

GENERAL ORTHOPAEDICS

How to prioritize patients and redesign care to safely resume planned surgery during the COVID-19 pandemic

A CLINICAL VALIDATION STUDY

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Aims

Restarting planned surgery during the COVID-19 pandemic is a clinical and societal priority, but it is unknown whether it can be done safely and include high-risk or complex cases. We developed a Surgical Prioritization and Allocation Guide (SPAG). Here, we validate its effectiveness and safety in COVID-free sites.

Methods

A multidisciplinary surgical prioritization committee developed the SPAG, incorporating procedural urgency, shared decision-making, patient safety, and biopsychosocial factors; and applied it to 1,142 adult patients awaiting orthopaedic surgery. Patients were stratified into four priority groups and underwent surgery at three COVID-free sites, including one with access to a high dependency unit (HDU) or intensive care unit (ICU) and specialist resources. Safety was assessed by the number of patients requiring inpatient postoperative HDU/ICU admission, contracting COVID-19 within 14 days postoperatively, and mortality within 30 days postoperatively.

Results

A total of 1,142 patients were included, 47 declined surgery, and 110 were deemed highrisk or requiring specialist resources. In the ten-week study period, 28 high-risk patients underwent surgery, during which 68% (13/19) of Priority 2 (P_2 , surgery within one month) patients underwent surgery, and 15% (3/20) of P_3 (< three months) and 16% (11/71) of P_4 (> three months) groups. Of the 1,032 low-risk patients, 322 patients underwent surgery. Overall, 21 P_3 and P_4 patients were expedited to 'Urgent' based on biopsychosocial factors identified by the SPAG. During the study period, 91% (19/21) of the Urgent group, 52% (49/95) of P_2 , 36% (70/196) of P_3 , and 26% (184/720) of P_4 underwent surgery. No patients died or were admitted to HDU/ICU, or contracted COVID-19.

Conclusion

Introduction

Our widely generalizable model enabled the restart of planned surgery during the COVID-19 pandemic, without compromising patient safety or excluding high-risk or complex cases. Patients classified as Urgent or P_2 were most likely to undergo surgery, including those deemed high-risk. This model, which includes assessment of biopsychosocial factors alongside disease severity, can assist in equitably prioritizing the substantial list of patients now awaiting planned orthopaedic surgery worldwide.

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The sudden emergence of SARS-CoV-2 led to a global pause of a projected 28 million planned surgeries, most commonly in orthopaedics.¹

A sizeable proportion of patients awaiting arthroplasty report that their quality of life is so diminished that it measures 'worse than death' using health-related quality of life metrics.² On the other hand, some patients may prefer to defer planned surgery due to fear of contracting the disease during hospitalization, which may result in loss of function and reduced life expectancy as a result of delay. Waiting is far from benign—patients are in physical and psychological distress,³⁻⁵ and may get worse⁶ and consequently benefit less from surgery.⁷ Furthermore, cancellation due to COVID-19 has compounded existing symptoms with significant anxiety, related to job insecurity and economic uncertainty.^{4,5} Restarting surgery is thus a clinical and societal priority, but must be done safely and equitably.⁸

There is an enormous demand-supply mismatch for planned surgery after COVID-19. Thus, all systemsregardless of how they are funded-should stratify patients using validated tools.^{9,10} Prioritization of patients is complex and contentious, determined by where patients are on a waiting list, what procedure they are undergoing, patient-specific characteristics, the disease severity, and biopsychosocial factors. Clinically urgent procedures in medically comorbid patients may be high-risk endeavours, and almost by definition concern patients with risk factors which place them at increased risk of harm from COVID-19.¹¹⁻¹³ If an estimate of the current global infection fatality rate (1.04%) is applied, the theoretical risk of a patient with an undetected infection being admitted for planned surgery and subsequently dying from COVID-19 is estimated at approximately 1 in 140,000.14

