



## Fuzzy cognitive maps for adverse drug event risk management



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### ABSTRACT

This work aims at developing a procedure for analysing the drug administration process in order to understand and highlight the criticalities and risks of the process as well as the cognitive mechanisms governing human decisions during the process. Drug therapy management and drug administration are recognised as expanding, complex, and crucial aspects of the health care system, which also help to limit unnecessary costs from complications or hospitalizations. Improved clinical outcomes can result from a more controlled drug administration process, reducing the probability of errors made by the involved operators. The whole drug administration process, starting from the patients' inlet to their entering the health unit up to the medication itself can hide potential causes of errors or lack of compliance procedures. The more complex the system there is to manage, the higher the liability of wrong operations. It is thus fundamental to deeply understand the cognitive mechanisms influencing the occurrence of errors and, to this end, a Fuzzy Cognitive Map (FCM) approach will be described in this study. FCMs helped the authors to highlight the cognitive mechanisms that influence decision-making processes in drug management and evidenced the critical factors affecting the drug therapy management process as a whole, thus pointing out corrective actions for the patient's better and continuous health-related quality of life.

### 1. Introduction and background

In UK hospitals, adverse events occur in 10% of admissions, and their total number is estimated at approximately 850,000 per year (Department of Health, 2001). A study conducted in Australia showed an adverse event rate of 16.6%, of which 13.7% caused permanent disability. It was also estimated that 50% of related adverse events were preventable (Wilson et al., 2007). The severity of the phenomenon requires greater openness from health professionals towards the reporting of events derived from medication errors. International experience in the clinical risk sector shows how one can learn from mistakes because, if properly reported, doing so allows an analysis of a mistake's causes and allows correction to prevent its recurrence or to reduce its severity. Consequently, adequate monitoring of adverse events related to the misuse of drugs and the subsequent evaluation of such events allows the adoption of preventive measures to minimize patient risk and, in addition, contain health spending. The Food and Drug Administration (FDA) studied the incidence of adverse events in drug administration and concluded that they increase health spending from 2.4 to 6.5% per facility, with an average rate of 4.3% (Moyen et al., 2008). Health care systems are very complex environments characterized by several interactions between involved participants. During the therapy process, doctors, pharmacists, nurses and patients can make a treatment error,

and each of them has a different risk perception. At the hospital, the drug-therapy management process consists of several steps (prescription, transcription, preparation, dispensing, administration and monitoring of therapy); in each step, medication errors can occur (Hussain and Kao, 2005). The improvement of safety in health care systems has proved a very difficult task. As discussed by Leape and Berwick (2005), although there has been a relevant increase in research funding for patient safety in the US, the resulting benefits have been lower than expected. Muller-Leonhardt et al. (2014) analysed the possible contribution of Critical Incident Stress Management (CISM) in hospitals from a health and safety point of view for both the organization and the employee. The findings in the paper highlight how the efficiency of a support program depends upon professional culture and organizational structure and policies. A crucial challenge in improving and/or maintaining the safety of complex systems is to understand the dynamics of emerging accidents even when the system is under normal operating conditions and all of the processes are under control. In particular, as discussed by Carayon et al. (2014), as far as healthcare quality and patient safety are concerned, human factors and ergonomics are recognized as a valuable framework for redesigning and reengineering healthcare systems and processes to improve patient safety and quality of care. The authors identify a set of elements for various work systems, stressing the concept that the correct interaction between people, tasks,

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tools and technologies, physical environment and organization based on the principles of Human Factors and Ergonomics (HFE) is crucial for the efficient performance of health care systems. For healthcare systems, inadequate inter-organizational communication practices have been listed as the major cause of Adverse Drug Events (ADEs) (Hansen et al., 2010) (Committee on Patient Safety and Health Information Technology, 2012). Modern healthcare organizations are often non-engineered systems, and improvement in their safety procedures is a complex task. A robust approach to such an environment's efficient management should therefore be based on proactive and adaptive processes, considering their intrinsic complexity (Bevilacqua et al., 2013). A recent study by Kannampallil et al. (2011) analysed the specific aspects of complexity and their relationship to modern healthcare environments' correct management, suggesting a framework of interpretation based on the number and degree of interrelated system components. From this point of view, a management process of health care system safety should be optimally steered by a control structure, ensuring that even in the presence of faults at any control level (technical, human, or organizational), their negative consequences can be mitigated (Carvalho et al., 2008). This vision is somehow referable to a resilient system management, i.e., an environment in which several players successfully address complex tasks under stress conditions (Woods and Hollnagel, 2006). As discussed by Costella et al. (2009), Resilience Engineering concepts can be efficiently applied to Health and Safety Management, covering three specific auditing areas: structural approach, operational approach and performance approach. In their paper, the authors identify four principles, i.e., flexibility, learning, awareness and top management commitment, for assessing the performance of Health and Safety Management Systems (MAHS) from a Resilience Engineering point of view. As discussed by Kannampallil et al. (2011), a new trend has emerged, that is, considering the possibility of studying and analysing health care systems as complex systems. The authors propose to use the degree of interrelatedness between system components to assess a system's complexity, showing how a complex system can be described as a set of smaller ones linked by specific relationships. Moreover, the knowledge and awareness of the relationships identified by the system's functional decomposition can help researchers to bring out hidden or latent interrelationships that might lead to, if not correctly managed, a set of unpredictable stress conditions. Linear causality in an accident analysis, as described by Reason (1990a, 1997), cannot describe the malfunctioning of a complex system because it does not consider the relationship and interconnections of the system components (Hollnagel, 2004). A recent study by Dekker et al. (2011) highlights that as far as systems safety is concerned, systems thinking rather than linear thinking should be considered; in other words, for complex systems, issues are derived from a network of causal interactions and not as the outcome of only one factor. Recent biomedical, technological, and normative changes have led healthcare organizations to implement clinical governance as a means of ensuring the best quality of care in an increasingly complex environment (Cagliano et al., 2011).

