

**RAPID SEQUENCE INTUBATION: A SURVEY OF CURRENT PRACTICE IN
THE SOUTH AFRICAN PRE-HOSPITAL SETTING**

By

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BTHJOH033

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PART A: LITERATURE REVIEW

Abbreviations

Abbreviation	Meaning
AAGBI	<i>Association of Anaesthetists of Great Britain and Ireland</i>
ALS	<i>Advanced Life Support</i>
ANT	<i>Ambulance Emergency Technician</i>
B. TECH	<i>Baccalaureus Technologiae</i>
BASICS	<i>British Association of Intermediated Care</i>
BLS	<i>Basic Life Support</i>
BTF	<i>Brain Trauma Foundation</i>
CCA	<i>Critical Care Assistant</i>
CME	<i>Continuous Medical Education</i>
CPD	<i>Continuing Professional Development</i>
CPP	<i>Cerebral Perfusion Pressure</i>
EC	<i>Emergency Centre</i>
ECP	<i>Emergency Care Practitioner</i>
ECT	<i>Emergency Care Technician</i>
EHAC	<i>European HEMS and Air Ambulance Committee</i>
EM	<i>Emergency Medicine</i>
EMC	<i>Emergency Medical Care</i>
EMS	<i>Emergency Medical Service</i>
EMSSA	<i>Emergency Medicine Society of South Africa</i>
EMT	<i>Emergency Medical Technicians</i>
EtCO ₂	<i>End-tidal Carbon Dioxide</i>
ETI	<i>Endotracheal Intubation</i>
ETT	<i>Endotracheal Tube</i>
FiO ₂	<i>Fraction of inspired oxygen</i>
GCS	<i>Glasgow Coma Scale</i>
HEI	<i>Higher Education Institutions</i>
HEMS	<i>Helicopter Emergency Medical Service</i>
HPCSA	<i>Health Professions Council of South Africa</i>
ICP	<i>Intracranial Pressure</i>
ILS	<i>Intermediate Life Support</i>
MeSH	<i>Medical Subject Headings</i>
MFI	<i>Medication Facilitated Intubation</i>
N. DIP	<i>National Diploma</i>
NMBAs	<i>Neuromuscular Blocking Agents</i>
PBEC	<i>Professional Board for Emergency Care</i>
PHEA	<i>Pre-hospital emergency anaesthesia</i>
QR	<i>Quick Response</i>
RCSA	<i>Resuscitation Council of Southern Africa</i>
RSI	<i>Rapid Sequence Intubation</i>
SOPs	<i>Standard Operating Procedures</i>
SpO ₂	<i>Peripheral capillary oxygen saturation</i>
SPSS	<i>Statistical Package for the Social Sciences</i>
UCT	<i>University of Cape Town</i>
UK	<i>United Kingdom</i>
USA	<i>United States of America</i>
VAL	<i>Video-Assisted Laryngoscopy</i>

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Background

Rapid Sequence Intubation (RSI) is a commonly performed advanced airway skill in the pre-hospital setting globally, practised by either physician or non-physician providers (1,2). Due to the constant advances in terms of newer techniques, medication and equipment, isolating a standard definition for RSI is difficult, however, it is generally defined as the administration of an induction agent to produce a state of unconsciousness, followed by a paralytic agent, to facilitate endotracheal intubation (ETI) (3).

Globally, differences in curricula and qualifications of non-physician emergency care providers or paramedics, that perform ETI either without any medication, medication facilitated intubation (MFI) and/or RSI in the pre-hospital setting, exist (4–7). It is therefore extremely difficult to draw clear comparisons between the practices of pre-hospital RSI in other countries and South Africa. Typically, non-physician providers that are licenced to perform RSI, received education and training pertaining to advanced airway management and are trained to an advanced life support (ALS) level (4,5).

In South Africa, not all ALS qualified emergency care providers are permitted to perform RSI (8). Exclusively emergency care providers who hold a higher education degree in EMC (e.g. B.Tech, BEMC and BHSc: EMC) and are registered as Emergency Care Practitioners (ECPs) are licenced to perform RSI (8,9). Considering that RSI was officially approved by the Health Professions Council of South Africa (HPCSA) in 2009, as an addition to the ECP scope of practice (9), it may be reasonable to say that it is a fairly new skill in the South African pre-hospital (8). Historically, emergency care providers registered with the HPCSA on the “Paramedic” or ANTs (registration number prefix: ANT: “*Ambulans Nood Tegnikus*”) register, were licenced to perform ETI either without medication or MFI, but not RSI. These providers obtained their Emergency Medical Care (EMC) qualification through either a short course method, which qualified them as Critical Care Assistants (CCA) or a tertiary level qualification, the National Diploma in EMC (N. Dip: EMC).

In 2019, the new Clinical Practice Guidelines (CPGs) for emergency care providers (8), published in 2018, came into effect that no longer permit ANT practitioners to perform ETI, using non-RSI (without medication or MFI) methods.

Worldwide RSI is regarded the gold standard in advanced airway management in critically ill and/or injured patients, mainly due to the optimal conditions created to facilitate ETI and limiting the physiological effects of the intubation (2,10). However, to allow for safe and effective RSI, the skill should be performed in a systematic manner that establish a safe

environment, including adequate patient preparation and management before the passage of an endotracheal tube (ETT) whilst ensuring optimal oxygenation, prevention of aspiration, normocapnia and normovolemia (2) and include post intubation care.

Furthermore, it is key to acknowledge that RSI is a high-risk skill and involves much more than merely ETI (11,12). Most RSI algorithms follow a similar sequence, although it may vary slightly from one organisation to the next. Usually, an RSI algorithm incorporates aspects of planning, preparation, protection of the cervical spine (when indicated), the positioning of the patient, preoxygenation, pre-intubation optimisation, induction, paralysis, placement of the ETT, confirmation of placement and lastly postintubation management (3,11–14). In addition, for safe and effective pre-hospital RSI there are specific requirements in terms of induction agents, paralytic agents, specialised equipment and an adequate amount of skilled team members to assist (3,11,15). Internationally it is recommended that RSI teams consist of at least three knowledgeable, skilled and proficient members to perform the skill (16). Furthermore, the role of appropriate education and training and clinical governance considerations are paramount to ensure the sound practice of the skill within the pre-hospital setting (17–19).

In 2011, a Position Statement was published by Stein et al (1), endorsed by the Emergency Medicine Society of South Africa (EMSSA) and the Resuscitation Council of Southern Africa (RCSA), which provided additional details on the requirements stipulated by the HPCSA in 2009 (9). The statement focused on three areas namely, training, system requirements and comprehensive clinical governance systems (Fig 1) in the hope to support the safe and effective implantation and delivery of pre-hospital RSI in South Africa. The authors indicated that the training component of RSI should incorporate the initial acquisition of theoretical knowledge and practical skill training (simulated and supervised clinical practice), to a point where a practitioner could be deemed proficient to perform RSI. However, the need for RSI and airway management specific continuous medical education (CME) activities was also highlighted. The second aspect that was addressed, was system requirements, which included the availability of adequate equipment for every attempted RSI and adequate personnel that are capable and knowledgeable to assist an ECP during advanced airway management. Lastly, the minimum standards explicitly indicate the necessity of a multidisciplinary comprehensive clinical governance system, which includes experienced oversight, clinical reviews and data collection that focus on RSI performance, complications and outcomes. Additionally, it was emphasised that RSI may not be achievable in all EMS

systems within South Africa, as resources to support ECPs to achieve high-quality care and safe practice, maybe lacking (1).



Fig 1 Minimum Standards of pre-hospital RSI in South Africa (1)

Since the approval of pre-hospital RSI in South Africa, many EMS services made efforts to support ECPs by providing specific equipment and medication to facilitate RSI and implemented policies or guidelines and training within their organisations. However, it is unknown is to what extent these arrangements filter down to the end-user level, which is necessary to support and enable ECPs to perform RSI. Furthermore, it is unknown whether the current practice aligns with the recommended standards of RSI in all public, private and/or non-governmental EMS systems.

Pre-hospital RSI remains a heavily debated topic, mainly due to inconclusive findings in terms of risks and benefits of non-physician performed prehospital RSI, skill maintenance and a lack of high-quality research in the specific setting (20). It could be argued that the minimum standards form the foundation and supportive framework for safe and effective pre-hospital RSI in South Africa. This research study, therefore, intends to highlight current pre-hospital RSI practices by ECPs and will broadly investigate all three components (training, system requirements and comprehensive clinical governance system) of the minimum standard to establish whether ECPs are supported by industry and educational institutions to perform safe and effective RSI. The rationale is to investigate from the bottom up, gathering information from the end-user, the ECP. Areas of concerns highlighted could produce a

starting point for further research and inform current pre-hospital RSI practices to produce system change and improvement.

Literature review objectives

A literature review was conducted, using two relevant electronic databases: PubMed and PubMed Central (PMC). These databases were selected based on their character to produce reliable, valid and applicable search results and index articles of various other databases (21). The literature review aimed to explore and describe research relevant to prehospital RSI in terms of existing minimum standards, which include the components of the three categories: education and training, system requirements and a comprehensive clinical governance system.

Search strategy

A systematic method using specific keywords and Boolean logic was employed for the search strategies. Free-text search terms were used, not to lose sensitivity in the searches and to allow for the inclusion of recent articles that may not have been indexed at the time.

A PubMed search was conducted on the 12th of July 2019 (9 results):

- Rapid Sequence Intubation OR Rapid Sequence Induction OR RSI AND Paramedic AND South Africa (3 results)
- Education AND Training AND Pre-hospital RSI (4 results)
- System Requirements AND Equipment Requirements AND Pre-hospital RSI (1 result)
- Clinical Governance System AND Pre-hospital RSI (1 result)

A PubMed Central search was conducted on the 12th of July 2019 (240 results)

- Rapid Sequence Intubation OR Rapid Sequence Induction OR RSI AND Paramedic AND South Africa (130 results)
- Education AND Training AND Pre-hospital RSI (63 results)
- System Requirements AND Equipment Requirements AND Pre-hospital RSI (26 results)
- Clinical Governance System AND Pre-hospital RSI (21 results)

Nine results were identified with the PubMed search and the PMC search yielding 240 results, in total 249 results. The titles were captured on separate spreadsheets in a Microsoft® Office Excel Workbook 2016, which included hyperlinks for easy internet retrieval. PubMed and PMC titles were evaluated for relevance to the research study. All the results were combined

and grouped alphabetically. A total of 39 duplicate titles were removed and the remaining 210 titles were evaluated against the inclusion/exclusion criteria.

Inclusion criteria were any keywords and/or phrases in the title and/or abstract that contained the following:

- Rapid Sequence Intubation or Induction or commonly referred to as RSI
- Paramedic and non-physician practitioner
- Pre-hospital, Prehospital, Emergency Medical Services/EMS, Ambulance, Critical Care
- Advanced airway management, emergency procedures, anaesthesia
- System and equipment requirements pertaining to RSI
- Clinical governance systems and education and training pertaining to RSI
- Any other titles that have relevance to the research study

Exclusion criteria were any keywords and/or phrases in the title/abstract that contained the following:

- Abstracts that are not relevant to the research study
- Poster presentations
- Conference proceedings
- Annual congresses and/or meetings
- Hospital, ED and/or intensive care unit airway management, intubation and/or RSI
- Animal studies
- Any other titles that do not hold any relevance to the research study topic

After applying the inclusion/exclusion criteria, a total of 64 titles remained. The full-text articles for all 64 titles were retrieved and re-evaluated against the inclusion/exclusion criteria. A total of 13 full-text articles were excluded and 52 full-text articles remained. The references of all 52 full-text articles were reviewed against the inclusion/exclusion criteria. A total of 45 full-text articles were identified, 12 full-text articles remained after duplications were removed.

Additional searches, using Medical Subject Headings (MeSH) terms were conducted on the 30th of October 2019. The following terms: "Intubation" [Mesh] OR "Intubation, Intratracheal" [Mesh] OR Rapid Sequence Intubation OR Rapid Sequence Induction AND Paramedic AND South Africa were used, on the PubMed (7 results) and PubMed Central (104 results) databases. All records identified were scrutinised. After removing duplicates and

applying the inclusion/exclusion criteria a total of 3 full-text articles remained. These 3 articles were subsequently excluded as they were found to be duplicates already included with the previous searches.

All records from the initial searches, the results from the full-text reference reviews and the additional MeSH searches combined with two additional records, published in 2019 and identified through other sources, were included (409). Eight-one duplicate records were excluded, after which 328 records were screened. The full-text articles of 84 records were retrieved and eligibility criteria applied while 244 record were excluded. After full-text assessment, a total of 66 studies were included in the qualitative synthesis of the literature review and 18 excluded. See below, a PRISMA diagram (Fig 2) presenting the literature review process.

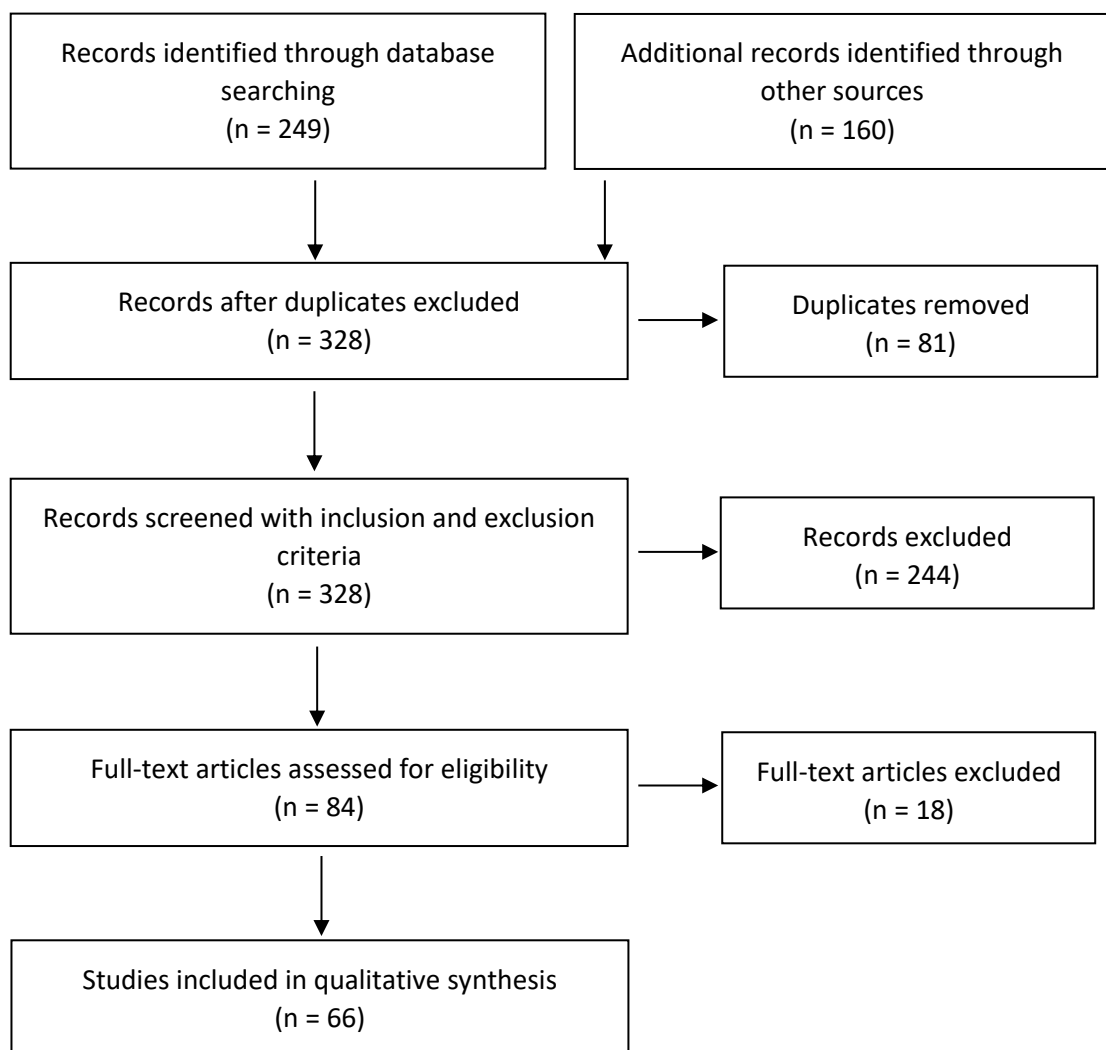


Fig 2 PRISMA diagram, detailing the literature review process

Literature review

The review identified literature on the topic of pre-hospital RSI, using the specified search strategies. An abundance of articles relating to pre-hospital ETI, MFI and/or RSI, some as recent as 2019, was found. Publications included systematic reviews and meta-analysis on the first pass and/or overall success rates of ETI and/or RSI in the pre-hospital setting, and, others, evaluating these findings according to the type of provider, physician vs. non-physician. Studies revealed serious concerns in terms of risks vs. benefits of the procedure and highlight specific adverse events that may contribute to increased mortality and morbidity rates. Recommendations were also made in terms of improvement of safety and efficacy of ETI and/or RSI in the pre-hospital setting.

The literature review aimed to contextualise this research study in terms of existing literature. During the literature review process, four themes emerged: RSI, an advanced airway skill in the pre-hospital setting, concerns regarding pre-hospital RSI, airway management equipment requirements in the pre-hospital setting and measures that support safe and effective RSI in the pre-hospital setting. The literature review will be presented using a thematic approach, following a descriptive and interpretive method.

RSI, an advanced airway management skill in the pre-hospital setting.

Desirable skill in selected pre-hospital emergency cases

Arguably the pre-hospital environment is not the ideal setting to perform high-risk procedures, such as RSI (22). In many emergencies, basic airway management may be suitable until the patient can be further managed at the Emergency Centre EC (23–25). However, there is evidence that supports pre-hospital RSI in some patients who may need immediate advanced airway interventions, which cannot be delayed until the EC or hospital arrival (24,26).

In 2007, an expert panel consisting of researchers in emergency medicine (EM) and trauma surgery was assembled by the Brain Trauma Foundation (BTF), located in the United States of America (USA), to interpret the literature and reach consensus regarding the appropriateness of pre-hospital paramedic RSI. They found that, the then current, literature pertaining to pre-hospital RSI were limited and often heterogeneous in nature, which made findings often inconclusive. Therefore, more detailed research was recommended. It was reported that the decision to perform pre-hospital RSI should incorporate other assessments, and not exclusively the Glasgow Coma Scale (GCS), as this practice may be inadequate. They advised that the reporting of successful paramedic RSI cannot only be viewed as ETT

placement and should include appropriate overall management of the patient, for example preventing hypoxia and delivering appropriate ventilation. They found variations in terms of provider education, training and skill maintenance in EMS systems. However, they reported that small groups of paramedics who were trained at a similar level compared to hospital providers and regularly perform RSI, showed high RSI success rates, low adverse events and no significant delays of transportation to definitive care. The importance of a supportive framework, which includes strong medical direction and oversight, protocol development, cognitive and technical training, appropriate pre-hospital triage, skill maintenance, and performance improvement were highlighted. Collaboration between pre-hospital and hospital providers and an improvement programme were emphasised. They acknowledged that pre-hospital RSI is controversial, however, patients with a severe traumatic brain injury (TBI) may benefit (27). In the context of these findings, considering the extreme levels of interpersonal violence (28,29) and motor vehicle accidents (30) in South Africa, the likelihood of ECPs encountering patients that sustained some degree of a TBI requiring immediate advanced airway management or RSI may be high. Which support the need for pre-hospital RSI in South Africa, as recognised and approved by the HPCSA (9).

In 2018, Crewdson et al (19) summarised research conducted on the topic of airway management in pre-hospital critical care since 2011. The authors deemed it a controversial subject in terms of risk vs. benefit. The article sheds light on some important aspects, especially related to advanced airway management or often referred to as pre-hospital anaesthesia. Instead of establishing whether there is a need for pre-hospital intubation or RSI, the search was to establish whether there are unmet needs in terms of patients that require ETI/RSI. The results found that approximately 10% of all patients that were admitted to emergency centres (ECs), in a USA study setting, required advanced airway management within the first few hours of admission (19). In contrast, an earlier United Kingdom (UK) study published by Lyon et al (31) in 2015 found that approximately 57% of patients which required basic airway interventions by ambulance crews, also required pre-hospital ETI/RSI by a physician-paramedic team. This suggests that there may be a varying number of patients (depending on EMS setting) encountered in the pre-hospital setting which requires ETI/RSI. Processing this information, it supports similar findings from other literature indicating that the heterogeneity of research impacts greatly on the conclusions that are made in terms of pre-hospital ETI/RSI. Crewdson et al (19) further reported that despite the high adverse events and complication risks associated with pre-hospital ETI, there are a specific group of patients that would most definitely require immediate intervention and pre-hospital ETT

placement. These patients, however, must be mindfully selected as the pre-hospital environment are, compared to an EC, a more challenging environment. The importance of apnoeic oxygenation and post-intubation care were highlighted, as both these interventions could significantly contribute to reducing the incidence of adverse events associated with performing pre-hospital ETI/RSI. The findings indicate the need to improve the reporting of information in the pre-hospital environment, as it may increase the validity and reliability of data and produce more trustworthy conclusions (19).

