# Emergency Surgery Or noT (the ESORT study)

**Statistical Analysis Plan**

**Version 1.0**

**July 1st, 2021**

Contents

# 1 Overview

The aim of this study is to evaluate the effectiveness of emergency surgery (ES) versus non-emergency surgery (NES) strategies for five common acute conditions: acute appendicitis, cholelithiasis, diverticular disease, abdominal wall hernia or intestinal obstruction that present as emergency admissions to NHS hospitals. The specific objectives are to evaluate the:

1. effectiveness of ES versus NES for common acute conditions presenting as emergency admissions across broad ICD-10 categories.
2. relative cost-effectiveness of ES versus NES across broad ICD-10 categories.
3. clinical and cost-effectiveness of ES versus NES for specific patient subgroups, including diagnostic subcategories and patient characteristics.

This analysis plan will focus on the analysis methods required to address objective 1. Subsequent analysis plans will address objectives 2 and 3. Within this analysis plan, we provide an overview of the study standpoints essential for contextualising the requisite analyses, but this document should be read in conjunction with the study protocol, available from the ESORT study website (https://www.lshtm.ac.uk/media/38711). The next sections briefly define: the populations of interest, comparators, and outcomes.

## 1.1 Population

The ESORT study uses admissions data from the Hospital Episode Statistics (HES) database linked to mortality data from the Office for National Statistics (ONS), to identify cohorts of emergency admissions to NHS trust hospitals. The broad acute conditions are defined according to ICD-10 diagnosis codes corresponding to each condition. We will define the target population from emergency admissions within the HES database, to ensure consistent definitions, for example of inclusion criteria, across the patient cohort.

An admission will be eligible for inclusion if a finished consultant episode meets the following general inclusion criteria: (i) occurred between 1/4/2010 and 31/12/2019; (ii) included a relevant main diagnosis; (iii) was an emergency admission via accident and emergency, or a direct general practice referral; (iv) the admission included an episode under a consultant general, colorectal or upper gastro-intestinal surgeon, or a surgeon working in the general surgery specialty; and (v) the episode under the surgical team was the first or second in the admission. The consensus from the expert clinical panel was used to determine the specific complications for inclusion related to each

pathology (see https://www.lshtm.ac.uk/media/38711). Individuals aged less than 18 years will be excluded. Those with an emergency admission for the same condition in the preceding 12 months of the index date will be excluded, as will those referred to tertiary referral centres for whom the instrumental variable design is less likely to be valid (see also sensitivity analyses). Admissions to specialist and non-acute trusts will also be excluded.

## 1.2 Case mix and potential confounders

Information from HES on patient characteristics will be available at the patient-level and will comprise socio-demographic characteristics: age (45-49; 50-54; 55-59; 60-64; 65-69; 70-74; 75- 79; 80-84; 85+ year), sex (male, female), ethnicity (White, Black/Black mixed, Asian/Asian mixed, other/not stated), quintile group of the index of multiple deprivation (IMD), route of hospital admission (Emergency Department, GP or elsewhere in hospital) and the secondary care administrative records frailty (SCARF) index. We will also control for the individual's condition-specific sub-diagnostic group. Comorbidities will be derived using HES records from all admissions for each patient in the year prior to and including the index admission using the Royal College of Surgeons (RCS) Charlson Comorbidity index (0; 1; 2; 3+ comorbidities). The definition of co-morbidities will use both information on past medical history according to chronic conditions, but also according to reasons for previous admissions. The SCARF index captures 32 deficits, defined using ICD-10 codes, that cover functional impairment, geriatric syndromes, problems with nutrition, cognition and mood, and medical comorbidities. To control for hospital quality which is unobservable here, we will control for the rate of emergency readmissions and mortality rates for the hospital at baseline (based on the 12 months preceding the study start date) and over a moving 12-month window preceding the index date. Sensitivity analysis will consider quality measures based on external information from the *National Emergency Laparotomy Audit* (*NELA*). We will include covariates for each financial year in the analysis to control for time dependent variation in the outcome and include for age and age-squared in addition to the categorical variables above.

## 1.3 Missing and miscoded data

Missing or unreported ethnicity data in eligible admissions (10%), and deprivation (1%) will be minimised by using ethnicity and deprivation data from patients' other linked episodes. For baseline covariates with missing values, we will examine whether this pattern of missingness differed across the intervention and comparator groups. We will use inverse probability weighting to upweight observed data to reflect missing data, under the assumption that the data are missing at random if deemed necessary.

