Minimizing Population Health Loss in Times of Scarce Surgical Capacity

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# Abstract

## Background

COVID-19 has put unprecedented pressure on healthcare systems worldwide, leading to a reduction of the available healthcare capacity. Our objective was to develop a decision model that supports prioritization of care from a utilitarian perspective, which is to minimize population health loss.

Methods

A cohort state-transition model was developed and applied to 43 semi-elective non-pediatric surgeries commonly performed in academic hospitals. We compared scenarios of delaying surgery from two weeks up to one year and no surgery at all. Model parameters were based on registries, scientific literature, and the WHO global burden of disease study. For each surgery, the urgency was estimated as the average expected loss of Quality-Adjusted Life-Years (QALYs) per month.

Results

If best available evidence was used, the two most urgent surgeries were bypass surgery for Fontaine III/IV peripheral arterial disease (0.23 QALY loss/month, 95%-CI: 0.09-0.24) and transaortic valve implantation (0.15 QALY loss/month, 95%-CI: 0.09-0.24). The two least urgent surgeries were placing a shunt for dialysis (0.01, 95%-CI: 0.005-0.01) and thyroid carcinoma resection (0.01, 95%-CI: 0.01-0.02): these surgeries were associated with a limited amount of health lost on the waiting list.

## Conclusion

Expected health loss due to surgical delay can be objectively calculated with our decision model based on best available evidence, which can guide prioritization of surgeries to minimize population health loss in times of scarcity. This tool should yet be placed in the context of different ethical perspectives and combined it with capacity management tools to facilitate large-scale implementation.

## Background

COVID-19 has put unprecedented pressure on healthcare systems worldwide. The healthcare demand of this pandemic supersedes available healthcare capacity, far beyond the demand that was imposed by the 2017 influenza pandemic.1,2 The pressure on the available healthcare capacity impacts the continuity of regular care. Among other things 1) because wards and operating theaters are converted to COVID-19 care facilities,3 2) because physicians are deployed to care for COVID-19 patients,4,5and 3) because the fear of contagion with SARS-CoV-2 may leave non-COVID patients reluctant to seek care 4,5, as was seen in similar health crises like the SARS epidemic.6

Delay in surgical care may dramatically impact health care quality and accessibility. In the first weeks of the COVID-19 crisis in the Netherlands, 75-90% fewer surgeries were performed compared to previous years.7 The delay in cancer surgery already has made a large impact in the life expectancy of oncological patients.8 Moreover, it may be impossible to treat the whole accumulating group of patients as estimated for orthopedic and cardiothoracic surgery in the US. 9,10 Because of these problems, hospitals are facing a dilemma: Which patients should be prioritized?

As stated by Emanuel et al., “*The question is not whether to set priorities, but how to do so ethically and consistently, rather than basing decisions on individual institutions’ approaches or a clinician’s intuition in the heat of the moment*”.2 In practice, individual surgical patients are most often triaged by experts from the respective surgical fields.11 Unfortunately the level of agreement on prioritization between experts is low.12 Additionally, prioritization across disciplines is complicated by the high degree of specialization in modern medicine. Most importantly, this approach does not systematically optimize population health. The perspective of maximizing population health, a utilitarian ethical perspective,18 has been described to be most defendable in times of scarcity. 2,13–17

To guide prioritization of semi-elective surgeries across disciplines from a utilitarian perspective, our study aims to develop a decision model to estimate the impact of postponing surgery on health.

## Methods

### Overview

We selected semi-elective[[1]](#footnote-1) surgeries most frequently performed in our institute. We collected data about these surgeries and used this data in a broadly applicable computer-based model to estimate the effect of surgical delay on survival and health related quality of life (QoL).

### Patients and setting

The evaluated surgeries in this study comprised of non-pediatric and non-obstetric, semi-electivei  surgeries in Erasmus University Medical Center, an academic tertiary referring hospital in the Netherlands. From the electronic patient registry (ChipSoft, HiX), we retrieved the number of surgeries, surgery time, length of stay at an intensive care unit (ICU), and length of stay at a non-ICU of all non-urgent surgeries from July 2017 to December 2019. Next, two senior clinicals selected the semi-elective surgeries from this list. Finally, the Value Based operation room (OR) team collaborators approved the selection. Ultimately, 43 semi-elective surgeries were selected that were performed more than 80 times during the inclusion interval. Where relevant, we distinguished mild and severe cases undergoing the surgery based on clinical insight of our collaborators.

