UNIVERSIDADE ESTADUAL DE CAMPINAS
Faculdade de Engenharia Elétrica e de Computação

LEONARDO NOVAES DO NASCIMENTO

PROSPECTIVE MAPPING OF RISK FACTORS IN THE SOCIO-TECHNICAL HEALTH CARE SYSTEM

MAPEAMENTO PROSPECTIVO DE FATORES DE RISCO NO SISTEMA SOCIOTÉCNICO DE ASSISTÊNCIA À SAÚDE

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DEDICATION

To my beloved parents and brother:

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“Though we cannot change the human condition, we can change the conditions under which humans work.”

James Reason

RESUMO

O grande número de mortes evitáveis na área de saúde revela a necessidade de mudar o modo como o sistema lida com eventos adversos. Apesar de esforços para promover uma abordagem sistêmica ao gerenciamento de risco, a cultura da culpa ainda predomina. O resultado é a resistência generalizada à investigação de incidentes e a incapacidade de promover mudanças sistêmicas duradouras. O problema é amplificado pelo uso de ferramentas que se limitam aos fatores de risco no nível do ambiente de trabalho. O objetivo primário deste estudo é desenvolver um método prospectivo para mapear fatores de risco em múltiplos níveis hierárquicos do sistema de cuidado à saúde que possam contribuir com a ocorrência de eventos adversos no ambiente de trabalho. A maior parte das referências usadas nesta pesquisa está associada a fatores de risco e gerenciamento de risco no cuidado à saúde, a modelos de formação de acidentes e a ferramentas de gerenciamento de risco aplicadas na área de cuidado à saúde e em outras áreas. Como nenhum sistema ou ferramenta única pareceu completamente compatível com o objetivo primário deste trabalho, um conjunto básico de conceitos de gerenciamento de risco foi extraído das referências, especialmente do modelo do 'Queijo Suíço' de Reason e da estrutura sociotécnica de Rasmussen. Os conceitos foram agrupados num modelo de formação de acidentes híbrido que abrange interações entre elementos do ambiente de trabalho e malhas de controle sociotécnicas. O modelo foi então usado como base para o desenvolvimento de um método prospectivo para o mapeamento de fatores de risco. Devido aos requisitos de escopo, o Mapa de Fatores de Risco resultante toma emprestados elementos estruturais do AcciMap, de Rasmussen e pode mesmo ser considerado como inspirado por ele, embora tenha como foco análises prospectivas, não investigações retrospectivas de incidentes críticos. Três estudos de caso foram feitos como teste para o método: o primeiro foi baseado num relatório de avaliação de risco feito com uma ferramenta diferente de gerenciamento de risco; o segundo se concentrou no nível regulatório do sistema brasileiro de cuidado à saúde; e o terceiro foi um mapa genérico de fatores de risco baseado na literatura sobre bombas de infusão. Os resultados mostram que o método pode ser usado prospectivamente e que ele abrange os múltiplos níveis hierárquicos do sistema sociotécnico de cuidado à saúde. A natureza distinta dos estudos de caso mostra que o método é flexível o bastante para ser aplicado a uma variedade de objetivos e escopos e, se adaptado, também a outras áreas. O Mapa de Fatores de Risco é trabalhoso e a qualidade das análises depende da experiência dos analistas, mas estudos adicionais são necessários para avaliar sua efetividade em comparação com outras ferramentas de avaliação de risco, especialmente o AcciMap. Outra limitação do Mapa de Fatores de Risco é sua natureza predominantemente qualitativa, que reduz sua utilidade para a priorização de correções no sistema. Pesquisas futuras podem reduzir essa limitação pela integração dos Mapas de Fatores de Risco com dados quantitativos de sistemas de notificação de incidentes.

Palavras-chave: AcciMap. Formação de Acidentes. Gerenciamento de Risco. Mapa de Fatores de Risco. Método Prospectivo. Sistema de Cuidado à Saúde. Sistema Sociotécnico.

ABSTRACT

The high volume of preventable deaths in health care reveals the necessity of adjusting how the system deals with adverse events. Despite efforts to promote a systemic approach to risk management, the culture of blame is still prevalent. The result is a general resistance to investigating incidents and inability to promote lasting systemic changes. The problem is amplified by the use of tools limited to risk factors at the workspace level of the system. The primary objective of this study is to develop a prospective method to map risk factors at multiple hierarchical levels of the health care system that may contribute to the occurrence of adverse events at the workspace level. Most references used in this research are related to risk factors and risk management in health care, to accident causation models, and to risk management tools employed in health care and elsewhere. Because no single system or tool seemed fully compatible with the primary objective, a set of basic risk management concepts was extracted from the references, especially Reason's Swiss Cheese Model and Rasmussen's Socio-Technical framework. The concepts were assembled into a hybrid accident causation model that encompasses both workspace element interactions and socio-technical controls. The model was then used as the foundation for developing a prospective risk factors mapping method. Due to scope requirements, the resulting Risk Factors Map borrows structure elements from Rasmussen's AcciMap and may be considered inspired by it, though it is focused on prospective analyses, not retrospective critical incident investigations. Three case studies were conducted as a test of the method: the first one was based on a risk assessment report made with a different risk management tool, the second was focused at the regulatory level of the Brazilian health care system, and the third one was a generic Risk Factors Map based on the literature on infusion pumps. The results show the method can be used prospectively and it encompasses the multiple hierarchical levels of the socio-technical health care system. The distinct nature of the case studies shows the method is flexible enough to be applied to a variety of objectives and scopes and, with adaptations, also to other domains. The Risk Factors Map requires much time to be completed and the quality of analyses depends on the expertise of the analysts, but additional studies are required to assess its effectiveness in comparison with other risk assessment tools, especially the AcciMap. Another limitation of the Risk Factors Map is its predominantly qualitative nature, which reduces its usefulness for prioritizing system corrections. Further research may reduce this limitation by integrating Risk Factors Maps with quantitative data from incident report systems.

***Keywords**: Accident Causation. AcciMap. Health Care System. Prospective Method. Risk Factors Map. Risk Management. Socio-Technical System.*

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LIST OF ABBREVIATIONS AND ACRONYMS

ABIMO	Associação Brasileira da Indústria de Artigos e Equipamentos Médicos, Odontológicos, Hospitalares e de Laboratórios
ABNT	Associação Brasileira de Normas Técnicas
ANVISA	Agência Nacional de Vigilância Sanitária
CFM	Conselho Federal de Medicina
CNPq	Conselho Nacional de Desenvolvimento Científico e Tecnológico
CPG	Coordenação de Pós Graduação
EMI	Electromagnetic interference
FDA	Food and Drug Administration
HFMEA	Health Care Failure Mode and Effect Analysis
HVAC	Heating, ventilation and air-conditioning
IT	Information Technology
OR	Operating Room
PRA	Probabilistic Risk Assessment
QRA	Quantitative Risk Assessment
RCA	Root Cause Analysis
STAMP	Systems-Theoretic Accident Model and Processes
WHO	World Health Organization

SUMMARY

1 INTRODUCTION

This chapter presents the general context of this thesis and the motivation behind some specific topic decisions. It also presents the primary and secondary objectives of this thesis.

1.1 CONTEXT

The first studies on "hospital-induced complications" (part of the incidents now called *adverse events*) were published by the middle of the twentieth century (Moser, 1956 *apud* Schimmel, 2003). Driven by the impact of technological innovations in health care, those studies revealed some "acceptable diagnostic or therapeutic measures deliberately instituted" in hospitals could cause harmful effects to patients (Schimmel, 2003). Quantitative studies presenting mortality rates associated with health care were published later and promoted the use of a human factors framework for the identification of factors related to error (Cooper et al., 2002; Cooper et al., 1984).

The concern about patient safety grew year by year and gained considerable momentum with the publication of *"To Err is Human"*, by the Institute of Medicine (Donaldson et al., 2000). Extrapolating data from previous studies, the authors estimated between 44000 and 98000 the number of annual deaths in the USA due to preventable medical errors. More recent research updates the estimated preventable deaths in the USA to even greater numbers: between 210000 and 400000 (James, 2013). Besides alerting the general public to the problem of preventable adverse events in hospitals, the *"To Err is Human"* report promoted a relevant increase on the interest of scholars in the topic of patient safety (Stelfox et al., 2006). A similar study - the *Canadian Adverse Events Study* (Baker et al., 2004) - was later developed and indicated, by extrapolation, an annual number of preventable deaths between 9250 and 23750 in Canada. Recent studies on the Brazilian health care system estimate over 36000 preventable deaths annually (Couto et al., 2018).

A 2008 review on the incidence of adverse events in health care in various countries (De Vries et al., 2008) revealed that almost one in ten patients admitted to a hospital may suffer some kind of harm, regardless of severity, and that almost half of those incidents are considered preventable. Besides human losses, those preventable incidents promote substantial

financial costs due to increased length of stay, additional treatment for the harm done to patients (Weingart et al., 2000), and litigation.

A comparison of death rates across different industries and human activities (Amalberti et al., 2005) shows that health care has a total death rate per exposure comparable to road transportation. Some health care specialties are more subject to unstable conditions, thus presenting higher death rates (emergency surgery rates are comparable to transport by ultralight aircraft) while others, more stable and more acquainted with tools from safer industries, present lower rates (anesthesiology rates are comparable to the petrochemical industry). This heterogeneity of incident rates across health care disciplines is observed in other studies, which place surgery as the activity most associated with adverse events in hospitals (Gawande et al., 2003; de Vries et al., 2008; Arora et al., 2010).

These data suggest health care presents a considerably high overall risk of serious adverse consequences to patients, despite the safety levels attained in some disciplines (such as anesthesiology). Leape and coauthors (Leape et al., 1998) indicate the safety model traditionally adopted by the health care system as one of the main causes for such levels of safety in the domain. Relying on the requirement of flawless performance from personnel, this model is enforced by intense peer pressure and considers error as "an expression of failure" (Wilf-Miron et al., 2003) that arises from "aberrant mental processes such as forgetfulness, inattention, poor motivation, carelessness, negligence, and recklessness" (Reason, 2000). Not surprisingly, most doctors and nurses that participated in a survey (Sexton et al., 2000) denied stressors (fatigue, emergency, and personal problems) caused negative effects on their performance and one-third of the professionals working in intensive care units also denied they make errors. On the other hand, more than half of those ICU professionals admitted that they find it difficult to discuss error.

Some important barriers to reporting and discussing error in health care are: the threat it poses to personal reputation (especially in areas, such as surgery, where practice is not highly standardized (Amalberti et al., 2005)); the culture of litigation, which raises doubts about a fair treatment of disclosed errors (Mavroudis et al., 2005); and the common attitude of responding to accidents by blaming and punishing the person at the "sharp end" who made the last identifiable error in the sequence of events (Cook & Woods, 1996a; Catchpole, 2009). By instilling constant fear of punishment (including job loss and legal prosecution) in the health care personnel, this "culture of blame" prevents safety measures introduced in some institutions from effectively reducing risk; resistance to reporting adverse events (Nieva & Sorra,

2003) for example, impedes the collection of reliable data for risk management (Helmreich, 2000).

In contraposition to the culture of blame (also called “person approach”), the “system approach” emerged from the research on safety in other complex industrial systems, such as civil aviation and nuclear energy: it is based on the premises that humans are fallible and that systems should be designed to prevent humans from making errors (Reason, 2000; Vincent et al., 2000; Helmreich, 2000; de Vries et al., 2008; van Beuzekom et al., 2010). This alternative approach also acknowledges that systems are imperfect, therefore “errors are to be expected even in the best organizations” (Reason, 2000). Another premise of the system approach is that accidents are generally caused by multiple factors originated in different levels of the system - some from inside the institutions; others, from outside (Reason, 1990; Rasmussen, 1997). The literature shows this systemic approach has not been ignored by health care authorities, as indicated by multiple patient safety initiatives started by associations, accreditation bodies, government and health care providers in the 1990s in the USA (Leape et al., 1998) - all built upon some of the systemic premises.

Researchers also took interest in the systems approach to safety, as indicated by the development, testing, and assessment of incident reporting mechanisms (Staender et al., 1997; Johnson, 2003). Techniques for the investigation of adverse events and near misses (Shepherd, 1998; Bagian et al., 2002) or for the prospective evaluation of process vulnerabilities (DeRosier et al., 2002) have also been developed specifically to health care or adapted from other domains.

In order to adapt safety principles that are effective in complex industries to health care, studies have compared the latter with other high complexity areas, especially aviation (Barach & Small, 2000; Helmreich, 2000; Hughes, 2000; Sexton et al., 2000; Wilf-Miron et al., 2003; Tamuz & Thomas, 2006).

Finally, other studies have assessed the influence of system factors on the performance of health care personnel, confirming that multiple system factors are generally involved in the occurrence of errors (Carthey et al., 2001; Gawande et al., 2003; Vincent et al., 2004; Christian et al., 2006; ElBardissi et al., 2007).

Despite all efforts, more work must be done to diffuse the system approach within health care and more research is needed to understand the peculiarities of accident causation in its domain to make risk management initiatives more effective.

One topic that requires more attention is the control structure related to safety in health care. Despite a few exceptions (Waterson, 2009; Waterson & Jenkins, 2010), studies of

factors associated with adverse events in health care have focused only on specific factors. Those which extended the discussion to a larger set of factors were limited to internal levels within the organizations. The influence of higher external decisory levels in complex systems (i.e., regulation and government) brought to light by Rasmussen with the socio-technical system framework (Rasmussen, 1997) and the dynamics of error causation in the system still require attention from health care researchers.

In addition to the cultural characteristics of health care already mentioned, a possible cause for a certain delay on the development of safety knowledge in the area is the scarcity of detailed accident reports required by external researchers, as noted by Reason (2004). It concurs with the analysis made by Dien and coworkers (2012), which indicates that reports upon major accident investigations and the work of scholars are required for improving the safety knowledge in industrial sectors. Because the relatively high rate of preventable deaths in health care is mainly due to a large number of adverse events with single victims instead of a low number of major accidents with multiple victims – as occurs in other industries – safety research in health care must take a different approach. Considering this characteristic of the health care domain, system safety researchers should focus on extracting systemic knowledge from analyses of regular adverse events and near misses. Similarly, risk management activities should focus on identifying and controlling the systemic factors related to the most common hazards.

The results of some initiatives on incident investigation in health care organizations (Vincent et al., 2000; Bagian et al., 2002) suggest that the use of formal and systematic procedures for investigating incidents fosters the cooperation of health care personnel, who feel less threatened than with traditional unstructured approaches. A well-structured risk management program should complement retrospective methods for incident investigations with prospective risk analysis tools. This strategy might be perceived by personnel as less threatening since it does not involve actual accidents (and the blame potentially associated with them). To promote patient safety, accreditation organizations, such as the Joint Commission (Senders, 2004) and regulatory agencies, such as the Brazilian Health Surveillance Agency (Brasil, 2013) require or recommend the organizations under their authority to produce prospective risk analyses of critical processes.

In many institutions, though, safety management is still in its infancy: they do not have well-developed safety cultures nor fully functioning incident reporting systems. Consequently, there is no local data available to aid in the selection of topics for prospective analyses. Besides looking for recommendations from accreditation organizations or regulatory

authorities, it might be suitable for risk management teams starting safety management programs to base their first prospective analyses on high profile accidents that occurred in other institutions.

1.2 OBJECTIVES

Given the influence of actors in different levels of the system and the relative scarcity of thorough incident investigation reports, the primary objective of this study is to develop a prospective method to map factors at different hierarchical levels of the health care system that may contribute to the occurrence of accidents in work areas.

This study has also some secondary objectives:

a. To merge some concepts that are present in different accident causation frameworks into a single model;
b. To test the risk factors mapping method with multiple case studies.

2 CONCEPTS AND TOOLS

This chapter presents concepts and tools that emerged during research as necessary to understand the dynamics of risk management in the health care domain and to model accident causation in a multi-hierarchical framework.

