Universitat de Girona
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A preprocedural checklist to improve patient safety during prehospital rapid sequence intubation

End of term project

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1. Abstract

Background: major traumatic injuries or severe medical conditions are life-threatening circumstances that may require the establishment of a definitive airway prior to hospital arrival to provide optimal oxygenation and ventilation, being the indicated procedure in most of these circumstances rapid sequence intubation (RSI). The prehospital setting encompasses several predisposing factors that make difficult intubation more likely to occur compared to in-hospital intubations (7.4-13% vs 5.8%), performing more intubation attempts that lead to an increased RSI complication incidence (16-30%). Those predisposing factors comprise patient biophysics, challenging environments and experience of the physician and the team who perform the procedure, including technical (TS) and non-technical skills (NTS), which can be reinforced by the use of a preprocedural RSI checklist.

Justification: prehospital airway management is more susceptible to entail an increased adverse event rate and a decrease in patient safety, leading to greater morbidity and mortality. The use of a RSI checklist is widely recommended in the existing literature, and mandatory in some countries. In Catalonia's prehospital setting, RSI is not standardized and entails a high interpersonal variability due to personal preferences rather than adherence to evidence-based guidelines and recommendations. A preprocedural RSI checklist was developed in 2016 by the medicalized helicopter crew from Girona and has been used by this unit since then, but its impact on the RSI complication rate has never been assessed.

Objectives: the main objective of this project is to assess whether the application of the preprocedural RSI checklist decreases the incidence of major adverse events during the RSI procedure in critically ill or injured patients of all ages in Catalonia's prehospital setting. Furthermore, this study aims to study the following unknown information of Catalonia's prehospital setting: determine the incidence of the prehospital RSI procedure, the first-pass intubation rate (FPS), the global RSI-complication incidence (and its occurrence by intubation attempts) and assess if the checklist application increases the FPS rate, lowers complications in all kind of patients and causes any harmful delays in patient care.

Methodology: this study is designed as a quasi-experimental before-and-after evaluation of an intervention to improve the quality of the RSI procedure in Catalonia's prehospital setting. This intervention is the application of a preprocedural RSI checklist, which will be implemented through formation and training under simulation. A non-probabilistic consecutive sampling method will be performed, including all patients who will undergo RSI in Catalonia's prehospital setting from May 2019 to March 2022. Thus, 1,456 patients will be required to carry out this project, 728 patients will be recruited for each period (pre- and postchecklist). The complications exhibited in both periods will be assessed and compared to determine the impact of the intervention.

Key words: *prehospital intubation, rapid sequence intubation, checklist, intubation complications, patient safety, human factors, non-technical skills, technical skills.*

2. List of abbreviations

AAGBI	Association of Anaesthetists of Great Britain and Ireland	**HR**	Heart rate
ANTS	Anesthetists' Non-Technical Skills	**HROs**	High Reliability Organizations
ASA	American Society of Anesthesiologists	**ICP**	Intracranial Pressure
BMI	Body Mass Index	**ICU**	Intensive Care Unit
bpm	Beats per minute	**ID**	Identification
BURP	Backward, Upward, Rightward Pressure	**LMA**	Laryngeal Mask Airway
CEIC	Comitè Ètic d'Investigació Clínica	**MAP**	Mean arterial blood pressure
CICO	Can't Intubate, Can't Oxygenate	**mmHg**	Millimeter of mercury
CO_2	Carbon dioxide	**NMBA**	Neuromuscular Blocking Agent
CPR	Cardiopulmonary resuscitation	**NOTSS**	Non-Technical Skills for Surgeons
CRM	Crew Resource Management	**NTS**	Non-technical Skills
DBP	Diastolic Blood Pressure	**OR**	Operating Room
DI	Difficult Intubation	**PHEMS**	Prehospital Emergency Medical System
ED	Emergency Department	**PHETI**	Prehospital Endotracheal Intubation
EKG	Electrocardiogram	**RSI**	Rapid Sequence Intubation
EMS	Emergency Medical System	**SAD**	Supraglottic Airway Device
$ETCO_2$	End-tidal CO_2	**SBP**	Systolic blood pressure
ETI	Endotracheal Intubation	**SD**	Standard deviation
ETT	Endotracheal Tube	**SEM**	Sistema d'Emergències Mèdiques
FONA	Front-Of-Neck Airway	**SOP**	Standard Operating Procedure
FPS	First-Pass Intubation Success	**SPLINTS**	Scrub Practitioners' List of Intraoperative Non-Technical Skills
GRANMO	Calculadora de Grandària Mostral	**SpO_2**	Percentage of Oxygen Saturation
HJT	Hospital Universitari Dr. Josep Trueta	**SPS**	Second Pass Success

SPSS	Statistical Package for Social Science	**UK**	United Kingdom
TPS	Third Pass Success	**VIR**	Rapid Intervention Vehicles
TS	Technical skills	**WMA**	World Medical Association
USVAi	Intermediate Advanced Vital Support Units	**y.o.**	Years old
USVAm	Medicalized Advanced Vital Support Units		

3. Introduction

3.1. Catalonia's prehospital Emergency Medical System

Catalonia's Emergency Medical System (EMS, or "SEM" as an abbreviation for the Catalan "*Sistema d'Emergències Mèdiques*") has mobile resources distributed throughout the Catalan territory, which is divided into 7 health regions. Catalonia disposes of non-physician-staffed ambulances: 253 Basic Vital Support Units (USVB) and 22 Intermediate Advanced Vital Support Units (USVAi), and physician-staffed vehicles: 31 Medicalized Advanced Vital Support Units (USVAm), 15 rapid intervention vehicles (VIRs) and 4 medicalized helicopters.[1]

If major traumatic injuries or severe medical conditions are suspected, a physician-staffed mobile resource is deployed. Under these life-threatening circumstances, one of core Technical Skills (TS) performed by the EMS team is the establishment of a definitive airway, accomplished by endotracheal intubation (ETI), prior to hospital arrival to provide optimal oxygenation and ventilation[2,3]. Since those patients are at risk of regurgitation and broncoaspiration Rapid Sequence Intubation (RSI) is the preferred method, inducing quick unconsciousness and neuromuscular paralysis and allowing intubation very rapidly[4-6].

As the ETI procedure will be performed in the prehospital setting it is also known as "Prehospital Endotracheal Intubation" (PHETI). In the same line, in this project the terms "EMS", "SEM" and "PHEMS", from Prehospital Emergency Medical System, will be used indistinctly.

The present study will be conducted intervening in the prehospital emergency teams who work in physician-staffed mobile resources by implementing a preprocedural RSI checklist. This intervention, in turn, will have an impact on the quality of the patient care provided during the RSI procedure.

3.2. Quality patient care: safety, errors and adverse events

The concept of quality patient care encompasses two main dimensions: (1) quality domains and (2) external factors, such as regulatory, legislative and economical activities. The first dimension refers to safety and is defined as the lack of accidental injuries or complications, the provision of updated health care and best practices and the individualization of patient care according to the needs of each patient[7].

An "error" can be described as an action not completed as planned, so the action is done wrongly (execution failure), or as the choice of an erroneous plan to achieve the intended aim, thus the action itself is wrong (planning failure). Execution failures include two basic error types: slips and lapses. Slips result from distraction and mostly appear with usual tasks, while lapses result from memory failure. The basic error of planning failure is the mistake[7,8]. If errors are not detected and corrected by healthcare providers, they can turn into adverse events.

An "adverse event" is a harm produced by medical care rather than by the pathologies or injuries affecting the patient[7,8]. In this project, the terms "adverse event", "complication" and "accident" will be used indistinctly.

People can be partly responsible of triggering critical situations, errors and accidents in two different ways. The first one, called active errors, are unsafe acts committed by the healthcare provider, which have immediate consequences (*i.e.* swapping drug ampules and administrating the wrong one). The second ones, called latent errors, are the result of decisions taken at managerial levels (*i.e.* choosing medical equipment, staff selection, *etc.*) which can take years until they have an impact on patient safety and are not exposed until an active error arises[8].

In 1990, James Reason proposed the most famous model of accident causation known as "The Swiss Cheese model" (*Figure 1*). He exposed that since system defensive barriers (organizational, environmental and personal) are intact only under ideal conditions, those weaknesses could be symbolized as the holes of swiss cheese slices. They arise from the combination of latent conditions at the organizational level, local triggering events (*i.e.* a healthcare professional "having a bad day", equipment sudden failure, etc.) and failures in the defenses-in-depth (active errors), which are physician's (and team's) technical and non-technical skills (NTS), lastly causing accidents[9]. The holes are continually fluctuating, opening, closing and shifting positions, and when they temporally line up, a path for the accident opportunity is created and all it needs is an active failure to unfold an accident[8,9].

Errors in healthcare are a main cause of preventable complications and death, so, identifying them and developing strategies to avoid them is of great importance to improve patient safety[7].

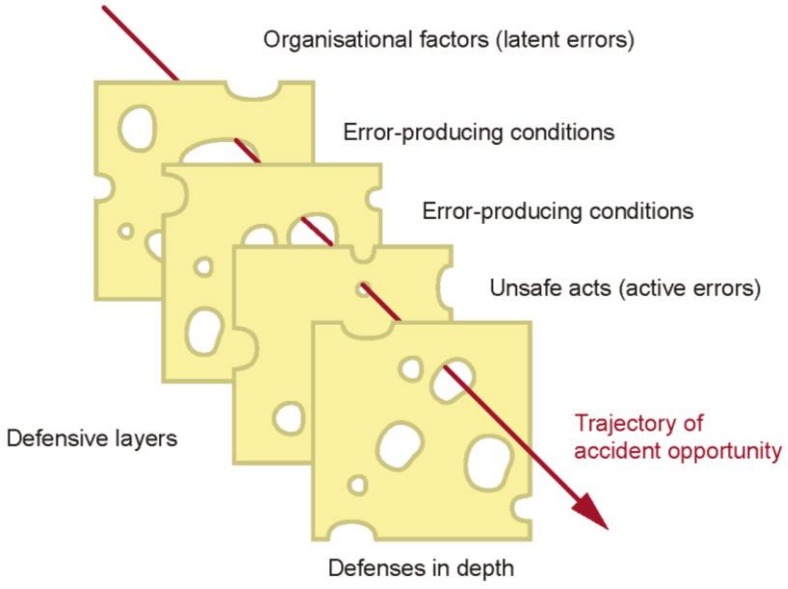


Figure 1.The dynamics of accident causation. Interaction between latent errors, local triggering conditions and active errors to create accidents. Inspired from James Reason 2000.

3.3. Prehospital Emergency airway management

During an emergency, the airway is always the number one priority[10]. Emergency airway management is performed in critically ill or severe injured patients to ensure airway permeability and an adequate ventilation.

As some airway management complications are apnea time-dependent, such as hypoxemia and death, the team needs to be prepared to act quickly if difficulties are encountered during the procedure so the time in which the patient is not oxygenated is as short as possible[11,12]. Thus, the team will undertake a preintubation briefing to ensure each member has a clear role assigned and a shared strategy to follow if intubation fails (plan A, plan B/C, plan D) (*Figure 2*). Also, this "preparation time" can be used to prepare the equipment and medication, to preoxygenate the patient and to look for difficult airway signs[13].

The plan A is the main strategy and aims the performance of ETI, which is the placement a cuffed tube in the trachea to ensure airway permeability and to protect it from broncoaspiration[14]. In the prehospital setting it must be assumed that all patients have a "full" stomach, thus facemask ventilation isn't initially indicated because it entails high risk of regurgitation and aspiration of gastric contents[15]. To skip the ventilation step, RSI is the method of choice because it minimizes the time between the loss of protective airway reflexes and ETI, so hypoxemia is less likely to occur[6]. RSI indications are wide (*Annex 1*) but can be comprehended into six categories: actual or impending airway failure, ventilatory failure, unconsciousness, humanitarian indications, unmanageable or severely agitated patients after a head injury and anticipated clinical course[16].

RSI facilitates ETI by providing: (a) analgesia, usually achieved using an opioid called fentanyl as the procedure is highly painful, and avoidance of vagal reflexes produced by the laryngoscopy and the intubation itself, which can trigger hypotension and bradycardia and can be avoided by the administration of atropine, (b) unconsciousness, achieved by the administration of a sedative-hypnotic drug in an induction dosage, which is followed almost immediately by (c) neuromuscular paralysis achieved by the administration of a quick-onset neuromuscular blocking agent (NMBA). NMBAs improve intubation conditions by abolishing the tone of the upper airway's and chest's musculature and, by that, the number of intubation attempts is reduced[4,13].

The choice of the induction drug is conditioned by the hemodynamic situation of the patient, being the most used ones Propofol or Midazolam in hemodynamical stability and Etomidate or Ketamine in hemodynamical instability[17]. The most used NMBAs in RSI are Succinylcholine, which is the only depolarizing NMBA that exists, and Rocuronium, a non-depolarizing neuromuscular blocking agent[13].

After RSI induction, the literature suggests the application of the BURP technique (Backward, Upward, Rightward Pressure to the thyroid cartilage) which is an external manipulation of the larynx that improves the visualization of the vocal cords during direct laryngoscopy[14]. To perform PHETI, the endotracheal tube (ETT) must go through these structures to reach the trachea and then, the proper

placement of the ETT needs to be verified through visual confirmation of the tube passing through the vocal chords during the laryngoscopy, auscultation of the chest (bilateral and symmetric breath sounds) and the epigastrium (absence of air sounds), and observation of a continuous waveform of end-tidal CO_2 ($ETCO_2$) in the Capnography [a,18].

Nevertheless, emergency airway management of critical patients is more likely to entail a difficult laryngoscopy, which is associated with repeated intubation attempts and an increased adverse event rate. Thus, any repeated attempt must incorporate improvements (*i.e.* optimizing patient's position, checking if the neuromuscular paralysis is adequate, changing laryngoscope's blade size, using a bougie or a stylet, suction removal of regurgitated gastric contents, *etc*.). Intubation attempts are restricted to three and then "failed intubation" is defined, thus the team should move to Plan B/C to avoid creating further airway trauma and additional complications[13,14]. Performing all the attempts is not mandatory, so if all improvements have been unsuccessfully addressed in less than three attempts no additional tries are indicated[13].

Failed intubation is more prone to produce complications, among which hypoxemia stands out. The aim of plans B and C is to maintain the oxygenation of the patient, and this can be achieved by using a Supraglottic Airway Device (SAD) (Plan B), or by facemask ventilation (Plan C)[14]. A lot of SADs exist, but the preferred one in the prehospital setting is the Laryngeal Mask Airway Fastrach (LMA®Fastrach™), because it allows ventilation and the placement of an ETT through it, so the patient can be intubated and protected from broncoaspiration. Facemask ventilation is performed between SAD insertion attempts (if percentage of oxygen saturation -SpO_2-decreases), which are also limited to three and require improvements before each one to optimize Fastrach insertion, such as ensuring that the patient remains properly anesthetized and checking if the size, inflation pressure and position of the SAD are suitable for the patient[13].

If plans A, B and C fail to establish effective ventilation, a "Can't Intubate, Can't Oxygenate" (CICO) situation is defined. This rarely occurs, having an incidence of 0.3%[20], but it entails high morbimortality so the team needs to be prepared to move quickly to Plan D, which involves the creation of a surgical or percutaneous infraglottic passage by which oxygen can be delivered, called front of neck airway (FONA), otherwise hypoxic brain damage and death will rapidly occur[14].

