Integrated therapy safety management system

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WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT

- Clinical work systems cannot be error free. The new paradigm is to increase their resilience.
- Their redesign is necessary using the knowledge of diverse disciplines; Designing proactively is a highly challenging process.
- The medico-ergonomic approach supports such design processes by establishing a comprehensive understanding of the complex coordination of clinical tasks on different granular levels.

WHAT THIS STUDY ADDS

- The six layer model is introduced to the subject of safe medication processes for the first time.
- The innovative concept 'integrated therapy safety management' is drafted.
- The concept demonstrates the significance of humans as the key element and final authority to cope with complexity.

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AIMS

The aim is to demonstrate the benefit of the medico-ergonomic approach for the redesign of clinical work systems. Based on the six layer model, a concept for an 'integrated therapy safety management' is drafted. This concept could serve as a basis to improve resilience.

METHODS

The concept is developed through a concept-based approach. The state of the art of safety and complexity research in human factors and ergonomics forms the basis. The findings are synthesized to a concept for 'integrated therapy safety management'. The concept is applied by way of example for the 'medication process' to demonstrate its practical implementation.

RESULTS

The 'integrated therapy safety management' is drafted in accordance with the six layer model. This model supports a detailed description of specific work tasks, the corresponding responsibilities and related workflows at different layers by using the concept of 'bridge managers'. 'Bridge managers' anticipate potential errors and monitor the controlled system continuously. If disruptions or disturbances occur, they respond with corrective actions which ensure that no harm results and they initiate preventive measures for future procedures. The concept demonstrates that in a complex work system, the human factor is the key element and final authority to cope with the residual complexity. The expertise of the 'bridge managers' and the recursive hierarchical structure results in highly adaptive clinical work systems and increases their resilience.

CONCLUSIONS

The medico-ergonomic approach is a highly promising way of coping with two complexities. It offers a systematic framework for comprehensive analyses of clinical work systems and promotes interdisciplinary collaboration.

Introduction

Medical and technological progress enables continuous improvement of patient care [1, 2]. At the same time, the challenges of a safe work system design increase due to the complex interaction of humans, technology and organization within the work system [3]. The performance of a single technical device may be predictable. However its flexible and dynamic interaction with other system elements, e.g. technical devices and humans within a system is less predictable [3]. Thus, the occurrence of errors appears inevitable [4–6].

The impossibility of eliminating errors within complex work systems is described by Perrow's theory of 'normal accidents' [7]. Accordingly, numerous studies show that errors in patient care are ubiquitous and they have a significant impact on the quality, safety and efficiency of patient treatment processes [8–11]. These errors do not only constitute a high risk of harm for patients, but may also drastically impact on the psychological well-being of the staff members [12, 13]. The economical loss is significant for both hospitals and society [14, 15].

Safety research asserts that work systems with a minimal risk of harm are not necessarily errorless, but error tolerant. Error tolerant work systems are able to detect occurring errors or critical events early enough, to respond adequately and to maintain system performance. These work systems are described as resilient [16]. Thus, the new paradigm of safety research is to increase the resilience of complex work systems. Resilient work systems are highly adaptive and therefore patient harm can be reduced or even avoided [16–22].

Today's clinical work systems are often not resilient [23]. A particularly error prone area with high optimization potential is drug therapy as part of a patient treatment process [2, 10, 24, 25].

To improve patient safety is the stated objective of many national and international activities. The Federal Ministry of Health (BMG) in Germany, for example, announced an action plan for patient safety, emphasizing the importance of safe medication processes [26]. Teams of physicians and nursing staff, pharmaceutical, medical and information technology, and hospital management have developed a wide range of concepts and activities to improve safety in drug therapy [2, 26].

Despite numerous activities, safety in clinical work systems is still unsatisfactory [2, 9–11, 27]. Individual activities are usually short-sighted and thus are not appropriate to cope with the complexity of the system. A comprehensive redesign is necessary, which integrates all required perspectives [2, 5, 12, 28, 29]. The challenge of such multidisciplinary design processes is in establishing a common understanding and a common language [30]. For this purpose, the 'systems ergonomics' or macroergonomic approach provides models and methods which have

already proven their high value in industrial work systems [3–6, 12, 29, 31].

The macroergonomic approach analyses the interaction between elements of the work system, such as workers and machines in the work process, in order to improve the performance and reliability of the entire system [3]. The work system has to be considered as an indivisible entity. This is a prerequisite for generating proposals for better design [3–6, 12, 29, 31].

