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Systemic safety management in anesthesiological practices

Riccardo Patriarca[a,*], Giulio Di Gravio[a], Francesco Costantino[a], Lorenzo Fedele[a], Massimo Tronci[a], Valentina Bianchi[a], Fabrizio Caroletti[b], Federico Bilotta[b]

[a] University of Rome "La Sapienza", Department of Mechanical and Aerospace Engineering, Rome, Italy
[b] University of Rome "La Sapienza", Department of Anesthesiology, Critical Care and Pain Medicine, Rome, Italy

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ABSTRACT

Anesthesiological practices are complex activities with inherent risks. Hazard assessment techniques based on cause-effect links and linear reasoning do not adequately represent the actual behavior of modern socio-technical systems, which are characterized by tight couplings and interactions among technical, human and organizational aspects. Analysing hazards following a linear perspective may result in a not completely effective management of process safety. This paper discusses the need for a systemic analysis for healthcare practices, applying such perspective to an anesthesiological process. More specifically, it aims to define process hazards, and unsafe control actions for preoperative and intraoperative anesthesiological activities, extending simple cause-effect reasoning through the System Theoretic Accident Model and Processes (STAMP) and its hazard analysis technique, i.e. System Theoretic Process Analysis (STPA). The outcomes of the study based on qualitative research techniques point out the relevance of a systemic approach, with implications for process management. It is argued that the adoption of strict procedures to constraint the variability of everyday work represents a valuable solution only for some specific tasks, while for many others variability has to be accepted as a means to enhance patient safety in a healthy work environment.

1. Introduction

Hospitals are closely regulated systems, with numerous rules, laws, protocols and standards. The traditional approach to education in healthcare fully reflects these general characteristics of the system. Doctors, nurses and medical staff are trained to follow rules, apply protocols, and conduct procedures (Rebbitt and Erickson, 2016). This approach aims to enhance patient safety, preserving at the same operators' efforts and equipment's safety. More generally, this traditional approach is commonly recognized under the name of Safety-I: safety is considered as a condition in which the number of adverse outcomes is as low as possible, based on a bimodal view of work and activities. According to this view, acceptable and unacceptable results are due to two different system states of functioning. Things go well, only if system functions as imagined. On the contrary, in case of adverse events, there shall be some deviations from the imagined and holistically prescribed work, causing the failure (Hollnagel et al., 2013). Since system functioning and system not-functioning are usually considered two separate and distinct states, traditional safety management aims to minimize the not-functioning scenarios (EUROCONTROL, 2013). A barrier-based approach for developing procedures or constraint for everyday work is necessary to define reactive countermeasures to eliminate, or at least mitigate, root causes of adverse events.

However, the limitations of this reasoning have been widely acknowledged in the last decade, especially for those systems characterized by non-negligible interactions among human, technical and organizational aspects (Patriarca et al., 2018; Patterson and Deutsch, 2015). In such cases, the number of rules, laws, protocols, and standards become overwhelming and sometimes even locally contradictory, so that working complying with every proceduralized aspects becomes unfeasible (O'Keeffe et al., 2015). Such complex systems do not allow a complete understanding of system's logic and behavior just following component analyses. It becomes hardly possible to predict a system accident because of one or a chain of components' failures. In this case, an adverse event is said to be emergent rather than resultant: the event generation mechanisms cannot be explained by the principles of linear causality, since the system becomes intractable. The intractability of a system acknowledges that its description is underspecified and humans represent a necessary resource for system's flexibility and resilience, since performance variability is inevitable and useful at the same time (Patriarca et al., 2017).

In a complex system as a hospital, doctors and nurses must comply

* Corresponding author at: Via Eudossiana, 18 – 00184 Rome, Italy.
E-mail address: riccardo.patriarca@uniroma1.it (R. Patriarca).

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everyday with limited resources (e.g. lack of time, short supply of materials), in an extremely dynamic environment. For this purpose, it is inevitable that they adjust their actions to meet the demands and the current conditions, balancing demands and resources, as described by the ETTO principle (Hollnagel, 2010). Systemic methods become necessary to capture the complexity of the work domain. In this regards, mainly FRAM (Functional Resonance Analysis Method) (Hollnagel, 2012) and STAMP (System Theoretic Accident Model and Process) (Leveson, 2004), are currently used to obtain systemic safety assessments.

This paper presents a systems theory-based approach relying on the STAMP for safety assessment in an anesthesiological process. The research has been conducted with three main aims: (i) develop a systematic framework to explore process' complexity; (ii) provide means to shift from individualistic knowledge to organizational knowledge; (iii) as a complement to previous phases, pave the way to the definition of mitigating actions for the identified risks. More specifically about the second aim, the research aims to encompass perspectives coming from individuals into a larger organizational dimension, not only deepening employees' knowledge, but also creating new organizational knowledge through participation and cooperation (Bhatt, 2002). About the third aim, starting from the process hazards, the paper aims to offer an analysis of unsafe control actions related to anesthesiological practices, confirming the need for mitigating actions, both specific for different process phases, and general at a management level.

The remainder of the paper is organized as follows: Section 2 explores the need for a systems theory-based approach in healthcare, discussing the inherent complexity and uncertainty of healthcare processes, also in light of STAMP based theory. Section 3 details the anesthesiological process analyzed in the study. Section 4 presents the STAMP and the STPA, respectively the core model and method of this research. Section 5 details the application of STPA for the discussed process. The conclusions summarize the outcome of the research, describing the limitations of the study and the potential for further research.

2. Safety management in healthcare: the need for a systemic approach

A Safety-I approach has strong roots in the healthcare domain, deriving from the well-established Taylorism and the cult of zero incidents (Dekker, 2017). Several studies consider healthcare adverse events resultant from human errors, occurring through a static and understandable cause-effect link. In the 1980s and 1990s, errors analysis generally focused on individuals, stopping the search for causes at the person or group closest to the accident (Chopra et al., 1992; Cooper et al., 1984; Craig and Wilson, 1981). Constraining work practices was imagined as a necessary step to increase patient safety: strict adherence to checklists was supposed to be the main driver for ensuring patient safety and effective resources management (Hales and Pronovost, 2006).

Nowadays in healthcare, as well in other sectors, this idea results in an increased number of rules and standards which could become hard to manage (Rebbitt and Erickson, 2016). Such scenario may generate hyper-compliance, which leads practitioners to follow procedures thoughtlessly: primarily to avoid penalties for noncompliance; and as a side effect, causing a reduction in the ability to face complexity and uncertainty of everyday work conditions. The need to shift from a human error perspective to an organizational perspective has to be addressed both in the investigation process and in the system design phase (Vincent et al., 2000), even with respect to recent trends in information technologies (Patriarca et al., 2019). Several safety assessments still consider errors as a product of a chain of causes in which the individual's psychological factors constitute the last and least manageable links. This idea is based on the Reason Swiss Cheese Model, where metaphorical barriers prevent errors at different levels, including both latent and active failures (Reason, 2000, 1990). Even though a barrier-based approach has led to significant enhancements in safety management, nowadays it has been acknowledged that linear causality does not completely address the treats of a socio-technical system.

A systemic approach becomes necessary to cope with the interactions among human, technical and organizational aspects, and with the high level of inherent uncertainty. These intertwined aspects contribute to increase the system's complexity and intractability, as well as reducing the time to recover from deviations. For this purpose, in case of analyzing adverse events, it is necessary to move from a philosophy of human error to one of system error (Mccarter et al., 2003). A system error acknowledges the importance to focus not only on components (individual agents), but on the system as a whole, i.e. considering interactions between humans (Bauer et al., 2013), equipment and organization (Cacciabue and Vella, 2008; Patriarca et al., 2018c). This systemic approach would enhance process analysis, focusing on the connections among agents in the work domain.

A cultural change is required to achieve this perspective. It is necessary to shift from a culture of blame and hiding information about risk and error, into a culture of safety, i.e. sharing information at different levels to prevent or quickly recover from mistakes before they lead to mishaps with potentially sever outcomes (Leape et al., 1998). Education and training largely contribute to create the preconditions for such culture (Dean et al., 2002). Workforce should be involved in proactive initiative aimed at enhancing organizational knowledge to reduce risk in the workplace by means of shared knowledge repositories built on personal experience, skills and individualistic initiatives (Chan, 2016). This concept underlines the importance for employees at all levels to be mindful, engaged and alert, paying attention to operations and able to move quickly to recover from unexpected failures (Carrol and Edmondson, 2002). A result that can be achieved through systemic analyses (Künzle et al., 2010).

In terms of systemic analyses, the Systems-Theoretic Accident Model and Processes (STAMP) provides a holistic approach to safety, dealing with accident analysis via the integration of direct and indirect factors in a control structure representation.

As a model, the STAMP has been applied in different contexts, (e.g.) in order to evaluate flight testing of a low-cost unmanned subscale blended-wing-body demonstrator (Lu et al., 2015), defining a safety guided design for spacecraft (Ishimatsu et al., 2014), or to improve hazard analysis and certification of integrated modular avionics (Fleming and Leveson, 2014). It has been applied in the Information Technology domain (Mason-blakley et al., 2014) also in terms of cyber security, taking advantage of the STPA-Sec (Young and Leveson, 2015) or in the medical context, in order to evaluate the safety effects on design of medical diagnostic devices (Balgos et al., 2012). Moreover there are several STAMP-based applications to analyse accidents: a water contamination accident and the U.S. Army friendly fire shootings (Leveson, 2011), the Korean Sewol ferry accident (Kim et al., 2016), the Deepwater blowout accident (Pereira et al., 2015). It is also relevant to notice some studies comparing STAMP with other traditional risk methods, for example Hickey and Hommes (2013) study the US Coast Guard aviation mishap with STAMP and also with the Reason Swiss Cheese model. Altabbakh et al. (2014) apply STAMP to an accident in the oil and gas industry, comparing the results with the HAZOP-based outcomes.