An ideal method of pre-hospital intubation

The new CPGs for emergency care providers in South Africa indicate RSI as the “*method of choice for facilitated intubation*” (8). In the context of RSI being regarded as the gold standard of advanced airway management, a recent prospective observational study published by Okubo et al (10) in 2017 in Japan aimed to compare the effectiveness of non-RSI with RSI in ECs. The study design favoured robust results with a reduced risk of selection bias and confounding variables (10). A secondary analysis of the data from the multicentre prospective observational registry at thirteen Japanese ECs identified 2365 eligible patients of which 761 (32%) underwent ETI using RSI and 1604 (68%) non-RSI. Of the 1604 patients, 54% received a sedative only (MFI) and 45% underwent ETI without the use of any medication. They found that RSI had a 2.3 (95%CI 1.8–2.9; $P<0.0001$) times higher success rate on the first attempt compared to those receiving non-RSI (73% vs. 63%). Although this study was conducted in an EC setting, which may be regarded as more ideal compared to the pre-hospital setting, the benefit of RSI over non-RSI in terms of higher first pass success rate is clear. However, the risks for adverse events, using the RSI method, were reported not significantly different when compared to non-RSI (10).

Myers et al (32), found that a substantial increase in success rates were achieved with the ability to visualise the glottic opening during pre-hospital ETI. A smaller ETT size (≤ 7.0 mm) was associated with an increased chance of ETI success rate, compared to a bigger ETT (≥ 7.5 mm) (OR 4.25; $p=0.01$). A higher likelihood of ETI success was associated with a partial view (OR 12.98; $p=0.001$) of the glottic opening or an entire view (OR 39.78; $p<0.001$) of the glottic opening, compared to little or no view. No other aspects were found to be associated with ETI success rates, after adjustment for the glottic view. The success rate was, however, self-reported by the paramedics (32). An improved glottic view may be achieved with the administration of a paralytic agent with RSI (8,9,33,34).

Concerns regarding pre-hospital RSI

Non-physician providers performing pre-hospital ETI and/or RSI

Another heavily debated and researched topic is non-physician pre-hospital ETI and/or RSI. In 2007, before approval of RSI as part of the scope of practice of ECPs in South Africa (9), Lockey and Porter (35) raised concerns with regards to poorly performed pre-hospital RSI in the UK that may result in unnecessary morbidity and mortality. Already then, they recommended that pre-hospital RSI should only be performed by appropriately trained and competent practitioners working in a properly structured pre-hospital system (35), which coincide with the findings of the BTF in the USA (27).

A year later, Haas and Nathens (24) published an opinion review, in which they debated whether EMS systems should rather reduce the number of advanced level interventions, such as ETI and/or RSI, in the pre-hospital setting, to allow for quicker transportation and access to definitive care. Although the literature reviewed produced conflicting evidence and evidence of heterogeneity of the research, concerns were still highlighted that pre-hospital ETI and/or RSI could potentially increase mortality and morbidity. It was concluded that potential harm and a delay in transportation may outweigh the benefits. However, they acknowledged that in some situations patients may benefit from pre-hospital advanced airway management, especially in places with long transport times, such as rural environments and/or in well-developed and efficiently developed EMS systems that deliver ALS care (24).

ETI success rates

In 2011, Lossius et al (7), published a systematic review pertaining to the value of pre-hospital ETI. They found it difficult to compare and interpret the literature mainly due to the heterogeneity in terms of providers, procedures, patients, systems and outcomes. The core variables mostly reported, such as patient type, had little significance in terms of the actual process of airway management, whereas other core variables that may have more value such as the number of airway intervention attempts and/or post-intervention End-tidal Carbon Dioxide (EtCO₂) readings were poorly recorded. They found incomplete records of the airway variables, as stipulated by the Utstein airway template (36). Regardless of the attempt made by the authors, in this case, it is extremely difficult to interpret and draw generalisable conclusions from such data. They indicated the need for standardisation of international documentation of pre-hospital advanced airway management. This would allow for data to be more reliable, which thus could be analysed to make recommendations and direct the

future of pre-hospital ETI in terms of utility, safety and efficacy (7). No known published literature pertaining to the completeness and quality of South African pre-hospital clinical recordkeeping exist, however, a retrospective case review of ETI documentation in two ECs in Cape Town, South Africa, found the quality to be poor (39). Similarly to what was suggested by Lossius et al (7), they recommended that the development and implementation of a standardised form could improve the quality of record-keeping for ETI (37). Recordkeeping and completeness thereof are extremely important in terms of clinical governance and improvement (38) as well as adverse event and risk monitoring (39).

A meta-analysis, published by Lossius et al (40) in 2012, focussed on intubation success rates amongst EMS providers. The studies were grouped according to provider profile, physician vs. non-physician (paramedic or nurse provider). A total of 29 non-physician and 7 physician studies were included. A weighted linear regression analysis was performed and found that on average physicians had an overall higher success rate (99%) compared with non-physicians (85%). However, in the non-physician studies, some utilised MFI and other RSI, which could have produced a lower success rate, as suggested by Okubo et al (10). The high failure rate in the non-physician group raised patient safety concerns, subsequently, it was suggested that basic and other advanced airway management techniques, other than ETI, should rather be performed by non-physician providers (40).

In 2013, Rognås et al (41) published a prospective descriptive study, in the Central Denmark Region. The aim of the study was to describe pre-hospital advanced airway management (41) performed in the same setting, where a previous study was conducted, describing the study population to be qualified and experienced physicians (42). They found that the ETI success rate (85.8%), amongst patients of all ages, was similar when compared to other studies that were conducted in the pre-hospital setting, staffed by physicians and non-physicians. The results indicated difficult or impossible pre-hospital ETIs were encountered in 47,2% of the cases. The complication rate pertaining specifically to RSI was found to be 22% (n=76). The reported complications of RSI performed by experienced anaesthesiologists included frequently reported adverse events, such as hypoxia, bradycardia, hypotension and oesophageal intubation. On average a critical care physician performs approximately 14,5 ETIs per month with only one ETI occurring in the pre-hospital setting (41). These findings concur with other published studies, which suggest that the practice of ETI and/or RSI are extremely complex when performed in the pre-hospital environment (25,43).

Jacobs and Grabinsky (44), reported in 2014, on the advances in pre-hospital airway management and acknowledged that airway management in the pre-hospital setting

remains a key component of EMC. However, the role of training, education and exposure to the procedure are major contributors to ETI success and improved patient outcome. They also found a relationship between experience in ETI and success rates. It was suggested that collaboration between anaesthesia departments and pre-hospital setting should occur, as anaesthesia departments have more experience and exposure to different airway management adjuncts and techniques (44).

A large systematic review and meta-analysis conducted in 2015 by Bossers et al (45), aimed to establish whether experience in pre-hospital ETI influences mortality of patients with severe TBI. They found that limited experience in performing pre-hospital ETI was associated with increased mortality. However, a notable trend towards improved mortality was observed with ETI performed by well-trained personnel, although their results were inconclusive (45). This may indicate that the amount of experience through practical exposure ECPs receive, before attempting autonomous pre-hospital RSI may be of value especially in patients with TBI.

An analysis of pre-hospital airway management was conducted in an EMS system in the USA by Prekker et al (46) in 2014. The study aimed to describe the challenges and solutions during paramedic ETI, from 2006 to 2011. Similar to South African ECPs (9), all paramedics were trained and registered to perform RSI (46). Data were retrospectively obtained from a registry. The criteria for an intubation attempt was defined as *“the introduction of the laryngoscope into the patient’s mouth, and the attempt concluded when the laryngoscope was removed from the mouth”*. The study included a total of 7523 advanced airway management procedures. They found a first pass success rate of 77% and an overall success rate of 99%. In 33% of patients, the inability to pass the ETT with the first attempt was contributed to obstruction of the laryngeal view with body fluids (50%), obesity (28%), patient positioning (17%) and facial or spinal trauma (6%) (46). Although there may be significant challenges associated with performing pre-hospital ETI, it may be possible for paramedics to achieve a high success rate and low adverse event rate in EMS systems that have standard operating procedures (SOPs), CPGs, appropriate equipment and provides continues education and training (46).

Brown et al (47), retrospectively reviewed data from a helicopter EMS (HEMS) in the USA staffed by non-physicians trained to perform advanced airway management. During a two-year period (2007 to 2009), 4871 patients received advanced airway management of which 55,1% were trauma-related emergencies and the remaining medical-related (44,9%). The first attempt success rate was 78.9% and the overall success rate 91.7%. The overall success

rate for medical patients (93.4%) was slightly higher compared to trauma patients (90.3%). In a similar, but a smaller descriptive study conducted in a non-physician HEMS system in South Africa, Stassen et al (48) reported a first pass success rate of 79% and overall success rate of 98%, predominantly in trauma patients.

An Australian study by Bernard et al (49) found a high success rate amongst paramedics performing RSI in non-traumatic coma patients. The study included 1152 paramedic RSI attempts, of which 551 (47.8%) were non-traumatic coma cases with a 97.5% success rate. Despite the high RSI success rate, a marked decrease in the mean systolic blood pressure (SBP) associated with paramedic RSI was observed (49), which may have a negative effect on cerebral perfusion pressure and possibly patient outcome, which is a similar concern in TBI patients (50).

A retrospective observational study, conducted in the pre-hospital setting of South Africa, by Gunning et al (51) reported that a total of 86 RSIs were performed during a one-year study period with no self-reported failed intubations by paramedics, although a significant adverse event rate (22%) was reported. Study limitations included the study design, small sample size and subjective completion of documentation (51).

Stein et al (52) published a case series, pertaining to student-ECP RSI in Johannesburg South Africa. The results also reported a high overall first pass success rate of 87,9% (student and supervisor) while the student success rate was 85,2%. Wahlin et al (53) obtained similar results, from a study conducted in Stockholm Sweden, pertaining to first pass ETI, in a research study that assessed the efficacy of pre-hospital intubation in TBI patients. Pre-hospital and hospital records were retrospectively reviewed. They found an 85% first pass success rate in patients that received ETI in the pre-hospital setting, provided by emergency care providers which include physicians, nurse anaesthetist and emergency medical technicians (EMTs) (53).

In 2017, Fouche et al (54), conducted a systematic review and meta-analysis, which included 83 studies. In terms of overall RSI success rate, it was found that non-physicians had an overall success rate of 97%, whilst physicians had a 99% success rate. They, furthermore, found that physicians had a higher first pass success rate of 88% compared to the 78% when performed by non-physicians (54). The results from this study were significantly higher, compared to the success rates published in a meta-analysis five years earlier (40).

Another systematic review and meta-analysis were published by Crewdson et al (17) in 2017, which included articles published between 2006 and 2016. Nineteen of the 38 articles that

were included were of non-physician providers. Similarly, to the methods used by Lossius et al in 2012 (40), a weighted linear regression analysis was performed to establish the association between ETI success rates and the type of provider. The overall ETI success rate was reported as 96,9% (95% CI 61.5-100), while the random-effects meta-analysis a 95,3% (95% CI 93.8-96.5) estimated overall ETI success rate was observed. For non-physicians the ETI success rate was 91,7% (95% CI 61.6-100), while for physicians it was reported as 98,8% (95% CI 78.1-100, $p=0.003$). Although an improvement was observed in the reported overall ETI success rate of pre-hospital ETI, nevertheless the difference between physician and non-physician was still found to be significant. The median first pass success rate for ETIs was found to be lower compared to the results published by Fouche et al (54) in both groups. The physician first pass success rate was 87.2% and 69.6% for non-physicians. An increase in mortality and morbidity are associated with poorer first pass success rates. It was therefore recommended that providers receive adequate training and practice, which will enable safe practice of the skill in the pre-hospital setting (23).

Another, systematic review and meta-analysis published in 2017 by Fevang et al (6) compared the mortality of pre-hospital and EC ETI in trauma patients. Twelve of the 21 studies that were included found an increase in mortality rate after pre-hospital ETI.

after pre-hospital intubation, in 7 studies there was no significant difference between pre-hospital and EC ETI, in one study there was a higher mortality rate was found in in EC ETI and the remaining study reported data beyond the scope of the article. One randomised control trial (RCT) and sixteen observational studies were included, which are lower-level clinical evidence and may be influenced by several confounding factors. The heterogeneity of the studies was found to be extremely high, 89% and 86% respectively, which makes comparing results impossible. It may be expected where a similar skill is performed in different environments that it would have different outcomes, similar as to intubation that is performed in an extremely optimised environment, even comparing ETI in an operating theatre with an EC. Nevertheless, they found that a median mortality rate in patients that received pre-hospital intubation to be 48%, compared to 29% in patients receiving intubation in an EC. Both the crude (OR 2.56, 95% CI: 2.06 - 3.18) and adjusted (OR 2.59, 95% CI: 1.97 - 3.39) mortality OR were found to be in favour of ED ETI. Further research was recommended to establish the causes related to the increased mortality rate in pre-hospital ETI, which was considered to be a complex procedure when performed in the pre-hospital setting (6).

Pre-hospital ETI and/or RSI in paediatrics

Airway management in paediatric patients is considered a special circumstance of RSI and maybe an additional challenge for some providers (55). Tarpgaard et al (56) conducted a study in the pre-hospital setting of Central Denmark, a similar setting as the study published by Rognås et al (41), wherein advanced airway management in children performed by highly trained, skilled and experienced physicians were described. A total of 73 patients required advanced airway management, of which the leading indications for ETI were decreased level of consciousness (n=24), cardiac arrest (n=15) and hypoxia (n=13). They found a first pass success rate of 75% in all children <16 years. A lower first pass success rate was found with younger patients, in patients <2 years the first pass success rate was only 54%. In addition, it was found that adverse events were much more in the <2 years group (38%) compared to the whole group which included all patients <16 years of age (20%). An overall success rate of ETI was reported as 99.7% for all patients <16 years of age (56).

In 2018, Heschl et al (57) published an article, in which they aimed to compare the mortality and functional outcomes of children who sustain a TBI and received either pre-hospital RSI or no intubation. Providers that performed the RSI, were Intensive Care Paramedics (ICPs) working in Victoria, Australia. Patients either received RSI by an ICP and flown with a rotor-wing air ambulance (2005–2013) or transported by ground ambulance where no ETIs were performed (2006–2013). Of the 106 patients that were included in the study, 87 received paramedic RSI and the remaining 19 were not intubated. A 93% first pass and a 99% overall success rate were reported. After 6 months, no difference was found in the unadjusted mortality and morbidity rates between the groups (57).

Adverse events associated with pre-hospital ETI and/or RSI

Although overall intubation success rates may seem to be improving and to some degree more in some systems than others, there are still concerns in terms of adverse events that occur as a direct result of ETI and/or RSI in the pre-hospital setting. A South African retrospective observational study, published in 2013, by Gunning et al (51) found that one out of every five (22%) patients that received pre-hospital RSI presented with an adverse event. Adverse events included haemodynamic instability (11.6%), tension pneumothorax (3.5%), difficult intubation (2.3%), low and high ETCO₂ (1.2%) and bronchospasm (1.2%). Six of the patients that reportedly presented with an adverse effect in the pre-hospital setting, presented with either hypotension (n=4, 4.7%) or hypoxia (n=2, 2.3%) at handover to EC or HEMS staff. Subsequently, the authors highlighted the importance of a comprehensive

clinical governance programme to improve practice in terms of patient safety and quality care (51), which reiterate the sentiments of an editorial review by Spaite and Criss (58) in 2003. The authors expressed concerns with the implementation and practice of pre-hospital RSI without trustworthy evidence that such interventions could be performed in a safe and effective manner (58). The systematic review and meta-analysis by Fouche et al (54) reported similar adverse events (oesophageal intubations, hypoxia, cardiac arrest, endobronchial intubation, bradycardia, hypertension, hypotension and airway trauma) compared to those found by Gunning et al (51).

Dunford et al (59) found that desaturation was reported in 57% of patients that received paramedic RSI in the USA. A huge number of patients, 84%, that experienced desaturation, measured with SpO₂ (n=26) presented with initial SpO₂ values greater or equal to 90% using basic airway management prior to RSI. Additionally, 19% of these patients experienced bradycardia during desaturation events. However, paramedics reported ease of intubation in 84% of all cases. Concerns were raised with regards to the understanding of the seriousness of the derangements in SpO₂ and pulse rates during paramedic RSI (59). Albeit a relatively small study, these findings are significant in terms of patient safety and secondary brain injury.

In South Africa, patients with a TBI are a frequent encounter (29). A retrospective chart review by Stassen and Welzel (60) aimed to establish the prevalence of pre-hospital hypotension and hypoxaemia in patients with a moderate to severe blunt TBI. The results found that the prevalence of pre-hospital hypotension was 33.3% (n=22), hypoxaemia 37.9% (n=25) and 21.2% (n=14) of patients presented with hypotension and hypoxaemia combined. Only 5 (7.6%) patients were found not to present with either hypotension or hypoxaemia and/or a combination of the two. From the data, it was reported that hypotension and hypoxaemia were associated with haemorrhage (p=0.011) and chest injuries (p=0.001), respectively (60). In light of these findings, the need to optimise the haemodynamic status of patients (11,12) that require advanced airway management should be emphasised to improve the quality of care and reduce the risk of adverse events in TBI patients.

In 2017, Stein et al (52) published an article on student-ECP RSI in Johannesburg, South Africa. From all 223 RSI cases that were analysed, 5% (n=10) of cases progressed into cardiac arrest within 15 minutes after drug administration. Before RSI, approximately half of all the patients were either hypotensive (n=36, 16.1%) and hypoxemic (n=76, 34.1%), which are indicative of the presence of physiologically difficult airway scenarios that may increase the risk of adverse events. However, taking into consideration that many of the patients that received RSI were

trauma-related it is to be expected that the patients would be significantly compromised in terms of haemodynamic, oxygenation and ventilation status, with a high likelihood of an anatomically difficult airway as well which may have been caused by the initial traumatic event. Furthermore, the results indicate that 24% of all patients continued to present with hypotension (n=26) and hypoxemia (n=27) at handover, indicating an improvement in the condition of 26% of all patients that received RSI and accompanied pre-hospital management according to their injury and/or illness related condition (52).

Comparing the results of Stein et al (52) describing student-ECP RSI, with results obtained from a much larger study conducted by Sunde et al (61), in a physician-staffed HEMS (Europe and Australia), similar post-RSI adverse events were reported. Patients that received pre-hospital RSI, either presenting with trauma (n=843) or medical (n=422) emergencies still presented with hypoxia (3%) or hypotension (19%) at hospital admission. Although hypotension and hypoxemia are possible adverse events of RSI, it was unclear whether it was caused by RSI or the primary injury/illness.

The major concern in the management of TBI patients are adverse events, such as hypotension and hypoxia, that may lead to secondary brain injury (62). In an article published by Spaite et al (63) in 2017, it was suggested that if hypoxia and hypotension, combined, is present in patients in the pre-hospital setting it significantly increase the mortality of patients that sustained a major TBI. The study was conducted among 13151 cases that were admitted to a Level I trauma centre in Arizona, USA. A large number of the patients did not present with hypotension, nor hypoxia (n=11 545 or 87.8%), 604 presented with hypotension only (4.6%), 790 (6.0%) had hypoxia only and 212 (1.6%) had both hypotension and hypoxia. Mortality for the four groups was 5.6% (no hypotension or hypoxia), 20.7% (hypotension only), 28.1% (hypoxia only) and 43.9% (hypotension and hypoxia) respectively (63). Therefore, advanced airway management of TBI patients should aim to prevent secondary brain injury, that may be caused by these adverse events, in an effort to reduce mortality and morbidity (63).

However, as smaller recently published prospective cohort study published by Choffat et al (64) in 2019, indicated that pre-hospital intubation may improve outcomes in patients that present with a severe TBI and an Injury Severity Score (ISS) ≥ 25 . It must be noted that all pre-hospital intubations were performed by specifically trained physicians in anaesthesia and EM and not by non-physician or paramedic providers (64).

