EACTS guidelines for the use of patient safety checklists

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Abstract

The Safety Checklist concept has been an integral part of many industries that face high-complexity tasks for many decades and in industries such as aviation and engineering checklists have evolved from their very inception. Investigations of the causes of surgical deaths around the world have repeatedly pointed to medical errors that could be prevented as an important cause of death and disability. As a result, the World Health Organisation developed and evaluated a three-stage surgical checklist in 2007 demonstrating that complications were significantly reduced, including surgical infection rates and even mortality. Together with the results from other large cohort studies into the utility of the surgical checklist, many countries have fully implemented the use of surgical checklists into routine practice. A key factor in the successful implementation of a surgical checklist is engagement of the staff implementing the checklist that did not cover issues particular to our specialty, and thus the European Association for Cardio-Thoracic Surgery embarked on a process to create a version of the checklist that might be more appropriate and specific to cardiothoracic surgery, including checks on preparations for excessive bleeding, perfusion arrangements and ICU preparations, for example. The guideline presented here summarizes the evidence for the surgical checklist and also goes through in detail the changes recommended for our specialty.

Keywords: Checklist • Thoracic surgery • Patient safety • Transplantation • Paediatric surgery

INTRODUCTION

In November 1999, the Institute of Medicine in the USA published the report 'To Err is Human–Building a Safer Health System', which showed that between 44 000 and 98 000 patients died each year as a result of in-hospital medical errors that could have been prevented [1].

It is a regrettable fact that surgical teams are far from perfect and that we have no room for complacency. High rates of preventable surgical site infections resulting from inconsistent timing of antibiotic prophylaxis administration persist. Anaesthetic-related complications remain high and despite many high-publicity cases throughout Europe, wrong-patient, wrongsite operations continue to occur. Surgical teams have often been criticized for their lack of formal briefings or preparation with other team members and, equally, there is no structured debriefing of the operating team after most operations. Errors of omission remain common and the increasing complexity of surgery and sometimes high turnover of staff in theatres mean that these issues are likely to become increasingly important.

Many lessons can be learned from the aviation industry, where human factor effects on safety have been well studied. Wilbur Wright in September 1900 said after one of his pioneering flights, 'in flying I have learned that carelessness and overconfidence are usually far more dangerous than deliberately accepted risks'. This is a sentiment equally applicable in surgery as it is in aviation. As aircraft became increasingly complex, the use of checklists by pilots became part of working in a safety conscious environment from the 1940s. In the 1970s, there were a series of preventable aviation accidents and, when analysed, it was shown that a combination of stress, fatigue, poor communication and preventable errors had caused up to 80% of accidents. Through the use of checklists and crew resource management training the incidence of aviation accidents has continued to fall despite significant increases in the volume of air traffic. In aviation, checklists are now an essential part of

SUIDELINE

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preparation for undertaking complex procedures. Checklists are used prior to all critical events such that there is a list of checks to be performed prior to starting the engine, taxiing the aircraft, taking off and landing. The use of a checklist provides an opportunity to correct any issues before proceeding and gives a shared responsibility for safety among the crew.

Checklists have been clearly demonstrated to facilitate multistep processes to improve team dynamics and minimize error and at a more basic level is always a backup to human memory [2-8].

So can the lessons from aviation be applied to the surgical team environment? We all agree that currently surgical teams do most of the right things on most patients most of the time, but using surgical checklists will assist us in doing all of the right things on all of the patients all of the time. In applying checklists to surgery, however, there have to be a number of important caveats. Firstly, the checklist needs to be adaptable to the local setting. It needs to be supported by evidence and therefore be credible to those who are using it. Checklists need to be evaluated in use and proven to be practicable and they should promote adherence to established safety practices within hospitals. Importantly, the introduction of checklists needs to consume only minimal resources.

THE SCOPE OF THIS GUIDELINE

This guideline covers the use of checklists for all patients undergoing cardiac surgery and thoracic surgery. Included in this definition are paediatric patients undergoing either heart or lung surgery.

METHODOLOGY OF THE GUIDELINE

A literature review was performed from using the OVIDSP interface. Medline was searched from 1948 to July 2011 and EMBASE was searched from 1988 to July 2011. Also the Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Cochrane Methodology Register, The Database of Abstracts of Reviews of Effects, The Health Technology Assessment and the NHS Economic Evaluation Database were all searched. Searches were performed using the words 'Surgical Checklist', 'Safety Checklist' or 'Checklist' as appropriate and reverse citation checking was performed on all selected papers.