### Input parameters

The model required 7 input parameters: 1) survival rates pre-surgery, 2) survival rate post-surgery, 3) QoL pre-surgery, 4) QoL post-surgery, 5) mean age of patients undergoing the surgery, 6) time until no effect of treatment can be expected on survival or 7) time until no effect of treatment can be expected on QoL (see Appendix A). The class of collected evidence was defined as class I (Randomized Controlled Trials (RCT) or systematic reviews of RCTs), class IIa (Prospective observational studies, before-after studies), class IIb (Retrospective observational studies, expert panels for the utilities, national registries), and class III (expert opinion).

### Markov model

We developed a three-state cohort state-transition model. This model simulates a hypothetical cohort of patients over a defined period in fixed time intervals, called cycles, to estimate the average time individuals spend in the various health conditions, called health states.19,20 Individuals could transition between a preoperative state, a postoperative state, and a dead state (Figure 1). Based on the time spent in these states, health benefits, like life years (LYs) or quality adjusted life years (QALYs) are calculated.20–22 The entire cohort started in the preoperative state, and was followed their entire remaining lifespan, until they were 100 years old, using weekly cycles. The transition from the preoperative state to the postoperative state was set to a specific week, depending on the scenario. We evaluated scenarios of surgical delay of two weeks up to surgical delay of a year using intervals of ten weeks. In addition, we evaluated the scenario where patients never received treatment: this was modeled by following patients their remaining lifespan in the preoperative health state. In all scenarios, the transitions from the pre- and postoperative states to the dead state were based on survival data. A description of the model parameters and assumptions can be found in Appendix C.

If the delay was longer than the time until no effect of surgery on survival or QoL, the postoperative survival and QoL were set equal to the preoperative survival.

### Health Effects of Surgery

The effects of delays in surgery on the health outcomes (LYs and QALYs) were evaluated. LYs disregard QoL (QoL = 100%), while QALYs incorporate QoL and are therefore preferred. The health outcomes without surgery were compared to the health outcomes with surgery at 2 weeks and 52 weeks to determine the overall health outcomes associated with surgery and health outcomes lost per 50 weeks. This measure of urgency was converted to loss per month (loss/month) and was used to rank the surgeries, with a high loss/month is considered an urgent surgery.

### Analysis

Probabilistic sensitivity analysis (PSA) was used to incorporate parameter uncertainty in the model outcome (Appendix C). Rankings based on different absolute health benefits and loss per unit of time were compared using Spearman’s rank correlation coefficient.

The available surgery resource should also be optimally used. Therefore, the model results were compared visually to the capacity requirements in our hospital, obtained from the electronic patient registry. Since OR room availability was the bottleneck in our hospital during the first COVID-19 wave, we focused on surgery time.

This manuscript was reported in accordance with the CHEER guidelines for reporting health-economical evaluations.23 The model was built with R software24 and adapted from previously published code.25,26 The full model code is available on GitHub: [ADD LINK IF JOURNAL AGREES].

# Results

## Data collection

We evaluated 12 cardiothoracic surgeries, 23 oncological surgeries, 2 transplantations (liver and living donor kidney), 5 vascular surgeries, and 1 other type of surgery (creation of a shunt to facilitate hemodialysis). These 43 evaluated surgeries comprised of 69% of the total semi-elective program in our hospital.

For all surgeries, survival with treatment could be obtained. Survival with treatment was mostly based on national registries (31/43). Survival without treatment could was mostly based on data from (inter)national registries (12/43 surgeries, 6 indirectly calculated through the treatment effect), but also frequently from RCT’s (10/43 surgeries, 7 indirectly calculated), and observational studies (9/43 surgeries, 3 indirectly calculated). For 14/43 surgeries, QoL was available through the WHO Global Burden of Disease study.27 For the remaining 29 surgeries, the QoL of the pre- and postoperative health state was estimated by the expert panel as described in Appendix C. For 6/43 surgeries, a “time-to-no-effect-on-QoL” within one year, our maximum period of delaying surgery, was applicable. For 23 surgeries, we assumed a “time-to-no-effect-of-treatment-on-survival” based on qualitative assessment of the literature. Most of these surgeries were oncological surgeries (20/23). The estimates for the time until surgery becomes ineffective was mostly based on class IIb evidence (retrospective and prospective observational studies, see table 1). Input parameters varied widely between surgeries (Figure 2). All input parameters, their sources27–83, and the corresponding model output for each semi-elective surgery are presented in Appendix A.