However, ergonomic analyses of clinical work systems require a domain-specific approach [4, 29, 32–35]. Ergonomic theories, models and methods proven in industry have to be adapted and extended accordingly [3, 4, 29, 32–35], subsumed under the term 'medico-ergonomics' [29, 32].

The aim of this paper is to demonstrate the benefit of medico-ergonomic models and methods for the (ergonomic) redesign of clinical work systems. Based on the medico-ergonomic six layer model, a new concept for an 'integrated therapy safety management' is drafted. A holistic 'integrated therapy safety management system' of this kind would foster the theoretical basis and thus the understanding of resilient clinical work systems. It could also serve as a tool for the interdisciplinary analysis and design of resilient clinical work systems.

Methods

The concept for an 'integrated therapy safety management system' is developed through a qualitative and theory-driven concept-based approach. The state of the art of safety and complexity research in human factors and ergonomics forms the basis. Relevant theoretical approaches, concepts and models from the literature are therefore introduced.

In the field of safety research, firstly the 'resilience engineering' approach and secondly the model of 'closed-loop systems' or 'feedback control systems' in accordance with quality and risk management, are summarized. In the field of complexity research related to human factors and ergonomics science, the 'systems engineering' approach and the medico-ergonomic six layer model are presented.

The scientific findings and approaches described in the literature are synthesized to a new holistic conceptual model for an 'integrated therapy safety management'. The conceptual model is applied by way of example for the 'medication process' to demonstrate its practical implementation and to discuss its impact on designing resilient clinical work systems.

Results

Theoretical background

The analysis of the current state of the art relating to safety and complexity research in human factors and ergonomics

revealed four particularly relevant approaches and models, as described in the following sections.

Safety research in human factors and ergonomics
According to Hollnagel, 'resilience' is defined as the

'intrinsic ability of a system to adjust its functioning prior to, during, or following changes and disturbances, so that it can sustain required operations under both expected and unexpected conditions' [22].

Hence, 'resilience' describes the resistance of a system to (external) influences and disturbances. A resilient system is able to tolerate errors or failures to a certain degree and maintain or recover system performance within a given time [16–22]. For this purpose, four system abilities are essential:

- 1 the ability to 'respond' 'to regular and irregular disruptions and disturbances either by implementing a prepared set of responses or by adjusting normal functioning' [22]
- 2 the ability to 'monitor' 'that which is or can become a threat in the near term. The monitoring must cover both that which happens in the environment and that which happens in the system itself, that is, its own performance' [22]
- 3 the ability to 'anticipate' 'developments, threats, and opportunities further into the future, such as potential changes, disruptions, pressures, and their consequences' [22]
- 4 the ability to 'learn' 'from experience, in particular how to learn the right lessons from the right experience-successes as well as failures' [22]

In order to improve the adaptability of a system, it should be designed proactively rather than reactively. Consequently, the scope of 'resilience engineering' is not only to investigate failures precisely, but also to understand a system's performance in general. To improve system safety, the observation of certain processes is crucial. Measures for increasing system resilience in complex systems cannot only be determined analytically, but must be based on expert knowledge of the system [16–22]. Hollnagel states that the aim of 'resilience engineering' is 'to increase the number of things that go right rather than to reduce the number of things that go wrong' [22] which will contribute not only safety but productivity [16–22].

The four abilities of resilient systems are similar to one of the central models in quality and risk management: the 'circular management model', also known as the 'PDCA cycle' (PDCA – Plan Do Check Act) [36–38]. This model resembles the 'closed loop control system' or 'feedback control system'. 'Control loops' occur in various, so-called 'cybernetic systems' used in biology, economics and engineering. A 'closed loop control system' consists of a 'con-

trolled system' and a 'control system'. The control task is to keep the 'controlled variable' close to a given 'reference'. A sensor regularly measures the 'controlled variable' and reports it to the 'control system'. The 'control system' compares the measured value with the reference. If deviation appears, the 'control system' sends a signal to an 'actuator'. The 'actuator' modifies the input or the setting causing the value of the 'controlled variable' to return to the reference [38].

