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Patient Priorities in Relation to Surgery for Gastric Cancer: Qualitative Interviews with Gastric Cancer Surgery Patients to Inform the Development of a Core Outcome Set.

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4 Title Page
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6 **Patient Priorities in Relation to Surgery for Gastric Cancer: Qualitative Interviews with Gastric**
7 **Cancer Surgery Patients to Inform the Development of a Core Outcome Set.**
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Conflicts of Interest

The authors report no conflicts of interest.

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Data Availability

Data are available upon reasonable request.

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Running Title

Patient Priorities Following Surgery for Gastric Cancer

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Structured Abstract

Objective

The reporting of outcomes in surgical trials for gastric cancer is inconsistent. The GASTROS study (GAstric Cancer Surgery TRials Reported Outcome Standardisation) aims to address this by developing a core outcome set (COS) for use in all future trials within this field. A COS should reflect the views of all stakeholders, including patients. We undertook a series of interviews to identify priorities, outcomes and themes important to patients which would be considered for inclusion in a COS.

Setting

All interviews took place within the United Kingdom. Interviews were carried out face-to-face at hospitals and cancer support centres or via the telephone.

Participants

Twenty participants at varying stages of recovery following surgery for gastric cancer with curative intent.

Design

Qualitative design using semi-structured interviews, supported by an interview guide which was iteratively modified; thematic analysis was used to explore patient priorities.

Results

Six themes enveloping 38 outcomes were identified; surviving and controlling cancer, technical aspects of surgery, adverse events from surgery, recovering from surgery, long-term problems following surgery and long-term life impact of surgery. The 'most important' patient priority was to be 'cured of cancer'.

Conclusion

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3 Surgical trials for gastric cancer should consider broader priorities of patients when choosing which
4
5 outcomes to report. This study highlighted the importance of longer-term outcomes such as cancer
6
7 survival. Outcomes identified in this study will be used to inform an international Delphi survey to
8
9 develop a COS in this field.
10

11
12 **KEYWORDS:**
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15 Surgical Oncology
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18 Stomach Neoplasms
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21 Outcome Assessment
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24 Patient Reported Outcome Measures
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27 Treatment Outcome
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30 Outcome reporting
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Article Summary

Strengths and Limitations of This Study

- This is the first in-depth qualitative study to examine the priorities and experiences of patients following surgery for gastric cancer, and the first to establish which outcomes are important to patients.
- The study forms part of a larger project (The GASTROS Study - www.gastrosstudy.org) to develop a 'core outcome set' (COS) for use in surgical trials for gastric cancer and was reviewed and funded by the National Institute of Health Research (UK). The study is based on a reproducible and transparent methodology which has been subjected to critical appraisal during a peer-review process.
- The term 'outcome' was described to participants in a manner relatable to them, such that they understood it and were able to identify which outcomes were most important.
- The patient population was limited to UK-based English speakers. The views of international patients may vary due to differences in culture and clinical practice.

Main Article

Introduction

Background

Gastric cancer is a leading cause of cancer-related death world-wide^{1,2}. Whilst surgery remains the only treatment which can offer a potential cure from this disease, it is associated with significant rates of morbidity in both the short and long-term^{3,4}. Ideally, the optimal surgical approach would minimise the risk of short and long-term complications without jeopardising the oncological resection.

Identifying the optimal surgical approach for gastric cancer should be based on comparing and combining robust clinical evidence from well-designed randomised control trials. One of the present challenges to achieving this is the inconsistency in the reporting of outcomes in this field⁵. This limits evidence synthesis and contributes to 'research waste'. The GASTROS study (GASTROS – GAstric Cancer Surgery TRials Reported Outcome Standardisation - www.gastrosstudy.org)⁶ aims to address this issue by developing a 'core outcome set' (COS) – a *minimum* group of standardized and well-defined outcomes, measured by all future gastric cancer surgery trials⁷.

A guiding principle in the development of COS is that outcomes reflect the views and priorities of key stakeholders, including patients, to maximise the relevance and impact of future research. Previous studies have demonstrated variations in the views and priorities of clinicians and patients⁸⁻¹⁰, which can result in trials reporting outcomes which bear little relevance to patients. A systematic review of outcome reporting in surgical trials for gastric cancer has demonstrated that outcomes which may be important to gastric cancer patients, such as 'quality of life' after surgery are poorly represented within this field⁵. It is therefore important to understand which outcomes are important for patients undergoing gastric cancer surgery.

Objective

This research forms part of the GASTROS study, for which the protocol has been previously described⁶. The first stage in the study involves identifying a 'long-list' of potentially important outcomes which will be prioritised in stage two by participants undertaking a Delphi survey. It is not

1
2
3 known to what degree outcomes reported in previously published trials represent the priorities of
4 patients undergoing gastric cancer surgery, and as such, solely relying on these as a source to populate
5 the 'long-list' may overlook potentially important outcomes. By exploring the experiences,
6 perceptions and priorities of patients who have undergone surgery for gastric cancer, this study aimed
7 to identify themes and outcomes which may not have been previously reported in the literature.
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Methods

Study Design

The role of qualitative research methods in the development of COS has been previously explored¹¹ and has been advocated by groups such as the COMET initiative⁷ as one of several approaches to ensure that outcome lists being considered for prioritisation are exhaustive. This qualitative study used a semi-structured interview approach to achieve the primary objective of identifying outcomes of importance to patients. A series of open questions were used to facilitate a patient-led discussion, guided by additional prompts from a pre-prepared interview schedule (table 1) to ensure key areas were covered.

Additional focused questioning around the use of outcomes in research was also included. In the context of clinical research, terms such as ‘outcomes’ may not be well understood by patients¹¹ and so a mixture of open and closed questioning was important. Participant interviews were undertaken in series of three following which transcript analysis (see below) was undertaken and the interview schedule was modified iteratively. This ensured that areas raised by earlier participants, but not included in the original schedule, were covered in subsequent discussions.

Sampling

The eligibility criteria for this study are summarized in table 2. A purposive sampling strategy was adopted across the following characteristics:

- Age (above and below 70 years).
- Gender (men and women)
- Time since surgery (less than a year, one to three years and more than three years)

Interviews were undertaken until ‘data-saturation’ was achieved. Data saturation was determined when there was no new data emerging that had interpretive value.

Participants were recruited from across the United Kingdom from three sources:

- 1
2
3 1. A regional specialist gastric cancer centre: patients were approached in the outpatient clinic
4
5 by their direct care team.
6
- 7 2. Patient organisations: patient groups were asked to contact their membership through e-mail
8
9 and social media.
10
- 11 3. Snowball sampling; patients who had been recruited or contacted to participate were asked to
12
13 identify other patients who would be interested in the study.
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18 Data Collection

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20 Interviews were undertaken between February and May 2017 and were conducted by BA, a
21
22 consultant surgeon and researcher with approximately ten years' experience of managing and
23
24 communicating with gastric cancer patients. Participants were invited to choose between a University
25
26 Teaching Hospital, two purpose-built patient cancer centres, or their home for the location of the
27
28 meeting. Participants were also offered the opportunity to have their interviews over the telephone.
29
30 Participants were offered travel expenses to minimise any financial burden on taking part in the study.
31
32

33 In addition to the purposive sampling strategy, the following demographic data was collected:

- 34 • Gender (male/female)
- 35
- 36 • Social circumstances (e.g. lives alone/with partner/lives with dependents)
- 37
- 38 • Age
- 39
- 40 • Time since surgery (in months)
- 41
- 42 • The type of gastrectomy (total or partial gastrectomy)
- 43
- 44 • The approach to their surgery (open or laparoscopic)
- 45
- 46 • Whether they had undergone additional treatment (e.g. chemotherapy)
- 47
- 48 • Whether they had suffered a post-operative complication
- 49
- 50 • Ethnicity
- 51
- 52 • Previous trial enrolment
- 53
- 54 • Participant post-code (to identify location and social deprivation score)
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3 Full written consent was taken immediately prior to the interview and the participant was reminded
4 that they were able to stop at any point or withdraw from the study without needing to give a reason.
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7 8 Data Analysis 9

10 All interviews were digitally recorded and professionally transcribed (intelligent verbatim
11 transcription). A thematic analysis was used to identify emerging themes. Themes were developed
12 using a three-step approach of open coding, axial coding and selective coding¹² of the transcripts.
13 Given the objective of this study was to identify themes and outcomes not previously reported in
14 trials, it was important not to base data analysis and outcome identification on a framework built on
15 previously published literature. BA and RM (a researcher with significant experience in qualitative
16 research methods) independently analysed the first two transcripts and through discussion identified
17 themes and adjustments to the interview schedule. Regular discussion between BA and RM took
18 place throughout the study to ensure that there was agreement with the analysis. Data analysis was
19 supported using NVivo 11 (http://www.qsrinternational.com/products_nvivo.aspx, QSR International,
20 Burlington, MA, USA).
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36 Approvals and Portfolio Adoption

37 The study was given ethical approval by the National Research Ethics Service North West—Cheshire
38 (11/NW/0739) and governance approvals by Central Manchester University Hospital NHS
39 Foundation Trust. The study was adopted by the National Institute for Health Research (NIHR)
40 Clinical Research Network Portfolio (ID 33312).
41
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47 Reporting

48 This paper uses the SRQR checklist to structure the report of the study findings¹³.
49
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51 Patient and Public involvement

52 A Study Advisory Group (SAG) forms part of the management structure of the wider GASTROS
53 study⁶, of which this qualitative study forms part of the first stage. The SAG is made up of key
54 stakeholder representatives including patients, oncology nurses and surgeons. The group provides
55 advice on the methodology of the study, general delivery of the study against its stated objectives and
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3 ensures that the viewpoints of all stakeholder groups are considered. The results of this study were
4 presented to a SAG meeting; the ensuing discussion influenced the design of the next stage of the
5 study in preparation for an international Delphi Survey.
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Table 1. Interview schedule.

1.	I understand you have (had) gastric cancer. Can you tell me about that?
2.	<p><i>Could you tell me about how you first found out you had gastric cancer?</i></p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>What questions did you most want to ask, when you were told that you had gastric cancer?</i>
3	<p>Were there were any areas you wanted more information about but were unable to find?</p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>Were you given any leaflets at the time of diagnosis? Did you find these useful?</i>
4	<p>What treatment was offered and how you decide about undergoing treatment.</p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>What information did you want about the treatment you would be receiving?</i> • <i>What factors did you consider when deciding on the treatment?'</i>
5	<p>What effects did the treatment have on you after surgery?</p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>Did the treatment affect your physical or mental well-being?</i> • <i>Did the treatment have an effect on relationships with those around you?</i> • <i>Did you have to make any changes to your behaviour as a result of treatment?</i>
6	<p>What long-term effects did the treatment have on you?</p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>Did the treatment affect your physical or mental well-being?</i> • <i>Did the treatment have an effect on relationships with those around you?</i> • <i>Did you have to make any changes to your behaviour as a result of treatment?</i>
7	What was the worst side effect of treatment?
8	What are your concerns for the future, especially those relating to their diagnosis/history of gastric cancer?

9	Did the explanation of what you should expect from surgery match your real experience?
10	In the context of research studies, can you explain what an outcome is in your own words? The interviewer will then provide a definition of the term 'outcome' is in the context of clinical research.
11	What, in your opinion, is the most important outcome to measure in gastric cancer surgery trials?
12	Are there any other outcomes which may be important to measure?
13	Has your perspective on what is important changed over time?
14	Is there anything else that you feel is important to talk about that we have not discussed?

Table 2. Eligibility criteria for study participants.

	Potential Participants Approached	Potential Participants Not Approached
Participant	<ul style="list-style-type: none"> • Male and females aged 18 years and older. • Individuals able to participate in an interview in the English language. 	<ul style="list-style-type: none"> • Patients unable to give informed consent • Patients too unwell to comfortably participate in an interview lasting approximately 30-60 minutes.
Pathology	<ul style="list-style-type: none"> • Adenocarcinoma and squamous cell carcinoma of the stomach, (which makes up 95 per cent of all stomach tumours). 	<ul style="list-style-type: none"> • Gastrointestinal Stromal Tumours • Neuro-endocrine tumours • Lymphoma • Benign disease
Intervention	<ul style="list-style-type: none"> • Total and partial gastrectomy • Open and laparoscopic approaches 	<ul style="list-style-type: none"> • Surgery with palliative intent • Endoscopic therapies such as EMR (endoscopic mucosal resection) and ESD (endoscopic Submucosal dissection)

Results

Overview

In total, 20 patients were interviewed. Table 3 summarises demographic data and treatment-related characteristics of participants. Interviews lasted a median of 50.5 minutes (29-75 minutes). No patients withdrew from the study. Data saturation was deemed to have been reached by 20 interviews; one new outcome was identified in interview number 18 (related to sexual activity), however, no further outcomes were identified from the following two transcripts.

Outcome Themes

Six broad themes enveloping 38 outcomes were identified;

1. Surviving and controlling cancer,
2. Technical aspects of surgery,
3. Adverse events from surgery,
4. Recovering from surgery,
5. Long-term problems following surgery and
6. Long-term life impact of surgery.

Appendix 1 provides a breakdown of how all themes were developed from outcomes identified during the interviews. Themes were well represented in each interview; each theme was discussed by at least 18 of 20 participants. Appendix 2 demonstrated the outcomes identified during the interviews and how often they were referenced.

Theme 1: Surviving and controlling cancer

For most, details of their initial consultation were sketchy; participants often described being given lots of information about their diagnosis, much of which was not absorbed. However, patients clearly remember their reaction to being told their cancer diagnosis; for most, the response was the same:

“When you hear the word, cancer, you think that’s it. I’m going to die.” (participant 6)

There was a range of personal experience with cancer within our patient group. Some had direct family members who had undergone chemotherapy and had an intimate knowledge of its effects.

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2
3 “it was my worst nightmare come true because I lost my dad to cancer and I always had it in
4 the back of my mind, well if one person in the family could get cancer from somewhere then
5 we could as well.” (participant 19)
6
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10 Some patients had a vague knowledge of friends or work colleagues who had undergone treatments
11 for cancer and others had no prior experience of cancer at all. Despite these differences, the initial
12 responses to their diagnosis were similar.
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16 All participants in our study had undergone radical surgery with curative intent. Once the discussion
17 with their surgeon moved away from the diagnosis and onto potentially curative treatments,
18 participants often focused their questions on ‘survival’:
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21
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23
24 “I wanted to know what the chances were of me having this removed and not, well, basically
25 not dying from it.” (participant 4)
26
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28

29 Despite radical surgery (and peri-operative chemotherapy in half of our participants), for many of the
30 participants the fear of recurrence remained a permanent anxiety. Many participants seemed to
31 understand that due to the aggressive nature of gastric cancer, recurrence is a possibility for many:
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34

35
36 “...you’re always worried that it’s going to come back...” (participant 7)
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38

39 The study cohort included participants who had undergone surgery between 5 months and 14 years
40 prior to the interviews. There did not seem to be a relationship between the length of time out of
41 surgery and concerns about cancer recurrence.
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45 *Theme 2: Technical aspects of surgery*

46 Several outcomes related to this theme were discussed by participants. Most importantly, participants
47 focused on whether the surgical team was able to excise the ‘cancer’ in its entirety. This priority was
48 often referenced in relation to the ‘success’ of surgery and its contribution to ‘curing’ participants of
49 cancer:
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56 “...thinking to yourself that, you know, everything has been done to the best of the hospital’s
57 ability, and, you know, they’ve taken absolutely everything out.” (participant 4)
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1
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3 Whilst participants mostly referred to the cancer as a single 'entity', there were a small number who
4 demonstrated some knowledge of the importance of different aspects of surgery such as lymph node
5 excision:
6
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8
9 "And yeah, I remember the news about the pathology on the bits they'd taken away, and the
10 lymph node system and what not, came a week or two before I was due to go back on the
11 chemo." (participant 20)
12
13
14

15 Six participants underwent a minimally invasive surgery with the remainder undergoing open surgery.
16 The size of the wounds or type of surgical approach was referred to by only a minority of our
17 participants. In the main, these were made in passing as little importance was placed on the surgical
18 approach:
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20
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22

23
24 Interviewer: "Okay, and what...what did that mean for you to have keyhole surgery?"

25
26 Respondent: "It didn't mean anything really, you know, I had...I'd heard about keyhole and
27 people who'd had it." (participant 5)
28
29
30
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32 33 *Theme 3: Adverse events following surgery*

34 Eleven participants suffered a complication following surgery; however, this theme was important to
35 all interviewees. Peri-operative death was the most frequently discussed surgical complication:
36
37
38

39
40 "...the fear of dying on the operating table is really real." (participant 2)
41
42

43 During their surgical consultation, participants retained some understanding of the risk of peri-
44 operative death and many were able to quote figures about how likely this complication was. Other
45 complications were highlighted when recounting a personal experience. While all complications
46 occurred in the post-operative period, there were several different causes attributed to these events
47 (e.g. direct surgical, anaesthesia-related and medication-related). The severity and consequences of
48 the complications also varied significantly; some were self-limiting and resulted in a minor extension
49 of the length of hospital stay:
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56
57 "But I was out of it for three days, I was just hallucinating and God knows what, probably
58 because of the morphine." (participant 7)
59
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1
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3 And those which were life-threatening and required significant clinical intervention:
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5

6 “It was a twisted bowel. Yeah, I was told it was a twisted bowel. Because I always
7
8 remember that when they brought me back from obviously having a look and everything, I
9
10 always remember [they] said...we're going to have to take you back to surgery.” (participant
11
12 15)
13
14

15 The severity of the complications suffered did not seem to shape the key priorities in relation to
16
17 participants’ ‘worst side effect’ of surgery or ‘most important outcome’; these almost entirely related
18
19 to ‘long-term impacts of surgery’ and ‘cure’ respectively (see below) regardless of how long ago their
20
21 operation was and which surgical approach (laparoscopic or open surgery) was employed.
22
23

24 Whilst participants recounted that some of the more serious complications (e.g. death, anastomotic
25
26 leak and cardio-pulmonary complications) were described by surgeons during the consent process,
27
28 some were exposed to other sources of information in the pre-operative stage. Participants were
29
30 regularly provided with written information about their cancer and its management, however the
31
32 quality and content of this varied depending on the location of their hospital. The response to this
33
34 format was varied:
35
36

37 “I’m going to be honest with you, I didn’t actually read them... because I didn’t want things
38
39 going in my head that I couldn’t take in.” (participant 17)
40
41

42 Participants that read the written information often found them difficult to digest for several reasons
43
44 including the volume of information and fear of the gravity of the diagnosis or prognosis:
45
46

47 “Well some of it were just waste of time, but others, you know, if you’ve got a book about
48
49 that thick and you read through it and half of it applies to you, and the others just
50
51 sort...doesn’t apply, you know.” (participant 5)
52

