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Deviation based safety analysis and justification of clinical services

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Abstract. The paper describes safety analysis and justification of a clinical service (accidents and emergencies), using a deviation based approaches.

Keywords. clinical safety case, safety justification, FMEA, HAZOP

Introduction

A clinical service is a collection of systems, processes, procedures, devices and medicine, as well as personnel. Collaboration of all these is not fortuitous but analysed and designed in a way to provide quality and efficient healthcare. One of the qualities of healthcare is the safety of patients due to the risks that occur from failures of this collection of systems. There has been growing awareness that proactive or prospective risk analysis methods, such as those that have been used in other high hazard industries, provide additional benefits for improving quality and safety in healthcare [1]. JCAHO² standard LD.5.2 requires that “leaders ensure that an on-going pro-active program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented.”. Understanding how the systems may fail, and how these failures may propagate through interfaces and collaboration, is essential to design the necessary measures that will eventually justify placing our assurance on their operation.

1. A systems engineering view to assuring clinical services

Analysing the operation of the system requires methodical representation of all the facets of its operation, resulting in unambiguous (domain specific) models that can be shared among the relevant stakeholders. Figure 1 presents one such model for the A&E³ (accidents and emergencies) service of a hospital. The figure shows the various steps of the service as well as the roles and the IT systems participating in each one (other facets of operation can be included depending on the scope of the model). Each

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² Joint Commission on Accreditation of Healthcare Organizations

³ This is fictional but realistic scenario based on the experiences of the authors

of the roles and IT systems will need to meet a collation of (safety) requirements, generated by analysing their contribution to all services (such as the A&E one illustrated here).

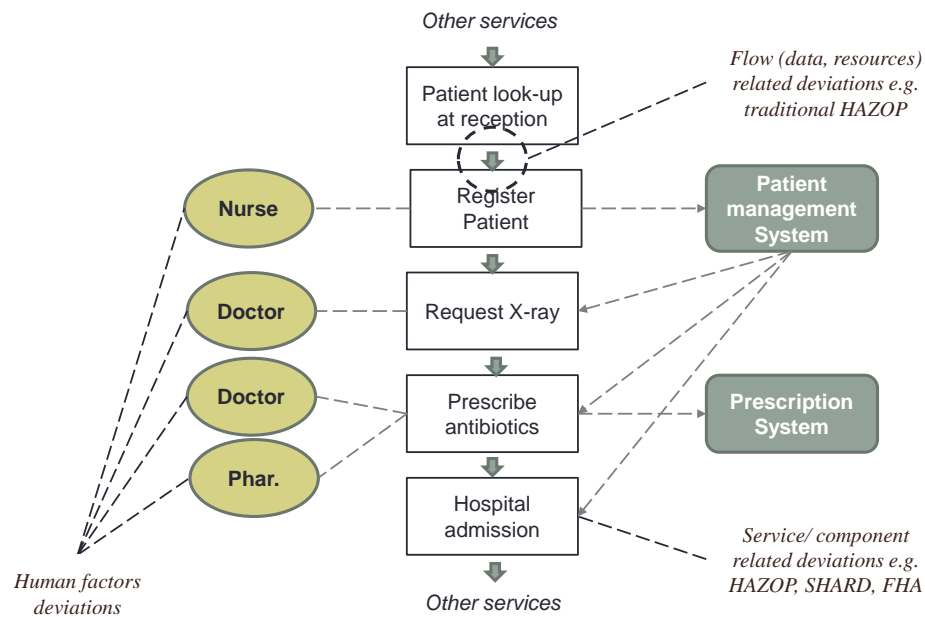


Figure 1. A model of an A&E service

Over the years, and motivated by a number of accidents, there has been significant interest on behalf of contractors, customers and independent authorities, in being able to capture and communicate assurance about the safe operation of a system. This has resulted in a number of standards and regulations requiring a system (e.g. the UK ISB 0160⁴) to be accompanied by a safety case. Although standards usually stipulate safety cases for particular aspects of the system (e.g. health IT), the concepts can be extended to the entire clinical practice, the benefits of which are also recognised in [2]. The safety case communicates an argument, supported by evidence that a system is acceptably safe in a given operational context. Safety cases explicitly capture a position about the safety of a system, and explain how the available evidence supports this position.

2. Deviation based analyses in healthcare

One of the prerequisites to justifying safety is analysis and understanding on how the elements of a system may contribute to hazards. Among other techniques and methodologies used, the safety analysis process includes a family of methods, described as deviation analysis techniques, such as Hazard and Operability Studies (HAZOP), Failure Modes and Effects Analysis (FMEA) and Functional Hazard

⁴ The standards are based upon “ISO 14971 Medical devices -- Application of risk management to medical devices” thereby maintaining a consistent approach to risk management in the healthcare domain

Analysis (FHA) [3]. For the last few years, the most prominent proactive risk assessment technique used within healthcare has been Failure Mode and Effects Analysis (FMEA). The use of FMEA in healthcare has been endorsed by a number of patient safety agencies such as the Joint Commission (see above), Institute for Healthcare Improvement (IHI) and the Institute for Safe Medication Practices (ISMP). During the past few years FMEA has been used in healthcare to assess the risks associated with, for example, organ procurement and transplantation, intravenous drug infusions, and communication in emergency care. Between 2004 and 2008, FMEA was introduced in 24 British hospitals as a method to improve patient safety as part of the Safer Patients Initiative (SPI) [4].