## Quality of Life

The preoperative and postoperative health state of 3 surgeries (one with a mild and severe subgroup) were estimated in both sessions, resulting in 8 double estimates of QoL. The gain in QoL due to surgery was not estimated different in the second session (the standardized mean difference was 0.025, 95% CI: -0.11 – 0.16, table 3 and figure 1 Appendix B).

The maximum expected benefit of surgery, i.e. in a scenario without delay, ranged from 0.48 QALYs (95% CI: 0.32 – 0.83) for resection of muscle invasive bladder cancer to 10.3 QALYs (95% CI: 8.7 – 11.9) for kidney transplantation (Figure 3). The ranking based on QALYs gained by surgery was correlated with the ranking based on LYs gained by surgery:The Spearman rank correlation coefficient between the ranking of surgeries based on LYs and QALYs was 0.45 (p=0.003).

## Urgency

Most surgeries had a clear linear descend in terms of QALYs per delay, except surgeries where a time until no effect of treatment on survival was used (figure 1, appendix B).

The urgency of the surgeries ranged from 0.01 QALY loss/month (95% CI: 0.00-0.01) for placing a shunt for dialysis, to 0.23 QALY loss/month (0.09-0.24) for a bypass surgery for Fontaine III/IV peripheral arterial disease (Figure 4, and table 1 Appendix B). This implies that if the latter would be postponed by a month, patients with this surgical indication lose approximately 84 days (0.23\*365) spent in perfect health of their remaining expected QALYs gained by surgery.

Surgeries that were associated with a higher expected QALY benefit, often lost more QALYs per month delay: The Spearman correlation coefficient between the ranking of health benefit, in terms of QALYs, and urgency, in terms of QALY loss/month, was 0.32 (p=0.04). The most urgent surgeries after bypass surgery for Fontaine III/IV peripheral arterial disease, was transaortic valve implantation (0.15 QALY loss/month, 95% CI: 0.09-0.24). After placing a shunt for patients with end-stage renal disease, the least urgent surgery was resection of thyroid cancer (0.01 QALY loss/month, 95% CI:0.01-0.02) (Appendix B).

Urgency was correlated with the LYs gained per surgery:The Spearman rank correlation coefficient between the ranking of surgeries based on LYs and QALY loss/month was 0.79 (p< 0.001).

## Capacity

Surgeries that are ranked high in terms of urgency and had relative short surgery time compared to other surgeries include repair of atrial septum defects (surgery time: 74 min [IQR: 56-131], 0.06 QALY loss/month [95% CI: 0.02-0.14]), pacemaker implantations (115 min [82-154], 0.11 QALY loss/month [0.04-0.22]), resection of mild larynx carcinoma (70 min [38-109], 0.07 QALY loss/month[0.04-0.11]), and valve replacements (99 min [77-125]; mitral valve replacement: 0.09 QALY loss/month [0.04-0.15]; aortic valve replacement: 0.09 QALY loss/month [0.06-0.17]) (Figure 5). Liver transplant is relatively urgent but requires an exceptional amount of OR-time (875 min [797-957], 0.08 QALY loss/month [0.07-0.09]) (table 2 Appendix B).

# Discussion

Our proposed decision model is an attempt to systematically guide prioritization of surgeries from a utilitarian perspective. We quantified urgency based on the expected health loss due to surgery delay. Our approach operationalizes ethical values that are the most appropriate in times of scarcity.2 Available evidence suggests that semi-elective surgeries can be ranked based on their urgency using a simple decision model. For survival after surgery, most evidence was based on national registries, while treatment effects were mostly derived from RCTs. The time until no effect of treatment on survival or QoL, however, was most often class IIb/III evidence.

We found that among the 43 surgeries analyzed, bypass surgery for Fontaine III/IV peripheral arterial disease and transaortic valve implantation were the most urgent surgeries. Less urgent surgeries were installment of a shunt for dialysis and resection of thyroid cancer. Liver transplantation shows to be a relatively urgent surgery but requires an exceptionally long surgery time. In times of scarce OR-capacity, this surgery is less efficient in the prevention of QALY loss.

