical information was revisited during the practice period, the multiple disruptions in delivery caused large time lags between sessions. We know in the

early stages of learning repetition is key for learning and that the disruptions incurred likely had a negative impact on solidifying the foundations. While outside the scope of this initial feasibility work, this highlights the importance of continued learning and maintaining competence which is well reported in the literature.

Trainee variability

When evaluating training it is important to consider the trainees and potential individual variability. While the nurses had similar demographics, background experience, and underwent the same training format, there was some variability in results and responses. Post-practice period MCQ scores were fairly consistent (range 83%-93%) but post-practice period the MCQ score for one nurse (nurse 3) was notably lower. Also, while all nurses' accuracy measures exceeded target level for LVSD detection, nurse 3 had the lowest specificity and overall accuracy for LVSD and second lowest kappa. Similar findings were reported in a study assessing the diagnostic accuracy of FoCUS by non-ultrasound expert nurses (n=8) to screen for rheumatic heart in children following an eight-week training programme (Engelman et al., 2016). They found the accuracy of one nurse was much lower than the others, with six of the nine false negatives having been screened by this operator (while others had either one or none).

There are multiple potential factors that can contribute to variations amongst trainees, and it is difficult to determine why one nurse (nurse 3) scored lower than the others. All four nurses were experienced but nurse 3 was the only one that was not an advanced nurse practitioner. It could be that nurse 3 has less knowledge, or she may not perform as well in assessment conditions. In addition to a lower post-practice period MCQ and video case score, nurse 3 had one of the lowest self-rated knowledge scores. This suggest that this nurse may have benefited from additional support such as one-on-one sessions to increase confidence and competence. In the cases of POCUS where decision making is based upon POCUS findings, perceived feelings are important as these can affect confidence which can subsequently affect decision making.

We must also appreciate that personality and behaviours are also recognised contributors to learning and personal interest and engagement are likely to influence learning. For example,

one nurse vocally expressed that she had undertaken POCUS related revision outside supervised sessions and scored highest in the post-practice period MCQs. The variability amongst the nurses' scores (measured and perceived), and my observations of variable nurse competence/confidence at different time points, supports the use of nurse-triggered assessments. Use of competency-driven training durations allow for variations in terms of clinical demand, nurse individuality and availability, and external factors (such as COVID-19). The sporadic delivery of training during the practice period hindered skill development (and confidence) and the amount of training needed was likely far longer than if trainees had received continual training. However, by utilising a nurse-triggered assessment when they felt confident and using achievement of competence as the end point, individuality in training needs and interruptions in training can be accommodated.

There is growing support amongst the current literature (including EACVI and ISCU guidance) for competency-based training that is guided by attainment of competence, rather than a set duration or volume (International Federation for Emergency Medicine, 2014; Jensen et al., 2018; McGaghie, 2015; Motola et al., 2013; Neskovic et al., 2014; Pelliccia et al., 2012). In a prior nurse study which developed, implemented, and analysed an intensive care nurse POCUS training and certification programme, additional practice was given until competence was reached (Tulleken et al., 2019). While they reported that all nurses (n=9) reached competence within a median 13 exams/26 weeks, the total time taken was seven-months and the time for LUS views ranged from 14 to 28 weeks and for cardiac (which was LV outflow velocity time integral only) 20 to 29 weeks which highlights variability amongst trainees. It is for this reason that training design included a nurse triggered OSCE when they felt competent rather than after a pre-defined time. The timeframes and numbers of scans proposed in the study design were intended only as a rough guide and instead competency-assessments were used to guide training and dictate when trainees were ready to move on to formal diagnostic accuracy testing.

It is difficult to compare results of this study with previous studies due to the marked heterogenicity amongst the literature in terms of the trainees included, training aims, and measures of competence. The disruptive nature of POCUS technology itself is a contributor to this. The potential widespread use in a vast range of clinical settings means that for many, training that is relatively quick and easy to deliver is preferential to enable uptake by large cohorts of people. Conversely, the aim of this training programme was not to provide brief

training to mass healthcare professionals but instead to teach a small cohort of nurses how to competently acquire and interpret POCUS in a specific patient population. There are no data available regarding POCUS training programmes dedicated at training non-specialist community nurses which prevents direct comparison of results with other training programmes. Instead, the suitability of this training is assessed via the preliminary assessment results obtained which support the appropriateness of the devised training programme, justifying progression to a formal assessment of training adequacy, in terms of diagnostic accuracy and reliability.

Recommendations

Since this is developmental work, a reflective approach was incorporated so that formats and content could be refined accordingly. Trainee and trainer feedback was encouraged to supplement this. Recommendations for future training based upon this are outlined in Table 4.9.

Table 4.9

Recommendations for future training

Topic	Experience	Recommendation(s)
Content	Unsure of nurse background knowledge prior to course.	-Pre-training questionnaire to assess background knowledge & course adjusted accordingly prior to delivery.
	Nurses needed additional anatomy, physiology, & pathophysiology training.	-Provide pre-course anatomy, physiology, & pathophysiology of HF learning material (online).
	Nurses informed us that repeatedly revisiting the views was useful.	-Start every session with a recap of the views & structures seen.
	Nurses expressed that they found completing case report forms more useful than just discussing.	-Use of POCUS report forms for case reviews during practice period & for future courses.
	Post-introductory course, for one MCQ, 3/4 nurses selected all walls need to be reduced when LVSD.	-Avoid using 'global/regional' & use 'all/some' walls. -Ensure good mix of example cases of LVSD.
	LUS teaching more detailed than required. Reduction in content may improve retention.	-Keep to the clinical focus of identifying signs of pulmonary congestion (identifying B-lines & PLE).
Delivery	Pre-course material provided earlier.	-distribute sooner to give trainees more opportunity to utilise the material pre-course.
	Introductory-course alone insufficient for adequate skill development.	-Period of practice needed to develop acquisition & analytical skills.
	Results support appropriateness of content/curriculum.	-Consider online elements, such as e-modules & online summative assessments- reduces classroom teaching time & allows trainees to access at own pace & revisit as needed.
	Continuity facilitated learning & after interruptions there was a notable reduction in competence (particularly in early stages).	-Dedicated weekly supervised sessions during practice period with some back-to-back scanning opportunity.
	Practice period prolonged due to COIVD-19 related interruptions & variability in trainee needs/competence.	-Competency-based training durations more suitable as allow for individual needs & external interruptions.
POCUS protocol	Nurse concern with what to select regarding regurgitation, felt more options needed, such as trace regurgitation and differentiating 'present' and 'red flag.'	-Compromised & trialled absent/trivial (no or trivial jet); present; red flag (moderate+ jet) for subsequent clinical study. But on reflection, focus is significant pathology so binary option with 'moderate+' threshold more appropriate.
Assess-ments	Inconsistencies in metric measures of competence and perceived knowledge (unconscious incompetence).	-Metric measures of competence needed to ensure competence (minimum standard). -Self-perceived useful for assessing confidence (which can influence competence). -Online self-assessments with online teaching modules to help increase perceived knowledge & confidence.

Limitations

There are limitations associated with this study. The programme focused on teaching non-specialist community nurses to use hand-held ultrasound to detect LVSD, ultrasound signs of congestion, and other significant cardiac pathology. This must be considered when considering generalisation of findings to other contexts.

While the results support the suitability of the training, the small number of trainees included must be considered (n=4). This limits the ability to draw patterns and one lower/higher result can markedly alter the average score. For example, one nurse scored notably lower than the other nurses for the MCQs post-practice period assessment (mean score 59%). If data for this nurse were excluded, the mean total score for the written assessment post-practice period would be 89% (range 83-97%) which is slightly higher (rather than lower) than the post-introductory course.

Considering practicalities and patient safety, the introductory course did not include hands-on practise on 'real' patients. Ethical approval is required before patient contact and at this initial stage it was felt more appropriate (mainly for patients) that the nurses gain initial experience on stable, well volunteers rather than potentially unwell patients. Instead, opportunity to scan 'real patients' was planned for the later clinical feasibility study.

Similarly, a recognised limitation of the assessment of acquisition skills is that the OSCE was performed in a clinical stable volunteer. While it was recognised that clinically stable volunteers are generally easier to scan, the intention at this stage was to assess scanning capabilities in an ideal scenario and to ensure the nurses were able to obtain the necessary POCUS views and follow the scanning protocol. The subsequent phase of feasibility testing assesses acquisition skills in real patients.

There are methodological limitations associated with the formal accuracy and reproducibility study. COVID-19 restrictions meant study methodology had to be modified so that patient involvement was removed and therefore acquisition skills (on patients) were not assessed. It should be recognised that any ratings of 'uncertain' were graded as positive (conservative trade-off) which has the potential to influence accuracy measures in a preferential/detrimental way. The methodology has selection bias in terms of video case selection based on

pathology rather than randomisation. However, this was necessary to ensure inclusion of the appropriate pathology. Since ultrasound image interpretation is subjective, a level of disagreement between operators is not unusual. Analysis guidance and broad distinctions between analysis options were provided to help minimise variation where possible. For the formal assessment of reproducibility, it must be recognised that while attempts were made to help subject and rating independence and avoid/minimise falsely increasing kappa value (independent analysis, blinding to clinical information, and altered sequencing of cases), complete independence is unachievable (Sim & Wright, 2005). A two-week period between testing sessions was selected to help minimise dependence as too brief a period may result in users remembering cases, and if too prolonged experience levels may have altered (Sim & Wright, 2005). This is consistent with the literature which has proposed that re-testing intervals ranging from approximately one to three weeks, or two-fourteen days (depending on the measurement) is appropriate for the scenario to be considered independent (Bujang & Baharum, 2017; Sim & Wright, 2005; Streiner & Norman, 2003). In addition to bias, the kappa coefficient is influenced by prevalence (Sim & Wright, 2005) therefore some statisticians adjust kappa to account for this (Byrt et al., 1993). This study does not involve sampling from a clinical population, but rather recognising multiple pre-defined (yet unknown to the reviewers) pathologies therefore prevalence cannot be used to guide methodology or make estimated prevalence adjustments.

Chapter Overview

This chapter details the design, delivery, and assessment of the nurse-tailored POCUS training programme designed for this body of research. Preliminary assessment results suggest that the devised training programme was appropriate. Following completion of training, community nurses learnt to detect LVSD accurately and reliably on POCUS images in a controlled environment. Results exceeded pre-defined target thresholds which supports progression to the subsequent feasibility study in the intended clinical environment.

While the existing literature is mixed in terms of the accuracy of novice assessments of some of the additional pathology, significant pathology was recognised in most cases. Small sample sizes precluded accuracy calculations but there were no cases of significant pathology missed by all nurses. Therefore, at this stage, the additional pathology will be included in the POCUS assessment for the subsequent phase of research.

Key take home points:

- *An introductory course alone is insufficient to allow community-nurses to develop adequate POCUS acquisition and analytical skills. An additional period of practice improves acquisition and analytical competence, as well as self-rated knowledge.*
- *Nurse agreement with the appropriateness of training, combined with the overall metric measures, supports the suitability of the devised POCUS training programme to allow community nurses to develop adequate POCUS theoretical and practical skills.*
- *The variability in terms of individual trainee needs, perceived ability, and potential external factors that may impact training, such as clinical demands and pandemics, adds to the growing literature supporting the use of competency-based training durations rather than completion of a set time or volume of scans.*

Chapter 5: Clinical Feasibility Study

Chapter Overview

The pre-clinical feasibility testing provided evidence that nurses could acquire POCUS images (in line with the developed protocol) in a stable volunteer and that they could accurately and reliably detect LVSD on previously acquired images in a controlled, non-clinical setting. Attention then moved to assessing use of nurse-led POCUS in the proposed clinical setting. The study sought to gain preliminary insight into the feasibility and acceptability, as well as the accuracy and clinical impact, of adding nurse-led POCUS to the current assessment of elderly patients in the domiciliary setting with acute dyspnoea.

This chapter describes an explanatory-sequential mixed methods approach to implementation research whereby quantitative data was complemented with qualitative data to help enrich understanding. A description of the methodological approach to data collection, analysis, and integration is provided before summarising and discussing the research findings.

Introduction

In healthcare, much intervention research focuses on effectiveness and fails to recognise the importance of implementation. For an intervention to be effective, sustainable, and scalable, it is important to know not only what effect it has but why it has the effect it does within a particular setting (De Silva et al., 2014). Contextual influences should be considered to facilitate understanding of service challenges and factors that influence behaviours (Craig et al., 2008). Use of conceptual frameworks, such as the CFIR (described in Chapter 2), aid assessment of contextual factors (Damschroder et al., 2022; Keith et al., 2017). There is evidence that incorporating implementation research helps promote effective application of research findings; helping to bridge the widely reported research-to-practice gap (Connell et al., 2014).

In implementation research, mixed-method designs are being increasingly used. A mixed-methods approach provides opportunity to gain standardised, generalisable quantitative data in conjunction with detailed contextualised understanding from qualitative data (Regnault et al., 2017). It allows researchers to test and confirm (quantitative) and explore and understand (qualitative) (Renjith et al., 2021). Incorporating qualitative research can provide rich descriptive data that facilitates better understanding of individuals' behaviour and experiences, healthcare need, and intervention design (Creswell, 2013; Renjith et al., 2021). While a mixed-methods approach can be more complex, time-consuming, and resource-heavy, it can help provide stronger evidence and balance the limitations associated with individual methods (Shorten & Smith, 2017). One approach to mixed methods research is the explanatory-sequential design. This begins with collecting and analysing quantitative data which is used to inform qualitative data collection and analysis (Ivankova et al., 2006). The intention of an explanatory-sequential approach is for qualitative data to help explain and contextualise the quantitative data; revealing deeper meaning of clinical experiences and behaviours (Shorten & Smith, 2017; Sorrell, 2013).

Different approaches to qualitative data collection and analysis exist. A focus group discussion is one method of qualitative data collection. It brings together a small group of people, to answer questions related to a topic of interest in a moderated setting (Kitzinger, 1995). A focus group can be used to discover what people think and why; to explore knowledge, perspectives, and attitudes about issues and seek explanations for behaviours that would be less easily accessible in response to direct questions (Kitzinger, 1995; Kreuger, 1994). Group, rather than individual, discussion allows conversation between individuals which can stimulate thinking regarding ideas and different and collective experiences and perspectives (Kitzinger, 1994).

Thematic analysis is a flexible, accessible method of qualitative data analysis (Braun & Clarke, 2006). It is based upon identifying, analysing, and reporting patterns (themes) within data. An inductive ('bottom up') approach refers to identifying codes and themes from the data (Braun & Clarke, 2006; Creswell, 2012) while a deductive ('top down') approach, involves the use of pre-conceived themes (Boyatzis, 1998; Braun & Clarke, 2006). An inductive approach is data-driven, reducing potential researcher bias. However, researchers are not independent of their theoretical and epistemological knowledge (Braun & Clarke, 2006).

Nurse-led POCUS has not been previously investigated in the domiciliary setting. Therefore, it is unclear whether use in this setting is feasible, accurate, or what clinical impact it has. The intention of this preliminary research was to test procedures for feasibility, perceived acceptability, accuracy, impact, and gain insight into contextual influences. Such data are needed to inform a future trial which would be necessary to support a change in service delivery.

The study was submitted, via the Integrated Research Application System (IRAS), for the permissions and approvals for health and social care/community care research in the UK and granted Health Research Authority (HRA) and Health Care Research Wales (HCRW) approval (REC ref: 21/EE/0253; IRAS 276876).

It should be noted that at this preliminary stage, the intention was to explore feasibility of scanning in the proposed clinical context and nurse perceived patient acceptability of the proposed intervention. It is recognised that patient perspectives provide crucial information for decision makers regarding changes to practice (Whitty et al., 2020) and that to comprehensively evaluate the impact of an intervention, its influence upon patients should be considered (Weldring & Smith, 2013). At this preliminary feasibility stage, given the new proposed context, we wanted to gain initial insight into whether existing validated patient reported outcomes measures (PROMs) were suitable for use in this population to help inform future studies which seek to assess perceived health or the impact of dyspnoea upon quality of life. To inform PROM selection, advice was sought from Navjot Kalra, at Swansea Bay University Health Board, and Professor Sally Lewis, National Clinical Lead for Value-based Healthcare in Wales. They advised the use of EQ-5D-5L and PROMIS Dyspnea Functional Limitations- Short Form 10a.

Generic and specific PROM tools provide complementary information and are therefore commonly used in conjunction (Devlin & Appleby, 2010). The EQ-5D-5L is a simple, brief, standardised measure of health status that provides a descriptive profile and a single index value that can be used in clinical and economic evaluations (Rabin & de Charro, 2001). It is the most widely used generic PROM instrument in the UK and Europe (Brooks, 1996) and, for measuring and valuing health effects, EQ-5D is NICE's preferred measure of health-related quality of life in adults (National Institute for Health and Care Excellence, 2022). Multiple disease or symptom specific PROM tools exist. Given that dyspnoea is the

presenting complaint under investigation in this body of research, a dyspnoea-specific PROM tool was sought. The PROMIS Dyspnea Functional Limitations- Short Form 10a assesses the impact of dyspnoea on someone's ability to perform specific daily activities.

The generic EQ-5D-5L and the specific PROMIS Dyspnea Functional Limitations- Short Form 10a are both validated, widely used PROM tools. There is evidence of the use of the EQ-5D in the context of chronic HF (Boczor et al., 2019; Jonsson et al., 2020) and PROMIS in the context of HF and older adults presenting to emergency care (Flynn et al., 2015; Fox et al., 2020). However, to my knowledge, neither tool has been used in the context of elderly acutely dyspnoeic community patients at home. Therefore, the suitability of these tools within the proposed context is unclear. Use of PROM tools at this stage of research was not to assess health related quality of life or dyspnoea related functional limitations, but to gain insight into potential suitability of the tools for the proposed clinical context to help guide the design of a future larger scale study including economic evaluations.

Aims and Objectives

This study sought to assess whether adding POCUS to patient examination during a home visit was feasible, acceptable and whether it improved the nurse's ability to decide what was causing the dyspnoea, whether hospital tests were needed, and what medicine was best. It sought to better understand contextual factors that influence outcome and fidelity of wider implementation. In addition, since the true prevalence of suspected and confirmed HF in the proposed population was unknown, the research sought to better understand the proposed patient population; to gain greater insight into the prevalence of suspected and confirmed HF to inform future sample size calculations. The overall study aim was to provide initial real-world clinical data intended to help support the need for, and guide the design of, a future trial.

Objectives

The primary quantitative research objectives were to:

1) Assess the feasibility of adding nurse-led POCUS by reviewing recruitment and participant agreement to enrol rate; percentage of diagnostic studies; adherence rate to scanning protocol; and time taken to perform POCUS. Assess acceptability by reviewing documented comments regarding patient attitudes and nurse perceived appropriateness, suitability, and convenience (initial insight as predominantly assessed in qualitative research questions).

2) Assess the diagnostic accuracy and reproducibility of nurse-led POCUS to detect/exclude significant LVSD in older people with new or worsening dyspnoea. Target sensitivity and specificity for LVSD ≥0.8 and target for nurse and sonographer analysis agreement Cohen's Kappa ≥0.7.

3) Determine whether remote specialist interpretation (reference test) offers a significantly better model than nurse acquired and analysed POCUS.

4) Estimate the clinical impact of adding POCUS to the current care pathway by:
   a) Measuring the change in diagnostic accuracy associated with adding POCUS in terms of confirming/excluding LVSD, and time-to-diagnosis.
   b) Recording the potential impact of POCUS on immediate patient management decisions.
   c) Describing resource use and potential implementation costs associated with adding POCUS to the existing pathway.

The secondary quantitative research objectives were to:

1) Assess nurse ability to detect ultrasound signs of pulmonary (B-line positivity, pleural effusion) and systemic (abnormal IVC) congestion and other significant common cardiac pathology including RV dilation/dysfunction, aortic and mitral valve disease, LV hypertrophy and LA dilation.

2) Assess the suitability of the EQ-5D-5L and the PROMIS Dyspnoea Functional Limitations- Short Form 10a in the proposed clinical context by evaluating:
   a) PROM response rates
   b) Questionnaire completeness
   c) Nurse comments regarding suitability

The central qualitative research question and subsections were to explore:

1) What were nurse perceptions of implementing POCUS
   a) how did they perceive acceptability (appropriateness, suitability, convenience/logistics)?
   b) what did they perceive as the clinical impact/advantage (attitudes to intervention/perceived effectiveness)?
   c) what perceived barriers and facilitators to implementation did they identify?
   d) what resources do they deem necessary for implementation?
   e) how did they perceive PROM tool suitability for the proposed population?

The mixed methods research objective was to explore:

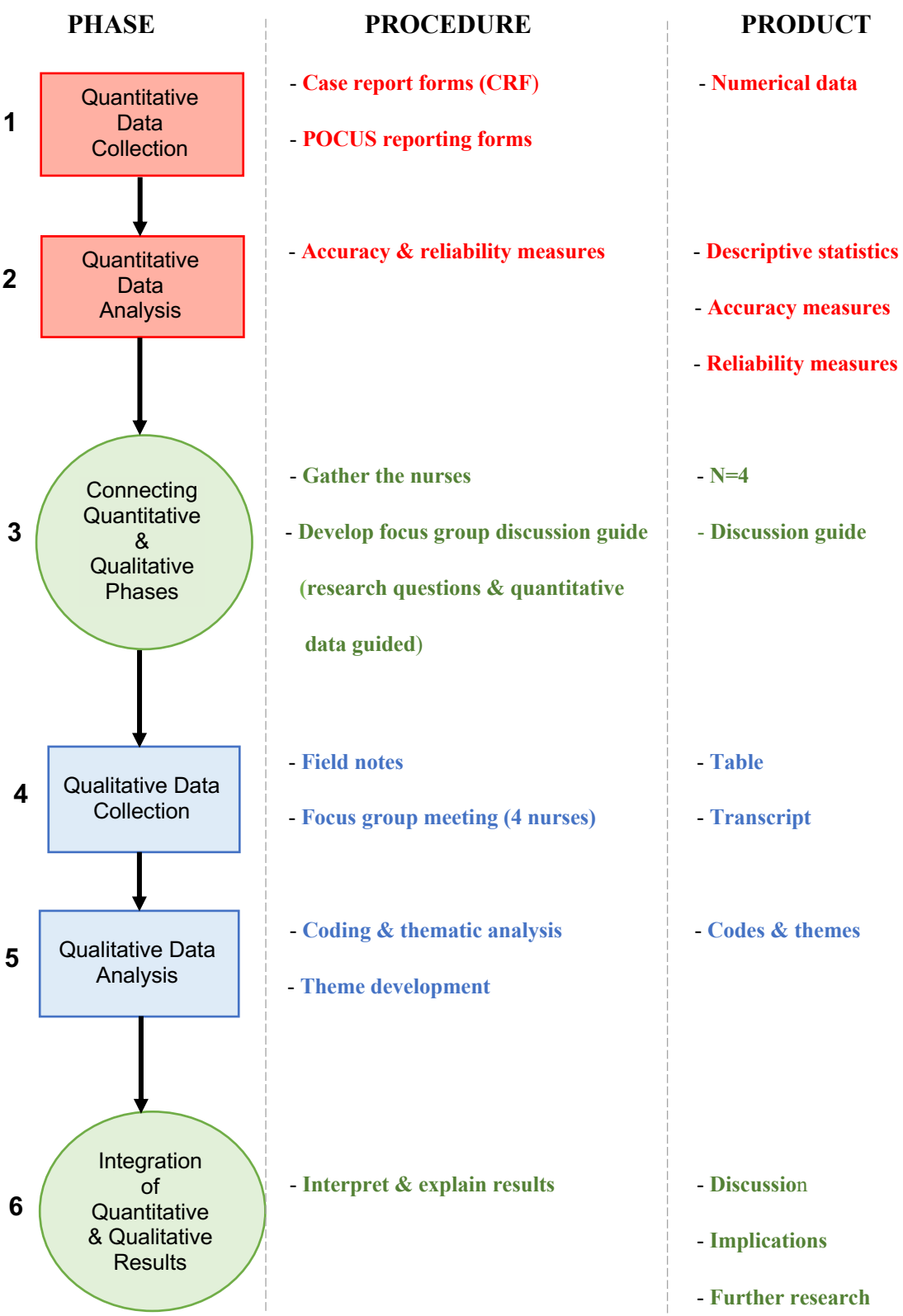
In what ways do nurse opinions of POCUS (qualitative focus group data) help to explain the quantitative data regarding implementation?

Methods

An overview of the explanatory-sequential mixed method approach is provided in Figure 5.0. This is based upon the format proposed by Ivankova et al. (2006).