As the risk is low, and the potential suffering great, there is a need to develop and prove the effectiveness of COVIDfree pathways for planned surgery. The American College of Surgeons and the Royal College of Surgeons of England have offered guidelines for resumption, highlighting economic and logistical preparedness, the delivery of high-quality, safe patient care,^{15,16} and COVID-free hospital sites to separate patients undergoing planned surgery from acute admissions and services. It is suggested that they maintain their COVID-free status by screening staff on a regular basis, screening patients and isolating them preoperatively, preferentially using regional anaesthesia, and minimizing the length of their stay. To this end, the NHS and NHS Improvement worked with the Independent Healthcare Providers Network in April 2020 to purchase most of the available operating capacity in independent hospitals and surgical centres.¹⁷ These sites should operate protocols which maintain their COVID-free sites so that they can protect patient safety while delivering timely and necessary surgery to even the most vulnerable.

The Federation of Surgical Speciality Associations (FSSA) provided a guide for prioritizing patients based on the urgency of the awaited procedure (Table I).¹⁸ The British Orthopaedic Association (BOA) recommends that for patients with the same condition and needing the same surgery, there will need to be a method for selecting the order of priority, taking into account waiting list

Table I. Procedural urgency levels determined by the Federation of Surgical Speciality Associations (Federation of Surgical Speciality Associations 2020).

Urgency level	Recommended time to surgery	
1a	< 24 hours (Emergency procedures)	
1b	< 72 hours	
2	< 1 month	
3	< 3 months	
4	> 3 months	

order, clinical priority, and COVID-19 risk.¹⁹ This severity and duration of symptoms, complexity, risks, and likely outcome of the proposed operation should all be considered in prioritization.

The aims of this study were to integrate national policy and guidelines to develop an evidence-based prioritization guide to restart planned surgery in an equitable manner; apply it to patients awaiting planned orthopaedic surgery in a high-risk/resource site or a COVID-free site; and validate it by assessing whether it enabled the resumption of service without jeopardizing patient safety.

Methods

In our institution, a multidisciplinary team of surgeons, anaesthetists, nurses, and hospital managers formed a surgical prioritization committee (SPC), as recommended by the American College of Surgeons.²⁰ This considered complex patient factors alongside local resources and demands. It developed a Surgical Prioritization and Allocation Guide (SPAG) (Figure 1) and two new COVID-free patient pathways for patients awaiting planned surgery. We included all adult patients who were on or added to the planned surgery waiting list prior to 28 August 2020. who had not had their operations prior to the cessation of routine surgery. Patients were excluded if their operation was classed as level 1 urgency (required within 24 hours or sooner), if they were under 17 years of age, or if their patient record had incomplete or anomalous data. Electronic hospital medical records for each patient were retrospectively examined at 30 days, documenting any subsequently positive COVID-19 tests, intensive care admissions, or mortalities.

SPAG considered three facets of planned surgery: safety (the safety of the procedure and the need for specialist equipment or expertise, and the risk profile of the patient); biopsychosocial factors (expediting patients for whom delay would impact their independence, work, or their own vulnerable dependents, or result in psychological distress or opiate dependence; biopsychosocial factors identified in validated clinical priority setting exercises in general and orthopaedic surgery were noted in patients' medical records or when patients were contacted for surgery);^{9,21,22} and procedural urgency (prioritizing the most efficacious procedures and

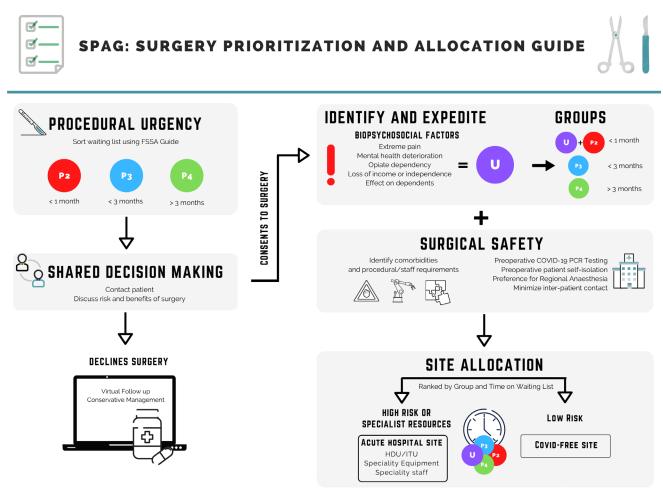


Fig. 1

Infographic demonstrating the Surgery Prioritization and Allocation Guide (SPAG). PCR, polymerase chain reaction; HDU, high dependency unit; ITU, intensive therapy unit.