Interestingly, the ranking of urgency is primarily driven by the gain in LY associated with surgery rather than the anticipated impact of delay. Surgeries that are associated with substantial gain in LY (e.g. mitral valve replacement), also lose more QALYs per month delay than surgeries that are associated with no gain in LY (e.g. creation of a shunt for hemodialysis). The larger the total health benefit associated with surgery, the more health can potentially be lost by postponing surgery.

To optimize OR triage, our metric for urgency should be weighed against hospital capacity. This is effectively a cost-effectiveness analysis, where resource constraints represent costs. For the scenario where OR-capacity is the most scarce in terms of hospital capacity, urgency can be plotted against surgery time. This simple method revealed that pacemaker implantation, resection of mild larynx carcinoma, and repair of ASD are the most efficient surgeries in our hospital to perform in this context. However, there are contexts where other types of capacity (e.g. beds or staff) are scarcer, and therefore more relevant to be weighed against urgency.

Although our modeling approach rationalizes and objectively quantifies urgency from a utilitarian perspective, it needs to be complemented by other perspectives to be used effectively in practice. First, an important consideration from the medical perspective may be the availability of alternative treatment strategies. In cancer treatment, (chemo-)radiation or systematic therapy alone may be considered instead of surgery, even when the effectivity would be lower, since waiting lists may be shorter and no scare capacity is needed. Second, a financial perspective might also be explored. This perspective might be less relevant in a crisis such as the COVID-19 pandemic, where the bottleneck mainly seems hospital capacity instead of costs. If this approach would be applied to the context of regular care, this perspective might be of increasing importance. Finally, other ethical perspectives (e.g. rule of rescue18) might be explored to assess the viability of our approach, and we need to establish whether our approach is applicable to all surgical procedures.

There are practical advantages of comparing “average patients” on urgency, despite the fact that there is no such thing as an “average patient”: It prevents our approach from systematically discriminating against a specific group of patients. Our approach would only discriminate if specific socioeconomic groups would suffer more frequently from diseases that are less urgent. It is known that lower socioeconomic groups are more prone to develop cancers that have clear association with unhealthy behavior, such as lung cancer.85 However, these diseases do not systematically rank low in our approach. Comparing the average patients across specialties on urgency may not be a personalized approach, but it can be tailored to an individual’s context by providing input for shared decision making. We feel that next to a quantitative estimation of urgency from a utilitarian perspective, individual patient’s preferences, social contexts, and operability should also be included in the decision making process.

Since all models are a simplification of reality, our model has several limitations. First, the survival data used were not always derived from high-quality evidence. Although survival with treatment might be validly estimated from national registries, the survival without treatment is harder to be unbiasedly estimated. The surgeries that we evaluate are often part of standard clinical practice. Therefore, data might be biased (e.g. selection bias in the survival without treatment because patients opt for palliative care), or not available (it would be unethical now to perform RCTs evaluating surgery versus no surgery). Instead, we often used best available evidence, which found adjusted estimates from observational studies. For some surgeries, however, we did have evidence from more historical RCTs. As such, data might be biased, and as a result, the estimates from our model might also be somewhat biased. Because of this limitation, our approach is simply to aggregate transparently and systematically the best currently available evidence using a model.

Second, we assume that all surgeries are successful. We do not simulate adverse events, like major bleedings or death due to surgery. We also did not incorporate the potential reduction of QoL due to these adverse events or QoL reduction of a temporary period of recovery after surgery. Because of these assumptions, the overall QALYs associated with the surgery should not be interpreted as an absolute estimate. They can be considered the maximum possible QALYs that can be acquired by performing the surgery. However, these assumptions were considered reasonable to achieve the main goal of this study: when surgery without delay is compared to surgery with delay, the harm in both scenarios is similar and therefore cancel out.

Third, because we simply converted the health loss in 50 weeks to loss per month, we effectively used a linear approximation to quantify urgency by delaying surgery up to a year. Some surgeries did show a slightly steeper decrease in the period up to 32 weeks delay. The data needed to validly model this decay in QALYs per unit of time for all surgeries likely don’t exist: most of the estimates of time to no effect on survival were based on observational studies, which are likely biased. A more detailed approximation would be possible using a more individualized model which also models the natural grow of tumors, or aneurysms, and validly model the development of metastasis. It was not feasible to develop this for all evaluated surgeries. Instead, we opted for a more pragmatic approach.

