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Research Paper

Safety of maintaining elective and emergency surgery during the COVID-19 pandemic with the introduction of a Protected Elective Surgical Unit (PESU): A cross-specialty evaluation of 30-day outcomes in 9,925 patients undergoing surgery in a University Health Board[☆]

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ABSTRACT

Background: The COVID-19 pandemic has caused unprecedented health care challenges mandating surgical service reconfiguration. Within our hospital, emergency and elective streams were separated and self-contained Protected Elective Surgical Units were developed to mitigate against infection-related morbidity. Aims of this study were to determine the risk of COVID-19 transmission and mortality and whether the development of Protected Elective Surgical Units can result in significant reduction in risk.
Methods: A retrospective observational study of consecutive patients from 18 specialties undergoing elective or emergency surgery under general, spinal, or epidural anaesthetic over a 12-month study period was undertaken. Primary outcome measures were 30-day postoperative COVID-19 transmission rate and mortality. Secondary adjusted analyses were performed to ascertain hospital and Protected Elective Surgical Unit transmission rates.
Results: Between 15 March 2020 and 14 March 2021, 9,925 patients underwent surgery: 6,464 (65.1%) elective, 5,116 (51.5%) female, and median age 57 (39–70). A total of 69.5% of all procedures were performed in Protected Elective Surgical Units. Overall, 30-day postoperative COVID-19 transmission was 2.8% (3.4% emergency vs 1.2% elective P < .001). Protected Elective Surgical Unit postoperative transmission was significantly lower than non–Protected Elective Surgical Unit (0.42% vs 3.2% P < .001), with an adjusted likely in-hospital Protected Elective Surgical Unit transmission of 0.04%. The 30-day all-cause mortality was 1.7% and was 14.6% in COVID-19–positive patients. COVID-19 infection, age > 70, male sex, American Society of Anesthesiologists grade >2, and emergency surgery were all independently associated with mortality.
Conclusion: This study has demonstrated that Protected Elective Surgical Units can facilitate high-volume elective surgical services throughout peaks of the COVID-19 pandemic while minimising viral transmission and mortality. However, mortality risk associated with perioperative COVID-19 infection remains high.

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INTRODUCTION

The COVID-19 pandemic has resulted in significant global disruption of surgical services with wide-reaching implications for patient care [1–4]. It is estimated that in England and Wales alone, greater than 1.5 million operations were cancelled in 2020, with modelling predicting this increasing to more than 2.3 million by the end of 2021 [5]. COVID-19 infection carries a substantial risk to surgical patients with a reported 30-day mortality of 23·8% and pulmonary complications occurring in 51·2% [4]. International guidance has challenged models of care and thresholds for operative intervention [3,6–10].

As the pandemic has evolved, adaption of services has been necessary to cope with the surges in COVID-19–related demands while maintaining elective surgery. A balance between surgical deferral and its negative impact on medium- and long-term health outcomes and minimising COVID-19 transmission in the elective stream have been the biggest challenge for most hospitals throughout the UK.

The “crisis within a crisis” necessitated a pressing need to implement safe operating services and procedures at an early stage of the pandemic. At our institution, we have been mindful that, in some circumstances, international reports of COVID-19 may not have been truly reflective of our experience. To maximise our surgical delivery while protecting patients and staff from COVID-19 transmission, self-contained surgical zones were created to ensure that elective surgical services could be maintained throughout the pandemic. There is however a paucity of large-volume evidence supporting the implementation of these zones in acute hospitals providing broad specialty surgical care [11,23,24]. We hypothesised that development of such units would provide a safe and deliverable service with good outcomes during the peak of a pandemic. The aim of this study was to assess the perioperative risk of COVID-19 transmission and mortality during the pandemic and whether the development of a Protected Elective Surgical Unit can minimise COVID-19–related morbidity.

METHODS

Design. An observational cohort study was performed of all patients undergoing surgery across a single Health Board (a local authority responsible for provision of health care to a region) from 15 March 2020 to 14 March 2021. All patients undergoing emergency and elective surgery under general, spinal, or epidural anaesthetic were included. Reoperations, within the same admission or for complications on readmission, were excluded. Procedures such as tracheostomies were excluded if the patient was already anaesthetised in intensive care, and anaesthetic or cardioversion procedures performed in theatre were excluded. Cases performed under local anaesthetic and/or endoscopy procedures were also excluded.

