

# BMJ Open Quality Consent for orthopaedic trauma surgery during the COVID-19 pandemic

Hussain Selmi,<sup>1</sup> Andrew Davies,<sup>2</sup> Joseph Walker,<sup>1</sup> Toby Heaton,<sup>1</sup> Sanjeev Sabharwal,<sup>1</sup> Melanie Dani,<sup>2</sup> Michael Fertleman,<sup>2</sup> Peter Reilly<sup>1</sup>

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## ABSTRACT

**Introduction** The COVID-19 pandemic has brought a series of new challenges to the management of surgical patients. The consent process relies on a foundation of open and non-coerced discussion between clinician and patient, which includes all the potential risks of surgery. This must be updated to incorporate the additional risks of surgery during the pandemic including infection with the SARS-CoV-2 and increased risks of complications with the potential requirement for intensive care support.

**Aim** The aim of this multi-cycle quality improvement project was to ensure all patients were fully informed of the risks of developing COVID-19 and the possible need for intensive care unit (ICU) support.

**Methods** We investigated the quality of the consent process for patients undergoing surgery for trauma at our major trauma centre. Our baseline data collection included a review of all orthopaedic trauma consent forms over a 4-week period in March 2020. We subsequently undertook three further Plan-Do-Study-Act (PDSA) cycles over separate 4-week periods. First, in June 2020, after education measures and presentation of baseline data, second in July 2020 after further education and regular digital reminders were sent to staff, and third in September 2021 after the implementation of an electronic consent form.

**Results** At baseline, only 2.6% of consent forms mentioned the risk of COVID-19 and none mentioned the risk of requiring ITU support. Through three PDSA cycles this increased to 97% of cases where consent forms displayed the additional risks of COVID-19 and the potential need for ITU admission.

**Conclusion** Our quality improvement project improved the informed consent procedure at our trust. By incorporating these additional risks into the template of an electronic consent form, we hope to achieve sustained improvement in practice.

## PROBLEM

The COVID-19 pandemic resulted in the postponement of elective operating services, diversion of trauma patients to specific hospitals and the redeployment of surgical staff.<sup>1</sup>

Our regional trauma centre continued to provide surgical care for emergency orthopaedic admissions with daily dedicated operating lists. There is a risk of patients contracting SARS-CoV-2 leading to COVID-19 disease while in hospital, and multinational collaborative work demonstrated an

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Patients undergoing surgery during the COVID-19 pandemic have an increased risk of SARS-CoV-2 infection and subsequent intensive care unit admission.

## WHAT THIS STUDY ADDS

⇒ We identified strategies to update our consent process and incorporate these additional risks of surgery.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ A new electronic consent process led to a substantial improvement in the preoperative consent of trauma patients and has the potential for a sustained improvement in practice.

increased risk of mortality in patients with confirmed SARS-CoV-2 infection undergoing elective and emergency surgery.<sup>2</sup> It has been important to update the patient consent process to incorporate the additional risks of surgery.

The aim of this multi-cycle quality improvement project is to assess if patients undergoing surgery for trauma are fully informed of the potential risks of developing COVID-19 and the need for intensive care unit (ITU) support. We aimed to ensure more than 95% of consent forms documented these additional risks.

## BACKGROUND

Informed consent in a patient with the capacity to make decisions about their care is imperative prior to any surgical procedure. Best practice for consent requires all risks, independent of severity, should be explained to the patient and all elements should be clearly documented.<sup>3</sup> Furthermore, alternatives to surgery and the associated risks must be discussed.<sup>4</sup>

The risk of surgery differs according to the COVID-19 status of the patient. In trauma patients from a large multi-centre study from the US, COVID-19 was associated with



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<sup>1</sup>Department of Trauma and Orthopaedics, Imperial College Healthcare NHS Trust, London, UK

<sup>2</sup>Centrale Perioperative and Aging Group, Department of Bioengineering, Imperial College, London, UK

## Correspondence to

Hussain Selmi; h.selmi@nhs.net

increased complications, length of stay and mortality.<sup>5</sup> An Italian study investigating the surgical management of proximal femoral fractures demonstrated that COVID-19 led to a more complex postoperative course, resulting in a significant increase in deaths in the first 3 postoperative weeks.<sup>6</sup> This is supported by the results of a further study of 259 patients with COVID-19, who underwent surgery for hip fractures, which reported higher ITU admissions and longer inpatient stays.<sup>7</sup> International multi-centre collaborative work investigating emergency adult surgical patients reported a risk of in-hospital mortality of 3.6% in those with a negative COVID-19 test compared with 15.5% in patients tested positive for COVID-19.<sup>8</sup>

The risk of acquiring COVID-19 during a patient's admission must be considered. An early meta-analysis reported that 44% of cases could be attributed to nosocomial infections.<sup>9</sup> A cohort study of 584 patients undergoing emergency surgery in the UK reported an infection rate of 5.1% while in hospital.<sup>10</sup> In a further UK study focused on urgent elective surgery, 1.4% of patients acquired COVID-19 within 30 days of the procedure.<sup>11</sup> It is vital that the risks of surgery and COVID-19 infection are carefully explained and documented during the consent process.

