Title

Healthy Volunteers In Distress: Creating A Guideline For Implementation Of Emergency Mock Trainings In A Phase I Clinical Pharmacology Unit

Introduction

Mock trainings have been proven effective in teaching personnel how to cope with emergency scenarios and improving patient outcome. This positive effect has been well established for emergency rooms [1], intensive care wards [2], pediatric [3] and obstetric wards [4] and many other disciplines. For Clinical Pharmacology Units (CPU), besides a national guidance document issued by the NHS [5,6] no guidelines for implementation of Mock trainings exist, although first-in-human compounds can give immediate and life-threatening results, unexpected by preclinical data [7]. Additionally, health authorities start to expect regular mock trainings as part of the emergency standard operating procedures from CPUs [10]. This poster intends to initiate the development of a guideline for implementing mock trainings, based on realistic scenarios that could occur during a phase-I trail.

Method and Materials

Guidelines from other areas were reviewed for effective training methods [1-4]. The training was divided in theoretical background training, practical scenario training, interval of trainings, the need for unexpected scenario trainings and how to give feedback on trainees.

Based on articles exploring adverse events seen in phase-I clinical trails [5, 7-10], a list of Severe Adverse Events and medical emergencies was formed. Based on clinical experience, these scenarios were evaluated for potential reoccurrence in other trails, and additional scenarios were added based on expert opinion.

Results

Lectures on theoretical background and practical scenario training are advised to be based on the immediate life support course provided by the European Resuscitation Council (ERC) and finetuned to potential emergencies in a Phase I unit. Via the standardized ABCDE approach, staff will provide support to the subject until further help arrives. An overview of the entire training program is schematically shown in figure 1. Table 1 provides a list of potential scenarios that can be used to train medical personnel working at a CPU.

Conclusion

Based on experience in mock trainings in other clinical settings, implementing a standardized guideline for mock trainings including specific scenario training, can enhance staff performance in coping with medical emergencies in phase-I clinical trials. These results can be used as a starting point for emergency training in other CPU's.

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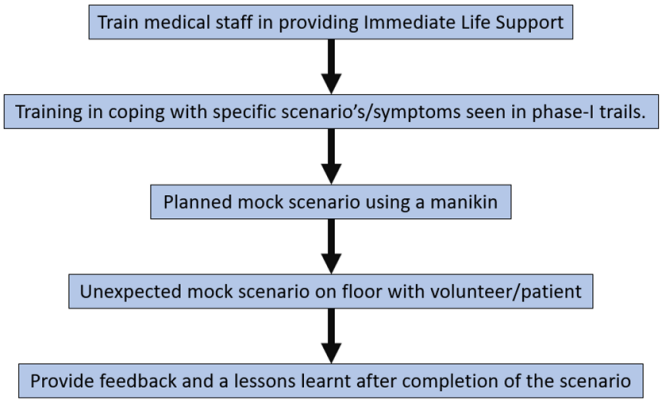

Medical emergency scenarios
Acute psychosis [8]
Anaphylaxis – Bronchoconstriction [5, 10]
Cardiac arrest [5, 10]
Hypotension [7, 9]
Prolonged loss of consciousness [5, 8, 9]
QT-prolongation - Torsades de pointes*
Seizures*
Suspected myocardial infarction [5, 8]
Tachycardia (including unstable AF) [7]

*Based on expert opinion

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