The topics were distributed in four main sections: the first section presents some domain-specific characteristics and factors associated with risk in health care; the second one presents a summary of Reason's accident causation model (Reason, 1990); the third section presents the socio-technical system framework described by Rasmussen (1997); and the last one describes five risk management tools used for incident investigations or risk analyses, including two developed specifically for health care.

It must be noted that the term "risk", as used in this thesis (unless specifically indicated), is related to safety science, i.e., to the occurrence of harm to people or damage to material resources due to adverse events; it should not be mistaken as the medical term associated with the incidence of disease or death among individuals with certain risk factors.

2.1 RISK IN THE HEALTH CARE SYSTEM

This section is divided into two parts: the first part presents some characteristics of health care that might prevent certain risk management approaches originated in other domains (e.g., aviation, nuclear energy) from being fully used in the health care domain; the second part discusses multiple factors that influence the safety of health care procedures.

2.1.1 Risk Analysis in Health Care

The success of some complex industries (especially aviation) in improving the safety levels of their operations led scholars, risk managers, and other professionals involved with safety in health care to adopt safety principles and tools from those industries.

While some of these tools, like the WHO Surgical Safety Checklist (Haynes et al., 2009), were adapted with relative success, others – like centralized error reporting (Tamuz & Thomas, 2006) – are undermined by the negative influence of some systemic factors.

Four characteristics of health care seem to influence the effectiveness of risk management in health care institutions: heterogeneity of risk factors, lack of standards, personalism, and the culture of blame.

The first characteristic, pointed out by Amalberti and coauthors (2005), is the heterogeneity of risks in health care: while other high complexity domains, such as aviation and nuclear energy, deal with a limited set of very specific operations and equipment, health care is distinguished by a multitude of disciplines, and "the enormous diversity of its operations and equipment" (Reason, 2004). The heterogeneity of risk across medical disciplines is caused, among other factors: by the inherent risk level of each procedure; by the vulnerability of patients, whose homeostatic control systems are often affected by illness; by the risk of the clinical decision, which is affected, among other factors, by the degree of uncertainty of the diagnostic methods available to each discipline; by the risk of implementing the selected therapy, which depends not only on professional expertise, but also on the overall conditions at the point of care; and by the frequency of emergencies, which degrade all the other factors, as they force health care personnel to quickly provide diagnosis (often, without access to patient records) and treatment to patients who are (also often) in critical condition. One manifestation of such heterogeneity, observed by Reason (2004), is that some safety control mechanisms are only available to certain health care disciplines. As an example, automated safety controls used by anesthetists and radiologists to protect their patients from harm are comparable to high technology industries while surgeons and nurses often have to rely only on their own skills and on procedures or protocols, which normally depend on human performance. Heterogeneity in health care might cause risk analyses to become too complex for some analytical tools – especially those tools based on homogeneous models, such as the energy flow model used in chemical and energy industries. Also, the multitude of factors (both general and organization-specific) in health care procedures might be overwhelming for the specialist background of analysts, especially in the beginning of risk management programs, when a well-balanced team of analysts might not yet be formed.

The second characteristic is the lack of standardization in health care, which has been perceived as a barrier for achieving higher levels of quality and safety in the area (Amalberti et al., 2005; Cuschieri, 2005). Despite the potential benefits of standardization, it is not possible to implement on sectors of health care where stable conditions cannot be reached (e.g., on emergency-oriented disciplines, such as trauma surgery). One consequence of the lack of detailed protocols in health care, noted by Taylor-Adams and collaborators (1999), is the need of modification and adaptation of well-established analytical methods used

in aviation, energy and other complex industries (such as task analysis and failure mode and effect analysis) in order to be useful in the health care system. Such adaptations are necessary because the most relevant tools were developed during studies in industrial settings, which are considerably more structured than health care organizations (Rasmussen, 2000).

The third characteristic is related to the personal nature of the health care domain. As observed by Reason (2004): "In most hazardous industries, a few individuals serve a large number of end users. But health care is provided in a one to one or, at most, a few to one fashion". One face of this characteristic is the closeness between patients and health care personnel: patients and their families generally know the names of the professionals treating them and the perceived quality of the treatment they received will be transferred to the professional reputation of the care provider. Another face is the dependence of safety upon the expertise of individuals, especially in circumstances where there are neither automated safety controls nor standards available, such as certain branches of surgery. In such scenarios, individuals in leading positions (e.g., surgeons) tend to gain more autonomy to reach their goals, which, according to Amalberti and coauthors (2005), might be detrimental to the goals of other professionals involved in the process and therefore to the overall safety within the organization. As a consequence of the personal nature of health care, safety analysts might find it difficult to separate the influence of organizational factors from the personal ones during risk analyses of certain procedures. Moreover, because of the weight of personal reputation in certain specialties, some professionals might be less inclined to cooperate with such analyses.

The fourth characteristic is the culture of blame already mentioned in the introduction. The effects of such organizational culture are easily observable in the blame and punish reactions by supervisors and managers to adverse events in health care facilities. Although this attitude is not exclusive to health care, it is reinforced by other characteristics of the domain such as the limited understanding of accident causation by health care personnel and the personal character of the health care practice. Also, the concept of 'health' itself is not reliable for judging 'error', because it is not precise (Rasmussen, 2000). Some of the consequences due to the culture of blame noted by Rasmussen (2000) are: the increase of health care costs due to insurance premiums, the use of more clinical tests than objectively necessary, and the reluctance on professionals (especially surgeons) to take risky actions even if they might yield better treatments for their patients. Other consequences are the low adhesion to the use of risk management tools such as incident reporting systems (Dolansky et al., 2013) and the low number of risk analyses and incident investigations performed as well as the poor quality of

their results because professionals fear that reports might be used to punish them or their peers.

2.1.2 Risk Factors in Health Care

Research on adverse events in health care and on human factors indicates the safety of health care procedures may be influenced by various factors related to the different elements present in health care workspaces. According to Vincent and coauthors (2004), many of these factors have been neglected due to a perceived primacy of patient factors and professional skill.

The increased focus on patient-related factors is understandable because they determine which health care procedures are necessary, which organizations are capable of providing such procedures, and the starting conditions to which the professionals in those organizations must adapt to adequately perform the necessary procedures. The assessment of the patient's health conditions might be influenced by the availability of medical information (Christian et al., 2006) and by communication barriers between the health care team and the patients or their families (Vincent et al., 2000; Wilf-Miron et al., 2003; McCabe, 2004). Patient factors such as anatomical and physiological peculiarities (Calland et al., 2002; Rogers et al., 2006), gender, age, body weight and overall health condition (Amalberti et al., 2005; Giger et al., 2006; Arora et al., 2010) might influence the risk of perioperative complications. Emergent patient conditions are also associated with increased organizational and team difficulties and with an increased risk of surgical error (Gawande et al., 2003).

Professional skill also receives a large share of attention because it is directly associated with the results of health care procedures, especially those, such as surgical interventions, where protocols and automated defenses are not prevalent. Another reason for the focus on skill is that procedural mishaps "are hard to disguise" (Weingart et al., 2000). To improve the comprehension of the role this factor plays within health care processes, different techniques were developed to quantitatively assess technical skill (Datta et al., 2001; Guerlain et al., 2005, Moorthy et al., 2005). One interesting finding is that surgeons are relatively accurate in assessing their own technical performances using simulators, despite experience (Arora et al., 2011). Although experience might not exert much influence on the surgeons' ability to assess their own technical skills in simulations, it does seem to be associated with surgical skill itself. As observed in multiple studies, the greater surgical experience is related with decreased rates of surgical complications and adverse events (Carthey et al., 2001; Gawande et al., 2003; Rogers et al., 2006). Other studies (Cooper et al., 1984; Weingart et al., 2000; Tang

et al., 2004) suggest that experience must be complemented by adequate training before surgeons can safely and effectively perform relatively new techniques in their specialties. Individual performance might also be affected by nontechnical factors such as memory, judgment, and vigilance/situational awareness (Staender et al., 1997; Moorthy et al., 2005; Rogers et al., 2006); Other factors also affecting individual performance are: the inherent complexity of some tasks, such as videoendoscopic surgery (Berguer, 1999) and drug dose calculations (Leape et al., 1998; Rothschild et al., 2005); and multiple system-induced problems, such as high workload (Amalberti et al., 2005; Christian et al., 2006), fatigue and sleep deprivation (Firth-Cozens & Cording, 2004; Owens, 2007), and cognitive overload (Helmreich, 2000).

Despite the importance of individual factors, most health care treatments involve various professionals and the result of their efforts ultimately depend on their ability to cooperate with each other in such a way that everyone can adequately execute their designated tasks for the patients. The most important factor related to teamwork is probably communication, either in its direct form (generally verbal), or in the indirect one (generally written). A prospective study by Christian and coworkers (2006) associated information loss or degradation to delays in surgery progression, increased workload, instances of uncertainty in patient management for other team members, waste of material resources, and increased patient exposure to injury. Communication deficiencies also play an important role in wrong-patient/side/site procedures, as exemplified by an incident examined by Chassin & Becher (2002) where a patient was confused with another and underwent an unnecessary invasive procedure.

The transmission of information and responsibility for a patient's case from one team to another, known as *handoff*, seems to be a particularly vulnerable communication task in health care, as indicated by some studies that associate handoff problems to error (Donchin et al., 1995; Cohen, Hilligoss & Amaral, 2012; Dolansky et al., 2013). Although handoffs have been recognized as critical activities for more than 30 years (Cooper et al., 2002), problems in their execution still persist. Recent discussions on cognitive factors associated with handoffs (Cohen, Hilligoss & Amaral, 2012) might provide a solid foundation for the development of effective guidelines in the future.

Cultural barriers for feedback on error (generally between different hierarchical levels) also degrade team communication and they might prevent incidents from being used as a source for organizational learning (Tamuz, Thomas & Franchois, 2004).

Besides communication, team performance also seems to depend on a balanced mix of skills among the team members (Vincent et al., 2000), including leadership

(Helmreich, 2000; Shapiro, Croskerry & Fischer, 2002; Cuschieri, 2006), and it might be degraded by organizational factors such as high staff turnover (Elbardissi et al., 2007). Among other effects, good teamwork has been indicated as a compensatory factor for fatigue among team members (Firth-Cozens & Cording, 2004) and it has been associated with reduced conversion rates of videoendoscopic-to-open surgeries (Berguer, 1999).

Christian and her coworkers (2006) also examined the effect of task management in patient safety and indicated that inadequate coordination of workload and competing auxiliary tasks during surgery might cause problems such as avoidable workload peaks and absence of personnel during critical phases of health care procedures (which might cause delays or even require the team to modify the planned technique). Inadequate task management, as well as other individual and organizational factors, is also related to the occurrence of disruptions in health care procedures. Disruptions have been acknowledged as a problem by operating room (OR) professionals in a study by Sevdalis et al. (2008), but participants of the study tended to consider that coworkers were more frequently and more severely affected by disruptions than themselves.

Adherence to protocols and regulations (where they are available) is another important factor on the outcome of health care procedures (Bann & Darzi, 2004; Amalberti et al., 2005) because they are designed to reduce the negative influence of some individual or team factors on certain tasks. Nevertheless, some system factors such as heavy workload and other exacerbating circumstances might result in violations of (or deviations from) protocols and regulations (Rothschild et al., 2005).

The factors related to devices and supplies used in health care procedures must also be considered because good instruments and supplies allow professionals to perform at their best, but inadequate ones might limit their ability to provide proper care. Some of the risk factors associated with these resources are intrinsic to their structures: drugs, for example, have active components that might cause side effects (most of which are generally identified during clinical trials); medical devices might also have undesirable effects, dependent upon their functioning principles (e.g., the damage that electrosurgery might cause to structures adjacent to the operating site or the increased risk of developing certain types of cancer associated with the use of ionizing radiation). Health care personnel are trained to be aware of these intrinsic factors and to minimize the risks associated with them.

On the other hand, some factors arise from inadequate consideration to interface design and other manufacturing decisions, or from inadequate maintenance of the devices or supplies (Shepherd, 1998): medical devices may malfunction during health care procedures

(Cooper, Newbower & Kitz, 1984; Wiegmann et al., 2007) due to manufacturing defects or improper maintenance; poor ergonomics may result in clumsy handling or inadequate posture for operators and, thus, improve fatigue and mental stress (Cooper et al., 2002; Berguer, 1999; Tang et al., 2004; Cuschieri, 2005); and complex operational controls might not only induce lapses but also discourage operators from using safety features (like drug libraries in smart pumps) if the workload cost of using such features is perceived as high and their use is not mandatory (Rothschild et al., 2005). Poor interface design might also require operators to perform complex configurations on the devices during high cognitive load phases of the procedures, and even require them to adapt their tasks to the limitations imposed by the interface (Cook & Woods, 1996a, 1996b).

Likewise, drugs and other supplies might be ineffective (or even cause harm) if they have manufacturing defects or deteriorate due to poor storage conditions. Labeling problems might also induce drug-related incidents. Poor device and supply management might also cause problems such as incompatibility between devices and accessories (e.g., temperature probe connector not compatible with monitor (Helmreich, 2000)), and unavailability of required resources during procedures (Christian et al., 2006; Wiegmann et al., 2007), which might cause delays and other disruptions.

Automation is another important risk factor related to devices. As discussed by Cook & Woods (1996a), automation of medical devices (e.g., anesthesia systems) might transfer to health care some cognitive challenges already identified in other areas (e.g., aviation) such as tracking the behavior of automation, shifting from automated to manual control, and managing what is called *clumsy automation* (increasing the number of activities required during peak workload periods despite decreasing overall workload).

Finally, there are factors related to the structures that provide the base conditions in the workspace: facility and environment. These factors are related to the utility systems required for health care institutions (e.g., water, gases, electricity, and heating, ventilation and air-conditioning - HVAC) and to environmental conditions in (and around) the workspace. Utility systems might present design, manufacturing, and maintenance problems similar to those of medical devices, but utility problems might have farther-reaching effects within a health care facility. One example of these problems is poor utility specification during facility design, which might result in unreliable utility systems, unable to provide adequate output (e.g., not enough O_2 to supply the whole facility during high occupancy periods; frequent voltage fluctuations in unbalanced grids). Another example is the inadequate layout of electrical and gas outlets in operating rooms, which may be hazardous for personnel and equipment,

as indicated by Berguer (1999). The physical space also influences safety, as exemplified by floor characteristics related to the occurrence of slips, trips, and falls (Bell, 2008).

An extensive study on HVAC systems and thermal conditions in hospital ORs by Balaras, Dascalaki, & Gaglia (2007) associated problems such as bad space ergonomics, poor maintenance, and understaffed technical departments to inadequate indoor environmental conditioning. The same study assessed indoor conditions (temperature, humidity and air changes per hour) in 20 operating rooms from 10 hospitals and revealed that most of them failed to conform to the conditions mandated or recommended by international standards, regulations, and guidelines. It also pointed out some negative effects of inadequate HVAC systems, such as thermal discomfort, increased growth of bacteria in the environment, increased blood coagulation during surgery, increased risk of static shocks (and, therefore, of surgical fires), and increased risk of airborne contamination and infection. It is important to note that some facility factors, such as indoor thermal regulation, are somewhat challenging to control: while low temperatures might reduce the ability of patients under general anesthesia to keep body temperature within homeostatic range (Morris & Wilkey, 1970), high temperatures might increase the risk of surgical field contamination due to perspiration of the surgeons (Mills, Holland & Hardy, 2000). Indoor thermal balance is made even more complex by the different personal perception of indoor conditions from professionals in different roles and working conditions in the OR (Balaras, Dascalaki, & Gaglia, 2007).

As discussed by Figueiro et al. (2006), the lighting conditions in the workspace also have a significant influence on professional performance, because background luminance levels affect visual acuity, visual performance, and color perception. Certain illuminance levels have also been associated with improved subjective alertness in humans during the early biological night (Cajochen et al., 2000), which might be beneficial to the performance of nightshift workers. Figueiro's group also point to the need for taking precautions to avoid glare in environments with glossy floors and other surfaces if daylight is used in health care environments.

