

# BMJ Open Stakeholder-identified barriers and enablers to ultrasound implementation in inflammatory bowel disease services in the UK: a qualitative interview study

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## ABSTRACT

**Objectives** The study sought to explore and better understand the perceptions and experiences of stakeholders in relation to the use of ultrasound for the assessment of inflammatory bowel disease (IBD) in adults in the UK.

**Design** A qualitative semistructured interview study, using template analysis and normalisation process theory, was undertaken.

**Setting** Interviews were conducted using virtual meeting software.

**Results** Fourteen participants were enrolled between 2nd of June 2021 and 6th of September 2021. Participants were from the following roles: medical gastroenterology and radiology doctors, IBD nurse specialists, patients living with IBD, healthcare service managers. Participants reported that perceived barriers included reliance on established imaging and care pathways, reluctance to change, lack of trust in ultrasound in relation to perceived lack of precision and the initial financial and time outlay in establishing an ultrasound service. Participants were enthusiastic for the uptake of ultrasound and discussed enablers to ultrasound uptake including the benefits to patients in terms of reduction in waiting times and earlier diagnosis and treatment allocation, reduced number of hospital appointments and patients having better understanding of their health.

**Conclusion** There are perceived barriers to achieving implementation of ultrasound. There is scant literature to effectively assess these reported barriers. Therefore, there is further research required in the areas of the impact of the use of ultrasound for the assessment of IBD in the UK.

## INTRODUCTION

Inflammatory bowel disease (IBD) refers to two conditions: Crohn's disease (CD) and ulcerative colitis, typically characterised by chronic inflammation of the gastrointestinal tract. Disease distribution in CD varies with up to 70% of patients having small bowel involvement.<sup>1</sup> To ensure optimal long-term clinical outcomes, the 'Selecting Therapeutic targets in IBD' recommendations<sup>2</sup> suggest using objective measures as treatment targets, rather than symptom resolution. A wide

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Using interviews to explore stakeholder perceptions gives unique perspectives on the possible barriers to implementation.
- ⇒ Extensive patient and public involvement work supported the design and undertaking of this research.
- ⇒ Using normalisation process theory in this work allows it to be better understood in terms of the work that people do to implement healthcare interventions.
- ⇒ The recruitment strategy employed in this work does allow for some bias, where only those individuals with interest in ultrasound would have volunteered to take part.

array of biological therapies are employed in treating IBD, and objectively assessing treatment response has significantly increased the projected IBD healthcare burden for the next decade.<sup>3</sup> To ensure cost-effective IBD practice, complex and expensive pharmacological interventions should be targeted at patients most likely to benefit.<sup>4</sup>

Cross-sectional imaging is used to diagnose and monitor disease activity in small bowel CD.<sup>5</sup> Magnetic resonance enterography (MRE) is often employed as a first modality in the UK for assessment and monitoring of ileal CD.<sup>5</sup> Waiting times for a National Health Service (NHS) MRE may be up to 4 weeks or in some instances longer, and have increased due to the impact of the COVID-19 pandemic. Radiological reporting is then undertaken at a later date, adding to possible delays. There is a clinical need to find quicker, more tolerable and cheaper alternatives for monitoring patients with IBD.

Small bowel ultrasound (SBUS) is an alternative to MRE, and has the potential to significantly reduce waiting times, speed up clinical decision-making and improve patient experience and outcomes.<sup>6</sup> Ultrasound is widely used for assessing and monitoring



IBD internationally, and the METRIC trial has demonstrated its relative diagnostic accuracy in comparison with MRE.<sup>7,8</sup> The study reported that sensitivity for detecting small bowel disease was 97% and 92% for MRE and ultrasound, respectively. Specificity was 96% for MRE and 84% for ultrasound.<sup>7</sup> These findings were concordant in both new diagnosis and suspected relapse.<sup>7,8</sup>

There is an eagerness for the introduction of SBUS into UK IBD clinical practice.<sup>9</sup> However, there remains questions regarding reasons why SBUS is not more widely used in the UK. In order to address these uncertainties and identify barriers to service expansion, semistructured interviews were undertaken with key stakeholders. The objective of undertaking this interview study was to better define the perceived barriers and facilitators to ultrasound service uptake in the UK, with results guiding the development of future research and implementation work in IBD services.

