

# BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email [editorial.bmjopen@bmj.com](mailto:editorial.bmjopen@bmj.com)

# BMJ Open

## Study Protocol: The National Audit of Small Bowel Obstruction

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-016796
Article Type:	Protocol
Date Submitted by the Author:	10-Mar-2017
Complete List of Authors:	Lee, Matthew; Sheffield Teaching Hospitals NHS FT, Department of General Surgery; South Yorkshire Surgical Research Group Sayers, Adele; Pinderfields General Hospital, General Surgery; South Yorkshire Surgical Research Group Drake, Thomas ; University of Edinburgh, 51 Little France Crescent, Edinburgh, EH16 4SA, United Kingdom, Department of Clinical Surgery, ; South Yorkshire Surgical Research Group Hollyman, Marianne; North Bristol NHS Trust; Severn and Peninsula Audit and Research Collaborative Bradburn, Mike; University of Sheffield School of Health and Related Research, Clinical Trials Research Unit Hind, Daniel; University of Sheffield School of Health and Related Research Wilson, Timothy; Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust, General Surgery; Association of Coloproctology of Great Britain and Ireland Fearnhead, Nicola; Addenbrooke's Hospital, Colorectal Surgery; Association of Coloproctology of Great Britain and Ireland Steering Group, NASBO; National Audit of Small Bowel Obstruction
<b>Primary Subject Heading</b>:	Surgery
Secondary Subject Heading:	Surgery, Nutrition and metabolism
Keywords:	SURGERY, Nutritional support < GASTROENTEROLOGY, HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™  
Manuscripts

**Study Protocol: The National Audit of Small Bowel Obstruction**

MJ Lee<sup>1,2</sup>, AE Sayers<sup>2,3</sup>, TM Drake<sup>2,4</sup>, M Hollyman<sup>5,6</sup>, M Bradburn<sup>7</sup>, D Hind<sup>7</sup>, TR

Wilson<sup>8,9</sup>, NS Fearnhead<sup>9,10</sup> on behalf of the NASBO Steering Group\*

1. Sheffield Teaching Hospitals NHS Foundation Trust, UK, S5 7AU
2. South Yorkshire Surgical Research Group, Sheffield, UK, S5 7AU
3. Mid-Yorkshire NHS Trust, Wakefield, UK, WF1 4DG
4. Department of Clinical Surgery, University of Edinburgh, Edinburgh, UK, EH16  
4SA
5. North Bristol NHS Trust, Bristol, UK, BS10 5NB
6. Severn and Peninsula Audit and Research Collaborative, Bristol, UK, BS10 5NB
7. Clinical Trials Research Unit, School of Health and Related Research,  
Sheffield, UK, S1 4DA
8. Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust,  
Doncaster, UK, DN2 5LT
9. Association of Coloproctology of Great Britain and Ireland, London, UK WC2A  
3PE
10. Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation  
Trust, UK, CB2 0QQ

\*Listed in Appendix 1.

**Corresponding author:**

1  
2  
3 Matthew Lee, Clinical Research Fellow, Sheffield Teaching Hospitals NHS Foundation

4  
5 Trust, Sheffield, S5 7AU

6  
7 Email: [m.j.lee@sheffield.ac.uk](mailto:m.j.lee@sheffield.ac.uk)

8  
9 Telephone: +44 (0) 114 243 43 43

10  
11 Fax: +44 (0) 114 243 43 43

12  
13 Twitter: @NASBO2017 / @wannabehawkeye

14  
15  
16  
17  
18  
19 **Funding:**

20  
21 This project has been funded by the Bowel Disease Research Foundation, Association  
22 of Coloproctology of Great Britain and Ireland, Association of Surgeons of Great  
23 Britain and Ireland, Association of Upper Gastrointestinal Surgeons, British  
24 Association of Parenteral and Enteral Nutrition, British Association for Surgical  
25 Oncology, British Society of Gastroenterology, Royal College of Surgeons of England,  
26 Royal College of Surgeons of Edinburgh, National Emergency Laparotomy Audit and  
27 Royal College of Anaesthetists.

28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41 **Provenance:**

42  
43 Not commissioned, externally peer-reviewed

44  
45  
46  
47  
48 **Author Contributions:**

49  
50 All authors and collaborators contributed to the development of the protocol for the  
51 project. Main drafts of text and revisions undertaken by MJL, AES, TMD, MH, MB,  
52 DH, NSF and TRW. All authors including collaborators have reviewed and approved  
53 the manuscript.  
54  
55  
56  
57  
58  
59  
60

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

**Conflicts of interest:**

The authors have no conflicts of interest to declare

**Word count:** 1849

**Figures:** 2

**Tables:** 1

**Keywords:**

Small bowel obstruction, surgery, nutrition

For peer review only

## ABSTRACT

### *Introduction*

Small bowel obstruction (SBO) is a common indication for emergency laparotomy in the UK, which is associated with a 90-day mortality rate of 13%. There are currently no UK clinical guidelines for the management of this condition. The aim of this multi-centre prospective cohort study is to describe the burden, variation in management and associated outcomes of SBO in the UK adult population.

### *Methods and analysis*

UK hospitals providing emergency general surgery are eligible to participate. This study has three components: i) a clinical preference questionnaire to be completed by consultants providing emergency general surgical care to assesses preferences in diagnostics and therapeutic approaches, including laparoscopy and nutritional interventions; ii) site resource profile questionnaire to indicate ease of access to diagnostic services, operating theatres, nutritional support teams and post-operative support including intensive care; iii) prospective cohort study of all cases of small bowel obstruction admitted during an eight-week period at participating trusts. Data on diagnostics, operative and nutritional interventions, and in-hospital mortality and morbidity will be captured, followed by data validation.

### *Ethics and dissemination*

This will be conducted as a national audit of practice in conjunction with trainee research collaboratives, with support from patient representatives, surgeons, anaesthetists, gastroenterologists and a clinical trials unit. Site-specific reports will

1  
2  
3 be provided to each participant site as well as an overall report to be disseminated  
4  
5 through specialist societies. Results will be published in a formal project report  
6  
7 endorsed by stakeholders, and in peer-reviewed scientific reports. Key findings will  
8  
9 be debated at a focussed national meeting with a view to quality improvement  
10  
11 initiatives.  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## STRENGTHS AND LIMITATIONS

- This study will be the largest prospective assessment of the management of Small Bowel Obstruction in adults in the UK.
- This study will highlight variation in resources and clinical practice, and assess the impact of variation on patient outcomes.
- The methodology limits data to easily measured key components of the treatment pathway that are routinely captured in patient notes.
- Accuracy of data-collection will be assessed in a short *post hoc* validation exercise.
- Potential inclusion of all hospitals providing emergency general surgery will ensure that findings are broadly representative of UK practice.



## BACKGROUND

Mechanical small bowel obstruction (SBO) is a common presentation to emergency general surgery. Eleven and a half thousand patients in England and Wales underwent emergency laparotomy for SBO in In the twelve months from 2014-2015 [1]. This was associated with indication with an associated 90-day mortality rate of 13%[1]. Similar findings have been noted in the United States of America[2].

Small bowel obstruction has several aetiologies, including congenital or post-operative adhesions, abdominal wall hernia and malignancy. Plain film radiography or computer tomography (CT) may be used to confirm the diagnosis and determine underlying cause. Depending on aetiology and comorbidities, patients may be selected for early surgical intervention or conservative management, typically with nasogastric decompression, urinary catheterisation and intravenous fluid therapy[3,4]. Around two thirds of patients managed conservatively for adhesive SBO will settle, but the remainder will require surgery[5] , with a prolonging of the treatment pathway and time to gastrointestinal recovery (Figure 1).

Guidelines already exist in the USA and Europe for the management of SBO[3,4]. The Royal College of Surgeons of England has described a pathway for the management of SBO, although this is presented in guidelines for the commissioning of emergency services, rather than clinical guidelines[6]. This advocates the use of early CT scanning, use of Gastrografin, and timely intervention. Limited specific guidance leads to greater variation in the management of SBO across the UK.

1  
2  
3 Currently available data do not provide a national overview of the management of  
4  
5 SBO: the National Emergency Laparotomy Audit (NELA) captures only the subset of  
6  
7 patients who undergo surgery, meaning that we have no high quality information on  
8  
9 those managed conservatively and their outcomes[1]. As SBO accounts for half of  
10  
11 emergency laparotomies, and likely many more conservatively managed patients,  
12  
13 data to inform policy, quality improvement programmes and clinical trials are an  
14  
15 audit priority[7][8].  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

**AIM**

The aim of this study is to describe the variation in management and outcomes of SBO in the UK.