## BASELINE MEASUREMENT

All orthopaedic trauma procedures over a 4-week period in March 2020 were reviewed, corresponding to the start of the first 'lockdown'. Written consent forms were analysed to determine whether they explicitly mentioned the risk of COVID-19 and sequelae such as ITU admission. Documenting non-specific 'infection' was not accepted. For patients who lacked capacity, consent was completed in the patient's best interests, after discussion with the next of kin and among the multi-disciplinary team about the best way to proceed. These patients were excluded from our analysis as the consent process is documented in a different format.

Forty-six consent forms were analysed. In 30 cases, the patient had capacity to make informed decisions about their care, in 7 cases a parent consented on behalf of their child, and in 9 cases the patient lacked capacity. Thirty-seven consent forms met our inclusion criteria. Only 1 of the 37 consent forms mentioned COVID-19 (2.7%) and none mentioned the risk of possible ITU admission (0.0%).

We published these preliminary results at our local audit meeting highlighting our poor adherence to best practice guidelines regarding COVID-19 and consent. We then planned further cycles of data collection and interventions.

## DESIGN

A QI team consisting of a consultant orthopaedic surgeon and orthogeriatrician, a cohort of junior doctors, IT support staff and additional team members was formed. We considered it important to have representation from

both the surgical team performing the operation and the medical team who support the care of patients on the ward. In preparation for this work, we reviewed the quality, service improvement and redesign (QSIR) tools provided by NHS England<sup>12</sup> and guidance provided by the Healthcare Quality Improvement Partnership.<sup>13</sup> We considered our methodology in the context of the quality improvement literature.

We focused on formal education of staff members at audit meetings and through messaging reminders. Any new members to the department were informed of the need to consent for COVID-19 and ITU admission. During the cycles, the team discussed new strategies for improvement and planned when data collection and analysis would take place.

Staff education and reminders may become less effective with time. To achieve a sustainable improvement in practice, we introduced an electronic consent with COVID-19 and ITU admission already available as risks on the consent form. This would act as a clear reminder to the clinician obtaining consent.

## STRATEGY

Our goal was to make appropriate interventions to ensure more than 95% of consent forms display additional risks of COVID-19 and the potential need for ITU admission. We undertook three Plan-Do-Study-Act (PDSA) test cycles.

### PDSA cycle 1

Our initial interventions included education of staff at the local audit meeting to increase awareness regarding consent for the additional risks of COVID-19 and sequelae such as ITU admission. Following this, the meeting minutes were circulated to all staff emphasising these points, and the work was published online.<sup>4</sup> Data was then collected over a 4-week period in June 2020. In total, 99 consent forms were analysed, of which 10 were excluded as the patient lacked the capacity to consent. We achieved an increase in compliance; 32 of 89 (36%) consent forms documented the risk of COVID-19 infection compared with only 2.7% during baseline measurement. Furthermore, we found that the risk of potential ITU admission secondary to COVID-19 was documented in 10 of 89 (11%) consent forms compared with 0% at baseline measurement. This represented a modest improvement. The feedback we received from members of the department and QI team demonstrated that ongoing reminders are required, rather than presenting data at a one-off meeting where not all relevant members of staff are present.

### PDSA cycle 2

In order to develop and enhance staff reminders, we regularly distributed material on consent guidance to all clinicians as well as sending digital reminders via email and mobile messaging services. We re-presented the collected data at an audit meeting to strengthen the message throughout the department. This led to improvement

in the consent process shown by our results in July 2020. During this period, 109 consent forms were analysed. Ninety-seven consent forms were for adults who had capacity and three were for children. We excluded nine consent forms for patients who lacked capacity. The risk of COVID-19 infection was mentioned in 73 of 100 (73%) consent forms and the risk of ITU admission documented on 26 (26%). Although this was a sizeable improvement, adherence to guidelines remained unsatisfactory. On busy on-call shifts, with rotating staff and large volumes of patients, this continued to be missed. We hypothesised that further improvement could be made by making the consent process more efficient and convenient.

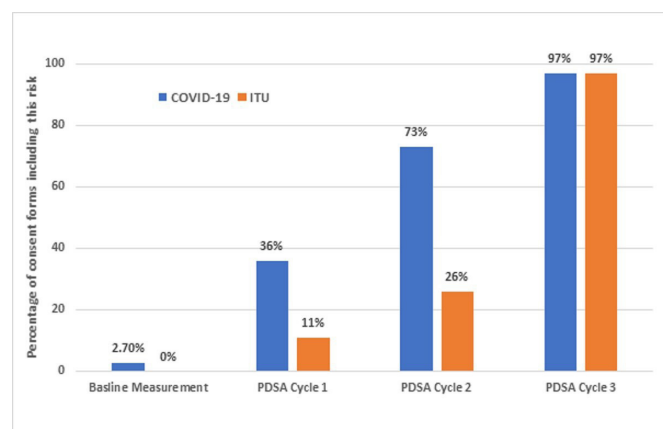
### PDSA cycle 3

In order to achieve our aim, we introduced a formal electronic consent process within our department which included these risks. When performing the electronic consent process, the clinician simply had to check the box following discussion with the patient, and these risks would automatically be added to the form for the patient to sign. A copy of the form was also uploaded to the patient's medical records. During this cycle, we reviewed 54 electronic consent forms over a 4-week period in September 2021. All were for adults with the capacity to consent. This intervention resulted in a significant improvement with 52 of 54 (97%) consent forms mentioning both COVID-19 and potential ITU admission.