Recent works also address the benefits of applying STAMP in health care practices, in particular, related to medication administration within domiciliary setting (Faiella et al., 2018; Parand et al., 2018); to the usage of Electronic Medical Record (Mason-Blakley et al., 2017); and to radiation oncology treatment (Pawlicki et al., 2016).

Overall, it is important to underline that using STAMP to analyze accidents generally reveals more hazards and potential failures in systems than other traditional hazard analysis or accident causation models (Meng et al., 2018; Stanton et al., 2019). STAMP's scope spans over multiple levels of the control structure with the purpose of

investigating control's adequacy with respect to environmental, human, technological, and contextual factors. Rather than focusing on root cause identification, STAMP is more focused on enforcing systems' safety constraints, through the recognition of scenarios, inadequate controls, dysfunctional interaction, and incorrect process models to be managed for making the system safer (Altabbakh et al., 2014).

Even though the STAMP has shown successful outcomes on exploring non-trivial organizational factors, if compared to other traditional methods (Bosse and Mogles, 2013), its applications mainly takes place within the academic context. This latter is a consequence of the general scepticism of most practitioners in safety-oriented businesses to prefer well-established methods, rather than in actual criticism for using the STAMP itself (Underwood and Waterson, 2013).

3. General anesthesia: description of the process

Anesthesia for surgery is intended to realize several endpoints: among these, the most important are to minimize potential -early and late- complications associated with painful and stressful stimuli: to maintain the physiological variables within normal limits (namely: cardiovascular function, peripheral perfusion, ventilation, renal function, etc.); and to warrant the best possible conditions of the surgical field. These targets can be achieved by inducing general anesthesia -with a complete abolition of consciousness, i.e. the ability to recall the surgical experience- or by using locoregional anesthesia techniques that prevent the conduction of painful stimuli to the central nervous system. The latter approach can imply complete preservation or partial blunting of consciousness. General anesthesia implies: unconsciousness, amnesia, analgesia and stillness (Rosa and Bilotta, 2006).

Drugs used to induce (to initiate) general anesthesia (anesthetics) can be administered in different ways: intravenous and inhalation ways are the most used since they allow for a more precise and accurate dosage and thus anesthetists can monitor and prevent the side effects of administration. Anesthetics can be categorized into 3 major groups: hypnotics, analgesics and muscle relaxant. Anesthesia induction and maintenance is based on the use of extremely sensitive and potentially dangerous and even lethal drugs and on techniques (e.g. endotracheal intubation or mechanical ventilation, invasive monitoring of physiological variable) which are inherently risky.

Surgical procedures can be categorized into two major classes: elective (from the Latin *eligere*, that means "to choose", are procedures scheduled in advance), and emergencies (procedures deeming immediate intervention). In elective procedures, the anesthetists are called to complete the "preoperative evaluation" that is intended to analyze the aspects specifically relevant for anesthesiological management (i.e. the accessibility to airway management, etc). Then the anesthetists have to "weight" associated diseases that might complicate the course of anesthesia and of the surgical procedure (endocrine dysfunction as an history of diabetes, red blood cells or coagulation disorder, chronic arterial hypertension or coronary artery diseases, pulmonary diseases, etc.) and assess if these conditions have been treated to the "best possible" way in the preoperative period. This process should bring together the potential to correct an associated disease (not the clinical problem for which the patient should receive surgery) and the necessity to minimize the preoperative time. This is especially relevant in patients undergoing surgical procedures for malignant cancer in whom the time between surgical indication and the actual procedure should be kept the shortest possible.

The case study included in this paper focuses on anesthesia in neurosurgical department of an academic hospital, where generally 6 interventions per day take place. The analyzed process can be summarized in 4 phases, as sketched in Fig. 1 and detailed in Appendix. Particular attention will be devoted to preoperative and intraoperative phases.

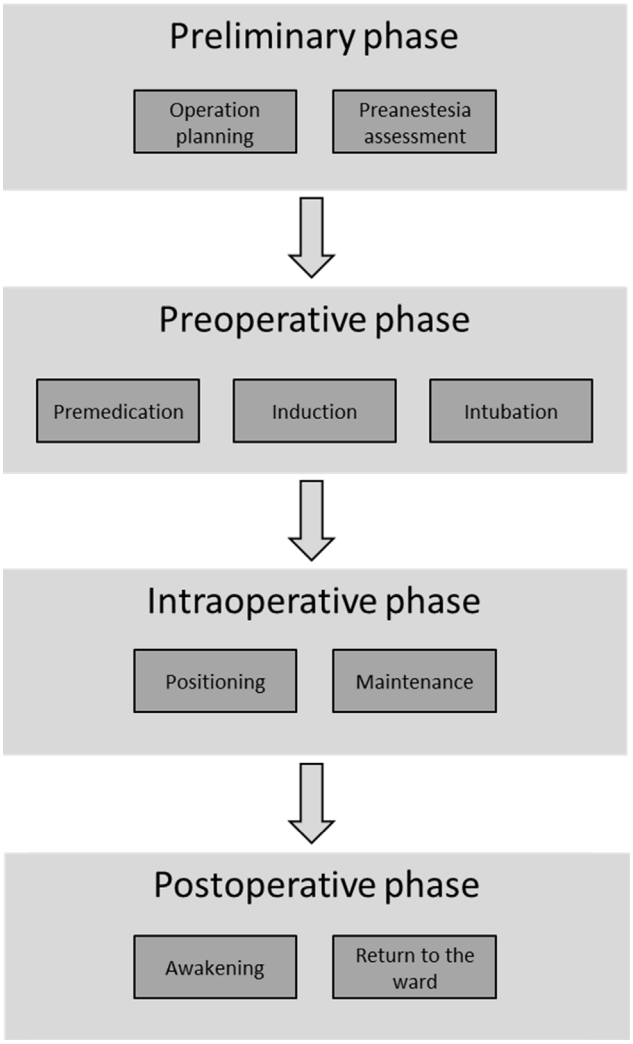

Fig. 1. Phases of the anesthesiological process and focus of the analysis.

4. Method: system theory, STAMP AND STPA

This paper presents a detailed application of STAMP in the medical context (in terms of STAMP-based hazard technique, the STPA), providing empirical support for methodological application in medical settings. The case study focuses on anesthesiological practices, a field currently not investigated in STAMP literature to the best of our knowledge. Adopting a systemic lens, this research deals with process hazards for the definition of mitigating actions to enhance system safety, clarifying how a similar method may have multi-disciplinary benefits.

4.1. STAMP basic principles

According to STAMP, safety is conceived as a control problem and thus accidents occur when component failures, external disturbances and dysfunctional interactions are not adequately handled by the management control system (Altabbakh et al., 2014). STAMP relies on three main principles, i.e. safety constraints, hierarchical control structure, and process models (Leveson, 2011):

– The safety constraints specify what relationships among system components allow achieving not-hazardous system states. Consequently, accidents are considered the result of the interactions among components that lead to the violation of safety constraints

rather than the result of single components' failures.
- The hierarchical control structures ensure the enforcement of safety constraints. Each level of the hierarchy enforces its own safety constraints on lower levels, and each level below has to give feedback on how these constraints are successfully implemented or ineffectively failed.
- Each hierarchical level of the safety structure must have a process model of the process being controlled. This model can be embedded in the control logic of an automated controller or in the mental model maintained by a human controller.

Being a model, the STAMP can be adopted as a theoretical foundation to develop systems theory-based safety methods, (e.g.) the STPA for hazard and risk analysis.

4.2. System Theoretic Process Analysis (STPA)

As a STAMP-based method, the STPA encompasses the analysis of processes and causes, focusing on identifying hazardous scenarios that involve accident causal factors. STPA aims to translate these factors into safety measures to prevent accidents (Lu et al., 2015). STPA can be used at any stage of the system life cycle to accumulate information about how the behavioural safety constraints, which are derived from the system hazards, can be violated. STPA consists of two main steps:

- Step 1 identifies the potential source for inadequate controls of the system that could lead to a hazardous state. Hazardous states result from inadequate control or enforcement of the safety constraints, which can occur due to:
  - o A control action required for safety is *not* provided or not followed.
  - o An unsafe control action is provided.
  - o A potentially safe control action is provided at the wrong time (too early or too late)
  - o A control action required for safety is stopped too soon or applied too long.

  For this purpose, following the identification of accidents related to the purpose of the analysis and their links to hazards, it is necessary to develop a control structure diagram. This latter is intended to show the interactions among system's components and processes in terms of input, output, control and feedback. The map allows discussing the potential source for inadequate control and features of the safety constraints (Leveson and Thomas, 2018).
- Step 2 determines how each potentially hazardous control action identified in Step 1 could occur, (Leveson, 2011). More in detail, if the controls in place are inadequate, recommendations should be developed for reinforcing the control structure or provide additional mitigation strategies.