The study was undertaken according to STROBE guidelines for observational studies [12]. Data was initially collected retrospectively via an electronic theatre record system (Theatreman, Trisoft Ltd, Nottingham UK), with demographics, operation performed, length of hospital stay, and 30-day mortality retrieved from the hospital electronic patient records and patient notes. For the first 3 months of the study window, data was verified by subspecialty clinical leads, and all positive swabs were cross-checked with Public Health Wales to ensure data accuracy.

COVID-19 infection was defined as positive test for SARS-CoV-2 from nasal/pharyngeal swab or bronchial secretions. *Preoperative infection* was defined as having a SARS-CoV-2 swab that was positive within the 14 days prior to undergoing surgery and postoperative infection in the 30 days following surgery. Pre- and postoperative SARS-CoV-2 PCR swab results and test dates were recorded from the Welsh Clinical Portal IT system, which captures any test taken across Wales. Results were cross-checked with Public Health Wales data to ensure all positive swabs were included. If any asymptomatic patient returned a “low-level” positive result, the hospital policy was to retest the patient to rule out any false positive. If the subsequent test was negative, then the patient was deemed negative after discussion with an infectious diseases consultant. If, however they had no follow-up test, then the patient was treated as positive.

The study was registered locally as a service improvement audit, and formal research ethical approval was not deemed necessary; as such, the local institutional review board was not involved.

Setting. The Health Board covers a population of more than 470,000 but also provides tertiary services for a much wider region for several subspecialties including regional major trauma. All but 2 of the 20 surgical specialties within the health hoard were included in this study. Paediatric surgery and obstetric surgery were both excluded. The classification of “general surgery” was used to categorise emergency operations such as appendicectomy and hernia repair which are not subspecialist in nature.

Evolution of services. Surgery is usually performed in the Health Board in the University Hospital main theatres and a 23-hour short stay surgical unit (both in Hospital A), and in an elective surgery unit in a large, second acute hospital (Hospital B). Routine elective surgery was cancelled on hospital sites A and B on 23 March 2020, and a local private sector hospital (Spire Cardiff Hospital) was contracted by the health board for NHS urgent and cancer cases across a range of specialties from 24 March 2020 (Hospital C).

Elective surgical cases were selected from waiting lists using The Royal College of Surgeons COVID-19 prioritisation guidelines [13] which consider the urgency of surgery, and during the first peak, this was used alongside a clinical assessment of the risk of mortality should the patient contract COVID-19. The availability of level 2 and 3 critical care beds also determined which cases were performed at different phases during the study.

From 14 April 2020, all of hospital site C was able to provide “protected elective surgery,” and by 11 May 2020, a similar separate “green” zone was commenced in Hospital A for all major specialties. A green zone was also implemented in Hospital B at this time to facilitate elective breast, cardiothoracic, and orthopaedic surgery. These elective cases undertook 14 days self-isolation preoperatively and were tested for SARS-CoV-2 72 hours prior to admission to ensure negative status prior to admission. Separate entrances were created with designated changing rooms, wards, corridors, postoperative high-dependency care areas, and operating theatres and referred to as “Protected Elective Surgery Units (PESUs)”. Staff were restricted to the unit for the day, and rules were designed in relation to PPE and the movement in and out of the units. For the purposes of the analyses within this paper, we have referred to this as a “green” stream.

Emergency admissions were swabbed for SARS-CoV-2 at the point of admission, and their perioperative pathway was determined at that point. Nonisolated patients were treated in non-PESU “amber” areas. This includes some elective surgical cases who were predominantly low-risk day-case patients or those that were unable to follow the green zone isolation policies. Designated COVID-19–positive areas were separated from the other areas and included 2 operating theatres and parts of the critical care unit. These patients are included within the “amber” category.

To ascertain hospital transmission rates, the following classifications were used for the secondary adjusted analysis of the data (visually represented in Fig 1):

- any patient testing positive less than or equal to 2 days after admission: likely community transmission prior to admission
- any patient testing positive **inpatient** day 3 to day 8: likely health care associated acquisition
- any patient testing positive more than or equal to 8 days following **discharge** home: likely community transmission

Any patients testing positive 8 days or more following transfer out of the protected elective “green” stream into an amber zone were analysed