Chowdhury et al (65), conducted a review of relevant literature to inform CPGs pertaining to the initial pre-hospital management of TBI patients. They found that 22% (n=19) of patients had adverse events. Adverse events included hemodynamic instability (11.6%), tension pneumothorax (3.5%), difficult intubation (2.3%), low ET_{CO}₂ (2.3%), high ET_{CO}₂ (1.2%), and bronchospasm (1.2%), hypotensive (4.7%) and hypoxic (2.3%) (65). Their results found that hypotension and hypoxemia are important predictors for mortality. Therefore, they recommended that SpO₂ should be monitored during attempted RSI to avoid even short periods of hypoxemia. It was recommended to ensure normocarbia in these patients, which could readily be monitored with continuous waveform EtCO₂ capnography (65,66). Lastly, maintaining a mean arterial pressure (MAP) of ≥80mmHg in TBI patients in the pre-hospital setting, where other more invasive diagnostics such as intracranial pressure (ICP) measurements are not available, are extremely important to maintain an adequate cerebral perfusion pressure (CPP) (65).

A recent study published in 2018 by Struck et al (67) reported on the incidence of mechanical complications, risk factors and outcome of airway management, including intubation in trauma resuscitation patients in Germany. Data were prospectively collected between January 2010 and December 2015. A total of 401 airway management interventions were performed in 383 patients (72.8%), producing an overall adverse event rate of 13.2% (n=53). Airway management in the pre-hospital setting was required in 239 (62.4%) patients, which included 224 (93.7%) ETIs. They found that the pre-hospital adverse event rate was 16.7%, which included 19 more than one ETI attempts, 10 oesophageal ETIs, 8 main-stem bronchial ETIs and 3 incorrectly placed supraglottic airway devices (SADs). A total of 16 patients received a SAD and 4 were ventilated with a BVMR device. SADs were placed, either due to ETI failure (n=11) or as initial airway management in entrapped patients (n=5). Five of these patients were intubated before admission to the EC. Nine other airway management cases tended to by a HEMS physician, were reported to be successful. Advanced airway management was performed in 67 (17.5%) patients in the EC, with an adverse event rate of 13.4% (n=9). No adverse events were reported in 74 (19.3%) of ETIs that were performed in the operating theatre (OT), although a 19.0% (n=4) adverse event rate was reported in the Intensive Care Unit (ICU) during 21 (5.5%) ETIs. Two deaths (0.5%) were associated with unnoticed pre-hospital oesophageal ETIs. The overall airway management adverse events were similar in the early treatment phase (EMS and EC) compared with the later treatment phase (OT and ICU) (14.4 vs. 9.5%; p=0.217). The study revealed that mechanical complications of invasive emergency procedures (airway management, intercostal drain

insertion and central venous catheterisation) occurred in 26.2% of all severely injured patients. The study found that mechanical complications were associated with pre-hospital airway management and ISS (67).

Airway management equipment requirements in the pre-hospital setting

Essential equipment

The HPCSA provided limited guidance with regards to mandatory RSI equipment requirements (9). In 2010, EMSSA published a practice guideline for RSI (3,14) in the South African emergency environment, however, the document clearly indicated that the intention of the publication was only to provide advice on the then current recommended practice of RSI for ECs, emergency personnel and emergency care activities (3,14). Recommendations included standard airway equipment, a variety of laryngoscope handles and blades, bougie, rescue devices, surgical airway kits and EtCO₂ monitoring and other “*appropriate*” monitoring equipment should be considered as necessities (14). In March 2011, the Position Statement on pre-hospital RSI briefly indicated that equipment requirements should include: “*standard airway (with airway bougie) and other mandatory devices including endotracheal confirmation devices (CO₂ detection devices and others), alternative intubation equipment, rescue oxygenation devices and surgical airway kits*” (1). The new CPGs for all emergency care providers, do not explicitly indicate recommended or mandatory airway management equipment for pre-hospital RSI, although they do indicate or advise that every patient that do undergo pre-hospital RSI should have ECG, HR, NIBP, SpO₂ and EtCO₂ monitoring (8). In some sections, the use or availability of some airway management equipment was referred to for example a video laryngoscope (VL), blades, stylets, bougie, surgical airway, suction unit, BVMR and a mechanical ventilator (8).

The Association of Anaesthetists of Great Britain and Ireland (AAGBI) guidelines on safer pre-hospital anaesthesia of 2017 suggest that equipment used in the pre-hospital setting should be robust, portable and able to withstand all weather and light conditions (17). From this statement alone, one could argue that equipping a pre-hospital environment for RSI may be more challenging compared to an EC. The AAGBI guidelines suggest similar required equipment compared to those indicated in the RSI practice guideline published by EMSSA (14,17). Taking into account the reputation of all the institutions that approved (AAGBI Board of Directors) and endorsed (Royal College of Emergency Medicine, the Royal College of Anaesthetists, the Faculty of Prehospital Care, the Royal College of Surgeons of Edinburgh, British Association of Intermediated Care (BASICS) and BASICS Scotland the Department of

Military Anaesthesia, the Department of Military Pre-hospital Emergency Medicine and the Royal College of General Practitioners) the AAGBI Guidelines, one may consider these recommendations to be of a high standard. Therefore, it can be reasoned, if these mandatory equipment requirements are adhered to, it may favourably impact on the safety and efficacy of pre-hospital RSI.

Alternative airway devices

In recent years many alternative airway devices became more readily available (68,69) although some still are expensive to acquire compared to ETTs (70). Emergency airway management should focus on fast, safe and effective securing of the patient's airway and providing ventilation (8,17) and therefore alternative airway devices, such as an LMA or LT, could be considered (71,72) over ETI/RSI that may produce greater risk to the patient in terms of potential adverse events that may occur (6,19). However, in some cases such as indicated in the research that was conducted by Länkimäki et al (72), approximately 24% of all unconscious patients may require ETI to provide definitive airway management in the pre-hospital setting (72).

Sunde et al (73) published a prospective multicentre observational study in 2015, assessing advance airway management amongst various international physician-staffed HEMS (73). Data were collected over a 12-month period and a total of 14,703 patients were attended to, of which 16% (n=2,327) required advanced prehospital airway interventions. ETI was attempted in 92% (n=2144) patients. The remaining 8% (n=183) of patients, received either airway management with SADs (67%), bag valve mask reservoir (BVMR) ventilation (30%) or continuous positive airway pressure (CPAP) (3%). First pass failure rates were 14.5% and overall failure rates were 1.2%. All ETI failures were successfully managed with either BVMR ventilation (n=8), SADs (n=15), surgical airway (n=3) or intubation via existing tracheostomies (n=2) (73).

Davis et al (74) indicated the importance of a reliable strategy for failed RSI in the pre-hospital setting, such as the insertion of a Combitube as a rescue device for airway management in trauma patients. The results found that Combitube insertion was successful in 95,1% of attempts (n=58), with no self-reported complications. However, compared to the ETI group (n=355), slightly higher mean (42.5 mmHg) and median (41.0 mmHg) PCO₂ values were recorded in the Combitube group, which were contributed to physiological dead space and possible proximal cuff leaks (74). The use of SADs in airway management was somewhat downplayed until recently, where research indicates the use of SADs may be more beneficial

compared to ETI, especially in cardiac arrest cases (75,76). In advanced airway management, SADs are often utilised as a backup or rescue device in a failed airway scenario (41,71–73). However, a major drawback for the regular use of SADs in advanced airway management is that it can only be successfully inserted in patients with absent or near absent airway reflexes.

Länkimäki et al (72) conducted a study to determine the feasibility of the LMA extreme®, a type of SAD, in the pre-hospital setting amongst paramedics. The results found that all 21 placements of the LMA were successful on the first attempt, with a median time of 9,8 seconds from the start of placement to first ventilation through the device. Paramedics reported that all placements (n=21) were easy to perform. However, due to an air leak occurring after placement, two cases required an exchange of the LMA with a Laryngeal Tube (LT) and three cases required removal of the LMA and replacement with an ETT by intubation. In addition, it was noted that regurgitation occurred in two cases where the LMA was placed (72). Nevertheless, from these findings, the necessity of alternative airway devices as part of the mandatory equipment for pre-hospital RSI is apparent. Moreover, the ability to successfully provide airway management with either basic airway management or alternative advanced airway management techniques are significant.

A case series of five patient encounters in a UK pre-hospital setting was published by Mason (43), evaluating the use of an intubating LMA (iLMA) in patients with severe polytrauma. In all cases, the patients sustained serious multiple injuries and were trapped inside the vehicles. The results found that iLMA, which is designed to facilitate blind intubation, were successfully inserted in all patients. All the cases could be classified as difficult airways requiring immediate airway interventions. The clinical records of all the patients were independently analysed and exhibit an extremely low mean probability of survival (37.4%) according to the Trauma Audit and Research Network (TARN) in the UK. Nonetheless, the actual survival rate was 80%. In four of the five cases, the insertion of the iLMA was facilitated with the use of varying dosages of Midazolam, mean dosage of 5.625 mg. In the four cases that received Midazolam, no neuromuscular blocking agents (NMBAs) were used, therefore the respiratory effort was still present during the insertion of the iLMA. The only concern, with medication, facilitated insertion of an iLMA is that any gag and/or cough reflex could potentially contribute to a secondary insult in TBI patients. The patient that did not receive sedation to facilitate the insertion of the iLMA, was found to be in cardiac arrest. All four patients with perfusing rhythms survived to discharge from hospital. Benefits of using an iLMA in pre-hospital emergencies were found to be the limited advanced airway

management training required, blind insertion technique, limited mouth opening required, allow for progression to ETI if required and ability to ventilate between or during intubation attempts. The case series included a very small number of patients, and consequently offer weaker evidence, nevertheless, there were certainly benefit proved in terms of rapid reversal of hypoxaemia and positive patient outcomes. The iLMA proved to be an ideal alternative airway device, especially in patients that require immediate advanced airway management and/or present with difficult airways, either in terms of the challenging environment, compromised or difficult patient anatomy and/or physiological difficult airways (43).

Indirect laryngoscopy

Williamson et al (26) found that loss of airway and/or breathing in trauma patients require immediate airway management in the pre-hospital setting, as it may lead to quick deterioration and death. The use of video-assisted laryngoscopy (VAL) was suggested, as it has the potential to improve the success rates and facilitate a process to secure an unprotected airway and enable ventilation, especially in trauma patients. They suggested that the implementation of VAL, with advantages especially during difficult airway intubation and trauma patients, may encourage pre-hospital intubation to be practised regardless of controversies that often involve the lack of intubation skill, minimal training or experience by non-physician providers (26).

Gellerfors et al (77) published a retrospective review, evaluating the success rate of using the Airtraq® device (optical laryngoscope) in a Swedish pre-hospital setting. Data were analysed between January 2008 and December 2012, which included 2453 ETIs performed by either anaesthesiologist or nurse anaesthetists. The Airtraq® was used in 28 cases, of which 19 was deemed successful, whilst the majority of the patients (n=2425) were intubated either using the method of MFI or RSI (77). The low use of the Airtraq® (1%) was contributed to operator choice, familiarity with the Airtraq® device and self-confidence level with direct laryngoscopy (DL). The low success rate (68%) with the Airtraq® was reported as an improvement on previous findings with the Airtraq®. It was concluded that an increase in training and familiarisation with the Airtraq® and/or other VL devices could be contributing to improved indirect laryngoscopy (IL) and/or VAL success rates. Further research was suggested to determine the role of the Airtraq® device in the pre-hospital setting compared to VL devices, to establish the safety and efficacy of the Airtraq® (77).

Similarly, Boehringer et al (33) published a retrospective review of intubations that were performed by critical care flight paramedics and nurses in the USA. The data were obtained

from charts for the period 2006 to 2014. A total of 790 advanced airway encounters were included in the review. They found that after implementation of the CMAC pocket monitor® the overall ETI success increased from 94.9% to 99%, while the combined first and second pass success rates increased from 89.2% to 97.4%. In addition, the mean number of ETI attempts for all airway encounters whether successful or unsuccessful decreased significantly from 1.33 (n=593) attempts with DL to 1.08 (n=195) when using VAL with the CMAC pocket monitor® ($p<0.0001$) (33). ETI and/or RSI using VAL differ dramatically compared to DL with a standard laryngoscope. Implementation of VAL and/or performing of RSI in the pre-hospital setting require education and training, maintenance of skill proficiency, ongoing training, continuous quality improvement processes and protocols to achieve success. Since the use of indirect and/or VAL are a new phenomenon in the pre-hospital setting, it could be argued that operator familiarity with each device could contribute towards the success rate of performing ETI with these devices. It is therefore important that adequate training and simulated and/or supervised skill practice opportunities are provided to support the operator (78). VAL devices may not be commonly available in the South African pre-hospital setting, probably due to financial implications, however, there are a few local EMS that is following international trends by procuring VAL devices. Recent developments internationally are placing emphasis on the use of alternative airway devices rather than performing ETI/RSI, the use of VAL is gaining more favour over DL. VAL may offer various advantages such as better visualisation of the vocal cords and angulated blades may assist in guiding the ETT through the cords. However, VAL also has some drawbacks in terms of pragmatism in patients with excessive blood or fluid in their airways, expensive devices and pricey disposable components (78).

EtCO₂ analysis and measurement devices

A prospective study by Davis et al (79) suggested the positive impact of ETCO₂ monitoring during mechanical ventilation after ETI of traumatic brain injury patients (79). In another study, published in 2004 by Davis et al (80) found that the use of EtCO₂ monitoring, after paramedic RSI, in patients that sustained a TBI was associated with a decrease in inadvertent severe hyperventilation. The authors found that patients with EtCO₂ monitoring had a lower incidence of accidental hyperventilation than those without EtCO₂ monitoring (5.6% vs. 13.4%, $p=0.035$). Patients that were hyperventilated had a significantly higher mortality rate of 56%, compared to the 30% of those that were not hyperventilated (80). A prospective descriptive trial published in 2005 by Davis et al (50), conducted over three and a half years, found that more than three-quarters of all patients that receive paramedic RSI presented

with EtCO₂ readings, either above or below the normal range (30-35mmHg). After passing the ETT, hypercapnia was predominantly observed, with hypocapnia seen in patients that were ventilated with high ventilation rates after ETI (50). The value of EtCO₂ monitoring and appropriate ventilation should be highlighted during RSI practice, as there is an association between increased mortality (81) and risk of adverse events caused by inappropriate post paramedic RSI care, including ventilation (50,82).

A prospective study by Poste et al (83) found that severe head injury patients that received paramedic RSI had improved outcomes when simplified and standardise RSI medication protocols were followed. Only 3 ETI attempts were permitted, where after the insertion of a Combitube was mandatory. Target ventilation parameters were provided, in terms of rate and tidal volume which were used in conjunction with spirometry and EtCO₂ monitoring. A decrease in mortality was observed (28% vs 31%, OR 0.9). This finding suggests that the difference in outcome is highly likely as a result of SOPs and CPGs, optimal post intubation care and improved ventilation using capnometry (83).

The CPGs for emergency care providers (8) in South Africa indicate the mandatory use of EtCO₂ in various clinical settings, including during RSI, similar to the recommendations of the EMSSA RSI Guidelines of 2010 (3). Owen & Castle (66) published a South African case study in 2006, wherein they highlighted the importance of using EtCO₂ in patients that are hand ventilated using a BVMR. It is extremely difficult to deliver optimal ventilation with a BVMR without continuous monitoring of EtCO₂. They recommended mandatory early EtCO₂ use and mechanical ventilator be adopted (66).

Recently a South African study published by Wylie et al (84), highlighted concerns with regards to the knowledge and application of EtCO₂ by ECPs. A survey was administered amongst paramedics (n=66). The results, from scenario-based questions, revealed that 33% of respondents did not recognise that the EtCO₂ reading will increase due to a decrease in minute volume, 23% of participants incorrectly indicated that an increase in the fractional inspired oxygen (FiO₂) would decrease the EtCO₂, while 48% of participants did not recognise that poor perfusion may cause a decrease in EtCO₂ readings. Only 84,1% of respondents indicated that they received education and training pertaining to the use of capnography during their formal education, 40,5% indicated attendance of a two-day professional course and 24,1% indicated that they received in-service training. The availability of EtCO₂ consumables was found to be low for 37% (n=25). Only 77% (n=51) of the participants indicated that they always use capnography (84). The findings are concerning, as high or low EtCO₂ levels are adverse events (65), that can only be prevented by continuous monitoring

with either capnography (51,66) or capnometry (83). The overall poor ability to interpret basic abnormalities of capnography, the lack of clinical application and the decrease clinical utility of the device, despite reported availability, are problematic. Various literature indicates the importance of a high level of education and training of providers that deliver advanced airway management (40,41,44). Although it seems that there are some discrepancies in terms of ETCO₂ tertiary education and training, shortcomings may be effortlessly addressed with CME activities. EtCO₂, especially capnography, could be an extremely useful tool in overall patient management, however correct clinical application is key (50,66,80–83).

ETT cuff manometer

In 2014, Hardcastle et al (85) conducted a retrospective review of 65 intubated patients on admission at a Level 1 Trauma Centre in KwaZulu Natal South, Africa to determine the correctness of the ETT placement and cuff pressure. The patients admitted were classified as interfacility transfers (57%) or primary emergencies (43%). Their results found that the ETT cuff pressure of 50 (77%) patients was incorrect and in 13 (20%) cases the ETT was found to be placed anatomically incorrect. Thirty-one (47.7%) ETIs were performed by non-physician EMC providers and 34 (52.3%) by physicians. The authors raised concerns with regards to the considerable amount of incorrect ETT placements and the vast amount of cases where ETT cuff pressure was incorrect and suggested mandatory ETT manometry in all intubated patients and radiological confirmation of ETT placement before interfacility transportation (85).

Measures that support safe and effective RSI in the pre-hospital setting

Comprehensive Clinical Governance System

Clinical governance is described as a framework that supports high standards of care and ensuring the improvement of quality of care. It consists of six distinct components: Education, Clinical audit, Clinical effectiveness, Risk management, Research and development and Openness (86). South African literature and guidelines published at the time of pre-hospital RSI implementation (1,3,9,14) clearly stipulated the necessity of a comprehensive clinical governance system to enable the implementation and practice of non-physician pre-hospital RSI. Clinical governance is key to quality care in pre-hospital environments and with future developments, it may be a likely driver for transformation and improvement. A comprehensive clinical governance system is complex, and the specifics may vary depending on the needs of the EMS system. Daniel et al (27) suggested that paramedic

or non-physician RSI in the pre-hospital setting, especially for patients with a TBI, requires supportive infrastructure including strong clinical governance (27).

In 2015, Pepe et al (87) confirm in a published review that the prehospital setting is a challenging environment. The authors indicated that in many EMS systems it may not be feasible to implement and practice advanced airway management including ETI/RSI as the risks will inevitably outweigh the benefits. In their view, important aspects to reduce the risks when delivering advanced airway management are to have an EMS system that activates the most appropriate and trained providers to manage the patient, rigorous medical oversight that provides training and supervision to the providers practising the skill and controlled ventilatory techniques. Similarly, to the sentiments of Stein et al (1), it was emphasised that EMS systems that do not have the appropriate education, system requirements and governance framework need to be discouraged from practising ETI/RSI unless alternative processes are established to optimise the success of ETT placement (87).

Education and Training

As previously discussed, adequate education and training in terms of RSI are important contributors to the first pass and overall success rates (23,40,44). In 2007, Reed (88) published an article of prospectively recorded hospital ETIs over a five year period from one student physician in EM. It was found that the major adverse event during the first year of the study period was oesophageal intubation, which decreased during the subsequent years. Overall, as the student's proficiency to perform the skill improved, the occurrence of adverse events reduced after approximately 30 ETI procedures (88).

It is important to constantly aim for improvement in current practice, more so in patient population groups less frequently encountered during emergency care. To determine which aspects of pre-hospital paediatric airway management may contribute to patient safety events, Hansen et al (55), conducted a 3-phase Delphi study amongst pre-hospital providers in the USA. An online questionnaire was administered to 492 participants, which held various degrees of pre-hospital qualifications, namely paramedics (50,8%), emergency technicians/first responders (22%) and physicians (11,4%). Participants identified that the deficiency of advanced airway management experience (75%) and clinical decision making in terms of airway management interventions (44%) as factors that may impact patient safety. The technical skills that concerned practitioners the most were advanced airway management (71%) and BVMR ventilation (18%). ETI was identified as the leading contributor, causing safety events, followed by BVMR ventilation. Concerns in the

assessment and decision making domains were topped by performing a respiratory assessment and deciding whether to perform advanced airway management (55).

Continuous Medical Education

CME is considered a component of clinical governance in healthcare and is vital in the clinical practice environment, in both hospital and pre-hospital settings. Literature published on pre-hospital ETI and/or RSI, suggest a higher level of education, training and skill could contribute to higher overall and first pass success rates (23,40,54).

A recent opinion piece, published by Crewdson et al (19) in 2018, indicated that training and skill retention are key elements to provide safe and effective ETI in the pre-hospital setting (19). A retrospective observational study published by Fullerton et al (89), found that non-anaesthetic physicians have a higher failure rate when performing RSI in the pre-hospital setting compared to anaesthetists. The finding was contributed to the possible rarity of clinical exposure to ETI and suggested that improvement in pre-hospital airway management including RSI are a necessity (89).

