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**Ultrasound assessment of  
small bowel Crohn's disease:  
A mixed methods exploration of barriers and  
facilitators to implementation in adult NHS IBD  
services.**

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I hereby declare that this thesis is all my own work, except as indicated in the text. I hereby declare that I have all necessary rights and consents to publicly distribute the dissertation via the University of Nottingham e-thesis archive.

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## **Abstract:**

Background: Crohn's disease (CD) is a long-term condition which requires repeated disease monitoring via medical imaging, where repeated burdensome medical investigations negatively impact on patients quality of life. Small bowel ultrasound scanning (SBUS) has been shown to be similar in accuracy when compared to magnetic resonance enterography (MRE), has the potential to be quicker, less costly and improve patient experience of care, but it is not routinely used in NHS IBD care.

Objectives: This thesis aims to provide insight on how best to support the implementation of SBUS in practice by collecting information about current national usage and appetite for SBUS uptake, stakeholder perceptions of the adoption of the intervention by health services and the potential impact of use of SBUS on care pathways in routine CD care. Findings from this work will contribute to the production of an implementation package to facilitate national uptake of SBUS in NHS IBD services.

Methods: A scoping literature review and three research studies were undertaken throughout this programme of work. The scoping literature review was undertaken to explore clinical utility of SBUS in IBD settings. A national survey was undertaken to uncover current usage and appetite for use of SBUS in IBD settings. A qualitative semi structured interview study was undertaken to explore stakeholder perceptions of SBUS use and implementation of ultrasound in IBD settings. A care pathway analysis and cost implications analysis were undertaken to gauge the impact of the introduction of SBUS into an NHS IBD service. The quantitative data were analysed using descriptive statistics. Qualitative data were analysed using template analysis.

Results: Ultrasound is reported as quicker, more acceptable to patients and safer when compared to MRE and has been shown to be similarly accurate in detecting presence and extent of small bowel CD. Ultrasound is used widely in central Europe and Canada but has not yet been embraced in the UK. Survey responses indicated that there is an appetite for the uptake of SBUS in NHS services. There is disparity in confidence levels when using ultrasound to make clinical decisions, compared to MRE. The interview study revealed that stakeholders believe that the introduction of SBUS into clinical services would be beneficial to patient experience, outcomes and cost reduction. There are concerns in relation to the availability of training for health

care professionals and the belief that there are still concerns relating to accuracy of SBUS compared to MRE. Interview participants believed that the largest barriers to implementation of SBUS in the NHS were the existing practices, beliefs and behaviours of healthcare professionals which are likely to be difficult to amend. Care pathway and costs implications analysis' showed that there are significant potential cost saving and waiting time reduction implications to the introduction of SBUS into NHS IBD services.

Conclusions: Recommendations from this work which will contribute to the generation of an implementation package for SBUS include the need for well-structured and supported training for health care professionals, tools for identifying and fostering leadership roles in promoting and sustaining change and mechanisms for reviewing and adapting SBUS over time to ensure it meets the needs of stakeholders and IBD services.

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## Presentations and publications by the researcher related to this thesis:

### Publications:

- Radford SJ, Clarke C, Shinkins B, Leighton P, Taylor S, Moran G. Clinical utility of small bowel ultrasound assessment of Crohn's disease in adults: a systematic scoping review. *Frontline Gastroenterol.* 2021 Jun 23;13(4):280-286
- Rohatinsky, N. Radford, S. Britt, C. et al "Crohn's Disease patients experience and preferences with disease monitoring: an international qualitative study" *Crohn's & Colitis* 360 (2023).
- Shaban N, Hoad CL, Radford, SJ, et al.(2022) Imaging in inflammatory bowel disease: current and future perspectives. *Frontline Gastroenterology.* doi:10.1136/flgastro-2022-102117
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## Abbreviations:

<b>BRC</b>	Biomedical Research Centre
<b>BSG</b>	British Society of Gastroenterology
<b>BWT</b>	Bowel Wall Thickness
<b>CCUK</b>	Crohn's and Colitis United Kingdom
<b>CD</b>	Crohn's Disease
<b>CR</b>	Critical Realism
<b>CPA</b>	Care Pathway Analysis
<b>ECCO</b>	European Crohn's and Colitis Organisation
<b>ESGAR</b>	European Society of Gastrointestinal and Abdominal Radiology
<b>GBP</b>	Great British Pound
<b>HCP(s)</b>	Health Care Professional(s)
<b>IBD</b>	Inflammatory Bowel Disease
<b>MRC</b>	Medical Research Council
<b>MRE</b>	Magnetic Resonance Enterography
<b>MRI</b>	Magnetic Resonance Imaging
<b>NIHR</b>	National institute of Health and Care Research
<b>NPM</b>	Normalisation Process Model
<b>NPT</b>	Normalisation Process Theory
<b>NHS</b>	National Health Service
<b>POCUS</b>	Point of Care Ultrasound
<b>PPI</b>	Patient and participant involvement
<b>PRISMA</b>	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
<b>(HR)QoL</b>	(Health Related) Quality of Life
<b>RCT</b>	Randomised Control Trial
<b>SBCD</b>	Small Bowel Crohn's Disease
<b>SBUS</b>	Small Bowel Ultrasound
<b>STRIDE</b>	Selecting Therapeutic Targets in IBD
<b>UC</b>	Ulcerative colitis.
<b>UK</b>	United Kingdom
<b>USA</b>	United States of America

## **Chapter 1: Introduction**

This thesis presents research regarding how best to support future implementation of ultrasound in inflammatory bowel disease (IBD) management in the National Health Service (NHS). Ultrasound is not routinely used in NHS IBD care despite evidence to support that it is similar in accuracy to magnetic resonance enterography (MRE), when in the hands of an appropriately trained clinician, in detailing disease presence and extent, is less costly, quicker and preferred by patients.<sup>2</sup> In the current NHS climate where waiting times for routine examinations are the longest they have ever been<sup>3</sup>, it is more important than ever to explore new ways of providing appropriate, timely care for patients living with IBD.

This chapter introduces Crohn's Disease (CD), including symptoms, aetiology, diagnosis and classification, treatment and routine assessment. Current clinical practices in relation to routine imaging assessments of CD and the challenges associated with these are discussed, along with information related to ultrasound use in the assessment of CD. The aim of this thesis is to contribute recommendations to the development of an implementation plan for ultrasound in NHS IBD services. Further information about the thesis rationale and overview are described at the end of this chapter.

### **1.1 Crohn's Disease**

The two main forms of IBD are CD and Ulcerative Colitis (UC). IBD is an immunologically mediated chronic, systemic, inflammatory disease of the gastrointestinal tract that is idiopathic and relapsing in nature.<sup>4</sup> UC involves inflammation along the superficial lining of the colon, CD has the potential to affect multiple areas of the gastrointestinal tract.<sup>5</sup>

Exact aetiology of IBD remains uncertain. Research results from animal models and human genetics studies indicate that CD and UC are heterogeneous diseases, characterised by various genetic abnormalities.<sup>6-8</sup> The role of genetic factors is indicated by familial cluster cases and higher incidence demonstrated in identical twins.<sup>9</sup> Large scale genome wide association studies have so far found 163 genetic loci linked with IBD onset.<sup>10,11</sup> The inception and relapse of disease is triggered by environmental factors that break the mucosal barrier which in turn stimulates immune responses and alters the balance between beneficial and pathogenic enteric bacteria.<sup>6-8</sup>

Diagnosis of IBD is based on symptom history alongside a combination of clinical tests and histological findings.<sup>12,13</sup> Symptoms can fluctuate, with periods where the symptoms are severe (flare-ups), followed by times when there are few or no symptoms at all (remission).<sup>14</sup> Distribution of CD varies; colonic disease is present in 25% of patients, 50% of patients have ileocolonic disease, with up to 70% of all patients with CD having small bowel involvement.<sup>15</sup> A further 33% present with perianal CD and 5-15% present with oral or gastro-duodenal disease.<sup>5,16</sup>

Incidence and prevalence of IBD is increasing globally.<sup>17,18</sup> Historically IBD incidence has varied according to geographical location, with higher incidence in the western world being linked to industrialisation. However, emerging data speculates that there is increasing incidence in eastern countries, theoretically linked to immigration, westernised diets, lifestyles and better healthcare systems.<sup>19,20</sup> In the UK it is estimated that there are 500,000 people affected by IBD.<sup>21</sup> Prevalence of IBD correlates with reported incidence rates, suggesting IBD is most prevalent in westernised cultures.<sup>22,23</sup> The prevalence of IBD varies widely from 30-200/100000 for UC and 1.2-106/100000 for CD.<sup>24</sup> The incidence of CD in western culture is estimated to be around 0.9-11.6 per 100000 per year, with a peak onset age of 20

years.<sup>22,23,25</sup> However, there are several studies that demonstrate that a diagnosis of IBD can occur at any age.<sup>26</sup>

The average per patient annual cost of care for adult (above 18 years of age) patients with CD in Europe is estimated to be around £1890- £3000<sup>27</sup>, with an overall annual cost to the NHS of up to £470 million.<sup>17,28</sup> Costs attributed to the first year following diagnosis are related to hospitalisations and diagnostic investigations, with 50-75% of the budget for managing IBD over the first 5 years of diagnosis linked to the use of biologic therapy.<sup>29</sup>

### **1.1.1 Classification of disease**

Accurate classification of CD has benefits with respect to better informing patients, assessing disease prognosis and pathophysiology, as well as guidance for choosing the most appropriate therapy.

In the past, CD has been classified based on anatomical distribution, operative history and clinical behaviours (inflammatory, fistulising or stenotic). However, this method of disease classification was deemed inappropriate for clinical application and was updated by the Vienna classification of CD in 1998.<sup>30</sup> The Vienna classification considered age of onset, disease location and disease behaviours, however was not widely used in clinical practice, but was frequently utilised by researchers.

The most commonly used classification system for CD is the Montreal classification (table 1.1), a revision of the Vienna classification.<sup>31</sup>

<b>Table 1.1: Montreal Classification of disease.</b>	
<b>Age at diagnosis</b>	<b>A1</b> <16 years <b>A2</b> 17-40 years <b>A3</b> >40 years
<b>Location</b>	<b>L1</b> Ileal <b>L2</b> Colonic <b>L3</b> Ileocolonic <b>L4</b> isolated upper disease*
<b>Behaviour</b>	<b>B1</b> Non-stricturing, non-penetrating <b>B2</b> Stricturing <b>B3</b> Penetrating <b>P</b> Perianal disease modifier
*L4 is a modifier that can be added to L1–L3 when concomitant upper gastrointestinal disease is present. “p” is added to B1–B3 when concomitant perianal disease is present.	

The Montreal classification recognises early onset of disease (<16 years of age), reflecting the body of evidence demonstrating that specific serotypes and genotypes are more frequently found in early onset CD.<sup>32</sup> There had also been some difficulties in the Vienna classification not allowing for upper GI involvement of CD to coexist with ileal and colonic disease, therefore in the Montreal classification these parameters are not mutually exclusive.<sup>33</sup> This also allows for perianal sub-classification as it has been shown that perianal involvement is not always linked with intestinal fistulising disease.<sup>34</sup>

An issue with disease classification is the observation that disease behaviour is dynamic over time. Recent studies have reinforced this, demonstrating that patients with predominant inflammatory disease behaviours at diagnosis are likely to develop either fistulising or stricturing complications over time.<sup>33,34</sup>

### **1.1.2 Clinical management of CD**

A treat-to-target approach is utilised by health care professionals (HCPs) to ensure best long term outcomes for IBD patients.<sup>35–37</sup> Assessing treatment response with more objective measures along with a wider array of biological therapies has significantly increased the projected IBD healthcare burden for the next decade.<sup>37</sup> To ensure a cost-effective IBD practice, complex and expensive pharmacological interventions should be targeted to patients most likely to benefit, and after initiation, continued assessment of efficacy should be undertaken to justify persistent use.<sup>38</sup>

#### **Medications**

There are many medications, with significant attached financial cost, used in the treatment of IBD with the aim of inducing and maintaining disease remission.

Initial treatment for active CD is the use of systemic corticosteroids.<sup>39</sup> For patients with ileocecal disease budesonide is often the initial choice, however if ineffective prednisolone is the next line of treatment.<sup>40</sup>

5-aminosalicylic acid (5-ASA) is an anti-inflammatory drug. 5-ASA is known to inhibit the production of cytokines and inflammatory mediators. However, the mechanism underlying the intestinal effects remains unknown.<sup>41,42</sup> UK data from 1990 to 2010 show over half of patients with CD were prescribed 5-ASA<sup>43,44</sup> however, oral 5-ASA has been shown to have no efficacy in maintaining clinical remission in CD.<sup>45,46</sup>

Immunomodulators such as azathioprine, mercaptopurine or methotrexate are effective in the maintenance of remission of CD.<sup>47,48</sup> Thiopurines are not used for induction of remission in active CD. Thiopurines are more effective than placebo in maintenance of remission in CD.<sup>49</sup> A systematic review and network meta-analysis



also showed the benefit of azathioprine/mercaptopurine compared with placebo in remission maintenance (OR 1.7 (95% CI 1.3 to 2.6)).<sup>50</sup>

Antagonists to tumour necrosis factor (anti-TNF), anti-integrins, inhibitors of interleukin (IL) 12/IL-23 and also biosimilar medications, are now available to treat CD. Biosimilars are biologic products similar to a previously approved originator biologic drug in terms of safety, purity, and efficacy.<sup>51</sup> These medications are increasingly being approved by global regulatory agencies in the hopes of reducing treatment costs. Anti-TNF have a wealth of research supporting their efficacy in the treatment of IBD, especially when used in combination with corticosteroids.<sup>52,53</sup> The decision to start biological therapy should consider factors such as stage of life, work absence and availability of other treatment options. Combination therapy with different classes of biologics may improve the efficacy of biologics and small molecules, although safety is an important issue when combining different immunosuppressive strategies.<sup>54</sup> Unfortunately, primary nonresponse to these medications is observed in 20–30% of patients, and another 30% of patients become refractory due to secondary loss of response.<sup>54</sup>

Janus kinase (JAK) inhibitors have been approved for use in ulcerative colitis, and are an attractive therapeutic option also in CD patients as their oral bioavailability is high.<sup>55</sup> A number of compounds have been approved for a variety of haematological and auto-immune diseases<sup>56,57</sup> However, the safety profile needs to be investigated in more detail, JAK inhibitors in CD patients has shown conflicting results in clinical trials.<sup>57,58</sup>

## **Surgery**

Indications for surgical intervention for patients with CD include obstruction, intra-abdominal or perianal abscess, enterocutaneous fistulas, and complex perianal disease.<sup>59,60</sup> Failure of effective medical management remains the most common indication for surgery in most series of patients with CD.<sup>61</sup>

Surgical conservatism is the current general rule due to the pan-enteric nature of CD leading to high reoccurrence rates.<sup>62</sup> Advances in the medical management of CD have decreased the need for surgical interventions<sup>16</sup>, however it is estimated that between 70-90% of patients will need surgery at some point during their disease.<sup>63</sup> Patients and HCPs are frequently hesitant to refer for surgical procedures. Often surgery will leave the patient with decreased health related quality of life (HRQoL) due to post-surgical indisposition.<sup>62,64</sup>

### **1.2 Living with CD**

IBD is incurable and, owing to the physical and psychological impact of the disease, significantly reduces patients health related quality of life (HRQoL).<sup>65</sup> Patients report that the factors of living with IBD that have the most negative impact on HRQoL for them are uncontrolled physical symptoms of disease such as pain, urgency and fatigue, broader impacts of symptoms on lifestyle, daily activities (including work and school), social and leisure activities, relationships and intimacy and psychological well-being.<sup>66-68</sup> Even during periods of remission patients report that they still endure impact on daily activities through regular healthcare interactions, taking medications and the psychological impact of living with a chronic health condition.<sup>68,69</sup> Altered self-image and fears about stigma caused participants to hold back sharing their diagnosis with friends, family, colleagues and employers.<sup>12,65,68,70</sup>

### 1.3 Imaging assessment of CD

The current optimal objective outcome in CD is the absence of ulceration on ileo-colonoscopy.<sup>35,71</sup> However, ileo-colonoscopy has several limitations; it is an invasive procedure associated with the risk of bowel perforation, does not allow for good quality ileal assessment, causes discomfort and is poorly tolerated by patients with a long recovery period.<sup>72</sup> Only 60% of patients grade ileo-colonoscopy as an acceptable experience, with only 75% of them willing to undergo the procedure repeatedly<sup>73</sup>; this is a problem in a chronic disease which requires repeated objective assessment.

It is standard of care in the UK for MRE cross sectional imaging assessment and monitoring of small bowel Crohn's disease (SBCD).<sup>36</sup> Waiting times for an NHS MRE may be up to 6 weeks, or in some instances longer, especially since the COVID-19 pandemic caused a backlog of referrals, with radiological reporting then undertaken at a later date. Imaging assessments are undertaken at baseline when a diagnosis of CD is established, with subsequent reassessment undertaken at regular intervals to review treatment efficacy, or more frequently should the patient experience a flare of disease or be undergoing treatment changes. Though MRE is a very accurate procedure, the complexity of reporting means it cannot provide an instant report at the point of care. Moreover, the continued use of gadolinium as contrast agent has a risk of allergy, is expensive and has been implicated with long-term brain deposition in exposed patients, although reduced use has been suggested in recent European guidance.<sup>71,74-77</sup> Further to this there is significantly less preparation required for SBUS compared to MRE, and much reduced recovery time following procedures. The scanning procedure takes much less time for SBUS than with MRE, therefore reducing the impact on time taken away from work, the need for childcare and time away from social and leisure activities.<sup>78</sup> Delayed clinical decision making whilst awaiting test results is associated with an increased

risk of disease complications and surgery, increased costs to both patients and the NHS as well as increased patient anxiety regarding health status.<sup>79–82</sup> Greater time without diagnosis and appropriate treatments may lead to irreversible damage to the intestines.<sup>53</sup> Such damage may reduce the responsiveness to medical treatments and increase the risks of intestinal surgeries. Earlier diagnosis may be associated with a better prognosis.<sup>81,82</sup>

#### **1.4 Ultrasound assessment in CD**

Small bowel ultrasound (SBUS) is an alternative to MRE for assessment of SBCD, and has the potential to significantly reduce waiting times, speed up clinical decision making, impacting the timely allocation of appropriate treatments, improving patient experience and outcomes.<sup>83</sup> SBUS is widely used for assessing and monitoring SBCD internationally, and the METRIC<sup>2,84</sup> study has demonstrated its relative diagnostic accuracy. However, SBUS is not commonly used in the NHS. Many authors report this is likely down to lack of available training for HCPs.<sup>83,85–87</sup> The NIHR-funded METRIC study (discussed further below) is the largest comparative diagnostic accuracy trial of MRE and SBUS in CD. These findings were concordant in both new diagnosis and suspected relapse.<sup>2,84</sup>

NHS tariff reports from 2022/2023 detail the cost for a MRE procedure with intravenous contrast to be £162, with a reporting cost of £22. In comparison the cost of an ultrasound assessment, including reporting, is £51, hence making it a less costly and potentially more cost-effective investigation. It would be a clinical and financial advantage to identify responders and non-responders to therapy in a timely and efficient manner, and switch patients to alternative therapies as appropriate using less expensive tests.<sup>38,71</sup> Further to all of the above, consideration of the cost to the patient of repeated lengthy follow ups is worth considering, along with associated social costs such as childcare and time away from work.

### 1.4.1 The METRIC study.

The METRIC study<sup>2</sup> presents results from a multicentre trial, which recruited 284 patients from outpatient clinics in the NHS. The study compared the diagnostic accuracy of MRE and SBUS for the presence, extent, and activity of SBCD in newly diagnosed or established disease with suspected relapse (table 1.2). All scanning was undertaken by radiologists with training in SBUS techniques. Of the recruited patients, 133 were newly diagnosed and 151 were placed in the disease relapse group. Detection rates presented by the METRIC investigators were at the upper end of estimates from previous research meta-analyses.<sup>88-93</sup> The METRIC study also indicates that there is no significant difference in clinical decisions based on magnetic MRE or ultrasound alone; in the METRIC study reports agreed with the final decision in 122 out of 158 (77%) cases and 124 out of 158 (78%) cases, respectively.<sup>2,94</sup> Following a baseline confirmation of disease, these rates of agreement are adequate for utilisation in healthcare settings.

<b>Table 1.2: Comparison of imaging modalities for SBCD assessment. (Data taken from the METRIC study.<sup>2</sup>)</b>		
	<b>SBUS</b>	<b>MRE</b>
<b>Sensitivity</b> <sup>2</sup>	92%	97%
<b>Specificity</b> <sup>2</sup>	84%	96%
<b>Preparation</b>	None	Oral and intravenous contrast
<b>Average duration of test</b>	20 minutes	45 minutes
<b>Average Waiting times (from referral to report)</b>	1-4 weeks (Range 0-8 weeks)	4-6 weeks (Range 2 days-28 weeks)
<b>Estimated NHS Cost (20/21 NHS tariff)</b>	£51.00	£162 plus £22 reporting costs

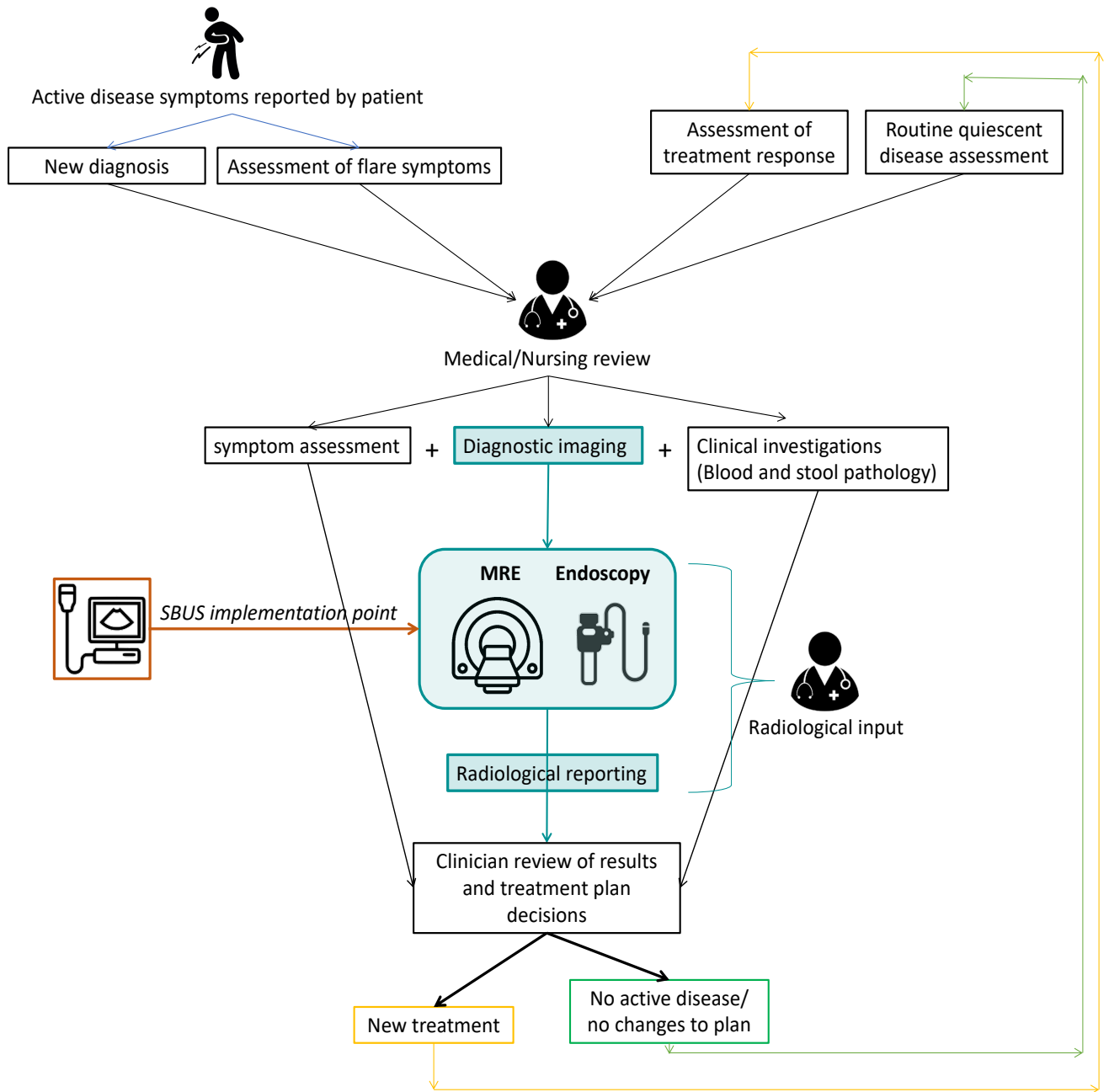
The interpretation of cost effectiveness undertaken in the MERTIC study indicated that although the probability of ultrasound being cost-effective is higher than the probability that MRE is cost-effective, there remains no significant differences in cost and outcomes overall between the two options when considered as quality adjusted life years.<sup>2,94</sup>

## 1.5 Complex interventions

There are many definitions of complex interventions.<sup>95,96</sup> Frequently these highlight that interventions have multiple interacting components, and non-linear causal pathways.<sup>95</sup> Complex interventions are often contrasted in health literature with 'simple' interventions, which are generally seen as having simple linear pathways linking the intervention and its outcome, however there is no sharp boundary between simple and complex interventions.<sup>95,97</sup> The Medical Research Council (MRC) guidance provides a detailed definition of complex interventions where the complexity of the intervention is determined by the number of interacting components; the number and difficulty of behaviours required by those delivering or receiving the intervention; the number of groups targeted by the intervention and the number and variability of outcomes.<sup>96</sup>

SBUS is considered a complex intervention for the purposes of this research, not due to the SBUS scanning process itself, but the multiple interacting parts of imaging pathways in IBD (figure 1.1), and the complex perspective with which it is being considered.<sup>98</sup> Figure 1.1 displays a simplified version of the existing imaging pathways and processes, and the stakeholders involved in the imaging and review pathways for people living with SBCD. The person experiencing symptoms of IBD enters the cycle via a need for assessment, undergoing medical review where the HCP requests and reviews results from a number of clinical investigations such as blood testing and stool pathology for inflammatory markers, assessment of symptoms from patient reports and review of diagnostic imaging results; usually MRE or colonoscopy, or both. Decisions are made by HCPs regarding treatment plans in collaboration with the patients they care for. Patients begin the relevant treatment plan, subsequently undergoing reassessment depending on their pathway, alternatively re-entering the pathway through active disease routes.

**Figure1.1: Care pathways for imaging in IBD**



## 1.6 Thesis rationale and overview

SBUS is a potentially quicker and more cost-effective test, that is more acceptable by patients when compared to MRE. SBUS has been shown to have relative diagnostic accuracy.<sup>2</sup> It remains unclear why SBUS is not readily utilised in the NHS. In order to successfully guide implementation of SBUS we first need to better understand the reasons behind why it is not currently available and gather real world feasibility data regarding SBUS implementation.

The aim of this thesis is to contribute recommendations to the development of an implementation plan for SBUS in NHS IBD services. This thesis is guided by the MRC framework for developing complex health interventions.<sup>95,99</sup> The MRC framework recommends selection of appropriate theory, identification of the evidence base and modelling process and outcomes through both qualitative and quantitative means. Identification of appropriate theory is discussed in chapter 3. Research aims were established through preliminary review of the existing literature, previous work from the METRIC study<sup>2</sup> and have been refined through the undertaking of scoping literature review (Chapter 2).

This thesis aimed to:

- I. Explore the existing evidence relating to the clinical utility of SBUS in the management of SBCD.
- II. Gather data on current use of ultrasound in the NHS for IBD assessment, and levels of interest for implementation at NHS sites that do not currently use ultrasound in IBD.
- III. Explore stakeholder perceptions of anticipated barriers and enablers to SBUS service development and implementation on wider scale.
- IV. Collect cost and resource use data through a care pathway analysis of a SBUS service for outpatients with SBCD, compared to existing MRE pathway.



### 1.6.1 Outline of the thesis

- **Chapter 2:** Clinical Utility of small bowel ultrasound assessment of Crohn's Disease in Adults: A scoping review.
- **Chapter 3:** Methods.
- **Chapter 4:** Ultrasound use to assess Crohn's Disease in the UK: a survey of British Society of Gastroenterology Inflammatory bowel disease group members.
- **Chapter 5:** Perceived barriers and enablers to US implementation in the NHS: a qualitative interview study.
- **Chapter 6:** Cost implications of SBUS implementation to an NHS IBD service.
- **Chapter 7:** Discussion and conclusions.

### 1.7 Chapter 1 Summary

This chapter has introduced IBD, CD and the standard assessment and management currently available in NHS IBD services. IBD is a long-term condition which requires repeated disease monitoring via medical imaging, where repeated burdensome medical investigations negatively impact on patients HRQoL. SBUS has been shown to be similarly accurate when compared with MRE, has the potential to be quicker, less costly and improve patient experience of IBD care, but it is not routinely used in NHS IBD care. There is evidence to suggest patients prefer SBUS compared to MRE, rating it was more acceptable and are more willing to undergo reassessment. This thesis will present a series of studies, undertaken to explore why this is the case, informing the development of key concepts to contribute to the development of an implementation package for widespread adoption of SBUS in NHS IBD services.

## **Chapter 2: Clinical utility of small bowel ultrasound assessment of Crohn's Disease in adults: A scoping review**

### **2.1 Introduction**

Chapter 1 introduced the possibility that SBUS may be a useful healthcare tool in NHS IBD care. There is a lack of evidence considering the use of SBUS in the NHS, however it is used internationally as a first line imaging modality in IBD care.

Chapter 2 will report a scoping review exploring clinical utility of SBUS, the main aim of this review being to identify factors related to the application of SBUS into clinical practice in the NHS. This review has been published in a peer review journal.<sup>100</sup>

Due to the vastness of the existing evidence related to the use of intestinal ultrasound globally, it was decided that a scoping review, rather than a systematic literature review, was more appropriate.<sup>101-103</sup> Scoping reviews are a type of evidence synthesis that aims to systematically identify and map the breadth of evidence available in a topic, often irrespective of source, within or across contexts.<sup>104</sup> A systematic literature review was not deemed as appropriate for addressing this research question as the precise and narrowed down nature of a systematic review of the literature would have limited the focus of the review too much in a way that would have detracted from the aims of the review, in the opinion of the researcher, with agreement from the supervisory team. Furthermore there has been recent Meta-analyses relating to the use of ultrasound in IBD, therefore there was little merit in repeating similar analyses.<sup>88,89,105-107</sup> For this review the topics identified and extracted were coded and then grouped into themes in relation to factors of clinical utility.

### **2.2 Clinical Utility**

Like any healthcare technology or intervention, diagnostic tests such as SBUS should be thoroughly evaluated before introduction into routine practice.

Increasingly, decision makers and other users of diagnostic tests request more than simple measures of a test's analytical or technical performance and diagnostic accuracy. Evaluation of the intervention and how it leads to health benefits, and assessment of the extent to which interventions can be applied successfully and cost effectively are just as important.<sup>108</sup>

Clinical utility can be described as a multi-dimensional judgement about the usefulness, benefits and drawbacks of an intervention. A judgement about the clinical utility of a new technology or technique involves asking whether the innovation is appropriate, accessible, practicable, and acceptable for the purposes of the task intended.<sup>109–111</sup> For diagnostic tests such as ultrasound, accurately identifying patients with suspected disease is a necessary condition for clinical utility<sup>112</sup>, this has previously been addressed by the METRIC study.<sup>2</sup> However, identification of disease does not equate to health benefit; clinical context, severity, clinical consequence and management strategies may vary across cases. The type of evidence of clinical utility must be flexible to accommodate a wide range of questions about the potential benefit, and drawbacks, of SBUS.<sup>113</sup>

Concerns about effectiveness and economics are also joined by matters of work practice when considering clinical utility. Work practice includes everyday matters that may affect feasibility of an intervention. Questions about how an innovation 'fits' into the existing treatment pathway may be asked by HCPs. In most cases, improvements in health outcomes from diagnostic testing will be generated by the way test results are used to guide downstream management. It is possible that a test has clinical utility without improving the primary health outcomes targeted by subsequent treatment. If the introduction of a test leads to health outcomes

comparable to those obtained with current standard of care practice, but these outcomes are achieved in a way which is more acceptable to patients, there may be clinical utility.<sup>108</sup>

Clinical utility is frequently a matter of judgement depending on a stakeholder's perspective of the supporting evidence.<sup>113,114</sup> Previous work by authors such as First *et al*<sup>115</sup> combined factors of effectiveness and economics, and also included matters of work practice. Work practice includes everyday matters that may affect feasibility.<sup>109</sup>

The model of dimensions of clinical utility presented by Smart<sup>109</sup> (Table 2.1) is useful in that it encompasses elements of work practice alongside other factors such as economic considerations, stakeholder acceptability and future planning for interventions and services. It was used to guide this research so as to utilise a robust definition of clinical utility, but also to incorporate widespread factors of clinical utility to include as much information as possible to best inform downstream research work.

