Guidelines for the use of Risk Prediction Tools in the Pre-Operative Setting

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Summary and Key Recommendations

- Risk prediction tools should be used to guide multi-disciplinary decision-making, the allocation of appropriate resources and communication with patients and their families.

- The ideal risk prediction tool incorporates information on patient health and fitness, and surgical magnitude and urgency.

- Evidence from national audits suggests that formal assessment and documentation of risk is poorly and infrequently performed by clinicians in the pre-operative setting. Where risks are documented patients are more likely to receive care that meets standards.

- There are a number of tools available to assist the clinician in pre-operative risk assessment. These can be divided into risk prediction scores (providing a numerical scale of risk) and models (providing a percentage estimate of risk).

- No tool is without limitations and all should be used alongside clinical judgment. Inter-hospital variation of the structure and process of care delivery may account for some performance limitation.

- The SORT is easy to use requiring readily available preoperative data and has better calibration and discrimination than P-POSSUM and SRS. A version of the SORT which incorporates clinical judgement could be used by MDTs and/or experienced perioperative clinicians, and the original SORT by other colleagues.

- Further research should focus on the clinical effectiveness of risk prediction tool implementation (i.e. does using risk assessment tools actually improve patient outcomes) and on predicting other patient-centred outcomes such as longer-term survival and health related quality of life.
INTRODUCTION

Over 310 million surgical procedures are performed worldwide each year, representing a significant healthcare and economic burden.[1] The annual number of surgical procedures performed by the NHS is estimated at almost 8 million with numbers expected to continue to increase year-on-year [2]. Post-procedural short-term mortality rates of up to 3.1% have been reported [2] and estimates of major post-operative morbidity in the UK are approximately 15%.[3,4] The impact of post-operative morbidity should not be underestimated, as it has been found to be associated with an increased risk of death for some years after surgery.[3] In Khuri’s seminal analysis of over 100,000 surgical procedures, the most important obstacle to survival in these patients was the occurrence of a complication in the 30 days immediately post-operatively, which reduced median survival by 69%. [5] Over recent years a variation in post-operative morbidity and mortality between UK hospitals has consistently been reported by national audit data.[4,6] This variation suggests that structures and processes aimed at improving post-operative outcomes are delivered more effectively in some hospitals than others, thus indicating the opportunity to improve outcomes by improving standards of care.

As well as there being a legal requirement within the UK to perform an individualised risk assessment of a patient’s risk of adverse outcomes,[7] the identification of high-risk patients is of importance when considering patients perioperative pathway and identifying steps to minimise their risk of adverse outcomes. This chapter details the recommendations over use of risk prediction tools and some principles for selecting and using these tools.

Recommendations from National Reports.

The 2011 NCEPOD report entitled ‘Knowing the Risk’, [8] studied the care provided for over 15,000 adult patients admitted for elective or emergency non-cardiac surgery over consecutive days, highlighting multiple areas where care was substandard. The report particularly stressed that risk was not well identified or acted upon by clinicians. ASA-PS grade was noted to be a poor predictor of risk on its own, with many patients who were thought by their anaesthetist to be high-risk, having an ASA-PS score of I or II. Of the cohort that anaesthetists had defined as high risk, only 20% were admitted to the intensive care unit (ICU) immediately post-operatively and nearly half of those who died were never admitted to the ICU. The highest mortality rate was found among those patients who were admitted to ICU after first being admitted to a ward immediately post-operatively. The authors found that there was a lack of consensus, even amongst their advisors, as to what constitutes perioperative risk.

As a result, the principle recommendation of the report was the adoption of a national pre-operative risk scoring system.

“Our Advisors are in no doubt that we need a UK-wide system that allows rapid and easy identification of patients who are at high risk, and that these people should be recognised as such and managed appropriately. That to me is the most striking take-home message of this Report.”

Mr Bertie Leigh, Chairman of NCEPOD.