## 1.4 Intervention strategy

The 'intervention' strategy comprises ES within the index hospital episode, defined according to the consensus of a clinical panel according to relevant Office of Population Censuses and Surveys (OPCS) procedure codes and within a requisite time window. The NES 'comparator' strategies are to defer or avoid ES and comprise: 'medical management', 'non-surgical' procedures, and the possibility of subsequent planned (elective) surgery. The index date is defined as the first date within the qualifying emergency admission when the patient is under the care of a surgical team.

For each acute condition, surgical intervention is defined as an operative procedure corresponding to one of a pre-determined set of OPCS Classification of Interventions and Procedures codes within the index emergency admission. Full details of the criteria for ES are provided in the report of the clinical panel (see https://www.lshtm.ac.uk/media/39151). Table 1 provides a summary of the criteria for ES for each condition (see also sensitivity analyses).

## 1.5 Comparator strategy

For each acute condition, the comparator, NES, is defined as an eligible admission whose care does not include an operative procedure considered to constitute the intervention. This includes patients receiving non-surgical treatment or diagnostic evaluation as identified by OPCS-4 codes, and those with no procedure recorded during their index admission. The comparator strategy also includes delayed surgery, defined as having a relevant surgical procedure but after the specified time-frame for the intervention.

**Table 1: Indicative number of patients who meet inclusion criteria for each condition, criteria for ES, and number who meet ES definition**

| | Acute Appendicitis | Cholelithiasis | Diverticular disease | Abdominal wall hernia | Intestinal obstruction |
|---|---|---|---|---|---|
| Number in target population who meet inclusion criteria | 272,520 | 244,299 | 140,857 | 108,856 | 140,303 |
| Number of OPCS procedures defined as ES from the overall OPCS categories | 21 of 33 | 11 of 48 | 45 of 57 | 52 of 59 | 111 of 140 |
| Maximum number of days between admission and procedure to qualify as ES | 7 days | 7 days | Any time | 3 days | 7 days |
| N (% of cohort) who meet definition of ES from those who meet criteria for target population | 249,165 (91.4) | 52,543 (21.5) | 15,464 (11.0) | 62,578 (57.5) | 41,656 (29.7) |
| Sample size required to detect a 1 day difference in mean days-alive and out of hospital at 90 days between ES and NES with 90% power assuming 70% compliance | 34,046 | 20,152 | 42,270 | 26,030 | 77,040 |

## 1.6 Outcomes

The primary outcome is 'days alive and out of hospital' prior to 90 days following index emergency admission' which has been shown to capture important aspects of patients' health for adults in perioperative medicine generally, and specifically following emergency general surgery (Jerath et al 2019; Lee et al 2020; Myles et al 2017; Myers et al 2020). This measure captures outcomes important to patients, namely mortality, and number of days in hospital during the index emergency admission and following any readmissions (LOS). The consensus from 18 participants in a Patient and Public workshop undertaken as part of the ESORT study, was that 'days alive and out of hospital' is

an important outcome for patients following an emergency admission to hospital with any of the five conditions in the target population. We will calculate the number of days alive and out of hospital before day 90 using the date of death through ONS linkage.

Secondary outcomes are mortality at 90 days and one year after the index emergency admission, LOS up to 90 days, readmissions for emergency surgery up to 30 days and 90 days, and 'days alive and out of hospital prior to one year'. We will describe mortality following ES versus NES for up to 10 years after the index admission.

The definition of mortality at 90 days and one year following the index admission will be according to indicators provided by NHS Digital and will use ONS date of death. Readmission will be defined as whether there are any emergency hospital admission within 30 or 90 days of the index admission.

# 2 Instrumental variable (IV) design

An important challenge raised by the comparison of outcomes following ES and NES that use administrative data, is that there may be unmeasured prognostic differences in outcomes between the comparison groups. Studies which apply traditional risk adjustment approaches with little information on case-severity may provide biased estimates of treatment effectiveness. We will therefore use an IV design to estimate treatment effectiveness in the presence of residual confounding (Baiocchi et al., 2014; Brookhart and Schneeweiss, 2007). A valid IV design can provide accurate estimates of treatment effectiveness even when there are unmeasured differences between the comparison groups. For a variable to be a valid instrument for receipt of ES, it has to: i) predict the receipt of ES; ii) be independent of baseline covariates; and iii) only affect the outcome indirectly through the patient having ES.