<b>Component</b>	<b>Aspects</b>	<b>Issues considered</b>
Appropriate	Effective Relevant	Formal evidence Existing treatment process Disruption to current care pathways Clinical decision making.
Accessible	Resource implications Procurement	Cost effectiveness Availability of resources Finance processes
Practicable	Functional Suitable Training or Knowledge	Are the materials, methods and practices adequate and working in the current context? Potential future needs Training needs Work practice boundaries
Acceptable	To Clinician To Patients, Families/Carers To stakeholders/public	Ethical, legal, social or psychological concerns that may affect practice, treatment process or acceptance. Preferences about service delivery.

### **2.3 Methods**

A preliminary search of MEDLINE, the Cochrane Database of Systematic Reviews and Joanna Briggs Institute evidence synthesis was conducted and no current or underway systematic reviews or scoping reviews on the same topic were identified at that time. Methods for this study were developed based on Arksey and O'Malley's<sup>102</sup> scoping review methodology, and Levac *et al*<sup>116</sup> methodological enhancement. Presentation of literature searches, literature selection, PRISMA-SCR<sup>117</sup> diagram and data extraction follows JBI guidance for scoping reviews.<sup>117,118</sup>

Through consultation with the supervisory research team and preliminary searches, the overall main research question developed was defined as: "What evidence is currently available on the clinical utility of ultrasound for the diagnosis and management of SBCD?". The initial literature search was conducted on 18<sup>th</sup> October 2020, with a subsequent literature search and review update undertaken on 31<sup>st</sup> October 2022

#### **Inclusion and exclusion criteria**

The literature search included any type of study design, including primary research, systematic reviews and meta-analysis. In addition, nonindexed and grey literature were also considered. Searches of electronic databases of the published literature included: MEDLINE, EMBASE, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and PsycINFO. Searches were also conducted of clinicaltrials.gov for current clinical trials, 'TRIP' and Epistemonikos. Reference lists of included studies were hand searched to identify additional sources of relevance.<sup>119,120</sup>

Terms were searched for as both keywords in the title and/or abstract and subject headings (MeSH) as appropriate. Search terms (Table 2.2) were determined

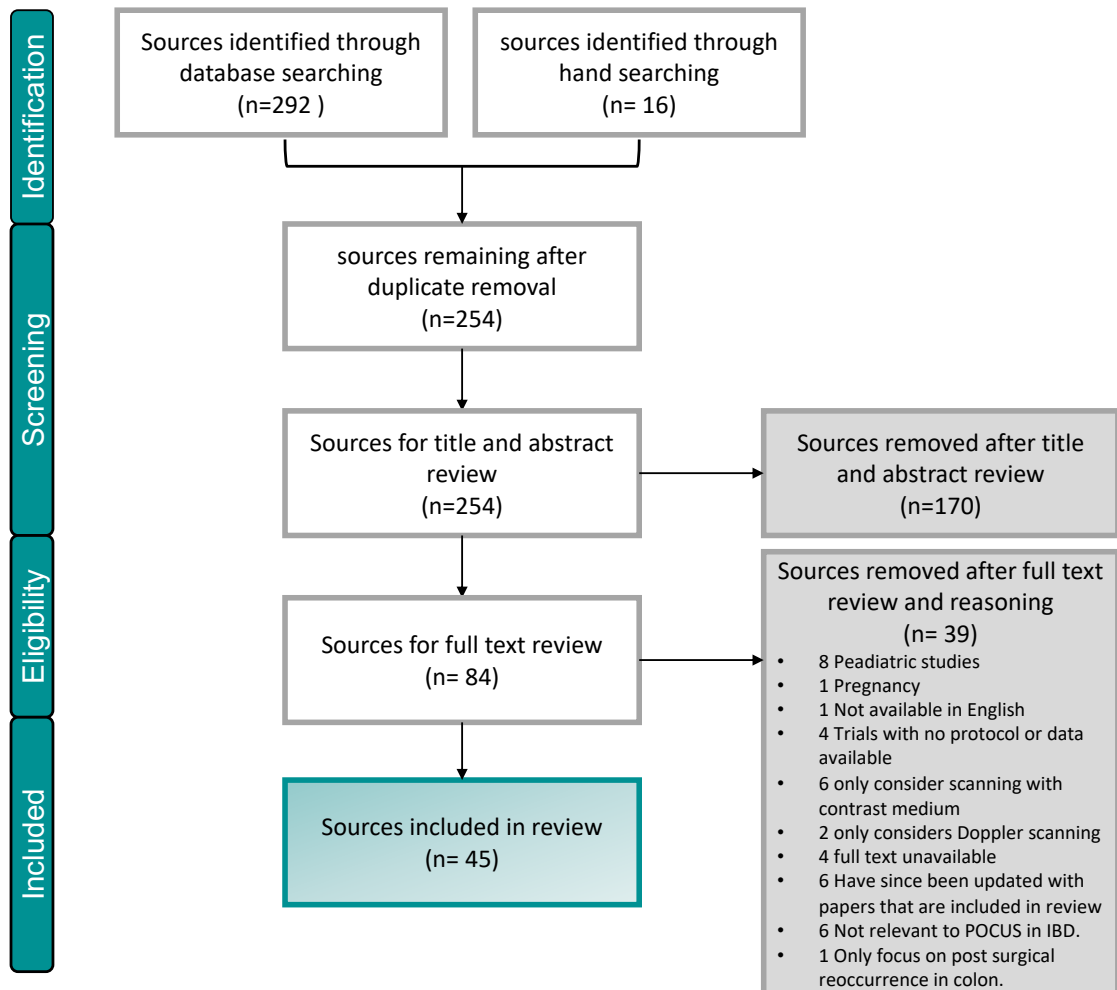
through consideration of previously reviewed literature and preliminary searches of Google Scholar. The Boolean operator 'OR' was used within each facet to maximise the searches, with the operator 'AND' used between facets to combine terms, truncation of terms was used to be as inclusive as possible during searches. Searches were performed with the 'suggested search terms' and 'explode' selection, and restricted to 'human', 'adult' and 'English language' publications. No date limits were applied to be as inclusive as possible. Exclusion criteria were sources not available in the English language. Paediatric studies were not included in this review as although there is vast evidence in this area, this research focuses on the utilisation of ultrasound in Adult IBD service.

Table 2.2: Key search terms		
Crohn's Disease (MeSH)	Small Bowel	Ultrasound (MeSH)
Crohn's Disease	Ileal	Ultrasound
Crohn's	Ileum	US
CD	Ileitis	Sonography
Crohn*		Echography
Inflammatory bowel disease		Point of care ultrasound
IBD		POCUS
		Ultrasonography

The review process consisted of two levels of screening: (1) title and abstract review and (2) full-text review. For the first level of screening, two investigators (Shellie Jean Radford and Professor Gordon W. Moran (primary academic supervisor) independently screened the title and abstract of all retrieved citations against inclusion criteria. No formal quality appraisal process was undertaken; however, quality of sources was considered informally when reporting findings. Through discussion between the two authors a ranking of quality was assigned to each source (low, medium, high) which was used as a way to interpret and combine data from each source in relation to the reliability of the findings. Secondly, the two investigators each independently assessed the full-text articles to determine if they met inclusion criteria. There were no disagreements about study eligibility at the full-text review stage that required discussion with a third investigator. Reasons for

exclusion of full text sources that were recorded and reported in the PRISMA<sup>117</sup> flow diagram (Figure 2.1). A narrative synthesis was conducted in order to explore relationships within and across the included sources.

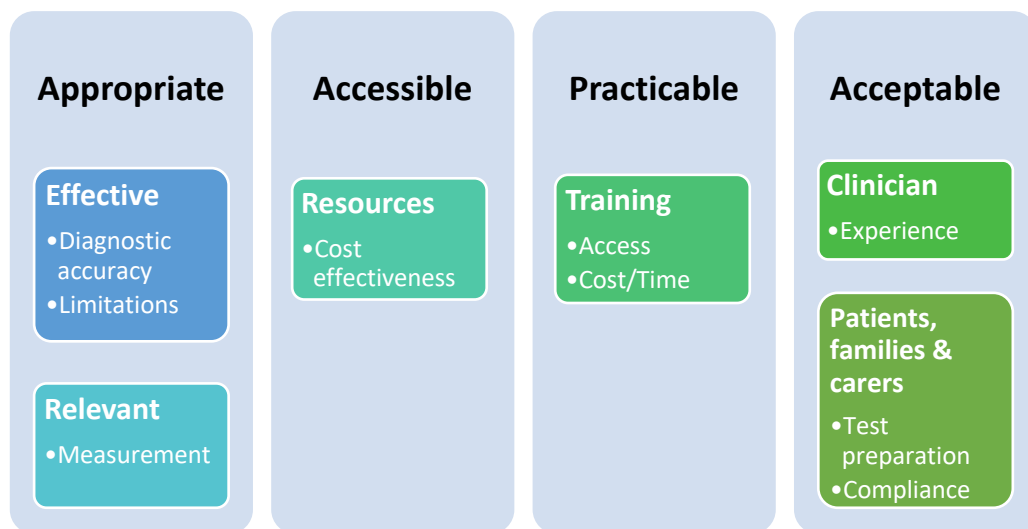
**Figure 2.1: PRISMA<sup>117</sup> flow diagram**



## 2.4 Results

The review included 45 sources (appendix a) consisting of ten literature reviews, six clinical practice reviews (one including a case report), four clinical practice guidelines, 19 cross-sectional research studies of various designs, one case series, three cohort studies, one national survey and one Delphi survey. Sources were from the UK, Europe (Italy, Germany, France, Spain, Hungary, Denmark, Netherlands), Israel, Japan, Canada and the USA. Sources were reviewed and data were coded, extracted and grouped together into themes guided by the factors of clinical utility presented by Smart<sup>109</sup> in table 2.1. There were nine codes, six-sub themes and four themes identified through review of the data (Figure 2.2).

**Figure 2.2: Themes and Codes.**



A common statement across 26 sources was that ultrasound is a non-invasive test that is acceptable and well tolerated by patients, is safe and is inexpensive.<sup>71,83,86,93,121–140</sup>

In central Europe, Canada and some parts of the USA, ultrasound is widely used, usually performed by gastroenterologists, specialised gastrointestinal radiologists or



sonographers.<sup>140</sup> Outside of the UK, the widespread availability, improved quality and more affordable technology, and the increasing expertise of practitioners, has boosted the uptake of ultrasound for assessing patients with CD.<sup>2,135,138,141</sup> The benefits of ultrasound being performed by a member of the clinical IBD team are increased capacity for real time interpretation of results, expediting decisions concerning disease management and strengthening the rapport between medical teams and the patients in their care through real-time conversations, explanation of clinical results and shared decision making.<sup>83,92,134,139,140</sup>

Ultrasound and MRE both achieve high diagnostic accuracy for the extent and activity of SBCD in newly diagnosed and relapsed CD.<sup>137</sup> A non-inferiority diagnostic study of an adult population of 249 patients with suspected CD, where 120 patients (48%) later had confirmed CD, indicated that ultrasound and MRE had comparable diagnostic accuracy in CD detection in terms of sensitivity (94% vs 96%) and specificity (97% vs 94%).<sup>142</sup>

The METRIC study, a prospective UK multicentre trial enrolling 284 CD patients, showed that both ultrasound and MRE had a diagnostic accuracy above 90% for detecting SBCD. Sensitivity of SBUS for small bowel disease presence and extent were 92% and 70% respectively.<sup>2</sup> The study found substantial agreement for the presence of SBCD in newly diagnosed patients, and patients with suspected relapse. There was substantial sonographic agreement for the presence of SBCD, both in newly diagnosed and relapsed disease.<sup>84</sup> Agreement for SBCD extent was inferior to that of presence alone; this is in contrast to previous work by Parente *et al*<sup>143</sup>, who reported near perfect agreement for segmental localisation between two experienced sonographers. Ultrasound has also been shown to have high sensitivity and specificity in the detection of CD complications such as stenoses, fistulas or abscesses.<sup>2,71,124,126–128,135,140,144–147</sup>

Ultrasound does have some limitations when used to assess SBCD. Higher body mass index can reduce image quality, although this partly offset by improved probe and software technology. While bowel gas may reduce sensitivity, carefully graded compression and meticulous scanning technique can overcome this.<sup>86</sup>

The most prominent parameter for the detection of inflammation used throughout the reviewed sources was bowel wall thickness (BWT), which correlates well with clinical disease activity markers such as the Harvey Bradshaw Index (HBI) and the CD activity index (CAI).<sup>71,83,92,93,121,123–128,130–133,136–139,141,148–152</sup> The exact BWT that is considered to be pathological is still a matter of debate. The most common cut off value was BWT exceeding 3mm being considered pathological and a BWT of 2mm or less considered normal for the small bowel.<sup>135,136,149</sup> Any increase in the cut off value of BWT will increase sensitivity but also subsequently decrease the specificity of detecting SBCD.<sup>139,149</sup> Using a cut off level of 3mm to represent normality, provided a sensitivity and specificity of 88% and 93% respectively, whereas when a cut off level of greater than 4mm was used, sensitivity was 75% and specificity 97%.<sup>138,141,153</sup>

A number of ultrasound scores have been developed, but most lack validation, are overly complex, were developed from small sample sizes or are limited to quantification of damage or the risk of surgery.<sup>131,154,155</sup> Novak *et al*<sup>131</sup> have developed a promising, simple ultrasound score for identifying CD activity comparing BWT to endoscopic activity, however the results reported have not yet been externally validated.<sup>131</sup> Intestinal ultrasound has been shown to be significantly correlated with measures of disease activity in the terminal ileum in comparison to MRI scoring tools such as the MARIA score.<sup>144</sup>

Multiple authors suggest that ultrasound may have a role as a useful examination for predicting disease course monitoring the response to treatment in CD patients.<sup>92,129,133,138,156</sup> Opportunity for detecting transmural healing has been shown by Paredes *et al*<sup>157</sup> who used ultrasound for assessing changes induced with an anti-TNF therapy in patients with CD. The study reported a significant reduction in BWT in patients receiving anti-TNF therapy, however the study reports that 'resolution' of inflammation visible on ultrasound was only achieved in 29% of subjects.<sup>138</sup> Results from Ripolles *et al*<sup>151</sup> showed that ultrasound may be able to predict that the one year response to anti-TNF therapy after 12 weeks of treatment with 85% (22/26) of patients showing a sonographic response at 12 and 52 weeks.

The METRIC<sup>2</sup> study found no major difference between MRE and ultrasound on therapeutic decision-making. Both tests agreed with a final therapeutic decision based on all tests in more than 75% of cases. Very little further investigation into the impact of the use of ultrasound on the clinical decision-making behaviours of clinicians has been undertaken.

Multiple sources refer to ultrasound being inexpensive, though there is little empirical evidence within the included sources to support this claim.<sup>2,86,126-129,158</sup> The METRIC<sup>2</sup> study presents data on a cost-utility analysis of MRE vs ultrasound indicating a trend towards ultrasound over MRE. However, given the small non-significant differences in costs and quality adjusted life years between the two options, it was not possible to endorse ultrasound or MRE on cost-effectiveness grounds.

Initial results from Grunshaw<sup>86</sup> indicate that in almost half of the cases they discussed, scans were performed and reported within 7 days, compared to the typical referral-reporting time of MRE of 6-12 weeks. Many centres have standalone IBD ultrasound lists.<sup>140</sup> The single site study from Luber *et al*<sup>144</sup> describes the

potential cost saving through the appropriate use of intestinal ultrasound when compared to MRE and ileocolonoscopy patient pathways. Due to the single site nature of the study, it is difficult to ascertain the generalisability of these findings. This study also identified that there were a significant proportion of patients undergoing both MRE and ileocolonoscopy where the same clinical diagnosing information could have been gleaned from undertaking intestinal ultrasound.

In centres operating ultrasound clinics, appointments typically last around 15-20 minutes, and requires minimal preparation.<sup>86,152</sup> Following the scan the report is immediately available, allowing for immediate decision making in some instances.<sup>86</sup> Patients requiring consultant review were able to be identified at the point of ultrasound examination.<sup>86</sup>

Throughout the included sources the results reported were from ultrasound being performed by individuals with extensive experiences of ultrasound.<sup>86,121-123,125-127,132-134,150,151,159</sup> For example, Taylor et al<sup>2</sup> reports that the team involved in the METRIC study had an average of 8 years (4-11 years) experience of interpreting ultrasound.

The Canadian association of gastroenterology and British society of gastroenterology (BSG), advocate the use of ultrasound to ascertain disease activity state, however both note that the ultrasound testing is operator dependant.<sup>158,160</sup> Multiple authors have speculated this is due to lack of training availability and the substantial training and experience requirements of those performing the test.<sup>138,160</sup> There is a reportedly long learning curve to develop competent ultrasound skills in gastroenterology.<sup>86,141,159</sup> However some authors suggest that gastroenterologists are equipped with the knowledge and dexterity to rapidly acquire ultrasound competency.<sup>83,140,159,161</sup> Interobserver agreement between sonographers with

variable experience in ultrasound has been reported in a few preliminary studies showing satisfactory results.<sup>84,121–123,138,140,149,159</sup> Initiatives such as European Crohn's and Colitis organisation (ECCO) imaging workshops and standardised training curricula developed by the international Bowel Ultrasound Group (IBUS) offer opportunities for training.<sup>152</sup> Intestinal ultrasound has been included in the training programme in several medical schools.<sup>162</sup> Training costs were not explored throughout the sources.

Patients experiences and perceptions of test burden and levels of physical and psychological discomfort can impact on compliance, even if the test is diagnostically superior to alternatives.<sup>73</sup> Ultrasound is very well tolerated and patients prefer to be assessed with ultrasound rather than with endoscopic procedures or other more invasive imaging techniques such as MRE.<sup>71,83,86</sup>

Recovery time for MRE scanning has been shown to be significantly longer than ultrasound.<sup>73</sup> The proportion of participants willing to repeat MRE was 127/147 (91%). This was lower than for ultrasound where 133/135 (99%) were happy to repeat the test.<sup>73</sup> Overall 128/145 (88%) patients rated MRE as very or fairly acceptable, while 144/146 (99%) participants rated ultrasound as very or fairly acceptable. Acceptability of the test was discussed in terms of test burden and the willingness to undergo repeated assessments as required with routine follow up in IBD. Issues reported by patients concerning MRE mainly reflected ingesting contrast, repeated breath holds and the after-effects of contrast such as diarrhoea and bloating. Nearly half of the patients (49%) reported ultrasound as being fine, with no least acceptable part of the imaging process.<sup>73</sup> One important result was that patients rated diagnostic accuracy as the most important attribute and more important than the challenges related to investigations.<sup>2,73,84,163</sup>

None of the included sources presented findings related to preferences of clinician or patients as to where and when ultrasound should be delivered. Grunshaw<sup>86</sup> described how a direct booking service and dedicated ultrasound slots reduced waiting times and improved patients experiences, but there was no comparison between outpatient ultrasound clinic appointments and point of care ultrasound use. Aside from the findings relating to the differences between ultrasound examination being undertaken by gastroenterologists or sonographers, there were no further findings regarding who, i.e. which HCP, should undertake the ultrasound examinations.

## 2.5 Discussion

The treat-to-target paradigm present in IBD management guidelines is similar in other chronic diseases.<sup>17,164–166</sup> Management strategies in CD reflect a step-up paradigm, where patients clinical symptoms in conjunction with markers of inflammation tend to guide investigation or medical intervention.<sup>134,167</sup> Patient symptoms do not necessarily correspond to inflammatory activity and current guidelines recommend that management should be based on objective evaluations.<sup>53,158,160</sup> Mucosal healing, defined by the absence of ulcerations, is recommended as the therapeutic goal in clinical practice.<sup>35,36,160</sup> The current standard for assessing SBCD is MRE, however it is expensive, time consuming and a challenging investigation for patients to tolerate.<sup>76,77</sup>

Meta-analyses suggest that MRE and ultrasound have similar accuracy for diagnosing and staging SBCD.<sup>88,89,105–107</sup> Ultrasound could be a good alternative to more invasive and expensive imaging techniques. Besides being quick, well tolerated, relatively inexpensive and readily available, ultrasound is reported and interpreted at the time of scanning and allows for early clinical decision-making in routine IBD care.<sup>83,140,144</sup>

Multiple sources referred to ultrasound as inexpensive.<sup>71,83,86,93,121–140</sup> However none of the included sources presented comprehensive data relating to cost or cost effectiveness of ultrasound. Therefore, more data on the cost, cost effectiveness and cost–benefit of ultrasound are needed to support the embedding of ultrasound in IBD services.<sup>83</sup>

Ultrasound is often seen as having limited clinical utility due to operator dependence.<sup>140</sup> However, every diagnostic technique, including endoscopy, has a degree of subjectivity and operator dependence and this criticism is perhaps more reflective of a previous lack of identifiable international performance and training standards.<sup>140</sup> The training needs for gastroenterologists are currently met with international training schools, however there could be UK based national training schemes to meet the needs of gastroenterologists, particularly if supported by abdominal radiology specialists and in partnership with radiology departments.<sup>83,86,140</sup> There is no current literature relating to any other IBD healthcare worker undertaking ultrasound training.

There are several scoring systems for disease activity assessment using ultrasound in CD, however until recently none had been completely validated.<sup>149,168,169</sup> The most widely used scoring system is the Limberg score incorporating BWT and vascularity.<sup>170,171</sup>

It would seem prudent to investigate broader stakeholder perceptions of the use of ultrasound in order to better understand perceived or potential barriers and enablers to ultrasound implementation in the world-wide healthcare systems and recognise and manage preferences for future service delivery.

## **2.6 Limitations**

Scoping reviews do not formally evaluate the quality of evidence gathering information from a wide range of study designs and methods, providing a descriptive account of available information leading to broad overview of the available literature rather than in-depth analysis. The scope of background information collected, disease activity levels, depth of data relating to ultrasound and its use in IBD appears to vary between sources, making comparison challenging. Some sources included in this scoping review were older (initial publication of more than 10 years ago), this was considered when gauging quality and it was noted that this work will have been advanced on since its initial publication. The outcomes represent an accurate response to the research question. Continuous conversations between authors occurred throughout to ensure a unanimous decision regarding article searches, thus limiting any potential bias.

## **2.7 Conclusions**

Ultrasound has been shown to be similarly accurate when compared to MRE in detecting presence and extent of SBCD. Ultrasound is reported as quicker, more acceptable and safer when compared to MRE. Ultrasound is used widely in central Europe and Canada but has not yet been embraced in the UK. The resources



required in terms of equipment, are readily available in most NHS hospitals, and training needs for gastroenterologists would be manageable through utilisation of international training courses. Future work to develop a national training programme in the UK would be advantageous in furthering the adoption of the use of ultrasound in NHS IBD services.

Multiple sources reported ultrasound as an inexpensive test, however there is scant literature to support this. Further research in this area would better inform decision makers regarding future intervention implementation. Ultrasound is reported as having positive influence on clinical IBD practice through expediting clinical decision making, but there is no evidence relating to the impact on the nature of clinical decision making by HCPs. Further research in this area would help us to better understand the impact of US on daily clinical practice, ultimately leading to better understanding of practicable and acceptable aspects of clinical utility.

Ultrasound was considered highly acceptable by patients when compared with MRE, however further exploration of experiences, perceptions and perceived barriers and enablers to ultrasound implementation in the NHS is warranted. This information will help guide researchers to areas of focus to successfully implement ultrasound as an NHS service for patients with SBCD.

## **2.8 Chapter Summary**

The clinical utility of SBUS has been investigated and it has been shown that SBUS has similar accuracy to MRE, SBUS is used widely in central Europe and Canada in IBD care and there is no difference in clinical decision making. This review did not highlight any certain barriers to the use of SBUS in the NHS but did indicate that

there are areas for further investigation. Areas that require further investigation and clarification are the perceptions of stakeholders in relation to the use of SBUS, the readiness of NHS IBD services to implement and sustain the use of SBUS and the impact of SBUS on the existing care pathways in NHS IBD services. The following chapters will explore these topics more in depth. Chapter 3 presents the methods, and methodologies, utilised to investigate these topics in more depth. Chapter 4, 5 and 6 will present the research studies undertaken.

## **Chapter 3: Methods**

### **3.1 Introduction**

The previous chapters presented an overview of CD clinical assessment and management to give a foundation for the rest of the thesis. Chapter 1 highlighted

the need to better understand the reasons why SBUS is not currently utilised in IBD care. Chapter 2 explored current literature and presented factors of clinical utility of SBUS in the management of CD. This literature review identified areas for further research to better understand the best ways to support implementation of SBUS. This chapter presents the thesis aims, objectives, research plan and methods used to reach the thesis objectives. The research undertaken in this thesis contributes key concepts to the development of an implementation plan for SBUS in the NHS.

### **3.2 Thesis aims and objectives.**

This thesis aim was to provide insight on how best to support the implementation of SBUS in practice by collecting information about current national usage and appetite for SBUS uptake, stakeholder perceptions of the adoption of the intervention by health services and the potential impact of use of SBUS on care pathways in routine CD care. In order to achieve these aims, this thesis addressed the following objectives:

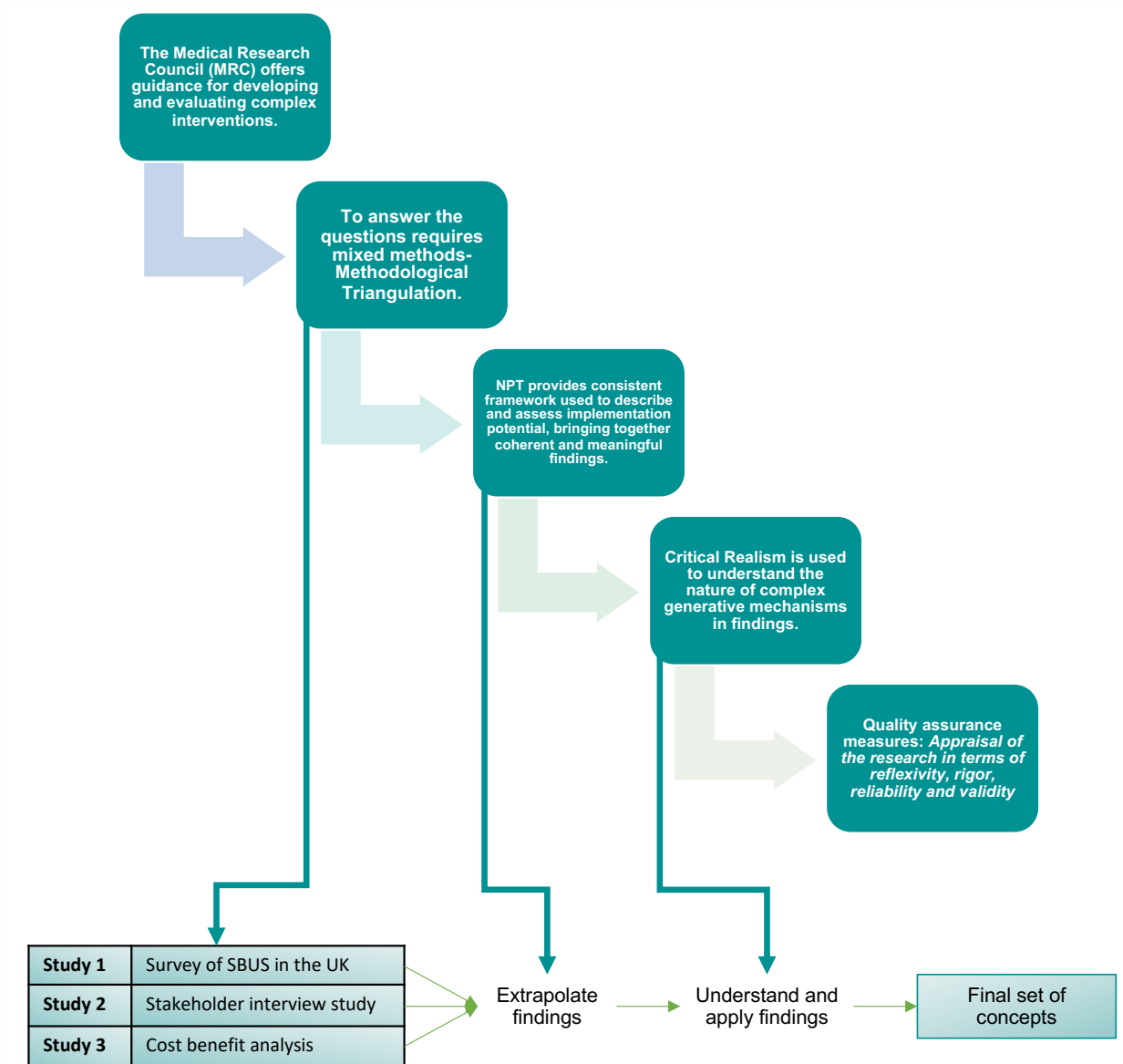
- I. Assess the clinical utility of SBUS through undertaking a systematic scoping literature review.
- II. Investigate the current usage of SBUS in the UK and gauge enthusiasm for SBUS in IBD care by undertaking a survey with national groups of gastroenterologists and IBD specialists.
- III. Explore stakeholder perceptions of SBUS and the process of its implementation through undertaking a qualitative interview study.
- IV. Better understand the impact of the implementation of SBUS on NHS care delivery through undertaking a cost implications analysis.

### **3.3 Methodology**

This thesis consists of a number of interconnected elements. These elements are underpinned by a number of concepts which help us to navigate the insight generated. Figure 3.1 displays the methodological principles, processes and tools

being utilised to collect, analyse, integrate and interpret research findings throughout this thesis. These will be discussed in more detail later in this chapter.

**Figure 3.1: Methodological processes**



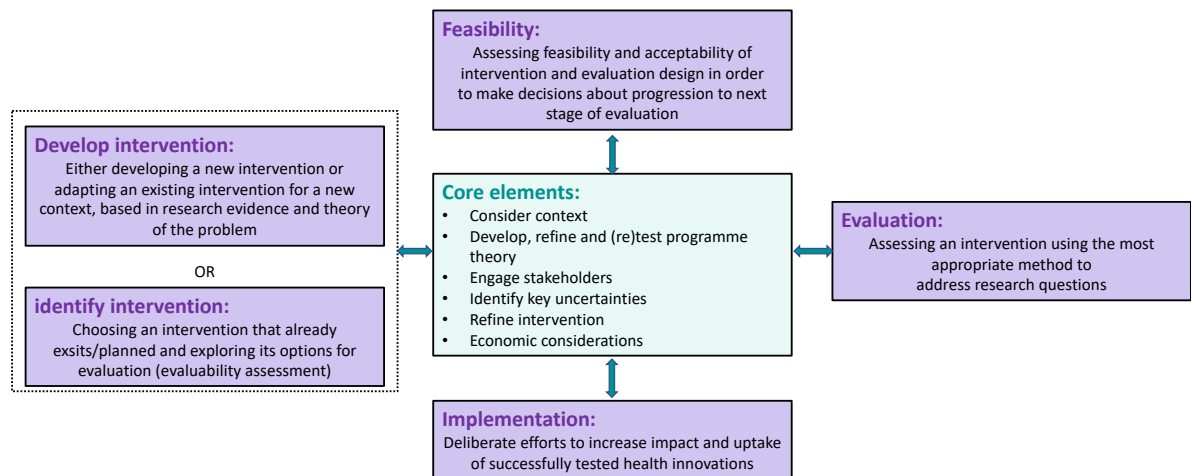
### 3.3.1 Medical Research Council guidance

The Medical Research Council (MRC) offers guidance for developing and evaluating complex interventions. It argues that only through close scrutiny of causal mechanisms will it be possible to develop effective interventions and

understand how results and findings might be translated across settings and populations.<sup>95,99</sup> Given the comprehensive knowledge on development and feasibility phases provided by the MRC framework, it was selected as the schema for this thesis.