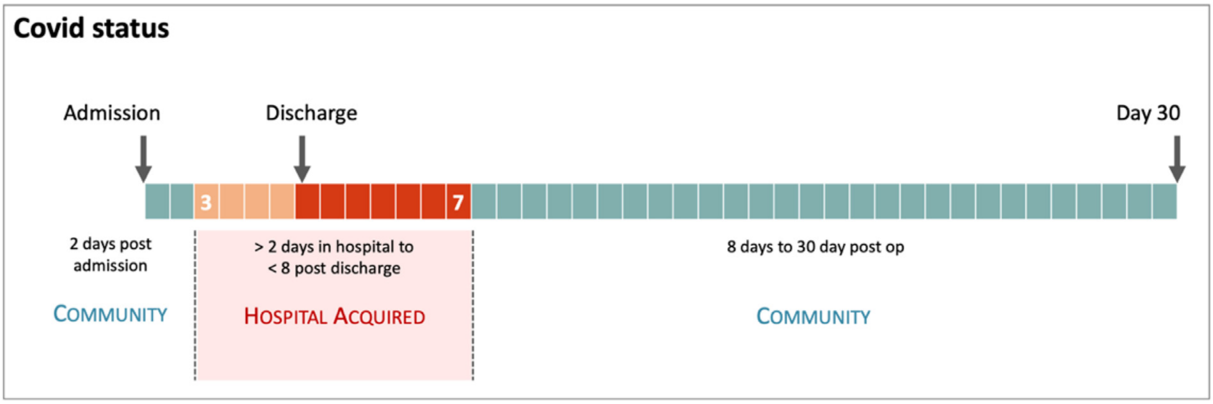

Fig 1. Classification of hospital/community transmission.

as an amber zone transmission in the secondary adjusted data. There were no routine postoperative testing protocols after discharge, and those undergoing tests did so in line with community and government guidance. Additionally, there was no routine testing for those postoperative patients within the green stream during their postoperative admission unless patients became symptomatic.

Outcomes. The primary outcome was the risk of contracting COVID-19 in the 30 days following surgery during the pandemic and whether the introduction of PESUs demonstrated a reduced incidence of COVID-19 transmission. Secondary outcomes were 30-day mortality associated with perioperative COVID-19 transmission, critical care admission, and length of hospital stay.

Statistical Analysis. Statistical analyses were performed using SPSS® statistics v25·0 (IBM, Armonk, NY). Continuous data were tested for distribution, with parametric data presented as mean and 95% confidence interval, and differences between groups were tested using the unpaired *t* test. Nonparametric data were presented as median and interquartile range (IQR), with differences between groups tested using the Mann–Whitney *U* and Kruskal–Wallis tests. The χ and Fisher exact tests were used for categorical data. There was no missing data and no loss to follow-up. Binary logistic regression was used to calculate odds ratios and 95% confidence intervals in identifying factors independently associated with 30-day mortality within the cohort.

RESULTS

A total of 9,925 patients underwent surgery between 15 March 2020 and 14 March 2021 and were included in the study with 30-day follow-up. The median age (IQR) of all patients was 57 (39–70), and 5,116 (51.5%) of the patients were female. Elective surgery accounted for 6,464 (65.1%) of the cases; of these, 4,495 (69.5%) were performed in the PESU and 1,969 (30.5%) in the amber stream due to inability to fulfill the preoperative requirements. All emergency operations were performed in the amber stream. Hospital A accounted for 6,769 (68.2%) operations with no emergency work carried out in Hospital C. Table 1 shows baseline characteristics of the cohort and a breakdown of the operations per specialty.

COVID 19 Transmission. Two hundred and eighty patients were diagnosed with COVID-19 perioperatively (2.8% [85 preoperatively and 195 postoperatively]). Figure 2 shows how positive SARS-CoV-2 swabs perioperatively were closely related to community incidence. Shortly following the peak of the pandemic (week commencing 20/12/2020), perioperative risk of COVID -19 transmission in all patients peaked at 9.9% (week commencing 3/1/2021).

Total postoperative COVID-19 transmission was higher in the emergency stream than in the combined green and amber elective streams (3.4% [116 of 3461] vs 1.2% [79 of 6464], $P < .001$). Table 2 provides a breakdown of COVID-19 positivity based on the patient stream. In the adjusted postoperative results, likely community transmissions based on government guidance were excluded, and 1 green elective patient was analysed in the amber stream after testing positive 11 days after being transferred out of the green zone to an amber ward for cardiac monitoring.