53 “As much as it’s alright handing leaflets out, I can...I am a bit of a reader so I will read stuff,
54
55 but when you think you’ve got a death sentence you think, what’s the point in reading that?”
56
57 (participant 13)
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59
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1
2
3 Several hospitals had patient-support groups which provide a 'buddy' system for those awaiting
4 surgery. These support groups became an important part of the recovery process and continue to be
5 relevant many years after surgery. Patients found these more useful as they had the opportunity to
6 speak to those with lived experience of the diagnosis and treatment. Whilst this served as an important
7 source of information to tackle the longer-term impacts of surgery (below), these groups also provided
8 comfort to patients:
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15
16 "I think the support group and speaking to people that have been through it, because it
17 can demystify it quite a lot." (participant 2)
18
19

20 Peer support also provided additional sources of information to participants in the pre-operative
21 period with respect to some of the complications that could arise:
22
23

24
25 "And I know one guy, where the oesophagus junction was, he'd had that leaking, and he
26 couldn't eat more than, like, grains of rice and things; so that would be pretty
27 horrendous." (participant 4)
28
29
30

31 As a result of verbal and written information from healthcare professionals and additional peer
32 support, participants were able to describe key adverse without necessarily having experienced them
33 firsthand.
34
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40 *Theme 4: Recovery from surgery*

41 Experiences during the immediate post-operative recovery period were referenced by 18 study
42 participants. Whilst some participants' experience of recovery from surgery was directly linked to
43 complications, there were aspects of recovery such as post-operative pain, mobility and the
44 recommencement oral intake that were common amongst all those who spoke this theme.
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51 Most participants did not mention post-operative pain as an important focus. Those that did, expected
52 to suffer a degree of pain, however experiences of its severity varied widely. Pain levels amongst
53 interviewees who had undergone similar operations through laparotomy incisions were not uniform.
54
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56
57
58 One participant who had open surgery described:
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60

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2
3 “I do remember waking up and really being in a hell of a lot of pain and being really out
4 of it.” (participant 6)
5
6

7 Whilst another who had undergone their surgery using the same approach recounted:

8
9 “I didn't really have much pain.” (participant 14)
10

11 Discussions around post-operative pain were not confined to discomfort from the surgical incisions,
12 but also related to post-operative complications:
13

14
15 “I was back in writhing in agony with a serious infection in the wound.” (participant 9)
16

17 Participants recounted the limitations in their mobility during the post-operative period. There were
18 many factors contributing to this, including physical weakness, not receiving appropriate
19 encouragement to mobilise and being restricted by surgical drains:
20
21

22
23 “...really difficult to be mobile I suppose, and move around, yourself, ‘cause obviously
24 you’ve got quite a lot of tubes and different things coming out. I felt very, very swollen.”
25
26
27
28 (participant 6)
29
30
31

32 33 *Theme 5: Long-term problems following surgery* 34

35 All participants described significant long-term symptoms related to surgery. For the most, this
36 represented the ‘worst side effect’ in relation to their treatment and outcomes from this theme were
37 referenced more than any other theme further emphasising its importance. All participants described
38 experience with struggling to eat and drink following surgery and the majority (16/20) talked
39 extensively about the impact of fatigue on their daily lives. Problems with maintaining weight, issues
40 with ongoing gastro-intestinal symptoms and chronic pain were discussed by most participants.
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49 Fatigue was described in many ways; ‘exhaustion’, ‘feeling tired all the time’, ‘feeling so weak’ and
50 ‘having no energy’. For the main, fatigue was a symptom which persisted for months after surgery
51 and could impact on a participant’s ability to undertake day-to-day activities or to socialise:
52
53

54
55 “Well, I'm so weak, I used to go out, you know, and do fishing and do things with my lads.
56
57 I'm just getting that little bit better now after eight months, but I'm so weak and tired.”
58
59 (participant 18)
60

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3
4
5 Adapting to fatigue was and for many continued to be a difficult challenge, however many
6 participants understood that this was s a recognised and acceptable symptom to them given the
7 magnitude of the surgery:
8
9

10
11 “I've come out with...more...appreciation for looking after myself and my...And if I'm tired, I
12 stop.” (participant 15)
13
14
15

16
17
18 There were several causes for the struggles participants associated with eating and drinking.
19 Participants often described having to eat and drink smaller volumes more frequently and some were
20 unable to tolerate certain food types or consistencies. This had a direct effect on the pleasure
21 associated with eating and an impact on where participants could eat:
22
23
24

25
26 “Well I don't eat what I would like to...But I know that for the rest of my life, I won't be able
27 to go out for big meals, to big venues and eat like I used to eat before, you know.” (participant
28 5)
29
30
31
32

33 Most participants recounted being told prior to their surgery that their diet would be different and that
34 they would have to ‘learn how to eat again’. Despite this, some participants felt that not enough
35 information was given to highlight the true impact of this long-term issue and methods to address it:
36
37
38

39
40 “I think it's a lot worse than what they tell you. Because like some days, I'll eat a certain thing
41 which I've ate before, and you just can't breathe properly, it's choking you.” (participant 18)
42
43
44
45

46
47 A broad range of gastro-intestinal symptoms were reported by participants. The time frame relating to
48 how long these persisted was similarly broad (sometimes months and years) and did not seem to
49 follow a pattern. Nausea, vomiting, diarrhoea, reflux and belching were the commonest problems
50 described. Many of these symptoms resulted in significant impacts on quality of life (see theme 6
51 below):
52
53
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56
57 “...I still get the bile reflux and I get this constant pain in the oesophagus which affects my
58 sleeping as well.” (participant 7)
59
60

1
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3
4
5 “The dumping syndrome was mentioned. Never understood it until it happened. You know,
6 how my body reacted to certain foods that I'd normally eat that it doesn't like anymore.”
7
8
9 (participant 15)
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13

14 *Theme 6: Long-term life impact of surgery*

15
16 The long-term effects on ‘normality’, quality of life, and psychological impact of surgery were
17 discussed extensively by all patients. A strong desire to return to a form of ‘normality’ was regularly
18 expressed. Whilst the reference point for ‘normality’ differed amongst patients, common
19 characteristics existed; namely a desire to do what they used to do such as working, exercising,
20 socialising with friends and family and being able to travel:
21
22
23
24
25

26 “it’s about living as I did before, and forgetting what had happened, and I do that quite often.”
27
28 (participant 6)
29
30
31
32

33 The experience of returning to normality varied amongst those interviewed. Many participants were
34 largely able to return to their ‘normal’ activities albeit with some modifications:
35
36

37 “Yes. I want to go on holidays again. I love cruises and I want...but until my eating’s
38 improved, I wouldn’t do that.” (participant 1)
39
40
41
42

43 “Now that it’s 18 months on, I am back to having what would be a normal life again, now,
44 albeit with smaller portions of meals and things” (participant 4)
45
46
47
48
49

50 Some participants however have not been able to return to activities that provided them with
51 significant enjoyment:
52
53

54 “I’ve never actually got back to my normal activity. I’ve never played golf since that day and
55 I used to love golf.” (participant 4)
56
57
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In general, participants understood that life after gastrectomy would be different:

1
2
3 “I’m still alive, and then I need to get back to normal. It takes a while for you to realise your
4 new normality is not like your old normality.” (participant 2)
5
6
7
8

9 Whilst much of the discussion relating to ‘normality’ centred around specific tasks which participants
10 valued or missed, the impact of gastrectomy on a participant’s overall general quality of life was
11 important to many. Many understood that quality of life needed to be redefined in comparison to life
12 before surgery, but nonetheless there was a minimum level that would need to be achieved:
13
14
15
16

17
18 “if I have some sort of quality of life, where I can get up and wash myself and do, that is
19 something that I’d live for. But I couldn’t be sat there and nursed 24/7” (participant 17)
20
21
22
23

24 The psychological burden on participants following gastrectomy is a significant one. Each of the
25 previously discussed themes could impact on a participant’s mental state and whilst certain phases of
26 the treatment pathway were time-limited, the psychological effects could persist for much longer;
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28
29

30
31 “You don’t just suffer from physical; you suffer from mental. And I think the mental is a lot
32 more powerful than the physical, because you can shut pain off by taking medication, but it’s
33 very hard to shut problems off mentally.” (participant 18)
34
35
36

37
38 “You know, ‘cause psychologically you think you’ve still got this poison in your body, as
39 much as I’ve got rid of, you know, my monster.” (participant 13)
40
41
42

43 Some of the psychological impacts were associated with participants having to adapt to a new
44 normality in relation to what they were able to do, what they were able to eat, how they looked
45 physically or how they felt around others:
46
47
48

49
50 “Well, it was a problem because like I say, I’ve always been a proud chap and proud of my
51 body because I kept myself fit and everything. When I looked in the mirror, quite distressing.
52 That was it, yeah. It makes you feel inferior.” (participant 18)
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3 “I feel a freak, I feel when I go into a big room with people that everybody has got a stomach
4 and I haven’t got one, it’s not that I want them to know, but I just don’t feel the same
5 anymore...” (participant 8)
6
7
8
9

10 11 Definition of ‘outcome’ by patients

12 All participants were asked what their understanding of the term ‘outcome’ was in the context of
13 clinical research. Two participants were able to provide a broad-ranging definition which
14 encompassed some of the benefits and adverse effects of treatment:
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16
17
18

19 “my perception of what would be meant by that phrase would...at a variety of levels; it could
20 be does the patient live or die? Does the patient recover to an acceptable state for an extended
21 period of time, and my understanding of what that might be, would be a, sort of, five year
22 period...” (participant 20)
23
24
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26
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30 One person stated that they did not know how to define the term, whilst the remainder defined
31 ‘outcome’ by recounting a single outcome, which was most important to them:
32
33

34 “Okay, my understanding is that at the...the outcome would be that the cancer would be
35 possibly all gone.” (participant 19)
36
37
38
39
40

41 Participants were asked to provide a single outcome that was ‘most important to them’. Fifteen
42 participants identified that the most important outcome was that they were ‘cured of cancer’ with the
43 remaining five describing outcomes related to ‘returning to normal’ and being able to enjoy a ‘good
44 quality of life’. These priorities did not alter with respect to how long-ago surgery was performed,
45 which approach was undertaken or how old the patient was.
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Table 3. Patient characteristics and demographic data.

Patient	Sex	Age	Ethnicity*	Social deprivation quintile**	Home circumstances	Months since surgery	Type of surgery	Approach to surgery	Post-operative complications	Peri-operative treatment
1	F	74	A	3rd	Lives alone	15	Partial Gastrectomy	Laparoscopic	Yes	Nil
2	M	59	B	3rd	Lives alone	27	Total Gastrectomy	Open surgery	Yes	Chemotherapy
3	M	71	A	1st	Lives alone	16	Partial Gastrectomy	Open surgery	Yes	Nil
4	M	43	A	2nd	Lives with parents	15	Total Gastrectomy	Open surgery	Yes	Chemotherapy
5	M	80	A	3rd	Lives alone	23	Partial Gastrectomy	Laparoscopic	Yes	Nil
6	F	52	A	2nd	Lives with children	32	Total Gastrectomy	Open surgery	No	Chemotherapy
7	M	79	A	1st	Lives with spouse	58	Total Gastrectomy	Laparoscopic	Yes	Chemotherapy
8	F	63	A	1st	Lives alone	5	Total Gastrectomy	Open surgery	No	Nil
9	M	61	A	3rd	Lives with spouse	170	Total Gastrectomy	Open surgery	No	Nil

10	M	61	C	1st	Lives alone	79	Total Gastrectomy	Open surgery	No	Chemotherapy
11	M	76	A	4th	Lives with spouse	110	Total Gastrectomy	Laparoscopic	Yes	Chemotherapy
12	F	82	A	4th	Lives alone	62	Partial Gastrectomy	Open surgery	No	Nil
13	F	59	A	2nd	Lives with spouse	19	Partial Gastrectomy	Open surgery	No	Chemotherapy
14	M	70	B	1st	Lives alone	11	Partial Gastrectomy	Open surgery	No	Nil
15	F	56	M	5th	Lives with parent	33	Total Gastrectomy	Open surgery	Yes	Chemotherapy
16	F	84	A	1st	Lives alone	17	Partial Gastrectomy	Laparoscopic	Yes	Nil
17	M	48	A	4th	Lives with parent	9	Total Gastrectomy	Laparoscopic	Yes	Chemotherapy
18	M	77	A	4th	Lives with spouse	78	Total Gastrectomy	Open surgery	Yes	Nil
19	Fe	58	A	3rd	Lives with spouse	11	Partial Gastrectomy	Laparoscopic	No	Nil
20	M	54	A	1st	Lives with	48	Partial Gastrectomy	Open surgery	No	Chemotherapy

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2
3 spouse
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8 *A=, B= , C= , M= . **Social deprivation quintile: 1st quintile being the least deprived, 5th quintile being the most deprived.
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For peer review only

Discussion

To our knowledge, this is the first in-depth qualitative study exploring the priorities of patients following surgery for gastric cancer. The themes identified highlight the profound and wide-ranging physical, social and psychological impacts that gastrectomy has on patients which can persist for months and years. We have previously described the reporting of outcomes in surgical trials for gastric cancer over a twenty-year period⁵. Most surgical trials in this field have focused on reporting short-term post-operative outcomes. Whilst these are important to patients, they are not representative of the whole picture. This work highlights how patient priorities for outcomes may differ from the traditional surgical focus. More work is now needed to develop the COS which incorporates views of all key stakeholders including patients.

More than half of the 'top-ten' most frequently discussed outcomes in our study related to longer-term issues such as problems with eating, returning to 'normality', fatigue, weight loss, gastro-intestinal symptoms and psychological impacts. These types of outcomes are infrequently reported in surgical trials and demonstrate that researchers within this field have not reflected the priorities of patients. This challenge needs to be addressed using an approach which is inclusive of patients and their views.

The GASTROS study aims to develop a COS; critically important outcomes which should be reported - as a minimum - by future surgical trials for gastric cancer⁶. By standardising the reporting of such outcomes, it aims to improve the ability to synthesise evidence, reduce research waste and ultimately aid researchers in answering important questions related to gastrectomy. The first stage in developing the COS consists of identifying a 'long-list' of outcomes which will then be prioritised by key stakeholders during an international online Delphi survey. The process of developing the long-list should be comprehensive and involve both healthcare professionals and patients in order to minimise the risk of omitting potentially important outcomes. Our study reaffirms the importance of a mixed-methods approach to identifying potentially important outcomes. As others COS developers have found, building a long-list based solely on outcomes reported in previous trials or as developed by clinicians often neglects the views of key stakeholders⁸⁻¹⁰. This ultimately runs the risk of producing a

1
2
3 COS which does not reflect the priorities of patients which does little to address the current challenges
4
5 with outcome reporting.
6
7

8 Understanding patient priorities following gastrectomy is invaluable for other reasons. Patients with
9
10 gastric cancer want detailed information about their condition and treatment¹⁴. With the knowledge
11
12 that long-term impacts of surgery are important, healthcare professionals can tailor the consent
13
14 process prior to surgery to ensure that the patient has a better understanding of these and is making an
15
16 informed decision. Considering patient priorities may also have implications for the future
17
18 development of national and international audits^{3,4}. For several pragmatic reasons, most
19
20 comprehensive gastric cancer surgery audits focus on short-term outcomes. Identifying methods to
21
22 report longer-term quality outcome measures may make such audits more relevant to patients. Studies
23
24 assessing patients' views in similar disease areas found similar things, that long term outcomes
25
26 (survival and long term quality of life) were important¹⁵.
27
28
29

30 **Strengths and weaknesses**

31
32 The study was able to gain an in-depth understanding of patient priorities based on the experience of
33
34 participants with a broad range of characteristics representative of those undergoing surgery for
35
36 gastric cancer in the UK⁴. Furthermore, our purposive sampling approach was established *a priori* in a
37
38 study protocol which had undergone a robust peer-review process.
39
40

41 This study was also able to highlight and address significant challenges associated with the
42
43 comprehension of medical language by patients; particularly terms central to the development of a
44
45 COS. Patients largely did not understand the use of the term 'outcome' within the context of medical
46
47 research. Once it was defined as an 'impact or effect of a treatment which may be beneficial or
48
49 harmful', participants were more easily able to describe their key priorities in outcome reporting for
50
51 future trials. This has several implications for the GASTROS study as well as other COS projects
52
53 moving forward. It highlights the importance of ensuring that the premise of the study is clear and
54
55 understood by all participants, especially patients; outcomes included in the Delphi survey must be
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1
2
3 presented and explained in a manner which is accessible to all; 'outcome' must be clear when
4
5 adapting it to other regions where there may be no direct translation for the term.
6
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8 The interviews were conducted by an expert in the field of gastric cancer surgery which may have
9
10 resulted in a degree of observer bias. To mitigate this potential limitation, the study management team
11
12 (which was made up primarily of members unfamiliar with gastric cancer surgery) was involved in
13
14 ongoing discussions during data collection and analysis. It is also possible that patients modified their
15
16 responses because of awareness of the background of the interviewer. Every effort was made to
17
18 follow the semi-structured interview schedule, to put the patients at ease and take time to let them
19
20 talk. The average length of the interviews (greater than 45 mins) reflects the time patients were given
21
22 to express their views. The GASTROS study aims to recruit healthcare professionals and patients
23
24 internationally to its online Delphi survey to prioritise potentially important outcomes. The results of
25
26 the Delphi survey will inform a consensus meeting to finalise the COS. A limitation of this present
27
28 interview study is a lack of international patient participation. Consequently, there may be outcomes
29
30 which are relevant to non-UK patients that have not been identified. Gastric cancer is an international
31
32 disease and cultural and regional influences may alter expectations and priorities of patients. Whilst
33
34 we have not identified evidence from COS developers in other fields that confirms these variations, it
35
36 remains a possibility. Our reasons for limiting the interviews to UK-only patients were primarily
37
38 down to pragmatism and finite resources. To mitigate this, the Delphi survey will be available in
39
40 several languages and during the first round, all participants will be able to submit additional
41
42 outcomes that they believe were omitted. These will be considered by the study team and presented
43
44 for prioritisation by participants in round two of the Delphi survey, if appropriate. Adopting this
45
46 approach also enables the exploration of regional variations in outcome priorities which may form the
47
48 basis of a future international qualitative study.
49
50
51

52 In summary, this study identified 38 unique outcomes which are important to patients following
53
54 surgery for gastric cancer. Many of these outcomes are poorly represented by trials within this
55
56 research field. These outcomes will be added to other potentially important outcomes to be considered
57
58 for prioritisation by key stakeholders to develop a COS for surgical trials in gastric cancer.
59
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Author Statement

Author contributions to the study - <https://www.casrai.org/credit.html>.