Among environmental factors, noise is possibly the most influential one in health care institutions. Besides causing distractions (Berguer, 1999), it has been associated with reductions in mental efficiency and short-term memory (Murthy et al., 1995), stress (Morrison et al., 2003), and to degraded robotic surgical performance (Siu et al., 2010). Noise has also been associated with disruptions in spoken communication between professionals (Kracht, Busch-Vishniac, & West, 2007) and it might also prevent health care personnel from hearing alarms and other important sounds, such as those associated with patients' breathing (Berguer,

1999). High noise levels, especially in specialties such as orthopedic surgery, might even cause hearing loss - both to patients and personnel (Willet, 1991; Nott & West, 2003; Kracht, Busch-Vishniac, & West, 2007), and they seem to affect anesthetic depth in patients under lighter levels of sedation (Kim, Kil, & White, 2001). The mere reduction of noise levels is not, though, the only solution suggested for the problems associated with sound: Cabrera & Lee (2000) suggest that the control of noise should be combined with the use of music therapy in health care institutions, due to certain benefits it might provide to patients and professionals.

2.2 REASON'S ACCIDENT CAUSATION MODEL

Current accident causation models are built upon the premise that the necessary conditions for the occurrence of an accident are generally provided by the combined influence of multiple factors that affect different elements (such as personnel, equipment, and safety mechanisms) in the system. Although these models were developed for aviation and other complex industries, the premise is also valid for health care and it is supported by observational (Christian et al., 2006; Wiegmann et al., 2007; Arora et al., 2010), interview (ElBardissi et al., 2007), and retrospective (Rogers et al., 2006) studies that associated multiple factors to accidents or to certain conditions that induce human error.

The concurrence of multiple factors in human error and accident causation in complex systems has been condensed by Reason (1990) in what has become known as the "Swiss Cheese Model", represented in Fig. 1.

According to Reason's model, high technology systems, such as nuclear energy and aviation, have several barriers to protect people and resources from hazards: some are engineered (e.g., alarms, physical barriers, and automatic shutdowns); some rely directly on individual performance; and others are based on protocols and administrative controls (Reason, 2000). Because there are multiple protective barriers, a breach in one of them will generally be compensated by the others, preventing the actual occurrence of an accident. Under certain circumstances, though, the system might depart from its normal stable state and allow holes in all barriers to align (as holes in slices of Swiss cheese), creating a trajectory of opportunity for an accident to occur. The three most important concepts for understanding Reason's accident causation model are *unsafe acts*, *latent conditions*, and *defense-in-depth*.

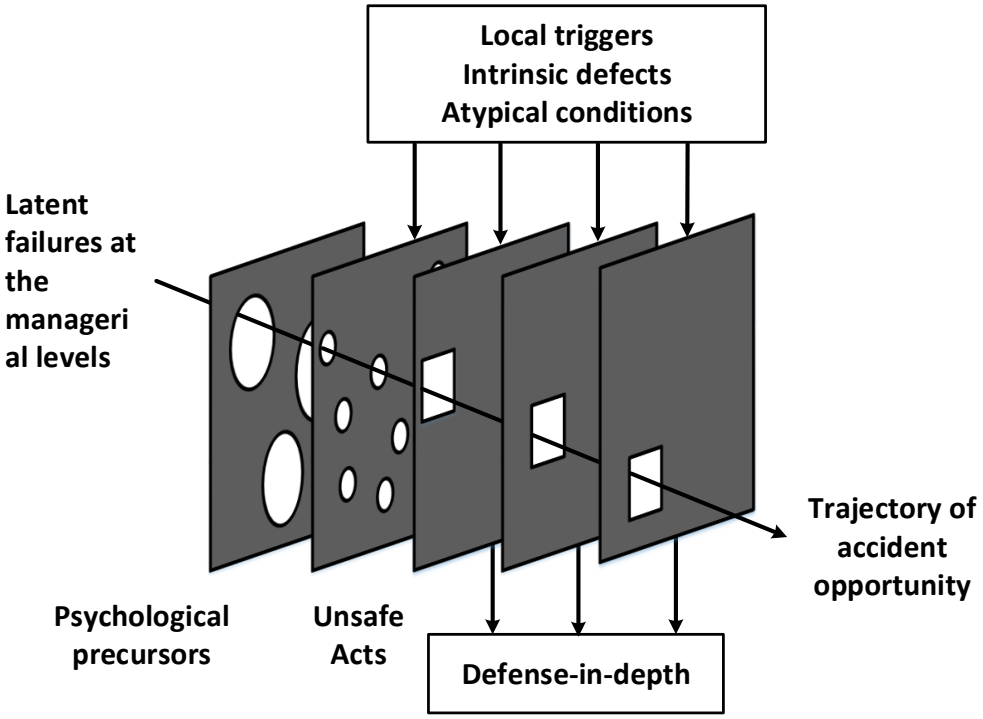

Fig. 1: The dynamics of accident causation (Source: Reason, 1990)

Unsafe acts are errors or violations committed in the presence of potential hazards (Reason, 1990) by people at the service delivery end of the system (Carthey, de Leval, and Reason, 2001). Although both errors and violations might be present in the same sequence of events, their origins are distinct: while errors emerge from cognitive processes of individuals, violations are deliberate deviations from practices deemed necessary to maintain safety in a system (Reason, 1990). Nevertheless, it is important to note that unsafe acts are not necessarily caused by negligence: some errors occur due to an involuntary misapplication of mental processes developed through training to perform very complex tasks very quickly (Catchpole, 2009); and many violations, despite of deriving from the natural human tendency to take the path of least effort, especially if the safer but costlier path is not enforced (Reason, 1990), are attempts made by professionals to deal with the increasing complexity of the systems in the workspace (Cook & Woods, 1996a; Rothschild et al., 2005).

Latent conditions, on the other hand, are system flaws caused by the actions of those whose activities are removed both in time and space from the workspace (e.g., designers, decision makers, manufacturers). When these flaws combine with certain unaccounted-for circumstances (local triggers), they might cause the breakdown of the system defenses (Reason, 1990; Carthey, de Leval, and Reason, 2001). According to Reason (2000; 2004), latent conditions can translate into error provoking circumstances within the workspace (e.g., time

pressure, inexperience, and lack of protocols (Shapiro et al., 2002)); and they might gradually erode the protective measures in the system (e.g., unreliable alarms and indicators, and unworkable procedures). As observed by Dien et al. (2012), the decisions that cause these conditions and the incidents associated with them do not have a clear cause-effect relation, so incident analyses should not be limited to direct chains of events.

Finally, *defense-in-depth* – a concept originated in the nuclear industry – refers to the existence of multiple layers of protective barriers in a system. In their original context, the objective of the series of barriers was "to prevent, mitigate, or contain unwanted releases of energy" (Saleh et al., 2010). These defenses comprise both personnel (e.g., via safety protocols) and engineered mechanisms (e.g., automatic safety devices, levels of containment). Although they are more common in relatively stable and predictable domains, such as nuclear power generation, chemical process plants, and commercial aviation, multiple barriers are also present in health care, especially in areas where more advanced devices are employed, such as anesthesiology and radiology (Reason, 2004). One problem of the defense-in-depth approach, observed by Rasmussen (1997), is that protective systems with redundancies are likely to degenerate because the erosion of one or more defenses might not have an immediate, visible effect. Therefore, the actual level of protection in the system might be lower than it is perceived by managers and operators. An example of defense degradation in health care is given by Rothschild et al. (2005), who conducted a trial of smart infusion pumps. Their study revealed that nurses might bypass drug libraries if the pump settings allow them to (which can be partially explained by workload pressure and device complexity): by doing that, the apparently safer smart pumps become no different from regular infusion pumps.

These elements of Reason's model are important because they provide a solid basis for a systemic approach to risk management. First, because understanding the role of latent conditions in accidents leads to prospective management of risk, since these conditions can be identified and corrected before accidents occur, unlike active failures (Reason, 2000); second, because the model recognizes the influence of multiple factors in the occurrence of accidents and the presence of multiple barriers in the system to prevent them, which helps explaining certain phenomena such as how one set of health care factors may be associated with different outcomes, as observed more than 30 years ago by Cooper et al. (2002) and confirmed by more recent studies (Barach & Small, 2000; Christian et al., 2006). These two characteristics of the model lead to the conclusion that accidents and near misses might be outcomes of the same factors, which places near-miss reporting as a valuable source of data about system safety (Carthey et al., 2001), especially because the analysis of near misses offers advantages over

actual incident investigations, such as the frequency of occurrence and the relative harmlessness of near-miss outcomes (Barach & Small, 2000), which might facilitate the cooperation of health care personnel.

2.3 THE SOCIO-TECHNICAL SYSTEM

A useful framework for complementing Reason's accident causation principles is Rasmussen's description of the socio-technical system involved in the control of safety (Rasmussen, 1997; Rasmussen & Svedung, 2000; Svedung & Rasmussen, 2002). According to Rasmussen, accidents occur where hazardous processes take place, i.e., at the workspace. But the workspace is only the bottom level of a complex socio-technical system where safety controls are modeled by laws, regulations, policies, and plans designed at higher hierarchical levels, as shown in Fig. 2.

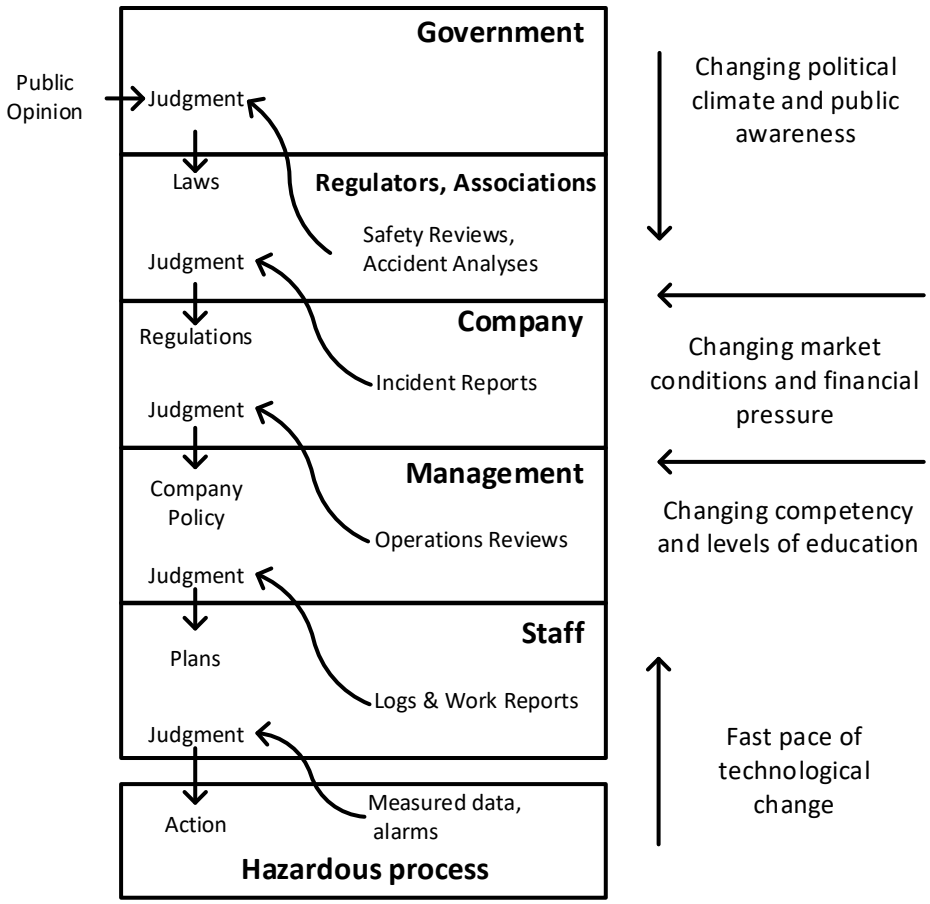

Fig. 2: The Socio-Technical System (Adapted from: Svedung & Rasmussen, 2002)

The concept of a socio-technical system helps to describe how decisions made at various levels of a system might cause the latent conditions that influence the behavior and performance of operational personnel (Leape et al., 1998; Carthey et al., 2001; Karsh et al., 2006) and other elements of the workspace. This framework thus represents a shift of focus on accident causation: from human error to mechanisms and factors that shape human behavior.

The multiple levels of the system are influenced by external factors and interact internally via top-down decisions (e.g., laws, regulations, policies) and bottom-up feedback (e.g., reports, operations reviews, incident analyses).

The two highest levels in the socio-technical hierarchy are *Government* and *Authorities* (i.e., regulators and associations) and they exist outside the organizations. The *Government*, at the top of the hierarchy, "seeks to control safety through the legal system" (Rasmussen, 1997). The next level, *Authorities*, is composed by regulatory agents (e.g., the National Health Surveillance Agency – ANVISA, in Brazil) and multiple associations (e.g., ABIMO, CFM, ABNT) that interpret the legislation and implement rules and guidelines to control the activities related to their specific domains.

The three system levels at the base of the hierarchical structure are located within the organizations. They are called *Company*, *Management*, and *Staff*. At the *Company* level, regulations are interpreted and policies are implemented in accordance with organizational context. The next level, *Management*, translates company policies and specific rules into operational plans adequate to local conditions and processes. Finally, the *Staff* carries out those plans, interacting with hazardous processes and equipment in the workspace.

Rasmussen adverts that "the classic command-and-control approach of deriving rules of conduct top-down" is not effective to control safety in a dynamic society. According to the author, models based on such an approach do not allow rule makers to take into account the local contingencies of the work context. He points out four characteristics of the present dynamic societies that set them apart from those of the past.

The first characteristic is the difference of pace between multiple levels: the pace at which technology changes at the workspace level is much faster than the pace of change in management levels and the pace of organizational changes is also faster than the response times of regulators and legislators.

The second characteristic is the scale of industrial installations, which is "steadily increasing with a corresponding potential for large-scale accidents" (Rasmussen, 1997). In

such circumstances, operations are only accepted by society if very low probabilities of accidents can be demonstrated, and it demands more detailed models of the system.

The third characteristic is the rapid development of information and communication technology, which "leads to a high degree of integration and coupling of systems" and might allow the effects of a single decision to propagate rapidly and widely through the socio-technical system (Rasmussen, 1997). Leveson (2004) also discusses the theme and observes the increased coupling associated with an increased complexity makes it "difficult for the designers to consider all the potential system states or for operators to handle all normal and abnormal situations and disturbances safely and effectively".

The last characteristic indicated by Rasmussen is the very aggressive and competitive environment where companies operate, which leads decision makers to focus more on production than on safety criteria. Such pressure for improving productivity is also present in health care and has been indicated as one of the cultural elements that threaten the safety of patients (Nieva and Sorra, 2003), especially because this pressure is not generally accompanied by an adequate improvement in the available resources (Cuschieri, 2006).

These characteristics listed by Rasmussen can be complemented by another four indicated by Leveson, who also discussed the limitations of traditional approaches to accident causation (Leveson, 2004).

The first one is the changing nature of accidents, caused by the introduction of digital technology systems and software: many of the approaches developed to deal with electromechanical components (e.g., redundancy) are not so effective at improving safety in digital systems.

The second characteristic is the introduction of new types of hazards: the increasing dependence on information systems ties the potential of physical, scientific and financial losses to the integrity of information, while common accident models are based on physical concepts, such as controlling the flow of energy in the system by the employment of protective barriers.

The third one is the increasing complexity of relationships between humans and automation, which defies the ability of interface designers to create systems whose states are simple to assess and which are simple to control.

The last characteristic listed by Leveson is related to the changes in regulatory and public views of safety: individuals demand the government to take more responsibility for controlling behavior through laws and other forms of regulation because they are no longer able to control the risks around them.