Given the infrequence of the CICO situation, training this TS may not be perceived as a priority thus when this circumstance unfolds, a fixation error is more likely to occur, causing the physician to become stuck in the previous plans and increasing the intubation or SAD insertion attempts and, therefore, the potentially mortal complication rate[21]. So, CICO generally arises from non-technical errors such an underestimated prediction, and judgmental and planning errors committed during the establishment of airway management strategies[22].

[a] Capnography measures carbon dioxide (CO_2) partial pressure non-invasively during the breathing cycle and provides information about ventilation, perfusion and metabolism. The presence of a waveform capnography is used to confirm the proper location of the ETT during the intubation procedure[19].

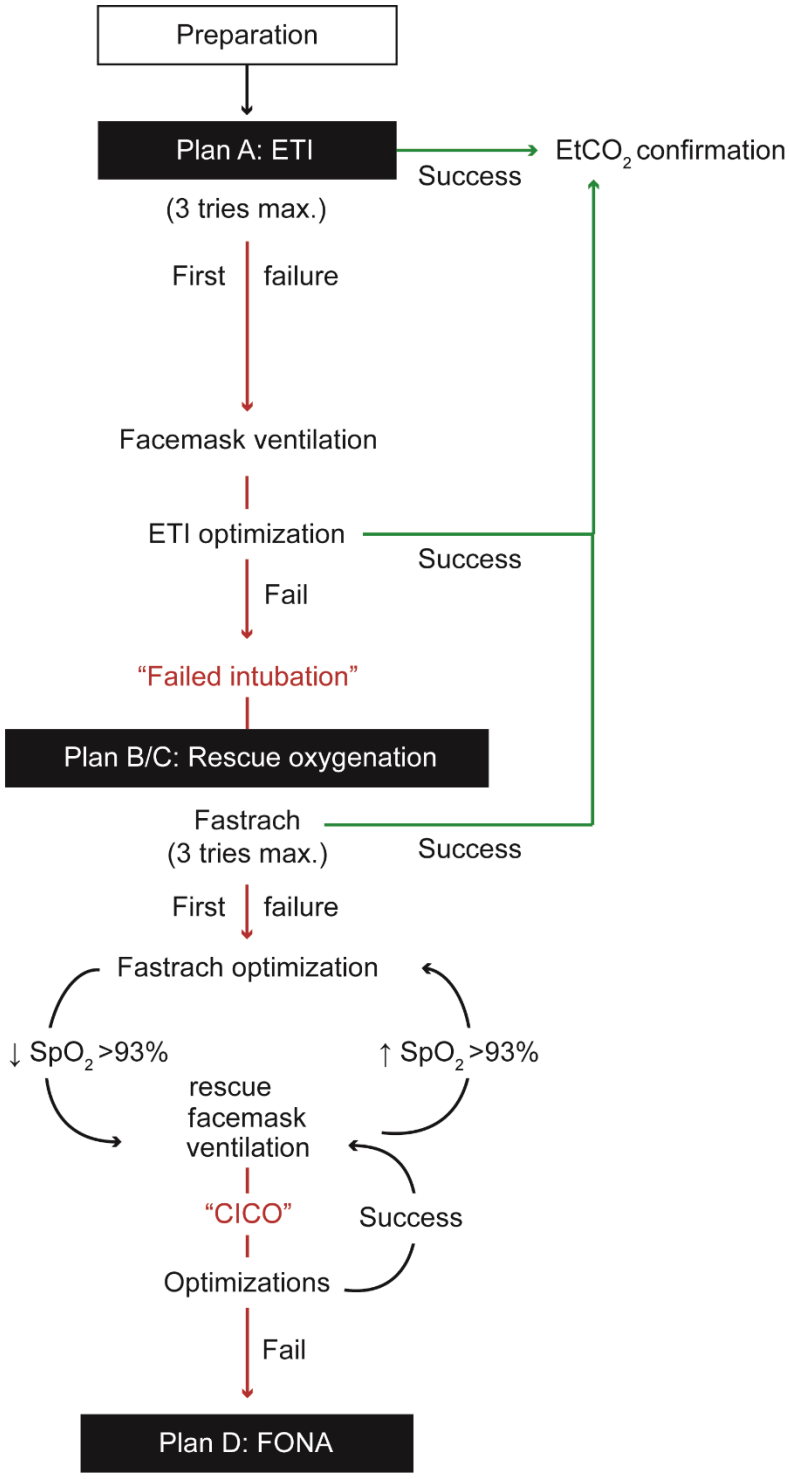


Figure 2. Algorithm of emergency airway management strategies. FONA: Front-Of-Neck-Airway.

3.4. Endotracheal intubation-related adverse events in the PHEMS

3.4.1. Technical endotracheal intubation-related complications

Airway management is mostly performed electively by anesthesiologists in the Operating Room (OR), where the technique is conducted under a controlled environment. However, it is often required in other clinical settings, such as in the Intensive Care Unit (ICU), the Emergency Department (ED) and the Prehospital Setting[23].

In the prehospital setting, the gold standard procedure used to ensure airway permeability and adequate ventilation is RSI[24,25]. Evidence has shown that the environment where airway management takes place is relevant[26] since ETI outside the OR entails a higher "difficult airway" incidence, increasing morbidity and mortality[27,28].

As the American Society of Anesthesiologists (ASA) reports in their Practice Guidelines, "difficult airway" is a complex concept, for which several definitions exist. The most used one is provided by the ASA, being "the clinical situation where a conventionally trained anesthesiologist experiences difficulty during the facemask ventilation of the upper airway, difficulty with ETI, or both"[29]. This situation can be explained by the interaction between patient biophysics, the clinical setting where the ETI takes place and the experience of the physician who performs the procedure[29]. Since anesthesiologists are usually not present outside the OR, the previous definition can't be strictly applied for all the clinical settings and needs to be adapted. Thus, in the prehospital setting a difficult airway exists when the PHEMS physician experiences difficulty to provide adequate ventilation, to accomplish ETI or when intubation fails, so an alternative airway device is required (SAD or FONA).

On the other hand, difficult intubation was defined in 1984 by Cormack and Lehane as "poor glottic visualization during direct laryngoscopy, or high-grade laryngeal view with no ability to see the vocal cords or the glottic aperture". Also, they proposed a 4-grade classification to quantify the glottic visualization during the laryngoscopy (

Annex **2**), in which grades III and IV allow poor visualization of the laryngeal inlet and are related to difficult intubation[30].

Difficult airway and difficult intubation (DI) are closely related concepts (*Figure 3*), and neither of them have a standardized definition. However, a definition is not as important as the determination of difficult airway predictors, which entail significant pragmatic relevance. It is important to early recognize patients at risk of DI because alternative techniques or airway rescue tools can be anticipated to increase the chance of first-pass success intubation (FPS)[3,28].

Prehospital DI incidence is reported to be between 7.4%[31] and 13%[25,28]. This data shows that DI is more frequent in the prehospital setting than in the OR, where it has a 5.8% incidence[32]. This can be explained by the unexpected difficulties encountered when ETI is performed out of the hospital, such as challenging and austere environments, suboptimal operator positions that hinder the technique, unfamiliarity with the patient and limited time for the assessment[32].

According to the existing literature, the more consensual predisposing factors for DI in the prehospital setting include (1) limited space on the scene and position of the operator (greater difficulty is experienced in the prone position)[25,31], (2) anatomical difficult airway signs such as (a) short neck, defined as a mental-hyoid distance of less than three fingers[25,28,31], and (b) airway obstructions, such as the presence of facial/neck trauma, history of ear/nose/throat disease or laryngeal edema[25,28,31,33]. The Cormack score is not a predictive factor of DI, because it is unknown before initiating the laryngoscopy[28]. Other studies found that the operator status (resident), anatomic abnormalities such as hypognathia, mouth opening below 3 cm and obesity >30 body mass index (BMI) were also DI predisposing factors, even so some of them remain highly controversial[34]. Thus, the prehospital setting itself encompasses enough difficulties apart from patient biophysics to "transform" anatomically non-difficult airways into difficult airways more often than in other environments.

Difficult airways lead more frequently to failed intubation attempts and traumatic ETIs than non-difficult airways. Data regarding PHETI remains limited, even though it is a usual procedure which have been performed for many years by Emergency Medical Systems from all over the world[35]. Few studies had assessed the prehospital FPS rate, such as Rognås *et al*. in 2013, who demonstrated that 85.8% of all patients were intubated within the first attempt when RSI was performed[36], and later, other studies showed to be consistent with this data[2].

As Thomas C. Mort *et al.* evidenced in 2004, failed intubation attempts, in turn, cause a significant increase of airway-related complications. He conducted a 119-month period observational study to determine whether the number of laryngoscopic attempts could be associated with an increased airway and hemodynamic complication incidence and concluded that it strikingly increases between two and ≥ three intubation attempts. The study compared the complications found in patients who underwent ≤2 laryngoscopic attempts and the ones that had >2 attempts, and evidenced the following adverse events: (1) hypoxemia (10.5% *vs* 70%), (2) severe hypoxemia (1.9% *vs* 28%) (3) esophageal intubation (4.8% *vs* 51.4%) (4) regurgitation of gastric contents (1.9% *vs* 22%), (5) aspiration of gastric contents (0.8% *vs* 13%), (6) bradycardia (1.6% *vs* 18.5%), and (7) cardiac arrest (0.7% *vs*

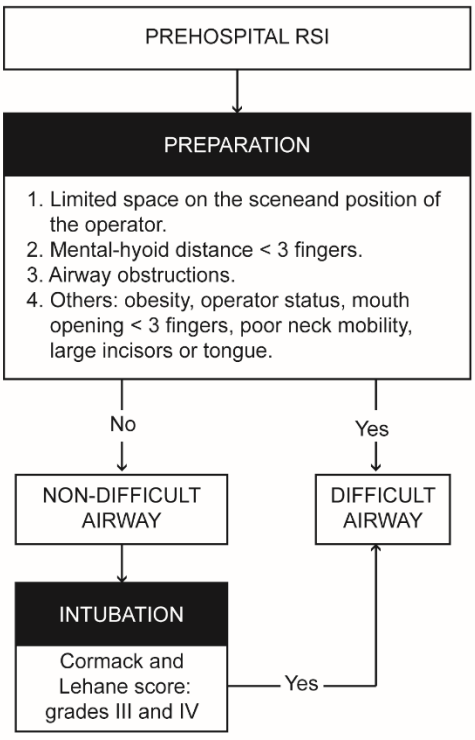


Figure 3. Algorithm constructed by the high-risk variables in predicting difficult intubation[37]. Adapted from Soyuncu *et al*. 2009

11%)[38,23], as represented in *Figure 4*. However, the incidence of tachycardia, hypotension and hypertension showed no relation with the number of intubation attempts performed[38].

Even though the laryngoscopic attempts are currently limited to three by recommendation of the ASA[14] the actual literature shows benefits of diminishing those attempts to two[38].

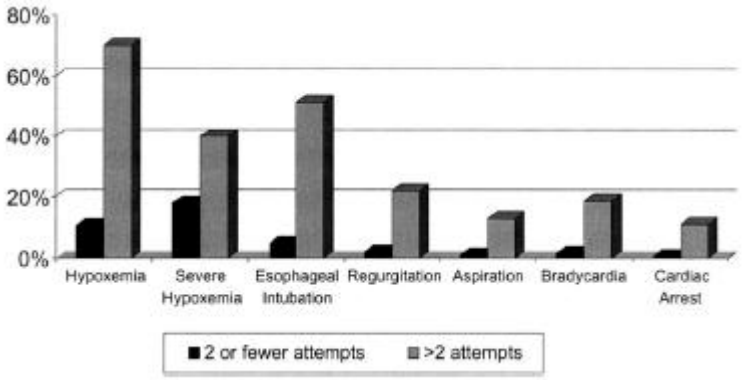


Figure 4. Graphic display of complications by intubation attempts. From Mort *et al*. 2004.

The global PHETI complication rate varies from 16%[28] to 30%[39] being esophageal intubation, hypoxemia, severe hypoxemia and hypotension the most frequently encountered. In addition to the ones mentioned above, other complications include hypertension[38,39] and hypertensive crisis, dysrhythmia[27,40], glottic edema, cuff leak[40], dental and lip injury[32,40], laryngospasm[39,40] and cardiac arrest[27,40]. Some of these complications can be triggered or perpetuated by the administration of the RSI drugs[5], as shown in *Table 1*.

In 2011, Cook *et al*. performed a study of the complications of airway management in the United Kingdom (UK) and revealed that hypoxemia was the adverse event which more frequently leaded to death. In those cases, a deficient airway management occurred[23].

Table 1. Potential side effects of the RSI drug administration.

Drug	**Potential side effect**
Premedication	
Fentanyl	Respiratory depression.
Atropine	Tachycardia.
Induction agents	
Propofol	Hypotension and bradycardia.
Ketamine	Tachycardia, hypertension, increase in cardiac output and in ICP.
Midazolam	Hypotension.
Etomidate	Increases ICP which, if maintained, can cause arrythmias or hypertensive peaks.
Neuromuscular blocking agents	
Succinylcholine	Tachycardia due to malignant hyperthermia and increased risk of arrythmias due to hyperkalemia and increases ICP.

RSI: rapid sequence intubation; ICP: intracranial pressure.

As the number of intubation attempts has a strong association with ETI adverse event rates, it can therefore be used as a marker of proficiency. Currently, the aim to improve emergency airway techniques is focused on increasing the FPS rates and consequently lowering the complications associated to the procedure[19].

3.4.2. Non-technical complications: The Human Factor approach

As stated above, some technical critical situations may occur during emergency airway management, which can develop ETI-related complications. Although active errors produced by TS are the easiest to detect, another type of underestimated skills can greatly condition patient safety: human factors.

Human factors are also known as "Non-Technical Skills" (NTS) as they don't arise from technical abilities. NTS refer to the way people feel, think, analyze reality and interact with each other and with their environment[7,8]. This term was initially used by the commercial Aviation industry, which, in the early 1980s was among the first ones to recognize that technical expertise was not enough to ensure a safe flight, so other skills were needed. Aviation reacted by introducing Crew Resource Management (CRM) training, which reinforces the performance of NTS[41-43]. Later on, it was transferred to other domains such as healthcare, showing a way to translate medical knowledge and skills into effective teamwork under demanding environments of stress, as emergency situations[44].

As Rall *et al.* exposes in the book *Miller's Anesthesia*, 70% of errors in medical care are related to human factors[44]. Furthermore, Cook *et al.* performed a study in 2011 which showed that human factors contributed to precipitate adverse events in more than 40% of the cases[23]. Those factors can condition patient safety through all different levels of the Healthcare System: as an individual, as a team member and at organizational level[8,14]. (1) Individually, cognitive skills are needed to maintain situation awareness, optimal information management, decision-making and task management[8,14,45]. (2) The role of the airway team is highly significant, thus social and behavioral skills that allow communication, teamwork and taking a leadership role are required to reach a shared mental model during airway management, so the whole team acts in coordination[13,42]. Weak NTS and stressful situations, such as unfolding emergencies, can affect internal team dynamics and generate active errors. (3) Organizations represent the subsystems of the healthcare system, such as hospitals or producers, which are independently managed and can have an impact on quality care and safety by generating latent errors[8].