Figure 5.0

Overview of the explanatory-sequential design (Ivankova et al., 2006)

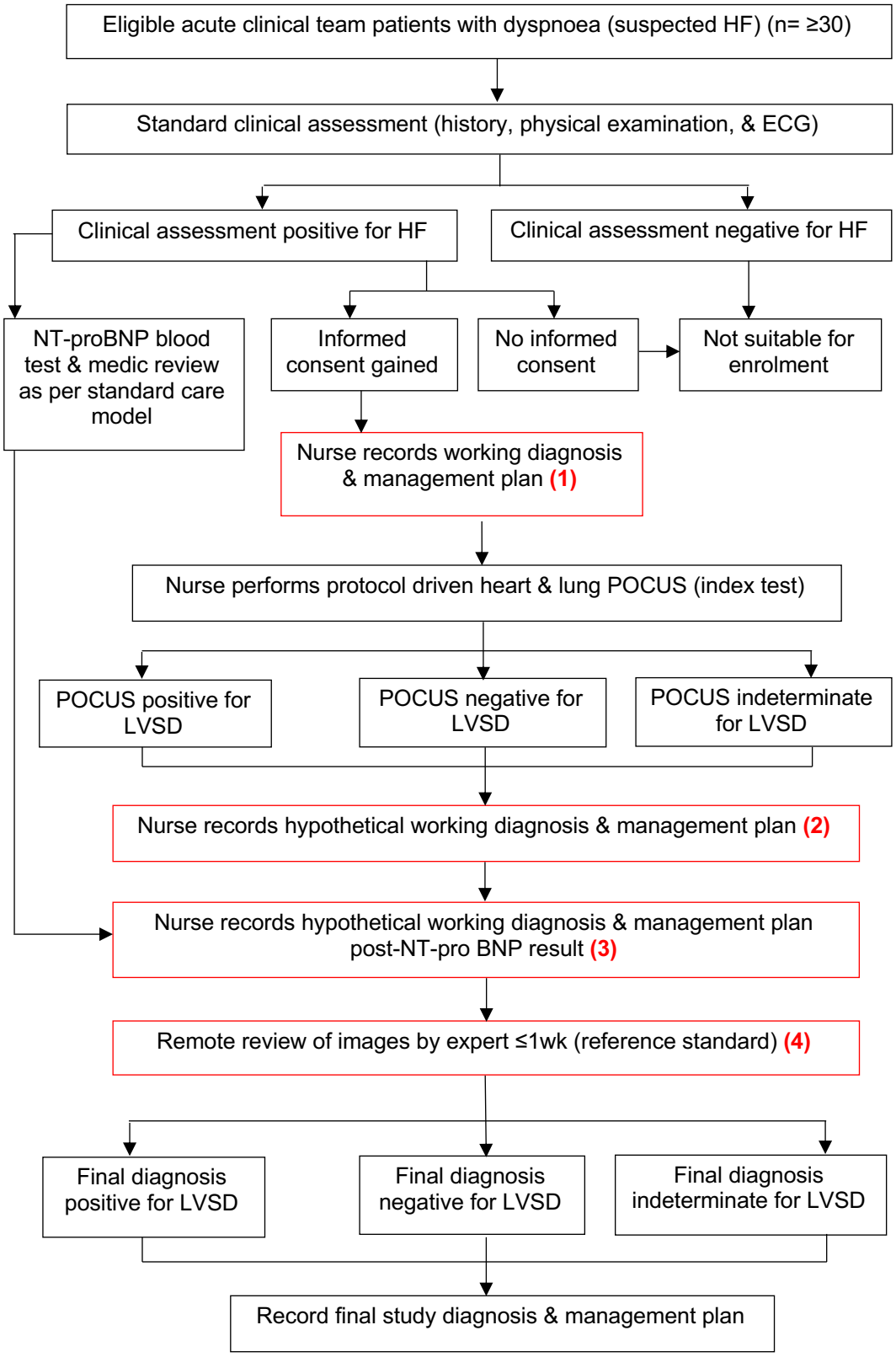


Quantitative data collection (Phase 1)

Study methodology was designed to allow assessment of the incremental change in diagnostic accuracy associated with adding POCUS to the current model of care and the potential (hypothetical) impact of POCUS on nurses' clinical decision-making. It allowed assessment of the diagnostic accuracy under the existing pathway (both with and without NT-proBNP); whether POCUS improved accuracy; and whether remote specialist analysis offered a significantly better model of care than nurse-led analysis of nurse-acquired images. Figure 5.1 provides a diagrammatic overview of the study methodology from which the quantitative data were collected. The relevant information was documented on the case reporting form (CRF) (Appendix D).

Figure 5.1

Overview of initial feasibility study of comparative clinical accuracy and impact



***If any clinically significant findings are seen on POCUS, on-call physician must be informed, & review by an expert (≤24hrs). The physician will decide on the appropriate management.**

Following on from prior training and assessment (Chapter 4), the same four nurses were involved with this study. I (BSE-accredited cardiac physiologist/sonographer) independently analysed and reviewed all nurse POCUS scans. This analysis was the gold standard for comparison (reference test).

The patient population comprised a convenience sample of at least thirty patients. Any patient seen by one of the POCUS-trained nurses who met the inclusion criteria was offered enrolment and subsequently consented by the nurse. Patient inclusion criteria included age ≥60years with new or worsening dyspnoea +/- other signs/symptoms associated with HF and capacity to consent. Exclusion criteria comprised highly contagious disease (such as COVID-19) and chest dressing obscuring two or more imaging windows. At this initial stage, the focus was on testing methods and assumptions on a small scale before refining for a larger trial. The intention was for the descriptive data from this feasibility study to help inform a future sample size calculation.

All POCUS scans were performed using one of two available GE Vscan Extend (GE, Wauwatosa, WI, USA) hand-held ultrasound devices. POCUS was performed in line with the scanning protocol designed for this body of research (Chapter 4, Table 4.1 and Figure 4.1). All 2D views were stored using autocycle standard configuration setting (4sec). Cardiac views (1-7) were obtained using the phased array (sector) end of the dual probe with the cardiac pre-set. The probe was placed perpendicular on the chest in a transverse orientation and images 1-7 obtained. For cardiac views 1-5 the patient, if able, was positioned in a steep left lateral decubitus position with their left arm extended. For views 6 and 7 participants were asked, if able, to lie flat on their back.

All lung views (8-15) were obtained with the probe in a longitudinal orientation. The linear probe (and lung pre-set) was selected for scanning the upper and lower points for assessing B-lines. The phased array end of the transducer was used for posterior assessment of pleural effusions as lower frequencies enable deeper penetration. For posterior scanning, the nurses located the liver and diaphragm on the right, and the spleen and diaphragm on the left, and looked for a pleural effusion above the diaphragm. Lung views 8-13 were routinely performed with patients in the supine position but if patients could not lie supine, an upright position was used. Views 12 and 13, or views 14 and 15, were performed in the supine, or

upright position, respectively to scan the dependent zones. Patient mobility and needs dictated which method was used.

Nurses were instructed to optimise images in terms of depth and gain. Depth should have been altered depending on patient size and area of examination; larger patients and/or deeper structures requiring greater depth. Gain should have been adjusted during scanning to ensure adequate structure visualisation and structure/boundary delineation.

The POCUS reporting protocol and guidance has been previously discussed in Chapter 4. The reporting guidance, with minor updates following results of non-clinical feasibility testing, is provided in Table 5.0.

Table 5.0

Modified methods of POCUS assessment and thresholds for abnormal

Assess	Method	View	Abnormal Appearance	Reporting Options	Threshold for Abnormal
Global LV systolic function	Visual	PLAX, PSAX, A4C, A2C, A3C	Reduced: wall thickening; inward endocardial movement; reduction in LV cavity size; MV annulus movement towards apex.	Grossly normal; Abnormal; Severely abnormal; Uncertain	Visual EF: Normal ≥50%; Abnormal 36-49%; Severely abnormal ≤35%.
LV dilation	Visual	PLAX & A4C	Visually large, often globular/spherical.	Absent; Present; Uncertain	Moderate-severely dilated
IVC size & collapsibility	Visual	S.IVC (~2cm RA entrance)	Dilated/engorged &/or reduced respiratory change in diameter.	Absent; Present; Uncertain	≥21mm &/or <50% collapse
Pericardial effusion	Visual	PLAX, S4C (plus A4C, A3C, A2C)	Fluid in pericardial sac/space. Tracks above descending aorta (PLAX).	Absent; Present; Uncertain	>10mm
Pleural effusion	Visual	PLAPS/DP, PLAX (plus A4C)	Fluid in pleural space. Tracks below descending aorta (PLAX). Fluid (black space) posteriorly above the diaphragm (PLAPS)	Absent; Present; Uncertain	>10mm
B-line Positive	Visual	UPA & LPA	B-line (vertical hyperechoic artefact extending from pleura to bottom of screen without fading)	Absent; Present; Uncertain	≥3 B-lines/zone= positive
LV wall thickness	Visual	PLAX	Wall thickness appears increased, may make LV cavity look small	Absent; Present; Uncertain	Moderate-severe LVH
LA dilation	Visual	PLAX	LA dimension > aortic root dimension (PLAX)	Absent; Present; Uncertain	LA size > aortic root dimension (PLAX)
RV dilation/ Dysfunction	Visual	A4C	RV equal to/bigger than LV (A4C). Reduced: wall thickening, inward endocardial movement, reduction in RV cavity size, reduced TV annulus movement towards apex.	Absent; Present; Uncertain	RV size ≥ LV size Moderate-severe dysfunction
Stenosis (AV or MV)	Visual	PLAX, A3C	Increased leaflet thickness; reduced excursion; turbulent colour flow.	Absent; Present; Uncertain	Moderate-severe stenosis
Regurgitation (AV or MV)	Visual	PLAX, A4C	Backward colour flow jet (size/width); flow disturbance downstream from valve; receiving chamber dilation.	Absent/trivial; Present; Red Flag; Uncertain	Absent/trivial= no or trace jet; present= mild-moderate; red flag= moderate+

Note A2C= apical two chamber; A3C= apical three chamber; EF= ejection fraction; RA= right atrium; PLAPS= PosteroLateral Alveolar &/or Pleural Syndrome; DP= dorsal posterior; AV= aortic valve; MV= mitral valve; UPA= upper point anterior; LPA= lower point anterior; TV= tricuspid valve

In addition to reporting the POCUS findings using tick box options, the POCUS reporting form (Appendix E) required the nurses to document time taken for POCUS, where the patient was scanned (including patient positioning) and whether the images obtained were of sufficient diagnostic quality, detailing which (if any) views were unobtainable. The POCUS analysis form ended with a conclusion section determining whether the POCUS was essentially normal or abnormal and whether an urgent review was required based upon whether they had ticked any of the boxes marked with a red flag/starred.

Diagnostic accuracy was assessed at four time-points: at the end of the clinical examination (includes ECG); after nurse-led POCUS; after the result of NT-proBNP blood test was known; and after remote sonographer (expert) interpretation of POCUS images. After standard clinical assessment and ECG, the nurse was required to document their working diagnosis and management plan (including medication and referral for additional testing decisions). In line with current practice, those with suspected HF had NT-proBNP blood test performed (results not available immediately). Post-clinical assessment the nurse performed POCUS (index test) in line with the POCUS protocol, recording whether it was positive, negative, or indeterminate for LVSD. They recorded if/how POCUS findings would hypothetically change their working diagnosis and management plan if they were to act upon the findings. Once results of the NT-proBNP blood test were back, the nurse was required to review the value and document if/how this would alter their initial management plan proposed post-clinical assessment in line with current practice.

Due to the absence of supporting evidence that POCUS improves care in this context, the standard pathway drove clinical decisions/patient management. However, any nurse concerns about severe or life-threatening pathology detected on POCUS were raised with an acute clinical team physician immediately so that the patient could benefit from more rapid triage if appropriate. If needed, the physician was able discuss any concerns about POCUS findings with the Consultant Cardiologist providing oversight for the study.

The accredited sonographer (expert) reviewed all archived POCUS images, blind to nurse interpretation and clinical information, and reported findings using the same format/guidance as the nurses. Sonographer decision on POCUS findings constituted the reference test and the impact of specialist decision was used to assess potential impact upon management

decisions. The 'gold standard' for assessing LVSD would usually be a Magnetic Resonance Imaging (MRI) scan or comprehensive TTE. The pragmatic approach chosen reflects the fact that moving older people to hospital for such tests undermines the purpose of the acute clinical team in delivering medical care at home wherever possible. In addition, there is a strong body of evidence showing that specialists can accurately diagnose LVSD from POCUS.

PROM data collection

EQ-5D-5L and the PROMIS Dyspnoea Functional Limitations- Short Form 10a questionnaires were completed during the home visits. For the EQ-5D-5L, part one (descriptive) involved rating health in five dimensions (mobility, self-care, usual activities, pain/discomfort, and depression), each of which had five levels of response (no problems, slight problems, moderate problems, severe problems, extreme problems/unable to). The second part comprised a visual analogue scale (EQ-VAS) whereby patients rated their perceived health score from 0 (worst health imaginable) to 100 (best health imaginable health). For the PROMIS Dyspnea Functional Limitations- Short Form 10a patients rated the difficulty of ten specific daily activities (no difficulty, a little difficulty, some difficulty, much difficulty, I did not do this in the past 7 days) over the preceding seven days. In addition to the scores, the PROM form included boxes regarding agreement to complete, completed by, and time taken to complete. Rates of completeness (ability to answer/complete) and frequency of 'not done in the past 7 days' (relevance/content suitability) were recorded to provide insight into suitability of the tools in the proposed setting.

Estimating intervention cost

The importance of economic consideration was recognised but at this early stage of research the attention was limited to providing a provisional exploration of resource use associated with POCUS. The intention was to provide a first step at understanding and describing the key drivers of resource use (and potential unit costs) associated with adding POCUS in this context to help inform future feasibility/pilot studies. A simple description of the identified

resources relating to the implementation of the intervention as seen in this small study were recorded and used to estimate cost.

A UK NHS perspective was taken. At this stage estimated costing was limited to execution of the intervention (POCUS) and included equipment capital costs and staff time. Estimations do not include development costs; POCUS training (resources and staff time) has not been costed at this stage. Cost accounting was used to determine the cost of POCUS based on unit capital cost, depreciation, and staff time. Estimates are based upon the assumption that depreciation would occur in a linear fashion. The method used for costing was consistent with that used in the previously detailed (Chapter 3) Health Technology Wales evidence appraisal report (009) (Health Technology Wales, 2019b). To estimate the equipment cost per point-of-care scan, device purchase cost (capital cost) was assumed to spread across a seven-year device lifetime to provide a yearly cost. To scale up the intervention costs to a year, the number of acute clinical team referrals received during the study period was used to estimate the number of referrals per year (as the service runs 365-days of the year). The percentage of referrals that met the study inclusion criteria during the data collection period was calculated and applied to the estimated number of yearly referrals to give an estimate of the number of scans per year . This uses the assumption that all those eligible for POCUS would undergo a scan and study data obtained is based upon the availability of two devices. No maintenance costs were added.

To estimate the cost of staff time, the Personal Social Services Research Unit (PSSRU) Unit Costs of Health and Social Care 2021 (Jones & Burns, 2021) were used to guide the cost per working hour of a Band 7 community nurse and the cost per working hour for a Band 7 hospital-based health care professional (based on radiographers). The study data obtained regarding time for nurse-led POCUS and time for expert review were combined with the PSSRU guidance to calculate estimated staff time costs. The intention had been for a cloud-based server to be available for image download however this was not in place at the time of the study. Instead, images were downloaded to an NHS shared drive which had no associated costs. There were no significant consumable costs associated with the procedures included in the pathways (current and proposed) therefore these were not included in the costings. Data were limited to initial tests in the pathway. Costs associated with management decisions or clinical outcomes and influence on downstream testing costs/savings is not included.

For comparative purposes the cost of the other tests in the pathway were estimated using published costings taken from the National Institute for Health and Care Research interactive costing tool (iCT) tariff data 2023/24, version 1.5 (National Institute for Health and Care Research, 2023) and physical examination cost estimated based on the assumption of requiring ten-minutes of nurse time using the PSSRU staff time costs (Jones & Burns, 2021).

Quantitative data analysis (Phase 2)

The relevant data was extracted from the CRF and collated on a Microsoft Excel spreadsheet. This included data regarding patient recruitment; patient demographics; initial examination findings; scanning location, ease, and time; POCUS findings; clinical decision making (medications and referrals) at each stage; nurse-perceived patient compliance, suitability, and appropriateness; and PROM feasibility (in terms of completion rate and appropriateness of questions in relation to daily activities). Where relevant, mean values, standard deviations and percentages were calculated.

To assess diagnostic accuracy, nurse sensitivity and specificity for detecting LVSD via POCUS was calculated using sonographer-reported POCUS images as the reference. Dichotomous categories of positive and negative were used to construct a 2x2 contingency table for diagnostic accuracy. As a conservative trade-off, any ratings of 'uncertain' were recorded as positive. A sensitivity and specificity of ≥0.80 were deemed acceptable. Cohen's Kappa statistic was calculated to assess inter-rater reliability between the nurses and specialist (sonographer) interpreting the images. Cohen suggested a value of 0.61–0.80 should be considered substantial agreement, and 0.81–1.00 as almost perfect agreement (McHugh, 2012). A Kappa value of 0.70 was the threshold for acceptable agreement.

Connecting quantitative and qualitative data (Phase 3)

Through building, quantitative data was used to inform qualitative data collection. Any areas of uncertainty or points requiring further elaboration highlighted from the initial quantitative data were combined with the qualitative objectives and used to guide the focus group

discussion. The comments section of the CRF and my field notes, both detailed below, were also used to guide focus group discussion.

Qualitative data collection (Phase 4)

The CRF included an open comments section for nurse comments regarding feasibility, patient acceptability of and attitude towards POCUS (intervention), and environment suitability of implementing POCUS. The nurses were directly asked to record any concerns/issues. In addition, I kept field notes during review of nurse scans, conversations with the nurses, and reflections from three early observation sessions. The observation sessions involved watching three random visits performed by the nurses whereby I solely observed them performing a home visit (no interaction). The intention was to review this information, alongside the quantitative data, prior to the focus group meeting to help inform the discussion guide.

The primary source of qualitative data was a focus group meeting. The focus group meeting occurred two-weeks after the last patient was recruited into the clinical study. Focus group attendees comprised of a moderator (myself) and the four nurses involved in the POCUS project. The focus group meeting took approximately one hour. The meeting was recorded, with the permission of attendees, to aid transcription.

To try and provide clarity and reduce expectancy bias, the meeting began with an initial introductory statement from the moderator (myself). It sought to clarify the purpose of the discussion, reiterating that the intention was to gain an insight into the nurses' knowledge and experiences. Nurses were encouraged to be open and honest during the discussion. It was emphasized that there were no right/wrong opinions and that their responses did not need to be congruent. As the moderator knew the nurses, it was reiterated that they should feel free to openly compliment or critique the process and that the only expectation was for them to be honest. The moderator explained that their presence was in a moderator role to facilitate the discussion, not to give opinions (neutral).

The role of the moderator was to facilitate group interaction; to encourage discussion of the groups experiences and opinions and provide everyone with the chance to talk, listen and discuss. As the moderator, I encouraged the nurses to share their experiences and opinions of using POCUS within community care in those with suspected HF. Discussions were focused on the feasibility and acceptability of implementing POCUS, how it influenced their management decisions, and potential facilitators and barriers to implementation. I attempted to avoid leading questions and to use open-ended questions that were unambiguous and unbiased. I sought to adopt active listening; paraphrase answers back and asking for clarification where necessary before moving on to different topics. This was to ensure opinions had been properly understood and to provide the nurses with opportunity to add any additional points. An attempt was made to encourage input from quieter members of the group by asking whether they had anything to add.

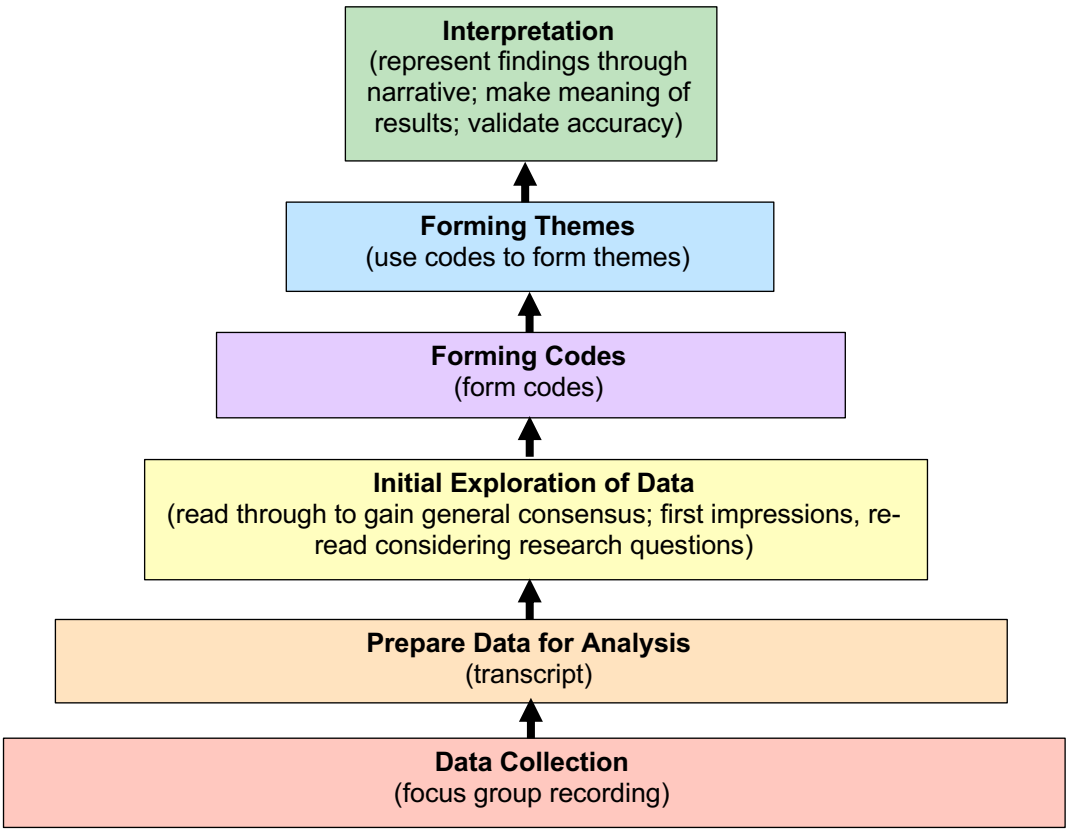
The meeting ended with a final summary. I summarised back the main points from the discussion, providing further opportunity for the nurses to add anything and to ensure their points had been adequately heard. There was a debrief with thanks to the nurses for participation. I noted initial (brief) impressions.

Qualitative data analysis (Phase 5)

A thematic analysis approach was taken involving identifying, analysing, and reporting patterns (themes) within the data (Braun & Clarke, 2006). An overview of the qualitative data analysis process is provided in Figure 5.2. It outlines the bottom-up approach, based upon recommendations by Creswell (2012), starting from initial data collection through to data analysis.

Figure 5.2

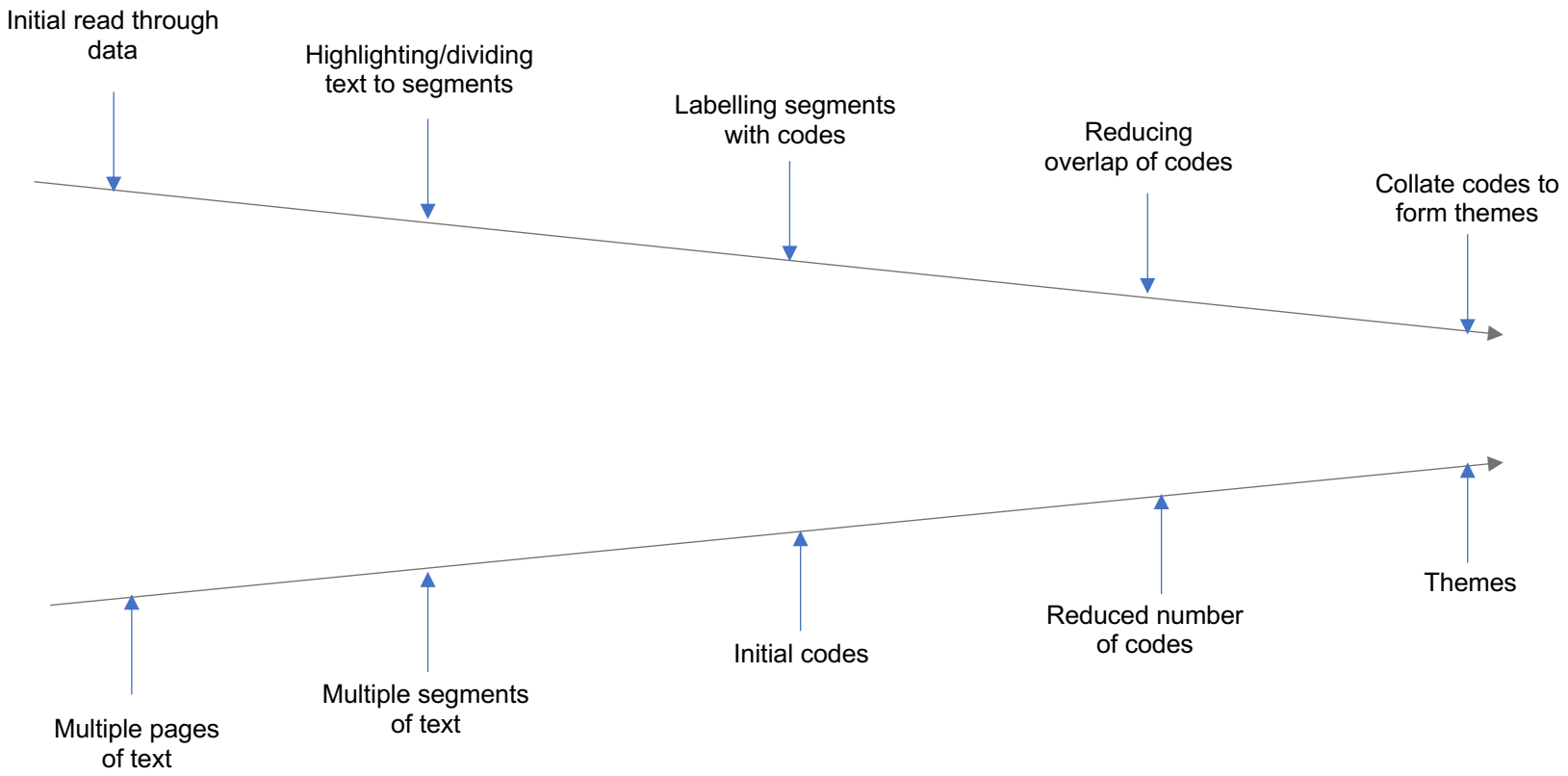
'Bottom-up' qualitative data analysis process (Creswell, 2012)



The transcription process involved assigning each nurse a letter. The video recording was then transcribed using Microsoft Word. An overview of the thematic analysis, based upon suggestions by Creswell (2012) is shown in Figure 5.3. It demonstrates the inductive process, moving from specific detail of transcribed words, to generalised codes, and then themes.

