HAS
HAUTE AUTORITÉ DE SANTÉ

KEYS POINTS & SOLUTIONS
PATIENT SAFETY

No Go in the operating theatre

How to reinforce the safety barriers?

Approved: October 2018 / Distribution: November 2018

What is it?

The analysis of the feedback database for the physician and medical team accreditation system allows the identification of declarations pertaining to the **immediate and unexpected interruption of a surgical procedure in the operating theatre before skin incision**. These situations have been named "*No Go* in the operating theatre" and are the topic of this **patient safety solution (PSS)**.

Originally, "*No Go*" is an expression routinely used in the aeronautical sector to indicate that the take-off of an aircraft at the start of the runway is stopped because not all elements of the procedure have been validated. Likewise, in surgery, *No Go* refers to the immediate interruption of a surgical procedure between the moment when the patient enters the operating theatre and the skin incision.

This interruption is related to the fact that not all of the elements essential for correct anaesthesia or surgery are in place, or to a problem of organisation coordination, communication and verification of the conditions required for the procedure to proceed. As such, to continue a procedure under these conditions would constitute an additional risk for the patient.

The *No Go* principle can thus apply from the moment of the patient's arrival in the operating theatre until the initial incision. In the patient's interest, it is CRITICAL to be able to abandon a surgical procedure before skin incision when not all safety conditions are met. The *No Go*, though not desirable, remains a downgraded procedure implemented primarily in the patient's interest and fits into the care quality process. Implementing this procedure automatically triggers a collective discussion, with experience feedback and a complete risk management process (analysis of causes, barriers and patient safety improvement actions).

This PSS is intended to avoid or manage the occurrence of a *No Go* in the operating theatre. It lists the existing systems and tools available for controlled risk management, emphasising the importance of correctly creating the check-list.

"Patient safety in the operating theatre" (HAS, 2015a), along with the guidelines for good cooperation between anaesthetists-resuscitation specialists and surgeons (HAS, 2015b). It enables the collective approach to be better structured around the surgical procedure, thus helping reinforce team safety culture.

This patient safety solution (PSS) applies to all types of surgery performed in the operating theatre. It is intended for care service and operating theatre teams, along with for professionals concerned by the management of surgical equipment and medical devices.
This PSS is based on feedback from treatment-associated adverse events (TAAEs) declared by Orthorisq members.
It proposes a number of concrete actions (safety barriers) allowing professionals to prevent, recover, or attenuate a *No Go* decision when the patient is in the operating theatre.

NB: in the event of an emergency, the benefit-to-risk ratio for the patient must be specifically assessed to better determine the consequences of a Go or a No Go.

In the context of the monitoring of this PSS, any difficulties encountered during its implementation must be submitted to the Haute Autorité de Santé (HAS – French national authority for health) that coordinated the work performed by the work group, such that this latter can assess the need to revise or update the PSS in collaboration with the approved body for orthopaedic and trauma surgery, Orthorisq (sponsor).

Sponsor

ORTHORISQ

Associated bodies

AFU ASSOCIATION FRANÇAISE D'UROLOGIE

Association française d'urologie

CFAR COLLÈGE FRANÇAIS DES ANESTHÉSISTES RÉANIMATEURS

Collège français des anesthésistes-réanimateurs

OA CHIRPED D P C

OA Chirped chirurgie infantile

Collège de Neurochirurgie

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Vascurisq

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Unaibode

Union Nationale des Associations d'Infirmiers(ères) de Bloc Opératoire Diplômés(ées) d'Etat

Union nationale des associations d'infirmier(e)s de bloc opératoire diplômé(e)s d'État

A solution for patient safety...

The "*No Go* in the operating theatre" PSS is the result of a collective effort by professional bodies approved for the accreditation of physicians, based on records drawn from the in-depth analysis of TAAEs occurring in the operating theatre and declared by surgeons in the accreditation system's feedback database (REX-HAS database).
The work was initiated by the Orthorisq approved body.

To avoid the recurrence of sometimes serious TAAEs, we must be able to act rapidly, as soon as the risk is identified. The events collected in the REX database provide qualitative information concerning the causes and consequences of their occurrence, allowing patient safety solutions to be proposed to professionals.