Objectives of the study are to describe:

- Variations in consultant practice in the management of SBO
- Variation in resources available to support the management of SBO
- Patient pathways and variation in the management of SBO
- Use of diagnostics in SBO (CT, plain film radiography)
- Interventions used in SBO (operative intervention, therapeutic trial of water soluble contrast agent)
- Use of nutritional assessment tools and resulting nutritional interventions

## METHODS

This project has three components: a survey of clinical practice, a site resource questionnaire, and a prospective cohort study (Figure 2). Site recruitment has been undertaken through specialty association conferences and electronic mailing, recruitment presentations at specialty meetings, through trainee research collaboratives, and through professional contacts. All UK hospitals providing emergency general surgery are eligible to participate.

### Survey of clinical practice

An anonymous survey of clinical practice has been designed for completion by consultant surgeons providing emergency general surgery care. This captures basic demographic data including specialty and year of graduation. To contextualise clinical data, respondents are asked to indicate the impact of specific clinical factors on the selection of primary operative or conservative management (e.g. multilevel obstruction due to disseminated malignancy, raised or normal inflammatory markers), the minimum investigations required for management, use of Gastrografin, and use of laparoscopy. The survey also investigates preferences around nutritional support in SBO.

### Site resource profile

The site resource profile is to be completed once for each participating site. This captures data on staffing levels, ease of access to diagnostics, theatres, and nutritional support teams. This will indicate frequency of handovers of care and

1  
2  
3 delays in access to diagnostics: these factors that may delay decision making for  
4  
5 these patients. Access to theatres, intensive care, and nutritional support teams will  
6  
7 indicate resource for implementing these decisions.  
8  
9

### 10 11 12 **Prospective cohort study**

13  
14  
15 Patients eligible for inclusion in the prospective cohort study must have met the  
16  
17 following criteria:

- 18  
19 • Have been admitted from the emergency department or primary care to the  
20  
21 acute surgery team or referred from an inpatient team to the emergency  
22  
23 surgery team  
24  
25
- 26  
27 • A clinical diagnosis of SBO made by a specialty trainee year 3 (ST3) or higher  
28  
29 in general surgery  
30

31  
32 These inclusion criteria are purposefully broad with the intention of capturing as  
33  
34 many patients with SBO as possible.  
35  
36

37  
38 Patients will be excluded if:

- 39  
40 • They have undergone abdominal surgery within the same hospital admission  
41  
42 prior to first symptoms of SBO  
43  
44
- 45  
46 • Pregnant women  
47
- 48  
49 • Patients under the age of 16 years old  
50
- 51  
52 • Patients with large bowel obstruction (even when signs of SBO are present)  
53  
54 e.g. obstructing rectal tumour
- 55  
56 • Patients with a length of stay <24 hours  
57  
58  
59  
60

1  
2  
3 Patients will be identified over an eight-week period. Data to be captured include  
4  
5 basic demographics, comorbidities in the form of the Charlson Comorbidity Index[9],  
6  
7 and usual place of residence (own home, residential home, nursing home) as a proxy  
8  
9 for frailty (Appendix 2). Height and weight are captured to calculate Body Mass Index  
10  
11 and Nutritional Risk Index as risk adjustment tools[10].  
12  
13

14  
15  
16  
17 Data will be recorded on initial and final management strategies, baseline  
18  
19 physiology, diagnostics and nutritional support strategies.  
20  
21

22  
23  
24 The primary outcome is in-hospital mortality. Secondary outcomes include in-  
25  
26 hospital morbidity, length of stay and 30-day readmission.  
27  
28

29  
30  
31 Data will be uploaded to an encrypted and password protected secure REDCap  
32  
33 server, hosted at the University of Sheffield[11]. No identifiable data is uploaded.  
34  
35 Collaborators will keep a local 'key' spreadsheet linking REDCap identifiers to NHS or  
36  
37 Hospital Numbers on their NHS network.  
38  
39

#### 40 41 42 43 *Data validation* 44

45 Only data sets with >95% data completeness will be accepted. Doctors at Core  
46  
47 Trainee level or above, who were not involved in initial data collection will act as  
48  
49 independent assessors, reviewing data collected at a local centre. Overall  
50  
51 independent assessors will validate a minimum of 10% of patient records, with a  
52  
53 target of >95% case ascertainment and >98% data accuracy.  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 The number of identified patients having surgery during the audit period will be  
4  
5 compared to those recorded in the NELA database for the same period. This will give  
6  
7 an indication of how representative the dataset is.  
8  
9

#### 10 11 12 *Pilot*

13  
14 The survey has undergone pilot at two separate sites, with minor revisions after each  
15  
16 round.  
17  
18

19  
20 The prospective audit and site profile questionnaire have undergone a two-week  
21  
22 pilot across eight UK centres to confirm acceptability of definitions and usability of  
23  
24 REDCap system.  
25  
26  
27

#### 28 29 30 31 *Anticipated recruitment*

32  
33 Based upon NELA data for 2014-2015[1] and pilot work, we anticipate mean  
34  
35 identification rates of 3 cases/week per centre. Across 100 centres, anticipated  
36  
37 recruitment would be 2,400 cases.  
38  
39  
40

#### 41 42 43 *Statistical analysis*

44  
45 Analysis will be performed by a statistician at the Clinical Trials Research Unit,  
46  
47 University of Sheffield. Descriptive analysis will be performed to describe raw rates  
48  
49 of mortality and morbidity, with sub-group analysis of primary operation,  
50  
51 conservative management, and failed conservative management. BMI, Nutritional  
52  
53 Risk Index[10], and Charlson Comorbidity Index[9] will be used for risk adjustment.  
54  
55 Descriptive reporting of the use of diagnostics, operative approach and nutritional  
56  
57  
58  
59  
60

1  
2  
3 support in the treatment pathway will be performed, and association with outcomes  
4  
5 recorded.  
6  
7  
8  
9

10 Data will be matched to site resource profiles to assess the relationship between  
11  
12 resource availability and management practices.  
13  
14

### 15 16 17 *Ethics and governance*

18  
19 This project has been assessed by the Scientific Officer of the South East Scotland  
20  
21 Research Ethics Service, who confirmed that the project did not require ethical  
22  
23 approval. All sites must secure local audit approval prior to collecting data, and  
24  
25 Information Governance or Caldicott approval prior to uploading data to REDCap.  
26  
27 Caldicott approval for Scotland will be secured through a single central application.  
28  
29  
30  
31  
32

### 33 34 *Funding*

35  
36 This project has received funding from the Bowel Disease Research Foundation,  
37  
38 Association of Coloproctology of Great Britain and Ireland, Association of Surgeons  
39  
40 of Great Britain & Ireland, Association of Upper Gastrointestinal Surgeons, British  
41  
42 Association of Parenteral and Enteral Nutrition, British Association for Surgical  
43  
44 Oncology, British Society of Gastroenterology, Royal College of Surgeons of England,  
45  
46 Royal College of Surgeon of Edinburgh, National Emergency Laparotomy Audit and  
47  
48 Royal College of Anaesthetists.  
49  
50  
51  
52

### 53 54 55 *Authorship*



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

All collaborators returning complete and validated datasets within the timelines will be eligible for collaborative authorship. This will be reported in line with the CRediT taxonomy[12]. We intend that each site has no more than four collaborators.

For peer review only

## DISCUSSION

Small bowel obstruction carries significant morbidity and mortality, however most work on this topic has focussed on specific diagnostic or therapeutic interventions, with little focus on how to address the associated high levels of mortality. The guidance from Eastern Association for the Surgery of Trauma, and World Society for Emergency Surgery offers extensive information on the use of CT scans to identify strangulation or 'high grade' SBO and the selection of patients for surgery (and operative approach), or conservative management[3,4]. This guidance does not substantially address other issues such as nutritional interventions, use of Total Parenteral Nutrition (TPN), or considerations in post-operative care.

This study will deliver the largest prospective assessment of the management of SBO in adults in the UK. Using clinical data on management of SBO, clinician management preferences, and a local resource profile, we will report variation in management of this condition. These data will also permit early exploration of factors associated with variation in practice, and their relationship to outcomes. This study will also provide preliminary data on interventions used in SBO to re-establish feeding. Other studies in the field have focussed only on specific areas of SBO management and to our knowledge, there is very limited data with regards to how nutrition is handled. The central aim of the NASBO project is to address this by delivering high quality data across multiple centres.