The 2010 report by the Royal College of Surgeons entitled ‘The Higher Risk Surgical Patient”, made similar recommendations for the care of high-risk, non-elective surgical patients. It advised that each patient should have their risk of death calculated and documented pre and post-operatively.[9] This risk score should then be used to decide whether the planned surgery is the most appropriate action for that patient. If surgery is deemed appropriate, the perceived risk should be used to determine the appropriate allocation of resources. The updated version of this report from 2018 aligns with the NCEPOD recommendation that patients with a predicted risk of mortality >5% should be admitted to a critical care unit after surgery.[10]
National audit programmes continue to highlight the importance of perioperative risk scoring. One of the main recommendations of the first National Emergency Laparotomy Audit (NELA) report published in 2015 [11] was that pre and post-operative risk scoring should be performed and documented for all patients in order to prioritise care and aid in the allocation of resources. Similarly, the most recent Perioperative Quality Improvement Programme (PQIP) Annual Report emphasises the need for individualised risk assessments and their important contribution to decisions in determining patients post-operative pathway of care.[4] It is notable that in the 10 years since the NCEPOD report was published, we have made some, but not complete progress, towards the ambition of universal individualized documented risk assessment and appropriate actions taken thereafter – recent reports from both NELA and PQIP indicate that there is still room for improvement.

How can we identify patients with a high peri-operative risk?

One approach would be to focus efforts on high-risk populations, for example, patients presenting for emergency surgery. Data from the national hip fracture audit and from the National Emergency Laparotomy Audit (NELA) demonstrates that these groups of patients are high-risk.[11,12] The most recent data from NELA suggest an overall mortality of 9.6%, which remains up to five times higher than mortality in high-risk elective surgery. [6,13,14]

However, limitations to focusing solely on the sub-populations of patients who present for high-risk procedures can be demonstrated by considering the ‘Prevention Paradox’. Whilst it is widely known that emergency surgery may carry a higher percentage risk of death for individual patients, the majority of surgical procedures that are performed are elective and it is in this elective group of patients that the highest numbers of deaths actually occur. Determinants of peri-operative risk include patient-level (age, fitness and co-morbidities), surgical-level (complexity and urgency of surgery) and system-related risk factors.[15,16] Basing risk assessment on specific types of surgery for example, emergency or major and complex surgery, may fail to capture a large number of patients who would also be considered high risk on the basis of their fitness or past medical history. An alternative approach is to focus on the individual risk scoring of all surgical patients. There are a variety of risk stratification tools available to help clinicians calculate individual risk and therefore identify those who fall into the highest risk categories.

How do we evaluate a risk prediction model?

1. Performance

The performance of a risk assessment tool should be assessed by testing it for both discrimination and calibration.[17]

**Discrimination**

This is the ability of a tool to successfully identify who will have the outcome of interest and who will not. To demonstrate this, Receiver operating characteristic (ROC) curve is made by plotting the relationship between sensitivity and 1-specificity. The frequency with which the prediction tool predicts an outcome that goes on to actually occur, is measured by the area under the ROC curve (AUROC).[18] Perfect discrimination has an AUROC of 1.0, no discrimination has an AUROC of 0.5. A good discriminator is considered to have an AUROC of greater than 0.9, and a poor discriminator, less than 0.7.[19]

**Calibration**

This is the comparison between the predicted outcome, as defined by the risk prediction tool, and the actual outcome. In other words it is the ratio of observed events to expected events. This relationship can be mapped on a calibration plot, with x=y indicating a perfectly calibrated model.
2. Generalisability

If the model is found to retain good levels of calibration and discrimination in different datasets to the one used to create the tool, it is considered to be generalisable. To truly test this, the tool must undergo a process of external validation, where it is tested against a group of patients which is independent of the original development cohort. Internal validation can give valuable insights into a model’s performance but is not a true test of generalisability and is often an over-estimation of a models predictive ability.

3. Utility

This relates to ease of use. An ideal tool would be simple and quick to use, easy to access, usable at the bedside and would not require expert knowledge or expensive equipment. A tool with optimal utility in the pre-operative setting would only require the input of readily available, pre-operative data.

4. Clinical effectiveness

The question of whether the tool is clinically effective is an important one. An effective risk prediction tool would offer information that could be used by the clinician to appropriately alter the patient journey and subsequently improve patient outcome.