... derived from the analysis of the feedback database (REX database)

Orthorisq (approved body of orthopaedic and trauma surgeons) looked into the *No Go* principle, in light of the increasing number of TAAEs spontaneously declared by its members, concerning surgical procedure interruptions. Over a single year, between 01 October 2014 and 30 September 2015, 101 TAAEs related to this issue were declared: 57 No Gos (56.5%) occurred after performing the anaesthesia, while 44 (43.5%) occurred before anaesthesia (Benfrech, 2016, Coudane 2018).
The causes of No Go most frequently encountered after TAAE analysis were problems associated with poor equipment and medical device management (37% of cases), defective sterilisation (16%), medicinal treatment management errors (anticoagulant or platelet suppressive agent) (13%) and skin problems in the vicinity of the surgical site (infection, etc.) (11%) (Benfrech, 2016). Moreover, an Internet questionnaire survey was sent out to the 1,828 Orthorisq members to determine the frequency and incidence of No Go in orthopaedic surgery practice (Coudane, 2008). Of the 663 (35.9%) responses analysed, the study showed that 72.6% of responding surgeons had been required, at least once in their professional practice, to stop a surgical procedure before or after anaesthesia and before making the incision.

In half of the *No Gos* that occurred, the "Patient safety in the operating theatre" check-list had been validated.
Among the responders, approximately 19.3% had been faced with 2 No Gos and 3% with more than 3 *No Gos* in their practice. The survey confirmed the caused identified during TAAE analysis: equipment management, equipment unavailability, etc.
In more than 80% of cases, the notion of *No Go* was not mentioned in the preoperative information document provided to the patient, and this information was not traced in their file.
No Gos represented a risk situation in patient management, leading to needless anaesthesia in more than half of all cases declared. Moreover, the *No Go* served to disrupt the patient's trust, also leading to disorganisation of activity (delay, postponement, cancellation).

The analysis of TAAEs declared ion the REX database thus allowed a new risk situation to be identified: the *No Go* in the operating theatre, a situation not previously described in the literature (Benfrech, 2016).

Part 1.

Key points for safe patient surgical management

PSS

- **Prerequisites**
- **Prevent** (the occurrence of the adverse event)
- **Recover** (cancel the consequences of an emerging adverse event)
- **Attenuate** (the consequences of an adverse event that has occurred)

Appendices

- Appendix 1. “Patient safety in the operating theatre” check-list, 2018 version
- Appendix 2. “POuR – DÉCider”: A cognitive aid in the event of an unexpected situation

Implementing the PSS

Key points for safe patient surgical management

The purpose of these key points is to help professionals question their practices and for teams to determine the best manner in which to manage a procedure postponement or cancellation (*No Go*) in the patient's interest, when not all conditions for surgery are met.

Safety prerequisites

- **The implementation of alerts and reminders in the establishment's information system** to help ensure that the tasks scheduled upstream of the procedure (ordering and receipt of specific equipment and medical devices, interruption of medicinal treatments, biological examinations) have been completed.

- **The HAS "Patient safety in the operating theatre"** check-list is available and used in accordance with HAS recommendations. It is intended to prevent risks associated with determination of the surgical site, patient positioning, the equipment used, its operation and traceability. It is based on adequate information and communication within the team in order to make decisions on whether to continue or interrupt the surgical procedure.

- **Communication** within the team, thanks to a **collective** and **shared** analysis the situation that could lead to a ***No Go*** situation, is essential. The "Cooperation between anaesthetists-resuscitation specialists and surgeons" PSS proposes 15 key points for working together better and hence improving patient safety through a peroperative risk management approach (HAS, 2015b).

- **Within the establishment, there is a procedure for the declaration of TAAEs and in-depth analysis** of their causes through a feedback process (MMR, CREX, etc.) for implementation of improvement actions. Feedback and information are shared with the operating theatre team.

PREVENT

The preoperative phase requires optimum organisation to ensure that all elements contributing to a successfully surgical procedure are present, guaranteeing that the correct device and equipment are used for the correct patient and that the correct side to operate has been defined. For this, a list of essential elements (key points) for the successful completion of this step is proposed.
These key points are adapted to the sector in question and integrated into existing tools, in particular the informational system (e.g.: patient pathway document, patient follow-up file, etc.), or may supplement an existing procedure. They must be taken into consideration before the patient enters the operating theatre. For each element proposed, the professional of the sector concerned checks his/her presence and forwards the information. This check thus requires coordination between care sector professionals and the operating theatre team

KEY POINTS

PREOPERATIVE CHECK

An “equipment” check-list should be drawn up 48 hours before the procedure.

The management arrangements and medicinal adaptations (anti-platelet agents, anticoagulants) must have been **scheduled**.

