

12. Were the responders invited by the affected country?  
By whom?
13. When was the intervention terminated? By whom?  
Why?
14. What were the differences in responses to different areas and why?
15. How will the effectiveness, efficiency, efficacy, benefits, and costs of each intervention be determined?  
By whom?
16. Was the responding unit self-sustaining?
17. How were the responders credentialed?

To learn what we must, it is essential that all of the above questions eventually be answered and reported in a structured way that is readily accessible and reproducible.

**Keywords:** coordination and control; earthquake; evaluation;

Guidelines; Indian Ocean; interventions; lessons learned; reports; responses; structure; templates; tsunami; Utstein

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## Free Papers—Theme 7: Prehospital Care—A Medical Speciality?

### Reporting Quality of Randomized, Controlled Trials in Prehospital Care

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**Background:** Emergency medical services (EMS) often provide the “golden hour” of care in most emergency and disaster settings. EMS systems utilize unique, disciplined, and sensitive approaches to the identification and stabilization of patients in the prehospital environment. Despite the increasing skill set of prehospital emergency practitioners, the majority of prehospital healthcare interventions have not been subjected to rigorous research in the form of randomized, controlled trials (RCTs). Many international, prehospital, clinical practice guidelines continue to reflect local needs and traditions rather than evidence-based practices. While RCTs are considered to be the “gold standard” of study design in primary research, they are difficult to conduct in out-of-hospital settings primarily due to the ethical issues involved and the uncontrollable and unpredictable nature of the prehospital environment. Therefore, the few RCTs that have been conducted in this setting may suffer from problems in methodology and quality. Trials with poor methodological quality have exaggerated estimates of treatment effect and incomplete reporting of trials cause difficulties in assessing trial methodological quality.

**Objective:** To examine the quality of reporting of randomized, controlled trials (RCTs) in prehospital care.

**Methods:** The CENTRAL database of the Cochrane Library will be searched for RCTs in prehospital or out-of-hospital settings. An exhaustive list of search terms will be used to identify prehospital trials. Two reviewers independently will assess trials using the consolidated standard of reporting trials (CONSORT) checklist. Disagreements will be resolved by consensus. Inter-rater reliability will be

assessed with percentage agreement. Mean number of checklist items will be reported across all trials. The influence of time (1970s, 1980s, 1990s, and 2000s) will be explored with logistic regression.

**Results:** The study is taking place currently and the results will be presented during the conference.

**Conclusion:** This study attempts to explore the methodological quality of RCTs conducted in prehospital settings, and thereby highlights the difficulty of conducting them.

**Keywords:** emergency medical services (EMS); out-of-hospital; prehospital; quality; randomized, controlled trial (RCT)

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### Feasibility of Informed Consent in Emergency and Prehospital Research: How Do We Ensure the Patient's Voice is Heard?

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Informed consent is a vital part of ethical research. However, in emergency care research fields, especially those studies involving ambulance services and emergency departments, it is sometimes necessary to conduct trial interventions without patient consent. When treatment is time critical, it also may be impossible to get consent from the next-of-kin within the treatment timeframe. Prehospital and emergency medicine is one of the few areas where informed consent laws can be relaxed to allow research to proceed under strict guidelines. In emergency health situations, even when informed consent is sought, there is no real assessment of the patient understanding of the proposed intervention or ability to appraise the potential outcomes. In times of a health emergency, patients and their lives are most vulnerable, and coercion, intended or otherwise, is a strong possibility. This presentation will explore the process of informed consent, and whether informed consent is feasible in emergency health research.

This presentation also will address issues relating to emergency health research such as proxy consent, medical staff influence, and the rights of the unconscious patient. The potential for conflict arising from differences in culture and values between patients and healthcare professionals also will briefly be discussed.

The prehospital and emergency care setting is a research situation where patients are particularly vulnerable to violation of their rights. These issues are relevant to all research requiring informed consent, in addition to research where the participant and proxy understanding of the possible outcomes and potential harm is questionable. Most of all, these issues affect anyone who may one day be in an emergency health situation, or have to make decisions about health for someone else.

**Keywords:** emergency; ethics; informed consent; next-of-kin; patients; prehospital; research

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