**The UK Foot and Ankle COVID-19 National (FAlCoN) Audit – Rate of COVID-19 infection and 30 Day Mortality in Foot and Ankle Surgery in the UK during the COVID-19 Pandemic**

**Abstract**

**Objectives:** The primary objective was to determine the incidence of COVID-19 infection and 30-day mortality in patients undergoing foot and ankle surgery during the global pandemic. Secondary objectives were to determine if there was a change in infection and complication profile with changes introduced in practice.

**Design:** Multicentre retrospective national audit.

**Setting:** UK-based study on foot and ankle patients who underwent surgery between the 13th January to 31st July 2020 – examining time periods pre- UK national lockdown, during lockdown (23rd March to 11th May 2020) and post-lockdown.

**Participants:** All adult patients undergoing foot and ankle surgery in an operating theatre during the study period included from 43 participating centres in England, Scotland, Wales and Northern Ireland.

**Main Outcome Measures:** Variables recorded included demographics, surgical data, comorbidity data, COVID-19 and mortality rates, complications, and infection rates.

**Results:** 6644 patients were included.In total 0.52% of operated patients contracted COVID-19 (n=35). The overall all cause 30-day mortality rate was 0.41%, however in patients who contracted COVID-19, the mortality rate was 25.71% (n=9); this was significantly higher for patients undergoing diabetic foot surgery (75%, n=3 deaths). Matching for age, ASA and comorbidities, the OR of mortality with COVID-19 infection was 11.71 (95% CI 1.55 to 88.74, p=0.017). There were no differences in surgical complications or infection rates prior to or after lockdown, and amongst patients with and without COVID-19 infection. After lockdown COVID-19 infection rate was 0.15% and no patient died of COVID-19 infection.

**Conclusions:** COVID-19 infection was rare in foot and ankle patients even at the peak of lockdown. However, there was a significant mortality rate in those who contracted COVID-19. Overall surgical complications and post-operative infection rates remained unchanged during the period of this audit. Patients and treating medical personnel should be aware of the risks to enable informed decisions.

**Keywords**

COVID-19; SARS-Cov-2, foot and ankle surgery; national audit; mortality; complications

**Introduction**

Since December 2019, a global pandemic has had a devastating effect on healthcare systems worldwide with 38,002,699 confirmed cases of COVID-19 and 1,083,234 deaths as of 14th October 2020.1 In the UK, NHS England declared a Level-4 National incident on the 30th January 2020, due to the COVID-19 global pandemic. As the hospital resources became overwhelmed, further announcements by NHS England asked NHS hospitals to reduce all elective activity, to the point of postponing all non-urgent elective procedures by the 15th April 2020, for a period of at least three months. Globally, Phillips et al found 11 reports of either selective or complete postponement of elective activity issued by orthopaedic governing bodies.2 On 23rd March 2020, the UK Government announced a national “lockdown” with the publication of guidance “Staying at home and away from others (social distancing)”.3 Guidance was produced by surgical governing bodies on rationing of services due to scarcity of hospital resources as the COVID-19 pandemic besieged the services.4

Regarding foot and ankle surgery in the UK, guidance was only issued specifically pertaining to the treatment of urgent orthopaedic conditions and trauma, aiming to maximise resource capacity, ensure patient and staff safety and enable triage and contraction of services as physical and personnel resources diminished .4 Further guidance to the prioritisation of cases in trauma and orthopaedics was issued by the Federation of Surgical Specialty Association, however only cases with removal of metal work across a joint and removal of intra-articular loose bodies were given an elective ‘high priority’.5 The impact of the COVID-19 and the risks it posed to health care personnel and patients who were to undergo surgery is still relatively unknown. The COVIDSurg collaborative published a multicentre observation study showing the significantly increased risks of mortality and morbidity in patients with COVID-19 infection at or around the time of surgical intervention. However, the risk of contracting the infection during or around the surgery was not assessed.6 Attempts have been made to estimate the risks to patients undergoing elective orthopaedic surgery, in asymptomatic patients with a negative SARS-CoV-2 test, however this remains theoretical.7 A recent national cohort study on upper limb surgery in the UK found that in 1093 surgically treated patients in April 2020, the risk of complication due to COVID-19 infection was 0.18%.8

***Aims and Objectives***

The primary objective of the study was to determine the percentage of patients receiving foot and ankle surgery in the UK, during the audit period, who were positive for COVID-19, and to audit their 30-day mortality rate. Secondary outcomes included comparing early complications of foot and ankle surgery in pre and post COVID-19 changes of practice.