Figure 5.3

Visual model of qualitative data analysis (Creswell, 2012)



This was built upon using Braun and Clarke's (2006) six-phase approach to thematic analysis which includes refining of themes and reporting. The six phases include:

1) Familiarizing yourself with your data
2) Generating initial codes
3) Searching for themes
4) Reviewing themes
5) Defining and naming themes
6) Producing the report

The transcription was read to gain insight. Coding was done manually using Microsoft Word. Initially any sections with information regarding POCUS implementation were highlighted and broad codes noted in margins and then refined. An inductive approach to coding was adopted; codes (descriptive) were derived from the data to help minimise preconceived ideas (bias) about the research problem and the data (Bingham & Witowsky, 2022; Boyatzis, 1998).

A mixed approach to results synthesis was undertaken. While an inductive approach was taken to understand the data, a deductive approach was performed to help organise the data into themes based upon the research questions and CFIR constructs (Bingham & Witowsky, 2022; Boyatzis, 1998). Categorical grouping was performed to connect codes based upon shared concepts to form themes. The themes were colour-coded and noted as 'comments' in the Word document. The CFIR constructs were considered to facilitate classification of barriers and enablers (deductive), along with the inductive codes to accommodate context specific details. The CFIR constructs and codes were merged into concepts and themes.

Integration of quantitative and qualitative results (Phase 6)

The different datasets were analysed collectively, and data integrated using a narrative approach. The "following a thread" framework for analytical integration was adopted. This involved individual analysis of the datasets and identification of key themes, then based upon the research questions, a theme from one dataset is followed across the other dataset(s) (thread) providing multi-factored information (Moran-Ellis et al., 2006). Data integration occurred through merging (Fetters et al., 2013). Based upon the identified themes (collated under CFIR domains), a data display of major quantitative and qualitative findings was created with points of convergence, divergence, and expansion.

Results

Quantitative data

A total of thirty-two patients were recruited and enrolled by the four nurses, mean age 81 ± 9yrs. Patient demographics are summarised in Table 5.1. A previous history of HF was noted in eleven patients (34%). On clinical examination, there were signs of fluid overload in eighteen (56%), consolidation in twelve (38%), and rales/crackles in four (13%). Collectively there were twenty-two cases in which there was at least one sign of congestion (fluid overload, consolidation, and/or rales/crackles). An ECG abnormality, defined as anything other than sinus rhythm/sinus bradycardia, was recorded in fourteen cases (44%).

Table 5.1

Patient demographic data

Characteristic	Number (%)
Participant (n)	32 (100)
Females (n)	17 (53)
Age years (mean, ± SD)	81 ± 9
NHS frailty score (mean, ± SD)	5.3 ± 1.5
New York Heart Association Functional Classification:	
-I	0 (0)
-II	11 (34)
-III	11 (34)
-IV	8 (25)
-Unspecified	2 (6)
Previous Cardiac History:	
-HF	11 (34)
-Valvular heart disease	4 (13)
-Ischaemic heart disease/Myocardial infarction	5 (16)
-Arrhythmia	10 (31)
-Pacemaker/Implantable cardioverter defibrillator	3 (9)
-Hypertension	7 (22)
-Pulmonary hypertension/Right HF	1 (3)
-Nil	8 (25)
-Syncope	1 (3)
-Cerebral vascular accident (CVA)	2 (6)
History of COPD	10 (31)
Clinical History Findings:	
-Breathlessness	32 (100)
-Orthopnoea	8 (25)
-Paroxysmal nocturnal dyspnoea (PND)	5 (16)
-Cough	5 (16)
-Unexplained weight gain	4 (13)
-Chest pain	1 (3)
-Palpitations	4 (13)
-Syncope	4 (13)
-Hypertension	8 (25)
-Postural hypotension	7 (22)
-Diabetes	9 (28)
-Obesity	10 (31)
-Smoker/Ex-smoker	2 (6) / 6 (19)
-Increased alcohol intake/Previously increased	4 (13) / 1(3)
-Positive family history of cardiac disease	5 (16)
Clinical Signs:	
-Nil	8 (25)
-Fluid overload	18 (56)
-Murmur	9 (28)
-Consolidation	12 (38)
-Rales/crackles	4 (13)
Heart Rate bpm (n=28, mean, ± SD)	83 ± 24.03
ECG Findings:	
-sinus rhythm (SR)	15 (47)
-sinus bradycardia (SB)	3 (9)
-sinus tachycardia	0 (0)
-atrial fibrillation (AF)	12 (38)
-left bundle branch block (LBBB)	3 (9)
-right bundle branch block (RBBB)	1 (3)
-ectopic beat(s)	5 (16)
-paced	1 (3)

The prevalence of cardiac pathology amongst the thirty-two cases, as determined by reference test, is outlined in Table 5.2. LVSD was confirmed on reference test in fourteen (44%) cases; four of which had severe LVSD. In terms of congestion, there was one confirmed case of abnormal IVC, one pericardial effusion, seven pleural effusions, and six cases with B-line positivity. Collectively, twelve cases had sign(s) of congestion, nine of which also had signs of congestion noted on the physical examination. There were seven cases with confirmed LVSD and at least one ultrasound sign of congestion (pleural effusion, B-line positive, pericardial effusion and/or abnormal IVC) on reference test; six of which had pulmonary signs of congestion (B-line positive ± pleural effusion) on LUS.

Table 5.2

Prevalence of cardiac pathology on reference test

Pathology	Present (N, %)		Absent (N, %)	Uncertain (N, %)
LV systolic dysfunction	14 (44)		16 (50)	2 (6)
	Abnormal *10 (31)*	***Severe*** *4 (13)*		
LV Dilation	3 (9)		24 (75)	5 (16)
Abnormal IVC	1 (3)		8 (25)	23 (72)
Pericardial effusion	1 (3)		30 (94)	1 (3)
Pleural effusion (PLE)	7 (22)		24 (75)	1 (3)
B-Line positive	6 (19)		25 (78)	1 (3)
LVH	3 (9)		28 (88)	1 (3)
LA Dilation	23 (72)		8 (25)	1 (3)
RV dilation/dysfunction	5 (16)		25 (78)	2 (6)
AS	3 (9)		19 (59)	10 (31)
MS	1 (3)		29 (91)	2 (6)
AR	5 (16)		20 (63)	7 (22)
MR	7 (22)		18 (56)	7 (22)

A clinical history and physical examination, ECG, NT-proBNP testing, nurse-led POCUS and sonographer (expert) analysis of nurse-acquired POCUS images (reference test) were carried out in all thirty-two cases. An overview of the ECG, NT-proBNP result, and main POCUS findings for the thirty-two participants is provided in Table 5.3. The NT-proBNP value was not available (system error) for two cases (indicted by an 'X'). The signs of congestion and other significant pathology relate to cases confirmed on POCUS, they do not include those reported as uncertain on reference test. The 'other significant pathology'

section does not include all pathology (LA dilation and LVH excluded) and only includes significant cases of regurgitation (hence the lower prevalence than that noted in Table 5.2). Accuracy of nurse-led POCUS is detailed in the later ‘accuracy and reliability’ section of the results.

Table 5.3

ECG findings, NT-proBNP result, and POCUS findings in terms of LVSD, congestion, and other significant pathology (n=32)

Case	ECG	NT-proBNP value (ng/l)	LVSD on POCUS		Signs of congestion on examination	Signs of Congestion on POCUS		Other significant pathology on POCUS		Significant Abnormality on POCUS		Abnormal NT-proBNP
			Nurse	Reference		Nurse	Reference	Nurse	Reference	Nurse	Reference	
1	SR, Ectopic	93	Present	Absent	FO	Nil	Nil	RV	RV	Y	Y	N
2	SR, LBBB, Ectopic	5851	Present	Present	Nil	Nil	Nil	Nil	Nil	Y	Y	Y
3	SB	479	Absent	Present	R, CONS	Nil	Nil	Nil	RV	N	Y	Y
4	SR	368	Absent	Absent	FO	P.Ef	Nil	Nil	Nil	N	N	N
5	SR	3634	Absent	Absent	CONS	PLE	PLE	Nil	Nil	Y	Y	Y
6	AF	1694	Present	Present	Nil	Nil	Nil	Nil	Nil	Y	Y	Y
7	Paced	8221	Present	Present	FO, CONS	Nil	Nil	RV	RV	Y	Y	Y
8	SR	94	Absent	Absent	FO	Nil	Nil	Nil	Nil	N	N	N
9	SR	142	Absent	Absent	CONS	Nil	Nil	?PFO	Nil	Y	N	N
10	SB	X	Absent	Absent	NIL	Nil	Nil	Nil	Nil	N	N	X
11	SR	4650	Absent	Absent	FO, CONS	PLE	PLE	Nil	AS	Y	Y	Y
12	AF	3075	Present	Absent	FO, R, CONS	Nil	Nil	AS	AS	Y	Y	Y
13	SR, Ectopic	401	Absent	Absent	FO, R	Nil	Nil	Nil	Nil	N	N	Y
14	AF	750	Absent	Absent	FO	Nil	Nil	Nil	Nil	N	N	Y
15	AF	2670	Absent	Absent	Nil	Nil	Nil	Nil	Nil	N	N	Y
16	SR, RBBB, Ectopic	X	Absent	Absent	Nil	Nil	Nil	Nil	Nil	N	N	X
17	SR	2686	Present (S)	Present (S)	FO	PLE	PLE	RV, MR, thrombus	RV, MR, thrombus	Y	Y	Y
18	SR	284	Uncertain	Uncertain	FO	Nil	Nil	Nil	Nil	N	N	N
19	AF	17188	Present	Present	FO, R, CONS	BL+	BL+	MS, MR	MS, MR	Y	Y	Y
20	AF, LBBB	>35K	Present (S)	Present (S)	FO, CONS	A.IVC, PLE, BL+	A.IVC, PLE, BL+	Nil	Nil	Y	Y	Y

21	SR, LBBB	4682	Present (S)	Present (S)	NIL	Nil	Nil	Nil	Nil	Y	Y	Y
22	AF	2085	Present	Present	NIL	BL+	BL+	Nil	Nil	Y	Y	Y
23	SR	175	Present	Present	FO	Nil	Nil	Nil	Nil	Y	Y	N
24	SR, Ectopic	888	Present	Present	NIL	BL+	BL+	MR	MR	Y	Y	Y
25	SR	2219	Absent	Absent	NIL	Nil	Nil	Nil	Nil	N	N	Y
26	AF	7437	Present (S)	Present (S)	NIL	PLE	PLE	MR	MR	Y	Y	Y
27	AF	419	Absent	Absent	FO	Nil	Nil	AS	AS	Y	Y	Y
28	AF	2376	Present	Present	CONS	Nil	Nil	MR	RV, MR	Y	Y	Y
29	AF	2248	Uncertain	Uncertain	FO	BL+	BL+	Nil	Nil	Y	Y	Y
30	AF	7099	Absent	Absent	FO, CONS	PLE, BL+	PLE, BL+	Nil	Nil	Y	Y	Y
31	AF	1663	Present	Present	FO, CONS	P.Ef	P.Ef	Nil	Nil	Y	Y	Y
32	SR	3428	Absent	Absent	FO, CONS	P.Ef, PLE	PLE	Nil	Nil	Y	Y	Y

Note SR=sinus rhythm; SB=sinus bradycardia; AF= atrial fibrillation; FO= fluid overload, CONS= consolidation, R= rales; P.Ef= pericardial effusion; PLE=pleural effusion; A.IVC= abnormal inferior vena cava; BL+= B-line positive; PFO= patent foramen ovale

Feasibility and acceptability

For the thirty NT-proBNP values recorded, 93% were available within 24hrs (minimum same day and maximum 48hrs). LV systolic function could be assessed from the POCUS images in 94% of cases by both the nurse and sonographer (reference test). The same two cases were deemed indeterminate for LV systolic functional status by the nurse and sonographer.

Information provided by the CRF and nursing teams referral database relating to recruitment and understanding the proposed patient population and environment; feasibility; and suitability of the PROMs tools are summarised in Table 5.4.

Table 5.4

Summary of the quantitative measures

Implementation Consideration	Quantitative Data Measure	Outcome/Result
Recruitment	-time taken to recruit	-2.6mths (80days) for 4 nurses to recruit 32 patients
	-referrals that met inclusion criteria	-30% of acute clinical team referrals met inclusion criteria (1% excluded on age)
	-enrolment	-43% of those eligible seen by a POCUS nurse, of which all were offered enrolment
	-patient enrolment rate	-100% agreement to enrol & 0% withdrawal request
	-nurse enrolment rate	-100% agreement to enrol & 0% withdrawal request
Understanding patient population	-age -frailty score -NYHA score -Body Mass Index (BMI)	-mean age 81 ± 9yrs, 53% male -mean frailty score 5.3 ±1.5 -mean NYHA 2.7 ± 1.05 (mode 2, median 3) -BMI available for 7 (remainder weight +/- height missing). Of the 7: 2 underweight (BMI<18.5); 2 normal (18.5-25); & 3 obese (BMI 30+) -mean weight (n=22): 81±30.2kg (4x<50kg & 6x≥100kg)
	-LVSD prevalence	-LVSD prevalence 44%
Feasibility (patients/ setting)	-scanning environment	-94% at home & 6% residential home
	-patient position/location	-50% scanned in chair, 38% bed, & 13% sofa -card views: 47% left, 47% upright, 6% supine -subcostal views: 50% supine, 50% upright
	-number of diagnostic scans	-POCUS performed in 100% -LV systolic function assessable in 94%
	-time taken to perform POCUS	-POCUS time logged for 84%, mean time 20.19 ± 7.5mins -machine scan time, mean 15.53 ± 6.1mins
	-sonographer review time	-mean review 4.7 ± 1.6mins per scan
	-scanning/reporting protocol	-POCUS performed in 100% ->1 images absent/unobtainable in 100% -non-diagnostic (sonographer judged): PLAX 9%; PSAX 44%; A4C 28%; A2C 66%; A3C 88%; S4C 47%, S.IVC 75%; Ant LUS 0%; PLAPS 9%
	-missing fields on CRF	-missing data: 2x NT-proBNP result & 1x PROM dataset -nurse POCUS time missing in 16% & 48% of the times logged were scanning time only -missing patient info: height 75%; weight 31%; BMI 78%; NYHA score 6%; heart rate 6%
PROM tools	-completion rate	-97% completion rate (x1 nurse forgot)
	-time to complete	-mean time to complete 12.6 ± 9.2min
	-EQ-5D-5L	-5-digit health state for all (no code the same)
	-Health state index score	-mean score 55.3 ± 22.87
	-PROMIS Dyspnoea score (form 10a)	-complete dataset (with no 'not done in last 7days' responses) in 11 of 31 patients (36%) -'not done in last 7days' response for every statement in 8 of 31 patients (26%)

The intention had been for the nurses to add comments to the open comments box regarding POCUS feasibility, acceptability (patient attitudes to intervention, appropriateness, suitability, and convenience), and environment suitability but after the first two cases the box had been left blank so instead tick-box comment options were provided (with the option of a comments box alongside each option). The nurses then completed this for the two original cases and all subsequent cases. Results of the comments section of the CRF regarding POCUS were collated (Table 5.5**)**. No difficulty with consent was noted in 72%. Patient positivity towards POCUS was recorded in 88% and there was no negativity or issues with compliance recorded. The environment was noted to be adequate in 47% and difficult in 34%. Difficulty with patient positioning was noted in three-quarters of patients and a difficult body habitus in 63%.

Table 5.5

Comments from the CRF

Comment No.	Comment	Frequency of cases comment noted (N, %)
1	No difficulty with consent	23 (72)
2	Some difficulty with consent	1 (3)
3	Patient/relative positive attitude to scan	28 (88)
4	Patient/relative negative attitude to scan	0 (0)
5	Patient compliance	14 (44)
6	Patient not compliant	0 (0)
7	Adequate environment	15 (47)
8	Difficult environment	11 (34)
9	Suitable patient positioning	5 (16)
10	Difficulty with patient positioning	24 (75)
11	Patient movement (restless)/discomfort	8 (25)
13	Limited mobility	15 (47)
14	Patient frailty	4 (13)
15	Relative/carer aid/support	3 (9)
16	Relative/carer interruption/negative input	1 (3)
17	Suitable operator position	4 (13)
18	Difficult operator positioning	7 (22)
19	Operator frustration	1 (3)
20	Difficult/challenging body habitus	20 (63)
21	Difficult/challenging due to dyspnoea/cough	9 (28)
23	Relatively easy scan	5 (16)
24	Difficult images	3 (9)
25	Operator limited time	0 (0)

Accuracy and reliability

Nurse accuracy (Table 5.6) and reliability measures for detecting LVSD exceeded the target thresholds of ≥0.8 and ≥0.7 respectively. Sensitivity and specificity for detecting LVSD were 0.94 and 0.88 respectively. Nurse LVSD agreement with sonographer had a kappa value of 0.81 (Landis & Koch, 1977).

Table 5.6

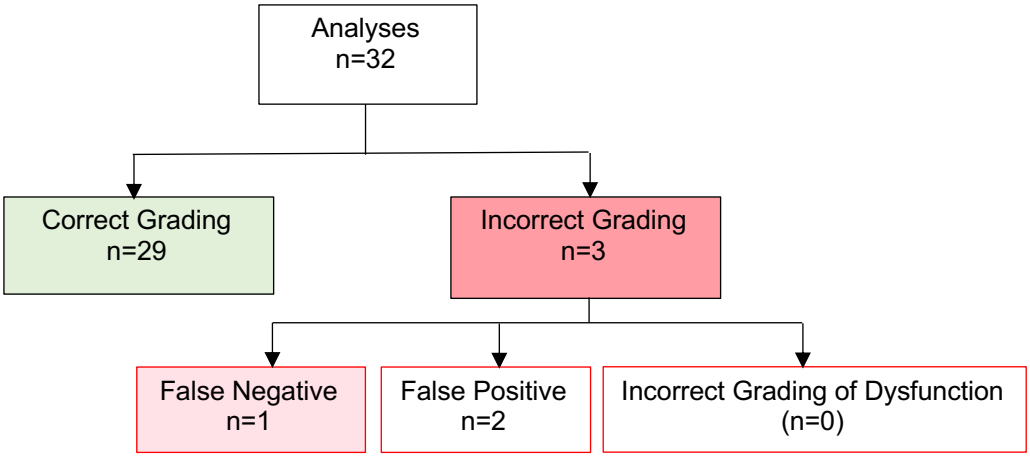
Nurse accuracy for detecting LVSD

LVSD	**Reference Test Positive**	**Reference Test Negative**	**Measures**
Index Test Positive	15	2	Positive predictive value = 0.88
Index Test Negative	1	14	Negative predictive value = 0.93
Measures	Sensitivity = 0.94	Specificity = 0.88	Accuracy = 0.91

In terms of categorical assessments of LV systolic function, the nurses correctly categorised LV systolic functional status into broad categories of 'grossly normal,' 'abnormal,' 'severely abnormal,' and 'uncertain' in 91% (Figure 5.4). LV systolic function was graded abnormal by the nurse when normal on reference (false positive) in two cases and classed as normal when abnormal on reference test in one case (false negative). The false negative case (case 3) had abnormal (not severe) LVSD and there were no ultrasound signs of congestion. RV dilation was reported on reference test. There were no cases of incorrectly grading the extent of dysfunction (abnormal when severe on reference or vice versa).

Figure 5.4

Accuracy of nurse grading of LV systolic function status



In terms of detecting other significant pathology on POCUS, the nurses correctly identified whether a significant abnormality was present (n=22) in 94% of cases (shown previously in Table 5.3). The nurses correctly identified whether an urgent review was required (n=12) in 91%. This was based upon whether a pathology with a red flag/starred had been ticked on the POCUS reporting form.

In terms of specific pathology other than LVSD, low prevalence prohibited the use of accuracy measures. Instead, the nurses' ability to detect specified significant pathology was assessed. Table 5.7 shows nurse assessments for each pathology compared with reference test (sonographer analysis).

Table 5.7

Nurse reporting of additional pathology compared to reference test across all cases (n=32)

Abnormality	No. of Present		No. of Absent		No. of Uncertain	
	Reference	Nurse	Reference	Nurse	Reference	Nurse
LV dilation	3	5	24	21	5	6
Abnormal IVC	1	1	8	8	23	23
Pericardial effusion	1	3	30	26	1	3
Pleural effusion	7	7	24	20	1	5
B-Line positive	6	6	25	26	1	0
LVH	3	1	28	27	1	4
LA dilation	23	14	8	15	1	3
RV dilation+/- dysfunction	5	3	25	23	2	6
Aortic stenosis	3	2	19	23	10	7
Mitral stenosis	1	1	29	27	2	4
Aortic regurgitation	5	4	20	19	7	9
Mitral regurgitation	7	11	18	19	7	2

In terms of volume status, the case of abnormal IVC, pericardial effusion, and all cases of pleural effusion and B-line positivity were detected by the nurses. There were two cases of pericardial effusion over-reporting. In terms of the additional other cardiac pathology there was more variability. There was some over-reporting of LV dilation (n=2) and mitral regurgitation (n=4) and under-reporting of LVH (n=2), LA dilation (n=9), RV dilation /dysfunction (n=2), and one case of aortic regurgitation. None of those under-reported cases were significant enough to be the cause of the acute dyspnoea. One case of aortic stenosis was also missed by the nurse but the PLE on that same case was detected meaning the case was reported as abnormal.

Most pathology occurred in the setting of LVSD but there were cases with a significant abnormality in the setting of normal LV systolic function reported by the nurses and on reference test (Table 5.8). In the interest of the reader, the NT-proBNP results are also included in the table.

Table 5.8

Cases with abnormalities in the setting of normal LV systolic function as determined by nurses and sonographer (reference test)

Case	LVSD on POCUS		Signs of Congestion on POCUS		Other significant pathology on POCUS		Significant Abnormality on POCUS		Abnormal NT-proBNP
	Nurse	Reference	Nurse	Reference	Nurse	Reference	Nurse	Reference	
1	Present	Absent	Nil	Nil	RV	RV	Y	Y	N
4	Absent	Absent	P.Ef	Nil	Nil	Nil	N	N	N
5	Absent	Absent	PLE	PLE	Nil	Nil	Y	Y	Y
9	Absent	Absent	Nil	Nil	?PFO	Nil	Y	N	N
11	Absent	Absent	PLE	PLE	Nil	AS	Y	Y	Y
12	Present	Absent	Nil	Nil	AS	AS	Y	Y	Y
27	Absent	Absent	Nil	Nil	AS	AS	Y	Y	Y
30	Absent	Absent	PLE, BL+	PLE, BL+	Nil	Nil	Y	Y	Y
32	Absent	Absent	P.Ef, PLE	PLE	Nil	Nil	Y	Y	Y

Note- P.Ef= pericardial effusion; PLE= pleural effusion; PFO= patent foramen ovale; AS= aortic stenosis

Note- For case 4, while the nurse ticked ‘present’ for pericardial effusion (incorrect as less than threshold) they correctly ticked ‘no’ for significant abnormality

On reference test, there were seven cases (cases 1, 5, 11, 12, 27, 30, 32) with a significant abnormality in the setting of normal LV systolic function, three of which had only cardiac abnormalities, three with lung only, and one both. Nurse-led POCUS reported all these as having a significant abnormality. One case of AS was missed (as mentioned) but the case was reported as abnormal because the PLE was detected. Under the current pathway, based upon NT-proBNP value, one case would have been missed as the NT-proBNP value was 93 yet there was RV dilation/dysfunction on reference test (case 1). Nurse-led POCUS reported seven cases with a significant abnormality in the setting of normal LV systolic function, two of which were cardiac and five of which were lung (cases 4, 5, 9, 11, 27, 30, 32). Of these, five were consistent with reference test, two were false positives (a non-significant pericardial effusion and a '?patent foramen ovale' which was not confirmed on reference test). It should be noted that the nurses also detected pathology on cases 1 and 5 but given that they noted both as having LVSD (incorrect), they were not included in their number of cases of other significant pathology in absence of LVSD.

This information highlights that in the elderly, acutely dyspnoeic cohort other, cardiac and non-cardiac (respiratory), potential causes for the acute dyspnoea, aside from LVSD, were detected via heart and lung ultrasound.