4.3. Developed approach

The project relies on focus groups and semi-structured interviews for knowledge elicitation, whose data have been managed by means of qualitative content analyses (Patton, 2002).

Focus groups have been used to gain an understanding of the fundamental issues, perceptions and attitudes of the work domain. Group interactions have been selected as they have been proved successful at encouraging informants to make connections to different concepts and perspectives (Kitzinger, 1995; Morgan, 1996). For the specific process at hand, two moderators have been selected, i.e. one researcher with experience in safety management and one staff anesthetist directly involved in the study design. The choice of having an *outside researcher* moderator (i.e. no training as an anesthetist, but as an engineer experienced in risk management) followed the opportunities documented in literature on having outside researchers in data collection, i.e. (i) looking at the patterns and symbols with fresh eyes, (ii) establishing a non-prestigious conversation atmosphere (Bergström, 2012; Wax, 1985), thus balancing technical aspects and safety concepts.

Two focus groups have been organized. The first one at the beginning of the project, to support the researchers at understanding the work domain and to provide the preliminary list of accidents, hazards, and safety constraints. It involved 3 staff anesthetists (15 years of experience on average), 2 resident anesthetists (3 years of experience on average), and 3 researchers (10 years of experience on average). The second one has been organized to help the identification of meaningful scenarios, based on the definition of Unsafe Control Actions. It involved 3 staff anesthetists (the same ones involved in the first focus group) and 2 researchers (2 out of 3 involved in the first focus group).

In addition to focus groups, semi-structured interviews have been used for further eliciting knowledge on the work domain. Interviews represent a good approach to understand the individual's perspective of a systems, i.e. how a human relates to his/her work environment. Semi-structured interviews have been used with the purpose of providing the researchers with systematic information on some sub-processes and specific tasks, after having analysed the outcomes of the first focus group. The interviewers used a basic script to guide the interactions with the interviewees and to maintain consistency across all interviewees (Patton, 2002). The interviews have been conducted by two interviewers jointly, the first one leading the interview and interacting with the interviewees, and the second one taking notes on the discussion (the two moderators of the focus group). The semi-structured interviews have been used specifically to confirm the identified control actions, and develop the respective control structure, as well as defining the unsafe control actions. The outcome of the interviews implied minor refinements for the list of accidents, hazards and safety constraints. The same 3 staff anesthetists involved in the focus groups have been interviewed (about 45 min each), as well as 3 nurses in order to gain specific clarifications on the process (about 20 min each).

Data from focus groups and interviews have been analysed mainly through notes taken by the two moderators (and, for the first focus group, by the third researcher as well). Following (Patton, 2002), data have been managed and interpreted according to an *analyst's triangulation perspective*: the moderators independently analysed data and compare their findings to reduce potential bias, and support a direct assessment of data consistency. More specifically, about the first focus group and semi-structured interviews, data have been managed by means of what is defined in (Patton, 2002), as *analytical framework approach*: organizing data highlighting important processes, and relative issues, as well as process variations based on personal statements. Oppositely, the second focus group has been managed in a combined *case study/storytelling* perspective: interviewees were asked to recall relevant episodes, describing how the event emerged and providing information about the working conditions. For the purpose of scenario generation, critical episodes constitute self-contained descriptive units of analysis. The data reported constituted the most relevant scenarios, i.e. excluding those ones emerged during the discussion, but not explicitly related to the focus of the analysis (pre-operative, intra-operative anesthesia). In all cases, the moderators' backgrounds (on technical aspects and safety management aspects) supported a joint process-/safety-oriented viewpoint.

Fig. 2 summarizes the adopted techniques and the STPA phases (cf. Sections 5.2–5.7).

5. Results: STPA of an anesthesiological process

5.1. Context of the analysis

The STPA aims to identify accidents, hazards and safety constraints that characterize the system (Leveson and Thomas, 2018). The analysis focuses on preoperative and intraoperative phases (cf. Appendix, Sections A.2 and A.3). During a surgery, it is usually tricky to distinguish the generic surgical activity from the strict anesthesia. Therefore, an

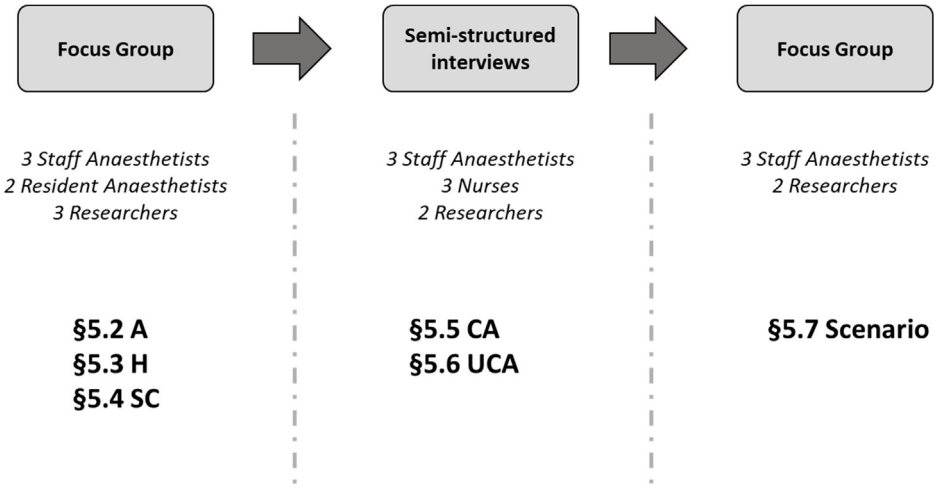

Fig. 2. Main techniques for data analysis.

operation can be successful based only on a comprehensive collaboration between main active agents, i.e. medical surgeon and anesthetist.

Note that the terminology and the analysis of this research rely on STAMP/STPA traditional approach (Leveson, 2011), and are influenced by the concepts of the PHL (Preliminary Hazard List). In particular, the PHL is useful to support in-depth hazard analyses and evaluations, as more system design details become available. The PHL's scale-free features allow to perform the analysis at a systemic level, then delving into sub-processes in order to identifying high-level system hazards and generic hazards that may exist in the system being studied.

It is important to underline that the identification of accidents, hazards, and safety constraints followed a functional perspective, rather than a physical implementation. The purpose of having high-level hazards relies on previous medical STPA studies which emphasize the benefits of keeping the list small in order to avoid missing sets of them, having redundancies, and mixing up causes and effects, see (e.g.) (Pawlicki et al., 2016).

Besides the extended discussion of the process included in the Appendix, further readings are recommended to get a deeper understanding of the terminology used throughout the remainder of Section 5 (Arbous et al., 2005; Collins, 1992; Dorsch and Dorsch, 2007).

Following STPA best practices (Leveson and Thomas, 2018), since the perioperative process' structure is highly variable from case to case, it was chosen to simplify the process' model attributing control actions to the categories (surgeons, anesthetists, nurses) and not to individual practitioners (a specific surgeon, anesthetist, nurse). This aspect, emerged from both the focus groups and the interviews, has been not explicitly modelled in the control structures, but it has been added as a SC (cf. Section 5.4, SC.10), and subsequently explored in the scenarios list (cf. Section 5.7). With reference to these aspects, the role of communication has been highlighted, in order to enforce the safety constraints leading to an effective and efficient exchange of information between the actors involved in the process.

5.2. Defining the accidents (A)

Following Leveson's description, in the language of STPA, the term accident indicates an "undesired or unplanned event that results in a loss, including loss of human life or human injury, property damage, environmental pollution, mission loss, etc." (Leveson, 2011; Leveson and Thomas, 2018). Possible accidents considered in the analysis are:

- A.1) Patient is injured
- A.2) Patient dies
- A.3) Equipment are damaged
- A.4) Staff is injured

5.3. Defining the hazards (H)

The term hazard indicates "a system state or set of conditions that, together with a particular set of worst-case environmental conditions, will lead to an accident (loss)" (Leveson, 2011). The identified hazards are linked to the previous accident (as sketched in Table 1) and can be summarized as follows:

- H.1) Type and dose of anesthesia are not adequate, for example:
  - o They are fit for the patient's condition, but they aren't fit for the type of intervention to be carried out
  - o They aren't fit for the patient's condition, but they are fit for the type of intervention to be carried out
  - o They aren't fit for the patient's condition and for the type of intervention to be carried out
- H.2) Problems occur in the induction phase, for example:
  - o Arterial hypotension (blood pressure arterial maximum of less than 100 mmHg, whereas the values recognized as normal in the healthy population oscillate between the 110–130 mmHg systolic)
  - o Bradycardia (decreased heart rate less than the value of 60 beats per minute)
- H.3) Unexpected complications occur in intubation, for example:
  - o Only soft tissue with no identifiable airway anatomy visible
  - o Asymptomatic lingual tonsil hypertrophy
  - o Other issues as for clinical reports (e.g.) (Davies et al., 2001; Goñi-Zaballa et al., 2012; Hosoya et al., 2009)
- H.4) Equipment and items are used improperly
- H.5) Anesthesia equipment does not function as expected
- H.6) Medical complications occur, for example:
  - o Bleeding complications
  - o Infectious complications
  - o Neurological complications
  - o Wrong side complications

Table 1
Accidents (A) vs Hazards (H).