1  
2  
3 This project uses multiple methods to accumulate data including surveys and clinical  
4  
5 data collection. Surveys have been carefully designed and piloted to ensure validity  
6  
7 and clarity of questions.  
8  
9

10  
11  
12 The snapshot clinical data-capture has been designed to capture key components of  
13  
14 the SBO pathway. Whilst it captures several key nodes of clinical practice, it does not  
15  
16 report on the use of nasogastric tubes or use of intravenous fluids. Whilst these are  
17  
18 commonly used, accurate data capture to describe them would require a significant  
19  
20 amount of resource for what is likely to be highly granular data. If required, these  
21  
22 factors could be explored in future studies delivered by the NASBO network. The  
23  
24 treatment pathway and pathophysiology of SBO is complex and varied. This  
25  
26 complexity, however, must be balanced with the ability to deliver high-quality,  
27  
28 usable data. This balance has been emphasised when designing the study and  
29  
30 developing data collection tools.  
31  
32  
33  
34  
35  
36  
37

38 Trainee research collaboratives have previously demonstrated the ability to deliver  
39  
40 large multicentre studies[13,14]. This study differs in that it is the first time UK  
41  
42 trainee research collaboratives have partnered with a number of specialty  
43  
44 organisations and policy makers. The complexity of patient pathways and variation  
45  
46 in clinical decision-making make SBO a prime target for intervention. Use and timing  
47  
48 of CT, nutritional support and surgical intervention are all potentially costly  
49  
50 interventions which are accompanied with risks to the patient. Therefore, it is  
51  
52 imperative to generate a high-quality evidence base in a condition which carries a  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 high mortality and morbidity rate. High quality data on SBO will also allow  
4  
5 appropriate assessment of the health economic impact of future interventions.  
6  
7

8  
9  
10 We envisage this project will allow a network to be formed of clinicians who have an  
11  
12 interest in improving outcomes following small bowel obstruction. This network will  
13  
14 permit the delivery of quality improvement projects and further, interventional  
15  
16 research studies to be performed based upon the results of the inaugural NASBO  
17  
18 study.  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## References

- 1 National Emergency Laparotomy Audit. The Second Patient Report of the National Emergency Laparotomy Audit (NELA) December 2014 to November 2015. London: 2016.
- 2 Scott J, Olufajo O, Brat G, *et al*. Use of National Burden to Define Operative Emergency General Surgery. *JAMA Surg* 2016;**151**:e160480.
- 3 Maung AA, Johnson DC, Piper GL, *et al*. Evaluation and management of small-bowel obstruction. *J Trauma Acute Care Surg* 2012;**73**:S362–9. doi:10.1097/TA.0b013e31827019de
- 4 Di Saverio S, Coccolini F, Galati M, *et al*. Bologna guidelines for diagnosis and management of adhesive small bowel obstruction (ASBO): 2013 update of the evidence-based guidelines from the world society of emergency surgery ASBO working group. *World J Emerg Surg* 2013;**8**:42. doi:10.1186/1749-7922-8-42
- 5 Fevang BT, Jensen D, Svanes K, *et al*. Early operation or conservative management of patients with small bowel obstruction? *Eur J Surg* 2002;**168**:475–81. doi:10.1080/110241502321116488
- 6 ASGBI, Royal College of Surgeons of England. Commissioning guide: Emergency General Surgery. London: 2014.
- 7 Boney O, Bell M, Bell N, *et al*. Identifying research priorities in anaesthesia and perioperative care: final report of the joint National Institute of Academic Anaesthesia/James Lind Alliance Research Priority Setting Partnership. *BMJ Open* 2015;**5**:e010006. doi:10.1136/bmjopen-2015-010006
- 8 Tiernan J, Cook A, Geh I, *et al*. Use of a modified Delphi approach to develop

- 1  
2  
3 research priorities for the association of coloproctology of Great Britain and  
4  
5 Ireland. *Color Dis* 2014;**16**:965–70. doi:10.1111/codi.12790  
6  
7  
8 9 Charlson ME, Pompei P, Ales KL, *et al*. A new method of classifying prognostic  
9  
10 comorbidity in longitudinal studies: Development and validation. *J Chronic Dis*  
11  
12 1987;**40**:373–83. doi:10.1016/0021-9681(87)90171-8  
13  
14  
15 10 The Veterans Affairs Total Parenteral Nutrition Cooperative Study Group.  
16  
17 Perioperative Total Parenteral Nutrition in Surgical Patients. *N Engl J Med*  
18  
19 1992;**327**:70–5. doi:10.1056/NEJM199207093270202  
20  
21  
22 11 Harris PA, Taylor R, Thielke R, *et al*. Research electronic data capture  
23  
24 (REDCap)-A metadata-driven methodology and workflow process for  
25  
26 providing translational research informatics support. *J Biomed Inform*  
27  
28 2009;**42**:377–81. doi:10.1016/j.jbi.2008.08.010  
29  
30  
31 12 Brand A, Allen L, Altman M, *et al*. Beyond authorship: Attribution,  
32  
33 contribution, collaboration, and credit. *Learn Publ* 2015;**28**:151–5.  
34  
35 doi:10.1087/20150211  
36  
37  
38 13 Bhangu A, Richardson C, Torrance A, *et al*. Multicentre observational study of  
39  
40 performance variation in provision and outcome of emergency  
41  
42 appendicectomy. *Br J Surg* 2013;**100**:1240–52. doi:10.1002/bjs.9201  
43  
44  
45 14 STARSURG Collaborative. Multicentre prospective cohort study of body mass  
46  
47 index and postoperative complications following gastrointestinal surgery. *Br J*  
48  
49 *Surg* 2016;**115**:7–72. doi:10.1002/bjs.10203  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

**Appendix 1: NASBO Steering Group (to be PubMed citable)**

John Abercrombie, Austin G Acheson, Derek Alderson, Iain Anderson, Simon Bach,  
Michael Davies, Zaed Hamady, John Hartley, John Northover, Christopher Lewis, Paul  
Marriott, Nicholas Maynard, Malcolm McFall, Aravinth Muraganathan, David  
Murray, Pritam Singh, Gillian Tierney, Azmina Verjee, Ciaran Walsh, Jonathan Wild.

For peer review only

## Appendix 2. Data fields collected for cohort study

Field	Options (definitions)
Age	In years
Height	In centimetres,
Weight	In kilograms
Sex	Male, Female
Comorbidities	Myocardial infarct Congestive heart failure Peripheral vascular disease Cerebrovascular disease (except hemiplegia) Dementia Chronic pulmonary disease Connective tissue disease Peptic ulcer disease Mild liver disease Diabetes (without complications) Diabetes with end organ damage Hemiplegia (or paraplegia) Moderate or severe renal disease Solid tumour (non-metastatic) Leukaemia Lymphoma, Multiple Myeloma... Moderate or severe liver disease Metastatic solid tumour AIDS
Source of referral	Emergency Department General Practice Surgical Clinic admission Referral from inpatient team



<b>Where was the patient living prior to admission to the hospital?</b>	Own Home/Sheltered Accommodation Residential Home Nursing Home
<b>Date admitted to hospital</b>	Day/Month/Year
<b>Date first seen by a member of the surgical team</b>	Day/Month/Year
<b>Date of last enteral intake</b>	Day/Month/Year
<b>Initial management strategy</b>	Conservative <input type="checkbox"/> Operative ( Palliative
<b>White Cell Count</b>	
<b>C-Reactive Protein</b>	
<b>Albumin</b>	
<b>Did the patient have an AKI at admission?</b>	Yes / No
<b>Was the patient identified as being malnourished, or at risk of malnourishment?</b>	Yes / No Day/Month/Year
<b>How was this identified?</b>	
<b>Was the patient reviewed by a dietitian or nutrition team during admission?</b>	Yes / No
<b>Were oral supplements (e.g. fortisips) started at any point started at any point during admission?</b>	Yes / No Day/Month/Year
<b>Was NG or NJ feed started during admission?</b>	Yes / No Day/Month/Year
<b>Was TPN started during the admission?</b>	Yes / No Day/Month/Year
<b>If TPN was used, when was it stopped?</b>	Day/Month/Year
<b>Was intravenous access established for nutrition?</b>	Yes / No