those where delay would jeopardize the outcome, as per national guidelines).¹⁸

Development of planned surgery pathways. The NHS multispeciality hospital was split to create a separate COVIDfree hospital-within-a-hospital. These inpatient wards and operating theatres were isolated from acute services and outpatient clinics of the main hospital with a separate pool of COVID-free staff, but had access to the highdependency and intensive care units if required. High-risk patients or those requiring specialist staff or equipment were allocated to this site. There were two sites designated for low-risk patients undergoing routine procedures: an NHS surgical centre, and a local independent surgical centre whose operating capacity was purchased en bloc to increase capacity.

Application of the SPAG. Orthopaedic surgeons retrospectively interrogated their own waiting lists for planned surgery. They contacted patients to discuss their condition and willingness to undergo surgery during the pandemic. Surgeons and patients engaged in shared decisionmaking,¹⁹ including discussing the risk of contracting COVID-19 during hospitalization and its sequelae in highrisk patients. Surgeons placed consenting patients into three priority groups based on the predicted procedural efficacy and urgency (Table II).¹⁸ Additionally, surgeons identified patients with additional biopsychosocial risk factors (extreme pain, mental health deterioration, opiate dependency, loss of income or independence, or effects on vulnerable dependents) (Figure 1). Any patient undergoing a Priority 3 (surgery to be performed within three months) or 4 (surgery to be performed after three months) procedure with a biopsychosocial risk factor was grouped as 'Urgent' and this group was prioritized ahead of Priority 3. If a shared decision deemed that a patient was unsuitable for surgery during the pandemic or if a patient declined surgery, this was communicated to the patient's general practitioner. In addition, the patient's condition was given optimal conservative managementincluding referral to physiotherapy or occupational therapy, the pain management team, fitting of orthoses, social services, or cognitive behavioural therapy-and provided with virtual orthopaedic outpatient follow-up.

Priority	Procedures					
Priority 2 (surgery within 1 month)	Spinal surgery for degenerative conditions with progressive neurology or neurological deficit	Knee extensor disruption	Locked joints	Peripheral nerve decompression: with pain/weakness/ muscle wasting, not responding to conservative treatment	Arthroplasty where o outcome	delay will prejudice
Priority 3 (surgery within 3 months)	Hip avascular necrosis with night pain/collapse of the joint/loss of mobility Recurrent prosthetic joint instability	Frozen shoulder: severe and not responding to conservative treatment	Tendon reconstruction or repair	Revision surgery Implant loosening without impending fracture	Locked knee Anterior cruciate ligament and other tendon reconstructions	Spinal surgery, injection or decompressive surgery for intractable radiculopathy
Priority 4 (surgery to wait more than 3 months)	Arthroplasty/arthrodesis, where delay will not prejudice outcome)	Hand and upper limb surgery, where not otherwise specified		Metalwork removal	Degenerative spinal disease withoutneurological compromise or refracto pain	

Table II. Suggested targets for orthopaedic procedures in the Federation of Surgical Specialty Associations clinical guide to surgical prioritization during the coronavirus pandemic.¹⁸

Ranking and site allocation. Patient allocations into each group were reviewed by the SPC to ensure accurate stratification. Patients' preoperative anaesthetic assessment was used to determine American Society of Anesthesiology (ASA) grade.²³ The surgical listing request, which is an electronically ticket submitted by surgeons to a centralized booking office, commonly notes any special equipment or resource requirements. Together, the anaesthetic assessment and the listing request enabled patients to be either for surgery at the acute site, where specialist resources or access to HDU/ICU was available.