The instrument for assessing effectiveness and cost-effectiveness of ES versus NES in the ESORT study, is the hospital's 'tendency to operate' (TTO), which is a measure of that hospital's preference for ES for the condition of interest at that time. TTO is defined for each acute condition, as the proportion of emergency admissions for that condition during which a procedure meeting our definition of ES is undertaken in the 12 months preceding the index admission (excluding the day of the index admission).Therefore for two patients with the same index admission for the same condition admitted to the same hospital, the TTO will be the same, while for admissions for other conditions, in different hospitals, or at different index dates the TTO will differ. Since the TTO is a moving average over 12 month windows, we anticipate it will be fairly stable over moderately long

time periods. Hospitals and surgeons will be identified from the HES provider/site of treatment codes, and the pseudonymised consultant codes. TTO will be defined at the hospital-level, to recognise that in the NHS, multidisciplinary team input informs the decision to operate and hospitals within a trust may differ in their TTO.

The ESORT analysis will follow the approach taken in most IV applications, and assume that there are 'no defiers', units who receive the opposite treatment he/she is assigned. We will also assume there are no 'always takers' or 'never takers' implying that there are no patients who receive ES simply because they present in a high TTO hospital and vice versa. We will therefore only include in the final analysis sample those patients whose (estimated) propensity for ES lies between 0 and 1.

## 2.1 Power calculation

The study will have access to HES data for all NHS trusts in England for eleven years. Table 1 indicates the sample size available for each condition along with the sample size required to have 90% power to detect a difference as small as a 1 day in the mean number of 'days alive and out of hospital up to 90 days' between the ES and NES groups assuming 70% compliance. For each condition we will have sufficient sample size to meet these criteria.

# 3 Analysis

## 3.1 Descriptive analyses

We will report the most prevalent emergency surgery procedures, and the most common clinical management strategies within 30 days for each arm of the study to characterise the intervention and comparator strategies.

### 3.1.1 Checking IV assumptions

We will carefully assess whether TTO meets the criteria for a valid and strong IV for each of the five acute conditions described for patients presenting as emergency admissions to NHS hospitals in England. First, we will assess whether the hospital-level TTO is strongly associated with receipt of emergency surgery for each condition using the Cragg-Donald F-statistic ($F < 10$ suggests instruments are weak (Staiger–Stock, 1997)). Secondly, while it is not possible to assess the assumption that the IV is uncorrelated with the outcomes, except through the intervention, we will assess whether the hospital-level TTO balances the observed covariates (Basu 2014; Basu, 2015). We will compare the IV

balance with the balance that would have been produced under randomization(Branson and Keele, 2020).

### 3.1.2 Kaplan-Meier Survival analysis

We will describe mortality up to 1 year, and out to 10 years, for each arm (ES vs NES) by plotting Kaplan-Meier survival curves and through a comparison between the treatment groups made using the log-rank test, under the null hypothesis of no difference in survival between the two treatment arms. We will also use discrete-time hazard models to explore effects on survival and will conduct appropriate sensitivity analyses.

### 3.1.3 Immortal time bias

'Immortal time bias' can arise when the determination of a patient's treatment status involves a delay during which follow-up time is accrued (Lévesque et al. 2010), since some study outcomes (e.g. death) cannot occur prior to treatment receipt for those assigned to the treated group, but may have occurred for those in the control group. The extent to which this is a concern depends on the probability of an event occurring and the length of the window used to decide treatment assignment. For many of the conditions in this study, mortality is likely to be low (<5% risk of 90 day mortality), while for intestinal obstruction (12% risk of 90 day mortality), the window for treatment assignment is relatively short (7 days) so this bias is unlikely to be large. We will carry out descriptive analysis to assess the extent to which this is a concern for each acute condition. If deemed necessary, we will undertake sensitivity analyses that consider recommended approaches for investigating the robustness of conclusions to immortal time bias (see sensitivity analyses).

## 3.2 Comparative analyses: ES versus NES

### 3.2.1 Preliminary analyses: Two stage Least Squares

We will use two stage least squares estimation to estimate the effect of ES on the outcomes of interest for each acute condition separately. In the first stage we will regress receipt of ES on the instrument, indicators for each financial year and the covariates (described above), and in the second stage we will regress the outcome of interest on the covariates and the predicted use of ES obtained from the first stage. The two stages will be estimated jointly so that standard errors reflect the uncertainty of both stages. We will report the generalized effect ratio (Baiocchi et al, 2010), that provides the same point estimates as two-stage least squares, but also correct confidence intervals (Keele et al., 2020).

Standard IV methods allow us to identify the Local average treatment effect, that is the effect for the subpopulation of compliers (those patients whose treatment assignment is actually altered by the level of the IV). Moreover, two-stage least squares (2SLS) is inappropriate in the presence of essential heterogeneity, that is heterogeneity in the effects of treatment according to unobserved characteristics (e.g. unmeasured prognostic measures), that are also predictive of treatment allocation (Basu et al., 2007). Hence the primary analysis will address these concerns by using a Local Instrumental Variable (LIV) approach (Heckman and Vytlacil, 1999; 2001).