A descriptive quality control study conducted by Trimmel et al (90) amongst non-anaesthesiologist EMS physicians working in both the hospital and pre-hospital settings in Austria. Base on the notion that low frequency of pre-hospital ETI encounters after initial training may contribute to skill decay a structured training program in anaesthesia, was implemented for EMS physicians. A retrospective evaluation of all the airway management cases for a twelve-year period found that the implementation of a comprehensive training programme, which assures >60 additional ETIs per year, appears to be feasible and was associated with lower failure rates (90).

Correspondingly, McQueen et al (91) conducted a retrospective review of data from a Medical Emergency Response Team (MERIT) in the UK to describe pre-hospital RSI practice. MERIT teams consist of a highly trained physician and non-physician providers. The team was dispatched to 1619 calls, attended to 1029 cases and performed 142 RSIs, during a period of twelve months. The ETI first pass success rate was 90%, with one reported failed ETI, requiring the placement of a SAD (0.7%). This study demonstrates that providers that operate in a system where there is a clinical governance system, high exposure and education and training, may lead to high performance of pre-hospital RSI (91).

Simulated practice

Simulated practice in airway management is not a new method in airway management education and training. In 1999, Ellis and Hughes (92) reported on the value and fidelity of simulation-based training in addition to existing teaching methods such as human patient simulation and theoretical assessments in emergency care education. They found that students were able to safely practise skills, including ETI, in a dynamic and interesting environment that is free of risk of injury to the patient. It was suggested that adding simulators to the emergency care teaching environment would be of great worth, especially in terms of the then already much anticipated evolution and advances in technology and innovation (92).

A recent literature review published by Abelson et al (93) in 2014, on the use of simulation in pre-hospital care aimed to provide an overview of the development and focus of research on the use of simulation in pre-hospital care. It was found that the use of simulated training, specifically for ETI contributed positively towards the improvement of the skill itself (93). Whalen et al (94) likewise recommended that the use of simulated scenarios which include innovation and technology could assist in teaching much needed skills to providers that may suffer from skill decay due to the low frequency of managing high acuity patients, for example in rural EMS systems (94).

RSI team composition

South Africa has a predominantly non-physician ALS (ECT, ANT and ECP), intermediate life support (ILS) and basic life support (BLS) provider population (8). Although some EMS services and organisations do have physicians within their structures, they mostly fulfil managerial, consultation and occasionally operational capacities (95).

Pre-hospital RSI by non-physician providers may be optimised by sometimes seemingly insignificant changes to current practice, as reported by Myers et al (32) that conducted a retrospective review in a pre-hospital setting. In 12527 emergencies attended to, a total of 200 ETI attempts were made in 150 patients, of which 113 (75%) was successful. They found that crew composition may play an important role in advanced airway management success. Crews consisting of paramedics only, compared to a paramedic and emergency medical technician (EMT) crews are reported to be three times more likely to achieve successful intubation (OR 3.30; p=0.03) (32) This finding may possibly be due to the similar level of education, knowledge and skill of both paramedic crew members, compared to a paramedic

and an EMT. The value of a skilled and knowledgeable assistant to the primary provider should be appreciated (32).

Key Performance Indicators

Raitt et al (39) aimed to develop Key Performance Indicators (KPI) for pre-hospital emergency anaesthesia, by using the AAGBI 2017 Guideline: Safer pre-hospital anaesthesia 2017 (17). A total of 82 cases were analysed and subjectively reviewed over a year. Domains with the highest percentage of achievement were the indication to perform emergency anaesthesia (96%), confirmation of tube placement or position (94%), full monitoring according to the AAGBI 2017 Guideline (89%) and a grade view of <3 (89%). Their results found an improvement in clinical records, equipment upgrades, educational initiatives and processes, which subsequently led to an improvement of practice and patient care (39).

Standard Operating Procedures and Clinical Practice Guidelines

The implementation and update of SOPs and CPGs to establish an agreed upon standard of practice for pre-hospital RSI are paramount to achieve good practice (25,38,86).

A review article published by Lockey et al (25) reiterated the sentiment of Haas and Nathens (24) with regards to the potential detrimental effect that poorly performed ETI and/or RSI in the pre-hospital setting may have on patients. Lockey et al (25), recognised that pre-hospital ETI and/or RSI may produce many challenges and therefore the implementation of SOPs and CPGs are compulsory (25).

A study conducted by Soti et al (96) reported that the implementation of pre-hospital advanced airway management SOPs (adopted from a London, UK HEMS system) into an established Hungarian HEMS system improved the ETI first pass and overall success rate, dramatically. After the implementation, first pass (95.4%) and overall success (99.1%) rates improved significantly (96). These results demonstrate that improvement, even in an established system, is doable when based on a proven model.

Three consecutive studies were published, by Rognås et al (41,42,97) in the pre-hospital setting of the Central Denmark Region. The first study gathered data amongst EMS physicians in terms of pre-hospital advanced airway management-training and expertise (42). They found that 98,1% were specialists in anaesthesiology, with an average of 17,6 years of experience in anaesthesiology and 7,2 years of experience as EMS-physicians. A total of 34 (64,2%) attended one or more advanced airway management course, however, only 13 (24,5%) fulfilled the suggested Danish curriculum for EMS physicians. Despite the reported

years of experience and education and training, a lack of equipment awareness was found (42). The second study (41) found similar ETI success rates and adverse events when performed by non-physicians. Therefore, the findings of these two studies combined, concur with the other published studies which allude that the practice of advanced airway management, intubation and/or RSI are extremely complex when performed in the pre-hospital environment (25,43). Both studies recommended the implementation of SOPs, CPGs and checklists, as it could possibly improve advanced airway management (41,42). Subsequently, Rognås et al (97) conducted a prospective quality control study amongst pre-hospital critical care teams and found a significant increase in the use of mechanical ventilation in TBI and patients presenting with a return of spontaneous circulation (ROSC) following pre-hospital cardiac arrest, after the implementation of a relevant SOP (97). These results support the notion that implementation of SOPs may produce a positive change in practice.

Recently Spaite et al (98) published an article that evaluated the association of implementing evidence-based pre-hospital TBI treatment guidelines, focussing on the prevention and treatment of hypoxia, hypotension and hyperventilation, with the outcomes in patients with TBI. The study was conducted in phases from the 1st of January 2007 to the 30th of June 2015. They found a significant improvement of SpO₂ in all patients managed only by agencies in the pre-intervention phase (P1, 35.6%) and patients managed only by agencies in the post-intervention phase (P3, 40.9%) and intubated cohort (P1, 44.2% and P3, 54.6%). The rates of administering intravenous fluid boluses and the volume infused increased in P3. Furthermore, after implementation, patients with hypotension were more likely to arrive at the EC with higher SBP compared with their pre-hospital SBP. Among patients receiving positive-pressure ventilation (PPV), the rate of basic airway management only, with a BVMR increased (P1, 15.1% and P3 21.8%). Among intubated patients, the rate of hypocapnia (EtCO₂ <35 mmHg, indicating hyperventilation) decreased significantly after implementation (P1, 60.5% and P3, 52.2%). Patients with severe TBI who received any method of PPV (BVMR, supraglottic/extraglottic airway, or ETI) showed marked survival improvement after implementation. The simultaneous increase in survival to hospital admission ($p < 0.001$), supported their conclusion that the implementation of pre-hospital TBI guidelines was associated with the improvement in patient outcomes. Although the state-wide implementation of the pre-hospital TBI guidelines was not associated with improved overall survival, they did conclude that survival doubled among patients with severe TBI and tripled in the patients with severe TBI who received PPV and/or ETI (98).

A new European guideline *“Best practice advice on pre-hospital emergency anaesthesia and advanced airway management”*, was published at the beginning of 2019 by Crewdson et al (18) and members of the European HEMS and Air Ambulance Committee (EHAC) medical working group. The guideline stipulate the standards for best practice of pre-hospital emergency anaesthesia (PHEA) in terms of training requirements and continuous professional development of providers performing RSI, planning for the event of RSI, essential equipment required for all RSI attempts, conduct of the RSI in terms of SOPs for individual services, utilisation of checklists, RSI preparation, post-RSI care, mechanical ventilation, mandatory monitoring parameters and KPIs pertaining to system, patient and post-RSI variables. This guideline, highlight the complexity and level of requirements needed to perform safe and effective pre-hospital ETI/RSI (18). Although the guideline was produced through rigorous processes, it does not specifically discuss all previously stipulated standards and guidelines. Nevertheless, it does provide recent and relevant detail to specific areas identified to improve pre-hospital anaesthesia and advanced airway management.

Summary and conclusion

Pre-hospital RSI is an extremely complex process, although it is more ideal compared to other ETI methods and may hold a benefit, albeit, only for a small selected group of patients that require immediate advanced airway management. It may also hold a benefit in EMS systems that has increased transport times to definitive care, such as rural pre-hospital settings in South Africa. Still, it is a high-risk procedure, with many risks to the patient in terms of mortality and morbidity rates and should therefore only be practised in EMS systems that are able to support safe and effective delivery.

The literature indicated that first pass and overall success rates of ETI, including the type and number of adverse events vary globally. Although recent evidence reports an improvement in terms of the pre-hospital first pass and overall success rates of ETI, studies are often limited due to self-reported success and heterogeneity of data. The occurrence of adverse events is expected with any high-risk procedure, such as RSI, even more so in a challenging environment such as the pre-hospital setting. Nevertheless, poor first pass and overall ETI success rates and high adverse events should be of great concern as it contributes to increased mortality and morbidity rates amongst patients that receive pre-hospital RSI. It is imperative to have appropriate measures that identify and seek causality in order to adjust or implement strategies to improve.

Although there may be many differences between the practice of pre-hospital RSI internationally in terms of SOPs, CPGs, RSI curriculums, team compositions etc., the literature clearly indicate key aspects such as a high level of education and training, experience to perform the skill, continuous education, skill retention, appropriate equipment and resources and a strong clinical governance system to support safe and effective pre-hospital RSI. In South Africa, there are only a limited number of ECPs (non-physician providers), that are licenced to perform pre-hospital RSI. Due to the dangerous nature of the skill and the notoriously difficult environment, it is important to ensure that all aspects of the minimum standards are adhered to, to ensure that the practice of the skill is safe, sound and comparable to internationally acceptable standards.

This research study, in fulfilment of an MPhil degree dissertation, aimed to describe the current practice of pre-hospital RSI in South Africa when performed by ECPs, approximately ten years after the introduction of the new scope of practice that included RSI.

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PART B: MANUSCRIPT IN ARTICLE FORMAT

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**RAPID SEQUENCE INTUBATION: A SURVEY OF CURRENT PRACTICE IN THE SOUTH
AFRICAN PRE-HOSPITAL SETTING.**

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Abstract

Background: Rapid sequence intubation (RSI) is an advanced airway skill commonly performed in the pre-hospital setting globally. In South Africa, pre-hospital RSI was first approved for non-physician providers by the Health Professions Council of South Africa in 2009 and introduced as part of the scope of practice of degree qualified Emergency Care Practitioners (ECPs) only. The aim of the research study was to investigate and describe, based on the components of the minimum standards of pre-hospital RSI in South Africa, specific areas of interest related to current pre-hospital RSI practice.

Methods: A descriptive cross-sectional study design in the form of an online survey were conducted amongst operational ECPs in the pre-hospital setting of South Africa, using convenience and snowball sampling strategies.

Results: A total of 87 participants agreed to participate. Eleven (12.6%) incomplete survey responses were excluded while 76 (87.4%) were included in the data analysis. The survey response rate could not be calculated. Most participants were operational in Gauteng (n=27, 35.5%) and the Western Cape (n=25, 32.9%). Overall participants reported that their education and training were perceived as being of good quality. An overwhelming number of participants (n=69, 90.8%) did not participate in an internship programme before commencing duties as an independent practitioner. Most RSI and post-intubation equipment were reported to be available, however, our results found that introducer stylets and/or bougies and EtCO₂ devices are not available to some participants. Only 50 (65.8%) participants reported the existence of a clinical governance system within their organisation. Furthermore, our results indicate a lack of clinical feedback, deficiency of an RSI database, infrequent clinical review meetings and a shortage of formal consultation frameworks.

Conclusion: The practice of safe and effective pre-hospital RSI, performed by non-physician providers or ECPs, rely on comprehensive implementation and adherence to all the

components of the minimum standards. Although there is largely an apparent alignment with the minimum standards, recurrent revision of practice needs to occur to ensure alignment with recommendations. Additionally, there are areas that may benefit from further research to improve current practice.

Keywords: Rapid sequence intubation (RSI), Pre-hospital, Minimum standards, Education and training, System requirements, Comprehensive clinical governance, South Africa

Background

Rapid sequence intubation (RSI) is an advanced airway skill commonly performed in the pre-hospital setting globally, by either physician or non-physician providers (1,2). RSI is regarded the gold standard for advanced airway management in critically ill and/or injured patients, mainly due to the optimal conditions created to facilitate endotracheal intubation (ETI) and by restricting the physiological effects of the procedure (2,3). Arguably, the pre-hospital environment is not the ideal setting to perform high-risk procedures, such as RSI, however, some research suggests that certain patient groups may require immediate advanced airway interventions that cannot be delayed until Emergency Centre (EC) arrival (4,5). These predominantly include severe traumatic brain injury patients (TBI) (6).

Worldwide, experts raised concerns about the safety, efficacy, harm and delays that non-physician pre-hospital RSI may cause (7,8). The heterogeneity of available research makes comparisons and generalisability of conclusions regarding the value of pre-hospital RSI problematic (9). More recent studies indicate higher first pass and overall success rates amongst paramedics and/or student paramedics compared to earlier research (10–13). Moreover, newer literature suggested that highly trained non-physician providers and increased experience may improve endotracheal tube (ETT) pass success rates and reduce adverse events (14). To deliver safe, quality patient care before, during and after ETI, ensuring optimal oxygenation, normocapnia, and normovolemia as well as preventing

aspiration and other adverse effects, associated with increased mortality and morbidity, is paramount and therefore the implementation of pre-hospital RSI necessitate a clinical governance system (15).

In South Africa, pre-hospital RSI was first approved to be performed by Emergency Care Practitioners (ECPs) (non-physician) by the Health Professions Council of South Africa (HPCSA) in 2009. With the addition of RSI to the scope of practice of ECPs, the HPCSA laid down the minimum standards forming the foundation and supportive framework to guide the implementation process and to ensure safe and effective practice (16). Moreover, a Position Statement published in 2010, endorsed by the Emergency Medicine Society of South Africa (EMSSA) and the Resuscitation Council of Southern Africa provided additional details regarding RSI practice (1). Since the approval, it is not known to what extent the minimum standards filtered down to the end-user level to support and enable ECPs to perform RSI in a safe and effective manner.

RSI is a high-risk skill which involves much more than merely passing of the ETT (17). To facilitate prehospital RSI, specific requirements need to be considered before implementation and practice, such as training, system requirements and an appropriate clinical governance framework (1). The aim of the research study was to investigate and describe, based on the components of the minimum standards of pre-hospital RSI in South Africa, specific areas of interest related to current pre-hospital RSI practice. The objectives of the study were to describe pre-hospital training, system requirements and clinical governance systems in South Africa.

Methods

Study design

A descriptive cross-sectional study was conducted among operational ECPs in the South African pre-hospital setting.

Study setting and population

South Africa is a low and middle-income country, in Southern Africa, with a population of approximately 58 million in 2019 (18). Pre-hospital Emergency Care (PEC) is provided by Public/Government and/or Private and/or Non-Governmental Organisations (NGO's) and includes the provision of care using different platforms, for example, road ambulances, response vehicles, specialised ambulances and/or aeromedical platforms.

Eligible study participants were operational ECPs, currently registered with the HPCSA, working in the South African pre-hospital setting. ECPs is the only group of emergency care providers that can perform pre-hospital RSI. With the implementation of the new clinical practice guidelines (CPGs), non-RSI and/or medication facilitated intubation (MFI) are no longer allowed. For the purpose of the study, the term "operational", entailed any PEC duties performed, in the capacity of an ECP, whether it is full-time or part-time with or without any form of compensation.

Non-probability, convenience and snowball sampling strategies were used, however, due to the lack of reliable or published information on the exact number of operational ECPs in the South African pre-hospital setting, a sample size could not be calculated. Many HPCSA registered ECPs are currently working abroad (19) and/or employed in non-operational positions within South African organisations.

Data collection

We collected our data, using a trustworthy online survey tool, SurveyMonkey®. The survey was mindfully designed, using a variety of reputable resources. Our focus was to design the data collection tool to be user-friendly, appealing, simplistic, unambiguous and succinct to minimise potential break-offs and prevent participant fatigue while the content concentrated on the research aim and objectives (Additional file 1).

We established face validity through a review process and a pilot survey. Individuals knowledgeable on the study content and questionnaire design evaluated and offered recommendations for enhancement. The survey was piloted amongst experienced, registered HPCSA ECPs working abroad. The data gathered as well as the recommendations received from the pilot survey were analysed and minor changes were made.

An electronic invitation and infographic, containing information and access to the online survey, were distributed to potential participants and key role-players across South Africa, who in turn was requested to further distribute (snowball sampling) the survey invitation to other potential participants known to them. Due to the sampling technique, it is not known how many potential participants received the electronic survey invitation. Data were collected between 18 July and 18 September of 2019. Electronic reminders were used during this period, as a follow-up technique to enhance study participation.

Data analysis

Data were analysed using SPSS Statistics, Version 25 (20). Shapiro-Wilk tests were conducted to assess for normality. Demographic information (frequencies, percentages, median, interquartile range (IQR) and ranges) and survey responses (frequencies and percentages) were expressed using descriptive statistics and presented with tables and graphs. Pearson chi-square test of independence was used to determine relationships between categorical variables and Phi correlation coefficient to determine the strength of association. A p-value of 0.05 was considered statistically significant.

Results

Demographics

A total of 87 participants agreed to partake. Incomplete responses of 11 (12.6%) participants were excluded whereas 76 (87.4%) were included in the data analysis. The completion rate was calculated as 87%, however a response rate for the survey could not be calculated as the

exact sample population could not be determined as a convenience and snowball sampling technique were used (denominator unknown).

Most participants were operational in Gauteng (n=27, 35.5%) and the Western Cape (n=25, 32.9%). More than half of the participants (n=43, 56.6%) reported their employment as private Emergency Medical Service (EMS) organisations of which 46 indicated permanent employment as operational ECPs (61.8%). The overall years of EMS experience ranged between <1 to 27 years with a median of 7 (IQR 5-13) years while the years of experience as an ECP ranged between <1 and 12 years and a median of 3 (IQR 2-6) years. Refer to Table 1 for additional participant characteristics.

Table 1 Participant characteristics

Characteristics	n (%)
<i>Province</i>	
Gauteng	27 (35.5%)
Western Cape	25 (32.9%)
KwaZulu-Natal	13 (17.1%)
Eastern Cape	5 (6.6%)
Free State	2 (2.6%)
Mpumalanga	1 (1.3%)
Northern Cape	1 (1.3%)
Limpopo	1 (1.3%)
North West	1 (1.3%)
	76 (100%)
<i>Qualifications before obtaining ECP registration</i>	
BAA/BLS	40 (52.6%)
AEA/ILS	25 (32.9%)
ECT	3 (4%)
CCA	3 (4%)
N. Dip: EMC	21 (27.6%)
	76 (100%)
<i>Job Title</i>	
Paramedic (ECP) – operational	47 (61.8%)
Lecturer/Instructor/Trainer in EMC/EM	17 (22.4%)
Flight Paramedic (ECP) – operational	7 (9.2%)
Manager/Administrative/Researcher in EMC/EM	4 (5.3%)
No response	1 (1.3%)
	76 (100%)

<i>Years of total experience in pre-hospital EMS systems</i>	
0-10 Years	49 (64.5%)
11-20 Years	21 (27.6%)
21-30 Years	6 (7.9%)
	76 (100%)
<i>Years of experience as ECP grouped</i>	
0-5 Years	56 (73.7%)
6-12 Years	20 (26.3%)
	76 (100%)
<i>Organisation:</i>	
Private	43 (56.6%)
Public (Government)	23 (30.3%)
University/Training Institution	6 (7.9%)
Non-Governmental Organisation (NGO)	4 (5.3%)
	76 (100%)
<i>Work environment:</i>	
Ground - Response Vehicle	51 (67.1%)
Ground – Ambulance	11 (14.5%)
Aeromedical - Rotor Wing	5 (6.6%)
Ground - Specialised Ambulance ^a	4 (5.3%)
Multiple platforms	3 (3.9%)
Aeromedical - Fixed Wing	2 (2.6%)
	76 (100%)
^a ICU/Paediatric or Neonatal transfer unit	

Training

For the theoretical (43.4%), simulated practical (40.8%), pharmacology (35.5%), mechanical ventilation (46.1%) and special circumstances (36.8%) components, most of the participants reported that their education and training were perceived as being of good quality (Figure 1). For the clinical practice component, more participants indicated that the quality of the clinical practice components was either average or excellent (28.9% each) and 25% reported it to have been of good quality. The theoretical component was perceived to be of the highest quality with 94.7% selecting average, good or excellent followed by pharmacology and simulated practice while special circumstances and clinical practice were reported to be of lower quality (Additional file 2: Table S1).