	Peripheral cannula
	Peripherally inserted central catheter (PICC)
	Central venous catheter (CVC/Central line)
	Hickmann line
<b>What type of line was initially used?</b>	
<b>What date was this inserted?</b>	Day/Month/Year
<b>Did the patient develop line sepsis related to this line?</b>	Yes / No
<b>Date line sepsis diagnosed</b>	Day/Month/Year
<b>Abdominal X-ray performed</b>	Yes / No
	Day/Month/Year
<b>CT scan performed</b>	Yes / No
	Day/Month/Year
<b>Did the patient receive water-soluble contrast agent (gastrografin) apart from when undergoing a CT scan?</b>	Yes / No
	Day/Month/Year
<b>Aetiology</b>	Congenital band adhesion Post-operative adhesions Right sided colon cancer Crohn's disease Disseminated intra-abdominal malignancy Incarcerated Hernia - Groin Incarcerated hernia - Midline Incarcerated hernia - Incisional Incarcerated Hernia - Parastomal Small bowel Volvulus Other_____
<b>Did the patient undergo an operation/procedure for SBO?</b>	Yes / No
	Day/Month/Year
<b>American Society of Anesthesiologist (ASA)</b>	Classified as:

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	<b>score</b>	1. A normal healthy patient 2. A patient with mild systemic disease 3. A patient with severe systemic disease 4. A patient with severe systemic disease that is a constant threat to life 5. A moribund patient who is not expected to survive without the operation
22 23 24 25 26 27 28 29 30	<b>Method of operation</b>	Laparoscopic Lap converted to open Open (midline) Open (groin) Open (other)
31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47	<b>What intervention?</b>	Division (single) band adhesion Adhesiolysis Hernia repair Small bowel resection Large bowel resection Formation jejunostomy Formation ileostomy Anastomosis of bowel Other
48	<b>Date resumed enteral nutrition</b>	Day/Month/Year
49	<b>In hospital death</b>	Yes / No
50	<b>Date patient medically fit for discharge:</b>	Day/Month/Year
51	<b>Date of discharge</b>	Day/Month/Year
52 53 54 55 56 57 58 59 60	<b>Readmitted within 30-days post discharge</b>	Yes / No

<b>Discharge destination</b>	Own Home/Sheltered Accommodation
	Rehabilitation Unit
	Residential Home <input type="checkbox"/>
	Nursing Home <input type="checkbox"/>
	Hospice
	Still acute inpatient on 30/4/17
	Deceased
<b>In hospital complications</b>	UTI
	Pneumonia
	Cardiac
	PE/DVT
	Delirium
	Superficial surgical site infection
	Intra abdominal sepsis
	Abdominal wall dehiscence
	Anastomotic leak
	Radiological drain
	Reoperation
	Unplanned HDU/ITU admission

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

**Figure headings:**

**Figure 1: Conceptual schematic of pathways in the management of Small Bowel**

**Obstruction, including typical diagnoses and nutritional outcomes.**

**Figure 2: Components of NASBO study, and how they are related.**

For peer review only

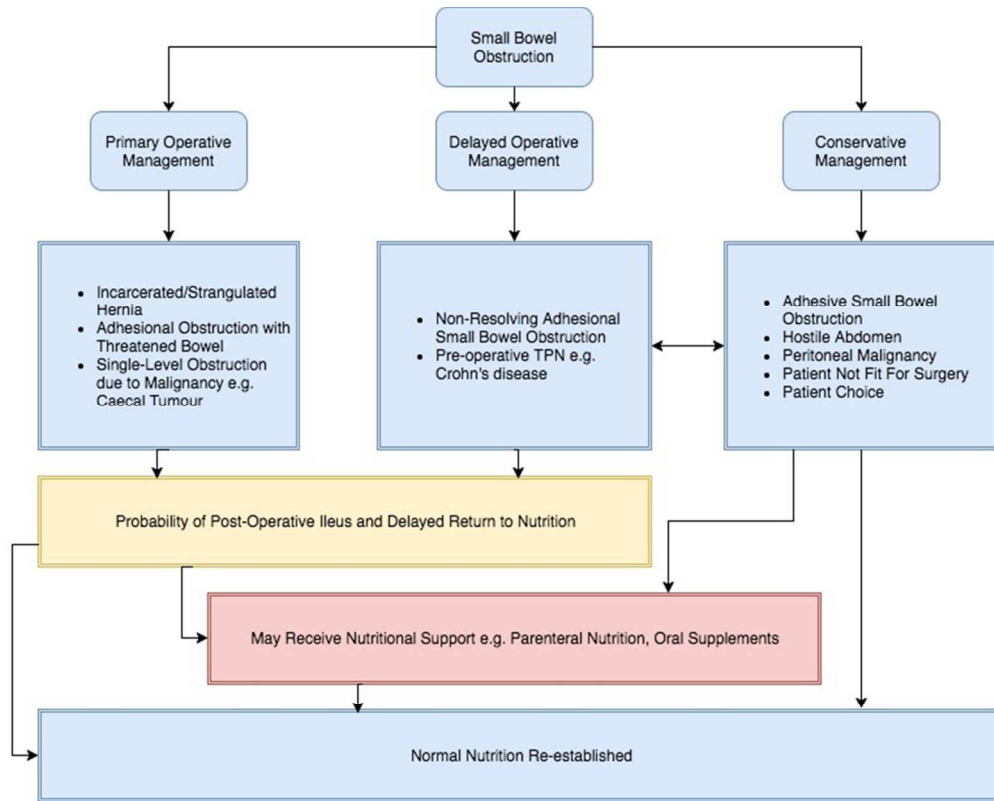


Figure 1: Conceptual schematic of pathways in the management of Small Bowel Obstruction, including typical diagnoses and nutritional outcomes.

270x215mm (72 x 72 DPI)

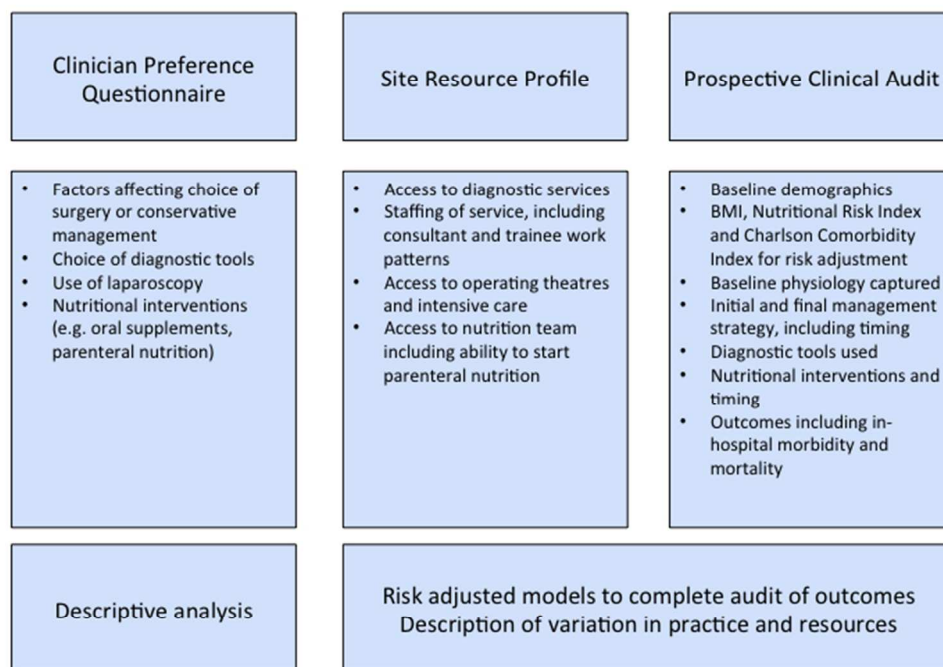


Figure 2: Components of NASBO study, and how they are related.