Although these characteristics were derived mainly from the study of industrial settings, they may also be observed, to some extent, in hospitals and other health care institutions. An example for that is the high number of deaths (estimated at 90) at the Maidstone and Tunbridge Wells NHS Trust, due to an infection outbreak during the period between April 2004 and September 2006 (Waterson, 2009): it was probably influenced by the scale of the healthcare installations involved in the incident.

The introduction of laparoscopic cholecystectomy to general surgery is a good example of how technological changes might influence a complex socio-technical system: the promising technique was quickly adopted by many surgeons who assumed (erroneously) that their skills at open surgery would easily transfer to the laparoscopic environment. Safety concerns were soon raised and, after some time, societies and regulatory bodies stipulated certain requirements for performing the technique, which promoted drastic changes to the teaching strategies used until then (Aggarwal, Moorthy & Darzi, 2004). Analogous problems seem to be common in the evolution of health care installations, which, according to Rasmussen (2000), "appear to evolve by a bottom-up aggregation of the latest equipment offered separately by the suppliers, not from a top-down work analysis of the activities ".

The effects of the public pressure for safety can also be observed in health care and result, among other effects, in a multitude of safety decisions being taken without clear proof of their benefits and without sufficient consideration of their effects on other levels of the system (Amalberti et al., 2005). Examples of these effects include quality improvement innovations seemingly based on no evidence (Goodman, 2000) and protocols for certain OR activities that might actually negatively interfere with other primary activities (Christian et al., 2006).

A good example of proper safety control in a large health care system is the introduction of a Root Cause Analysis system in the Veteran's Affairs facilities, described by Bagian et al. (2002), which considered the relations between multiple levels in the initial design.

Rasmussen's socio-technical system framework was used in the analysis of incidents, such as the Maidstone and Tunbridge Wells infection outbreaks (Waterson, 2009). It is also the basis for the AcciMap tool, developed by Rasmussen and Svedung (2000) (described in section 2.4.4) and it influenced Leveson's (2004) STAMP model (described in section 2.4.5).

2.4 RISK MANAGEMENT TOOLS

Discussing safety in industrial settings, Saleh et al. (2010) indicate that the interest in system safety generally increases as a response to high visibility accidents and they suggest that the focus on such a small fraction of the organizational accidents may have prevented the progress of research in system safety.

Similarly, high visibility accidents in health care are relatively rare when compared to the actual number of accidents and, had the *To Err is Human* (Donaldson et al., 2000) report not been published, many of the current patient safety initiatives would, probably, still be in earlier stages.

This section briefly presents some tools used for risk management in different domains, part of them specifically in health care. The selected tools represent complementary approaches with different purposes in the risk management process and different levels of detail in their analyses.

2.4.1 Root Cause Analysis

The American Department of Energy defines Root Cause Analysis (RCA) as "any technique that identifies the underlying deficiencies in a safety management system that, if corrected, would prevent the same and similar accidents from occurring" (DOE, 2012). This definition indicates that RCA is not a uniform tool and also points to the main goal of RCA systems: to understand *why* an accident occurred.

The heterogeneity of RCA approaches can be observed in the differences both in form and comprehensiveness of its applications: it has been presented as one step in a larger accident analysis process recommended to energy facilities in the USA (DOE, 2012); it has been used as the core technique of an integrated accident analysis program implemented in a nationwide health care service (Bagian et al., 2002); and it has also been used to run single case studies of health care incidents (Williams, 2001; Dolansky et al., 2013). Examples of features found across different RCA systems include: prioritization rules for selecting the adverse events that should be analyzed; use of multidisciplinary teams; graphical representations of the incident sequences; cognitive aids that consider human factors engineering principles in the analysis of causal factors; classification charts (labels) for identifying dominant factors among different events; selection of the most significant causal factors by voting; and guide-

lines for the selection of the proper corrective action for each root cause (Williams, 2001; Bagian et al., 2002; DOE, 2012).

The implementation of the RCA system in the US Department of Veterans Affairs (VA) showed that the tool can help shift the focus of investigations from blaming individuals to identifying systemic factors associated with the adverse event (Bagian, 2002). VA's experience with RCA also shows that it is possible to formulate corrective actions for a nationwide system if data from multiple facilities are integrated. Wu and coauthors (2008) note that there are several requirements for high-level interventions to occur and, since such requirements are generally not met, recommendations drawn from root cause analyses tend to be restricted to the facility where they were made, which is neither effective nor efficient.

Even ignoring facility-specific problems, RCA presents additional limitations. First, it is retrospective by nature, which means it generally depends on the occurrence of adverse events to be used (Senders, 2004). Although the use of near misses (Bagian et al., 2002) may circumvent this limitation, it requires the existence of a solid near miss reporting system in the institution. Second, the application of the tool requires a certain amount of judgment (Sklet, 2004). Third, like other risk management tools, it relies on pragmatic, subjective stop-rules that depend on the aim of the analysis (Rasmussen, 1990), on the ability of the analyst to propose corrective measures to the causes identified (Dien et al., 2012), and on other factors, such as the lack of backwards information on the event (Svenson, 2001). Fourth, it may be very time-consuming (Wu et al., 2008). Finally, RCAs will not provide good results in organizations where the safety culture is not well developed (Nieva & Sorra, 2003).

2.4.2 Shepherd's System

Another incident investigation tool is the *Shepherd's System™ for Medical Device Incident Investigation and Reporting* (Shepherd, 1998), which is focused on the analysis of "device-related incidents".

Shepherd's System™ was developed to aid clinical engineers and biomedical equipment technicians/technologists (BMETs) in the investigation of incidents involving biomedical devices. The method describes a generic device-related system as a set of five *components*: Device, Facility, Patient, Operator, and Environment. It associates some *subcomponents* to each component, as shown in Fig. 3. The components, then, are the basic elements that constitute a system where a device is used in the care of a patient; and the subcomponents are "administrative causes" which "are useful in making reporting decisions and in corrective actions".

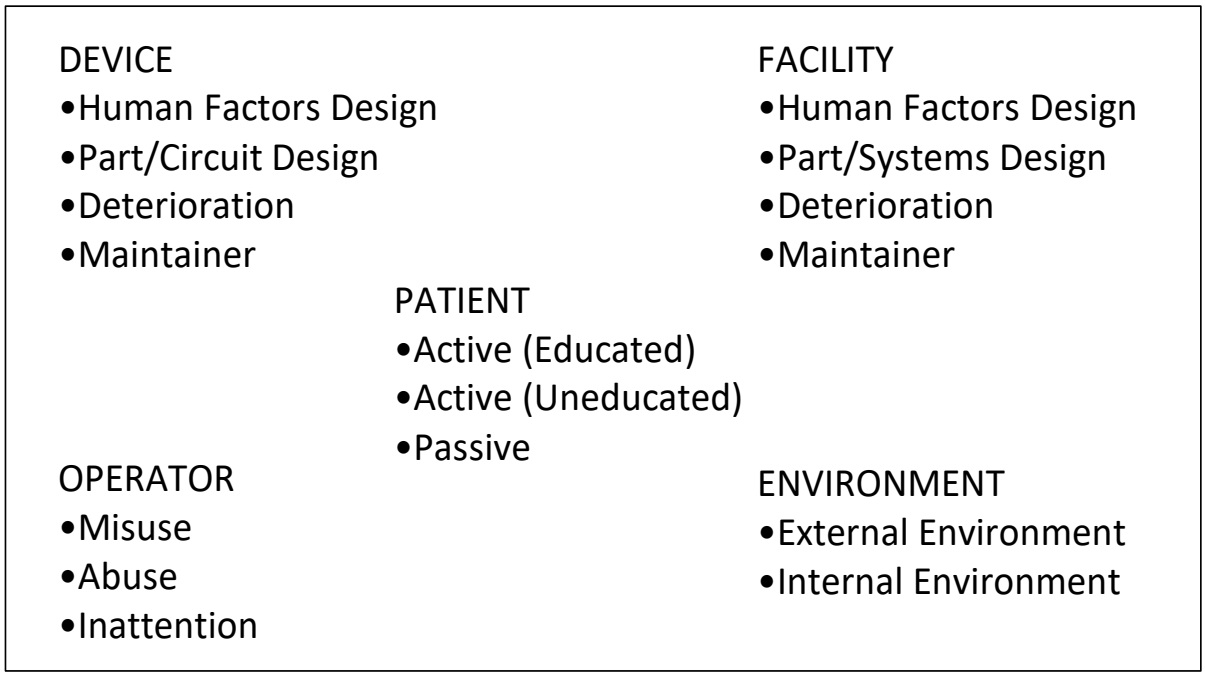

Fig. 3: Components and subcomponents involved in a device-related incident (Source: Shepherd, 1998)

Incident analyses with this tool are conducted by first identifying the components involved in an incident and then the subcomponents associated with each of them. After that, the most relevant subcomponents are selected and corrective recommendations are made.

Perhaps due to the focus of the tool on device-related incidents, the subcomponents seem to represent modes of interaction between the Device component and the other components that may cause a failure of the former (e.g.: Operator – Misuse, Patient – Educated), or factors that may render the Device component more likely to fail or to cause damage to the patient (e.g.: Device – Deterioration, Patient – Passive).

One important characteristic of Shepherd's System™ is the structured approach to the investigation of device-related incidents: because it is supported by a simple, yet comprehensive, classification of failure causes, it provides a thorough and clear method to identify the causes of those incidents. Besides, the system's guide provides some useful aids, such as a list of fundamental conditions associated with common hazards (partially reproduced in

Table 1), which is useful for identifying the immediate causes of the incident; and a list of the groups or persons mainly responsible for the prevention of incidents related to each subcomponent, which might be helpful in the allocation of resources from the organization's safety program.

Table 1: Injury Types, Mechanisms, Fundamentals and Examples (excerpt from Shepherd, 1998)

Injury	Mechanism	Examples	Fundamental Conditions
Ventricular Fibrillation	Electricity	60 Hz through heart	2 Conductive sources, contact with the body, & electricity
Burn, Electrical	Electricity	Electrosurgical	Electrical intensity, area, time
Burn, Convective	Heated gases	Incubators	Temperature, time
Burn-Like	Contact Dermatitis (allergenic reaction)	Reaction to adhesive tape	Patient Dependent
Injury/Death	Functional loss	Respirator	Loss of Critical Function

On the other hand, the system also has some limitations: first, because it is focused on device-related incidents (which defines both components/subcomponents and table of fundamental conditions), it might not be of much use in the investigation of incidents where medical devices play only a minor role; second, the indication of groups or persons administratively responsible for preventing incidents might be misused as a method to identify the person to blame for the incident under investigation; and, finally, the analyses provided by the tool are not expected to cause repercussions in the higher levels of the socio-technical system, because they are primarily aimed at the workspace (except, possibly, in organizations particularly driven by risk and safety management considerations).

2.4.3 Health Care Failure Mode and Effect Analysis™

Based mainly upon Failure Mode and Effect Analysis (FMEA), a technique that has been used for decades in industry, the Department of Veterans Affairs (VA) National Center for Patient Safety (NCPS) developed the Health Care Failure Mode and Effect Analysis™ (HFMEA™) (DeRosier et al., 2002).

HFMEA™ is a structured system designed for the prospective analysis of health care processes. Analyses conducted with this system must follow five basic steps: first, the HFMEA™ topic is defined, based on the level of risk or vulnerability of the area, which must be deemed high enough to merit the investment of time and resources; second, a multidisciplinary team is assembled in order to assure that various points of view are considered; third, a process flow diagram is developed to help in the selection of sub-processes to be analyzed; fourth, the potential failure modes associated with the sub-processes are identified and each of them goes through a multistep hazard analysis; and fifth, the team defines actions to reduce the risk associated with the causes of the failure modes and outcome measures for their completion and then assigns the persons responsible for implementing each corrective action

(Derosier et al., 2002). Despite the use of some specific tools, the general structure of HFMEA™ is similar to the risk management process adopted in industrial settings (Main, 2004) and to the process recommended for medical devices manufacturers (e.g., in ISO 14971).

The prospective nature of HFMEA™ is beneficial to its execution because it dissociates the identification and correction of system problems from the occurrence of adverse events – and thus avoids blame reactions. Besides, it might be used to fulfill certain accreditation requirements, such as the periodical prospective assessment of high-risk processes demanded from the Joint Commission (DeRosier et al., 2002; Senders, 2004).

Because HFMEA™ is based upon the identification of the failure modes of systems' components, it might not provide good analyses of human components, as human failure modes may manifest in various ways depending on the circumstances (Reason, 1990; Senders, 2004). The effectiveness of this tool also depends on the strength of the safety culture in the organization (Nieva & Sorra, 2003), especially in the decisory levels, responsible for balancing the cost and effectiveness of the corrective actions (Main, 2004). Like other risk management tools, HFMEA™ is very time-consuming.

The tool has been applied in multiple areas, including medication safety (Esmail et al., 2005), sterilization of surgical instruments (Linkin et al., 2005), clinical engineering (Florence & Calil, 2006), radiotherapy (Vlayen, 2011), and central line-associated bloodstream infections (Chandonnet, 2013).

2.4.4 AcciMap

The AcciMap technique was developed by Rasmussen and Svedung (2000; 2002) and, as indicated in section 2.3, it is based on Rasmussen's research on organizational accidents in complex socio-technical systems (Rasmussen, 1997).

Following Rasmussen's model for complex socio-technical systems (Rasmussen, 1997), the AcciMap diagram distributes processes, conditions, actions, and decisions in multiple levels associated with a hierarchical representation of system control mechanisms, as observed in Fig. 4.

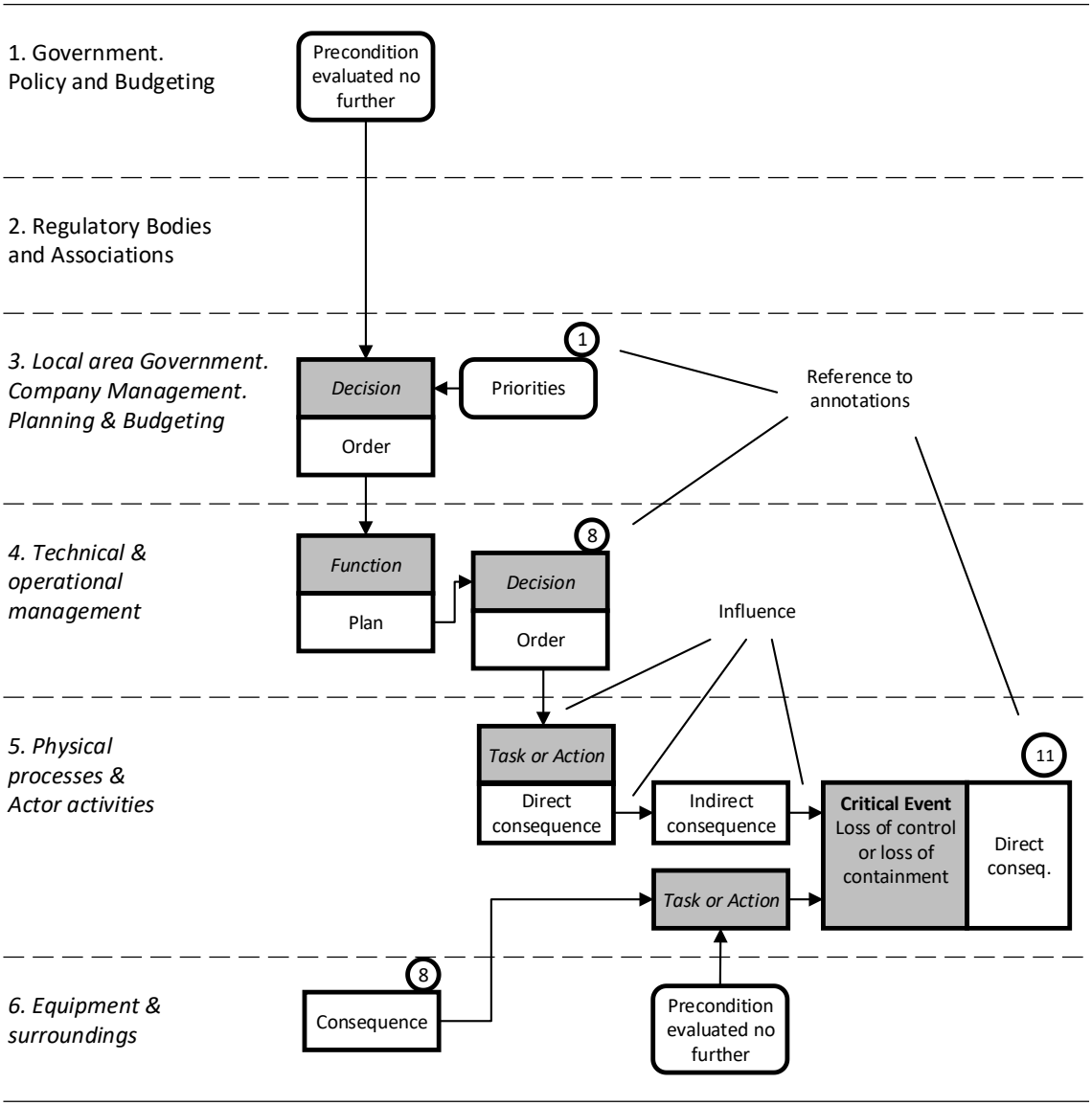

Fig. 4: Basic AcciMap structure (Source: Rasmussen & Svedung, 2000)

The construction of an AcciMap starts with the selection of a critical event related to an accident, which is placed in the second level from the bottom of the diagram (level 5); then, the main preceding events in the accident sequence are depicted in the same level; after that, the equipment and environmental conditions associated with the events are placed at the bottom level (level 6); and finally the decisions and actions made in higher decisory levels that influenced the occurrence of the accident are placed in their proper levels (levels 1 to 4), above the level where the critical incident is placed.