	H.1	H.2	H.3	H.4	H.5	H.6
A.1	x	x	x	x	x	x
A.2	x	x	x	x	x	x
A.3				x	x	
A.4			x	x	x	x

About H.4, note that Equipment refers to reusable artifacts (e.g. anesthesia machine), while items refer to consumable objects (e.g. PPE).

5.4. Defining the safety constraints (SC)

Following STPA, hazards can be translated into safety constraints that must be enforced by the system to limit the occurrence of accidents. The SCs have been defined through a content analysis of notes taken during the first focus group, which have conducted in order to fulfill the basic logic (Leveson and Thomas, 2018):

< Safety Constraint > = < System component > & < Condition to enforce > & < Link to Hazards >

It should be noted that the label < System component > refers to any agent (technical, human, organizational) in the system at hand. Furthermore, in line with STPA approach, it has been considered not only one-to-one relationships between SC and H, but possibly m-to-n relationship.

- SC.1) Anesthetic must be correct: adequate for patient's condition and for type of intervention to be made
- SC.2) Anesthetic assessment should bring out all the risk factors for induction phase
- SC.3) The Operating Room and medical equipment has to be properly organized before the intervention following operational guidelines
- SC.4) The anesthetist has to be trained to manage risks and follow clinical guidelines
- SC.5) The equipment has to be safely maintained
- SC.6) Surgical interventions has to be planned in advanced and accurately
- SC.7) Equipment has to be tuned accordingly to the process being investigated
- SC.8) Operators have to wear proper Personal Protective Equipment (PPE)
- SC.9) Bio-waste items has to be managed properly
- SC.10) Communications among the components of the medical team have to be managed properly, ensuring accurate transmission of patient's key information

5.5. Defining the control structures

The STPA analysis requires the development of hierarchical control structures to represent the process under analysis, underlying abstract functions and respective controllers. The functional control structure is different from the organizational structure, because each controller is described through a function as opposed to his/her job title. The analysis starts with a high-level control structure, which is then drilled down into control structures at lower levels of abstraction.

5.5.1. High-level control structure

Fig. 3 depicts the high-level control structure, indicating high-level abstract functions and describing relationships among agents and activities. Note that "surgery planning" and "surgical operation" (the highlighted boxes) represent the focus of the analysis, as further discussed in Section 5.5.2, through a more detailed control structure.

- **National Health Service**. This institution includes a set of different authorities that contribute to protect the health of citizens as Board of Health, the Health Council, the National Institute of Health. For the analysis, this controller will not be explored in detail, but rather assumed as the source of procedures, ministerial decrees, qualitative, technological and quantitative standards related to hospital care.
- **Hospital General Management**. The hierarchical structure within the hospital is highly inter-related. Under the General Direction there are the Administrative Department and the Health Department and, in case of university hospitals, a Scientific Direction. The General Medical Director, head of the General Direction, controls different departments, manages and legally represents the hospital. He/she is the legal responsible for the overall management of the hospital and he/she has also to verify the impartiality and the efficiency of administrative actions. The General Medical Director supported by the Health Director and the Administrative Director, defines the budget and the most functional business strategies to achieve the set goals.
- **Neurosurgery Department Management**. The Director of the Neurosurgery Department is elected by the General Medical Director of the hospital. This role has both professional responsibilities for clinical organizational and prevention, and management responsibilities for planning and allocation of resources into the department. To this end, the Department Director compiles annually activities and resources plan.
- **Medical staff of Neurosurgery Department**. Practitioners of the Department of Neurosurgery considered in the STPA are the core of surgeries. Staff consists of resident and staff surgeons and anesthetists, nurses and servants.
- **Surgery planning**. This block includes all activities preliminary to the arrival of the patient in the operating department. It includes planning of interventions, made by the surgeon and thereafter subject to any changes, and evaluation of type and dose of anesthesia, performed by anesthetist based on patient exams and an interview with the patient at the time of recovery. Based on the description in Appendix Section A.1, it includes the preliminary phase.
- **Surgical operation.** This item includes all the activities associated with the operation. As clarified in the Appendix, there are three main phases within the operative block: preoperative activities, intraoperative and postoperative.
- **Material and Machinery Supplies**. This item represents all the necessary materials for any operating activities within the hospital, i.e. drugs, disposable and/or sterilized tools, uniforms and personal protective equipment, specialized equipment for operation and monitoring, etc. The procurement of supplies is weekly performed by the head nurse through online procedure and the order size is based on previous orders.
- **Technical Maintenance staff**. It is mandatory for the hospital to guarantee specific quality and safety standards, following the National Health Service guidelines and prescriptions. For this reason, the equipment must be safe and functioning and the technical maintenance staff is responsible of providing technical assistance to check the proper functioning of the equipment. The controls can be periodic and routine maintenance (annually) or can be requested specifically by the department staff in case of failure or malfunction.

5.5.2. Detailed structure

Fig. 4 shows the detailed control structure for the surgical operation.

It is important to notice that in OR there are many more agents compared to the ones represented in this model: the surgeon, anesthetist and nurse should be considered as representative respectively of a set of surgeons, a set of anesthetists and a set of nurses necessary for a proper conduction of a surgery.

The identification and labelling of CAs followed a progressively less abstract modelling of the responsibilities of each agent (Leveson and Thomas, 2018). The purpose of the semi-structured interviews in this phase (cf. Section 4.3) was mainly conceived to collect the proper details for lower abstraction levels of control with specific questions. Lastly, to finalize the control structure, feedback have been derived

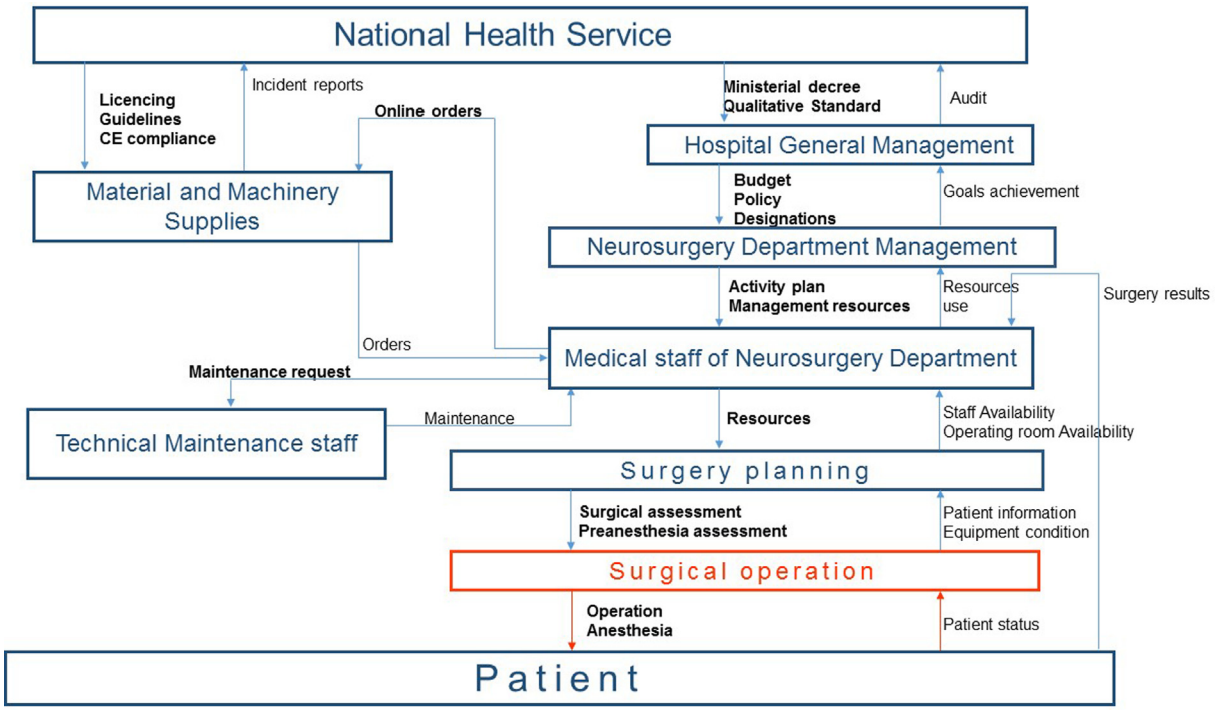

Fig. 3. High-level control structure for the anesthesiological process.

from the control actions and responsibilities of controllers.

Table 2 summarizes the relationships between every CA and H. Here follows a brief description of the control actions:

CA.1) Require patient conditions: This control action is considered repeated several times during the procedure, as it represents the interaction between surgeon and anesthetist. The surgeon can advance specific requests that the anesthetist may, or may not, support, depending on the monitoring instruments. The interaction can also be considered as a request of details on the patient conditions.

CA.2) Manage: The anesthetist is responsible for the management of the anesthesia equipment. Electrodes on the patient must be connected to the machine to activate the monitoring process. Through observation and processing all the available information, the anesthetist may modify -if needed- in real time, the drugs and fluids needed by the patient during anesthesia and surgery.