254x190mm (72 x 72 DPI)

# BMJ Open

## A UK based, multi-site, prospective cohort study of Small Bowel Obstruction in acute surgical services: National Audit of Small Bowel Obstruction (NASBO) protocol.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-016796.R1
Article Type:	Protocol
Date Submitted by the Author:	08-Aug-2017
Complete List of Authors:	Lee, Matthew; Sheffield Teaching Hospitals NHS FT, Department of General Surgery; South Yorkshire Surgical Research Group Sayers, Adele; Pinderfields General Hospital, General Surgery; South Yorkshire Surgical Research Group Drake, Thomas ; University of Edinburgh, 51 Little France Crescent, Edinburgh, EH16 4SA, United Kingdom, Department of Clinical Surgery, ; South Yorkshire Surgical Research Group Hollyman, Marianne; North Bristol NHS Trust; Severn and Peninsula Audit and Research Collaborative Bradburn, Mike; University of Sheffield School of Health and Related Research, Clinical Trials Research Unit Hind, Daniel; University of Sheffield School of Health and Related Research Wilson, Timothy; Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust, General Surgery; Association of Coloproctology of Great Britain and Ireland Fearnhead, Nicola; Addenbrooke's Hospital, Colorectal Surgery; Association of Coloproctology of Great Britain and Ireland Steering Group, NASBO; National Audit of Small Bowel Obstruction
<b>Primary Subject Heading</b>:	Surgery
Secondary Subject Heading:	Surgery, Nutrition and metabolism
Keywords:	SURGERY, Nutritional support < GASTROENTEROLOGY, HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™  
Manuscripts



1  
2  
3 **A UK based, multi-site, prospective cohort study of Small Bowel Obstruction in**  
4  
5 **acute surgical services: National Audit of Small Bowel Obstruction (NASBO)**  
6  
7 **protocol.**  
8  
9

10  
11  
12 MJ Lee<sup>1,2</sup>, AE Sayers<sup>2,3</sup>, TM Drake<sup>2,4</sup>, M Hollyman<sup>5,6</sup>, M Bradburn<sup>7</sup>, D Hind<sup>7</sup>, TR  
13  
14 Wilson<sup>8,9</sup>, NS Fearnhead<sup>9,10</sup> on behalf of the NASBO Steering Group\*

- 15  
16  
17  
18  
19 1. Sheffield Teaching Hospitals NHS Foundation Trust, UK, S5 7AU
- 20  
21 2. South Yorkshire Surgical Research Group, Sheffield, UK, S5 7AU
- 22  
23 3. Mid-Yorkshire NHS Trust, Wakefield, UK, WF1 4DG
- 24  
25 4. Department of Clinical Surgery, University of Edinburgh, Edinburgh, UK, EH16  
26  
27 4SA
- 28  
29 5. North Bristol NHS Trust, Bristol, UK, BS10 5NB
- 30  
31 6. Severn and Peninsula Audit and Research Collaborative, Bristol, UK, BS10 5NB
- 32  
33 7. Clinical Trials Research Unit, School of Health and Related Research,  
34  
35 Sheffield, UK, S1 4DA
- 36  
37 8. Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust,  
38  
39 Doncaster, UK, DN2 5LT
- 40  
41 9. Association of Coloproctology of Great Britain and Ireland, London, UK WC2A  
42  
43 3PE
- 44  
45 10. Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation  
46  
47 Trust, UK, CB2 0QQ
- 48  
49  
50  
51  
52  
53  
54  
55  
56

57 \*Listed in Supplementary File for Editors  
58  
59  
60

**Corresponding author:**

Matthew Lee, Clinical Research Fellow, Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, S5 7AU

Email: [m.j.lee@sheffield.ac.uk](mailto:m.j.lee@sheffield.ac.uk)

Telephone: +44 (0) 114 243 43 43

Fax: +44 (0) 114 243 43 43

Twitter: @NASBO2017 / @wannabehawkeye

**Funding:**

This project has been funded by the Bowel Disease Research Foundation, Association of Coloproctology of Great Britain and Ireland, Association of Surgeons of Great Britain and Ireland, Association of Upper Gastrointestinal Surgeons, British Association of Parenteral and Enteral Nutrition, British Association for Surgical Oncology, British Society of Gastroenterology, Royal College of Surgeons of England, Royal College of Surgeons of Edinburgh, National Emergency Laparotomy Audit and Royal College of Anaesthetists.

**Provenance:**

Not commissioned, externally peer-reviewed

**Author Contributions:**

All authors and collaborators contributed to the development of the protocol for the project. Main drafts of text and revisions undertaken by MJL, AES, TMD, MH, MB,

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

DH, NSF and TRW. All authors including collaborators have reviewed and approved the manuscript.

**Conflicts of interest:**

The authors have no conflicts of interest to declare

**Word count:** 1849

**Figures:** 2

**Tables:** 1

**Keywords:**

Small bowel obstruction, surgery, nutrition

For peer review only

**ABSTRACT***Introduction*

Small bowel obstruction (SBO) is a common indication for emergency laparotomy in the UK, which is associated with a 90-day mortality rate of 13%. There are currently no UK clinical guidelines for the management of this condition. The aim of this multi-centre prospective cohort study is to describe the burden, variation in management and associated outcomes of SBO in the UK adult population.

*Methods and analysis*

UK hospitals providing emergency general surgery are eligible to participate. This study has three components: i) a clinical preference questionnaire to be completed by consultants providing emergency general surgical care to assesses preferences in diagnostics and therapeutic approaches, including laparoscopy and nutritional interventions; ii) site resource profile questionnaire to indicate ease of access to diagnostic services, operating theatres, nutritional support teams and post-operative support including intensive care; iii) prospective cohort study of all cases of small bowel obstruction admitted during an eight-week period at participating trusts. Data on diagnostics, operative and nutritional interventions, and in-hospital mortality and morbidity will be captured, followed by data validation.

*Ethics and dissemination*

1  
2  
3 This will be conducted as a national audit of practice in conjunction with trainee  
4  
5 research collaboratives, with support from patient representatives, surgeons,  
6  
7 anaesthetists, gastroenterologists and a clinical trials unit. Site-specific reports will  
8  
9 be provided to each participant site as well as an overall report to be disseminated  
10  
11 through specialist societies. Results will be published in a formal project report  
12  
13 endorsed by stakeholders, and in peer-reviewed scientific reports. Key findings will  
14  
15 be debated at a focussed national meeting with a view to quality improvement  
16  
17 initiatives.  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

### STRENGTHS AND LIMITATIONS

- This study will be the largest prospective assessment of the management of Small Bowel Obstruction in adults in the UK.
- This study will highlight variation in resources and clinical practice, and assess the impact of variation on patient outcomes.
- The methodology limits data to easily measured key components of the treatment pathway that are routinely captured in patient notes.
- Accuracy of data-collection will be assessed in a short *post hoc* validation exercise.
- Potential inclusion of all hospitals providing emergency general surgery will ensure that findings are broadly representative of UK practice.

## BACKGROUND

Mechanical small bowel obstruction (SBO) is a common presentation to emergency general surgery. Eleven and a half thousand patients in England and Wales underwent emergency laparotomy for SBO during the twelve months from April 2014-March 2015 [1]. This was associated with an associated 90-day mortality rate of 13%[1]. Similar findings have been noted in the United States of America[2].

Small bowel obstruction has several aetiologies, including congenital or post-operative adhesions, abdominal wall hernia and malignancy. Plain film radiography or computer tomography (CT) may be used to confirm the diagnosis and determine underlying cause. Depending on aetiology and comorbidities, patients may be selected for early surgical intervention or conservative management, typically with nasogastric decompression, urinary catheterisation and intravenous fluid therapy[3,4]. Around two thirds of patients managed conservatively for adhesive SBO will settle, but the remainder will require surgery[5], with a prolonging of the treatment pathway and time to gastrointestinal recovery (Figure 1).

Guidelines already exist in the USA and Europe for the management of SBO[3,4]. The Royal College of Surgeons of England has described a pathway for the management of SBO, although this is presented in guidelines for the commissioning of emergency services, rather than clinical guidelines[6]. This advocates the use of early CT scanning, use of Gastrografin, and timely intervention. Limited specific guidance leads to variation in the management of SBO across the UK.

1  
2  
3 Currently available data do not provide a national overview of the management of  
4  
5 SBO: the National Emergency Laparotomy Audit (NELA) captures only the subset of  
6  
7 patients who undergo surgery, meaning that we have no high quality information on  
8  
9 those managed conservatively and their outcomes[1]. As SBO accounts for half of  
10  
11 emergency laparotomies, and likely many more conservatively managed patients,  
12  
13 data to inform policy, quality improvement programmes and clinical trials are an  
14  
15 audit priority[7][8].  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60



**AIM**

The aim of this study is to describe the variation in management and outcomes of SBO in the UK.