NTS can be trained and learned through CRM techniques[41-43,46,47]. As Rall *et al.* describes, "CRM techniques encompass: (1) individual factors and skills, such as level of training and education, (2) team abilities such as communication and teamwork and (3) systemic aspects regarding to establishment of a safety culture." As a part of this safety culture, the use of checklists is recommended and is an essential part of CRM[44]. The healthcare settings where this training becomes more relevant are high-stake medical fields such as Emergency medicine, Surgery and Anesthesia. In those environments effective teamwork and communication are of critical importance, nevertheless those

have been neglected and training have been lacking, even though their failure has proved to be an important cause of patient harm[23,43]. CRM training includes practicing through clinical cases and patient simulators under the supervision of an experienced instructor, who provides structured feedback that help handling those critical situations and applying the learned skills in the daily clinical practice[42,44,47].

NTS can be adapted for specific settings and can also be evaluated in some clinical fields through behavior-rating systems. Some examples are Non-Technical Skills for Surgeons (NOTSS)[48], Anesthetists' Non-Technical Skills (ANTS)[41,49] and Scrub Practitioners' List of Intraoperative-NTS (SPLINTS)[42], but no specific behavioral markers exist for PHEMS.

As mentioned, both TS and NTS are of great importance to guarantee patient safety during acute medical care and to ensure a competent management under critical situations. Some studies have inquired whether NTS could influence the technical performance, or *vice versa*. The existing studies took place in both the OR[46,50,51] and in the simulation room[52] and showed that a correlation does exist between them[42,50,51]. Some of these studies concluded that after an intervention to enhance NTS, technical outcomes also improved[46] while other literature reported that expertise in TS could lead to more competent NTS[52].

The prehospital environment entails working continuously under high levels of stress and fatigue, and it has been demonstrated that those circumstances negatively affect cognitive function[53]. Also, during a critical situation an information excess may occur, producing memory lapses and compromising decision-making and internal team dynamics even further[14] thus, simplifying and standardizing procedures through the implementation of cognitive aids is a way to improve optimal judgment and decision-making, compliance with standard procedures and by that, reduce the circumstances that lead to errors[7,54].

3.5. Checklist use to improve patient safety

Emergency RSI is a complex procedure in which unintentional but avoidable patient harm may occur. As mentioned, if unexpected circumstances occur during the procedure, elapsed time and successful patient outcomes are closely related[11,12]. Those potential time-critical events include delays caused by unavailable or unfunctional equipment, practitioner inexperience, inadequate or lack of planning and other NTS deficiencies, such as situation awareness or team communication[11,12,55,56].

Guidelines and protocols have been developed for some prehospital emergency situations, but its compliance entails more difficulties due to personnel's adherence to personal preferences. The quality of care provided in the prehospital setting should meet in-hospital quality standards[57]. So, in order to promote good and updated clinical practice, other quality assurance tools such as standard operating procedures (SOPs[b])[58] and checklists, have been developed[59].

b SOPs are "specific set of practices that are required to be initiated and followed when specific circumstances arise"[58].

A checklist is a structured tool that provides a reminder of the most critical steps or criteria for a specific complex technique[60], thus it is used as a cognitive aid to standardize a procedure and reduce errors of omission, errors caused by outdated information and inconsistent procedures[12,56] by verifying the critical tasks of the procedure under mutual supervision, simplifying task completion and making it more effective[61]. They can entail two clinical risks: causing delays in patient care and the so called "Checklist fatigue"[c,60], which can be both avoided by using a brief and concise checklist design[60].

Other High reliability organizations[d] (HROs)[62], such as aviation industry or the military, have been using checklists for a long time because those have proved to decrease human error under the stressful situations that those environments entail[12,56].

Checklists have also been successfully implemented in healthcare to enhance care processes, particularly in highly demanding medical fields such as Prehospital[63-66] and Emergency medicine[3,23,67], Surgery[68,69], ICU[70,71] and Anesthesia[11,12,72]. They have proved benefits with their application[56,57,71,73], as Haynes *et al*. showed in 2009, a pre-operative surgical checklist reduced mortality up to 40%[68].

Regarding to the intubation procedure, Cook *et al*. performed a study in 2011 establishing that the ICU and the ED had more ETI-related complications compared with anesthetic practice. The authors proposed improvement recommendations, among which the use of a preprocedural intubation checklist was suggested[23]. Five years later, they evaluated the impact of their recommendations by analyzing the reduction of the "safety gap" between the ideal and the existing practice and showed that the largest persisting gap in the ED was the use of the intubation checklist, which was never used by 55% of the physicians, although they were aware of its importance[74]. Those studies highlight the usefulness and importance of using an intubation checklist and recommend its development and application. In the same line, other authors also claim for the need to improve patient safety during airway management and endorse the use of checklists in all emergency intubations[13,19,23,75].

The Association of Anaesthetists of Great Britain and Ireland (AAGBI) recommend the use of checklists to support the prehospital RSI procedure[60] as a method of error and safety management[59]. A properly designed RSI checklist should include critical task reminders that are frequently neglected under stressful conditions, such as equipment availability, monitoring and RSI drugs required in order to compensate for inherent limitations of human memory and alertness[59,60]. Furthermore, they improve team dynamics and the sense of confidence that the procedure is carried out meticulously, allowing the team to keep situation awareness and, consequently, promote quality care[55,56,72,76].

RSI cognitive aids have been developed mostly for in-hospital procedures[3,13,23,55,67,77] but also some checklists[60,61] and SOPs[16,78-80] are used in the prehospital setting. Prehospital RSI checklist use is mandatory in other countries, such as the UK, where between 2009 and 2014 their use has risen

c "Checklist fatigue" happens with exhaustive designs, causing the practitioner to skip critical steps to conclude the checklist sooner[60].

d HROs are organizations in which accidents rarely occur despite having an environment where accidents can be expected due to risk factors and complexity. *i.e.* nuclear power plants, military, commercial aviation and wildland firefighting[62].

from 65% to 83%[60] and required to achieve standards for best practice[57]. Although its application is extended in other PHEMS, the literature revision performed has not been able to find prehospital studies that assess and quantify its impact.

In March of 2016 the PHEMS crew of Girona's Medicalized Helicopter reviewed the existing literature[23,39,55,74,77] and the practice guidelines[24] referring to the development and application of RSI checklists. Then, they developed one (*Annex 3*) adapted to Catalonia's local prehospital setting's resources, which contains 33 safety items grouped in four sections: team, patient, material and lastly plan and execution. This checklist was designed to be performed prior to induction, in a "challenge-confirm" or "read-confirm" format to verify the already completed tasks.

Onaga *et al.* performed a study carried out in Girona's Medicalized Helicopter to assess whether the application of the mentioned RSI checklist was useful to standardize the procedure and if it could improve the adherence to the airway management recommendations (*Annex 4*). It revealed that the perception of adherence to airway management recommendations was low in the prechecklist period, as well as the perception of safety and preparation standards. The study concluded that the checklist application was useful to decrease the general variability of the procedure and to improve compliance of airway management recommendations and safety and preparation standards. The most outstanding improvement was in the area of human factors, NTS and the maintenance of procedural standards.

Also, it concluded that further studies were necessary to determine the impact of the checklist application in the occurrence of RSI complications.

4. Study justification

The establishment of a definitive airway prior to hospital arrival may be required in critically ill or injured patients, being RSI the indicated procedure in most of these circumstances. It is estimated that Catalonia's SEM perform the RSI procedure approximately 517 times per year, probably more since it has been estimated conservatively.

Airway management in the prehospital setting shows differences from hospital environments, not only because of the stressful characteristics of the scene that easily entails slips, the multiple distractions that produce memory lapses, time restriction and challenging patient positions, but also because it requires specialized technical and non-technical skills such as rapid conflict resolution and seamless team coordination to perform a successful intubation.

For these reasons, out-of-the-hospital airways involve more intubation difficulty[25] and lead more frequently to the performance of multiple ETI attempts, increasing complications considerably with every failed attempt[38,39]. Thus, prehospital airway management is more susceptible to decrease patient safety and to cause greater morbidity and mortality.

Checklist use during the RSI procedure is strongly advised[23] and even mandatory in some countries[60], but in Catalonia's prehospital setting this procedure is currently not standardized and

performed without any cognitive aid, entailing a high interpersonal variability due to personal preferences rather than adherence to evidence-based guidelines and recommendations. Thus, a safety culture should be strengthened to reach higher levels of quality and safety; this can be achieved by the implementation of checklists, SOPs and CRM techniques[63].

A preprocedural RSI checklist was developed in 2016 by the medicalized helicopter crew from Girona and has been used by this unit since then. It proved to decrease the general variability of the procedure and to improve compliance of airway management recommendations and safety and preparation standards, but its impact on the RSI complication rate has never been assessed. No studies comparing the complications before and after the application of a RSI checklist for the prehospital setting could be found in the literature. Therefore, the aim of this project is to evaluate its impact in decreasing the incidence of adverse events during RSI in Catalonia's prehospital environment.

In addition, the present study will shed light to several non-assessed data from Catalonia's prehospital system. First, it will provide the incidence of the RSI procedure performed in Catalonia's prehospital setting, a data that is currently lacking due to the PHEMS collection data system, which doesn't include the mentioned element. Second, Catalonia's PHEMS global RSI complication rate have not yet been assessed, so this data will be addressed and evaluated according to number of intubation attempts. Third, this study will evaluate the global PHETI success rate when RSI is performed, and analyze the first, second and third pass intubation success (FPS, SPS and TPS, respectively). The FPS can be used as a marker of proficiency, reflecting the quality of the prehospital intubations, and be used as a benchmark for future improvements. Fourth, it will quantify the "failed intubation" situation, the use of SADs and the performance of the FONA procedure. Finally, this study will compare the pre- and postchecklist periods to assess for modifications in those parameters.

5. Hypothesis of the study

The application of a preprocedural RSI checklist can decrease the incidence of the major adverse events of the procedure in critically ill or injured patients of all ages in Catalonia's Prehospital Setting.

6. Study objectives

6.1. Main objective

The main objective of this study is to assess whether the application of the preprocedural RSI checklist decreases the incidence of major adverse events, defined as a composite variable, during the RSI procedure in critically ill or injured patients of all ages in Catalonia's prehospital setting.

6.2. Secondary objectives

1. Determine the incidence of the prehospital RSI procedure in Catalonia's prehospital setting.
2. Determine the FPS intubation rate in RSIs performed by PHEMS physicians before and after the application of the RSI checklist.

3. Assess the global immediate PHETI-complication incidence in Catalonia's prehospital setting.
4. Assess the RSI-complication rate within one, two and three or more intubation attempts.
5. Assess the incidence of failed intubation, SAD use and FONA procedure in Catalonia's PHEMS.
6. Evaluate if the RSI checklist implementation lowers the major RSI complication rate in all RSI indications.
7. Evaluate if the use of the RSI checklist lowers the major RSI complication rate in patients of all ages.
8. Evaluate the adherence to the RSI checklist among PHEMS physicians.
9. Assess if the checklist implementation delays the execution of the procedure.

7. Material and methods

7.1. Study design

This study is designed as a quasi-experimental study. It will be a before-and-after evaluation of an intervention to improve the quality of the RSI procedure in Catalonia's prehospital setting (*Figure 5*). This intervention is the application of a preprocedural RSI checklist, which will be implemented through formation and training under simulation.

7.2. Study setting

This study is designed to be multicenter. It will be established in the 49 physician-staffed vehicles of Catalonia's SEM which are capable of providing RSI.

7.3. Study population, inclusion and exclusion criteria

The study population will be composed by all patients intubated by a PHEMS physician-staffed unit using the RSI procedure in Catalonia's prehospital setting between May 2019 and March 2022, with the following inclusion and exclusion criteria (*Table 2*):

Table 2. inclusion and exclusion criteria of the study population.

Inclusion criteria
All patients who undergo rapid sequence intubation performed by an EMS physician in Catalonia's prehospital setting.
Exclusion criteria
1. Patients who will undergo RSI performed by physician-staffed resource whose team already has knowledge about the preprocedural RSI checklist, as they could act according to a cognitive aid they are already familiarized with. This mainly refers to Girona's medicalized helicopter crew. 2. Patients or relatives who don't give their consent to participate.

EMS: emergency medical system; PHETI: prehospital endotracheal intubation; RSI: rapid sequence intubation.

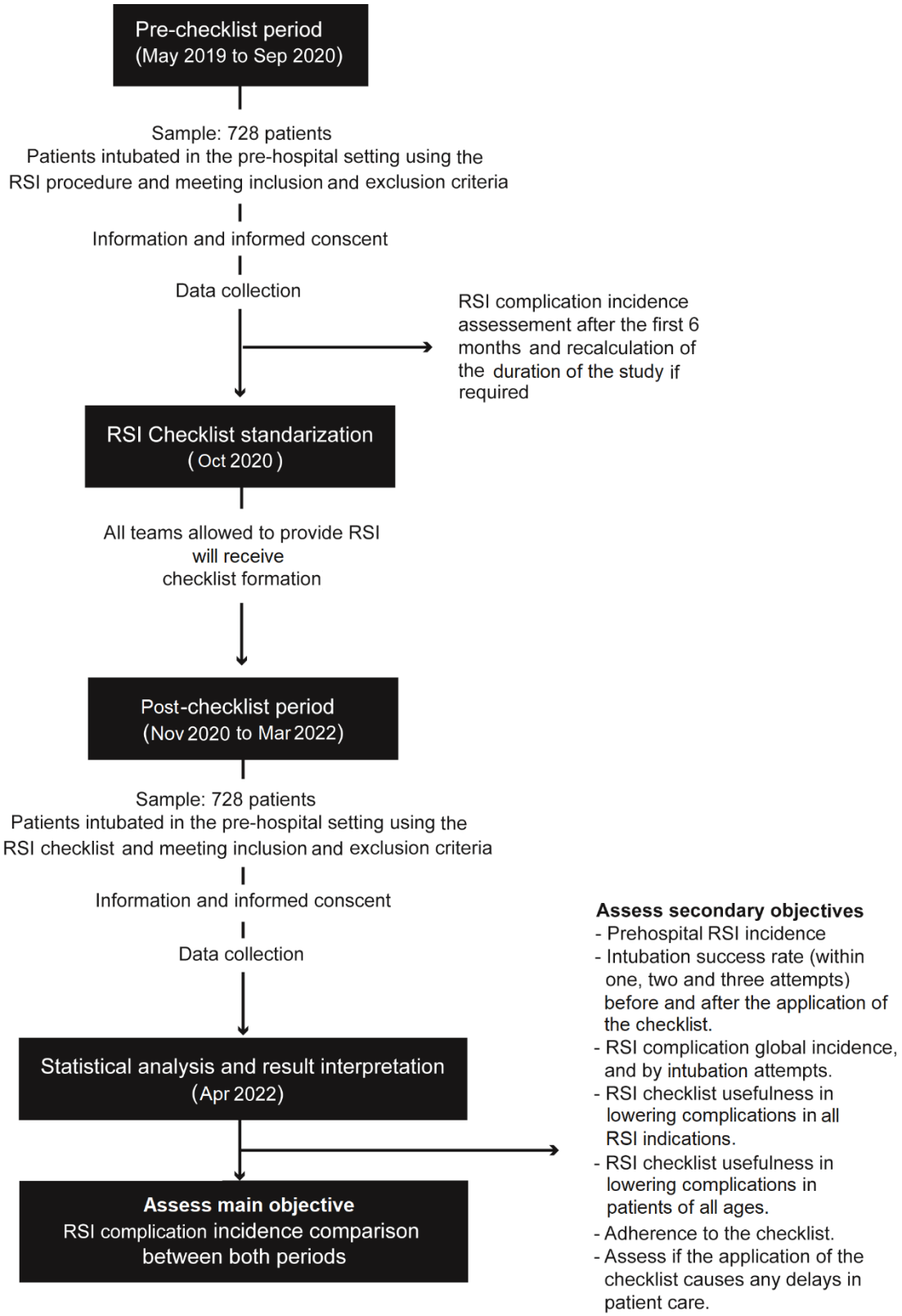


Figure 5. Algorithmic representation of the study.