The committee ranked patients within each procedural level (Levels 2, Urgent, 3 and 4) based on their time on the waiting list. Patients were then consecutively allocated to a site-specific operating theatre for surgery to be performed by an appropriate sub-speciality surgeon. In this way, the SPAG integrated patient and procedural risk factors, patient suffering, predicted procedural efficacy, and the length of time a patient had spent on the waiting list.

Performing surgery during the COVID-19 pandemic. In accordance with national guidance from NHS England,²⁴ planned operations were temporarily stopped on 17 March 2020 in order to free up inpatient and critical care capacity in response to the pandemic. On 21 May 2020, a staggered restart of routine surgery was initiated at the three sites.

Local COVID-19 surgical protocol. Patients were required to self-isolate for two weeks prior to their surgery date. All patients were tested for COVID-19 using reverse transcription-polymerase chain reaction (RT-PCR) nasal and oral swabbing within 72 hours of surgery.²⁵ Healthcare professionals underwent RT-PCR testing weekly, or within 24 hours of the operating list if they had been at a COVID-facing hospital. Only asymptomatic patients and staff with negative RT-PCR tests were permitted to attend routine surgery, and screening for symptoms and fever was performed prior to entering the hospitals. Patients signed a consent form confirming their understanding of

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the potential risk of contracting COVID-19 during hospitalization. For the surgical procedure, regional anaesthesia was preferred, and staff followed national guidelines on the use of appropriate personal protective equipment (PPE).²⁶ Only patients who underwent surgery at the independent sector hospital stayed in single-occupancy rooms and were not permitted visitors.

Outcomes. The primary outcome was the proportion of patients in each prioritization category who successfully underwent surgery following the restart of planned surgery. Secondary outcomes were the number of inpatient postoperative HDU/ICU admissions, COVID-19-positive tests within 14 days of surgery, and 30-day mortality.

Statistical analysis. Data were first tested for normality using the Shapiro-Wilk test and by visually inspecting the histograms. Continuous parametric variables were compared using the independent-samples *t*-test and non-parametric continuous variables were compared using the Mann-Whitney U test. Categorical variables were compared using the chi-squared test or Fisher's exact test where individual cell numbers were < 5. A p-value < 0.05 was considered significant.

Results

A total of 1,279 eligible cases were initially identified; 90 were excluded due to missing or erroneous data and 47 declined surgery, leaving 1,142 cases to be included in the analysis. Of these, 1,032 cases were deemed low-risk and allocated to the two elective surgery sites, and 110 patients were considered high-risk or required specialist equipment and were allocated to the acute NHS site.

A total of 114 were considered $P_{2^{2}}$ 216 level 3, 791 level 4, and 21 were reclassified as urgent level 4s based on the surgery prioritization guide (ten patients due to biopsy-chosocial factors and 11 due to severe pain or functional limitations). In total, 349 procedures were performed on 349 patients during the ten-week study period (25 May to 3 August 2020). In total, 322 (92%) were performed at

 Table III. Low-risk planned procedures performed at elective surgical sites in COVID-free pathways.

Procedure type	Procedures, n	
Spinal injections	99	
Knee arthroplasty	52	
Hip arthroplasty	41	
Shoulder and elbow procedures	29	
Foot and ankle procedures	26	
Spinal decompression and/or discectomy	19	
Knee ligament reconstruction	16	
Removal of metal	12	
Knee arthroscopy	11	
Peripheral nerve decompression	9	
Manipulation under anaesthesia of prosthetic knee joint	3	
Other open knee procedures	3	
Hip injections	2	
Knee osteotomy	1	

the elective sites and 28 (8%) at the acute site. The most performed procedures were spinal injections (99; 28%) and hip (49; 14%) and knee arthroplasties (65; 19%) (Tables III and IV).