Although the AcciMap requires a short description of the events leading to a critical incident, the purpose of the technique is not to identify the persons involved or to simply

describe the direct causal flow of events, but to identify the factors in multiple levels of the socio-technical system that shaped the conditions for the occurrence of the accident.

The AcciMap was originally presented (Rasmussen & Svedung, 2000; Svedung & Rasmussen, 2002) in combination with two other tools: the ActorMap, which identifies the actors contributing to the accidents at each level; and the InfoMap, which depicts the flow of information amongst the actors in the ActorMap. The data gathered in multiple single-event analyses in a specific domain would then be condensed in a model representing the safety control structure of that domain, the *generic AcciMap*.

The tool has been adapted and applied in various analyses since its origins (Waterson et al., 2017). The various domains where it was applied include space launch (Johnson & de Almeida, 2008), police operations (Jenkins et al., 2010), led outdoor activities (Salmon et al., 2012; Goode et al., 2017), offshore drilling (Tabibzadeh & Meshkati, 2015), transport and storage industry (Goode et al., 2014, Lee et al., 2016; Gonçalves Filho et al., 2019), and disaster response (Salmon et al., 2014), but most studies were associated with single adverse events.

The main advantage of the AcciMap in comparison to other tools is its broader scope of analysis: while other tools used in incident investigation and other risk management activities only focus on workspace processes or go, at most, up to the company level, AcciMap also includes other potentially involved organizations (third-party manufacturers, service companies, etc.), and regulatory and governmental agents in the analysis of factors related to an incident (Sklet, 2004; Branford, Naikar and Hopkins, 2009). Other advantages include the large amount of information that can be compiled in a single AcciMap diagram and the assistance it gives to the development of safety recommendations (Branford, Naikar and Hopkins, 2009).

A major limitation of the tool is its inaccessibility to new users (Sklet, 2004; Branford, Naikar and Hopkins, 2009), which is due, in part, to the lack of guidelines for its execution in the original publications (Rasmussen & Svedung, 2000; Svedung & Rasmussen, 2002). Because of that, multiple studies present different approaches to the tool. Based on those multiple iterations of the technique, Branford and coauthors (2009) proposed a standard AcciMap format and provided guidelines for its completion, but it is aimed at incident investigations, not prospective analyses, although the importance of adapting the tool for prospective analyses has been noted (Grant et al., 2018). Another problem, when compared with other methods, is the absence of domain-specific taxonomies of failure modes (Salmon et al., 2012),

which might limit the reliability of the tool and make it difficult for analysts to aggregate multiple analyses.

2.4.5 Systems-Theoretic Accident Model and Processes

Similarly to AcciMap, Leveson's (2004) Systems-Theoretic Accident Model and Processes (STAMP) model is built upon Rasmussen's socio-technical framework. Although STAMP also shifts the focus of analysis from the event chains to the performance-shaping mechanisms present in the system, it takes a control theory approach to the analysis of incidents.

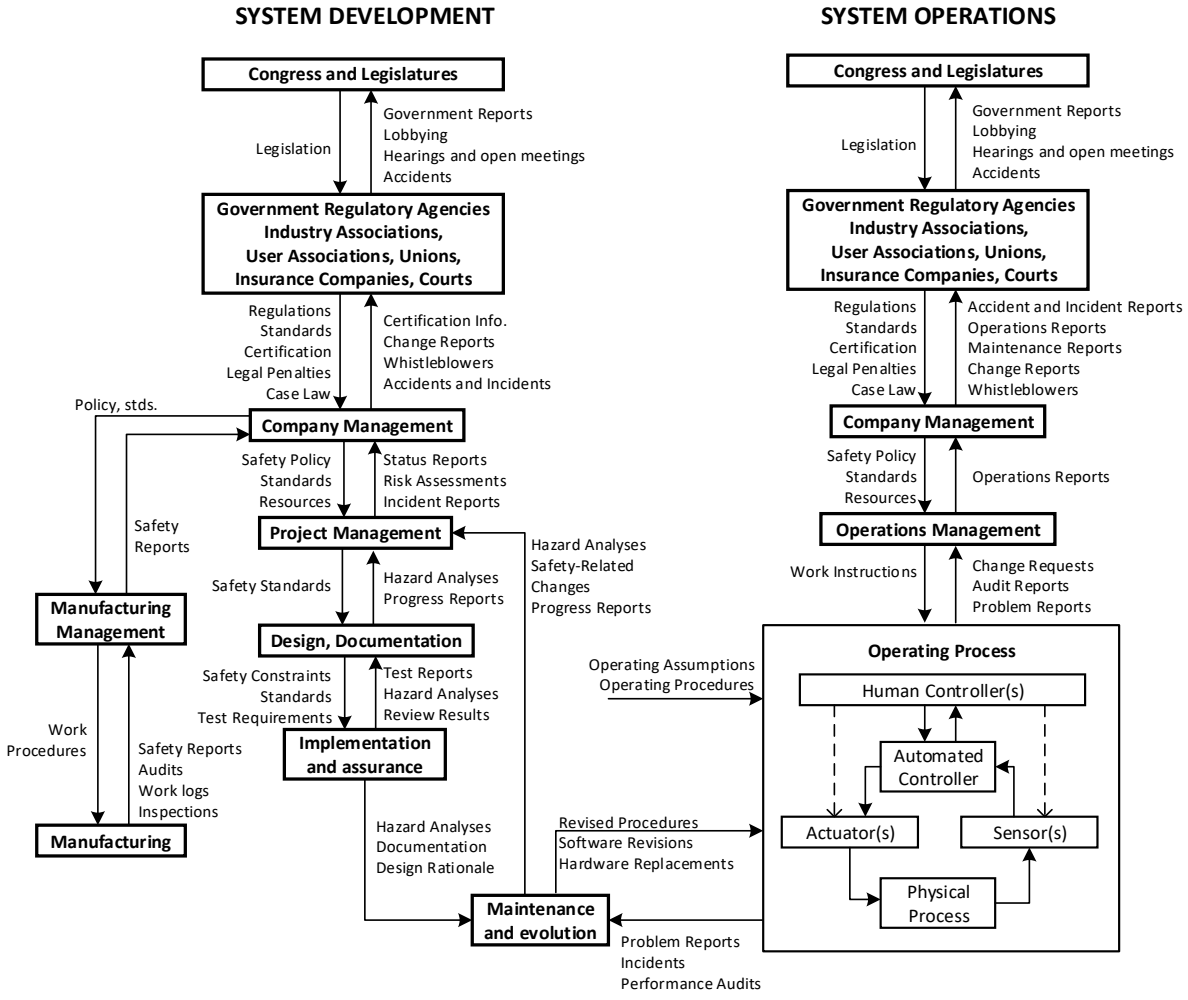

Fig. 5: Generic socio-technical system control structure (Source: Leveson, 2004)

The most basic concept in this model is not an event, but a constraint. Accidents, thus, are viewed as the result of inadequate enforcement of constraints in the system. As observed in Fig. 5, the general socio-technical control model in STAMP is similar to Rasmussen's, but it is formed by two parallel control structures, one for system development and oth-

er for system operations. These structures interact at the workspace level: manufacturers (development) provide instructions about safe operating procedures (and the environmental conditions for which those procedures were developed) and operators provide feedback about the performance of the system during operations.

The general factors leading to an accident are identified with the aid of a taxonomy of control flaws, distributed in three classes: *Inadequate Enforcement of Constraints (Control Actions), Inadequate Execution of Control Action,* and *Inadequate or Missing Feedback*.

STAMP has been used in the analysis of incidents in multiple domains, such as water contamination (Leveson et al., 2003), space launch (Johnson & de Almeida, 2008), led outdoor activities (Salmon et al., 2012), and maritime transportation (Gonçalves Filho et al., 2019).

Salmon and coauthors (2012) note that the tool is potentially as comprehensive as AcciMap since both systems share Rasmussen's socio-technical framework in their bases, but, due to the need to construct detailed control structure diagrams representing the control loops present in the domains under analysis, it requires more data. They also note that the method is more suitable for the analysis of technical control failures, as opposed to complex human decision making and organizational failures.

Due to its taxonomy being based on control flaws, STAMP analyses seem to be less subjective than AcciMaps, but the control theory elements present in the model might make it less accessible to new users without a background in control theory.

2.4.6 Task Analysis

Task analysis can be defined as "any process that identifies and examines the tasks that must be performed by users when they interact with systems" (Kirwan & Ainsworth, 1992).

The term covers a wide range of techniques used to describe and evaluate the human factors associated with human-human and human-machine interactions in a system. The comprehensive task analysis guide edited by Kirwan and Ainsworth (1992) presents many of those techniques, distributed in five classes, according to their purposes: data collection, task description, task simulation, task behavior assessment, and task requirement evaluation.

Data collection techniques are used to collect data on human-system interactions and are generally used to generate input for other techniques. Examples: observational techniques, questionnaires, and structured interviews.

Task description techniques are used to present the data collected in a structured format. Examples include decomposition methods, hierarchical task analysis, and multiple charting techniques such as flow diagrams and process charts.

Task simulation methods are used to create a dynamic model of the events expected to happen during the execution of a task. Examples: computer modeling and simulation, simulators/mock-ups, walk-throughs and talk-throughs, and tabletop analysis.

Task behavior assessment methods are concerned with system performance evaluation, usually from a safety perspective. They are primarily aimed at identifying what events may lead to system failure. Examples include barrier and work safety analysis, event trees, failure modes and effects analysis, and fault trees.

Task requirement evaluation methods are used to assess the adequacy of the available facilities to support the execution of the intended tasks. Examples: ergonomics checklists and interface surveys.

Although most task analysis techniques were developed for industrial settings, many of them have already been adapted to health care (Cassano-Piché et al., 2015) and they may greatly improve risk management activities in the domain, especially during data collection and task description stages of risk analyses.

3 THE ACCIDENT CAUSATION MODEL

This chapter describes an accident causation model that integrates concepts present in multiple different models and tools from the literature on system safety and accident causation into a single system directed to the health care domain.

The reason for describing this accident causation model is that none of the existing systems or tools seemed suitable for the primary objective of this study, i.e., to develop a prospective method to map factors at different hierarchical levels of the health care system that may contribute to the occurrence of accidents in work areas.

Although Rasmussen's socio-technical system model provides a good framework for understanding accident causation in multiple hierarchical levels, its causal sequence approach is more adequate for retrospective analyses, where specific adverse event sequences can be reconstructed. Prospective analyses, even if based on potential undesirable events, would benefit more from the analysis of workspace conditions than from trying to predict complex chains of events because analysts would not need to predict multiple specific scenarios.

The selected approach for achieving the primary objective was to first develop an accident causation model based on a combination of complementary concepts dispersed among multiple sources.

The concepts that seemed necessary for understanding the accident causation process from the workspace level to the top of the health care socio-technical system were extracted and condensed mainly from the systems and tools presented in the previous chapter – which represent general themes in the risk management literature.

Each of the first six sections of this chapter describes one element of the integrated model and briefly discusses the concepts upon which it is based. The last section describes the relations between the various elements from a socio-technical perspective.

3.1 IMMEDIATE HEALTH CARE SYSTEM

The first building block in this model is the *Immediate Health Care System*, which is based upon the premise that the workspace can be modeled as a subsystem formed by specific groups of elements.

The Immediate Health Care System corresponds to the environments where the processes associated with health care delivery are executed. Because many of those processes are not directly related to actual patient care activities, but are indispensable to their execution (e.g., maintenance, device reprocessing, quality control), the Immediate Health Care System includes the multiple workspaces where staff (e.g., physicians, nurses, biomedical equipment technicians) interacts directly with devices, protocols, patients and other elements to perform their (non-managerial) activities. It is equivalent to the combination of the two lowest levels in Rasmussen's (1997) socio-technical system model: "Staff" and "Hazardous Process".

This element of the model requires special attention because it represents the places where professionals interact with hazardous processes and thus where adverse events will occur – even though they are generally originated from chains of failures at higher levels of the system (van Beuzekom et al., 2010).

Rasmussen (2000) alerts that representations of task performance in terms of action sequences and errors are unreliable for the dynamic work context of health care. Instead, he suggests that work systems should be modeled in terms of the mechanisms that generate behavior.

In order to move towards Rasmussen's recommendation and avoid a personal approach to the risk analysis, it seems beneficial to shift the focus from the actions performed by health care personnel to the conditions of the diverse elements present in the workspace. Analytical tools such as Ishikawa's causal diagram with its 6M+E (man, machine, material, method, management, measurement and environment), used in industry (Gwiazda, 2006), DEPOSE (design, equipment, procedure, operators, supplies, and environment), used in health care (Anderson & Webster, 2001), and SHELL (software, hardware, environment, liveware, liveware), used in aviation (Sian et al., 1996), have shifted the focus from people to conditions by arranging the multiple elements of the systems under analysis in specific categories that encompass all the possible elements in their respective domains.

Similarly, Shepherd's System™ (Shepherd, 1998) represents a specific domain (a *"device-related system"*) as a combination of specific categories of elements, the *components*, but all of Shepherd's categories are directly associated with the structure of the domain (device, facility, patient, operator, and environment). Its structural classification of the workspace elements seems advantageous in a socio-technical system such as health care, where many systems of different nature interact (e.g., equipment manufacturers, energy and water companies, the pharmaceutical industry, medical associations, etc.), because it makes the primary level of the model more tangible – and, thus, simpler. Because of that, a slightly modified

version of Shepherd's *components*, with the addition of "Supply" will be the base for the Immediate Health Care System.

Before describing the components, it is necessary to clearly express what was implicit in Shepherd's method: that the components represent the physical elements and the whole subsystems associated with their operational activities, including (but not limited to) protocols, training and maintenance mechanisms, and design considerations that might be more or less relevant to the processes in which they are involved. Because of that, some analyses might require the inclusion of elements related both to operations and to design, i.e., both in health care facilities and in manufacturing plants, which agrees with Leveson's (2004) socio-technical control structure, where operation control and design control interact at the workspace level of the system.