## RESULTS

Each subsequent intervention resulted in improvement in the consent process. There was an increased percentage of consent forms documenting these additional risks of COVID-19 and ITU admission, from 2.7% in baseline measurement to 97% after PDSA cycle 3 (figure 1).

Through cycles of education and the introduction of a convenient and efficient electronic consent process, we improved adherence to best practice guidelines on COVID-19 and consent.<sup>12</sup>



**Figure 1** Percentage of consent forms that recorded the risks of COVID-19 infection and ITU support across the PDSA cycles. ITU, intensive care unit; PDSA, Plan-Do-Study-Act.

## LESSONS AND LIMITATIONS

The aim of this work was to improve our consent process and the documentation of the risks of COVID-19 and ITU admission in patients undergoing trauma operations. This required us to re-design the way we document consent to ensure these important risks are not overlooked, especially with large volumes of patients and emergencies at our major trauma centre. The work highlighted the importance of PDSA cycles, which allowed constant re-evaluation and optimisation of interventions prior to dissemination across the department.

Following the first intervention, we noticed a modest improvement in results. We attributed this to not all staff members being aware of initial work due to redeployment and sickness, and well-established consent practices. Additionally, with the scientific evidence and hospital policy surrounding the pandemic constantly evolving, it was difficult for staff to provide up-to-date and reliable information regarding the risks of surgery. This project highlighted that positive change can take time to establish when routines and staff roles are constantly changing.

The greatest improvement was seen following implementation of regular educational measures locally. However, a potential limitation was that despite education, the changing staff meant that the message was not received by everyone. We attempted to overcome this by informing new doctors of this project at departmental induction and sending reminds. Continuing such education is vital until new practice is fully established and becomes part of the routine consent process. We did not specifically evaluate what staff had learnt following our educational interventions. This would provide greater insight about the effectiveness of this approach. Highlighting positive links between educational interventions and patient outcomes to staff may result in behavioural change, which leads to long-term improvements.<sup>14</sup> The Kirkpatrick Model<sup>15</sup> may be used to assess the strength of educational interventions. This widely used four-stage model evaluates the reaction of the participants and their learning, subsequent behavioural changes and definitive results of the training.

Furthermore, as the impact of the pandemic worsened, staff became more vigilant about including the risk of COVID-19 and subsequent ITU admission on consent forms, which also contributed to the improvement in compliance. However, as no formal evaluation of education was done, it is important to note that an increase in compliance may also have occurred due to the staff gaining knowledge from other sources and personal experiences.

Going forward, by consenting patients electronically, the process has become more reliable and efficient and may reduce the risk of errors. It will ensure we continue to align our practice with British Orthopaedic Association guidelines on informed consent during COVID-19, which included discussion regarding the risk of developing SARS-CoV-2 infection.<sup>16</sup>



The risks of COVID-19 and ITU admission are presented as options on the electronic form, which will serve as a constant reminder for clinicians to discuss these risks with the patient. We continue to rely on surgeons to tick the pertinent box on the consent form and discuss this with the patient, and there is still a risk of omission. We will continue to collect data on compliance with feedback to surgeons. This will aid in ensuring we consent for COVID-19 and subsequent ITU admission for all trauma patients.

## CONCLUSION

Our quality improvement project improved the informed consent procedure at our trust. Through three PDSA cycles we achieved our goal of more than 95% of consent forms displaying the additional risks of COVID-19 and subsequent ITU admission. At this major trauma centre, surgical teams rotate on a daily basis, multiple surgeons were responsible for consent. By incorporating these additional risks into the template of an electronic consent form, we aim to achieve sustained improvement in practice. Furthermore, this work can be easily replicated at other trusts who use electronic consent forms.

Infection with COVID-19 can result in substantial morbidity and mortality, and therefore patients should be fully aware of the additional risks prior to having surgery. The consent process relies on the foundation of open and non-coerced discussion between clinician and patient.<sup>17</sup> By continuing to evaluate this at regular intervals, we aim to maintain the highest standards of informed consent.

**Contributors** HS contributed to planning, interventions used in PDSA cycles, data collection, analysis, as well as writing and editing the manuscript. AD contributed to study concept, planning, interventions used in PDSA cycles, data collection, analysis and editing the manuscript. JW and TH contributed to data collection, analysis and interventions used in PDSA cycles, such as local presentation and dissemination of electronic reminders. SS and MD contributed to study design and editing the manuscript. MF and PR contributed to study concept, planning and approving the manuscript, as well as overall supervision and are guarantors of the study.

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