7.4. Sample

7.4.1. Sample size

The online free application *Calculadora de Grandària Mostral* (GRANMO) was used to calculate the sample size[81].

In order to calculate the size of the sample, the prechecklist and postchecklist period PHETI-complication proportion is needed. For the first assessment, the existing study with the most similar complication variables is selected[39], showing a 30% complication rate. For the second assessment, the complication rate is not evaluated within the existing literature, as there are no existing studies that assess the variation of the complications when implementing a preprocedural RSI checklist in the prehospital setting, thus a 20% reduction of the complications in the postchecklist period, compared to the prechecklist period, will be foreseen.

Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, 728 subjects are necessary to recognize as statistically significant a difference consisting in an initial proportion of 0.3 and a final proportion of 0.24. Thus, 1,456 patients will be required to carry out this project, 728 patients will be recruited for each period (pre- and postchecklist). It has been anticipated a dropout rate of 10% because of the possibility of incomplete data collecting sheets or their misplacing.

As stated before, Catalonia's Emergency Medical System doesn't have a proper data collection system, so the prehospital intubation prevalence remains unknown. Only the data of intubations performed to polytraumatic patients are recorded. In 2017, which is the last year for which completed information is available, Catalonia's PHEMS performed airway management using the RSI procedure in a total of 346 polytraumatic patients. This is not completely representative of the frequency in which this procedure is carried out because some not registered medical conditions also require the RSI procedure, so the incidence of the technique is expected to be higher. To address this situation an estimation of the incidence of the RSI procedure have been made based on that the RSI in medical patients was the 50% of those performed in polytraumatic patients, resulting in 171 RSIs performed due to medical conditions and a total of 517 RSIs in Catalonia per year. In order to achieve more accuracy, this incidence will be assessed after the first 6 months of the study in order to confirm this conservative estimate and if it shows differences then the study duration will be recalculated. The recruitment period begins at summer (May 2019), which is a period of greater incidence of RSI because more traffic accidents occur. Thus, in order to avoid this already known seasonality, the RSI incidence will be assessed after 6 months from the beginning.

7.4.2. Sample selection

A non-probabilistic consecutive sampling method will be performed including the patients who will undergo PHETI in Catalonia's prehospital setting. Sample recruitment will take place during 34 months (17 months for each period) to reach the necessary sample size, which is 728 for each group (1,456 patients in total).

7.5. Variables and methods of measurement

All the variables of the study will be collected prospectively for 34 months (from May 2019 to March 2022) and are summarized in *Table 3*.

7.5.1. Independent variable

The independent variable is the application of a preprocedural checklist in the Rapid Sequence Intubation procedure.

7.5.2. Dependent variables

The dependent variable of the main objective is the development of adverse events during the RSI procedure, which is a composite variable. The encompassed adverse events of the main dependent variable are detailed and grouped by severity in *Table 4* and can be organized according to their causal mechanism in the following five groups:

1. Mechanical complications: recognized or inadvertent esophageal intubation and failures of the material used such as ETT cuff leak.
2. Airway trauma-related complications: glottic edema, dental or lip trauma.
3. Parasympathic, sympathetic and spinal reflexes-related complications: laryngospasm, regurgitation, apnea, bradycardia, hypotension, hypertension, bradyarrhythmia, tachyarrhythmia and cardiac arrest.
4. Induction drug-related complications: tachycardia with the administration of atropine, ketamine or succinylcholine (if malignant hyperthermia occurs), hypotension with the administration of propofol or midazolam, bradycardia with propofol use, hypertension with ketamine use and cardiac arrest mostly associated to arrythmias developed when succinylcholine-related hyperkalemia occurs and increased ICP with the use of etomidate.

   All drugs used for the induction have a very short onset of action (from 15-45 seconds for etomidate, ketamine and propofol and to 1-2 minutes for atropine and succinylcholine), and their adverse effects develop in the same way, rapidly. Thus, it will be assumed that a complication is triggered by the medication used if it occurs within 2 minutes of the induction.
5. Other RSI-related complications: hypoxemia and severe hypoxemia, which can occur secondary to an inadvertent esophageal intubation or secondary to delays from the RSI drug administration to the intubation, and broncoaspiration.

The complications of the RSI procedure unfold quickly, not just the induction drug-related ones, but also those that occur during laryngoscopy and intubation. Thus, an adverse event RSI-related will be defined as the one that develops from 2 minutes after the induction until the verification of the proper location of the ETT.

Table 3. Variables of the study and measure instruments

Variable	Type of data	Categories or values	Measure instrument
Patient basic demographic characteristics and general information			
Age	Continuous quantitative	Years	Patient's ID card or other documentation
Gender	Nominal qualitative	Male / female / unknown	Patient's ID card or other documentation
Anticipated difficult airway signs	Nominal dichotomous qualitative	Yes / no	Physical examination
RSI indication	Nominal qualitative	Airway failure, ventilatory failure, unconsciousness, humanitarian reasons, agitation, anticipated clinical course.	Operator's clinical decision
Time from RSI decision to drug administration	Continuous quantitative	Seconds	Video recording
Time from RSI decision to intubation success	Continuous quantitative	Seconds	Video recording
Endotracheal intubation procedure information			
Cormack score	Discrete quantitative	I / II / III / IV	Visualization during laryngoscopy
First-pass intubation success	Nominal dichotomous qualitative	Yes / no	Physical examination and capnograph
Number of intubation attempts	Discrete quantitative	Number of attempts	Operator reference and video recording
Intubation success	Nominal dichotomous qualitative	Yes / no	Visual confirmation, auscultation and capnograph
"Failed intubation"	Nominal dichotomous qualitative	Yes / no	Operator reference
SAD use	Nominal dichotomous qualitative	Yes / no	Operator's decision
FONA procedure	Nominal dichotomous qualitative	Yes / no	Operator's decision
Adherence to the checklist	Nominal dichotomous qualitative	Yes / no	Operator reference and video recording
ETI-related complications information			
Esophageal intubation	Nominal dichotomous qualitative	Yes / no	Capnograph
Regurgitation	Nominal dichotomous qualitative	Yes / no	Physical examination
Broncoaspiration	Nominal dichotomous qualitative	Yes / no	Physical examination
Laryngospasm	Nominal dichotomous qualitative	Yes / no	Physical examination
Glottic edema	Nominal dichotomous qualitative	Yes / no	Visualization during laryngoscopy
Oxygen saturation	Continuous quantitative	%	Pulse oximeter
Blood pressure	Continuous quantitative	mmHg	Automatic aneroid
Heart rate	Discrete quantitative	Beats per minute	Automatic aneroid
Arrhythmias	Nominal dichotomous qualitative	Yes / no	EKG
Cardiac arrest	Nominal dichotomous qualitative	Yes / no	EKG, central pulses palpation
Dental or lip injury	Nominal dichotomous qualitative	Yes / no	Physical examination
Cuff leak	Nominal dichotomous qualitative	Yes / no	Physical examination

EKG: electrocardiogram; ID: identification; PHETI: prehospital endotracheal intubation.

According to the composite variable, an individual will present a complication (minor or major) if at least one of the following occurs (*Table 4*):

Table 4. Main variables definition: PHETI-related complications

Minor complications	**Definition**
Immediately recognized esophageal intubation	Immediately recognized placement of the ETT in the esophagus requiring ETT removal and reintubation[40].
Regurgitation	Gastric contents requiring suction removal during laryngoscopy in a previously clear airway[38].
Hypoxemia	SpO_2 <93% but >80% during a laryngoscopic attempt[80]. In patients experiencing desaturation prior to ETI, ETI-related desaturation was considered when SpO_2 further decreased or failed to improve within the first 5 min following ETI[39].
Hypertension	SBP >160 mmHg if >20% increase from baseline[38].
Sinus tachycardia	HR >100 bpm if >20% increase from baseline[38].
Dental or lip trauma	Dental or lip trauma produced during the laryngoscopy[4].
Cuff leak	Air leak around the cuffed ETT, requiring replacement of the ETT[40].
Major complications	
Inadvertent esophageal intubation	Inadvertent placement of the ETT in the esophagus requiring removal and reintubation, defined by the lack of a capnography wave after the ETT placement[40].
Laryngospasm	Sudden adduction of the bronchial vocal cords, preventing passage of the ETT through the glottic inlet[40].
Glottic edema	Swelling of the soft tissues of the larynx, hindering ETI[13].
Broncoaspiration	Visualization newly regurgitated gastric contents below glottis or suction removal of contents through the ETT[38].
Severe hypoxemia	SpO_2 <80% during a laryngoscopic attempt[38].
Hypotension	SBP <90 mmHg (MAP <60 mmHg) if >20% decrease from baseline. If hypotension was present before RSI (SBP <90 mmHg and MAP <60 mmHg), any post-ETI reduction was attributed to the procedure. If vasoactive drugs were used before the administration of the induction drugs to maintain the hemodynamic stability of the patient, any further needs of vasoactive drugs were considered as hypotension[38].
Hypertensive crisis	SBP >180 mmHg and/or a DBP >120 mmHg[82].
Bradyarrhythmia	HR <60 bpm if >20% decrease from baseline or presence of conduction blocks during intubation[83]
Tachyarrhythmia	Abnormal heart rhythms with a HR ≥ 100 bpm[40].
Cardiac arrest	Asystole, pulseless electric activity or dysrhythmia with non-measurable MAP[4].

SpO_2: percentage of oxygen saturation; ETT: endotracheal tube; SBP: systolic blood pressure; mmHg: millimeter of mercury; DBP: diastolic blood pressure; bpm: beats per minute; MAP: mean arterial blood pressure; ETI: endotracheal intubation; HR: heart rate; CPR: cardiopulmonary resuscitation.

The variables hypoxemia, severe hypoxemia, hypotension, hypertension, bradycardia and tachycardia will be collected as quantitative variables (measuring oxygen saturation, blood pressure and heart rate), as stated in *Table 3* but then they will be categorized as qualitative (yes / no) variables and then will be expressed as rates for the interpretation of the results.

The dependent variables of the secondary objectives include the following:

1. FPS intubation: measured as the verification of the ETT placement by physical examination and the observation of a continuous waveform end-tidal CO_2 in the capnography at first intubation attempt[18]. It will be expressed as a proportion.
2. Intubation success: measured by visual confirmation, auscultation and by the observation of a continuous waveform end-tidal CO_2 in the capnography[18], achieved in any attempt. It will be expressed as a proportion.
3. Adherence to the RSI checklist: measured as the frequency in which each PHEMS team follows the checklist to perform the intubation procedure. It will be expressed as a proportion.
4. Elapsed time between the decision to intubate and the administration of the RSI drugs (seconds).
5. Elapsed time between the decision to intubate and the verification of the proper location of the ETT (seconds).
6. Failed intubation: described as the impossibility to intubate in 3 attempts (or less if all improvements had been unsuccessfully assessed). It will be expressed as a proportion.
7. Supraglottic airway device use (Fastrach). It will be expressed as a proportion.
8. FONA procedure performed. It will be expressed as a proportion.

7.5.3. Covariables

1. Age of the patient: measured as a continuous quantitative variable and then will be grouped into age clusters, so it will finally become a discrete variable, defined as follows: (a) Young population: infants <5 years old (y.o.), children up to 14 y.o., adolescents up to 19 y.o., (b) Adult population: young adults up to 39 y.o., intermediate adults up to 49 y.o. and mature adults up to 59 y.o., and (c) Elderly population: early or primary stage between 60 and 69 y.o., intermediate phase from 70 to 84 y.o. and advanced phase ≥85 y.o.
2. Gender: male, female or unknown.
3. Indication to perform RSI: actual or impending airway failure, ventilatory failure, unconsciousness, humanitarian indications, unmanageable or severely agitated patients after a head injury and anticipated clinical course.
4. Number of intubation attempts: is an intermediate variable of the complications of the procedure, increasing their incidence as the number of attempts increase.

   A laryngoscopic attempt is described as the insertion of the laryngoscope into the oral cavity[14] and an intubation attempt occurs after the performance of the laryngoscopy, when the operator attempts to pass the ETT through the vocal chords. Both procedures entail submitting the patient to an equal time of apnea, manipulation of his/her anatomy and exposure to vasovagal reflexes, so in the methodological part of this project a "laryngoscopy attempt" and an "intubation attempt" be labelled under the variable "intubation attempts".

5. Anticipated difficult airway signs: limited space on the scene, prone position of the operator, short neck or airway obstructions, as described before and as represented in *Figure 3*.
6. Cormack score: laryngeal inlet view during laryngoscopy (grade I, II, III or IV), as defined in
7. *Annex* **2**.

7.6. Data collection methods

All data will be collected prospectively during the 34 months of the patient recruitment using two data collection methods (*Table 5*): data collection sheets (*Annex 5*) and high-definition video recording, recorded by all Catalonia's SEM physicians using a sports camera.

Before joining the study, all patients will receive information about its aims (*Annex 6*) and then the physician will ask them to participate in it, highlighting the confidentiality and the voluntary aspect to join. Then, they will be asked to sign the informed consent (*Annex 7*) to be included and video-recorded. As the patient will not be able to give his consent before the data collection due to the severity of his/her condition, the consent will be required to first-degree relatives if they are present. If not, patient's data will be collected and the consent will be requested afterwards. If the patient is under-aged, remains unconscious or inevitably dies, then the informed consent will be required to his/her first-degree relatives.

Also, for the purpose of this study all emergency personnel attending these medical situations will be asked to sign a voluntary informed consent to be video-recorded (*Annex 8*). If the intubation is performed in another clinical setting such as in a primary care medical center, all the not-required staff will be asked to leave the patient's bedside and if it's not possible they will be asked to voluntary sign the informed consent to be video-recorded.

The informed consents and study information sheets will be available in Catalan, Spanish and English but only their Catalan version is annexed.

7.6.1. Prechecklist period data collection

During the 17 months of the prechecklist period, the recruited patients will be studied in order to quantity: (1) the global intubation success rate (within any attempt), (2) the FPS, (3) SPS and (4) TPS rates, (5) the PHETI immediate complication rate, (6) the elapsed time between the decision to intubate and the administration of the RSI drugs (7) the time spent between the decision to intubate and the verification of the proper location of the endotracheal tube (ETT) in order to detect any potential delays of the application of the checklist, (8) the "failed intubation" situation, (9) the SAD use and (10) the performance of the FONA procedure.