#	Role	Definition	Authors
1	Conceptualization	Ideas; formulation or evolution of overarching research goals and aims.	BA, JMB, IAB, RM
2	Data curation	Management activities to annotate (produce metadata), scrub data and maintain research data (including software code, where it is necessary for interpreting the data itself) for initial use and later re-use.	BA
3	Formal analysis	Application of statistical, mathematical, computational, or other formal techniques to analyse or synthesize study data.	BA, RM
4	Funding acquisition	Acquisition of the financial support for the project leading to this publication.	BA, JMB, IAB
5	Investigation	Conducting a research and investigation process, specifically performing the experiments, or data/evidence collection.	BA, RM
6	Methodology	Development or design of methodology; creation of models.	BA, IAB, RM
7	Project administration	Management and coordination responsibility for the research activity planning and execution.	BA, IAB, RM
8	Resources	Provision of study materials, reagents, materials, patients, laboratory samples, animals, instrumentation, computing resources, or other analysis tools.	BA, IAB
9	Software	Programming, software development; designing computer programs; implementation of the computer	BA

		code and supporting algorithms; testing of existing code components.	
10	Supervision	Oversight and leadership responsibility for the research activity planning and execution, including mentorship external to the core team.	BA, JMB, IAB, RM
11	Validation	Verification, whether as a part of the activity or separate, of the overall replication/reproducibility of results/experiments and other research outputs.	BA, RM
12	Visualization	Preparation, creation and/or presentation of the published work, specifically visualization/data presentation.	BA, JMB, IAB, RM
13	Writing – original draft	Preparation, creation and/or presentation of the published work, specifically writing the initial draft (including substantive translation).	BA
14	Writing – review & editing	Preparation, creation and/or presentation of the published work by those from the original research group, specifically critical review, commentary or revision – including pre- or post-publication stages.	BA, JMB, IAB, RM

Appendix 1. Development of themes

Theme: Surviving and Controlling Cancer

Issues identified on initial coding	Outcome	Outcome theme
Being cured of cancer	Recurrence of Cancer	Surviving and Controlling Cancer
Cancer returning to other parts of the body		
Cancer returning in the abdomen		
Possibility of cancer returning		
Being able to live (a little/a lot) longer	Survival	
Being alive/surviving for a 'long time'		
Chances of (not) dying from cancer		
Chances of survival		

Theme: Adverse events following surgery

Issues identified on initial coding	Outcome	Outcome theme
Complications related to anaesthesia	Anaesthetic complications	Adverse events following of Surgery
Anastomotic leak	Anastomotic complications	
Anastomotic stricture		
Internal bleeding requiring further intervention	Bleeding	
Concern about cardiac complications in context of previous myocardial infarction	Cardiac complications	
Racing heart beat		
Stroke following surgery	Cerebro-vascular complications	
Bowel perforation	Intestinal complications	
Gastro-intestinal symptoms e.g. constipation		
Obstruction of bowel		
Epidural related complications	Medication related complications	
Hallucinations		
Overdose of medications such as morphine		
Side effects of sedatives		
Drains and tubes to manage complications	Need for re-intervention	
Endoscopic treatment of anastomotic stricture		
Requiring further surgery to manage complications		

Surgery for incisional hernia		
‘Surviving’ surgery		
Dying from a complication of surgery	Peri-operative death	
Dying on the operating table		
Hospital acquired pneumonia		
Pleural effusion	Respiratory complications	
Pneumothorax		
Re-admission due to complications such as infections	Re-admission to hospital	
Re-admission due to pain		
Wound dehiscence		
Wound infection	Wound complications	
Wound leak		
Wound numbness		
Catheter-related problems	Urinary complications	

Theme: Long-term impact of surgery

Issues identified on initial coding	Outcome	Outcome theme
Being able to enjoy a good quality of life		
Uncertainty as to what life will be like following surgery	Overall ‘quality of life’	
Changes in mood		
Clinical depression		
Feeling ‘abnormal’ and ‘different’ to others	Psychological impact	
Feelings of insecurity		
Feelings of isolation		
Issues related to body image		Long-term impact of surgery
Low mood		
Being able to enjoy eating again		
Being able to exercise again		
Being able to interact and socialise with others	Returning to ‘normality’	
Being able to live ‘as they did before’		
Being able to rely on oneself to undertake tasks		
Being able to undertake household activities		

such as shopping and gardening		
Returning to employment		

Theme: Technical aspects of surgery

Issues identified on initial coding	Outcome	Outcome theme
'Cutting' the cancer out	Complete resection of cancer	Technical aspects of surgery
Ensuring no cancer is left behind		
Getting 'rid' of the cancer		
Inability to resect cancer at surgery		
Removing all lymph nodes		
Removing spleen if necessary	Size of incisions	
Ability to perform laparoscopic 'keyhole' surgery		
Large scars		
Duration of surgery	Duration of surgery	

Theme: Long-term problems following surgery

Issues identified on initial coding	Outcome	Outcome theme	
Amounts able to eat and drink	Eating and Drinking	Long-term problems following surgery	
Being able to eat 'properly'			
Being able to eat at home			
Change in diet and types of food patient can consume			
Difficulties swallowing			
Requirement for ongoing nutritional support	Nutritional problems	Long-term problems following surgery	
Vitamin B12 deficiency			
Feeling persistently tired	Fatigue		Long-term problems following surgery
Feeling extremely weak/lethargic/tired			
Having no energy or stamina			
Loss of energy following simple tasks			
Abdominal bloating	Gastro-intestinal symptoms	Long-term problems following surgery	
Belching			
Diarrhoea			
Dumping syndrome			
Excessive flatus			
Nausea			

Reflux symptoms (acid or bile)		
Vomiting		
Abdominal pain or cramps	Chronic Pain	
Headaches and migraines		
Long-term wound related pain		
Muscle cramps		
Pain on swallowing		
Painful abdominal distension or bloating		
Inability to regain weight to desired level	Weight problems	
Readjusting to new weight		
Speed of weight loss		
Weight loss in general		

Theme: Recovery Following surgery

Issues identified on initial coding	Outcome	Outcome theme
Post-operative plan for physiotherapy	Ambulation	Recovery following surgery
Restricted mobility due to drains and tubes attached		
Time to be able to undertake tasks such as standing up, walking or bathing		
Time before being allowed to eat and drink	Return of gastrointestinal function	
Time before bowel function returned		
Concern about being too unwell for further chemotherapy	Ability to have more chemotherapy	
Length of time in hospital	Duration of hospital stay	
Length of time in intensive care		
Length of time in pain	Post-operative pain	
Patterns of pain		
Requirement for analgesia		
Severity of pain		

Appendix 1. Summary of outcomes and outcome themes identified from interviews.

Outcome Theme	Outcome	How many interviews outcome was referenced in	Total number of references in all interviews
Surviving and controlling cancer <ul style="list-style-type: none"> • Referenced in 20 interviews • Referenced 90 times in all interviews. 	Curing Cancer	4	6
	Recurrence of Cancer	18	28
	Survival	20	56
Technical aspects of surgery <ul style="list-style-type: none"> • Referenced in 18 interviews • Referenced 52 times in all interviews. 	Complete Excision of Cancer	18	52
	Excision of Lymph Nodes	5	5
	Need for splenectomy	1	1
	Operative time	1	2
	Wound Size	7	11
Adverse events <ul style="list-style-type: none"> • Referenced in 20 interviews • Referenced 97 times in all interviews. 	Ability to have adjuvant chemotherapy	1	1
	Anaesthetic Complications	1	1
	Anastomotic Leak	6	9
	Anastomotic Stricture	1	1
	B12 Deficiency	5	5
	Bleeding	1	2
	Cardiac Complications	2	2
	Catheter related complications	1	1
	Cerebro-vascular complications	1	1
	Gastrointestinal problems	1	1
	Hernia	1	1
	Intestinal complications	4	10
	Medication-related complications	10	12
Need for reintervention	8	13	

	Peri-operative death	12	20
	Re-Admission to Hospital	3	4
	Respiratory complications	3	3
	Wound Complications	8	10
Recovery from surgery	In Hospital Recovery	11	23
	Length of Stay Following Surgery	11	18
<ul style="list-style-type: none"> • Referenced in 18 interviews • Referenced 57 times in all interviews. 	Peripheral Oedema	1	1
Long-terms problems following surgery	Eating & Drinking	20	75
	Fatigue	16	38
	Gastrointestinal symptoms	11	27
<ul style="list-style-type: none"> • Referenced in 20 interviews • Referenced 175 times in all interviews. 	Pain	10	14
	Weight Loss	12	21
Long-term impacts of surgery	Necessity of long-term feeding	1	1
	Overall QoL	8	10
<ul style="list-style-type: none"> • Referenced in 20 interviews • Referenced 133 times in all interviews. 	Psychological impact	11	40
	Returning to normality	20	82

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med.* 2014;89(9):1245-1251.

	Reporting Item	Page Number
Title		
	#1 Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
Abstract		
	#2 Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	4
Introduction		
Problem formulation	#3 Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	7

1	Purpose or research	#4	Purpose of the study and specific objectives or	7
2	question		questions	
3				
4	Methods			
5				
6				
7	Qualitative approach and	#5	Qualitative approach (e.g. ethnography, grounded	9
8	research paradigm		theory, case study, phenomenology, narrative research)	
9			and guiding theory if appropriate; identifying the	
10			research paradigm (e.g. postpositivist, constructivist /	
11			interpretivist) is also recommended; rationale. The	
12			rationale should briefly discuss the justification for	
13			choosing that theory, approach, method or technique	
14			rather than other options available; the assumptions	
15			and limitations implicit in those choices and how those	
16			choices influence study conclusions and transferability.	
17			As appropriate the rationale for several items might be	
18			discussed together.	
19				
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26	Researcher characteristics	#6	Researchers' characteristics that may influence the	10
27	and reflexivity		research, including personal attributes, qualifications /	
28			experience, relationship with participants, assumptions	
29			and / or presuppositions; potential or actual interaction	
30			between researchers' characteristics and the research	
31			questions, approach, methods, results and / or	
32			transferability	
33				
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36				
37	Context	#7	Setting / site and salient contextual factors; rationale	10
38				
39				
40	Sampling strategy	#8	How and why research participants, documents, or	9
41			events were selected; criteria for deciding when no	
42			further sampling was necessary (e.g. sampling	
43			saturation); rationale	
44				
45				
46	Ethical issues pertaining to	#9	Documentation of approval by an appropriate ethics	11
47	human subjects		review board and participant consent, or explanation for	
48			lack thereof; other confidentiality and data security	
49			issues	
50				
51				
52				
53	Data collection methods	#10	Types of data collected; details of data collection	10
54			procedures including (as appropriate) start and stop	
55			dates of data collection and analysis, iterative process,	
56			triangulation of sources / methods, and modification of	
57				
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59				
60				

1		procedures in response to evolving study findings;	
2		rationale	
3			
4	Data collection	#11 Description of instruments (e.g. interview guides,	11
5	instruments and	questionnaires) and devices (e.g. audio recorders)	
6	technologies	used for data collection; if / how the instruments(s)	
7		changed over the course of the study	
8			
9			
10	Units of study	#12 Number and relevant characteristics of participants,	16
11		documents, or events included in the study; level of	
12		participation (could be reported in results)	
13			
14			
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16	Data processing	#13 Methods for processing data prior to and during	11
17		analysis, including transcription, data entry, data	
18		management and security, verification of data integrity,	
19		data coding, and anonymisation / deidentification of	
20		excerpts	
21			
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23			
24	Data analysis	#14 Process by which inferences, themes, etc. were	11
25		identified and developed, including the researchers	
26		involved in data analysis; usually references a specific	
27		paradigm or approach; rationale	
28			
29			
30			
31	Techniques to enhance	#15 Techniques to enhance trustworthiness and credibility	11
32	trustworthiness	of data analysis (e.g. member checking, audit trail,	
33		triangulation); rationale	
34			
35			
36	Results/findings		
37			
38			
39	Syntheses and	#16 Main findings (e.g. interpretations, inferences, and	16
40	interpretation	themes); might include development of a theory or	
41		model, or integration with prior research or theory	
42			
43			
44	Links to empirical data	#17 Evidence (e.g. quotes, field notes, text excerpts,	16
45		photographs) to substantiate analytic findings	
46			
47			
48	Discussion		
49			
50	Intergration with prior	#18 Short summary of main findings; explanation of how	29
51	work, implications,	findings and conclusions connect to, support, elaborate	
52	transferability and	on, or challenge conclusions of earlier scholarship;	
53	contribution(s) to the field	discussion of scope of application / generalizability;	
54		identification of unique contributions(s) to scholarship in	
55		a discipline or field	
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1	Limitations	#19	Trustworthiness and limitations of findings	30
2				
3	Other			
4				
5	Conflicts of interest	#20	Potential sources of influence of perceived influence on	3
6			study conduct and conclusions; how these were	
7			managed	
8				
9				
10				
11	Funding	#21	Sources of funding and other support; role of funders in	2
12			data collection, interpretation and reporting	
13				
14				

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BMJ Open

Patient Priorities in Relation to Surgery for Gastric Cancer: Qualitative Interviews with Gastric Cancer Surgery Patients to Inform the Development of a Core Outcome Set.

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Primary Subject Heading:	Surgery
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Keywords:	Adult surgery < SURGERY, Gastrointestinal tumours < ONCOLOGY, ONCOLOGY, SURGERY

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4 Title Page

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6 **Patient Priorities in Relation to Surgery for Gastric Cancer: Qualitative Interviews with Gastric**
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8 **Cancer Surgery Patients to Inform the Development of a Core Outcome Set.**
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10
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Conflicts of Interest

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Data Availability

Data are available upon reasonable request.

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Author Contributorship Statement

Conceptualization - BA, JMB, IAB, RM; Data curation - BA; Formal analysis - BA, RM; Funding acquisition - BA, JMB, IAB; Investigation - BA, RM; Methodology - BA, IAB, RM; Project administration - BA, IAB, RM; Resources - BA, IAB; Software – BA; Supervision - JMB, IAB, RM; Validation - BA, RM; Visualization - BA, JMB, IAB, RM; Writing (original draft) - BA; Writing (review & editing) - BA, JMB, IAB, RM.

Running Title

Patient Priorities Following Surgery for Gastric Cancer

Word Count: 5660

Number of tables: 3

Number of appendices: 2

Structured Abstract

Objective

The reporting of outcomes in surgical trials for gastric cancer is inconsistent. The GASTROS study (GAstric Cancer Surgery TRials Reported Outcome Standardisation) aims to address this by developing a core outcome set (COS) for use in all future trials within this field. A COS should reflect the views of all stakeholders, including patients. We undertook a series of interviews to identify outcomes important to patients which would be considered for inclusion in a COS.

Setting

All interviews took place within the United Kingdom. Interviews were carried out face-to-face at hospitals and cancer support centres or via the telephone.

Participants

Twenty participants at varying stages of recovery following surgery for gastric cancer with curative intent.

Design

Qualitative design using semi-structured interviews, supported by an interview guide which was iteratively modified; thematic analysis was used to explore patient priorities.

Results

Six themes enveloping 38 outcomes were identified; surviving and controlling cancer, technical aspects of surgery, adverse events from surgery, recovering from surgery, long-term problems following surgery and long-term life impact of surgery. The 'most important' patient priority was to be 'cured of cancer'.

Conclusion

Surgical trials for gastric cancer should consider broader priorities of patients when choosing which outcomes to report. This study highlighted the importance of longer-term outcomes such as cancer

1
2
3 survival. Outcomes identified in this study will be used to inform an international Delphi survey to
4
5 develop a COS in this field.
6
7

8 **KEYWORDS:**
9

10 Surgical Oncology
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12

13 Stomach Neoplasms
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16 Outcome Assessment
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19 Patient Reported Outcome Measures
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22 Treatment Outcome
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25 Outcome reporting
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Article Summary

Strengths and Limitations of This Study

- This is the first in-depth qualitative study to examine the priorities and experiences of patients following potentially curative surgery for gastric cancer, and the first to establish which outcomes are important to patients.
- The study forms part of a larger project (The GASTROS Study - www.gastrosstudy.org) to develop a 'core outcome set' (COS) for use in surgical trials for gastric cancer and was reviewed and funded by the National Institute of Health Research (UK). The study is based on a reproducible and transparent methodology which has been subjected to critical appraisal during a peer-review process.
- The term 'outcome' was described to participants in a manner relatable to them, such that they understood it and were able to identify which outcomes were most important.
- The patient population was limited to UK-based English speakers. The views of international patients may vary due to differences in culture and clinical practice.

Main Article

Introduction

Background

Gastric cancer is a leading cause of cancer-related death world-wide^{1,2}. Whilst surgery remains the only treatment which can offer a potential cure from this disease, it is associated with significant rates of morbidity in both the short and long-term^{3,4}. Ideally, the optimal surgical approach would minimise the risk of short and long-term complications without jeopardising the oncological resection.

Identifying the optimal surgical approach for gastric cancer should be based on comparing and combining robust clinical evidence from well-designed randomised control trials. One of the present challenges to achieving this is the inconsistency in the reporting of outcomes in this field⁵. This limits evidence synthesis and contributes to 'research waste'. The GASTROS study (GASTROS – **G**Ast^ric **C**ancer **S**urgery **T**Rials **R**eported **O**utcome **S**tandardisation - www.gastrosstudy.org)⁶ aims to address this issue by developing a 'core outcome set' (COS) – a *minimum* group of standardized and well-defined outcomes, measured by all future gastric cancer surgery trials⁷.

A guiding principle in the development of COS is that outcomes reflect the views and priorities of key stakeholders, including patients, to maximise the relevance and impact of future research. Previous studies have demonstrated variations in the views and priorities of clinicians and patients⁸⁻¹⁰, which can result in trials reporting outcomes which bear little relevance to patients. A systematic review of outcome reporting in surgical trials for gastric cancer has demonstrated that outcomes which may be important to gastric cancer patients, such as 'quality of life' after surgery are poorly represented within this field⁵. It is therefore important to understand which outcomes are important for patients undergoing gastric cancer surgery.

Objective

This research forms part of the GASTROS study, for which the protocol has been previously described⁶. The first stage in the study involves identifying a 'long-list' of potentially important outcomes which will be prioritised in stage two by participants undertaking a Delphi survey. It is not

1
2
3 known to what degree outcomes reported in previously published trials represent the priorities of
4 patients undergoing gastric cancer surgery, and as such, solely relying on these as a source to populate
5 the 'long-list' may overlook potentially important outcomes. By exploring the experiences,
6 perceptions and priorities of patients who have undergone surgery for gastric cancer, this study aimed
7 to identify outcomes which may not have been previously reported in the literature.
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For peer review only

Methods

Study Design

The role of qualitative research methods in the development of COS has been previously explored¹¹ and has been advocated by groups such as the COMET initiative⁷ as one of several approaches to ensure that outcome lists being considered for prioritisation are exhaustive. This qualitative study used a semi-structured interview approach to achieve the primary objective of identifying outcomes of importance to patients. A series of open questions were used to facilitate a patient-led discussion, guided by additional prompts from a pre-prepared interview schedule (table 1) to ensure key areas were covered.

Additional focused questioning around the use of outcomes in research was also included. In the context of clinical research, terms such as ‘outcomes’ may not be well understood by patients¹¹ and so a mixture of open and closed questioning was important. Participant interviews were undertaken in series of three following which transcript analysis (see below) was undertaken and the interview schedule was modified iteratively. This ensured that areas raised by earlier participants, but not included in the original schedule, were covered in subsequent discussions.

Sampling

The eligibility criteria for this study are summarized in table 2. A purposive sampling strategy was adopted across the following characteristics:

- Age (above and below 70 years).
- Gender (men and women)
- Time since surgery (less than a year, one to three years and more than three years)

Interviews were undertaken until ‘data-saturation’ was achieved. Data saturation was determined when there was no new data emerging that had interpretive value.