Green Zone Transmission. COVID-19 postoperative transmission was lower in the green elective pathway than in the combined elective and emergency amber pathway (0.42% [19 of 4495] vs 3.2% [176 of 5430], $P < .001$). This was also significantly lower when compared to the amber elective stream only (3.0% [60 of 1969], $P < .001$).

Adjusted secondary analysis of the postoperative green zone positive results to ascertain likely hospital green zone transmission led to the exclusion of 17 patients (16 likely community transmissions and 1 amber zone transmission for additional cardiac requirements), leaving

Table 1
Baseline operative demographics

		All	*Elective*	*Emergency*
Median age (IQR)		57 (39–70)	59 (45–71)	50 (33–68)
Sex	Male	4809	3072	1737
	Female	5116	3392	1724
ASA	1–2	6345	4149	2197
	3–5	3142	1932	1210
	Not recorded	438		
Specialty	Breast	323	322	1
	Cardiac	389	342	47
	Colorectal	992	485	507
	Endocrine	145	140	5
	ENT	489	413	76
	General surgery	881	267	614
	Gynaecology	885	614	271
	Hepatobiliary/pancreatic	261	168	93
	Neurosurgery	677	298	379
	Ophthalmology	92	82	10
	OMFS	230	116	114
	Renal/transplant	137	113	24
	Spinal	318	279	39
	Thoracic	361	341	20
	T + O	2089	1191	898
	UGI	360	274	86
	Urology	1136	969	167
	Vascular	180	70	110
Hospital site	A	6769	3870	2899
	B	2013	1451	562
	C	1143	1143	0

Abbreviation: OMFS, Oral and MaxilloFacial Surgery.

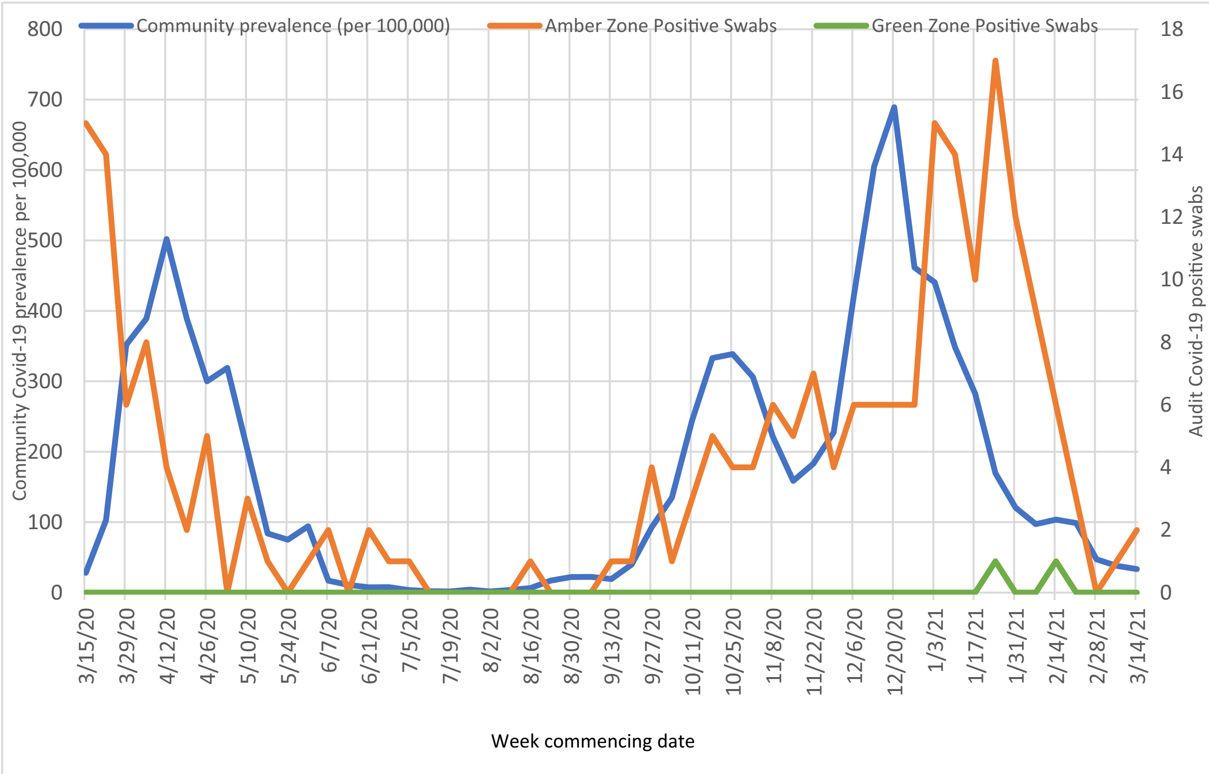

Fig 2. Community prevalence of positive swabs compared with in-hospital positive results.