- **During the preoperative consultations**, the patient or his/her legal representative will be informed that all precautions have been taken by the team to guarantee the patient’s safety, but that there is always a possibility that the procedure may be cancelled before making the incision if the situation demands, even once anaesthesia has been induced.
- **Between operation programming and 48 hours before surgery, schedule the availability of the following:**
  - specific implantable medical devices (prostheses, implants, etc.);
  - equipment required for surgery (instrument boxes, image intensifier, autotransfusion system, etc.);
  - any other specific equipment (dressings, plaster, etc.).
- **24 before the procedure:**
  - ensure that all equipment required for the procedure is availability (“equipment” check-list performed);
  - call an outpatient on the phone, or perform a preoperative visit for a hospitalised patient, to:
    - check the medicinal treatments (anticoagulants, anti-platelet agents, antibiotics, etc.),
    - ensure that the requested examinations have been performed and that the results are available;
  - ensure that the side to operate has been specified in the patient’s record;
  - check the consistency of surgical site information: patient’s declaration, traceability in the patient’s record, any additional examinations that may be required.
- **On the day of the procedure (before the patient arrives at the operating theatre):**
  - check the patient’s skin condition;
  - review current treatments, recent biological examinations, etc.

All elements are recorded in the patient’s record;
the healthcare establishment information system most facilitate these verifications.

The role of each professional during patient care is defined in writing, known and observed
(see key point 10 of the “Cooperation between anaesthetists-resuscitation specialists and surgeons” PSS).

RECOVER

Correct completion of the "Patient safety in the operating theatre" check-list should allow 3 goals to be met: **check**, **together**, to make a **joint decision** (*Go* or *No Go*). Feedback from *No Go* situations, however, shows that effective team communication, along with decision-making (*Go* or *No Go*) and decision traceability are essential. Indeed, very often, only the first goal (check) is performed correctly.
To achieve these goals a change to the HAS "Patient safety in the operating theatre" check-list information system proposed, adding a section specific to the traceability of the *Go* or *No Go* decision. The other check-list items remain unchanged. The 2018 version (see check-list appendix on next page) emphasises effective team participation in performing the check-list to make a joint decision, prior to patient incision, of whether continue (*Go*) or immediately stop (*No Go*) a surgical procedure (time 2 of the check-list). This version serves to justify and trace the decision made.

ATTENUATE

When a *No Go* decision is nevertheless made, for safety reasons the decisions to be made must arise from a collective and shared discussion.
For this, a cognitive aid is proposed to structure the decision-making process in this unexpected situation. The "POuR – DÉCider" (to decide) procedure (see appendix 2) is particularly appropriate to allow the team to opt for the best possible solution in the patient's interest. It serves to best assess the benefit-risk ratio and to justify the decision made.

Moreover, the occurrence of a *No Go* in the operating theatres requires that its declaration, informing the patient and/or their legal representative, along with appointing the physician(s) to manage it, should be discussed between the anaesthetist and surgeon in the operating theatre (see key point 12 of the "Cooperation between anaesthetists-resuscitation specialists and surgeons" PSS).

Table 1. Key points in the event of the occurrence of a *No Go* in the operating theatre.

In the operating theatre	■ Collective discussion and decision-making (possible use of the "POuR – DÉCider" decision assistance tool).
With the patient	■ Information concerning the occurrence of a No Go and its consequences.
In the patient's record	■ Not the information communicated to the patient, precisely stating the words used for this information.
With the establishment	■ Declare the incident in the establishment's declaration system. ■ Report the incident to the establishment's contact persons. ■ Perform an in-depth analysis of the incident to identify the causes (MMR, CREX, etc.). ■ Implement corrective actions and measure their effectiveness.
With the manufacturer	■ Declare the incident in the event of an equipment problem.

Patient identification

Patient label, or Last name, first name and date of birth

"PATIENT SAFETY IN THE OPERATING THEATRE" *CHECK-LIST*

2018 version

« Check together to decide »

Theatre: ..... Room: .....

Procedure date: ..... Time (start) : .....

"Operating" surgeon: .....

"Operating" anaesthetist: .....

Check-list coordinator(s): .....

BEFORE ANAESTHETIC INDUCTION

Pause time before anaesthesia

1. ▪ The patient's **identity** is correct. ❑ Yes ❑ *No**
   ▪ The **authorisation to operate** has been signed by the parents or legal representative. ❑ Yes ❑ *No** ❑ N/A
2. The **procedure** and **surgical site** are confirmed:
   ▪ *ideally* by the patient, and in all case, by the file or specific procedure; ❑ Yes ❑ *No**
   ▪ the necessary clinical and para-clinical documents are available in the theatre. ❑ Yes ❑ *No**
3. The mode of **installation** is known to the theatre team, consistent with the site/procedure and non-hazardous for the patient. ❑ Yes ❑ *No**
4. The **operated patient's skin preparation** is documented in the service/operating theatre follow-up file (or other procedure in place within the establishment). ❑ Yes ❑ *No** ❑ N/A
5. The equipment required for the procedure has been checked and is adapted to the patient's weight and height:
   ▪ for the surgical part; ❑ Yes ❑ *No**
   ▪ for the anaesthesia part. ❑ Yes ❑ *No**
   Procedure performed without anaesthesia ❑ N/A
6. Does the patient present with:
   ▪ **risk of allergy**; ❑ No ❑ *Yes**
   ▪ **risk of inhalation**, of **intubation** or mask **ventilation** difficulties; ❑ No ❑ *Yes** ❑ N/A
   ▪ risk of significant **bleeding**. ❑ No ❑ *Yes**