CA.3.1) Premedication: This control action relates to drugs administration before patient arrives in the OR. The anesthetist firstly

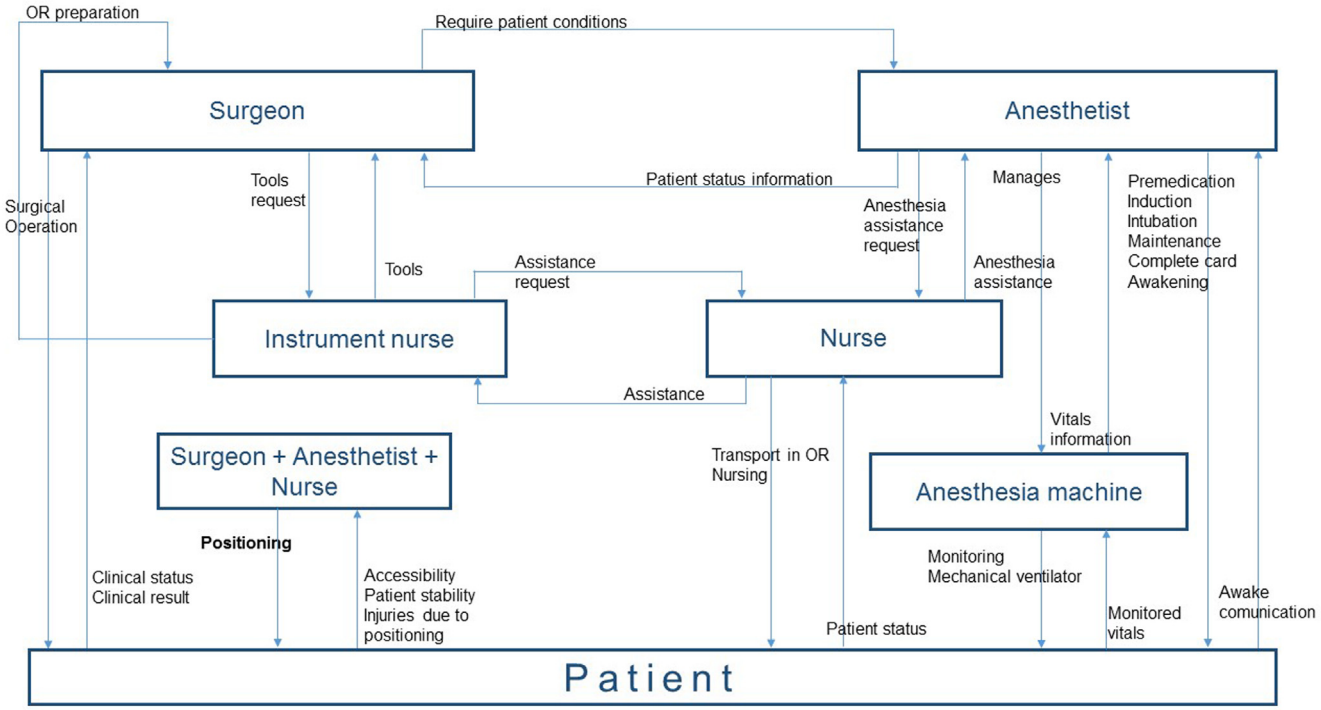

Fig. 4. Detailed control structure for the surgical operation.

Table 2
Control Actions (CAs) vs Hazards (H).

	H.1	H.2	H.3	H.4	H.5	H.6
CA.1		x	x		x	x
CA.2				x	x	
CA.3.1	x	x				x
CA.3.2		x				x
CA.3.3			x			
CA.3.4				x	x	x
CA.3.5						
CA.3.6	x					x
CA.4.1				x	x	
CA.4.2				x	x	
CA.5		x	x			x
CA.6	x	x	x	x		
CA.7.1				x		x
CA.7.2	x			x		x
CA.8				x	x	x
CA.9		x		x	x	x
CA.10		x	x	x		x
CA.11				x	x	

realizes a venous access that will allow the administration of the different drugs before and during the intervention. The anesthetist may administer anxiolytic drugs (such as benzodiazepines Midazolam) to reduce the patient's anxiety, anti-emetic drugs, painkillers or gastroprotective. The drugs administrations shall be registered on the patient folder and reported on the anesthesia record.

CA.3.2) Induction: This phase occurs when the patient is positioned on the operative desk and represents the phase in which the patient loses consciousness. Drugs used are here are hypnotics (Thiopentone, Propofol, and Midazolam). To facilitate the next phase of intubation, muscle relaxants drugs are administered to inhibit the motor response. The commonly used drugs in this circumstance are curare (Vecuronium, Pancuronium, Atracurium). The anesthetist can also use opioids (such as fentanyl, remifentanil, Alfentanil) to reduce glare neurodegenerative reflex during induction and intubation. Hypnotics are intended to abolish consciousness. Muscle relaxant (also known as “curare drugs” by the name of the alkaloids poison used for hunting in central and south America) are necessary to place the endotracheal tube (gag reflexes are important and strong “defensive reflexes”), to establish a mechanical ventilation and to prevent muscle contraction that in some individuals might interfere with optimal surgical exposure (abdominal muscle might “squeeze” the gastrointestinal tract out of the surgical incision). The ability of the patient to ensure adequate ventilation (intake of oxygen and optimal discharge of carbon dioxide) is abolished by muscle relaxant thus making it mandatory to prosthesize the ventilatory function (cf. CA.3.3).

CA.3.3) Intubation: After the anesthetist proceeds with tracheal intubation, other drugs may be administered to promote the intubation itself (e.g. Succinylcholine). This phase may be inherently complicated, depending on the conformation of the patient's mouth.

CA.3.4) Maintenance: The maintenance in the case of intravenous anesthesia is guaranteed by two uninterrupted infusion drugs: the hypnotic to maintain the state of unconsciousness (generally used Propofol) and the opioid to ensure analgesia (generally used Remifentanil). Analgesics (mostly belong to “opioids derivatives”) prevent the pathophysiological consequences associated with pain (i.e. increase in heart rate, arterial blood pressure, cardiac work, etc.).

CA.3.5) Awakening: The awakening phase is particularly delicate because the patient gradually returns to consciousness state. Once the surgery ends, the anesthetist stops drugs administration and makes sure that the patient works off the effects. Then the nurse requires the anesthetist’s consensus to bring back the patient in the ward.

CA.3.6) Complete card: During the surgery, the anesthetist must complete the anesthesia register. This document contains general patient information, diagnosis, operative treatment and all information as general conditions, neurological status, preoperative and postoperative requirements and the measured vitals.

CA.4.1) Monitoring: This control action is performed by the machine for anesthesia on the patient, through the electrodes applied on the patient by the anesthetist. The monitoring can be continuous (e.g. ECG monitoring, temperature, ventilation, the concentration of CO2 and oxygen saturation) or periodic, i.e. regularly repeated at short intervals. The equipment supports also audible alarms, emergent in case of patient’s parameters overstepping previously established safe ranges.

CA.4.2) Mechanical ventilator: Once properly intubated, the patient is connected to the mechanical ventilator that guarantees artificial respiration during the intervention, thanks to a mixture of oxygen and anesthetic gases (Sevoflurane and Desflurane).

CA.5) Positioning: The patient positioning is especially delicate and must be followed by the entire staff in the OR. The patient must be positioned in such a way to ensure the whole operating area accessible during the surgery. During positioning maneuvers, the surgeon dictates the requirement for the intervention and the anesthetist ensures that the patient intubation is not compromised. Time duration of the positioning maneuvers is variable in the range 30–120 min. The positioning is considered concluded when the patient is stable and accessibility to the surgical area is guaranteed.

CA.6) Anesthesia assistance request: This control action represents the interaction between anesthetist and nurse. Requests can be different, (e.g.) passage of a drug, instrumental assistance in intubation, physical support in positioning, monitoring of patient’s parameters.

CA.7.1) Transport in OR: The patient coming from the ward is transported in the pre-anesthesia room. Once ready, he/she will be conducted in the OR by the nurse.

CA.7.2) Nursing: Nurses in the operating theater perform different support tasks to accommodate needs of anesthetists and/or surgeons, and take care of the patient.

CA.8) Surgery tools request: This control action refers the interaction between surgeons and nurses, as a support for managing the operating table. During the surgery, the instrument nurse should execute (and possibly anticipate) surgeon’s requests.

CA.9) Request assistance: This action refers to any other support task (except instruments on the operation desk) requested to the nurse, who has mobility during the intervention to accommodate unexpected requests by the instrument nurse.

CA.10) Surgical Operation: To simplify the model, the set of surgical activities performed by the team are summarized by a single control action that aims to represent the entire surgical intervention. This control action will not be in-depth analyzed, because not directly referring to anesthesiological practices.

CA.11) OR preparation: The instrument nurse is responsible for preparing the operating table with the necessary tools for the operation at hand.

5.6. Defining the Unsafe Control Actions (UCA)

Once defined accidents (Section 5.2), hazards (Section 5.3), safety constraint (Section 5.4) and control structure (Section 5.5), it is possible to proceed with Step 1 of the STPA, i.e. identifying the unsafe control actions (UCAs).

For each control action in the detailed control structure presented in Section 5.5.2, it is possible to analyze possible ways for the control action being unsafe. More specifically (Leveson and Thomas, 2018):

– A control action required for safety is not provided or not followed.

Table 3
Example of detailed UCAs.