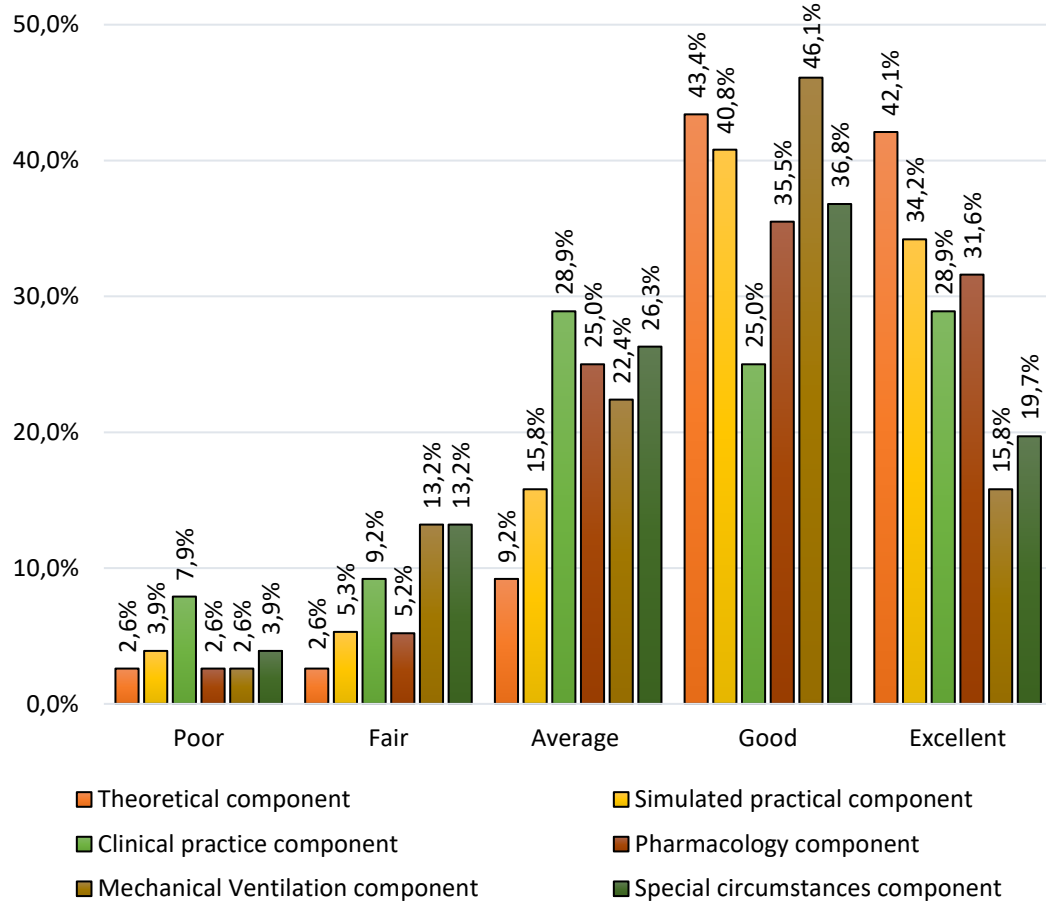


Fig 1 Perceived quality of RSI training received during tertiary education

Most participants (n=69, 90,8%) did not partake in an internship programme (e.g. working with a qualified ECP for a period after qualification) before commencing duties as an independent practitioner while 7 (9.1%) participants did (Table 2). No association was found between years' experience as an ECP (<5 years and 6-12 years) and participation in an internship programme (yes/no) ($\chi^2(1, n=76) = 0.020, p=0.877$).

Almost 60% of participants (n=45, 59.2%) indicated not having participated in formal education and training activities specifically focusing on RSI since graduating from university, while 31 (40.8%) did. No association was found between years' experience as an ECP (<5 years, 6-12 years) and participation in formal RSI activities since graduation (yes/no) ($\chi^2(1, n=76) = 2.269, p=0.132$).

Table 2 Participation in an internship programme after qualification as an ECP

Internship period	n (%)
No participation	69 (91%)
< 1 month	4 (5%)
1-3 months	2 (3%)
> 3 months	1 (1%)
	76 (100%)

System requirements

The reported available equipment to perform RSI and post-intubation management are indicated in Figure 2. All 76 (100%) participants reported having an alternative airway device available, although the type of device varied. Sixty-eight (89%) participants reported to have either a bougie or a stylet available, 63 (82.9%) of which reported having both while 3 (4%) reported having neither devices available. EtCO₂ availability was reported as 31 (40.8%) having a capnometer and 67 (88.1%) a capnograph whereas 5 participants reported not having any EtCO₂ device available. Forty-one (53.9%) participants reported no equipment sharing amongst ECPs when working, while 32 (42.1%) reported some equipment sharing, 3 results were excluded due to missing data. Equipment shared amongst ECPs is summarised in Additional file 2, Table S2 and S3.

Eight participants (10.5%) indicated the availability of a video laryngoscope (VL) while 4 (50%) reported that a VL was shared amongst ECPs or is kept at the base. Six (75%) of the participants that indicated VL availability are operational in the Western Cape, with the remaining two in Kwa-Zulu Natal and Gauteng provinces, respectively. Table 3 depicts VL availability by EMS organisations.

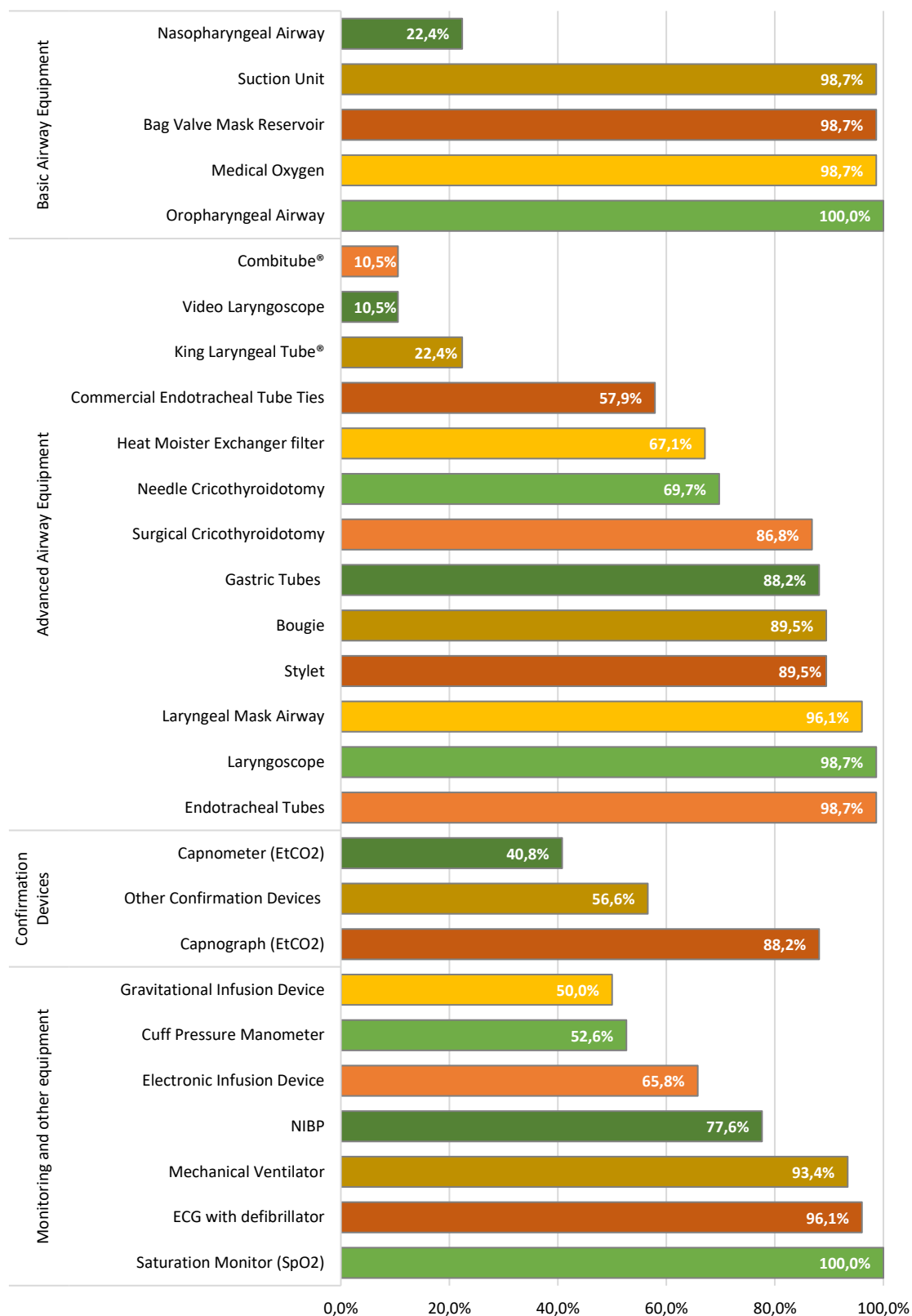


Fig 2 Equipment available to perform RSI and post-intubation management

Forty (52.6%) participants reported the availability of an ETT cuff pressure manometer (Table 4), almost half (n=18, 45%) of which were working in Gauteng, followed by the Western Cape

(n=13, 32.5%), Kwa-Zulu Natal (n=6, 15%) and the Eastern Cape (n=1, 2.5%), Mpumalanga (n=1, 2.5%) and Northwest province (n=1, 2.5%).

Table 3 Availability of a Video Laryngoscope

Type of EMS organisation	n (%)
Public (Government)	2 (2.6%)
Private	3 (3.9%)
Non-Governmental Organisations (NGO)	3 (3.9%)
University/Training Institution	0 (0%)
	8 (10.5%)

Our results found that Ketamine, Midazolam and Morphine were more regularly available (99% each), compared to Etomidate (92%) and Fentanyl (8%). Similarly, Rocuronium (97%) and Suxamethonium (92%) were more available, compared to Vecuronium (9%).

Table 4 Availability of an ETT cuff manometer

Type of EMS organisation	n (%)
Public (Government)	5 (6.6%)
Private	27 (35.6%)
Non-Governmental Organisations (NGO)	4 (5.3%)
University/Training Institution	4 (5.3%)
	40 (52.6%)

Thirty-four (44.7%) participants specified that they have at least one dedicated assistant available during an RSI attempt, 29 (38.2%) at least 2, 10 (13.2%) at least 3 while 3 (3.9%) participants have no assistants available. It was reported that ECPs always (n=19, 25%), sometimes (n=56, 73.7%) and never (n=1, 1.3%) have at least one assistant that has previously performed RSI with them.

The qualification held by the available RSI assistants is summarised in Additional file 1, Table S4. Most (n=34, 44.74%) participants reported the perceived level of knowledge and skills of non-ECP emergency care providers to assist them during attempted RSI as average (Figure 3). Seventy-one (93.4%) participants were not aware of any short courses available to non-ECP practitioners to obtain the necessary knowledge and skills to assist ECPs during RSI. Five participants indicated, to their knowledge, 3 airway management short courses namely,

Evidence-Based Management of Oxygenation, Ventilation and Airway (EMOVA), Airway Interventions & Management in Emergencies (AIME) and Advanced Airway & Ventilation course, are available in South Africa. Most participants reported that non-ECPs acquired the necessary knowledge and skills to assist during RSI, by working with an ECP (n=60, 78.9%) and/or through informal training by an ECP (n=8, 10.5%) (Additional file 2, Table S5).

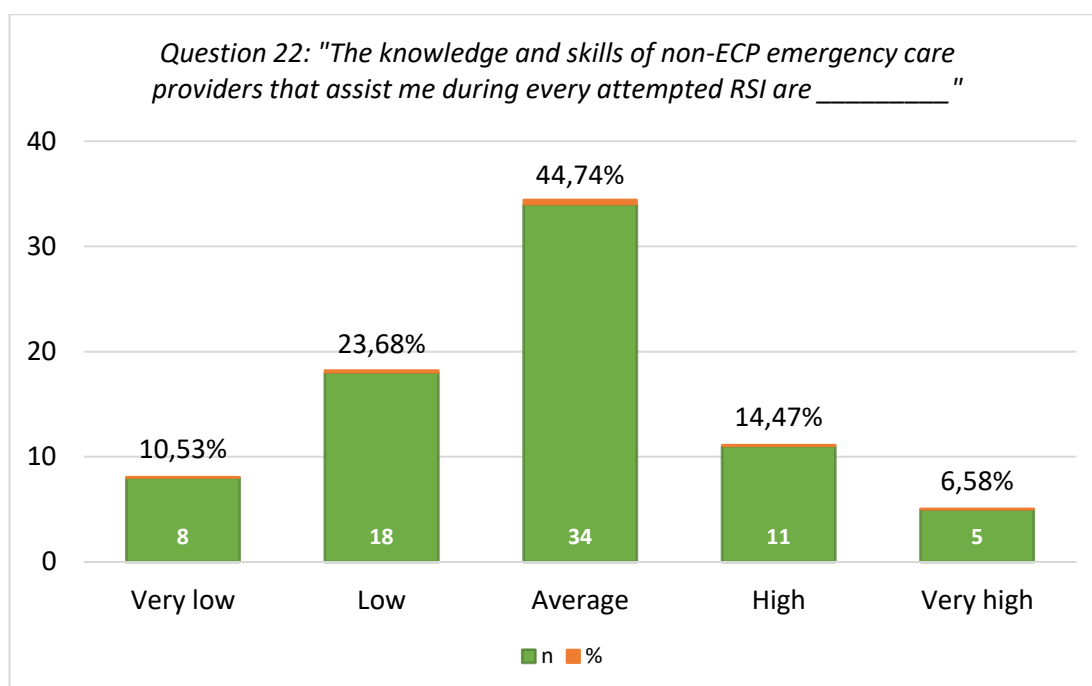


Fig 3 ECP's perceived level of knowledge and skill of non-ECPs that assist during RSI

Comprehensive Clinical Governance system

Fifty (65.8%) participants reported the existence of a continuous quality improvement (CQI) or quality assurance (QA) department or representative within their organisation. Of these, 11 (22%) never, 28 (56%) sometimes and 11 (22%) always receive feedback regarding attempted or performed RSI.

Some participants describe the CQI in terms of RSI as *"positive"*, *"constructive"*, *"discussions taking place"*, *"problem identification"* and *"restorative"*. In some instances, peer reviews of clinical documentation are performed. Individuals that hold responsibilities for CQI are described as *"Doctor"*, *"EM Physician"*, *"Senior ECP"* and *"person from outside the organisation"*. To a lesser degree, the CQI process was described as *"investigative in nature"*

with “no continuous training and quality”. In some cases, the person responsible for CQI holds a “lower qualification”, compared with that of an ECP, that “was not formally taught to perform RSI”.

The submission of clinical documentation for an attempted/performed RSI is always required of 62 (81.6%) participants, sometimes of 4 (5.3%) and never of 10 (13.2%) participants. Most (n=50, 65.8%) participants indicated that clinical review/mortality & morbidity meetings to discuss attempted/performed RSI cases occur within the organisation however the frequency of occurrence varied (Table 5). Thirty-one (40.8%) participants reported that all RSI cases are captured on an RSI database within the organisation, while the remaining was unsure (n=24, 31.6%) or reported no (n=21, 27.6%) RSI database. A statistically significant association was found between organisations with a CQI/QA department/representative and organisations with an RSI database ($\chi^2(1, n=76) = 7.605, p=0.006$). Organisations with a CQI/QA department/representative were more like to have an RSI database. The strength of association was moderate ($\phi: 0.316$).

Table 5 Clinical Review and/or Mortality & Morbidity meetings

Number of meetings	n (%)
Never (zero per year)	26 (34.2%)
Rarely (once a year)	19 (25.0%)
Sometimes (every 6 months)	11 (14.5%)
Usually (every 3 months)	7 (9.2%)
Always (every month)	12 (15.8%)
Missing data	1 (1.3%)

Fifty-two (68.4%) participants reported the presence of a formal consultation framework (e.g. Senior ECP, Peer and/or Physician) within their organisation while 60 (78.9%) indicated that they occasionally consult informally with regards to performing RSI. A statistically significant association was found between organisations with a formal consultation framework and organisations with a CQI/QA department/representative ($\chi^2(1, n=76) = 25.930, p<0.001$) but not between the presence of a CQI/QA department/representative

and practitioners who occasionally consult informally ($\chi^2(1, n=76) = 2.245, p=0.134$). Organisations with a formal consultation framework were more likely to also have a CQI/QA department/representative. The strength of association was strong ($\phi: 0.583$).

Discussion

To our knowledge, this study is the first of its kind investigating and describing based on the components of the minimum standards, specific areas related to South African pre-hospital RSI practice and therefore the findings will be valuable in terms of understanding current practice, making recommendations for improvement and further research.

Demographics

Considering the transformation of PEC education and training and the relatively recent introduction of degree programmes in South Africa (21), a less clinically experienced ECP workforce, like we found, may be expected. Additionally, career progression to teaching, managerial, administrative or research positions or to the international market (19) may further compound the limited clinical experience of the workforce. In terms of pre-hospital RSI, this may be a concern as literature suggests an increase in experience in advanced airway management and RSI are associated with higher ETI success rates and less adverse events contributing to lower mortality and morbidity (22–24).

Training

Tertiary education

We found the overall perceived quality of RSI tertiary education and training components to be commendable. The two components reported to be of lower quality were clinical practice and special circumstances which could be due to various factors, including the method of delivery and/or inadequate learning opportunities during practical shifts. Evidence suggest that the current method of education and training in South Africa does not seem to meet clinical practice learning objectives leading to the potential inadequate preparation of

paramedics for post-qualification independent practise (25). Various clinical practice components may require enhancement and to improve the current learning experience, extensive collaboration between universities and all other stakeholders are required to set clear standards and guidelines and ensure student preparedness (22,25).

As mentioned, a limited number of opportunities to perform supervised RSI as a student ECP may be an additional factor. This, may potentially impact the safety and quality of newly qualified practitioners as the complication rate associated with RSI improves only after about 30 procedures (24). Various other experts in the field of pre-hospital RSI reported that the proficiency or competency in the skill of ETI requires much higher numbers to achieve at least a 90% success rate, irrespective of being a physician or non-physician provider (26,27). Students completing a degree in EMC at a South African university, require a total of 35 supervised ETIs and/or RSIs during their studies (12). Eleven in the pre-hospital setting and the remaining 24 performed in an operating room under the supervision of an anaesthesiologist (12), which are contextually very different from performing pre-hospital RSI. This low frequency of supervised ETIs and/or RSI may be contributing to the perceived lower quality of this component. Other contributory factors may be a lack in the variety of clinical cases and patient types during student RSI, or only the opportunity to observe ETI and/or RSI during clinical practice placements (28). Supervised pre-hospital RSI for ECP students may be limited and insufficient in South Africa.

Internship programme

Although there is no known legislation that requires qualified ECPs to participate in an internship programme, some South African EMS organisations have such programmes in place. The features of these existing internship programmes, however, is not known. As part of continuous learning to prevent skill decay and promote safe and effective delivery of the skill, the literature recommends supervised practice for qualified non-physicians and physicians, especially in terms of advanced airway management or RSI (14,15,24,29). Recent

evidence suggest that, although newly qualified paramedics were found to be competent, there were a reported lack of organisational and health systems knowledge, leadership, critical judgement and clinical decision making skills (30). As recommended by Moodley (25), we support the development and implementation of a structured internship programme aimed at supporting practitioner growth to deliver safe and effective pre-hospital RSI, for all newly qualified ECPs in South Africa.

Continuous professional development for ECPs

ECPs in South Africa are responsible to maintain and update their knowledge and skills post-qualification (16). Although the HPCSA has a Continuous Professional Development (CPD) programme that requires all practitioners to accumulate Continuing Education Units (CEU) in a 12 month period, it does not specify the contents (31). Continuous RSI education and training is as important as initial knowledge and skills acquisition. In the context of fast developing airway management approaches, research sources indicate that Continuous Medical Education (CME), which include theoretical, simulated, and clinical practice activities are crucial to prevent skill decay and perform safe and effective RSI.

Our findings did report the existence of short courses tailored to provide continuous advanced airway management and RSI education and training in South Africa. However, ECPs are not necessarily required to attend these or similar short courses. It is assumed that attendance may be influenced by practitioner preference, course availability, accessibility, affordability, and/or specific employee requirements in terms of currency certification. We, therefore, recommend that participation in an RSI and/or advanced airway management specific CME activity need to become mandatory. It may be considered to form part of the accumulation of CEUs towards the existing CPD programme to ensure ECPs are up to date with current best practice.