Objectives of the study are to describe:

- Variations in consultant practice in the management of SBO
- Variation in resources available to support the management of SBO
- Patient pathways and variation in the management of SBO
- Use of diagnostics in SBO (CT, plain film radiography)
- Interventions used in SBO (operative intervention, therapeutic trial of water soluble contrast agent)
- Use of nutritional assessment tools and resulting nutritional interventions
- Rate of in-hospital mortality in patients treated for SBO
- Rates of 30-day readmission following treatment for SBO
- Rates of unplanned escalation to intensive care

## METHODS

This project has three components: a survey of clinical practice, a site resource questionnaire, and a prospective cohort study (Figure 2). Site recruitment has been undertaken through specialty association conferences and electronic mailing, recruitment presentations at specialty meetings, through trainee research collaboratives, and through professional contacts. All UK hospitals providing emergency general surgery are eligible to participate. This project has been registered with the Healthcare Quality Improvement Partnership (HQIP).

### Survey of clinical practice

An anonymous survey of clinical practice has been prepared. This is to be completed only by Consultant Surgeons who provide emergency general surgery care – these clinicians are ultimately responsible for the inpatient management of this group and their preferences should influence care rather than other grades of doctor or other specialties. This captures basic demographic data including specialty and year of graduation. To contextualise clinical data, respondents are asked to indicate the impact of specific clinical factors on the selection of primary operative or conservative management (e.g. multilevel obstruction due to disseminated malignancy, raised or normal inflammatory markers), the minimum investigations required for management, use of Gastrografin, and use of laparoscopy. The survey also investigates preferences around nutritional support in SBO. Based on previous experience of surveying surgeons in areas with limited guidance, concerns have been expressed about providing responses out of line with the majority of the profession.

1  
2  
3 In order to maximise returns, we decided to make this anonymous. This means that  
4  
5 we cannot link back to institutions.  
6  
7  
8  
9

### 10 **Site resource profile**

11  
12 The site resource profile is to be completed once for each participating site. This  
13 captures data on staffing levels, ease of access to diagnostics, theatres, and  
14 nutritional support teams. This will indicate frequency of handovers of care and  
15 delays in access to diagnostics: these factors that may delay decision making for  
16 these patients. Access to theatres, intensive care, and nutritional support teams will  
17 indicate resource for implementing these decisions. The questionnaire also assesses  
18 availability of resources on weekdays, weekends and overnight.  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30

### 31 **Prospective cohort study**

32  
33 Patients eligible for inclusion in the prospective cohort study must have met the  
34 following criteria:  
35  
36

- 37  
38 • Have been admitted from the emergency department or primary care to the  
39 acute surgery team or referred from an inpatient team to the emergency  
40 surgery team  
41  
42
- 43 • A clinical diagnosis of SBO made by a specialty trainee year 3 (ST3) or higher  
44 in general surgery  
45  
46  
47  
48

49  
50 These inclusion criteria are purposefully broad with the intention of capturing as  
51 many patients with SBO as possible.  
52  
53  
54  
55

56  
57 Patients will be excluded if:  
58  
59  
60

- They have undergone abdominal surgery within the same hospital admission prior to first symptoms of SBO
- Pregnant women
- Patients under the age of 16 years old
- Patients with large bowel obstruction (even when signs of SBO are present) e.g. obstructing rectal tumour
- Patients with a length of stay <24 hours (discharged home)

Where the initial diagnosis changes, patients will be excluded retrospectively.

Patients will be identified over an eight-week period. This period has been selected based on pilot data and NELA reports – to ensure a representative sample of cases and facilitate meaningful analysis, we set a target of 1,500 cases. Extrapolation of numbers from a multi-site pilot suggested that >2,000 cases would be identified during a two week period, with an exclusion rate of around 20%. Consideration was also given to rotation of junior medical staff, who undertake the majority of data collection, and the period avoids most rotation dates. Data to be captured include basic demographics, comorbidities in the form of the Charlson Comorbidity Index[9], and usual place of residence (own home, residential home, nursing home) as a proxy for frailty (Appendix 1). Height and weight are captured to calculate Body Mass Index and Nutritional Risk Index as risk adjustment tools[10].

1  
2  
3 Data will be recorded on initial and final management strategies, baseline  
4  
5 physiology, diagnostics and nutritional support strategies.  
6  
7  
8  
9

10 The primary outcome is in-hospital mortality. Secondary outcomes include in-  
11  
12 hospital morbidity, length of stay and 30-day readmission.  
13  
14

15  
16  
17 Data will be uploaded to an encrypted and password protected secure REDCap  
18  
19 server, hosted at the University of Sheffield[11]. No identifiable data is uploaded.  
20  
21

22 Collaborators will keep a local 'key' spreadsheet linking REDCap identifiers to NHS or  
23  
24 Hospital Numbers on their NHS network.  
25  
26  
27

#### 28 29 *Data validation*

30  
31 Only data sets with >95% data completeness will be accepted. Doctors at Core  
32  
33 Trainee level or above, who were not involved in initial data collection will act as  
34  
35 independent assessors, reviewing data collected at a local centre. Overall  
36  
37 independent assessors will validate a minimum of 10% of patient records, with a  
38  
39 target of >95% case ascertainment and >90% data accuracy.  
40  
41  
42  
43  
44

45 The number of identified patients having surgery during the audit period will be  
46  
47 compared to those recorded in the NELA database for the same period. This will give  
48  
49 an indication of how representative the dataset is.  
50  
51  
52  
53  
54

#### 55 *Pilot*

56  
57  
58  
59  
60

1  
2  
3 The survey has undergone pilot at two separate sites, with minor revisions after each  
4  
5 round.  
6  
7  
8

9  
10 The prospective audit and site profile questionnaire have undergone a two-week  
11  
12 pilot across eight UK centres to confirm acceptability of definitions and usability of  
13  
14 REDCap system.  
15  
16  
17

### 18 19 *Anticipated recruitment*

20  
21 Based upon NELA data for 2014-2015[1] and pilot work, we anticipate mean  
22  
23 identification rates of 3 cases/week per centre. Across 100 centres, anticipated  
24  
25 recruitment would be 2,400 cases.  
26  
27  
28

### 29 30 *Statistical analysis*

31  
32 Analysis will be performed by a statistician at the Clinical Trials Research Unit,  
33  
34 University of Sheffield. Descriptive analysis will be performed to describe crude rates  
35  
36 of mortality and morbidity, with sub-group analysis of primary operation,  
37  
38 conservative management, and failed conservative management. BMI, Nutritional  
39  
40 Risk Index[10], and Charlson Comorbidity Index[9] will be used for risk adjustment.  
41  
42 Descriptive reporting of the use of diagnostics, operative approach and nutritional  
43  
44 support in the treatment pathway will be performed, and association with outcomes  
45  
46 recorded.  
47  
48  
49  
50  
51  
52

53  
54  
55 Variation in patient characteristics were taken into account during study design and  
56  
57 will be taken into account during statistical analysis. Due to the expected  
58  
59  
60

1  
2  
3 heterogeneity across all patients, only clinically valid comparisons will be made  
4  
5 according to the care pathways outlined in figure 1 (i.e. initial operative  
6  
7 management, successful conservative management or failed conservative  
8  
9 management). During statistical analysis, multilevel modelling will allow differences  
10  
11 across centres to be taken into account. Multilevel logistic regression models will be  
12  
13 constructed using clinically plausible variables to identify predictors of mortality and  
14  
15 morbidity following small-bowel obstruction. Effects of predictor variables will be  
16  
17 presented as odds ratios (OR), alongside the corresponding 95% confidence interval.  
18  
19 Sensitivity analyses stratified by number of cases per centre (in the case where  
20  
21 hospitals have fewer than 5 cases) will be performed to assess identify any changes  
22  
23 to the direction and effect size which may be influenced by the inclusion of centres  
24  
25 with few cases.  
26  
27  
28  
29  
30  
31  
32

33  
34 Data will be matched to site resource profiles to assess the relationship between  
35  
36 resource availability and management practices.  
37  
38  
39

#### 40 *Ethics and governance*

41  
42  
43 This project has been assessed by the Scientific Officer of the South East Scotland  
44  
45 Research Ethics Service, who confirmed that the project did not require ethical  
46  
47 approval. All sites must secure local audit approval prior to collecting data, and  
48  
49 Information Governance or Caldicott approval prior to uploading data to REDCap.  
50  
51 Caldicott approval for Scotland will be secured through a single central application.  
52  
53  
54