The data collection sheets will be used to register demographic information, the reason to perform the intubation, assess the nature and number of RSI complications experienced during a medical service and the number of intubation attempts performed until the verification of the proper placement of the ETT.

All PHETI will be video-recorded and reviewed in order to assess the following items: (1) to evaluate whether the application of the RSI checklist causes any unnecessary or harmful delays between the decision to intubate and the administration of the RSI drugs, or any delays between the decision to intubate and the verification of the proper location of the ETT, (2) to verify the number of intubation attempts performed, and (3) to review the complications encountered during the procedure.

7.6.2. Postchecklist period data collection

During the 17 months of the postchecklist period all data will be collected likewise as in the prechecklist period, including one more item to be reviewed in the video recording and to be incorporated to the data collection sheets, which is the adherence of the physician to the checklist.

Then, after the 39 months period including the prechecklist period, the checklist standardization period and the postchecklist period all the data collection sheets will be collected and introduced in a database created for this study, in order to analyze the information obtained.

Table 5. Data collected and methods used in the study.

1. Data collection sheets	
Patient information:	
Patient basic demographic characteristics. Reason to perform RSI. Anticipated difficult airway signs.	
Endotracheal intubation procedure information:	
Cormack score. Number of ETI attempts performed. "Failed intubation" situation encountered	
ETI-related complications	
Minor complications. Major complications.	
Alternative airway management plans used:	
SAD use. "CICO" situation encountered. FONA procedure performed.	
2. Video-recording	
Checklist application times:	
Time (seconds) between the decision to intubate and the administration of the RSI drugs. Time (seconds) between the decision to intubate and the ETI confirmation.	
Cross-checking items:	
Verify the number of intubation attempts performed. Review the nature and number of complications encountered.	

RSI: rapid sequence intubation; ETI: endotracheal intubation; SAD: supraglottic airway device; CICO: "can't intubate, can't oxygenate"; FONA: front-of-neck-airway.

7.7. RSI checklist formation

As the application of the RSI checklist is based on effective teamwork, the complete team should receive checklist formation. A total of 762 people work in a unit capable to provide the RSI procedure, including emergency technicians, nurses and physicians. Catalonia's SEM staff who works in those resources (124 from Girona, 358 from Barcelona, 124 from Tarragona and 156 from Lleida) will be gathered in 76 groups to accomplish the training. In order to reach the whole catalan territory, formation of trainers will take place and then these will be in charge of carrying out the formation of the staff groups.

The 76 groups will be distributed according to the location of their work base (provinces of Girona, Barcelona, Tarragona and Lleida) to receive training and simulation, distributed as shown in *Table 6*. It will take place in medical patient simulators equipped with technology that allow the performance of intubation and that are capable of reproducing the complications of the procedure. Those simulators are located in the Medical Faculties of Girona, Barcelona, Tarragona and Lleida, and also can be found and rented in other locations.

Each group will receive a total of 3 hours of formation (1 hour of lecture and 2 hours of simulation), thus the formation period requires a total of 228 hours to be accomplished. Consequently, one month has been scheduled for the accomplishment of the training by all workers.

Table 6. Distribution of Catalonia's SEM staff with formation purposes.

	Number of workers	Number of groups	Days of training
Girona	124	12	4
Barcelona	358	36	12
Tarragona	124	12	4
Lleida	156	16	6

8. Statistical Analysis

8.1. Descriptive analysis

A descriptive analysis of the variables will be performed using Statistical Package for Social Science (SPSS) version 25 and Apache OpenOffice Calc tool will be used to manage the computed data. The descriptive analysis of the variables will be performed to compare the characteristics of the population of both groups (pre- and postchecklist). It is expected that the basic demographics of the participants and RSI indications during the study will be similar and, therefore, comparable groups.

Qualitative variables (dependent variables and covariables) will be summarized as proportions stratifying pre- and post-intervention data. Quantitative variable's results will be expressed by means and standard deviation (SD) and by medians and interquartile range depending on whether the variables are symmetrically distributed (normal) or asymmetrically (not normal), respectively. Again, stratification pre- and post-intervention data will be performed.

8.2. Bivariate inference

The difference of proportions of the qualitative variables (dependent and covariables) pre- and post-intervention will be contrasted applying the Chi square test ($\chi 2$) and Fisher's exact test when the expected frequencies are < 5.

To compare the means and the medians of the quantitative variables pre- and post-intervention the Student's T test and Mann-Whitney's U test will be used.

8.3. Multivariate analysis

For the main dependent variable "development of an RSI complication", a Logistic Regression will be carried out where the response variable will be the dependent one and the explanatory of interest will be pre- and post-intervention, adjusted by the covariates.

In the case of the secondary dependent variables, which are all quantitative continuous variables (either because they are quantitative or because they have been expressed as rates), Linear Regressions will be estimated with the same independent variable, and adjustment for the same covariates will be performed. Furthermore, in order to investigate if the type of complications varies between the pre- and post-intervention periods, all the complications that are encompassed in the composite variable "development of an RSI complication" will also be studied performing Linear Regressions, adjusting for the covariates.

The existence of possible interactions between the intervention and/or the covariates will be assessed.

It will be considered that a significant difference between both groups exists when p-value <0.05.

9. Ethical considerations

The present study will be conducted according to the ethical principles for medical research established by the World Medical Association (WMA) in the *Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects*[84] (June 1964). Last revision was on October 2013.

Furthermore, according to *Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales*[85], all patient data will be anonymous, and for that purpose the database will use the medical record number instead of the names of patients to guarantee the anonymity of all patient's data.

All participants will be personally informed by a PHEMS physician and an information document about the study will be given to them (*Annex 6*) together with the informed consent to collect their personal information and to be video-recorded (*Annex 7*) which participants will have to voluntarily sign before joining the study. The recording will guarantee the anonymity of the patient by positioning the camera in an angle from which the face won't be seen and if this can't be achieved, the patient's

face will be blurred afterwards. If the patient is under-aged, remains unconscious or inevitably dies, the informed consent will be requested to first-degree relatives.

The present project and the informed consents will be presented and evaluated by the Clinical Research Ethics Committee (CEIC, "*Comitè Ètic d'Investigació Clínica*") of the *HJT*, and its approval will be obtained before initiating the study.

As the present study involves the realization of an endotracheal intubation, which is an invasive procedure, the study will meet the *Ley 14/2007, de 3 de julio, de investigación biomédica*[86]. Autonomous community authorization and civil liability insurance will be required. As endotracheal intubation is the usual procedure performed in the current clinical practice and it is not conducted specifically for study purposes, no further insurances will be needed.

The investigators of this project declare that there are no conflicts of interest.

10. Study limitations

This study is designed as a before-and-after. Therefore, it can demonstrate association between the dependent and independent variables but can't assure that the changes that have arisen are due to the intervention itself, so other circumstances may contribute to the observed results. Other designs, such as a community intervention trial, won't have the limitations that we face but finding two comparable groups of patients would be very difficult because of the different characteristics of the cities (rural/urban areas), which entail different circumstances that require intubation. Furthermore, no technological advances or training in intubation are expected during the study period, therefore the impact that is expected to occur can be mostly attributed to the implementation of the study's intervention.

Patients who will undergo PHETI performed by any physician who already know the preprocedural RSI checklist will be excluded from the study. This mainly refers to Girona's medicalized helicopter because, as its crew developed the preprocedural RSI checklist, they could perform the procedure according to a cognitive aid they are already familiarized with.

The incidence and prevalence of the PHETI remains unknown in Catalonia's prehospital setting due to the EMS's data collection system, which doesn't register the performance of this procedure when it is due to medical conditions; only the PHETIs performed in polytraumatic patients is registered. Thus, the data used to calculate the length of the study is from the polytraumatic patients who underwent PHETI and, as this entails an underestimation, the number of PHETI due to medical conditions per year has been estimated in order to achieve a more realistic incidence. In order to do that, the monthly consumption of laryngoscope blades has been evaluated. After the first 6 months of the study, the RSI incidence will be assessed and if it shows differences with the estimated one, the length of the study will be recalculated.

One of the data collection methods selected is a data collection sheet. This can entail several limitations. Personnel from the Catalonia's PHEMS will have to fill it after the performance of a PHETI meeting the study population criteria, which may cause an information bias if the data collection sheet is misplaced, incomplete or erroneously filled. In order to face this problem, a 10% dropout rate has been anticipated. Also, due to the Hawthorne effect, physicians could be more prone to feel that they are being evaluated and may change their decisions. Still, we think that using a form is a proper way to standardize and reduce the inter-observer variability that a multicenter study could entail.

Finally, due to the study design it is difficult to control the possible confounding variables. In order to avoid this problem, we will analyze the variables in a multivariate analysis to reduce the confusion.

11. Feasibility and working plan

The study is feasible because of the following:

First, the present study will take place in Catalonia's prehospital setting, which is divided into 7 sanitary regions covered by the SEM. This system has physician-staffed resources distributed within those regions, specifically a total of 49 resources (including ambulances, rapid intervention vehicles and medicalized helicopters) are able to perform PHETI. Those teams approximately perform 346 RSI procedures due to traumatic reasons per year, and it is estimated that 171 more patients undergo RSI due to medical causes every year. Thus, a total of 517 RSIs are carried out in Catalonia every year. Therefore, a period of 34 months will be enough to achieve the sample required, which is 1,456 patients (728 patients in each group).

Second, it doesn't require many resources nor a big budget. The SEM personnel performing the RSI procedure will collect all the data required for the study and will not receive any financial compensation for their contribution to the study, thus no additional staff will be needed apart from the data manager and the statistician, allowing an affordable budget. Although the staff in charge of data collection will not receive a financial compensation, they will receive a retribution as a collaborating researcher when the study will be published.

Third, in order to try to maximize the adherence to the use of the checklist there will be 2 periodic meetings to evaluate its compliance and to receive feedback from the emergency staff (*Annex 9*).

The sequence of activities developed during the study period is detailed in the work plan below (*Table 7*) and represented in the chronogram (*Figure 6*):

Table 7. Work plan of the study.

Stage	Activities performed		Time period
0	**Study design and preparation**		M1-M6
	Activity 1.	Bibliographic research and protocol elaboration.	
	Activity 2.	Ethical evaluation of the protocol of the study. The protocol and informed consents will be presented to the CEIC from HJT. With the acceptance of this institution, the Stage 1 of the study can proceed.	
	Activity 3.	Presentation of the study to the SEM's clinical board to obtain authorization to carry out the study.	
1	**Study coordination**		M7-M8
	Activity 4.	Meeting of the investigators with the PHEMS teams to inform about the study and train them on the data collection methods.	
	Activity 5.	All emergency personnel will be asked to sign a voluntary informed consent to be video-recorded.	
2	**Patient recruitment (prechecklist period) and data collection**		M9-M25
	Activity 6.	Patient recruitment.	
	Activity 7.	Data collection.	
	Activity 8.	Assess RSI incidence after 6 months.	
3	**Data treatment and generation of the database**		M26-M27
	Activity 9.	Generation of the database with the information obtained.	
4	**Checklist standardization**		M26
	Activity 10.	Checklist formation.	
5	**Patient recruitment (postchecklist period) and data collection**		M27-M43
	Activity 11.	Patient recruitment.	
	Activity 12.	Data collection.	
	Activity 13.	Periodic meeting.	
6	**Statistical analysis**		M44
	Activity 14.	Statistical analysis performed by a hired statistician.	
7	**Interpretation of the results**		M45-M46
	Activity 15.	Results interpretation.	
	Activity 16.	Paper elaboration and revision.	

M: month; CEIC: Comitè Ètic d'Investigació Clínica; HJT: Hospital Josep Trueta; SEM: Sistema d'emergències mediques; PHEMS: prehospital emergency medical service.

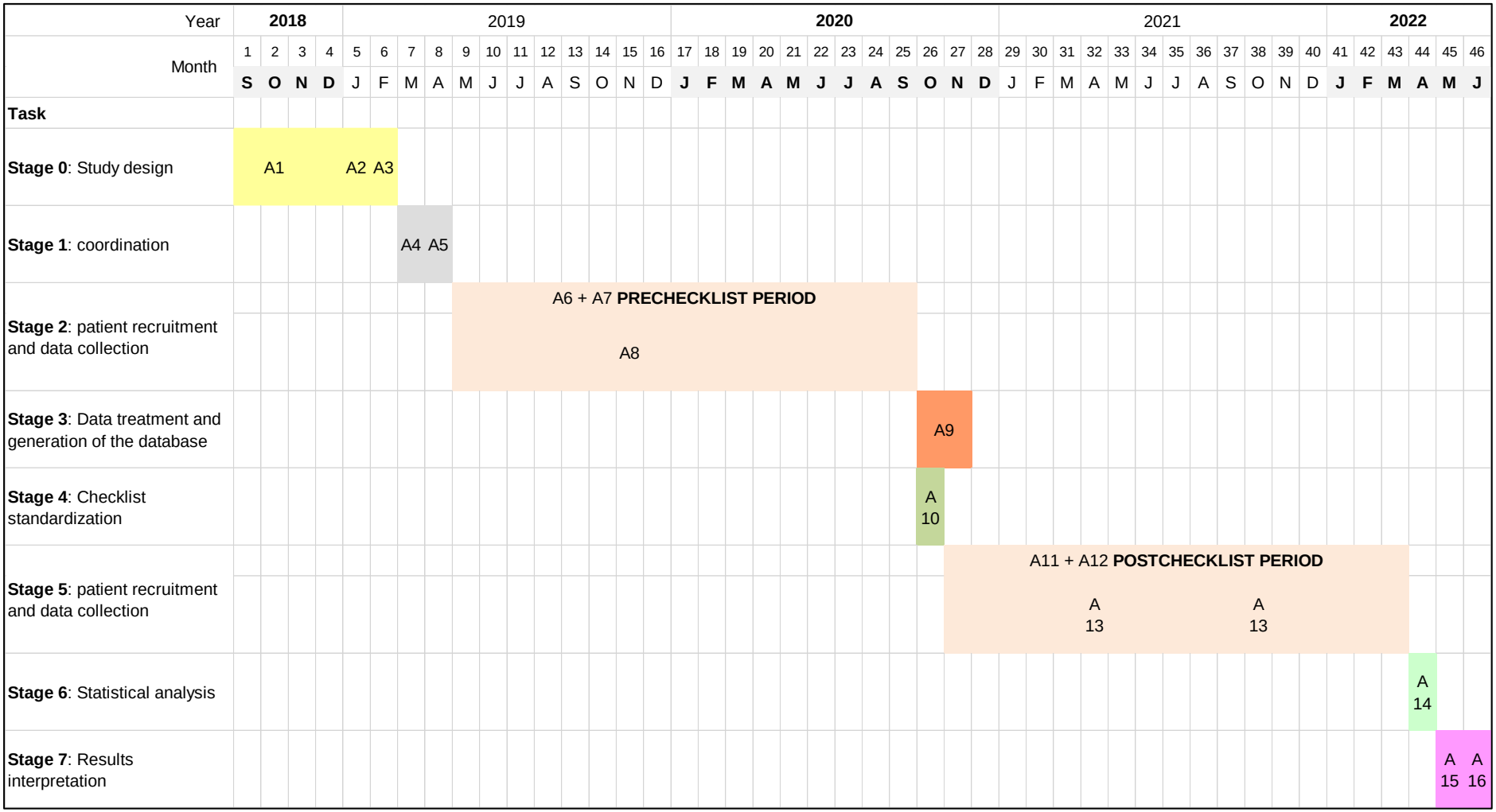


Figure 6. Chronogram of the study. A: activity.