**Methods**

***Study design***

This was a retrospective national audit of foot and ankle procedures, which had occurred in 43 UK centres (appendix 1) between 13th January 2020 and 31st July 2020. All patients who had undergone a foot and ankle surgical procedure were included in this study. Data was collected and anonymised by each participating NHS trust site and transferred securely to University Hospitals of Leicester NHS Trust (primary trust). Data collected was on comorbidities, physiological state, treatment/operation, and outcome. Data governance was dictated by European general data protection regulations. The study was approved and registered as a clinical audit at the lead centre (Ref No. 10795). To participate, each local project lead needed to confirm local audit approval.

In each unit, patients were identified retrospectively if they had undergone foot and ankle surgery in an operating theatre. Patients were categorised into those who had COVID-19 at the time of surgery (identified as patients who had test-proven or clinically diagnosed COVID-19 infection up to 7 days before surgery), patients who had developed COVID-19 after their surgery (identified as patients in whom COVID-19 was first suspected during their index admission or within the 30 days following surgery), or patients who did not contract COVID-19 or contracted COVID-19 outside of the period above. The thresholds for these different cohorts are in keeping with other COVID-19 surgical studies.6

# The inclusion criteria for this audit, were all patients undergoing any foot and ankle surgery in an operating theatre. Each theatre attendance was recorded as a separate event, and any multiple events required secondary analysis due to the theoretical increase in risk of COVID-19 infection. Diagnosis of COVID-19 was based on either a positive SARS-CoV-2 lab test orcomputed tomography (CT) chest scan or a clinical diagnosis (no COVID-19 lab test or CT chest performed) as per study protocols of other COVID-19 surgical studies.6

Site investigators were provided with a range of written materials, including study protocols, data collection sheets, audit enrolment advice and data protection agreements. In addition, investigators were invited to contact the national project leads for the purpose of troubleshooting site-specific recruitment issues and shared learning. These learning experiences were then shared across sites via electronic communication and displayed on the British Orthopaedic Foot and Ankle Society study specific website pages.

***Data Collection***

Laboratory testing for COVID-19 infection was based on SARS-Cov-2 viral RNA detection by quantitative RT-PCR. Sampling, including nasal swabs or bronchoalveolar lavage, and analyses were done according to individual hospital protocols. All work was done in National Health Service hospitals in the UK, where the procedures for COVID-19 identification were standardised as per government guidelines. Due to the limited testing availability in the early part of the COVID-19 outbreak, patients were also included based on either clinical or radiological findings. Clinical diagnosis consistent with COVID-19 infection was made by a senior physician and based on clinical presentation of symptoms highly indicative of COVID-19 infection, including a new continuous cough, fever (37.8º) or an inability to smell or taste.9 Radiological diagnosis was based on thorax CT, in keeping with locally implemented protocols. All patients included initially based on clinical or radiological criteria who subsequently had laboratory testing for SARS-CoV-2 infection and returned a negative result were excluded from the study.

Anonymised data was collected locally on encrypted spreadsheets before being uploaded to the Research Electronic Data Capture web application (REDCap, Vanderbilt, Tennessee). Data was collected from the 13th January 2020 to the 31st July 2020, allowing final 30-day mortality data to be collected on the 30th August 2020. Time periods were divided according to national guidance on the UK National lockdown (March 23rd 2020) and easing of the lockdown (May 11th 2020).3 Two data sheets required completion locally, the first indicating if the site had ‘blue’ pathways, ‘green’ pathways or both (defined as a split site). If the site had launched ‘green’ pathways, date of commencement was required. A ‘blue’ pathway was defined as all patients who were admitted to an acute hospital which has an accident and emergency/medical admissions unit where COVID-19 patients were also being admitted. However, foot and ankle procedures termed to have been undertaken with prevention processes in place to contracting COVID-19 (e.g. segregated clean unit, isolation period perioperative etc) was termed to have been undertaken on a ‘green’ pathway. Centres which do not admit acute patients (i.e. purely elective units) were also termed ‘green’ pathways.

The second data sheet comprised of the main data where patient demographics such as sex, age, ethnicity10, American Society of Anesthesiologists (ASA) physical status classification were collected. The primary outcome for COVID-19 diagnosis was recorded with the timing of COVID-19 diagnosis as either preoperative or postoperative. The method of COVID-19 diagnosis was entered as categorical data based on clinical or laboratory-based diagnoses. COVID-19 related complications and treatment of COVID-19 were entered as categorical data.

