MEDICAL DEVICE FAILURE AND MDD REPORTING FORM – THE NEED FOR TAILORED STANDARD OPERATING PROCEDURES

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Abstract: Appropriate retrospective analysis of critical incidents should be made accessible in due time and anonymous form to the community on a European wide level. Such a comprehensive data collection would allow individual institutions to tailor their strategies and adapt policies aimed at reducing the risks of critical incidents in a pre-emptive approach. In respect to the reporting system standard operating procedures tailored to the specific needs of the department involved and complying with the MDD may help in overcoming present deficits.

Introduction

Practising medicine is prone to errors, especially when performed in a complex environment [1]. Significant contributions to safety in medicine has originated from different groups of physicians, beginning with the implementation of safety check procedures to eliminate faults in equipments [2] and continuing with the systematic analysis of (confidential) reports of adverse events as observed in routine treatment in intensive care units [3]. Patient safety may also be increased by appropriate preventive strategies such as proper safety design of medical devices but also minimizing treatment risks and (latent) system errors. Nevertheless the question may be raised why progress seems to be rather slow in medicine when learning from mistakes in contrast to the high risk businesses like aviation, nuclear power plants and oil industry. In these industries various reporting systems on errors and incidents, both voluntary and mandatory, have been practised for decades. In addition major sources of quality improvement arise from customers complaints (service businesses). Meanwhile national or transnational adverse incident reporting systems have been established or enforced (Adverse Incident Centre – Medicines & Healtcare products Regulatory Agency http://www.medical-devices.gov.uk, Medical Device Reporting (MDR) / Med Watch program (FDA; Final Regulation July 31, 1996), The Austrialian and New Zealand Medical Device Incident Report Investigation Scheme (http://www.medsafe.govt.nz/) aso. The objective behind the " European Vigilance System" is to protect patients and other users by reducing the chance of the same types of incidents reoccurring in different places across the European Economic Area (EEA). Therefore the European Vigilance System is based on mandatory reporting of critical incidents in the context of equipment failure. By such, the Directives fully recognise the importance of stringent post-market surveillance, one key element of which involves the reporting of certain device related incidents to and between the regulatory authorities of member states (competent authorities). The medical device directive [MDD; 4] gives a straightforward procedure how to respond and report and what to do with a failing medical device involving patient injury. However, at least on several occasions we have noted that, confronted with the medical device failure, the staff was not sufficiently prepared and trained to handle the serious adverse events and its straightforward reporting in order to provide objective and comprehensive information in the course of actions (to be) taken after the equipment failure.

Materials and Methods

Within the last two years we experienced three incidents all causing severe patient injury.
In consequence of the MDD [4], each recorded incident caused by an error made by a member of staff, or by a failure of equipment (that could have lead (if not discovered or corrected in time) or did lead to an undesirable outcome, ranging from increased length of hospital stay to death) must be described in detail by a person who was involved in or who observed the incident occurring while the patient was under care (also patients in transit) and should be reported in due time.

Results

The three incidents

Case 1: Malfunction of an anaesthesia machine due to an apparent breakdown of the inlet to a micro filter protecting a pressure transducer used for monitoring

Case 2: Missing gas flow from the y-piece

Case 3: Foreign body displaced into the lung
were reported in due time to the manufacturer and the national body. However, when the (legally authorized) investigator tried to fully trace the device failure in retrospective, he was surprised by missing docu-

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mentation on the one hand. On the other hand (case 1 and 2) he found the equipment promptly repaired without in depth root cause analysis. Details on the actions taken after the critical incidents are given in Table 1 and 2.

Table 1: Pulmonary hyperinflation

On-the-spot actions

- Disconnection of the equipment, manual bag inflation
- Consultation with hospital safety manager
- Immediate equipment check by service personnel of the manufacturer's representative, device fault found, imme-diate repair
- No photos taken of the equipment status, messy documentation

Subsequent actions

- Retrospective description of time course from memory
- Failing part sent to the manufacturer for further investigation without picture archiving
- Manufacturer contacted the wrong OEM, failing part discarded
- Poor and improper follow up by the manufacturer
- Poor handling by the department in respect to authorization of the communication with the equipment manufacturer

Table 2: Missing gas flow from the y-piece

On-the-spot actions

- Replacement of equipment leads to loss of stored monitoring data in the faulty device
- Delayed consultation of hospital safety manager
- After the incident, the departmental staff performed a technical check, found the fault and exchanged the failing subunit, no documentation of parameters, no photos

Subsequent actions

- Retrospective description of time course from memory
- Incident reported in due time to the manufacturer and the national authority
- External expert investigation in cooperation with the manufacturer

In case of the foreign body displaced into the lung (detected after suspect pneumonia) only the detached part was secured. Missing information could be collected retrospectively. Immediate in-hospital consequences resulted in rewriting of SOPs for more detail, in revised hospital internal guidelines for cleaning procedures, and extended training of staff. The manufacturer´s responses included improved quality control of manufacturing processes by the OEM microfilter supplier, extended guidelines for service personnel, amendments for checking procedures before equipment use and additional detailed outline of pre-use checking procedure in the user's manual. Though marketing in non Western hemisphere countries is ongoing, no equipment redesign in respect to early warning or fault detection was considered necessary (case 1). As far as we know, disclosing information on the incidents was not distributed nation- or EC-wide in public.

Discussion

Steps involved in handling a critical incident caused by a medical device failure should cover: (i) Development of internal systems to identify device-related events, determination which events must be reported, prepa-ration of a medical device incident reporting form tailored to the institutional needs including the documentation of decisions taken. (ii) Report as required by national authorities (in general "what-where-when" approach), (iii) An in-depth cause root analysis by the manufacturer in cooperation with the customer and (iv) the claim-closing procedure which should fully clarify the incident´s cause. Do not close the claim without obtaining adequate authorization from the risk management department. (v) Disseminate relevant information in a scientific journal as soon as possible.

With medicinal products the medical staff seems to be experienced in post market reporting of serious side effects of medicinal drugs whereas lacking experience is to be suspected with medical devices.

According to a recent report [5] 1004 critical incidents with a total of 20 deaths (12 due to device failures) have been collected within a 1-year period. 33% of the incidents were related to ventilation equip-ment (5 deaths) triggering equipment redesign at least in 2 cases. In Austria approx. 80 critical incidents are reported to the authorities each year. However there is no similar to the French [5] overview of national registers on a European wide level even though there is little doubt that post marketing vigilance is a most useful way of improving the quality of medical devices.

In the process of dissemination of information, which seems to be culture-dependent among EC member states, some present shortcomings in reporting of vigilance cases and should be overcome:

- Hospital risk managers examine their system within his/her purview and take preventive steps.
- Discussions of these incidents (and measures) are rarely shared with other hospitals, health care professionals etc.
- As predominantly the primary care giver is involved in the frontline of such incidents special training in the relevant procedures may be warranted.
- Little (institutional) experience with all procedural steps in reporting and handling of incidents involving medical devices.

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- Medical equipment failures are rare but in 2% with severe consequences, possibly resulting in low incentive for very few systems, institutions, individuals, etc. to make changes.
- A local (nation wide) register of critical incidents involving equipment failures as implemented in Sweden by the biomedical engineering profession might provide an even more rapid access to relevant information in order to reduce the chance of the same types of incidents reoccurring.

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