System requirements

Equipment and medication availability

To allow for implementation and practice of pre-hospital RSI, specified airway management equipment and medications are mandatory. We found most to be available to ECPs, however minimal reporting of equipment sharing amongst ECPs were noted. This practice may result in equipment not always being accessible to perform RSI.

Some equipment needs mentioning. In line with recommendations, we found that all ECPs had some type of alternative airway device available during RSI. This is in contrast with the recent findings that alternative airway devices are inadequately stocked at public ECs in the Western Cape (32). The limited availability of the King Laryngeal Tube™ and Combitube™ may be due to cost, practitioner preference, user friendliness and/or practicality. The availability and use of an intubating stylet or bougie are recommended by local and international guidelines and the lack may affect first pass and overall success rates and possibly increase the risk of adverse events. Although EtCO₂ capnography is an important and mandatory tool for the confirmation of ETT placement and a valuable diagnostic tool that could promote safe and quality patient care and optimal mechanical ventilation (33), a lower than expected availability was reported. EMS organisations in low resource settings may consider VL, an expensive modality, subsequently, other expenditures and equipment purchase priorities may limit procurement. Nevertheless, prehospital VL may improve RSI success rates, decrease associated adverse events and facilitate faster ETI especially in trauma patients and patients with a difficult airway (5,34,35) and should be supported by organisations and policy makers.

Correct inflation pressure with continuous cuff pressure monitoring has become an important aspect of ETI. Using the estimated predetermined volume of air to inflate the ETT cuff has been reported to be imprecise (36). A recent South African study, found ETT cuff pressure to be incorrect in 77% of patients on EC admission (37). Although the complications

of over and under inflation of ETT cuffs may not be noted in the emergency environment, both hold significant risk to patients. Over inflation may cause trauma to the airway structures and trachea, nerve damage, necrosis, stenosis or even tracheal rupture while under inflation, may cause aspiration and subsequent ventilator associated pneumonia. To establish good practice, the use of an ETT cuff pressure manometer is recommended. The cost of commercial ETT cuff pressure manometers may contribute to the low availability, however, there is an alternative low cost method to determine cuff pressure (38) and should therefore be considered where commercial devices are unavailable.

Medication availability

Limited availability of Fentanyl was noticed, although it may be due to the recent addition of the medication to the CPGs (39). Although Suxamethonium was regarded as the recommended medication of choice for most RSI cases (40), Rocuronium appears to be more frequently available. Various factors may contribute to this finding, such as practitioner and/or organisational preference, financial implications, the use of Rocuronium for RSI and post intubation NMBA etc. The increase in publications and ongoing research debating and exploring the benefits and perceived lower adverse effects profile of Rocuronium compared to Suxamethonium to facilitate RSI may also have contributed to this finding.

Assistants to perform RSI

Most international literature indicates and refer to a “team” that conduct pre-hospital RSI, which highlights the need for more than one competent person to assist in performing pre-hospital RSI. EMSSA guidelines recommend at least one assistant, preferably two (41). More recent literature suggests that at least three knowledgeable and proficient team members should perform and assist during RSI (42).

To our knowledge, no short course specifically designed to equip non-ECPs with the necessary knowledge and skills to assist ECPs with RSI are available in South Africa. Although

three airway management short courses were reported to be available, these short courses primarily focus on educating and training providers that perform RSI, such as ECPs or physicians. Nonetheless, these courses may provide some insight for non-ECP providers. An RSI assistant short course, with the intent to train emergency care providers as RSI assistants may be extremely beneficial.

Comprehensive Clinical Governance system

The implementation and practice of safe and effective RSI in the pre-hospital setting cannot be guaranteed without the support of a system that provides guidance, oversight, clinical governance and improvement of current practice (1,9,15,43). A good clinical governance system relies on a dynamic programme that supports and emphasises quality care, consultation, case feedback and clinical case reviews as part of independent practice and continuous learning (15,43,44). Our results found a suboptimal reporting of the existence of clinical governance systems. The necessity of ongoing quality assurance, quality control and performance review were clearly stipulated (1,16). Recording all RSI, whether attempted or performed, on a database are recommended (45), as it is an important component of clinical governance which can be used to facilitate improvement. We found an association with EMS organisations that have a CQI programme and the presence of both an RSI database and a formal consultation framework, which validate the purpose of having a comprehensive clinical governance system to improve the safety and quality of pre-hospital RSI. In both hospital and pre-hospital settings, the implementation of a robust advanced airway programme, which includes the application of airway management algorithms, training, data collection and clinical reviews, have shown to significantly increase the first pass success rates and safety of RSI (46,47).

Study limitations

To maximise validity the questionnaire was mindfully designed, using reputable resources, received expert input and was piloted. However, survey responses may have been influenced by personal beliefs and perceptions leading to the potential for bias, including social desirability bias as pre-hospital RSI performed by paramedics is a heavily debated topic internationally. The nature of the data collection tool, an online survey, may have influenced the results as breakoffs, participant fatigue and misinterpretation of questions is likely. Non-response bias may have been introduced if the respondents that participated were systematically different from those that did not or if some eligible participants were not reached. Furthermore, the non-probability sampling techniques could have produced a sampling bias that underrepresents certain demographic groups and individuals and restricted data analysis. In particular, the data analysis was restricted by the limited representation of participants from certain provinces. Subsequently, the findings may not be generalisable to all EMS systems in South Africa. Our study did not intend to provide a detailed description of current practice according to the components of the minimum standards, but rather aimed to provide an overview of aspects that were deemed important for safe and effective pre-hospital RSI.

Conclusion

In this descriptive cross-sectional study, we found that there is plentiful alignment between the components of the minimum standards of pre-hospital RSI and current practice as perceived by ECPs, however, there are also some areas for improvement.

We found specific areas of university education and training that require more in-depth investigation and possible improvement initiatives. The implementation of an internship programme for newly qualified ECPs could complement pre-hospital clinical RSI encounters while the lack of availability and minimal participation of RSI specific CPD and/or CME

activities should be addressed. The importance of capable RSI assistants should be underscored and therefore the need for the development and implementation of an RSI specific education and training intervention for non-ECPs should be strongly considered.

A trustworthy and purposeful clinical governance system including various aspects for example monitoring, evaluating, and managing risks, an RSI database, provision of education and training initiatives, etc. is needed in all EMS organisations that intends to provide pre-hospital RSI in South Africa. The operational utility of existing quality assurance, control and improvement tools in some EMS organisations should be evaluated while frequent revision of practice is needed to ensure alignment with recommendations and current best practice.

Declarations

Ethics approval

Ethical approval for this study was obtained from the Human Research Ethics Committee (HREC) of the University of Cape Town (UCT) (HREC REF 204/2019).

Consent

Informed consent was obtained from each participant by means of a checkbox in the online survey.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

JB – Conceptualisation of the study, study and survey design, data collection, analysis and interpretation, manuscript preparation.

WS – Study design and final manuscript review.

AL – Study design, data analysis and interpretation and final manuscript review.

All authors read and approved the final manuscript.

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Additional file 1

Online survey, see Appendix 2 (page 82-93)

Additional file 2

Table S 1 Perceived quality of education components (n=76)

Education components (combined results: average, good and excellent)	n (%)
Theoretical ^a	72 (94.7%)
Pharmacology ^b	70 (92.1%)
Simulated practice ^c	69 (90.8%)
Mechanical ventilation ^d	64 (84.2%)
Special circumstances ^e	63 (82.9%)
Clinical practice ^f	63 (82.9%)

^a All theoretical aspects of RSI, ^b Theoretical and practical aspects of RSI medication and administration, ^c Practical classroom learning using various levels of fidelity simulation, ^d Theoretical and practical aspects of mechanical ventilation, ^e Unusual patient conditions to perform RSI, e.g. Raised Intracranial Pressure, Acute Pulmonary Oedema, Asthma, Haemodynamically Unstable Patient, Patient population, etc. , ^f Supervised practice in a hospital or pre-hospital environment

Table S 2 Equipment sharing amongst ECPs by Organisation (n=32)

Type of EMS organisation	n (%)
Private	17 (22.4%)
Public (Government)	12 (15.8%)
Non-Governmental Organisations (NGO)	2 (2.6%)
University/Training Institution	2 (2.6%)

Table S 3 Type of equipment shared amongst ECPs (n=32)

Type of equipment	n (%)
Mechanical ventilator	30 (93.8%)
Electrocardiograph (ECG)	27 (84.3%)
EtCO ₂ ^a	26 (81.3%)
Non-invasive blood pressure monitor	20 (62.5%)
Electronic infusion device	20 (62.5%)
Video laryngoscope	4 (12.5%)

^aEnd Tidal Carbon Dioxide (CO₂)

Table S 4 Qualifications of RSI assistants (n=76)

Assistant qualifications	n (%)
BAA/BLS	12 (15.0%)
AEA/ILS	40 (52.6%)
ECT	6 (7.9%)
CCA	5 (6.6%)
ECP	4 (5.3%)
EMC students	9 (11.8)

Table S 5 Non-ECP education and training methods assist during RSI (n=76)

Method of education and training	n (%)
RSI assistant short course	4 (5.3%)
Working in the pre-hospital setting with an ECP	60 (78.9%)
Working in an EC ^a with a Physician	13 (17.1%)
FOAMed ^b	9 (11.8%)
Social media platforms	12 (15.8%)
Medical textbooks	11 (14.5%)
Other ^c	8 (10.5%)
Don't know	13 (17.3%)

^a Emergency Centre, ^b Free open access medical education, ^c Other described as informal training, the overall theme was working with an ECP or taught by the ECP

PART C: ADDENDA

Appendix 1: Instructions to author

International Journal of Emergency Medicine

The journal selected for publication is the International Journal of Emergency Medicine as the findings and recommendations made in our study are applicable to an international audience and open access is available.

A brief summary of the submission guidelines:

1. Title page

- present a title that includes, if appropriate, the study design
- list the full names and institutional addresses for all authors
- indicate the corresponding author

2. Abstract

- not exceed 350 words
- minimize the use of abbreviations
- do not cite references
- must include the following separate sections:
 - Background: the context and purpose of the study
 - Results: the main findings
 - Conclusions: a brief summary and potential implications
 - Keywords (3-10 keywords representing the main content of the article)

3. Background

- should explain the background to the study
- its aims
- a summary of the existing literature
- why this study was necessary

4. Results

- include the findings of the study
- results of statistical analysis (in the text or as tables and figures)

5. Discussion

- should discuss the implications of the findings in context of existing research
- highlight limitations of the study

6. Conclusions

- state clearly the main conclusions and provide an explanation of the importance and relevance of the study to the field

7. Methods

- the aim
- design and setting of the study
- the characteristics of participants
- description of materials
- clear description of all processes, interventions and comparisons
- type of statistical analysis used, including a power calculation if appropriate

8. Declarations

- must contain the following sections
- ethics approval
- consent to participate
- consent for publication
- availability of data and materials
- competing interests
- funding
- authors' contributions
- acknowledgements
- authors' information (optional)

The comprehensive instructions for Authors can be found at the following link:

<https://intjem.biomedcentral.com/submission-guidelines/preparing-your-manuscript/original-research>

Appendix 2: Online Survey

Rapid sequence intubation: A survey of current practice in the South African pre-hospital setting.

Research Study Information

Pre-hospital Rapid Sequence Intubation (RSI), performed by non-physician emergency care providers, remains a heavily debated topic worldwide. However, what could be agreed upon is that RSI is the golden standard of advanced airway management, if performed in a safe and effective manner.

Endotracheal intubation using the method of RSI in the South African pre-hospital environment is fairly new, considering that it was only approved by the Health Professions Council of South Africa (HPCSA) in July 2009, as part of the scope of practice for registered Emergency Care Providers (ECP's). In addition to the approval of this skill [the HPCSA published several minimum standards, in November 2009 \(click to open link\)](#), that was intended as requirements for the implementation and subsequent practice of the skill within emergency medical services. [In 2011 a Position Statement on pre-hospital RSI was published \(click to open link\)](#) by key role players within the industry, endorsed by the Emergency Medicine Society of South Africa (EMSSA) and the Resuscitation Council of Southern Africa (RCSA). The Position Statement elaborated and provided clarification on three specific components (training, system requirements and clinical governance systems) pertaining to the already published minimum standards to support safe and effective delivery of pre-hospital RSI performed by ECP's in South Africa.

Recent literature highlighted a high adverse event rate with paramedic RSI in South Africa, which is concerning in terms of patient safety. It was further reported that the effectiveness of paramedic RSI, in terms of the ability to pass the endotracheal tube, was NOT found to be a concern.

The purpose of this research study is to collect data from registered ECP's in an aim to describe the current practices of Pre-hospital Rapid Sequence Intubation in South Africa in terms of the minimum standards as laid down by the HPCSA. It is important to understand the environment, conditions and the system in which RSI is taking place and how it could possibly affect the safety of RSI. Therefore, this research study aims to describe the system, and NOT the individual.

Please note that due to the nature of the research study, the survey is exclusively aimed at registered Emergency Care Practitioner (ECP) that holds a degree in Emergency Medical Care (e.g. B.Tech: EMC/BEMC/BHSc: EMC) and that are operationally active (full time, part time, voluntary) within the pre-hospital setting in South Africa.

The research study was approved by the University of Cape Town Human Research Ethics Committee (HREC) and comply with the ethical principles of the Declaration of Helsinki. For further information pertaining to the ethical considerations of this research study, the HREC can be contacted +27 21 650 3002.

This research study is in partial fulfilment of the degree M.Phil in Emergency Medicine at the University of Cape Town.

Thank you for your time and interest to participate in this research study and survey. Please feel free to contact me if you have any questions, jcbatha.vinkie@gmail.com

Researcher: Ms. J.C. Botha

Supervisor: Dr W. Stassen

Co-Supervisor: Ms. A. Lourens

Please click the "OK" tab below to proceed to the consent section, that will enable you to participate in the survey

Rapid sequence intubation: A survey of current practice in the South African pre-hospital setting.

Informed Consent

Your participation in this research study is voluntary and therefore you may choose not to participate, without any disadvantage.

If you do decide to participate, you will be afforded an opportunity to withdraw at any time.

Participation in this survey do not offer any form of individual incentives, although the disseminated findings of the research study may contribute towards improved and safe patient care.

The survey is very short and would take less than 10 minutes to complete.

Please ensure that you complete all the questions, as incomplete surveys would be deemed futile.

1. I have read the information section and understand the background and purpose of the research.
2. I am registered as an Emergency Care Practitioner (ECP) at the Health Profession Council of South Africa.
3. I practice (full time/part time/voluntary) as an Emergency Care Practitioner (ECP) in the pre-hospital setting in South Africa.
4. I voluntarily agree to participate in the research study.

* 1. If you agree to the above statements, please select the "Agree" option and then click "OK" to proceed to the survey.

If you answered "NO" to any of the above statements OR wish NOT to participate in the survey, please select the "Disagree" option below.

- ☐ Agree
- ☐ Disagree

Rapid sequence intubation: A survey of current practice in the South African pre-hospital setting.

Basic Demographic Information

The purpose of this section is to acquire basic, non-identifying demographic information of the participants.

IS ESTIMATED THAT THE SURVEY WOULD ONLY TAKE 12 MINUTES TO COMPLETE. LET'S GET STARTED! IT

Please click on the "OK" button below to proceed to the questions.

2. Indicate ALL your qualifications that you obtained in emergency care during your career (you may select more than one option).

- | | |
|--|---|
| <input type="checkbox"/> Basic Ambulance Assistant (BAA/BLS) | <input type="checkbox"/> Emergency Care Technician (ECT) |
| <input type="checkbox"/> Ambulance Emergency Assistant (ANA/ILS) | <input type="checkbox"/> National Diploma in Emergency Medical Care (ANT) |
| <input type="checkbox"/> Critical Care Assistant (CCA/ANT) | <input type="checkbox"/> B.Tech/BEMC/BHSc:EMC (ECP) |

3. Indicate the first ever YEAR of registration as an emergency care provider (e.g. BAA, ANT etc.) with the HPCSA (if ECP registration is the first/only registration with the HPCSA, enter as such).

4. Indicate the YEAR of registration as an independent ECP (B.Tech/BEMC/BHSc:EMC) with the HPCSA

5. In which province of South Africa do you predominantly practice in as an ECP?

- | | |
|-------------------------------------|-------------------------------------|
| <input type="radio"/> Eastern Cape | <input type="radio"/> Mpumalanga |
| <input type="radio"/> Free State | <input type="radio"/> Northern Cape |
| <input type="radio"/> Gauteng | <input type="radio"/> North West |
| <input type="radio"/> KwaZulu-Natal | <input type="radio"/> Western Cape |
| <input type="radio"/> Limpopo | |

6. How would you best describe your job title within the organisation that you are employed in?

- ☐ Paramedic (ECP) - operational
- ☐ Flight Paramedic (ECP) - operational
- ☐ Lecturer/Instructor/Trainer in Emergency Medical Care/Emergency Medicine
- ☐ Manager/Administrative/Researcher in Emergency Medical Care/Emergency Medicine
- ☐ NOT permanently employed within EMS/EMC/EM (please specify)

7. When you do work operationally as an ECP (permanently/voluntary/part time), which of the following best describe the organisation/emergency medical service that you predominantly practice in?

- ☐ Public (Government)
- ☐ Private
- ☐ University/Training Institution
- ☐ Non-Governmental Organisation (NGO)
- ☐ Other (please specify)

8. How would you best describe the predominant work environment when you are operational as an ECP?

- | | |
|---|--|
| <input type="radio"/> Ground - Ambulance | <input type="radio"/> Special Events (e.g. sport standby, concerts, festivals, movie sets) |
| <input type="radio"/> Ground - Response Vehicle | <input type="radio"/> Aeromedical - Rotor Wing |
| <input type="radio"/> Ground - Specialised Ambulance (e.g. ICU/Paediatric/Neonatal Transfer Unit) | <input type="radio"/> Aeromedical - Fixed Wing |
| <input type="radio"/> Other (please specify) | |

Rapid sequence intubation: A survey of current practice in the South African pre-hospital setting.

Training

The purpose of this section is to acquire some information with regards to the training/education that you received on a tertiary level at and subsequent continuous professional development activities.

THIS IS A SHORT SECTION! - ONLY EIGHT QUICK QUESTIONS!

Please click on the "OK" button below to proceed to the questions.

9. How would you describe the **OVERALL theoretical component of the RSI** education that you received at university level (e.g. airway anatomy, airway equipment, advance airway algorithms, the steps of RSI, pertinent pathophysiology etc.).

Poor	Fair	Average	Good	Excellent
☆	☆	☆	☆	☆

10. How would you describe the **OVERALL simulated practical component** of the RSI education that you received at a university level (e.g. OSCE's and Patient Simulation)?

Poor	Fair	Average	Good	Excellent
☆	☆	☆	☆	☆

11. How would you describe the **OVERALL clinical practice component** of the RSI education that you received at a university level (e.g. Clinical Placement/Operational Shifts/Emergency Department/Theater etc.)?

Poor	Fair	Average	Good	Excellent
☆	☆	☆	☆	☆

12. How would you describe the **pharmacology component** of the RSI education that you received at a university level?

Poor	Fair	Average	Good	Excellent
☆	☆	☆	☆	☆

13. How would you describe the **mechanical ventilation component** of the education that you received at a university level?

Poor	Fair	Average	Good	Excellent
☆	☆	☆	☆	☆

14. How would you describe the **special circumstances component** (e.g. obese patients, traumatic brain injury patients, respiratory disorders etc.) pertaining to RSI education that you received at a university level?

Poor	Fair	Average	Good	Excellent
☆	☆	☆	☆	☆

15. After you obtained your degree, indicate the duration of the **internship programme** (worked with a qualified ECP) that you participated in, before commencing duties as an independent practitioner?

- ☐ Zero - I did not participate in any for of an internship programme (worked with a qualified ECP)
- ☐ < 1 month
- ☐ 1 - 3 months
- ☐ >3 months

16. Since you qualified/graduated from university, did you participate in any **formal** (e.g. RSI specific short course/workshop/continuous professional development activity) education/training pertaining to RSI?

- ☐ Yes
- ☐ No

If you answered "Yes", briefly provide some detail (e.g. name of the course, training provider, approved by the HPCSA, type of activity)

Rapid sequence intubation: A survey of current practice in the South African pre-hospital setting.

System Requirements

The purpose of this section is to acquire some information with regards to adequate equipment & personnel to enable you to attempt safe and effective RSI.

YOU HAVE PASSED THE HALFWAY POINT IN THE SURVEY! - ALMOST DONE! ONLY 2 SECTIONS TO GO!