We searched 326 abstracts and we selected and presented 26 articles of interest to the committee for assessment.

LEVELS OF EVIDENCE AND GRADING OF RECOMMENDATIONS

We support the recommendations for formulating and issuing Guidelines and Expert Consensus Documents which can be found on the European Society of Cardiology website (http:// www.escardio.org/knowledge/guidelines/rules) and which have been used previously in formulating EACTS guidelines [9].

In brief, with regard to grading the level of evidence derived from published papers:

Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses.

Level of Evidence B: Data derived from a single randomized clinical trial or large non-randomized trials.

Level of Evidence C: Consensus of opinion of the experts and/ or small studies, retrospective studies, registries.

Then once recommendations are made, they are then classed by the strength of their recommendation:

Class I: Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.

Class II: Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.

Class IIa: Weight of evidence/opinion is in favour of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.

THE WHO CHECKLIST

In 2007, the World Health Organisation (WHO) developed a simple patient safety checklist [10], which was divided into three sections. One undertaken before the induction of anaesthesia, the second undertaken before skin incision at the start of surgery and the final section being completed when the patient leaves the operating room. The checklist comprised of very basic checks, such as the identity of the patient and the procedure that they were to have performed, the site of operation and simple checks of anaesthesia and monitoring equipment. There were also checks regarding patient allergies, airway and bleeding risks as well as anticipating critical events. In broad terms, the checklist division into the three stages mirrored the take-off, cruise and landing checklist phases present in the aviation environment. The WHO checklist was trialled in eight different countries across a spectrum of health-care systems and environments. The results were published in The New England Journal of Medicine (NEIM) with the hypothesis that a simple programme to implement a 19-item surgical safety checklist might improve team communication and consistency of care in the surgical environment and therefore reduce complications and deaths [11, 12]. The results from 3733 patients operated on before the use of the checklist compared with 3955 patients operated on using the checklist showed quite dramatic effects. The risk of death from surgery fell from 1.5 to 0.8% (P = 0.003), complications were reduced by 30% (P < 0.001) and surgical site infections were reduced by up to 50% (P < 0.001). Similarly, there were reductions in the frequency of unplanned re-operations in the patient cohort studied.

THE SURPASS STUDY (SURGICAL PATIENT SAFETY SYSTEM)

A comprehensive multi-disciplinary surgical safety checklist was assessed by the SURPASS collaborative group in Holland and published in the NEJM in 2010 [13]. This study not only implemented a perioperative checklist but also took all other checking processes in the patient pathway, and combined this into one uniform checklist for the full patient journey from arrival on the ward to discharge. This checklist is available for free download in the NEIM full text version of the paper [13]. A total of 3760 patients were observed before implementation of the checklist and then 3820 patients were observed after implementation. The total number of complications per 100 patients decreased from 27 to 17, which was an absolute risk reduction of 10% (P < 0.001). In hospital mortality decreased from 1.5 to 0.8% (P = 0.003) with no outcome changes observed in the control hospitals. This study differs from the WHO study in that all hospitals were academic or teaching hospitals in Holland and thus had a high standard of care even before the study. In addition, the checklist covered the entire surgical pathway rather than just the perioperative period. The mortality and morbidity benefits persisted even with an analysis for potentially confounding variables such as age, ASA score and urgency in the two groups of patients, which were mainly general surgical, trauma or vascular patients. Also they showed that the more completely the checklist was filled in, the lower the complication rate of the patients.

RECOMMENDATION

Surgical Checklists have been proved to reduce both morbidity and mortality in multi-centre cohort studies across multiple surgical specialties and as such are recommended for use for all patients undergoing cardiac or thoracic surgery.

Class I recommendation based on two non-randomized studies (Level B).