The MRC framework<sup>99</sup> divides complex intervention research into four phases: development or identification of the intervention, feasibility, evaluation, and implementation (figure 3.2). Each phase feeds back findings and results into the core elements central section. This research will present findings from the ‘feasibility and piloting’ stage of the framework.<sup>95,172</sup> Research may take place at any point in the MRC framework depending on the key uncertainties about the intervention being studied.

**Figure 3.2: Framework for developing and evaluation of complex interventions.**<sup>99</sup>



Due to the long history of ultrasound in medical practice, the various medical uses of ultrasound have been through the MRC cycle numerous times. SBUS is not currently used in the NHS as part of routine SBCD care. Some of the processes of applying SBUS to the context of IBD care have already been worked through, in

such studies as the METRIC study<sup>2</sup>, as previously discussed. Here is presented another process of the cycle as SBUS is considered for wider application in outpatient IBD care in the NHS on a national level. The key challenge requiring investigation is how to best prepare for and support implementation of SBUS in NHS IBD services. This will involve exploratory study work with a mixture of qualitative and quantitative study methods, considering outcomes at different levels, not just at the level of the individual, but also the community and organisational level.<sup>173,174</sup> Mechanism of implementation is most frequently examined through testing and refining causal assumptions through combining quantitative assessments of pre-specified variables and qualitative investigation of stakeholder responses.<sup>172,175</sup> This allows identification of unanticipated pathways and an in-depth exploration of pathways which are too complex to be captured quantitatively.<sup>176</sup>

The term 'implementation' is used within the literature to describe both post-evaluation scale up, and delivery of an intervention during a trial.<sup>95</sup> The MRC guidance states that, where possible, economic evaluation should be undertaken, as this makes results more useful for decision makers.<sup>177,178</sup> The main purpose of an economic evaluation is estimation rather than hypothesis testing, so therefore it is worth undertaking even if it cannot provide clear cost differences.<sup>179–181</sup>

Implementation is a critical stage of the MRC framework which to be successful requires careful planning, ensuring that the intervention can be repeated and maintained over time.

### **3.3.2 Normalisation process theory**

The MRC guidance suggests that there is value in utilising theory-based approaches to assess what works in which circumstances and how.

Normalisation process theory (NPT) is a widely utilised theory of implementation that can be used to explain the processes by which an intervention becomes, or indeed fails to become, normalised into routine practice.<sup>182</sup> Therefore it is ideal to address the research in question, where the challenges faced are service integration and normalisation. It offers a framework for assessing the conditions in which interventions become practically workable in healthcare. This research will use NPT in order to guide the structure of the initial research design, sampling and data collection plan. NPT will be used to evaluate the findings to better understand the current status and factors that influence the implementation process of SBUS.

NPT is a theory of implementation that focuses on what people, both individuals and groups, do rather than what they believe or intend.<sup>183-187</sup> A large body of literature that employs NPT to inform feasibility studies and process evaluations of complex healthcare interventions has now emerged.<sup>186,187</sup> NPT identifies factors that foster and inhibit the routine incorporation of complex interventions into everyday practice.<sup>183,188</sup> It also explains how these interventions work, looking not only at early implementation, but beyond this to the point where an intervention becomes embedded into routine practice, i.e., it is 'normalised'.<sup>189</sup> 'Normalisation' is defined as the embedding of an intervention as a routine element of clinical practice and focuses on how this comes about through the 'work' of implementation.<sup>186</sup>

There are four components to NPT; coherence, cognitive participation, collective action and reflexive monitoring which are displayed in table 3.1, which has been recreated by the researcher for this thesis.<sup>186</sup> These components are not linear, but are in dynamic relationships with each other and with the wider context of the intervention, such as organisational context, structures, social norms, group processes and conventions. Each component looks at how the intervention is implemented and 'normalised' through engagement with those using or coming into contact with it, or 'participants'. 'Coherence' is concerned with finding meaning and

sense making by participants. 'Cognitive participation' considers commitment and engagement by participants, where 'collective action' describes work participants do to make the intervention function. 'Reflexive monitoring' participants reflect on or appraise the intervention.

<b>Table 3.1 Components of NPT in implementing complex interventions<sup>186</sup></b>	
<b>NPT components</b>	<b>Questions to consider within the NPT framework</b>
coherence	<ul style="list-style-type: none"> <li>○ Is the intervention easy to describe?</li> <li>○ Is it clearly distinct from other interventions?</li> <li>○ Does it have a clear purpose for all relevant participants?</li> <li>○ Do participants have a shared sense of purpose?</li> <li>○ What benefits will the intervention bring and to whom?</li> <li>○ Will these benefits be valued by potential participants?</li> <li>○ Will it fit with the original overall goals and activity of the organisation?</li> </ul>
Cognitive Participation	<ul style="list-style-type: none"> <li>○ Are target groups likely to think the intervention is a good idea?</li> <li>○ Will they see the point easily?</li> <li>○ Will they be prepared to invest time, energy and work in it?</li> </ul>
Collective Action	<ul style="list-style-type: none"> <li>○ How will the intervention affect the work of user groups?</li> <li>○ Will it promote or impede their work?</li> <li>○ What effect will it have on consultations?</li> <li>○ Will staff require extensive training before they can use it?</li> <li>○ How compatible is it with existing work practices?</li> <li>○ What impact will it have on division of labour, resources, power and responsibility between different professional groups?</li> <li>○ Will it fit with the overall goals and activity of the organisation?</li> </ul>
Reflexive monitoring	<ul style="list-style-type: none"> <li>○ How are users likely to perceive the intervention once it has been in use for a while?</li> <li>○ Is it likely to be perceived as advantageous for patients or staff?</li> <li>○ Will it be clear what effects the intervention has had?</li> <li>○ Can users/staff contribute feedback about the intervention once it is in use?</li> <li>○ Can the intervention be adapted/improved on the basis of experience?</li> </ul>

Normalisation is not an evaluation of effectiveness nor quality. Normalisation is only one possible outcome of collective action. Others include adoption, where a complex intervention is taken up but does not become routinely embedded in everyday work; and rejection, where users disregard or otherwise refuse a complex intervention. De-normalisation may also occur during the lifetime of a complex intervention when a previously normalised intervention is superseded.<sup>186</sup>

### **3.3.3 Mixed methods research**

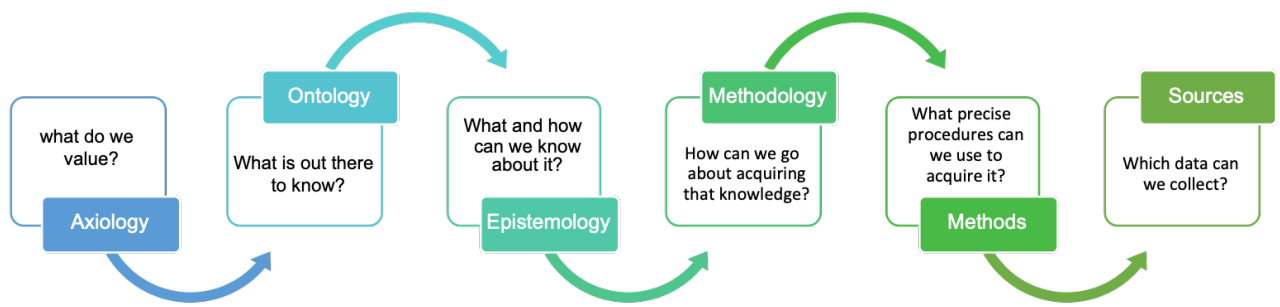
MRC guidance encourages the incorporation of different types of data which establish varied findings and meanings, providing different insights to enhance our



understanding of the best way to support implementation of healthcare interventions.<sup>190</sup> This research will employ a combination of qualitative and quantitative methods in order to collect these varied types of data in order to reach multiple research aims.<sup>14</sup> Combining quantitative and qualitative methods data is recommended by the MRC to develop a comprehensive analysis of the data to investigate influences impacting implementation.<sup>95,96,172,191,192</sup> The strength of quantitative methods is that they may be used to develop reliable descriptions and provide accurate comparisons of those things that can be observed and measured.<sup>193</sup> The strength of qualitative methods is that they are open ended, allowing themes to be generated during the course of an inquiry that could not have been anticipated in advance.<sup>194</sup> The research plan is discussed in more depth later in this chapter.

The challenge when planning for implementation of complex interventions by gathering information utilising mixed methods research, is how to collect, interrogate and integrate findings from data obtained using methods, with differing underpinning research paradigms. A paradigm is a consistent and coherent world view which frames how the world is perceived. It shapes how we conceptualise research questions and subsequently how we go about addressing them.<sup>195,196</sup> Figure 3.3 displays an adapted version of Grix's<sup>195</sup> paradigmatic building blocks to support the research planning process. This figure was created by the researcher for this thesis.

**Figure 3.3 Adapted version of Grix's paradigmatic building blocks.**<sup>195</sup>



Researchers make assumptions at every stage of the research process, whether consciously aware of them or not.<sup>197</sup> Assumptions about human knowledge, what constitutes acceptable and legitimate knowledge, how we communicate knowledge (epistemological assumptions) about the realities we encounter in our research (ontological assumptions) and the extent and ways our own values influence research process (axiological assumptions). These assumptions shape how we understand research, research questions, the methods used and how research findings are interpreted.<sup>198</sup>

The use of NPT to facilitate this research challenges the researcher to investigate how an intervention becomes normalised. Chapter 2 clarified the potential role that SBUS has in the assessment and management of SBCD but highlighted that we do not yet know why it is not more readily utilised in the NHS. In order to effectively examine why SBUS is not currently used and to determine if there is a need, or want, of the service and if so, research much be undertaken to better understand how we can determine what is required and how best to support widespread implementation.

### 3.3.3.1 Triangulation

Methodological triangulation will be used in this thesis to bring together findings from different research methods, enhancing the reliability and validity of the findings by counteracting biases of the research methods.<sup>199,200</sup> Triangulation is a way to consider data from different sources by comparing, contrasting and combining the findings with others.<sup>201,202</sup> This will allow the researcher to incorporate findings from different perspectives and interpret data on multiple levels in order to better understand the phenomena under investigation.<sup>203</sup>

Triangulation is often employed for one of three main reasons; confirmation, completeness or retrodution.<sup>202,204</sup> The use of triangulation for confirmation describes techniques that are used to enhance the reliability and validity of the findings by counteracting the biases that are associated with single method studies.<sup>200,202,204–206</sup> Triangulation of sources can result in corroboration of findings, deepening understanding and enhancing the trustworthiness of the analysis. However, triangulation may also uncover inconsistent or conflicting findings.<sup>201</sup> Inconsistent and conflicting findings require researchers to explain why they exist. It may be due to an undetected variability of something that required further consideration or unanticipated anomalies and outliers in the phenomena being studied. Whilst inconsistent or conflicting findings can indicate that there were errors made in the research process, they can also indicate that the different data collection and analysis methods, and the combined effect of the findings, build on each other to create a broader and deeper understanding of the phenomenon being examined.<sup>207</sup>

### **3.3.4 Critical realism**

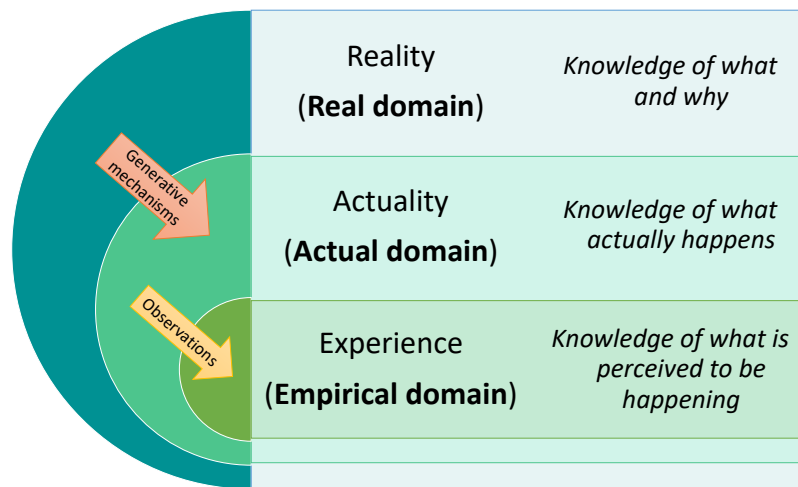
NPT is a theory of implementation that explains how practices become normalised. This can be further investigated and understood by considering findings using factors of realist methodology, which is concerned with understanding and explaining causation.<sup>208</sup> Critical Realism (CR) has increasingly been applied as a theory to underpin evaluation of healthcare intervention implementation.<sup>209</sup> CR also proposes that the choice of research methods should be dictated by the nature of the research problem. Much like the MRC guidance it is suggested that often the most effective approach will be to use a combination of quantitative and qualitative methods.<sup>210</sup>

The main goal of CR research is not to identify generalisable laws (positivism) or to identify the lived experience or beliefs of individuals (interpretivism); it is to develop deeper levels of explanation and understanding.<sup>211</sup> CR is a perspective that offers an alternative to the established paradigms of positivism and interpretivism.<sup>212,213</sup> CR looks at various causal tendencies that exist within a system, investigating the influences of the environment and social behaviour that interact with it.<sup>214</sup> That which is observed is shaped, and limited, by our individual perspectives. Hence all individuals can have a different understanding of a phenomena whilst the 'real' nature of the phenomena exists unobserved.

CR separates agency (intentional causality) from structure (contextually located social norms).<sup>209,215</sup> Although such separation of agency from structure has been widely debated in the literature,<sup>216,217</sup> it allows exposure of restrictions upon agency that would otherwise go undetected, and allows more informed calculations about how to transform the social world in ways that diminish the impact of such restriction, though it should be noted it cannot be eliminated entirely.<sup>197,218</sup>

This approach facilitates investigation of the ‘empirical’, ‘actual’ and ‘real’ domains of reality as defined by Bhaskars’ tripartite CR model<sup>219</sup> (figure 3.4, recreated by the researcher for this thesis), giving depth to the data collected but also contextual and inter-relatable factors helping to define causal mechanisms across and between domains.<sup>194,219–222</sup>

**Figure 3.4: Critical realism concept diagram**



Generative mechanisms are the underlying concepts of experience and are part of the ‘real’ domain of ontology.<sup>223</sup> Each generative mechanism concept is multifactorial, with no factor defining a definitive link between the real and the empirical. Therefore, when exploring generative mechanisms in the real, it is important to be aware that often what may be thought of as a distinctive generative mechanism operating in isolation is not and that factors may be influenced by different generative mechanisms.<sup>224</sup> The real is the outermost area of Bhaskar’s model and the generative mechanisms of the real domain give rise to people’s experiences in the innermost area of this tripartite ontology – the ‘empirical’ domain, which is how people perceive and experience events.<sup>193,225</sup> The notion of generative mechanisms is central to CR worldview, focusing on providing an explanation for observable organisational events by investigating underlying causes and

mechanisms. Characterised not by successivist causation (where A leads to B) but rather generative causation wherein the interplay of conditions from the domain of the real give rise to the events we observe in the domain of the actual.<sup>209,219,222,226</sup>

The researcher chose to take neither the objectivist nor the subjectivist approach, instead combining approaches with the use of CR research philosophy in order to be as inclusive as possible. Data were captured, analysed and interpreted in relation to the social world through observable, measurable facts, from which generalisations can be made about the universal social reality whilst being able to consider that phenomena are witnessed through a subjective lens, with each subjective perspective being equally valid, however different.<sup>197</sup>

Methodologically, the CR research process to understand generative mechanisms follows a retroductive process.<sup>215,224</sup> Retroduction aims to utilise information from both qualitative and quantitative data to move from a description of phenomenon to a description of a context which produces it or is a condition for it.<sup>209</sup> Retroduction moves back and forth between observable phenomena, utilising information from both qualitative and quantitative data, and possible explanations in an endeavour to gain deeper knowledge of complex generative mechanisms, and the context they are present in.<sup>215</sup>

### 3.3.5 Context

CR highlights that the working of generative mechanisms is contextually contingent.<sup>224</sup> 'Context' includes anything external to the intervention that may act as a barrier or facilitator to its implementation, or its effects.<sup>172</sup> Contexts are dynamic, the behaviours that define them are constantly negotiated and renegotiated by those who frequent and work in them.<sup>227</sup> It is argued that we cannot understand or explain findings related to implementation of healthcare interventions without looking at the context in which the intervention is embedded.<sup>187,228</sup> Experiences and observed outcomes are individually as well as contextually dependant, which implies that the researcher requires an understanding about enabling as well as inhibiting mechanisms to better understand how to tailor the intervention for stakeholders to promote future successful implementation.<sup>59</sup>

Nilsen *et al*<sup>229</sup> state that contextual cues promote certain behaviours. Where these behaviours may initially be internally driven (e.g. behaviour stemming from attitudes and beliefs), they soon become the normative response to naturally occurring cues within the context.<sup>229</sup> Some studies highlight the perceptions and attitudes of individuals as key components of context. Other studies adopt a different perspective suggesting that the perceptions of teams rather than individuals are important contextual features.<sup>230</sup> Context was considered throughout this research, with the researcher taking time to understand the role of context in the collection, analysis and interpretation of the findings and results. Ultimately context was considered alongside the triangulation of results to allow richer, deeper understanding and meaning to the research findings.

### **3.4 Quality assurance**

Researchers need to develop reflexivity in order to actively shape the relationship between philosophical position and how research is undertaken.<sup>231</sup> Reflexivity in qualitative research is well established as a means to make regular efforts to consider a researchers own thoughts, actions and potential bias in light of different contexts.<sup>232</sup> Quantitative and mixed methods research has been shown to benefit from reflexivity, enabling efficient review of outcomes and informing future research practices.<sup>233</sup> Reflexivity involves drawing attention to and the acceptance of the fact that the researcher is part of the research.<sup>234</sup> A reflexive examination should go beyond one's conduct in a research project and consider the positionality of the wider research discipline. Part of this consideration is role conflict; this is discussed further below. The concept of trustworthiness or rigour is essential in any kind of research, helping to ensure the methodological and ethical soundness of the research and its quality.<sup>235</sup> Appraisal of the research in terms of reflexivity, rigor, reliability and validity will be discussed further in Chapter 7.

### **3.5 Role conflict**

There is evidence to suggest that it is common for boundaries between professional and research roles for nurses to become blurred; Nurse researcher versus experienced registered Nurse.<sup>236</sup> In developing the interpersonal relationship that is critical to qualitative research, investigator and participant engage in a dialogic process that often evokes stories and memories that are remembered and reconstituted in ways that otherwise would not occur.<sup>237</sup> This problem has been well documented in the nursing literature on nursing research.<sup>238,239</sup> The researcher paid particular attention to role definitions and to precisely introduce herself as a researcher, separating the roles of clinical nurse and nurse researcher from the outset. The consideration and possible impact of role conflict is discussed in the strengths and limitations in chapter 7.



### **3.6 Risk**

There has been some impact on the research plan and the data collection work due to the COVID-19 pandemic. Due to social distancing measures the qualitative interview study was conducted virtually with interviews being undertaken using virtual meeting software. This may have had some impact on the data, potentially impacting on the depth of data collected due to a limitation in the building of rapport between researcher and participant.<sup>236,240–242</sup> Recent data suggests that remote data collection has highlighted potential for there to have been interaction and involvement with individuals who normally would not have been able or willing to take part, as virtual meeting software allows people to interact from their own homes, without the need for travel.<sup>241</sup> This will be fully assessed during data analysis and reporting of the findings in chapter 5.

There were no issues related to recruitment to any part of the conducted research due to the COVID-19 pandemic. However, the pandemic has caused significant increase in patient waiting times for MRE, which may skew the results if not appropriately addressed. This will be assessed further during data analysis and reporting of the findings of the care pathway model presented in chapter 6.

All research plans and progress were continually assessed through the supervision process. Any necessary changes or amendments were targeted early and implemented in a timely manner to have the least possible negative impact on research progress.

### 3.7 Research plan

Table 3.2 displays the research plan, describing study designs and the objectives met. Further information for each study is given below.

<b>Table 3.2 Research plan.</b>				
<b>Study</b>	<b>Study title</b>	<b>Study design</b>	<b>Objective</b>	<b>Chapter</b>
Scoping literature review	Clinical Utility of small bowel ultrasound assessment of Crohn's Disease in adults	Scoping literature review	1: Explore the existing evidence relating to the clinical utility of SBUS in the management of SBCD	2
Study 1	Current use of US to assess CD in the UK: a survey of BSG IBD group members	Online survey	2: assess the current usage of US throughout the UK.	4
Study 2	Assessing stakeholder identified barriers and enablers to US implementation	Qualitative semi-structured interview study	3: identify barriers to SBUS service expansion	5
Study 3	Cost implications of SBUS implementation on an NHS IBD service	Care pathway modelling and costs analysis.	4: better understand the impact of the implementation of SBUS on NHS care delivery	6

A mixed methods approach was employed, combining qualitative and quantitative methods, in order to effectively capture the multifactorial data necessary to meet the thesis objectives. Where appropriate the term 'findings' is used when discussing qualitative data, and 'results' is used to describe quantitative data, combined qualitative and quantitative data will be discussed using the term 'findings' in order to avoid confusion. Both CR and NPT were utilised to interrogate study findings, compare and contrast the data, ultimately combining the findings utilising methodological triangulation in chapter 7 in order to understand and interpret the findings from multiple perspectives. As shown above in figure 3.1, NPT will be used to extrapolate findings in relation to dynamics of implementation. Findings will be considered from the viewpoint of CR to evaluate and consider the subtleties of the subjective data gathered and generative mechanisms influencing the observable findings from the research.

### **3.7.1 Patient and participant involvement**

The researcher conducted a preliminary patient and participant involvement (PPI) work through undertaking a patient questionnaire, facilitated by Crohn's and Colitis UK, with 20 respondents. Overwhelmingly patients reported they would prefer to undergo US instead of MRE. Respondents reported that that 53% of the group had never had an US scan, yet all of these patients responded that they would be more willing to undergo an US scan rather than the standard MRE for various reasons; time for scan to be completed, reduced waiting times for scans, comfort and requirements for preparation. Further PPI focus group work was undertaken with the Nottingham NIHR BRC PPI group. This consisted of five patients who had undergone a US scan for IBD monitoring, and five that had never undergone an US scan. After discussing the METRIC study<sup>94</sup> all patients agreed that they would be willing to undergo US scanning, with confidence that it would be effective in monitoring their level of disease activity. PPI group members have reviewed and had input on this research plan, and subsequent research protocol, to ensure patient voice is central to the project throughout. Further PPI involvement in development of study protocols and participant documentation for all relevant work packages was undertaken via reviewing was undertaken throughout the research work. Results of the research have been shared with the PPI groups who contributed to the preliminary and planning stages of this work.

**Study 1 – Current use of US to assess CD in the UK: a survey of BSG IBD group members.**

An online survey was designed and conducted to address objective 2 and assess the current usage of US throughout the UK. The survey was undertaken by BSG IBD group members between 9 June 2021 - 25 June 2021. Responses were anonymous, respondents were able to skip questions. 103 responses were included in the data analysis. Responses came from 14 different regions of the UK, from 66 individual NHS trusts. This study utilises CR to look beyond the surface level data to explore the underlying generative mechanisms that lead to the variance in use of SBUS and enthusiasm for future use.

**Study 2 – Assessing stakeholder identified barriers and enablers to US implementation: a qualitative interview study.**

In order to address objective 3 and identify barriers to service expansion, as set out in the thesis aims and objectives, semi structured interviews were undertaken with key stakeholders. Fourteen participants were enrolled in the interview study. Participants were enrolled between 02/06/2021 and 06/09/2021, with interviews taking place during the same time period. This study utilises CR to investigate the subjective nature of the interview data collected from participants opinions and experiences. To guide coding and theme development during data analysis, an NPT codebook was utilised in order to better understand and interpret the data in relation to underpinning principles of implementation.

### **Study 3 – Cost implications of SBUS implementation on an NHS IBD service.**

In order to address objective four and better understand the impact of the implementation of SBUS on NHS care delivery, a care pathway model was developed through the analysis of clinical audit data from real-world patient cases from Nottingham University Hospitals NHS trust (NUH). These data were also used to undertake an economic analysis to present some preliminary data on the possible organisational impact of the introduction of SBUS in the NHS. This study used CR to investigate the underlying generative mechanism that led to the observable care pathway and healthcare interaction variances in the analysis.

### **3.8 Chapter 3 summary**

A scoping literature review has highlighted gaps in the knowledge surrounding real-world cost-effectiveness of US in comparison to MRE and the impact of US on the confidence of gastroenterologists' clinical decision making. In order to effectively assess barriers to implementation of US, further assessment of stakeholder perceptions need to be undertaken. This research has been undertaken from a critical realist perspective, utilising the NPT framework and factors of methodological triangulation in order to design, conduct and analyse a series of studies employing a mixed methods research approach to meet the research objectives. The data from these studies will contribute key concepts to the development of an implementation package to support the widespread adoption of SBUS in the NHS. The following chapters will present the studies undertaken (chapters 4, 5 and 6) and the thesis discussion and conclusions are presented in chapter 7.

## **Chapter 4: Current use of Ultrasound to assess Crohn's Disease in the UK: a survey of British Society of Gastroenterology Inflammatory bowel disease group members.**

### **4.1 Introduction**

Many interventions fail to achieve the outcomes observed when tested in research settings once they are implemented in real-world settings. This difference in effectiveness has been linked to reduced fidelity to the intervention when disseminated outside the academic realm into clinical settings.<sup>243-245</sup> A number of strategies for guiding implementation have been proposed<sup>246,247</sup>, many of which focus on appropriately introducing new interventions by; (a) determining when an organisation is "ready" to adapt or adopt an intervention, and (b) working with stakeholders to overcome barriers to adaptation.<sup>248,249</sup> Following this guidance, this chapter presents a national survey of members of the BSG IBD group in order to meet thesis objective two and better understand the current usage of SBUS in the UK and gauge enthusiasm, or 'readiness', for the uptake of US in IBD care as well as identify the differences and similarities between NHS sites nationally. This chapter presents work that has been published in a peer reviewed journal.<sup>250</sup>

### **4.2 Ethical approval**

This survey was part of a programme of work given ethical approval by the University of Nottingham faculty of medicine and health sciences research ethics committee. Approval was granted on 4<sup>th</sup> June 2021, and the University of Nottingham acted as research sponsor.

### 4.3 Methods

An online survey was designed using Microsoft Forms™ to assess the current usage of SBUS throughout the UK. The survey was undertaken by BSG IBD group members between 9 June 2021 - 25 June 2021. The BSG IBD group consists of consultant and trainee gastroenterologists with a special interest in IBD and IBD specialist nurses. There were 1410 members of the BSG IBD group (as of December 2021). The survey was sent to all members on the 9<sup>th</sup> and 22<sup>nd</sup> of June 2021, the survey was sent twice as the deadline for responses was extended by a week. Consent was gained through participants ticking a box on the front of the online form agreeing to take part in the survey. Responses were anonymous, respondents were able to skip questions if they were unsure of the answers or if the question was not relevant to them (i.e., they do not currently use ultrasound). The survey was accessible via online link, no reminders were sent.

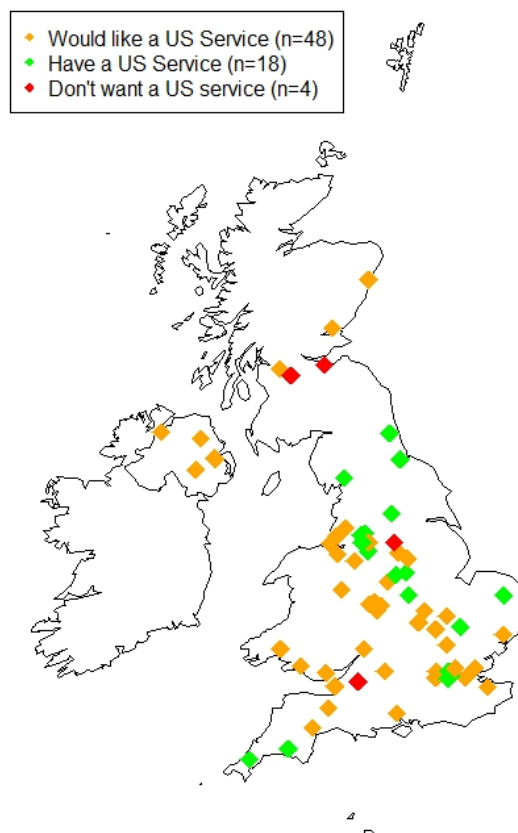
The questionnaire comprised of 14 closed questions (appendix c). Questions were developed by the researcher in collaboration with an academic supervisor and a senior research collaborator with expertise in this area of research. Questions were derived from results from chapter 2 and previous research work undertaken by the expert collaborator through the METRIC study.<sup>84</sup> Questions were focused on the respondents' experiences of MRE and ultrasound use in relation to the clinical IBD care they deliver and the current utilisation of SBUS in their own clinical practice. Questions were a mix of direct and closed to extract specific data relating to the current usage of SBUS. Respondents were asked to report only on plain SBUS examinations. Data regarding other forms of ultrasound examination such as elastography or doppler were not collected.

#### 4.4 Results

There were 106 respondents, this is a response rate of 7.5%. There were two incomplete forms, these were removed, and one international respondent, was also removed given the UK focus of the survey. In total, 103 responses were included in the final data analysis.

Responses were received from 14 different regions of the UK, from 66 individual NHS trusts. Figure 4.1 shows the distribution of the responding centers, showing those that currently use SBUS, those that would like to in the future and those that do not.

**Figure 4.1: Distribution of NHS centres in the UK who responded to the BSG survey on the use of ultrasound.**

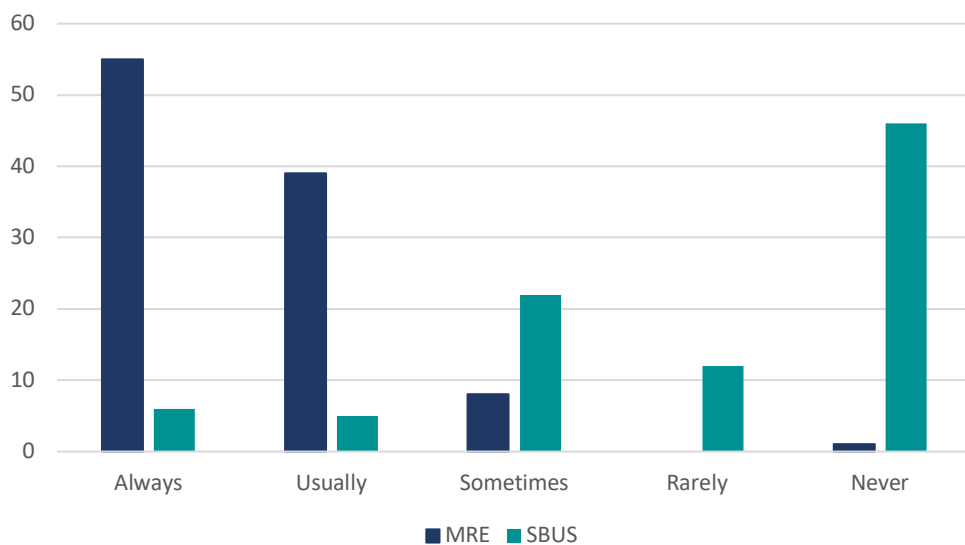




All 103 respondents reported that they currently have a MRE service for CD, where only 31 had access to ultrasound service. Of those respondents who did not have access to an ultrasound service, 72 stated that they would be interested in developing an ultrasound service.