Please click on the "OK" button below to proceed to the questions.

17. Which of the following airway equipment/adjuncts are available to you EVERY time that you attempt RSI?

- | | |
|--|--|
| <input type="checkbox"/> Suction Unit | <input type="checkbox"/> Video Laryngoscope |
| <input type="checkbox"/> Oropharyngeal Airway | <input type="checkbox"/> Capnometer (EtCO ₂) |
| <input type="checkbox"/> Nasopharyngeal Airway | <input type="checkbox"/> Capnograph (EtCO ₂) |
| <input type="checkbox"/> Bag Valve Mask Reservoir | <input type="checkbox"/> Other Confirmation Devices (e.g. Esophageal Intubation Detector/Colorimetric Carbon Dioxide Detector) |
| <input type="checkbox"/> Medical Oxygen | <input type="checkbox"/> Electrocardiograph (ECG) with defibrillator |
| <input type="checkbox"/> Endotracheal Tubes | <input type="checkbox"/> Saturation Monitor (SpO ₂) |
| <input type="checkbox"/> Laryngeal Mask Airway | <input type="checkbox"/> Automated Oscillometric Device/NIBP |
| <input type="checkbox"/> Combitube | <input type="checkbox"/> Mechanical Ventilator |
| <input type="checkbox"/> King Laryngeal Tube | <input type="checkbox"/> Endotracheal Tube Cuff Pressure Manometer |
| <input type="checkbox"/> Needle Cricothyroidotomy | <input type="checkbox"/> Electronic Infusion Device |
| <input type="checkbox"/> Surgical Cricothyroidotomy/Quicktrac | <input type="checkbox"/> Gravitational Infusion Device/Dial-a-flow |
| <input type="checkbox"/> Stylet | <input type="checkbox"/> Heat Moisture Exchanger (HME) filter |
| <input type="checkbox"/> Bougie | <input type="checkbox"/> Gastric Tubes (Orogastric/Nasogastric Tubes) |
| <input type="checkbox"/> Laryngoscope | <input type="checkbox"/> Commercial Endotracheal Tube Ties (e.g. Thomas tube holder) |
| <input type="checkbox"/> Other equipment to perform RSI (please specify) | |
| <div></div> | |

18. Are there any of the following equipment that is shared with another ECP unit(s) and/or kept at the base?

- | | |
|---|--|
| <input type="checkbox"/> NONE | <input type="checkbox"/> Automated Oscillometric Device and/or Non-Invasive Blood Pressure Monitoring Device |
| <input type="checkbox"/> Electrocardiograph (ECG) | <input type="checkbox"/> Electronic Infusion Device |
| <input type="checkbox"/> Mechanical Ventilator | <input type="checkbox"/> Video Laryngoscope |
| <input type="checkbox"/> Capnograph/meter (EtCO2) | |
| <input type="checkbox"/> Other (please specify) | |

19. Which of the following medication are available to you every time that you attempt RSI and post intubation management?

- | | |
|--|-------------------------------------|
| <input type="checkbox"/> Etomidate | <input type="checkbox"/> Rocuronium |
| <input type="checkbox"/> Ketamine | <input type="checkbox"/> Vecuronium |
| <input type="checkbox"/> Midazolam | <input type="checkbox"/> Morphine |
| <input type="checkbox"/> Suxamethonium | <input type="checkbox"/> Fentanyl |

Other (please specify)

20. Indicate the average number of dedicated assistant(s) that you would have available to assist you when you attempt RSI.

- | | |
|-------------------------|--------------------------|
| <input type="radio"/> 0 | <input type="radio"/> 3 |
| <input type="radio"/> 1 | <input type="radio"/> >3 |
| <input type="radio"/> 2 | |

21. Indicate the qualification of the assistant that predominantly assist you when you attempt RSI.

- | | |
|---|---|
| <input type="radio"/> BAA/BLS | <input type="radio"/> Paramedic (CCA) |
| <input type="radio"/> AEA/ILS | <input type="radio"/> Paramedic (N.Dip) |
| <input type="radio"/> Emergency Care Technician (ECT) | <input type="radio"/> Emergency Care Practitioner (ECP) |

22. Complete the following statement: "The knowledge and skills of emergency care providers (non-ECP's) that assist me during every attempted RSI are _____."

☐ A very high level

☐ A low level

☐ A high level

☐ A very low level

☐ An average level

23. Indicate your opinion pertaining to the following statement: "When I attempt RSI, there is at least ONE team member that I know and have worked with previously when I performed the skill of RSI"

☐ Always

☐ Sometimes

☐ Never

24. Do you know of any short courses that are available for **emergency care providers (non-ECP's)** that would provide them with the necessary knowledge and skills to adequately assist an ECP during an attempted RSI?

☐ Yes

☐ No

If you answered "Yes", briefly provide some detail (e.g. name of the course, training provider, approved by the HPCSA, type of activity)

25. To the best of your knowledge, how did **emergency care providers (non-ECP's)** acquire the necessary knowledge and skills to assist an ECP to attempt RSI, as it is not a component of their curricula/training (you may select more than one option, except if you select the option "I do not know").

☐ I do not know

☐ Free open access medical education (FOAMed)

☐ RSI assistant short course/certification

☐ Social Media Platforms (e.g. Facebook, YouTube)

☐ Experience/Knowledge gained from working in the Pre-hospital Setting (e.g. with an ECP)

☐ Medical Textbooks

☐ Experience/Knowledge gained from working in an Emergency Department (e.g. with a Physician)

☐ Other (please specify)

Rapid sequence intubation: A survey of current practice in the South African pre-hospital setting.

Comprehensive Clinical Governance System

The purpose of this section is to acquire some information with regards to the Comprehensive Clinical Governance System within the organisation/emergency medical service that you practice in as an ECP.

LAST EIGHT QUESTIONS TO GO!

Please click on the "OK" button below to proceed to the questions.

26. Which of the following statements best describe the clinical practice guidelines, pertaining to RSI, within the organisation that you are operationally active in? (Please indicate the **MOST** correct option)

- ☐ HPCSA Clinical Practice Guidelines
- ☐ Organisational Clinical Practice Guidelines, that are aligned with the HPCSA Clinical Practice Guidelines
- ☐ Organisational Clinical Practice Guidelines
- ☐ Autonomous practice according to provider preferred local and/or international Clinical Practice Guidelines

27. Do you know of any **formal** consultation framework (e.g. consultation with a Senior ECP, Peer and/or a Physician) within the organisation that you are working for?

- ☐ Yes
- ☐ No

28. Do you occasionally consult **informally** with a Senior ECP, Peer and/or Physician with regards to performing RSI?

- ☐ Yes
- ☐ No

29. Is there a continuous quality improvement/quality assurance department/representative within the organisation/emergency medical service that you work in?

- ☐ Yes
- ☐ No

If YES, please provide a brief description

30. Are you required to submit any form of patient care report forms/documentation/reports/checklists for an attempted/performed RSI?

- ☐ Always
- ☐ Sometimes
- ☐ Never

31. Do you receive any feedback from a continuous quality improvement/quality assurance department/representative with regards to EVERY attempted/performed RSI?

- ☐ Always
- ☐ Sometimes
- ☐ Never
- ☐ Not applicable, there is NO CQI/QA department/representative within the organisation

32. Are there clinical review/mortality & morbidity meetings within the organisation that discuss cases pertaining to attempted/performed RSI?

- ☐ Always (every month)
- ☐ Usually (every 3 months)
- ☐ Sometimes (every 6 months)
- ☐ Rarely (once a year)
- ☐ Never (zero per year)

33. Is there a RSI database within the organisation, that all attempted/performed RSI cases are captured?

- ☐ Yes
- ☐ No
- ☐ Unsure

Rapid sequence intubation: A survey of current practice in the South African pre-hospital setting.

Thank you for your time and participation, your contribution is appreciated.

This research study uses a non-probability snowball sampling or chain-referral sampling technique.

Please share the link (<https://www.surveymonkey.com/r/QTZ6W5J>) and/or QR (see below) of the survey with all other eligible individuals (ECPS in South Africa) that you know.

"Every system is perfectly designed to get the results it gets" - IHI

Thank you once again for YOUR participation in this research study!

QR Code



Appendix 3: Email request for pilot online study

From: jcbotha.vinkie@gmail.com

Hi ALL/SAFFAS!

Thank you for your time to assist me. I am conducting a research study, in partial fulfilment of the degree M. Phil in Emergency Medicine at UCT. The aim of the research study is to describe the current practices of Pre-hospital Rapid Sequence Intubation in South Africa in terms of the minimum standards as laid down by the HPCSA.

Because you are all qualified ECPs and have worked in the South African pre-hospital setting, I need your help and valuable input to pre-test and pilot the online survey. Your feedback will help me to make improvements on the current version before I will distribute it to the sample population (ECPs currently practising in SA) for actual data collection.

Please complete the survey as if you were still working in SA (e.g. Q5: *In which province of South Africa do you predominantly practice in as an ECP? - "Western Cape"*) - as well as you can remember.

After completing the survey, please send all feedback via email to me, e.g. spelling & grammatical errors, comments and suggestions. You are welcome to indicate any concerns e.g. *"I do not understand Question 9"*, *"A specific option was not available at Question 12"*, *"The survey is too boring and is taking too long to complete"*, *"I do not feel comfortable to provide an answer for Question 5"*. Indicate what device did you use to complete the survey: "Laptop", "PC", "Tablet", "Smartphone" etc. - and any comments with regards to the user-friendly aspect of the online survey on the specific device.

Click on the following link or scan the QR code to access the online survey:

<https://www.surveymonkey.com/r/QTZ6W5J>

Please ignore the last message on the online survey that requests participants to distribute the survey link to other ECPs, as this is only a pilot survey, you can just click the "Finish" tab once you are done.

Thank you very much for your help! It is greatly appreciated!

Feel free to contact me if you have any questions.

JC Botha (Vinkie)

Appendix 4: Invitation email

From: jcbotha.vinkie@gmail.com

18 July 2019

YOU are invited to participate in a **NATIONAL** anonymous online survey for Emergency Care Practitioners - working operationally in the pre-hospital setting of South Africa - whether full-time, part-time or voluntary (Operational, Lecturer, Adhoc, Other full-time Occupation).

What is the PURPOSE OF THE SURVEY?

To find out what YOUR VIEWS are, as the ECP & the "end-user", on the current practice of RSI in the pre-hospital setting of SOUTH AFRICA in terms of:

- Training
- System Requirements
- Clinical Governance System

The survey is NOT about...

- Your ability to perform the skill of RSI
- The number of times you perform RSI
- Your success rate or proficiency of RSI
- The techniques or medication choices when you perform RSI

Why is this research study important?

The Minimum Standards of pre-hospital RSI were laid down to support ECPs to accomplish high-quality care and safe practice in terms of performing RSI in the pre-hospital setting - thus it is supposed to be in place to support us.

The invitation:

I, therefore, invite YOU to PLEASE participate in the research study by completing the online survey (estimated 12 minutes to complete): Click here to access the survey or scan the attached QR code. Please try to complete the whole survey, until you reach the **DONE button!** The survey will only be available for a limited period of time. As the research study uses a snowball/chain referral sampling strategy, you may receive this email via various avenues.

The survey NEEDS YOU:

The quality of the RESEARCH study **relies heavily on the number of participants AND the representation of all 9 provinces** of South

Africa. Once finished, the results of the research study will be published in a peer-review journal.

The research study uses a snowball sampling technique, PLEASE PRIVATELY SHARE THIS EMAIL ELECTRONICALLY TO OTHER ELIGIBLE PARTICIPANTS THAT ARE KNOWN TO YOU that might be interested to participate.

Supporting documentation:

Additionally, attached is the research study information (also available in the online survey), relevant documents referred to in the background of the study, infographic for the survey (which you may distribute privately to other eligible participants that you know) and the QR code which would alternatively provide access to the online survey when scanned.

Thank you for your assistance & participation:

If you have any questions, please email:

jcbotha.vinkie@gmail.com

Ms JC Botha

Appendix 5: Reminder emails

Reminder email

From: jcbotha.vinkie@gmail.com

21 August 2019

Hi all,

This just a reminder of the online survey (previously send).

If you have completed it, thank you very much, if not - would you please consider to take the survey (it should only take 12 minutes to complete, and designed to be quick and easy).

<https://www.surveymonkey.com/r/KWRZKHH>

Please pass it on (all ECPs in SA)

Thank you very much,

JC Botha (Vinkie)

Last reminder email

From: jcbotha.vinkie@gmail.com

11 September 2019

7 days left to participate in the NATIONAL survey RAPID SEQUENCE INTUBATION: A survey of current practice in the South African Pre-hospital setting.

For those who have already taken the survey - THANK YOU VERY MUCH!
- a substantial amount of responses was received thus far.

If you have not participated this is your chance to be part of this research study - you have time until **the 18th of September 2019**, where after the survey will be closed.

Click here to access the survey or use the link/copy into browser <https://www.surveymonkey.com/r/KWRZKHH>

Thank you for your assistance & participation:

If you have any questions, please email:

jcbotha.vinkie@gmail.com

Ms JC Botha

Appendix 6: Invitation infographic



Appendix 7: Quick response (QR) code – online survey access



Appendix 8: Research Proposal

Rapid sequence intubation: A survey of current practice in the South African pre-hospital setting.

STUDENT:

Ms Johanna Catharina Botha
BTech Emergency Medical Care
University of Cape Town
BTHJOH033

SUPERVISOR(s):

Dr Willem Stassen
BTech Emergency Medical Care
MPhil in Emergency Medicine
PhD in Emergency Medicine
University of Cape Town

Ms Andrit Lourens
BTech Emergency Medical Care
MSc in Clinical Epidemiology
University of Cape Town

This study is in partial fulfilment of the degree MPhil in Emergency Medicine

Declaration

I, Johanna Catharina Botha, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree.

Signature: 

Date: 28/03/2019

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Title:

Rapid sequence intubation: A survey of current practice in the South African pre-hospital setting.

Abstract/SummaryIntroduction

The practice of Rapid Sequence Intubation (RSI) by non-physician emergency care providers in South Africa was approved in 2009. With the addition of the skill of RSI on the Emergency Care Practitioner's (ECP) scope of practice, the Health Professions Council of South Africa (HPCSA) published minimum standards to serve as implementation and practice guidelines. The purpose of this research study is to, based on the minimum standards published by the HPCSA, broadly describe the current practices of pre-hospital RSI as reported by ECPs in South Africa. In recent years concerns were raised with regards to the safety and efficacy of pre-hospital RSI by ECPs in South Africa. Safe and effective RSI is dependent on a good system that supports the practice of RSI as much as the proficiency of the practitioner to perform the skill.

Methodology

Two non-probability techniques, convenience and snowball sampling, will be used for this research study. The initial group of participants will be recruited by using convenience sampling and thereafter exponential non-discriminative snowball sampling to increase the number of participants. An online survey tool will be used to gather data for the research study and will consist of six sections that would focus on the components of the minimum standards of pre-hospital RSI.

Conclusion

Therefore, an investigation that describes the current practices of RSI in terms of the minimum standards of pre-hospital RSI may highlight possible shortcomings that could potentially place patients at risks for adverse events during and after performing the skill. The findings of the research study could be utilised to improve current practices of pre-hospital RSI and are intended to serve as starting points for further research pertaining to safety and efficacy of practices of pre-hospital RSI when performed by ECPs.

Background and Rationale

Rapid Sequence Intubation (RSI) is a commonly performed advanced airway skill in the pre-hospital setting, practised by physicians and/or non-physician emergency care providers globally. It is difficult to isolate a standard definition for RSI, which could possibly be due to the constant advances in terms of newer techniques, medication and equipment. In the emergency setting, RSI can be broadly defined as the administration of an induction agent to produce a state of unconsciousness, followed by the administration of a paralytic agent, to facilitate ETI (2).

Worldwide a variety of emergency care providers are qualified and permitted to perform RSI in the pre-hospital setting. Typically, the non-physician emergency care providers that are licenced to perform the skill are trained to advanced life support (ALS) level, which is diverse in terms of curricula and may differ from each other. In South Africa, only ALS providers, that hold a university degree in Emergency Medical Care (EMC), e.g. B.Tech/BEMC/BHSc:EMC and that are registered as Emergency Care Practitioners (ECPs), with the Health Professions Council of South Africa (HPCSA) are licenced to do so (3). Currently, the only other group of ALS providers that are licenced to perform the skill of intubation (the act of passing an endotracheal tube) are registered on the Paramedic/Ambulance Emergency (Afrikaans: "*Ambulans Nood Tegnikus*") Technician (ANT) register with the HPCSA. Emergency care providers that are registered on the ANT register have either obtained their qualification through the short course method, which qualified them as Critical Care Assistants (CCA) or a three-year university degree qualifying them with a National Diploma in EMC (N. Dip: EMC). These ALS providers registered on the ANT register are only licenced to perform intubation if no administration of medication is indicated to facilitate the intubation (e.g. cardiopulmonary arrest) and/or MFI (4).

The available literature is extremely vague as to exactly when RSI was first introduced in the pre-hospital setting globally. Some literature indicates that RSI may have been performed by paramedics (non-physicians) in the United States of America (USA) in the early '70s (5). Hedges *et al* (6), suggested that Succinylcholine (a paralytic agent) was introduced into the practice of performing intubation during the 1980s (6), which essentially deem such a practice of intubation a practice of RSI. In another article, it is mentioned that neuromuscular blocking agents (NMBAs) were used by aeromedical medical services in the '80s, however, it is still unclear whether the skill of RSI was performed by paramedics or physicians (7). Comparing RSI practice in the pre-hospital setting in South Africa with global trends, it may

be reasonable to conclude that the practice of pre-hospital RSI is fairly new in South Africa, as it was only officially approved by the HPCSA in 2009, as an addition to the ECP scope of practice (3).

Worldwide RSI is regarded as the gold standard in advanced airway management in critically ill and/or injured patients, mainly due to the optimal conditions that are established to facilitate ETI and limiting the physiological effects of the procedure on the patient (8). The process of RSI should be performed in a systematic manner to optimise a safe environment, adequate preparation of the environment and the management of the patient before the passage of an endotracheal tube whilst ensuring optimal oxygenation, prevention of aspiration, normocapnia and normovolemia (8). In consideration of the foregoing, RSI remains a heavily debated topic in the pre-hospital setting, mainly due to inconclusive findings in terms of risks and benefits when performed by paramedics during emergencies, skill maintenance and a lack of research in the specific setting (9). It is crucial to comprehend that RSI is a high-risk skill and involves much more than merely the passing of the endotracheal tube. Most RSI algorithms follow a similar sequence, although it may vary slightly from one organisation to the next. Usually, an RSI algorithm incorporates aspects of planning, preparation, protection of the cervical spine (when necessary), the positioning of the patient, preoxygenation, pre-intubation optimisation, induction, paralysis, placement of the endotracheal tube, confirmation of the endotracheal tube placement and lastly postintubation management (10). In addition, for safe and effective RSI to occur in the pre-hospital setting, there are specific requirements in terms of induction agents, paralytic agent, specialised equipment and an adequate amount of team members that are knowledgeable and capable to assist in performing the skill (2) (11). Internationally it is recommended that RSI teams consist of at least three members that are knowledgeable and proficient to perform the skill (12).

In 2009, with the approval of RSI as a supplemental skill to the already existing Scope of Practice for ECPs, the HPCSA provided several minimum standards for pre-hospital RSI. These minimum standards were laid down, serving as requirements for the implementation and practise of the skill (3). The minimum standards that were set by the HPCSA stipulated that all registered ECPs and upcoming ECPs are required to familiarise themselves with the then-current ALS Protocols of 2006 and any applicable supplements thereof. The protocols and supplemental material referred to in the latter, primarily include guidance on the procedure and medication pertaining to RSI. In addition, it was advised by the HPCSA Professional Board of Emergency Care (PBEC) that each ECP should maintain and update their knowledge and

skills through active participation in continuing professional development (CPD) activities. It was proposed that these CPD activities would be available at and facilitated by Higher Education Institutions (HEI) within South Africa in the form of workshops or seminars. Furthermore, it was specified that these activities would include theoretical and practical assessments and experiential exposure in an authentic environment within the hospital setting. In addition, it was required that each ECP submit a portfolio of evidence prior to practising the then newly approved skills (RSI and Fibrinolysis). A continuing quality assurance, quality control and performance review were proposed that would review clinical aspects of the skills performed in the pre-hospital setting. The document indicated that a database was set up, to provide an online platform for all ECPs to submit relevant case data pertaining to performed RSI (3).

