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Patient Safety in Research Projects on Computer-Assisted Surgery

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Patient safety is one major issue in the development of computer-assisted surgery (CAS) systems especially if intraoperative navigation is involved. We have been working in the field of CAS for many years. Scientific CAS-systems in different clinical domains were developed including different tracking hardware and specific tracked sterile instruments. The aim of this work is to analyze scientific CAS-projects to identify measures to increase patient safety in a research setting.
As a basic result we found that methods of software engineering, software testing, documentation and quality assurance as required by the MDR (Medical Device Regulations) contribute to a high level of patient safety. More specifically we experienced in our projects that certified tracking hardware and instruments should be used. As an example we developed a CAS-prototype for femoral derotation where a certified electromagnetic navigation system including sterializable sensors from a company (Fiagon GmbH) was utilized for an initial clinical study.
Another approach uses the development of research systems that communicate with a commercial navigation system utilizing a software framework like OpenIGTLink (Open Network Interface for Image-Guided Therapy). We clinically evaluated a multimodal navigation system in neurosurgery which was connected to a Brainlab navigation system. In this setting the Brainlab system as a certified medical product was used as primary navigation tool and our research system was displaying navigated visualizations from additional information sources which were clearly tagged with a warning note.
Such measures help to minimize the intraoperative patients' risks and therefore increase the likelihood to get a positive ethics committee vote for a first evaluation of a new CAS prototype. It is important to keep in mind, that in research settings, usually a fully MDR-compliant software development is not possible, because of limited ressources and therefore a sensible trade-off between effort and requirements must be found.

Living Lab for Intensive Care and Emergency Medicine used as Usability Lab to Improve Patient Safety

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The technical progress enables new medical devices and new medical procedures. This development leads to new fields of applications, for example, an intensive homecare with invasively ventilated patients. By extending functionality of devices, the consequence is that the usage of the devices can be more complex.
Medical processes can be optimized and supported by technology, but they can also cause harm. Software errors, device errors but above all errors in human-machine interaction can endanger patient safety. The regulatory requirements of the medical devices define the software and device development process with regard to patient safety and harm reduction. A regulatory-required usability engineering process can also ensure human-machine interaction. The focus of the DIN 62366 is primarily on fault tolerance in the use of medical software. Hazardous interactions are identified where a potential misuse may result in patient harm (e.g., overlooked drug side effects). A risk management process is intended to identify usage errors and often results in improved device interaction. However, the testing of the prototypes is not specified in the standardization DIN 62366. Our approach is therefore, to test the medical devices and medical software in a living lab with a mankind patient simulator in a realistic clinical scenario. The influencing factors such as e.g. stress, distraction and team-communication have an inherent effect on the usage of the devices and the medical software. Therefore, we can standardize simulated rare adverse events in a realistic manner in order to improve evidence-based health informatics.

Context-aware medical technologies - relief or burden for clinical users?

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The open, cross-vendor interoperability of medical devices is an enabling technology for the implementation of context-aware biomedical systems in daily clinical routine. The surgical working environment is both a valuable field of application and a particular challenge.

In structured interviews, which we conducted, experienced clinicians also commented on automation of supportive tasks. Besides the SDC integration features, the initial case-specific pre-configuration of medical devices, the context-aware automation of display configuration and of adaptation of OR light conditions, and an automated toggle of the endoscopic light source were demonstrated in a realistic setting. Three senior ear-nose-throat (ENT) surgeons, two ENT assistants, two experienced heart surgeons, a senior anaesthesiologist, and two scrub nurses participated in the interviews.

The participants agreed that automation of such supportive tasks is valuable and would help to streamline work processes. Depending on the surgical use case, a reduction of the complexity of interaction with the biomedical technology may be achieved. Robustness, intelligible behaviour, preoperative configurability, and the opportunity to manually override automated actions were frequently mentioned as desired features of future context-aware active assistance technology.

Both, users and research communities, begin to recognize the potential benefits of context-aware biomedical technology. A design of context-aware medical technologies that shows intelligent behaviour and ensures safe operation is demanding; thus implementations are yet limited to prototypes and specific surgical use cases. Context-awareness for a clinical environment cannot be realized by a stand-alone system but demands a highly interconnected technical environment, where each biomedical device provides data and can profit from contextual information shared by others. An implementation in daily clinical routine will require novel strategies for the indispensable risk management and regulatory approval. Many open research questions need to be addressed to empower context-aware medical systems to be a relief and not a burden for the clinical user.