### 3.2.2 Primary analyses: Local Instrumental Variable

By comparing outcomes for two groups of patients defined according to small differences in the TTO (the IV), but with similar risk profiles, we can provide estimates of the causal effect of ES for those patients who are regarded as 'marginal' in that they would be nudged towards having ES versus NES, by a small increase in the TTO that they face for that admission to that hospital at that time. By repeating this contrast across different levels of the TTO, we will estimate the required treatment effects for sets of marginal patients with different characteristics. The person-level effects of ES will then be estimated by averaging the effects for those marginal patients who share the same observed characteristics. The LIV approach will exploit information about the choice of ES for each individual according to their observed characteristics, and this relationship between the choice and the observed risk factors will be informative about the level of each patients unobserved characteristics.

***Overview of local IV Estimation:***

First, we will estimate each patient's propensity for ES according to their observed characteristics (covariates described above), indicators for each financial year and the hospital TTO using a probit model. Second, we will estimate the relationship of the observed patient characteristics, surgical volume for relevant emergency and elective procedures in the hospital over the preceding year, indicators for each financial year and their propensity for ES with each outcome. For binary outcomes (30-day, 90 day and 1 year mortality and emergency readmission) we will use probit models, for count outcomes (Days alive and out of hospital within 90 days), we will consider Poisson models, and for survival we will use a discrete-time hazard formulation as in Basu and Gore (2015).

From these regression models we will estimate the effect of a change in the propensity for ES on each outcome, that is the causal effects of ES for marginal patients providing person-level treatment (PeT) effect estimates for each patient. The resultant PeT effects can be interpreted for each patient as the difference in their predicted outcomes for ES versus NES. These person-level treatment

effects for each acute condition will be aggregated to report each relevant measure of the relative clinical effectiveness of ES vs NES for that condition, for example the mean difference in days-alive and out-of-hospital at 90 day. We will also report 95% CI for all effects, obtained using bootstrapping to capture estimation uncertainty in both the propensity for ES and the outcome models (Basu, 2015).

### 3.2.3 Subgroup analyses

After estimating personalized treatment effects, we will consider a limited number of subgroup analyses for each of the outcomes of interest, broadly defined in keeping with objective 1. Specifically, the subgroups will include: age (45-49; 50-54; 55-59; 60-64; 65-69; 70-74; 75- 79; 80-84; 85+ years), sex (male, female), ethnicity (White, Black/Black mixed, Asian/Asian mixed, other/not stated), deprivation (IMD quintile), number of co-morbidities in the Charlson index (coded 0, 1, 2, ≥3) and route of hospital admission (Emergency Department, GP or elsewhere in hospital), the Secondary Care Administrative Records Frailty (SCARF) Index (0–1, 2–3, 4–5, 6 or more deficits) and the individual's condition-specific sub-diagnostic group. The Study management committee will consider these groups and combinations of the groups for inclusion or exclusion of these subgroups once the descriptive analysis is complete, and define more granular subgroup definitions within a separate statistical analysis plan for objective 3.

The PeT estimates will be aggregated to the subgroup level and standard errors will be obtained using bootstrapping of the entire estimation process. We will explore alternative data-driven methods to identify unanticipated groups for whom ES is beneficial/harmful.

### 3.2.4 Sensitivity analyses

We will consider alternative, but plausible, selection criteria for the subpopulations, interventions and comparators of interest informed by the views of the clinical panel, and present alternative methods to consider the main assumptions that underlie the analyses, by considering these eight alternative scenarios:

1. For those conditions where there was a reasonable level of disagreement (at least 3/12 expressing a divergent view) amongst the clinical panel on the inclusion/exclusion criteria we will make few/further exclusions according to diagnostic subcategory. For those conditions, where there was disagreement about the appropriate time window for ES, we will consider shorter time windows.

2. We will contrast the results from reporting different causal quantities of interest by contrasting the results from the initial analysis that uses 2SLS ('compliers') with that from the local IV approach ('all patients who meet inclusion criteria')
3. We will compare the base case results from the local IV approach that assumes TTO is a valid instrument, with those of a OLS regression approach that assumes there is no unobserved confounding.
4. We will assess the sensitivity of results to excluding observations in hospitals with low surgical volume.
5. We will investigate whether our results are robust to alternative statistical models by estimating results using the plug-in principle for estimation (Keele et al. 2017).
6. To assess the sensitivity of result to immortal time bias, we will consider alternative thresholds for the time window used to classify as ES and if deemed necessary, we will use the cloning, censoring and weighting (CCW) approach as described in Hernán et al (2016).