CHECKLISTS FOR CARDIOTHORACIC SURGERY

Following the success of this initiative on patient safety, the National Health Service (NHS) via the National Patient Safety Agency made a pledge to implement WHO Surgical Safety Checklists in all hospitals in the UK such that they would become mandatory for all operations undertaken in the NHS from February 2010 [14]. The checklist was modified for use within this health-care organization but was very much geared to the general surgical or orthopaedic surgical environment. It was clear that there were significant omissions for cardiac and thoracic surgery and therefore a lost opportunity to enhance patient's safety in the environment of cardiothoracic surgery [15]. In particular, insufficient attention was paid to preparations for excessive bleeding, inclusion of perfusionists and perfusionrelated issues, the use of theatre briefings and debriefings with the operating team and anaesthetic colleagues and provision for checking cardiovascular monitoring and transfer arrangements for patients back to Intensive Care Unit. The use of a generic checklist therefore missed many opportunities to enhance safety and a cardiac surgery-specific checklist was clearly warranted.

The Society of Cardiothoracic Surgery in Great Britain and Ireland developed a national standard checklist for cardiac surgery within the constraint that NHS checklist items could not be removed and only additions were permitted (www.scts.org). Subsequently, this checklist was evaluated by the National Patient Safety Agency and approved for use across the NHS in cardiac surgery [14]. The cardiac surgical safety checklist retains the three-section format common to the WHO checklist but adds in essential safety checks relevant to the specialty. Indeed, the Society of Thoracic Surgeons in the USA has also developed checklists in cardiac, thoracic and paediatric cardiac surgery as templates which can be modified by individual units rather than making it a mandatory process as in the UK (www.sts.org and see patient safety resources).

There is little doubt that the use of a surgical checklist improves teamwork and communication and is a focal point for starting an operation and sharing any concerns or expectations regarding the procedure. It adds redundancy to existing safety processes but is not a panacea in itself and requires sensitive introduction, local adaptation and human factors awareness and training to be successful.

Further studies on surgical safety checklists have continued to demonstrate significant advantages. A prospective trial of 1750 patients in a non-cardiac surgical environment was published by Weiser et al. [16]. This study showed a reduction from 18.4 to 11.7% (P = 0.0001) in terms of complications and reduction from 3.7 to 1.4% (P = 0.0067) in postsurgical mortality. Compliance with existing safety measures and standards rose from 18.6% before the checklist was introduced to 50.7% afterwards (P < 0.0001). An analysis following the implementation of surgical safety checklists among NHS Trusts in the UK in June 2010 indicated that 77% of Trusts felt that teamwork had improved as a result of introducing the checklist and that safety had improved in 68%. Of the total respondents, 41% indicated that near-miss incidents had been captured and that in 35% of Trusts procedures were now smoother and guicker than before the introduction of the checklist (implementing the Surgical Safety Checklist www.patientsafetvfirst.nhs.uk).

In terms of preoperative briefing, the effect of this is not to be underestimated. Henrickson *et al.* [17] showed reduction of surgical flow disruptions, procedural knowledge deficits and miscommunication by 50% simply by undertaking preoperative briefings.

In introducing a European checklist, there are certainly practical challenges ahead. Initial reactions are often mixed towards the concept and there is likely to be variability in the use of and compliance with the checklist such that there are requirements for good leadership and an understanding of human factors. There are issues over responsibility for the checklist and the omission of sections of the checklist or distractions while performing it; interruptions, apathy and individualism are all enemies to the success of this safety initiative. In individual units, there may be concern that this duplicates existing bureaucracy, but the use of a European checklist may make such additional paperwork redundant and replace it, either in part or completely, and assist uniformity. It is important to ensure the relevance of surgical safety checklists rather than try to have a generic format and miss important safety elements. It is crucial therefore to have checklists for cardiac, thoracic, cardiopulmonary transplant and congenital heart surgery.

In summary, checklists have been proven in the aviation industry to enhance safety, teamwork and communication. There is little doubt that this can be translated into the surgical environment if we ensure that checklists are specialty specific, relevant and rapid to use. Their introduction however will require strong leadership. The use of surgical safety checklists has been demonstrated in many studies to enhance patients' safety, and reduce mortality and the rate of complications. This will have undoubted economic benefits. The additional opportunity to build in formal preoperative briefings and postoperative debriefings with the operating team and to share the responsibility for the safety of the patient can only improve teamwork and communication between surgeons and their colleagues. GUIDELINE

RECOMMENDATION

Surgical safety checklists have been shown consistently to reduce mortality and morbidity. Specialist checklists are likely to reduce morbidity and mortality more effectively than the available generic general surgical checklists. Additional checklist items, based on the expert opinion of multiple specialty groups and societies, are likely to improve safety further.