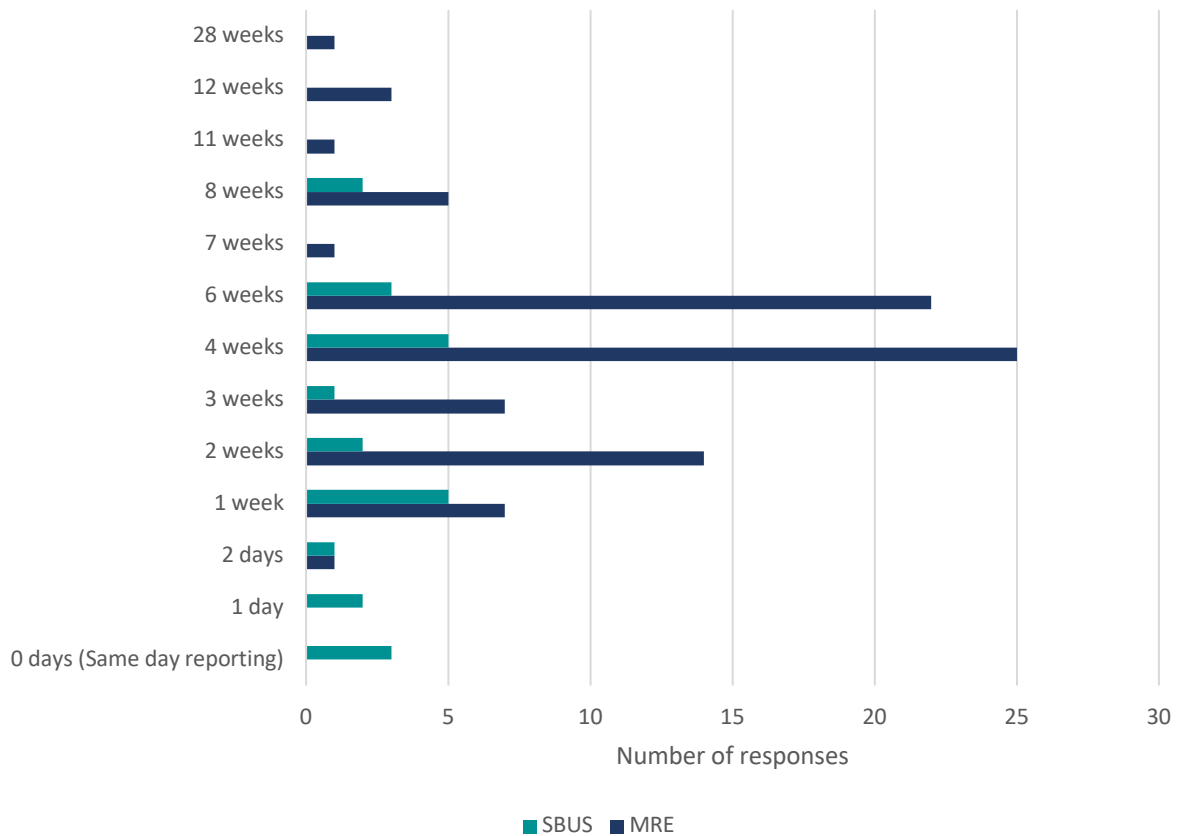
When asked about frequency of test usage, 55 of respondents reported that they always use MRE when clinically appropriate, 39 reported they 'usually' utilised MRE, 8 stated sometimes and one person stated that they never use MRE. In total, 46 respondents reported that they never use ultrasound, 12 rarely use it, 22 sometimes with only 5 respondents usually using it, and 6 always using ultrasound (Figure 4.2).

**Figure 4.2: frequency of test usage.**



The reported number of MREs performed per month was reported as an average of 15, with a range of 3-75. The average number of ultrasounds undertaken was reported as 8 per month, with a range of 0-50. Average time from referral for results to be reported for MRE scans was reported as between 4-6 weeks, with a range of two days to 28 weeks. The average time for an ultrasound to be reported was stated as one-4 weeks, with a range of 0-8 weeks.

**Figure 4.3: average time from referral to results.**

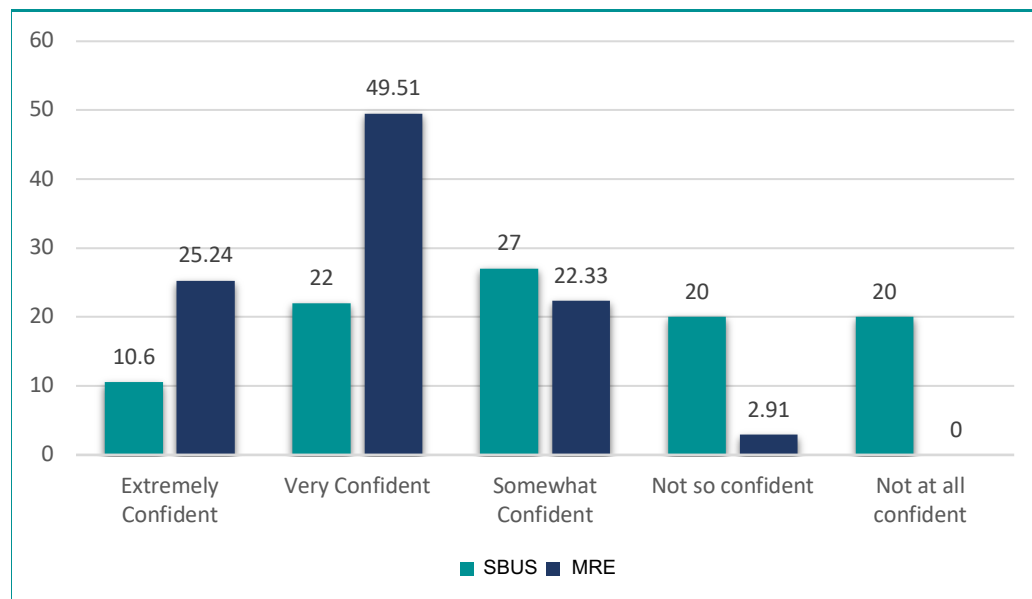


Nine different sites were reported to have access to both MRE and ultrasound, with five of those being University Hospitals Trusts, and four NHS Foundation trusts. 21 respondents did not complete which NHS trust they were currently employed by. 25 of respondents with access to both modalities submitted data relating to waiting times; in these centres the average waiting time from referral to report was reported as 4.6 weeks for MRE and 3.4 weeks for ultrasound.

When asked about their confidence in using imaging reports, 26 respondents were 'extremely confident' when using MRE data to make clinical decisions, five were 'very confident', 23 reported they were somewhat confident and 3 were not so confident. Conversely, only 6 respondents stated they would be extremely confident in using ultrasound to make clinical decisions, 17 people stated they would be very confident, 20 were somewhat confident, 15 not so confident and 15 not at all

confident (See Figure 4.4). Those respondents from the centres with access to both MRE and ultrasound more frequently responded as being extremely or very confident in using ultrasound. Respondents from University hospital NHS trusts were more likely to respond as being extremely, very, or somewhat confident.

**Figure 4.4: Confidence of clinical decision-making using ultrasound Vs MRE (%).**



#### 4.5 Limitations

This chapter presents results from an online survey which was responded to by gastroenterologist consultants and specialist trainees from around the UK. The results display some variance in results, however they are likely to be biased as respondents were invited via the BSG IBD groups, so are most likely to come from a pool of gastroenterologists already engaged in sharing of best practice and from secondary and tertiary care with access to perhaps a wider range of imaging modalities than some smaller healthcare centres such as district general hospitals and non-teaching hospitals. All responses were considered as estimates rather than precise reporting of a centres scanning pathway. It similarly was taken into consideration that responses likely represent a bias towards the use of SBUS, with preconceptions regarding the potential role it could have in NSH IBD services.

#### **4.6 Chapter summary**

This chapter has explored the current national usage of SBUS and the interest in developing a SBUS service for use within NHS IBD services. Waiting times in the NHS have all been affected by the COVID-19 pandemic, but it is evidence that SBUS has the potential to reduce waiting times for examinations when compared to MRE, if only marginally. The survey also uncovered that there were differences in the professed confidence in using SBUS as compared to MRE, but the reasons why this may be the case remain unclear and require further exploratory investigation.

This survey uncovered and satisfied some uncertainties about the implementation of SBUS. It is evident that there is enthusiasm for SBUS uptake, and that there is distinction around the differences in SBUS compared to MRE in line with coherence in NPT. However, there remains some key uncertainties; It remains unclear what impact ultrasound implementation would have on the current practices and care pathway of an NHS IBD service, what impact it would have on roles and responsibilities of the HCPs delivering the intervention and what the possible training needs would be in order to support routine use in IBD care. The survey indicated that there is an enthusiasm for the uptake of ultrasound across NHS institutions, however there are ambiguities surrounding whether stakeholders in those institutions are prepared to invest the time and effort required to implement and adapt the use of ultrasound in IBD services over time to meet the service needs.

The following chapter will present a qualitative interview study investigating the barriers and facilitators to the successful implementation of SBUS in the NHS, as perceived by stakeholders.

## **Chapter 5: Assessing stakeholder identified barriers and enablers to US implementation: a qualitative interview study.**

### **5.1 Introduction**

This thesis so far has presented results from a scoping literature review and a nationwide survey, both of which have identified areas for further work to assess the barriers and enablers to the implementation of SBUS for the assessment of SBCD in the UK.

In order to address remaining uncertainties and identify barriers to service expansion, as set out in the thesis aims and objectives, semi structured interviews were undertaken with key stakeholders. Semi-structured interviews were chosen because these types of interviews allow for detailed accounts to be shared by participants, with scope for the researcher to follow up on potential areas for further discussion.<sup>251</sup> It was felt that interviews were best suited to collecting the most appropriate data to answer the research question; information regarding peoples understanding, opinions, perceptions and experiences with enough depth to investigate contributing factors, but not too in depth as to detract from the research purpose.<sup>252,253</sup>

Stakeholder engagement helps groups, organisations and researchers to proactively consider the needs and desires of those who have a stake in their organisation or projects. This engagement can foster connections, trust, confidence and buy-in for key initiatives.<sup>99</sup> Stakeholder engagement can mitigate potential risks and conflicts, reduce uncertainty, disengagement and resistance to change.<sup>99</sup> It is for these reasons that stakeholder engagement is strongly encouraged by the MRC when developing and evaluating new healthcare interventions.<sup>99</sup>

NPT was used as the framework to guide the collection, analysis and interpretation of this data as it is a toolkit that can be used to understand the dynamics of implementing and integrating a complex intervention.<sup>254</sup>

Findings from this interview study complement existing literature on this topic, and the further work undertaken in this thesis, by offering insight into the qualitative aspects of implementation of SBUS.

## **5.2 Ethical approval**

Favourable ethical opinion was given to this study by the Nottingham research ethics committee and overall study approval was granted through the health research authority (HRA) on the 26<sup>th</sup> of March 2021 (IRAS project ID: 295783). Confirmation of capacity from Nottingham University Hospitals (sponsor) was granted on 26th May 2021.

## **5.3 Methods**

### **5.3.1 Sample size and recruitment**

Purposive sampling was used to ensure that data was being collected from the most appropriate cohort to answer the research question.<sup>255</sup> The interview schedule (appendix e) was reviewed by academic supervisors to improve data collection quality.

Using guidance from literature regarding qualitative sampling and previous research with similar cohorts of patients and research area, an estimated sample size of 20 participants was chosen.<sup>256–259</sup> The adequacy of the final sample size was continually assessed during the data collection process, when a point of ‘data saturation’ was established recruitment to the interview study was closed.<sup>260</sup> ‘Data saturation’ in this instance is defined according to the deductive approach; data

saturation is said to have been reached when “it was deemed that there was no more exploration required to adequately answer the research question”.<sup>260</sup>

Transcription and data analysis occurred at the same rate as recruitment, therefore the researcher was able to ascertain whether there were any signs of data saturation during the transcription and coding processes. When confident that data saturation had been met, the recruitment to the interview study was closed.

Data saturation is a methodological principle in qualitative research, originating from grounded theory.<sup>261</sup> It indicates that, on the basis of the data collected or analysed previously, further data collection and analysis is unnecessary. However, there is uncertainty as to how saturation should be measured, and inconsistencies in its use.<sup>262</sup> Saturation is defined within the literature in varying ways, at times it is not defined at all.<sup>263</sup> Some researchers claim that a failure to reach saturation has a negative impact on the quality of the research.<sup>264</sup> Saturation is the most commonly billed measure of qualitative rigour offered by authors.<sup>258,265,266</sup> It has been suggested that saturation usually occurs after conducting and analysing 12 interviews, however it could also occur as early as the completion of 6 interviews, suggesting it is an imperfect concept which cannot be predicted, hence this study used an estimated sample size.<sup>266,267</sup>

As an extra quality measure, concepts of information power were also used to assess the quality of the information gathered in relation to the ability to address the research aims.<sup>260</sup> Information power indicates that the more information the sample holds, relevant for the research question, the lower number of participants required.<sup>258</sup> Hence, information power of a sample is not very different from being sufficiently large and varied to elucidate the aims of the study but can be considered a specification of how to accomplish it.<sup>268</sup>

Access to participants was facilitated through existing collaboration with National Institute of Health Research (NIHR) Nottingham Biomedical Research Centre (BRC), advertisement on social media and via the BSG members newsletter. Participants from stakeholder groups identified as NHS Healthcare professionals (IBD nurse specialists, consultant gastroenterologists, consultant radiologists and service managers) and people living with SBCD currently under the care of an NHS team were invited to take part in this study. Participants were given a participant information sheet (PIS) for the interview study when they responded to a call for expressions of interest for participants.

### 5.3.2 Eligibility criteria and consent

Participants were assessed for inclusion and exclusion criteria when responding to expressions of interest, prior to completion and receipt of valid informed consent (appendix d). Inclusion and exclusion criteria for the interview study are detailed in table 5.1.

Table 5.1: inclusion and exclusion criteria.	
Inclusion criteria	Exclusion Criteria
<ul style="list-style-type: none"> <li>• Able to give valid informed consent.</li> <li>• Aged 18 years or over.</li> <li>• One of the following roles               <ul style="list-style-type: none"> <li>○ NHS Gastroenterology consultant</li> <li>○ NHS IBD Nurse Specialist</li> <li>○ NHS Consultant Radiologist</li> <li>○ NHS business managers working in gastrointestinal services.</li> <li>○ Patient under the care of the NHS for small bowel CD.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Unable to communicate clearly in verbal and written English.</li> </ul>

### 5.3.3 Data collection

Interviews were organised around an interview schedule of pre-determined, open ended, questions (appendix e), with further questions emerging from interview discourse. Interviews were conducted in this manner to gain greater clarification through exploration of detailed descriptions of the studies topic from participants.<sup>255,269</sup> No face-to-face interviews were able to be undertaken due to the



COVID-19 pandemic. The iterative nature of the qualitative research process in which preliminary data analysis coincides with data collection can result in alterations to the interview questions as researchers are able to better focus the interviews questions according to the topics emerging as data collection progresses.<sup>270,271</sup> The researcher actively engaged in a process called reflective questioning.<sup>272</sup> Reflective questioning creates opportunities for individuals to reflect aloud and be prompted to expand and extend thinking through follow-up questions, deepening and enriching the collected data.<sup>273</sup>

### **Interview preparation**

Interview preparation included the formulation of an 'interview schedule' (appendix e), identifying topics to be covered rather than particular questions.

During in depth interviews it is necessary for the interviewer to develop rapport with the interviewee.<sup>274,275</sup> Rapport involves trust and respect for the interviewee and the information they share. It is a means of establishing a safe and comfortable environment for sharing experiences. It is important to establish an environment where the interviewee feels safe to share their experiences.<sup>251,255,276,277</sup> Establishing this rapport can be difficult, particularly if the participant is nervous or feels uncomfortable. The challenges that face the researcher in establishing rapport with the participant are ensuring the correct environment, introduction and interview process. An added consideration was that all interviews were undertaken virtually due to COVID-19 pandemic restrictions. This is discussed further in the 'strengths and limitations' section of chapter 7.

The researcher ensured that all participants were in an environment where they were able to talk freely without being interrupted by asking participants to verbally confirm they were happy to proceed. To establish rapport, but also to gain insight

into the participants mindset, the researcher asked the participants how they were feeling and about their day so far before commencing the interview. This allowed the researcher to set a tone for the interview early on and consider the variations in the participants professional backgrounds and experiences before moving through the interview process.

### **Interview process**

It was important to establish background information to contextualise the rest of the interview.<sup>278</sup> This enabled the researcher to access a deeper understanding of the data, guide the interview and interview questions, obtaining richer data.<sup>278</sup> During this phase broad open-ended questions were used to help the participant establish confidence. This helps participants 'settle into' the interview, reducing feelings of anxiety and increasing willingness to share personal experiences, opinions and detailed responses.

The direction and content of the interview was dictated by those topics that arose and those deemed interesting and relevant by the interviewer.<sup>279</sup> This enabled thorough exploration of topics and allowed the interviewee to provide detailed, in depth responses to questions that were also sensitive to the nature and depth of the information willing to be disclosed by the participant.<sup>280</sup> During the core phase of interviewing a technique used to help with recall, the critical incident technique<sup>281</sup>, was used to extract details of specific incident or examples. This involved asking people to focus on the details of specific experiences rather than generalisations and allowed the collection of much more detailed responses than might have been given with open ended questioning.

The interviews were undertaken virtually which allowed for more precise recording and better audio quality, however there was a potential higher risk of interruptions

e.g., from family members. There were no incidences during the data collection process where it was felt that this was the case. Careful consideration was given to the quality of audio recording and the environment that the interview was conducted in order to reduce such issues as poor recording quality and background noise.<sup>282</sup>

### **Transcription and field notes**

Following the interview, the researcher transcribed the digital recording, destroying the recording afterwards. Through the researcher completing their own transcription it offered an additional opportunity to familiarise with the data.<sup>283</sup> Transcribers often have difficulty in converting the spoken word into text form because of sentence structure, the use of quotations, omissions and mistaking words or phrases for others.<sup>283</sup> This raises the issues of editing transcription text; fully detailed, phonetic and timed transcriptions are appropriate for a detailed phenomenological assessment, where corrected and tidied transcripts are more fit for pragmatic analysis methods. This analysis is somewhat between the two options mentioned, though not a phenomenological study it was important to gather contextual data about participants experiences and opinions, therefore there are general transcriptions conventions that the researcher followed from each; the use of punctuation and capital letters, and devices used to communicate how the transcriber heard the spoken word, such as using a series of dots to indicate a pause.<sup>284</sup> The researcher took into consideration the balance between editing and readability of the transcription, as well as confidentiality and ethical practice. To enhance readability, some researchers choose to remove idioms such as the 'ums' and 'ers' and 'you know', as well as the repetition of words that occur naturally during conversations. One argument for doing this was that reading such words would be tedious, there are pragmatic reasons such as reducing word counts.<sup>285</sup> However the researcher chose to use the 'light tidying-up' technique, leaving in verbal hesitations as they add context to the discourse and are important for

analysis.<sup>285</sup> To maintain confidentiality, with no loss of contextual data, only those quotes that represent specific places, names or other recognisable items were edited, replaced with general or explanatory terms in square brackets.<sup>286</sup>

#### **5.4 Data analysis**

Thematic analysis was considered the most appropriate method to gain an overall exploratory understanding of the pattern of experience and perceptions in this population. Thematic analysis is a method for identifying, analysing and reporting patterns within data.<sup>287</sup> A form of thematic analysis called 'template analysis' was chosen as the data analysis methods for this research. The use of the NPT coding manual<sup>288</sup> to support the undertaking of a template analysis provided pointed data whilst allowing for the generation or alteration of codes and themes throughout analysis.<sup>254</sup> The term 'template analysis' refers to a particular way of thematically analysing qualitative data. Template analysis involves the development of a coding 'template', which summarises a priori themes identified by the researcher as important and organises them in a meaningful and useful manner. Hierarchical coding is emphasised, using broad themes developed from successively narrower, more specific subthemes. Template analysis is not inextricably bound to any one epistemology. The flexibility of the technique allows it to be adapted to the needs of a particular study and that study's philosophical underpinning.

Template analysis is similar to framework analysis; they can be seen as evolving in parallel to address many of the same needs. Both are examples of what Crabtree and Miller<sup>289</sup> discuss as "codebook" approaches, where a coding structure is developed from a mixture of a priori considerations and initial review of the data, which is then applied to the full data set. The most notable difference is that template analysis is more concerned with providing detailed guidance on the development of the coding structure than framework analysis, and less concerned

with describing techniques to aid in the interpretation of the data once fully coded. Studies using framework analysis do not typically show the depth of coding seen in template analysis. Template analysis is often seen as being a more receptive approach, allowing for the addition of codes to the established code book, presenting a more hierarchical coding book in order to interpret data.

#### **5.4.1 NPT Coding manual**

The NPT coding manual<sup>288</sup> was chosen as the guide for generating a priori codes for analysis. The coding manual is distinct from NPT as a concept, and has been designed as a pragmatic tool to support the application of NPT in research.<sup>182</sup>

Coding manuals are useful tools to support analytic work in qualitative research.<sup>288</sup> They reduce cognitive load and at the same time render the assumptions underpinning qualitative analysis transparent and easily shared amongst teams of researchers. This was particularly important to the researcher as this was an academic undertaking which required clear discussion and ease of sharing with academic supervisors.

The NPT coding manual<sup>288</sup> consists of 12 primary and 16 subsidiary concepts, as shown in table 5.2. This table was used as guidance when developing the initial coding template for analysis. The authors of the NPT coding manual emphasise the need for a layered approach to analysis, where the template offers only one part of the review of the data, allowing the researcher to thematically analyse the data and make their own meanings.<sup>188,290</sup>

**Table 5.2: NPT coding manual.**<sup>288</sup>

<b>Themes</b>	<b>Description</b>	<b>Sub-themes</b>	<b>Source Reference</b>
<b>Context</b>	<i>Domains in which implementation work is done</i>	Strategic intentions	Contexts in which an intervention can be formulated and plans for enacting it can be put in train.
		Adaptive execution	Contexts in which an intervention can be made workable.
		Negotiating capacity	Contexts in which an intervention can be integrated.
		Reframing organizational Logics	Contexts that are expected to be changed by an intervention.
<b>Mechanism</b>	<i>The work that people do to make implementation happen</i>	Coherence building	collaborative work that makes interventions and their components meaningful.
		Cognitive participation	The work that participants undertake to build up and sustain a community of practice around an intervention.
		Collective action	People work collaboratively to realize, perform, and operationalize and intervention and its components.
		Reflexive monitoring	People work collaboratively to appraise the effects of an intervention and its components and utilize that knowledge to reconfigure social relations and action.
<b>Outcomes</b>	<i>The results of implementation work.</i>	Sustainment	Sustainment activities through which the normalization of an intervention and its embedding in everyday practice are carried forward as continuous translational action.
		Normative restructuring	Changes to norms, rules and resources that happen as a result of working with interventions and their components.
		Relational restructuring	Changes to the ways that people are organized and relate to each other that happen as a result of working with interventions and their components.
		Intervention performance	How interventions and their components are operationalized, enacted, reproduced, over time and across settings.

## 5.4.2 Stages of data analysis

The main procedural steps undertaken during data analysis are outlined below in seven stages.<sup>291,292</sup> Coding processes were followed and themes revisited several times in a reflexive process to develop the final themes.<sup>293</sup> Given the substantive dataset generated from the study, coding and organisation of the data was conducted within NVivo 12 software.<sup>1</sup>

### *i. Defining a priori themes and initial coding template:*

The researcher defined the initial coding template. This was completed using the NPT codebook<sup>288</sup> and review of themes thought to be relevant to the research question.

<b>Table 5.3: a priori themes.</b>	
<b>Themes</b>	<b>Sub-themes</b>
<b>Context</b>	Strategic intentions
	Adaptive execution
	Negotiating capacity
	Reframing organizational Logics
<b>Mechanism</b>	Coherence building
	Cognitive participation
	Collective action
	Reflexive monitoring
<b>Outcomes</b>	Sustainment
	Normative restructuring
	Relational restructuring
	Intervention performance

### *ii. Transcription of interviews*

Transcription was undertaken in parallel to conducting the interviews.

*iii. Initial coding of data*

The initial template was developed after a sub-set of four transcripts had been coded. Preliminary coding of the data was undertaken by highlighting anything in the transcript text that might contribute toward understanding of barriers and facilitators to implementation of ultrasound. Tentative a priori themes were applied to the subset of transcripts, identifying codes that were relevant to the analysis. These a priori themes were reviewed and redefined throughout the analysis according to their relevance throughout the process. Themes were grouped as they were identified in the selected transcripts, and later joined into a smaller number of higher-order codes which described broader themes in the data. Appraisal of information power was repeated along the process, supported by preliminary analysis.

*iv. Production initial coding template*

The first four initial sub-set of transcripts, which included participants from three different 'roles' and four different healthcare settings, were coded and themes were grouped together to produce the initial coding template (table 5.4). A fourth theme was added to the template for the coding of concepts that related to participant opinions and experiences of behaviours and habits relating to the implementation of healthcare interventions and the use of SBUS. This was added as the concepts being discussed did not clearly fit into any one of the three existing themes and required further exploration in order to fully understand their meaning and relation of these new sub-themes in relation to concepts of NPT.



<b>Table 5.4: Initial coding template.</b>		
<b>Themes</b>	<b>Description</b>	<b>Sub-themes</b>
<b>Context</b>	<i>Domains in which implementation work is done</i>	Strategic intentions
		Adaptive execution
		Negotiating capacity
		Reframing organizational Logics
<b>Mechanism</b>	<i>The work that people do to make implementation happen</i>	Coherence building
		Cognitive participation
		Collective action
		Reflexive monitoring
<b>Outcomes</b>	<i>The results of implementation work.</i>	Sustainment
		Normative restructuring
		Relational restructuring
		Intervention performance
<b>Barriers to implementation-behaviours and beliefs</b>	<i>Pre-existing beliefs and habitual behaviours.</i>	Preconceptions of SBUS/US
		Habitual behaviors

v. *Apply the initial template to further data and modify as necessary.*

The initial coding template was applied to further study data as interviews were undertaken and transcribed. Where existing themes did not readily fit the new data, modification of the template was undertaken. New themes were inserted, and existing themes were modified, amalgamated, or removed if considered redundant. A new version of the template was then constructed.<sup>291</sup>

vi. *Final template and creation of thematic map*

The 'final' version of the coding template is the one that was developed from analysing the whole data set and was used to develop the final thematic map (figure 5.1).<sup>293,294</sup> Development of a template cannot be seen as sufficient if there remain substantial sections of data clearly relevant to the research question(s) that have not been coded to it. A final code book developed for this study is presented in appendix f, with definitions of themes and subthemes, with examples of coding

presenting in appendix g. . The final coding template reveals the removal of the fourth theme “barriers to implementation - behaviours and beliefs”, as codes attributed to this theme, and its sub themes, were reviewed via further exploration during interviews and integrated into other domains of the template, namely collective action and cognitive participation. There were several sub themes from the initial template that were not exposed throughout the coding of transcripts. ‘Strategic intentions’ and ‘reframing organisational logics’ sub-themes within the ‘context’ theme were less frequent throughout interviews and were removed from the final template. Codes relating to ‘normative restructuring’ and ‘relational restructuring’ were fewer throughout the transcripts, however there were some concepts that correlated with the definitions of these sub themes that were difficult to place due to the overlapping nature of some of the quotes and discussions. These sub-themes were absorbed into ‘sustainability’ as the concepts discussed throughout the interviews related to embedding ultrasound into everyday practice.

<b>Table 5.5: Final coding template.</b>		
<b>Themes</b>	<b>Description</b>	<b>Sub-themes</b>
<b>Context</b>	<i>Domains in which implementation work is done</i>	Negotiating capacity
		Adaptive execution
<b>Mechanism</b>	<i>The work that people do to make implementation happen</i>	Coherence building
		Cognitive participation
		Collective action
		Reflexive monitoring
<b>Outcomes</b>	<i>The results of implementation work.</i>	Sustainment
		Intervention performance

## 5.5 Findings

### 5.5.1 Study population

Fourteen participants were enrolled in the interview study (table 5.6). Participants were enrolled between 02/06/2021 and 06/09/2021, with interviews taking place during the same time period. Enrolled were three patients living with CD (21.4%), two IBD nurse specialists (14.3%), two IBD nurse consultants (14.3%), one surgical IBD nurse specialist (7.1%), two consultant gastroenterologists (14.3%), two consultant radiologists (14.3%) and two gastroenterology service managers (14.3%). There were 10 females recruited (71.4%), and 4 males (28.6%).

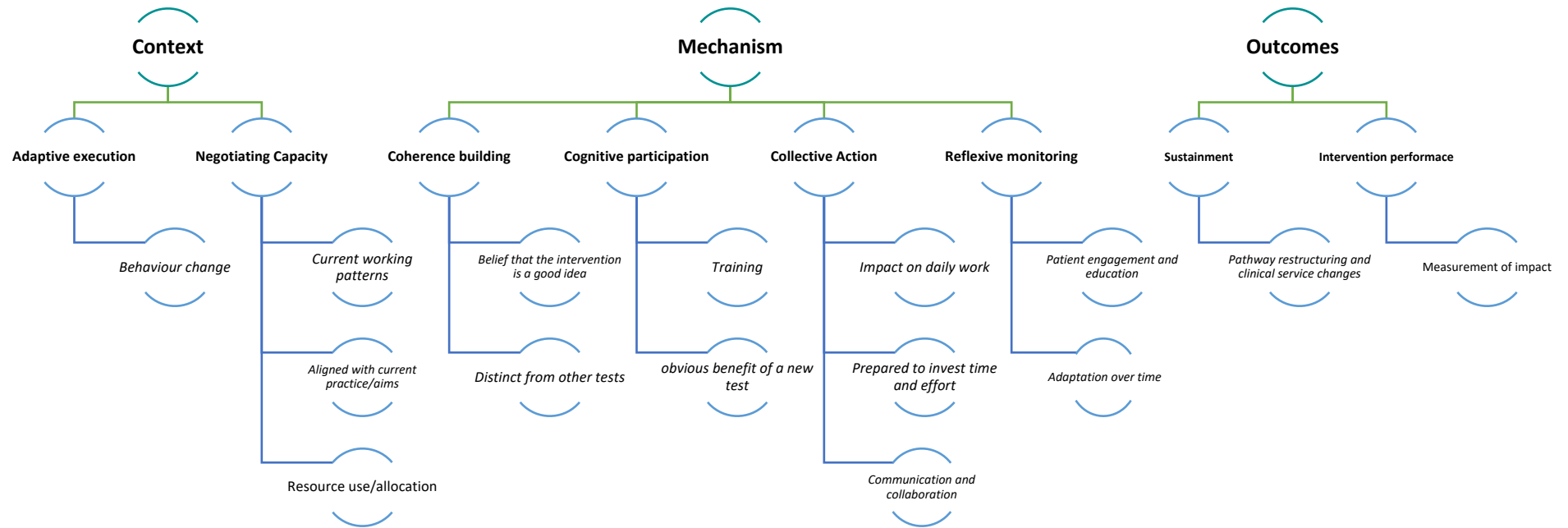
Participants were asked if they had experience of either undergoing, performing or interpreting results from SBUS examinations; 9 participants (64.3%) reported that they had SBUS experience. Interviews lasted for an average time of 50:47 minutes (range=35:41-61:34 minutes).

