

# Safety and Reliability of Clinical Work Processes

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**Abstract:** Human error is a significant hazard for hospital patients. In contrast to other domains, risk and error aspects are barely researched in medical work system until now. This is due to a lot of specific attributes of clinical work processes, in particular its complexity and variability. An optimized patient safety would require an increased flexibility of task organization, technical equipment and team work organization. On the conceptual side, an interdisciplinary theoretical framework is required to meet the future demands of integrated safety concepts in complex work systems.

**Keywords:** Human error, Patient safety, Clinical work system, Risk management.

## 1. Situation: Health risks due to human error

In the last years an increasing number of papers reports high risks for patients' health in hospitals due to human errors. For example, medical mistreatment is estimated to be one of the 8 most frequent causes of death (Rall et al., 2001), provoking death in 40000 to 100000 patients in USA. Thus, there would be a higher risk to die in hospital due to human error than to die in public traffic. Other studies estimate even higher risks for specific areas and medical domains.

Although there is much uncertainty to separate human error from other causes, such data point out an urgent necessity for Human Factors research in order to reduce patient risks.

A first screening lines out possible causes:

- The increasing workload due to shortage of manpower and economic pressure abets the occurrence of human error.
- The increasing complexity of medical processes makes it more and more difficult to ensure system control, and, consequently, human error more likely leads to patient impairment.
- The increasing amount and complexity of technical equipment causes interaction errors.
- Compared with other domains, human factors research is still underdeveloped in the medical domain.
- The existing knowledge and experience from other domains, such as air traffic and nuclear power plants are very difficult to be transferred to medical work processes.
- Finally, risks are vast in number, but even in case of collapse, the loss of one single life does not catch enough public attention.

Whatever constellation might contribute to human harm, it should be checked for its optimization potential in terms of patient safety.

## 2. Particular aspects of clinical work systems

Patient treatment and medical work systems differ from other domains in regard to a number of specific attributes. Some examples:

- Applying physical treatment means an intentionally injury of the human body. Thus, such crisis is normality and crisis management is part of everyday life in hospital.

- The large variation of cases makes it impossible to implement standardized procedures which would help to simplify the identification of human errors in an early state.
- The large variation of patient's reactions makes it difficult to differentiate between normal state, crisis and disaster. Even for basic physiological measures such a differentiation requires human expertise until now. Above all, monitoring and analyses of bio-physiological parameter are fuzzy and disturbed by artifacts.
- In general the effects of treatment measure are not accessible to monitoring directly. Reaction feedback is strongly delayed for most patient related actions. Hence, no correction is to be applied in the case of undesired results. This is true for strategic treatment decisions (e.g. selection of a therapy) as well as for simple motor actions (e.g. infection caused by deficient hygiene).
- Any treatment decision is based on an anticipation of possible consequences. In spite of a large reaction variability on the patients' side, medical doctors are obliged to minimize any risk for the patient. Although medical doctors thus decide maximum conservatively, just this fact induces additional variability into the work process.
- A lot of decisions have to be made under time pressure with incomplete sets of information.
- For most failures in patient treatment it is impossible to recognize if it originates from human error, missing information (what is not necessarily caused by error, e.g. an allergic reaction which was unknown at that time), false strategy or just the missing transparency of the complex biologic organism of the patient. But, this missing information would be essential to experience in order optimize safety of treatment.
- Most training must be done in clinical routine (learning by doing) because of many lacks in theory, laboratory and simulator exercises. Thus, training has a tightrope to walk between experiencing medical novices and ensuring maximum patient safety by experienced experts.
- Safety does not only mean patient safety but also personnel safety. In particular during crucial situations the demands for both subjects often conflict with each other. Due to the fact that patients are in a more destabilized position, clinical staff members often risk their own health (e.g. needlestick caused by time pressure and crowded workplaces).

As a preliminary result, methods and experiences from other domains partially may and partially may not be transferred to the medical domain. Whether or not this transfer would be appropriate mainly depends on the question if a strict regime is fruitful or hazardous.

### **3. Approach**

Conceptual approaches concerning the different types of errors are widely published, even for the medical domain (e.g. Reason, 1994; Cooper & Gaba, 1989; Rall et al., 2001): the sequences of error development, effects of human attention and resource allocation, experience and expertise, etc.

For Human Factors engineering with its emphasis on real work system design, further questions arise concerning strategies to minimize human error in medical treatment, including the question how to estimate (system) error probability.

The expression "human error" associates first of all a human being responsible. In fact, humans are mostly involved when errors occur, but numerous studies (e.g. Zimolong, 1982; Vincent et al., 2000) show that in most cases (50 to 90%) inadequate equipment design and work organization deficits caused human error. Thus, most errors origin during the interactions between system elements (human-human, and human-machine) and due to

inappropriate environmental and organizational conditions. A first, elementary approach is to optimize work systems ergonomically. In spite of its theoretical consistency, this approach comprises a lot of antagonisms. First of all it would be very costly, because of its extensive resource allocation demands to meet daily variability of cases and patients. Furthermore, ergonomic demands vary with patient state: To avoid errors a mostly straight process organization is required. In contrast to this, recognizing possible errors in an early state requires flexible and dynamic structures, and tools for process monitoring. Especially during crisis and disasters a most flexible organization and a highly experienced personnel is required. Technical equipment should support process flow and process stability in a way that process monitoring (by man or machine) must detect and recognize critical situations and, in this case, support the activation of appropriate corrections by providing all functions required for crisis management with easy and safe access and control. Above all, actors change frequently, even during crisis development. Although the relevancy of user errors is recognized (Rasmussen, 1983; Committee Draft EN-IEC 60601, 2002) we are actually far away from having user interface concepts available which meet such demands.

A second challenge is to be sought in the development of crises and disasters. Due to the fact that the occurrence of an error depends whether or not a system deviation contributed to a failure, a reverse analysis - from error to origin - can not be performed in highly dynamical and complex (non stationary and non linear) environments. Error analyses for system optimization does not cover all causes of crises and disasters. Inversely, all sources of errors need to be recognized in order to stop multi causal error development in an early state (Grube et al. 2002).

Third challenge - variability: Schematization of processes and organization rules facilitates analyses, but does not meet the structural dynamics and the variability requirements of clinical patient treatment. Thus, reliability must not be interpreted in the sense of reproducibility but rather as a kind of robustness. From a modeling point of view the transfer function of a cascaded and intermeshed closed-loop feedback system seems more appropriate than the transfer function of a serial black box system.

#### 4. Research prospects

The large puzzle of conceptual frameworks concerning human error and patients' safety on the one hand and the methods of (clinical) work system analysis on the other hand need to be arranged in a way that the preconditions of error development may be detected in real work systems in order to reduce error occurrence and detected crises in an early stage.

On the structural side, a quite simple work system with objects, resources, interactions, processes and environmental interferences serves for an abstract treatment flow view. The factors describing such treatment flow in terms of information units and its transformation rules are not elaborated yet. This is due to the fact that very different aspects, such as problem solving tasks, motor actions, nonverbal communication and confidence between team members contribute to a whole information flow network.

Significant effort must be spent for interdisciplinary research in order to integrate all aspects in a common meta-model structure.

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