Class Ib recommendation based on expert consensus (Level C).

EACTS PATIENT SAFETY CHECKLISTS

In addition to the WHO and SURPASS checklists, there are many other checklists. Checklists were looked at by the Clinical Guidelines Committee from multiple countries [18-25] and also from multiple specialities [26-32]. In addition, the committee fully supported the call in the British Medical Journal for checklists modified by specialty, especially in cardiothoracic surgery [15]. The final decision was to opt for a checklist most like the recommended WHO checklist, noting that a more comprehensive alternative such as that analysed by SURPASS would be more appropriately generated locally by units that could incorporate the checklists presented here. The EACTS surgical safety checklists maintain the same style and format as the WHO checklist, consisting of three sections to be performed sequentially. The first section is the sign-in section to be performed before induction of anaesthesia. This is followed in the operating room by the time-out phase, which is performed immediately before the start of surgery. The sign-out phase is performed before the patient leaves the operating theatre to be transferred to the intensive care unit or high dependency area or the ward. Patient can only improve teamwork and communication between surgeons and their colleagues.

RECOMMENDATION

Cardiothoracic surgeons must show strength and leadership in the introduction of patient safety checklists into their operating environment and ensure compliance with the concept among operating room staff. Only with good management can the full benefit to patients be realized.

Class IIa recommendation based on expert consensus (Level C).

SIGN IN

For cardiac and thoracic surgical safety checklists, there are generic checklist items, which are consistent among all of the safety checklists. These include a confirmation of the identity of the patient, which encompasses a check of the site of the operation and the procedure to be performed, and that the consent form has been correctly filled out and signed by the patient.

There continue to be many instances of wrong site and wrong procedure operations performed throughout Europe every year and this is a simple check that all is in order. It is important to perform this while the patient remains conscious before the induction of anaesthesia and is an active participant in this process. There is another check that the operating site has been marked. Whilst important in thoracic operations, this of course may not be applicable for most cardiac procedures. Of note, centres could decide to mark the legs that are suitable for vein harvest or alternatively mark when a leg is not suitable for harvest if, for example, there is a history of varicose vein surgery. There is then an important check that all ward preparations have been completed. This would include ensuring that the patient has been fasted, that the patient has been showered in antiseptic and that hair at the operative site has been removed. It is also a chance to ensure that glycaemic control has been achieved and that blood or blood products (if needed) are present in the operating theatre complex ready for use. The methicillin-resistant Staphylococcus aureus and methicillin-sensitive Staphylococcus aureus status is then checked. The anaesthetic team is then able to confirm that the anaesthesia machine and monitoring systems are all in order as well as relevant medications prepared and checked. For cardiac operations, this is also an opportunity to check the perfusion regime and prescription and that this is agreed between the anaesthetist and perfusionist. Main allergies are then checked so that the entire theatre team is aware of any issues.

The patient is then assessed regarding their airway and whether this will present a difficulty for intubation or whether there is an aspiration risk in their particular case. There should then be a discussion regarding the risk of excessive blood loss and if this is likely to be the case, the surgeon should discuss at this point the relevant preparations and plan with the anaesthetic team to ensure that the required drugs, blood and blood products are available at the end of the case. There should then be a procedure briefing with the anaesthetic team to ensure that the plan for the operation has been agreed. Any special items of equipment that may be required can be identified at this stage to allow sufficient time for them to be acquired before the operation commences. A locally agreed protocol should be implemented as to who has the responsibility for the sign-in (and also the sign-out) phase. Local teams may elect to ask the surgeon performing the operation to be in charge of these phases of the checklist, or logistically it may be necessary for the anaesthetist to be in charge of these phases. This should be discussed and agreed upon prior to implementation of checklists in units and then adhered to.

TIME OUT

There are common checklist items to be carried out at this stage prior to commencement of the operation. This would be performed when the patient is in the operating room and the operating team is ready to start the surgery. These will include an introduction of the personnel in theatre. This gives an opportunity for any new staff or visitors to make themselves known and welcomed. The patient and procedure is then verbally confirmed by the surgeon who is to perform the procedure and the procedure, site and positioning of the patient is checked. The surgical incision and any additional surgical access are then agreed upon. There is then an opportunity to carry out a theatre team briefing to discuss the procedure to be performed and identify any particular items of equipment or special equipment that may be required for the operation.