Participants were recruited from across the United Kingdom from three sources:

- 1
2
3 1. A regional specialist gastric cancer centre: patients were approached in the outpatient clinic
4
5 by their direct care team.
6
- 7 2. Patient organisations: patient groups were asked to contact their membership through e-mail
8
9 and social media.
10
- 11 3. Snowball sampling; patients who had been recruited or contacted to participate were asked to
12
13 identify other patients who would be interested in the study.
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18 Data Collection

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20 Interviews were undertaken between February and May 2017 and were conducted by BA, a
21
22 consultant surgeon and researcher with approximately ten years' experience of managing and
23
24 communicating with gastric cancer patients. Participants were invited to choose between a University
25
26 Teaching Hospital, two purpose-built patient cancer centres, or their home for the location of the
27
28 meeting. Participants were also offered the opportunity to have their interviews over the telephone.
29
30 Participants were offered travel expenses to minimise any financial burden on taking part in the study.
31
32

33 In addition to the purposive sampling strategy, the following demographic data was collected:

- 34 • Gender (male/female)
- 35
- 36 • Social circumstances (e.g. lives alone/with partner/lives with dependents)
- 37
- 38 • Age
- 39
- 40 • Time since surgery (in months)
- 41
- 42 • The type of gastrectomy (total or partial gastrectomy)
- 43
- 44 • The approach to their surgery (open or laparoscopic)
- 45
- 46 • Whether they had undergone additional treatment (e.g. chemotherapy)
- 47
- 48 • Whether they had suffered a post-operative complication
- 49
- 50 • Ethnicity
- 51
- 52 • Previous trial enrolment
- 53
- 54 • Participant post-code (to identify location and social deprivation score)
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3 Full written consent was taken immediately prior to the interview and the participant was reminded
4 that they were able to stop at any point or withdraw from the study without needing to give a reason.
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7 8 Data Analysis 9

10 All interviews were digitally recorded and professionally transcribed (intelligent verbatim
11 transcription). A thematic analysis was used to identify emerging themes and was guided by a general
12 inductive approach^{12,13}. This was used to create the framework applied to subsequent interviews.
13
14 Themes were developed using a three-step approach of open coding, axial coding and selective
15 coding¹⁴ of the transcripts. Given the objective of this study was to identify themes and outcomes not
16 previously reported in trials, it was important not to base data analysis and outcome identification on
17 a framework built on previously published literature. BA and RM (a researcher with significant
18 experience in qualitative research methods) independently analysed the first two transcripts and
19 through discussion identified themes and adjustments to the interview schedule. There were no
20 disagreements about coding, but had there been, these would have been discussed with the study
21 management team. The final themes were agreed by all authors through discussion. Data analysis was
22 supported using NVivo 11 (http://www.qsrinternational.com/products_nvivo.aspx, QSR International,
23 Burlington, MA, USA).
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40 Approvals and Portfolio Adoption

41 The study was given ethical approval by the National Research Ethics Service North West—Cheshire
42 (11/NW/0739) and governance approvals by Central Manchester University Hospital NHS
43 Foundation Trust. The study was adopted by the National Institute for Health Research (NIHR)
44 Clinical Research Network Portfolio (ID 33312).
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51 Reporting

52 This paper uses the SRQR checklist to structure the report of the study findings¹⁵.
53
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56 Patient and Public involvement

57 A Study Advisory Group (SAG) forms part of the management structure of the wider GASTROS
58 study⁶, of which this qualitative study forms part of the first stage. The SAG is made up of key
59
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3 stakeholder representatives including patients, oncology nurses and surgeons. The group provides
4
5 advice on the methodology of the study, general delivery of the study against its stated objectives and
6
7 ensures that the viewpoints of all stakeholder groups are considered. The results of this study were
8
9 presented to a SAG meeting; the ensuing discussion influenced the design of the next stage of the
10
11 study in preparation for an international Delphi Survey.
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14 Best practice guidelines for patient and public engagement were followed as set out by INVOLVE
15
16 (part of and funded by the United Kingdom's National Institute for Health Research)¹⁶.
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For peer review only

Table 1. Interview schedule.

1.	I understand you have (had) gastric cancer. Can you tell me about that?
2.	<p><i>Could you tell me about how you first found out you had gastric cancer?</i></p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>What questions did you most want to ask, when you were told that you had gastric cancer?</i>
3	<p>Were there were any areas you wanted more information about but were unable to find?</p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>Were you given any leaflets at the time of diagnosis? Did you find these useful?</i>
4	<p>What treatment was offered and how you decide about undergoing treatment.</p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>What information did you want about the treatment you would be receiving?</i> • <i>What factors did you consider when deciding on the treatment?'</i>
5	<p>What effects did the treatment have on you after surgery?</p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>Did the treatment affect your physical or mental well-being?</i> • <i>Did the treatment have an effect on relationships with those around you?</i> • <i>Did you have to make any changes to your behaviour as a result of treatment?</i>
6	<p>What long-term effects did the treatment have on you?</p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>Did the treatment affect your physical or mental well-being?</i> • <i>Did the treatment have an effect on relationships with those around you?</i> • <i>Did you have to make any changes to your behaviour as a result of treatment?</i>
7	What was the worst side effect of treatment?
8	What are your concerns for the future, especially those relating to their diagnosis/history of gastric cancer?

9	Did the explanation of what you should expect from surgery match your real experience?
10	In the context of research studies, can you explain what an outcome is in your own words? The interviewer will then provide a definition of the term 'outcome' is in the context of clinical research.
11	What, in your opinion, is the most important outcome to measure in gastric cancer surgery trials?
12	Are there any other outcomes which may be important to measure?
13	Has your perspective on what is important changed over time?
14	Is there anything else that you feel is important to talk about that we have not discussed?

Table 2. Eligibility criteria for study participants.

	Potential Participants Approached	Potential Participants Not Approached
Participant	<ul style="list-style-type: none"> • Male and females aged 18 years and older. • Individuals able to participate in an interview in the English language. 	<ul style="list-style-type: none"> • Patients unable to give informed consent • Patients too unwell to comfortably participate in an interview lasting approximately 30-60 minutes.
Pathology	<ul style="list-style-type: none"> • Adenocarcinoma and squamous cell carcinoma of the stomach, (which makes up 95 per cent of all stomach tumours). 	<ul style="list-style-type: none"> • Gastrointestinal Stromal Tumours • Neuro-endocrine tumours • Lymphoma • Benign disease
Intervention	<ul style="list-style-type: none"> • Total and partial gastrectomy • Open and laparoscopic approaches 	<ul style="list-style-type: none"> • Surgery with palliative intent • Endoscopic therapies such as EMR (endoscopic mucosal resection) and ESD (endoscopic Submucosal dissection)

Results

Overview

In total, 20 patients were interviewed. Table 3 summarises demographic data and treatment-related characteristics of participants. Interviews lasted a median of 50.5 minutes (29-75 minutes). No patients withdrew from the study. Data saturation was deemed to have been reached by 20 interviews; one new outcome was identified in interview number 18 (related to sexual activity), however, no further outcomes were identified from the following two transcripts.

Outcome Themes

Six broad themes enveloping 38 outcomes were identified;

1. Surviving and controlling cancer,
2. Technical aspects of surgery,
3. Adverse events from surgery,
4. Recovering from surgery,
5. Long-term problems following surgery and
6. Long-term life impact of surgery.

Appendix 1 provides a breakdown of how all themes were developed from outcomes identified during the interviews. Themes were well represented in each interview; each theme was discussed by at least 18 of 20 participants. Appendix 2 demonstrated the outcomes identified during the interviews and how often they were referenced.

Theme 1: Surviving and controlling cancer

For most, details of their initial consultation were sketchy; participants often described being given lots of information about their diagnosis, much of which was not absorbed. However, patients clearly remember their reaction to being told their cancer diagnosis; for most, the response was the same:

“When you hear the word, cancer, you think that’s it. I’m going to die.” (participant 6)

There was a range of personal experience with cancer within our patient group. Some had direct family members who had undergone chemotherapy and had an intimate knowledge of its effects.

1
2
3 “it was my worst nightmare come true because I lost my dad to cancer and I always had it in
4 the back of my mind, well if one person in the family could get cancer from somewhere then
5 we could as well.” (participant 19)
6
7
8
9

10 Some patients had a vague knowledge of friends or work colleagues who had undergone treatments
11 for cancer and others had no prior experience of cancer at all. Despite these differences, the initial
12 responses to their diagnosis were similar.
13
14
15

16 All participants in our study had undergone radical surgery with curative intent. At the time of
17 interview, no participants had confirmed evidence of disease recurrence although one was being
18 investigated for potential recurrence. Once the discussion with their surgeon moved away from the
19 diagnosis and onto potentially curative treatments, participants often focused their questions on
20 ‘survival’:
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22
23
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26

27
28 “I wanted to know what the chances were of me having this removed and not, well, basically
29 not dying from it.” (participant 4)
30
31
32

33 Despite radical surgery (and peri-operative chemotherapy in half of our participants), for many of the
34 participants the fear of recurrence remained a permanent anxiety. Many participants seemed to
35 understand that due to the aggressive nature of gastric cancer, recurrence is a possibility for many:
36
37
38
39

40 “...you’re always worried that it’s going to come back...” (participant 7)
41
42

43 The study cohort included participants who had undergone surgery between 5 months and 14 years
44 prior to the interviews. There did not seem to be a relationship between the length of time out of
45 surgery and concerns about cancer recurrence.
46
47
48
49

50 *Theme 2: Technical aspects of surgery*

51 Several outcomes related to this theme were discussed by participants. Most importantly, participants
52 focused on whether the surgical team was able to excise the ‘cancer’ in its entirety. This priority was
53 often referenced in relation to the ‘success’ of surgery and its contribution to ‘curing’ participants of
54 cancer:
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56
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1
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3 “...thinking to yourself that, you know, everything has been done to the best of the hospital’s
4 ability, and, you know, they’ve taken absolutely everything out.” (participant 4)
5
6

7 Whilst participants mostly referred to the cancer as a single ‘entity’, there were a small number who
8 demonstrated some knowledge of the importance of different aspects of surgery such as lymph node
9 excision:
10
11

12 “And yeah, I remember the news about the pathology on the bits they’d taken away, and the
13 lymph node system and what not, came a week or two before I was due to go back on the
14 chemo.” (participant 20)
15
16
17
18

19 Six participants underwent a minimally invasive surgery with the remainder undergoing open surgery.
20 The size of the wounds or type of surgical approach was referred to by only a minority of our
21 participants. In the main, these were made in passing as little importance was placed on the surgical
22 approach:
23
24
25
26
27

28 Interviewer: “Okay, and what...what did that mean for you to have keyhole surgery?”
29

30 Respondent: “It didn’t mean anything really, you know, I had...I’d heard about keyhole and
31 people who’d had it.” (participant 5)
32
33
34
35
36

37 *Theme 3: Adverse events following surgery*

38

39 Eleven participants suffered a complication following surgery; however, this theme was important to
40 all interviewees. Peri-operative death was the most frequently discussed surgical complication:
41
42

43 “...the fear of dying on the operating table is really real.” (participant 2)
44
45
46

47 During their surgical consultation, participants retained some understanding of the risk of peri-
48 operative death and many were able to quote figures about how likely this complication was. Other
49 complications were highlighted when recounting a personal experience. While all complications
50 occurred in the post-operative period, there were several different causes attributed to these events
51 (e.g. direct surgical, anaesthesia-related and medication-related). The severity and consequences of
52 the complications also varied significantly; some were self-limiting and resulted in a minor extension
53 of the length of hospital stay:
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3 “But I was out of it for three days, I was just hallucinating and God knows what, probably
4 because of the morphine.” (participant 7)
5
6
7

8 And those which were life-threatening and required significant clinical intervention:
9

10 “It was a twisted bowel. Yeah, I was told it was a twisted bowel. Because I always
11 remember that when they brought me back from obviously having a look and everything, I
12 always remember [they] said...we're going to have to take you back to surgery.” (participant
13 15)
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19

20 The severity of the complications suffered did not seem to shape the key priorities in relation to
21 participants’ ‘worst side effect’ of surgery or ‘most important outcome’; these almost entirely related
22 to ‘long-term impacts of surgery’ and ‘cure’ respectively (see below) regardless of how long ago their
23 operation was and which surgical approach (laparoscopic or open surgery) was employed.
24
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28

29 Whilst participants recounted that some of the more serious complications (e.g. death, anastomotic
30 leak and cardio-pulmonary complications) were described by surgeons during the consent process,
31 some were exposed to other sources of information in the pre-operative stage. Participants were
32 regularly provided with written information about their cancer and its management, however the
33 quality and content of this varied depending on the location of their hospital. The response to this
34 format was varied:
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40
41

42 “I’m going to be honest with you, I didn’t actually read them... because I didn’t want things
43 going in my head that I couldn’t take in.” (participant 17)
44
45
46

47 Participants that read the written information often found them difficult to digest for several reasons
48 including the volume of information and fear of the gravity of the diagnosis or prognosis:
49

50
51 “Well some of it were just waste of time, but others, you know, if you’ve got a book about
52 that thick and you read through it and half of it applies to you, and the others just
53 sort...doesn’t apply, you know.” (participant 5)
54
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56
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1
2
3 “As much as it’s alright handing leaflets out, I can...I am a bit of a reader so I will read stuff,
4 but when you think you’ve got a death sentence you think, what’s the point in reading that?”
5
6 (participant 13)
7
8
9

10
11 Several hospitals had patient-support groups which provide a ‘buddy’ system for those awaiting
12 surgery. These support groups became an important part of the recovery process and continue to be
13 relevant many years after surgery. Patients found these more useful as they had the opportunity to
14 speak to those with lived experience of the diagnosis and treatment. Whilst this served as an important
15 source of information to tackle the longer-term impacts of surgery (below), these groups also provided
16 comfort to patients:
17
18
19
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23

24 “I think the support group and speaking to people that have been through it, because it
25 can demystify it quite a lot.” (participant 2)
26
27
28

29 Peer support also provided additional sources of information to participants in the pre-operative
30 period with respect to some of the complications that could arise:
31
32

33 “And I know one guy, where the oesophagus junction was, he’d had that leaking, and he
34 couldn’t eat more than, like, grains of rice and things; so that would be pretty
35 horrendous.” (participant 4)
36
37
38

39 As a result of verbal and written information from healthcare professionals and additional peer
40 support, participants were able to describe key adverse without necessarily having experienced them
41 firsthand.
42
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44
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48 *Theme 4: Recovery from surgery*

49

50 Experiences during the immediate post-operative recovery period were referenced by 18 study
51 participants. Whilst some participants’ experience of recovery from surgery was directly linked to
52 complications, there were aspects of recovery such as post-operative pain, mobility and the
53 recommencement oral intake that were common amongst all those who spoke this theme.
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3 Most participants did not mention post-operative pain as an important focus. Those that did, expected
4 to suffer a degree of pain, however experiences of its severity varied widely. Pain levels amongst
5 interviewees who had undergone similar operations through laparotomy incisions were not uniform.
6
7

8
9 One participant who had open surgery described:

10
11 “I do remember waking up and really being in a hell of a lot of pain and being really out
12 of it.” (participant 6)
13
14

15
16 Whilst another who had undergone their surgery using the same approach recounted:

17
18 “I didn't really have much pain.” (participant 14)
19

20 Discussions around post-operative pain were not confined to discomfort from the surgical incisions,
21 but also related to post-operative complications:
22

23
24 “I was back in writhing in agony with a serious infection in the wound.” (participant 9)
25

26 Participants recounted the limitations in their mobility during the post-operative period. There were
27 many factors contributing to this, including physical weakness, not receiving appropriate
28 encouragement to mobilise and being restricted by surgical drains:
29
30

31
32 “...really difficult to be mobile I suppose, and move around, yourself, ‘cause obviously
33 you’ve got quite a lot of tubes and different things coming out. I felt very, very swollen.”
34
35 (participant 6)
36
37
38
39
40

41 *Theme 5: Long-term problems following surgery*

42
43 All participants described significant long-term symptoms related to surgery. For the most, this
44 represented the ‘worst side effect’ in relation to their treatment and outcomes from this theme were
45 referenced more than any other theme further emphasising its importance. All participants described
46 experience with struggling to eat and drink following surgery and the majority (16/20) talked
47 extensively about the impact of fatigue on their daily lives. Problems with maintaining weight, issues
48 with ongoing gastro-intestinal symptoms and chronic pain were discussed by most participants.
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3 Fatigue was described in many ways; 'exhaustion', 'feeling tired all the time', 'feeling so weak' and
4 'having no energy'. For the main, fatigue was a symptom which persisted for months after surgery
5 and could impact on a participant's ability to undertake day-to-day activities or to socialise:
6
7

8
9 "Well, I'm so weak, I used to go out, you know, and do fishing and do things with my lads.
10
11 I'm just getting that little bit better now after eight months, but I'm so weak and tired."
12
13 (participant 18)
14
15
16
17

18 Adapting to fatigue was and for many continued to be a difficult challenge, however many
19 participants understood that this was a recognised and acceptable symptom to them given the
20 magnitude of the surgery:
21
22

23
24 "I've come out with...more...appreciation for looking after myself and my...And if I'm tired, I
25
26 stop." (participant 15)
27
28
29
30

31 There were several causes for the struggles participants associated with eating and drinking.
32 Participants often described having to eat and drink smaller volumes more frequently and some were
33 unable to tolerate certain food types or consistencies. This had a direct effect on the pleasure
34 associated with eating and an impact on where participants could eat:
35
36
37

38
39 "Well I don't eat what I would like to...But I know that for the rest of my life, I won't be able
40
41 to go out for big meals, to big venues and eat like I used to eat before, you know." (participant
42
43 5)
44
45

46 Most participants recounted being told prior to their surgery that their diet would be different and that
47 they would have to 'learn how to eat again'. Despite this, some participants felt that not enough
48 information was given to highlight the true impact of this long-term issue and methods to address it:
49
50

51
52
53 "I think it's a lot worse than what they tell you. Because like some days, I'll eat a certain thing
54
55 which I've ate before, and you just can't breathe properly, it's choking you." (participant 18)
56
57
58
59
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1
2
3 A broad range of gastro-intestinal symptoms were reported by participants. The time frame relating to
4 how long these persisted was similarly broad (sometimes months and years) and did not seem to
5 follow a pattern. Nausea, vomiting, diarrhoea, reflux and belching were the commonest problems
6 described. Many of these symptoms resulted in significant impacts on quality of life (see theme 6
7 below):
8
9
10
11
12

13 “...I still get the bile reflux and I get this constant pain in the oesophagus which affects my
14 sleeping as well.” (participant 7)
15
16

17
18
19 “The dumping syndrome was mentioned. Never understood it until it happened. You know,
20 how my body reacted to certain foods that I'd normally eat that it doesn't like anymore.”
21
22
23
24 (participant 15)
25
26
27