#### 55 *Funding*

1  
2  
3 This project has received funding from the Bowel Disease Research Foundation,  
4  
5 Association of Coloproctology of Great Britain and Ireland, Association of Surgeons  
6  
7 of Great Britain & Ireland, Association of Upper Gastrointestinal Surgeons, British  
8  
9 Association of Parenteral and Enteral Nutrition, British Association for Surgical  
10  
11 Oncology, British Society of Gastroenterology, Royal College of Surgeons of England,  
12  
13 Royal College of Surgeon of Edinburgh, National Emergency Laparotomy Audit and  
14  
15 Royal College of Anaesthetists.  
16  
17  
18  
19  
20

### 21 *Authorship*

22  
23  
24 All collaborators returning complete and validated datasets within the timelines will  
25  
26 be eligible for collaborative authorship. This will be reported in line with the CRediT  
27  
28 taxonomy[12]. We intend that each site has no more than four collaborators.  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60



## DISCUSSION

Small bowel obstruction carries significant morbidity and mortality, however most work on this topic has focussed on specific diagnostic or therapeutic interventions, with little focus on how to address the associated high levels of mortality. The guidance from Eastern Association for the Surgery of Trauma, and World Society for Emergency Surgery offers extensive information on the use of CT scans to identify strangulation or 'high grade' SBO and the selection of patients for surgery (and operative approach), or conservative management[3,4]. This guidance does not substantially address other issues such as nutritional interventions, use of Total Parenteral Nutrition (TPN), or considerations in post-operative care.

This study will deliver the largest prospective assessment of the management of SBO in adults in the UK. Using clinical data on management of SBO, clinician management preferences, and a local resource profile, we will report variation in management of this condition. These data will also permit early exploration of factors associated with variation in practice, and their relationship to outcomes. This study will also provide preliminary data on interventions used in SBO to re-establish feeding. Other studies in the field have focussed only on specific areas of SBO management and to our knowledge, there is very limited data with regards to how nutrition is handled. The central aim of the NASBO project is to address this by delivering high quality data across multiple centres.

1  
2  
3 This project uses multiple methods to accumulate data including surveys and clinical  
4  
5 data collection. Surveys have been carefully designed and piloted to ensure validity  
6  
7 and clarity of questions.  
8  
9

10  
11  
12 The snapshot clinical data-capture has been designed to capture key components of  
13  
14 the SBO pathway. Whilst it captures several key nodes of clinical practice, it does not  
15  
16 report on the use of nasogastric tubes or use of intravenous fluids. Whilst these are  
17  
18 commonly used, accurate data capture to describe them would require a significant  
19  
20 amount of resource for what is likely to be highly granular data. If required, these  
21  
22 factors could be explored in future studies delivered by the NASBO network. The  
23  
24 treatment pathway and pathophysiology of SBO is complex and varied. This  
25  
26 complexity, however, must be balanced with the ability to deliver high-quality,  
27  
28 usable data. This balance has been emphasised when designing the study and  
29  
30 developing data collection tools.  
31  
32  
33  
34  
35  
36  
37

38 Trainee research collaboratives have previously demonstrated the ability to deliver  
39  
40 large multicentre studies[13,14]. This study differs in that it is the first time UK  
41  
42 trainee research collaboratives have partnered with a number of specialty  
43  
44 organisations and policy makers. The complexity of patient pathways and variation  
45  
46 in clinical decision-making make SBO a prime target for intervention. Use and timing  
47  
48 of CT, nutritional support and surgical intervention are all potentially costly  
49  
50 interventions which are accompanied with risks to the patient. Therefore, it is  
51  
52 imperative to generate a high-quality evidence base in a condition which carries a  
53  
54 high mortality and morbidity rate. High quality data on SBO will also allow  
55  
56  
57  
58  
59  
60

1  
2  
3 appropriate assessment of the health economic impact of future interventions.  
4

5 Findings of this study will be used to inform development of clinical guidelines,  
6

7 quality indicators, and support development of clinical trials in the field.  
8  
9

10  
11  
12 We envisage this project will allow a network to be formed of clinicians who have an  
13

14 interest in improving outcomes following small bowel obstruction. This network will  
15

16 permit the delivery of quality improvement projects and further, interventional  
17

18 research studies to be performed based upon the results of the inaugural NASBO  
19

20  
21 study.  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## References

- 1 National Emergency Laparotomy Audit. The Second Patient Report of the National Emergency Laparotomy Audit (NELA) December 2014 to November 2015. London: 2016.
- 2 Scott J, Olufajo O, Brat G, *et al.* Use of National Burden to Define Operative Emergency General Surgery. *JAMA Surg* 2016;**151**:e160480.
- 3 Maung AA, Johnson DC, Piper GL, *et al.* Evaluation and management of small-bowel obstruction. *J Trauma Acute Care Surg* 2012;**73**:S362–9. doi:10.1097/TA.0b013e31827019de
- 4 Di Saverio S, Coccolini F, Galati M, *et al.* Bologna guidelines for diagnosis and management of adhesive small bowel obstruction (ASBO): 2013 update of the evidence-based guidelines from the world society of emergency surgery ASBO working group. *World J Emerg Surg* 2013;**8**:42. doi:10.1186/1749-7922-8-42
- 5 Fevang BT, Jensen D, Svanes K, *et al.* Early operation or conservative management of patients with small bowel obstruction? *Eur J Surg* 2002;**168**:475–81. doi:10.1080/110241502321116488
- 6 ASGBI, Royal College of Surgeons of England. Commissioning guide: Emergency General Surgery. London: 2014.
- 7 Boney O, Bell M, Bell N, *et al.* Identifying research priorities in anaesthesia and perioperative care: final report of the joint National Institute of Academic Anaesthesia/James Lind Alliance Research Priority Setting Partnership. *BMJ Open* 2015;**5**:e010006. doi:10.1136/bmjopen-2015-010006
- 8 Tiernan J, Cook A, Geh I, *et al.* Use of a modified Delphi approach to develop

- 1  
2  
3 research priorities for the association of coloproctology of Great Britain and  
4  
5 Ireland. *Color Dis* 2014;**16**:965–70. doi:10.1111/codi.12790  
6  
7  
8 9 Charlson ME, Pompei P, Ales KL, *et al*. A new method of classifying prognostic  
9  
10 comorbidity in longitudinal studies: Development and validation. *J Chronic Dis*  
11  
12 1987;**40**:373–83. doi:10.1016/0021-9681(87)90171-8  
13  
14  
15 10 The Veterans Affairs Total Parenteral Nutrition Cooperative Study Group.  
16  
17 Perioperative Total Parenteral Nutrition in Surgical Patients. *N Engl J Med*  
18  
19 1992;**327**:70–5. doi:10.1056/NEJM199207093270202  
20  
21  
22 11 Harris PA, Taylor R, Thielke R, *et al*. Research electronic data capture  
23  
24 (REDCap)-A metadata-driven methodology and workflow process for  
25  
26 providing translational research informatics support. *J Biomed Inform*  
27  
28 2009;**42**:377–81. doi:10.1016/j.jbi.2008.08.010  
29  
30  
31 12 Brand A, Allen L, Altman M, *et al*. Beyond authorship: Attribution,  
32  
33 contribution, collaboration, and credit. *Learn Publ* 2015;**28**:151–5.  
34  
35 doi:10.1087/20150211  
36  
37  
38 13 Bhangu A, Richardson C, Torrance A, *et al*. Multicentre observational study of  
39  
40 performance variation in provision and outcome of emergency  
41  
42 appendicectomy. *Br J Surg* 2013;**100**:1240–52. doi:10.1002/bjs.9201  
43  
44  
45 14 STARSURG Collaborative. Multicentre prospective cohort study of body mass  
46  
47 index and postoperative complications following gastrointestinal surgery. *Br J*  
48  
49 *Surg* 2016;**115**:7–72. doi:10.1002/bjs.10203  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

