



## Was muss eine SOP können?

6. Kongress Herzanästhesie Österreich - "***HerzensSchicksal***"

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# How to Write Effective Standard Operating Procedures (SOP)

A standard operating procedure is a document providing explicit directions for completing a certain task. Here, we talk about why SOPs are important, and how to create them.



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# Inhalt

- ▶ SOP - woher kommt's?
- ▶ Gibt es Literatur zu dem Thema?
- ▶ Was muss eine SOP können = wie schreibt man eine gute SOP?
- ▶ Beispiele



# Hintergrund

- ▶ standard operating procedure  
= standing operating procedure
- ▶ Historie nicht vollständig bekannt
- ▶ Abkürzung bereits im 2. Weltkrieg verwendet
- ▶ Verwendung in medizinischen/wissenschaftlichen,  
industriellen und militärischem Kontext
  - ▶ Paradebeispiel Luftfahrt
  - ▶ „high risk organisation“



# International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

- ▶ “Detailed, written instructions to achieve uniformity of the performance of a specific function.”



Home \ About ICH \ Mission

## Mission

### Harmonisation for Better Health

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has gradually evolved, to respond to the increasingly global face of drug development. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. Harmonisation is achieved through the development of ICH Guidelines via a process of scientific consensus with regulatory and industry experts working side-by-side. Key to the success of this process is the commitment of the ICH regulators to implement the final Guidelines.




# Bezug zu Guidelines?


- ▶ Umsetzung von Guidelines passend für örtliche Gegebenheiten/Strukturen in die klinische Praxis
- ▶ Ergänzung durch weitere Literatur bzw. Ausweitung des Themenumfangs möglich




# Literatur?



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# Patientensicherheit



„When we assess healthcare quality,  
we should pay attention not only to how  
efficient a certain medical intervention has  
turned out to be, but also to  
how safe it has been for a patient.”







# PLOS COMPUTATIONAL BIOLOGY

EDITORIAL

## Ten simple rules on how to write a standard operating procedure

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# Ten simple rules on how to write a standard operating procedure



Rule 1: Knowing when to write an SOP

Rule 2: Write the introduction: describe the purpose (the why)

Rule 3: Set up the document structure

Rule 4: Fill in the content

Rule 5: References and definitions: Specify tools required for the task

Rule 6: Set up responsibilities and nominate reviewers and approvers

Rule 7: Test with a colleague: Perform training

Rule 8: Review and approve

Rule 9: Update document: Specify validation and periodic review date

Rule 10: Publish



# Wann macht eine SOP Sinn?

- ▶ Bezogen auf eine spezifische Tätigkeit und Aufgabe
- ▶ Wiederholende Prozesse, die reproduzierbare Ergebnisse liefern sollen
  - ▶ Erhöhung des Behandlungsstandards
  - ▶ Compliance
- ▶ komplexe Aufgabe für die Anwendung in der Praxis aufarbeiten - bestenfalls simplifizieren
- ▶ Grundlage für Einschulung neuer Mitarbeiter



# Compliance erhöht? - Ja

ORIGINAL RESEARCH

Open Access

## Standard operating procedure changed pre-hospital critical care anaesthesiologists' behaviour: a quality control study

Leif Rognås<sup>1,2,3,4\*</sup>, Troels Martin Hansen<sup>3,4</sup>, Hans Kirkegaard<sup>5</sup> and Else Tønnesen<sup>6</sup>

### Abstract

**Introduction:** The ability of standard operating procedures to improve pre-hospital critical care by changing pre-hospital physician behaviour is uncertain. We report data from a prospective quality control study of the effect on pre-hospital critical care anaesthesiologists' behaviour of implementing a standard operating procedure for pre-hospital controlled ventilation.