12. Budget of the study

The required budged for the project is summarized in *Table 8* below:

Table 8. Budget of the study.

Type of cost	Unit cost	Hours / units	Total
Personnel / staff			
Formation of trainers	84.87 €	8h	678.96 €
Data manager	40 €	40 h	1,600 €
· Creation of the database · Data introduction			
Statistician	60 € / h	48 h	2,880 €
Subtotal			**5,158.96€**
Material costs			
Sports camera	49.99 €	49	2,449.51 €
Camera harness	14.99 €	49	734.51 €
Printings:			
· Checklist	0.30 €	49	14.7 €
· Study information por the patient	0.03 €	1,456 (x 2 pages)	87.36 €
· Patient's informed consent	0.03 €	1,456	43.68 € €
· PHEMS's personnel informed consents	0.03 €	6,820	204.6 €
· Data collection sheets	0.03 €	1,456 (x 2 pages)	87.36 €
Subtotal			**3,621.72 €**
Publication and diffusion costs			
Linguistic correction			150 €
Article publication			1,500 €
Subtotal			**1,680 €**
TOTAL			**10,460.68 €**

As mentioned, formation of trainers will take place in order to reach the whole catalan territory more efficiently, entailing a total cost of 678.96€. Then, the 762 people who will undertake the formation will be gathered in 76 groups and will receive a total of 3 hours of formation. Thus, the formation period requires a total of 228 hours and 19,350.36€ to be accomplished.

The cost of the trainers' formation will be assumed by the study, but the staffs' formation cost (19,350.36 €) will be included within the SEM's formation program or the budget for the formation of the staff of each entity attached to the SEM, as appropriate.

13. Bibliographic references

1. Generalitat de Catalunya. Sistema d'Emergències Mèdiques [Internet] Catalunya: Gencat; c2017. **Emergències Mèdiques**; 2017 [reviewed 2017 Mar; cited 2018 Dec 19]. Available from: http://sem.gencat.cat/ca/sem_emergencies_mediques/distribucio_territorial/ Catalan, Spanish, English.
2. Diggs LA, Yusuf JE, De Leo G. **An update on out-of-hospital airway management practices in the United States**. *Resuscitation*.2014;85(7):885-892.
3. Smith TL, Van Meter J. **Maximizing success with rapid sequence intubations**. *Advanced Emergency Nursing Journal*. 2018;40(3):183-193
4. Okubo M, Gibo K, Hagiwara Y, *et al*. **The effectiveness of rapid sequence intubation (RSI) versus non-RSI in emergency department: an analysis of multicenter prospective observational study.** *International Journal of Emergency Medicine*.2017;10(1):1-9
5. Stollings JL, Diedrich DA, Oyen LJ, *et al*. **Rapid-Sequence Intubation: A Review of the Process and Considerations When Choosing Medications**. *Annals of Pharmacotherapy*. 2014;48(1):62-76
6. Gebremedhn EG, Gebeyehu KD, Ayana HA, *et al***. Techniques of rapid sequence induction and intubation at a university teaching hospital**. *World journal of emergency medicine*. 2014;5(2):107-111
7. Kohn LT, Corrigan JM, Donaldson MS, editors**. To Err Is Human: Building a Safer Health System** [Internet]. 1st ed. Washington, DC: National Academies Press; 2000 Mar 1 [cited 2018 Dec 10] Available from: https://www.nap.edu/catalog/9728/to-err-is-human-building-a-safer-health-system
8. St. Pierre M, Hofinger G, Buerschaper C. **Crisis Management in Acute Care Settings** [Internet]. 1st ed. Berlin: Springer; 2008 [reviewed 2010 Nov 19; cited 2018 Dec 10] Available from: https://www.researchgate.net/profile/Michael_StPierre/publication/200130282_Crisis_Management_in_Acute_Care_Settings/links/555c322408aec5ac2232ad4c/Crisis-Management-in-Acute-Care-Settings.pdf
9. Reason J. **Human error: Models and management**. *Western Journal of Medicine*. 2000;172(6):393-396
10. Patel SA, Meyer TK. **Surgical Airway**. *Airway Management*. 2014;4(1):203-221
11. Bowie P, McKay J, Kelly M. **Maximizing harm reduction in early specialty training for general practice: Validation of a safety checklist**. *BMC Family Practice*. 2012;13(1):1-10
12. Thomassen Brattebø G, Søfteland E, Lossius HM, *et al*. **The effect of a simple checklist on frequent pre-induction deficiencies**. *Acta Anaesthesiologica Scandinavica*. 2010;54(10):1179-1184
13. Higgs A, McGrath BA, Goddard C, *et al*. **Guidelines for the management of tracheal intubation in critically ill adults**. *British Journal of Anaesthesia*. 2018;120(2):323-352
14. Frerk C, Mitchell VS, McNarry AF, *et al*. **Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults**. *British Journal of Anaesthesia*. 2015;115(6):827-848
15. Weingart SD. **Preoxygenation, reoxygenation, and delayed sequence intubation in the Emergency Department**. *Journal of Emergency Medicine*. 2011;40(6):661-667

16. Chesters A, Keefe N, Mauger J, *et al*. **Prehospital anaesthesia performed in a rural and suburban air ambulance service staffed by a physician and paramedic: A 16-month review of practice**. *Emergency Medicine Journal*. 2014;31(1):65-68
17. Maluenda F, Aguilera P, Kripper C, *et al*. **Secuencia rápida de intubación en el Servicio de urgencia**. *Revista Chilena de Medicina intensiva*. 2015;30(1):23-32
18. Rehn M, Hyldmo PK, Magnusson V, *et al*. **Scandinavian SSAI clinical practice guideline on prehospital airway management**. *Acta Anaesthesiologica Scandinavica*. 2016;60(7):852-864
19. Long B, Koyfman A, Vivirito MA. **Capnography in the Emergency Department: A Review of Uses, Waveforms, and Limitations**. *Journal of Emergency Medicine*. 2017;53(6):829-842
20. Park L, Zeng I, Brainard A. **Systematic review and meta-analysis of first-pass success rates in emergency department intubation: Creating a benchmark for emergency airway care**. *Emergency Medicine Australasia*. 2017;29(1):40-47
21. Fioratou E, Flin R, Glavin R. **No simple fix for fixation errors: Cognitive processes and their clinical applications**. *Anaesthesia*. 2010;65(1):61-69
22. Onrubia X, Frova G, Sorbello M. **Front of neck access to the airway: A narrative review**. *Trends in Anaesthesia and Critical Care*. 2018;22(1):45-55
23. Cook TM, Woodall N, Harper J, *et al*. **Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 2: intensive care and emergency departments**. *British Journal of Anaesthesia*. 2011;106(5):632-642
24. Lockey DJ, Crewdson K, Davies G, *et al*. **AAGBI: Safer prehospital anaesthesia 2017**. *Anaesthesia*. 2017;72(3):379-390
25. Breckwoldt J, Klemstein S, Brunne B, *et al*. **Difficult prehospital endotracheal intubation - predisposing factors in a physician based EMS**. *Resuscitation*. 2011;82(12):1519-1524
26. Cook TM, Macdougall-Davis SR. **Complications and failure of airway management**. *British Journal of Anaesthesia*. 2012;109(SUPPL1):68-85
27. Bowles TM, Freshwater-Turner DA, Janssen DJ, *et al*. **Out-of-theatre tracheal intubation: Prospective multicentre study of clinical practice and adverse events**. *British Journal of Anaesthesia*. 2011;107(5):687-692
28. Freund Y, Duchateau FX, Devaud ML, *et al*. **Factors associated with difficult intubation in prehospital emergency medicine**. *European Journal of Emergency Medicine*. 2012;19(5):304-308
29. Caplan R, Benumof JL, Berry F, *et al*. **Practice guidelines for management of the difficult airway**. *Anesthesiology*. 2013;118(3):251-70
30. Cormack R, Lehane L. **Difficult tracheal intubation in obstetrics.** *Anaesthesia*. 1984;39(11):1105-1111.
31. Combes X, Jabre P, Jbeili C, *et al*. **Prehospital Standardization of Medical Airway Management: Incidence and Risk Factors of Difficult Airway**. *Academic Emergency Medicine*. 2006;13(8):828-834
32. Martin LD, Mhyre JM, Shanks AM, *et al*. **3,423 Emergency Tracheal Intubations at a University Hospital**. *Anesthesiology*. 2011;114(1) 3-6

33. Jabre P, Avenel P, Combes X. *et al*. **Morbidity related to emergency endotracheal intubation-A substudy of the KETAmine SEDation trial**. *Resuscitation*. 2011;82(5):517-522
34. Wang T, Sun S, Huang S. **The association of body mass index with difficult tracheal intubation management by direct laryngoscopy: a meta-analysis**. *BMC Anesthesiology*. 2018;18(1):1-13
35. Lockey D, Crewdson K, Weaver A, *et al*. **Observational study of the success rates of intubation and failed intubation airway rescue techniques in 7256 attempted intubations of trauma patients by prehospital physicians**. *British Journal of Anaesthesia*. 2014;113(2):220-225
36. Rognås L, Hansen T, Kirkegaard HM, *et al*. **Prehospital advanced airway management by experienced anaesthesiologists: A prospective descriptive study**. *Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine*. 2013;21(1):1-10
37. Soyuncu S, Eken C, Cete Y, *et al*. **Determination of difficult intubation in the ED**. *American Journal of Emergency Medicine*. 2009;27(8):905-910
38. Mort TC. **Emergency tracheal intubation: Complications associated with repeated laryngoscopic attempts**. *Anesthesia and Analgesia*. 2004;99(2):607-613
39. Caruana E, Duchateau FX, Cornaglia C, *et al*. **Tracheal intubation related complications in the prehospital setting**. *Emergency Medicine Journal*. 2015;332(11):882-887
40. Sakles JC, Chiu S, Mosier J, *et al*. **The importance of first pass success when performing orotracheal intubation in the emergency department**. *Academic Emergency Medicine*. 2013;20(1):71-78
41. Fletcher G, Flin R, McGeorge M, *et al*. **Anaesthetists' non-technical skills (ANTS): Evaluation of a behavioural marker system**. *British Journal of Anaesthesia*. 2003;90(5):580-588
42. Kodate N, Ross AJ, Anderson JE, *et al*. **Non-Technical Skills (NTS) for Enhancing Patient Safety: Achievements and Future Directions**. *Japanese Journal of Quality and Safety in Healthcare*. 2012;7(4):360-370
43. Leonard M, Graham S, Bonacum D. **The human factor: The critical importance of effective teamwork and communication in providing safe care**. *Quality and Safety in Health Care*. 2004;13(SUPPL. 1):85-91
44. Rall M, Gaba DM, Howard SK, *et al*. *Miller's Anesthesia*. Philadelphia: Elsevier; 2014. 8th ed. 7; **Human Performace and Patient Safety**; p. 106-166
45. Carayon P, Xie A, Kianfar S. **Human factors and ergonomics as a Patient safety practice**. *BMJ Quality and Safety*. 2014;23(3):196-205
46. McCulloch P, Mishra A, Handa A, *et al*. **The effects of aviation-style non-technical skills training on technical performance and outcome in the operating theatre**. *Quality and Safety in Health Care*. 2009;18(2):109-115
47. Flin R, Maran N. **Identifying and training non-technical skills for teams in acute medicine**. *Quality and Safety in Health Care*. 2004;13(SUPPL. 1):80-85
48. Sharma B, Mishra A, Aggarwal R, *et al*. **Non-technical skills assessment in surgery**. *Surgical Oncology*. 2011;20(3):169-177
49. Marshall SD, Mehra R. **The effects of a displayed cognitive aid on non-technical skills in a simulated 'can't intubate, can't oxygenate' crisis**. *Anaesthesia*. 2014;69(7):669-677

50. Moorthy K, Munz Y, Adams S, *et al*. **A human factors analysis of technical and team skills among surgical trainees during procedural simulations in a simulated operating theatre**. *Annals of Surgery*. 2005;242(5):631-639
51. Hull L, Arora S, Aggarwal R, *et al*. **The impact of nontechnical skills on technical performance in surgery: A systematic review**. *Journal of the American College of Surgeons*. 2012;214(2):214-230
52. Riem N, Boet S, Bould MD, *et al*. **Do technical skills correlate with non-technical skills in crisis resource management: A simulation study**. *British Journal of Anaesthesia*. 2012;109(5):723-728
53. Hales BM, Pronovost PJ. **The checklist—a tool for error management and performance improvement**. *Journal of Critical Care*. 2006;21(3):231-235
54. Gurses AP, Ozok AA, Pronovost PJ. **Time to accelerate integration of human factors and ergonomics in patient safety**. *BMJ Quality & Safety*. 2012;21(4):347-351
55. Sherren PB, Tricklebank S, Glover G. **Development of a standard operating procedure and checklist for rapid sequence induction in the critically ill**. *Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine*. 2014;22(1):41-51
56. Hales B, Terblanche M, Fowler R, *et al*. **Development of medical checklists for improved quality of patient care**. *International Journal for Quality in Health Care*. 2008;20(1):22-30
57. Crewdson K, Lockey D, Voelckel W, *et al*. **Best practice advice on pre-hospital emergency anaesthesia & advanced airway management**. *Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine*. 2019;27(6):1-7
58. Sathyanarayana Rao TS, Radhakrishnan R, Andrade C, **Standard operating procedures for clinical practice**. *Indian Journal of Psychiatry*. 2011;53(1):1
59. Chen C, Kan T, Li S, *et al*. **Use and implementation of standard operating procedures and checklists in prehospital emergency medicine: a literature review**. *American Journal of Emergency Medicine*. 2016;34(12):2432-2439
60. Burgess MR, Crewdson K, Lockey DJ, *et al*. **Prehospital emergency anaesthesia: An updated survey of UK practice with emphasis on the role of standardisation and checklists**. *Emergency Medicine Journal*. 2018;35(9):532-537
61. Mommers L, Keogh S. **SPEEDBOMB: A simple and rapid checklist for Prehospital Rapid Sequence Induction**. *EMA - Emergency Medicine Australasia*. 2015;27(2):165-168
62. Christianson MK, Sutcliffe KM, Miller MA, *et al*. **Becoming a high reliability Organization**. *Critical Care*. 2011;15(6):1-5
63. Kerner T, Schmidbauer W, Tietz M, *et al*. **Use of checklists improves the quality and safety of prehospital emergency care**. *European Journal of Emergency Medicine*. 2015;24(2):114-119
64. Bosse G, Schmidbauer W, Spies CD, *et al*. **Adherence to Guideline-based Standard Operating Procedures in Pre-hospital Emergency Patients with Chronic Obstructive Pulmonary Disease**. *Journal of International Medical Research*. 2011;39(1):267-276
65. Francis RC, Bubser F, Schmidbauer W, *et al*. **Effects of a standard operating procedure on prehospital emergency care of patients presenting with symptoms of the acute coronary syndrome**. *European Journal of Emergency Medicine*. 2014;21(3):236-239