BEFORE SURGERY

Pause time before incision (also known as time-out)

7. "Final" check performed by the team in the presence of the surgeon(s), anaesthetist(s), state-registered anaesthesia nurse/ state-registered scrub nurse/state-registered nurse ❑ Yes ❑ *No**
   ▪ **patient identity** confirmed ❑ Yes ❑ *No**
   ▪ **scheduled procedure** confirmed ❑ Yes ❑ *No**
   ▪ **surgical site** confirmed ❑ Yes ❑ *No**
   ▪ **correct installation** confirmed ❑ Yes ❑ *No**
   ▪ **required documents** available (in particular imaging) ❑ N/A
8. **Verbal sharing of essential information** concerning risk elements/critical steps, within the team (time-out)
   ▪ at the **surgical level** ❑ Yes ❑ *No**
   (difficult operating time, specific points concerning the procedure, identification of equipment required, confirmation of their operationality, etc.)
   ▪ at the **anaesthetic level** ❑ Yes ❑ *No**
   Procedure performed without anaesthesia [potential risks related to diathesis (hypothermia, etc.) or to any treatments that may have been maintained, etc.] ❑ N/A
9. **Prophylactic antibiotic treatment** has been performed according to guidelines and protocols in force in the establishment ❑ Yes ❑ *No** ❑ N/R
   Preparation of the **surgical site** has been performed according to the protocol in force dans l'établissement ❑ Yes ❑ *No** ❑ N/A

AFTER THE PROCEDURE

Pause before leaving the operating theatre

10. Verbal confirmation to the team by the staff:
    ▪ that the **procedure has been recorded**; ❑ Yes ❑ *No**
    ▪ of the correct **final count** of compresses, needles, instruments, etc.; ❑ Yes ❑ *No** ❑ N/A
    ▪ of **labelling** of samples, surgical specimens, etc.; ❑ Yes ❑ *No** ❑ N/A
    ▪ whether **adverse** or **high medical risk** events occurred: were these reports/ declared? ❑ Yes ❑ *No** ❑ N/A
    If no adverse events occurred during the procedure, tick the N/A box
11. **Prescriptions** and **postoperative monitoring** (including the specific alert thresholds) have **been performed jointly** by the surgical team and are adapted to the patient's age, weight and height. ❑ Yes ❑ *No**

*Joint and justified decision in the event of an answer in a box marked with an **

⚠ CAUTION FOR CHILDREN!

- Involve the parents in checking the identity, procedure and surgical site.
- Authorisation to operate signed.
- Installation, equipment and prescription adapted to weight, age and height.
- Prevention of hypothermia.
- Postoperative alert thresholds defined.

➔ FINAL DECISION

❑ *GO* = OK for incision

❑ *NO GO* = No incision!

If *No Go*: impact on the procedure? ❑ Delay ❑ Cancellation

ACCORDING TO PROCEDURE IN PLACE WITHIN THE ESTABLISHMENT

Certification that the check-list has been filled in after sharing information between the team members

Surgeon | Anaesthetist/state-registered anaesthesia nurse | CL coordinator

The role of the check-list coordinator, assisted by the surgeon(s) and anaesthetist(s) in charge of the procedure, is to tick the items on the check-list: 1. if the check has been performed, 2. if the check was performed verbally in the presence of the members of the team concerned and 3. if the answers marked with a * we made jointly by the team after discussion.

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N/A: Not Applicable to this procedure; N/R: Not Recommended for this procedure

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"PATIENT SAFETY IN THE OPERATING THEATRE" CHECK-LIST

2018 Version

Instructions for use

"Check together to decide"

The HAS "Patient safety in the operating theatre" check-list contains essential and non-modifiable elements to be checked together as a team in the operating theatre, in order to make decisions on whether to continue or interrupt a surgical procedure.

It may, however, give rise to all developments desired by the professionals in the context of the professional associations/approved accreditation bodies.

