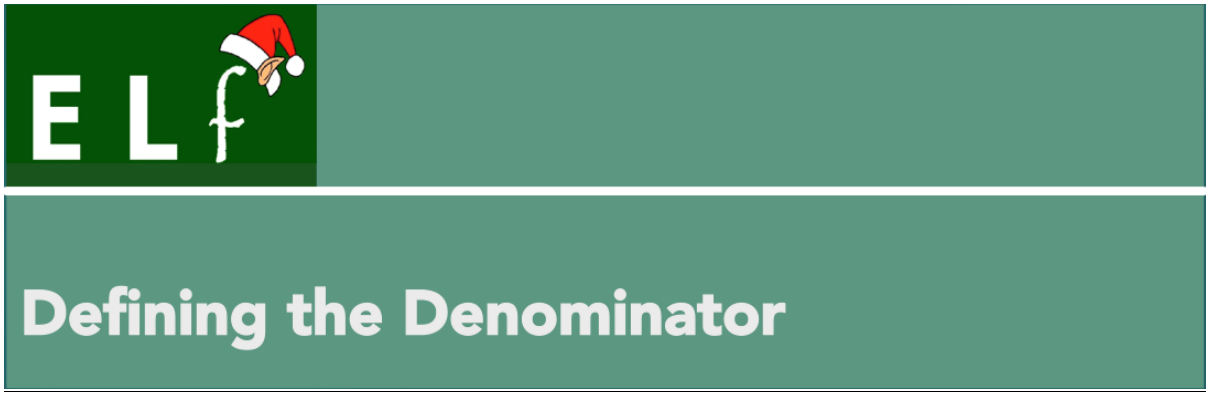
Protocol



Defining the Denominator:

Emergency Laparotomy and Frailty Study 2.

Version 2.2

Date 21st August 2019.

Welsh Barbers Research Group

SSRG Scottish Surgical Research Group

Swansea University Prifysgol Abertawe
Swansea Trials Unit
Uned Dreialon Abertawe

OPSOC.
OLDER PERSONS SURGICAL OUTCOMES COLLABORATION

Supported by:

NELA National Emergency Laparotomy Audit

ELLSA Emergency Laparoscopic and Laparotomy Scottish Audit

Contents

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Funding Body

Applications under review.

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Ben Carter	OPSOC	Statistician
Jonathan Hewitt	OPSOC	Collaborator
Erin McIlveen	SSRG	Mentor to Trainees
Kat Parmar	OPSOC	Mentor to Trainees
Lyndsay Pearce	OPSOC	Co-Lead
Susan Moug	OPSOC	Chief Investigator
Gillian Tierney	Surgeon	NELA/ EGS liaison
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STUDY SYNOPSIS

Title of Study:	**Defining the Denominator: Emergency Laparotomy and Frailty Study 2.**
Study Centre:	Multicentre
Duration of Study:	25 months
Primary Objective:	Identify a U.K. consecutive series of older adults presenting with acute abdominal pathology potentially treatable by emergency laparotomy where the decision is made not to undergo surgery (NoLAP) and their associated 90-day mortality.
Secondary Objective:	Collect, define and characterise the reasoning behind the NOLAP decision.
Primary Endpoint:	Characterise NoLAP patient populations and document 90-day mortality.
Rationale:	Older patients that require, but do not undergo emergency laparotomy (NoLAP) are an undefined and uncharacterised population. In contrast to those older adults that undergo emergency surgery, it is not known how many patients constitute this NoLAP group, what characteristics they have, what the reasons are for not undergoing surgery and what their short-term outcomes are.
Methodology:	Prospective cohort study
Sample Size:	700
Screening:	n/a
Registration/ Randomisation:	Via REDCap database.
Main Inclusion Criteria:	• 65 years or older • requires emergency laparotomy for pathology consistent with inclusion into NELA • does not undergo emergency laparotomy • had review by trained surgeon
Main Exclusion Criteria:	• under 65 years of age • no surgical review • failed conservative management
Product, Dose, Modes of Administration:	N/A
Duration of Treatment:	N/A
Statistical Analysis:	Detailed later.