Control Action (CA)	Not providing the CA causes hazard	Unsafely providing the CA causes hazard	Wrong timing or order of the CA causes hazard	CA stopped too soon or applied too long causes hazard
Premedication (CA.3.1)	Anesthetist does not administer anxiolytics that the patient can assume and that are necessary for surgery	Anesthetist realizes bad venous access	Anesthetist administers anti-anxiolytic drugs too late and the patients' conditions are not suitable before induction	N/D
		Anesthetist administers useless drugs or drugs not suitable for the patient	Anesthetist administers anti-anxiolytic drugs too soon and the effect on the patient vanishes before induction	
	Anesthetist does not administer other essential drugs: analgesic, antiemetic, etc.	Anesthetist administers other useless drugs (analgesic, antiemetic, etc.) or not suitable for the patient		
Intubation (CA.3.3)	Anesthetist does not intubate the patient	Anesthetist wrongly intubates esophagus	Anesthetist awaits too much time to intubate the patient (meantime, he/she is not able to breathe independently)	Patient's intubation takes more time than expected
			Anesthetist intubates the patient without waiting that muscle relaxants drugs take effect	
Positioning (CA.5)	Patient is not positioned when instead it is required specific placement	Patient is positioned in order to disallow accessibility to the site interested by the surgery	Positioning starts too early before the beginning of the surgery, so the patient is exposed to not-necessary positioning risks	Positioning requires more time than expected
		Patient is positioned but the intubation is compromised	Positioning, which requires too much time, is started too late, causing delays throughout the surgery schedule	

– An unsafe control action is provided.
– A potentially safe control action is provided too early or too late, that is, at the wrong time or in the wrong sequence.
– A control action required for safety is stopped too soon or applied too long.

In summary, the control structures discussed in Section 5.5 defines 18 CAs that lead to identify 78 UCAs; and each UCA is linked to one or more hazards, as shown in Table 2. For example, Table 3 details the UCAs for CA.3.1, CA.3.3 and CA.5.

5.7. Determining how unsafe control actions could occur

Step 2 of the STPA consists of determining how each UCA identified in Step 1 may occur. Step 2 can be developed through multiple approaches, depending on the system's characteristics. The STPA discussed in this paper relies on a linguistic approach. The detailed UCAs referred to the same potential source for inadequate control (i.e. not providing, unsafely providing, wrong timing or order, inadequate duration) are summarized to address potential scenarios that could lead to one or more UCAs. Following STPA definition, a scenario represents "the causal factors that can lead to the UCAs and to Hs" (Leveson and Thomas, 2018).

The scenario identification and analysis relies on the second focus group, during which discussion started from questions such as "How would < this Unsafe Control Action > occur?", "How could control action be improperly executed or not executed, leading to hazards?".

Table 4, derived from Table 3, defines some relevant scenarios, briefly discussed for the purpose of this paper in Sections 5.7.1–5.7.3.

5.7.1. Scenarios related to premedication (CA.3.1)

– *UCA - Missed premedication of the patient*

Scenario 3.1.1: Missed preliminary assessment, i.e. not providing drugs that would be otherwise required for the patient at hand.

Scenario 3.1.2: Mistake in drugs delivery, the anesthetist is sure of previous administration (not performed in real practice) and proceeds with the intubation.

Scenario 3.1.3: Mistake in drugs delivery, the anesthetist delegates the administration of drugs to a junior anesthetist, since he/she is too busy in other activities.

– *UCA - Drugs unsuitable for the patient and/or for type of planned anesthesia*

Scenario 3.1.4: Wrong preliminary assessment that does not properly assess patient's status, i.e. mainly age, associated diseases or other essential features for the choice of the right drugs.

Scenario 3.1.5: The administered anxiolytic is not appropriate to calm the patient, who is still too rough.

Scenario 3.1.6: The drug administration is not transcribed in the patient's folder, and then erroneously repeated by another anesthetist.

Scenario 3.1.7: The drug administered is wrong because the anesthetist makes a mistake in loading the drug into the syringe.

– *UCA - Premedication drugs used too early or too late*

Scenario 3.1.8: Anesthetist thinks that the antibiotic has already been administered in the ward, after realizing it, he/she administers antibiotic too close to the induction phase.

Scenario 3.1.9: Anesthetist administers anxiolytic but when the patient is ready, the OR is not yet available. Therefore, the drug effect decreases, and the patient begins to distress.

Table 4
Example of generalized UCAs.

Control Action (CA)	Not providing the CA causes hazard	Unsafely providing the CA causes hazard	Wrong timing or order of the CA causes hazard	CA stopped too soon or applied too long causes hazard
Premedication (CA.3.1)	Missed premedication of the patient	Drugs unsuitable for the patient and/or for type of planned anaesthesia	Premedication drugs used too early or too late	N/D
Intubation (CA.3.3)	The patient is not intubated	Incorrect use of the necessary tools for intubation	Intubation performed too early (before the induction) or too late	Intubation requires too much time
Positioning (CA.5)	Positioning is not executed	Positioning is executed without following evaluation	Positioning performed too early or too late	Positioning requires too much time

5.7.2. Scenarios related to intubation (CA.3.3)

– *UCA - The patient is not intubated*

Scenario 3.3.1: Anesthetist is unable to intubate the patient by the traditional laryngoscope due to factors not previously considered. He/she uses several methods of intubation (Videolaryngoscope, fiberoptic endoscope etc.) or he/she proceeds with awake intubation.

Scenario 3.3.2: Anesthetist is not aware that the patient is ready to be intubated or that he/she is assigned to that determined OR. For these reasons, he/she does not reach the OR to proceed with intubation.

Scenario 3.3.3: Anesthetist is ready to proceed with intubation but the bronchoscope (or other instrument used in the specific case) is not available or it does not work properly.

Scenario 3.3.4: Anesthetist is not able to perform the intubation due to special psychological conditions (e.g. time pressures by the team), or due to the low experience with intubation practice, or possibly respective to unpredictable factors about the specific patient.

– *UCA - Incorrect use of the necessary tools for intubation*

Scenario 3.3.5: Anesthetist mistakenly intubates the oesophagus instead of the trachea. In this case, the maneuver must be repeated.

Scenario 3.3.6: The blade of the laryngoscope used by anesthetist is not adequate for the size of the patient and it allows only a limited perspective.

Scenario 3.3.7: The endotracheal tube used has a diameter unsuitable for the patient, resulting too large (intubation can fail) or too small.

– *UCA - Intubation performed too early (before the induction) or too late*

Scenario 3.3.8: Anesthetist, after the patient's induction, hurries to make laryngoscopy without waiting for the effect of muscle relaxants. The vocal cords of the patient are still closed and prevent the passage of the endotracheal tube.

Scenario 3.3.9: The drugs administered for induction paralyze the lungs of the patient, so he/she is unable to breathe. The anesthetist, after the induction, does not proceed promptly with intubation.

– *UCA - Intubation requires too much time*

Scenario 3.3.10: During the patient intubation, anesthetist discovers a critical situation not previously assessed, emerging from the lack of important predictors. This situation forces the anesthetist to use other tools with potentially critical implications for the duration of the intubation.

5.7.3. Scenarios related to positioning (CA.5)

– *UCA - Positioning is not executed*

Scenario 5.1: The patient is not positioned correctly due to a misunderstanding related to surgery. This may happen in case of not proper communication with the patient, or when the folder is not accessible, or possibly in case of a lack of dialogue with the nursing staff.

– *UCA - Positioning is executed without following evaluation*

Scenario 5.2: The patient is positioned so that the surgical area is accessible. The anesthetist makes sure that ventilation is not compromised, and he/she makes different assessment, but he/She does not realize that the patient's weight rests entirely on his arm.

Scenario 5.3: The nurse has not verified the correct physical patient locking (with bands and stops walking), so the patient, after being positioned, starts to slide down.

Scenario 5.4: Anesthetist does not carefully follow the positioning of the patient and the manoeuvres made by the rest of the team cause early extubation of the patient. The anesthetist must repeat the intubation procedure.

Scenario 5.5: The patient must undergo an operation on the brain right/left side. The patient is positioned by the entire staff, but when the surgeon arrived, he/she realizes that the patient has been positioned on the wrong side, making it inaccessible to the right/left side.

– *UCA - Positioning is performed too early or too late*

Scenario 5.6: The patient must undergo an operation of less than 2 h, following a prone positioning but the beginning of the operation delays since the surgeon is not available. The total duration prolongs (4 or more hours), causing problems for due to excessive pronation positioning time.

Scenario 5.7: The positioning operation starts later than the time indicated for the start of surgery. This delay is caused by the incomplete team and due to the lack of supports for correct positioning.

– *UCA - Positioning requires too much time*

Scenario 5.8: During positioning operations, the patient is temporarily disconnected from the ventilator for the time strictly necessary. The positioning needs more time than expected resulting in a potentially superficial anesthesia.

5.8. Analysis of the scenarios: safety recommendations

The analysis of the scenarios leads to the identification of revisions in the safety control structures for agents involved in the process, and for the organization itself. The revisions lead to define safety requirements to be translated as systemic process re-design actions, or as control actions to be executed in everyday work to enhance safety levels.

5.8.1. Premedication

About premedication, several scenarios show the need of assessing the patient's status accurately (Scenarios 3.1.1, 3.1.4, 3.1.5). The problem often relies on different approaches to anesthesia evaluation, based on a first analysis of the patient. More specifically, the anesthetist assesses more accurately those patients considered particularly problematic at a first sight (e.g. old, apparently unhealthy), and aims to have a picture of their condition as much complete as possible, to avoid unexpected complications during intubation. On the contrary, anesthetic assessment for apparently healthy patients (generally young people) is often more superficial. The anesthetist may limit his/her assessment of the patient's status since, being under pressure, he/she prioritizes other -apparently- more critical patients. A healthy work environment counting on team collaboration may (at least partly) limit this issue. This observation encourages the need of more homogeneous approaches, regardless of the physician's first impression on the patient's condition.