BEFORE ANAESTHETIC INDUCTION

Pause time before anaesthesia

1. Professionals insist on the importance of having the patient give his/her identity. For patients incapable of giving their identity, verification is performed by the operating theatre staff as per the identovigilance procedure in force in the establishment (bracelet, information cross-checking, accompanying staff, etc.)

2. The procedure and surgical site are confirmed, ideally by the patient himself/herself and, in all cases, via the file or through any other procedure in force in the establishment (e.g.: staff meeting, shuttle forms) or recommended by the professional associations of the specialty (marking, etc.)

3. The team receiving the patient in the theatre possesses information stating the nature of the scheduled procedure, along with the patient installation details, and verifies that the correct platform has been selected and that the accessories are available, etc.

4. Skin preparation is documented in the service/operating theatre patient follow-up form. Preparation is performed as per the guidelines/procedures in force in the establishment (shower or wash for dependent patients, depilation if necessary, specifying the method used).

5. The qualified staff checks the availability and operation of the instruments power sources (electrotome, etc.) and medical devices required for the procedure. The anaesthetic safety verification procedures are performed as per regulations, by qualified anaesthesia staff.

6. The anaesthetic team and nurse communicates concerning certain critical points and adopts the appropriate measures; as such, the anaesthetists ensure:
   - in the event of a risk of inhalation/difficult intubation/mask ventilation, that confirmation has been received of equipment availability along with the necessary assistance;
   - in the event of a risk of significant bleeding (estimated at more than 500 ml or 7ml/kg in paediatrics), of the availability of documents (blood group, IAT, etc.), venous access, transfusion products and equipment, etc.;
   - Compliance with the preoperative protocol concerning anticoagulant and/or anti-platelet treatment has been verified.

BEFORE SURGERY

Pause time before incision (time-out)

7. These cross-checks of the patient's identity, scheduled procedure and surgical site may appear repetitive, but they are essential to improve patient safety in the operating theatre; these are the final checks before the surgical procedure starts.
   The surgeon also ensures that patient installation is consistent with the surgical site/procedure and is not dangerous for the patient.
   It is also necessary, no later than at this point in the procedure, to ensure that the necessary clinical and para-clinical documents, particularly any imaging, are available in the theatre.

8. During the preoperative pause (time-out), it is also crucial for the surgical, anaesthetic and nursing teams to communicate any essential information in order to anticipate any risk factors, in particular:
   - at the surgical level: inform all team members of those steps that could potentially expose the patient to a risk of significant bleeding, trauma, or any other cause of major morbidity. This also represents an opportunity to review;
   - the steps that may require special equipment, implants or special preparations;
   - at the anaesthesia level: to communicate, if necessary, concerning any co-morbidities or current treatments (anti-platelet agents, anticoagulants, anti-hypertensives, anti-diabetics);
   - at the nursing level: the staff must confirm that there are no specific problems with the equipment required for the procedure (electrotome plate, suction, video system, MD).

9. The team ensures that prophylactic antibiotic treatment, if indicated, has been performed as per the guidelines and protocols in force in the establishment.
   It is also during this step that surgical site preparation, performed as per the protocol in force in the establishment, is confirmed.

Following phases 1 and 2 of the check-list, the final decision to continue or interrupt the procedure is traced and justified.

AFTER THE PROCEDURE

Pause before leaving the operating

10. The team verbally confirms the type of procedure recorded, and whether it was performed, with the correct count of compresses, instruments and needles, along with the identification of all samples and surgical specimens.
    It is important that any equipment problem occurring during a procedure is reported and declared by the team.

11. Prescriptions for immediate postoperative follow-up are drawn up jointly for patient postoperative care (in particular, prevention of thromboembolism).

For answers marked by an asterisk*, the decision made by the team must be traced and justified.

The decision to ask the professionals to certify their active participation in filling in the check-list is determined by the establishment's administrative and medical authorities and is intended solely to promote optimum use of the check-list.

⚠ KEY POINTS FOR A CHILD

- Involve the parents in checking the identity, procedure and surgical site.
- Possess a signed authorisation to operate.
- Provide an installation, equipment and prescriptions adapted to the child's age, weight and height.
- Prevent preoperative hypothermia.
- Define the specific alert thresholds for the postoperative period.