## METHODS

Semistructured interviews were undertaken; the method was chosen as it was found to be the most appropriate to gather the depth and richness of data required to meet the research aim. Each participant was invited to participate in a single interview to share their views. Access to participants was facilitated through existing collaboration with National Institute for Health Research Nottingham Biomedical Research Centre, advertisement on social media and via the British Society of Gastroenterology (BSG) members newsletter. Participants from stakeholder groups identified as NHS healthcare professionals (HCPs) (IBD nurse specialists, consultant gastroenterologists, consultant radiologists and service managers) and people living with CD currently under the care of an NHS team were invited to take part in this study. Participants were assessed for inclusion and exclusion criteria (table 1) when responding to expressions of interest, prior to completion and receipt of valid informed consent.

Purposive sampling was used to ensure that data are being collected from the most appropriate cohort to answer the question.<sup>10</sup> 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>11–13</sup>

Interviews were organised around a list of predetermined, open-ended questions (online supplemental appendix), with further questions emerging from interview discourse. Interviews were conducted in this manner to gain greater clarification through exploration of detailed descriptions from participants.<sup>10,14</sup> No face-to-face interviews were able to be undertaken due to the COVID-19 pandemic; all interviews were undertaken using virtual meeting software with audio-visual capabilities. The researcher actively engaged in reflective questioning.<sup>15</sup> Following the interview, the researcher transcribed the digital recording, destroying the recording afterwards. The ‘light tidying up’ technique was used, leaving in verbal hesitations to add context to the discourse which was important for analysis.<sup>16</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>17</sup>

A form of thematic analysis called ‘template analysis’ was chosen as the data analysis methods for this research. Normalisation process theory (NPT) was used as the framework to guide the analysis and interpretation of this work as it is a toolkit that can be used to understand the dynamics of implementing and integrating a complex intervention.<sup>18</sup> NPT is a widely used theory of implementation that can be used to explain the processes by which an intervention becomes ‘normalised’ into routine practice, focusing on the work that people within the system do. The use of the NPT coding manual to support the undertaking of a template analysis provided pointed data while allowing for the generation or alteration of codes and themes throughout analysis.<sup>18,19</sup> Analysis began by classifying a priori codes, developed using factors of NPT, which identified themes strongly expected to be relevant to the analysis. However, these codes were able to be modified in response to the data examined allowing for a comprehensive analysis of the data.<sup>20</sup> The adequacy of the final sample size was continually assessed during the data collection process; when a point of ‘data saturation’

**Table 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>

CD, Crohn's disease; IBD, inflammatory bowel disease; NHS, National Health Service.

**Table 2** 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	University Hospital NHS trust
011	Consultant radiologist	Male	Yes	University Hospital NHS trust
012	IBD nurse	Female	No	University Hospital NHS trust
013	Consultant radiologist	Female	Yes	University Hospital NHS trust
014	Service manager—gastroenterology	Female	Yes	University Hospital NHS trust

CD, Crohn's disease; IBD, inflammatory bowel disease; NHS, National Health Service.

was established, recruitment to the interview study was closed.<sup>21</sup> ‘Data saturation’ was defined as when ‘it was deemed that there was no more exploration required to adequately answer the research question’.<sup>21</sup> Transcription and data analysis occurred at the same rate as recruitment. Coding processes were followed and themes revisited several times in a reflexive process to develop the final themes.<sup>22</sup>

### Patient and public involvement

Patient and public involvement group members were involved in the study design; Nottingham Biomedical Research Centre patient and participant group reviewed the study plan and the study documentation and have given feedback to the study team. We adjusted the study documentation in relation to their feedback, removing jargon and other terms which might be confusing or dissuade patients from taking part.

## RESULTS

Fourteen participants were enrolled in the interview study (table 2). Participants were enrolled between 2nd of June 2021 and 6th of September 2021, with interviews taking place during the same time period. We enrolled three patients living with CD, two IBD nurse specialists, two IBD nurse consultants, one surgical IBD nurse specialist, two consultant gastroenterologists, two consultant radiologists and two gastroenterology service managers. All participants were from different NHS institutions. There were 10 women and 4 men recruited. Participants were asked if they had experience of either undergoing, performing or interpreting results from SBUS examinations; nine participants reported that they

had SBUS experience. Interviews lasted for an average time of 50:47 min (range=35:41–61:34 min).

