

**The Medical Emergency Team:  
Hospital Outcomes after a Day (METHOD) study  
Version 2 – 15/12/2013**

**The METHOD Study Investigators:**

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**1. Study Organisation and Administration**

**1.1. Management committee Protocol Authorisation Page**

We the management committee have read the attached protocol (Version dated 20 May 2012) and authorize it as the official protocol for the study entitled

**The Medical Emergency Team: Hospital Outcomes after a day (METHOD) Study**

Chief Investigator  
**Christian Subbe**



..... Date 30 August 2012

Management Committee  
**Daryl Jones**

..... Date .....

Management Committee  
**Rinaldo Bellomo**

..... Date .....

**1.2. Investigator Protocol Agreement Signature Page**

I have received and read the **METHOD study** protocol Version date 15/12/2013 and agree to conduct the study in accordance with:

- a. the attached protocol (subject to amendments)
- b. the stipulations and requirements of my hospital research ethics committee (HREC)

I am also willing to participate in this study with the understanding that authorship will be attributed as outlined in the section entitled ***“Authorship and publications”***

Name of Participating Site .....

Signature of Investigator 1: ..... Date

Name of Investigator 1 .....

Signature of Investigator 2: ..... Date

Name of Investigator 2 .....

### **1.3. Administrative Structure**

#### **1.3.1. Management/Writing Committee**

##### Responsibilities:

Overseeing all aspects of the study management including:

- approval of:
  - final protocol
  - data collection tools
  - data analysis plan and manuscripts
- general study management issues
- data analysis
- drafting and revision of manuscripts
- submission and revision of manuscripts

##### Members:

Chris Subbe	Chief Investigator Chair of management/writing committee
Daryl Jones	Intensive Care Specialist Austin Health Adjunct Senior Research fellow Monash University
Prof Rinaldo Bellomo	Intensive Care Specialist Austin Health

##### Meetings:

Meetings and teleconference as needed.

#### **1.3.2. Participating hospitals**

##### Responsibilities:

- Obtaining ethics approval for study, prior to commencing data collection
- Overall management of study at own site in line with the study protocol
- Collection of data from hospital databases
- Data collection and data transfer / submission to management committee
- Data query resolutions
- Liaison with local HREC
- Adherence to local HREC guidelines and reporting requirements.
- **The site investigator will be responsible and accountable for the accuracy and integrity of the data collected by the data collector at each site.**

## **2. Study Aims and Objectives:**

We plan to conduct a multi-centre international study to examine the outcomes of patients in the 24hr period after review by a Medical Emergency Team (MET), Rapid Response Team (RRT) or Critical Care Outreach Team (CCOT). The term MET is used predominantly in Australia, the term RRT in the USA and Canada and the term CCOT in the United Kingdom, respectively. For the purpose of this study the term "MET" will be used to represent MET, RRT and CCOT services.

We will conduct a prospective observational study of all patients subject to MET review over a one-week period in multiple hospitals in the United Kingdom, Australia, and North America. We will collect data on:

1. The baseline characteristics of patients subject to MET review, including the presence of pre-existing limitations of medical therapy.
2. The physiological trigger for the MET call
3. A number of outcomes in the patient within the first 24 hr after the MET review.
  - a. Admission to the critical care unit
  - b. Transfer of the patient to the operating room
  - c. Delays (defined as a period > 4hr) between onset of the MET and transfer to the Critical care unit or operating room, and the perceived reasons for such delays
  - d. Occurrence of repeat MET calls in < 24hr, and whether it was due to the same physiological trigger.
  - e. Implementation of limitation of medical therapy after the MET and whether this was carried out by:
    - i. Members of the MET
    - ii. Members of the ward-based staff
  - f. Death with a limitation of medical therapy in place (palliative)
  - g. Cardiac or respiratory arrest, and the timing of this in relation to MET activation
4. For the purpose of this study a 24 hr event is defined as an event occurring between 16 and 28 hours after the primary MET call.

## **3. Study Background and rationale**

Patients admitted to hospital wards have increasingly complex conditions and a growing number of co-morbidities<sup>1,2</sup>. Medical emergency teams (METs) have been introduced into hospitals to identify, review and treat acutely deteriorating ward patients in an attempt to reduce cardiac arrests, serious adverse events and unplanned admissions to the intensive care unit<sup>3,4</sup>

The majority of literature related to MET calls evaluates the effect of introducing a MET into a hospital system on the outcomes of all hospitalised patients. Much less information exists on the epidemiology of patients subject to MET review<sup>5</sup>. A small number of studies have assessed the reason for MET calls occurring<sup>6</sup>. Even less information exists on the interventions performed by the MET, and the immediate outcomes of patients after MET review. This information is important, as patients subject to MET review have an in-hospital mortality rate in the order of 20%<sup>7-10</sup>.

Possible interventions following MET review may include admission to a Critical care unit, transfer to the operating room, or implementation of a DNR or other limitation of medical therapy. Undesirable outcomes after RRT review may include the occurrence of cardiac arrest, delayed transfer to the ICU<sup>11</sup> or operating room, lack of improvement in patients who remain on the ward, and repeated MET calls for the same physiological trigger. The factors that contribute or affect such undesirable outcomes after MET review may relate to factors specific to the MET, or due to other variables associated with general hospital care and resourcing. The purpose of this study is to conduct a multi-centre international study to examine the outcomes of patients in the 24hr period after MET review.