RISK PREDICTION TOOLS

There are a variety of tools available to allow the clinician to make an estimate of perioperative risk for an individual patient. These can be divided into risk scoring systems and risk prediction models. Both systems are usually developed using multivariable analysis to identify risk factors for a specific outcome. Risk scores add a weighting to each risk factor depending on the strength of the regression co-efficient and then calculate a total score for each patient.[20] The patient can be placed on a scale in which they are compared to other patients but cannot be provided with their own individual risk of an outcome occurring. In comparison, a complex risk prediction model can offer this. By entering patient information into the model, an individual probability of a particular outcome can be obtained.

1. Risk Scores

1.1 ASA-PS

The American Society of Anaesthesiologists Physical Status score (ASA-PS) is probably the most commonly used risk score by anaesthetists. The ASA-PS score allows clinicians to place a patient’s physical status into one of five categories depending on their co-morbid state and perceived functional status. Originally reported in 1941 and including six categories at that stage, it was designed to serve as a score to enhance statistical records only and not to prognosticate risk.[21] Following discussion of the many variables that contribute to a patent’s prognosis after surgery, the author of the original report concludes “No attempt should be made to prognosticate the effect of a surgical procedure upon a patient of a given “Physical State”.

The ASA-PS has many attributes. It is familiar to all anaesthetists and has good interdisciplinary understanding. It is simple, easy to use and a high ASA score has been shown to correlate with poor outcome.[22,23] Its validity as an assessment of functional capacity has been demonstrated, which may go some way to explaining this predictive ability.[24] However, there are a number of
limitations to its use as a sole risk-scoring tool. As an inherently subjective score, inter-rater reliability can be poor, and training is required to support clinical use.[25-27] It crudely differentiates between high and low risk patients, with the population mortality of ASA 3 patients estimated at 3% and ASA 4 patients around 16%.[28] It cannot therefore be used for an individualized risk assessment for a specific patient. Crucially, it does not consider the severity or urgency of the proposed surgery – an ASA 4 patient having a minor procedure under local anaesthetic is unlikely to have a poor outcome as a result of the surgery.

1.2 The Charlson Co-morbidity Index

The Charlson Index was first published in 1987 and was designed to classify co-morbid disease to enable prediction of mortality in medical patients.[29] Whilst perhaps not frequently used by the perioperative practitioner in risk assessment of individuals prior to surgery, it remains relevant as the method used to risk-adjust Hospital Episode Statistics data. Co-morbid diseases are weighted according to the strength of their association with one-year mortality and the number of co-morbidities per patient is taken into account. The sum of these weighted scores gives a patient an overall score of risk. When compared to other risk scoring tools in the surgical setting, it has been found to be a poor predictor of short-term mortality.[30]

1.3 RCRI

Lee’s revised cardiac risk index, published in 1999 is a validated and well-established tool for estimating perioperative risk of major adverse cardiac events (MACE).[31] It does not provide an estimation of mortality or other organ specific morbidity. The authors, through a large observation study identified six independent predictors of risk, one of which was the severity of anticipated surgical insult. Patients with two or more risk factors are considered high risk of MACE. A recent systematic review found that the Lee Revised Cardiac Risk Index was, the only index they identified which, had been both internally and externally validated and that despite its age it remains one of the most useful perioperative cardiac risk prediction indices.[32]

2. Risk Prediction Models

2.1 POSSUM tools

The original Physiological and Operative Severity Scoring for the enumeration of Mortality and morbidity (POSSUM) was developed to compare mortality and morbidity across a wide range of surgical procedures. This risk-adjusted scoring system used 18 variables (12 physiological and 6 operative) and calculated the risk of morbidity and mortality for each surgical patient. It was found to over-predict adverse outcomes, especially for low risk patients and therefore its use was cautioned against.[33]

As a response to this, a group in Portsmouth used the same variables but introduced modifications to the mathematical model (for the prediction of mortality only) and this is known as the P-POSSUM score.[33,34] The P-POSSUM score is currently widely used and has been validated in several countries and in many heterogeneous and surgery specific cohorts.[35-38] Despite this however, there are a number of limitations to this model.