It should be encouraged that the theatre team discuss any potential, critical or unexpected events and the plans for dealing with this to ensure that relevant items of equipment are present in the operating theatre. Instrument sterility is then confirmed and relevant arrangements for thromboprophylaxis are checked. There is then a check of equipment and staffing concerns so that there is minimal disruption to the operation. It is then important to check that the surgical site infection bundle has been administered. In particular, one should check that prophylactic intravenous antibiotics have been administered within 60 min of skin incision and that iodophor-impregnated drapes have been used.

Finally, any relevant imaging should be confirmed as having been reviewed or that it is displayed in the operating room.

SIGN-OUT PHASE

The sign-out phase should be carried out before the patient leaves the operating room. This confirms that the instrument, sharp and swab count has been performed and is correct. There should then be a debriefing of the operating theatre team to discuss any equipment or procedural problems that occurred during the case and that these have been addressed to prevent a similar occurrence in future. There should be a confirmation that the operation note has been done by the operating surgeon and a check that any concerns for recovery and postoperative care have been discussed and recorded among the surgical and anaesthetic team. For thoracic cases this may include instructions regarding chest drain management to the recovery area staff and for cardiac patients this may include checks of pacing box mode and thresholds. Intensive care unit documentation and drug charts should then be checked and filed prior to the patient leaving the operating theatre.

SPECIALITY SPECIFIC CHECKLIST ITEMS

Thoracic surgical safety checklist

For thoracic surgery the airway management plan should be agreed upon and checked during the sign-in stage. This may include discussion of double- or single-lumen intubation or the use of bronchial blockers and requirements for a bronchoscope to be available. The patient positioning and safety should also be checked at this stage in particular checking for safety of pressure areas to protect the patient. Before the start of surgery in the time-out section the position of the endo-tracheal tube should be checked. At sign out there should be a check that specimen requests have been completed and specimens have been sent to the laboratory and also a check of the analgesia strategy for the patient's recovery (Fig. A1).

Cardiac surgical safety checklist

The sign-in items are standard and have no particular additions. In the time-out phase before the start of surgery, there should be a perfusionist check and briefing to ensure that the perfusionist is fully aware of the plan for cardiopulmonary bypass or any special requirements that are needed. The myocardial protection strategy should also be agreed upon. If there is a trainee present or multiple surgeons involved in the operation, the surgeon may use the briefing to highlight which parts of the operation each surgeon is likely to perform. In addition, the surgeon should estimate the number of grafts that are likely to be performed or the type of valve he would like to use (Fig. A2).

Cardiopulmonary transplant organ retrieval checklist

Cardiopulmonary transplantation is a uniquely complex process with a far greater number of factors to consider in order to achieve a successful outcome. Organ retrieval is invariably performed at very short notice, outside of working hours, in an environment that staff are not familiar with, on patients that the retrieval team will not have met, and assisted by staff who may never have seen the operation before. In addition, there must be considerable coordination and information transfer to the receiving hospital. Thus, a checklist specifically designed for organ retrieval is considered to be mandatory.

We have split the preliminary stage of the checklist into two parts. Firstly, before leaving the base hospital, a check should be made that all equipment has been packed, the team is aware of the details of the donor and recipient, any particular requirements are known, such as redo surgery or congenital abnormalities in the recipient and that the transplant coordinator is aware that the team is about to depart. The second important preliminary stage is on arrival at the donor hospital. With the local physicians, the donor identity should be confirmed, and blood, virology, microbiological, anatomical and physiological tests should be performed or confirmed including confirmation of brain stem death tests. Also the theatre team and local anaesthetist should be met and briefed prior to scrubbing.

Then, prior to the commencement of the operation, it is particularly important for the teams in theatre to brief each other about the retrieval protocol. There will invariably be staff members in theatre who will never have seen this procedure before and thus they must have an understanding of what is expected of them.

The sign-out will include an operation note in the donor's notes. The organs will also be labelled and the start of ischaemia reported to the coordinator (Fig. A3).