66. Rognås L, Hansen TM, Kirkegaard H, *et al*. **Standard operating procedure changed pre-hospital critical care anaesthesiologists' behaviour: a quality control study**. *Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine*. 2013;21(1):1-7
67. Conroy MJ, Weingart GS, Carlson JN. **Impact of checklists on peri-intubation care in ED trauma patients**. *American Journal of Emergency Medicine*. 2014;32(6):541-544
68. Haynes AB, Weiser TG, Berry WR, *et al*. **A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population**. *New England Journal of Medicine*. 2009;360(5):491-499
69. Weiser TG, Haynes AB, Dziekan G, *et al*. **Effect of a 19-item surgical safety checklist during urgent operations in a global patient population**. *Annals of Surgery.* 2010;251(5):976–80
70. DuBose JJ, Inaba K, Shiflett A, *et al*. **Measurable outcomes of quality improvement in the trauma intensive care unit: the impact of a daily quality rounding checklist**. *Journal of Trauma - Injury, Infection and Critical Care*. 2008;64(1):22–27
71. Goeschel CA, Holzmueller CG, Cosgrove SE, *et al*. **Infection preventionist checklist to improve culture and reduce central line-associated bloodstream infections**. *Joint Commission Journal on Quality and Patient Safety*. 2010;36(12):571-575
72. Thomassen Ø, Espeland A, Søfteland E, *et al*. **Implementation of checklists in health care; learning from high-reliability organizations**. *Scandinavian Journal of trauma, resuscitation and emergency medicine*. 2011;19(1):53-60
73. Newkirk M, Pamplin JC, Kuwamoto R, *et al*. **Checklists change communication about key elements of patient care**. *Journal of Trauma and Acute Care Surgery*. 2012;73(2 SUPPL. 1):75–82
74. Cook TM, Woodall N, Frerk C. **A national survey of the impact of NAP4 on airway management practice in United Kingdom hospitals: Closing the safety gap in anaesthesia, intensive care and the emergency department**. *British Journal of Anaesthesia*. 2016;117(2):182-190
75. Rognås LK, Hansen TM. **EMS-physicians' self reported airway management training and expertise; a descriptive study from the Central Region of Denmark**. *Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine*. 2011;19(10):1-7
76. Health Research & Educational Trust. **Checklists to improve patient safety**. [Internet] Chicago, Illinois: Health Research & Educational Trust, 2013 [cited 2018 Dec 5] Available from: www.hpoe.org
77. Smith KA, High K, Collins SP, *et al*. **A Preprocedural Checklist Improves the Safety of Emergency Department Intubation of Trauma Patients**. *Academic Emergency Medicine*. 2015;22(8):989-992
78. Harris T, Lockey DJ. **Success in physician prehospital rapid sequence intubation: What is the effect of base speciality and length of anaesthetic training?** *Emergency Medicine Journal*. 2011;28(3):225-229
79. McQueen C, Crombie N, Hulme J, *et al*. **Prehospital anaesthesia performed by physician/critical care paramedic teams in a major trauma network in the UK: A 12 month review of practice**. *Emergency Medicine Journal*. 2015;32(1):65-69
80. Von Vopelius-Feldt J, Benger JR. **Prehospital anaesthesia by a physician and paramedic critical care team in Southwest England**. *European Journal of Emergency Medicine*. 2013;20(6):382-386

81. **Calculadora de grandària mostral GRANMO** [Internet]. Barcelona: Institut Municipal d'Investigació Mèdica; 2012 [cited 2018 Dec 11]. Available from: http://www.imim.cat/ofertadeserveis/software-public/granmo/, Catalan, Spanish, English.
82. Lloyd-Jones DM, Morris PB, Ballantyne CM, *et al*. **2017 Focused Update of the 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways**. *Journal of the American College of Cardiology*. 2017;70(14):1785-1822
83. American College of Cardiology (US). **2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients with Bradycardia and Cardiac Conduction Delay** [Internet]. Washington DC (US): American College of Cardiology; c2019 [updated 2019 Jan 12; cited 2019 Jan17]. Available from: http://www.onlinejacc.org/content/early/2018/10/29/j.jacc.2018.10.044?_ga=2.156903099.1829716509.1548322852-1905174981.1547472159, English.
84. World Medical Association. **Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects** [Internet]. World Medical Association; 2013 [cited 2018 Dec 14]. Available from: http://www.wma.net/en/30publications/10policies/b3/, English.
85. **Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales** [Internet]. Boletín Oficial del Estado, núm. 294, (6-12-2018). [cited 2018 Dec 14] Available from: https://www.boe.es/boe/dias/2018/12/06/pdfs/BOE-A-2018-16673.pdf Spanish.
86. **Ley 14/2007, de 3 de julio, de Investigación biomédica** [Internet]. Boletín Oficial del Estado núm. 159, (2-6-2011). [cited 2018 Dec 14] Available from: https://www.boe.es/buscar/pdf/2007/BOE-A-2007-12945-consolidado.pdf, Spanish.

14. Annexes

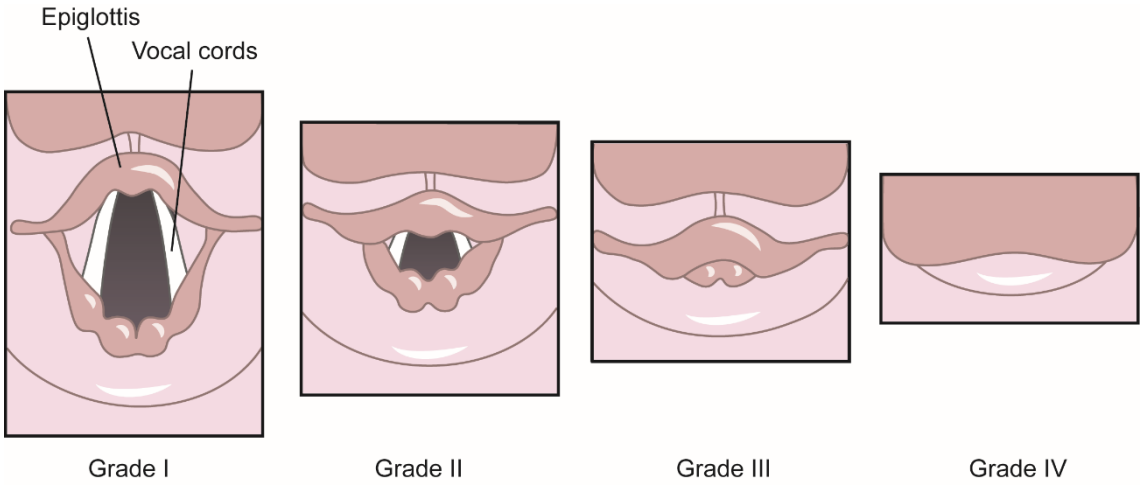
Annex 1. Primary disease leading to intubation.

Any of the following situations that lead to respiratory insufficiency or potential airway obstruction which can't be reversed by other methods of oxygen therapy or ventilation:

Medical encounters	
Cardiac	Congestive heart failure, arrythmia, cardiogenic shock
Pulmonary	Pneumonia, aspiration, chronic obstructive pulmonary disease, secretions, asthma, pulmonary embolus.
Sepsis-SIRS	Septic shock.
Neurological	Cerebral vascular event, seizure, status epilepticus, elevated ICP.
Metabolic	Diabetic ketoacidosis, renal or liver failure, overdose.
GI bleeding	
Coma	
Anaphylaxis	
Humanitarian indications	
Trauma encounters	
Trauma	Head injury, airway/ general / facial / neck trauma.
Trauma - combative	
Burn / inhalation	
Traumatic shock	

SIRS: systemic inflammatory response syndrome; ICP: intracranial pressure; GI: gastrointestinal. Adapted from Mort 2004 and Walls 2011.

Annex 2. Cormack and Lehane score.



Classification of the laryngeal inlet view during laryngoscopy. Grade I: view of most of the glottis; grade II: only the posterior portion of the glottis is visible; grade III: only the epiglottis is visible; grade IV: glottis and epiglottis are not visible. Inspired from Breckwoldt *et al.* 2011.

Annex 3. RSI preprocedural checklist.

SEQÜÈNCIA RÀPIDA D'INTUBACIÓ SOP1 UMA GIRONA. V03 Març/2017

emergències mèdiques

EQUIP

A: AWARNESS

□ RSI indicada aquí i ara?
□ Causa reversible inconsciència?
□ Comunicació H0/família

B: BRIEFING

□ Briefing i ROLS.
Material
Farmacs
Control cervical
Control temps laringoscòpia
Monitor
Ajudant via aèria

□ Esquema RSI
Estable/Inestable.

PACIENT

C: CHECK

□ 360º accés al pacient?
□ Senyals de via aèria difícil?
□ Dificultat VPP mascareta?
□ Posició pacient i operador òptimes?
□ Estabilitat HD?
□ Preoxigenació 3 min?
□ Accés venós permeable?

MATERIAL

C: CHECK

□ Previsió O2 >80 bar?
□ Ambú?
□ Laringoscopi
Pala Nº ___ TOT ____ (CHECK)

□ Fiador, Lubricant, Pinces Magyl?

□ Xeringa 10 ml, Bena?

□ Sonda EtCO2 i corba al monitor?

□ Aspirador i Yankauer?

□ Farmacs preparats?

□ Pla B 1 □ FROVA
□ FASTRACH

□ Pla no intubable no ventilable CRICO/revertir.

□ DUBTES, PREGUNTES, ROLS CLARS?

PLA i EXECUCIÓ

D: DEVELOPMENT

• Declarar Nº intent: _____
• Pla inicial màxim 2 intents.

• Temps laringoscòpia < 30s: _____
• Avortar si □ Sat<93%* o
□ Arrítmia.

E. EXIT?

□ **NO**: REOXIGENAR--1er intent falla-valorar pala, fiador, posició, angle, BURP, repetir Succinilcolina? pla B millor opció?

□ **NO**: REOXIGENAR-- 2on intent falla-passar a pla B

□ **NO**: Situació no intubable no ventilable? CRICO/revertir.

□ **SI: ONA EtCO2, present i <u>mantinguda</u>, AR bilateral, A Gàstrica negativa**
Registrar longitud introduïda, SNG?, relax/sed manteniment, VMI.

Annex 4. Standardization of the intubation procedure through a checklist in a medicalized helicopter.

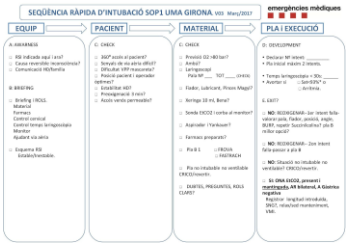
ESTANDARITZACIÓ DE LA MANIOBRA D'INTUBACIÓ MITJANÇANT UNA CHECKLIST EN UN HELICÒPTER MEDICALITZAT

Hisao Onaga Pueyo ; Teia Camps Dausà ; Joan Soler Yebra; Gina Rognoni Amrein; Elena Sánchez González; David Cortès Gonzàlez.

INTRODUCCIÓ

La maniobra d'intubació orotraqueal amb sedació i relaxació (RSI) és el "Gold Standard" en el maneig de la via aèria en emergències. A la pràctica la variabilitat del procediment és molt alta i, en ocasions, les complicacions són catastròfiques[1,2]. El consens internacional actual recomana realitzar la RSI en emergències prehospitalàries sota estàndards de preparació i seguretat equiparables a l'entorn de quiròfan. Entre les mesures que es proposen hi ha l'ús de les Checklist de Procediment[3,4](CL).

Figura 1.



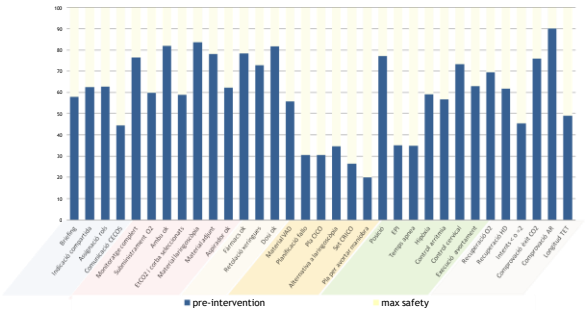
OBJECTIUS

- Avaluar l'impacte d'una CL en la reducció de la variabilitat en l'execució de la RSI (estandardització) en un helicòpter medicalitzat (HM).
- Avaluar el compliment de les recomanacions de maneig de la via aèria (RVA) i els estàndards de preparació i seguretat (SS) disponibles en medi prehospitalari.

METODOLOGIA

- Revisió RVA i CL en la literatura[4,5,6,7]. Confecció d'un CL pròpia per dirigir la RSI posant especial atenció en el Factor Humà (Figura 1). Validació i entrenament sota simulació en els assistencials del HM (SEM Girona) previ a l'ús en serveis reals.
- Enquesta validada sobre l'experiència prèvia als assistencials (n=15) en el compliment de 33 ítems, 32 relacionats amb treball en equip, adherència a RVA i SS i 1 sobre riscos laborals (marge de puntuació entre el 20 i el 95%).
- Avaluació posterior amb la mateixa enquesta després de tres anys d'ús de la CL.

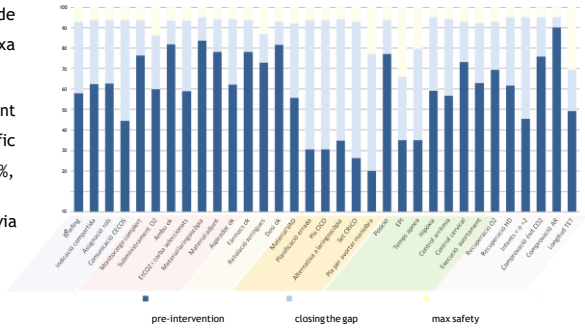
Gràfic 1. Percepció del compliment en la preparació i estàndards de seguretat de la maniobra de RSI previs a l'ús d'una Checkist de Procediment



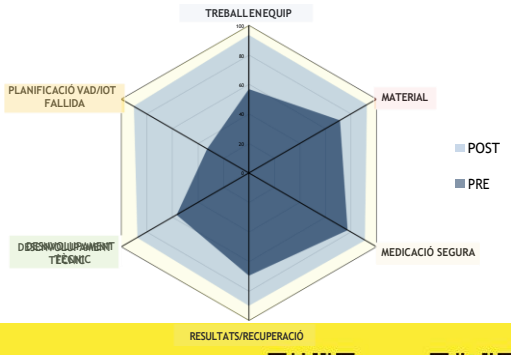
RESULTATS

- S'han obtingut 11 enquestes del període previ a la implantació de la CL i 13 del període posterior. La percepció del compliment amb les RVA i SS previ a la intervenció és baixa (Gràfic 1).
- L'ús de la CL ha eliminat la variabilitat general. S'ha aconseguit millorar el compliment de tots els ítems de les RVA i SS arribant per sobre del 90% en 27 dels 33 ítems (Gràfic 2). Destaquen els ítems relacionats amb la planificació (aproximadament 33% vs 90%, Gràfic 3) i el compliment en la limitació a 2 dels intents de laringoscòpia directa en via aèria difícil (45% vs 95%).

Gràfic 2. Impacte en la preparació i estàndards de seguretat en la maniobra de RSI d'una Checkist de Procediment.