For peer review only

**Figure headings:**

**Figure 1: Conceptual schematic of pathways in the management of Small Bowel**

**Obstruction, including typical diagnoses and nutritional outcomes.**

**Figure 2: Components of NASBO study, and how they are related.**

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

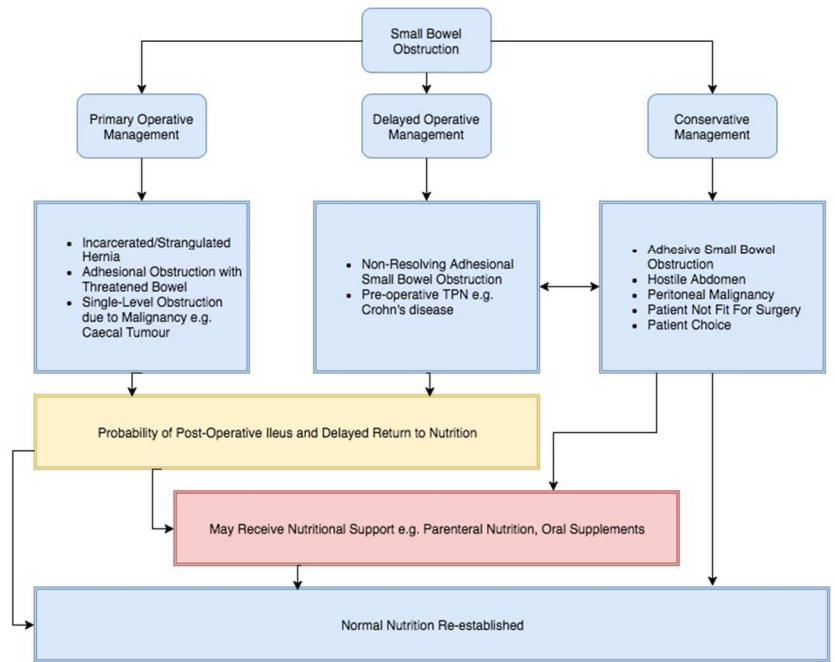


Figure 1: Conceptual schematic of pathways in the management of Small Bowel Obstruction, including typical diagnoses and nutritional outcomes.

78x60mm (300 x 300 DPI)

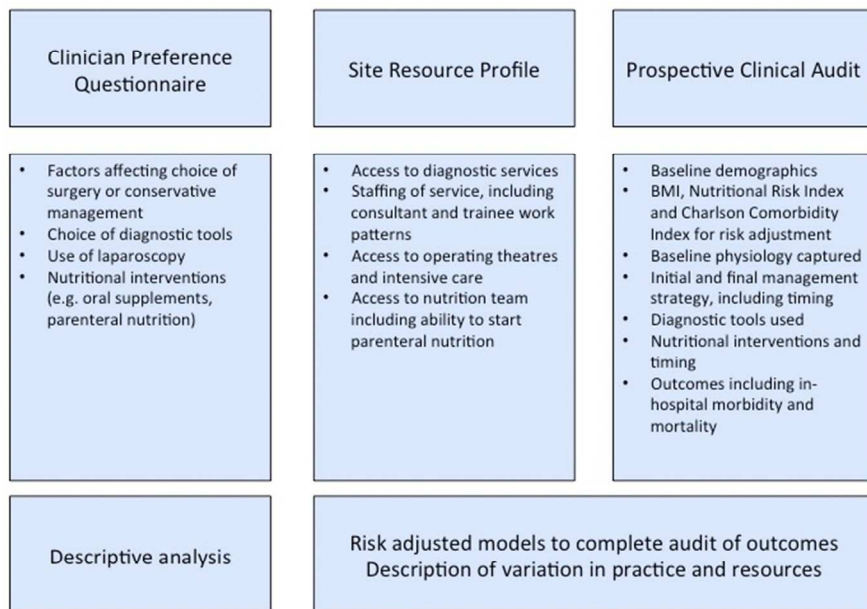


Figure 2: Components of NASBO study, and how they are related.

66x47mm (300 x 300 DPI)

ew only



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

### Appendix 1. Data fields collected for cohort study

Field	Options (definitions)
Age	In years
Height	In centimetres,
Weight	In kilograms
Sex	Male, Female
Comorbidities	Myocardial infarct Congestive heart failure Peripheral vascular disease Cerebrovascular disease (except hemiplegia) Dementia Chronic pulmonary disease Connective tissue disease Peptic ulcer disease Mild liver disease Diabetes (without complications) Diabetes with end organ damage Hemiplegia (or paraplegia) Moderate or severe renal disease Solid tumour (non-metastatic) Leukaemia Lymphoma, Multiple Myeloma... Moderate or severe liver disease Metastatic solid tumour AIDS
Source of referral	Emergency Department General Practice Surgical Clinic admission Referral from inpatient team

<b>Where was the patient living prior to admission to the hospital?</b>	Own Home/Sheltered Accommodation Residential Home Nursing Home
<b>Date admitted to hospital</b>	Day/Month/Year
<b>Date first seen by a member of the surgical team</b>	Day/Month/Year
<b>Date of last enteral intake</b>	Day/Month/Year
<b>Initial management strategy</b>	Conservative Operative ( Palliative
<b>White Cell Count</b>	
<b>C-Reactive Protein</b>	
<b>Albumin</b>	
<b>Did the patient have an AKI at admission?</b>	Yes / No
<b>Was the patient identified as being malnourished, or at risk of malnourishment?</b>	Yes / No Day/Month/Year
<b>How was this identified?</b>	
<b>Was the patient reviewed by a dietitian or nutrition team during admission?</b>	Yes / No
<b>Were oral supplements (e.g. fortisips) started at any point during admission?</b>	Yes / No Day/Month/Year
<b>Was NG or NJ feed started during admission?</b>	Yes / No Day/Month/Year
<b>Was TPN started during the admission?</b>	Yes / No Day/Month/Year
<b>If TPN was used, when was it stopped?</b>	Day/Month/Year
<b>Was intravenous access established for nutrition?</b>	Yes / No

<b>What type of line was initially used?</b>	Peripheral cannula Peripherally inserted central catheter (PICC) Central venous catheter (CVC/Central line) Hickmann line
<b>What date was this inserted?</b>	Day/Month/Year
<b>Did the patient develop line sepsis related to this line?</b>	Yes / No
<b>Date line sepsis diagnosed</b>	Day/Month/Year
<b>Abdominal X-ray performed</b>	Yes / No Day/Month/Year
<b>CT scan performed</b>	Yes / No Day/Month/Year
<b>Did the patient receive water-soluble contrast agent (gastrografin) apart from when undergoing a CT scan?</b>	Yes / No Day/Month/Year
<b>Aetiology</b>	Congenital band adhesion Post-operative adhesions Right sided colon cancer Crohn's disease Disseminated intra-abdominal malignancy Incarcerated Hernia - Groin Incarcerated hernia - Midline Incarcerated hernia - Incisional Incarcerated Hernia - Parastomal Small bowel Volvulus Other _____
<b>Did the patient undergo an operation/procedure for SBO?</b>	Yes / No Day/Month/Year
<b>American Society of Anesthesiologist (ASA)</b>	Classified as:

<p><b>score</b></p>	<ol style="list-style-type: none"> <li>1. A normal healthy patient</li> <li>2. A patient with mild systemic disease</li> <li>3. A patient with severe systemic disease</li> <li>4. A patient with severe systemic disease that is a constant threat to life</li> <li>5. A moribund patient who is not expected to survive without the operation</li> </ol>
<p><b>Method of operation</b></p>	<p>Laparoscopic</p> <p>Lap converted to open</p> <p>Open (midline)</p> <p>Open (groin)</p> <p>Open (other)</p>
<p><b>What intervention?</b></p>	<p>Division (single) band adhesion</p> <p>Adhesiolysis</p> <p>Hernia repair</p> <p>Small bowel resection</p> <p>Large bowel resection</p> <p>Formation jejunostomy</p> <p>Formation ileostomy</p> <p>Anastomosis of bowel</p> <p>Other</p>
<p><b>Date resumed enteral nutrition</b></p>	<p>Day/Month/Year</p>
<p><b>In hospital death</b></p>	<p>Yes / No</p>
<p><b>Date patient medically fit for discharge:</b></p>	<p>Day/Month/Year</p>
<p><b>Date of discharge</b></p>	<p>Day/Month/Year</p>
<p><b>Readmitted within 30-days post discharge</b></p>	<p>Yes / No</p>

<b>Discharge destination</b>	Own Home/Sheltered Accommodation
	Rehabilitation Unit
	Residential Home
	Nursing Home
	Hospice
	Still acute inpatient on 30/4/17
	Deceased
<b>In hospital complications</b>	UTI
	Pneumonia
	Cardiac
	PE/DVT
	Delirium
	Superficial surgical site infection
	Intra abdominal sepsis
	Abdominal wall dehiscence
	Anastomotic leak
	Radiological drain
	Reoperation
	Unplanned HDU/ITU admission