Cardiopulmonary transplant surgical safety checklist

The organ retrieval checklist will confirm that the timing of the recipient's operation is correctly organized. The transplant checklist will therefore commence as with the general checklists with a sign-in process prior to induction of anaesthesia. However, in addition to the usual sign-in checks, a check on the sepsis screen, blood grouping and virology, and the height and weight is advised as the patient may again have come into hospital at very short notice and details may have changed since the patient was seen previously in a clinic.

In the time out before surgery commences, an additional check that the surgeons are aware of the timings of the donor organ is made, as optimal coordination of the timing of surgery will minimize bypass time and organ ischaemic time.

The sign-out will, in addition to usual checks, specifically ask teams to verify the immunosuppression plan and look at the medication chart as many new drugs will be commenced at this stage (Fig. A4).

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Congenital heart surgery safety checklist

In addition to the standard sign-in items, ward preparation review includes checks of weight, height and haemoglobin concentration, which are important determinants of the perfusion protocol. The anaesthesia safety review includes checking for a functioning pulse oximeter, planning for intravenous access, which is especially important for neonates and infants, and ensuring availability of blood products. The perfusion regime is agreed upon. In the time-out phase, before the operation starts, it is important to confirm that pressure points and diathermy ground are well addressed to prevent pressure or electrical injury. Relevant imaging, such as the preoperative transoesophageal echo must be reviewed, highlighting important issues to be considered during the procedure. A detailed review of the planned perfusion and myocardial protection strategy is paramount. Finally, the operating room team briefing is completed by reviewing the operative approach and plans for critical potential events. In the sign-out phase, after completion of the operation, plans and concerns for postoperative recovery are reviewed, making special note of blood products used and remaining to be used. Confirmation of adequate communication with the ICU regarding anticipated postoperative issues and that any special patient needs will be met upon patient arrival there is essential (Fig. A5).

Sustainability

There are many barriers to the successful implementation of a surgical checklist into clinical practice. But experience of implementation of the WHO checklist has shown that the best centres ensure adoption of a team culture, with the operating surgeon visibly supporting the process but also acknowledging the important contribution of all members of the theatre team [20]. Studies by centres implementing the WHO checklist found that it took no more than 2 min to perform and was felt to increase patient safety 18 months later, and importantly the overwhelming majority of staff participating in this process would want a checklist themselves if they became a patient [33]. Morbidity and Mortality meetings are an integral part of our practice and routinely highlight issues such as preoperative planning, surgical strategy, prescription errors and transfer errors [34]. Checklists may well be able to address many of these recurring factors. Equally institutions should not consider these checklists to be cast in stone. We have created these EACTS checklists in order to facilitate easy implementation of the checklist policy in units currently not adopting the checklist system. If locally a new issue arises from review of practice or other issues, it is perfectly acceptable to modify the checklist in order to increase compliance and improve practice locally.

SUMMARY

Checklists have been clearly demonstrated to facilitate multi-step processes to improve team dynamics and minimize error. Multiple International Organizations including the World Health Organisation, The Society of Thoracic Surgery and The National Patient Safety Agency support their use in surgery. Checklists are an integral and accepted part of other specialties including the Aviation and Engineering Industries. The European Association for Cardio-Thoracic Surgery presents a series of well-validated checklists for use in our specialty and supports the use of these checklists for all cardiothoracic surgical operations performed in Europe.

Conflict of interest: none declared.