Deviation analyses are exploratory approaches and are used to methodically prompt each part of the system (e.g. patient registration function) with candidate deviations from intended behaviour, usually represented by a guideword (e.g. omission). The analysis then focuses on the interpretation of the deviation (i.e. patient will not be registered in the system), examining its plausibility, effect, as well as the impact of the effect on the behaviour of the entire system. Table 1 presents an extract from a deviation analysis method (HAZOP) applied to elements of the A&E service. Once a deviation is considered credible, the analysts will investigate potential causes and the consequences. Consequences can be described both in terms of what the deviation ‘means’ for the system element (local effects), as well as in terms of how it affects the entire system (system contribution). For example failure mode 3 (FM3) contributes to Hazard 3 (incorrect treatment of patient). Understanding a deviation from a local viewpoint always is more straightforward, as in order to understand effects on the entire system, the analysts will need to examine propagation of this behaviour (and possibly to transformation to other deviations). The various methods are optimised to be used for different parts of the system (shown in Figure 1), the discussion of which is outside the scope of this paper.

Table 1 - Excerpt from the A&E deviation analysis

<i>ID</i>	<i>System Element</i>	<i>Type</i>	<i>Guideword</i>	<i>Effect</i>	<i>Contribution</i>	<i>HazID</i>
FM1	Patient registration	Activity	Sequence	Patient not registered in the system	Patient not treated or treated with delay	H1, H2
FM2	Patient triage	Activity	Omission	Patient not receiving triage may not be treated when critical	Patient not treated or treated with delay	H1, H2
FM3	Prescription of antibiotic	Activity	Mistake	Patient receives incorrect medication	Patient receives incorrect treatment	H3

3. Making a case to justify safe operation of the service

Identification of the safety related failure modes is followed by identified measures that will remove the failure modes from the system, or reduce their impact. Figure 2 shows the safety justification (or safety case [5]) of the A&E system in a graphical layout (not

uncommon with safety justification to improve clarity). The justification makes a claim about safety, explaining how this was achieved, by means of safety measures (i.e. procedural checks and electronic checks), eventually referencing tangible evidence (provided by the clinical organisation or the manufacturer of systems participating to the scenario).

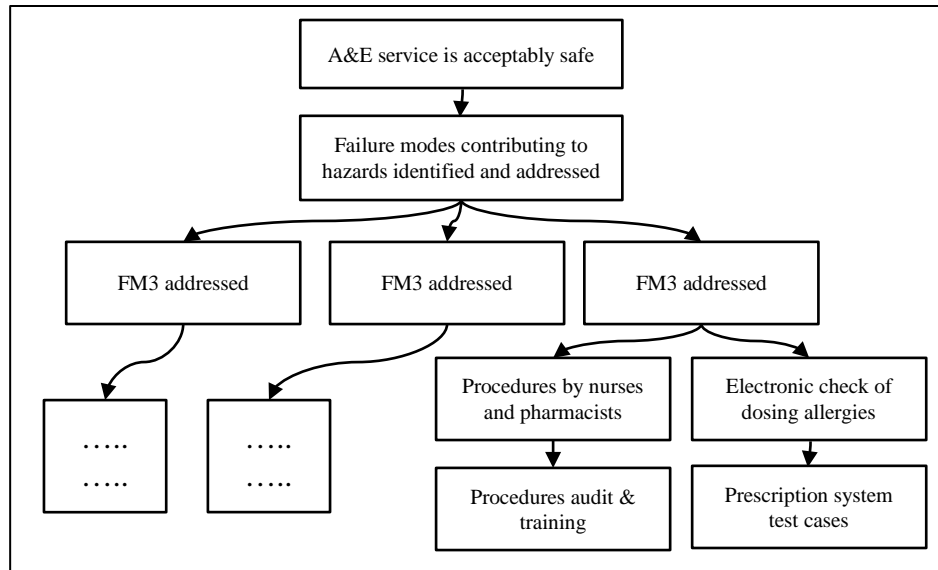


Figure 2 – Excerpt from the A&E scenario safety justification (graphically rendered)

4. Summary

Safety justification includes explains why stakeholders such as a clinical organisation or the regulator should be confident about the safety operation of the provided services. Deviation based analysis is a popular class of methods offering a way to analyse the system, identifying safety measures, as well as the evidence that will support the justification, making a convincing case about safety.

References

- [1] Kohn T. L., Corrigan M. J., Donaldson S. M., (Editors), To Err is Human: Building a Safer Health System, Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, 2000
- [2] Health Foundation, Using safety Cases in Industry and Healthcare, December 2012, Available at: <http://www.health.org.uk/publications/using-safety-cases-in-industry-and-healthcare/>
- [3] C. A. Ericson, Hazard Analysis Techniques for System Safety, 2005, Wiley-Blackwell.
- [4] Health Foundation, Learning report: Safer Patients Initiative, 2011, Available at: <http://www.health.org.uk/publications/safer-patients-initiative/>
- [5] G. Despotou, T. Kelly, S. White, M. Ryan, Introducing Safety Cases for Health IT, proceedings of 4th International Workshop on Software Engineering in Health Care, 4-5 June 2012, Zurich