Table 5.6: Participant information.				
Study ID	Role	Gender	Ultrasound experience	Setting
001	Patient with CD	Female	No	University Hospital NHS trust
002	Patient with CD	Female	No	University Hospital NHS trust
003	Consultant Gastroenterologist	Male	Yes	University Hospital NHS trust
004	Service manager - Gastroenterology	Female	Yes	University Hospital NHS trust
005	Patient with CD	Female	Yes	NHS District General Hospital
006	IBD Nurse (Surgical)	Male	No	University Hospital NHS trust
007	IBD Nurse	Female	Yes	NHS District General Hospital
008	IBD Nurse consultant	Female	Yes	University Hospital NHS trust
009	IBD Nurse consultant	Female	Yes	University Hospital NHS trust
010	Consultant Gastroenterologist	Male	Yes	NHS Foundation trust
011	Consultant Radiologist	Male	Yes	University Hospital NHS trust
012	IBD Nurse	Female	No	NHS foundation trust
013	Consultant Radiologist	Female	Yes	University Hospital NHS trust
014	Service manager - Gastroenterology	Female	Yes	NHS foundation trust

### **5.5.2 Themes and codes**

Three themes and 8 sub-themes were generated (figure 5.1). Four themes were established early in analysis and were part of the template used for analysis, these were modified and adapted to the codes being established through coding of the data, and final themes were developed through combining minor overlapping themes.

Figure 5.1: thematic map



### 5.5.3 Context

#### Adaptive execution

Interviewees reported that there was a sense of reluctance to change within some clinical teams, sometimes reportedly linked to perceived seniority of staff; where “old habits of the more senior doctors” (006, IBD Nurse) were responsible for the lack of uptake of US. The opposite was reported by some interviewees, mainly from university hospital trusts:

*“All of the team were keen to get this up and running and we are a relatively junior team with some really enthusiastic senior clinicians who are all research active and open to working in new ways.” (014, Service manager).*

It was suggested that reluctance to adopt SBUS could be linked to the perception that there is no need to change from established clinical practice pathways;

*“I guess the reliance on what you have known for so long will take some time to change.” (001, patient).*

One participant reported that there is reluctance to change regardless of the subject, suggesting that there is sometimes even opposition to change as a process in itself;

*“Some people just don’t like change and won’t help, or even some will dig their heels in and try and stop change.” (008, IBD Nurse consultant).*

## **Negotiating capacity**

Capacity in this context is referred to as resources in terms of financial, clinical capacity, clinicians time and integration into the current practices and goals of the organisation. Some interviewees expressed their experiences and worries over the perception that setting up an SBUS service would require significant resource input;

*“That would take a lot of money to set up, not just the training and the equipment, but also the rest of the stuff, so the extra staffing to cover the training time.” (005, Patient).*

However, a frequent statement was that staffing requirements for a patient SBUS pathway, in comparison to MRE, would likely be significantly less expensive over the long term;

*“Labour side of things surely it is more effective and cheaper” (003, Gastroenterologist).*

One participant expressed that cost wasn't always the most significant part of daily practice for clinicians working in the NHS;

*“There are some significant advantages with the NHS, we have pretty much any test we want at our disposal, cost is often secondary to what we need clinically.” (010, Gastroenterologist).*

It was also discussed by one interviewee that there may be no cost benefit if SBUS is not used effectively and appropriately;

*“We know that ultrasound is cheaper per test, but what about the rest, like are we going to send them [patients] for an MRI anyway and then it's just an additional charge” (010, Gastroenterologist).*

Sourcing equipment was a concern for around half of the participants, however all acknowledged that in most cases the equipment required already exists, and can be used in collaboration with other specialities in the institution, the resource most required was appropriately trained staff;

*“it’s really a case of that most hospitals have the equipment that they need and even sometimes they have the people that they would need, those people just time to do training and [need] support” (011, Radiologist).*

Patients also reported that it was important for them to have someone performing and interpreting the results of the scans to give them confidence in their clinical team and in the decisions that they make, to make them feel well cared for and that they were getting the most appropriate treatment;

*“I think it’s about there being access to the team, or the people with the knowledge and the speed of results being available, it makes all the difference” (001, Patient).*

Waiting times were discussed as a sign of overall pathway appropriateness, where patients and clinicians alike expressed that reducing waiting times for patients to have diagnostic imaging tests and receive their results would be beneficial;

*“The system here taking months and months before anybody gets back to you. your test results can be very important in the management of this care and if you’re not getting a result that you need for some months because you have to wait to the next clinic or whatever you’re going to start thinking, and ultimately it might lead to there being something wrong that’s actively harming you or making things worse for that amount of time” (002, Patient).*



#### 5.5.4 Mechanism

##### Coherence building

There were consistent reports from all participants that in order for an intervention to be implemented there must be a sustained and shared understanding amongst clinical teams and patients that the new intervention is appropriate and required;

*“Sharing the knowledge base that led to deciding to change something, it should always be a group or service decision anyway, something that people are prepared for and can see the benefit in trying to moving towards doing in the future.” (004, Service manager)*

Patient and HCP participants with experience of SBUS in IBD were keen to express that they were unsure why it was not more readily adopted;

*“Having seen how effective this can be, having used it myself to see patients, I am surprised we don’t use it more readily in the UK” (011, Radiologist).*

For most participants it was clear to them what perceived benefits could be brought to patients and the NHS through the implementation of SBUS, and there was links between understanding the use of SBUS and believing that change is a good idea;

*“I actually find that most people are enthusiastic about doing a test which is able to help us make decisions quicker for our patients, lots of waiting around for decisions to be made otherwise” (006, IBD Nurse).*

For others there was still a sense that some HCPs and patients may not understand the reasons for change;

*“ [people] that haven’t ever had any ultrasound training or exposure to its use, they are just very used to using MRI and because it’s what they know and because it’s the tried and tested method they won’t deviate from it unless the new process is easier or of real significant benefit.” (010, Gastroenterologist).*

All participants agreed that HCPs and patients would understand what SBUS was, but there were apprehensions raised about preconceptions of its use;

*“I guess all patients are used to it in terms of they are aware of what an ultrasound is, even if just from maternity, even seeing it on TV or something, I think that might be new to them is using it for something new to them like abdominal issues and diseases like IBD.” (005, Patient).*

In order to successfully implement SBUS participants felt it was important to give as much detail as possible regarding the uses for the new intervention, how it is different to MRI, and why it is being implemented;

*“I think it’s about making it as obvious as possible that what you’re doing is just as good as what the old way was, but its better in some way – so either clinically better, achieves better results, or it’s the same, then its quicker, or easier or cheaper” (004, service manager).*

Participants who were HCPs were keen to stress the uses and benefits, but also the limitations, of SBUS and that implementation would depend on there being appropriate placement for the test within existing pathways;

*“Obviously, we will still need to MRI some patients, but for things like knowing whether they need immediate care, immediate steroids or surgical referral, it’s the reassurance that you’ve got the treat them correctly much quicker than you might have been able to before” (009, IBD Nurse).*

### **Cognitive participation**

During interviews participants discussed that there is a clear rationale to implement SBUS, reasons discussed included less invasive procedures and improved patient safety;

*“I guess they mean quicker and easier... It is certainly better for some of our older patients in terms of them not needing to be prepped anymore. [patients] don’t need to have the contrast drink, and they don’t need the cannula and the IV Contrast drugs. This makes it safer too I guess.”(006, IBD Nurse).*

There was a consensus amongst the interviewees that implementation of SBUS into IBD practice would be beneficial to patients, HCPs and NHS organisations in multiple ways;

*“It’s not invasive, it’s quick. There’s no real prep other than, you know potentially being nil by mouth and drinking some water, I think patients experience and cost scale wise. It’s hugely beneficial” (008, IBD Nurse consultant).*

HCPs from institutions with SBUS experience and expertise expressed that they were not concerned at all in relation to the reliability of the SBUS result;

*“I have no reason to not be confident in the decision” (002).*

It was suggested that this potential barrier could be overcome, although there was no consideration of how this might be achieved;

*“Really laying out the benefits of using ultrasound in IBD, making it clear that there’s no deficit in accuracy or in not using MRI” (010, Gastroenterologist)*

Participants identified that training was a major barrier to implementation of SBUS, with a lack of availability not just locally but also on a national scale;

*“It works really well for us; I know that other centres don’t use it because they don’t have the staff or the training.” (007, IBD Nurse).*

In particular, nurse interviewees displayed an enthusiasm for undertaking further training and upskilling to include SBUS in the extended role of an IBD nurse, but reported significant barriers to nurses having access to training opportunities;

*“Being a nurse asking for the time and training to do this kind of work is nearly impossible, we have the specialist[s] who do the ultrasound lists, but they need referrals. I have not been able to until recently request MRI or ultrasound, I have needed a consultant to do the referral.” (009, IBD Nurse consultant ).*

The resources required to sustain future services and training were discussed by participants;

*“we’re having a significant issue with the fact that we can’t find a training slot for the people who want to learn to do the ultrasound, mainly because there aren’t enough people already trained who can me their sign offs. We just about keep up with clinical demand, but moving forward, as we want to embrace this more and use it more, we will need more trained people, more experienced trained people.” (004, Service manager).*

Future proofing access to SBUS training was a potential barrier reported by most interviewees;

*“I think the training thing will become an issue later, when more people want to do it and then it turns out there aren’t enough people to keep up with demand” (001, Patient).*

### **Collective action**

One of the most common phrases used to describe a collective focus on implementing SBUS was ‘buy in’;

*“Just important to have that support, the buy in” (010, Gastroenterologist).*

There were discussions surrounding the need for collective focus and understanding of intervention aims;

*“Lots of support and the buy in from the team and the whole MDT to make it part of the pathway like any other test.” (010, Gastroenterologist),*

and how this is often linked to one individual leading the way;

*“a lot of it is finding the right person with the right enthusiasm, someone open to discussions and change with the enthusiasm and let’s be honest, with the power and a person that the people will listen to and take advice from” (009, IBD Nurse consultant).*

The opposite was also reported;

*“there’s often one or two interested people who have the training and the willingness to try and do the quicker, better for patient things, most of the team just stick to what they know, you know, it can be quite difficult to try and cascade the training when people think that they don’t need it” (010, Gastroenterologist).*

Alongside collective focus there was discussion surrounding shared workload and allocation of responsibilities;

*“Like kind of levelling of responsibilities so that it’s not just gonna fall into to one team is going to trial it and then you know it’s going to fail because there are only like a couple of people.” (005, Patient).*

One major barrier to implementation described by participants was the inference of ‘silo working’ where there is a lack of collaborative working and communication within and between clinical teams;

*“If we could all work a bit more cohesively and share our experiences and have them heard then yes, we would move so much quicker in the NHS and start doing things differently instead of always saying ‘but this is how we have always done it’ (012, IBD Nurse).*

This extended to the ways that participants could foresee future training needs being met;

*“I think we’re going to find it easier to try and learn through radiology colleagues in larger university hospitals and try and do something together” (003, Gastroenterologist).*

All HCPs who were interviewed expressed that they thought that SBUS should be part of their service, but there were differences in opinions concerning who should undertake the examination, and therefore who should have access to SBUS training. Participants expressed that they had no preference over which HCP received training, so long as;

*“Everyone [needs] to be trained up [to] the same standard” (012, IBD Nurse).*

Two patient participants suggested that established consultant gastroenterologists should be the first to learn and use SBUS, but that the consultants may not want to, or have the time to, learn;

*“I think that consultants should be trained in it I think the consultants would push back on doing it” (002, Patient).*

There was a sense that established consultant gastroenterologists would not be willing to direct time and effort to learning a new skill;

*“[gastroenterologists] feel like they don’t have time to learn how to do something new” (004, Service manager).*

It was discussed that even with available training, there would still need to be enthusiasm from individuals to engage in the intervention;

*“It can be quite difficult to try and cascade the training when people think that they don’t need it” (012, IBD Nurse).*

Patient participants were also keen to discuss who they thought should be the responsible clinician when performing SBUS and making clinical decisions and how this might benefit the patient pathway overall;

*“I think even if you Put some time and money into training IBD specialist staff, probably nurses are best placed because they are the first ones to hear from unwell patients, if money could be spent on training them up to do the scanning, then that reduces the need for an extra person in the room, so the sonographer, and then the results are right there and then, if is a nurse who can make treatments decision and prescribe, its missing out a whole step and reduces the time, the waiting time, for everyone.” (005, Patient).*

When asked what they felt might be required to successfully implement SBUS in centres where it is not currently used, over half of the interviewees said that they would benefit from a framework or package of evidence to inform practice;

*“A good, robust, piece of work that shows the benefits in time, cost and in patient benefit.” (010, Gastroenterologist).*

Participants felt that clear and concise guidance would benefit HCPs in guiding SBUS implementation;

*“What works for the clinicians or what has the least moving parts in order to do as much as possible with as few a steps” (010, Gastroenterologist).*



## **Reflexive monitoring**

When discussing outcomes of the implementation of SBUS both patients and HCPs discussed possible benefits in terms of allowing patients to become more involved in their healthcare, improving a patients understanding and engagement in their health;

*“There is so many ways that we can use [US] to make the hospital engagement better” (006, IBD Nurse).*

There were particular mentions of building therapeutic relationships with patients and shared decision making;

*“I think a sense of having someone who understands, or that will be able to discuss what the results today mean in relation to the story so far and what we might need to do in the future” (010, Gastroenterologist).*

HCPs predict, and report experiences of, patients who undergo SBUS and are able to discuss their scan results with the HCP in real time will be better informed regarding their CD and therefore will be more engaged with their health. Anecdotal responses from participants reported that when using SBUS;

*“You can interact with the patients much more easily...The nurses or whoever can actually be in the room with the patients and offering advice or knowledge and education right there and then” (008, IBD Nurse).*

### 5.5.5 Outcomes

#### Intervention performance

All interviewees reported that the experienced or expected outcome of the introduction of SBUS into routine care would be cost saving when compared to MRE use;

*“Patients seen quicker and giving them the treatment, they need sooner, so maybe saving time and money for everyone. Patients aren’t coming into hospital as often; we aren’t giving them medications they don’t need. Ultrasound itself costs less than MRI so if we can get less people needing MRI by getting them seen using ultrasound then that will save money too”* (007, IBD Nurse).

There were some comments from HCPs that patients living with IBD may have concerns relating to accuracy of SBUS compared to MRE scanning,

*“As a patient, maybe you’d wonder whether you’re getting the same level of care, like there less fuss with an ultrasound where an MRI can take hours with the prep, maybe it would seem like without all the bells and whistles that you’re getting less of an examination, where we know that’s not the case.”* (010, Gastroenterologist)

However, patients reported that they had no such concerns and actually rated SBUS as far more preferable as an assessment when compared to MRE;

*“I have no doubt in my mind that is a preferable option for any and all patients”* (002, Patient).

Participants described a decreased social cost to the patients living with CD, where implementation of SBUS would mean less hospital visits and shorter waiting times leading to a lessened impact of IBD on daily life, when compared to MRE;

*“Ohh well patients won’t be having to wait as long for scans and results, sometimes it stops them having to come to the hospitals several times.”*

(006, IBD Nurse).

In particular participants reported the positive impact of not having to take time away from work and not having to find childcare to attend multiple hospital appointments;

*“I had to leave work once a month to go do this and it was just a really bad thing that made me feel like I was letting people down, but also made me look and feel like an invalid... having to take half a day off work to go and have this is scheduled every six months or whatever it is to then offering something where you only have to pop in for an hour” (002, Patient).*

Many participants suggested that the best way to review and adapt the implemented IBD service over time would be to conduct audits of various parts of the pathway;

*“Audit it regularly to make sure that it’s not a resource that’s being over or underutilised.” (004, Service manager)*

and

*“it’s really important to keep assessing it in the view of everyone involved, adapting as you go along to make sure it’s the right fit and that you’re getting what you expected from it.” (014, Service manager).*

Some participants with experience of SBUS highlighted their experience of areas that required review and adaptation;

*“There were [also] lots of inappropriate referrals in the beginning”.*

(013, Radiologist).

### **Sustainment**

Interviewees agreed that it was important to ensure the sustainability of the SBUS service when planning and measuring the success of implementation;

*“it’s fixed in my mind where I’m thinking about how I’m going to be able to support teams like this sustainability, how to keep it going”* (003, Gastroenterology).

Participants linked the role of an implementation framework to the degree to which a service would be successfully implemented but also as key to sustainability;

*“Implementing it solidly with a long-term plan and probably something to give to sites like a plan or a framework for them, and networking across sites where there are places with more experience or expertise they can come and support the smaller places learning how to do it.”* (005, Patient).

Time to develop and sustain a service was cited as one of the biggest predicted barriers to the implementation of SBUS in the NHS;

*“Time might actually be the biggest factor you have here, keeping the momentum over time to see it through to fruition to get all of the pieces of the puzzle to put it into place.”* (010, Gastroenterologist).

## **5.6 Assessing and ensuring quality.**

In order to assure quality when undertaking and presenting this research, the researcher used concepts from Flick<sup>295</sup> and Rubin and Rubin.<sup>295</sup> Rubin and Rubin suggest that quality and validity can be increased by recording and detailed transcription of interviews and by transcribing immediately after the interview, both of which was undertaken during this study.

Rigour was established through engagement with the topic and the participants, completed thorough data collection and analysis. Transparency and coherence were achieved through making it clear how the data was analysed and how the conclusions have been drawn. Utilising a close link between the data and the conclusions enables a clear trajectory that is open to interpretation of the layers of analysis.<sup>296</sup> Impact and importance of the research was established through presentation of the research findings at national and international academic conferences and publication in peer reviewed journals. Due to the nature of the study and the financial and time constraints it was not possible to include other validity measures such as employing multiple coders.

## **5.7 Limitations**

Social distancing and travel restrictions related to the COVID-19 pandemic required that all interviews be conducted virtually. This was not found to have any limiting factors for the study. HCPs and patients from around the UK were able to take part in the study with no need to travel, and with more flexibility in terms of finding time slots in schedules.<sup>297</sup> Participants were recruited without any withdrawals or non-attendance. A further potential issue was the researchers familiarity with some of the participants; the researcher had worked with some of the participants in the professional role of Research Nurse and IBD Nurse specialist. This familiarity might have led to some participants to feel uncomfortable sharing personal details and

opinions. This was overcome, to the best of the ability of the researcher, by reminding the participants that their contributions to the study would remain anonymous outside of the interview and that all participation is voluntary.<sup>100,298</sup>

Further discussion relating to the topic of role conflict is presented in chapter 7.

## **5.8 Chapter Summary**

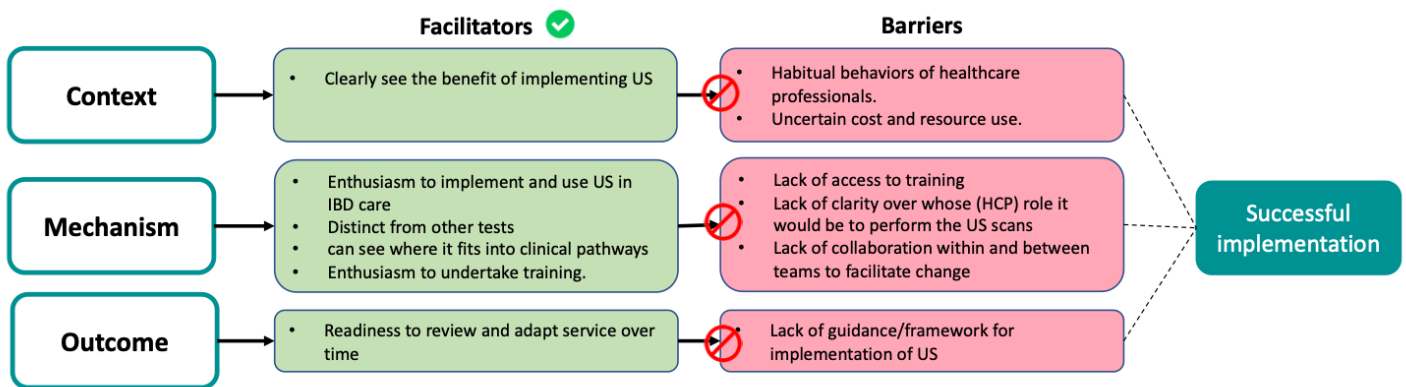
This Chapter has investigated stakeholder perceptions of barriers and facilitators to the implementation of SBUS in the NHS for the assessment of SBCD through the undertaking of a qualitative, semi structured interview study. Participants were recruited from numerous stakeholder roles and NHS institutions, some with and some without active SBUS services in IBD.

This research has identified the facilitators and barriers to the implementation of SBUS in IBD care in the NHS, as perceived by stakeholders. Figure 5.2 displays those concepts identified through the interview study in relation to the concepts of NPT.<sup>288</sup>

Findings from this study indicated that there are several factors of NPT that stakeholders perceive to be important to the successful implementation of SBUS in NHS IBD care. In particular it was highlighted that there are significant perceived barriers in relation to changing the habitual behaviours of HCPs to include US in their daily practice. However, there was shared enthusiasm amongst the interviewees that the implementation of SBUS into IBD care in the NHS would be of benefit. These findings will guide intervention implementation by informing areas for further research and areas to focus on for developing implementation plans. The use of NPT to examine the interview findings distinguishes this work by framing it in relation to the work that people do in order to implement healthcare interventions. The recommendations for the undertaking of mixed methods research in the MRC

framework guide provides the rationale for inclusion of a qualitative study, complimenting the research presented in chapters 4 and 6.<sup>95</sup>

**Figure 5.2 – Facilitators and barriers to implementation of ultrasound.**



## **Chapter 6: Cost implications of SBUS implementation to an NHS IBD service.**

### **6.1 Introduction**

Previous chapters in this thesis have put forward data exploring current national usage and enthusiasm for the use of SBUS and a qualitative interview study exploring stakeholder perceptions of the use of SBUS in NHS IBD services. This chapter explores and analyses the cost implications of the introduction of the SBUS model into the IBD service at one NHS site in England. This chapter aimed to add value to the existing research already undertaken throughout this thesis through identifying measurable outputs and potential benefits of the implementation of SBUS in NHS IBD services. The undertaking of a formalised cost-benefit analysis was considered however was later rejected due to the rigid methodology and data not being available for analysis. In order to undertake a full economic costing, detailed data on the activities of the staff is required, with resources being recorded in natural units of activity such as staff time.<sup>299</sup> In the current study, retrospective data and expenditure were used as the basis of the costing exercise, and this information provides a useful representation of the resources expended.<sup>300</sup>

This chapter presents a care pathway analysis with combined cost implications analysis utilising retrospective data, undertaken in order to meet objective four and better understand the effect on the patient care pathway and the economic impact of the implementation of SBUS at one NHS site. Results from this chapter will be analysed in chapter seven in the contexts derived from the previous work undertaken in this thesis so far.



Care pathway mapping is the method of modelling a care pathway in a healthcare system. It is a type of systems or process analysis.<sup>301</sup> Care pathway mapping is the starting point for assessing the cost and value of a healthcare service, and how this would change should a new technology be adopted.<sup>302</sup> By detailing each step of the care pathway we are better able to assess the resource use and impact of any new intervention. Using the model, there is then the opportunity to see how costs could be reduced.<sup>303,304</sup> The term “care pathway” is used in a variety of ways throughout the literature; the patient’s view of their journey through the healthcare system, the healthcare system’s view of the services provided, including workflows and information flows and the range of delivered practices (e.g. as documented by a clinical audit).<sup>302,305</sup> The use of “care pathway” to mean the healthcare system’s perspective of the services provided was adopted and is explicit when discussing the patient’s view of their journey, service evaluation, and guidelines. The approach adopted to produce the care pathway models is based on the notion of low-fidelity process models. A low-fidelity model seeks to capture the essence of a process, while abstracting away as many details as possible.<sup>306</sup> The application of a low fidelity model does not seek to capture every detail and nuance of a knowledge-intensive process. Rather, it documents the major activities of a process, and the primary sequence in which they are performed. The resulting model is shown graphically as a systems diagram or map of the services provided to a typical patient. Standard symbols used for flowcharting are used.

The role of costs is noted as a significant factor in implementation approaches and outcomes in a number of frameworks.<sup>307,308</sup> Many inefficiencies in healthcare delivery result from overuse of unnecessary services and underuse of beneficial interventions.<sup>309</sup> One challenge with economic evaluations is providing enough context by which decision makers can easily determine the generalisability of the findings to their own systems. A lack of economic data is often cited as a barrier to

implementation, especially when decision makers are asked to allocate finite resources and face competing demands.<sup>310</sup> Such knowledge is necessary if there is a desire to spread and replicate this work in other systems.<sup>311</sup>

## **6.2 Ethical approval**

This study took the form of a service evaluation, the data collection plan for this study was included in the study protocol for “The SBUS study” (IRAS: 295783). Favourable ethical opinion was given to this study by the Nottingham REC and overall study approval was granted through the HRA on the 26<sup>th</sup> of March 2021. Confirmation of Capacity from Nottingham University Hospitals (sponsor) was granted on 26th May 2021.

## **6.3 Methods**

Initial research planning included a multicentre prospective study to assess the impact of the introduction of SBUS into NHS IBD services. However, the survey study in chapter 3 presented results indicating there were fewer centres utilising SBUS than previously thought, and therefore a multicentre study would not have been feasible. Furthermore, due to the COVID-19 pandemic services were significantly disrupted affecting prospective data collection, and no research passports were issued during this time further impeding multisite research. A new single site research study was planned. Data were collected from a clinical service evaluation of imaging pathways at a single NHS site, Nottingham University Hospitals NHS trust (NUH). Analysis of patient care episodes and flow through the established imaging and IBD care pathways was undertaken, data relating to patient flow, waiting times, resource use and healthcare engagement of patients were collected from care episodes between 01/01/2021 – 30/03/2022.

Costs were calculated per care episode. The time horizon was defined as the length of the episode of care from consultation where the patient was referred for imaging investigations to the time point where a treatment decision was acted upon, either by starting (or restarting) a medication, deescalating treatment by stopping one or more medical therapies, or if the patient underwent surgical intervention. This time horizon was chosen as it was expected that within this period all patients would be equally likely to be assessed by HCPs and care decisions made. During analysis, disease severity in CD was measured as factors including disease duration, location and behaviour alongside history of surgery and biologic therapy exposure, as these are seen as intrinsic factors contributing to disease severity.<sup>312-316</sup>

Calculating costs related to the medications given in IBD is complicated due to the number of different medications, doses and lengths of courses prescribed across the whole spectrum of prescribing practices in IBD. To simplify the process throughout this analysis, it was assumed that all corticosteroid prescriptions were for the same duration and dose of prednisolone. At the time of the analysis, for treatment of flares in CD, typically the standard prescription was 40mg of prednisolone orally, once daily for a week then reducing by 5mg weekly thereafter, in a reducing course for a total of 8 weeks.<sup>160</sup>

### **6.3.1 Statistical analysis**

The sample size was not pre-determined due to the feasibility nature of the study. There was no a priori hypothesis, therefore no attempt at statistical comparison has been undertaken. The results are descriptive and hypothesis-generating. A variety of data sources were used to acquire information about resource use as several patient care episodes had incomplete or imperfect data. Mean costs for each item of resource use were calculated and then aggregated to estimate the total cost per patient. Statistical testing was therefore not possible at the level of total resource

use per patient. Quantitative data will be presented as a mean, +/- Standard deviation (SD).

## 6.4 Results

Data from a service evaluation relating to 192 imaging referrals from IBD clinics, and patient flow through the pathway were collected between 01/01/2021 – 30/03/2022 (Figure 6.1). This generates a compliance percentage rate based on the number of referrals made and the number of appointments attended (table 6.1). Compliance for MRE was 36%, and for SBUS 68%. These were seemingly very low compliance percentages for both imaging modalities however this was a period of significantly reduced clinic capacity where fewer appointments were offered due to the COVID-19 pandemic restrictions.

Month	MRE Referral	MRE attendance	SBUS Referral	SBUS attendance
Jan-21	13	9	11	8
Feb-21	14	2	12	8
Mar-21	13	4	3	7
Apr-21	20	5	11	9
May-21	15	4	13	8
Jun-21	23	9	9	8
Jul-21	20	9	17	14
Aug-21	11	5	18	13
Sep-21	20	7	14	4
Oct-21	22	6	21	12
Nov-21	13	5	34	21
Dec-21	18	8	20	14
Jan-22	15	5	18	12
<b>Total</b>	<b>217</b>	<b>78</b>	<b>201</b>	<b>138</b>
Compliance (%)		36		68

### 6.4.1 Care pathway model

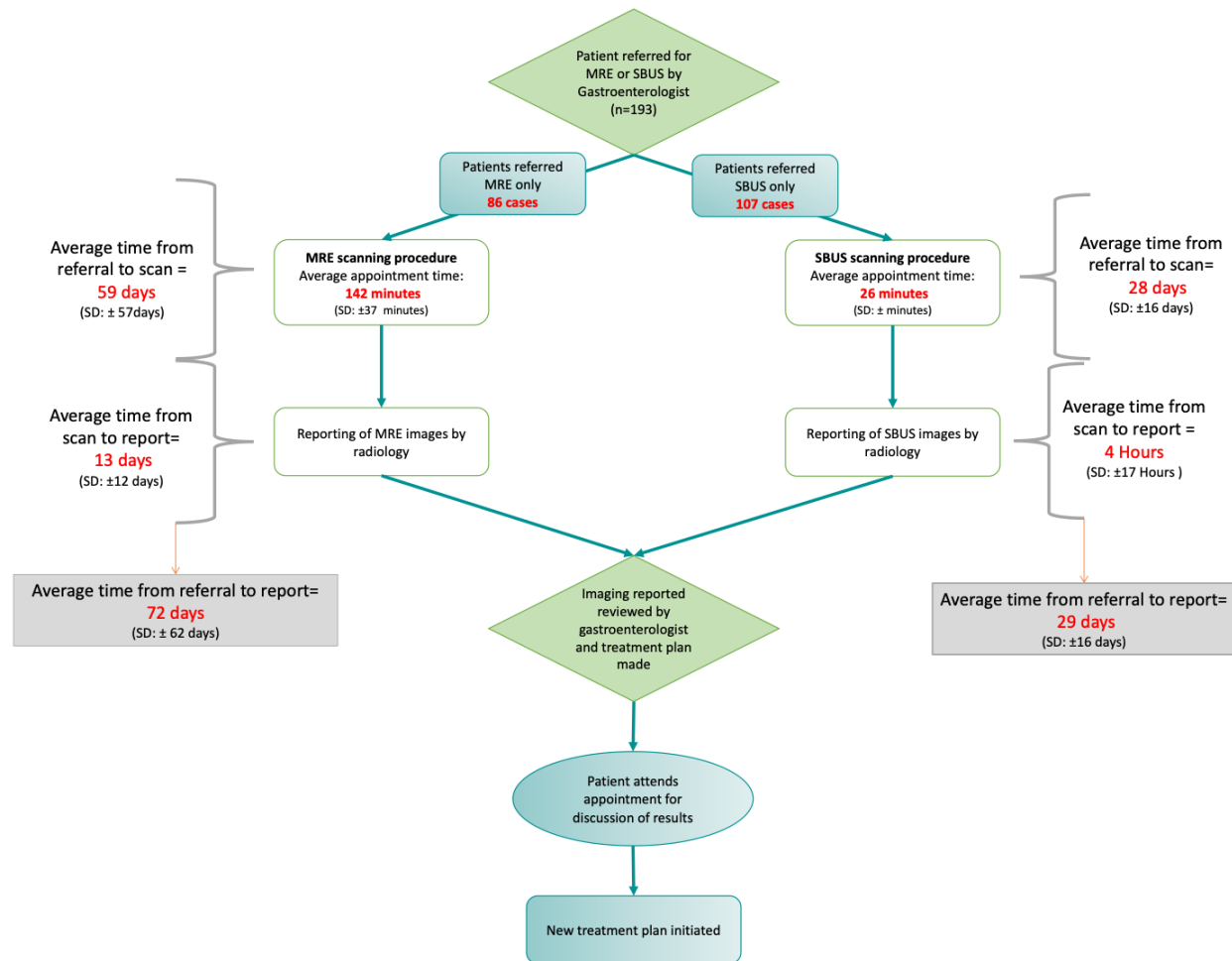
The pathway model (figure 6.1) was developed and analysed to compare the number of healthcare interactions, number of corticosteroid prescriptions, number of treatment changes (initiation, switch or de-escalation), waiting time to start treatment and the costs accrued in each imaging modality pathway. A combined

total of 193 patient care episodes were reviewed, 107 from the SBUS pathway and 86 from the MRE pathway between 01/01/2021 – 30/03/2022 (figure 6.1). These patients' pathways were followed from the time that a referral for either MRE or SBUS imaging was requested, to the point at which a treatment decision was acted upon; either by starting (or restarting) a medication, undergoing surgical intervention or by deescalating treatment by stopping one or more medical therapies. Table 6.2 displays demographics of the patients who cases were reviewed in the CPA.

