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Health informatics - Safety procedures for identification of patients and related objects

Informatique de Santé - Procédures de sûreté pour l'identification des patients et des objets associés

Sicherheitsvorschriften für die Identifikation von Patienten und dazugehörigen Objekten

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Foreword

This document (CEN/TR 15299:2006) has been prepared by Technical Committee CEN/TC 251 “Health informatics”, the secretariat of which is held by NEN.

This document has been prepared by working group (WG) III - Safety, Security and Quality. The authors of this document were A. Sanna, M. Wilikens, A. Borio di Tigliole, G. Klein and P.A. Bonini.

This work addresses how the procedures for identification of Patient and Patient Related Objects can be carried out in the healthcare process with the active support of Information Technologies, in order to minimize the risk of errors with potential serious safety hazards.

The Patient Related Objects include:

— pure information objects (i.e. electronic/physical records as physiological data or prescriptions), and

— physical objects obtained from the Patients (i.e., blood samples or other biological materials) and intended to be used for a specific Patient (i.e., medications or prostheses).

The overall aim of this document is to provide a road map for the development of Patient safety related standards in the domain of health informatics that will actively support Patient safety in the healthcare process.

0 Executive summary

The increasing organizational complexity of the healthcare system is widely recognized as a factor of risk for the Patient in the healthcare process. Thus, Patient safety is becoming an emerging issue for the professional and social community. Healthcare professionals and Citizens are both calling for appropriate solutions, as it is evident when considering the high frequency and the contents of Patient Safety related articles in the scientific literature and in the mass media.

US President Clinton on December 7, 1999 "… took strong new steps to ensure Patient safety through the prevention of medical errors…" according to the results of a study released by the US Institute of Medicine estimating that "… more than half of the adverse medical events occurring each year are due to preventable medical errors, placing as many as 98 000 Americans at unnecessary risk. In addition to the severe health consequences these errors can cause, their cost in lost income, disability, and health care is as much as $29 billion annually."

President Clinton's initiatives include the creation of a task force to submit recommendations, the emission of a directive to federal agencies which administer health plans (serving over 85 million Americans) to implement error reduction techniques, the approval of a multi-million dollar investment in research and additional budget for error prevention initiatives in 2001.

It is important to highlight that the adverse medical events can be generated in the healthcare process either as a result of the overwhelming complexity of a specific clinical case and as a result of trivial errors in a well known procedure (e.g. the mix up of medications, biological samples and Patient records, the misinterpretation of objective data).

In this respect, the healthcare system performance in a given clinical case is but the result of the system as a whole, i.e. the result of interdependent performances of innumerable co-operating subsystems, most of them being, or depending from, the performances of human operators.

The system performance (a very complex issue indeed) includes the risk of failure due to the human component, i.e. the operator performance: in order to minimise the impact of human fallibility in the safety critical environment of the healthcare system, it is important to design processes that addresses the positive control of Patient safety critical data.

The procedures of identification of Patient and Patient Related Objects is the unique intervention point with the highest potential for minimising the risk of human errors and violations in the healthcare system and for deploying an appropriate infrastructure for maximising the performance of the interaction of the health informatics systems with the real world.

In order to obtain such a result, the present CEN/TR defines a framework for:

— the definition of safety critical objects in the healthcare process (MOS: Minimum Object Set) and the related safety critical data (MDS: Minimum Data Set) according to modelling methodologies as IDEF or UML,

— the definition of the rules of interaction among safety critical objects in the process, and

— the acquisition and processing of safety critical data by health informatics systems.

Finally, the present CEN/TR defines a possible roadmap for a stepwise approach for an effective standardisation activity in the area of Patient Safety, including the main health sub-processes that involve the hospitalised Patient as: Laboratory Medicine and Pathology, Bio-imaging, Drug Therapy Management, Blood Transfusion Management, Surgery Management. Such sub-processes can be considered, from a process modelling perspective, a case-mix that covers most of the process requirements of Patient safety for the hospitalised Patient and an appropriate starting point for the health processes that involve non-hospitalised Patients.