First, it requires intra-operative data such as intra-operative blood loss and presence of intra-peritoneal soiling before a risk can be generated, and therefore guesswork is required to use it in the preoperative setting. Second, P-POSSUM requires the input of 18 variables and as such may not be considered user-friendly by the clinician. Third, several of the variables are subjective such as interpretation of a chest x-ray, which therefore risks measurement error.
A number of surgery specific POSSUM models (e.g. CR-POSSUM for colorectal surgery, O-POSSUM for oesophageal surgery, V-POSSUM for vascular surgery) have been more recently developed but different studies have shown varying degrees of utility with regard to their suitability as a tool to predict post-operative risk. For example, Hong et al concluded that P-/O- POSSUM were better predictors of mortality in gastric cancer patients than POSSUM [39] but Eichelmann et al found that O-POSSUM failed to predict mortality and POSSUM was superior.[40]

2.2 NSQIP

The American College of Surgeons National Surgical Quality Improvement Programme (ACS-NSQIP) Surgical risk calculator is a multivariable model to predict a range of outcomes within 30 days of surgery inclusive of morbidity, serious morbidity and mortality. The universal model [41] was published in 2013 following the publication of previous surgery specific models.[42] Data from 393 hospitals incorporating over one million patients were used to construct the model. It is necessary to input the type of surgery and 21 patient specific variables in order for the model to calculate individualised risk predictions for specific post-operative complications and for overall post-operative mortality.

In 2016, the model was updated to include three additional outcomes (serious morbidity, return to operating room, discharge destination) and was recalibrated. The initial model performed well with AUROC for mortality of 0.94 and an AUROC for morbidity of 0.82 [41] but there was a slight tendency for risk to be overestimated for low- and high- risk patients and underestimated for mid-risk patients. Following recalibration the authors report the elimination of this distortion and the tool now providing accurate estimates of surgical risk.[43]

There are a few limitations when considering its overall performance. First, it is a web-based model and as such requires availability of the necessary IT resources. It is significantly more complex than some other risk prediction tools requiring the input of 21 variables, which may be considered time consuming for the busy perioperative clinician. Second, it requires the input of subjective variables such as ASA scoring leaving it open to inter-rater variability.[44] Third, although the calculator takes 21 pre-operative risk factors into account, the authors consider that there may be other factors a surgeon would consider to have an influence on risk. To allow room for this clinical judgment, the tool incorporates a ‘surgeon adjustment score’. This allows the surgeon to adjust the degree of calculated risk, within the confidence interval for that particular predicted risk, according to their clinical acumen. This is another area where the model may introduce inaccuracy. Finally, the model has not been validated outside NSQIP hospitals, which account for 10% of all hospitals in the United States. This raises questions regarding its generalisability to different countries and institution types.

2.3 Surgical Outcome Risk Tool (SORT)

The SORT was developed in the UK in response to the 2011 NCEPOD report ‘Knowing the Risk’, which called for a national system to identify high-risk patients pre-operatively.[29] The authors used data from this large, prospective, multi-centre, observational cohort study to derive this risk prediction model. Data from over 11,000 patients were used to derive the model and data from a further 5,000 patients were used to internally validate it.

SORT predicts 30-day mortality in adults undergoing non-cardiac and non-neurological inpatient surgery. It is a simple to use model requiring the input of only 6 pre-operative variables along with the planned surgical procedure and as such, may be considered more user-friendly than some other risk prediction models. The six variables are: (i) ASA-PS (ii) urgency of surgery (iii) surgical specialty (iv) severity of surgery (v) cancer and (vi) age. No blood, imaging or intra-operative results are required which allows risk prediction by clinicians early in the preoperative assessment phase.[29]
Data were generated from a range of surgical specialties and emergency and elective cases across a range of UK hospitals. Internal validation demonstrated the SORT to be more accurate than the ASA-PS and the SRS.[29] Recent work by Wong et al. has demonstrated better external validation of SORT than P-POSSUM or SRS and good to excellent discrimination of SORT with an AUROC of 0.9.[45] While a morbidity model has also been developed [46] this has yet to be externally validated in a large heterogeneous dataset.