Background

The work of the National Emergency Laparotomy Audit (NELA) has drastically improved the U.K. landscape for acute surgical units performing emergency laparotomies (ELAP) [1]. NELA has allowed characterisation of the ELAP population and the short and long-term outcomes have allowed each acute surgical unit to identify areas of clinical priority leading to quality improvement intervention and the development of peri-operative pathways that have improved outcomes for patients.

One successful example of a result of NELA, is the Emergency Laparotomy and Frailty Study (ELF) [2]. Frailty, a relatively new concept within the medical world, is defined as 'a medical syndrome with multiple causes and contributors that is characterised by diminished strength, endurance, and reduced physiologic function that increases an individual's vulnerability for developing increased dependency and/or death' [3].

Research so far has suggested that high frailty scores pre-operatively correlate with increased post-operative complications, length of stay, 30 and 90-day mortality and likelihood of institutionalisation (e.g. nursing home). However, the majority of these previous studies have been performed with elective rather than emergency patients [4,5]. ELF assessed the influence of frailty solely on older adults (65 years and above) undergoing ELAP finding that, independent of age, as the frailty score increased the risk of 90-mortality did too. Similar findings were reported with 30-day mortality, post-operative complications and length of critical care (High Dependency Unit or Intensive Care Unit) and overall hospital stay. The authors concluded by stating that frailty scoring provided much needed new knowledge to inform and guide older adults as they consider the implications of undergoing emergency laparotomy [6].

Despite this significant progress, there is one surgically important area that remains unknown: older patients that require, but do not undergo emergency laparotomy (NoLAP). Similar to emergency laparotomy patients before NELA started, the NoLAP population remain uncharacterised with unknown outcomes. It is not known how many patients constitute this group, what characteristics they have, what the reasons are for not undergoing surgery and what their short-term outcomes are.

There are only two published works that have reported on the NoLap population. The Perth (Australia) Emergency Laparotomy Audit prospectively collected NoLAP numbers as part of analysing ELAP patients and found them to account for only 6% of the overall population being considered for emergency laparotomy [7]. However, this small number limits characterisation of NoLAP patients and more importantly, comparison to ELAP patients. The second study prospectively recorded over three hundred patients requiring ELAP for over 14 months [8]. Patients were included according to the NELA criteria with both groups having the same data recorded. In addition, the casenotes were reviewed to ascertain the reason for the NoLAP decision. This study found NoLAPs accounted for a third of all patients (32%) requiring an ELAP with a third of these being alive at 30 days with normal admission creatinine and lactate levels increasing the likelihood of survival. This is the first work that has attempted to characterise the U.K. NoLAP population, but is limited by being both single centred and by providing limited information on the decision behind NoLAP.

We aim to apply the findings and challenges from this work into the design of this multi-centred cohort study, to definitively define the denominator.

Aims

This study aims to:

1) Identify a U.K. consecutive series of older adults presenting with acute abdominal pathology potentially treatable by emergency laparotomy where the decision is made not to undergo surgery (NoLAP) and their associated 90-day mortality.

2) Collect, define and characterise the reasoning behind the NOLAP decision.

3) Define potential prognostic markers for mortality that could aid decision-making in the future (including frailty, NELA score and sarcopenia).

4) Compare aims 1 and 3 to those that underwent surgery (ELAP) during the same time frame as the NoLAP population.

Outcomes

Primary Outcome Characterise NoLAP patient populations and document 90-day mortality.

Secondary Outcomes: Reasons for decision not to operate.

Prognostic scores: NELA score; Clinical Frailty Score.

Surgical diagnosis

Blood markers pre-operatively: lactate; C reactive protein; creatinine and WCC.

Length of critical care stay (ICU and HDU combined).

Length of hospital stay.