Clinical impact

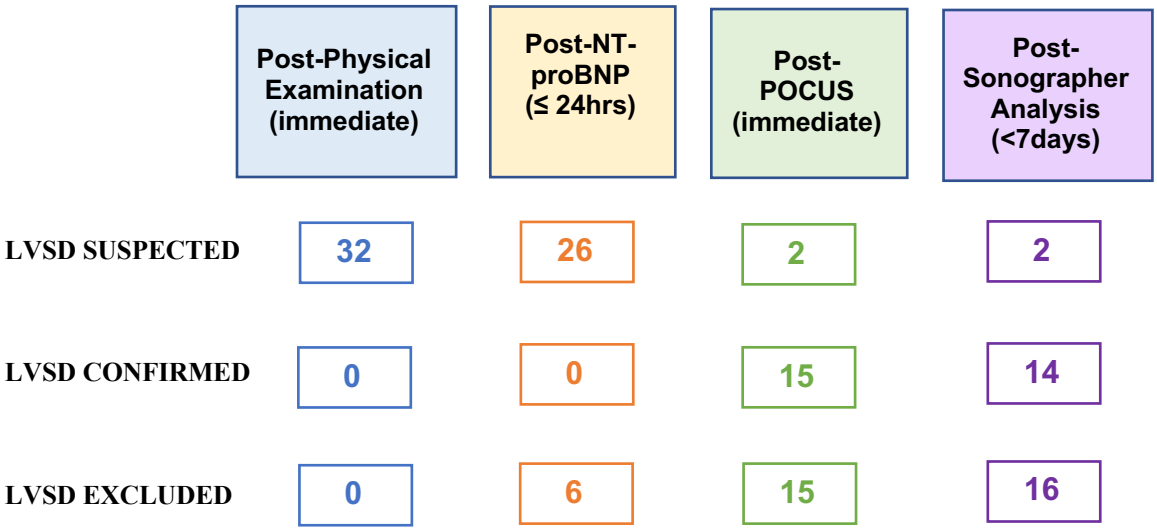
The nurses recorded their working diagnosis at three different time points: after completing the clinical history and physical examination; after the NT-proBNP result was available (in line with standard care); and after completing POCUS (proposed model of care). There was some (≥1) alteration in the listed initial working diagnoses recorded post-physical examination compared with post-NT-proBNP result and post-POCUS in 41% and 97% respectively.

Rates of suspected (including 'uncertains'), confirmed, or excluded LVSD were compared post-examination, post-NT-proBNP result, post-nurse led POCUS, and post-sonographer analysis (Figure 5.5). Under the current model of care within 24hrs LVSD was excluded in 19% and remained uncertain in 81% (elevated or unavailable NT-proBNP result). Adding nurse-led POCUS to the initial assessment enabled immediate confirmation of LVSD in 47%

and 44%, and exclusion in 47% and 31% respectively depending on whether nurse or sonographer analysed.

Figure 5.5

Diagnosing LVSD at the different time points (n=32)



In terms of diagnostic accuracy for detecting congestion, while clinical signs can allude to congestion, they lack the necessary sensitivity/specificity to confirm a cause/diagnosis. Therefore cardiogenic/non-cardiogenic congestion could not be confirmed in any cases under the current model of care. Ultrasound signs of congestion have higher sensitivity and specificity than clinical signs and in combination with cardiac ultrasound can help identify a cardiac or non-cardiac cause. Adding POCUS at the initial point-of-care enabled immediate confirmation of ultrasound signs of congestion in twelve cases on reference (sonographer analysis) and one additional case of pericardial effusion (false positive) via nurse analysed POCUS. For all except one, LVSD was confirmed or excluded in these cases.

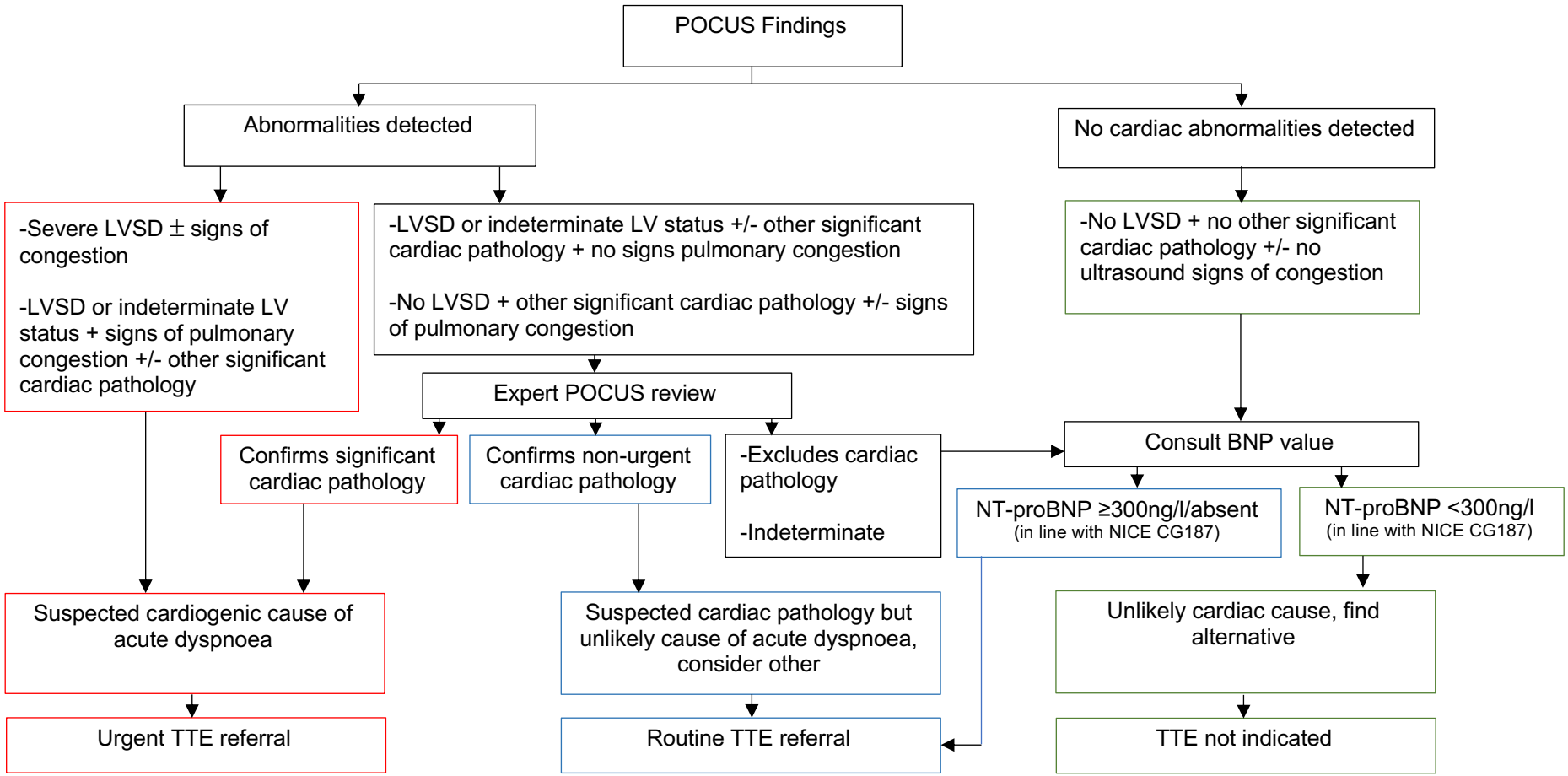
In the setting of acute dyspnoea, improved diagnostic accuracy and knowledge of cardiac status and whether pulmonary congestion is present (and whether it is cardiogenic) at the initial point-of-care, has the potential to improve the effectiveness of immediate clinical decision making by allowing earlier initiation of appropriate first line medication and appropriate referral to specialist services and/or determine whether hospitalisation is needed.

Under the current model of clinical care, TTE referral is indicated in all with suspected HF with an abnormal (or absent) NT-proBNP value. The threshold they use for abnormal is ≥400ng/l. Using this, twenty-six of the thirty-two cases (81%) would be referred for TTE. Given the acute context in which POCUS use is being proposed, presence of LVSD in isolation could be chronic and may not be the cause of the acute dyspnoea. Therefore, knowledge of LV systolic function, congestion, and other significant cardiac pathology combined could be used to guide the need for, and speed, of TTE referral. Based upon a hypothetical model (Figure 5.6), severe LVSD (+/- congestion) and LVSD or uncertain LV status + sign(s) of congestion could facilitate immediate initiation of medication and urgent TTE referral. Conversely in those with non-severe LVSD or indeterminate LV systolic functional status and no signs of congestion, an alternative cause could be considered for the acute dyspnoea with routine referral for TTE to confirm (and grade) LVSD and look for a potential cause. Similarly, in the absence of LVSD on POCUS, but other cardiac abnormalities and/or pulmonary congestion, routine referral for TTE to confirm/exclude pathology and assess for diastolic dysfunction (HFpEF). For the less clear-cut abnormalities, expert review of images could be included to confirm the urgency of the referral (Figure 5.6).

Recognising that the accuracy of POCUS is yet to be proven on a larger scale, the hypothetical model proposes a cautious approach to excluding the need for TTE if the POCUS examination is essentially normal. In the proposed model, if pathology on POCUS is excluded, the NT-proBNP value is then consulted, given the proven high negative predictive values of a normal natriuretic peptide (Ponikowski et al., 2016), and only if that is also normal is the need for TTE excluded.

Figure 5.6

Hypothetical model to guide TTE triaging based upon LV systolic function status, pulmonary congestion, other significant cardiac pathology, and NT-proBNP value



Under the nurses' current model of clinical practice, they use a NT-proBNP value <400ng/l as the threshold for normal. However, current NICE acute HF diagnosis guidance (CG187) recommends the threshold for normal is <300ng/l in the acute setting. In terms of urgency of referrals, under the current model, referrals for suspected HF are received by the hospital and NT-proBNP values are normally reviewed to help determine the urgency of referrals. Based upon NICE guidance, a BNP value >2000ng/l is commonly termed urgent and levels between 400-2000ng/l routine (National Institute for Health and Care Excellence, 2018).

In line with NICE guidance, based upon NT-proBNP results, TTE would have been indicated in twenty-seven cases; seventeen of which would be urgent and ten routine (Table 5.9). Using the proposed hypothetical model (Figure 5.6) to guide TTE referral, TTE would have been indicated in twenty-nine; eleven of which would have been urgent and eighteen routine (Table 5.9).

Table 5.9

TTE referral rates based upon LVSD, signs of pulmonary congestion, and other significant cardiac pathology via POCUS and via NT-proBNP value

	LVSD on POCUS		Signs of Congestion on POCUS		Other significant finding on POCUS		NT-proBNP value	TTE referral via proposed model (R/U/N)	TTE referral via NT-proBNP
	Nurse	Ref	Nurse	Ref	Nurse	Ref			
1	P	A	Nil	Nil	RV	RV	93	R	N
2	P	P	Nil	Nil	Nil	Nil	5851	R	U
3	A	P	Nil	Nil	Nil	RV	479	R	R
4	A	A	P.Ef	Nil	Nil	Nil	368	R	R
5	A	A	PLE	PLE	Nil	Nil	3634	R	U
6	P	P	Nil	Nil	Nil	Nil	1694	R	R
7	P	P	Nil	Nil	RV	RV	8221	R	U
8	A	A	Nil	Nil	Nil	Nil	94	N	N
9	A	A	Nil	Nil	?PFO	Nil	132	N	N
10	A	A	Nil	Nil	Nil	Nil	X	R	R
11	A	A	PLE	PLE	Nil	AS	4650	R	U
12	P	A	Nil	Nil	AS	AS	3075	U	U
13	A	A	Nil	Nil	Nil	Nil	401	R	R
14	A	A	Nil	Nil	Nil	Nil	750	R	R
15	A	A	Nil	Nil	Nil	Nil	2670	R	U
16	A	A	Nil	Nil	Nil	Nil	X	R	R
17	S	S	PLE	PLE	RV, MR, thrombus	RV, MR, thrombus	2686	U	U
18	I	I	Nil	Nil	Nil	Nil	284	N	N
19	P	P	BL+	BL+	MS, MR	MS, MR	17188	U	U
20	S	S	A.IVC, PLE, BL+	A.IVC, PLE, BL+	Nil	Nil	>35000	U	U
21	S	S	Nil	Nil	Nil	Nil	4682	U	U
22	P	P	BL+	BL+	Nil	Nil	2085	U	U
23	P	P	Nil	Nil	Nil	Nil	175	R	N
24	P	P	BL+	BL+	MR	MR	888	U	R
25	A	A	Nil	Nil	Nil	Nil	2219	R	U
26	S	S	PLE	PLE	MR	MR	7437	U	U
27	A	A	Nil	Nil	AS	AS	419	U	R
28	P	P	Nil	Nil	MR	RV, MR	2376	R	U
29	I	I	BL+	BL+	Nil	Nil	2248	U	U
30	A	A	PLE, BL+	PLE, BL+	Nil	Nil	7099	R	U
31	P	P	P.Ef	P.Ef	Nil	Nil	1663	U	R
32	A	A	P.Ef, PLE	PLE	Nil	Nil	3428	R	U

Note P= present; S= severe; A= absent; I= indeterminate; Ref= reference test; P.Ef= pericardial effusion; PLE= pleural effusion; A.IVC = abnormal IVC; U= urgent; R= routine; N= no (not indicated); Y= yes (indicated)

If sonographer analysis findings were applied to the model, decision making regarding TTE referral would have been consistent with the nurse for all but one of the cases (97%). For this case (case 11) sonographer analysis would have triggered an urgent TTE referral (significant aortic stenosis) whereas nurse analysis would have triggered routine referral (PLE but aortic stenosis not confirmed).

Focusing on cases where TTE would incorrectly not be indicated (since these have greatest potential clinical implications due to missed pathology), and using sonographer analysis as the reference test, there would not have been any cases in which TTE was incorrectly not indicated based upon nurse-led POCUS. Based upon NT-proBNP result, two cases would have incorrectly not had TTE indicated. One (case 1) showed RV dilation/dysfunction and the other LVSD. However, both abnormalities were mild cases prompting routine referrals (unlikely causes of acute dyspnoea).

The hypothetical model for TTE referral is intended as a potential guide only. Prospective research, such as a prospective randomised trial, would be required to assess its safety. If adequate POCUS accuracy is proven on a larger scale, a less cautious approach to excluding the need for TTE could be adopted, particularly since there are multiple causes of an elevated NT-proBNP value in the elderly. Such an approach has been proposed in prior studies whereby reductions in TTE referrals have been reported when the POCUS scan is negative (detailed previously in Chapter 3, Theme 7). Based upon the data obtained, if the need for TTE was excluded in those in which LVSD, other cardiac pathology, and pulmonary congestion were excluded on POCUS then eight and nine cases would not require TTE based upon whether nurse or sonographer analysed POCUS respectively (compared to five based upon an NT-proBNP value <300ng/l).

It should be recognised that there are causes (cardiac and non-cardiac) of volume overload without LVSD, such as diastolic dysfunction (HFpEF), kidney failure, pulmonary emboli, and acute respiratory distress syndrome. Therefore, given the abbreviated nature of POCUS, if clinical suspicion of a cardiac cause remains high, TTE should be indicated despite the absence of pathology seen on POCUS.

Resource use and costs

At this stage, estimated costing was limited to execution of the intervention (POCUS) and included equipment capital costs and staff time (UK NHS perspective). Cost accounting was used to determine the cost of POCUS based on unit capital cost, depreciation, and staff time. Estimates are based upon the assumption that depreciation would occur in a linear fashion.

University-based (pathway to portfolio) funding was received for the purchase of two GE Vscan Extends. The direct cost of purchase from GE was £6,289 per device. The capital cost was assumed to spread across a seven-year device lifetime to provide a yearly cost of £898.42. To scale up the intervention costs to a year, the referrals received over the study period (250 in 2.6mths) equates to 1154 requests per year as the acute clinical team service runs 365 days a year. 30% of the referrals received during the study period met the inclusion criteria which would equate to 346 scans/year (30% of 1154). This uses the assumption that all those eligible would undergo a POCUS scan. Study data obtained were based upon the availability of two devices. No maintenance costs were added.

Using these estimates, the estimated equipment cost per POCUS scan was:

-Yearly cost = Vscan cost / device lifetime in years
= 6,289 / 7
= £898.43

-POCUS cost = (yearly cost x no. devices) / no. scans per year
= (898.43 x 2) / 346
= £5.19

Using the Personal Social Services Research Unit (PSSRU) Unit Costs of Health and Social Care 2021 (Jones & Burns, 2021), cost per working hour of a Band 7 community nurse is £66. Based on the data obtained, time for POCUS (scan/ report/upload) was estimated at 20-25 minutes which equates to a staff time cost of £22.00-£27.50 (average approximately £24.75). In addition to the estimated cost of adding nurse-led POCUS, the cost of expert review would need to be considered. In this study every study was reviewed (and analysed)

by a sonographer which took mean five-minutes per scan. Using the PSSRU Costs of Health and Social Care 2021 (Jones & Burns, 2021), cost per working hour for a Band 7 hospital-based health care professional (based on radiographers) is £65 giving an estimated cost of £5.42 for a five-minute sonographer review. Given that images were downloaded to an NHS shared drive, there were no associated costs. There were no significant consumable costs associated with the procedures included in the pathways (current and proposed) therefore these have not been included in the costings.

The identified resources related to the implementation of the intervention and their estimated costs, as seen in this small study, are summarised in Table 5.21.

Table 5.21

Estimated cost of adding a POCUS scan to the current pathway

POCUS Costing Consideration	Estimated Cost
Unit equipment cost per POCUS scan	£5.19
Staff time cost per POCUS scan	£24.75
Staff time cost for expert review per scan	£5.42
Image storage (shared accessible drive)	£0
Total Cost	£35.36

In this study the option of cardiologist input was available if needed for case review discussion but was not required. If hospital-based registrar, or consultant, input was included this would need to be costed and based on a ten-minute case discussion for example, the cost would be £8.67 and £20.50 respectively per scan (Jones & Burns, 2021).

For comparative purposes the cost of the other tests in the pathway were estimated using published costings (Table 5.22). Estimated unit cost for an ECG (93005 - Electrocardiogram, routine ECG (EKG) with at least 12 leads, 12 lead ECG, 12-lead ECG: Tracing only) and NT-proBNP (83880- Natriuretic peptide, brain nucleic peptide (BNP), substance P; NT Pro

BNP) were taken from the National Institute for Health and Care Research interactive costing tool (iCT) tariff data 2023/24, version 1.5 (National Institute for Health and Care Research, 2023). Physical examination cost was estimated based on the assumption of requiring ten-minutes of nurse time using the PSSRU staff time costs (Jones & Burns, 2021).

Table 5.22

Estimated cost of tests in the current pathway

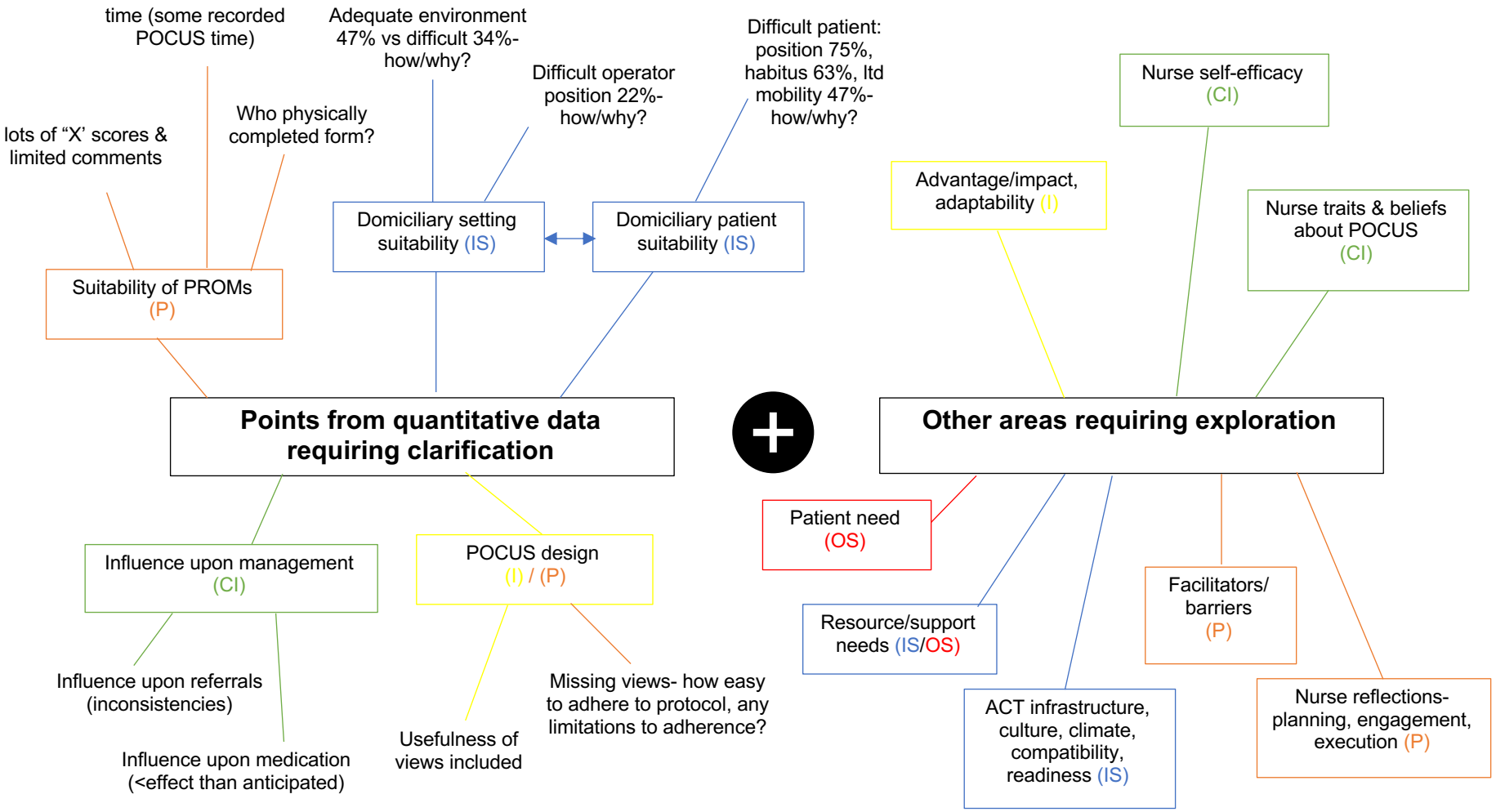
Step/Test in the current pathway	Estimated Cost
Physical examination	£11
Unit cost ECG	£23
NT-pro BNP	£33

Connecting quantitative and qualitative phases

The field notes were reviewed and tabulated based upon topics relevant to the study objectives (recruitment; patient population; setting; the scan; PROM tools; nurse characteristics; the CRF). Reviewing the quantitative data and field notes, areas of uncertainty (absence or requiring greater clarification) were identified. The areas requiring further exploration are outlined in Figure 5.7 (colour coding consistent with Figure 2.2, Pg 33).

Figure 5.7

Areas to address during qualitative data collection



This information was used to construct the focus group discussion guide. The purpose of the discussion guide was not to influence discussions but to help keep discussions on track and ensure necessary topics were covered. Questioning was simple, open-ended, and non-biased. Recognising the need to avoid wording bias and double-barrelled questions, and appreciating the novice status of the moderator, example probing questions were listed on the guide to try and help stimulate further discussion. Table 5.23 provides an overview of the constructed focus group guide.

Table 5.23

Focus group discussion guide

Topic Prompt	Phrases to Probe
-Nurse thoughts on/attitudes to POCUS -Nurse opinions on capability/opportunity/convenience/motivation -Nurse thoughts on patient need & patient suitability -Attitudes/engagement/acceptability- patients, ACT -Feasibility/appropriateness/suitability of POCUS in the community - Setting - Practicalities/logistics (workflow) - POCUS protocol suitability - PROM suitability -Environment- infrastructure, culture, priorities, readiness -Influence upon clinical management (hypothetically) – reference to medication and referral choices as some uncertainty -Resources needed for implementation -Barriers/aids (what helped/hindered) -Reflection- needs, planning, execution, engagement	• Could you elaborate further? • Can you tell me more? • Would you give me an example? • How did …? • Do you have anything to add?

Qualitative data (focus group)

A total of sixty-eight codes were initially noted, twelve of which related to training. The frequency of each assigned code was identified using the 'find' feature on Microsoft Word. The codes were refined and reduced to fifteen. Training featured heavily in the focus group discussion therefore 'training' was subdivided into five sub-themes. The codes were used to form eleven themes which were formulated with the research objectives and CFIR domains in mind. As part of the qualitative data content analysis, code frequency was calculated. Table 5.24 provides the frequency of the individual codes and the frequency within themes.

Table 5.24

Code frequency and corresponding themes and CFIR domains

	Code	Frequency	Reduced Codes	Frequency	Theme	CFIR Domain
1	Consent	3	Recruitment	9	Planning	**Process**
2	Patient support	6				
3	Clinical Aid	5	Advantage	22	Beliefs about Intervention	**Characteristics of individuals**
4	Improved Certainty (confirm/confidence)	7				
5	Additional Info	2				
6	Upskill	2				
7	Quality of Care	3				
8	Broaden Services	3				
9	Diagnosis	4	Clinical Impact	19	Advantage	**Intervention**
10	Decisions	4				
11	Treatment	6				
12	Referrals (includes triage referrals)	3				
13	Triage Referrals	2				
14	Positivity	3	Nurse Feelings	16	Attributes & Self-Efficacy	**Characteristics of individuals**
15	Conscientious	1				
16	Confidence	3				
17	Doubt	5				
18	Pressure	1				
19	Frustration	3				
20	Support	6	Patient Acceptability	7	Culture	**Inner Setting**
21	Engagement	1				
22	Supportive	4	Acute Clinical Team Acceptability	8		
23	Engagement/Interest	3				
24	Encourage	1				
25	Criteria	2	Patient Population	14	Population	**Inner Setting**
26	Disability	2				
27	Transport	2				
28	Patient Position	5				
29	Habitus	3				
30	Location	3	Setting	8	Environment	
31	Space	3				

32	Operator Position	2				
33	Feasible	3	Logistics	9	Compatibility	**Inner Setting**
34	Time	3				
35	Paperwork	3				
36	Views	3	The Scan	11	Design	**Intervention**
37	Image Quality	2				
38	Analysis	4				
39	Machine	2				
40	Adequate	1	Resources	13	Resources	**Inner Setting**
41	Equipment	5				
42	Suitable Patients	1				
43	Expertise/Support	6				
44	Training (includes training; practice/volume; continuity; competency)	17	Facilitators	38	Facilitators/ Barriers	**Process**
45	Support Network (includes expertise/support, mentors)	11				
46	Equipment	4				
47	Drive	3				
48	Engagement	3				
49	Covid Interruptions (critical event- outer setting)	6	Barriers	14		
50	Clinical Pressures (includes clinical demands & staffing)	3				
51	Resources/Funding	1				
52	Management Vision	4				
53	Suitability	2	PROM Suitability	8	Planning	**Process**
54	Confusion	3				
55	Time	1				
56	Completion	2				
57	Practice -Scenarios	6	Training	44	Planning (reflection)	**Process**
58	-Simulator	2				
59	-Volume	6				
60	Theory -Content	5				
61	-Time	1				
62	-Other Views	3				
63	Delivery: -E-learning/interactive	3				
64	-Continuity	5				
65	-Atmosphere	5				
66	Assessment: -Assessments	3				
67	-Competency	3				
68	Feasibility: -Planning	2				

Integration of quantitative and qualitative results

To integrate the quantitative and qualitative data, the "following a thread" technique was used (Moran-Ellis et al., 2006; O'Cathain et al., 2010). Each theme was selected and followed across the other dataset (the thread) to look for convergence, divergence, or expansion (tabulated data available on request). A summary of the main findings, presented under the CFIR domains, are shown in Figure 5.8 and Figure 5.9.