Fourth, we relied on QoL weights derived from expert-opinion. In this approach the patient is not involved. Experts interpret the health states and give weights, thereby our approach takes a societal perspective. There are also multiple methodological, ethical, and contextual disadvantages of using QALYs, but it should be noted that most of those discussion are more about utilitarian principles.87

Fifth, we did not include the potential impact on QoL of delaying a semi-elective surgery. This impact might differ across surgeries. It might be hypothesized that surgeries performed after already a long disease history (e.g. kidney transplant) might have less “waiting time disutility” than recently diagnosed diseases (e.g. mammacarcinoma).

Sixth, we found that absolute QoL was estimated higher in the second expert session. However, the relevant measure of QoL in our model, the difference between preoperative and postoperative QoL, did not differ significantly between the sessions. Although our estimates remain valid, it might be reasonable to validate our QoL estimates in a larger sample of experts.

Part of the input parameters were based on national registry data, but a substantial amount of the input originated from various international sources. Therefore, with some modifications, the model can easily be adapted to different contexts. Therefore, this study can be considered the first step towards a triaging strategy which optimizes surgical benefit in times of scarcity in surgical capacity, such as during the COVID-19 pandemic. To improve validity, it is however essential to periodically review the literature and update the model with higher quality evidence, much like a living systematic review.88 If accepted, a wider range of surgeries should be considered, implementation strategies should be explored and evaluated, and the model should be applied to a variety of settings.

# Conclusion

By transparently aggregating best available evidence, our decision model support prioritization of surgical care in times of scarce surgical capacity (e.g. during pandemics) from a utilitarian perspective. Our approach quantified the expected health loss due to delay for semi-elective surgeries in an academic hospital in the Netherlands. This approach can help to minimize health losses when trying to overcome delay in surgeries across disciplines. This approach is more transparent, more evidence-based, and more consistent than the alternative strategy of triaging based on expert opinion.

It should be noted that evidence from well-controlled comparison studies is often lacking. Instead, adjusted estimates from observational studies are often the best available evidence for benefit of surgery and the effects of delay on survival. Therefore, model inputs should be periodically updated with newer, higher quality evidence.

Finally, our approach should be placed in the context of other ethical perspectives and combined with capacity management tools. If accepted, we believe this tool should be implemented on a large scale, in order to minimize health loss of the accumulating group of patients awaiting surgery.

# Figures legends

Figure 1, state-transition diagram of the cohort model. The model is a state transition model with three health states, a preoperatieve health states (Preop), a postoperatieve state (Postop) and Dead. All patients start in the Preop health states. This is the health states where patient eligible for surgery start in our simulation. We follow these patients over time using fixed time intervals of 1 week, these fixed time intervals are called cycles. Every cycle, patients can transition to one of the other health states or they can remain in the health states they currently are. From the Preop state they either die (transition to dead state) or continue to wait for their surgery (stay in the Preop state, the arrow points back into the health state). At the time of surgery, which is determined by us, all individuals still alive in the Preop health state transition to the Postop health state. The remaining lifetime the cohort is followed. They can die (transition from the Postop state to Dead state) or stay alive in the Postop health state (transition back to the Postop state). Finally, patients in the Dead state remain dead, so every cycle they stay in the dead state.

Figure 2, input parameters for the model. For a full list of input parameters per disease and source, see appendix A. **Abbreviations Figure titles**: Qol\_no\_tx: Quality of Life without treatment; QoL\_tx: quality of life with treatment; Surv\_no\_tx: 1-year survival probability without treatment; Surv\_tx: 1-year survival probability with treatment; Time\_noeff\_surv: days until no treatment is effective. **Abbreviations surgery/indications:** AAA: aneurysm of the abdominal aorta; AP: angina pectoris; ESRD: end-stage renal disease; ASD: atrial septum defect; ca.: carcinoma; CABG: coronary artery bypass graft; ESHF: end-stage heart failure; ESLD: end-stage liver disease; EVAR: endovascular aortic repair; HIPEC: hyperthermic intraperitoneal chemotherapy; HCC: hepatocellular carcinoma; NSCLC: non-small cell lung carcinoma; PAD: peripheral arterial disease; PCI: percutaneous coronary intervention; UUT: upper urinary track; VATS: video assisted thoracoscopic surgery