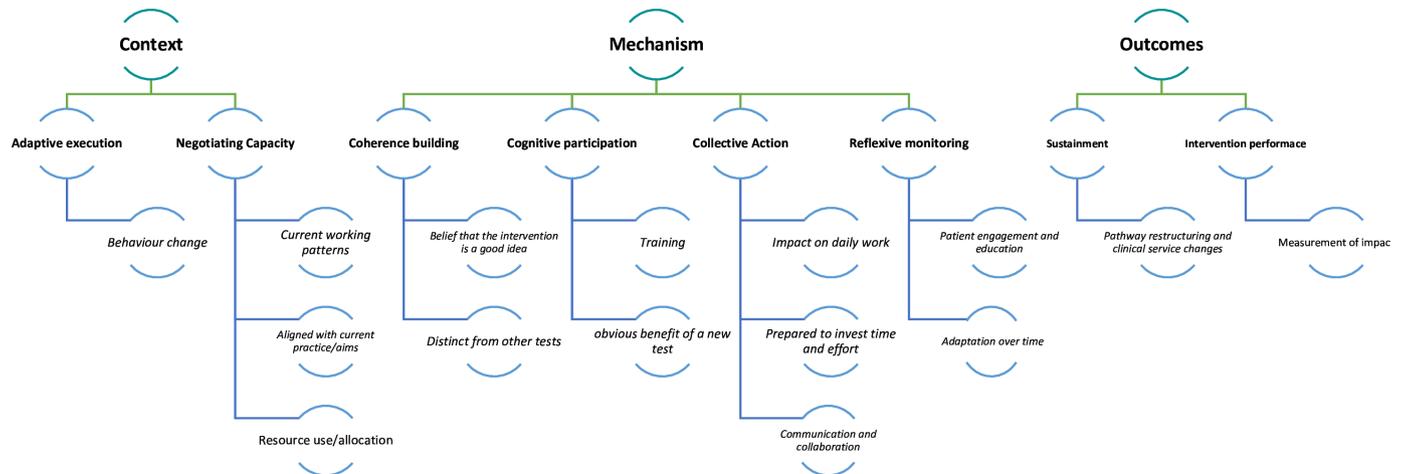
### Themes

Three themes and eight subthemes were generated (figure 1). Four themes were established early in analyses; these were modified and adapted through coding of the data, and final themes were developed through combining minor overlapping themes. Results are presented in sections reflecting the NPT codebook and framework in order to better represent relevance to the study aims. The three themes are derived from concepts borrowed from factors of NPT. ‘Context’ refers to the domains in which work is done and incorporates contextual factors such as environment and capacity. ‘Mechanism’ refers to the work that people do to make an implementation successful and focuses on how the work is done, individual and group buy-in and communicates of practice. The ‘Outcomes’ theme focuses on the results of the implementation work and how individuals and groups interpret intervention performance.

### Context

#### Adaptive execution

Interviewees reported that there was a sense of reluctance to change within some clinical teams, sometimes 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 SBUS. 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



**Figure 1** Themes and codes.

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 such as financial, clinical 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 with 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 was not always the most significant part of daily practice for HCPs: ‘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). Availability of equipment was a concern for around half of the participants; however, all acknowledged that in most cases, the equipment required already exists. Patients also reported that it was important for them to have someone knowledgeable performing and interpreting the results of the scans to give them confidence in their clinical team. 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 and would likely come around from the introduction of SBUS into IBD services.

### *Mechanism*

#### *Coherence building*

All participants reported that in order for an intervention to be implemented, there must be a sustained and shared understanding among HCPs and patients that the new intervention is appropriate and required. 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 were 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).

All participants agreed that HCPs and patients would understand what SBUS was, but there were apprehensions raised about preconceptions of its use. 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 MRE and why it is being implemented. Participants from the HCP group were keen to stress not only 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*

Reasons for implementing SBUS included less invasive procedures and improved patient safety. There was a consensus among the interviewees that implementation of SBUS into IBD practice would be beneficial to patients, HCPs and NHS organisations in multiple ways. 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 by '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), although there was no consideration of how this might be achieved.

Participants identified that training was a major barrier to implementation of SBUS 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). Availability and access to training was reported as being limited: 'it can be quite difficult to find support both in terms of financial and in time, like supported study time can be quite difficult' (011, radiologist). 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. Future proofing access to SBUS training was a potential barrier to sustained rollout of SBUS 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). Alongside collective focus, there was discussion surrounding 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 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. 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. 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).

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).

### *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 patient's 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). HCPs predict, and report experiences of, patients who undergo SBUS and are able to discuss their scan results in real time will be better informed regarding their CD and therefore will be more engaged with their health: '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).

### *Outcomes*

#### *Intervention performance*

All interviewees reported that the expected outcome of the introduction of SBUS into routine care would be cost-saving when compared with MRE use. There were some comments from HCPs that patients living with IBD may have concerns relating to accuracy of SBUS compared with MRE scanning: 'as a patient, maybe you'd wonder whether you're getting the same level of care' (010, gastroenterologist). However, patients reported that they had no such concerns, rating SBUS more preferable compared with MRE. Participants described that implementation of SBUS would mean less hospital visits and shorter waiting times leading to a lessened impact of IBD on daily life: '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. Participants suggested that the best way to review and adapt the SBUS 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).