30-day complications

Discharge destination

30-day and 90-day mortality

Death at 1 year.

Defining the Denominator Steering and Study groups

Trial Management Group (TMG)

Five collaboratives form the DtD TMG: the Welsh Barbers (surgical trainees); Scottish Surgical Research Group (SSRG) (surgical trainees) and the Older Persons Surgical Outcomes Collaboration (OPSOC) which is comprised of consultant and trainee general surgeons, geriatricians, statisticians and epidemiologists interested in surgery in older people. Susan Moug and Lyndsay Pearce will lead the study with the former being the Chief Investigator. NELA (National Emergency Laparotomy Audit) and ELLSA (Emergency Laparoscopic and Laparotomy Scottish Audit) are the remaining collaboratives. Each collaborative will appoint one lead who will attend the TMG meetings and delegate to their own collaborative.

Both trainee collaboratives will have two mentors with experience relevant to ELF 2: Erin Mcilveen (lead author on U.K. NoLAP study) and Kat Parmar (NWRC and main contributor to ELF study). The training package and interpretation of sarcopenia will be led by Daniel Dolan (undergraduate medical student with published experience in sarcopenia measurement) and The SSRG.

The DtD TMG will be responsible for protocol design, data handling, analysis, and dissemination of results and the preparation of manuscripts. The CI is responsible for the use of data resulting from this project. Contributing sites will register their team at the start of the study and will form the Defining the Denominator Study Group. Each site will be allowed up to 5 team members with trainees, medical students, surgical nurse practitioners, advanced nurse practitioners and nursing research staff strongly encouraged to be included.

Corporate authorship will be used for the first publication from this work (the primary aim) as described here: Welsh Barbers, SSRG, NELA, ELLSA and OPSOC on

behalf of the Defining the Denominator Study group. Each collaborator will be individually citable within their own collaborative. The CI and Lyndsay Pearce will determine further published work. Using ELF Study as our guideline we would hope to publish at least 3 more papers.

Study group (Local leads)

The local leads are responsible for co-ordinating and organisation of local DtD teams. The local lead will sponsor the registration of the audit and ensure that collaborators act in accordance with local clinical governance and guidelines and Good Clinical Practice. The local leads act as a link between the DtD steering group and will be responsible for the dissemination of information to local collaborators from the DtD Steering Group.

Finance and Indemnity

The DtD Study is covered by NHS Greater Glasgow and Clyde. The sponsor will be liable for negligent harm caused by the design of the trial. NHS indemnity is provided under the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS).

Method

Ethics

Ethical approval will be obtained from IRAS. As per ELF, this will involve a proportionate ethical review given that this is merely an observational study and not altering patient care. Permission with be sought by the study team from the Caldicott Guardian for entry of pseudoanonymised data into REDCap (Scotland: Public Benefir and Privacy Panel for Health and Social Care, PBPP; England and Wales: Confidentiality Advisory Group).

No data will be entered from any site that has not provided such written evidence (electronically or paper). In addition, each site will be individually responsible for ensuring that all members of their team have an up to date Good Clinical Practice (GCP). REDCap will be provided and maintained by the Swansea Clinical Trials Unit.

Profile of Centre

Each site will be asked to complete a site profile questionnaire when they register. This will record the proposed site, NELA or ELLSA participation, number of ELAPs per month and names of team. In addition, each site will be asked for confirmation of their participation in the other arm of the study: sarcopenia. Each site will be asked for their radiological imaging system (e.g. PACS) and clarification of their local process of having the images transferred to the DtD Steering group to analyse.

Patient Inclusion and Exclusion

All patients 65 years or older on the date of them presenting with a condition that may be treatable by an emergency laparotomy (ELAP). Previous work suggests the majority of NoLAPs arise from the older adult population.

NoLAP patients are defined as requiring an emergency laparotomy by the responsible surgical team (trainee and/ or consultant). Such a requirement could be decided by clinical judgement and/ or radiological.