Elective sites. At the elective sites, 322 procedures (31% of the waiting list) were performed in the ten-week study period. The mean age of the operated patients was 60 years (SD 18); 34% (108/322 procedures) were American Society of Anesthesiologists (ASA) grade I and 67% (214/322) ASA grade II.²³ No patients operated at the elective sites were ASA III or above. When stratified by prioritization category, 91% (19/21) of patients awaiting surgery in the Urgent group, 52% (49/95) of the P₂ patients, 36% (70/196) of the P₃ patients, and 26% (184/720) of the P₄ patients underwent surgery.

High-risk site. At the high-risk site 28 patients underwent surgery in the study period (25 were ASA grade III and three required specialist equipment, two for access to a cardiac electrophysiologist for perioperative management of their implantable cardiac defibrillator, and one patient had severe obstructive sleep). The mean age (72 years (SD 11)) was significantly higher when compared to the elective sites (p < 0.001, independent-samples *t*-test). ASA grades were also significantly higher; 11% (3/28) ASA I, 21% (6/28) ASA II and the remaining 68% (19/28) were ASA III (p < 0.001, chi-squared test). When stratified by prioritization group, 68% (13/19) of patients awaiting surgery in the P₂ group, 15% (3/20) P₃ patients, and 16% (11/71) of P₄ patients underwent surgery.

Safety. In the two weeks following surgery there were no patients who tested positive for COVID-19. There were no patients admitted postoperatively to intensive care from surgery performed at any of the three sites. Mortality at 30 days was 0% for all patients.

 Table IV. Planned procedures deemed high-risk or requiring specialist

 resources performed at acute hospital site in a COVID-free pathway.

Procedure type	Procedures, n	
Knee arthroplasty	13	
Hip arthroplasty	9	
Shoulder and elbow procedures	3	
Removal of metal	2	
Ankle arthroplasty	1	

Discussion

This study presents the design and validation of a prioritization and allocation guide (SPAG) to aid in the equitable resumption of planned surgery following a national mandated hiatus. Our approach was feasible implemented at a busy multispecialty NHS hospital. It resulted in 349 patients undergoing surgery over ten weeks, with patients in higher-priority groups undergoing surgery before those lower-priority groups. In our study, 47 patients (9%) declined surgery due to fears of contracting COVID-19 during their admission or other personal reasons. This is similar to a recent American survey of 360 patients awaiting hip or knee arthroplasty during the COVID-19 pandemic, of whom 12% wished to delay surgery.⁷

By incorporating the identification of biopsychosocial factors, SPAG enabled expedited surgery for patients who would otherwise have been on the lowest priority if procedural urgency were considered in isolation. Patients awaiting planned orthopaedic surgery typically suffer from degenerative or inflammatory joint conditions which deteriorate over time. Therefore, patients within priority groups were ranked by their time on the waiting list. Finally, we did not discriminate against patients considered high-risk for perioperative complications or those requiring specialist resources by creating a COVID-free hospital within an acute hospital setting for this purpose. The zero incidence of early mortality, HDU/ICU admission, and contracting COVID-19 confirmed the safety of the SPAG approach.

Our approach and results are of particular importance as countries are in different phases of their COVID-19 curve and some have entered a second or even third wave.²⁷ Multimorbid patients, including those with cardiorespiratory disease, obesity, or diabetes, are at highest risk of mortality from COVID-19.13 A recent global study showed an overall mortality rate of 19% in patients with a preoperative diagnosis of COVID-19 who underwent planned surgery.²⁸ The authors suggested that all non-critical surgery should be postponed. However, to the patient, delay of planned surgery may result in significant harm to physical and mental health,^{2,3} irreversible disability, loss of income, and in some conditions such as cancer, reduced life expectancy.^{29,30} To society, delay is likely to result in missed education, unemployment, and an increased demand on the healthcare system and welfare state.³¹ If there is capacity to do so, our data suggest that it is safe to resume planned surgery. In our study, the creation of a COVID-free pathway within an acute hospital with access to HDU/ICU and specialist care allowed 28 highrisk/resource patients to safely undergo surgery. A total of 144 of 349 patients in the present study spent at least one night in hospital. This indicates that with appropriate prioritization and allocation, and strict adherence to infection control guidelines for screening and PPE, it is feasible and safe to perform planned surgery on even high-risk patients who do not have COVID-19.