Table 2
COVID-19 positivity across patient operative cohorts

	Emergency (n = *3461*)	*Elective green* (n = *4495*)	*Elective amber* (n = *1969*)
COVID-19 + postoperatively	116 (3.4%)	19 (0.4%)	60 (3.0%)
COVID-19 + postoperatively adjusted	92 (2.7%)	2 (0.04%)	44 (2.3%)
COVID-19 + perioperatively	183 (5.3%)	19 (0.4%)	78 (3.9%)

only 2 positive postoperative transmissions. Of the 2 remaining cases, 1 patient tested positive with symptoms 4 days postoperatively; however, the second patient tested "low-level" positive only 4 days postoperatively while being asymptomatic as part of standard protocol at their dialysis unit. Unfortunately, there was no follow-up test to ascertain the validity of the low-level positive, and therefore, the patient was deemed positive for the purpose of the study. Both positive tests occurred during the highest rate of in-hospital positive results in the weeks commencing 29/1/21 and 17/2/21, respectively, which closely followed a community peak.

COVID 19 Mortality. The overall all-cause 30-day mortality was 1.7% (3.6% [124 of 3461] emergency vs 0.79% [51 of 6464] elective, $P < .001$). Mortality was higher in patients that had contracted COVID-19 perioperatively (14.6% [41 of 280] vs 1.4% [134 of 9645], $P < .001$). The COVID-19 associated mortality can be further stratified in regard of likely transmission as per Fig 1. Likely hospital transmission accounted for 61% of cases (25 of 41), with prehospital transmission and postdischarge community transmission being 29.3% (12 of 41) and 9.8% (4 of 41), respectively.

On binary logistic regression analysis, COVID-19 infection, age >70 years, male sex, American Society of Anesthesiologists (ASA) grade >2, and emergency surgery were independently associated with mortality (see Table 3).

There was 1 recorded green zone postoperative COVID-19–related mortality. This is the same patient that tested positive after being transferred out of the green zone, with the death occurring 23 days after entering the amber stream. This is likely to be a mortality related to amber zone transmission.

DISCUSSION

The arrival of the COVID-19 pandemic in South Wales precipitated a major reconfiguration in the delivery of both elective and emergency surgical services to balance the provision of ongoing patient health care needs with infection-related morbidity in an ever-evolving clinical environment. This study is the largest single-center comprehensive cross-specialty evaluation of surgical practice to be undertaken over a 12-month period which has evaluated the provision of surgery during the COVID-19 pandemic. In line with the literature reported, this

Table 3
Binary logistic regression analysis of factors associated with mortality*

	Odds ratio	*95% Confidence interval*		*P value*
		Lower	*Upper*	
Sex (female/male)	1.384	1.007	1.903	.045
Age (<70 y/70 y or above)	2.659	1.904	3.714	<.001
COVID-19 status (− or +)	5.247	3.508	7.848	<.001
ASA (1–2/3–5)	8.033	1.108	58.240	.039
Urgency (elective: emergency)	3.905	2.774	5.497	<.001

* The first variable in each category is the reference for the odds ratios calculated.

study has clearly shown a link between COVID-19 transmission and poor patient outcomes, with perioperative infection alone leading to a 5-fold increase in the risk of mortality [4].

Through a coordinated collaborative response, led by clinicians, operational managers, and estates, the development of protected elective "green zones" within each hospital was implemented early in the study period, allowing for separation of the emergency patient flow from complex and urgent elective surgery [14].

In almost 10,000 patients requiring general or regional anaesthetic that were included in the study, the risk of developing COVID-19 and subsequent 30-day mortality was significantly higher when surgery was undertaken in an emergency or elective setting within an "amber" nonprotected elective surgical stream.

Importantly, despite perioperative COVID-19 infection rates mirroring the community prevalence within our institute, this study has undoubtedly shown that the development of PESU can break this association and deliver safe high-volume elective surgery throughout the peak of the pandemic, with very low (0.04%) nosocomial COVID-19 infection rates.