28 *Theme 6: Long-term life impact of surgery*

29
30 The long-term effects on ‘normality’, quality of life, and psychological impact of surgery were
31 discussed extensively by all patients. A strong desire to return to a form of ‘normality’ was regularly
32 expressed. Whilst the reference point for ‘normality’ differed amongst patients, common
33 characteristics existed; namely a desire to do what they used to do such as working, exercising,
34 socialising with friends and family and being able to travel:
35
36
37
38
39

40
41 “it’s about living as I did before, and forgetting what had happened, and I do that quite often.”
42
43 (participant 6)
44
45
46
47

48 The experience of returning to normality varied amongst those interviewed. Many participants were
49 largely able to return to their ‘normal’ activities albeit with some modifications:
50

51 “Yes. I want to go on holidays again. I love cruises and I want...but until my eating’s
52 improved, I wouldn’t do that.” (participant 1)
53
54
55
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57

58 “Now that it’s 18 months on, I am back to having what would be a normal life again, now,
59 albeit with smaller portions of meals and things” (participant 4)
60

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5 Some participants however have not been able to return to activities that provided them with
6
7 significant enjoyment:

8
9 “I’ve never actually got back to my normal activity. I’ve never played golf since that day and
10
11 I used to love golf.” (participant 4)
12
13

14
15
16 In general, participants understood that life after gastrectomy would be different:

17
18 “I’m still alive, and then I need to get back to normal. It takes a while for you to realise your
19
20 new normality is not like your old normality.” (participant 2)
21
22

23
24 Whilst much of the discussion relating to ‘normality’ centred around specific tasks which participants
25
26 valued or missed, the impact of gastrectomy on a participant’s overall general quality of life was
27
28 important to many. Many understood that quality of life needed to be redefined in comparison to life
29
30 before surgery, but nonetheless there was a minimum level that would need to be achieved:

31
32
33 “if I have some sort of quality of life, where I can get up and wash myself and do, that is
34
35 something that I’d live for. But I couldn’t be sat there and nursed 24/7” (participant 17)
36
37

38
39 The psychological burden on participants following gastrectomy is a significant one. Each of the
40
41 previously discussed themes could impact on a participant’s mental state and whilst certain phases of
42
43 the treatment pathway were time-limited, the psychological effects could persist for much longer;

44
45
46 “You don’t just suffer from physical; you suffer from mental. And I think the mental is a lot
47
48 more powerful than the physical, because you can shut pain off by taking medication, but it’s
49
50 very hard to shut problems off mentally.” (participant 18)
51

52
53 “You know, ‘cause psychologically you think you’ve still got this poison in your body, as
54
55 much as I’ve got rid of, you know, my monster.” (participant 13)
56
57
58
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3 Some of the psychological impacts were associated with participants having to adapt to a new
4 normality in relation to what they were able to do, what they were able to eat, how they looked
5 physically or how they felt around others:
6
7
8

9 “Well, it was a problem because like I say, I've always been a proud chap and proud of my
10 body because I kept myself fit and everything. When I looked in the mirror, quite distressing.
11 That was it, yeah. It makes you feel inferior.” (participant 18)
12
13
14
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16
17

18 “I feel a freak, I feel when I go into a big room with people that everybody has got a stomach
19 and I haven't got one, it's not that I want them to know, but I just don't feel the same
20 anymore...” (participant 8)
21
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25
26

27 Definition of ‘outcome’ by patients

28 All participants were asked what their understanding of the term ‘outcome’ was in the context of
29 clinical research. Two participants were able to provide a broad-ranging definition which
30 encompassed some of the benefits and adverse effects of treatment:
31
32
33

34 “my perception of what would be meant by that phrase would...at a variety of levels; it could
35 be does the patient live or die? Does the patient recover to an acceptable state for an extended
36 period of time, and my understanding of what that might be, would be a, sort of, five year
37 period...” (participant 20)
38
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45 One person stated that they did not know how to define the term, whilst the remainder defined
46 ‘outcome’ by recounting a single outcome, which was most important to them:
47
48
49

50 “Okay, my understanding is that at the...the outcome would be that the cancer would be
51 possibly all gone.” (participant 19)
52
53
54
55

56 Participants were asked to provide a single outcome that was ‘most important to them’. Fifteen
57 participants identified that the most important outcome was that they were ‘cured of cancer’ with the
58 remaining five describing outcomes related to ‘returning to normal’ and being able to enjoy a ‘good
59
60

1
2
3 quality of life'. These priorities did not alter with respect to how long-ago surgery was performed,
4
5 which approach was undertaken or how old the patient was.
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For peer review only

Table 3. Patient characteristics and demographic data.

Patient	Sex	Age	Ethnicity *	Social deprivation quintile**	Home circumstances	Months since surgery	Type of surgery	Approach to surgery	Post-operative complications	Peri-operative treatment
1	F	74	A	3rd	Lives alone	15	Partial Gastrectomy	Laparoscopic	Yes	Nil
2	M	59	B	3rd	Lives alone	27	Total Gastrectomy	Open surgery	Yes	Chemotherapy
3	M	71	A	1st	Lives alone	16	Partial Gastrectomy	Open surgery	Yes	Nil
4	M	43	A	2nd	Lives with parents	15	Total Gastrectomy	Open surgery	Yes	Chemotherapy
5	M	80	A	3rd	Lives alone	23	Partial Gastrectomy	Laparoscopic	Yes	Nil
6	F	52	A	2nd	Lives with children	32	Total Gastrectomy	Open surgery	No	Chemotherapy
7	M	79	A	1st	Lives with spouse	58	Total Gastrectomy	Laparoscopic	Yes	Chemotherapy
8	F	63	A	1st	Lives alone	5	Total Gastrectomy	Open surgery	No	Nil
9	M	61	A	3rd	Lives with spouse	170	Total Gastrectomy	Open surgery	No	Nil

1											
2											
3	10	M	61	C	1st	Lives alone	79	Total Gastrectomy	Open surgery	No	Chemotherapy
4											
5						Lives with					
6	11	M	76	A	4th	spouse	110	Total Gastrectomy	Laparoscopic	Yes	Chemotherapy
7											
8											
9	12	F	82	A	4th	Lives alone	62	Partial Gastrectomy	Open surgery	No	Nil
10											
11						Lives with					
12	13	F	59	A	2nd	spouse	19	Partial Gastrectomy	Open surgery	No	Chemotherapy
13											
14											
15	14	M	70	B	1st	Lives alone	11	Partial Gastrectomy	Open surgery	No	Nil
16											
17						Lives with					
18	15	F	56	M	5th	parent	33	Total Gastrectomy	Open surgery	Yes	Chemotherapy
19											
20	16	F	84	A	1st	Lives alone	17	Partial Gastrectomy	Laparoscopic	Yes	Nil
21											
22						Lives with					
23	17	M	48	A	4th	parent	9	Total Gastrectomy	Laparoscopic	Yes	Chemotherapy
24											
25						Lives with					
26	18	M	77	A	4th	spouse	78	Total Gastrectomy	Open surgery	Yes	Nil
27											
28						Lives with					
29	19	Fe	58	A	3rd	spouse	11	Partial Gastrectomy	Laparoscopic	No	Nil
30											
31											
32						Lives with					
33	20	M	54	A	1st	Lives with	48	Partial Gastrectomy	Open surgery	No	Chemotherapy
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8 *A=, B= , C= , M= . **Social deprivation quintile: 1st quintile being the least deprived, 5th quintile being the most deprived.
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For peer review only

Discussion

To our knowledge, this is the first in-depth qualitative study exploring the priorities of patients following potentially curative surgery for gastric cancer. The study focussed on this cohort as one of the main aims was to identify outcomes which would be considered for inclusion in a COS for potentially curative surgical trials in gastric cancer. This present study will be used to help generate a list of outcomes that will be presented for prioritisation to healthcare professionals and patients in an international, multi-language online Delphi survey. The results of the Delphi survey will inform a consensus meeting to finalise the COS. Whilst other COS studies in the field of cancer¹⁷⁻¹⁹ may have identified similar important outcomes such as survival, it was important to consider our participants separately given the unique problems which arise with gastrectomy. These include distinctive short and long-term problems related to surgery such as anastomotic leak and reactive hypoglycaemia (Dumping syndrome) which would not be relevant in other COS.

The themes identified highlight the profound and wide-ranging physical, social and psychological impacts that gastrectomy has on patients which can persist for months and years. We have previously described the reporting of outcomes in surgical trials for gastric cancer over a twenty-year period⁵. Most surgical trials in this field have focused on reporting short-term post-operative outcomes. Whilst these are important to patients, they are not representative of the whole picture. This work highlights how patient priorities for outcomes may differ from the traditional surgical focus. More work is now needed to develop the COS which incorporates views of all key stakeholders including patients.

More than half of the 'top-ten' most frequently discussed outcomes in our study related to longer-term issues such as problems with eating, returning to 'normality', fatigue, weight loss, gastro-intestinal symptoms and psychological impacts. These types of outcomes are infrequently reported in surgical trials and demonstrate that researchers within this field have not reflected the priorities of patients.

This challenge needs to be addressed using an approach which is inclusive of patients and their views.

The GASTROS study aims to develop a COS; critically important outcomes which should be reported - as a minimum - by future surgical trials for gastric cancer⁶. By standardising the reporting of such outcomes, it aims to improve the ability to synthesise evidence, reduce research waste and ultimately

1
2
3 aid researchers in answering important questions related to gastrectomy. The first stage in developing
4 the COS consists of identifying a ‘long-list’ of outcomes which will then be prioritised by key
5 stakeholders during an international online Delphi survey. The process of developing the long-list
6 should be comprehensive and involve both healthcare professionals and patients in order to minimise
7 the risk of omitting potentially important outcomes. Our study reaffirms the importance of a mixed-
8 methods approach to identifying potentially important outcomes. As others COS developers have
9 found, building a long-list based solely on outcomes reported in previous trials or as developed by
10 clinicians often neglects the views of key stakeholders⁸⁻¹⁰. This ultimately runs the risk of producing a
11 COS which does not reflect the priorities of patients which does little to address the current challenges
12 with outcome reporting.
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16 Understanding patient priorities following gastrectomy is invaluable for other reasons. Patients with
17 gastric cancer want detailed information about their condition and treatment²⁰. With the knowledge
18 that long-term impacts of surgery are important, healthcare professionals can tailor the consent
19 process prior to surgery to ensure that the patient has a better understanding of these and is making an
20 informed decision. Considering patient priorities may also have implications for the future
21 development of national and international audits^{3,4}. For several pragmatic reasons, most
22 comprehensive gastric cancer surgery audits focus on short-term outcomes. Identifying methods to
23 report longer-term quality outcome measures may make such audits more relevant to patients. Studies
24 assessing patients’ views in similar disease areas found similar things, that long term outcomes
25 (survival and long term quality of life) were important²¹.
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46 Strengths and weaknesses

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48 The study was able to gain an in-depth understanding of patient priorities based on the experience of
49 participants with a broad range of characteristics representative of those undergoing surgery for
50 gastric cancer in the UK⁴. Furthermore, our purposive sampling approach was established *a priori* in a
51 study protocol which had undergone a robust peer-review process.
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3 This study was also able to highlight and address significant challenges associated with the
4 comprehension of medical language by patients; particularly terms central to the development of a
5 COS. Patients largely did not understand the use of the term ‘outcome’ within the context of medical
6 research. Once it was defined as an ‘impact or effect of a treatment which may be beneficial or
7 harmful’, participants were more easily able to describe their key priorities in outcome reporting for
8 future trials. This has several implications for the GASTROS study as well as other COS projects
9 moving forward. It highlights the importance of ensuring that the premise of the study is clear and
10 understood by all participants, especially patients; outcomes included in the Delphi survey must be
11 presented and explained in a manner which is accessible to all; ‘outcome’ must be clear when
12 adapting it to other regions where there may be no direct translation for the term.
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25 The interviews were conducted by an expert in the field of gastric cancer surgery which may have
26 resulted in a degree of observer bias. To mitigate this potential limitation, the study management team
27 (which was made up primarily of members unfamiliar with gastric cancer surgery) was involved in
28 ongoing discussions during data collection and analysis. It is also possible that patients modified their
29 responses because of awareness of the background of the interviewer. Every effort was made to
30 follow the semi-structured interview schedule, to put the patients at ease and take time to let them
31 talk. The average length of the interviews (greater than 45 mins) reflects the time patients were given
32 to express their views.
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42 A further potential limitation of this present interview study is a lack of international patient
43 participation. Consequently, there may be outcomes which are relevant to non-UK patients that have
44 not been identified. Gastric cancer is an international disease and cultural and regional influences
45 may alter expectations and priorities of patients. Whilst we have not identified evidence from COS
46 developers in other fields that confirms these variations, it remains a possibility. Our reasons for
47 limiting the interviews to UK-only patients were primarily down to pragmatism and finite resources.
48 To mitigate this, the Delphi survey will be available in several languages and during the first round,
49 all participants will be able to submit additional outcomes that they believe were omitted. These will
50 be considered by the study team and presented for prioritisation by participants in round two of the
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3 Delphi survey, if appropriate. Adopting this approach also enables the exploration of regional
4 variations in outcome priorities which may form the basis of a future international qualitative study.
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8 Recruitment to the study stopped when no new data with interpretative value was identified²².
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10 However, 'data saturation' is a topic which deserves further discussion as there is no way of knowing
11 for certain that no new outcomes would have been identified had further interviews been undertaken.
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13 Some argue that the term 'data saturation' is often mis-used and misunderstood and should be
14 operationalised in a way consistent with the scope of the study being undertaken²³. As described
15 above, the ability of patients and healthcare participants to suggest further outcomes in round one of
16 the Delphi survey aims to mitigate against this potential limitation.
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23 Most participants had undergone their surgery at least 12 months prior to this study. As such, it should
24 be acknowledged that there may have been a greater exploration of and emphasis on shorter-term
25 outcomes had we recruited more participants from a shorter post-operative time-period. Again, to
26 address this potential limitation, we plan to recruit participants for the Delphi survey from all post-
27 operative periods and will have the opportunity to examine whether 'time from surgery' affects
28 patient priorities.
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37 In summary, this study identified 38 unique outcomes which are important to patients following
38 surgery for gastric cancer. Many of these outcomes are poorly represented by trials within this
39 research field. These outcomes will be added to other potentially important outcomes to be considered
40 for prioritisation by key stakeholders to develop a COS for surgical trials in gastric cancer.
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For peer review only

Appendix 1. Development of themes

Theme: Surviving and Controlling Cancer

Issues identified on initial coding	Outcome	Outcome theme
Being cured of cancer	Recurrence of Cancer	Surviving and Controlling Cancer
Cancer returning to other parts of the body		
Cancer returning in the abdomen		
Possibility of cancer returning		
Being able to live (a little/a lot) longer	Survival	
Being alive/surviving for a 'long time'		
Chances of (not) dying from cancer		
Chances of survival		

Theme: Adverse events following surgery

Issues identified on initial coding	Outcome	Outcome theme
Complications related to anaesthesia	Anaesthetic complications	Adverse events following of Surgery
Anastomotic leak	Anastomotic complications	
Anastomotic stricture		
Internal bleeding requiring further intervention	Bleeding	
Concern about cardiac complications in context of previous myocardial infarction	Cardiac complications	
Racing heart beat		
Stroke following surgery	Cerebro-vascular complications	
Bowel perforation	Intestinal complications	
Gastro-intestinal symptoms e.g. constipation		
Obstruction of bowel		
Epidural related complications	Medication related complications	
Hallucinations		
Overdose of medications such as morphine		
Side effects of sedatives		
Drains and tubes to manage complications	Need for re-intervention	
Endoscopic treatment of anastomotic stricture		
Requiring further surgery to manage complications		

Surgery for incisional hernia		
‘Surviving’ surgery		
Dying from a complication of surgery	Peri-operative death	
Dying on the operating table		
Hospital acquired pneumonia		
Pleural effusion	Respiratory complications	
Pneumothorax		
Re-admission due to complications such as infections	Re-admission to hospital	
Re-admission due to pain		
Wound dehiscence		
Wound infection	Wound complications	
Wound leak		
Wound numbness		
Catheter-related problems	Urinary complications	

Theme: Long-term impact of surgery

Issues identified on initial coding	Outcome	Outcome theme
Being able to enjoy a good quality of life		
Uncertainty as to what life will be like following surgery	Overall ‘quality of life’	
Changes in mood		
Clinical depression		
Feeling ‘abnormal’ and ‘different’ to others	Psychological impact	
Feelings of insecurity		
Feelings of isolation		
Issues related to body image		Long-term impact of surgery
Low mood		
Being able to enjoy eating again		
Being able to exercise again		
Being able to interact and socialise with others	Returning to ‘normality’	
Being able to live ‘as they did before’		
Being able to rely on oneself to undertake tasks		
Being able to undertake household activities		

such as shopping and gardening		
Returning to employment		

Theme: Technical aspects of surgery

Issues identified on initial coding	Outcome	Outcome theme
'Cutting' the cancer out	Complete resection of cancer	Technical aspects of surgery
Ensuring no cancer is left behind		
Getting 'rid' of the cancer		
Inability to resect cancer at surgery		
Removing all lymph nodes		
Removing spleen if necessary	Size of incisions	
Ability to perform laparoscopic 'keyhole' surgery		
Large scars		
Duration of surgery	Duration of surgery	

Theme: Long-term problems following surgery

Issues identified on initial coding	Outcome	Outcome theme	
Amounts able to eat and drink	Eating and Drinking	Long-term problems following surgery	
Being able to eat 'properly'			
Being able to eat at home			
Change in diet and types of food patient can consume			
Difficulties swallowing			
Requirement for ongoing nutritional support	Nutritional problems	Long-term problems following surgery	
Vitamin B12 deficiency			
Feeling persistently tired	Fatigue		Long-term problems following surgery
Feeling extremely weak/lethargic/tired			
Having no energy or stamina			
Loss of energy following simple tasks			
Abdominal bloating	Gastro-intestinal symptoms	Long-term problems following surgery	
Belching			
Diarrhoea			
Dumping syndrome			
Excessive flatus			
Nausea			

Reflux symptoms (acid or bile)		
Vomiting		
Abdominal pain or cramps	Chronic Pain	
Headaches and migraines		
Long-term wound related pain		
Muscle cramps		
Pain on swallowing		
Painful abdominal distension or bloating		
Inability to regain weight to desired level	Weight problems	
Readjusting to new weight		
Speed of weight loss		
Weight loss in general		

Theme: Recovery Following surgery

Issues identified on initial coding	Outcome	Outcome theme
Post-operative plan for physiotherapy	Ambulation	Recovery following surgery
Restricted mobility due to drains and tubes attached		
Time to be able to undertake tasks such as standing up, walking or bathing		
Time before being allowed to eat and drink	Return of gastrointestinal function	
Time before bowel function returned		
Concern about being too unwell for further chemotherapy	Ability to have more chemotherapy	
Length of time in hospital	Duration of hospital stay	
Length of time in intensive care		
Length of time in pain	Post-operative pain	
Patterns of pain		
Requirement for analgesia		
Severity of pain		

Appendix 2. Summary of outcomes and outcome themes identified from interviews.