Surgery related variables were included. The foot and ankle diagnosis was recorded as categorical data. The diagnosis was classified based on limited variables based broadly on trauma, diabetic and elective practice. This was further divided by anatomical region and procedure. Operative variables included urgency (elective or emergency surgery), primary procedure completed (classified into manipulation under anaesthetic/plaster, percutaneous surgery, external fixation, open surgery, injection and arthroscopic procedure as categorical data), and anaesthesia used (local, regional, general or combination). Other surgical data included length of stay (days, COVID-19 positive length of stay recorded to point of diagnosis), urgency of surgery, and length of operation (recorded in minutes, including anaesthetic time). Dates recorded included date of injury for trauma and date of listing for elective, date of admission, date of surgery and date of discharge. Emergency surgery was defined as procedures classified by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) as immediate, urgent, or expedited.11 Comorbidities were entered as binary data into columns for current smoker, asthma/COPD, cancer, chronic kidney disease, cardiac disease, dementia, diabetes mellitus, hypertension, peripheral vascular disease and stroke. It was possible for other comorbidities to be entered by free text.

The secondary outcomes included surgical related infection (recorded as either superficial or deep), complications as binary data (surgery related and non-surgery related) and the ability to free text. Mortality was entered as categorical data (alive, died on table, died on day 0-7 and died on day 8-30 with the day of surgery defined as day 0. Before locking of the dataset for analysis, the senior local principal investigator for each hospital was asked to confirm data completeness and that all eligible patients had been entered into the database.

***Statistical analysis***

The study was completed according to STROBE guidelines for observational studies.12 Continuous variables were tested for normality distribution, and presented as means and 95% confidence intervals. Whereas categorical and qualitative variables are expressed as numbers and percentages. The Student t-test and ANOVA was used for continuous variables if the criteria for normality and equality of variances were fulfilled. Alternatively, the Mann-Whitney U test was performed. Categorical variables were analysed using the Chi-square test for sample sets greater than 5, otherwise the Fisher’s exact test was used. Missing data were included in flowcharts and descriptive analyses, allowing denominators to remain consistent in calculations.

In order to eliminate confounding demographic variables, propensity matching was performed with a 1:3 ratio for patients with COVID-19 infection and patients who died. The demographics to match with were chosen based on those which differed significantly between groups on ANOVA. The ratio of 1:3 was chosen so as to not discard usable data and matching was done with a random seed.

A binomial or multinomial logistic regression analysis was performed including all variables with p-values of < 0.15 from initial univariate analysis. For COVID-19 and mortality groups the regression was performed on matched data. The results were reported as odds ratios (OR) with 95% confidence intervals (95% CI). In general, a two-sided P < .05 was considered to be statistically significant. The primary adjusted model included preoperative variables to identify predictors of 30-day mortality. All data were assessed using SPSS Version 26.0 (SPSS Inc., IBM, Chicago, IL).

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***Role of the funding source***

This study was a collaborative effort of the Outcomes committee and Scientific committee of the British Orthopaedic Foot and Ankle Society who were involved in study design, data analysis, data interpretation, and writing of the report. The funders of the study had no role in the aforementioned aspects of the study. The corresponding author and analysis group had full access to all the data in the study and the corresponding author and the writing committee had final responsibility for the decision to submit for publication.

**Results**

A total of 43 UK centres participated in the audit and submitted cases as per the audit protocol. The total number of submitted episodes of surgically treated foot and ankle pathology was 7,413. As per flow diagram in figure 1, following exclusion of cases as per audit protocol, there were 6,644 cases left for further analysis. There was a 92.14% completion rate of all continuous and categorical data with length of surgery being the most common missing continuous variable and ethnicity being the most common categorical missing variable. The breakdown of variable completion is documented in appendix 1. All COVID-19 specific cases had 97% completion of continuous data and 100% completion rate of categorical data. Normality tests were completed for all continuous variables as illustrated in Appendix 2. The vast majority of continuous variables were normally distributed regardless of subset breakdown with the exception of age, length of stay and duration of surgery for patients positive for COVID-19 and for overall mortality. A summary of overall continuous variables is illustrated in table 1.

***Cases Positive for Symptomatic COVID-19***

There were a total of 35 patients who were confirmed positive for symptomatic COVID-19. All except one case was diagnosed subsequent to the surgical procedure. The one patient who developed COVID-19 pre-operatively was a trauma patient aged 32 years with ASA grade 2 (hypertension and asthma). They sustained their injury after their diagnosis of COVID and underwent urgent open fixation of an ankle fracture under regional anaesthesia. They suffered only minor respiratory complications, requiring ward-based oxygen during their admission. They recovered uneventfully and were discharged 5 days post-operatively.