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# Outputs

**Illustrative Example Tables and Figures**

**Figures 1 to 5:** Balance of covariates with respect to the instrumental variable for each condition (acute appendicitis, cholelithiasis, diverticular disease, abdominal wall hernia or intestinal obstruction)

**Figures 6(a,b) to 10(a,b):** Kaplan-Meier survival curves for (a) 1 year and (b) 10 year mortality for each condition (acute appendicitis, cholelithiasis, diverticular disease, abdominal wall hernia or intestinal obstruction)

**Figures 11 to 15:** Forest plot of Estimated Treatment Effects of Emergency Surgery versus non-Emergency Surgery on days alive and out of hospital prior to 90 days based on OLS, 2SLS and LIV methods for each condition (acute appendicitis, cholelithiasis, diverticular disease, abdominal wall hernia or intestinal obstruction). **[Similar graphs for other outcomes of interest]**

**Figures 16 to 20:** Forest plot of Estimated PeT effects of Emergency Surgery versus non-Emergency Surgery on days alive and out of hospital prior to 90 days according to subgroup variables for each condition (acute appendicitis, cholelithiasis, diverticular disease, abdominal wall hernia or intestinal obstruction). **[Similar graphs for other outcomes of interest]**

**Figures 21 to 25:** Forest plot comparing estimates using alternative inclusion/exclusion criteria for each condition and alternative time windows to define emergency surgery (Acute Symptomatic Hernia, Intestinal obstruction, Cholecystitis, Appendicitis, or Diverticulitis). **[Similar graphs for other outcomes of interest]**

**Tables 1-5.** Baseline characteristics of all patients receiving Emergency Surgery versus Non-emergency surgery by condition for each condition (Acute Symptomatic Hernia, Intestinal obstruction, Cholecystitis, Appendicitis, or Diverticulitis)

| | **Emergency Surgery** | **Non-Emergency Surgery** | **Standardized Difference** |
|---|---|---|---|
| **Number of observations:** | | | |
| | **Mean (SD)** | **Mean (SD)** | |
| **Age** | | | |
| **Sex:**<br>Male<br>Female | | | |
| **Ethnicity:**<br>White<br>Black/Black mixed<br>Asian/Asian mixed<br>Other/not stated | | | |
| **Index of multiple deprivation (IMD)** | | | |
| **Secondary care administrative records frailty (SCARF) index** | | | |
| **Royal College of Surgeons (RCS) Charlson Score** | | | |
| **Surgical volume for relevant emergency and elective procedures** | | | |
| **Financial year** | | | |

**Tables 6-10.** Baseline Characteristics for patients where tendency to operate was above vs below the median for each condition (Acute Symptomatic Hernia, Intestinal obstruction, Cholecystitis, Appendicitis, or Diverticulitis)

| | **TTO above the median** | **TTO below the median** | **Standardized Difference** |
|---|---|---|---|
| **Number of observations:** | | | |
| | **Mean (SD)** | **Mean (SD)** | |
| **Age** | | | |
| **Sex:**<br>Male<br>Female | | | |
| **Ethnicity:**<br>White<br>Black/Black mixed<br>Asian/Asian mixed<br>Other/not stated | | | |
| **Index of multiple deprivation (IMD)** | | | |
| **Secondary care administrative records frailty (SCARF) index** | | | |
| **Royal College of Surgeons (RCS) Charlson Score** | | | |
| **Surgical volume for relevant emergency and elective procedures** | | | |
| **Financial year** | | | |

**Tables 11-15.** Estimated PeT effects of Emergency Surgery versus non-Emergency Surgery for each outcome according to subgroup variables for each condition (Acute Symptomatic Hernia, Intestinal obstruction, Cholecystitis, Appendicitis, or Diverticulitis).

| | **Naïve estimate**<br><br>**Point estimate (Confidence interval)** | **2SLS**<br><br>**Point estimate (Confidence interval)** | **PeTIV**<br><br>**Point estimate (Confidence interval)** |
|---|---|---|---|
| **Number of observations:** | | | |
| | **Mean (SD)** | **Mean (SD)** | |
| Days alive and out of hospital:<br>- 90 days<br>- 30 days<br>- 1 year | | | |
| **Mortality:**<br>- 30 days<br>- 90 days<br>- 1 year | | | |
| **Readmissions (emergency surgery):**<br>- within 30 days<br>- within 90 days | | | |

**Timelines (2021 unless stated)**

- Provisional results to be available by Summer 2021
- Final results to be available by Autumn 2021
- Draft report to be submitted to NIHR by 14th October 2021

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