Figure 5.8

Quantitative & qualitative data relating to the inner & outer setting CFIR domains

INNER SETTING

Priority: "should provide traditional hospital-based interventions in home"

Compatibility: mean scan time 15.53±6.1mins. "Doable, fitted in ok," "time depends on where patient is & if need positioning," "quicker than thought."

Environment: 94% at home. 50% scanned in chair & 38% in bed. "More difficult in house than ideal settings," "some houses cluttered with limited space," "tricky positioning yourself & patient, sometimes patients chair bound…sometimes big double bed hard leaning over"

Population: frailty score 5.3 ±1.5. Weight (n=22) 4<50kg & 6≥100kg. PMHx HF 34% & PMHx COPD 31%. LVSD prevalence 44%. "Some can't/won't leave the house due to physical/mental health," "one so thin just ribs, some very obese," "had a pectus & couldn't get parasternal views," "community patients harder-difficult body habitus, often limited mobility," "lots were very upright which made it harder."

Culture: 100% agreement to enrol rate. 88% positive & 0% negative patient attitude to POCUS. "Happy, liked it could be done in the house," "really positive, all thought it was a good idea," Dr X definitely supportive & can see the clinical use," "great team support; welcome change & support & encourage each other," "Team positive, lots want to do it," "presented to professional nursing collaboration- interested & keen to work with Uni."

Resources: 2x GE Vscan. Shared file for image download. 1 sonographer for image review. "had what we needed," "need process for expert oversight-someone to ring/email for remote review and feedback to us," "remote googles would be great so support over shoulder if needed."

OUTER SETTING

Critical Event: COVID-19: "wanted to learn but covid got in the way," "delays due to staff shortages and covid affected confidence."

Referral: Referral network includes GPs, Welsh Ambulance Service, and inpatient & outpatient services from local hospitals. Elderly dyspnoeic patients represent 30% of acute clinical team referrals- approximately 29 eligible patients/month.

External pressures: Government pressures to provide care closer to home & improve out-of- hospital diagnostic testing (Chapter 1). "HF services are expanding so staff should be able to do this at home not just hospital," "hospital at home service so should provide traditional hospital-based interventions in homes."

Figure 5.9

Quantitative & qualitative data relating to the intervention, individual characteristics, and process CFIR domains

INTERVENTION CHARACTERISTICS

Advantage:
Diagnosis- Se & Sp ≥0.9 & k=0.81; correctly identified significant & urgent finding in 94% & 91% respectively. 94% immediate LVSD confirm/exclude. "Confirm a more reliable diagnosis- improve decision making, "added to the working diagnosis, consolidated your thoughts."
Medication- Inconsistencies in quantitative data. "Can start treatments with confidence, otherwise air on side of caution," "we're a clinical team, good to start treatments immediately," "pre-empt treatment plan as go along, don't think POCUS really changed but more confident," "good for those where GP given 4x antibiotics for chest infection & it's HF," "paperwork re medication decisions bit confusing…free text may be easier to explain."
Referrals- Current model TTE referral in 81%. Based on LVSD & congestion, post-nurse led POCUS urgent TTE referral in 28%, routine in 28%, not needed in 44%. POCUS "help triage requests; useful to expedite TTE referrals," "patients shouldn't be going to hospital for tests if not necessary," "about deciding if we need to send a patient to hospital, POCUS can guide & give us confidence."

Adaptability: performed in 100%. LV systolic function assessable in 94%. "Feasible most of the time."

Design: No study had all views. Non-diagnostic PLAX 9%; PSAX 44%; A4C 28%; A2C 66%; A3C 88%; S4C 47%, S.IVC 75%; Ant LUS 0%; PLAPS 9%. High no. 'uncertain' for IVC reporting (72% on reference). "Couldn't get some of the views that had been able to get in practice," "struggled with subcostal, especially as lots upright," "sometimes definitely saw IVC collapse & then clipped bit didn't show it," "A3C easier than A2C, others generally ok and easier," sometimes clear when scanning but less clear when reviewed."

CHARACTERISTICS OF NURSES

Need/Beliefs: "Definitely worthwhile…aids in diagnosis & management decisions," "consolidates thoughts, increasing confidence," "extension of stethoscope- confirms what you're hearing," "opportunity to upskill professionally," "POCUS helps confirm, without it you're in the dark guessing on history & examination."

Motivation/Commitment: 100% nurse completion. "Happy/excited to implement."

Capability/Self-efficacy:
Assessed LVSD in 94% & Se & Sp ≥0.9 & k=0.81. Correctly identified significant & urgent finding in 94% & 91% respectively. "Frustration when couldn't get all views," "worry is it me or is the view unobtainable," "confident scanning volunteers but less with patients, "wanted to get it right all the time," "told relative no results but felt some pressure when asking questions."

PROCESS

Recruitment: 2.6mths to recruit 32. 100% agreement to enrol. "All patients happy to be involved," "no negativity," "some struggled to physically sign 3 forms."

Paperwork: 2x missing BNP (system error). POCUS time missing 16%. BMI missing 78%. "Scope to give more history to explain medication decisions."

Facilitators: "Training & support key," "expert oversight, maybe virtual acquisition support," "POCUS champions to support/mentor," "drive to want to do it," "continuity so more confident," "yearly updates/mandatory training"

Barriers: 3% relative interruptions during scan. "Staff shortages & covid prevented training" "clinical duties can affect availability for training," "funding & resources could be an issue", "management need to see longer-term gains, they can be short sighted."

PROM: 97% completion (1x nurse forgot). Time to complete (n=27) 12.6±9.2min. Dyspnoea score, only full dataset for 35%. Mobility related limitations 70%. "Asked patient questions but completed form for them," "lots couldn't walk that far. Lots not able to do the tasks," "bit long winded for elderly, had to explain a few times."

Discussion

The purpose of this initial feasibility study was to assess whether community nurses could perform limited POCUS in the intended clinical setting (feasibility and acceptability), whether they could do it accurately, and what clinical impact adding POCUS might have. POCUS had not been previously explored in this context, therefore this study sought to improve understanding of the contextual influences that affect outcomes using a mixed-methods approach. For reader clarity, the discussion is divided into sections relating to research objectives based upon combined quantitative and qualitative data. This feasibility study also sought to test methods and help inform future larger scale studies which is addressed at the end of the discussion.

Feasibility and acceptability

Initially the study aimed to gain information regarding the acceptability (nurse-perceived) and feasibility of adding nurse-led POCUS to the current pathway. At this preliminary feasibility stage, study design did not assess acceptability via direct input from patients (or the wider clinical team). This in part was due to the COVID-19 pandemic and wanting to reduce in-person contact in an elderly, frail cohort (justification provided previously Chapter 3, Pg 87 and Pg 90). However, it included opportunity for the nurses to provide their experience of perceived patient and perceived acute clinical team acceptability of POCUS. Reported comments regarding patient attitude/concern towards POCUS were enriched by the qualitative data from the nurses focus group discussion (which included discussion of patient and colleague opinions). This information was collectively used to infer insight into patient and staff opinions. It is acknowledged that in a larger trial it would be preferential to gain direct information from patients and possibly the wider acute clinical team.

All eligible patients seen by a trained nurse were offered enrolment. This was higher than predicted as we had anticipated that it might not always be possible to offer POCUS within the confines of a home visit. Data from the focus group discussion was congruent with the quantitative data; none of the nurses reported insufficient time to offer enrolment. Of those offered, 100% of participants agreed to enrol. While it is difficult to directly compare the

enrolment rates to previous studies due to variation in study design, the agreement to enrol rate in this study appears high. In a study looking at predicting poorer health outcomes in older (>70yrs) community-dwelling patients by comparing accuracy of medication-based and diagnosis-based multimorbidity measures, they assumed a 50% response rate for recruitment and found 61% agreed to participate (Sasseville et al., 2019). While the patient population were similar, the context of research was different preventing direct comparison. In terms of previous POCUS intervention studies, patient agreement to enrol rates have not generally been reported. However, one prospective observational study of the use and impact of POCUS in general practice assumed a participation rate of 80% and of those eligible reported only 13% were excluded due to no informed consent or time constraints (Andersen et al., 2020). However, in that study the population was not limited to the elderly or domiciliary setting.

The high agreement to enrol rate in this study is supported by the nurses' recorded comments on the CRF and focus group discussion. In 84% a positive patient/relative attitude to POCUS was noted in the comments of the CRF. No patient or carer negativity towards study enrolment or having POCUS performed at home were recorded. Difficulties with consent were only noted in 3% of comments. These difficulties were elaborated on in the group discussion, highlighting physical limitations with signing the forms rather than consent issues. While it is difficult to provide conclusive rationale for the high agreement to enrol, outcomes of the focus group revealed widespread patient/carer positivity and support for improving care in the home ("patients really positive- all thought it was a really good idea"). The nurses expressed that patients/relatives liked that the scan could be done in the house. During an observation, a patient expressed support for increasing care in the home due to difficulties getting to hospital appointments and "reliance on family who are busy with their family and work." While in different scanning settings, previous studies have similarly noted patients' preference at having scans done locally (Pertierra-Galindo et al., 2019; Wordsworth & Scott, 2002). Positivity towards POCUS with improved patient satisfaction has been previously reported in other contexts (Andersen et al., 2019; Claret et al., 2016; Howard et al., 2014). The increased interaction time associated with POCUS has been previously discussed as a potential contributor to improved patient satisfaction (Chapter 3) however in this context, this is less likely a contributor given that the nurses already spend a fairly prolonged time period with the patients as part of the home visit. The attitudes and behaviours of the nurses may have contributed to the patient positivity however without

direct patient questioning this cannot be confirmed. The patient population was limited to those with capacity to consent therefore it is possible that individuals with cognitive impairment may have different levels of compliance. The small sample size must also be recognised and with a larger cohort, rates of refusal could be higher.

Nurse opinions of POCUS were similarly very positive. Focus group data revealed that the nurses saw clinical advantage in adding POCUS as it helped consolidate their initial impressions and increased their confidence in their diagnosis and management decisions. 64% of the nurse-perceived intervention "advantage" codes (clinical aid; improved certainty; additional information) related to POCUS being a clinical aid that increased certainty. They also saw POCUS as an opportunity to "upskill and become better equipped professionally" and felt it improved their existing service, aligning with their 'hospital at home' service goals ("we should be providing traditional hospital-based interventions in peoples' homes").

The nurses' perception of the wider acute clinical team's attitude to POCUS was very positive. They expressed that the lead Consultant was very supportive and could see clinical advantage from incorporating POCUS. They noted that colleagues not directly involved in this study had expressed interest in learning POCUS and desire to be involved in any subsequent studies. One nurse reported that there had been great team support and that the team collectively welcome and support change. This acute clinical team are very dynamic; they are frequently expanding and developing their services therefore trialling a new intervention is not unfamiliar to them. It should be recognised that the same may not be the case for other community-based teams as culture and tension for change are recognised influencers and as such are CFIR constructs (Damschroder et al., 2009).

Given that POCUS had not been tested in the proposed setting prior to this study, the feasibility of scanning in this context was unknown. While data revealed several contextual challenges associated with scanning in the domiciliary setting and the proposed patient population, results support that adding POCUS in this context is feasible. POCUS was performed in all thirty-two patients with no studies being completely non-diagnostic.

It is evident from the quantitative and qualitative data that scanning an elderly patient cohort in whom frailty and mobility limitations are high is much more challenging than scanning a general population of healthy volunteers ("more difficult in the house than ideal settings we

practiced"). Over half (53%) of frailty scores were consistent with at least mild frailty and nearly a quarter (22%) consistent with at least severe frailty (score ≥7). Nurse CRF comments noted difficulties with patient positioning in three-quarters of patients, limited mobility in nearly half (47%), issues with patient restlessness/discomfort in a quarter, and excessive breathlessness in around a fifth (19%). The focus group discussion echoed this; nurses reported difficulties positioning patients with limited mobility, particularly chair bound patients that were upright. For those where weight was available (69%), nearly half were at the extreme ends of under- (18% <50kg) or over-weight (27% >100kg). The CRF comments noted difficult body habitus in 63% and during the focus group discussion nurses' expressed difficulties with very thin and obese patients.

Unlike hospital settings, the domiciliary environment is unpredictable. Until the nurse arrives at the patients' place of residence, the space and layout of the environment is unknown. Most scans (94%) were performed in patients' private homes with half being scanned in a chair and 38% in a bed. The environment was noted as being adequate in nearly half of cases (47%) but difficulties with the environment and operator positioning within the environment were noted in 34% and 22% respectively. During the focus group discussions, the nurses revealed difficulties included limited space and clutter, and challenges positioning themselves and the patient, particularly when patients were in a chair or leaning over a large bed. This was evident during an observation where I could visibly see the nurse struggling with apical views in an upright chair-bound patient as the chair arms restricted probe positioning/angling and another where the patient's dog kept getting in the nurses' way whilst scanning.

Despite the patient and environmental challenges described, data supports the feasibility of POCUS in the proposed setting. LV systolic function was assessable via POCUS in 94% by both the nurses and sonographer with both identifying the same two cases as non-diagnostic for LV systolic function assessment. This is higher than that reported in a study assessing POCUS by medical students, where cardiovascular (heart, lungs and IVC) images were deemed acceptable in 74% (95% CI 63.1-82.6) (Andersen et al., 2014). The shortened training (nine-hours) may have contributed to their lower rate. Multiple other studies, although with different scanning protocols and different trainees and training, have shown rates of obtainment of diagnostic studies to be around 90% (range 87-94%) (Brennan et al.,

2007; Croft et al., 2006; Mjolstad, Snare, et al., 2012; Panoulas et al., 2013) which is in keeping with our results.

In terms of the compatibility of POCUS within the current assessment process, the nurses felt that adding POCUS was "doable" and highlighted that the scan took less time than they anticipated. In the comments section of the CRF, nobody noted 'limited operator time.' The average scan time (machine-derived) was 15.53 ± 6.1mins and average logged POCUS time was 20.19 ±7.5mins. Therefore, it would appear reasonable to assume that the addition of POCUS should require no more than an additional thirty-minutes. However, during the discussion it was mentioned by the nurses that the scanning time was variable depending on where the patient was and whether they needed to be moved for the scan. Re-visiting the quantitative data, the scan time range was broad (8-29mins, mode 10mins) but with most (81%) taking no more than twenty-minutes and 59% taking up to fifteen-minutes. This suggests that in most cases it took no more than fifteen to twenty-minutes to perform the scan.

Not all prior POCUS studies have provided scan times and, for those that have, there are marked variations in scanning protocols and user experience which have resulted in highly heterogenous times. For two prior nurse studies, they reported a median scan time of nine minutes (Gustafsson et al., 2015) and thirteen minutes (range 7-19mins) (Graven et al., 2015) however they included assessment of fluid status only. In a study utilising cardiac and lung ultrasound (LuCUS protocol) scanning time was reported at 12±4mins (Russell et al., 2015). While not the same protocol and not a novice-user study (experienced emergency physician), the scan time for our nurses appears in keeping with this. This suggests that our logistical planning and estimated costings are appropriate and do not requiring modifying.

As the POCUS scanning and reporting protocol was designed for this research project based upon the clinical questions, it had not been tested in a clinical setting prior to this study. Therefore, suitability and adherence were assessed. The intention being to trial its suitability and refine (if necessary) prior to larger scale subsequent studies. All views were obtained at some point across the thirty-two cases, but no single case contained every view. Scanning adherence was not formally assessed at this stage but during the focus group discussion, the nurses noted that they were confident with the POCUS views but expressed protocol adherence was limited by the inability to obtain certain views in certain patients. They

described difficulties in obtaining views that they had been able to get during training and in the comments section 'a relatively easy scan' was noted on the CRF in only 16% of case.

Lung views were more frequently obtained than cardiac views with obtainment of anterior lung views in every case and PLAPS views in most (91%). This was mirrored by nurse discussions during which they stated finding "the LUS views ok and clinically useful." This was expected given the widespread reporting of ease of obtainment and reproducibility of LUS (Lichtenstein et al., 2004.; Lichtenstein & Meziere, 1998; Platz & Solomon, 2012). In a study assessing the feasibility of hand-held ultrasound by medical students, Andersen et al. (2014) reported that students performed best when acquiring images of the lungs (and renal system) (>93% (95% CI: 84.3-98.2) and found it most difficult to acquire acceptable images of the heart (71.2% (95% CI: 58.7-81.5) and free fluid (73.2% (95% CI: 41.4-92.7).

Given the study context, inclusion of LUS (in addition to cardiac ultrasound) is clinically useful. Including LUS allows detection of ultrasound signs of pulmonary congestion. In an elderly cohort in whom the prevalence of existing HF and COPD was reported at 34% and 31% respectively, using a combined technique can help the nurses differentiate HF from COPD exacerbations, and HF from pneumonia. When signs of pulmonary congestion are detected on LUS, the combined approach helps determine whether the cause is cardiogenic or non-cardiogenic. In our study, pleural effusion and B-line positivity were both found in approximately one fifth of patients (22% and 19% respectively). There were eleven cases in which a pleural effusion and/or B-line positivity was seen, of which LVSD was present in six; a different cardiac abnormality was seen in the absence of LVSD in one case; no cardiac abnormality seen in three cases; and uncertain LV status in one case. In the setting of acute dyspnoea, knowledge of cardiac status in the setting of pulmonary congestion is clinically important as patient management differs depending on whether the congestion is cardiac or non-cardiac in origin. Presence of LVSD may be chronic, therefore LVSD on POCUS in isolation may not be the cause of the acute dyspnoea but by incorporating LUS presence of pulmonary congestion can be assessed. The use of LUS in the evaluation of suspected HF to assess for pulmonary congestion is already recognised by several imaging societies (Lancellotti et al., 2015; Mebazaa et al., 2015; Sicari et al., 2011).

For the cardiac views, the PLAX and A4C views were obtained (sonographer determined) most of the time (91% and 72%), and the PSAX and S4C obtained in just over half (56% and 53% respectively). The apical three chamber (A3C), apical two chamber (A2C) and S.IVC were less frequently obtained (12%, 25% and 34% respectively). Sonographer review notes similarly noted that the A2C and A3C were frequently suboptimal or absent. The nurses noted greater difficulty obtaining apical views. Similarly, the field observation noted difficulty with apical alignment in a chair bound patient. Since half of patients were scanned in a chair, this may have contributed to the reduced obtainment rates for the A2C and A3C views. The focus discussion revealed a potential cause for the lower rates of S.IVC view obtainment, noting difficulty with subcostal views when patients were very upright. This is to be expected as the optimal positioning for subcostal views is supine.

Most POCUS studies do not report obtainment of specific views. However, in a study of hand-carried ultrasound by medical residents, they similarly reported the PLAX view was obtainable in most patients (96%) and that the A2C was most difficult to obtain (obtainable in 68%) (Croft et al., 2006). Their protocol did not include A3C or subcostal views. The study was conducted in a younger cohort (55yrs±14yrs) in a medical clinic which implies the patients are likely to be more clinically stable and mobile, and therefore easier to scan, than those included in this study.

In the focus group, the nurses noted that they did not realise how common it was to not get all views and one mentioned that they found it reassuring when, during a case review, I reiterated that not all views are always obtainable. While I felt this had been repeated numerous times during training, it should be recognised that they had not personally experienced cases where multiple views were unobtainable in training. Therefore, for future studies it is important to reiterate that scanning in clinical practice is often more challenging, and while they should attempt to follow the protocol where possible, if a view is unobtainable within a couple of minutes they should move on to the next. This point was further echoed during the focus group where the nurses collectively suggested that future training should include hands-on scanning practice with real patients and different clinical scenarios to increase confidence and competence. There was a notable reduction in image quality during the study compared with images obtained in training, particularly for the apical views. Therefore, training that includes clinical scenarios may help improve image quality and/or

mean that the nurses are better informed in terms of their expectations of scanning in clinical practice. This may reduce the feelings of frustration and doubt that were reported during the focus group, "worry is it just me or is the view unobtainable."

The literature is fairly conclusive in terms of using visual assessment methods (detailed in Chapter 3) but there is some variability in terms of the use of binary or categorical reporting options. For LV systolic function, broad categorisations were selected for our study due to the added clinical utility of knowing whether LV systolic function is severely reduced. Using the broad categories (grossly normal/abnormal/severely abnormal), the nurses correctly categorised the LV systolic function in 91%, with one false negative (which was mildly reduced) and two false positives. Other prior studies in which good/mild/moderate/severe type grading have been used have obtained lower accuracy rates (Evangelista et al., 2016; Panoulas et al., 2013) compared with studies using broader categorisations (Croft et al., 2006). While our findings support the use of the broad categorisations, it must be recognised that for trainees who have undergone less extensive training, with less exposure to various LV status case reviews, gradings may be less accurate. If binary options were to be used, I would propose use of a high threshold for abnormal (at least moderate) because in the acute setting it is important to identify significant (not mild) pathology.

Diagnostic accuracy and reproducibility

Despite reported challenges of scanning in the proposed context, the nurses were able to accurately (sensitivity and specificity ≥0.9) and reliably (K=0.81) detect LVSD via POCUS in patients with new/worsening dyspnoea and suspected HF in the community. The nurses accurately (91%) categorised LV systolic function into broad categorisations of normal, abnormal, severe, and correctly identified the two cases where LV systolic function could not be assessed from the images acquired. This suggests development of adequate analytical knowledge and supports their ability to use broad categorisations to grade LV systolic function.

This adds to the growing pool of evidence showing that ultrasound novices can be taught to accurately use POCUS. It is difficult to directly compare the nurses' LV assessment results to previous studies given the variation in clinical context. Numerous prior POCUS studies

have shown proven nurse accuracy at assessing volume status (Dalen et al., 2015; Gustafsson et al., 2015) or emergency ultrasound (Henderson et al., 2010) but fewer focus on LVSD detection and none have assessed community nurse-led POCUS in the domiciliary setting.

A small (n=63), early study of nurse-led ultrasound to screen for LVSD in an outpatient diabetic clinic reported high sensitivity and specificity (1.0 and 0.83 respectively) (Kirkpatrick et al., 2005), in keeping with our results. While sensitivity was slightly higher in this study, LVSD prevalence was low (4.7%) and while all three cases of LVSD were detected, ten false positives were reported. With a less comprehensive scanning protocol (LV systolic function assessment from PLAX and PSAX views), binary reporting options, and a higher pathology threshold (EF>40%), one would expect higher accuracy measures than those obtained in our study. However, the shortened training may account for the differences with training limited to four-hours acquisition practice (plus a CD with fifty sample cases demonstrating various LV functional status') and performance of twenty-five supervised exams compared to the five-day course and extended practice period used in our study.

Less comprehensive training, in addition to less broad LV categorical assessment options (mild/moderate/severe), may have accounted for the lower LVSD accuracy measures reported in a large (n=1312) primary care-based study assessing the usefulness of POCUS by GPs in patients with suspected cardiovascular disease (Evangelista et al., 2016). While the views and parameters to assess were similar to our study (but included the aorta and excluded LUS), GP sensitivity, specificity, and kappa value for detecting LVSD (4% prevalence) were all lower at 0.5, 0.93, 0.51 respectively.

Recognising the other pathologies included in the POCUS assessment (a secondary objective), the nurses were able to correctly identify whether a significant abnormality (not limited to LVSD) was present/absent in most (94%) cases and whether an urgent review was required (severe LVSD; echo signs of congestion; significant RV dilation +/- dysfunction; significant aortic or mitral stenosis; moderate+ aortic or mitral regurgitation) in 91%. This suggests that the nurses can identify significant pathology and recognise (based on the protocol) when an urgent review is needed. This is important if POCUS is to be implemented without routine expert review of all POCUS cases.

In terms of specific pathology, the small sample size and subsequent low pathology prevalence prohibited use of accuracy measures. Instead, the nurses' ability to detect the presence of significant pathology was assessed. The nurses detected the case with an abnormal IVC, and all cases of pericardial effusion, pleural effusion and B-line positivity (congestion) with two cases of over-reporting pericardial effusions (false positives) where fluid was present but less than the predefined threshold. This suggests that the nurses can accurately identify signs of congestion on ultrasound. This is in keeping with the existing literature which supports that nurses can learn to accurately detect ultrasound signs of congestion. In the context of HF, two nurse-based studies, although with differing scanning and reporting protocols, showed high nurse accuracy for detecting pulmonary congestion and pleural effusions (sensitivities and specificities ≥0.8) (Dalen et al., 2015; Gustafsson et al., 2015). Existing data regarding IVC assessment accuracy is more variable with differing methods of assessment (size/collapsibility/both) and users, and sensitivities and specificities varying between 0.51-0.98 (Anderson et al., 2013; Brennan et al., 2007; Dalen et al., 2015; Gustafsson et al., 2015; Lucas et al., 2009). In our study, nurse assessments of the IVC were consistent with the sonographer in every case but the high number (twenty-three) of 'uncertains' on reference test made it difficult to assess accuracy given that on reference test an abnormal IVC could only be confirmed in one case and excluded in eight cases.