The categorising of cases into both surgical type (trauma surgery, diabetic surgery and elective surgery) and time period is illustrated in table 2. More COVID-19 positive cases were seen in trauma and diabetic patients (p<.001) with the highest percentage being in diabetic patients during lockdown (10%). Variables which correlated significantly with being positive for COVID-19 included an increase in age (COVID-19 negative mean 51.83 years (SD 17.92) vs COVID-19 positive mean 64.46 (SD20.38), p<.001), length of stay (COVID-19 -negative mean 3.74 days (SD 8.86) vs COVID-19 positive mean 14.06 (SD13.18) p<.001), increase in urgency on NCEPOD (p<.001), higher ASA grade (p<.001) and presence of comorbidities (p<.001). Using propensity matching controlling for age, comorbidities and ASA grade there was a significantly lower risk of COVID-19 in elective group and in the post-lockdown time period. This data is summarised in table 4. There were 237 patients who underwent multiple surgical procedures. Having multiple surgical procedures did not increase the incidence of COVID-19 in this cohort. There was no significant difference in incidence in symptomatic COVID-19 cases between blue and green pathways.

***Mortality***

In the entire cohort there was a total of 27 deaths with 9 occurring in COVID-19 positive patients. Therefore, the all-cause mortality rate in foot and ankle surgery in this cohort was 0.41%. Excluding the COVID-19 cases from analysis, the all-cause mortality reduces to 0.27%. The further breakdown of numbers depending on surgical type and time-period is illustrated in table 3. The highest rate of 30-day all-cause mortality, excluding COVID-19 cases was witnessed in diabetic surgery post lockdown (2.38%). The highest rate of both 30 day all-cause mortality was witnessed in diabetic foot and ankle surgery during lockdown (6.67%) and the highest rate of mortality associated with COVID-19 was witnessed in diabetic foot and ankle surgery group pre-lockdown (100%, although there was only 1 patient in this subgroup).

On analysis of only the COVID-19 positive cases, the overall mortality rate was 25.71%. The factors that correlated with COVID-19 cases on regression analysis were also found to correlated with mortality. There were significant differences between COVID-19 negative related and COVID-19 positive related mortality rates pre-lockdown (p<.001) and during lockdown (p=.001), however post lockdown there was no difference. There has not been a COVID-19 related death in the post-lockdown time-period (Figure 2).

On propensity matched regression analysis (1:3 matching), the strongest independent risk for mortality was a positive diagnosis of COVID-19 (OR 11.7, 95% CI 1.55 to 88.74, p =.017). Urgency of surgery was the next major factor in increasing all cause 30 day mortality with immediate surgery having an OR of 39.31 (95% CI 1.31 to 1175.23), compared to elective surgery however urgency was not significant overall. There was a reduced risk of death in elective surgery and an increased risk of death in patients with non-surgical complications, but this was not statistically significant. The analysis for mortality can be seen in tables 4, 5 and 6.

***Complications***

Complications were recorded initially as surgical and non-surgical related. Across all surgical procedures there was a 6.07% incidence (n=403) of surgical and 2.05% incidence (n=1.9%) of non-surgical complications. The highest incidence of both surgical and non-surgical related complications occurred in the diabetic foot and anke surgery group (14.98% and 14.49% respectively). The breakdown of complications by surgical type is illustrated in table 7.

Regression analysis (Table 8) on the overall risk of surgical related complications showed the highest independent risk factor was the urgency of surgery, with immediate surgery having an OR of 7.47 (95% CI 2.37 to 23.51, p = 0.001) increased risk of complications compared to elective surgery. No other measured surgery related factors showed a significant increase in risk of overall non-surgical complications. Of the comorbidities recorded, dementia had a small increase in risk of developing surgical complications.

Specifically, regarding surgical related infections, small increases in risk for superficial infections were seen in longer operations, smokers, diagnosis of diabetes, longer surgery procedure time and increased time from injury to surgery. For deep infections there was an increased risk with length of stay, however this could be an effect rather than a cause.