There are six components in the Immediate Health Care System – five of them direct adaptations from Shepherd's System's components:

Device: like the original, it represents the biomedical equipment, instruments, and accessories used in health care procedures and also the personnel and infrastructure related to the maintenance of those elements (but not the devices' operators).

Facility: represents the health care facility's infrastructure systems (e.g.: water, medical piped gases, heating, ventilation, and air conditioning, etc.) and also includes personnel and resources related to their maintenance that are not directly involved with health care procedures. Information technology systems were also included in this component, but IT-intensive analyses might benefit from allocating these systems to an exclusive seventh component.

Patient: represents the patients and their accompanying persons. It might also refer to patient data relevant to the procedure (e.g., the patient's medical record).

Team: refers to personnel directly involved in health care procedures (e.g.: scrub nurses, physicians, technicians).

Supply: this component, inexistent in Shepherd's tool but present in DEPOSE, represents the supplies consumed in health care processes and the infrastructure and personnel involved in their management, including personnel not directly involved in the health care procedures (e.g.: pharmacy personnel).

Environment: refers to the environment surrounding the workspace, which might influence the other components (e.g.: electromagnetic interference, external noise, weather, etc.). Part of the environmental factors is controlled by utility systems and might, thus, be more related to the *Facility* component (e.g., facility's temperature and humidity).

Fig. 6 shows the Immediate Healthcare System as a combination of the six components described above.

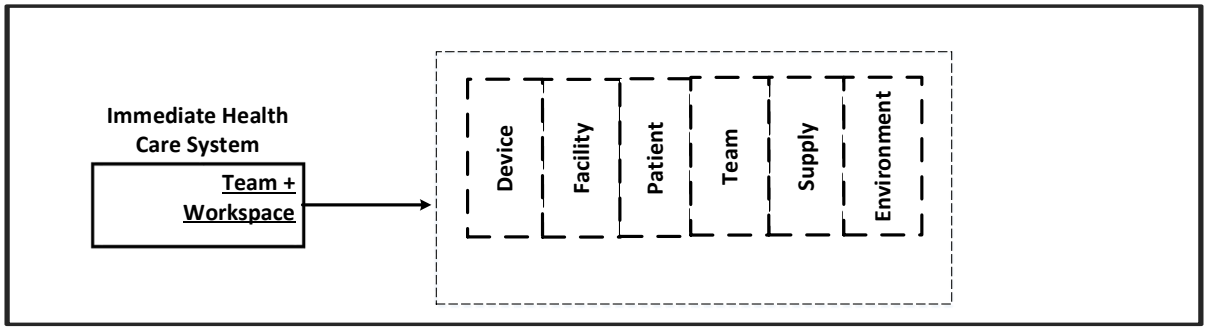

Fig. 6: The Immediate Healthcare System

3.2 ACCIDENT PREVENTION BARRIERS

As indicated by Reason in his accident causation model (described in section 2.2), an incident may only occur after all the protective barriers present in the system have failed (Reason, 1990), or, as later formulated by Rasmussen (1997), after system behavior crosses the "boundary of functionally acceptable performance".

The concept of safety barriers, as explained by Saleh and coauthors (2010), "is an embodiment of the 'defense' part of defense-in-depth safety principle, in the sense that defenses are realized through barriers." Such barriers have been defined as the combination of engineered defenses, personal performance and safety protocols in a system (Reason, 2000). The concept has been integrated into tools that analyze safety in processes by evaluating the multiple barriers present in their different stages (Svenson, 2001; Duijm, 2009). Although such tools might be helpful to the analysis of some health care processes – such as drug delivery – they are based on a flow of energy model, such as the one used for nuclear installations (DOE, 2012) and are not adequate for the major part of the domain, where engineered defenses are not available and safety depends mostly on the performance of personnel (Reason, 2004).

An alternative to the defense-in-depth approach to barriers is presented by Carthey and coauthors (2001), who also considered the concept of barriers, but described them as a combination of structural levels and operational phases in a system influenced by latent and active failures. The authors also drew attention to the fact that near misses are generally asso-

ciated with some form of recovery from error, which, like error itself, is associated with certain characteristics of the various elements in the workspace.

Considering that a socio-technical approach shifts the focus of analysis from inadequate performance – i.e., error – to performance-shaping conditions (Rasmussen, 1997); that risk in health care processes is influenced by heterogeneous factors, as discussed in section 2.1.2; and that the model now presented adopts a structural representation of the components in the Immediate Health Care System; the concept of barrier in the model should, then, be associated with the conditions that affect the performance of each group of elements in the workspace.

Assuming such performance-shaping factors are associated with certain attributes of each element in the workspace, then each barrier in this model can be defined as the combination of characteristics of the elements in each component that allow them to properly perform their functions in the workspace, as presented in Fig. 7.

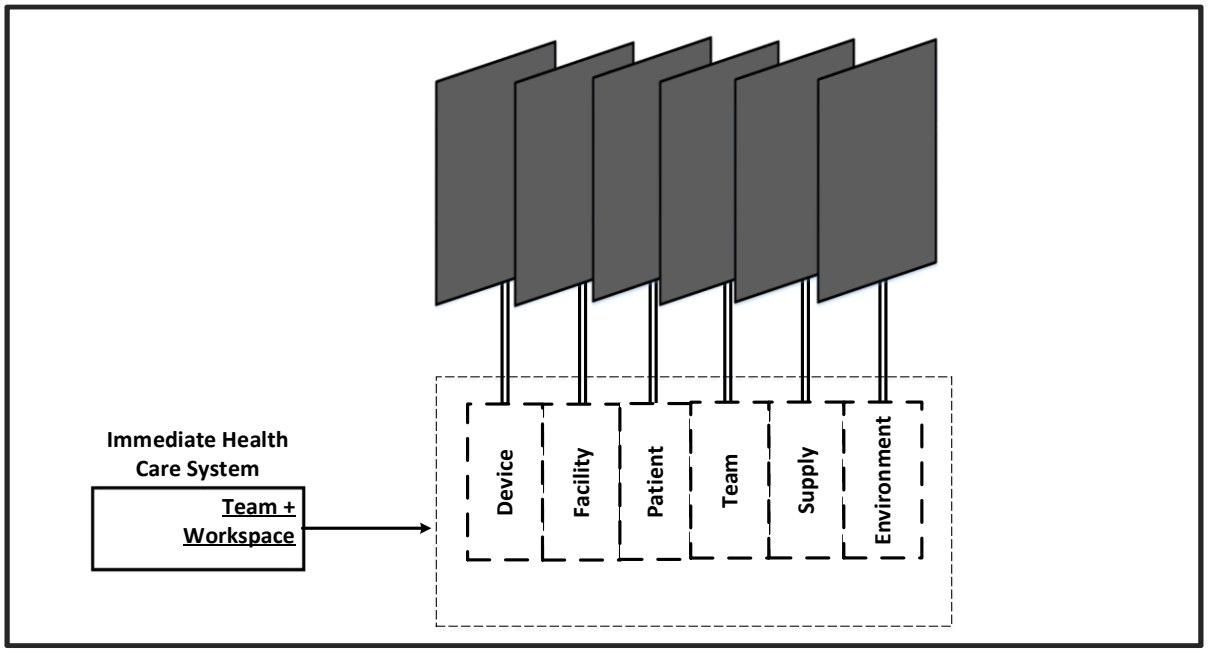

Fig. 7: The Accident Prevention Barriers

Some of these characteristics are associated with engineered defense mechanisms, which Duijm (2009) describes as “physical and/or non-physical means planned to prevent, control, or mitigate undesired events or accidents”, but others are associated with specific conditions of the elements in each component (e.g., conservation state of medical devices, physical and psychological conditions of personnel, compatibility between systems, etc.).

Defining the collective set of characteristics of multiple elements in the workspace as the accident prevention barriers in the system necessarily leads to the next part of the model.

3.3 IMMEDIATE RISK FACTORS

In an ideal workspace, every element would always perform its functions adequately and accidents would never occur, but actual workspace elements are imperfect and, thus, might occasionally be involved in adverse events or other incidents.

Assuming the safety breaches that provide the conditions for an adverse event are caused by inadequate performance of certain elements within the workspace (i.e., in the Immediate Health Care System) and that such performance is due to certain characteristics of those elements, then such characteristics can be considered as direct factors for the occurrence of an incident. They are thus called *Immediate Risk Factors* in this accident causation model.

Part of those factors is represented by faulty mechanisms, inadequate professional training, and other deviations from expected system conditions. Other part includes characteristics that work adequately under normal conditions but might, under uncommon circumstances, introduce hazards in the system. The existence of multiple infusion pump models from multiple manufacturers in a hospital, for example, is completely normal, but it might become a potential source of harm to patients if incompatible intravenous lines are mistakenly stored in the same site of certain device models.

Although not all *Immediate Risk Factors* are associated with actual management or design errors, they work similarly to what Reason (1990) calls *latent errors* (or *latent conditions*), since they remain dormant in the system until they combine with other factors and provoke incidents.

Considering the same Swiss cheese analogy used for Reason's model (depicted in Fig. 1), the *Immediate Risk Factors* represent the holes in the cheese slices (i.e., in the *Accident Prevention Barriers*), as presented in Fig. 8. Similarly to the original model, the holes are not assumed to be static: their shape and numbers may change due to system changes as time passes.

The mechanisms behind the changes in the configuration of barrier holes involve higher socio-technical levels and, since this is a bottom-up explanation of the model, they will be explained later. It suffices to note now that changes in the intrinsic characteristics of the

workspace elements do not generally occur suddenly, so other mechanisms are necessary for better explaining how the alignment of holes in the existing barriers is triggered, providing the trajectory for an accident.

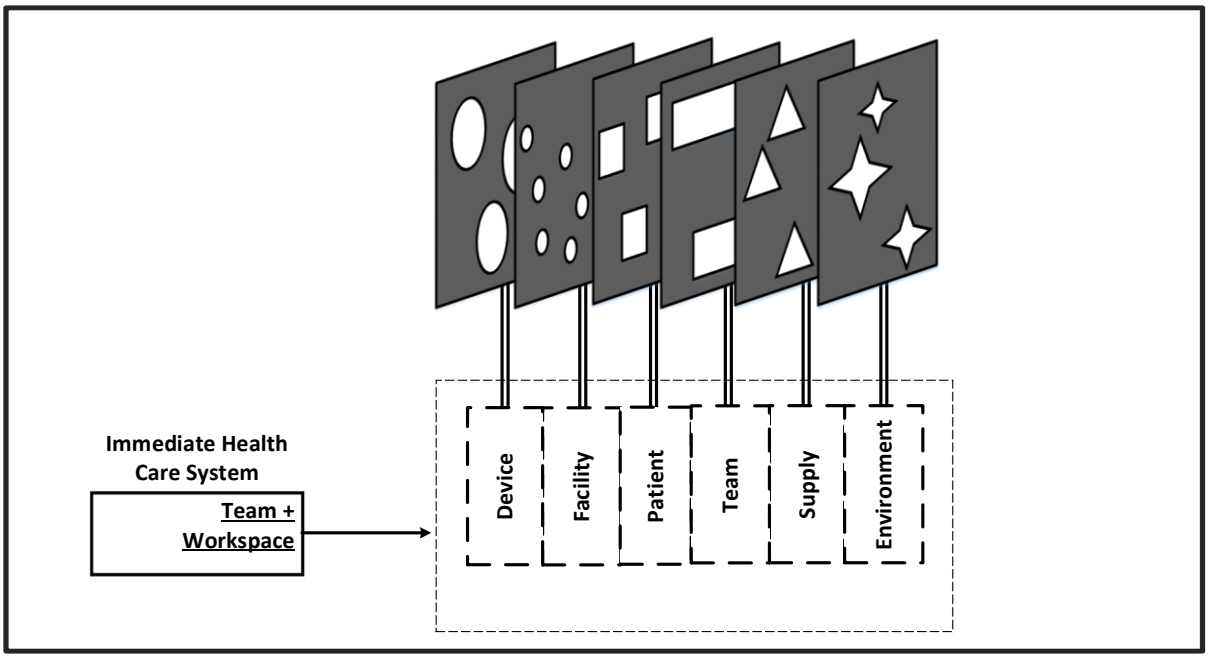

Fig. 8: The Immediate Risk Factors

3.4 TRIGGERS

The idea that seems to better connect the concept of Immediate Risk Factors to accident causation is that incidents are triggered by *adverse interactions* among workspace elements.

The concept of "interaction" is not new in the safety literature, and it has been used as the base for Svenson's Accident Evolution and Barrier Function (AEB) method (Svenson, 2001), which "models the evolution towards an adverse event as a series of interactions between human and technical systems". Leveson (2004) also uses the concept, indicating "system accidents can be explained in terms of inadequate control over component interactions" and Karsh and coauthors (2006) affirm "it is typically the interaction between inputs that can influence patient safety", not single factors by themselves. Although the term "interaction" is not used in Shepherd's System™, the concept is present in its "subcomponents", as noted in section 2.4.2.

Based on those uses of the “interaction” concept, this model adopts the premise that certain attributes of each element involved in a process might influence the way it interacts with other elements, and thus make their interactions more likely to produce one or more of the fundamental conditions for an adverse event. Long working hours, for example, might only slightly affect a nurse’s ability to operate the simplest medical devices, but might greatly improve the risk of misuse of complex or unfamiliar ones.

It should be noted that the expression “fundamental conditions” is used by Shepherd (1998) to indicate the conditions required for an injury to occur. Since the objective of this model is not to explain “injury causation”, but rather “accident causation”, *fundamental conditions* indicate here the necessary conditions for a specific critical event to occur.

Similarly to Reason’s (1990) “unsafe acts” (defined as errors or violations committed in the presence of potential hazards), interactions that produce fundamental conditions for an accident are not intrinsically hazardous. They only become potential triggers for an adverse event when the remaining fundamental conditions for certain injury/damage are already present in the system.

Because not all events that may provide *fundamental conditions* for a critical incident are intrinsically adverse and because not all of them are actual interactions between multiple elements in the workspace, but rather results of single-element processes (e.g., deterioration of supplies or device parts), the term “adverse interactions” is dismissed in favor of the more comprehensive “*triggers”* in this model.

Continuing the Swiss cheese analogy, *triggers* might be represented in the model as relative movements between barriers. The events that provide fundamental conditions for critical incidents would then be depicted as barrier movements towards the alignment of holes, as depicted in Fig. 9.

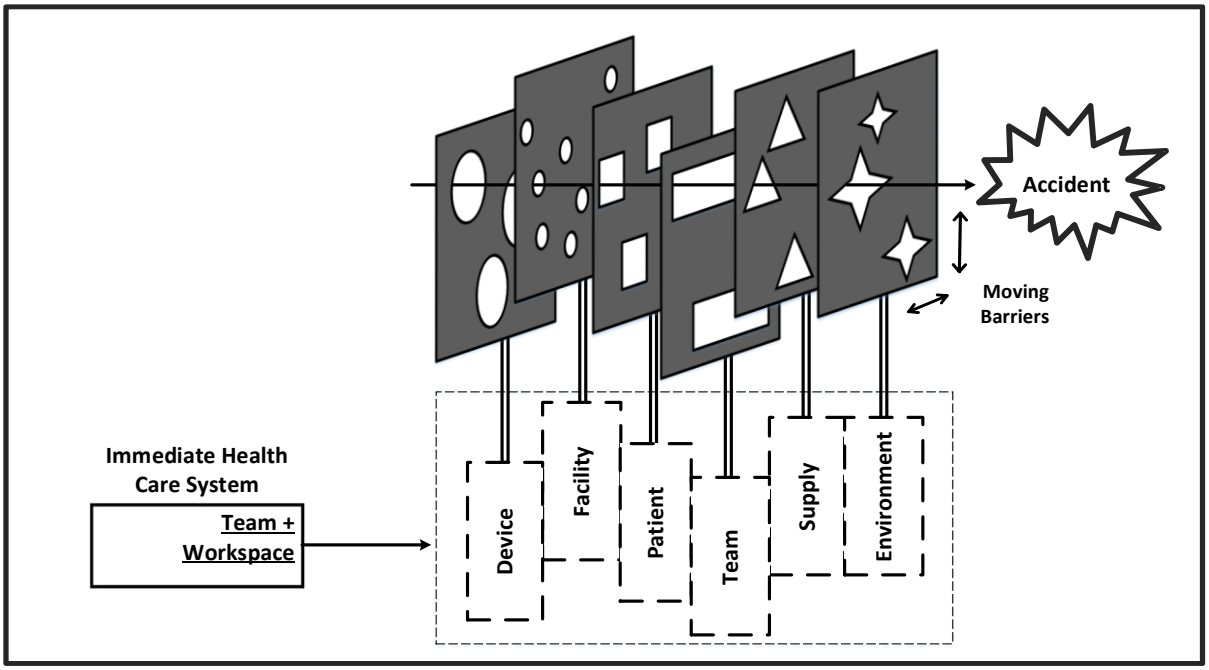

Fig. 9: Triggers promote a trajectory for an accident

3.5 REMOTE HEALTH CARE SYSTEM

Based on the premise that the attributes and, to a certain extent, the behavior of workspace elements are shaped by external actors in decisory positions, the aggregation of such actors is represented in this model as the *Remote Health Care System*.