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The European Multicenter Study about Spinal Cord Injury (EMSCI) registry for controlling quality of treatment of individuals after acute spinal cord injury

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The functional outcome after an injury of the central nervous such as spinal cord injury (SCI) is strongly depending on extrinsic (initial rehabilitation regime, treatments) and intrinsic (confounders, comorbidities) factors. For quality control of the rehabilitation procedures on a patient-individual basis and benchmarking between hospitals detailed knowledge about the typical neurological and functional recovery after SCI is necessary. The European Multicenter Study on Human Spinal Cord Injury Study (EMSCI) was founded to provide these data after traumatic or ischemic SCI. In 2001, 5 European centers started documenting their acute SCI patients in a standardized manner over the first year after injury. The standardized EMSCI assessment scheme includes neurological (International Standards for Neurological classification of SCI – ISNCSCI) and functional (Spinal Cord Independence Measure – SCIM III, walking tests) tests conducted at predefined time points after injury (0-2, 4, 12, 24, 48 weeks). From the very start, patient data have been entered in an electronic database at each participating center. The pseudonymized data are regularly transferred to and merged into the central database in Zuerich. In the meantime, approximately 4.000 core-sets (complete early (< 4 weeks) and late (> 6 months) datasets) are available with currently 20 centers actively collecting data. This huge amount of high-quality data (EMSCI is ISO9001-certified since 2010) allows for determination of neurological (ISNCSCI upper and lower motor scores) and functional (SCIM III) recovery profiles (RP, median +/- quartiles) of patient subgroups categorized by level and severity of the lesion. With these reference RPs several confounders such as a higher age or polytrauma have been identified, which lead to a delayed functional recovery. By this, EMSCI's large data pool represents an effective instrument for controlling a high level of care, pointing to unusual recovery courses, and identifying measures for improvement on a patient-individual level.

As the App Enters the Team - Sociotechnical Aspects of Decision Support Systems

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Ubiquitous computing based on mobile or even wearable devices has the potential of disruptively changing clinical information management and medical decision support. Wearable sensors combined with health apps provide big data streams monitoring the patients' daily life quasi-continuously. Apps may also provide first opinion and advice to patients with health problems and guide them through the healthcare system. Doctors can profit from context-specific information and decision support delivered at the point of care. Against the background of these opportunities, however, the risks to patient safety by technology induced adverse events must also be taken into account. Based on a systematic literature review, it can be seen that apart from the intrinsic quality of the apps, their effects on user behaviour and on the interaction and communication of professional teams deserves special attention. It has been known for years that intelligent monitoring and alarm systems, for example, can lead to alert fatigue and thus reduce critical vigilance. As a relatively new insight there are clear indications that the use of dedicated apps not integrated into the user interfaces of routine systems can reduce the risk of alert fatigue. As a consequence, functional integration of decision support needs critical reflection and – possibly – revision. Furthermore, unexpected and sometimes harmful effects have been observed to rise from altered team collaboration and interaction especially during the roll-out phase of decision supporting apps. Mobile/wearable devices also enable new, detailed, and quantitative studies of team processes. Thus, a thorough study of the effect of decision support apps on clinical workflows is feasible and required – as a prerequisite of their secure roll-out and routine use. Furthermore, such studies also inspire targeted interventions, such as accompanying training or user nudging.

Risk Post-Infarction Patients

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Sudden Cardiac Death (SCD) is the most common cause of death in the industrialized world. There is a large body of evidence that presence of cardiac autonomic dysfunction after MI is linked to increased susceptibility to malignant arrhythmias, including SCD. Current guidelines recommend prophylactic treatment with an implantable-cardioverter defibrillator (ICD) in post-MI patients with reduced left ventricular ejection fraction (LVEF ≤35%). However, most deaths after MI occur in patients with LVEF >35%. Currently there is no treatment strategy for this high-risk group. Cardiac autonomic dysfunction after MI provides important prognostic information in post-MI patients in this group. Deceleration Capacity (DC) and Periodic Repolarization Dynamics (PRD) are strong and independent electrocardiographic risk markers and capture the vagal and sympathetic functional status of the cardiac autonomic nervous system. Abnormal DC and/or PRD identifies a new high-risk group of patients with only moderately reduced LVEF that has a comparable poor prognosis as the established high-risk group of post-MI patients with LVEF ≤35%. The SMART-MI-DZHK9 trial (Clinical-Trials.gov NCT02594488) is an investigator-initiated randomized prospective multicenter trial funded by the Deutsches Zentrum für Herz-Kreislauf-Forschung (DZHK) that tests a new prophylactic strategy in this new high-risk group based on remote monitoring. Post-MI patients with LVEF 36-50% are screened for presence of cardiac autonomic dysfunction by means of DC and PRD. High-risk patients are randomized in an 1:1 fashion to implantation of a cardiac monitor or conventional follow-up. Primary endpoint is time to occurrence of actionable serious arrhythmic events. Clinical endpoints are tested secondary.