Study protocol and statistical analysis plan

Title:

Detection of deteriorating patients on peripheral surgical wards by an automated notification system

Protocol code: DrePaSiNet

Dresdner Patienten Sicherheits- Netzwerk

ClinicalTrials.gov ID: not yet assigned (by 2018-03-04)
IRB approval: EK DD 291072016

Protocol version: V1.0
Protocol date: 2015-01-01

Responsible Party:

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Data collection

After approval of the institutional review board (EK DD 291072016) data from four clinical routine databases were collected and analyzed over two 12 months periods. Individual informed consent was waived by the IRB.

On 2016-07-01 a Multiparameter Early Warning Score (MEWS) – based vital monitoring and paging system (Intelligent Guardian Solution (IGS), Phillips, Hamburg, Germany) was deployed on two surgical wards with 56 beds in total. Medical staff received intense training on the handling of the IGS before deployment over two months.

All measurements from the monitors were transmitted via a wireless local area network to a central server connected to the hospital data network and to a paging server (Digitaler Anruf- und Kommunikationsserver (DAKS), Siemens, Erlangen, Germany) for automated notification of the attending surgeon or the MET. All notifications were given via text message on custom DECT phones, including room, and bed number, as well as the present MEWS score and the time over which it changed.

Handling protocol

The handling and escalation/ de-escalation protocol for measurement intervals and devices is displayed in Figure 1.

Text prompts on the spotcheck monitors directly advised the nurses according to the handling protocol. According to the protocol the density of measurements was adapted to the patient's condition. When the MEWS reached 7 or higher the surgical registrar was automatically paged by the system to take care for the deteriorating patient. It was to his discretion to call the MET if necessary. In case of an obviously life threatening condition, the MET could directly be called by a button on the monitor.

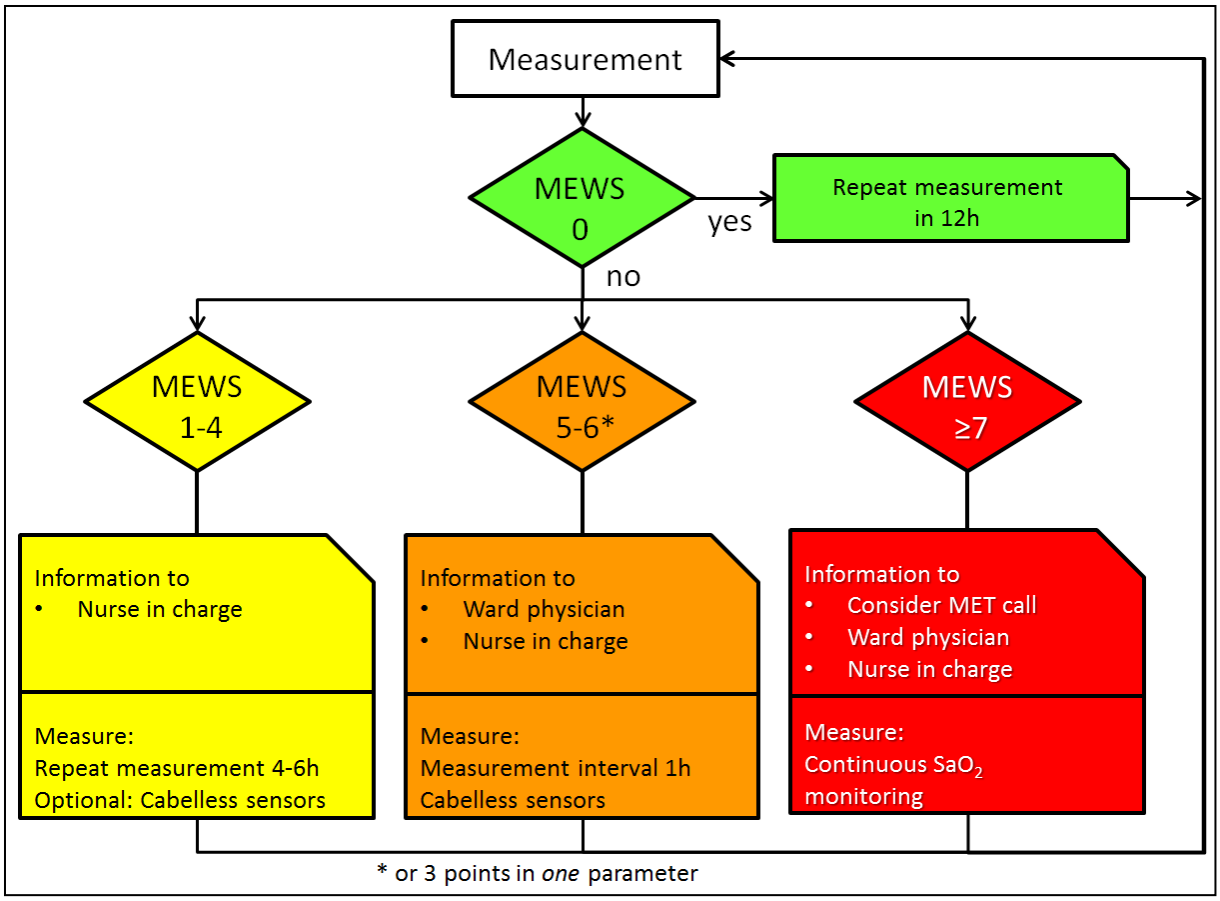

Figure 1 Flowchart for patient condition- adapted measurement, handling of IGS components, and communication.

Database management

Deployment of the IGS was accompanied by data acquisition in four routine databases from 2016-07-01 to 2017-06-30. The complete year of 2015 served as control period. Data on length of stay, ICU admissions, age, gender, survival, G-DRG- codes and case weight originate from the hospital information system (ORBIS, AGFA HealthCare, Bonn, Germany). Data on comorbidities derive from the anesthesia information system (ANDOK, DATAPEC, Pliezhausen, Germany). The local dataset of the German Resuscitation registry provided all data recorded during the MET missions with or without cardiac arrest. In the intervention phase the IGS database (Philips, Hamburg, Germany) provided all data on MEWS and individual physiologic parameters of all measurements. Aggregation of databases was conducted by use of the key variable “FALLNUMMER” which was part of each dataset.

Statistical analysis

Data are presented as absolute number of patients with respective percentage per group or as parameter mean ± SD. For comparisons of interval-scaled variables between the observation periods, two tailed, unpaired t-tests were performed. Levene's test was used to check these variables for Gaussian distribution. Nonparametric between group testing was achieved with two tailed Mann-Whitney U- test. Additionally, the chi-square test or Fisher's exact test was applied to nominal-scaled data. To address the fact that patient condition was significantly poorer during the intervention period e.g. in terms of DRG- case weight, comorbidity, and surgical complexity as indicated by duration of surgery, statistical comparisons between the observation intervals were completed regarding the respective G-DRG case weight as a statistical confounder.

SPSS software (IBM SPSS statistics, version 24.0.0.1, Armonk, NY, USA) was used for all calculations. In all statistical comparisons, significance was accepted with an error probability of $p < 0.05$.