2.4 National emergency laparotomy audit (NELA) calculator

The NELA risk prediction tool was developed using data from over 38,000 patients entered into the NELA between 2014 and 2016. It estimates risk of death within 30 days of emergency abdominal surgery. P-POSSUM was originally used to predict mortality for NELA patients but was found to overestimate mortality for patients whose predicted risk fell into the >15% cohort (i.e. a significant proportion of patients undergoing emergency laparotomy).[47] The NELA-specific risk calculator was found to be more accurate than P-POSSUM in the NELA cohort of patients.[48]

A NELA smartphone app has been developed on which both P-POSSUM and NELA calculators are available facilitating its use by busy clinicians. Its main advantage is its specificity for emergency laparotomies. Its limitations include the requirement of an extensive data set similar to P-POSSUM including intra-operative findings and it does not generate a morbidity risk. In contrast to the P-POSSUM score, the NELA calculator includes ASA scoring which gives rise to inter-rater variability.

2.5 Combining subjective and objective risk assessment measures

Clinicians frequently rely on their own clinical acumen based on previous knowledge and experience to make an assessment of a patient’s perioperative risk. The ability of clinicians to predict post-operative outcomes compared with predictive risk tools to date have produced mixed findings. Several studies have demonstrated the ability of clinicians to define and predict risk is inconsistent.[8, 49] Yet one study specific to major hepatobiliary and gastrointestinal surgery found that a surgeon’s ‘gut feeling’ was more accurate in the prediction of morbidity than P-POSSUM.[50] These findings suggest that clinical judgment is important but alone it is not enough to accurately predict outcomes post-operatively.

Recent work compared the accuracy of three objective surgical risk tools (P-POSSUM, SRS and SORT) with subjective clinical assessment in predicting 30-day mortality in almost 300 hospitals in the UK, Australia and New Zealand.[45] This prospective observational study included of over 22,000 adult patients undergoing surgery requiring at-least a one night stay in hospital. The study found that all objective surgical risks tools over-predicted risk but the SORT was found to have the best calibration and discrimination of the objective tools. Further findings were that subjective assessment was as accurate as SORT for predicting death in hospital within 30 days of surgery and the combination of a subjective assessment with a risk model improved perioperative risk estimation further.

The SORT-clinical judgment model appears to be a very promising tool, which would aid with clinical decision-making, allocation of resources and communication with patients and their families. It is important to recognize that the ‘clinician judgment’ estimate was provided by the perioperative team, and therefore will have been the estimate of an experienced multidisciplinary team. It may therefore be worth considering using the combined objective-subjective estimate when senior or MDT colleagues are able to provide the subjective perspective, and reverting to the objective SORT model alone, when less colleagues less experienced in perioperative risk and outcome are undertaking risk assessment.
WHY ARE WE NOT USING RISK PREDICTION TOOLS?

Despite the availability of many risk prediction tools, widespread adoption of their use is poor. The NCEPOD report stated that, according to the case notes of the 496 patient's identified as high risk, only 7.5% of patients were given an estimate of mortality pre-operatively.[8] Similarly, a recent study which included over 22,000 patients undergoing surgery, found that clinicians used subjective assessment alone in almost 90% of cases.[45]

There are a number of possible reasons why clinicians may not use risk prediction tools. First, there may be uncertainty about which tool to use and when. The number of tools available and the differing opinions on their use may be overwhelming. Secondly, clinicians may prefer to use their clinical experience and judgment in assessing risk particularly when the accuracy of subjective compared with objective methods is unclear.[51] Third, there may be concerns regarding the accuracy of risk prediction tools. As demonstrated for the tools explored above, limitations can be found with all risk prediction tools. Even if they are deemed highly discriminative, with AUROC > 0.9, that still means that there is a 10% room for error. Often when a tool is made more generalizable, it sacrifices its power of discrimination and level of calibration. Finally, many tools require the availability of multiple investigations (some of which are not available pre-operatively) that can be time-consuming to input. This in itself may be a barrier to clinicians using risk prediction tools.

WHAT IS THE ‘PERFECT’ RISK PREDICTION TOOL?