Other scenarios suggest discussing a problem related to the communication (Scenarios 3.1.6, 3.1.8) among anesthetists, specifically concerning the continuity of the assessment process and execution of anesthesia. The anesthetist in charge of the patient's anesthetic assessment is not necessarily the same who will manage the anesthetic procedure during the surgical operation. This change generally increases the patient's anxiety and involves many other hidden risks. If the anesthetist knows that he/she will not deal with a patient, consciously, he/she may be less accurate during the preoperative assessment. Furthermore, also a different assessment strategy (e.g. based on personal experience, previous cases) may lead to unexpected differences between the assessment and the actual procedure. As a safety recommendation, it is thus suggested to ensure a proper communication among colleagues and to provide documented evidence on the treatment and on the decisions made by the assessor, promoting thus a healthy organizational culture.

These first two recommendations have been acknowledged as relevant for being explicitly stressed during the upcoming training events and toolbox meetings among anesthetists.

Other scenarios (Scenarios 3.1.2, 3.1.3, 3.1.7) show the need to record the drug administrations, immediately after performing the treatment to the patient. It would be appropriate to create a specific form for premedication which remains with the patient's file since his/her arrival on the ward until the entrance in the OR. Then, before administering any drugs, the anesthetist would consult the form on the patient's file, following best-practices (Scenarios 3.1.2, 3.1.3). Drugs for premedication must be arranged neatly and labelled by categories. As a safety re-design, it is recommended to provide labels of the same color (also developing a well-visible legend) to indicate the same types of drugs, and support the anesthetist's assessment (Scenario 3.1.7), as already done in several hospitals.

A further need emerging from the analysis of scenarios relates to operations scheduling (Scenarios 3.1.9). Punctuality of the entire team (nurses, surgeons, anesthetists) must be a precondition to avoid overlapping. The hospital management company should ease this coordination, providing work shifts that could be more suitable for the company and considering the need for reallocating workforce among the various departments (Scenario 3.1.9), in case of emergency management. As confirmed by the agents involved in this research, currently there is no long-term plan for work-shift scheduling and the monthly-plan is developed manually, with large efforts for trying to accommodate - and often failing - individual requests. Adopting computational algorithms for resource scheduling would be a solution to test effective solutions for dealing with this issue. This observation refers to an organizational recommendation for the Hospital General Management (cf. Fig. 1) of taking advantage of IT solutions which could reduce workload, and increase efficiency, effectively, and not compromising safety.

5.8.2. Intubation

Aligned to premedication, different scenarios suggest a more accurate assessment of the patient's status (Scenarios 3.3.1, 3.3.7, 3.3.8, 3.3.11), in order to limit the emergence of unexpected situations during the intubation phase. The chance of intubating an awake patient requires careful explanations by the anesthetist to the patient. This latter must previously sign a written informed consent, requiring a timely scheduling.

Even though it is extremely unlikely to completely miss the airways assessment, it is relatively common to miss a comprehensive and detailed rating of some characteristics of the patient. The last scenario (3.3.10 in Section 5.7.2) shows how dehumanizing the assessment of some simple indicators (e.g. age, clinical history, etc.) does not guarantee a holistic assessment if not related to critical reflections by the anesthetist.

To avoid errors caused by the psychological pressure (Scenarios 3.3.5, 3.3.6) the anesthetist should work in a serene work environment, where a healthy organizational culture plays a crucial role. More operationally, it would be useful to train the interns on the job, possibly with simulations in case of emergency or under psychological stress, both individually and as a team. As emerged by the analysis of scenarios, team training would limit many effects of process risks.

For these two observations, it is thus recommended to organize toolbox meetings, i.e. meetings among operators to share successful stories, critical scenarios, and reflect on rationality for possible actions and solutions. This informal storytelling is conceived as an additional inherent control action, meant to shift from individualistic sense-making to organizational sense-making, helping creating an organizational learning framework (Bhatt, 2002).

To overcome the problems of communication related to re-

scheduling of surgical operations (Scenario 3.3.2), it is important displaying the operating list in a common dashboard, detailing changes in scheduled rooms, in a user-friendly dynamic visualization. A system redesign recommendation thus refers to developing a dynamic dashboard to be easy to read and to update, using tools coming from the Business Intelligence area (e.g. PowerBI, Tableau).

Instrumentation (Scenario 3.3.3, 3.3.4) must be present in sufficient number to be used in all ORs and the respective routine maintenance must be a prioritized aspect for management. Furthermore, considering the inherent unpredictability of failures, it would be appropriate to have a spare instrumentation (in the case of the bronchoscope at least one in common to multiple ORs) and guarantee operations' continuity. Staff questionnaires would represent a useful solution to understand the satisfaction level, with respect to the actual availability of the specific instruments, and thus helping prioritizing resources (about questionnaire development, cf. Section 5.8.4) to ensure healthy working conditions.

5.8.3. Positioning

Many problems related to positioning (Scenarios 5.1, 5.5) result from a lapse in the medical team about the specific surgical operation, as in case of the so-called "side-errors". The folder with the surgical indication must be complete and must accurately indicate the surgical area, in order to prevent these problems. To ensure that the whole team will be aware of before entering the room, it can be useful that the surgeon in charge of the operation would schematically indicate the type of surgery and the respective area (a graphic support is recommended). In this case, the use of these tools must be imagined as a simple, cheap and apparently trivial checklist to deal with incidents recurring partly due to inattention of staff or lack of communication in the OR. This checklist, even if conceived as a limitation of variability or as a source of the so-called checklist-fatigue, in this specific case, has the potential to bring local safety benefits (Shekelle et al., 2013).

Furthermore, as expectable, attention during positioning maneuvers (Scenarios 5.2, 5.3, 5.4) has a relevant role for a safe positioning. For this purpose, even if guidelines should be well-established and well-known, it is strongly recommended to train the operators at performing a quick check of patient's main sensitive points before starting the maneuver, currently conceived only as a best practice by some experienced anesthetists. A correct time schedule for interventions has also relevant benefits to reduce risks related to positioning, allowing a minimum positioning time (Scenarios 5.6, 5.7, 5.8). Such aspects might be proactively discussed during the organized toolbox meetings, particularly helpful to increase organizational sense-making (cf. Section 5.8.2).

5.8.4. General safety recommendations

It is important to observe that the specific safety recommendations discussed in Sections 5.8.1–5.8.3 would require larger organizational interventions. A healthy organization acknowledges that (e.g.) excessive workload, inadequate supervision, lack of training, stressful environment and inadequate communication, cannot be considered as individual causal factor but as latent conditions and consequently managed accordingly (Dekker and Breakey, 2016).

On this path, several researchers developed instruments to measure organizational culture, in terms of safety climate, envisioning leadership, policies, procedures, staffing, communication and reporting as its most relevant dimensions (Colla et al., 2005). A relevant instrument in this sense is the Hospital Survey on Patient Safety Culture (HSOPSC) discussed in literature as an adequate tool for understanding workers' and patients' safety cultures (Nieva and Sorra, 2003); or the Resilience Analysis Grid (RAG) used to measure the organizational resilience of a system. The proposition of such approaches is intended to gather data on everyday work performance and explore - in relative terms – potential drifts (Falegnami et al., 2018; Patriarca et al., 2018b). Assessing such variation becomes crucial since the safety climate positively affects both patients' and workers' conditions (Jackson et al., 2010; Mark et al., 2007).

A recent research (Arfanis et al., 2011a) also highlights the priority to evaluate how more informal aspects of safety culture, such as individual personalities, perceptions and feelings interactions affect everyday work, mainly individual workers' risk assessment (Arfanis et al., 2011b). Some relevant aspects and discussions on practical aspects of safety culture in anesthesia are discussed in (Gillespie et al., 2013; Hill et al., 2015; Nieva and Sorra, 2003; Nurok et al., 2011).

In addition, systemic training actions would be necessary to support doctors in their everyday work. A complete training in anesthesia should include both theoretical knowledge and practice in OR. The hospital management should not abandon operators in deciding how to balance these two aspects, but it should rather ease an integrated education, promoting focus groups, and toolbox meetings on past events, imagined episodes, to further stimulate critical discussions and continuous learning.

6. Conclusions

Activities in the OR are characterized by inherent complexity, where anesthetists, surgeons and nurses work together in order to deliver safe and efficient medical care. The specific processes discussed in this paper relates to peri-operative and intra-operative phases of the general anesthesia, discussed following the anesthetist's perspective. STPA proved itself useful to develop a systemic description of the system, based on high-level and detailed control structures. These control structures, obtained gathering information at different abstraction levels and by different system agents, allow managing system knowledge holistically. By the identification of potential accidents and hazards, and control actions of the system, it has been possible to identify a list of unsafe control actions leading to hazardous situations. Then, narratively, several scenarios have been explored in terms of potential accidents and incidents generation. Lastly, based on these scenarios, it has been possible to develop safety recommendations to enhance patient safety. However, even though specific safety recommendations entail specific phases of the process, it would be necessary to include them within larger organizational changes in terms of organizational culture, education and training.