For the additional pathologies, missed pathology has greater (potential) clinical significance than over-reporting given that TTE may not be indicated, and pathology left undiagnosed. Therefore, assessment focused on the nurses' ability to detect pathology. The nurses' identified most cases (81%) of significant additional pathology (RV dilation+/- dysfunction and valvular stenosis/regurgitation). The one case with significant mitral stenosis and two-of-three cases of aortic stenosis were detected by the nurses. One case of aortic stenosis was missed but the case was reported abnormal given that a pleural effusion was detected. All cases of significant mitral and aortic regurgitation were detected with one case of aortic regurgitation under-reporting (mild jet missed) and four cases of mitral regurgitation over-reporting. This is in keeping with existing data which has recognised the tendency to over-report regurgitation using hand-held devices (Kono et al., 2011; Williams et al., 2019). This preliminary data suggests that nurses can accurately identify significant valvular pathology. While the existing POCUS data regarding inclusion of valve assessments is more variable, the EACVI position statement recognises the utility of hand-held ultrasound in screening for valvular heart disease in out-of-hospital settings (Neskovic et al., 2018) and study data adds

to the growing pool of evidence that supports gross valvular assessments via POCUS by novices (Croft et al., 2006; Lucas et al., 2009; López-Palmero et al., 2015; Panoulas et al., 2013). However, further investigation in a larger population is needed to comprehensively assess accuracy of nurse assessments.

RV dilation +/- dysfunction was identified in three-of-five cases. Of the two missed cases, one was in the setting of LVSD which was detected and the other was a case of RV dilation (normal RV function). Given the low number of confirmed cases it is difficult to accurately assess the nurses' ability to assess RV dilation +/- dysfunction. Nurse detection was lower for LVH and LA dilation with two and nine missed cases (false negatives) respectively. The absence of measurements in the protocol and limited exposure may have added to this. These missed cases are less clinically significant because in isolation they are unlikely to be the cause of the patients' acute dyspnoea and are often associated with other abnormalities in an elderly cohort. The variability in the reporting of these additional parameters is consistent with the existing literature where expert and novice accuracies (sensitivity and specificity) have been reported between 0.68-0.9 (Andersen et al., 2011; Frederiksen et al., 2013; Lucas et al., 2009; Mjolstad, Dalen, et al., 2012). There is also heterogenicity in thresholds for abnormal in the existing literature. It would appear reasonable that, if included in the assessment, higher thresholds are used given that more significant pathology is easier to detect and milder cases in isolation have little clinical significance in the acute setting.

Model of implementation

Given the heterogenicity amongst the literature in terms of whether expert input is required to support novice delivered POCUS, study design allowed assessment of whether remote specialist interpretation (reference test) offered a significantly better model than fully nurse-led (acquisition and interpretation) POCUS. Results showed nurse led POCUS to be accurate and reliable in detecting LVSD and pulmonary congestion. Data suggests routine sonographer-analysis adds little benefit in terms of diagnosis. There was at least substantial agreement between the nurses and sonographer in terms of whether a significant abnormality was present and whether an urgent review was required which further supports the notion that nurses can reliably identify and act upon the presence of significant pathology in terms of obtaining urgent reviews. Nurse referral rates for TTE were in keeping with the sonographer

in most cases (detailed further in 'potential clinical impact' section). Given that remote review is often associated with some form of delay (unless immediate) and that nurse assessments were accurate and reliable, preliminary findings suggest that routine expert-analysis is unnecessary and that a nurse-led model is adequate. Less favourable results were previously described in a GP study by Evangelista et al. (2016). However, the GPs received less comprehensive POCUS training which further highlights the importance of training and demonstrating competence prior to implementation to maximise effectiveness of implementation. Preliminary data revealed that nurse-led POCUS allowed improved diagnosis and therefore could potentially improve decision making in terms of the need and speed of TTE referrals at the initial point of care without potential routine external input from a qualified expert and a time-related delay in remote review.

While preliminary data suggests that sonographer analysis of nurse-acquired images adds little clinical value over nurse-analysis of nurse acquired images in terms of diagnostic accuracy and referral rates for TTE, the small sample size must be considered. In addition, study methodology precludes assessment of the potential clinical impact of sonographer guided nurse-acquired images or fully sonographer led POCUS.

Potential clinical impact

There is an abundance of data supporting the added diagnostic value of POCUS over physical examination alone. In different contexts, POCUS has been shown to enable and influence diagnoses (Andersen et al., 2015; Cardim et al., 2011; Mjolstad, Dalen, et al., 2012) which is mirrored by our results.

POCUS supported the nurses in providing a more accurate diagnosis of LVSD in a shorter timeframe than physical examination and NT-proBNP testing alone. Quantitative data showed that POCUS allowed immediate confirmation or exclusion of LVSD in 94% compared to uncertainty persisting in 81% after 24hrs under the current pathway. A study of hospitalists similarly found that POCUS significantly reduced time to decision (0 versus 2days, $p<0.001$) however this was in an inpatient setting (Lucas et al., 2011). Despite the differing study context, it similarly supports the immediate provision of diagnostic

information by POCUS. Focus group data suggested that the nurses' perceived the biggest clinical impact of POCUS to be upon diagnosis. All expressed that POCUS helped in their working diagnosis and "helped consolidate your thoughts," and 'diagnosis' and 'decisions' made up 42% of the clinical impact codes. They described that POCUS increased their diagnostic confidence; "after the examination you have differential diagnoses in your head, POCUS can confirm a more reliable diagnosis."

In the acute setting, whether (and how) POCUS findings impact upon the effectiveness of immediate clinical decision making at the initial point-of-care is clinically important. It is widely accepted that earlier diagnosis is linked to better patient outcomes by enabling earlier initiation of appropriate treatments. The expectation had been that if diagnostic accuracy improved at the initial point of care this would support more effective immediate clinical management decisions in terms of first line treatments and specialist referrals. For example, if new significant LVSD and congestion were detected we had anticipated that this would trigger (hypothetically) initiation of first-line HF medication and fluid offloading. Conversely if, for example, cardiac abnormalities had been excluded and pulmonary congestion seen, we had foreseen that this may prompt a non-cardiac referral in the first instance. However, quantitative data from the CRF were highly variable and there were no obvious trends. This is likely to be influenced by the complexity of decisions for initiating new medicines in an elderly cohort where pre-existing comorbidities exist. Results of the focus group revealed that the nurses experienced some difficulties/uncertainty with the paperwork regarding medication decisions before and after POCUS. They stated confusion when patients were already on HF medication or if decisions were impacted by other comorbidities, such as acute kidney injury. They explained that they felt their plan may not seem clear due to other factors and that a free text option may facilitate explanation of their decisions.

Due to the inconsistencies in the quantitative data, nurses were questioned about decision making during the focus group. One nurse expressed that the history and examination drove most medication decisions and that while POCUS did not really change her plan, it gave her more confidence in her decisions. Conversely others expressed that POCUS has potential impact upon medication decisions describing that it "allows you to start treatments with confidence, otherwise you may air on side of caution with treatment plan" and "good for those where GP given four lots of antibiotics for chest infection when it's actually HF." To

allow more definitive assessments of the impact of POCUS findings upon medication decision making, future research would need to capture relevant information better. Use of a decision-making algorithm may increase consistency and allow meaningful inferences to be drawn from the data.

Numerous studies have noted reductions in TTE referral rates based upon the exclusion of specified pathology on POCUS. In different contexts, reported reductions in TTE referrals range between 28-32% (Cardim et al., 2011; Di Bello et al., 2015; Evangelista et al., 2016; Greaves et al., 2005; Trambaiolo et al., 2007). Based upon the presence/absence of LVSD only, our data are consistent with these findings. Adding nurse led POCUS, allowed LVSD to be excluded in fifteen cases (47%) meaning referral for TTE would have been (hypothetically) reduced to seventeen (53%) compared to twenty-three cases (72%) under the current model (based upon NT-proBNP value).

However, unlike other studies, the context of POCUS use in this research is an acute clinical team with elderly acutely dyspnoeic patients in the community. The focus is on immediate clinical management decisions and deciphering whether LVSD is the cause, and if so, initiating appropriate medications, or whether an alternative cause should be sought. Presence of LVSD in isolation may not be the cause of acute dyspnoea, particularly in an elderly cohort where HF presence is higher, and dysfunction may be chronic. Therefore, we considered the presence of LVSD and pulmonary congestion to allow cardiogenic congestion to be differentiated from non-cardiogenic congestion which has the potential to help guide the need for and urgency of TTE referral. Based upon the cautious hypothetical model previously outlined (Figure 5.6), while overall referral numbers for TTE under the current and proposed models were similar, POCUS driven decision making resulted in more routine referrals (eighteen versus ten) and fewer urgent referrals (eleven versus eighteen). It should be recognised that the hypothetical model was based upon confirmed pathology on POCUS and does not refer to decision making in terms of 'uncertain' pathology, except for LVSD where TTE is indicated if uncertain.

Focus group discussions supported the quantitative data. The nurses discussed the advantage of POCUS helping to triage requests expressing that POCUS findings could help them "decide which requests should be expedited" and allowing them to "give the echocardiography team more information." They reiterated the importance of not sending

patients to hospital for appointments unnecessarily. This is important for hospital echocardiography services which are already struggling to meet increasing demand. Relying on clinical examination and/or NT-proBNP value alone to triage echocardiography timing in an elderly cohort with multiple comorbidities lacks specificity.

In terms of the referral rates to specialists and for additional diagnostic testing (aside from TTE), there was marked variation in the nurses' documented practice. Much like the medication decisions, this made it challenging to draw any definitive conclusions based upon POCUS findings alone. There are numerous factors that could have influenced this, including pre-existing comorbidities, however the CRF failed to capture sufficient data to enable deductions to be made. I would, again, propose the use of decision-making algorithm to provide consistencies and support generation of useful data.

By improving diagnostic accuracy at the initial point-of-care, nurse-led POCUS has the potential to improve the effectiveness and efficiency of immediate nurse management; helping them decide if LVSD is the likely cause of the acute dyspnoea and whether they should initiate appropriate medication and refer for TTE urgently, or whether they should consider an alternative cause for the acute dyspnoea and instead refer for TTE non-urgently and/or other specialists depending on findings. However, this requires testing in a larger cohort that comprehensively captures sufficient data to allow deductions to be made regarding the influence of POCUS on immediate clinical decision making.

Resource use and cost

The resources available included two hand-held ultrasound devices, a shared drive for image download, and expert review availability. According to the nurses they "had what they needed" in terms of resources. One nurse suggested it would be useful to have a machine each moving forward to increase capacity. However, the data obtained did not support this as all eligible patients seen by a POCUS-trained nurse were offered enrolment. However, it may be worth considering that during the data collection period the acute clinical team were working at a staffing deficit therefore, if at full capacity more than two of the nurses were on shift at the same time, it may be that not all potential participants could be offered enrolment without additional machines.

In addition to the BSE accredited cardiac physiologist (contactable for urgent reviews and to conduct all sonographer-analyses), an additional BSE accredited healthcare scientist and Consultant Cardiologist were available for advice/urgent review if needed. They were not called upon during the study period. This suggest that for future studies additional support may not be necessary. However, in a larger sample size with a higher volume of scans and longer study period more than one reviewer may be required.

At initial study design, the hope had been to have an operational cloud-based server that all POCUS studies could be uploaded to for remote review. Unfortunately, this was not available meaning all POCUS studies were uploaded to a folder on a shared NHS drive. As this was not accessible to the reviewing sonographer, an in-person site visit and analysis of the studies directly from the machine was required. A positive to this approach was that nurse and sonographer analyses were performed in the same format which ensures no alteration in image quality. However, outside of a research setting, it is not feasible (or cost-effective) to have an expert travel to site due to time constraints, limited availability, and additional costs (financial and environmental). While I had flexibility to coordinate reviews around the nurses' work schedules, it should be recognised that in clinical practice expert review on the machine restricts machine availability for scanning, which in other settings could impact recruitment time and lengthen time to expert review.

Given increasing clinical pressures and limited expert availability, I would propose the need for remote expertise for future studies. The need for remote support was echoed by the nurses in the group discussions. They reiterated the importance of external expertise and having access to remote review and feedback when needed if POCUS was to be implemented. When discussing potential facilitators, they emphasised the importance of support and proposed that, particularly in the early stages of learning, "remote goggles" could be useful to provide real-time support whilst scanning during challenging cases. However, a comparative study would be required to comprehensively evaluate the benefit of adding remote acquisition support.

Costing in this preliminary research was limited to describing resource use and potential implementation costs associated with adding POCUS to the existing pathway. Considering the cost of the hand-held ultrasound device, device depreciation, staff time, and estimated 346 scans/year, the cost per POCUS scan was estimated to be £29.94 (unit cost £5.19 and

staff time £24.75). In this study images were downloaded to an NHS shared drive which had no associated costs. When considering implementation, the need for a cloud-based server or shared drive that is accessible to those providing expert oversight must be considered which, depending on choice/context, may have associated costs. Cost of staff time was based upon POCUS taking 22.5minutes however with increased confidence and competence scan time may reduce and, with it, staff costs. In this study every case was reviewed (and analysed) by a sonographer. Based on the mean scan time of five-minutes, cost of a sonographer review (Band 7) was estimated at £5.42. However, given the high accuracy and reproducibility of LVSD assessments by nurses, routine review of all cases may not be necessary and instead could be limited to cases with abnormal findings or severe pathology (red flag prevalence in this study 37%). However larger scale research would be needed to test this and inform the review process.

POCUS training has not been costed because the multiple interruptions in training delivery caused by COVID-19 meant that training durations were difficult to predict. Therefore, when considering the costs of future studies, it is important to recognise the costs associated with training novices in POCUS in terms of resources, staff trainer time (planning and delivery) and trainee time to attend training (fixed costs of implementation).

At this stage the objective was to describe the cost of adding nurse-led POCUS to the existing pathway to help inform a subsequent clinical trial. While a comprehensive evaluation of cost-effectiveness is outside the scope of this initial feasibility work, the potential for additional cost savings should be considered.

In the context of LVSD, the data obtained suggests little benefit from routine NT-proBNP testing when POCUS is added to the initial assessment. If BNP testing was limited to cases where POCUS is indeterminate (n=2), this would have reduced total BNP cost from £672 to £42. However, LVSD is not the only cause of a raised BNP and the use of BNP testing in the setting of POCUS use requires further exploration. There is the potential for reductions in TTE costs if TTE referrals are reduced. Based on the data obtained in this study and using the hypothetical model proposed previously, TTE was not indicated in eleven cases following nurse-led POCUS compared with six cases under the current model. Based upon the National Schedule of NHS Costs 2020-21 (under the Healthcare Resource Groups) the unit cost for TTE (Simple Echo, 19yrs+, RD51A) is £149 (NHS England, 2022), this would

(potentially) equate to a £745 lower spend on TTE. Given the age and frailty of the population, many rely on hospital transport to attend hospital appointments which has additional healthcare costs. However, to assess cost-effectiveness, the impact of not referring for TTE needs to be considered. The current literature lacks research into the possible long term downstream effects of not referring for TTE. Therefore, further research is needed where cost-effectiveness is comprehensively evaluated. Future cost-evaluations should consider potential benefits of an earlier diagnosis, potential earlier initiation of appropriate medication, and subsequent (potential) reductions in unscheduled hospital admissions which could provide cost savings but must also assess the potential for missed pathology.

Suitability of the PROM tools

At this initial feasibility stage, the rationale for including PROM tools was to gain insight into their potential suitability in the proposed clinical context to help guide subsequent research in which cost-effectiveness evaluation would be included. The intention was not to assess PROM scores since the PROM data itself has little clinical value when used on a single occasion due to individual variability (subjectivity) in terms of scoring. They have greater clinical value when comparing a persons' scores over time (such as before and after an intervention).

The PROM response rate was high (97%). PROM data was missing for one case which was the result of the nurse forgetting (not patient refusal). It was unclear from the quantitative data whether the nurse or the patient had completed the form however focus group discussion revealed that, given the increased age and high incidence of reduced mobility, all four nurses found it more feasible to read the questions/statements out to the patient and then record the patients' responses. The time taken to complete the PROM questionnaires was recorded in 84% and mean time to complete was 12.6±9.2 (mode 5, median 10).

Data suggests that the specific PROM tool used (PROMIS Dyspnoea Functional Limitations-Short Form 10a) is inappropriate for this elderly cohort with limited mobility whose daily activities are restricted by multiple comorbidities. Collectively 48% of scores were 'Xs' which indicates 'not done in the last seven days' and for 26% of the patients they gave "X'

scores for all ten questions. Results of the focus group discussion supported this with nurses stating that they found the form a "bit long-winded for some of the more elderly patients" and expressed that while the patients were happy to complete the forms, many were unable to perform the specified tasks. In an elderly population, with increased frailty and high prevalence of comorbidities it would be difficult to assess whether scores reflect solely dyspnoea/suspected HF, or whether they are influenced by other existing comorbidities/limitations.

The generic PROM tool appeared more suitable, with patients being able to provide scores for all five sections. One nurse noted that a few patients were confused with which way round to score their health score on the scale but "with additional explanation they got it." For subsequent studies, use of this generic PROM tool may be useful to provide a simple generic measure of health for clinical and economic appraisal. In the proposed clinical context, it could, for example, be used to compare patient's scores pre- and post-initiation of HF medications in newly diagnosed LVSD. However, given the high burden of other comorbidities it is unclear what the potential impact upon scores may be.

Potential facilitators and barriers

If an intervention is to be implemented successfully, it is important to consider how successful implementation can be supported and what could potentially hinder or prevent successful implementation.

It was clear from the focus group discussion that the nurses' perceived training and support as the most pertinent contributors to implementation success. When discussing potential facilitators, 74% of the facilitator codes related to training and an adequate support network. The nurses emphasised the importance of regular practice and continuity of training to maintain knowledge and competence. They proposed yearly updates or mandatory training modules, to ensure competence and to "prevent bad habits" developing. The importance of maintaining competency is well-reported in the literature and is included in imaging society recommendations (Labovitz et al., 2010; Pelliccia et al., 2012; Spencer et al., 2013). The nurses suggested the appointment of POCUS champions or mentors to promote and support POCUS uptake and implementation. The importance of engagement and use of leaders and

champions is recognised in the 'process' domain of the CFIR framework as support is a recognised contributor to implementation success.

Discussion revealed that the nurses felt remote real-time support, such as virtual googles, would be useful in the early stages of implementation to provide opportunity for support during image acquisition. This could be considered for future research projects but given the high feasibility and accuracy of assessments without these in this study, cost-benefit analysis should be considered.

The nurses identified internal attitude and drive as a potential facilitator to implementation. The nurses said it was important that people "want to make a difference and improve their practice" and noted "people have to have the drive and want to do it." They highlighted the need to be open to change and accepting a new normal; "years ago, stethoscope was new, now that's a standard assessment tool.' As an observer, the nurses were very engaged and motivated throughout the process and expressed they would be "happy to implement POCUS." The CFIR recognises the importance of personal attributes upon implementation success. The nursing team (collectively) are well adapted to change "this team welcome change and everyone supports and encourages each other." The influence of behaviour upon outcomes is well reported and while this team are very engaging and receptive to change it may not be the same in other contexts and theory, such as the Social Cognitive Theory (Bandura, 1986) or Theory of planned behaviour (Ajzen, 1991), may need consideration to encourage behavioural change.

Barriers to implementation can be at patient, provider, or organisational level (Damschroder et al., 2009). The potential barriers identified by the nurses' included provider and organisational factors. The principal nurse-perceived barrier to implementation was COVID-19. COVID-19 not only prevented training due to government lockdown restrictions, but also impacted upon the nurses' clinical workload due to their involvement with initial screening and then subsequent field hospital set-up, as well as staffing levels due to direct infection and isolation restrictions. The focus group discussion regarding potential barriers was dominated by the impacts of COVID-19: "staff shortages and COVID-19 delays affected confidence" and "the increased clinical demands at the time made it difficult to fit in training." Under the CFIR framework this would be identified as a critical event and while COVID-19 was an unprecedented period, the possibility of other unanticipated events should

be recognised. While COVID-19 was the main limiting factor identified by the nurses, it was the interruption in training that caused the negative impact. This was emphasised by the nurses who identified continuity of training as a facilitator to gaining confidence and competence.

When considering wider implementation, additional potential limiting factors identified by the nurses included a lack of funding and resources, and lack of management vision. They discussed that management can be "short-sighted and fail to see the longer-term gains" and "management don't understand the whole hospital at home service." This emphasises the importance of stakeholder engagement from the offset, as recognised in the MRC guidance (Skivington et al., 2021a), if implementation is to be successful.

While not identified by the nurses as a barrier, the focus group data revealed some feelings of doubt amongst the nurses; "because I'm a non-expert, I sometimes felt frustrated because I couldn't get the views," "worry is it just you, or is the view unobtainable," and "because new to it, bit unsure and wanted to get it right all the time." Self-efficacy is a recognised construct of the CFIR. While collectively this did not affect the nurses support of POCUS implementation, it may have influenced engagement. One nurse (nurse 3) was visibly less confident throughout the process and performed less scans (16%) compared with the others and the outwardly most engaged nurse (nurse 2) performed the most (38%). While this difference may be the result of work pressures or simply down to what patients they saw, self-efficacy should not be ignored, and it is important that users feel confident and competent if clinical utility of the intervention is to be maximised.

While there is an absence of data in the domiciliary setting, in different contexts similar barriers have been reported. From the available data, insufficient (and non-standardised) training has been widely identified as a potential barrier to implementation (Bhagra et al., 2016; Jaques et al., 2017; Smallwood et al., 2015). Consistent with our study, the importance of expert support was highlighted in a small study of eight intensive care nurses which revealed that trainer availability (and enthusiasm) ranked first among barriers (and facilitators) to implementing nurse-performed POCUS (Tulleken et al., 2019). Similarly, in hospital and GP settings a lack of training and supervision have been identified as potential barriers to POCUS, along with finance and equipment availability, confidence in interpreting,

and quality assurance (Hall et al., 2015; Mengel-Jørgensen & Jensen, 2016; Wong et al., 2020).

Study limitations

For quantitative data collection, the potential bias of the reference test (remote sonographer review) is recognised. The 'gold standard' for assessing LVSD would routinely be via comprehensive TTE (or magnetic resonance imaging) however in an elderly community patient cohort it is not feasible to send them to hospital for such tests and undermines the purpose of the acute clinical team service (delivering medical care at home and reducing hospital admissions wherever possible). However, it is well established that specialists can accurately recognise LVSD via POCUS which supports the choice of reference test. To reduce variability in reviewing, one reviewing sonographer was used to act as the gold standard for POCUS analysis (reference test) as intra-variability tends to be less variable than inter-variability. The subjective nature of ultrasound interpretation means we must accept the possibility of a small degree of error in our method. However, the sonographer is an experienced, qualified cardiac physiologist with BSE adult transthoracic accreditation and POCUS analysis is based on selecting absent/present and broad categories, not in-depth analysis or specific gradings, therefore we would expect far less variation amongst expert POCUS analyses compared to comprehensive TTE analyses.

For qualitative data to be useful and reliable, rigor is essential. There are numerous terms and proposed strategies for enhancing credibility, however demonstrating rigor is challenging because there is currently no universally accepted consensus for evaluating qualitative research (Noble & Smith, 2015). While validity was considered from the offset, and checklists, such as the Consolidated Criteria for Reporting Qualitative Research (COREQ) (Tong et al., 2007) and Critical Appraisal Skills Program (Critical Appraisal Skills Programme, 2017) were reviewed to help promote obtainment of valid data and comprehensive reporting, potential limitations to validity must be considered. Attempts have been made to try and be clear and transparent when describing the research process. However, there are potential limitations associated with the research process which must be acknowledged.

Those conducting qualitative research are integral to the process and therefore influence outcomes (Polit & Beck, 2014); subjective perspective is fundamentally interwoven within the research process and cannot be avoided (Creswell, 2013). Therefore, my influence must be considered. My critical realist stance has likely influenced study design. I sought to understand what works, for who, where, when, how, and why. Realist inquiry questions how and why interventions are effective or ineffective by exploring the influence of individuals and the wider context on outcomes (Ellaway et al., 2020; Sturgiss & Clark, 2019; Wong et al., 2016). Experiences and beliefs of researchers shape their interpretations. I am writing from the point of view of a cardiac physiologist trained in echocardiography which could be seen as a potential for bias. While, I have a direct interest in exploring new ways in which echocardiography services are delivered and how echocardiography access within primary care can be improved, I did not have any preconceived ideas as to whether adding nurse-led POCUS would/would not improve the current pathway. Therefore, I believe that I was able to be very open in my approach and feel that I was unlikely to have influenced the nurses' perception of the proposed intervention since I had an indeterminate stance on the proposed intervention myself.

In terms of interpersonal relationships, I spent prolonged periods of time with the nurses during POCUS training and developed a good rapport. While I reiterated from the offset of the focus group discussion that I had no preconceptions and that the only requirement was for the nurses to be open and honest, the potential impact of expectancy bias cannot be excluded. It was the nursing team that originally proposed the idea of POCUS implementation to the university research team and the nurses positively engaged with the project over a couple of years (due to COVID-19 related delays). Therefore, their investment in the project and potential desire for the intervention to work may have influenced their responses.