There were no COVID-19–related mortalities in patients within the "green" elective stream in any of the 3 hospital sites. The development of the PESUs has allowed surgical care of any urgency and complexity to be delivered in an uninterrupted, planned environment, ensuring that patients get the right care at the right time. Three separate PESUs were created, providing a different mix of surgical specialties and complexity in 3 different buildings of different design. We would propose that any surgical unit could adopt this model of care either in part or, more likely, in full to significant patient and system benefit. This approach would avoid returning to a pre-COVID era where elective surgical services were largely unprotected and thus vulnerable to and regularly compromised by winter pressures or bed occupation by medical rather than surgical patients.

All-cause mortality in all patients was low; however, COVID-19 infection alongside increasing age, ASA, male sex, and emergency surgery were independent predictors of 30-day mortality. Although our 30-day mortality rate of 14.8% in COVID-19–positive patients is lower than that of the COVIDSurg collaborative multicenter study (23.8%), it provides further justification for the separation of the emergency and elective surgical streams. These results can possibly help clinicians counsel patients regarding the risks of succumbing to COVID-19 in the perioperative period and may inform decision making regarding nonoperative management in some select patients in the emergency setting at times of increased community and hospital prevalence.

It is important that the public are provided with the necessary reassurance that non–COVID-19 related NHS care is safe and that robust measures have been implemented within primary and secondary care to ensure transmission risk to patients remains low. A study within the UK estimated that up to 45% of patients with red flag symptoms did not contact their doctor during the first wave due to a fear of COVID-19 transmission and the worry of putting unnecessary strain on the NHS [15]. This has led to detrimental unintended consequences of delayed or missed diagnoses of non–COVID-19 disease [16,17]. The longer-term consequences in terms of cancer diagnosis and survival may take years to materialise with a recent UK-wide study quoting more than 20% of respondents were less likely to attend cancer screening tests [18].

The strengths of this study are that a clearly defined date range was used which encompassed the local and national peaks of community and hospital infections. The study included almost all specialties and procedures in a large teaching hospital and resulted in nearly 10,000 patients being included with no loss to follow-up. There are currently no directly comparable studies, with literature to date focusing on single surgical specialties, on only elective or cancer surgery, or solely on COVID-19–positive patients, which can introduce selection bias and lacks the comparison of a control group [4,19–22].

There may have been some selection bias within the PESU cohort, particularly early in the study as patients with potentially surgically treatable disease were managed nonsurgically due to the perceived mortality risks associated with developing COVID-19 perioperatively. It is also important to consider that, initially, only urgent elective operations were carried out during this study period, with routine surgery restarting later in the study window. As only symptomatic patients were swabbed postoperatively, the rate of asymptomatic carriers is unknown, and therefore, transmission rates may indeed be higher in both streams. Although this study shows COVID-19 infection to be an independent risk factor for mortality, the study was not designed to examine known risk factors for mortality such as ethnicity and comorbidities such as diabetes or hypertension.

In summary, population-wide interventions (such as lockdown restrictions and mass vaccination) have undoubtedly had the greatest impact on community prevalence of COVID-19, and this has been reflected in perioperative transmission rates in the nonprotected "amber" surgical stream. This study has demonstrated that the mitigating factor of a PESU, including both infrastructure and human resource outlays, has led to a demonstrably safe way of maintaining essential elective surgical services throughout the peak of pandemic, and we predict that it will continue to reliably deliver such services through any future periods of disruption.

Ethical Approval

Ethical approval deemed not required as no identifiable information was included.

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Author Contributions

Conceptualisation- Kynaston, Abdelrahman, Tomkinson, Theron, Wheat. Methodology- Kynaston, Abdelrahman. Software- Jones. Validation- Kynaston, Abdelrahman, Tomkinson, Theron, Wheat, Jones, Seddon, Trickett, Cronin, Ansell. Formal analysis- Abdelrahman, Minto, Jones. Investigation- Abdelrahman, Minto, Jones, Shivakumar, Behera, Johnson, Towler, Sagua, Sultana, Clark, Mckay. Resources- Jones, Abdelrahman. Data curation- Jones, Abdelrahman. Writing- Abdelrahman, Minto, Wheat, Kynaston, Tomkinson. Review- All authors. Visualisation- Abdelrahman, Minto, Wheat, Tomkinson, Kynaston. Project Administration- Kynaston.

Conflict of Interest

There was no identified conflict of interest by any authors.

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