<b>Table 6.2 : Demographics of patients from CPA.</b>		
<b>Characteristics</b>	<b>SBUS</b>	<b>MRE</b>
Gender (n)		
Male (%)	50 (47%)	57 (66%)
Female (%)	57 (53%)	29 (34%)
Disease duration (years) (Mean) [Standard deviation [SD]]	7.8 [±5.2]	5.6 [±3.9]
Disease location (%)		
Ileal (L1)	73 (68%)	57 (66%)
Ileocolonic (L3)	34 (32%)	29 (34%)
Disease behaviour (%)		
Inflammatory (B1)	95 (89%)	77 (90%)
Stricturing (B2)	12 (11%)	9 (10%)
Previous thiopurine exposure (%)	45 (42%)	35 (41%)
Previous biological exposure (%)	21 (20%)	23 (27%)
Previous surgery (%)	2 (2%)	4 (5%)

Figure 6.1 displays the average waiting times; MRE pathway patients waited an average of 59 days (SD: ±57) from referral to test, with an additional average of 13 days (SD: ±12) before the report was available for review by the Gastroenterologist. The average time from referral to report for patients in the MRE pathway was 72 days (SD: ±62). Patients in the SBUS pathway waited an average of 28 days (SD: ±16) from referral to test, with an additional 4 Hours (±17 hours) from test to available report. The average time from referral to report was 29 days (±16).

Figure 6.1: SBUS and MRE pathways care pathway model.



The patient care episode was considered ended at the point where a new treatment was initiated or where treatment de-escalation was initiated. Table 6.3 displays the proportion of patients where there was a treatment initiation or change. Details included the type of medication (corticosteroids, thiopurine or biological) escalation or de-escalation, or if the patient underwent colorectal surgery for their CD during the period in question.

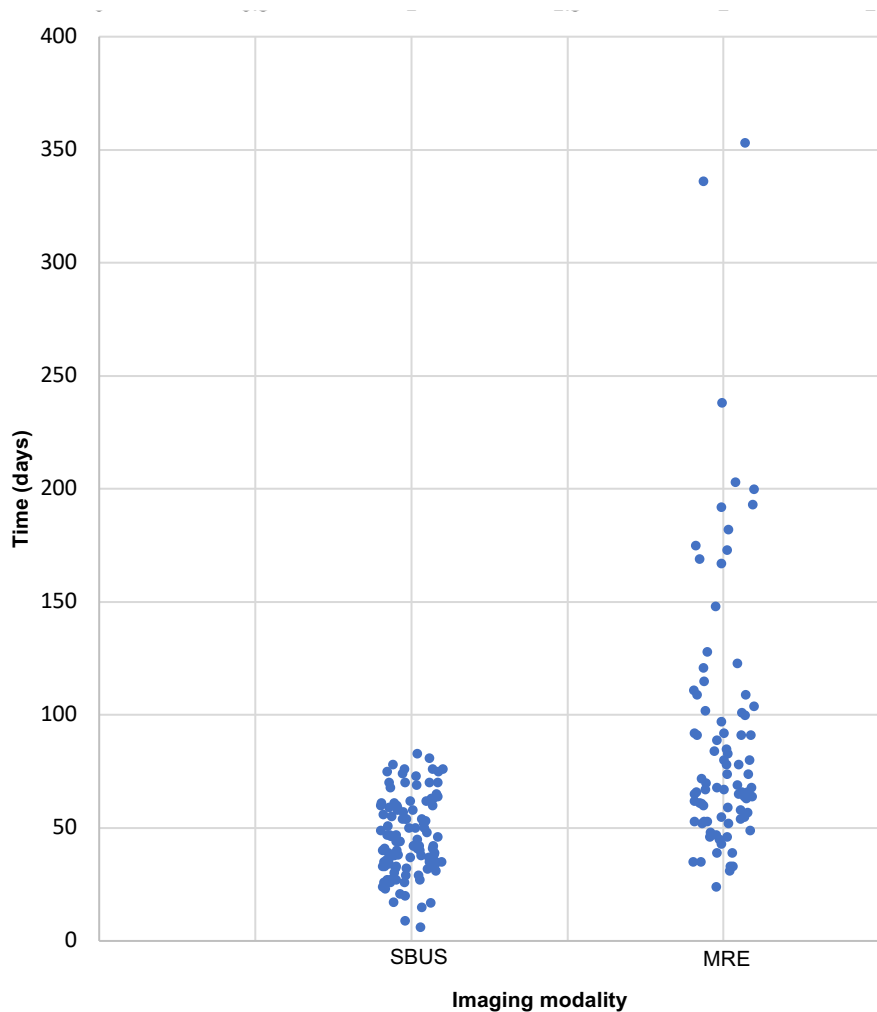
<b>Table 6.3: Proportion of patients with treatment changes.</b>		
<b>Treatment change</b>	<b>SBUS</b>	<b>MRE</b>
corticosteroids	0.56	0.76
Thiopurine start/change/escalation	0.31	0.4
Thiopurine de-escalation	0.05	0.04
Biological start/change/escalation	0.22	0.24
Biological de-escalation	0.02	0.05
Surgery	0.02	0.06

Table 6.4 presents the average times between pathway time points; Patients in the SBUS pathway-initiated treatments in an average of 46 days (SD:  $\pm 17$ ) from the date of referrals for imaging, with patients from the MRE pathway starting their new treatment plans in an average of 91 days (SD:  $\pm 61$ ) from the date of referrals for imaging. There was little difference between the SBUS and MRE pathways for the time from report to treatment initiation.

<b>Table 6.4: Average (mean) time between care pathway time points.</b>						
<b>Pathway</b>	<b>Time from referral to scan (days) [SD]</b>	<b>time from scan to report (days) [SD]</b>	<b>time from referral to report (days) [SD]</b>	<b>Time from report to treatment start (days) [SD]</b>	<b>Time from scan to treatment start (days) [SD]</b>	<b>Time from referral to treatment start (days) [SD]</b>
<b>SBUS</b>	28 [ $\pm 16$ ]	4 hours [ $\pm 17$ hours]	29 [ $\pm 16$ ]	18 [ $\pm 7$ ]	17 [ $\pm 7$ ]	46 [ $\pm 17$ ]
<b>MRE</b>	59 [ $\pm 57$ ]	13 [ $\pm 12$ ]	72 [ $\pm 62$ ]	19 [ $\pm 8$ ]	32 [ $\pm 13$ ]	91 [ $\pm 61$ ]

Figure 6.2 demonstrates the distribution of the data, across the time between referral for imaging and the initiation of treatment. These data were collected from a period of time during the COVID-19 pandemic.

**Figure 6.2: Distribution of the time taken from referral for medical imaging to treatment initiation.**



This analysis of distribution of the waiting times allows inference that the waiting times for patients in the MRE pathway are more likely to have longer waiting times between the date of referral for imaging and treatment initiation, than those in the SBUS pathway. Raw data were reviewed by the statistician, and it was deemed that there was no need to statistically analyse the data further as the inference was clear and unaffected by the factors of disease severity. Variance of disease severity across the two groups was equal.



## Healthcare interactions

Patients in the MRE pathway had a total of 104 IBD helpline interactions, patients in the SBUS pathway had a total of 80 helpline interactions (table 6.5). The number of OPA were also extracted; patients in the MRE pathway had a total of 159 Nurse OPA, with patients in the SBUS pathway having a total of 78 Nurse OPA. Patients in the MRE pathway had a total of 66 medic OPA, with patients in the SBUS pathway having a total of 26 medic OPA.

<b>Table 6.5 : Number of healthcare interactions of patients in each pathway.</b>						
<b>Number of interactions</b>	<b>Helpline interactions</b>		<b>Nurse OPA interactions</b>		<b>Medic OPA interactions</b>	
	<b>SBUS</b>	<b>MRE</b>	<b>SBUS</b>	<b>MRE</b>	<b>SBUS</b>	<b>MRE</b>
<b>0</b>	0	35	47	13	89	38
<b>1</b>	24	20	43	19	9	32
<b>2</b>	26	20	13	33	7	14
<b>3</b>	9	5	3	17	1	2
<b>4</b>	8	4	0	2	0	0
<b>5</b>	5	1	0	0	0	0
<b>6</b>	0	0	0	2	0	0
<b>7</b>	0	0	0	0	0	0
<b>8</b>	1	1	0	0	0	0
<b>9</b>	0	0	0	0	0	0
<b>10</b>	0	0	0	0	0	0
<b>Total number of interactions</b>	<b>80</b>	<b>104</b>	<b>78</b>	<b>159</b>	<b>26</b>	<b>66</b>
<b>Number of patients with at least one or more interaction</b>	<b>73</b>	<b>51</b>	<b>59</b>	<b>73</b>	<b>17</b>	<b>48</b>
<b>Average number of interactions per pathway</b>	<b>0.75</b>	<b>1.2</b>	<b>0.73</b>	<b>1.8</b>	<b>0.24</b>	<b>0.77</b>

## Medications and treatment initiation

Table 6.6 displays the number of corticosteroid prescriptions given to patients from each pathway from the date of referral to the time that they started on a new treatment plan. This was evaluated through reviewing the clinical follow ups and healthcare interactions of the patients in each pathway. Patients in the MRE pathway received a total of 101 prescription for corticosteroid treatment, 57 received one prescription, 14 received two prescriptions and five patients received three corticosteroid courses. There were 65 patients from the MRE group that received steroid treatment.

Patients from the SBUS pathway received a total of 85 prescriptions; 43 received one prescription, 15 patients received two prescriptions and four patients received three prescriptions for corticosteroids during this timeframe. There were 60 patients from the SBUS group that received one or more courses of steroid treatment.

<b>Table 6.6 : Number of corticosteroid prescriptions in each pathway.</b>		
<b>Number of prescriptions</b>	<b>SBUS</b>	<b>MRE</b>
0	47	10
1	43	57
2	15	14
3	4	5
<b>Total number of patients with one or more steroid courses</b>	<b>60</b>	<b>65</b>
<b>Total number of prescriptions</b>	<b>85</b>	<b>101</b>
<b>Average number of prescriptions per pathway per patient</b>	<b>0.8</b>	<b>1.2</b>

#### **6.4.2 Cost**

This thesis presents a CPA of the SBUS and MRE pathways. An ingredients approach was utilised because costs in imaging pathways are usually fixed, or semi fixed; therefore recording individual patient-based costings is not helpful in this situation.<sup>310</sup> Data for this analysis were taken from the clinical cases described above.

#### **Healthcare interactions**

Costs of healthcare interactions are calculated using the number of interactions between the dates of referral for medical imaging and the date of treatment initiation and the cost to the service for each type of healthcare professional with which the interaction encounters. Item costs are taken from the annual costs of Nottingham University Hospitals NHS trusts outpatient costs in 2021 and requirements of outpatient treatment recommendations (i.e., length of time of appointments) from NICE and NHS England across all clinical specialties.<sup>317-321</sup> Costs are based on helpline interactions being approximately 20 minutes of Band 6 NHS Nurse specialist time from allocated office space, Nurse OPA is 30 minutes of nurse time

from an allocated clinic room, and Medic OPA is 30 minutes of consultant time from an allocated clinic room (table 6.7).<sup>322</sup>

<b>Table 6.7: Healthcare interaction costs.</b>					
Healthcare interaction	Cost per interaction (£,GBP)	SBUS		MRE	
		Number of interactions	Cost (£,GBP)	Number of interactions	Cost (£,GBP)
Helpline calls	9.41	80	752.80	104	978.64
Nurse OPA	14.92	78	1163.76	159	2372.28
Medic OPA	40.91	26	1063.66	66	2700.06
<b>Total pathway costs for healthcare interactions</b>			2980.22		6050.98
<b>Average costs for healthcare interactions per patient</b>			27.85		70.36

## Medications

Table 6.8 displays the number of prescriptions for prednisolone given to the two patient groups. This prescription is for a total of 252 5mg tablets of prednisolone, typically dispensed as nine packets of 28 tablets at a cost of 40 pence per packet, or £3.60 per prescription. Patients in the SBUS pathway were prescribed a total of 85 prescriptions, with a total pathway cost of £306.00, there were 101 prescriptions given in the MRE pathway group with a total cost of £363.60.

<b>Table 6.8: Corticosteroid treatment costs.</b>					
Medication	Cost per prescription (£,GBP)	SBUS		MRE	
		Number of Prescriptions	Cost (£, GBP)	Number of Prescriptions	Cost (£, GBP)
Prednisolone	3.60	85	306	101	363.6
<b>Average cost per patient</b>			2.85		4.23

Costs for other IBD medications have not been calculated for this analysis.

Demographics and proportion of treatments (tables 6.2 and 6.3) indicated that there is no significant difference in the prior treatment exposure and treatment decisions between the two groups except for in the case of treatment with corticosteroids.

## 6.5 Cumulative costs and potential benefits

Per scan, MRE was almost 5 times more costly than SBUS examinations (£305 versus £51 respectively). Patients from the SBUS pathway had fewer healthcare interactions across all three categories. Patients from the SBUS group had 80 helpline calls (£752.80), 78 Nurse OPA (£1163.76) and 26 Medic OPA (£1063.66). In contrast patients from the MRE group had 104 helpline calls (£978.64), 159 Nurse OPA (£2372.28) and 66 Medic OPA (£2700.06). Steroid prescriptions were assessed as the number of prescriptions given across the whole patient group in each pathway. Patients from the MRE pathway received 101 prescriptions at a total cost of £363.60, patients from the SBUS pathway received 85 prescriptions at a total cost of £306.00.

Table 6.9 displays the estimated mean unit costs per patient for both the SBUS and MRE pathway. Estimated costs per patient in the SBUS pathway were £81.72, and £379.58 per patient in the MRE pathway. Further to this the waiting times for MRE were significantly longer than those for SBUS; Patients in the MRE pathway had an average time from referral for imaging to treatment initiation of 91 days (SD= ±61), patients from the SBUS pathway waited an average of 46 days (SD= ±17).

<b>Pathway item</b>	<b>SBUS</b>	<b>MRE</b>
Scanning	51	305
Helpline	7.04	11.38
Nurse OPA	10.88	27.58
Medic OPA	9.94	31.39
Steroid prescription	2.86	4.23
Total cost per patient	81.72	379.58

Alongside the measurable costs reported above, there are other cost considerations that are not included in this analysis. The initial set up costs of a new SBUS service can be costly inclusive of equipment, training and service costs such as clinic space and admin support. Expenses outside of the NHS service were not considered as part of this analysis, these include items such as patient travel costs, loss to workplace productivity through appointments and/or ill health. There was no straightforward way to calculate the full expenses incurred due to the delays due to COVID-19.

## **6.6 Impact of COVID-19**

Early into the COVID-19 pandemic, NHS hospitals were urged to restructure daily activities to provide the facilities to treat COVID-19 patients. The restructuring of the health care system did not by-pass clinical IBD management.<sup>323–326</sup> Due to decreased hospital capacity for non–COVID-19 care, many IBD-related appointments and procedures were cancelled or postponed. In addition, initial ‘shielding’ measures to prevent the spread of COVID-19 had an emphasis on safeguarding vulnerable populations, including IBD patients. Most outpatient appointments (OPA) transitioned to tele-health or were postponed. Additionally, fear of COVID-19 increased the risk of delayed care-seeking behaviour by patients.<sup>327</sup> All of these factors contributed to delays in healthcare, and whilst the length of delay can be calculated, the magnitude of the impact of the contributing factors is much more difficult to assess. Throughout this analysis it was taken into consideration that the COVID-19 pandemic had immeasurable impact on the results. There is further consideration of the impact of the COVID-19 pandemic on the findings of this thesis in chapter 7.

## **6.7 Limitations**

Results from this work are limited due to their lack of generalisability and retrospective nature. This analysis does not reflect everyday clinical practice where there are multiple kinds of medications that may be given at the discretion of the clinical prescriber. More robust, prospective, real-world multicentre data is required to conduct a comprehensive analysis to provide generalised data for the whole of NHS based IBD care. Without a full prospective randomised control trial (RCT) it is difficult to ascertain if there could be any sustainable cost saving to an IBD service in the NHS through the increased use of SBUS, whereby reducing unnecessary use of MRE. However, this analysis can make some assumptions about the use of SBUS in comparison to MRE. These assumptions, although not widely generalisable due to the data being retrospective and from a single site. Costs that are also worth considering but are difficult to quantify on this level are the administration support and clinical support costs as well as overheads such as heating, lighting and resources (paper, printing). For this reason, the costs of the use of an office space and a clinic room are being considered in how much is costed to the service.

## **6.8 Chapter 6 Summary**

This chapter presents results from a clinical service evaluation of an existing pathway in order to meet objective four, therefore data available is limited in its transferability. This chapter poses that the use of SBUS is a potential cost saving option when compared to MRE use for adult patients with SBCD. There was also a difference between the SBUS and MRE pathways in the waiting times for both the medical imaging scans, the reports of the scans and the initiation of an appropriate treatment plan. SBUS waiting times were shorter in all aspects except for the time between scanning report and the treatment initiation, indicating that it is the waiting times for the scans and the respective reporting that cause delays in treatment initiation rather than any inherent differences between the two patient groups which were evenly matched in this analysis.

Chapter 7 will combine the results from all three study chapters (chapters 4, 5 and 6), presenting a comprehensive discussion and review the overall findings of the research thesis, taking into consideration risks and the strengths and limitations of the overall thesis.

## **Chapter 7: Discussion and Conclusions**

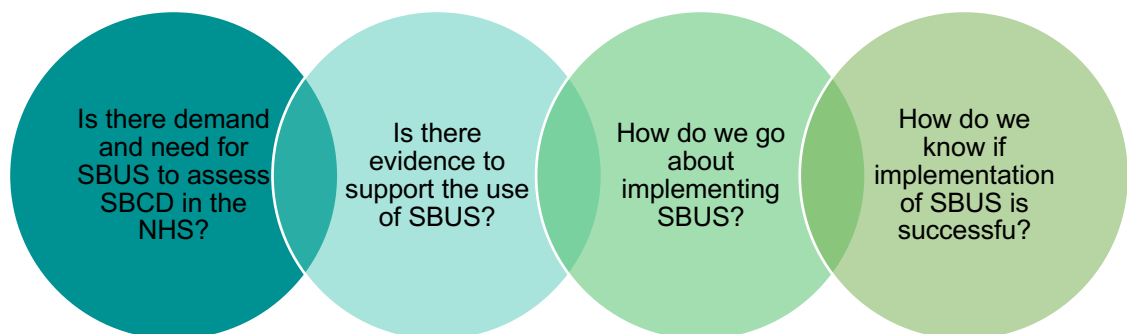
### **7.1 Introduction**

The thesis presents novel research and results which will contribute to the development of an implementation plan which will be used nationally to support SBUS implementation in the NHS. This final chapter provides a summary of the key research results and findings, and the conclusions drawn from triangulation of mixed methods data. Overarching strengths and limitations of thesis methodology and studies are presented later in this chapter alongside future implications for clinical practice and research.

### **7.2 Summary of key results and findings**

Triangulation has been used as an approach whereby the agreement and disagreement of results of related research data obtained from different methodologies, approaches or sources were explored in order to answer key questions regarding implementation of SBUS in NHS IBD services alongside meeting the research objectives of this thesis (Figure 7.1).<sup>328,329</sup> It is possible to answer the first three questions posed below, however only by considering future research work can we consider answering the fourth question presented concerning successful implementation of SBUS into NHS IBD services.

**Figure 7.1: key questions**





### **7.2.1 Objective 1: Explore the existing evidence relating to the clinical utility of SBUS in the management of SBCD.**

The scoping literature review<sup>100</sup> demonstrated that ultrasound is reported as quicker, more acceptable and safer when compared to MRE, and has been shown to be similarly accurate in detecting presence and extent of SBCD after initial diagnosis. This was not dependant on any other patient demographic factor such as age, gender or prior therapy exposure. Ultrasound is used widely in central Europe and Canada but has not yet been embraced in the UK. It was reported that the resources required in terms of equipment, are readily available in most NHS hospitals. Multiple sources reported ultrasound as an inexpensive test, however there is limited literature to support this. Ultrasound is reported as having positive influence on clinical IBD practice through expediting clinical decision making, but there is no evidence relating to the impact on the nature of clinical decision making by HCPs.

The survey study<sup>250</sup> (Chapter 4) and interview study (Chapter 5) both suggest that there is an appetite for developing and implementing SBUS services; it is acceptable as an alternative to all relevant stakeholders and is an appropriate intervention for the task at hand. There were further findings from the interview study to suggest that the resources necessary to implement SBUS are in place, however the significant barrier lies in the accessibility of training for HCPs. It was suggested strongly throughout the interview study that the reason that SBUS is not more widely used in the UK is due to lack of training opportunities for HCPs, and therefore there is lack of experience using the technology, and a subsequent lack of confidence in utilising SBUS to make clinical decisions regarding IBD management. Throughout the literature review the data extracted were from countries and institutions where SBUS has been used for a significant amount of time. There are also sources from authors in countries where ultrasound training is part of specialist

training in gastroenterology. This difference between the amount of exposure, experience and access to training between countries with established ultrasound services and the UK, could account for the disparity in the reported confidence in using and interpreting ultrasound results to inform clinical decision making in IBD as seen in chapter 4.<sup>100</sup> These results imply that in order to facilitate the uptake of SBUS services in NHS IBD services there would need to be better access to training opportunities, by increasing the number of courses, enabling clinical mentorship in practice and improving the communication between expert sites.

### **7.2.2 Objective 2: Gather data on current use of ultrasound in the NHS for IBD assessment, and levels of interest for implementation at NHS sites that do not currently use ultrasound in IBD.**

Final data analysis from the survey study<sup>250</sup> included 103 responses, from 14 different regions of the UK, across 66 individual NHS trusts. All 103 respondents reported that they currently have a MRE service for CD, where only 31 had access to an ultrasound service. Of those respondents who did not have access to an ultrasound service, 72 stated that they would be interested in developing an ultrasound service. The survey also uncovered that there were differences in the declared confidence of HCPs in using SBUS, with fewer HCPs reporting that they felt confident to use SBUS compared to MRE.

Findings from the survey study<sup>250</sup> and the interview study showed that whilst there is an appetite for the uptake of ultrasound, there is a lack of real-world data from the UK to freely guide implementation. The lack of current use of ultrasound throughout the UK illustrates that there would also not be a readily available network of support in the first instance for those sites wishing to establish a new SBUS service.

Throughout the interview study it was discussed that an implementation guide would

be of benefit, this would also provide a framework for assessing use over time, adjusting to meet service needs.

Results from study 3, the care pathway and costs implications analysis in chapter 6, indicated that there is an appropriate and available patient pathway for the assessment of SBUS in NHS IBD services. In a single NHS centre, there were significant waiting-time and cost reductions with appropriate SBUS use, with no negative impact on patient care.

### **7.2.3 Objective 3: Explore stakeholder perceptions of anticipated barriers and enablers to SBUS service development and implementation on wider scale.**

Throughout the interview study all interviewees reported that the outcome of the introduction of SBUS into routine care would be cost saving when compared to MRE and would reduce waiting times for imaging examinations. However, many also reported drawbacks in their local practices where they felt that there would not be support from colleagues and senior leaders to successfully implement ultrasound. It was felt that the progress towards implementation of ultrasound would only come about if there were individuals who were enthusiastic about the use of ultrasound, leading the way for others to follow.

Service managers who participated in study 2 (chapter 5) described that the biggest barrier to adoption of SBUS in IBD is to change the working patterns or behaviours of the clinicians using the interventions. Gastroenterologists, IBD nurses and IBD nurse consultants reported that changing the behaviours and 'habits' of experienced Gastroenterology consultants would be the biggest challenge of all when implementing SBUS. It was reported by stakeholders across all categories that HCPs would be more likely to choose to use MRE because that is what they have

always done. This apparent lack of 'buy in' could also be inferred from the lack of current ultrasound use displayed in the survey in chapter 4, despite responses seemingly indicating there is interest in developing ultrasound use in NHS IBD services. Participants indicated that there are unclear roles and responsibilities in relation to both the initial implementation of SBUS but also the sustained daily use in clinical practice. This implies that in order for implementation of SBUS to move forward there must be 'buy in' from the relevant stakeholders with identifiable leaders who facilitate and motivate change behaviours in their local teams and services and help to establish the pathway and flow of the service with support from local, regional and national networks.

There remained some uncertainty explored in chapter 5 regarding HCPs hesitancy regarding the use of SBUS due to concerns about accuracy of the scan and its subsequent report when compared to MRE. This was also apparent through reported confidence levels in chapter 4, which were lower when using SBUS compared to when utilising similar types of results from MRE imaging investigations. This indicates that there is an element of training and mentoring required in highlighting accuracy and suitability of scanning techniques for HCPs learning to undertake and interpret SBUS scanning. This in turn would have a positive impact in expediting 'buy in' from appropriate HCPs and services.

#### **7.2.4 Objective 4: Collect cost and resource use data through a care pathway analysis of a SBUS service for outpatients with SBCD, compared to existing MRE pathway.**

Study 3 (chapter 6) indicated that estimated costs per patient in each pathway were £81.72 for SBUS, and £379.58 from MRE. Further to this the waiting times for MRE were significantly longer than those for SBUS; Patients in the MRE pathway had an average time from referral for imaging to treatment initiation of 91 days (SD= ±61), patients from the SBUS pathway waited an average of 46 days (SD= ±17). At every time point assessed along each pathway, patients from the SBUS consistently had shorter waiting times. Waiting times were important to participants throughout the interview study. All HCP participants reported that the potential benefit they could see from the implementation of SBUS into routine practice in IBD care was to reduce waiting times for patients, obtaining tests results sooner and initiating appropriate treatments sooner.

After reviewing the data, it was apparent that MRE was needed in only 21% of cases, were SBUS would have been an inadequate test due to precluding factors such as previous abdominal surgery or stoma presence. It is possible to make the observation that the appropriate use of SBUS to assess SBCD, has the potential to reduce both costs and patient waiting times to start new treatment plans in IBD services in the NHS. However, these findings are based on a small sample from a single NHS site and therefore are not widely generalisable.

### 7.3 Discussion

In healthcare the concept of change is complicated by the human interactions involved.<sup>330,331</sup> Change in healthcare is not solely about altering how a service operates across organisations, but requires a fundamental rethink to find new and better solutions to current issues.<sup>234,332–336</sup> Diagnostic tests, such as SBUS, deliver information that can benefit patients by enabling the selection of the right treatment or therapeutic intervention and providing vital prognostic data that can optimise care pathways and management.<sup>337,338</sup> The acceptance by HCP leaders in the use of a healthcare intervention can determine how readily it is adopted by the wider healthcare team, it is therefore important that the implementation guide include some form of leadership development and support to facilitate buy in and implementation.<sup>332,333,339,340</sup> Behavioural and cultural barriers are often cited as major reasons for the lack of innovation for adoption in the NHS.<sup>332,339,341</sup> In many cases HCPs only learn and adopt new information gradually, creating the possibility of a delay to the provision of the best evidence based care.<sup>342</sup> It is also worth considering whether the referral for imaging is made following guidance, or whether the clinician has considered the appropriateness, or even the necessity, of ordering and then subsequently requesting the patient undergo an imaging assessment. Imaging assessments should be targeted to the most appropriate test, at the most appropriate time for that patient. The risk is that unnecessary, expensive and out-of-date care could be provided when there is resistance to moving away from established pathways, even if they are no longer efficient or effective. These inefficient clinical actions have considerable consequences in terms of personal and societal costs to patients, HCPs and NHS services.<sup>343</sup>

Further issues identified in the literature include HCPs lack of time to identify areas for improvement and innovation, combined with a lack of incentives in the system to

make time.<sup>332,337</sup> One of the biggest barriers to adopting innovation is that too often it is not embedded in routine processes and daily work of HCPs.<sup>342</sup> IBD remains a costly condition with modest potential cost savings.<sup>21,303</sup> Timely therapeutic interventions can be applied, reducing the risk of disease progression and the long-term costs of poor disease management.<sup>82,83,140,344–346</sup> People living with IBD also incurred greater costs through out of pocket expenditures such as travel and over the counter medicines, as well as workplace productivity losses.<sup>29,347</sup> Therefore the financial incentives for changing practice in IBD are often seen as lacklustre. Financial motivations are indicative of the supply-focused, top-down change management approach that previous researchers felt impeded innovation adoption.<sup>332</sup> From an institutional perspective however, implementation of SBUS would be meaningful as it has been shown in the METRIC<sup>2</sup> study that the relative cost effectiveness of ultrasound versus MRE is not driven by the impact that it has on the quality adjusted life years of the patients, but the cost of the test itself. SBUS is significantly less costly per scan than MRE per scan as shown in chapter six.<sup>100</sup> It is frequently seen as an unnecessary extra rather than improving quality and efficiency of healthcare services.<sup>332</sup> It is therefore key to emphasise the potential benefits of an intervention to the stakeholders to encourage collective action to support the implementation process. Other individual fears related to a reluctance to change may consist of trepidation of the degree of change (too many changes at once), changes to personal status (roles and responsibilities), and ultimately 'what's in it for me?'.<sup>333,348,349</sup> Where HCPs have not identified a particular problem that requires a solution, approaching them with evidence of something that works better than traditional methods can be perceived as a threat to their professional judgement and autonomy.<sup>342</sup>

It was important to gather insight regarding stakeholders perceptions and preferences regarding how to best support implementation of SBUS as it is

increasingly recognised that the manner in which interventions are implemented is as important as the features and functions of the interventions themselves to realise the anticipated benefits.<sup>350</sup> Engaging with stakeholders to understand the perceived barriers to implementation of a new healthcare intervention can improve the chances of successful implementation, as was the case throughout this thesis.<sup>99</sup>

Implementation practices of reviewing implementation based on action (such as audit and feedback) and various types of education tend to be more likely to successfully change professional behaviour than those based on persuasion, such as local consensus processes and opinion leaders. Interventions more likely to be successful seem to act through the NPT constructs of collective action and reflexive monitoring.<sup>341</sup> The importance of regular audit is reported as beneficial to implementation success<sup>340</sup> Individual and group recognition is also a necessary component of change management in order to cement and reinforce the change in the organisation.<sup>339,348,351</sup> Effective communication, as well as ongoing monitoring and feedback, are vital to any service innovation, particularly where complex innovations are concerned that may involve a wide range of diverse, multidisciplinary organisations.<sup>352</sup> Performance standards and governance by targets might be beneficial whenever there is pressing need to improve quality in any complex system such as healthcare services.<sup>353–356,357</sup> Interactive and multifaceted medical education programs including training with audit and feedback, and clinical decision support systems were found to be of benefit in achieving sustained successful intervention implementation in healthcare.<sup>349,358</sup>

Every diagnostic technique has a degree of subjectivity and operator dependence, therefore this criticism of SBUS accuracy seen in the literature and revealed in the interview study is perhaps more reflective of a previous lack of identifiable international performance and training standards.<sup>71,83,86,140</sup> There is no current



literature relating to any other HCP from the IBD team undertaking ultrasound training. Training is the cornerstone for building knowledge about the reasons for change and required skills, knowledge and behaviours necessary to implement the change.<sup>339</sup> Repeated training and awareness campaigns have been shown to reinforce new processes and behavioural patterns.<sup>340</sup> The only training courses specific to bowel and IBD ultrasound currently available are in central Europe and Australia.<sup>139,359</sup> It is therefore vital that the implementation guidance includes a comprehensive plan for establishing more training opportunities for HCPs, alongside the building of a national network of support for learners, and ongoing support for users, to embed and sustain SBUS in practice.