Defining the Denominator

NoLAP patients must have been reviewed by a surgeon, but can be on any ward in a hospital (e.g. gynaecology).

Indication for NoLAP is exactly the same as the NELA inclusion criteria. Trauma, non-abdominal pathology excluded as per NELA (vascular, urology, gynaecology).

Patients initially requiring ELAP, but where surgical decision was made to manage conservatively will be excluded, even if that decision is subsequently changed and ELAP is performed. This includes cases where radiological drainage has failed (e.g complex diverticulitis).

Identification of the NOLAP

Each participating site will develop their own strategies for identifying the NoLAP patients. The DtD group has suggested highlighting to their colleagues their participation in the DtD study to ensure vigilance and accurate prospective data collection. Participation advertising material can be distributed for local promotion. Each site will be made aware that all potential patients can be recruited from any site in the hospital with particular attention being paid to record patients from non-surgical wards: e.g. ITU; HDU; gynaecology; orthopaedics; acute medical unit; geriatrics. Local teams should try to contact the surgical on-call team on a daily basis to ensure consecutive and data collection and are encouraged to review the daily emergency CT abdomen and pelvis scans list to optimise data completeness.

Variables collected

The following clinical parameters will be collected for NOLAP population: age; sex; place of residence (home with no carers, home with carers, intermediate care, residential home, nursing home); ASA (American Society of Anaesthesiologists); surgical diagnosis (pre-operatively); NELA score; Clinical Frailty Score (Rockwood, 1 to 7); co-morbidities (Charlson; total number of co-morbidities); polypharmacy (5+ medications: yes/no) CT performed within 48 hours of decision (yes/ no); CT

diagnosis; date of assessment for laparotomy, time of day and location (most relevant according to the following list: general surgical ward; other surgical ward; orthopaedics; gynaecology; geriatrics; acute medical ward; other medical ward). Pre-operative (within 8 hours of surgical decision) blood markers will also be recorded: lactate; C reactive protein; creatinine and WCC. The actual procedure performed will be recorded for the ELAP patients only.

For comparison to ELAP. This data will be retrieved directly from NELA and ELLSA databases with no extra data required by each participating site.

Remaining variables: length of hospital stay; length of critical care stay (ICU and HDU combined). Both groups will then be followed up for: 30-day complications (Clavien-Dindo Grading); date of discharge; discharge destination (home with no carers, home with carers, intermediate care; residential home, nursing home); 30-day and 90-day mortality and death at 1 year. Actual date of death and cause of death (1a on death certificate) will be recorded.

Decision-making in NoLAP Patients

For each NoLAP patient, the local team will be asked to select from 5 options who or what specialty was involved in making the decision: patient, surgical, anaesthetic, intensive care or other speciality. If more than one option is selected, the local team will be asked to specify the main two. Next, a list of potential influencing factors will be selected by the local team to improve our understanding of the decision-making process [Appendix]. A patient's decision is defined as either by the patient themselves or next of kin (as determined by clinical team) or patient's wishes already known and documented e.g. living will). Highest level of clinical seniority involved in the decision-making can be in person or by telephone. Free text will be added to allow further reasoning.

Sarcopenia Measurement: CT Scan Analysis

To measure sarcopenia on each patient, the total cross-sectional area of the psoas muscles (Total Psoas Area, TPA) will be measured using one of the following techniques: a manual technique or a semi-automated CT planimetry using validated software (ImageJ). Each site will have the option of undergoing a teaching package to train them in muscle mass measurement. Or, alternatively the PAC images can be sent centrally to the study team to analyse.

For the manual technique, psoas muscle will be measured at the level of the L3 vertebra on pre-operative CT (must be within 3 days of laparotomy decision). To ensure standardisation, the exact level of measurement is defined as the CT slice in which both transverse processes were maximally in view. Area will be measured using a free-hand drawing technique on Picture Archiving and Communication System (PACS) software. The outline of each individual psoas muscle will be traced, the area calculated, and summated to provide the TPA (mm^2). The TPA will then be standardised for patient height using the formula TPA (mm^2) / height (m^2) to provide the total psoas index (TPI) for each patient.