Relating to COVID-19 positive cases, respiratory complications were reported in 51.43% of the 35 cases, with minor respiratory complications in 17.14% (n=6) and major respiratory complications in 34.29% (n=12). Diabetic surgery had a higher rate of respiratory complications. Renal complications were reported in 17.14% of COVID-19 positive cases (n=6), again more commonly in diabetic surgery as compared to trauma or elective surgery (25.00%, 17.86% and 0% respectively). Summarised in Figure 3.

**Discussion**

The primary objective of this national audit was to determine the percentage of patients receiving foot and ankle surgery in the UK during the audit period who were positive for COVID-19, and to audit their 30-day mortality rate. Although the audit did not include all centres in the country, the percentage of patients receiving foot and ankle surgery who had a positive diagnosis for COVID-19 in the perioperative period was determined to be 0.52%. A number of authors have discussed the concept of establishment of non-COVID-19 Care zones including stand-alone hospitals, separate units on site or specialised wards to facilitate patient admission and discharge.13 In our audit, COVID-19 infections occurred in both blue and green pathways, with no significant difference between the pathways however there was a trend toward reduced numbers in green pathways. In comparison, Glasbey et al published results on ‘safe’ pathways in elective cancer surgery, and found a significant reduction in risk (2.1% *v* 3.6%; OR, 0.53; 95% CI, 0.36 to 0.76) with the use of dedicated ‘safe’ pathways as compared to not.14 Before lockdown there were three positive COVID-19 cases in elective foot and ankle surgery, of which one died. Therefore, the use of ‘safe’ pathways and the reinstitution of elective practice should not be seen as without risk.

The total all-cause 30 day mortality rate in our study was found to be 0.41%, decreasing to 0.27% if COVID-19 positive patients were excluded. In patients positive for COVID-19, there was a 25.71% chance of mortality. This rate is not dissimilar to rates reported in hip fracture patients who underwent surgery for proximal femoral fractures, with a Spanish multicentre observational study on 136 proximal femoral fractures reporting a mortality rate for 23 patients who tested positive for COVID-19 to be 30.4% (7 of 23 patients) at a mean follow-up of 14 days.15 A large multicentre review in the UK compared 340 COVID-19 negative patients with 82 COVID-19 positive patients undergoing surgery for hip fractures, and also reported a significant increase in mortality rates (30.5% (25/82) vs 10.3% (35/340).16 A national cohort study on upper limb surgery in the UK in April 2020 found the overall 30-day mortality was 0.09% (1 pre-existing COVID-19 pneumonia) and the mortality of day case surgery was zero.8 They also report that there were 19 confirmed cases of COVID-19 in their cohort (1.7%), but if only including the confirmed cases the percentage of mortality in COVID-19 positive patients was 5.25%. The COVIDSurg collaborative reported a 30 day mortality of 23.8% in 1128 COVID-19 positive patients undergoing surgery of any kind.6 Therefore, at this time it is prudent to counsel patients of the increased risk of mortality when undergoing foot and ankle surgery in the COVID-19 pandemic period.

Our audit may not be comparable to the previous studies in other surgical specialties due to the larger numbers in our cohort and the longer period of time it analysed. For example, the upper limb study by Dean et al, only analysed the reported UK peak of April, however 45.71% of our positive cases and 66.67% of our COVID-19 related deaths occurred prior to their date of analysis.8 The mortality rate across the three time periods has significantly reduced, with no cases of deaths related to COVID-19 reported after lockdown. Similarly, the studies relating to hip fractures and all surgery reported on the early stages of the pandemic.6,15,16 There are many factors contributing to the relative reduction over time of the mortality rate in our study, like reducing prevalence in the population, triaging of surgical practice4 and an improvement in the care of the respiratory sequalae of the COVID-19 infection.17 In our cohort, all but one patient developed COVID-19 post-surgery. The COVIDsurg collaborative recently published evidence that waiting greater than 4 weeks post positive test for COVID-19 was protective of both pulmonary complications and mortality.18 In our series, the patients underwent urgent ankle surgery under regional anaesthesia and did not develop any major pulmonary or renal complications.

Our audit also established that there was no difference between surgical and non-surgical complications of foot and ankle surgery between the time periods of pre-lockdown, lockdown and post-lockdown. There was however a significant difference in rate of complications between surgical types, with diabetic foot and ankle surgery carrying the highest risk, followed by trauma surgery, and with elective surgery carrying the lowest risk. Therefore, any system changes that have occurred during or post-lockdown, do not appear to have increased the risk of complications in patients. Smeeing et al reported an increased risk of wound complications in ankle fractures with increasing age, ASA grade and smoking. 19 Our audit has shown these factors to be ubiquitous across all foot and ankle surgery regardless of relation to COVID-19 infection. The main overall factor however for the development of complications across the audit was the urgency of surgery.