Figure 3, the maximum expected QALYs and LYs per surgery, in descending order of urgency (see figure 4). The estimates (gray bars) and 95% confidence intervals (black lines) are shown. The model output for no surgery was subtracted from the model output for a delay of 2 weeks. The actual data are presented in Appendix B. **Abbreviations Figure titles**: QALY: Quality of Life without treatment; LY: life years. **Abbreviations surgery/indication**: AAA: aneurysm of the abdominal aorta; AP: angina pectoris; ESRD: end-stage renal disease; ASD: atrial septum defect; ca.: carcinoma; CABG: coronary artery bypass graft; ESHF: end-stage heart failure; ESLD: end-stage liver disease; EVAR: endovascular aortic repair; HIPEC: hyperthermic intraperitoneal chemotherapy; HCC: hepatocellular carcinoma; NSCLC: non-small cell lung carcinoma; PAD: peripheral arterial disease; PCI: percutaneous coronary intervention; UUT: upper urinary track; VATS: video assisted thoracoscopic surgery; COPD: chronic obstructive pulmonary disease; PAD: peripheral arterial disease (F: Fontaine classification); AV: aortic valve; AVR: aortic valve replacement; MVR: mitral valve replacement; TAVI: transaortic valve implantation.

Figure 4, the average loss of QALYs and LYs per month of delay for the investigated surgeries based on the simulation of surgery delay of 52 weeks. The estimates (gray bars) and 95% confidence intervals (black lines) are shown. The actual data are presented in appendix B. **Abbreviations Figure titles**: QALY: Quality of Life without treatment; LY: life years **Disease abbreviations**: AAA: aneurysm of the abdominal aorta; AP: angina pectoris; ESRD: end-stage renal disease; ASD: atrial septum defect; ca.: carcinoma; CABG: coronary artery bypass graft; ESHF: end-stage heart failure; ESLD: end-stage liver disease; EVAR: endovascular aortic repair; HIPEC: hyperthermic intraperitoneal chemotherapy; HCC: hepatocellular carcinoma; NSCLC: non-small cell lung carcinoma; PAD: peripheral arterial disease; PCI: percutaneous coronary intervention; UUT: upper urinary track; VATS: video assisted thoracoscopic surgery; COPD: chronic obstructive pulmonary disease; PAD: peripheral arterial disease (F: Fontaine classification); AV: aortic valve; AVR: aortic valve replacement; MVR: mitral valve replacement; TAVI: transaortic valve implantation.

Figure 5, showing the mean duration of the surgeries and the urgency in terms of QALY loss per month. Liver transplant is excluded in this plot, because it was an outlier in terms of duration of surgeries (median: 875 minutes, IQR: 797-957 and -0.08 QALY per month, 95% CI: -0.09--0.07). **Abbreviations Figure titles**: QALY: Quality of Life without treatment. **Disease abbreviations**: AAA: aneurysm of the abdominal aorta; AP: angina pectoris; ESRD: end-stage renal disease; ASD: atrial septum defect; ca.: carcinoma; CABG: coronary artery bypass graft; ESHF: end-stage heart failure; ESLD: end-stage liver disease; EVAR: endovascular aortic repair; HIPEC: hyperthermic intraperitoneal chemotherapy; HCC: hepatocellular carcinoma; NSCLC: non-small cell lung carcinoma; PAD: peripheral arterial disease; PCI: percutaneous coronary intervention; UUT: upper urinary track; VATS: video assisted thoracoscopic surgery; COPD: chronic obstructive pulmonary disease; PAD: peripheral arterial disease (F: Fontaine classification); AV: aortic valve; AVR: aortic valve replacement; MVR: mitral valve replacement; TAVI: transaortic valve implantation.

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## Appendix A

An overview per disease of the distribution and source of the input parameters and a graphical representation of the output of the model.

## Appendix B

A summary of the estimates of the decision model and an overview of the counts, duration, and length of stay of the included surgeries in our hospital.

## Appendix C

In-dept methods description.

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1. A semi-elective surgery is defined as a surgery that should ideally be performed within three days up to three weeks. [↑](#footnote-ref-1)