Complexity research in human factors and ergonomics
The 'systems engineering' approach addresses the development and design of complex systems [34, 39, 40]. The framework of the 'systems engineering' approach consists of two basic parts, the 'systems thinking' as a tool for structuring the investigation field and the solution alternatives. The second part is the process model, which divides the development process of a problem-solving solution into manageable steps. The following four principles are essential and postulated by this approach. The basic principle is to structure the observed system hierarchically 'from general to detail' on different layers. Thus, a holistic analysis is more accessible. This concerns the investigation of the problem area, as well as the design of solutions. The second principle is to 'compose alternative solutions'. Thinking in alternatives allows all possible solutions to be considered comprehensively. An extension to the two principles is the third principle of 'structuring into phases'. Processes are divided into manageable sequences, allowing phased planning, decision-making and controlling with the option of correction. The fourth principle is to solve problems in cycles. The cycle analysis provides guidance for the completion of tasks in each phase and comprises the procedures 'goal seeking', 'search for solutions' and 'selection' [39].

These principles are implemented in the medico-ergonomic six layer model [41, 42], which is a conceptual framework for analyzing, structuring and describing patient treatment processes. In medicine the tasks and processes are characterized by high complexity [1–4, 34] and therefore hierarchical structuring of tasks and processes is required. Thus, the basis of the six layer model is the recursive hierarchical task-process-task model (TaPTa®, Task – Process – Task) [28].

The six layer model [41, 42] vertically divides a patient treatment task into a process of sub-tasks through six layers, starting from diagnosis-related groups (e.g. diabetes) down to single activities (e.g. insulin injection). The left side describes patient treatment as a result of medical tasks and decisions (defined in medical guidelines) which require certain resources (e.g. staff, medical devices). The request for resources is defined by the medical tasks/sub-tasks on the left side, the provision of resources is described on the right side of the model. On each layer, the quality, efficiency and safety can be assessed [41, 42].

Table 1

Description of the 6 layers in the six layer model

Layer	Description	Example
Layer 1	'Case group'	Patient population in one geographic region classified into case groups, e.g. diabetes mellitus type II
Layer 2	'Case'	Provision of health care of one case divided into different stages of patient treatment, e.g. outpatient clinic, hospital, general practitioner
Layer 3	'Stage'	Patient treatment within one stage (e.g. hospital) divided into different stations of patient treatment, e.g. emergency department, internal medicine general ward
Layer 4	'Section'	Patient treatment within one section (e.g. emergency department) divided into different phases of patient treatment, e.g. admission phase, intervention phase, discharge phase
Layer 5	'Phase'	One phase of a patient treatment (e.g. admission) divided into treatment modules, e.g. first examination, drug therapy management
Layer 6	'Module'	One module of patient treatment (e.g. first examination) divided into different medical procedures/activities, e.g. drug application, vital parameter check

Bridges connect both sides. On each system layer there is a 'medical bridge manager' in charge of planning, co-ordinating and monitoring therapy and a 'resource bridge manager' in charge of resource deployment. 'Bridge managers' describe 'roles' and not persons. Thus, the role of one 'bridge manager' may be performed by one person (e.g. physician or nurse) or a team; a person or team can perform several roles [41, 42]. The six layers correspond to the established organizational structures in the health care sector and are described in Table 1.

The scope of the investigation determines which layer is in the focus. Depending on which medical procedure is defined as a work task of interest, a more distinguished picture can be defined by breaking down the task into a sequence of sub-tasks on the layer below [32, 41, 42].

The abilities and principles of the theoretical approaches and models presented above are included in the concept of the 'integrated therapy safety management system'.

Concept of an 'integrated therapy safety management system' – requirements and principles

The analysis of the theoretical approaches has shown that for the development of an 'integrated therapy safety management system', the following principles and abilities are required. Firstly, to increase the resilience of the system, 'feedback control principles' are needed, which support the four abilities (i) to 'anticipate', (ii) to 'monitor', (iii) to 'respond' and (iv) to 'learn'. Secondly, to cope with complexity, tasks must be divided hierarchically into sub-tasks with different granularity.

Representation of the 'medication process' as a closed loop control system The representation of a 'medication process' as a 'closed loop control system' supports a better understanding of the workflow and potential disruptions and disturbances affecting the performance of the clinical work system. Elements of the 'medication process' can be applied to the basic model of a 'closed loop control system', such as:

- the 'control system' corresponds to a physician or nurse, including
- the 'regimen' (prescription of a substance, dosage, application form, etc.)
- the 'actuator' corresponds to the 'drug application' according to the prescription
- the 'controlled system' is the patient
- the 'sensor' corresponds to the devices measuring the 'controlled variable'
- the 'controlled variable' corresponds to the current status of the vital signs affected by the drug
- the 'reference input variable' corresponds to the therapeutic objective
- the 'disturbances' are influencing the 'controlled system', e.g. adverse drug effects, pathophysiological reactions

The transfer of the 'medication process' into the sphere of a 'closed loop control system' is shown in Figure 1.