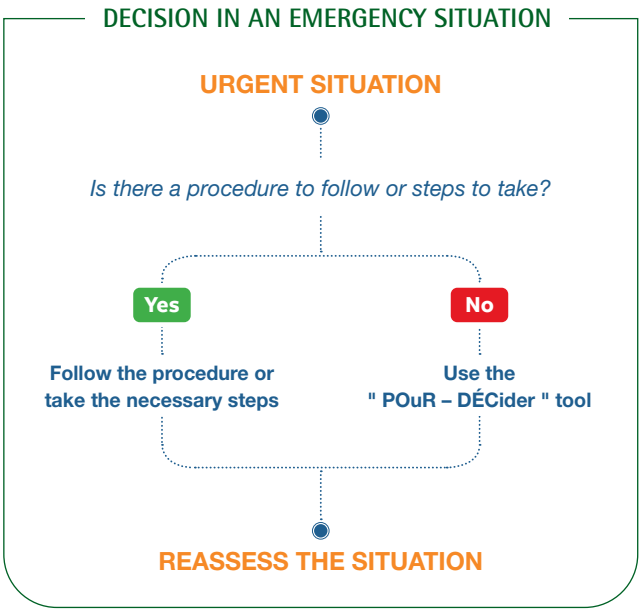
Appendix 2

"POUR – DÉCider"

A cognitive aid in the event of an unexpected situation

The purpose of the "**POuR – DÉCider**" cognitive aid is, in the event of an unexpected situation, to provide a decision-making structure tool if there are no pre-existing procedures or rules and when a poor decision can have serious consequences.

The concept was developed by H-J Hörmann (German Aerospace Center) (Hörmann, 1995 and Soll, 2016), taking into account the decision-making characteristics in humans placed in a complex and changing situation. Indeed, in the event of an unexpected situation, the resulting stress can trigger cognitive mechanisms that may impair the decision-making process and lead to accidents (e.g.: formulating a hypothesis and seeking to confirm it at any cost, adopting the first solution that comes to mind, overestimating the probability of a favourable outcome, resisting change, even after the emergence of new data, making a decision alone without first consulting the team, etc.).



This easy-to-use cognitive aid can thus guide the decision, while calling upon the teams skills. It should be noted that this type of cognitive aid is currently routinely used by many airlines.

This cognitive aid consists of 3 parts:

- the "**POuR**" part concerns the cognitive process (reflection) that must be conducted.
- **the hyphen** – connecting POuR and DÉCider represents the essential team exchange time.
- The "**DÉCider**" part concerns the **decision** process and the implementation of the chosen solution.

P	**Problem**	What is the problem?
Ou	**Useful options**	What are the useful and possible options?
R	**Risks**	What are the risks and advantages of each option?
-	**Exchange**	Team exchanges and sharing
D	**Decision**	What should we do?
E	**Execution**	Who does what? When? How?
Decide	**Check**	Did everything go to plan?

An example in the event of *No Go* in the operating theatre is given on the following page.

Of course, this cognitive aid is not a magic wand that can simply be waved at all problems encountered. But beyond its occasional use, it sheds light on the importance of so-called managed safety, as yet underdeveloped and which involves collective intelligence and teamwork to deal with complex and unexpected situations. Indeed, this managed safety is rightfully placed alongside so-called regulated safety (guidelines, procedures, steps take, check-list, etc.). Besides, both are developed at the highest levels in high-reliability organisations (HROs). This managed safety and its accompanying tools are intended to be applied to the CRM (crew management resource) training modules that have been used for the past several years in aeronautics and which are currently being developed in the healthcare sector, including in simulation.

Example of "POuR – DÉCider" tool use: no imaging in the operating theatre

P	**Problem**	**What is the problem?** ➔ *No Go* situations caused by the lack of patient imaging in the operating theatre.
Ou	**Useful options**	**What are the useful and possible options?** ➔ 3 possible options: - incise without imaging; - wait for the imaging to arrive in the operating theatre; - cancel the procedure.
R	**Risks**	**What are the risks and advantages of each option?** ➔ benefit-risk analysis of each option: - incise: safety risk +++ due to lack of important information (location, side); - wait: risk of surgical programme disruption, prolonged anaesthesia and procedure; - cancel: anaesthesia pointless = TAAE.
-	**Exchange**	**Team exchanges and sharing** Time allowing the team to question the situation encountered (have we ever been faced with this problem before?) and to exchange and share points of view based on respective experience, along with possible solutions.
D	**Decision**	**What should we do?** **The safest option is chosen after discussion with the other team members.** ➔ wait for imaging before incising.
E	**Execution**	**Who does what? When? How?** **We do what we chose. The tasks to perform are assigned.** ➔ an operating theatre porter is dispatched urgently to collect the patient's imaging that was left in the care unit.
Decide	**Check**	**Did everything go to plan?** **If yes** ☛ end of the *No Go* situation ➔ OK, with a 15-minute delay ☛ end **If no** ☛ repeat "POuR – DÉCider" to assess the new problem or to understand what went wrong. ➔ Not OK New "POuR – DÉCider" applied to the new problem = no porter available to bring the patient's imaging to the operating theatre... … finally, the care unit nursing auxiliary brings the imaging to the operating theatre.