A recent UK-based study by Gammeri et al³² reported on 309 NHS patients who underwent planned surgery at a COVID-free independent sector hospital. Like the present study, there were no adverse outcomes and no mortality within 30 days of surgery. However, the patient cohort was different: Gammeri et al³² only performed surgery on low-risk patients undergoing procedures that could be performed as day cases or within 23 hour stays. Our study presents a simple method to prioritize patients, based on the FSSA procedural guide and incorporating additional biopsychosocial factors. The FSSA guide considers that depending on the underlying disease and progression, a given procedure may be expedited to avoid prejudicing its outcome.¹⁸ Gammeri et al³² did not report the use of a procedural prioritization method but did employ a risk assessment tool to identify the lowest-risk patients. Anoushiravani et al³³ present an orthopaedic procedural prioritization guide, but recommend that all arthroplasty (which was the second most common and therefore urgent procedure performed in our study) is performed within three to six months. This would not have enabled a nuanced triage of these patients, and we consider the FSSA guide to be superior in this regard. Two studies have described as yet unvalidated patient score-cards which assign scores for patient, procedural, and disease-related factors with suggested maximum points-based thresholds for offering planned surgery.^{33,34} Neither considered biopsychosocial factors for expediting surgery or time spent on the waiting list. In our study, we chose not to assign scores to patients, but rather allowed the patient's surgeon and the SPC to engage patients in shared decision-making and understand their individual perception and acceptance of risk. The identification of comorbid patients and those undergoing procedures which required specialist resources was used only to allocate patients to hospital sites, and not for points-based ranking.

A large recent global study²⁸ suggested that all noncritical surgery should be postponed. Multimorbid patients, including those with cardiorespiratory disease, obesity, or diabetes, are at highest risk of mortality from COVID-19. Despite their risk, these patients should not be prejudiced against when offering planned surgery. In the present study, the creation of a COVID-free pathway within an acute hospital with access to HDU/ICU and specialist care allowed 28 high-risk/resource patients to undergo surgery with no adverse outcome.

In the present study, 47 patients (9%) declined surgery due to fears of contracting COVID-19 during their admission or other personal reasons. This is similar to an American survey of 360 patients awaiting hip or knee arthroplasty, in which 12% wished to delay surgery.⁷

This study has several limitations. First, it focused on small number of patients undergoing planned orthopaedic surgery in the UK just prior to a second wave of COVID-19. Therefore, our results may not be applicable to other specialities or healthcare systems responding during a different phase of the pandemic. The FSSA procedural urgency guide offers advice on all surgical specialties, so the SPAG could be applied and tested more broadly. Second, we did not collect data on the incidence of COVID-19 infections in healthcare workers based at the three operative sites, so we cannot comment on the safety of resuming elective care for staff. Third, in our cohort, more patients in the highest Priority groups underwent surgery during the ten-week study period, yet 49% of low-risk P₂ patients and 13% of specialist resource/highrisk P2 patients were still awaiting surgery, outside of the one month FSSA guideline. We have reported our early results and it is likely that further increases in planned surgery capacity will result in more expeditious surgery. Finally, we investigated COVID-19 infection within two weeks of surgery using a regional electronic database. While the hospital's catchment area is local, it is possible that we missed patients with positive COVID-19 tests registered outside of our region.

Restarting planned surgery is contingent on ensuring patients are free of infection prior to admission to hospital, minimizing their risk during hospitalization, and having adequate resources available. Surgeons should engage in shared decision-making with patients, and ensure that those at higher risk of perioperative complications are not prejudiced against.¹⁹ Our valid and generalizable model facilitated the resumption of planned surgery at COVIDfree sites. It expedited surgery for patients in greatest suffering, undergoing the most efficacious procedures, and/or at highest risk of deterioration, without compromising patient safety.

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