#### **7.4 Contribution to the literature**

This PhD thesis provides an original contribution to the body of knowledge on the implementation of SBUS in NHS IBD services. Studies in this thesis addressed the primary need for the exploration and better understanding of barriers and enablers to implementation of SBUS in NHS IBD care. This work has been presented at national and international conferences, in both posters and oral presentation form.<sup>360,361</sup> The research from this thesis has been published in peer reviewed journals and has contributed to further work on the subject of imaging in IBD and the use of ultrasound to assess SBCD.<sup>100,250,362</sup>

Previously, recent literature regarding ultrasound use in IBD was predominantly focused on the technical aspects of the scanning processes and the nuances associated with specific locations or diagnosis'. The evidence base was dominated by research from central Europe and Canada. This body of work is the first in the UK to discuss the wider use of ultrasound in the NHS. This work challenged the perception that SBUS was an 'obvious' alternative to MRE and presented the first scoping literature review which interrogated the clinical utility of SBUS in IBD,

providing insight into remaining uncertainties related to SBUS implementation in the UK.

The interview study presented in this thesis was the first to bring together stakeholders from the IBD community to discuss SBUS and capture the opinions and thoughts of the population who would use the intervention. Doing so has improved the understanding of this area of the implementation process and has contributed enormous insight into future research work.

This research has furthered the utilisation of NPT in feasibility implementation work. By utilising key concepts of NPT it was possible to emphasise the malleability of the framework, whilst still being free to develop independent meanings of the findings using CR. This combination aided the researcher in uncovering deeper meaning from the results and findings, at the same time as contributing to the development of new ways to utilise established methodology.

Through collaboration and networking this research has gone on to inform further exploration of designing training packages for HCPs learning to undertake and interpret abdominal ultrasound scanning in collaboration with international expert groups.

### **7.5 Implications for clinical practice**

The implementation of SBUS has the potential to improve experiences for people living with SBCD. It is a quicker examination with a shorter waiting time than MRE and has the potential to gather the same level of clinical diagnostic information with which HCPs can make appropriate informed healthcare decisions. The scanning process for SBUS is less burdensome for patients than undergoing MRE imaging, as SBUS requires no preparation or contrast. The appropriate use of SBUS has the

potential to be cost saving in comparison to the current standard of care, MRE. This work will contribute to the development of future research on the development of an implementation package to support the widespread uptake of SBUS in NHS IBD services.

Prior to the research undertaken during this doctoral programme there was little use of SBUS in the UK. A small number of specialist NHS sites and a small number of enthusiasts utilised bowel ultrasound in IBD assessment. From the outset, and subsequent networking and collaboration, there has been a significant increase in national awareness of the potential benefits of implementation of ultrasound in IBD services. There is more engagement from the gastroenterologist and radiologist community and efforts of stakeholders to implement training for consultants and medical trainees in the UK is underway.

## **7.6 Implications for future research**

Additional publications stemming from this thesis will be concluded following completion of this doctoral programme. The researcher has ongoing national and international research projects investigating the current and 'preferred' training methods for HCPs learning to undertake intestinal ultrasound assessments.

Future areas for research identified through the undertaking of this thesis are the need for a thorough prospective investigation of the impact of the introduction of SBUS into NHS IBD services including impact on resource use, waiting times, patient experience and overall costs. There is also minimal existing literature on the impact of SBUS on the confidence of clinical decision making for HCPs.

Acknowledging the limited training opportunities available for gastroenterologists and radiologists means that in order to effectively investigate the impact of SBUS services, there would first need to be a national drive for training. Investigating the

confidence of clinical decisions being made utilising ultrasound in the real world in comparison to MRE data would benefit planning and targeting areas for sustainable training and education for HCPs.

### **7.7 Strengths and limitations of this thesis**

Throughout the research process the researcher was guided by academic supervisors. Academic supervisors offered advice and guidance relating to research methods, data collection and analysis and the interpretation of findings. Although this work was undertaken independently by the researcher, the input of the academic supervisors provided an extra quality assurance for the undertaking of this research study, ensuring that all work was undertaken appropriately and efficiently. The major strengths of this work have been the careful planning and undertaking of high-quality research, where the findings from multiple studies of differing methods have been combined utilising recognised guidance in order to obtain sufficient information to meet the research objectives.

This work builds on previous high quality efficacy work,<sup>2</sup> and findings from this research are corroborated and being built upon in ongoing research in other parts of the UK and internationally. It has been well received at multiple national and international conferences and in multiple peer review journal articles, and future collaborations have been fostered in order to best support the implementation of SBUS into NHS IBD care.

Sources utilised in the scoping literature review in chapter 2 were not formally quality appraised, although quality was considered when discussing the findings. This meant a combination of high, medium and low-quality studies were included. The potential for inclusion of research findings with a high risk of bias is minimised where possible due to the scoping nature of the review and the authors

consideration of quality when reporting findings, but it cannot be ruled out completely.

The research questions asked at the start of this thesis were multidimensional and in order to effectively answer them a mixed methods approach was utilised.<sup>363</sup> Underlying assumptions of mixed methods research are that it can address some research questions more comprehensively by using quantitative and qualitative methods combined, and has the potential to harness the strengths and counterbalance the weaknesses of both approaches.<sup>99,364,365</sup> Utilisation of triangulation and CR facilitated the amalgamation of mixed methods data in order to effectively meet research objectives.<sup>99,211,366</sup>

Social distancing and travel restrictions related to the COVID-19 pandemic required that all interviews be conducted virtually. The survey was also undertaken online, both to avoid any unnecessary contact but also to avoid any time delays. This was not found to have any limiting factors for the Studies. Participants from around the UK were able to take part in the studies with no need to travel, and with more flexibility for scheduling.<sup>297,367</sup> There were no withdrawals, incomplete survey submissions or non-attendance for interviews.

The survey was undertaken on a national scale utilising collaborative links with the BSG. There was variation present within the results, and results were collected from a mix of NHS trusts of varying size, however results are at risk of bias as respondents were invited via the BSG IBD groups, who are HCPs already engaged in clinical research, from secondary and tertiary care, likely with access to a wider range of imaging modalities than smaller centres.

Results from the pathway analysis work are limited due to their lack of generalisability, due to it being a single site study, and retrospective nature. Results do not reflect everyday clinical practice. Without a full prospective multisite study it is difficult to ascertain if there could be any sustainable cost saving or impact on waiting times for diagnostic imaging investigations and reports to an IBD service in the NHS through the increased use of SBUS.

Utilisation of NPT allows for the research to focus on action of implementation, the things that people do and the collective action that results from complex patterns of social relations and interactions, rather than beliefs, attitudes and intentions.<sup>341,368</sup>

The use of NPT alongside the MRC guidance<sup>99</sup> provided direction to identify and explore the complex entangled interactions between agents, processes and contextual conditions within and the NHS organisations where SBUS is intended to be implemented. Nuanced understandings gained through this approach developed understandings beyond descriptions of determinants to explain how change may be facilitated, or not, during implementation. However, the researcher found that it was easy to place emphasis on agency of those involved in implementation throughout the analysis, at the expense of context and the impact on the individuals who experience the effects of the implementation. This is something that was corrected through thorough investigation of the findings when triangulating results and reflexive practices. This phenomenon is reported by other authors utilising NPT framework in similar ways, therefore the researcher was able to ascertain that this is likely a limitation of the framework used, rather than an error made during analysis.

182,369,370

Although originally deemed appropriate and analysed in a manner consistent with CR, the 'resource use' and costs calculated in the quantitative analysis (chapter 6) were, perhaps, too far removed from the concepts they were originally designed to measure. This quantitative stage ultimately added little to the analysis of barriers and facilitators to implementation of SBUS in the UK although its inclusion did not detract from the study outcomes, instead contributing valuable information to the evidence base supporting the possible positive impact of implementation of SBUS. The role of the researcher in this situation presents an interesting point surrounding possible role conflict during this study; nurse researcher versus experienced registered nurse. When a researcher is identified as a registered nurse, this has the potential to influence the researcher-participant interaction.<sup>238,371-373</sup> There is evidence to suggest that it is common for boundaries between professional and research roles for nurses to become blurred.<sup>236,238,239</sup> Every effort to ensure the participants of the study knew that the research they were part of was an academic project was made. To minimise role conflict, researchers need to be able to clearly define and articulate their roles to participants.<sup>371,373</sup> The researcher identified herself as a nurse researcher to participants throughout the research. The researcher undertook specific training provided by the University of Nottingham for researching sensitive or distressing topics in order to be better prepared to work within a topic participants might find difficult to discuss. Other support offered to participants included referral to specialist clinicians and IBD nurses if clinically required, signposting to counselling services and other support networks such as official Crohn's and Colitis UK social media groups. Having clinical experience in the specialism of IBD and care of patients with IBD enabled the researcher to be able to better understand some of the clinical details discussed by participants. At times being a researcher can be an asset allowing one to ask important questions that would be overlooked by someone with more domain experience, such as asking the participant to explain something they said as it might not be familiar, could in fact

offer a better understanding of the participants meaning of the terms or words they used.

### **7.8 Reflections of researcher**

Reflection refers to the process of thinking retrospectively on an event in order to learn from it where reflexivity is an active process of dynamic self-awareness which takes place as an event is happening.<sup>374</sup> In qualitative research, reflexivity has emerged as a way to manage how personal understanding, knowledge and perspectives of the researcher can influence the research itself.<sup>234</sup> Although, this is not predominantly a qualitative PhD thesis, the opportunity to reflect retrospectively on the process of conducting the research was valuable in interpreting its conclusions. The principles of reflection were incorporated throughout this PhD and in the process of writing this chapter.

IBD is a complex physical illness and an understanding of its symptoms and medical management is crucial in being able to appreciate the impact of IBD on patients' lives. Throughout a portion of my PhD, I took the opportunity to work as an IBD nurse specialist within an NHS specialist centre. Taking on this role allowed me to develop an awareness of the condition as a whole and better appreciate the clinical management pathways in IBD care.

I believe that making the decision to write a thesis incorporating publications as chapters has influenced my experience of undertaking this research. Having the opportunity to disseminate my work enabled me to receive external feedback on my research by experts in the field from its initial stages. Benefitting from feedback from reviewers, alongside guidance from my supervisory team, aided me to scale the quality of my work against what is expected within my discipline, and to better understand the nature of academic research. Publishing my research in peer



reviewed journals and presenting at national and international gastroenterology-specific conferences cultivated my sense of achievement during the course of my research and improved my motivation in progressing from one stage to the next. I have developed my professional and academic roles through joining and being part of national and international groups, being elected to both the BSG and ECCO committees. Furthermore, being part of a research group at the Nottingham BRC and networking with national and international groups has allowed me to be part of research projects outside of my PhD programme related to IBD and clinical management of IBD. This has allowed me to develop my independent researcher skills and allowed me to pursue my own avenues of research interest.

Throughout the research process, the project has had to adapt to the limitations applied to healthcare research during the COVID-19 pandemic. The research objectives were not altered greatly, but the research undertaken to meet them did. The research plan at the outset of this PhD programme included prospective multisite research studies. These were unable to take place due to the pressures on NHS services. The researcher was not able to travel and work in multiple NHS and international IBD centres which restricted the collection of pathway modelling data to a single site. At times it was frustrating to not be able to conduct the research, which was planned, however upon reflection it is now clearly an example of how research plans often have to adapt to meet the requirements of environment or circumstances, the study population or funding limitations. This work was still able to meet the research outcomes and will contribute meaningful data to an implementation plan for SBUS in NHS IBD services.

The immense burden that COVID-19 posited on health care systems and the global economy is one of the biggest medical concerns of the 21st century so far.<sup>375</sup> Early into the pandemic, hospitals were urged to restructure their daily activities to provide the facilities to treat COVID-19 patients. The restructuring of the health care system did not circumvent IBD management. Consequently, the risks of secondary harm emerged, as the latter resulted in reduced access to diagnostic endoscopy, lack of face-to-face clinics, difficulties in continuing day-case infusions, issues in performing routine blood and/or stool monitoring as well as patients' fears which may have reduced their attendance in hospitals.<sup>323–326</sup> Even though COVID-19 had a range of detrimental effects on health care systems globally, it also opened a space for improvements and innovation in clinical practice. Some of the healthcare innovations implemented during this time could be used long after the COVID-19 pandemic resolves. An example is the continued use of telemedicine, i.e., the implementation of virtual technologies in routine clinical practice. Which has been implemented quickly and in many cases is continuing to be used due to patient preference. The COVID-19 pandemic dictated that changes had to be made to the original study protocol relating to the studies undertaken in this thesis. The Research plan had to change to facilitate data collection without visiting several hospital sites or meeting research participants face to face. Overall, the impact of the COVID-19 pandemic was lessened by a change in the research plan. These changes subsequently caused limitations in the generalisability of some of the research findings.

## **7.9 Thesis conclusions**

This PhD thesis has provided an important and unique contribution to the literature and understanding of the barriers and facilitators to implementation of SBUS in NHS IBD services. Targeting this area of IBD practice has demonstrated there is scope to improve patient experience through reduced waiting times and improved test acceptability, as well as the potential to reduce costs to the NHS through suitable scanning referrals and more timely, appropriate treatment allocation.

This PhD has provided opportunity for key concepts from the NPT framework to be utilised in a novel process alongside CR, utilising the MRC guidance, allowing for development of novel insights and generation of new evidence to support the work being undertaken to implement SBUS effectively and sustainably. This work will contribute to the utility of the NPT framework in research akin to this, as well as further develop the role of CR in healthcare implementation research.

The study findings regarding the perception of SBUS and the potential benefits of implementing in the NHS was of note. The potential cost saving and waiting time reducing implications of the implementation of SBUS have been explored throughout the literature and at a single NHS site. A larger prospective, multisite study could investigate the impact on patient outcomes alongside more robust measurements of costs, resource use and allocation alongside healthcare service utilisation and patient experiences and HRQoL. The rate and reasoning of referral for imaging assessments should be investigated, including the appropriateness of referrals for imaging in order to best understand clinical decision-making behaviours. The current disparity between the confidence of HCPs when making decisions utilising SBUS and MRE has the potential to impact the level of support and collective action towards adopting and utilising SBUS. This is likely due to lack

of exposure to SBUS and reinforces the need for increased access to SBUS training. Improving access to training opportunities for HCPs has been identified by the literature and findings from the studies. There is minimal current usage of SBUS in the UK, therefore national support and networks must be factored into training mechanisms as well being utilised to help sustain successful implementation of SBUS.

Recommendations from this work which will contribute to the generation of an implementation package for SBUS include the need for well-structured and supported training for HCPs to enhance understanding of SBUS and increase confidence in using it to aid in clinical decision making. The implementation package should include tools for fostering leadership roles in promoting and sustaining change to encourage enthusiasm and collective action of the whole HCP team to embed SBUS into routine care. There should be standardised mechanisms for reviewing and adapting SBUS over time to ensure it meets the needs of stakeholders and IBD services.

This research will contribute to the implementation of SBUS on a national scale in NHS IBD services. Through supporting the successful implementation of SBUS this work will positively impact on the NHS through reducing waiting times and costs, with the potential to also reduce the costs of stopping or changing from unnecessary therapies for patients living with IBD. Regional and local NHS organisations will benefit from imaging assessments and results being available sooner, allowing for quicker allocation and initiation of appropriate treatments. Networking and ultrasound training will be improved, contributing to a more joined working across regions as well as improving, and expanding the skills of the healthcare workforce in order to better meet the needs of patients. In time this has the potential to expand to include other members of the IBD healthcare team, such as the IBD nursing

workforce, which could open up a whole separate area for exploration as regards the impact of SBUS on the practice of the IBD nurse specialist.

Patients will benefit from imaging assessments that are more tolerable to them, with shorter waiting times for assessment and results, real time answers to questions and improved clinical outcomes from appropriate treatments being targeted to those that require them sooner.

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## Appendices:

### a. Table of included sources

Authors	Location	Year	Title of Source	Type of source	Relevant data for review.	Quality level (Low, Medium, High)	In text citation
Carretero, C.	Spain	2022	Small bowel Crohn's disease: optimal modality for diagnosis and monitoring	Literature review article	Available technologies such as MRE and IUS have shown good accuracy parameters in CD patients. Cross sectional studies are superior for penetrating and stricture disease, however capsule endoscopy is a viable option also. Local expertise and availability may lead to choice and accuracy between modalities, but they should not be considered as competitors but as complimentary tools.	High	<sup>145</sup>
Luber, R.P, Petri, B., Meade S. <i>et al.</i>	UK	2022	Positioning intestinal ultrasound in a UK tertiary centre: significant estimated clinical roles and cost saving	Cross sectional study	73 of 260 LGIEs (28.1%) and 58 of 105 MREs (55.2%) met the criteria for US suitability. The predicted cost saving over 1 month if US was used instead was £8642, £25 866 and £5437 for MRE, colonoscopy and flexible sigmoidoscopy patients, respectively.	Low	<sup>144</sup>
Livne, M., Amital, M.M., Klang, E., <i>et al.</i>	Israel	2021	Qualitative sonographic assessment of transmural ileal inflammation in Crohn's disease: a comparison with MRI activity score	Cohort study	Two variables were found to be independently significant. Terminal ileal thickness and mesenteric fat proliferation. A model was constructed and demonstrated that US is significantly correlated with MaRIA score in the terminal ileum.	Medium	<sup>147</sup>
Smith, R.L., Taylor, K.M., Friedman, A.B., <i>et al.</i>	Australia	2021	Inter-rater reliability of the assessment of disease activity by gastrointestinal ultrasound in a prospective cohort of patients with inflammatory bowel disease.	Cross sectional study	There is substantial agreement between operators of varying experience in gastrointestinal ultrasound findings in patients with Crohn's disease or ulcerative colitis and this is repeatedly demonstrated over time	Medium	<sup>159</sup>
Allocca, M., Furfaro, F., Fiorino, G., <i>et al.</i>	Italy, France	2020	Point-of-care ultrasound in inflammatory bowel disease	Literature review article	US represents a well-tolerated, non-invasive and cost-effective modality to manage IBD in clinical practice. Similar accuracy to MRE and endoscopy, it can be performed at the point of care and therefore allow for real time clinical decision making.	High	<sup>83</sup>

Bollegala, N., Griller, N., Bannerman, h., <i>et al.</i>	Canada	2019	Ultrasound vs Endoscopy, Surgery, or Pathology for the Diagnosis of Small Bowel Crohn's Disease and its Complications	Literature review article	US can be used to diagnose SBCD in those with known or suspected CD. It can be used to detect postoperative re-occurrence and can accurately identify further complications such as abscesses and fistulas.	Medium	<sup>137</sup>
Fraquelli, M., Castiglione, F. Calabrese, E., <i>et al.</i>	Italy	2019	Impact of intestinal ultrasound on the management of patients with inflammatory bowel disease: how to apply scientific evidence to clinical practice	Literature review article	Standard parameters of BWT are accurate in detecting active CD showing similar accuracy to MRI. US shows evidence of transmural healing may have role in prognosis.	High	<sup>138</sup>
Grunshaw, N.D	UK	2019	Initial experience of a rapid-access ultrasound imaging service for inflammatory bowel disease	Clinical practice review article	69% of examinations were performed and reported in under 14 days. 43% of patients underwent a change in treatment, 35% had follow up within a week. Using US as the primary imaging modality has the potential to significantly improve patient management.	Low	<sup>86</sup>
Lamb, C., Kennedy, N., Raine, T., <i>et al.</i>	UK	2019	British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults	Clinical Practice Guidelines	Ultrasound can be performed without bowel distension using only oral contrast agents. Similar accuracy has been shown in several studies. Diagnostic accuracy for abscess, fistulae and stenosis is also largely equivalent between techniques. US is generally preferred because of safety.	High	<sup>160</sup>
Maaser, C., Sturm, A., Vavricka, S.R., <i>et al.</i>	Europe wide	2019	ECCO-ESGAR Guideline for Diagnostic Assessment in IBD Part 1: Initial diagnosis, monitoring of known IBD, detection of complications	Clinical practice guidelines	Small bowel US is a useful tool in assessing and diagnosis IBD. All newly diagnosed CD patients should undergo small bowel assessment including US. US is a tool to be used in the assessment if SBCD, US is accurate in assessing disease activity by measuring BWT.	High	<sup>71</sup>
Panaccione, R., Steinhart, A.H, Bressler, B. <i>et al.</i>	Canada	2019	Canadian Association of Gastroenterology Clinical Practice Guideline for the Management of Luminal Crohn's Disease	Clinical Practice Guidelines	Small bowel US is a useful tool for diagnosis and assessing CD, even in new diagnosis IBD. US is a tool to be used in the assessment if SBCD, US is accurate in assessing disease activity by measuring BWT.	High	<sup>158</sup>
Yuksel, I., Kilincalp, S., Coskun, Y., <i>et al.</i>	Turkey	2019	Diagnostic accuracy of intestinal ultrasound and magnetic resonance enterography for the detection of endoscopy-based disease activity in ileocolonic Crohn's disease	Cross sectional study	The sensitivity of IUS and MRE for detecting endoscopic activity was found similar with regard to bowel wall thickening and mesenteric fibrofatty proliferation ( $P>0.05$ ). IUS showed higher specificity for bowel wall thickening, loss of wall stratification and stenosis ( $P=0.009$ , $P<0.001$ and $P<0.001$ , respectively).	Medium	<sup>376</sup>
Bots, S., Nylund, K., Lowenberg, M., <i>et al.</i>	Norway, The Netherlands	2018	Ultrasound for assessing disease activity in IBD patients: a systematic review of activity scores	Literature review article	Several US indices for assessing disease activity in IBD are available; however, the methodology for development was suboptimal in most studies. BWT is the most widely used measurement.	High	<sup>154</sup>



Bryant, R.V., Friedman, A.B., Wright, E.K., <i>et al.</i>	Australia	2018	Gastrointestinal ultrasound in inflammatory bowel disease: an underused resource with potential paradigm-changing application	Clinical practice review article	US is accurate in diagnosing IBD, detecting complications of disease including fistulae, strictures and abscesses, monitoring disease activity and detecting postoperative disease recurrence. International groups increasingly recognise US as a valuable tool with paradigm-changing application in the management of IBD.	Medium	<sup>140</sup>
Kucharzik, T. and Maaser, C.	Germany	2018	Intestinal ultrasound and management of small bowel Crohn's disease	Clinical practice review article	US has been shown to have high accuracy in detecting small bowel CD and determining intra- and extramural complications such as stenoses, fistulae and abscesses. US has also been shown to be highly effective in determining postoperative disease recurrence and in follow up of patients under treatment.	Medium	<sup>139</sup>
Lichtenstein, G., Loftus, E., Isaacs, K. <i>et al.</i>	USA	2018	ACG Clinical Guideline: Management of Crohn's Disease in Adults	Clinical Practice Guidelines	Small bowel ultrasound has been used largely outside the United States for evaluation of CD. It has been used to assist in the diagnosis of CD, for detection of extramural complications, for the detection and evaluation of stenotic strictures, and for follow-up of the disease course.	Medium	<sup>146</sup>
Miles, A., Bhatnagar, G., Halligam, S. <i>et al.</i>	UK	2018	Magnetic resonance enterography, small bowel ultrasound and colonoscopy to diagnose and stage Crohn's disease: patient acceptability and perceived burden	Cross sectional study	128 (88%) patients rated MRE as very or fairly acceptable, lower than US (144, 99%; $p < 0.001$ ), but greater than colonoscopy (60, 60%; $p < 0.001$ ). MRE recovery time was longer than US ( $p < 0.001$ ), but shorter than colonoscopy ( $p < 0.001$ ). Patients were less willing to undergo MRE again than US (127 vs. 133, 91% vs. 99%; $p = 0.012$ ), but more willing than for colonoscopy (68, 75%; $p = 0.017$ ).	High	<sup>73</sup>
Taylor, S., Mallett, S., Bhatnagar, G., <i>et al.</i>	UK	2018	Diagnostic accuracy of magnetic resonance enterography and small bowel ultrasound for the extent and activity of newly diagnosed and relapsed Crohn's disease (METRIC): a multicentre trial	Cross sectional study	233 (82%) patients had small bowel Crohn's disease. The sensitivity of MRE for small bowel disease extent (80% [95% CI 72–86]) and presence (97% [91–99]) were significantly greater than that of ultrasound (70% [62–78] for disease extent, 92% [84–96] for disease presence); a 10% (95% CI 1–18; $p = 0.027$ ) difference for extent, and 5% (1–9; $p = 0.025$ ) difference for presence. The specificity of MRE for small bowel disease extent (95% [85–98]) was significantly greater than that of ultrasound (81% [64–91]); a difference of 14% (1–27; $p = 0.039$ ). The specificity for small bowel disease presence was 96%	High	<sup>2</sup>

					(95% CI 86–99) with MRE and 84% (65–94) with ultrasound (difference 12% [0–25]; p=0.054). There were no serious adverse events.		
Conti, C.B., Giunta, M., Gridavilla, D., <i>et al.</i>	Italy	2017	Role of bowel ultrasound in the diagnosis and follow up of patients with Crohn's Disease.	Literature review article	US is particularly attractive thanks to its widespread availability, non-invasiveness, low cost and good reproducibility, as it can be easily repeated during follow-up.	Medium	<sup>136</sup>
Kucharzik, T., Kannengiesser, K. and Petersen, F.	Germany	2017	The use of ultrasound in inflammatory bowel disease	Literature review article	The evolution of US equipment and the growing expertise of examiners have both enhanced the role of intestinal US in the assessment of the gastrointestinal tract in IBD patients. Intestinal US has been shown to have high sensitivity and specificity, as well as high positive and negative predictive value, in the detection or exclusion of intestinal inflammatory activity in IBD.	Medium	<sup>135</sup>
Kucharzik, T., Wittig, B., Helwig, U., <i>et al.</i>	Germany	2017	Use of intestinal ultrasound to monitor Crohn's Disease Activity.	Cross sectional study	After 3 and 12 months, US examination showed significant improvements of nearly all parameters, including reductions in BWT or stratification, decreased fibrofatty proliferation (P < .01 for all parameters at months 3 and 12). Median Harvey-Bradshaw index scores decreased from 10 at baseline to 2 after 12 months. Improvement in BWT correlated with reduced levels of C-reactive protein after 3 months (P ≤ .001).	Medium	<sup>136</sup>
Novak, K.L., Kaplan, G.G., Panaccione, R.	Canada	2017	A simple ultrasound score for the accurate detection of inflammatory activity in Crohn's disease	Cross sectional study	Retrospective data from 160 patients were assessed comparing US and colonoscopy, two of 5 parameters were found to correlate, BTW (P=<0.0001) and Doppler. Simple score has been developed but is not yet validated.	Low	<sup>131</sup>
Taylor, S.A., Avni, F., Cronin, C.G. <i>et al.</i>	Europe Wide	2017	The first joint ESGAR/ ESPR consensus statement on the technical performance of cross-sectional small bowel and colonic imaging	Delphi survey study	There is little evidence on optimal patient preparation prior to US, and recommendations with regard to the period of nil by mouth for food and liquids were based on mainly on expert opinion.	High	<sup>152</sup>
Calabrese, E., Maaser, C., Zorzi, F., <i>et al.</i>	International: Canada, USA, Europe	2016	Bowel Ultrasonography in the Management of Crohn's Disease. A Review with Recommendations of an International Panel of Experts	Literature review article	Bowel US is a tool for evaluation of CD lesions in terms of complications, postoperative recurrence, and monitoring response to medical therapy; it reliably detects postoperative recurrence and complications, as well as offers the possibility of monitoring disease progression. Bowel US showed 79.7% sensitivity and 96.7% specificity for the diagnosis of suspected CD, and	Medium	<sup>93</sup>

					89% sensitivity and 94.3% specificity for initial assessment in established patients with CD. Bowel US identified ileal CD with 92.7% sensitivity, 88.2% specificity.		
Ripolles, T., Paredes, J.M, Martininez-Perez, M.J., <i>et al.</i>	Spain	2016	Ultrasonographic changes at 12 weeks of anti-TNF drugs predict 1-year sonographic response and clinical outcome in Crohn's disease: a multicentre study	Cohort study	One-year sonographic evolution correlated with clinical response; 28 of the 29 (96.5%) patients with sonographic improvement at 52 weeks showed clinical remission or response. Patients without sonographic improvement at 52 weeks of treatment were more likely to have a change or intensification in medication or surgery (13/20, 65%) during the next year of follow-up than patients with improvement on the sonography (3/28, 11%). Stricturing behaviour was the only sonographic feature associated to a negative predictive value of response (P = 0.0001).	Medium	<sup>151</sup>
Wilkens, R., Novak, K.L., Lebuf-Taylor, E., <i>et al.</i>	Canada/Denmark	2016	Impact of Intestinal Ultrasound on Classification and Management of Crohn's Disease Patients with Inconclusive Colonoscopy	Cross sectional study	Changes in management were significantly attributed to US in 22 of these 29 patients. US may make a significant contribution to correct classification of disease extent and severity of Crohn's disease.	Low	<sup>132</sup>
Calabrese, E., Zorzi, F., Lilli, E., <i>et al.</i>	Italy	2015	Positioning Ultrasonography into Clinical Practice for the Management of Crohn's Disease	Clinical practice review article	US has become an alternative first line imaging procedure in patients with CD. Drawbacks of US are false negative results due to operator inexperience, limitation due to body habitus and duration of the examination. US is an important tool especially for the monitoring of the progression of disease over time.	Low	<sup>92</sup>
Novak, K., Tanyingoh, D., Petersen, F., <i>et al.</i>	Canada	2015	Clinic-based Point of Care Transabdominal Ultrasound for Monitoring Crohn's Disease: Impact on Clinical Decision Making	Cross sectional study	Clinical decisions were changed after ultrasound assessment in 30/49 [60%] and 28/48 [58%] of cases, for each physician respectively [p < 0.0001 for each]. Many [59%] of the patients seen in clinic were asymptomatic with an HBI of 3 or less [n = 29]; however, 52% [n = 15] of these had active disease found on US, resulting in alterations in clinical management. The agreement in overall score between the US reviewers was good, $\kappa = 0.749$ [0.5814, 0.9180], p < 0.001.	Medium	<sup>134</sup>
Castiglione, F., Mainenti, P., De Palma, G.D., <i>et al.</i>	Italy	2013	Non-invasive Diagnosis of Small Bowel Crohn's Disease: Direct Comparison of Bowel Sonography and Magnetic Resonance Enterography	Cross sectional study	diagnosis of small bowel CD was made in 120 of 249 subjects (48%). Sensitivity, specificity, positive predictive value, and negative predictive value for CD diagnosis were 94%, 97%, 97%, and 94% for BS and 96%, 94%, 94%, and 96% for MR enterography, respectively. US	Medium	<sup>142</sup>

					was less accurate than MR enterography in defining CD extension ( $r = 0.69$ ), whereas the concordance in terms of CD location between the 2 procedures was high ( $k = 0.81$ ). Also, MRI showed a fair concordance with US about strictures ( $k = 0.82$ ) and abscesses ( $k = 0.88$ ), with better detection of fistulas ( $k = 0.67$ ).		
Castiglione, F., Testa, A., Rea, M., <i>et al.</i>	Italy	2013	Transmural healing evaluated by bowel sonography in patients with Crohn's disease on maintenance treatment with biologics	Cohort study	Remission and mucosal healing were assessed in accordance with current literature, whereas transmural healing was recorded using US.	Low	<sup>129</sup>
Novak, K.L. and Wilson, S.R.	Canada	2012	Sonography for surveillance of patients with Crohn Disease	Case report and clinical practice review	US is particularly sensitive in detecting SBCD capered to the reference standard colonoscopy and it therefore a useful screening tool. US is effective at detecting complications of CD such as strictures and fistulae. US is preferred for monitoring for assessment of treatment efficacy and routine follow-up.	Low	<sup>127</sup>
Calabrese, E., Zorzi, F. and Pallone, F.	Italy	2011	Ultrasound of the small bowel in Crohn's Disease	Literature review article	US is easy to use and offers good repeatability and accuracy, the most important indication of bowel US is currently in the follow-up of patients known to have CD	Medium	<sup>149</sup>
Hafeez, R., Greenhalgh, R., Rajan, J., <i>et al.</i>	UK	2011	Use of small bowel imaging for the diagnosis and staging of Crohn's disease – a survey of current UK practice	Survey study	63 (27%) departments of radiology (20 in teaching hospitals and 43 in district general hospitals and 73 (29%) departments of gastroenterology replied. These departments were in 119 institutions. 29 (46%) SBUS and 24 (38%) small bowel MRI. SBUS was used mostly for patients younger than 40 years of age with low index of clinical suspicion for Crohn's disease (in 44% of radiology departments (28/63)). MRI was most frequently used in patients under 20 years of age for staging new disease. Gastroenterological referrals largely concurred with the imaging modalities chosen by radiologists, although gastroenterologists were less likely to request SBUS and MRI.	Medium	<sup>163</sup>
Girlich, C., Ott, C., Strauch, U., <i>et al.</i>	Germany	2010	Clinical feature and bowel ultrasound in Crohn's disease - does additional information from magnetic resonance imaging affect therapeutic approach and when does extended diagnostic investigation make sense?	Cross sectional study	Ultrasound should be performed by an experienced examiner, and a proctological examination should be added. MRE is justified in cases of discrepancy between clinical findings and the results of diagnostic ultrasound and, moreover, if Crohn's lesions are suspected at sites proximal to the terminal ileum.	Low	<sup>122</sup>