For the purposes of this study the threshold values used for the diagnosis of sarcopenia are the same as those used by Prado et al in their widely cited 2008 paper [9]. This entails a figure of 524 mm^2/m^2 for males, and 385 mm^2/m^2 for females. All individuals with a TPI below this threshold for their gender were classified as sarcopenic. Intra- and Interclass correlation coefficients will be performed on twenty randomly selected CT scans for 2 blinded analysers to measure sarcopenia. ICCC is expected to be at least 0.75 for both sets of scores.

For the semi-automated technique, whole-slice analysis at the L3 level will be measured using semi-automated CT planimetry through the validated software package ImageJ (ImageJ) [10-15]. DICOM images from Picture Archiving and Communication System (PACS) will allow for the measurement of tissue radio-density, including muscle and adipose tissue will be taken, while conversion calculations will be performed to allow for the analysis of all types of CT scan (plain/arterial/portal venous). Calculated values will be stratified by BMI and

compared to validated threshold values used for the diagnosis of sarcopenia Clinical frailty scores will be used as an objective measure of sarcopenia in accordance with the European Working Group on Sarcopenia in Older People (EWGSOP statement) with comparisons made with CT-diagnosed sarcopenia through the calculation of correlation coefficients.

Data Collection Period

Prospective patient identification will be undertaken over a three-month period – 31st October 2019 to January 31st 2020. Patients will then be followed by for 90 days – 30th April 2020. For one-year follow-up, NELA and ELLSA databases (already collecting such data) will be accessed and both have already provided provisional approvals.

DtD Study Timeline

Finalising of protocol	June 1st 2019	31st July 2019
IRAS and REDcap set up	June 1st 2019	30th September 2019
Drafting of protocol paper	June 1st 2019	31st December 2019
Funding Applications	July 1st 2019	January 31st 2020
Advertising for sites	July 4th 2019	31st October 2019
Site registration	July 4th 2019	31st October 2019
Local Approvals	July 4th 2019	30th November 2019
REDcap data upload	31st October 2019	January 31st 2020
Follow-up data uploaded	January 31st 2020	30th April 2020
1st Data completion	31st May 2020	
1st Data analysis	30th April 2020	31st July 2020
1st write up completed	1st September 2020	
Dissemination	1st September 2020	1st December 2020
2nd data completion	30th April 2021	
2nd Data analysis	30th April 2021	31st July 2021
2nd write up completed	1st September 2021	
Dissemination and End of study	1st November 2021	

Shading indicates the one year follow-up period.

Patient numbers and power calculation

ELF Study recruited 957 patients from 49 sites and had a mortality of 20% at 90-days, similar to NELA findings (17-25% with increasing age). For aim 1: From previous work it is estimated that the proportion of patients to experience an NoLAP is approximately 32%. We will estimate this proportion with a 95% within +/- 3.75% by following up 590 patients, and assuming a small loss to follow up rate of 10%, we will recruit 700 patients.

With 25 000 ELAPs recorded every year in England and Wales, 32% of NoLAPs gives an estimate of 8000 NOLAPS per year. For a 3-month recruitment window we predict that the recruitment pool is 2000 making the study target of 700 achievable.

Data Input Procedure

Data collection will be using the secure REDcap system. All data will be handled in accordance with the Data Protection Act 1998 and GDPR 2018. Each local lead will be provided with a unique username and password and collected prospectively for maximum accuracy. Completed datasheets will be entered into the secure REDcap system REDcap will be hosted by the University of Swansea.

REDcap accounts will not be issued until evidence is provided via hospital local leads that the following approvals are in place at each centre:

i. Successful registration of ELF at the hospital site
ii. Caldicott Guardian permission for data to be submitted to REDcap

Training Materials:

As with previous multicentre studies, we will deliver online training to ensure standardisation. This will be delivered through online presentation of the project rationale, how to complete the pro forma, and how to use the REDcap system for data entry.