We can thus suggest how a STAMP-based approach supports knowledge elicitation at large, supporting a systemic shift of knowledge from an individualistic to an organizational level. The application of STPA supported indeed not only a hazard analysis, but also a systemic and efficient (considering just two focus groups and six interviews) analysis of organizational aspects. As an overall feedback on the methodology, we want to emphasize the positive reactions of people involved in the data gathering phases, who actively contributed to the research understanding the no-blame no-fault oriented dimension of the analysis. In line with previous literature, these results that are expected to be domain-independent, reinforcing the validity of the proposed approach.

The purpose of the case study achieves an explorative contribution, while further research should address effective strategies to be applied and prioritize the identified mitigating actions, even with respect to cost-benefit analysis and actual applicability of them. In some cases, (e.g.) referring to the mitigating actions related to color-labelling of drugs, or additional checks in patient's conditions for positioning, it would be important to develop a further subset of control actions. More specifically, the model sections referring to those actions might be further expanded at a lower abstraction level, in order to gain an in-depth understanding of the process at hand. In this case, it is expected to combine the qualitative data gathering techniques already adopted in this study with naturalistic observations as well as interviews with the involved experts, in order to gather real data on the effectiveness of the proposed actions.

Since healthcare activities are also dynamic, it would be extremely

valuable to iterate the STPA application, in order to validate the effectiveness of safety recommendations and assessing other emergent unsafe control actions, possibly related to the implemented countermeasures. In this regard, following the development of an appropriate reference ontology, further research may explore the usage of artificial intelligence techniques to support human creativity and imagination and automatically create lists of scenarios to enhance the scope of the analysis.

Appendix A. Description of the process

A.1. Preliminary phases

A.1.1. Operation planning

For elective procedures, the surgeons propose and draw up the operating list for the operation scheduling. This list should be planned in agreement with anesthetists and posted on the bulletin board in the doctors' lounge of the operating department. This list may be subjected to changes by physicians or nurses due to limited staff resources, unexpected events (for example if a patient develops fever) and incomplete preoperative testing. By definition, it is not possible to "schedule" those interventions that are emergencies procedures. Nevertheless, these latter have a "priority" and, as such, they usually contribute to the rescheduling of election interventions.

Except for "ambulatory surgery", for which patients reach the hospital and are discharged on the same day of surgery, elective cases are generally hospitalized one day before surgery. Pre-surgical hospital stays might be longer if preoperative testing is incomplete or if the patient has several co-morbidities that need to be assessed by distinct consultants (cardiologist, pneumologist, infective disease specialist, hematologist, etc.) and if the progression of the operating list does not accomplish with all scheduled cases (e.g. in case of unscheduled emergencies).

A.1.2. Pre-anesthesia assessment

The pre-anaesthetic patient assessment identifies individual risk factors and underlying physiologic situations that bring crucial information for the development of the anaesthetic plan. Its aim is identifying the most appropriate anesthetic techniques to be used, to ensure the safety of perioperative care, with respect to the individual and procedure-related risk factors and circumstances (Rosa and Bilotta, 2006). For this purpose, it is important to define the initial conditions of the patient through laboratory and/or instrumental analyses. In agreement with the guidelines of the American Society of Anesthetists (see https://www.asahq.org) preanesthetic assessment must ensure a complete clinical screening. A relevant factor is the patient' medical history, in terms of responses to previous anaesthetic events, main hereditary and chronic diseases, lifestyle (e.g. smoking, alcohol consumption), allergies and chronic use of drugs. A physical examination is also required to potentially reveal latent risk factors, (e.g.) heart murmur and/or arrhythmia or abnormal lung sounds. Other traditional investigations are blood tests, electrocardiogram (ECG), chest X-ray (RX), pneumatological rating (Rosa and Bilotta, 2006).

Risk factors and individual patient' s assessment provide a framework for developing individualized patient plans and may indicate the need for additional diagnostic testing or stabilization before the administration of drugs. Once acquired these exams, the anesthetist can integrate them with more personal information, gathered directly from the patient. It is recommended the evaluation of three fundamental parameters: the Mallampati score (on the difficulty of tracheal intubation), the chin-thyroid distance, and the atlanto-occipital joint. These parameters allow the anesthetist to get a complete picture of the patient's mouth structure and his/her respiratory tract in order to evaluate any potential difficulty for the intubation. The Mallampati score is based on the distance between the tongue and the palate, and then assesses the space available to operate when endotracheal intubation is completed. A high score in the Mallampati index (Class III and IV) corresponds to a relevant difficulty in intubation maneuvers, while classes I and II are associated with a relatively easy intubation. Preanesthesia assessment ends with patient's categorization using the American Society of Anesthetists physical status classification system (the so-called ASA). The higher the ASA, the greater the risks for anaesthetic complications and thus additional precautions are generally required to ensure a positive outcome. Based on these assessments, the anesthetist must provide the preoperative requirements and suggest the more adequate type of anesthesia. During this phase, the communication between anaesthesiologists and patients acquires a crucial role. It is necessary to obtain a written informed consent after discussing with the patient the associated risks, the proposed anesthetic plan, and any available medical or surgical alternatives. Therefore, this phase requires non-technical skills (e.g. ability to take information, focus and take decisions, communication skills) to underpin and enhance the technical assessment.

A.2. Preoperative phase

The preparation phase of the surgery can be subdivided into premedication, induction of anesthesia and intubation. The operating room (OR) is set up by nurses and anesthetists before the arrival of the patient, in order to limit the time spent by the patient in operating ward. The anesthetist makes sure of having the instruments required to proceed with anesthesia, i.e. mainly systems monitoring vital signs, ventilation and intubation systems. At the moment of the operation, the patient is brought into the premedication room and the anesthetist must ask again the identity of the patient to make sure that information on the department folder are correct. Afterwards, the anesthetist makes a peripheral venous access, usually in his/her arm. This access will allow the administration of all intravenous drugs and the fluid infusion during surgery, avoiding direct injections.

A.2.1. Premedication

The premedication is the first phase in which the anesthetist administers drugs to the patient. Drugs for anesthetic premedication include analgesics, anxiolytic-sedatives, antiemetic agents, and proton pump inhibitions. These drugs limit patient's anxiety, protect him from complications related to stress and reduce the intraoperative application of others anesthetic drugs. It is important that the anesthetist supplies psychological support to the patient, providing clear information on the procedure that will be performed and how the patient is expected to collaborate (if relevant). The anesthetist must register a potential administration on the patient medical record that hereafter shall stay with the patient in his/her pathway.

The anesthesia registry is the official document developed by the anesthetist during the entire surgery. The information in the card includes the following data: patient's general identification data, preoperative diagnosis, type of intervention, name of the surgeon, date and time scheduled for surgery, neurological status of the patient, further general conditions. Other relevant information included in the card are: presence of allergies, prosthesis, blood requirements laid and diseases such as hepatitis, AIDS, syphilis. The anesthetist must also report the activities he/she undertakes, where, supported by specific diagrams, he/she can insert the beginning and the end time of each administration, and values of relevant parameters being monitored.

After the premedication, the patient is ready to be moved in OR, by a nurse. The anesthetist prepares the patient applying electrodes for heartbeat detection, blood pressure cuff and pulse oximeter to measure oxygen saturation. Then, the anesthetist administers fluid therapy through the venous access previously realized.

A.2.2. Induction

Anesthesia induction is a particularly delicate phase because the patient passes from a state of consciousness to a state of general

anesthesia. The anesthetist administers hypnotic drugs for the suppression of consciousness, analgesics for the abolition of pain and muscle relaxants for the abolition of motor response. Since the administrated drugs paralyze the patient's musculature and prevent the natural breathing of the patient, a continuous and reliable management of the airway is necessary.

A.2.3. Intubation

During general anesthesia, it is important to cope with continuous demand of oxygen. The process of intubation involves the positioning of an endotracheal tube connected to the circuit breathing, allowing the patient to breathe through mechanical ventilation.

A.3. Intraoperative phase

Once the patient is intubated, he/she is placed in the most suitable and functional position for the specific operation. The positioning is a very delicate phase and requires a strong collaboration: while the surgeon makes sure to have free access to the operation area, the anesthetist shall check that the tube is correctly positioned. The surgeon alerts the anesthetist before proceeding with the skin cut to make sure that there are the best conditions to proceed. For this purpose, the anesthetist monitors the patient's vital parameters and the conditions which indicate sensitivity to pain such as tachycardia and hypertension.

The patient during the operation is kept in a state of analgesia, hypnosis and paralysis (if necessary), hemodynamic stability and adequate ventilation through the administration of appropriate drugs (maintenance phase). The administration of a mixture gas and vapor and anesthetic drugs continues for the entire surgeon to avoid the patient's awakening. During the surgery, the anesthetist must constantly monitor vitals: ECG, pressure, saturation and temperature and he/she can possibly provide additional drugs in response to the needs of surgeon compatibly with the patient conditions.

A.4. Postoperative phase

After the end of the surgical procedure, when physiological variables are "normalized" and according the patient's need and surgeon's indications, the "awakening phase" begins. This phase might start immediately (early awakening) or with some delay (minutes/hours) when the anesthetist discontinues the anesthetic drugs. The residual effects on the patient depends on the type and amount of anesthetic used and on his/her capacity to metabolize the drug itself. After awakening and extubation, the patient is moved to the recovery room and, following an observation period, back to the ward (return to the ward phase). In case of complications, it may be required to transfer the patient to an intensive care where the he/she will be kept under continuous hemodynamic monitoring, possibly intubated and ventilated.

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