To determine the right 'actuator' (drug application) and to achieve an adequate adaption of the 'controlled variable' to the 'reference input variable', many patient-specific input parameters have to be considered [43]. Disruptions and disturbances can occur in six of the eight elements of the 'closed loop control system' and are marked by flashes in Figure 1.

Examples for such disruptions and disturbances are:

- A wrong prescription due to a lack of information and/or knowledge. The physician defines the current drug therapy on the basis of the available information/knowledge, which may be incomplete [25, 43–46].
- The wrong application due to a mistake: handwritten prescriptions can lead to interpretation problems; sound-alike/look-alike can lead to confusion between drugs [24, 45].
- The incorrectly reported 'controlled variable' due to a lack of reliability of the technology: a sensor for measuring the 'controlled variable' might work incorrectly [45].
- Disturbances due to (unexpected) adverse drug effects or (unexpected) pathophysiological reactions [24, 25, 45].

A lack of standards, both in the workflows and in the documentation of the procedure, could cause incorrect application forms, mix-up of infusion additives and dosage errors. In addition, the lack of standards could also lead to errors due to unavailable knowledge about specific drugs [24, 25, 43, 45, 46].

Figure 1

Description of the 'medication process' as a 'closed loop control system'. ⚡, disruptions/disturbances; →, influence; 👤, patient; 🧑, physician/nurse

According to 'resilience engineering', a resilient 'medication process' is able to 'respond' to such disruptions and disturbances. A precondition is anticipation and reliable monitoring of critical processes (treatment and workflows) including risk management. The ability to 'learn' from previous incidents is essential and enables the development of a set of responses to probable disruptions and disturbances. To implement those abilities within the 'medication process', a more detailed consideration on several layers is required.

Recursive-hierarchical structure of the 'medication process' – a cascade control system The medico-ergonomic 'six-layer model', with its recursive-hierarchical structure, enables one to cope with the complexity of the clinical work system and offers a comprehensive approach for developing an 'integrated therapy safety management system' including the 'medication process'.

For example, the procedure 'drug application' (e.g. insulin injection) is represented on layer six 'module'. The sub-task is to apply a certain drug to a certain patient according to the 'regimen' or the prescription. The procedure, understood as a 'closed loop control system', is performed by the role of the 'medical bridge manager 6', which is accomplished by the responsible physician/nurse. The 'medical bridge manager 6' has to anticipate probable mistakes, such as interpretation problems, sound-alike/look-alike of drugs etc. During drug application, the

'medical bridge manager 6' (e.g. nurse) has to monitor the patient and their reaction to the drug and has to be prepared to respond with corrective action. If something unexpected happens (e.g. unexpected increase of blood pressure), the 'medical bridge manager 6' also has to document and communicate the incident in order to initiate preventive measures for future drug application procedures. The procedure 'drug application' is a 'controlled system' controlled by the 'medical bridge manager 5' (e.g. prescribing physician). Thus, reported incidents like 'adverse drug effects' lead to an adaption of the prescription on layer 5.

In summary, the scope of interest of the several 'bridge managers' varies depending on which layer they are performing. With a decrease in the temporal horizon of the course of patient treatment, the therapy planning and action becomes more detailed. For this reason, the planning and actions of the 'bridge manager 6' (e.g. nurse) are short term, operational and more detailed than the planning and actions of the 'bridge manager 5' (e.g. prescribing physician), which are middle term, less detailed, but depending on the therapy they are more holistic and strategic. Accordingly, strategic decisions about the therapy take place on layer 5 in this example, while short-term treatment decisions are made at the operational layer 6, i.e. by 'bridge manager 6' (e.g. nurse).

Corrective actions ('monitor' and 'respond') to prevent harm and assess potential risks ('anticipate' and 'learn') are

Figure 2

Description of the 'medication process' as a 'cascade control system': ⚡, disruptions/disturbances; →, influence; 👤, patient; 👤, physician/nurse

therefore also anchored on different layers. Actions such as the 'time out' are embedded on layer 6, while the more comprehensive patient treatment 'risk assessment' is done by 'bridge manager 5' on layer 5. Hence, 'bridge managers' form a 'cascade control system'. Figure 2 shows the 'medication process' as a 'cascade control system'.