#### *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 sustainably, how to

keep it going' (003, gastroenterologist). Participants linked the role of an implementation framework to the degree to which a service would be successfully implemented: '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 [other] 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).

## DISCUSSION

Despite sound theoretical basis and empirical support, many interventions do not produce real-world change, as few are successfully implemented and fewer still are sustained long term.<sup>23</sup> 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>24</sup> Engaging with stakeholders to understand the perceived barriers to implementation in a new healthcare intervention can improve the chances of successful implementation.<sup>25</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>26</sup> These inefficient clinical actions have considerable consequences in terms of personal and societal costs to patients, HCPs and NHS.<sup>27</sup> Behavioural and cultural barriers are often cited as major reasons for the lack of innovation adoption in the NHS.<sup>26 28 29</sup> 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 (loss of recognition of expertise or knowledge) and ultimately 'what's in it for me?'.<sup>30</sup>

All interviewees reported that the experienced or expected outcome of the introduction of SBUS into routine care would be cost-saving when compared with MRE use. Financial motivations are indicative of the supply-focused, top-down change management approach that many participants felt impeded innovation adoption.<sup>28</sup> It has been shown in the METRIC<sup>7</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 than MRE per scan.<sup>31</sup>

Obtaining correct and timely diagnoses is important for maximising potential benefits of treatment.<sup>32</sup> However, failure to manage diagnostic uncertainty can lead to delayed diagnoses, treatment delays, and unnecessary tests and treatments.<sup>33</sup> Diagnostic uncertainty may affect patients by decreasing care satisfaction, as well as negatively impacting on confidence and trust in the healthcare

system and HCPs.<sup>34 35</sup> For healthcare systems, uncertainty leads to overtesting and increased healthcare costs.<sup>36 37</sup> The ability to share a focus and recognise a benefit to a new intervention is a crucial step in the adoption of a new intervention.<sup>26 28</sup>

Training of clinical staff to undertake and interpret SBUS scanning was a shared theme in all of the interviews undertaken. Participants identified that availability and access to training was a major barrier to wider implementation of SBUS on a national scale. Training is the cornerstone for building knowledge about the change and the required skills, knowledge and behaviours necessary to implement the change.<sup>29</sup> The only training courses specific to bowel/IBD ultrasound currently are in central Europe and Australia.<sup>38 39</sup>

The METRIC Study detailed that there is relative diagnostic accuracy of SBUS when compared with MRE, and that inter-related reliability was high indicating that there is little discrepancy in relation to both the scanning and reporting procedures.<sup>7</sup> There was further discussion that suggested that patients are trusting in the IBD team to perform the right test and make the appropriate clinical decisions. Therefore, patient fears of diagnostic accuracy could be alleviated through interaction with their HCPs. This has been shown to improve symptom management, quality of life and care satisfaction.<sup>40</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>41-43</sup>

The importance of regular audit is reported as beneficial to implementation success.<sup>23</sup> Many participants suggested that the best way to review and adapt the service would be to conduct audits of various parts of the pathway. However, it is often reported that organisations as a whole look to innovations to produce short-term cash-releasing savings, rather than identifying where innovations can transform care pathways and lead to more efficient services.<sup>28</sup>

## LIMITATIONS

The main limitation of this study is the recruitment strategy employed. This may well lead to bias as those individuals willing to participate are more likely to already have an interest in SBUS use. Therefore, the conclusions may not be representative of the whole stakeholder population. A second limitation of the study is that 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.

## CONCLUSIONS

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 SBUS in their daily practice. Access to training was seen as a significant barrier to the uptake of HCPs performing SBUS in practice. Further research is being undertaken to explore the training needs and wants of HCPs. There was shared enthusiasm among 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 for use in the UK.

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**Contributors** SR—study development, HRA and REC applications, study recruitment, data collection, data analysis and interpretation and manuscript development. PL—data analysis and interpretation guidance, and whole manuscript review. JC—whole manuscript review. GWM—study development and whole manuscript review. SR—guarantor.

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**Competing interests** GM is in receipt of research funding from Janssen, Arla foods and AstraZeneca, and is a consultant for Alimentiv.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not required.

**Ethics approval** This study involves human participants. 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 26 March 2021. Confirmation of Capacity from Nottingham University Hospitals (sponsor) was granted on 26 May 2021 (IRAS Project ID: 295783). Participants gave informed consent to participate in the study before taking part.

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**Data availability statement** All data relevant to the study are included in the article or uploaded as supplemental information.

**Supplemental material** This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

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