#### **4. Study design and data collection**

The study design is a prospective observational study. We will use a pro-forma case report form and data dictionary to guide data collection. Data will only be derived from the patients file and charts representing usual care. No information will be collected that does not pertain to usual patient care. No interventions that are not part of routine patient care will be performed.

#### **5. Study participants**

Participants will include all patients who are subject to MET review over a one week period in the participating hospitals.

#### **6. Ethical Considerations**

The study involves collection of de-identified information resulting from standard care provided by the MET, and the outcome of patients during such care. The study does not involve any interventions. As such, the study constitutes audit activity. Waiver of informed consent from study participants will be requested in the HREC submissions.

## **7. Data Management**

### **7.1. Data collection and data sources**

Data will be collected by a dedicated data collector at each institution. This will either be a member of the MET team, a research fellow or a clinical fellow. We will collect data on the following:

#### **7.1.1. Patient demographics**

- a. Age, gender, parent unit, source of admission (home, nursing home, supported accommodation)

#### **7.1.2. Details of the MET call**

- a. Date, day and time of the call
- b. Physiological trigger leading to MET review

#### **7.1.3. Outcomes within the first 24 hr after MET review**

- a. Was the patient admitted to a critical care area (includes ICU, HCU, CCU (Y/N))
  - i. In patients admitted to critical care area, what was the time interval between the onset of the MET call and arriving in the critical care area
  - ii. What were contributing factors to the delay
    1. No bed available
    2. Patient was initially stable on the ward
    3. Required investigation or intervention prior to admission
    4. Others
- b. Was the patient transferred to the operating room after MET review (Y/N)
  - iii. In patients transferred to the operating room, what was the time interval between the onset of the MET call and arriving in the operating room
  - iv. What were contributing factors to the delay
    1. No theatre available
    2. Patient was initially stable on the ward
    3. Required investigation or intervention prior to going to O/R
    4. Others

- c. Did the patient have a new or escalated limitation of medical therapy (Y/N) including “Do not Resuscitate”, “Not for ICU”, “For limited ICU”, “Not for Intubation”, “Not for Inotropes”
  - v. In these patients, who contributed to the implementation of this plan
    - 1. MET staff
    - 2. Ward staff
    - 3. Both MET and ward staff
- d. Did the patient have a repeat MET call within < 24hr of the initial MET call (Y/N)
  - vi. In these patients, was the MET call criteria
    - 1. Identical to the original call
    - 2. Different to the original call
- e. Did the patients MET trigger resolve within < 24hr of the initial MET call (Y/N)  
(i.e. in patients with a physiological trigger did blood pressure, respiratory rate etc improve below the level that should have triggered another MET call).
- f. Did the patient die within < 24 hr of the MET call (Y/N)
  - vii. In these patients, was the death
    - 1. In the presence of a DNR (expected death, no CPR given)
    - 2. In the absence of a DNR (unexpected death, CPR given)
    - 3. In the absence of a DNR (unexpected death, no CPR given)

## **7.2. Standardisation of data collection**

A standardised case report form (CRF) will be used to guide data collection. This will contain definitions and explanations for each of the data fields.

## **7.3. Data handling**

The electronic database will be stored on a password protected computer. Only investigators involved in the study will have access to the database.

## **7.4 Data analysis**

Data will be analysed to answer the questions outline in the study aims and objectives. Descriptive data will be presented as raw numbers and percentages of totals, and numerical data will

be presented as median and inter-quartile range (IQR). Differences in proportions will be assessed using the chi-square test (with Yates contingency correction) or Fishers exact test, and expressed as an odds ratio (OR) with 95% confidence interval (95% CI). Differences in the central tendency of distributed data will be assessed using the Mann-Whitney U test. A p-value of  $< 0.05$  will be taken to indicate statistical significance.

## 8. Organisation AND Collaboration

### 8.1. Authorship and Publication

The study will be conducted in the name of the “**The METHOD study Investigators**”. All publications arising from this study will be under the name of the “**The METHOD study Investigators**”. A detailed appendix will be submitted to acknowledge the relative contribution of all participants. It is proposed that the following headings will be employed.

1. Study conception and design
2. Management committee
3. Writing committee
4. Data analysis and statistics
5. Site participants and investigators
  - a. Sites will be listed alphabetically
  - b. Site investigators will be listed as agreed within each site.

Only the members of the study management committee will be eligible to present study material at conferences, which will be in the form of standardized slides. Individual sites must agree (by signing the Investigator protocol agreement signature page) to not publish data outside of this study.

## 9. Investigator Checklist

The site investigator should ensure that the following occur:

1. HREC approval obtained or need for HREC approval been waived locally
2. The most recent protocol version has been obtained
3. The HREC approval and Investigator Protocol Agreement Signature Page is signed and faxed to Chris Subbe (0044-1248-384330)
4. Data is entered onto the case report forms and the site specific spreadsheet in accordance with the data dictionary definitions and returned in excel format electronically

## 10. Outcomes and significance

Patients subject to MET review have a high in-hospital mortality. Thus, understanding the outcome of patients within the first 24hr of MET review is important in developing quality improvement and interventional studies to reduce this mortality. The present study will provide an initial analysis of these outcomes, and the inter-hospital variability of them.

## 11. References:

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