Outcome Theme	Outcome	How many interviews outcome was referenced in	Total number of references in all interviews
Surviving and controlling cancer <ul style="list-style-type: none"> • Referenced in 20 interviews • Referenced 90 times in all interviews. 	Curing Cancer	4	6
	Recurrence of Cancer	18	28
	Survival	20	56
Technical aspects of surgery <ul style="list-style-type: none"> • Referenced in 18 interviews • Referenced 52 times in all interviews. 	Complete Excision of Cancer	18	52
	Excision of Lymph Nodes	5	5
	Need for splenectomy	1	1
	Operative time	1	2
	Wound Size	7	11
Adverse events <ul style="list-style-type: none"> • Referenced in 20 interviews • Referenced 97 times in all interviews. 	Ability to have adjuvant chemotherapy	1	1
	Anaesthetic Complications	1	1
	Anastomotic Leak	6	9
	Anastomotic Stricture	1	1
	B12 Deficiency	5	5
	Bleeding	1	2
	Cardiac Complications	2	2
	Catheter related complications	1	1
	Cerebro-vascular complications	1	1
	Gastrointestinal problems	1	1
	Hernia	1	1
	Intestinal complications	4	10
	Medication-related complications	10	12
Need for reintervention	8	13	

	Peri-operative death	12	20
	Re-Admission to Hospital	3	4
	Respiratory complications	3	3
	Wound Complications	8	10
Recovery from surgery	In Hospital Recovery	11	23
	Length of Stay Following Surgery	11	18
<ul style="list-style-type: none"> • Referenced in 18 interviews • Referenced 57 times in all interviews. 	Peripheral Oedema	1	1
Long-terms problems following surgery	Eating & Drinking	20	75
	Fatigue	16	38
	Gastrointestinal symptoms	11	27
<ul style="list-style-type: none"> • Referenced in 20 interviews • Referenced 175 times in all interviews. 	Pain	10	14
	Weight Loss	12	21
Long-term impacts of surgery	Necessity of long-term feeding	1	1
	Overall QoL	8	10
<ul style="list-style-type: none"> • Referenced in 20 interviews • Referenced 133 times in all interviews. 	Psychological impact	11	40
	Returning to normality	20	82

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med.* 2014;89(9):1245-1251.

	Reporting Item	Page Number
Title		
	#1 Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
Abstract		
	#2 Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	4
Introduction		
Problem formulation	#3 Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	7

1	Purpose or research	#4	Purpose of the study and specific objectives or	7
2	question		questions	
3				
4	Methods			
5				
6				
7	Qualitative approach and	#5	Qualitative approach (e.g. ethnography, grounded	9
8	research paradigm		theory, case study, phenomenology, narrative research)	
9			and guiding theory if appropriate; identifying the	
10			research paradigm (e.g. postpositivist, constructivist /	
11			interpretivist) is also recommended; rationale. The	
12			rationale should briefly discuss the justification for	
13			choosing that theory, approach, method or technique	
14			rather than other options available; the assumptions	
15			and limitations implicit in those choices and how those	
16			choices influence study conclusions and transferability.	
17			As appropriate the rationale for several items might be	
18			discussed together.	
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26	Researcher characteristics	#6	Researchers' characteristics that may influence the	10
27	and reflexivity		research, including personal attributes, qualifications /	
28			experience, relationship with participants, assumptions	
29			and / or presuppositions; potential or actual interaction	
30			between researchers' characteristics and the research	
31			questions, approach, methods, results and / or	
32			transferability	
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37	Context	#7	Setting / site and salient contextual factors; rationale	10
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40	Sampling strategy	#8	How and why research participants, documents, or	9
41			events were selected; criteria for deciding when no	
42			further sampling was necessary (e.g. sampling	
43			saturation); rationale	
44				
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46	Ethical issues pertaining to	#9	Documentation of approval by an appropriate ethics	11
47	human subjects		review board and participant consent, or explanation for	
48			lack thereof; other confidentiality and data security	
49			issues	
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53	Data collection methods	#10	Types of data collected; details of data collection	10
54			procedures including (as appropriate) start and stop	
55			dates of data collection and analysis, iterative process,	
56			triangulation of sources / methods, and modification of	
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1		procedures in response to evolving study findings;	
2		rationale	
3			
4	Data collection	#11 Description of instruments (e.g. interview guides,	11
5	instruments and	questionnaires) and devices (e.g. audio recorders)	
6	technologies	used for data collection; if / how the instruments(s)	
7		changed over the course of the study	
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11	Units of study	#12 Number and relevant characteristics of participants,	16
12		documents, or events included in the study; level of	
13		participation (could be reported in results)	
14			
15			
16	Data processing	#13 Methods for processing data prior to and during	11
17		analysis, including transcription, data entry, data	
18		management and security, verification of data integrity,	
19		data coding, and anonymisation / deidentification of	
20		excerpts	
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24	Data analysis	#14 Process by which inferences, themes, etc. were	11
25		identified and developed, including the researchers	
26		involved in data analysis; usually references a specific	
27		paradigm or approach; rationale	
28			
29			
30			
31	Techniques to enhance	#15 Techniques to enhance trustworthiness and credibility	11
32	trustworthiness	of data analysis (e.g. member checking, audit trail,	
33		triangulation); rationale	
34			
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36	Results/findings		
37			
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39	Syntheses and	#16 Main findings (e.g. interpretations, inferences, and	16
40	interpretation	themes); might include development of a theory or	
41		model, or integration with prior research or theory	
42			
43			
44	Links to empirical data	#17 Evidence (e.g. quotes, field notes, text excerpts,	16
45		photographs) to substantiate analytic findings	
46			
47			
48	Discussion		
49			
50	Intergration with prior	#18 Short summary of main findings; explanation of how	29
51	work, implications,	findings and conclusions connect to, support, elaborate	
52	transferability and	on, or challenge conclusions of earlier scholarship;	
53	contribution(s) to the field	discussion of scope of application / generalizability;	
54		identification of unique contributions(s) to scholarship in	
55		a discipline or field	
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1	Limitations	#19	Trustworthiness and limitations of findings	30
2				
3	Other			
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5	Conflicts of interest	#20	Potential sources of influence of perceived influence on	3
6			study conduct and conclusions; how these were	
7			managed	
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11	Funding	#21	Sources of funding and other support; role of funders in	2
12			data collection, interpretation and reporting	
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16 American Medical Colleges. This checklist was completed on 05. October 2019 using
17 <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with
18 [Penelope.ai](#)
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BMJ Open

Patient Priorities in Relation to Surgery for Gastric Cancer: Qualitative Interviews with Gastric Cancer Surgery Patients to Inform the Development of a Core Outcome Set.

Journal:	<i>BMJ Open</i>
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Article Type:	Original research
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Primary Subject Heading:	Surgery
Secondary Subject Heading:	Oncology, Qualitative research
Keywords:	Adult surgery < SURGERY, Gastrointestinal tumours < ONCOLOGY, ONCOLOGY, SURGERY

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Title Page

Patient Priorities in Relation to Surgery for Gastric Cancer: Qualitative Interviews with Gastric Cancer Surgery Patients to Inform the Development of a Core Outcome Set.

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Reprints

Reprints will not be available from the authors.

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The authors report no conflicts of interest.

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Data Availability

Data are available upon reasonable request.

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Author Contributorship Statement

Conceptualization - BA, JMB, IAB, RM; Data curation - BA; Formal analysis - BA, RM; Funding acquisition - BA, JMB, IAB; Investigation - BA, RM; Methodology - BA, IAB, RM; Project administration - BA, IAB, RM; Resources - BA, IAB; Software - BA; Supervision - JMB, IAB, RM; Validation - BA, RM; Visualization - BA, JMB, IAB, RM; Writing (original draft) - BA; Writing (review & editing) - BA, JMB, IAB, RM.

Running Title

Patient Priorities Following Surgery for Gastric Cancer

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Structured Abstract

Objective

The reporting of outcomes in surgical trials for gastric cancer is inconsistent. The GASTROS study (GAstric Cancer Surgery TRials Reported Outcome Standardisation) aims to address this by developing a core outcome set (COS) for use in all future trials within this field. A COS should reflect the views of all stakeholders, including patients. We undertook a series of interviews to identify outcomes important to patients which would be considered for inclusion in a COS.

Setting

All interviews took place within the United Kingdom. Interviews were carried out face-to-face at hospitals and cancer support centres or via the telephone.

Participants

Twenty participants at varying stages of recovery following surgery for gastric cancer with curative intent.

Design

Qualitative design using semi-structured interviews, supported by an interview guide which was iteratively modified; thematic analysis was used to explore patient priorities.

Results

Six themes enveloping 38 outcomes were identified; surviving and controlling cancer, technical aspects of surgery, adverse events from surgery, recovering from surgery, long-term problems following surgery and long-term life impact of surgery. The 'most important' patient priority was to be 'cured of cancer'.

Conclusion

Surgical trials for gastric cancer should consider broader priorities of patients when choosing which outcomes to report. This study highlighted the importance of longer-term outcomes such as cancer

1
2
3 survival. Outcomes identified in this study will be used to inform an international Delphi survey to
4
5 develop a COS in this field.
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7

8 **KEYWORDS:**
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10 Surgical Oncology
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13 Stomach Neoplasms
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16 Outcome Assessment
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19 Patient Reported Outcome Measures
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22 Treatment Outcome
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25 Outcome reporting
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Article Summary

Strengths and Limitations of This Study

- This is the first in-depth qualitative study to examine the priorities and experiences of patients following potentially curative surgery for gastric cancer, and the first to establish which outcomes are important to patients.
- The study forms part of a larger project (The GASTROS Study - www.gastrosstudy.org) to develop a 'core outcome set' (COS) for use in surgical trials for gastric cancer and was reviewed and funded by the National Institute of Health Research (UK). The study is based on a reproducible and transparent methodology which has been subjected to critical appraisal during a peer-review process.
- The term 'outcome' was described to participants in a manner relatable to them, such that they understood it and were able to identify which outcomes were most important.
- The patient population was limited to UK-based English speakers. The views of international patients may vary due to differences in culture and clinical practice.

Main Article

Introduction

Background

Gastric cancer is a leading cause of cancer-related death world-wide^{1,2}. Whilst surgery remains the only treatment which can offer a potential cure from this disease, it is associated with significant rates of morbidity in both the short and long-term^{3,4}. Ideally, the optimal surgical approach would minimise the risk of short and long-term complications without jeopardising the oncological resection.

Identifying the optimal surgical approach for gastric cancer should be based on comparing and combining robust clinical evidence from well-designed randomised control trials. One of the present challenges to achieving this is the inconsistency in the reporting of outcomes in this field⁵. This limits evidence synthesis and contributes to 'research waste'. The GASTROS study (GASTROS – GAstric Cancer Surgery TRials Reported Outcome Standardisation - www.gastrosstudy.org)⁶ aims to address this issue by developing a 'core outcome set' (COS) – a *minimum* group of standardized and well-defined outcomes, measured by all future gastric cancer surgery trials⁷.

A guiding principle in the development of COS is that outcomes reflect the views and priorities of key stakeholders, including patients, to maximise the relevance and impact of future research. Previous studies have demonstrated variations in the views and priorities of clinicians and patients⁸⁻¹⁰, which can result in trials reporting outcomes which bear little relevance to patients. A systematic review of outcome reporting in surgical trials for gastric cancer has demonstrated that outcomes which may be important to gastric cancer patients, such as 'quality of life' after surgery are poorly represented within this field⁵. It is therefore important to understand which outcomes are important for patients undergoing gastric cancer surgery.

Objective

This research forms part of the GASTROS study, for which the protocol has been previously described⁶. The first stage in the study involves identifying a 'long-list' of potentially important outcomes which will be prioritised in stage two by participants undertaking a Delphi survey. It is not

1
2
3 known to what degree outcomes reported in previously published trials represent the priorities of
4 patients undergoing gastric cancer surgery, and as such, solely relying on these as a source to populate
5 the 'long-list' may overlook potentially important outcomes. By exploring the experiences,
6 perceptions and priorities of patients who have undergone surgery for gastric cancer, this study aimed
7 to identify outcomes which may not have been previously reported in the literature.
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For peer review only

Methods

Study Design

The role of qualitative research methods in the development of COS has been previously explored¹¹ and has been advocated by groups such as the COMET initiative⁷ as one of several approaches to ensure that outcome lists being considered for prioritisation are exhaustive. This qualitative study used a semi-structured interview approach to achieve the primary objective of identifying outcomes of importance to patients. A series of open questions were used to facilitate a patient-led discussion, guided by additional prompts from a pre-prepared interview schedule (table 1) to ensure key areas were covered.

Additional focused questioning around the use of outcomes in research was also included. In the context of clinical research, terms such as ‘outcomes’ may not be well understood by patients¹¹ and so a mixture of open and closed questioning was important. Participant interviews were undertaken in series of three following which transcript analysis (see below) was undertaken and the interview schedule was modified iteratively. This ensured that areas raised by earlier participants, but not included in the original schedule, were covered in subsequent discussions.

Sampling

The eligibility criteria for this study are summarized in table 2. A purposive sampling strategy was adopted across the following characteristics:

- Age (above and below 70 years).
- Gender (men and women)
- Time since surgery (less than a year, one to three years and more than three years)

Interviews were undertaken until ‘data-saturation’ was achieved. Data saturation was determined when there was no new data emerging that had interpretive value.

Participants were recruited from across the United Kingdom from three sources:

- 1
- 2
- 3 1. A regional specialist gastric cancer centre: patients were approached in the outpatient clinic
- 4 by their direct care team.
- 5
- 6
- 7 2. Patient organisations: patient groups were asked to contact their membership through e-mail
- 8 and social media.
- 9
- 10
- 11 3. Snowball sampling; patients who had been recruited or contacted to participate were asked to
- 12 identify other patients who would be interested in the study.
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19 Data Collection

20 Interviews were undertaken between February and May 2017 and were conducted by BA, a
21 consultant surgeon and researcher with approximately ten years' experience of managing and
22 communicating with gastric cancer patients. Participants were invited to choose between a University
23 Teaching Hospital, two purpose-built patient cancer centres, or their home for the location of the
24 meeting. Participants were also offered the opportunity to have their interviews over the telephone.
25 Participants were offered travel expenses to minimise any financial burden on taking part in the study.
26

27 In addition to the purposive sampling strategy, the following demographic data was collected:

- 28 • Gender (male/female)
- 29 • Social circumstances (e.g. lives alone/with partner/lives with dependents)
- 30 • Age
- 31 • Time since surgery (in months)
- 32 • The type of gastrectomy (total or partial gastrectomy)
- 33 • The approach to their surgery (open or laparoscopic)
- 34 • Whether they had undergone additional treatment (e.g. chemotherapy)
- 35 • Whether they had suffered a post-operative complication
- 36 • Ethnicity
- 37 • Previous trial enrolment
- 38 • Participant post-code (to identify location and social deprivation score)
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3 Full written consent was taken immediately prior to the interview and the participant was reminded
4 that they were able to stop at any point or withdraw from the study without needing to give a reason.
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7 8 Data Analysis 9

10 All interviews were digitally recorded and professionally transcribed (intelligent verbatim
11 transcription). A thematic analysis was used to identify emerging themes and was guided by a general
12 inductive approach^{12,13}. This was used to create the framework applied to subsequent interviews.
13
14

15 Themes were developed using a three-step approach of open coding, axial coding and selective
16 coding¹⁴ of the transcripts. Given the objective of this study was to identify themes and outcomes not
17 previously reported in trials, it was important not to base data analysis and outcome identification on
18 a framework built on previously published literature. BA and RM (a researcher with significant
19 experience in qualitative research methods) independently analysed the first two transcripts and
20 through discussion identified themes and adjustments to the interview schedule. There were no
21 disagreements about coding, but had there been, these would have been discussed with the study
22 management team. The final themes were agreed by all authors through discussion. Data analysis was
23 supported using NVivo 11 (http://www.qsrinternational.com/products_nvivo.aspx, QSR International,
24 Burlington, MA, USA).
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40 Approvals and Portfolio Adoption

41 The study was given ethical approval by the National Research Ethics Service North West—Cheshire
42 (11/NW/0739) and governance approvals by Central Manchester University Hospital NHS
43 Foundation Trust. The study was adopted by the National Institute for Health Research (NIHR)
44 Clinical Research Network Portfolio (ID 33312).
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51 Reporting

52 This paper uses the SRQR checklist to structure the report of the study findings¹⁵.
53
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56 Patient and Public involvement

57 A Study Advisory Group (SAG) forms part of the management structure of the wider GASTROS
58 study⁶, of which this qualitative study forms part of the first stage. The SAG is made up of key
59
60

1
2
3 stakeholder representatives including patients, oncology nurses and surgeons. The group provides
4
5 advice on the methodology of the study, general delivery of the study against its stated objectives and
6
7 ensures that the viewpoints of all stakeholder groups are considered. The results of this study were
8
9 presented to a SAG meeting; the ensuing discussion influenced the design of the next stage of the
10
11 study in preparation for an international Delphi Survey.
12

13
14 Best practice guidelines for patient and public engagement were followed as set out by INVOLVE
15
16 (part of and funded by the United Kingdom's National Institute for Health Research)¹⁶.
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For peer review only

Table 1. Interview schedule.

1.	I understand you have (had) gastric cancer. Can you tell me about that?
2.	<p><i>Could you tell me about how you first found out you had gastric cancer?</i></p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>What questions did you most want to ask, when you were told that you had gastric cancer?</i>
3	<p>Were there were any areas you wanted more information about but were unable to find?</p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>Were you given any leaflets at the time of diagnosis? Did you find these useful?</i>
4	<p>What treatment was offered and how you decide about undergoing treatment.</p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>What information did you want about the treatment you would be receiving?</i> • <i>What factors did you consider when deciding on the treatment?'</i>
5	<p>What effects did the treatment have on you after surgery?</p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>Did the treatment affect your physical or mental well-being?</i> • <i>Did the treatment have an effect on relationships with those around you?</i> • <i>Did you have to make any changes to your behaviour as a result of treatment?</i>
6	<p>What long-term effects did the treatment have on you?</p> <p>Prompts:</p> <ul style="list-style-type: none"> • <i>Did the treatment affect your physical or mental well-being?</i> • <i>Did the treatment have an effect on relationships with those around you?</i> • <i>Did you have to make any changes to your behaviour as a result of treatment?</i>
7	What was the worst side effect of treatment?
8	What are your concerns for the future, especially those relating to their diagnosis/history of gastric cancer?

9	Did the explanation of what you should expect from surgery match your real experience?
10	In the context of research studies, can you explain what an outcome is in your own words? The interviewer will then provide a definition of the term 'outcome' is in the context of clinical research.
11	What, in your opinion, is the most important outcome to measure in gastric cancer surgery trials?
12	Are there any other outcomes which may be important to measure?
13	Has your perspective on what is important changed over time?
14	Is there anything else that you feel is important to talk about that we have not discussed?

Table 2. Eligibility criteria for study participants.