There are many reasons why the creation of a perfectly precise, well-calibrated and fully generalizable risk tool poses a huge challenge. Surgical outcome is not just dependent on the patient’s co-morbid state and the nature of the procedure they are having. Hospitals differ in their structural organization and in the processes of care that they deliver. This variation in structure and process is well demonstrated in our national audits and databases.[4,6,8,12]

Emergency surgery poses its own challenges for risk scoring. Patients often present with acute physiological derangement and with limited time for improvement pre-operatively. Again, hospitals differ greatly in the way in which they provide emergency care, for example, the seniority of out of hours staff, the provision of a dedicated emergency theatre or the availability of unplanned ICU care post operatively.[8,52,53] Such structure and process variation was evident in both the organisational (structure) and patient-level (process) reports of the UK National Emergency Laparotomy Audit.[6]

In view of the difficulties associated with predicting risk in groups of patients presenting for emergency surgery several procedure specific risk calculators have been developed such as the NELA calculator and the Nottingham Hip Fracture Score.[48,54] In general, surgery specific risk models have shown some promise in more accurately predicting risk for sub-groups of patients but continued work is needed. On the other hand, busy clinicians may favour a single risk tool, which is generalizable to all surgery types and patient groups. To this end, the SORT and SORT-clinical judgement models provide good estimates of risk in individual specialty specific cohorts of patients.[45]

There is debate about which outcome measures should be our focus. Most highly validated tools can only accurately give predictions of mortality, whereas perhaps morbidity and likelihood of disability free survival is of greater importance to our patients and for the optimal distribution of healthcare resources.[55] Morbidity is a more common occurrence post-operatively than mortality. However, morbidity prediction models tend to be less accurate than mortality prediction models, when discrimination is assessed in large multi-centre databases. This is likely to be due (at least in part) to the inter-rater variability in measuring and reporting postoperative complications, and the variation in how complications may be defined.
The Standardised Endpoints in Perioperative Medicine (StEP) initiative has recently defined measures, which may provide a more objective measure than those traditionally used by researchers and which they suggest should be used in future research to measure patient-centred outcomes in perioperative medicine.[56] The measures with strong recommendations include one health related quality-of-life measure (EuroQol 5 Dimension), one functional-status measure (WHO Disability Assessment Schedule) and one life-impact measure (days alive and out of hospital at 30 days after surgery). A standardisation of measured outcomes would facilitate the comparison between studies and enable evaluation of interventions for patient benefit. The Perioperative Quality Improvement Programme (PQIP) is a UK based study of the perioperative care of patients undergoing major non-cardiac surgery and measures complication rates and a variety of patient reported outcomes as well as the more usual outcome measures of mortality and length of stay.[57] PQIP now has data on over 30,000 patients which will be used to develop models to predict perioperative outcomes other than death including inpatient complications, and longer-term survival and health related quality of life.

With the discussion of a multitude of limitations it may be questioned as to the validity and purpose of using risk prediction tools at all. However, it is considered that such tools are a particularly important part of preoperative assessment for multiple reasons. First, risk prediction scores provide a universally understood language, which can be used by members of the multidisciplinary team. Second, risk prediction tools may offer patients a comprehensible assessment of risk that will facilitate shared decision-making conversations with patients. Third, risk prediction tools allow planning of resource use in the perioperative period such as enhanced or critical care for patients who are deemed to be high-risk and conversely, the avoidance of inappropriate admissions of low-risk patients to critical care. Fourth, risk prediction tools may be used to identify patients who may benefit from targeted pre-operative intervention to modify risk. Finally, risk prediction tools are important where the preoperative assessment is conducted by a variety of healthcare professionals, of different levels of experience, and who may have varying understanding of the rates and reasons for adverse postoperative outcomes. As with all prognostic markers, the aim of using risk stratification tools is to improve the consistency of approach to risk assessment, and as such, these methods should only to be used in conjunction with clinical judgment and within the context of the organisation.

CONCLUSION

While generally a safe and effective intervention, major surgery can pose significant risk of complications, reduced health related quality of life and death for high-risk patients. There is a need for perioperative clinicians to identify these high-risk individuals pre-operatively and to plan their care accordingly whilst considering the appropriate distribution of a finite set of resources. National guidance recommends the use of evidence-based risk-prediction tools, which, alongside sound clinical judgment and a good understanding of the working environment, can help to identify high-risk individuals. Further research should focus on developing tools to predict other patient-centred outcomes, and on measuring the impact that the use of risk prediction tools may have on surgical outcome.
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