Furthermore, in 2011 a Position Statement was published by Stein *et al* (1), endorsed by the Emergency Medicine Society of South Africa (EMSSA) and the Resuscitation Council of Southern Africa (RCSA), and provided additional detail on the minimum standards already published by the HPCSA. The Position Statement focused on three areas: training, system requirements and clinical governance systems in the hope to support the safe and effective delivery of pre-hospital RSI performed by ECPs in South Africa. The authors of the document suggested that the training aspect incorporate theoretical knowledge that focuses on all aspects of understanding the skill and actual practise of performing the skill, to a point where a practitioner could be deemed proficient. The second area that was required was system requirements, that needs to be made available within the Emergency Medical Service (EMS) that the ECP would perform RSI. The systems requirements included adequate equipment and personnel, which are both considered essential to perform the skill in a safe manner. Lastly, the minimum standards suggest the implementation of a multidisciplinary comprehensive clinical governance system, which includes experienced oversight, clinical reviews and data collection of RSI that focus on performance, complications and outcomes. Furthermore, the authors emphasised that RSI may not be achievable in all EMS systems within South Africa, as it was known that resources may lack to support ECPs to accomplish high-quality care and safe practice in terms of performing RSI in the pre-hospital setting (1).

Internationally the composition of pre-hospital emergency care teams differs vastly from each other and this makes it difficult to draw clear comparisons between the practices of RSI in other countries and South Africa. South Africa has a predominantly non-physician ALS provider population, with only ECP that can perform RSI. However, some services and organisations do have physicians within their structures, which mostly include managerial,

consultation and occasionally operational capacity. An article published, more than fifteen years ago, by Spaite and Criss (13) in the USA noted that although RSI may be deemed as an appropriate advanced airway skill in the pre-hospital setting with high success rates (90%), there are significant concerns with regards to the safety and efficacy of RSI and almost no reporting of adverse events that were encountered during and after the procedure.

Recently in South Africa, concerns have also been raised informally and formally pertaining to the safety and efficacy of the practice of RSI performed by paramedics in the pre-hospital setting. In 2012 concerns have been raised by Gunning *et al* (14) at the London Trauma Conference questioning the safety of RSI performed by paramedics in the South African pre-hospital context. In this retrospective observational study, 86 RSI's were performed during the one-year study period with no self-reported failed intubations, but a concerning number of adverse events was recorded. Adverse effects recorded by the paramedics as complications of RSI included haemodynamic instability, tension pneumothorax, difficult intubation, low and high EtCO₂ and bronchospasm. In addition, it was found that patients presented with hypotension and hypoxia on arrival at the hospital. It was concluded that one out of every five patients that received RSI by paramedics presented with an adverse effect, which was highlighted as a safety concern. Subsequently, the authors emphasised the importance and role of a clinical governance programme for RSI in the pre-hospital setting that could contribute towards patient safety and quality care in this regard (14) (15).

In 2014 Hardcastle *et al* (16), conducted a retrospective review of data, pertaining to patients that were already intubated on admission at a Level 1 Trauma Centre in KwaZulu Natal South Africa. Data of 65 patients were reviewed to determine the correctness of the endotracheal tube (ETT) placement and ETT cuff pressure on arrival at a health care facility. The patients admitted were either classified as interfacility transfers (57%) or primary emergencies (43%). From all the cases that were reviewed (n=65), the ETT cuff pressure was recorded as incorrect in 77% (n=50) and the ETT was found to be placed anatomically incorrect in 20% (n=13) of the cases. Forty-seven per cent (n=31) of the ETIs were performed by ALS paramedic providers (non-physicians), 51%(n=33) by medical officers (physicians) and 2% (n=1) was performed by a registrar level trainee (physician). The authors raised concerns with regards to the considerable amount of incorrect ETT placements and the vast amount of cases where ETT cuff pressure was found to be incorrect, whether the ETI was performed by either non-physicians or physicians (16).

A common trend in most research findings with regards to pre-hospital non-physicians RSI, was that it supports the fact that RSI is the optimal method of ETT placement and that there

was a high success rate of passing the ETT (although in many cases it was self-reported success), however concerns were universally raised with regards to a high adverse event rate and unreported complications during and after RSI by paramedics throughout.

In the South African context, after the approval of pre-hospital RSI in 2009, it is known that some EMS, which includes private and provincial public/government services, have made efforts to support ECPs by providing specific equipment and medication to facilitate RSI and implemented policies/guidelines and training within their organisations. However, what is unknown is to what extent these measures filter down to support and enable ECPs to perform RSI in a safe and effective manner. It is also unknown whether the current standards align with the recommended practice of RSI in all public/government and private and/or non-governmental EMS systems. Since the approval of RSI in the pre-hospital setting, there were some EMS systems that made efforts to implement and align RSI practice to the minimum standards as laid down by the HPCSA, however it cannot be assumed that all EMS systems followed suit.

The minimum standards of pre-hospital RSI in South Africa were laid down by the HPCSA in 2009, to guide the implementation process and to ensure the safe and effective practice of pre-hospital RSI when performed by non-physician ECPs. It could be argued that these guidelines form the foundation and supportive framework, that should be provided by universities and EMS, for safe and effective pre-hospital RSI. This research study, therefore, intends to highlight the current practices of pre-hospital RSI that could affect the safety and efficacy of pre-hospital RSI by ECPs. It is therefore proposed to broadly investigate all three components which include the training, system requirements and comprehensive clinical governance system, to establish whether ECPs are supported by EMS to perform safe and effective RSI. The idea is to investigate from the bottom up, therefore gathering information from the end-user of the pre-hospital RSI system within South Africa. Areas of concerns that may be highlighted during the research study could produce a starting point for further research and in addition, inform current practices of pre-hospital RSI and thereby produce system changes to improve on current patient care by ECPs.

Research Question

What is the current practice, in terms of training, system requirements and clinical governance, of RSI in the South African pre-hospital setting?

Specific Aim

The aim of the research study is to investigate and describe, based on the components of the minimum standards of pre-hospital RSI in South Africa, specific areas of interest related to current prehospital RSI practice.

Objectives

1. To describe the ECP's view of the quality of RSI training received during tertiary education.
2. To describe the availability of and participation in an internship programme (after qualification as an ECP) and formal continuing medical education (CME) activities specifically focusing on RSI.
3. To describe the availability of the required equipment and medication, necessary to perform RSI.
4. To describe the availability, qualifications, training and perceived capabilities of team members assisting ECPs to perform RSI.
5. To describe the availability, basic structures and procedures of formal clinical governance systems pertaining to pre-hospital RSI in South Africa.

Methodology:

Study design

The study would be conducted as a quantitative descriptive cross-sectional study design.

Study population and sampling

The target population of this research study is ALS providers that are registered as ECPs with the HPCSA and working as operational ECPs in the South African pre-hospital setting. The term "operational", in the context of this research study, would entail any emergency medical care duties performed in the pre-hospital setting, in the capacity of an ECP, whether it is full-time or part-time with or without any form of compensation.

In January 2019, the HPCSA iRegister displayed 723 registered ECPs (17), however, it should be recognised that not all of these ECPs are operational in the South African pre-hospital setting. Many ECPs that are registered with the HPCSA are currently working abroad and/or employed in non-operational positions within South African organisations (17). Unfortunately, it is unclear how many ECPs are operational in the South African pre-hospital setting and I was unable to find this information from either the HPCSA or any other source, thus making it difficult to determine the exact size of the study population.

The research student obtained permission to access potential participants through a privately-owned database. The database contains information and contact details of approximately 194 ECPs that are registered with the HPCSA. All the ECPs that are registered on the database provided permission to the owner of the database, Mr Patrick Wallett, to distribute industry related communication to them, which include invitations to participate in research studies pertaining to their industry. The research student will, therefore, email the invitation to participate in the research study and online survey to the owner of the database, without having direct communication to the ECPs on the database. The owner of the database will subsequently email the invitation to participate in the research study and online survey to the ECPs that are voluntarily listed on the database. The research student would not have direct access to the database, and therefore the contact details of those ECPs that are on the database would not be disclosed in any means to the research student. In addition, the research student will also electronically distribute invitations to potential participants that are known to the research student to partake in the research study and online survey, which may or may not be listed on the above-mentioned privately-owned database. Secondly, snowball sampling will be used by asking initially invited participants to disseminate the information and access to the online survey to other interested and potential participants, that are known to them.

The initial convenience sampling and subsequent snowball sampling strategy are deemed to be the best suitable sampling strategy for this research study, due to a variety of factors that make it nearly impossible to accurately determine the actual sample population such as the ever-changing activity status and amount of operational ECPs in the South African pre-hospital setting. This type of sampling strategy would enable the research student to specifically target the desired participants more effectively in terms of subject knowledge and distribution of the survey to other potential participants, especially in terms of ECPs that are currently known to be operational in South Africa. The research student will monitor the participation of the survey in an attempt to obtain a sufficient sample, that is based on the estimated sample size calculation.

To illustrate the operational characteristics of the sample population, a matrix was created that indicate the different sectors that represent the diverse nature of EMS delivery in South Africa (see table 1). The number of ECPs that currently work in each of these sectors are unknown, however the research student will strive to obtain a sample that includes all the sectors (public/government, private/non-governmental organisation and high education institutions) of the study population, as it is expected that the operational environment in

each of these sectors may differ dramatically from each other. The actual representation of the different sectors, in terms of the participation in the research study, would be included in the analysis of the data.

Table 1 A matrix of the sectors that represent the sample population

Sector	Description of the population	Function/Duties as ECP
Public/Government	<ul style="list-style-type: none"> • All nine provincial EMS Systems (Ambulance Services) • Predominantly road responses with ambulances or response vehicles • Training departments and/or institutions officials • Management officials • Other public/government departments that are not recognised as primarily ambulance services e.g. disaster management services, military services, fire and rescue services etc. 	<ul style="list-style-type: none"> • Primary and Secondary pre-hospital response to emergencies • Interfacility transportation of the ill and/or injured • Organised special events in the pre-hospital setting • Clinical practice shifts with students in the pre-hospital setting • Major incident responses • Other emergency medical care responsibilities
Private and/or Non-Governmental Organisations (NGO's)	<ul style="list-style-type: none"> • Local, provincial and national private organisations and/or NGO's that provide pre-hospital emergency medical care (ambulance services) • Road responses with ambulances or response vehicles • Aeromedical and/or helicopter emergency medical care services 	<ul style="list-style-type: none"> • Primary and Secondary pre-hospital response to emergencies • Interfacility transportation of the ill and/or injured • Organised special events in the pre-hospital setting • Clinical practice shifts with students

	<ul style="list-style-type: none"> • Training departments and/or institutions officials • Management officials • Sea and/or mountain rescue organisation officials 	<ul style="list-style-type: none"> • in the pre-hospital setting • Major incident responses • Other emergency medical care responsibilities
Higher Education Institutions (HIEs)	<ul style="list-style-type: none"> • Operational duties as part of teaching and learning • Part-time and/or voluntary duties with other organisations 	<ul style="list-style-type: none"> • Primary and Secondary pre-hospital response to emergencies • Interfacility transportation of the ill and/or injured • Organised special events in the pre-hospital setting • Clinical practice shifts with students in the pre-hospital setting • Other emergency medical care responsibilities

Although this study is of a convenience sample, an estimated sample size calculation was performed to determine confidence and error at different sample sizes. The population size was obtained from the HPCSA iRegister. The online sample size calculator by SurveyMonkey® was used to calculate the sample size (see table 2). With an estimated study population of 450, the margin of error of 8% and a confidence interval of 95%, a sample size of 113 participants was calculated (18).

Table 2 Sample size calculations

Study Population	Confidence Interval	Margin of Error	Sample Size
450	95%	5%	208
450	95%	8%	113
450	95%	10%	80

Lastly, in light of the aim and objectives of the research study, no other emergency care providers would be eligible to partake in the research study, which would include all other levels of care such as Basic Life Support Providers (BLS), Intermediate Life Support Providers (ILS) and other ALS Providers such as Emergency Care Technicians (ECT), CCA and N. Dip: EMC emergency care providers.

Survey: Design and administration

Data collection would be achieved through a trustworthy secure online survey tool, SurveyMonkey®. In recent years access to the internet, via a variety of devices, has become increasingly available in South Africa and therefore it is hoped that this method would reach a large group of potential participants. The online survey was designed using the software tool, SurveyMonkey® and through consultation of a variety of reputable resources during the planning and design phase of the survey. The online survey was specifically designed for this research study and the content was based on the components of the minimum standards. To align the survey questions with the objective of the research study the research student considered all the variables that will be measured with the data that will be obtained from the survey. The survey was therefore compiled by dividing it into six sections namely, Research Study Information, Informed Consent, Basic Demographic Information, Training, System Requirements and Comprehensive Clinical Governance System sections. The questions in the survey focus on specific areas pertaining to the practice of RSI in the pre-hospital setting and the content was primarily derived from key areas within the minimum standards of pre-hospital RSI (3) and the position statement on pre-hospital RSI (1), which was deemed as important to support and enable ECPs to perform RSI. The self-administered online questionnaire was designed by the principal investigator with the assistance of a peer review process, pertaining to the inclusion and relevance of the content. It was designed to be appealing and easy to complete.

In addition, the research student aimed to keep the questions simple, concise and specific to avoid confusion and subsequent inappropriate or incorrect data (19) (20). It was also considered that the limited amount of questions per section would aim to keep the participants interested and promote the completion of the survey. The questionnaire was mindfully designed to be concise and to prevent participant fatigue, which may lead to incomplete surveys that would be futile (21). Questions within each section were sequenced to allow flow within the survey and to allow a natural crescendo of the survey (22).

Web surveys, in general, are notorious to suffer breakoffs. A survey break-off is defined as the act of a respondent starting a survey and subsequent failure to complete it (23). A variety of reasons could be responsible for high break-off rates, such as the design of the survey, the characteristics of the respondents and the questions itself. However, some research indicates that an information section and/or an encouraging message added to the survey may improve break-off rates (24). To reduce the risk of break-off rates for this research study, it was deemed sensible to at the beginning of each section, provide a brief description informing the participant of the content and purpose of that specific section. These sections, also indicate the number of questions that it contains, written to psychologically encourage the participant to continue with the survey and to prevent respondent fatigue. The information provided would also aim to place the participant in a favourable state of mind to provide answers pertaining to that component of the survey (25). At the end of the questions section of the survey, a short message of thanks and appreciation is written, directed specifically to the participant, which aim to display a sincere message that the information provided is of real value to the research student. In order to encourage respondents to distribute the survey to other potential participants, either via a direct link to the survey or using the QR code, the last reminder with additional information on the sampling technique is provided. A pilot of the survey will be conducted, before launching the survey to participants. The pilot survey (26) will be distributed to at least five qualified ECPs that are known to the research student and will be selected based on their ability to provide constructive criticism towards improving the survey before the roll-out phase.

The survey information and actual survey will be electronically distributed to the primary participants which will be requested to disseminate access to other interested and potential participants, which are known to them. The invitation to participate in the online survey will include a description of the proposed research study and a graphic invitation (see Appendix D) which will be intended to be privately distributed to other potential participants that are deemed to be interested to participate in the research study. The information on the invitation would focus on the relevance and importance of participating in the research study, by explaining the potential value that the findings may have on their individual current practice in the pre-hospital setting in South Africa.

As previously indicated, the research student will monitor the survey completion process, in terms of basic demographic data of the participants and completeness of the survey. The research student to promote participation will be resending invitations two weeks after the initial roll-out phase of the survey to all known eligible participants that were invited, either

via the owner of the privately-owned database or by contacting the eligible participants, via email, who is known to the research student.

Measurements

The survey questions aim to produce variables, which are mostly categorical, using both bipolar and unipolar Likert Scales. Most questions would require binary responses, although there will be ordinal data generated from certain sections. To a lesser extent, there would be discrete numerical variables that will be measured. Data analysis would be performed by using the statistical software Statistical Package for the Social Sciences (SPSS) version 25. Descriptive statistical analysis will be used to calculate measures of frequency (count, percentage/proportion and ratio), measures of central tendency (mode, median and mean) and measures of variation (range, quantiles and standard deviation) depending on the type of data (categorical or numerical) and will be presented in the form of graphs and tables. If appropriate, further analyses of data will be undertaken to determine differences between EMS settings, participant groups and provinces. Statistical analysis of the data will be performed depending on the type and distribution of the data and subsequently, the appropriate statistical test will be selected.

Data management

The survey will be conducted in its entirety online, using the tool SurveyMonkey®. Access to this tool is available through UCT, Division of Emergency Medicine (EM), which is secured, and password protected. Once the data collection period is completed, all the data from the survey would be extracted and stored on a secure password encrypted external hard drive. All the data from the completed surveys and subsequent data analysis would only be accessible to the researcher, supervisors and/or statistician.

Statistical Considerations and Data Analysis Plan

After the proposed data collection period of approximately two months, analysis of the data would be performed, with the assistance of a statistician using SPSS. Data analysis would include categorical (nominal or ordinal) and numerical (discrete or continuous) variables.

Ethical considerations

All participants would participate in a voluntary and anonymous basis. None of the participants would receive any form of incentive for participation in the research study. Informed consent would be achieved through an online tick box, that requires each participant to complete before answering any questions of the survey. The survey is designed

in such a manner, that no personally identifiable information is required, nor any identifiable information with regards to organisations, companies and/or educational institutions. Participants can withdraw at any time during the survey, either by not completing the survey and/or interrupting the online process of the survey, once the survey is completed and submitted all participants will be anonymised. The analysis of data would not require any personal or identifying information. The data would only be available to the researcher, supervisors and other research assistants.

Strengths and limitations

The research study is anticipated to be an inexpensive and easy method to generate a body of knowledge about the research question in a short period of time. The sampling technique that will be used for the research study is a limitation, due to it being subject to sampling bias. Therefore, representativeness of the sample is unlikely to be achieved, and generalisability of the findings is limited. However, the decision was made to use this sampling technique, as the sample population was deemed to be difficult to reach.

The design of the research study does not allow for an in-depth description and investigation about all the components of the minimum standards and will only broadly generate results, which will focus on areas deemed to be important to support and enable ECPs to perform pre-hospital RSI. However, this research study would serve as a foundation and a starting point for further research endeavours to improve the current practices of pre-hospital RSI in South Africa by ECPs.

The contentious nature of current discussions within industry pertaining to the topic of pre-hospital RSI by ECPs within South Africa (due to proposed changes in clinical practice guidelines) may hinder participation in the survey. Therefore, the survey invitation and Research Study Information section of the survey clearly describe the intended aim and objectives of the research study. Ensuring that potential participants are clear with regards to the above, may assist with the participation in the research study.

Data dissemination plan

The results of this research study would be disseminated to all stakeholders within EMS and EM in South Africa, including the PBEC at the HPCSA, with the expectation to improve current standards of care pertaining to the safety and effectiveness of pre-hospital RSI in South Africa. The findings of the research study will be published as an article, in a peer review journal, that will be accessible to all other interested individuals and organisations locally and internationally.

Furthermore, findings from this research study would be used as a foundation to explore further opportunities to conduct research in this specific domain of quality care and patient safety in the pre-hospital setting.

Table 3 Project timeline

2019	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT
EMDRC	X	X	X							
Ethics			X	X	X	X				
Data Collection							X	X		
Data Analysis									X	
Report writing							X	X	X	
Submission										X

Resources and budget

The research study is expected to be inexpensive, due to the nature and the availability of free resources to the principal investigator. All work will be performed electronically, which would include the use of a laptop and external hard drive.

Data collection and analysis software are available, free of charge, to the research student through the University of Cape Town: Emergency Medicine Department, which includes access to SurveyMonkey® and SPSS®. Other software programs such as Microsoft Word and Excel, would not require a purchase as it is already available to the researcher. The assistance and services of an editing service and research assistant/statistician would be funded by the researcher to assist with the writing and data analysis process. All other unforeseen expenses will be the responsibility of the research student (see Table 4).

Table 4 Budget

Item	Description	Unit Cost	Number of Units	Total Cost
SurveyMonkey®	Survey tool	Access via UCT	1	R 0
SPSS®	Statistical software	Access via UCT	1	R 0
Statistician	Data analysis	R 600/hour	2	R 1 200
Editing service	Proofreading & editing	R20/page	60	R1 200
Data	Internet connection	R 500/month	10	R 5 000
Total Cost				R 7 400

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Appendix 9: HREC Approval Letter



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room E53-46 Old Main Building
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Observatory 7925
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Website: www.health.uct.ac.za/fhs/research/humanethics/forms

24 June 2019

HREC REF: 204/2019

Dr W Stassen
Division of Emergency Medicine
c/o Ms Vathiswa Mzamo
F-51, OMB

Dear Dr Stassen

PROJECT TITLE: RAPID SEQUENCE INTUBATION: A SURVEY OF CURRENT PRACTICE IN THE SOUTH AFRICAN PRE-HOSPITAL SETTING (MPHIL CANDIDATE - MS JC BOTHA)

Thank you for your response letter dated 28 May 2019, addressing the issues raised by the Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 June 2020.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Ms J Botha will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely


PROFESSOR M. BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: RRC-210208-007