Diabetic surgery had the highest risk of respiratory and renal complications related to COVID-19, although diabetes as a comorbidity did not carry an increased risk across the entire audit population. This may represent this difference of ‘complicated’ diabetes as termed by Gougoulias et al where the act of undergoing diabetic surgery, is evidence to the presence of chronic poor glycaemic control.20 A number of studies have reported changing practices globally in an effort to reduce the exposure of Diabetic patients with related foot pathology to COVID-19.21,22 However, our audit has shown the significant increase in risk diabetic surgery incurs in this time of COVID-19 and therefore all effort needs to be made in prevention of foot and ankle complications that may result in surgical requirement.

Our audit has limitations. This was a retrospective audit of observational data. Although it is the largest audit of its kind in foot and ankle surgery, it does not fully represent the UK practice. This study included all patients undergoing foot and ankle surgery in an operating theatre, however during the lockdown period a number of patients may have had interventions outside of an operating theatre or may have been treated non-operatively; this may include patients who had sedation in the emergency department or patients who may have had COVID-19. These patients would not be captured by this audit. We included patients who had COVID-19 between seven days prior and 30 days after their procedure; it is not currently known whether one week is sufficient to reduce the peri-operative risk. It may be that we have therefore not captured complications in patients who had COVID pre-operatively, but longer than seven days prior to surgery. However, our protocol is in line with other large published studies such as COVIDSurg.6 In the early phase of our study COVID-19 swab testing was not widespread and patients were considered to have COVID-19 based on symptoms – therefore it is possible that the incidence of COVID-19 was higher than reported for this time period. Similarly, identification of COVID-19 status post-discharge was based on local / regional databases and data from readmissions. Patients who had asymptomatic COVID-19 or who travelled to another region post-operatively and developed COVID-19 may not have been captured. As such, the number of COVID-19 positive patients may be an underestimate. As a retrospective series, some datasets were incomplete and there is a higher chance of errors in dates recorded. However, with a large cohort size of over 6000 patients we feel that the data presented is representative. Our primary outcome measures looked at rates of COVID-19 infection and mortality, however the numbers of cases of COVID-19 and mortality were small. Therefore, even small increases in numbers could change significance and some of the percentages presented may provide a misleading picture. It is therefore important that absolute numbers be considered when using this data to plan future interventions or counselling patients. Finally, there were significant differences in age, ASA grade and co-morbidity profile between patients who died and contracted COVID-19 versus those who did not. These factors are to be expected, but to mitigate for these we performed propensity matching with a 1:3 ratio. This allowed us to better compare groups, but it is possible that other factors played a role that we did not capture in this audit.

**Conclusion**

The national audit in foot and ankle surgery across the UK before, during and after the UK national lockdown showed that the percentage of patients receiving foot and ankle surgery who had a positive diagnosis for COVID-19 in the perioperative period was determined to be 0.52%.The 30 day mortality rate in our audit was found to be 0.41%, decreasing to 0.27% if COVID-19 positive patients were excluded. In patients positive for COVID-19, there was a 25.71% chance of mortality. Patients and treating medical personnel need to be aware of the risks to enable informed decisions.

**Figure Captions:**

**Figure 1** – Flow diagram displaying data cleansing of submitted data, with different levels of case exclusion.

**Figure 2** – Graphical representation of mortality rates for patients diagnosed with COVID-19 categorised into time periods and by case type.

**Figure 3** – Graphical representation of type of treatment received by patients with COVID-19 and the COVID-19 related complications these patients experienced.

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**Data sharing statement**

Data was collected by each participating NHS trust site and transferred securely to University Hospitals of Leicester NHS Trust (primary trust). The data collected locally on encrypted dated sheets was then uploaded to the Research Electronic Data Capture web application. All data was anonymised.

Only anonymised data was transferred to the primary trust. All data complied with the requirements of the current legal framework in relation to data processing and with the *Regulation (EU) 2016/679* of the European Parliament and of *the Council of 27 April 2016* on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing *Directive 95/46/EC* (General Data Protection Regulation) as set out in the data processing agreement (uploaded separately).

The study will be carried out in accordance with national and international guidelines, as well as the basic principles of the protection of the rights and dignity of Human Beings, as set out in the Helsinki Declaration (64th Assembly Fortaleza, Brazil, in October 2013), and according to current legislation.