The chosen qualitative data collection method was a focus group which was selected because it allows interactive group discussion. The downside to this approach is that participant opinions may be influenced by others. To try and reduce this the meeting began with an opening statement where the intention of the meeting was explained, emphasising that there were no right or wrong viewpoints and that the only requirement was to be open and honest. However, there is evidence that the last respondents tend to conform to previous responses (Asch, 1951) which poses the risk that findings may reflect the opinions of those that answer first rather than the whole group. Varying the order in which participants speak, and

encouraging debate, can help reduce conformity bias however individuality amongst group members can make this difficult. Dominance and shyness bias have been previously reported (Vecchi, 2017) and while recommendations suggest allocating a fixed amount of time to each respondent, I found it challenging to mitigate equal opportunity to speak when certain members dominated discussions and others, particularly one, provided less input. To ensure the quieter individuals' opinion was represented, I questioned her directly at the end and provided opportunity for her to add any additional information with which she engaged.

The potential influence of my lack of experience as a moderator should be considered. While I have undertaken learning in qualitative research, this was the first qualitative research project I had been involved with. As the focus group moderator, I sought to act in line with recommendations however an accepted limitation of the study design is the presence of only one, inexperienced moderator. It has been previously proposed that it is preferential to have two people conduct a focus group; one experienced person in the moderator role to lead discussion and one to take notes (Wong, 2008). However, given the preliminary nature of the research, resource constraints prevented multiple moderators.

In terms of gaining information regarding opinions of POCUS implementation, sampling was limited to the four POCUS-trained acute clinical team nurses. The nurses were asked to provide their perceived opinions of patient and wider acute clinical team colleagues attitudes to POCUS, but study design did not include direct sampling of patient or wider staff opinions. As a research team, which includes robust personal and public involvement and nursing representation, serious thought was given to the conduct of qualitative interviews in this study. However, in the context of COVID-19, the clinical team felt it may not be appropriate for a university researcher to conduct a face-to-face interview. Additionally, given the advanced age and frailty of the patient group, online/telephone interviews were felt to be unsuitable. This issue should be reconsidered in subsequent larger scale studies.

There are accepted limitations associated with the qualitative data analysis approach. While the initial focus group transcription provides a descriptive account of the discussion, the codes and themes identified are subjective and open to interpretation (Basit, 2003). Due to limited resources available, I moderated, transcribed, and coded the qualitative data. Multiple coders are preferential due to likely truth in agreement. In the absence of multiple coders, it can be useful to verify findings with other data, however nurse-led POCUS in the

community has not been previously explored which prohibits direct comparisons. To try and validate findings, triangulation was undertaken (Creswell, 2012) whereby the different data sources (qualitative and quantitative) were searched to find corroborating evidence to support a theme and increase reliability.

Study design meant that hypothetical rather than true clinical outcomes was assessed. To ensure patient safety (as community nurse accuracy was yet to be tested in a clinical setting), study design tested the hypothetical impact of POCUS compared to the standard, delivered care. The small, initial feasibility nature of this study should be considered when drawing conclusions.

Recommendations for future studies

One of the intentions of this feasibility study was to test methods and provide guidance and propose possible refinements for subsequent studies based upon study findings. Recommendations are provided in Table 5.25.

Table 5.25

Guidance for future studies

Area	Guidance/recommendation
Recruitment	• Fewer eligible patients than predicted (estimated 60-70% of 120 referrals/month) • 80days to recruit 32 patients. • Approximately 90 referrals/month with 30% meeting inclusion criteria (new/worsening dyspnoea & ≥60yrs) which equates to ~29 eligible patients/month. • Of those eligible, 43% seen by 1-of-4 POCUS-trained nurses (predicted 50%) which suggests potential recruitment of 12-13 patients/month. • Need to consider team capacity & staff absence during recruitment window. • Data based on 4 whole-time-equivalent nurses trained. Collective absence during recruitment period was 60-days (mean 15 ± 9.13 days). • Consider: -study conducted June-Sept so annual leave rates higher -team nurse practitioner deficit higher than average during study period (32% vs 14%) which may have impacted capacity to accept new referrals -conducted post-COVID-19 pandemic which may have impacted no./type referrals
Sample Size	• Precise LVSD prevalence in local population of older people referred to acute clinical team previously unknown. Study data estimates prevalence ~40% (44%). • Based on current evidence, estimated sensitivity & specificity of existing pathway likely~0.60. Sample size needed to detect a change associated with POCUS from 0.6 to 0.80 (80% power, p<.05), with 40% prevalence of LVSD, would be 112 for sensitivity & 75 for specificity (Bujang & Adnan, 2016). • Suggest recruiting >112 participants to adjust for any attrition. • If a conservative approach is taken, & prevalence estimated at 30% to accommodate potential fluctuations in prevalence, sample size requirements for sensitivity & specificity would be higher at 150 & 64. • Based upon ~100 referrals/month with 30% eligibility, estimate it would take 3.7-5months to accrue 112-150 eligible participants. Based on 43% seen by a trained nurse, estimated time frame to accrue 112-150 would be 8-11months respectively.
Training	• High accuracy measures support suitability of devised training programme. • Focus group revealed need for practice in scenarios consistent with clinical practice -nurses were "confident scanning volunteers but not as much with patients" & "knowing now not all views are always obtainable is reassuring." -inclusion of practice in clinically similar scenarios may help manage expectations & increase confidence. -ASE recognise importance of gaining experience in settings consistent with clinical practice (Neskovic et al., 2014; Spencer et al., 2013). • Nurses expressed desire for further anatomy & physiology sessions, suggesting this was an area of weakness within their profession generally -consistent with post-training assessment data (Chapter 4) • Nurses acknowledged receipt of pre-introductory course manual but suggested something more interactive & online e-learning (proposed in Chapter 4, Table 4.9). • Differences in opinions regarding preference of informal or formal training delivery. Well reported in educational literature that people learn differently therefore training needs to be flexible to help support individuality. Having tested content/curriculum, future delivery could incorporate online & in-person options to provide variability.
Scanning	• Main limiting factor to protocol adherence was inability to obtain all views. • Lower rates of obtainment of A2C & A3C, & existing literature (Chapter 3) are mixed regarding their utility. -contribution of these views to global LV systolic function assessment unclear -would need analyses including/excluding the views to determine

	-given the potential for better detection of regional wall motion abnormalities & that views require only rotation (little added time) I would recommend they remain included in subsequent exploratory study -then, if rates of acquisition remain low & added diagnostic yield is not impacted, it may be pragmatic to remove them from the scanning protocol thereafter. • Tick-box reporting format appears appropriate as all boxes completed. • LV systolic function grading options appeared suitable given LV systolic function was correctly graded in 91%.
POCUS protocol	• Greater emphasis on identifying the presence/absence of significant pathology as discrepancies between nurses & expert occurred for borderline cases. Previous evidence milder pathology is most frequently missed (Evangelista et al., 2016). • Keep volume status thresholds same but threshold of >10mm for pericardial effusions as inconsistencies in reporting of small amounts of fluid. • Threshold of 'moderate+' with binary options (yes/no) for all additional parameters since intention is to identify significant pathology (cause of acute dyspnoea) & well reported that greater experience is needed to identify milder cases. • Separate RV dilation & dysfunction because if one or other is abnormal I wonder if there may have been confusion as to whether to tick present (despite box saying ±). • Data more variable for LVH & LA dilation. Rationale for inclusion was that presence may allure to presence of diastolic dysfunction. However, since LUS is included & pulmonary congestion can be assessed, in isolation they would not cause acute dyspnoea. Therefore, I would consider potential removal from the assessment.
CRF	• Charted medication information was insufficient to allow definitive conclusions to be drawn regarding medication & general referral decisions. • Recommend use of decision-making algorithms to help ensure collective consistency in decision making & provision of clinical useful information from which conclusions can be drawn. • Prevalence of pre-existing HF was based on nurse having ticked 'HF' box under 'previous medical history.' Criteria was unclear & type/severity of HF & previous HF medications were not documented. For future studies I would recommend better clarity regarding previous history of HF & documentation of any current HF medications. This will make it easier to identify if changes in the severity of HF and whether POCUS influences current medication.

Conclusion

While there is an abundance of data supporting the use of POCUS in a range of settings by a range of users, data were absent regarding the feasibility, acceptability, accuracy, and impact of adding community nurse-led POCUS in the domiciliary setting.

This preliminary data shows that while nurse-led POCUS in elderly patients in the domiciliary setting was challenging due to high rates of reduced patient mobility and suboptimal scanning positions, it was feasible in most patients. The provision of diagnostic testing in the home was perceived to be (by the nurses) well-received by patients and welcomed by the nurses themselves who termed POCUS a useful clinical aid. The nurses could accurately and reliably assess, and broadly grade, LV systolic functional status and most ultrasound measures of volume status at the initial point of care. Given the high nurse accuracy, sonographer-analysis of nurse-acquired images provided little clinical advantage over fully nurse-led POCUS. Nurse-led POCUS had greater sensitivity and specificity for detecting LVSD, and more quickly, than the current model of care. The improved diagnostic accuracy at the initial point of care has the potential to provide more effective and more efficient immediate management decisions, including helping to decide which patients require TTE and with what urgency.

Nurses perceived adequate training and support, and internal drive as the key determinants to implementation success and identified COVID-19, or more specifically lack of training continuity, as the biggest barrier to learning and developing confidence and competence. The nurses foresaw a lack of management engagement and funding as potential barriers to clinical implementation.

Given the proven feasibility, acceptability, obtainment of predetermined accuracy and reliability thresholds, and potential impact upon point-of-care decision making, progression to an exploratory trial appears justified.

Chapter Summary

This chapter details an exploratory-sequential mixed-methods approach to assessing whether nurse-led POCUS was feasible, accurate, and what clinical impact it may have in an elderly population with acute dyspnoea and suspected HF in the domiciliary setting. Preliminary data showed the addition of nurse-led POCUS to be feasible, accepted (by nurses), accurate, and reliable. Adding nurse-led POCUS improved the diagnostic accuracy of the initial assessment and has the potential to act as a useful triage tool for TTE. Data highlights contextual implementation challenges associated with implementing POCUS in the proposed clinical context. It discusses study limitations and proposes refinements to study design to help inform subsequent research.

Key take home points:

- *Despite contextual challenges associated with limited patient mobility, frailty, and space constraints, nurse-led POCUS was feasible in most cases.*
- *Logistically, POCUS was compatible with workflow (adding <30mins).*
- *Data suggests POCUS was well received by nurses and there was nurse-perceived patient and acute clinical team staff acceptance and positivity towards POCUS.*
- *Nurse assessments of LVSD were accurate and reliable, supporting use of a fully nurse-led POCUS model of implementation.*
- *The presence of a significant abnormality and need for urgent review was correctly identified in most cases (94% and 91% respectively).*
- *POCUS improved the diagnostic accuracy of the assessment, reduced time-to-diagnosis for LVSD, and could guide the need for, and urgency of, TTE referral.*
- *POCUS cost is estimated at £29.94 per scan and £5.42 for a five-minute remote sonographer review.*
- *The EQ-5D-5L appeared appropriate for the proposed cohort while the PROMIS Dyspnoea Functional Limitations- Short Form 10a was unsuitable given the high incidence of reduced mobility.*
- *Nurses perceived adequate training and support, and internal drive as key determinants to implementation success while a lack of training continuity was identified as the biggest barrier to learning and developing confidence and competence in POCUS.*

Chapter 6: General Discussion

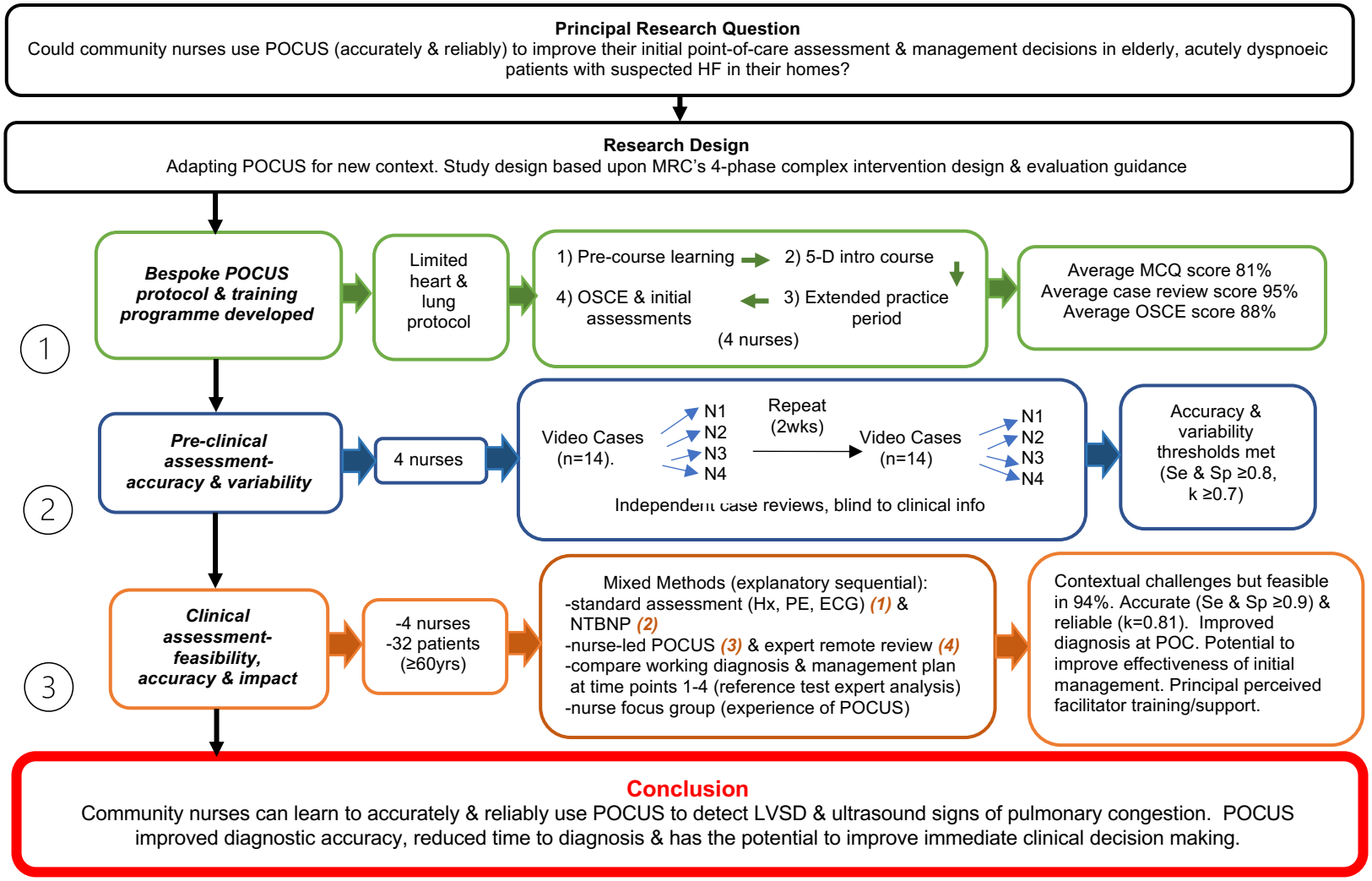
This novel thesis explores the use of nurse-led POCUS in the domiciliary setting in elderly patients with acute dyspnoea and suspected HF. While the potential suitability of hand-held POCUS for different settings is well reported, detailed accounts of how to adapt POCUS to different contexts are missing. The existing literature is dominated by studies showing the impact of POCUS upon diagnostic accuracy and/or referrals for TTE. Despite the importance of context being widely reported within interventional research, there is a notable absence of data relating to contextual influences upon POCUS implementation outcomes. Uniquely, this thesis details a comprehensive approach to POCUS development based upon the MRC framework. It details an iterative process of intervention adaptation for a new context and a staged approach to the assessment of feasibility, acceptability, and methodology, with refinements made (and further proposed), based upon contextual needs. The evidence presented provides an early indication that nurse-led POCUS is feasible, acceptable, accurate, and has clinical utility in this context thereby providing justification and recommendations for the next stage of exploratory evaluation.

Thesis Findings

An overarching summary of this thesis is provided in Figure 6.0.

Figure 6.0

Overarching thesis summary



Note Hx= clinical history; PE= physical examination; N1= nurse 1; N2= nurse 2; N3= nurse 3; N4= nurse 4; Se = sensitivity; Sp= specificity; k= Cohen's kappa; POC= point-of-care

The current pathway for suspected HF lacks accuracy in elderly patients with comorbid conditions (Chapter 1). This is contributing to inefficient triage and late diagnosis which leads to delays in treatment and unscheduled admission. Detailed exploration of the patient pathway with nurses and service users suggested that extending the initial clinical examination with POCUS may improve diagnostic accuracy and add value to the pathway.

From the offset, the complexities of adding nurse-led POCUS to the current community pathway were recognised and so relevant theory was used to guide research design (Chapter 2). Unlike existing POCUS studies, this research sought to explore the implementation challenges and contextual influences of adding POCUS in the proposed setting using established guidance (CFIR) to help improve the interpretability of the findings. The core elements of the MRC framework for complex interventions were at the centre of intervention development and evaluation.

Initial intervention development, or in this case adaptation of an existing intervention for a new context, established the current evidence base pertaining to potential POCUS implementation (Chapter 3). Uncertainties in the existing literature, process mapping (identifying current shortfalls and aspects amenable to change), and discussion with service users and providers drove research design.

Given the uniqueness of the proposed study setting, development of a context-specific POCUS protocol was required (need identified in Chapter 3, protocol described in Chapter 4). A combined heart and lung protocol was devised as knowledge of LV systolic functional status and pulmonary congestion is important in differentiating potential causes of acute dyspnoea. Incorporating LUS allows pulmonary congestion due to (or independent of) ventricular dysfunction to be identified. This is clinically important given that congestion frequently causes the acute presentation and is a known cause of hospital admission. Three of the four cases of severe LVSD had one or more signs of pulmonary congestion and three of ten with abnormal LV systolic function had an ultrasound sign of pulmonary congestion. The absence of spectral Doppler and inability to accurately quantify diastolic function using hand-held ultrasound machines is a recognised limitation. However, inclusion of LUS means that if diastolic dysfunction (HFpEF) is significant enough to cause pulmonary congestion, this can be detected. If signs of pulmonary congestion are absent, then diastolic dysfunction is unlikely to be the cause of acute dyspnoea at rest. Results of clinical feasibility testing

(Chapter 5) provides support for the suitability of the protocol with minor proposed modifications for future studies (key points highlighted in Table 6.0). While not all views were obtainable in all patients, collectively the developed POCUS protocol supported accurate detection of LVSD, ultrasound signs of pulmonary congestion, and cases of significant valvular stenosis and/or regurgitation (aortic and mitral).

The lack of clarity regarding POCUS training requirements for ultrasound novice community nurses (highlighted in Chapter 3) meant that development of a bespoke nurse-tailored POCUS training programme was required. Unlike previous studies, this research provides comprehensive training detail and evaluation which can provide guidance for others (Chapter 4). Data showed that the POCUS training programme enabled prior ultrasound novice nurses to develop adequate acquisition and analytical skills and was deemed appropriate by nurses. As anticipated, the extended period of practice was necessary to support development of adequate acquisition and analytical skills. The variability in terms of individual trainee needs, perceived ability, and external events (in our case COVID-19) further supports the use of competency-based training rather than use of set times or volumes of scans as training endpoints. While the training assessment results and nurse evaluation forms supported the overall suitability of the devised training programme, data revealed potential recommendations for future training. The principal recommendation, revealed by the focus group discussion, was for inclusion of hands-on scanning practice in scenarios consistent with the proposed clinical setting. This may help manage trainee expectations and subsequent confidence, hopefully reducing the early frustration/doubt noted when suboptimal images (compared to training) were obtained in clinical practice. My perceived core and flexible elements regarding POCUS training are outlined in Table 6.1 ('Future Research' section).

For the first time this preliminary research has evidenced the feasibility of nurse-led POCUS in the assessment of elderly acutely dyspnoeic patients with suspected HF in the domiciliary setting (Chapter 5). The domiciliary setting is highly variable. Quantitative and qualitative data revealed that there is heterogenicity in terms of where the patient is scanned, in what position, and the available space. Nurse discussions revealed that population characteristics add to the complexity of implementation due to the high prevalence of co-morbidities, extreme body habitus (high and low), mobility restrictions, and frailty. Despite these challenges, LV systolic function and ultrasound signs of pulmonary congestion (pleural

effusion and B-lines) were assessed in most patients and added less than thirty-minutes (approximately fifteen-minutes scan time) to the assessment process. Focus group data revealed that the nurses perceived the addition of POCUS to be logistically "doable," taking "less time than anticipated." All patients offered enrolment enrolled, and nurses reported positivity towards POCUS in all patients. There was no documented patient negativity. The nurses noted that many of their patients have difficulties (physical and mental) getting to hospital and that patients expressed support for delivering diagnostic testing in the home. The nurses considered POCUS to be a useful clinical aid; helping to "increase confidence" in their decision making. For the service, they felt POCUS aligned with their 'hospital at home' service goal of delivering traditional hospital-based interventions in the home.

For accurate, reliable assessments in clinical practice it is vital that pathology is correctly identified and excluded. Acknowledging early service user/public concerns regarding nurse competence, and ensuring adoption of a pluralistic approach, competence was initially assessed in a controlled environment (pre-clinical). Data showed very good accuracy and reliability (intra-variability) to diagnose LVSD with measures exceeding the pre-defined thresholds for competence (sensitivity and specificity ≥ 0.8 and kappa ≥ 0.7) and detection of most cases of pulmonary congestion on lung ultrasound. Subsequent clinical feasibility results showed that the high accuracy and reliability transferred to clinical practice.

Novel data revealed that community nurses could be taught to detect, and broadly grade, LVSD accurately and reliably (Chapter 5). They correctly identified signs of pulmonary congestion on ultrasound, with minor over-reporting of pericardial effusions (present but less than threshold). Nurses identified most cases of significant valvular disease (aortic and mitral), missing one case of aortic stenosis which was reported as 'uncertain' not absent. There was minor over-reporting (five cases) of non-significant mitral regurgitation. The nurses accurately detected the presence of additional significant cardiac pathology and identified when an urgent review was needed (in 94% and 91% respectively). This adds another cohort of healthcare professionals to the growing list that can, with adequate training, learn to acquire and interpret POCUS.

Data revealed that adding nurse-led POCUS improved the diagnostic accuracy of the initial point-of-care assessment. POCUS had greater sensitivity and specificity for detecting LVSD than either ECG and/or NT-proBNP testing. POCUS reduced time to confirmation/exclusion

of LVSD and pulmonary congestion compared to the current pathway. Using a combined heart and lung ultrasound protocol allows pulmonary congestion to be confirmed/excluded and, if present, whether the congestion is likely cardiogenic or non-cardiogenic in nature. This research proposes that nurse-led POCUS could be a useful triage step in the decision-making process regarding referral for comprehensive echocardiography. Preliminary data suggests that adding POCUS has the potential to improve the appropriateness of decision making at the initial point-of-care. POCUS findings could guide first line medication decisions to prevent, or start tackling, acute decompensation and/or determine what specialist referral is most appropriate (in the first instance) and whether hospitalisation is required.

The existing literature was mixed regarding what the optimal method of POCUS implementation may be. It was unclear whether novice POCUS required expert analytical input. Data revealed that sonographer-analysis of nurse acquired images added little clinical value given the limited variability in diagnosis and referrals for TTE. There was substantial agreement between the nurses and sonographer in terms of whether a significant abnormality was present and whether an urgent review was required which supports the notion that nurses can reliably identify and act upon the presence of significant pathology in terms of obtaining urgent reviews. While the data support nurse-led POCUS, showing little benefit from using expert-analysis of nurse acquired images, the impact of expert-acquired images or remote-guidance of nurse-acquisition cannot be assessed in this study.

Despite the proven accuracy of POCUS in this preliminary study, I would suggest POCUS is an additional test within the current pathway rather than a replacement test. I believe routine ECG testing is necessary in the context of acute dyspnoea because it provides immediate important cardiac information, such as exclusion of arrhythmia or acute coronary syndrome. In this small study, preliminary data suggests that when POCUS was performed post-physical examination, routine BNP testing added little clinical value. If BNP testing was limited to those with indeterminate LV systolic function on POCUS, BNP referrals would have reduced by 94%. However, LVSD is not the only cause of an elevated BNP and its utility for other contexts would require further exploration before considering modifying its place within the current pathway.

Then rule-in or rule-out utility of POCUS in the proposed setting was unclear from the existing literature. While sensitivity, specificity, negative predictive value, and positive

predictive value were all high for LVSD, preliminary data suggests that POCUS may have the greatest impact as a rule-out test. The clinical implications of incorrectly missing LVSD are greater than those associated with incorrectly diagnosing LVSD (in the short term). While the risk of over-diagnosing (false positives) has implications in terms of potential further testing, inappropriate treatments, and unnecessary patient worry, those with positive results would undergo TTE where pathology would be confirmed/excluded. Conversely, for those with a false negative result, TTE may not be requested and LVSD could go unrecognised and untreated. Using POCUS as a rule-out test has the potential to reduce the number of TTE referrals if the POCUS examination is negative and in prior studies there is evidence of potential cost savings from reductions in TTE referrals where POCUS examinations are normal (described in Chapter 3). In terms of ruling-in potential, confirming the presence of LVSD (and/or pulmonary congestion) at the initial point-of-care and potentially facilitating immediate initiation of appropriate evidence-based treatments/medication would need to be assessed to compare rule-in and rule-out utility.

