Volume of surgery during the COVID-19 pandemic in England and Wales: comparative analysis using routinely collected population level data

Statistical Analysis Plan

15.06.2020

Introduction

The healthcare response to the COVID-19 pandemic has required rapid changes to the provision of secondary care services, requiring re-deployment of staff and equipment from other departments. Surgical services represent a large portion of healthcare activity, accounting for 8-million hospital admissions to the United Kingdom (UK) National Health Service (NHS) every year. On 11th April 2020 National Health Service (NHS) issued guidance that postponed the majority of all non-urgent surgery. However, the full extent of the number of cases postponed and the volume of surgical activity that continued is unknown.

As the NHS response to the pandemic develops, there is a planned reintroduction of urgent elective surgical procedures. This will be complicated by many factors, and full service will take many months, if not years to resume. Meanwhile the waiting list for elective surgical procedures will continue to grow The associated disruption of diagnostic pathways during the pandemic has meant that many referrals have yet to make it into the system, likely resulting in significant 'pent up demand' and more advanced presentations of disease in the future.

In previous (under review) work we have used published Hospital Episode Statistics (HES) data to estimate the number of postponed surgical procedures in the NHS in England due to COVID-19. We then modelled multiple scenarios for the reintroduction of urgent and elective surgical activity over a nine-month period from June 2020. The proposed work here will build on this using routinely collected real time data on surgical volume during the pandemic response. Here, we will map the volume of surgery undertaken in England and Wales during the pandemic and compare this to expected numbers of procedures using a historical counterfactual.

Objectives of the study

Primary Objective

- To report the number of surgical procedures, undertaken between 1st January 2020 – 31st May 2020 in England and Wales.

Secondary Objectives

- To estimate the deficit in the number of surgical procedures that have occurred in England and Wales between 1st January 2020 – 31st May 2020, compared to the expected number of procedures according to activity data from the previous three years.
- To calibrate our existing surgical volume prediction model.
- To report the demographic details of the patients that underwent surgical procedures during the study period.
- To establish the type of surgery and admitting speciality of surgery during the study period.
- To establish the total bed days required to provide surgical care during the study period.
- To establish the number and proportion of day case procedures performed during and pre-Covid
- To use the results of the study to improve the previously developed model to predict the shortfall in surgical volume and likely burden this will place on the NHS in years to come.

Study design

An e-cohort study using routinely collected, population level data from NHS England and NHS Wales. A "COVID" cohort will be established from the Hospital Episode Statistics (HES) database and Patient Episode Database (PEDW) for all patients receiving surgical treatment in England and in Wales, respectively, between 1st January 2020 and 31st May 2020. These cohorts will be analysed separately due to data transfer restrictions but will be reported together.

Each patient will enter the cohort on the date of the admission in which the patient had their first procedure in the study window. Exit from the cohort will be determined by the last day of the cohort, death or moving out of the country.

Ethical Approval

Approval for Welsh data will be provided via a generic COVID best interest Information Governance Review Panel application which has already been put in place. Access to NHS England data will be via

NHS Digital. HRA approval will be obtained for the study with Barts Health NHS Trust as the sponsor for the English data approvals (application under review). An application to the Independent Group Advising on the Release of Data (IGARD) at NHS digital is in preparation.

Eligibility

Inclusion criteria

- All residents of England and Wales that receive surgical procedures as defined by three-character Office for Population Censuses Surveys Classification of Interventions and Procedures (OPCS) version 4.7 codes during the study period.

Exclusion criteria

- All procedures performed outside of the study periods.
- Patients with recorded OPCS codes that do not relate to surgical procedures (e.g. CT scan).

Data Analysis

Identification of surgical procedures

All eligible patients will be identified from HES and PEDW datasets during the study period. We will include all patients that underwent a surgical procedure according to a previously published definition of surgery.

All procedures will be classified into one of five groups as designated by NHS England on 11th April 2020 to define the number of operations that should have been stopped during the initial pandemic response. These are:

- *1a – Emergency operations needed within 24 hours*
- *1b – Urgent operations needed within 72 hours*
- *2 – Surgery that can be deferred for up to 4 weeks*
- *3 – Surgery that can be delayed for up to 3 months*
- *4 – Surgery that can be delayed for more than 3 months.*

Detailed patient demographics and their corresponding episode data will be described for each surgical category and for each admitting surgical speciality between 1st January 2020 and 31st May

2020. Continuous data will be reported as mean with standard deviation or median with interquartile range. Categorical data will be reported as number with a proportion.

The number of procedures that took place between 1st January 2020 and 31st May will be compared against the number of procedures predicted, using published data from HES and PEDW for the period 1st January 2016 – 31st December 2019. We will calculate the expected monthly frequency of surgical activity until 31st March 2021 by calculating the annual change in activity during the three-year period by procedure groupings from 1st January 2016 to 31st December 2019, which will be extrapolated using a linear growth assumption. We will adjust for monthly variation in elective and emergency admissions by weighting the estimates according to the proportion of elective and emergency admissions reported to NHS England and NHS Wales.

The following breakdowns will be reviewed:

- Total number of procedures;
- Number of procedures per speciality;
- Number of procedures per surgical category;
- Number of bed days.
- Number of pre-operative CT thorax performed
- Number of critical care admissions

A chi squared test will be used to determine whether there is a statistically significant difference between the observed number of cases and predicted number of cases. The null hypothesis is that of no difference between the observed and predicted number of procedures. Statistical significance will be assumed where $p < 0.05$. This analysis will be performed on the total number of procedures and per each of the pre-defined surgical categories, as described above.

The difference between the observed number of cases and predicted number of cases for the period 1st January – 31st May 2020 will be critically assessed. In the scenario that the predicted model is not accurate for this time period then a further model will be created based upon the results of this study.

Modelling analysis

The previous model was developed utilising data on patients based in England. In the scenario that this model does not successfully estimate the number of procedures in England and Wales that took place during the suspension of surgical services a further model will be created using additional Welsh data.

We will calculate the deficit of surgical procedures on 1st June 2020 with a 95% confidence interval, based on the difference between the expected and actual number of cases that took place. Following this we will use the same, previously described, model of surgical resumption from 1st June 2020, increasing to pre-pandemic levels. If a difference in class 1 procedures was seen during the pandemic, return to usual levels will be modelled from 1st June 2020. For class 2 procedures, we will assume a linear increase in activity over the three months from 1st June to 31st August 2020. We will add class 3 procedures into the model on 1st September and class 4 procedures on 1st December 2020. Finally we will assume that pre-pandemic levels of surgical activity would have resumed by 1st March 2021.