**Materials and methods:** Anaesthesiologists from eight pre-hospital critical care teams in the Central Denmark Region prospectively registered pre-hospital advanced airway-management data according to the Utstein-style template. We collected pre-intervention data from February 1<sup>st</sup> 2011 to January 31<sup>st</sup> 2012, implemented the standard operating procedure on February 1<sup>st</sup> 2012 and collected post intervention data from February 1<sup>st</sup> 2012 until October 31<sup>st</sup> 2012. We included transported patients of all ages in need of controlled ventilation treated with pre-hospital endotracheal intubation or the insertion of a supraglottic airways device. The objective was to evaluate whether the development and implementation of a standard operating procedure for controlled ventilation during transport could change pre-hospital critical care anaesthesiologists' behaviour and thereby increase the use of automated ventilators in these patients.

**Results:** The implementation of a standard operating procedure increased the overall prevalence of automated ventilator use in transported patients in need of controlled ventilation from 0.40 (0.34-0.47) to 0.74 (0.69-0.80) with a prevalence ratio of 1.85 (1.57-2.19) ( $p = 0.00$ ). The prevalence of automated ventilator use in transported traumatic brain injury patients in need of controlled ventilation increased from 0.44 (0.26-0.62) to 0.85 (0.62-0.97) with a prevalence ratio of 1.94 (1.26-3.0) ( $p = 0.0039$ ). The prevalence of automated ventilator use in patients transported after return of spontaneous circulation following pre-hospital cardiac arrest increased from 0.39 (0.26-0.48) to 0.69 (0.58-0.78) with a prevalence ratio of 1.79 (1.36-2.35) ( $p = 0.00$ ).

**Conclusion:** We have shown that the implementation of a standard operating procedure for pre-hospital controlled ventilation can significantly change pre-hospital critical care anaesthesiologists' behaviour.

**Keywords:** Pre-hospital, Out-of-hospital, Prehospital emergency care (MeSH), Emergency medical services (MeSH), Helicopter emergency medical service, Critical care (MeSH), Controlled ventilation, Standard operating procedure, Airway management (MeSH), Endotracheal intubation (MeSH), Patient safety



# Compliance erhöht? - Nein

Dan Med J 59/4 April 2012

DANISH MEDICAL JOURNAL 1

## Prehospital guidelines for use of hypertonic saline are not followed systematically

Julie Hejselbaek, Jacob Steinmetz & Lars Simon Rasmussen

### ABSTRACT

**INTRODUCTION:** Hypertonic saline (HS) was introduced in our physician-based mobile emergency care unit (MECU) in September 2006 for patients with severe traumatic brain injury and hypotension. HS has, however, rarely been used and we sought to identify barriers to its implementation.

**MATERIAL AND METHODS:** We conducted a survey based on a questionnaire administered to all 40 anaesthesiologists employed at the MECU in Copenhagen as per August 2010.

**RESULTS:** A total of 31 anaesthesiologists (84%) returned the questionnaire. Three physicians were excluded because of leave. Almost half of the physicians considered the evidence for use of HS insufficient, and 29% found that guidelines were lacking. Noticeable barriers were inadequate familiarity with and unawareness of the guideline. Some believed that they may have failed to use HS because the option did not occur to them during the relevant incidents. Many physicians stated that training at the MECU should be more thorough and that instructions were missing.

**CONCLUSION:** Barriers to the implementation of HS were lack of familiarity with the guideline and disagreement regarding the evidence supporting its use. Possible solutions to these implementation issues include additional instructions and internal MECU meetings.



# Wann macht eine SOP Sinn? (2)

- ▶ „Monitoring“ des gewünschten Ergebnisses
- ▶ Inhalt sollte in der Praxis umsetzbar sein („Testläufe“)
- ▶ Ohne Schulung fragliche Adhärenz



# Form und Layout

- ▶ Standardisiertes Layout / Struktur
  - ▶ Schnelles Auffinden der rel. Information
- ▶ Gültigkeit im Vorhinein definieren und entsprechend aktualisieren
- ▶ Aktualisierungshistorie
- ▶ Graphische Zusammenfassung