This study uniquely provides POCUS user perceptions of potential facilitators and barriers to POCUS implementation within the context of suspected HF in elderly patients in the domiciliary setting. When considering potential clinical implementation (Chapter 5), the nurses identified training as the principal contributor to success. Training was identified as both a potential facilitator, if adequate, and barrier, if insufficient. The nurses expressed the need for dedicated training, with extensive hands-on practice opportunity in different scenarios, and ongoing assessment. They emphasised the importance of an established support network and clear pathways for escalation/urgent reviews. Internal attitude and drive of those delivering POCUS were also identified as potential facilitators. The nurses involved were very driven and part of a dynamic team that are receptive to change but they suggested that for widespread implementation POCUS champions may be needed to support and encourage uptake.

The nurses identified a lack of training continuity (caused predominantly by COVID-19) as the biggest barrier to learning and developing confidence and competence. A lack of management engagement and funding were foreseen as potential barriers to clinical implementation. This aligns with MRC intervention guidance which identifies stakeholder engagement as a core element and promotes engagement from the offset (Skivington et al., 2021a). At this initial feasibility stage, we engaged with providers (nurses) and service users

to help provide broader perspectives and increase implementation success but for larger scale investigation stakeholder engagement should be broadened to involve management and decision-makers.

Training aside, the resource requirements for implementing nurse-led POCUS include hand-held ultrasound devices, a means of image download and storage, and a support (expertise) network. Patient volume and the number of nurses involved should drive decisions regarding the number of hand-held ultrasound devices needed. For effective implementation of nurse-led POCUS, access to expertise is paramount. While data suggests that routine review may not be required, clear escalation pathways and access to expert advice are important for effective implementation. Nurses expressed the importance of expertise availability and established case review processes. To facilitate effective utilisation of expertise, remote support options are preferable. Remote image review was not possible in this study which resulted in on-site reviews which is neither practical nor cost-effective in a clinical setting. For clinical implementation, I would propose that a remote image review platform (such as a cloud-based server) is integral with timely access to qualified experts as needed.

Future Research

The usefulness of this preliminary research has already been recognised by Health and Care Research Wales who have awarded funding for the programme of research to continue. A data science study of the Welsh population will map the current real-world patient pathway, outcomes, and resource use for elderly patients with acute dyspnoea (including sub-group analysis for those receiving community medical care). An exploratory trial will adopt the recommendations of this feasibility study and use refined methods to confirm the clinical effectiveness and implementation factors on a larger scale. The study protocol is currently being finalised. It is hoped that this additional evidence will provide sound justification to key NHS stakeholders and funding bodies of the need to fund a multi-centre, national randomised trial which might impact on national guidelines to improve healthcare outcomes for the oldest in society.

This research sought to test methods and provide recommendations for the subsequent larger study. Throughout the thesis refinements have been made at the different stages. Table 6.0 summarises the principal recommendations for future research.

Table 6.0

Summary of main considerations for future research based upon thesis findings

Topic	Consideration
Recruit	In this setting, based on ~29 eligible patients/month with 43% seen by POCUS trained nurse & 100% agreement to enrol, estimate an enrolment rate of 12-13 patients/month.
Sample size	Sample size needed to detect a change associated with POCUS from 0.6 to 0.80 (80% power, $p<.05$), with 40% prevalence of LVSD, would be 112 for sensitivity & 75 for specificity (Bujang & Adnan, 2016). Suggest recruitment of ≥112 participants.
Training	Trainee requests for hands-on practice in scenarios consistent with clinical practice.
	Continuity & repetition important- back-to-back scanning improved acquisition skills.
	Additional anatomy, physiology & pathophysiology material pre-course .
	Human scanning practice earlier in introductory course (nurse request).
	Having tested the curriculum, adapt pre-course manual to online modules (with questions/answers) accessible pre & during training to allow trainee control.
	Greater emphasis on identifying presence/absence of significant (not mild) pathology.
POCUS Protocol	LV systolic function assessment using broad categories is suitable.
	Given acute presentation, greater emphasis on presence/absence of significant pathology – 'moderate+' thresholds (except specific IVC & B-line guidance).
	As A2C, A3C, & S.IVC views frequently unobtainable, consider clinical utility in higher volume of patients to determine wider feasibility & clinical utility.
	Possible exclusion of LV dilation, LA dilation, & LVH from reporting protocol. Unlikely to be significantly abnormal in isolation &, in isolation, unlikely to be cause of acute dyspnoea. Multiple causes of LA dilation in elderly other than diastolic function. Further testing in a larger number of patients needed to assess suitability further.
Clinical Decision Making	Consider decision-making algorithm for medication & referral decisions to limit ambiguity.
	Additional open text box to give nurses opportunity to explain medication choices.
	Greater emphasis on confirming/excluding cause for acute dyspnoea (not just detection of any pathology) & impact of this on immediate clinical decision making.
Resources/ Cost	Necessary resources include hand-held ultrasound device(s), means of image download/storage with remote image review platform, and access to expertise (remote). Estimated cost per POCUS scan- unit cost £5.19 & staff time £24.75; per sonographer review (Band 7) £5.42; & shared drive image storage £0 (cost depends on image upload system used). Training costs/resources are not included but require consideration.
Consent	Consent forms that allow a single signature for multiple copies given patient frailty.
	Video clip option of patient information not used by any patients (used sheet & poster only) therefore consider whether necessary in subsequent study.
PROM tools	EQ-5D-5L suitable for use within the proposed cohort.
	PROMIS Dyspnea Short Form 10a unsuitable in this cohort of patients given the high prevalence of mobility issues (many of the tasks listed were inappropriate & not routinely performed). Consider alternative tool.
Case Report Form	For feasibility comments section, provide tick box options & space for comments- open box alone left blank & if no space for comments may limit breadth of information gained.
	Provide greater clarity regarding added time needed to include POCUS process- make CFR wording more explicit (time to explain, time to perform, time to report).

From this feasibility research, I believe that there are certain core elements of POCUS implementation, applicable across different contexts of use, and perceived flexible elements, adaptable to specific contextual needs. My perceived core and flexible elements regarding POCUS implementation are outlined in Table 6.1, however these need to be confirmed (and potentially refined) in the subsequent exploratory trial. If, in future studies POCUS is shown to add clinical value on a larger scale and clinical implementation of nurse-led POCUS is proposed, formalised training and nurse accreditation should be considered to ensure consistency in terms of competence and maintenance of competence.

Table 6.1

My perceived core and flexible elements regarding POCUS implementation

Topic	Core Elements	Flexible Elements
Training	• Inclusion of widely agreed core curriculum topics (listed in Chapter 4) • Introductory course supplemented with extended period of practice • Hands-on opportunity in clinical scenarios consistent with intended clinical practice • Case review (relevant to intended scope of practice) • Competence-based training -pre-defined competence -novice-triggered assessments	• Amount of anatomy, physiology & pathophysiology content • Opportunity for additional one-on-one sessions • Delivery of hand-on scanning & case review opportunity
POCUS protocol	• Clear scanning & reporting protocol -including thresholds for abnormal • Focus on presence/absence of significant pathology	• Protocol clinically driven dependent upon intended context of use
Implementation	• Engagement with service users/providers from the offset • Established decision making algorithms with clear review/escalation processes • Expert support • Remote image review platform	• Extent of stakeholder engagement dependent upon stage of research • Delivery of expert support (analysis +/- acquisition) -dependent upon expert availability, resources & trainee competence • Routine expert review dependent upon trainee competence

Limitations

Despite the novel contribution of this research there are recognised limitations. While this research has examined the possibility of improving the diagnostic accuracy of the current pathway, findings come from a small convenience sample in which the prevalence of existing HF was relatively high. It is unclear if this is typical of the proposed population. However, data allows planning of the sample size for an exploratory trial and suggests that fewer participants may be needed than originally predicted.

We believe that the team included in this body of research are highly motivated with a positive attitude to change which may not be consistent with other teams. However, this was not formally assessed. It may be useful to draw upon theory to better assess readiness to implement an intervention.

While my research knowledge has developed significantly throughout this research project, my novice status as a researcher must be recognised, particularly in terms of qualitative and mixed-methods design, thematic analysis, and integration of quantitative and qualitative results. I recognise that this may have influenced the interpretation of findings.

When considering the generalisability of thesis findings, it must be acknowledged that data are limited to POCUS use by community nurses in the setting of suspected HF in elderly, acutely dyspnoeic patients in their homes. Training needs of other novices and application in different settings would likely raise different contextual challenges. However, the detailed guidance-based approach to intervention adaptation can be followed and applied to different contexts.

Conclusion

This thesis provides novel insight into the feasibility, acceptability, accuracy, and clinical impact of adding community nurse-led POCUS in the assessment of elderly, community patients with acute dyspnoea. This original research provides comprehensive detail about adaptation (development) of the intervention for the proposed context, including training, assessment, and evaluation of accuracy and reliability among users.

The clinical feasibility study concludes that in this context, extending the clinical examination with nurse-led POCUS is acceptable, feasible, accurate, and adds significant clinical value. It allows immediate confirmation/exclusion of LVSD (and ultrasound signs of pulmonary congestion), outperforming the standard pathway, and potentially facilitating more effective clinical decision-making at the initial point-of-care, including triaging referrals for TTE.

Contextual insight has revealed potential facilitators and barriers to implementation within this setting and recommendations for future research studies in this context (Table 6.0). The data have already led to initiation of a fully funded data science and exploratory trial where comparative diagnostic accuracy and a formal evaluation of implementation constructs can be more rigorously assessed.

POCUS undoubtedly has the potential for widespread clinical use in a range of clinical settings. While the results of this research are specific to the context or older people with acute dyspnoea, the adopted comprehensive approach to intervention development, including exploration of contextual influences, can inform and be applied to other research settings. I believe such an approach is pivotal in ensuring effective clinical implementation of POCUS, or any other healthcare intervention, in new contexts.

Appendices

Appendix A - OSCE Marking Criteria

General	**Yes (2 pts)**		**No (0 pts)**
1. Positions the subject & themselves appropriately			
2. Correctly enters subject details into the machine			
3. Selects appropriate probe/preset for each view			
4. Has the indicator on the correct side for all views			
5. Adequately optimises images (depth/gain/centre)			
6. Stores images/ends exam correctly			
7. Cleans machine appropriately			
Cardiac	**Excellent (2 pts)**	**Satisfactory (1 pts)**	**Poor (0 pts)**
8. PLAX view obtained & saved			
9. Colour over AV & MV obtained & saved			
10. PSAX view obtained & saved			
11. A4C view obtained & saved			
12. Colour over MV obtained & saved			
13. A2C view obtained & saved			
14. A3C view obtained & saved			
15. S4C view obtained & saved			
16. IVC view obtained & saved			
Lung			
17. Upper point obtained & saved			
18. Lower point obtained & saved			
19. Posterolateral/PLAPS point &/or Posterior (if appropriate) obtained & saved			
Analysis	**Fully correct (2pts)**	**Satisfactory (1 pts)**	**Incorrect (0 pts)**
20. Image quality assessment			
21. LV size & systolic function interpretation			
22. IVC size & collapsibility interpretation			
23. Pericardial effusion assessment			
24. Pleural effusion assessment			
25. Interpretation of B-line presence			
26. Conclusion			
Additional:			
27. Identified if significant RV dilation ± dysfunction			
28. Identified if significant AS			
29. Identified if significant AR			
30. Identified if significant MS			
31. Identified if significant MR			
32. Identified if significant LVH			
33. Identified if significant LA dilation			
34. Identified if significant 'other' finding			

	Total Possible	**Final Score**
Total (not incl additional)	**52**	
Total incl additional	**68**	

Appendix B – Training evaluation form

POCUS Training Workshop Evaluation Form

Title of event: Point-of-care ultrasound training workshop

Date of event: 1st – 5th April 2019

Location of event: Swansea University

Trainers: Sophie Moosavi & Dr Emma Rees

Nurse Name (Optional):
Nurse Grade (Specify):

Please review the following list of knowledge & skills statements. Give some thought to what you knew before this training workshop & what you have learnt during it. Circle the number that best represents your knowledge & skills **before & after**.

RATING SCALE:
1 = No knowledge **3 = Adequate for POCUS** **5 = Fully competent**

BEFORE TRAINING					SELF-ASSESSMENT OF KNOWLEDGE AND SKILLS REGARDING:	AFTER TRAINING				
1	2	3	4	5	POCUS- what it is, uses, indications & limitations	1	2	3	4	5
1	2	3	4	5	Physical examination- limitations, guiding POCUS focus	1	2	3	4	5
1	2	3	4	5	Basic cardiac & lung anatomy & physiology	1	2	3	4	5
1	2	3	4	5	Basic ultrasound physics & image optimisation	1	2	3	4	5
1	2	3	4	5	Using the GE Vscan	1	2	3	4	5
1	2	3	4	5	Assessing whether image quality is adequate (diagnostic)	1	2	3	4	5
1	2	3	4	5	Performing cardiac & lung POCUS	1	2	3	4	5
1	2	3	4	5	Reporting cardiac & lung POCUS	1	2	3	4	5
1	2	3	4	5	Recognising normal cardiac & lung images	1	2	3	4	5
1	2	3	4	5	Recognising common cardiac & lung abnormalities on ultrasound (ventricular dysfunction, gross valvular abnormality, fluid overload)	1	2	3	4	5

Please review the following statements regarding the workshop. Circle the number that best represents how much you agree/disagree with the statements.

RATING SCALE where:

1 = Strongly Agree 2 = Agree 3 = Disagree 4 = Strongly Disagree

SELF-ASSESSMENT OF:	RATING				
My personal expectations for the course were met	1	2	3	4	
The outlined training objectives were met	1	2	3	4	
The facilitators gave clear explanations of the topics	1	2	3	4	
The information delivered was relevant/appropriate	1	2	3	4	
The methods of information delivery were appropriate	1	2	3	4	
The facilitators welcomed questions & responded to them appropriately	1	2	3	4	
The course length was appropriate	1	2	3	4	
The pace of the course was appropriate to the content & attendees	1	2	3	4	
The activities included were helpful & relevant	1	2	3	4	
There were sufficient hands-on scanning opportunities	1	2	3	4	
There was sufficient exposure to 'normal' cases	1	2	3	4	
There was sufficient exposure pathology relevant to my patient cohort	1	2	3	4	
The size of the group was appropriate	1	2	3	4	
The information delivered was relevant to my clinical practice	1	2	3	4	
I would recommend the workshop to my colleagues	1	2	3	4	

Please take a moment to answer the following questions. Your comments are an **important contribution** to designing learning experiences to meet your professional needs.

What did you find most useful?

Was there anything included in the workshop that you felt was unnecessary?

How could delivery of the subject matter be improved?

Do you require any additional training regarding any particular aspect of POCUS? (please specify)

Thank you for completing this evaluation form. We appreciate your feedback & it will be used to provide improvements to future events.

Completed evaluation forms should be given to the training facilitators.

Appendix C - Original diagnostic accuracy & reproducibility study overview

Full study title:	Diagnostic accuracy of point-of-care ultrasound by community nurses for the detection of left ventricular systolic dysfunction
Short title:	Feasibility & Accuracy of Nurse-Performed POCUS
IRAS Project ID:	255744
Protocol:	Protocol Version 2.0, dated 27/02/2020
Chief Investigator:	Dr Emma Rees
Study Centre:	Health & Wellbeing Academy (Swansea University) Morriston Hospital (Patient Identification centre)
Areas of investigation:	Community care, diagnosis, cardiorespiratory
Study duration:	Estimated at 6-12 months
Primary Objectives:	To assess whether nurses can accurately detect and exclude significant left ventricular (LV) systolic dysfunction using a protocol driven point-of-care ultrasound (POCUS) scan of the heart and lungs.
Secondary Objective:	To assess whether nurses can accurately detect or exclude other significant cardiac pathology using POCUS i.e., right ventricular (RV) dilation and systolic dysfunction, aortic and mitral valve disease, left ventricular hypertrophy and left atrial dilation.
Study population:	Older adults (≥60y) with and without left ventricular systolic dysfunction confirmed by prior comprehensive echocardiography or MRI
Recruitment Target	100 (80 without and 20 with LV ventricular systolic dysfunction)
Recruitment Window:	Estimated at 6 months
Methodology:	Double-blind diagnostic accuracy study. Index test comprises POCUS of heart and lungs by a nurse and by an accredited sonographer. Reference test comprises comprehensive echo (or MRI) confirming LV systolic function. Repeated test and interpretation to assess inter- and intra-variability in 20% of participants, 1 month later.
Eligibility criteria:	**Inclusion criteria:** • ≥60years old • Written consent obtained • LV function status previously confirmed on comprehensive echocardiogram or MRI (within 3mths)
	Exclusion criteria: • highly contagious disease, such as active Tuberculosis • large chest dressing obscuring ≥2 imaging windows
Primary outcomes measures :	Sensitivity and specificity to detect LV systolic dysfunction (target >0.8). Repeated test agreement of >0.7 (Cohen's Kappa).

Appendix D - Case report form (CRF)

Nurse Name:		**Study Date:**
Patient Study ID:		
Patient Age (yrs)**:**		
Patient Gender:		
Height/Weight:	**H=**	**W=**

Referral Indication:

NYHA Classification (tick appropriate classification):

I	No limitation during ordinary activity	
II	Slight limitation by SOB/fatigue during moderate exertion or stress	
III	Symptoms with minimal exertion that interfere with normal daily activity	
IV	Inability to carry out any physical activity without SOB which may be present even at rest.	

Known Cardiac History? (circle) **Yes / No**
If **yes**, please state:

Clinical findings (tick all that apply):

-Hx:

Dyspnoea	
Orthopnoea	
Postural Nocturnal Dyspnoea	
Unexplained significant weight gain	
Persistent cough/wheeze	
Chest pain	
Palpitations	
Dizzy/Syncope	
Atrial Fibrillation	
Hypertension	
Postural Hypotension	
Diabetes	
Obesity	
Smoking Hx If **yes,** circle: **Smoker or Ex**	
Increased alcohol	
Positive FHx Cardiac disease	

-Signs:

Signs of fluid overload (e.g., raised JVP, bilateral peripheral oedema, abdominal fullness/distension)	
Murmur +/- added heart sound	
Rales/crackles	
Signs of consolidation (e.g., dullness on percussion, absent/muffled breath sounds)	

Other *(please state):*

ECG Findings:

HR = _____ bpm Rhythm = _____

Working Diagnosis BEFORE scan (based on standard assessment):

Management Plan/Action Plan BEFORE scan (based on standard assessment):
Tick all that apply

a) Medication

	Start	**Stop**	**↑ Dose**	**↓Dose**	**Change to Alternative**
Beta-blockers					
ACE Inhibitors					
ARBs (Angiotensin II Receptor Blockers)					
Aldosterone antagonist					
Oral Diuretics					
Metolazone					
IV Diuretics					
IV fluids					
Anticoagulation					
Digoxin					
Antibiotics (oral or IV)					
Iron/blood infusion					
Nebulised therapy					
Other *(specify):*					
None					

b) Action

Admission to hospital	
NT-proBNP blood test	
Refer for comprehensive echocardiogram	
Request chest X-ray	
Request other cardiac investigation *(please state):*	
Refer to cardiology	
Palliative care input & support	
Other *(specify):*	
None	

Main Indication for POCUS:

Working Diagnosis AFTER Scan:

Assuming your analysis is accurate…
Would the POCUS findings influence (hypothetically) your original patient management plan?
(circle) **Yes / No**

If **yes,** complete the new management plan below.
If no, move to "comments" box.

Management Plan/Action Plan AFTER scan:
Tick all that apply

a) Medication

	Start	**Stop**	**↑ Dose**	**↓Dose**	**Change to Alternative**
Beta-blockers					
ACE Inhibitors					
ARBs (Angiotensin II Receptor Blockers)					
Aldosterone antagonist					
Oral Diuretics					
Metolazone					
IV Diuretics					
IV fluids					
Anticoagulation					
Digoxin					
Antibiotics (oral or IV)					
Iron/blood infusion					
Nebulised therapy					
Other *(specify):*					
None					

b) Action

Admission to hospital	
NT-proBNP blood test	
Refer for comprehensive echocardiogram	
Request chest X-ray	
Request other cardiac investigation *(please state):*	
Refer to cardiology	
Palliative care input & support	
Other *(specify):*	
None	

Comments relating to: POCUS feasibility, acceptability, attitude, environment suitability
(please complete, DO NOT LEAVE BLANK):

Consider:

- **Patient attitude to having the scan done at home - your perspective & theirs**
- **Logistics**
- **How easy/difficult it was to do the scan**
- **Suitability of the environment for performing the scan**
- **Any limitations/barriers or facilitators**

Sign & Date:

BNP Result

Nurse Name:		**Date:**
Patient Study ID:		

NT-pro BNP RESULT *(state value):* _____ng/litre

Working Diagnosis AFTER BNP Result:

Management Plan/Action Plan AFTER BNP result:
Tick all that apply

a) Medication

	Start	**Stop**	**↑ Dose**	**↓Dose**	**Change to Alternative**
Beta-blockers					
ACE Inhibitors					
ARBs (Angiotensin II Receptor Blockers)					
Aldosterone antagonist					
Oral Diuretics					
Metolazone					
IV Diuretics					
IV fluids					
Anticoagulation					
Digoxin					
Antibiotics (oral or IV)					
Iron/blood infusion					
Nebulised therapy					
Other *(specify):*					
None					

b) Action

Admission to hospital	
NT-proBNP blood test	
Refer for comprehensive echocardiogram	
Request chest X-ray	
Request other cardiac investigation *(please state):*	
Refer to cardiology	
Palliative care input & support	
Other *(specify):*	
None	

Sign & Date:

Added comments options given:

Data collection form completion guidance for section on:

"Comments relating to: POCUS feasibility, acceptability, attitude, environment suitability, limitations/barriers/facilitators"

Please do NOT LEAVE BLANK. Consider the box below to help. Tick those that are relevant & add detail in comments box. Add additional free text for any other comments.

Comment	Tick	Comments
No difficulties with consent		
Difficulties consenting		
Patient/family positive attitude to POCUS		
Patient/family negative attitude to POCUS		
Adequate environment		
Suitable patient positioning		
Suitable operator positioning		
Patient compliant		
Unsuitable environment (e.g. ltd space)		
Unsuitable patient positioning		
Patient restless/Patient discomfort		
Pt limited mobility/immobile		
Relative/carer support		
Relative/carer interruption/negativity		
Operator limited time		
Operator discomfort/frustration		
Relatively easy scan to perform		
Difficult scan- body habitus		
Difficult scan- environment		
Difficult scan- patient positioning/compliance		
Difficult scan- dyspnoea/lung disease		
Difficult scan- operator difficulties		

Appendix E - POCUS reporting form

Nurse POCUS Reporting Template

Study ID:		**Date:**	
Scan Location:			
Nurse Name:			
Scan Start Time:		**End Time:**	

Where was patient scanned? (circle)	*Bed*	*Chair*	*Other (state):*

Patient position for cardiac views (excl subcostal) (circle)	*Upright, on left*	*Upright*	*Supine*

Patient position for subcostal views (circle)	*Upright*	*Supine*

Patient position for lung views (circle)	*Upright*	*Supine*

Overall were the images of sufficient diagnostic quality? (circle)	*Yes*	*No*
If **'No'**, please specify **why**:		
Were any specific views 'non-diagnostic/unobtainable?' (circle)	*Yes*	*No*
If **'Yes'**, please specify **why**:		

POCUS FINDINGS:

1) What was the left ventricular systolic function? *(tick the appropriate boxes):*

	Grossly Normal	Abnormal	Severely Abnormal	Uncertain
LV Systolic Function				

Was the LV dilated?

	Absent	Present	Uncertain
LV Dilation			

2) Were there signs of congestion? *(tick appropriate boxes):*

2a)	Absent	Present	Uncertain
Abnormal IVC (dilated &/or <50% collapse)			

2b)	Absent/Insignificant (≤5mm)	Present	Uncertain
Pericardial Effusion			
-If yes, any haemodynamic compromise? (e.g. RV/RA collapse, 'swinging', septal bounce)			

2c)	Absent/Insignificant (≤5mm)	Present	Uncertain
Pleural Effusion			

2d)	
Positive B-Lines (circle for each point) Positive= ≥3lines per zone	**Upper Point (Right)** *Positive / Negative / Uncertain* | **Upper Point (Left)** *Positive / Negative / Uncertain* **Lower Point (Right)** *Positive / Negative / Uncertain* | **Lower Point (Left)** *Positive / Negative / Uncertain*

3) Were any other abnormalities seen? *(tick appropriate boxes):*

	Absent	Present	Uncertain
Significant LV hypertrophy			
Significant left atrial (LA) dilation			
Significant RV dilation &/or impaired function			
Significant aortic valve stenosis			
Significant mitral valve stenosis			

	Absent/Trivial	Present (>trivial)	Red Flag	Uncertain
Aortic regurgitation				
Mitral regurgitation				

Other clinically significant findings e.g., mass *(please specify)*	

CONCLUSION

Was a significant abnormality seen? *(circle):* **Yes / No**

If 'yes', is it due to *(tick all appropriate boxes & for valves also circle type(s)):*

Impaired LV systolic function (if selected abnormal or severely abnormal)	
Signs of congestion (if selected present to any of q.s 2a-2d)	
Significantly impaired RV systolic function +/- RV dilation	
Significant valvular abnormality *Please circle type(s):* Aortic Stenosis Aortic Regurgitation Mitral Stenosis Mitral Regurgitation	
Other *(please state)*	

Does the scan/patient require urgent review? *(circle):* **Yes / No**

(If ticked any boxes answer 'yes,' notify on-call physician & log below)

If 'yes' details of review:

Name/Title of reviewer	
Date/Time of discussion	
Outcome of discussion	

Sign & Date:

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