Adverse Drug Event (ADE) management is one of the most relevant aspects of clinical governance. As stated by Nebeker et al. (2004), an ADE can cause a patient injury due to a reaction to an incorrect drug or to dangerous drug administration. In the literature, several studies discuss in detail the effects of an ADE. For example, a recent paper analyses risk factors due to ADEs in a hospital's Emergency Department, highlighting that correct drug prescription management could mitigate their social and economic consequences (Chen et al. 2014). As discussed by Koutkias et al. (2012), the process of drug Prescribing, Ordering, Dispensing, and Administration can be heavily influenced by human factors. Based on the definition of rules for Clinical Decision-Support System design and functionality, the traditional approach of human factor analysis is considered more suitable (Marcilly et al., 2011). Instead, as a possible development of ADE knowledge engineering, the authors propose the introduction and study of tools to define advanced

rules to reduce the negative outcomes of ADEs ascribable to parameters related to human factors.

The focus of this paper is to analyse the hospital's Drug Administration process to highlight the potential paths leading to ADEs and to suggest measures to bind and/or to remove their unwanted consequences. Hospitals are service structures called upon to provide health services to patients according to specific protocols. The complexity of such a task suggests that it be managed according to process management principles. Process management can be described as a sequence of different phases that aim at mapping relevant activities, highlighting improvement areas and supporting the effort to adopt best practices (Benner and Tushman, 2002).

The first reference to the "Clinical Governance" concept can be found in a report (Department of Health, 1998) that describes the process of setting, delivering and monitoring standards for a first-class service for UK healthcare. As discussed by Freedman (2002), clinical governance can refer to the World Health Organisation (WHO) framework (World Health Organisation, 1983) that identifies the following four drivers for implementing quality systems in healthcare organizations: professional management, use of resources, risk management and satisfaction of patients. For the efficiency and efficacy of healthcare organizations, giving strict attention to risk management, skills, competencies and staff willingness is clearly crucial because the consequences of an ADE can lead to significant costs, in terms of both the patient's disease and economic burden.

One of the first studies which cast light on verified adverse events was one in which 30,195 patients were admitted to hospital of which 1133 (3.7%) were harmed by medical treatment (Leape et al., 1991). Furthermore, ADEs have been found to constitute 19% of the total sample of adverse events. As found in Hohl et al. (2011), ADEs reduce a drug's therapeutic value and are responsible for incremental resource utilization of the health care system. Several studies, such as the one published by Lundkvist and Jonsson (2004), highlight how ADEs are the fourth to sixth cause of death in the United States. From an economic point of view, Hohl et al. (2011) estimate that ADEs are responsible for more than 1.5 million hospital days, leading to hospital costs between \$2.2 to \$5.6 (2008 values). Another recent and interesting study by Rottenkolber et al. (2012), analysing a thorough set of recent papers addressing the economic consequences of ADEs, indicates an incremental cost per case varying from approximately \$1000 to \$6000. The study discusses an interesting and easy-to-use approach to estimating the use of ADE resources. Technical and/or management tools that help to limit ADE effects are therefore advisable. For example, the adoption of clinical decision support systems has proved to be an efficient tool for ADE prevention, as discussed by Reckmann et al. (2009). From a risk management point of view, healthcare risk has been widely analysed by researchers, who describe techniques of risk analysis for the management of healthcare processes. Feldman and Robin (1997) used the Failure Mode Effect Analysis (FMEA) technique (IEC 60812 Ed. 1.0 b, 1985) to investigate healthcare system accidents. Williams and Tailey (1996) propose Failure mode Effect & Criticality Analysis (FMECA) to identify the most critical medical events on a quantitative basis. At the USA National Center for Patient Safety, De Rosier et al. (2002) developed an FMEA approach specific to the healthcare sector called "Healthcare Failure Mode and Effect Analysis" (HFMEA). Pradhan et al. (2001) have proposed a UML-based approach to "risk assessment" for modelling healthcare structure processes. They developed a quantitative risk analysis model based on an economic assessment and expected losses. Human factors causing ADEs were analysed by Lane et al. (2006) through HTA (Hierarchical Task Analysis). Embrey (1986) used SHERPA (Systematic Human Error Reduction & Prediction Approach) to identify and assess mental maps, built based on causal relationships perceived by the operators of nuclear power plants.

A model for analysing risks in drug management has been proposed by Trucco and Cavallin (2006). Their model, called CREA (Clinical Risk

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