Implementing the PSS

The *No Go* key points and solutions in the operating theatre represent a new tool that can be integrated into the care quality improvement and risk management policy for the surgical and operating theatre sectors in particular. It is aimed to reinforce the safety barriers through close collaboration between the various care sectors and surgical equipment management sectors, prior to patient admission into the interventional sector.
These key points and solutions are intended to help in diagnosing strong points and identifying opportunities for improvement.

By assessing existing elements, along with lacks or deviations from the proposed guidelines, an improvement plan adapted to the size of teams and activities can be defined. This may involve the reinforcement of existing measures such as the unfolding of phases 1 and 2 of the check-list, or the creation of additional safety barriers. An example improvement approach is proposed in the following pages; it can be adapted to the sector of activity in question.

Example of possible implementation

Should you so wish, based on these key points, you can define an improvement approach for team-based professional practices. For this:

- **Step 1: organise your approach** (project group set-up, organisation and provisional schedule).
- **Step 2: assess the key points** of the PSS. The following ranking system is proposed:
  0: missing
  1: in project phase
  2: under development, or partially met
  3: completed
  4: monitored and assessed according to procedures adapted to your sector of activity (supporting documents, investigation, meeting minutes, audit, tracer patient, etc.).
  N/A: if the criterion is not applicable. Non-applicability must be justified.
- **Step 3: draw up an overview of the assessment performed** (see sheet appended) and define improvement goals.
- **Step 4: make a joint decision concerning the improvement actions to implement and monitor** (see sheet appended).

Some examples of possible improvement actions:

- Revision of equipment and medical device management protocols.
- Implementation of a preoperative “equipment” check-list.
- Implementation of alerts and reminders in the establishment’s information system for tasks to be performed upstream of the surgical procedure (availability of equipment, IMDs and biological/X-ray examination results, management of medicinal treatments, etc.).
- The operating theatre committee, or the intervention site manager regularly addresses (agenda) issues associated with a *No Go* situation: communication of TAAE data, etc.
- Implementation of the HAS “Patient safety in the operating theatre” check-list, 2018 version and its instructions for the operating theatre.
- In-depth analysis and monitoring of TAAEs related to a *No Go* decision (e.g.: MMR, CREX, etc.).
- Analysis of practices by means of a grid drawn up from the PSS.
- Monitoring of indicators (number of TAAEs associated with a *No Go*).

Assessment overview

Date:

List of participants: last names, first names, positions:

Sector of activity:

Analysis results, strong points, points to be improved:

Improvement goals:

Conclusions and action plan (to be supplemented by one or more action sheets):

Action sheets

N.B.: fill in 1 sheet per action implemented.

Key point(s) concerned/problems identified: Action implemented:	
Objective	
Description	
By whom?	
When?	
How?	

Follow-up	
Implementation schedule	
Monitoring and assessment procedures	

In charge of monitoring	
Who?	

Progress:	☐ Not ☐ Plann ☐ In ☐ Compl ☐ Assess date:

Part 2.
PSS drafting note

Study organisation

- Work group composition
- PSS drafting
- PSS monitoring and updating over time

Bibliographic note

- Analysis overview
- References

Study organisation

Work group composition

A multi-profession and multidisciplinary work group (18 members) was formed, consisting of:

- nine approved bodies for accreditation;
- two scrub nurses.

Last name	First name	INSTITUTION
AL NASSER	Bassam	CFAR (anaesthesia-resuscitation approved body)
BELLAMY	Jean	SFCTCV (société française de chirurgie thoracique et cardio-vasculaire)
BENFRECH	Éric	Orthorisq (orthopaedic and trauma surgery approved body)
BREAUD	Jean	OA Chirped (paediatric surgery approved body)
DELEUZE	Alain	FCVD (visceral and digestive surgery approved body)
DELCAMPE	Pascal	Maxillorisq (stomatology and maxillofacial surgery)
DROUVOT	Valérie	Operating theatre quality manager for the East Parisian university hospitals
FAILLOT	Thierry	College of neurosurgery (approved body)
FRIEH	Jean-Philippe	SFCTCV
GARIGNON	Cynthia	OA Chirped
KARAM	May	State-registered scrub nurse
LE ROUZIC-DARTOY	Catherine	OA Chirped
MILLAT	Bertrand	FCVD
MOREAU	Patrick	Vascurisq (vascular surgery approved body)
POLITI	Robert	OA Chirped
TRACOL	Philippe	Orthorisq
VAVDIN	Frédéric	AFU (urological surgery approved body)
VERHEYDE	Isabelle	CFAR

For HAS, the department of assessment and tools for treatment quality and safety (EvOQSS)

Dr Bruno BALLY, deputy head of department.