Validation

Validation will be performed on 25% of data fields for 10% of cases. The validated fields will include key demographic and outcome data.

Data analysis

Statistical support will be provided by the study statistician (Ben Carter) throughout the project.

Description of demographics of included patients including their demographics (gender, age), baseline clinical characteristics (frailty score, NELA score, co-morbidities and polypharmacy). Complications and outcomes (Clavien-Dindo, discharge destination, 30 and 90-day mortality) will also be described. Missing/incomplete data will be presented and explored.

The Primary outcome to estimate the NoLAP proportion will be carried out with an asymptotic method, and presented with a 95% confidence interval.

The primary outcome to estimate the difference in 90-Day mortality between those with a NOLAP and ELAP will be carried out with a multi-level logistic regression, fitting patients within hospitals as a random site effects. The model will be adjusted for pre-operative patient: age; sex; and frailty status.

A full Statistical analysis plan will be reported prior to the data lock, and will be largely described in the published protocol.

Following analysis, each unit will be offered to receive their own raw data, and a summary of national data. This will allow comparison to local performance and enable local quality improvement work.

Quality assurance

The TMG will hold meetings every 3-4 months or more as required. Face-to-face meetings where possible will be accompanied by teleconferencing via Zoom and Google hang out.

Expertise in the team.

The study is led by CI **Susan Moug** who was CI on ELF. **Lyndsay Pearce** also led on ELF and is an experienced collaborative researcher with NWRC.

OPSOC consists of trainee and consultant surgeons, geriatricians and statisticians. With an expanding network across the UK, Europe and USA, they have published over 25 papers during the last 5 years.

Dr Ben Carter, a Senior Lecturer in Medical Statistics with expertise of delivering large multicentre RCTs. Dr Carter is the Senior Statistician for 10 current NIHR/MRC funded studies (including 4 CTIMPs), and 2 Observational studies and is the KCTU Statistics group lead. Dr Carter have published over 100 peer reviewed manuscripts, and has a ResearchGate score of 42.25 and is the OPSOC and ELF Study statistician.

NELA (National Emergency Laparotomy Audit) is one of the leading prospective emergency laparotomy databases in the world. **ELLSA** (Emergency Laparoscopic and Laparotomy Scottish Audit) started in 2018 and published its' first report in 2019.

Study Dissemination

In addition to local meetings for local collaborators, we plan to submit for presentations to ASGBI, ACPGBI, ASCRS, Tripartite 2020.

The following are all potential papers and are subject to change.

Paper 1. Protocol Paper.

Paper 2: Characterisation and short-term outcomes of the NOLAP Patient in the U.K.

Paper 3: Decision-making in the NoLap population.

Paper 4: Long-term outcomes for the NOLAP patient in the U.K.

Paper 5: Comparison of Pre-operative Prognostic Markers in NoLAP versus ELAP UK Patients.

Appendix A. Decision-making Options for NoLAP.

Must select at least one of these factors as the MAIN influencing factor.

Patient Factors	**Yes/ No**	**Surgical Factors**	**Yes/ No**
Patient does not wish to have surgery (Drop down menu of reasons if selecting 'yes': chronic pain, management of stoma, does not want to lose independence i.e. institutionalisation, other – free text)		Poor Pre-op Fitness (Drop-down menu options if selecting 'yes': home oxygen; nursing home resident; bed bound; housebound; advanced comorbidity; other – free text)	
Has Living will in place		Poor prognostic pathology (Drop-down menu options if selecting 'yes': global ischaemia, advanced malignancy; other –free text)	
Patient involved in decision (Drop-down options if selecting 'no': Reduced GCS; severe dementia; acute delirium; power of attorney in place; other – free text)		High prognostic score (Drop-down menu options if selecting 'yes': high NELA score; high frailty score; high P-Possum score, high SORT score) If frailty score used: define which score If yes selected for any score, record actual value (frailty score value or predicted mortality value)	
Anyone else representing the patient involved in the decision (Drop down options if selecting 'yes': next of kin, legal guardian, friend, other)		Surgeon involved in decision (Drop-down menu if selecting 'yes': consultant, associate specialist, staff grade, registrar, core trainee)	