Calabrese, E., Kucharzik, T., Maaser, C., <i>et al.</i>	International: Italy, Germany, USA, Canada, Japan.	2006	Real-time Interobserver Agreement in Bowel Ultrasonography for Diagnostic Assessment in Patients with Crohn's Disease: An International Multicentre Study	Cross sectional study	All operators agreed on the presence/absence of CD lesions and distinguished absence of/mild activity or moderate/severe lesions in all patients. S values were moderate for bowel wall thickness (s = 0.48, P = n.s.), bowel wall pattern (s = 0.41, P = n.s.), vascularization (s = 0.52, P = n.s.), the majority of the US parameters used in CD showed moderate/substantial agreement. The development of shared US imaging interpretation patterns among sonographers will lead to improved comparability of US results	Low	123
Maconi, G., Radice, E., Greco, S., <i>et al.</i>	Italy	2006	Bowel ultrasound in Crohn's disease	Clinical practice review article	The most important application of bowel US is in the follow-up of patients already diagnosed with Crohn's disease, in whom it may be useful to assess the site and extent of the lesions and to ensure the early detection of intra-abdominal complications, particularly abscesses and strictures. the persistence of a thickened bowel wall or increased high bowel wall thickening at ultrasound following surgery has been identified as an index of early surgical recurrence.	Low	141
Calabrese, E., La Seta, F., Buccellato, A., <i>et al.</i>	Italy	2005	Crohn's Disease: A Comparative Prospective Study of Transabdominal Ultrasonography, Small Intestine Contrast Ultrasonography, and Small Bowel Enema	Cross sectional study	Sensitivities in the detection of small bowel lesions were 96% for SBUS and 100% for contrast enhanced US. Compared with SBUS, contrast enhanced US detected the presence of 4 lesions in the jejunum that had been missed by SBUS. The mean (+/-SD) extent of the ileal disease was 22 +/- 12.5 cm when measured during SBE, 14.5 +/- 8.6 cm when measured during TUS, and 19.5 +/- 12.5 cm when measured during contrast enhanced US [P = 0.05 (contrast enhanced US versus SBUS)].	Low	125
Pascu, M., Roznowski, A.B., Muller, H.P., <i>et al.</i>	Germany	2004	Clinical Relevance of Transabdominal Ultrasonography and Magnetic Resonance Imaging in Patients with Inflammatory Bowel Disease of the Terminal Ileum and Large Bowel	Cross sectional study	segment-by-segment analysis revealed an overall accuracy of 89% for US and 73% for MRI in identifying active IBD. The accuracy was better in patients with UC than in patients with CD for both US and MRI. The correlation of US and MRI activity indices with endoscopic activity measurements was better in patients with UC compared with patients with CD. All three imaging methods showed a significant correlation with clinical disease activity in patients with UC but not in patients with CD.	Low	121

Sturm, E.J.C., Cobben, L.P.J., Meijssen, M.A.C., <i>et al.</i>	Netherlands	2004	Detection of ileocecal Crohn's disease using ultrasound as the primary imaging modality	Cross sectional study	initial imaging study was an abdominal US. Using US, a confident diagnosis of ileocecal Crohn's disease was made in 35 of the 47 patients, Crohn's disease was suggested among the differential diagnosis in 10, and an incorrect diagnosis was made in 2 patients. In 28 of 47 patients, the referring physician did not consider Crohn's disease when requesting the initial US examination.	Low	126
Maconi, G., Carsana, L., Fociani, P., <i>et al.</i>	Italy	2003	Small bowel stenosis in Crohn's disease: clinical, biochemical and ultrasonographic evaluation of histological features	Cross sectional study	Ultrasound and, to a lesser degree, clinical and laboratory indices discriminate between inflammatory and fibrotic ileal stenoses complicating Crohn's disease, thus allowing appropriate medical and/or surgical treatment to be defined.		124
Parente, F., Maconi, G., Bollani, S., <i>et al.</i>	Italy	2002	Bowel ultrasound in assessment of Crohn's disease and detection of related small bowel strictures: a prospective comparative study versus x-ray and intraoperative findings	Cross sectional study	sensitivity and specificity of US in assessing the anatomical distribution of CD were 93% and 97%, respectively. The extent of ileal disease measured at US correlated well with that determined by x ray ( $r=0.52$ , $p<0.001$ ) in medically treated patients as well as with that measured intraoperatively in surgical patients ( $r=0.64$ , $p<0.001$ ). In experienced hands, bowel US is an accurate technique for assessing CD extent and location and is very helpful in detecting small bowel strictures, especially in very severe cases that are candidates for surgery.	Low	150
Pothast, S., Rieber, A., Von Tirpitz, C., <i>et al.</i>	Denmark	2001	Ultrasound and magnetic resonance imaging in Crohn's disease: a comparison	Cross sectional study	MRI is superior to US in the localization of affected bowel segments (sensitivity: MRI 97.5%; US 76%) and in recognizing fistulae (sensitivity: MRI 87%; US 31%), stenoses (sensitivity: MRI 100%; US 58%) and abscesses (sensitivity: MRI 100%; US 89%).	Low	130
Valette, P.J., Rioux, M., Pilleul, F., <i>et al.</i>	France	2001	Ultrasonography of chronic inflammatory bowel diseases	Literature review article	US may display the transformation of the intestinal wall from normal to pathological state in inflammatory diseases. Furthermore, intestinal US may serve as a diagnostic clue if typical patterns of the bowel wall are demonstrated.	Low	128
Tarjan, Z., Toth, G., Gyorke, T., <i>et al.</i>	Hungary	2000	Ultrasound in Crohn's disease of the small bowel	Case series study	sensitivity, specificity and accuracy of ultrasound were 88.4, 93.3 and 90.4%, respectively. US was superior to CT in detecting stenoses and skip lesions. In known Crohn's disease for following disease course, evaluating relapses and extramural manifestations US is an excellent tool.	Low	377

Hollerbach, S., Geissler, H., Schiegl, H., <i>et al.</i>	Germany	1998	The accuracy of abdominal ultrasound in the assessment of bowel disorders	Cross sectional study	Of 227 patients, 168 had pathologic findings of the bowel as final diagnosis. The overall sensitivity of US was 76%, whereas the positive predictive value was 98%. Overall specificity was 95%. The negative predictive value for bowel disorders was only 58%, since US missed pathologic findings in 48 patients. Subgroup analysis showed a sensitivity of 84% for Crohn's disease.	Low	133
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## b. Ethical approval



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26 March 2021

Dear Dr Moran

**HRA and Health and Care  
Research Wales (HCRW)  
Approval Letter**

<b>Study title:</b>	<b>Implementation of Point Of Care UltraSound in the assessment of Crohn's Disease</b>
<b>IRAS project ID:</b>	<b>295783</b>
<b>Protocol number:</b>	<b>21GA005</b>
<b>REC reference:</b>	<b>21/HRA/1053</b>
<b>Sponsor</b>	<b>Nottingham University Hospitals NHS Trust</b>

I am pleased to confirm that [HRA and Health and Care Research Wales \(HCRW\) Approval](#) has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, [in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.](#)

### **How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?**

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.



**c. Survey questions.**

<b>Question asked:</b>		<b>Available responses:</b>
1	Do you have an MRI service for Crohn's disease?	<i>Yes or no</i>
2	How often do you use it in your practice when clinically appropriate?	<i>Always, Usually, Sometimes, Rarely, never.</i>
3	How many MRIs do you do for IBD per month in your hospital? (If unknown leave blank)?	<i>Free text</i>
4	What is your typical waiting time (weeks) to get a result?	<i>Free text</i>
5	How confident are you in your clinical decision making when using MRI data?	<i>Extremely Confident, Very Confident, somewhat confident, not so confident, not at all confident.</i>
6	Do you have a small bowel ultrasound (US) service for Crohn's disease?	<i>Yes or no</i>
7	How often do you use it in your practice when clinically appropriate?	<i>Always, Usually, Sometimes, Rarely, never.</i>
8	How many US do you do for IBD per month in your hospital? (If unknown leave blank)?	<i>Free text</i>
9	What is your typical waiting time (weeks) to get a result?	<i>Free text</i>
10	How confident are you in your clinical decision making when using US data?	<i>Extremely Confident, Very Confident, somewhat confident, not so confident, not at all confident.</i>
11	if you do not have an US service would you be interested in developing one?	<i>Yes or no</i>
12	What is the name of the Trust that you work in?	<i>Dropdown box selection of Hospital or Healthcare trust of the UK.</i>
13	Which region do you work in?	<i>Dropdown box selection of region of the UK.</i>
14	If you wish to be contacted at a later date about small bowel US implementation research please enter your email address here	<i>Free text</i>

## d. Interview study Consent form

**INFORMED CONSENT FORM**  
version 1.0  
30-March-2021

**IRAS Project ID:** 295783

**Title of Study:** Implementation of Point Of Care UltraSound in the assessment of Crohn's Disease

**Sub Study:** interview study

**Name of Chief Investigator:** Dr Gordon W. Moran

**Participant study ID:**

**Please initial box**

1. I confirm that I have read and understand the information sheet version number **1.0** dated **30-March-2021** for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.
3. I understand that relevant sections of my data collected in the study may be looked at by the research group and regulatory authorities where it is deemed relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential.
4. I agree to share my views by taking part in an interview, which will be digitally recorded, and understand that anonymous direct quotes from the study may be used in the study reports.
5. I understand that information about me recorded during the study will be kept in an anonymised format, in a secure database. Data will be kept for a minimum of 7 years after the study has ended.
6. **(Optional)** I would like to be contacted in the future regarding any results, publications and any future research relating to this study, and agree to the investigators collecting, storing and using my contact information.
7. I agree to take part in the above study.

Name of Participant

Date

Signature

\_\_\_\_\_  
Name of Person receiving consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

The POCUS study: interview study  
ICF Version 1.0  
30-march-2021  
IRAS: 295783

## e. Interview study interview schedule



**Semi-structured interview Schedule**  
**Version 1.0**  
**(30-March-2021)**

**IRAS: 295783**

**Study Title:** Implementation of Point Of Care UltraSound in the assessment of Crohn's Disease

**Qualitative interview study.**

1. Can you tell me of your experience(s) of ultrasound (US) use in inflammatory bowel disease (IBD) or any other abdominal examination?
  - a. Experiences of having used US
  - b. Experiences of having undergone US examination
2. Can you explain to me what you think a point of care ultrasound (POCUS) service in IBD might look like?
  - a. What would the patient pathway look like?
  - b. What would the clinical decision pathway look like?
3. Can you tell me how you think the integration of POCUS into IBD services might impact;
  - a. Care delivery
  - b. Patient experiences/outcomes
  - c. Business/budget/service delivery
4. How easy do you think it would be to implement POCUS nationally in the NHS?
5. Do you think that there are any hurdles to implementing POCUS nationally in the NHS?
6. Do you think that POCUS should be implemented nationally in the NHS?

f. Table of codes and themes with definitions.

Themes	Description	Sub-themes	NPT definition <sup>288</sup>	Contributing concepts from analysis
Context	<i>Domains in which implementation work is done</i>	Negotiating capacity	<i>Contexts in which an intervention can be integrated.</i>	<ul style="list-style-type: none"> <li>○ Effort is required to change current working patterns of HCPs can be adapted to incorporate ultrasound.</li> <li>○ The purpose of ultrasound is aligned with current practice aims.</li> <li>○ Further clarification regarding resource use and allocation is required to facilitate implementation</li> </ul>
		Adaptive execution	<i>Contexts in which an intervention can be made workable.</i>	<ul style="list-style-type: none"> <li>○ Effort is required to change the behaviors, and underlying reasoning and beliefs, of healthcare professionals to begin utilising ultrasound in everyday practice.</li> </ul>
Mechanism	<i>The work that people do to make implementation happen</i>	Coherence building	<i>collaborative work that makes interventions and their components meaningful.</i>	<ul style="list-style-type: none"> <li>○ There is a shared belief the introduction of ultrasound into IBD services is a good idea and that it is distinct from other types of imaging.</li> </ul>
		Cognitive participation	<i>The work that participants undertake to build up and sustain a community of practice around an intervention.</i>	<ul style="list-style-type: none"> <li>○ There are significant barriers to the availability and access to training for HCPs to undertake and interpret ultrasound assessments.</li> <li>○ There is a shared belief that there is an obvious benefit to patients and the NHS of the introduction of ultrasound into NHS IBD services.</li> </ul>
		Collective action	<i>People work collaboratively to realise, perform, and operationalize and intervention and its components.</i>	<ul style="list-style-type: none"> <li>○ Healthcare professionals are prepared to invest time and effort, and work collaboratively to implement ultrasound into BD services.</li> <li>○ Communication within, and between, clinical teams is key to successful implementation.</li> <li>○ The impact on daily working patterns is uncertain, with unclear roles and responsibilities in relation to the undertaking of scanning.</li> </ul>
		Reflexive monitoring	<i>People work collaboratively to appraise the effects of an intervention and its components and utilise that knowledge to reconfigure social relations and action.</i>	<ul style="list-style-type: none"> <li>○ Patient engagement and education could be improved with the use of ultrasound in IBD services.</li> <li>○ Reviewing and revising the role and use of ultrasound in IBD services, allowing for adaptation over time, is important for sustained implementation.</li> </ul>
Outcomes	<i>The results of implementation work.</i>	Sustainment	<i>Sustainment activities through which the normalisation of an intervention and its embedding in everyday practice are carried forward as continuous translational action.</i>	<ul style="list-style-type: none"> <li>○ Changes are required to the current care pathways, with restructuring and clinical service level changes to ensure the successful implementation and sustained continued use of ultrasound.</li> </ul>
		Intervention performance	<i>How interventions and their components are operationalized, enacted, reproduced, over time and across settings.</i>	<ul style="list-style-type: none"> <li>○ It will be important to review the use of ultrasound and effectively measure the impact of its introduction into everyday practice.</li> </ul>

g. Examples of interview coding using NVivo 12 software.<sup>1</sup>

Initial node name	Files	References
Behaviors and beliefs	13	74
reassurance	4	5
Reliance on MRI- belief that is more accurate	12	24
Silo Working- lack of communication and collaboration	10	20
Trust - in the test (intervention)	9	16
US- preconceptions of use	4	4
Cognitive participation	14	90
Cognitive Participation - Easily see the point of new test	12	30
Cognitive participation - belief it's a good idea	11	23
Cognitive participation - prepared to invest time, energy and work	13	37
Habit & reluctance to change	10	32
Coherence	12	67
Coherence - fits with goals of original activity	10	35
Coherence- Benefit to whole group	6	8
HCP benefit	7	13
patient benefit	12	44
Coherence- distinct from other tests	11	21
Coherence- easy to describe	3	3
Collective action	14	164
Collective action - how compatible with existing practices	1	1
Collective action - training requirements	14	50
Collective action - affect group work & actions	9	21

Initial node name	Files	References
Collective action - does it fit with organisational goals	9	19
Collective action - impact on resources (all)	14	50
Collective action - promote or impede workflow	10	23
Patient preference	12	46
Patient engagement & involvement	8	15
Reflexive monitoring	7	18
Reflexive Monitoring - perceptions after time	2	2
Reflexive monitoring - Adaption and improvement over time	3	3
Reflexive monitoring-feedback	3	3
Reflexive monitoring-will effects of intervention be clear	6	7

## Codebook: 'Coherence' Theme (Example extract).

Files\001 - § 4 references coded.

### Reference 1

*I can understand the reasons for an ultrasound because it is less invasive.*

### Reference 2

*it just makes more sense to me to be doing the quicker test.*

### Reference 3

*I guess the benefit of having the doctor there, or the nurse, is that they there isn't that gap in getting the message, the report back, but this is already so much quicker that that short delay won't make much difference.*

### Reference 4

*The same could be said for patients, there might be this feeling that they aren't getting as good of a test when they have an ultrasound, but what needs to happen is that its need to be said that this is just as good for this kind of scan, for what is needed.*

Files\002 - § 7 references coded.

### Reference 1

*I have just been thinking about is that it must be cheaper to this US instead or MRIs all the time.*

### Reference 2

*labour side of things surely it is more effective and cheaper to grab a handheld wand and squeeze some jelly on someone's belly and do it like that rather than, I mean how many people do I encounter when I have to go for MRI, at least three.*

### References 3-5

*it is very unpleasant environment noise alone is pretty scary let alone the fact that you have to get canulated you have to drink all this stuff which then for IBD people presents an entirely different set of problems you're trapped in there for up to 45 minutes that is a traumatic experience for people like me and even if you take all that away and you also introduced the possibility that right will then having to take half a day off work to go and have this is scheduled every six months or whatever it is to then offering them something where you only have to pop in for an hour at the end of the day you know pull your jeans down, lift your top up get some gel placed on your belly and have a chat to the doctor who will be having a look at the same time I mean I can't I cannot see a negative at all.*

### Reference 6

*though I don't like the looks of this let's look at this bit more or that send you upstairs for an Xray right now or you know whatever needs to happen rather than 7 months later and all you want are complications or a fistula in that time to decide for you what the plan is.*

### Reference 7

*like a one stop shop where I can get all that done in one go I mean that is the dream to be honest*

Files\003 - § 2 references coded.

Reference 1

*Say anything we can do to reduce the MRI wait and help- get patients seen sooner, get them started on treatment would be beneficial.*

Reference 2

*wasting less time and the patient can be seen the same day as their scan and there's no need for multiple visits, or at least there's no need for long extended visits as with the MRI.*

Files\004 - § 4 references coded.

Reference 1

*it was quite a clear case that was able to use US instead of other things then great, but I think the problem is patients when they have too many steps so you might get your US and then they go for flexi then they go the full scope and then they're going why didn't you just come straight full scope yeah, it's quite uncomfortable and stress and anxiety and delays in the treatment whereas if you can get quite clear one (US) you get really good buy in from the patient themselves, they seem happy, and they get their results much quicker which I think they like.*

Reference 2

*For the patient, the first outpatient appointment or the full appointment can be daunting, and you then go and have any number of other appointments for tests and imaging, then come back to clinic and you could just bring it (US) in and use it there and then and talk to the patient about what going on and where their disease is. Then there's no need for further imaging if it's not actually required, and the patient has some answers there and then. It was quite effective way of doing it.*

Reference 3

*I think it's about making it as obvious as possible that what you're doing is just as good as what the old way was, but its better in some way – so either clinically better, achieves better results, or it's the same, then its quicker, or easier or cheaper. Cheaper doesn't always mean much to clinicians because they don't watch the bottom line but making it a safer and better for patients experience does. It's important to make clear comparisons.*

Reference 4

*making it as normal as possible for them to do the new things, until it doesn't feel as new anymore.*

Files\005 - § 7 references coded.

References 1-2

*So in my own opinion, I think, like MRI, are not as accurate.as maybe people think they are and this I know that when I've had it for my small bowel in particular cause this inflammation is right at the joint of my large and my small bowel and the MRI practically discarded the inflammation that was there, where the ultrasound picked it up and I started treatment, now I have pain again and again I have had my ultrasound way before the MRI.*

Reference 3

*That would take a lot of money to set up, not just the training and the equipment, but also the rest of the stuff, so the extra staffing to cover the training time and the patients potentially having reduced access to rained staff. But I still would argue that I think it's a cheaper option than even doing MRIs unnecessarily for patients who could have been seen by a nurse with ultrasound.*



#### Reference 4

*Unlike the clinical side of things, but I guess from like a patient POV like it is a little more it less labour intensive for them unlike the MRI obviously, Ultrasound is it's easier with liquid and things, but it is such a shorter time if you're If you're fasting on it rather than an MRI.*

#### Reference 5

*it's like it's just about trusting it, isn't it? Because I think a lot of changes quite difficult for many people, and the fact that expose the NHS's quite stretched in quite a lot of ways that adding another single on it is about clarifying. How it's gonna work? Who's going to be doing it? Kind of the. Like kind of levelling of responsibilities so that it's not just gonna fall into to one team is going to trial it and then you know it's going to fail because there are only like a couple of people.*

#### Reference 6

*implementing it solidly with a long-term plan and probably something to give to sites like a plan or a framework for them, and networking across sites where there are places with more experience or expertise they can come and support the smaller places learning how to do it. And so it does need to be adapted in some kind of social way, I guess to figure out the pretty rich data and people opinions and what it will take to make it become the normal thing that they choose to do for their patients. I imagine that will be hard, but that's what this study is all about I guess.*

#### Reference 7

*I think the big hurdle for you will be training and giving people guidance on what it should look like, using platforms I guess like CCUK and IBDUK would be really helpful for that sort of thing, giving a standardised package to sites for them to use however it fits with them is probably the best way I could think of doing it. You'll need lots of experiences people to support the new learners, that will be an issue, but I am sure you have already thought of this.*

Files\006 - § 10 references coded.

#### Reference 1

*the ultrasound is much quicker, and we can come to the patient and do it and get the response there and then, rather than request and wait and send the patient down to the MRI suite.*

#### Reference 2

*I guess they mean quicker and easier. It is certainly better for some of our older patients in terms of them not needing to be prepped anymore. They don't need to have the contrast drink, and they don't need the cannula and the IV Contrast drugs. This makes it safer too I guess.*

#### Reference 3

*I think that the doctors and surgeons I work with like it on the whole, there are some that still choose to send patients for camera, endoscopy, or MRI anyway as they think there might be more going on than we can see.*

#### Reference 4

*I mean like that they know that they are, they know what they are looking for in the scan, they are used to working with them and are confident in knowing what they are planning for the patient.*

#### Reference 5

*ohh well patients won't be having to wait as long for scans and results, sometimes it stops them having to come to the hospitals several times. I think that medical doctors like it because it is quick and easy, so long as they have the training.*

#### Reference 6

*Half of the trouble is finding the right patient to request it for and a doctor who is on board with trying ultrasound as the first test.*

#### Reference 7

*I actually find that most people are enthusiastic about doing a test which is able to help us make decisions quicker for our patients, lots of waiting around for decisions to be made otherwise.*

#### References 8-9

*yes, for sure, there is less radiation, less medications required, we can get patients booked into theatre sooner or even separate out those patients that need MRI and those that don't because the ultrasound made it easier to find out the problem. Patients are in the hospital already, so doing the extra scan isn't a problem, but I guess if it was in a situation where they would have to come back for an MRI and we would be able to save them the trip by doing the ultrasound on the same day, then there's a big difference and I think patients would like that.*

#### Reference 10

*it would just be quicker for everyone to know what was going on sooner, and the patient wouldn't be waiting around for more decisions or tests.*

*Files\007 - § 10 references coded.*

#### Reference 1

*I am a nurse who often goes with my patients to their ultrasound scans, we are in the room with them when they have the scan so we can talk about what treatment options or what the next step is for the patient*

#### Reference 2

*Yes, when needed, there are some we can do just by using the ultrasound, then there are some, especially if newly diagnosed or have a complex history including surgery, that automatically go for an MRI instead of ultrasound unless there is something acute we want to look at?*

#### Reference 3

*Yes we would be able to get the patients their treatment and make decision there and then, there wouldn't be a need to employ someone else to do the scan.*

#### References 4-5

*patients are getting through the system quicker, they are being seen by one of the team, having their ultrasounds and getting results and a plan much quicker than if they were waiting for the MRI.*

#### Reference 6

*The US results are given to the patient when they are having the scan, which is why we always try and be there, one of the nurses, because then they don't need to come back and see us.*

#### Reference 7

*I think different patients have different preferences, there are some patients that have never had an US. Those with complicated anatomy due to surgery maybe.*

#### Reference 8

*well outcomes I hope wouldn't change really, there's no difference in what they scan can tell us. Patient experiences I know would be better. Patients don't like waiting for scans or having to have the contrast agents.*

#### Reference 9

*well we are getting patients seen quicker and giving them the treatment they need sooner, so maybe saving time and money for everyone. Patients aren't coming into hospital as often; we aren't giving them medications they don't need. US itself costs less than MRI so if we can get less people needing MRI by getting them seen using US then that will save money too.*

#### Reference 10

*I just think people should be doing it, patients need to understand that this is a quicker but just as good test.*

Files\008 - § 5 references coded.

#### Reference 1

*there are many specialist centres that do use it, just not many in the UK for some reason. They'll use it in slightly different ways, so some people have these referral pathways to an ultrasound list like we do. Some people use it as a sort of clinical tools, so it's inside the clinic room. We've got a really good ultrasound apartment, so we've got [Clinician] and [Clinician], so we're really fortunate because we do use ultrasound a lot, it's something that we do alongside MRIs as well, but we have definitely got used to using less MRI and quite a few routine follow ups are now US only. ultrasound is a big part of our practise.*

#### Reference 2

*I think we do use it in some really good ways to meet the needs of our patients. We have a couple of patients who will refuse MRI because of bad experiences, because of the contrast that they've had to have which has caused horrible diarrhoea, so we will have the odd patient who is claustrophobic and will refuse to do it as well, so if we can get a good enough image on an ultrasound, we're happy with that ultrasound cause we know their good quality images and reports so we know that if [clinician] or [clinician] report says yes, there is clearly 20 centimetres of TI disease then we know what we are dealing with. If there is a good US Report that said clearly what it was, you know, they're pretty confident when we would be confident in their reporting as well. So I think we're quite lucky in that sense. Obviously US is very good with younger or adolescent patients, particularly if it got learning disabilities. We have quite a few. We've got a big adolescent service where we get quite complex patients, learning disabilities or physical disabilities, and actually ultrasounds and that calmer environment without the noise and the time it takes is so much easier to manage.*

#### Reference 3

*you know because it's quicker and you can interact with the patients much more easily. The nurses or whoever can actually be in the room with the patients and offering advice or knowledge and education right there and then, it can make a big difference to a patients level of understanding.*

#### Reference 4

*I think if I looked into it did find ultrasound is cheaper. I would say I suppose is a bit of patient preference as well as is a cost to consider, patients waiting time spent away waiting and coming back to get things. With an MRI you go away and then you have to wait for your next appointment to Get the results.. I'd say the ultrasound scan would be better all round really.*

#### Reference 5

*It's not invasive, it's quick. There's no real prep other than, you know potentially being nil by mouth and drinking some water, I think patients experience and cost scale wise. It's hugely beneficial and although I think they need to understand the other times you might need to do further investigations as well, so you know it's, I always tell my patients that every test is part of a jigsaw puzzle, and we don't just go on a blood test or a stool sample. You know we did and put everything together to see the bigger picture. If we had loads of all that equipment and the right people trained and everything, I think we may use it more if it was quicker, maybe you know, but it's a really good tool in the right hands.*

Files\009 - § 7 references coded.

#### Reference 1

*SBUS is really easy for us to use, its quick and offers us some fast and reliable answers to simple questions, things like whether to start or continue a biologic, rather than doing the whole MRI thing so it has been really good but what I would be really keen on ,and I keep asking, is whether I can learn it.*

#### Reference 2

*I think that patients would get the care they need quicker, there would be the need for waiting around for scan appointments or need to come back to the hospital, to the scan or to the clinic, it would be done, and I can prescribe on the day.*

#### Reference 3

*I think it's a shame, all we need to do is look at America even some of the European countries, we went to Belgium, and there it is the gastroenterologist doing the scanning in the room at the same appointment, and the patients really benefitted from that sort of arrangement. we could do that in the NHS, I think it is totally achievable, but it rests on people's ability to accept change and adapt the way that they work. That's not easy. But I like to set a boundary and work towards that mentality. we can do so much I have got an opportunity to learn to do SBUS next year as our radiologist is going on Maternity leave, and I will keep asking until they say yes. I think it's a really important skill and Nurses should definitely learn to do it.*

#### Reference 4

*they do get their results on the same day, but sometimes they come back because we need to discuss a change in treatments or escalation.*

#### Reference 5

*I don't see how that could be a negative for anyone. Especially as SBUS is so much Quicker and cheaper than MRI too.*

#### Reference 6

*Obviously, we will still need to MRI some patients, but for things like knowing whether they need immediate care, immediate steroids or surgical referral, it's the reassurance that you got the treat them correctly much quicker than you might have been able to before.*

#### Reference 7

*Embedding this as a skill within the IBD team would really help. I don't think that there needs to be another trained person, like a radiographer, or even a radiologist once there are plenty of trained people because it will add to the therapeutic relationship that's built between the patient and the nurse, or the Medic. It's about making it an at hand test, stop making it seem like it's something extra.*

Files\010 - § 8 references coded.

#### Reference 1

*the other option is MRI, which quite a few patients do get referred to as standard practice, US tends to be for the patients who are fairly well and haven't had surgery, dare I say our straightforward patients who have a clear plan should we see some inflammation. Certainly those patients who are young and not overweight, which can be difficult to find but there are just some people who are suitable for it.*

#### Reference 2

*I think reducing waiting times and getting patients seen and settled on therapy sooner will mean that we are seeing fewer sick patients, less frequently, if we can get them scanned and a plan sooner it just makes sense.*

#### References 3-4

*Just important to have that support, the buy in, and the continued care of the patient, because IBD won't be changing, the therapy and the surgery won't be changing, so it needs to fit in, meet the needs of the IBD patients and the care that they need. I know that there is always going to be the need for MRI, there will never be a replacement for people with complex disease, those heading for surgery or for very widespread disease. But there are a great many patients who would be just fine, having had a baseline, going for US to keep an eye on their disease in terms of inflammation and progression.*

#### References 5-6

*I guess all patients are used to it in terms of they are aware of what an ultrasound is, even if just from maternity, even seeing it on TV or something, I think that might be new to them is using it for something new to them like abdominal issues and diseases like IBD.*

#### Reference 7

*what works for the clinicians or what has the least moving parts in order to do as much as possible with as few as steps.*

#### Reference 8

*We know that US is cheaper per test, but what about the rest, like are we going to send them for an MRI anyway and then it's just an additional charge, or are we going to save money by stopping as many MRIs as possible and possibly avoiding things like admissions and ineffective treatments because we are getting patients through the pathway quicker. We need a clear comparison of the pathways really, MRI versus US and see what the difference in time and money, and if needed the patient outcomes too but I assume that's already been done otherwise you wouldn't have got this far.*

Files\013 - § 1 reference coded.

#### Reference 1

*yes certainly, I find it more shocking that there aren't many NHS hospitals that have a routine US service for gastroenterology.*

Files\014 - § 2 references coded.

Reference 1

*all of the team were keen to get this up and running and we are a relatively junior team with some really enthusiastic senior clinicians who are all research active and open to working in new ways.*

Reference 2

*it's important to make it very explicit what the new intervention is for*