Christiane DOSSEH, project manager.

Management of conflicts of interest

Participation in the work group is subject to a public declaration of interests by the members.
All 18 members of the work group published a public declaration of interests on the DPI-SANTE website (www.dpi.sante.gouv.fr). No conflicts of interest pertaining to the topic covered were detected.

■ PSS drafting

The work method was based on the PSS drafting guide approved by the HAS College in May 2012. It combines analysis of the REX database, the expert opinions of a multidisciplinary work group (see composition on previous page) and the data from the literature, when available.
The work group (WG) initially convened on 15 January 2017. The various exchanges highlighted the fact that a *No Go* can constitute a risk situation in patient management and this latter must be informed. It may lead to needles anaesthesia (this is the case in more than half of all declarations). Moreover, postoperative complications related to this incident may occur. Finally, the *No Go* serves to disrupt the patient's trust, also leading to disorganisation of activity. Given these observations, the WG members defined the orientations enabling the decision to cancel a surgical procedure to ensure the operated patient's safety. For this purpose, a decision-assistance tool was proposed.
Following this initial meeting, a draft of the PSS was created (version V1) concerning which the work group members were asked to make comments and/or add to the document. The comments received led to a document revision (version V2). This version was then reviewed by the work group members and by the 14 approved bodies actively involved in the accreditation process.
The review groups' comments were analysed and debated by the work group convened in plenary session on 15 June 2018 on HAS premises.
A new version drafted during the meeting following the various arbitrations, was approved by all WG members.

■ PSS follow-up and updates

The PSS will initially be included in the annual accreditation programme in the form of a general recommendation for operating theatre surgical specialties. Its implementation will be a prerequisite for meeting the requirements of the accreditation system (individual or team). Each concerned approved body will be in charge of compiling the declarations into a report, with dysfunctions following PSS application. It will then be possible, 24 months after implementation, to assess practices based on use of the key points and solutions. This could take the form of a survey conducted by the approved bodies and submitted to the approved physicians, in terms of satisfaction (legibility, PSS availability, suggested improvements, etc.), knowledge (is the content of the PSS known?), practices (improvements achieved, MMR, procedures) and results (number of TAAEs declared).
An update may be considered depending on equipment developments, or changes to practises.

Bibliographic note

Few publications are available on the particular phenomenon of *No Go* in the operating theatre; the few articles found pertain to orthopaedic surgery. In this specialty, surgery postponement/cancellation factors are most often linked to equipment unavailability and to the organisation of the operative procedure (Jain, 2015). The solution proposed by Jain is to conduct a daily preoperative team meeting during which all of the day's cases to operate are reviewed in order to identify and share any potential problems that could arise during one of the day's procedures. This solution would serve to reduce the risks of procedure postponement/cancellation.
Moreover, concerning the "Patient safety in the operating theatre" check-list, studies have shown that team involvement varies with practitioners, whereas these latter represent the main barrier to check-list implementation (Gillespie, 2015). One article demonstrated that check-list implementation significantly improves team communication and work (Russ, 2013). Beyond its technical effects, the author insists on the aspect of communication between professions: the check-list appears as a care quality improvement tool for the operative team.
Finally, in the context of the accreditation system, one orthopaedic surgeon pointed out in 2015 that performing the "Patient safety in the operating theatre" check-list does not take sufficient account of equipment management in the orthopaedic surgery specialty (Thomasson, 2015). It should be noted that J. Reason (Reason, 2000) highlighted a new approach to risk by developing a theory according to which we should search, beyond the immediate causes, for all contextual elements and factors (root causes) that promoted the onset of the adverse events. This approach, considered systematic, frequently highlights factors linked, in particular, to team operation and care organisation. These factors were also identified in orthopaedic surgery (Benfrech, 2016). Indeed, the equipment problems in this specialty gave rise to adverse events that in turn led to *No Go* decisions (Benfrech, 2016 and Coudane, 2018). For these authors, the risk management approach should seek to process system failures in order to efficiently combat the occurrence of avoidable *No Gos* and to avoid their recurrence (Coudane, 2018).
Finally, in the event of a *No Go*, the surgical procedure stops and no trace of this stoppage is found (HAS, FAQ). The "Patient safety in the operating theatre" check-list, 2016 version does not provide for this traceability (HAS, FAQ). Hence the importance of adapting the check-list, 2016 version to a *No Go* situation.

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For further information

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