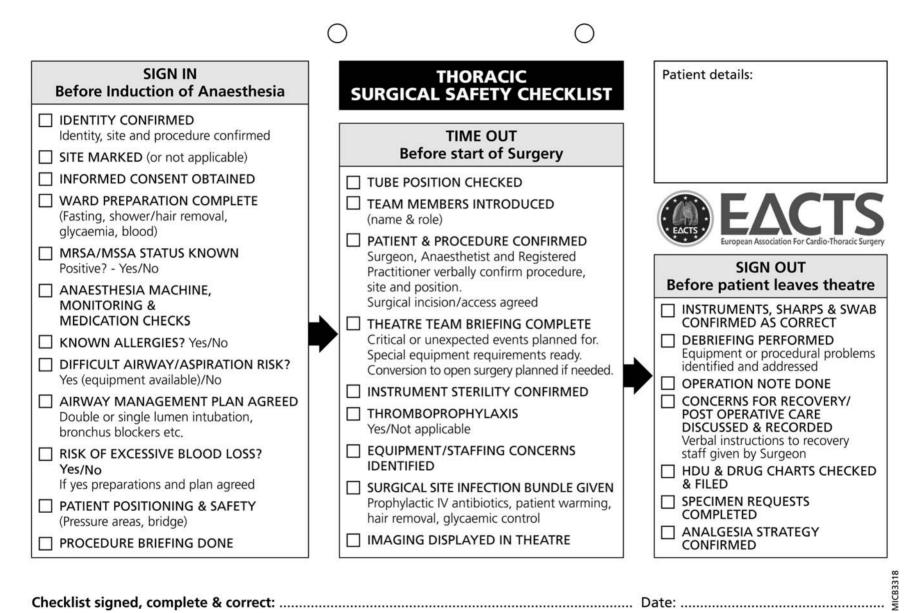
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GUIDELINE

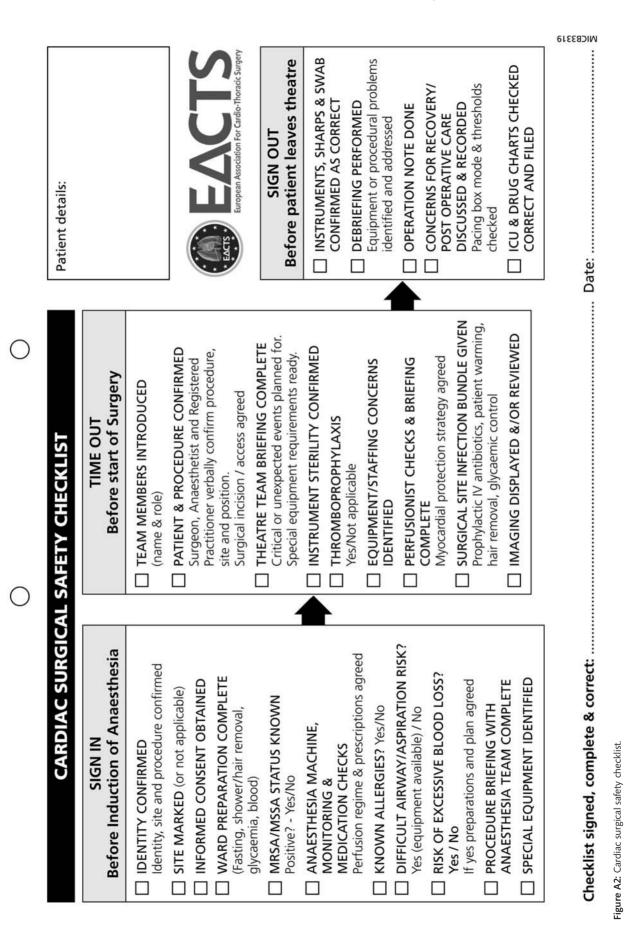
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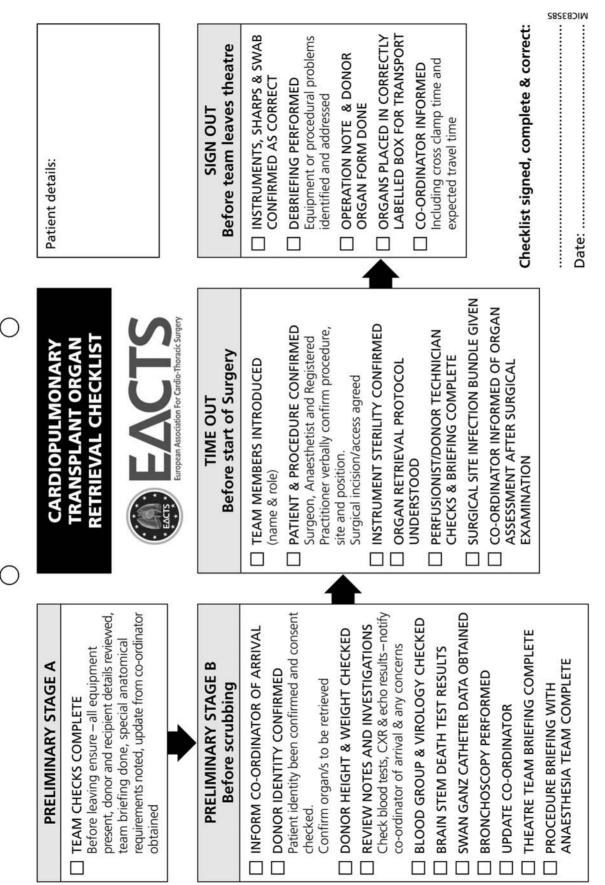
APPENDIX, CHECKLISTS



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Figure A1: Thoracic surgical safety checklist.