	Potential Participants Approached	Potential Participants Not Approached
Participant	<ul style="list-style-type: none"> • Male and females aged 18 years and older. • Individuals able to participate in an interview in the English language. 	<ul style="list-style-type: none"> • Patients unable to give informed consent • Patients too unwell to comfortably participate in an interview lasting approximately 30-60 minutes.
Pathology	<ul style="list-style-type: none"> • Adenocarcinoma and squamous cell carcinoma of the stomach, (which makes up 95 per cent of all stomach tumours). 	<ul style="list-style-type: none"> • Gastrointestinal Stromal Tumours • Neuro-endocrine tumours • Lymphoma • Benign disease
Intervention	<ul style="list-style-type: none"> • Total and partial gastrectomy • Open and laparoscopic approaches 	<ul style="list-style-type: none"> • Surgery with palliative intent • Endoscopic therapies such as EMR (endoscopic mucosal resection) and ESD (endoscopic Submucosal dissection)

Results

Overview

In total, 20 patients were interviewed. Table 3 summarises demographic data and treatment-related characteristics of participants. Interviews lasted a median of 50.5 minutes (29-75 minutes). No patients withdrew from the study. Data saturation was deemed to have been reached by 20 interviews; one new outcome was identified in interview number 18 (related to sexual activity), however, no further outcomes were identified from the following two transcripts.

Outcome Themes

Six broad themes enveloping 38 outcomes were identified;

1. Surviving and controlling cancer,
2. Technical aspects of surgery,
3. Adverse events from surgery,
4. Recovering from surgery,
5. Long-term problems following surgery and
6. Long-term life impact of surgery.

Appendix 1 provides a breakdown of how all themes were developed from outcomes identified during the interviews. Themes were well represented in each interview; each theme was discussed by at least 18 of 20 participants. Appendix 2 demonstrated the outcomes identified during the interviews and how often they were referenced.

Theme 1: Surviving and controlling cancer

For most, details of their initial consultation were sketchy; participants often described being given lots of information about their diagnosis, much of which was not absorbed. However, patients clearly remember their reaction to being told their cancer diagnosis; for most, the response was the same:

“When you hear the word, cancer, you think that’s it. I’m going to die.” (participant 6)

There was a range of personal experience with cancer within our patient group. Some had direct family members who had undergone chemotherapy and had an intimate knowledge of its effects.

1
2
3 “it was my worst nightmare come true because I lost my dad to cancer and I always had it in
4 the back of my mind, well if one person in the family could get cancer from somewhere then
5 we could as well.” (participant 19)
6
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10 Some patients had a vague knowledge of friends or work colleagues who had undergone treatments
11 for cancer and others had no prior experience of cancer at all. Despite these differences, the initial
12 responses to their diagnosis were similar.
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16
17 All participants in our study had undergone radical surgery with curative intent. At the time of
18 interview, no participants had confirmed evidence of disease recurrence although one was being
19 investigated for potential recurrence. Once the discussion with their surgeon moved away from the
20 diagnosis and onto potentially curative treatments, participants often focused their questions on
21 ‘survival’:
22
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27
28 “I wanted to know what the chances were of me having this removed and not, well, basically
29 not dying from it.” (participant 4)
30
31
32

33 Despite radical surgery (and peri-operative chemotherapy in half of our participants), for many of the
34 participants the fear of recurrence remained a permanent anxiety. Many participants seemed to
35 understand that due to the aggressive nature of gastric cancer, recurrence is a possibility for many:
36
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38
39

40 “...you’re always worried that it’s going to come back...” (participant 7)
41
42

43 The study cohort included participants who had undergone surgery between 5 months and 14 years
44 prior to the interviews. There did not seem to be a relationship between the length of time out of
45 surgery and concerns about cancer recurrence.
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50 *Theme 2: Technical aspects of surgery*

51
52 Several outcomes related to this theme were discussed by participants. Most importantly, participants
53 focused on whether the surgical team was able to excise the ‘cancer’ in its entirety. This priority was
54 often referenced in relation to the ‘success’ of surgery and its contribution to ‘curing’ participants of
55 cancer:
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1
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3 “...thinking to yourself that, you know, everything has been done to the best of the hospital’s
4 ability, and, you know, they’ve taken absolutely everything out.” (participant 4)
5
6

7 Whilst participants mostly referred to the cancer as a single ‘entity’, there were a small number who
8 demonstrated some knowledge of the importance of different aspects of surgery such as lymph node
9 excision:
10
11

12 “And yeah, I remember the news about the pathology on the bits they’d taken away, and the
13 lymph node system and what not, came a week or two before I was due to go back on the
14 chemo.” (participant 20)
15
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18

19 Six participants underwent a minimally invasive surgery with the remainder undergoing open surgery.
20 The size of the wounds or type of surgical approach was referred to by only a minority of our
21 participants. In the main, these were made in passing as little importance was placed on the surgical
22 approach:
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28 Interviewer: “Okay, and what...what did that mean for you to have keyhole surgery?”
29

30 Respondent: “It didn’t mean anything really, you know, I had...I’d heard about keyhole and
31 people who’d had it.” (participant 5)
32
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34
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37 *Theme 3: Adverse events following surgery*

38

39 Eleven participants suffered a complication following surgery; however, this theme was important to
40 all interviewees. Peri-operative death was the most frequently discussed surgical complication:
41
42

43 “...the fear of dying on the operating table is really real.” (participant 2)
44
45
46

47 During their surgical consultation, participants retained some understanding of the risk of peri-
48 operative death and many were able to quote figures about how likely this complication was. Other
49 complications were highlighted when recounting a personal experience. While all complications
50 occurred in the post-operative period, there were several different causes attributed to these events
51 (e.g. direct surgical, anaesthesia-related and medication-related). The severity and consequences of
52 the complications also varied significantly; some were self-limiting and resulted in a minor extension
53 of the length of hospital stay:
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3 “But I was out of it for three days, I was just hallucinating and God knows what, probably
4 because of the morphine.” (participant 7)
5
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7

8 And those which were life-threatening and required significant clinical intervention:
9

10 “It was a twisted bowel. Yeah, I was told it was a twisted bowel. Because I always
11 remember that when they brought me back from obviously having a look and everything, I
12 always remember [they] said...we're going to have to take you back to surgery.” (participant
13 15)
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20 The severity of the complications suffered did not seem to shape the key priorities in relation to
21 participants' ‘worst side effect’ of surgery or ‘most important outcome’; these almost entirely related
22 to ‘long-term impacts of surgery’ and ‘cure’ respectively (see below) regardless of how long ago their
23 operation was and which surgical approach (laparoscopic or open surgery) was employed.
24
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29 Whilst participants recounted that some of the more serious complications (e.g. death, anastomotic
30 leak and cardio-pulmonary complications) were described by surgeons during the consent process,
31 some were exposed to other sources of information in the pre-operative stage. Participants were
32 regularly provided with written information about their cancer and its management, however the
33 quality and content of this varied depending on the location of their hospital. The response to this
34 format was varied:
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42 “I’m going to be honest with you, I didn’t actually read them... because I didn’t want things
43 going in my head that I couldn’t take in.” (participant 17)
44
45
46

47 Participants that read the written information often found them difficult to digest for several reasons
48 including the volume of information and fear of the gravity of the diagnosis or prognosis:
49

50
51 “Well some of it were just waste of time, but others, you know, if you’ve got a book about that
52 thick and you read through it and half of it applies to you, and the others just sort...doesn’t
53 apply, you know.” (participant 5)
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1
2
3 “As much as it’s alright handing leaflets out, I can...I am a bit of a reader so I will read stuff,
4 but when you think you’ve got a death sentence you think, what’s the point in reading that?”
5
6
7 (participant 13)
8
9

10
11 Several hospitals had patient-support groups which provide a ‘buddy’ system for those awaiting
12 surgery. These support groups became an important part of the recovery process and continue to be
13 relevant many years after surgery. Patients found these more useful as they had the opportunity to
14 speak to those with lived experience of the diagnosis and treatment. Whilst this served as an important
15 source of information to tackle the longer-term impacts of surgery (below), these groups also provided
16 comfort to patients:
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25 “I think the support group and speaking to people that have been through it, because it can
26 demystify it quite a lot.” (participant 2)
27
28

29 Peer support also provided additional sources of information to participants in the pre-operative period
30 with respect to some of the complications that could arise:
31
32

33 “And I know one guy, where the oesophagus junction was, he’d had that leaking, and he
34 couldn’t eat more than, like, grains of rice and things; so that would be pretty horrendous.”
35
36
37 (participant 4)
38
39

40 As a result of verbal and written information from healthcare professionals and additional peer support,
41 participants were able to describe key adverse without necessarily having experienced them firsthand.
42
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46 *Theme 4: Recovery from surgery*

47

48 Experiences during the immediate post-operative recovery period were referenced by 18 study
49 participants. Whilst some participants’ experience of recovery from surgery was directly linked to
50 complications, there were aspects of recovery such as post-operative pain, mobility and the
51 recommencement oral intake that were common amongst all those who spoke this theme.
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3 Most participants did not mention post-operative pain as an important focus. Those that did, expected
4 to suffer a degree of pain, however experiences of its severity varied widely. Pain levels amongst
5 interviewees who had undergone similar operations through laparotomy incisions were not uniform.
6
7

8
9 One participant who had open surgery described:

10
11 “I do remember waking up and really being in a hell of a lot of pain and being really out
12 of it.” (participant 6)
13
14

15
16 Whilst another who had undergone their surgery using the same approach recounted:

17
18 “I didn't really have much pain.” (participant 14)
19

20 Discussions around post-operative pain were not confined to discomfort from the surgical incisions, but
21 also related to post-operative complications:
22

23
24 “I was back in writhing in agony with a serious infection in the wound.” (participant 9)
25

26 Participants recounted the limitations in their mobility during the post-operative period. There were
27 many factors contributing to this, including physical weakness, not receiving appropriate
28 encouragement to mobilise and being restricted by surgical drains:
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31
32 “...really difficult to be mobile I suppose, and move around, yourself, ‘cause obviously you’ve
33 got quite a lot of tubes and different things coming out. I felt very, very swollen.” (participant
34 6)
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41 *Theme 5: Long-term problems following surgery*

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43 All participants described significant long-term symptoms related to surgery. For the most, this
44 represented the ‘worst side effect’ in relation to their treatment and outcomes from this theme were
45 referenced more than any other theme further emphasising its importance. All participants described
46 experience with struggling to eat and drink following surgery and the majority (16/20) talked
47 extensively about the impact of fatigue on their daily lives. Problems with maintaining weight, issues
48 with ongoing gastro-intestinal symptoms and chronic pain were discussed by most participants.
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3 Fatigue was described in many ways; 'exhaustion', 'feeling tired all the time', 'feeling so weak' and
4 'having no energy'. For the main, fatigue was a symptom which persisted for months after surgery and
5 could impact on a participant's ability to undertake day-to-day activities or to socialise:
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8
9 "Well, I'm so weak, I used to go out, you know, and do fishing and do things with my lads. I'm
10 just getting that little bit better now after eight months, but I'm so weak and tired." (participant
11 18)
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18 Adapting to fatigue was and for many continued to be a difficult challenge, however many participants
19 understood that this was a recognised and acceptable symptom to them given the magnitude of the
20 surgery:
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24 "I've come out with...more...appreciation for looking after myself and my...And if I'm tired, I
25 stop." (participant 15)
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31 There were several causes for the struggles participants associated with eating and drinking.
32 Participants often described having to eat and drink smaller volumes more frequently and some were
33 unable to tolerate certain food types or consistencies. This had a direct effect on the pleasure associated
34 with eating and an impact on where participants could eat:
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39 "Well I don't eat what I would like to...But I know that for the rest of my life, I won't be able
40 to go out for big meals, to big venues and eat like I used to eat before, you know." (participant
41 5)
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47 Most participants recounted being told prior to their surgery that their diet would be different and that
48 they would have to 'learn how to eat again'. Despite this, some participants felt that not enough
49 information was given to highlight the true impact of this long-term issue and methods to address it:
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53 "I think it's a lot worse than what they tell you. Because like some days, I'll eat a certain thing
54 which I've ate before, and you just can't breathe properly, it's choking you." (participant 18)
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3 A broad range of gastro-intestinal symptoms were reported by participants. The time frame relating to
4 how long these persisted was similarly broad (sometimes months and years) and did not seem to follow
5 a pattern. Nausea, vomiting, diarrhoea, reflux and belching were the commonest problems described.
6
7 Many of these symptoms resulted in significant impacts on quality of life (see theme 6 below):
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11 “...I still get the bile reflux and I get this constant pain in the oesophagus which affects my
12 sleeping as well.” (participant 7)
13
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18 “The dumping syndrome was mentioned. Never understood it until it happened. You know,
19 how my body reacted to certain foods that I'd normally eat that it doesn't like anymore.”
20
21 (participant 15)
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26 *Theme 6: Long-term life impact of surgery*

27
28 The long-term effects on ‘normality’, quality of life, and psychological impact of surgery were
29 discussed extensively by all patients. A strong desire to return to a form of ‘normality’ was regularly
30 expressed. Whilst the reference point for ‘normality’ differed amongst patients, common characteristics
31 existed; namely a desire to do what they used to do such as working, exercising, socialising with friends
32 and family and being able to travel:
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39 “it’s about living as I did before, and forgetting what had happened, and I do that quite often.”
40
41 (participant 6)
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46 The experience of returning to normality varied amongst those interviewed. Many participants were
47 largely able to return to their ‘normal’ activities albeit with some modifications:
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49

50 “Yes. I want to go on holidays again. I love cruises and I want...but until my eating’s
51 improved, I wouldn’t do that.” (participant 1)
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56 “Now that it’s 18 months on, I am back to having what would be a normal life again, now,
57 albeit with smaller portions of meals and things” (participant 4)
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3 Some participants however have not been able to return to activities that provided them with significant
4
5 enjoyment:

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7 “I’ve never actually got back to my normal activity. I’ve never played golf since that day and
8
9 I used to love golf.” (participant 4)
10

11
12
13 In general, participants understood that life after gastrectomy would be different:

14
15 “I’m still alive, and then I need to get back to normal. It takes a while for you to realise your
16
17 new normality is not like your old normality.” (participant 2)
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22 Whilst much of the discussion relating to ‘normality’ centred around specific tasks which participants
23
24 valued or missed, the impact of gastrectomy on a participant’s overall general quality of life was
25
26 important to many. Many understood that quality of life needed to be redefined in comparison to life
27
28 before surgery, but nonetheless there was a minimum level that would need to be achieved:
29

30
31 “if I have some sort of quality of life, where I can get up and wash myself and do, that is
32
33 something that I’d live for. But I couldn’t be sat there and nursed 24/7” (participant 17)
34
35

36
37 The psychological burden on participants following gastrectomy is a significant one. Each of the
38
39 previously discussed themes could impact on a participant’s mental state and whilst certain phases of
40
41 the treatment pathway were time-limited, the psychological effects could persist for much longer;

42
43 “You don’t just suffer from physical; you suffer from mental. And I think the mental is a lot
44
45 more powerful than the physical, because you can shut pain off by taking medication, but it’s
46
47 very hard to shut problems off mentally.” (participant 18)
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49

50
51 “You know, ‘cause psychologically you think you’ve still got this poison in your body, as much
52
53 as I’ve got rid of, you know, my monster.” (participant 13)
54
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56 Some of the psychological impacts were associated with participants having to adapt to a new normality
57
58 in relation to what they were able to do, what they were able to eat, how they looked physically or how
59
60 they felt around others:

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2
3 “Well, it was a problem because like I say, I've always been a proud chap and proud of my body
4 because I kept myself fit and everything. When I looked in the mirror, quite distressing. That
5 was it, yeah. It makes you feel inferior.” (participant 18)
6
7
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9

10
11 “I feel a freak, I feel when I go into a big room with people that everybody has got a stomach
12 and I haven't got one, it's not that I want them to know, but I just don't feel the same
13 anymore...” (participant 8)
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18 19 20 Definition of 'outcome' by patients

21 All participants were asked what their understanding of the term 'outcome' was in the context of
22 clinical research. Two participants were able to provide a broad-ranging definition which
23 encompassed some of the benefits and adverse effects of treatment:
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29 “my perception of what would be meant by that phrase would...at a variety of levels; it could
30 be does the patient live or die? Does the patient recover to an acceptable state for an extended
31 period of time, and my understanding of what that might be, would be a, sort of, five year
32 period...” (participant 20)
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38 One person stated that they did not know how to define the term, whilst the remainder defined
39 'outcome' by recounting a single outcome, which was most important to them:
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41

42
43 “Okay, my understanding is that at the...the outcome would be that the cancer would be
44 possibly all gone.” (participant 19)
45
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48

49 Participants were asked to provide a single outcome that was 'most important to them'. Fifteen
50 participants identified that the most important outcome was that they were 'cured of cancer' with the
51 remaining five describing outcomes related to 'returning to normal' and being able to enjoy a 'good
52 quality of life'. These priorities did not alter with respect to how long-ago surgery was performed,
53 which approach was undertaken or how old the patient was.
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Table 3. Patient characteristics and demographic data.

Patient	Sex	Age	Ethnicity *	Social deprivation quintile**	Home circumstances	Months since surgery	Type of surgery	Approach to surgery	Post-operative complications	Peri-operative treatment
1	F	74	A	3rd	Lives alone	15	Partial Gastrectomy	Laparoscopic	Yes	Nil
2	M	59	B	3rd	Lives alone	27	Total Gastrectomy	Open surgery	Yes	Chemotherapy
3	M	71	A	1st	Lives alone	16	Partial Gastrectomy	Open surgery	Yes	Nil
4	M	43	A	2nd	Lives with parents	15	Total Gastrectomy	Open surgery	Yes	Chemotherapy
5	M	80	A	3rd	Lives alone	23	Partial Gastrectomy	Laparoscopic	Yes	Nil
6	F	52	A	2nd	Lives with children	32	Total Gastrectomy	Open surgery	No	Chemotherapy
7	M	79	A	1st	Lives with spouse	58	Total Gastrectomy	Laparoscopic	Yes	Chemotherapy
8	F	63	A	1st	Lives alone	5	Total Gastrectomy	Open surgery	No	Nil
9	M	61	A	3rd	Lives with spouse	170	Total Gastrectomy	Open surgery	No	Nil

10	M	61	C	1st	Lives alone	79	Total Gastrectomy	Open surgery	No	Chemotherapy
11	M	76	A	4th	Lives with spouse	110	Total Gastrectomy	Laparoscopic	Yes	Chemotherapy
12	F	82	A	4th	Lives alone	62	Partial Gastrectomy	Open surgery	No	Nil
13	F	59	A	2nd	Lives with spouse	19	Partial Gastrectomy	Open surgery	No	Chemotherapy
14	M	70	B	1st	Lives alone	11	Partial Gastrectomy	Open surgery	No	Nil
15	F	56	M	5th	Lives with parent	33	Total Gastrectomy	Open surgery	Yes	Chemotherapy
16	F	84	A	1st	Lives alone	17	Partial Gastrectomy	Laparoscopic	Yes	Nil
17	M	48	A	4th	Lives with parent	9	Total Gastrectomy	Laparoscopic	Yes	Chemotherapy
18	M	77	A	4th	Lives with spouse	78	Total Gastrectomy	Open surgery	Yes	Nil
19	Fe	58	A	3rd	Lives with spouse	11	Partial Gastrectomy	Laparoscopic	No	Nil

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20	M	54	A	1st	Lives with spouse	48	Partial Gastrectomy	Open surgery	No	Chemotherapy
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*A=, B= , C= , M= . **Social deprivation quintile: 1st quintile being the least deprived, 5th quintile being the most deprived.