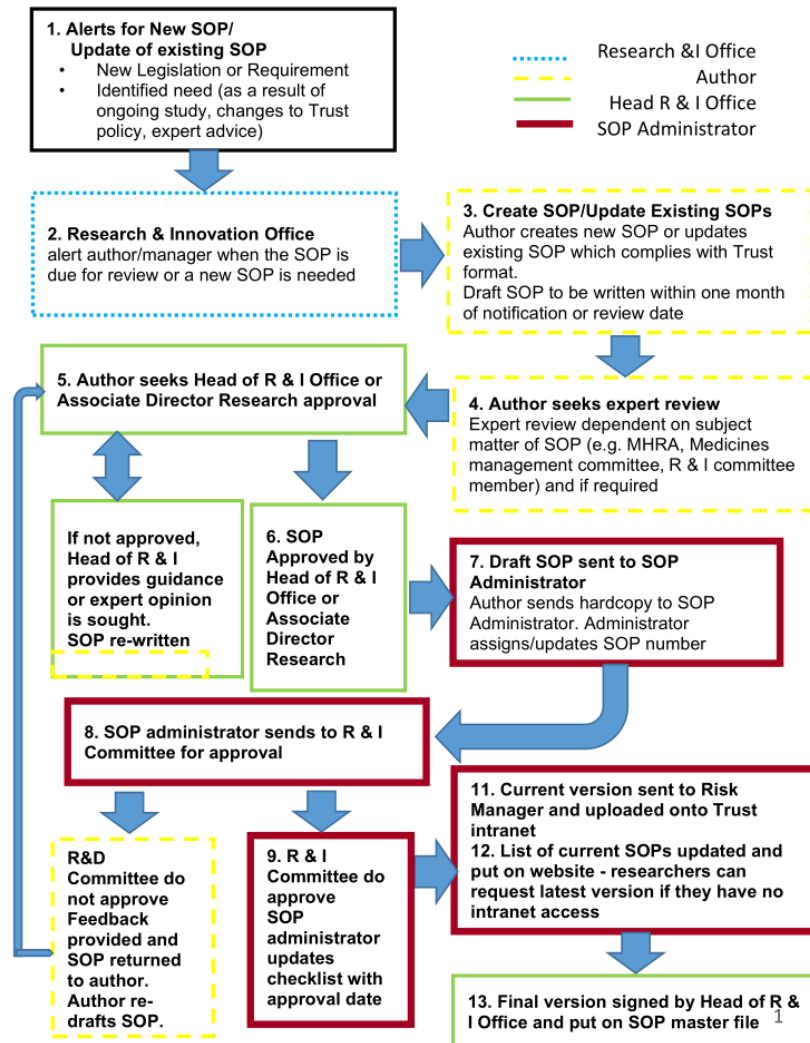
<b>Title of Standard Operating Procedure:</b>		RDSOP01 Preparation, Approval and Maintenance of Research & Innovation Standard Operating Procedures			
<b>Document Summary:</b>		To describe the procedure for preparing and approving Trust R & I SOPs within the Trust, and also the procedure for review and archiving of these SOPs			
<b>Document Author:</b>		Jennifer Higham Research Governance Manager, updates by Anya Sekula Research Initiation and Delivery Manager			
<b>Target Audience:</b>		Trust-wide, Research Community, Internal and External Researchers			
<b>Consultation:</b>		R & I Office, research community and R & I Committee members			
<b>Approval Committee:</b>		R & I Committee			
<b>Cross Reference Document(s):</b>		Research Approval Policy All Trust R & I SOPs			
<b>Contact details for further information:</b>		Sarah Leo Head of R & I Office 0161 271 0076 <a href="mailto:researchoffice@gmmh.nhs.uk">researchoffice@gmmh.nhs.uk</a>			
<b>Minimum Monitoring Requirement</b>	<b>Frequency</b>	<b>Process for monitoring</b>	<b>Evidence</b>	<b>Responsible Individual(s)</b>	<b>Response Committee(s)</b>
Review of SOP content	Every 3 years	Review by Author, redraft, submission to R & I Operational Group	Minutes of R & I Operational Group	Head of R & I Office	Research & Innovation Committee