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CARDIOPULMONARY **TRANSPLANT SURGICAL** SAFETY CHECKLIST

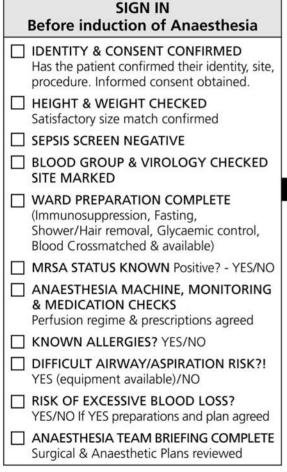
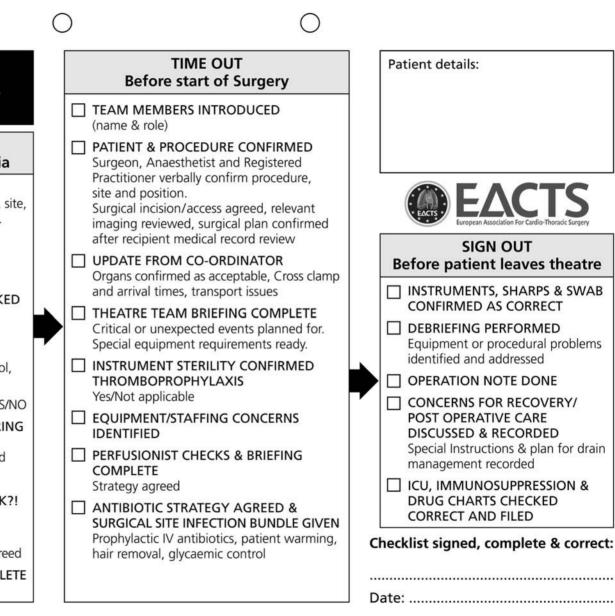


Figure A4: Cardiopulmonary transplant surgical safety checklist.



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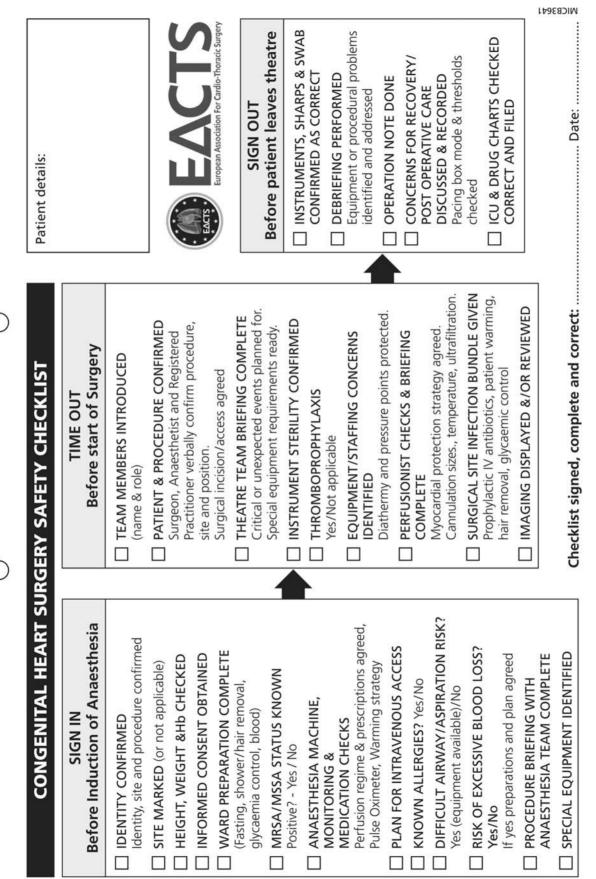


Figure A5: Congenital heart surgery safety checklist.