Anaesthetic Factors	Yes/ No	Intensive Care Factors	Yes/ No
Poor Pre-op Fitness (Drop-down menu options: home oxygen; nursing home resident; bed bound; housebound; advanced comorbidity; other – free text)		Poor Pre-op Fitness (Drop-down menu options: home oxygen; nursing home resident; bed bound; housebound; advanced comorbidity; other – free text)	
Poor prognostic pathology (Drop-down menu options: global		Poor prognostic pathology (Drop-down menu options: global ischaemia,	

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ischaemia, advanced malignancy; other – free text)		advanced malignancy; other –free text)	
High prognostic score (Drop-down menu options if selecting 'yes': high NELA score; high frailty score; high P-Possum score; high SORT score) If frailty score used: which score If yes selected for any score, record actual value (frailty score value or predicted mortality value)		High prognostic score (Drop-down menu options if selecting 'yes': high NELA score; high P-Possum score; high SORT score; high frailty score) If frailty score used: which score If yes selected for any score, record actual value (frailty score value or predicted mortality value)	
Unlikely to be weaned from ventilator (Drop-down – reasons for this concern)		Unlikely to be weaned from ventilator (Drop-down – reasons for this concern)	
Anaesthetist involved in decision (Drop-down menu if selecting 'yes': consultant, associate specialist, staff grade, registrar, core trainee)		Intensivist involved in decision (Drop-down menu if selecting 'yes': consultant, associate specialist, staff grade, registrar, core trainee)	
Other Specialities	Yes/No	Other factors	
Were any other specialities involved in this decision-making process? (Drop-down menu options: palliative care; geriatrics; accident and emergency; medicine; other –free text) (For all where 'yes' is answered: Drop-down menu to specify most senior grade of additional speciality involved in decision)		DNACPR in place?	
		Any other factors which influenced the decision (free text)	

Appendix B: Proforma

Q1	Study ID	
Q2	Age at admission to study (years)	
Q3	Sex	Male Female
Q4	Comorbidities	CCF Y/N COPD Y/N CVA Y/N Dementia Y/N Hemiplegia Y/N CKD Y/N Leukaemia Y/N DM(complicated) Y/N Lymphoma Y/N DM(uncomplicated) Y/N Mild liver disease Y/N IHD Y/N Severe liver disease Y/N PVD Y/N Solid tumour Y/N Metastatic tumour Y/N AIDS Y/N Other:_____
Q5	Polypharmacy (≥5 medications)	Yes No
Q6	Place of Surgical review (choose most relevant)	Emergency Department General Surgical Ward Other Surgical ward Orthopaedics Geriatric ward Acute medical ward Other medical ward
Q7	Care level prior to admission	Home (no carers) Home (with carers) Residential Home Nursing home Intermediate care

		Other: _____
Q8	Frailty score	1,2,3,4,5,6,7
Q9	NELA score	---%
Q10	Interval between admission and laparotomy (days)	
Q11a Q11b Q11c Q11d	Pre-decision Creatinine Pre-decision CRP Pre-decision WCC Pre-decision Lactate (all within 8 hours of decision)	
Q11	Pre-operative clinical diagnosis	
Q12	CT performed pre-operatively (within 24 hours of decision)	Yes/ no
Q13	CT diagnosis	
Q14	Psoas muscle mass (TPI) [TPA/ height)	
Q15	ELAP?	Yes/ no
Q16	Day of decision	Monday to Thursday Friday to sunday
Q17	Time of decision (24 hour)	--:--
Q18	Operation performed at laparotomy	
Q19	Length of stay post-operative or NOLAP decision (days)	
Q20	Length of critical care stay (ICU and HDU) (days)	