Ref: RDSOP01	Issue date: 15/10/2021	Version number: 2.0
Status: Final	Next review date: 15/10/2024	Page 1 of 7





**Appendix A**  
**Approval Stages for Research related Standard Operating Procedure**  
**Writing and Update**



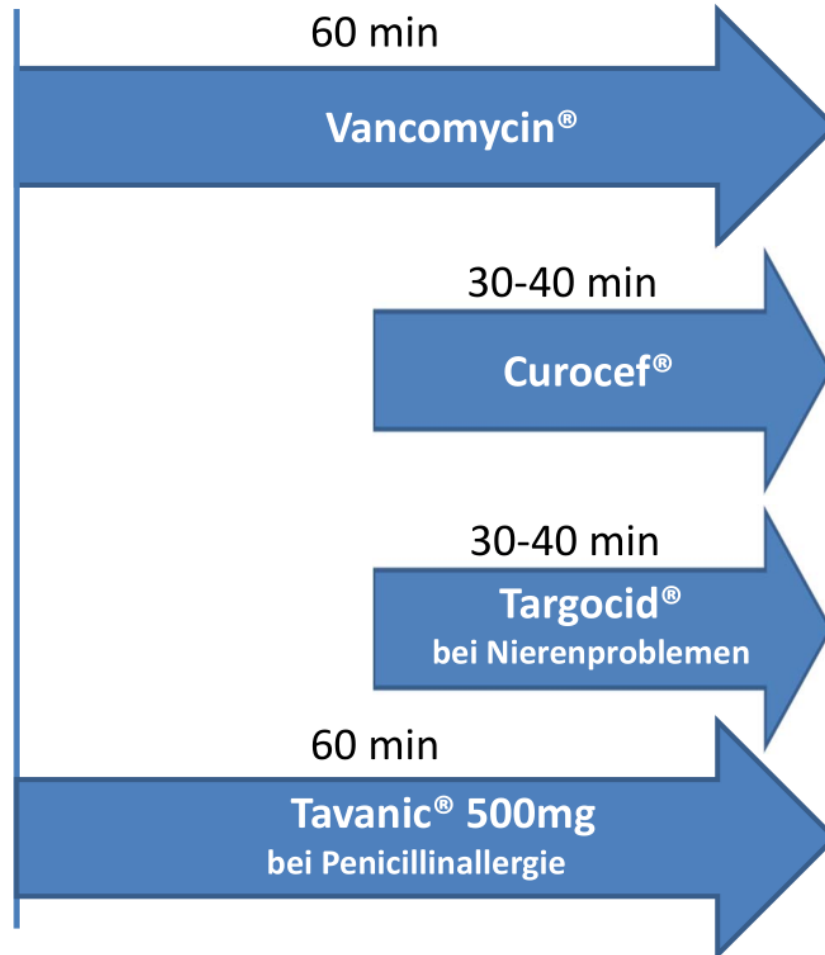
Ref: RDSOP01	Issue date: 15/10/2021	Version number: 2.0
Status: Final	Next review date: 15/10/2024	Page 7 of 7



# Antibiotikaprophylaxe 2015 im Herz-OP

7:30

8:30-8:40  
Hautschnitt



# Umlagerung & Transport & Mobilisation



## Allgemein

Bei Umlagerung & Transport und Mobilisation des Patienten - System wie in Folge gegen unbeabsichtigtes Drainieren von Liquor sichern:

### 3. Schritt

Druckaufnehmer zur Umgebung hin schließen (wie abgebildet)

### 2. Schritt

Zweiwegehahn der Patientelinie schließen (wie abgebildet)

### 1. Schritt

Zweiwegehahn zum Drainagezylinder hin schließen





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