Although the dual control structure proposed by Leveson (2004) is not graphically represented in this model, it should be noted decision makers involved with development (e.g., standards, design) and operational control (e.g., policies, protocols) are all part of the *Remote Health Care System*.

Additionally, as explained in section 3.1, multiple subsystems (and their control structures) converge to provide health care. Therefore, when trying to explain accident causation, it might be necessary to include some actors from outside of health care, such as energy companies and water distribution regulators, as part of the remote health care systems associated with certain health care processes.

Considering Rasmussen's socio-technical system framework, the *Remote Health Care System* corresponds to the combination of the four levels above the *Staff* level: *Management, Company, Authorities (Regulators and Associations), and Government*, as described in section 2.3.

3.6 REMOTE RISK FACTORS

The *Immediate Risk Factors* were defined in section 3.3 as the characteristics of the workspace elements that might directly influence the occurrence of an incident. In that section, it was also noted that those factors might change over time, though not as quickly for those changes to be directly associated with accidents. Considering the *Remote Health Care System* plays a central role in shaping the attributes and behavior of the workspace elements, it is clear that inadequate decisions or omissions (orders, protocols, standards, laws and other acts) made in the upper levels of the socio-technical hierarchy remotely produce the conditions for reducing the general safety level in the workspaces. Those decisory mishaps are called *Remote Risk Factors* in this model.

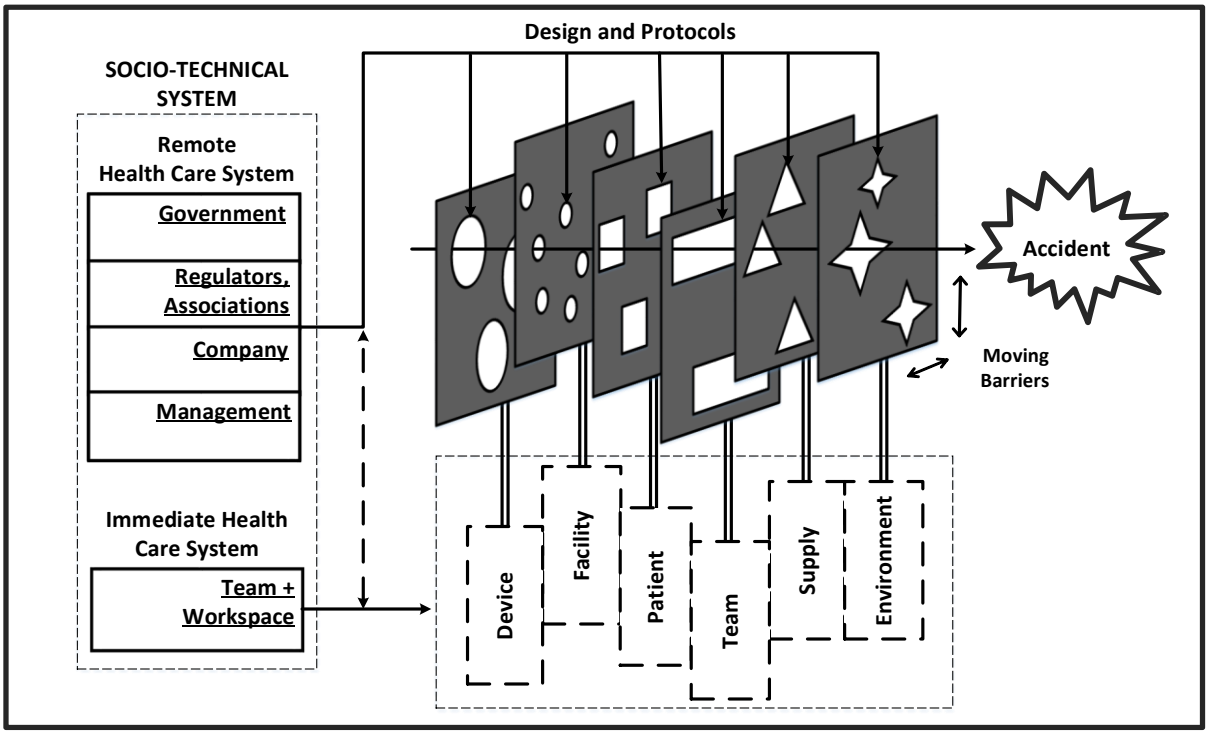

Fig. 10: The Remote Health Care System shapes the holes in the system barriers

Some of the reasons that may help explaining how decisions made at the upper levels may cause undesirable consequences at the workspace level are: the difference of time frames between the socio-technical levels (e.g.: technologies change much faster than management structures); the difficulty to predict all the relevant consequences of some decisions, due to the high degree of integration and coupling between systems; the focus of organiza-

tions in short-term criteria, due to a highly competitive environment; and the application of management theories independent of the health care setting (Rasmussen, 1997).

Examples of remote risk factors include requirements for operating room staffing (Smith et al., 2010); weak protocol enforcement (van Beuzekom et al., 2010); and product variability/lack of standardization (Chandonnet et al., 2013).

3.7 DYNAMICS OF THE ACCIDENT CAUSATION MODEL

The complete model, depicted in Fig. 10, combines all the concepts presented in the previous sections. It is composed of three main blocks: the barriers, in the center; the socio-technical system, to the left (formed by the Remote Health Care System and the Immediate Health Care System); and the six components in the Immediate Health Care System, in the bottom.

Each of the six barriers is directly connected to one workspace component and the dynamic behavior of the elements in the components is the main influence on the interactions between barriers. The holes in the barriers, representing the combinations of inadequate characteristics of all the elements in each component, are connected to the Remote Health Care System, responsible for designing systems and protocols.

Interactions make barriers move in parallel planes and might sometimes, make some of their holes align, i.e., might cause inadequate characteristics of two or more elements (e.g., noisy environment and inaudible alarms) to combine. These combinations do not generally cause accidents, because it requires all barriers involved in the process to have holes aligned. Partial alignments might, though, represent *near misses*.

Under certain circumstances, holes in all barriers might align (e.g., by adding a critical condition to the patient and a workload-related distraction to a nurse working in a noisy environment with inaudible device alarms) and provide all the fundamental conditions for an accident.

The model diagram itself cannot be used to describe a specific critical incident scenario, but the dynamics of accident causation presented in it provide guidelines to build a map of socio-technical risk factors and their influence on potential critical incidents. A method for building such a map is described in the next chapter.

4 RISK FACTORS MAP

This chapter describes a prospective method to build the *Risk Factors Map*: the map of risk factors in the multiple levels of the socio-technical health care system associated with a hypothetical critical incident.

Because one of the objectives of the method is to map factors in different hierarchical levels of the health care system, the framework for the *Risk Factors Map* was mainly based on Rasmussen and Svedung's *AcciMap* (2000; 2002). The graphical representation of the map, though, approaches the *Standard AcciMap* format proposed by Branford and coworkers (2009), which simplifies the hierarchical levels represented in the map (by merging the "Management" and "Company" levels into "Organizational", and "Regulators and Associations" and "Government" into "External") and places all the causes above the critical incident level (Fig. 11).

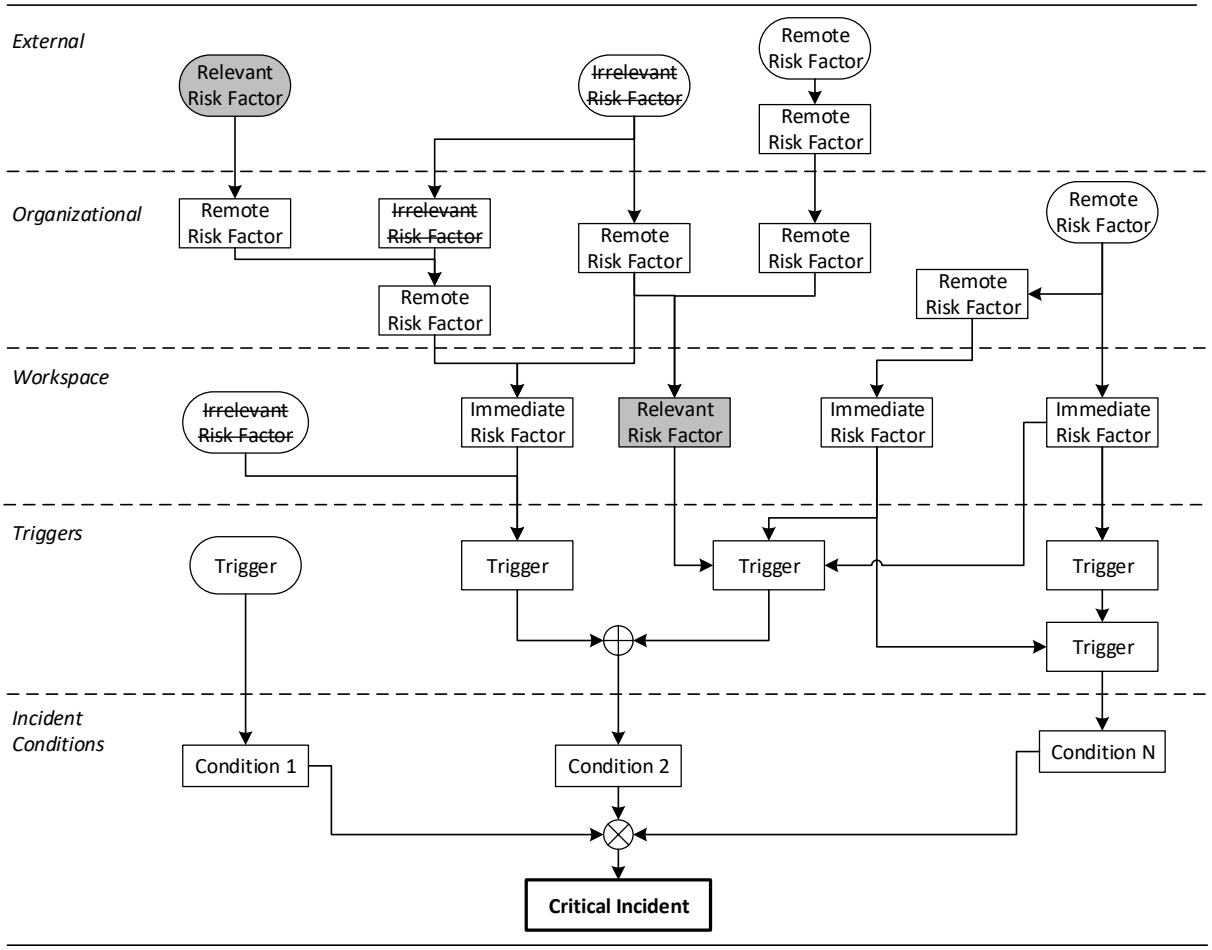

Fig. 11: Basic elements of the Risk Factors Map. Rounded edges indicate elements not further evaluated (adapted from Branford, Naikar & Hopkins, 2009)

The major departure from the AcciMap framework is the prospective nature of the method presented here. Although the paper from Svedung and Rasmussen (2002) claims that version of AcciMap to be both retrospective and prospective, it does not provide instructions for designing a map and although the Standard AcciMap paper, by Branford and coauthors (2009), provides the instructions, it was specifically designed for retrospective analyses.

Differences in nature also bring conceptual differences: AcciMap is based upon the identification of specific chains of actions and decisions at the different system levels leading to the investigated critical incident; the *Risk Factors Map* is based upon the identification of chains of risk factors (system flaws) at different system levels that may contribute to the emergence of the necessary fundamental conditions for a hypothetical critical incident.

Despite the conceptual differences, the *Risk Factors Map* may be considered an AcciMap-inspired tool for prospectively mapping socio-technical risk factors that is based upon the accident causation model described in the previous chapter.

The following sections describe the eight steps for mapping risk factors in the health care system: selection of a hypothetical critical incident and assemblage of a team; gathering of the initial data; identification of fundamental conditions and scope definition; description of processes and workspace; identification of triggers; identification of immediate risk factors; identification of remote risk factors; and map factors classification. Fig. 12 presents a flowchart for the method.

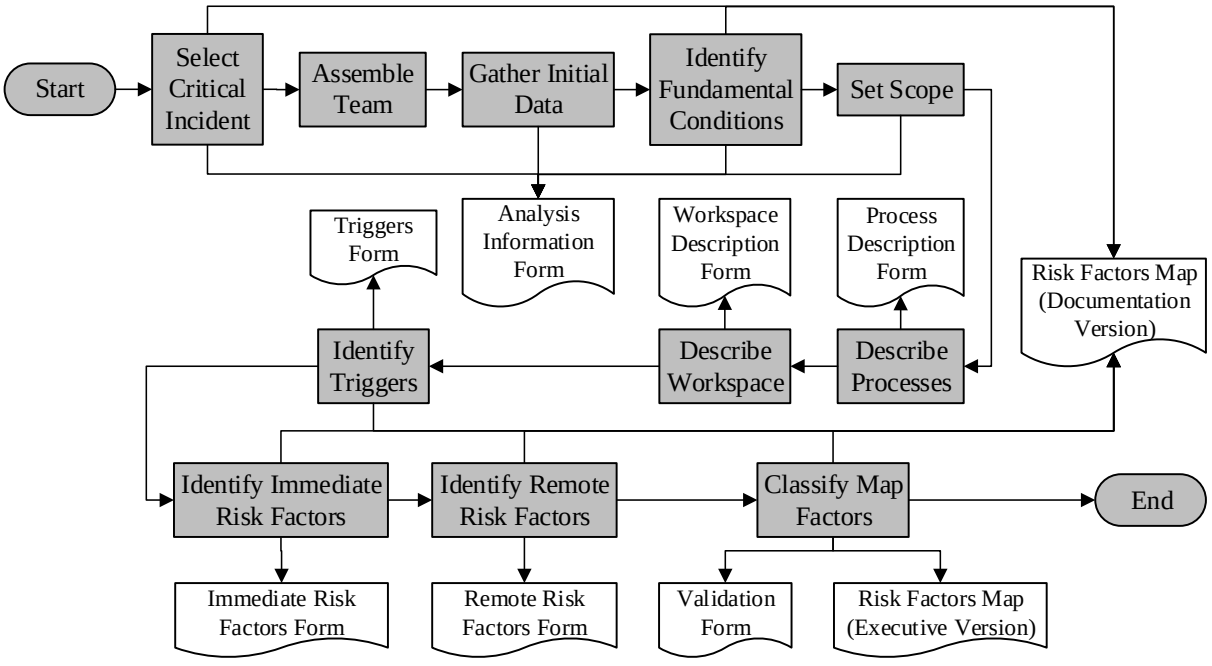

Fig. 12: Flowchart for the risk factors mapping process. Tasks are in gray and outputs are in white.