Q21a Q21b	Post-operative complication within 30 days Grade of complication	Yes No
Q22	Care level on discharge	Home (no carers) Home (with carers) Residential Home Nursing home Intermediate care Other: _____
Q23	30 day mortality	Yes No
Q24	30 day re-admission	Yes No
Q25	90 day mortality	Yes No
Q26	1 year mortality	Yes No

Definitions

Q4. These are comorbidities as defined by the Charlson Comorbidity Index. Each should be marked as present if there is any previous documented history of each diagnosis.

Myocardial infarct	History of medically documented myocardial infarction
Congestive heart failure	Symptomatic congestive heart failure w/ response to specific treatment
Peripheral vascular disease	Intermittent claudication, peripheral arterial bypass for insufficiency, gangrene, acute arterial insufficiency, untreated aneurysm (≥6cm)
Cerebrovascular disease (except hemiplegia)	History of TIA, or CVA with no or minor sequelae
Dementia	Chronic cognitive deficit
Chronic pulmonary disease	Symptomatic dyspnoea due to chronic respiratory conditions (inc. asthma)
Connective tissue disease	SLE, polymyositis, polymyalgia rheumatic, moderate to severe rheumatoid arthritis
Ulcer disease	Patients who have required treatment for peptic ulcer disease
Mild liver disease	Cirrhosis without portal hypertension, chronic hepatitis
Diabetes (without complication)	Diabetes with medication
Diabetes with end organ damage	Retinopathy, neuropathy, nephropathy
Hemiplegia (or paraplegia)	Hemiplegia or paraplegia
Moderate of severe renal disease	Creatinine>265umol/L, dialysis, transplantation, uraemic syndrome
Solid tumour (non-metastatic)	Initially treated in the last 5 years exclude non-melanomatous skin cancers and in situ cervical carcinoma
Leukaemia	CML, CLL, AML, ALL, PV
Lymphoma, Multiple myeloma	Non-Hodgkin's Lymphoma, Hodgkin's, Waldenstrὸm, multiple myeloma
Moderate or severe liver disease	Cirrhosis with portal hypertension +/- variceal bleeding
Metastatic solid tumour	Metastatic solid tumour
AIDS	AIDS & AIDS-related complex

Q8. Rockwood Frailty Score

1 – Very fit	**Robust, active, energetic, well motivated and fit; these people commonly exercise regularly and are in the most fit group for their age.**
2 – Well	**Without active disease, but less fit than people in category 1.**
3 – Well, with treated comorbid disease	**Disease symptoms are well controlled compared with those in category 4.**
4 – Apparently vulnerable	**Although not frankly dependent, these people commonly complain of being "slowed up" or have disease symptoms.**
5 – Mildly frail	**With limited dependence on others for instrumental activities of daily living.**
6 – Moderately frail	**Help is needed with both instrumental and non-instrumental activities of daily living.**
7 – Severely frail	**Dependent on others for activities of daily living, or terminally ill.**

Q21a. Clavien-Dindo Classification of Surgical Complications

Clavien-Dindo Classification of Surgical Complications	
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are: drugs such as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.
Grade II	Requiring pharmacological treatment with drugs other than allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
Grade IIIa	Surgical, endoscopic, or radiological intervention that is not under general anesthesia
Grade IIIb	Surgical, endoscopic, or radiological intervention that is under general anesthesia
Grade IVa	Life-threatening complication requiring intermediate care or intensive care unit management, single organ dysfunction (including dialysis, brain hemorrhage, ischemic stroke, and subarrachnoidal bleeding)
Grade IVb	Life-threatening complication requiring intermediate care or intensive care unit management, multi-organ dysfunction (including dialysis)
Grade V	Death of a patient
Suffix "d"	If the patient suffers from a complication at the time of discharge, the suffix "d" (for "disability") is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication

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