Gràfic 3. Impacte en la preparació i estàndards de seguretat en la maniobra de RSI d'una Checkist de Procediment



CONCLUSIONS

- **L'ús d'una CL és efectiva** per estandaritzar la maniobra de RSI i augmentar l'adherència a les **RVA** i els compliment dels **SS**.
- La millora es situa majoritàriament en l'àmbit dels **Factors Humans i les habilitats no tècniques**: treball en equip, la planificació (alternatives, intubació fallada, emergències) i el manteniment dels estàndards de procediment (Gràfic 3 per categories)
- Cal un estudi prospectiu per determinar l'impacte en l'aparició d'esdeveniments adversos durant la RSI o en la gestió i resolució d'aquests quan s'utilitza una CL .

Limitacions: Els resultats obtinguts provenen d'un grup reduït d'assistencials i amb formació prèvia en Factor Humà i familiaritzats amb procediments estandarditzats.

Agraïments: Volem agrair la col·laboració imprescindible en el projecte a tots els integrants de la Base SEM H2 i les tripulacions de vol que han col·laborat en el disseny i utilització de la CL en RSI.

Generalitat de Catalunya
Departament de Salut

emergències mèdiques

Annex 5. Data collection sheet.

FULL DE RECOL·LECCIÓ DE DADES A OMPLIR PEL SEM

Data: ..... / ..... / .....

Informació referent al pacient

Característiques demogràfiques bàsiques:

Edat: ..... **Gènere**: ☐ Home. ☐ Dona. ☐ Desconegut.

Motiu principal pel qual es realitza la intubació orotraqueal (IOT) amb seqüència ràpida:

☐ Deteriorament de la via aèria. ☐ Inconsciència.
☐ Respiració inadequada. ☐ Agitació després de lesió cranial.
☐ Anticipació del curs clínic. ☐ Altres: .....

Signes de via aèria difícil? ☐ No ☐ Sí. En cas afirmatiu, quins?

☐ Espai limitat durant la RSI. ☐ IOT metge en posició decúbit *prono*.
☐ Coll curt (distància mentó-hioides < 3 dits).
☐ Obstrucció de la via aèria:
☐ Traumatisme facial. ☐ Traumatisme cervical. ☐ Hª de malaltia ORL.
☐ Edema de laringe. ☐ Altres: .....

Informació referent al procediment d'intubació

Cormack score: ☐ I ☐ II ☐ III ☐ IV
Nº intents d'IOT: ☐ 1 ☐ 2 ☐ 3 ☐ > 3 ☐ Amb canvi d'operador.
Intubació fallida? ☐ Si. ☐ No.

Complicacions relacionades amb la intubació

Degudes als fàrmacs de la RSI?

	Sí	**No**
☐ $SatO_2$<93%.	☐	☐
☐ $SatO_2$<80%.	☐	☐
☐ Bradiarítmia[1]	☐	☐
☐ Taquiarítmia[2].	☐	☐
☐ Taquicàrdia sinusal[3].	☐	☐
☐ Hipotensió[4].	☐	☐
☐ Hipertensió[5].	☐	☐
☐ Crisi hipertensiva[6].	☐	☐

☐ Edema de glotis.
☐ Aturada cardiorespiratòria.
☐ Broncoaspiració.
☐ Intubació esofàgica no reconeguda.
☐ Intubació esofàgica immediatament reconeguda.
☐ lesió dental / llavi.
☐ Intubació selectiva.
☐ Fuga del baló del tub endotraqueal.
☐ Laringospasme.

Ús d'altres dispositius pel maneig de la via aèria

☐ Dispositiu supraglòtic (Fastrach)
☐ Cricotiroidotomia percutània (amb agulla) o amb bisturí.

Definició de les complicacions:

1. Bradiarítmia: FC<60 bpm si disminució >20% des de la base o presència de bloquejos de conducció durant la intubació.
2. Taquiarítmia: ritmes cardíacs anormals amb FC ≥100bpm.
3. Taquicàrdia sinusal: FC >100 bpm si augment >20% des de la base.
4. Hipotensió: TAS <90mmHg, TAM <60mmHg si disminució >20% des de la base o augment dels requeriments de fàrmacs vasoactius si ja han hagut de ser administrats abans de la inducció.
5. Hipertensió: TAS >160mmHg si augment >20% des de la base.
6. Crisi hipertensiva: TAS >180mmHg i/o TAD >120mmHg.

Seran degudes als fàrmacs de la seqüència d'intubació ràpida si: succeeixen durant els primers 2 minuts després de l'administració dels fàrmacs.

Seran degudes a la intubació si: succeeixen des de 2 minuts després de realitzar la inducció fins a la verificació de la IOT.

TAS: tensió arterial sistòlica; mmHg: mil·límetres de mercuri; TAD: tensió arterial diastòlica; FC: freqüència cardíaca; bpm: batecs per minut; TAM: tensió arterial mitja.

Annex 6. Information document for the study.

FULL D'INFORMACIÓ PEL PACIENT

Benvolgut / da Sr / a. Vostè/el seu familiar presenta una patologia greu que requereix la realització de un procediment invasiu per tal de proporcionar-li una correcte oxigenació anomenat intubació orotraqueal. Aquest és un procediment habitual en assistència a emergències mèdiques i es realitzarà de manera normal seguint les guies de pràctica clínica. El cap de l'equip assistencial SEM que l'està atenent el convida a participar a l'estudi:

AVALUACIÓ DE L'IMPACTE DE L'APLICACIÓ D'UN CHECKLIST PRE-PROCEDIMENTAL EN LA SEQÜÈNCIA D'INTUBACIÓ RÀPIDA PER DISMINUIR LES COMPLICACIONS DERIVADES DEL PROCEDIMENT EN L'ÀMBIT EXTRAHOSPITALARI.

Aquest estudi el durà a terme l'investigador / a: Hisao Onaga, Alba Castellanos

Abans de confirmar la seva participació en l'estudi de recerca, és important que entengui en què consisteix. Llegiu detingudament aquest document i faci totes les preguntes que li puguin sorgir.

Objectiu de l'estudi:

Aquest estudi pretén analitzar si l'aplicació d'un checklist en la Seqüència d'Intubació Ràpida disminueix les complicacions del procediment en els pacients en estat crític atesos per les unitats SEM del territori de Catalunya.

Participació voluntària:

Vostè és completament lliure de triar participar o no en l'estudi. La seva decisió no influirà en la seva atenció mèdica.

Nombre de pacients i durada estimada de la participació dels pacients:

En aquest estudi es preveu la participació d'un total de 1456 pacients atesos per les diferents unitats SEM del territori de Catalunya (estudi multicèntric) que precisin intubació orotraqueal mitjançant una seqüència d'intubació ràpida. No es realitzarà seguiment dels pacients més enllà de l'atenció sanitària prestada pel SEM.

Procediments de l'estudi

El procediment d'intubació orotraqueal mitjançant una seqüència d'intubació ràpida no variarà si vostè decideix participar o no. Es farà de la mateixa manera en qualsevol cas. L'equip, durant o al final de l'assistència recollirà unes dades referents a la intubació i les possibles complicacions ocorregudes que serviran per analitzar el procediment. Aquesta recol·lecció de dades es farà a través de formularis que completarà el personal sanitari i a través de gravació en vídeo del procediment durant la prestació de l'atenció sanitària per part del personal del SEM, ja que és un mètode útil per avaluar l'aplicació del checklist, el desenvolupament de la tècnica d'intubació i precisar les possibles complicacions.

Beneficis i riscos esperats

Vostè no obtindrà beneficis directes, però amb aquest estudi es podrà conèixer si l'aplicació d'un checklist en el procediment d'intubació de seqüència ràpida és útil per disminuir les possibles complicacions derivades d'aquesta tècnica, que seria beneficiós per futurs pacients atesos per les unitats SEM de Catalunya. Vostè no corre cap risc esperat derivat de la participació en l'estudi.

Confidencialitat

D'acord amb la Llei Orgànica 15/1999, de 13 de desembre, de protecció de dades de caràcter personal (LOPD) i Reial Decret 1720/2007, les dades personals i de salut (ja constin en la seva història clínica ja els hagi proporcionat com conseqüència de la seva participació en aquest estudi) que es recullin amb motiu d'aquest estudi són els necessaris per cobrir els objectius d'aquest. Aquestes dades seran identificats per mitjà d'un codi per garantir la confidencialitat de la seva identitat i únicament el metge tindrà accés a aquesta informació.

Tanmateix, els representants autoritzats del promotor poden necessitar accedir a la seva història clínica que conté dades personals (no codificats) per tal de garantir que l'estudi s'estigui duent a terme de forma adequada i que les dades documentats són correctes. També podran accedir a aquestes dades les autoritats sanitàries i el Comitè Ètic d'Investigació Clínica. Tots ells mantindran en tot moment la confidencialitat d'aquesta informació.

Les dades que es recullin amb motiu d'aquest estudi, entre els quals es trobaran dades personals i de salut (ja constin en la seva història clínica ja els hagi proporcionat com a conseqüència de la seva participació en aquest estudi) seran processats i analitzats per el SEM amb la finalitat d'avaluar-les científicament. Si vostè decideix participar en aquest estudi estarà consentint expressament en el tractament de les seves dades personals i de salut pel promotor. Tot això de conformitat amb la LOPD i amb la normativa que la desenvolupa.

Vostè podrà exercitar en qualsevol moment els seus drets d'accés, rectificació, cancel·lació i oposició dirigint-se al metge que l'atén en aquest estudi el qual ho ha de posar en coneixement del promotor.

Així mateix, els resultats de l'estudi poden ser comunicades a les autoritats sanitàries i eventualment a la comunitat científica a través de congressos i publicacions sense que la seva identitat sigui revelada en cap moment.

Preguntes / Informació:

Per fer alguna pregunta o aclarir algun tema relacionat amb l'estudi, o si necessita ajuda per qualsevol problema de salut relacionat amb aquest estudi, si us plau, no dubti en posar-se en contacte amb:

Dr: ..... Telèfon: .....

L'investigador li agraeix la seva inestimable col·laboració.

Annex 7. Informed consent of the study for the patient.

CONSENTIMENT INFORMAT PER A LA REALITZACIÓ DE L'ESTUDI

Gener 2019

TÍTOL DE L'ESTUDI: Avaluació de l'impacte de l'aplicació d'un checklist pre-procedimental en la seqüència d'intubació ràpida per disminuir les complicacions derivades del procediment en l'àmbit extrahospitalari.

CODI DEL PROMOTOR: .....

PROMOTOR: .....

INVESTIGADOR PRINCIPAL: Hisao Onaga, Alba Castellanos

CENTRE: .....

..... *(nom i cognoms),* com a representant de *nom i cognoms del participant),* .....

☐ He llegit el full d'informació que se m'ha lliurat.

☐ He pogut fer preguntes sobre l'estudi.

☐ He rebut prou informació sobre l'estudi.

☐ He parlat amb: ……..

☐ Comprenc que la meva participació és voluntària.

☐ Comprenc que puc retirar-me de l'estudi:

- Quan vulgui.
- Sense haver de donar explicacions.
- Sense que això repercuteixi en les meves cures mèdiques.

☐ Comprenc que tinc els drets d'accés, rectificació, supressió, oposició, limitació del tractament de dades i, fins i tot, a traslladar les meves dades a un tercer autoritzat (portabilitat), d'acord amb el que disposa el nou Reglament de Protecció de Dades (UE) 2016/679 del Parlament Europeu i del Consell, de 27 d'abril de 2016, relatiu a la protecció de les persones físiques en referència al tractament de dades personals i a la lliure circulació d'aquestes dades, i en el seu defecte, la Llei orgànica 15/1999, de 13 de desembre, de protecció de dades de caràcter personal, i el Reglament que la desplega.

☐ Presto lliurement la meva conformitat per participar en l'estudi i dono el meu consentiment per a l'accés i la utilització de les meves dades en les condicions que es detallen en el full d'informació al pacient i per la gravació durant l'atenció sanitària.

[Rúbrica del pacient] [Rúbrica de l'investigador]

Nom: ..... Nom: .....

Data: ..... / ..... / .....

Aquest document s'ha de firmar per duplicat i se n'ha de quedar una còpia l'investigador i una altra el pacient.

Annex 8. Informed consent of the study for the SEM personnel.

CONSENTIMENT INFORMAT PER A LA REALITZACIÓ DE L'ESTUDI

Gener 2019

TÍTOL DE L'ESTUDI: Avaluació de l'impacte de l'aplicació d'un checklist pre-procedimental en la seqüència d'intubació ràpida per disminuir les complicacions derivades del procediment en l'àmbit extrahospitalari.

CODI DEL PROMOTOR: .....

PROMOTOR: .....

INVESTIGADOR PRINCIPAL: Hisao Onaga, Alba Castellanos

CENTRE: .....

.....*(nom i cognoms del treballador)*

☐ He assistit a la reunió explicativa de l'estudi i rebut la informació suficient.

☐ Entenc que l'estudi inclou la gravació en vídeo de l'atenció sanitària que presto en les intubacions de seqüencia ràpida.

☐ Comprenc que la meva participació és voluntària.

☐ Comprenc que puc retirar-me de la participació en l'estudi:

- Quan vulgui.
- Sense haver de donar explicacions.

☐ Comprenc que tinc els drets d'accés, rectificació, supressió, oposició, limitació del tractament de dades i, fins i tot, a traslladar les meves dades a un tercer autoritzat (portabilitat), d'acord amb el que disposa el nou Reglament de Protecció de Dades (UE) 2016/679 del Parlament Europeu i del Consell, de 27 d'abril de 2016, relatiu a la protecció de les persones físiques en referència al tractament de dades personals i a la lliure circulació d'aquestes dades, i en el seu defecte, la Llei orgànica 15/1999, de 13 de desembre, de protecció de dades de caràcter personal, i el Reglament que la desplega.

☐ Presto lliurement la meva conformitat per participar en l'estudi i dono el meu consentiment per a ser gravat, si s'escau, durant l'atenció sanitària prestada en els procediments d'intubació de seqüència ràpida.

[Rúbrica del treballador] [Rúbrica de l'investigador]

Nom: ..... Nom: .....

Data: ..... / ..... / .....

Annex 9. RSI checklist evaluation sheet.

AVALUACIÓ DEL CHECKLIST PEL PROCEDIMENT D'INTUBACIÓ DE SEQÜÈNCIA RÀPIDA (RSI) EN L'ÀMBIT EXTRAHOSPITALARI PER PART DEL PERSONAL

Creus que el checklist de RSI és útil per estandarditzar el procediment?

☐ Sí.

☐ No.

Creus que els checklist restringeixen la llibertat de decisió dels metges/metgesses?

☐ Sí.

☐ No.

Utilitzes el checklist de RSI?

☐ Sempre. ☐ Sovint. ☐ Mai.

☐ Quasi sempre. ☐ Gairebé mai.

Creus que el checklist de RSI té un disseny clar i és fàcil de llegir/aplicar?

☐ Sí.

☐ No.

Creus que el checklist de RSI conté masses ítems a revisar?

☐ Sí. Quins creus que són prescindibles? .....

☐ No.

Creus que el checklist de RSI requereix massa temps en aplicar-lo?

☐ Sí.

☐ No.

Quines millores proposaries?

.....

.....

.....

.....

.....

.....

.....

.....

.....