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Discussion

To our knowledge, this is the first in-depth qualitative study exploring the priorities of patients following potentially curative surgery for gastric cancer. The study focussed on this cohort as one of the main aims was to identify outcomes which would be considered for inclusion in a COS for potentially curative surgical trials in gastric cancer. This present study will be used to help generate a list of outcomes that will be presented for prioritisation to healthcare professionals and patients in an international, multi-language online Delphi survey. The results of the Delphi survey will inform a consensus meeting to finalise the COS. Whilst other COS studies in the field of cancer¹⁷⁻¹⁹ may have identified similar important outcomes such as survival, it was important to consider our participants separately given the unique problems which arise with gastrectomy. These include distinctive short and long-term problems related to surgery such as anastomotic leak and reactive hypoglycaemia (Dumping syndrome) which would not be relevant in other COS.

The themes identified highlight the profound and wide-ranging physical, social and psychological impacts that gastrectomy has on patients which can persist for months and years. We have previously described the reporting of outcomes in surgical trials for gastric cancer over a twenty-year period⁵. Most surgical trials in this field have focused on reporting short-term post-operative outcomes. Whilst these are important to patients, they are not representative of the whole picture. This work highlights how patient priorities for outcomes may differ from the traditional surgical focus. More work is now needed to develop the COS which incorporates views of all key stakeholders including patients.

More than half of the 'top-ten' most frequently discussed outcomes in our study related to longer-term issues such as problems with eating, returning to 'normality', fatigue, weight loss, gastro-intestinal symptoms and psychological impacts. These types of outcomes are infrequently reported in surgical trials and demonstrate that researchers within this field have not reflected the priorities of patients.

This challenge needs to be addressed using an approach which is inclusive of patients and their views.

The GASTROS study aims to develop a COS; critically important outcomes which should be reported - as a minimum - by future surgical trials for gastric cancer⁶. By standardising the reporting of such outcomes, it aims to improve the ability to synthesise evidence, reduce research waste and ultimately

1
2
3 aid researchers in answering important questions related to gastrectomy. The first stage in developing
4 the COS consists of identifying a 'long-list' of outcomes which will then be prioritised by key
5 stakeholders during an international online Delphi survey. The process of developing the long-list
6 should be comprehensive and involve both healthcare professionals and patients in order to minimise
7 the risk of omitting potentially important outcomes. Our study reaffirms the importance of a mixed-
8 methods approach to identifying potentially important outcomes. As others COS developers have
9 found, building a long-list based solely on outcomes reported in previous trials or as developed by
10 clinicians often neglects the views of key stakeholders⁸⁻¹⁰. This ultimately runs the risk of producing a
11 COS which does not reflect the priorities of patients which does little to address the current challenges
12 with outcome reporting.
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16 Understanding patient priorities following gastrectomy is invaluable for other reasons. Patients with
17 gastric cancer want detailed information about their condition and treatment²⁰. With the knowledge
18 that long-term impacts of surgery are important, healthcare professionals can tailor the consent
19 process prior to surgery to ensure that the patient has a better understanding of these and is making an
20 informed decision. Considering patient priorities may also have implications for the future
21 development of national and international audits^{3,4}. For several pragmatic reasons, most
22 comprehensive gastric cancer surgery audits focus on short-term outcomes. Identifying methods to
23 report longer-term quality outcome measures may make such audits more relevant to patients. Studies
24 assessing patients' views in similar disease areas found similar things, that long term outcomes
25 (survival and long term quality of life) were important²¹.
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46 Strengths and weaknesses

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48 The study was able to gain an in-depth understanding of patient priorities based on the experience of
49 participants with a broad range of characteristics representative of those undergoing surgery for
50 gastric cancer in the UK⁴. Furthermore, our purposive sampling approach was established *a priori* in a
51 study protocol which had undergone a robust peer-review process.
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3 This study was also able to highlight and address significant challenges associated with the
4 comprehension of medical language by patients; particularly terms central to the development of a
5 COS. Patients largely did not understand the use of the term ‘outcome’ within the context of medical
6 research. Once it was defined as an ‘impact or effect of a treatment which may be beneficial or
7 harmful’, participants were more easily able to describe their key priorities in outcome reporting for
8 future trials. This has several implications for the GASTROS study as well as other COS projects
9 moving forward. It highlights the importance of ensuring that the premise of the study is clear and
10 understood by all participants, especially patients; outcomes included in the Delphi survey must be
11 presented and explained in a manner which is accessible to all; ‘outcome’ must be clear when
12 adapting it to other regions where there may be no direct translation for the term.
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25 The interviews were conducted by an expert in the field of gastric cancer surgery which may have
26 resulted in a degree of observer bias. To mitigate this potential limitation, the study management team
27 (which was made up primarily of members unfamiliar with gastric cancer surgery) was involved in
28 ongoing discussions during data collection and analysis. It is also possible that patients modified their
29 responses because of awareness of the background of the interviewer. Every effort was made to
30 follow the semi-structured interview schedule, to put the patients at ease and take time to let them
31 talk. The average length of the interviews (greater than 45 mins) reflects the time patients were given
32 to express their views.
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42 A further potential limitation of this present interview study is a lack of international patient
43 participation. Consequently, there may be outcomes which are relevant to non-UK patients that have
44 not been identified. Gastric cancer is an international disease and cultural and regional influences
45 may alter expectations and priorities of patients. Whilst we have not identified evidence from COS
46 developers in other fields that confirms these variations, it remains a possibility. Our reasons for
47 limiting the interviews to UK-only patients were primarily down to pragmatism and finite resources.
48 To mitigate this, the Delphi survey will be available in several languages and during the first round,
49 all participants will be able to submit additional outcomes that they believe were omitted. These will
50 be considered by the study team and presented for prioritisation by participants in round two of the
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3 Delphi survey, if appropriate. Adopting this approach also enables the exploration of regional
4 variations in outcome priorities which may form the basis of a future international qualitative study.
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8 This study focusses primarily on the impact of gastrectomy from the perspective of patients.
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10 However, we acknowledge that major complex surgery such as gastrectomy inevitably results in both
11 direct and indirect effects on family members and caregivers. Whilst these wider impacts warrant
12 further examination, we limited participation in this present study to patients, as the scope of the COS
13 aims to consider the perspective and priorities of patients, surgeons and oncology nurses. Part of our
14 planned future work is to review the COS to ensure that it remains up-to-date and relevant. At this
15 point, it will be possible to widen participation beyond these three groups to include caregivers and
16 other allied healthcare professionals.
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25 Recruitment to the study stopped when no new data with interpretative value was identified²².
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27 However, 'data saturation' is a topic which deserves further discussion as there is no way of knowing
28 for certain that no new outcomes would have been identified had further interviews been undertaken.
29

30 Some argue that the term 'data saturation' is often mis-used and misunderstood and should be
31 operationalised in a way consistent with the scope of the study being undertaken²³. As described
32 above, the ability of patients and healthcare participants to suggest further outcomes in round one of
33 the Delphi survey aims to mitigate against this potential limitation.
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40 Most participants had undergone their surgery at least 12 months prior to this study. As such, it should
41 be acknowledged that there may have been a greater exploration of and emphasis on shorter-term
42 outcomes had we recruited more participants from a shorter post-operative time-period. Again, to
43 address this potential limitation, we plan to recruit participants for the Delphi survey from all post-
44 operative periods and will have the opportunity to examine whether 'time from surgery' affects
45 patient priorities.
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54 In summary, this study identified 38 unique outcomes which are important to patients following
55 surgery for gastric cancer. Many of these outcomes are poorly represented by trials within this
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3 research field. These outcomes will be added to other potentially important outcomes to be considered
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5 for prioritisation by key stakeholders to develop a COS for surgical trials in gastric cancer.
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Appendix 1. Development of themes

Theme: Surviving and Controlling Cancer

Issues identified on initial coding	Outcome	Outcome theme
Being cured of cancer	Recurrence of Cancer	Surviving and Controlling Cancer
Cancer returning to other parts of the body		
Cancer returning in the abdomen		
Possibility of cancer returning		
Being able to live (a little/a lot) longer	Survival	
Being alive/surviving for a 'long time'		
Chances of (not) dying from cancer		
Chances of survival		

Theme: Adverse events following surgery

Issues identified on initial coding	Outcome	Outcome theme
Complications related to anaesthesia	Anaesthetic complications	Adverse events following of Surgery
Anastomotic leak	Anastomotic complications	
Anastomotic stricture		
Internal bleeding requiring further intervention	Bleeding	
Concern about cardiac complications in context of previous myocardial infarction	Cardiac complications	
Racing heart beat		
Stroke following surgery	Cerebro-vascular complications	
Bowel perforation	Intestinal complications	
Gastro-intestinal symptoms e.g. constipation		
Obstruction of bowel		
Epidural related complications	Medication related complications	
Hallucinations		
Overdose of medications such as morphine		
Side effects of sedatives		
Drains and tubes to manage complications	Need for re-intervention	
Endoscopic treatment of anastomotic stricture		
Requiring further surgery to manage complications		

Surgery for incisional hernia		
‘Surviving’ surgery		
Dying from a complication of surgery	Peri-operative death	
Dying on the operating table		
Hospital acquired pneumonia		
Pleural effusion	Respiratory complications	
Pneumothorax		
Re-admission due to complications such as infections	Re-admission to hospital	
Re-admission due to pain		
Wound dehiscence		
Wound infection	Wound complications	
Wound leak		
Wound numbness		
Catheter-related problems	Urinary complications	

Theme: Long-term impact of surgery

Issues identified on initial coding	Outcome	Outcome theme
Being able to enjoy a good quality of life		
Uncertainty as to what life will be like following surgery	Overall ‘quality of life’	
Changes in mood		
Clinical depression		
Feeling ‘abnormal’ and ‘different’ to others	Psychological impact	
Feelings of insecurity		
Feelings of isolation		
Issues related to body image		Long-term impact of surgery
Low mood		
Being able to enjoy eating again		
Being able to exercise again		
Being able to interact and socialise with others	Returning to ‘normality’	
Being able to live ‘as they did before’		
Being able to rely on oneself to undertake tasks		
Being able to undertake household activities		

such as shopping and gardening		
Returning to employment		

Theme: Technical aspects of surgery

Issues identified on initial coding	Outcome	Outcome theme
'Cutting' the cancer out Ensuring no cancer is left behind Getting 'rid' of the cancer Inability to resect cancer at surgery Removing all lymph nodes Removing spleen if necessary	Complete resection of cancer	Technical aspects of surgery
Ability to perform laparoscopic 'keyhole' surgery Large scars	Size of incisions	
Duration of surgery	Duration of surgery	

Theme: Long-term problems following surgery

Issues identified on initial coding	Outcome	Outcome theme
Amounts able to eat and drink Being able to eat 'properly' Being able to eat at home Change in diet and types of food patient can consume Difficulties swallowing	Eating and Drinking	Long-term problems following surgery
Requirement for ongoing nutritional support Vitamin B12 deficiency	Nutritional problems	
Feeling persistently tired Feeling extremely weak/lethargic/tired Having no energy or stamina Loss of energy following simple tasks	Fatigue	
Abdominal bloating Belching Diarrhoea Dumping syndrome Excessive flatus Nausea	Gastro-intestinal symptoms	

Reflux symptoms (acid or bile)		
Vomiting		
Abdominal pain or cramps	Chronic Pain	
Headaches and migraines		
Long-term wound related pain		
Muscle cramps		
Pain on swallowing		
Painful abdominal distension or bloating		
Inability to regain weight to desired level	Weight problems	
Readjusting to new weight		
Speed of weight loss		
Weight loss in general		

Theme: Recovery Following surgery

Issues identified on initial coding	Outcome	Outcome theme
Post-operative plan for physiotherapy	Ambulation	Recovery following surgery
Restricted mobility due to drains and tubes attached		
Time to be able to undertake tasks such as standing up, walking or bathing		
Time before being allowed to eat and drink	Return of gastrointestinal function	
Time before bowel function returned		
Concern about being too unwell for further chemotherapy	Ability to have more chemotherapy	
Length of time in hospital	Duration of hospital stay	
Length of time in intensive care		
Length of time in pain	Post-operative pain	
Patterns of pain		
Requirement for analgesia		
Severity of pain		

Appendix 2. Summary of outcomes and outcome themes identified from interviews.

Outcome Theme	Outcome	How many interviews outcome was referenced in	Total number of references in all interviews
Surviving and controlling cancer <ul style="list-style-type: none"> • Referenced in 20 interviews • Referenced 90 times in all interviews. 	Curing Cancer	4	6
	Recurrence of Cancer	18	28
	Survival	20	56
Technical aspects of surgery <ul style="list-style-type: none"> • Referenced in 18 interviews • Referenced 52 times in all interviews. 	Complete Excision of Cancer	18	52
	Excision of Lymph Nodes	5	5
	Need for splenectomy	1	1
	Operative time	1	2
	Wound Size	7	11
Adverse events <ul style="list-style-type: none"> • Referenced in 20 interviews • Referenced 97 times in all interviews. 	Ability to have adjuvant chemotherapy	1	1
	Anaesthetic Complications	1	1
	Anastomotic Leak	6	9
	Anastomotic Stricture	1	1
	B12 Deficiency	5	5
	Bleeding	1	2
	Cardiac Complications	2	2
	Catheter related complications	1	1
	Cerebro-vascular complications	1	1
	Gastrointestinal problems	1	1
	Hernia	1	1
	Intestinal complications	4	10
	Medication-related complications	10	12
Need for reintervention	8	13	

	Peri-operative death	12	20
	Re-Admission to Hospital	3	4
	Respiratory complications	3	3
	Wound Complications	8	10
Recovery from surgery	In Hospital Recovery	11	23
	Length of Stay Following Surgery	11	18
<ul style="list-style-type: none"> • Referenced in 18 interviews • Referenced 57 times in all interviews. 	Peripheral Oedema	1	1
Long-terms problems following surgery	Eating & Drinking	20	75
	Fatigue	16	38
	Gastrointestinal symptoms	11	27
<ul style="list-style-type: none"> • Referenced in 20 interviews • Referenced 175 times in all interviews. 	Pain	10	14
	Weight Loss	12	21
Long-term impacts of surgery	Necessity of long-term feeding	1	1
	Overall QoL	8	10
<ul style="list-style-type: none"> • Referenced in 20 interviews • Referenced 133 times in all interviews. 	Psychological impact	11	40
	Returning to normality	20	82

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med.* 2014;89(9):1245-1251.

	Reporting Item	Page Number
Title		
	#1 Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
Abstract		
	#2 Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	4
Introduction		
Problem formulation	#3 Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	7

1	Purpose or research	#4	Purpose of the study and specific objectives or	7
2	question		questions	
3				
4	Methods			
5				
6				
7	Qualitative approach and	#5	Qualitative approach (e.g. ethnography, grounded	9
8	research paradigm		theory, case study, phenomenology, narrative research)	
9			and guiding theory if appropriate; identifying the	
10			research paradigm (e.g. postpositivist, constructivist /	
11			interpretivist) is also recommended; rationale. The	
12			rationale should briefly discuss the justification for	
13			choosing that theory, approach, method or technique	
14			rather than other options available; the assumptions	
15			and limitations implicit in those choices and how those	
16			choices influence study conclusions and transferability.	
17			As appropriate the rationale for several items might be	
18			discussed together.	
19				
20				
21				
22				
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25				
26	Researcher characteristics	#6	Researchers' characteristics that may influence the	10
27	and reflexivity		research, including personal attributes, qualifications /	
28			experience, relationship with participants, assumptions	
29			and / or presuppositions; potential or actual interaction	
30			between researchers' characteristics and the research	
31			questions, approach, methods, results and / or	
32			transferability	
33				
34				
35				
36				
37	Context	#7	Setting / site and salient contextual factors; rationale	10
38				
39				
40	Sampling strategy	#8	How and why research participants, documents, or	9
41			events were selected; criteria for deciding when no	
42			further sampling was necessary (e.g. sampling	
43			saturation); rationale	
44				
45				
46	Ethical issues pertaining to	#9	Documentation of approval by an appropriate ethics	11
47	human subjects		review board and participant consent, or explanation for	
48			lack thereof; other confidentiality and data security	
49			issues	
50				
51				
52				
53	Data collection methods	#10	Types of data collected; details of data collection	10
54			procedures including (as appropriate) start and stop	
55			dates of data collection and analysis, iterative process,	
56			triangulation of sources / methods, and modification of	
57				
58				
59				
60				

1		procedures in response to evolving study findings;	
2		rationale	
3			
4	Data collection	#11 Description of instruments (e.g. interview guides,	11
5	instruments and	questionnaires) and devices (e.g. audio recorders)	
6	technologies	used for data collection; if / how the instruments(s)	
7		changed over the course of the study	
8			
9			
10	Units of study	#12 Number and relevant characteristics of participants,	16
11		documents, or events included in the study; level of	
12		participation (could be reported in results)	
13			
14			
15			
16	Data processing	#13 Methods for processing data prior to and during	11
17		analysis, including transcription, data entry, data	
18		management and security, verification of data integrity,	
19		data coding, and anonymisation / deidentification of	
20		excerpts	
21			
22			
23			
24	Data analysis	#14 Process by which inferences, themes, etc. were	11
25		identified and developed, including the researchers	
26		involved in data analysis; usually references a specific	
27		paradigm or approach; rationale	
28			
29			
30			
31	Techniques to enhance	#15 Techniques to enhance trustworthiness and credibility	11
32	trustworthiness	of data analysis (e.g. member checking, audit trail,	
33		triangulation); rationale	
34			
35			
36	Results/findings		
37			
38			
39	Syntheses and	#16 Main findings (e.g. interpretations, inferences, and	16
40	interpretation	themes); might include development of a theory or	
41		model, or integration with prior research or theory	
42			
43			
44	Links to empirical data	#17 Evidence (e.g. quotes, field notes, text excerpts,	16
45		photographs) to substantiate analytic findings	
46			
47			
48	Discussion		
49			
50	Intergration with prior	#18 Short summary of main findings; explanation of how	29
51	work, implications,	findings and conclusions connect to, support, elaborate	
52	transferability and	on, or challenge conclusions of earlier scholarship;	
53	contribution(s) to the field	discussion of scope of application / generalizability;	
54		identification of unique contributions(s) to scholarship in	
55		a discipline or field	
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1	Limitations	#19	Trustworthiness and limitations of findings	30
2				
3	Other			
4				
5	Conflicts of interest	#20	Potential sources of influence of perceived influence on	3
6			study conduct and conclusions; how these were	
7			managed	
8				
9				
10				
11	Funding	#21	Sources of funding and other support; role of funders in	2
12			data collection, interpretation and reporting	
13				

14
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17 <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with
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