This network of decentralized responsibilities guarantees a high adaptivity and thus the required resilience. The recursive-hierarchical structure of the network provides a holistic view and allows a better understanding of correlations. If disruptions or disturbances occur, responses are faster and more comprehensive.

For the improvement of the overall therapy safety the control tasks, control processes and workflows of the 'bridge managers' and their mutual relationships must be

defined. A systematic analysis of potential errors and risks is needed to anticipate potential patient harm within the drug therapy and the patient treatment processes. The workflows must also be supported by sufficient sensors for monitoring and by appropriate information and guidelines for responding in the case of disruptions and disturbances. Unexpected disruptions and disturbances must be reported and, based on an analysis of the associated causes; a set of responses must be derived for the future. This feedback process provides a continuous learning of the system. The cascading involvement of the 'bridge managers' on multiple layers is an organizational measure that ensures the resilience of the clinical work system. The physician/nurse as an expert and therefore as a 'control system' is crucial. However, it should be considered that humans can make mistakes. Therefore it is essential to

support these experts with adequate information technology. Profound qualification of the experts is a must.

Discussion

Due to their complexity, clinical work systems cannot be error free. Hence, the new paradigm is to increase the resilience of complex work systems. This demands an integrated comprehension of related tasks, workflows and cause–effect relations of potential errors and resulting harm to the patient. Designing a clinical work system proactively in order to improve patient safety and productivity is a highly challenging process, not only in drug therapy, but also throughout the entire patient treatment process.

Enhanced collaboration of many experts from different disciplines, such as medical caregivers from various departments, the pharmacy and the pharmaceutical industry, as well as information technology and medical device manufacturers is indispensable. A precondition for the successful collaboration between different disciplines is the establishment of a common understanding, a common language and shared knowledge [30]. The medico-ergonomic approach supports such interdisciplinary design processes by establishing a comprehensive understanding of the complex co-ordination of clinical tasks on different granular levels and their related workflows [29, 32, 42].

In accordance with the 'six-layer model', the 'integrated therapy safety management' introduced is constituted by the 'bridge managers'. The 'six-layer model' supports a detailed description of specific work tasks, the corresponding responsibilities and related workflows at different layers by using the concept of 'bridge managers'. This representation supports an integrated perspective on the mutual relationships and enhances the observation of various activities improving patient safety [41, 42]. The conceptual model of an 'integrated therapy safety management system' demonstrates that in complex clinical work systems, the human factor is the key element and final authority to cope with the residual complexity. 'Bridge managers' anticipate potential errors and monitor the controlled system continuously. If disruptions or disturbances occur, they respond with corrective actions which ensure that no harm results and they initiate preventive measures for future procedures. For the completion of these control tasks, it is important to support the 'bridge managers' by providing tailored technical design solutions. This particularly concerns the exchange of communication and information. The challenge here is to provide the right information at the right time in the correct aggregation and to avoid information overload. The expertise of the 'bridge managers' provides the required flexibility and responsiveness. The recursive-hierarchical structure enables monitoring of single activities, as well as monitoring of competing therapy modules and their interaction.

This results in highly adaptive clinical work systems and increases their resilience. To maintain the high level of resilience, design solutions need to be monitored continuously and need to be developed on an evolutionary basis in an iterative procedure.

The 'integrated therapy safety management system' presented has been theoretically developed as a conceptual model so far. The application by way of example for the 'medication process' demonstrates its practical implementation and offers first insights into its potential impact on designing resilient clinical work systems on a qualitative level. However, practical implementation is crucial to evaluate empirically the benefits described above in reality.

In conclusion, the medico-ergonomic approach is a highly promising way of coping with two complexities. It offers a systematic framework for comprehensive analyses of complex health care delivery systems and also promotes complex interdisciplinary collaboration. The medico-ergonomic approach has already been successfully applied in several use cases in different contexts such as:

- the design and evaluation of web-based electronic health records [32]
- the planning and design of work environments in emergency departments [47, 48] and
- the analysis of information workflows and information management in intensive care units [49].

However, further applications are desirable in order to assess its impact on designing effective, efficient and safe work systems in patient care also on a quantitative level.

Competing Interests

All authors have completed the Unified Competing Interest form at http://www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare no support from any organization for the submitted work, no financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years and no other relationships or activities that could appear to have influenced the submitted work.

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