As indicated in the flowchart, the risk factors mapping process has various forms as products of its various steps. They were developed as a means to properly register the data collected and generated during the production of the *Risk Factors Map*. Although analysts are free to develop their own forms, they should at least take a look at those referenced throughout this chapter and presented as appendices, because they were specifically developed for this method.

4.1 SELECT THE CRITICAL INCIDENT AND ASSEMBLE TEAM

The first step, as in the traditional AcciMap, is to select the *critical incident* for which risk factors will be mapped.

The selection of an undesirable system state as the starting point for risk assessment is not new and it has been an important characteristic of other prospective tools, such as *Quantitative Risk Assessment* (QRA) (Apostolakis, 2004) and *Probabilistic Risk Assessment* (PRA) (Reason, 1990).

The *critical incident* to be analyzed should be selected according to specific needs of the health care provider: it might be based, for example, on a past accident that occurred within the organization, on a hypothetical event based on a high profile accident that occurred in another institution, or on a realistic adverse consequence that could derive from the use of certain technology newly acquired by the organization.

Based on considerations for selecting a topic for an HFMEA™ (DeRosier et al., 2002), it is recommended that analysts focus their efforts on critical incidents associated with high-risk devices or processes (such as those featured by ECRI's *Top 10 Health Technology Hazards* publications), or incidents that might affect the performance of critical areas of the organization (e.g.: pharmacy, sterilization plant), because risk analyses might require the employment of a considerable amount of resources.

The *critical incident* should be stated as a simple sentence, indicating at least the nature of the undesirable event and some of the main elements potentially involved in it (e.g., type of technology, sector, type of injury or failure, etc.). Not much detail is required at this time, as long as the definition provides useful keywords for the next step – data gathering. Although the first incident definition is formulated at this time, it might be modified later, in response to scope definition and changes throughout the analysis.

A short sentence representing the *critical incident* must be placed at the bottom of the *Risk Factors Map*, at the *Incident Conditions* level, as indicated in Fig. 11.

It is highly recommendable to have a multidisciplinary team assembled at this stage to provide expertise on the various topics related to the critical incident and share the analysis' workload.

It will be easier to assemble a risk analysis team and select a critical incident in organizations with permanent risk management commissions, since they presumably have continuing methods for assessing risk within the organization, but they might need to invite new members – from outside the commission – for specific analyses.

Analyses in organizations without permanent commissions will most probably be requested by high-level managers with a specific critical incident in mind. In such cases, the manager would need to find a 'champion' to assemble and lead the analysis team.

Regardless of the preexistence of a risk management structure in the organization, certain recommendations aimed at risk management practices in industrial (Main, 2004) and health care settings (DeRosier et al., 2002) should be considered when assembling the team: the analysis team leader should be able to manage a team and should also be familiar with the method to map risk factors; it is recommendable to have at least one expert on the main topic – or topics – related to the critical incident; it might also be useful to have people with no direct involvement in the main topics, since they can provide unbiased input on the standards and practices related to the processes potentially associated with the critical incident; and personnel from the management level would also be valuable to the analysis, since they have better knowledge about the factors at higher levels in the system.

The short sentence for the critical incident, a brief description, and the names and positions of the analysis team members should be registered in the *Analysis Information Form* (Appendix A) or an equivalent document with basic information about the analysis.

4.2 GATHER INITIAL DATA

The second step is to gather data related to the selected critical incident, to the processes potentially associated with it, and to the devices, materials, and environments involved in those processes.

This step is placed right after the selection of the critical incident and the formation of the analysis team to represent the initial research about the selected topic, but additional data might be required throughout the whole risk factors mapping process as it evolves.

The analysts must extract keywords from the critical incident definition and use them as reference points for data research.

One source of data is the technical literature about the processes or technologies associated with the critical incident, such as technical papers, manuals for medical devices and utility systems, procedure guidelines and protocols, and standards. This kind of source should provide the base information about the technology (e.g., principles, applications, limitations, etc.).

Other sources of data are reports and alerts related to past accidents, near misses or risk management techniques (e.g., RCA or HFMEA reports). These documents might come from within the institution, if there is already an incident reporting system in place, from non-governmental organizations that emit safety alerts, such as ECRI or accreditation organizations, or from governmental organizations, such as regulatory agencies.

Finally, other fundamental sources of data are the professionals involved with the processes or technologies under analysis or involved with risk management. Although the analysis team is ideally multidisciplinary, it might be necessary to consult other experts to gather information on certain specific subjects related to the incident keywords.

A brief list of the main references may be registered at the *Analysis Information Form* in Appendix A, but the analysts should also document a complete reference list separately, especially if there are many references.

4.3 IDENTIFY FUNDAMENTAL CONDITIONS AND SET SCOPE

After selecting a potential critical incident for analysis and gathering relevant data, the following steps are to identify what conditions are necessary for such incident to occur, based only on the nature of the incident, and to limit the scope of analysis.

As described in section 2.4.2, *Shepherd's System for Medical Device Incident Investigation and Reporting* (Shepherd, 1998) presents an approach to identifying fundamental conditions that is based on a table – excerpted at

Table 1. Although a table is not adequate for a more comprehensive method such as this, the idea of focusing on fundamental conditions instead of sequences of events is useful for a prospective method.

The fundamental conditions must be extracted from the critical incident description, based on the data gathered in the previous step. The conditions should be independent of each other and all of them must be necessary – either by themselves or in combination with others – for the occurrence of the selected critical incident. Unlike Shepherd's table, this approach is subjective and depends only on the analysts' judgment.

At this point, only the concepts related to the specific type of critical incident should be considered, so the analysts must ignore specific conditions of the organization where the analysis takes place and of other organizations that might be indirectly related to the analysis.

Depending on how specific the definition of the critical incident is done, certain conditions might be presented in different ways. Burn injuries, for example, might be caused by distinct mechanisms, such as fire, electricity, chemicals, radiant sources, and heated surfaces.

In such cases, analysts should refine the critical incident definition before proceeding or create a separate map for each set of conditions in order to keep the map as clear as possible. They might, alternatively, use logical operators to indicate alternative sets of conditions in the same map.

Like the critical incident itself, the fundamental conditions must be placed at the *Incident Conditions* level (Fig. 11) and each condition will generate a distinct branch of risk factors in the higher levels of the *Risk Factors Map*.

After identifying the fundamental conditions, the analysts should define the scope of analysis. Considering the present accident causation model, the scope of analysis in this method might be aimed at specific components (e.g.: only Device or Environment-related triggers) or even specific elements of a certain component (e.g.: only maintenance-related Device triggers and risk factors). The scope might also be restricted by other criteria, such as work shift, location, clinical specialty, potential victims of the critical incident, or connection to a specific fundamental condition.

Organizational limitations, such as unavailability of experts in very specialized topics should also be taken into account when setting scope.

Restrictions exclusively based on hierarchical levels should be avoided if analysts wish to use the method's capability to address all levels of the socio-technical system.

Besides directing the analysis to topics of interest to the organization, adjusting the scope is only the first effort to keep the size of the potential critical incident analysis under control. As the analysis progresses, further adjustments might be necessary to include new data or to address unexpected developments that might affect the analysts' ability to complete the analysis in a timely manner. Reductions in the scope should be discussed among the analysis team members and should not be made unless certain branches of information are not considered essential or the effort to map them adequately is beyond the team's capacity – in which case the team must decide whether to cut the branch or reduce the depth of analysis by simplifying it.

Fundamental conditions and scope description complete the initial information for the analysis and the *Analysis Information Form* (Appendix A) includes space for them.

4.4 DESCRIBE PROCESSES AND WORKSPACE

The objective of this step is to describe how the processes potentially associated with a critical incident normally occur in the organization and to identify the workspace elements associated with them.

The concept of interactions (or triggers) presented in the previous chapter (section 3.4) requires thorough descriptions of the processes associated with the *Fundamental Conditions* in order to define which workspace elements are present and how they interact within the system.

Some processes might be extremely complex, so analysts should focus on identifying subprocesses that are likely to provide the fundamental conditions for the incidents. It is important to note that some conditions might be provided by multiple processes, possibly separated in time and space (e.g., certain device problems might be due to inadequate acquisition, maintenance, or operation), and all these processes should be considered during analysis if they are deemed relevant.

The first step should be to study references about the general structure of the processes, such as written protocols, instruction manuals, and guidelines. This should make analysts more familiar with specific procedures outside their areas of expertise.

Because users often deviate from protocols in order to work in a more efficient way, sometimes to the detriment of safety, as noted by Rasmussen (1997), processes' descriptions must not be exclusively based on written protocols. For the purpose of analyzing the

processes as close as possible to how they are actually carried out within the institution, it might be beneficial to employ techniques such as direct observations, interviews, and questionnaires.

Processes' descriptions should be as detailed as necessary to identify the subprocesses and elements potentially associated with fundamental conditions (personnel, devices, facilities, etc.). It is recommended to describe processes and subprocesses with a combination of text and diagrams because while text can be used to record even the smallest details, diagrams can quickly present the relations between multiple activities and elements. Task analysis techniques (e.g., charting and network techniques, decomposition methods, hierarchical task analysis) might be helpful to develop graphical descriptions of the processes, but analysts should use the techniques with which they are most familiar.

The resulting descriptions should be reviewed by process stakeholders to ensure fidelity to the actual processes.

After describing the processes, analysts should register all the subprocesses and elements involved with them. The *Process Description Form* (Appendix B) is a model of how such data might be registered.

A systematic way to verify the thoroughness of the table of elements associated with each process is to check if *components* from each of the six classes in the accident causation model (*Device, Facility, Patient, Team, Supply*, and *Environment*) were identified. Although not all processes involve elements from all six components, this simple verification will help to identify elements from missing classes. The complete set of elements associated with the processes is the *Immediate Health Care System*, described in section 3.1.

Depending on the volume and complexity of subprocesses and elements identified in this step, it may become clear that the following steps in the analysis cannot be executed in a timely manner with the available resources. If that is the case, it might be necessary to reduce the scope of analysis to a more feasible level.

According to our accident causation model, triggers are associated with certain characteristics of the workspace elements. Analysts should, thus, take advantage of the process data collection to also get descriptions of the workspace elements associated with each process.

Analysts must thoroughly describe each element associated with each relevant sub-process. The term 'element' must be understood here as the collection of persons, materials or other resources that play a specific role in a trigger. Consider, for example, an infusion pump element: its description should include characteristics of the different models which

may be used in the specific sub-process (e.g., age, maintenance schedule, known issues) and characteristics of the whole collection of pumps (e.g., number of different models and/or manufacturers present in the institution, training profile of operators). Reports from previous device usability tests conducted within the organization or elsewhere and from analyses of environmental conditions might be helpful for these descriptions.

Depending on the motivation of the organization for mapping risk factors, it might be necessary to conduct some of those analyses before completing this step, especially if the focus of the study is on factors associated with environmental characteristics of the workspace or with specific devices.

It must be noted that descriptions of the elements should be based on their actual conditions within the organization, not on ideal representations of the system or solely on tests performed under ideal conditions.

Although there might be a greater focus on identifying problems or limitations of each type of element (e.g.: “some infusion pumps are almost 10 years old” or “less than 20 percent of users have received training in the operation of the new pumps”), characteristics that might be considered positive should not be ignored (e.g.: “at least 20% of the infusion pumps have integrated drug libraries” or “all operating room personnel have received training in surgical crew resource management”), because they are the *accident prevention barriers* in the system (as described in section 3.2). In this step, analysts should try to fill descriptions with as many characteristics that might (positively or negatively) affect the performance of the elements as possible.

The *Workspace Description Form* (Appendix C) is a simple example of how elements’ descriptions might be arranged.

4.5 IDENTIFY TRIGGERS

The objective of this step is to identify possible events within the subprocesses that might provide the fundamental conditions for the critical incident – called *triggers* in section 3.4.

As stated in the previous chapter, our accident causation model is based on the presumption that accidents occur when elements in the system fail to perform as expected. Since this method shifts the focus from the critical incident to its multiple fundamental condi-

tions, the logical approach is to identify which mechanisms (*triggers*) might cause those conditions to emerge from the processes.

Because triggers are related to specific processes in the organization, analysts must consider each subprocess as a potential source for a fundamental condition. For each subprocess, they must first consider combinations of the workspace elements in pairs and verify if they might credibly interact in some way to produce or drive the system closer to producing one or more of the fundamental conditions. Then, analysts must assess elements individually to check if they might provide any condition by themselves (e.g., due to natural processes such as deterioration).

Both intended and unintended potential triggers should be considered during analysis because some fundamental conditions might be ordinarily produced by regular tasks. The presence of the remaining fundamental conditions for a critical incident, though, generally requires the concurrence of unintended events. As an example, we may consider that electrosurgical procedures ordinarily provide one condition for burning patients, i.e., a flow of electric current through the body, but measures are generally taken to prevent the current density to reach harmful levels and to limit its duration. Harm may ensue, though, if a certain trigger, such as the unintended contact between the patient's body and a conductive surface, provides a path for high-density electric currents.

Table 2 provides a simple taxonomy – mainly based on Reason's (1990) "unsafe acts", but expanded with general classes of triggers – that might help analysts envision ways the workspace elements might produce the fundamental conditions.

It is important to note that certain fundamental conditions might be provided by multiple triggers at different phases of a health care process. For example, one of the fundamental conditions for a pump-infused drug overdose might be a high infusion rate: aside from pump malfunctions, it might be produced, among other triggers, by failure to program the pump, incorrect dilution or incorrect labeling of the drug by a pharmacist, or incorrect concentration delivered by the manufacturer.

Besides active failures of professionals and other components, passive failures, such as those associated with faulty protective measures (barriers), should also be included in the list of triggers associated with certain fundamental conditions.

Task analysis techniques such as barrier and work safety analysis and fault trees might also help in the identification of triggers.

The *Triggers Form* (Appendix D) provides a simple layout to register the relations between triggers, subprocesses, and fundamental conditions.

The triggers on the list and their associations must be placed at the *Triggers* level of the *Risk Factors Map*. It might be necessary to use logical operators (AND/OR) to adequately describe the relations between potential triggers and fundamental conditions, because, as in PRA (Reason, 1990; Apostolakis, 2004), the method deals with multiple possibilities, not with linear chains of events.

Table 2: Classes of Triggers

Class	**Description**	**Examples**
	HUMAN-ONLY TRIGGERS	
Slips	Unintended deviation of action from intention. Potentially observable. Includes wrong force/movement.	Pharmacist intends to select drug A from the shelf but picks up drug B.
Lapses	Unintended deviation of action from intention generally associated with failures of memory. Not observable. Includes monitoring failures.	Operator forgets one step in the programming of a ventilator.
Mistakes	Selection of an inadequate plan for the desired goal.	The physician selects inadequate drug for the patient's condition.
Violations	Deliberate deviation from practices deemed necessary for safe care. Includes misuse/abuse due to exacerbating conditions.	Nurse bypasses the drug library when programming a smart pump.
	GENERAL TRIGGERS	
Regular	The ordinary behavior of elements in a regular task.	An electrosurgical unit provides an electric current flow through a patient's body.
Component Failure	Device, infrastructure system, accessory or supply fail to function as expected.	A cardiac defibrillator does not charge.
Incompatibility	Elements expected to work in combination cannot be properly combined. Interference between elements. Includes allergic reactions.	Available IV lines cannot be connected to an infusion pump. Tissue avulsion due to the adhesive on the tape.
Unavailability	Element expected to be used in a specific task is not available in the workspace. Includes delays.	Bone screws not available during orthopedic surgery.

4.6 IDENTIFY IMMEDIATE RISK FACTORS

Based on the descriptions of the workspace elements, the next step is to identify which of their characteristics might affect their performance and make them more likely to set a trigger. Such characteristics are the *Immediate Risk Factors* – as described in the accident causation model (section 3.3).

Triggers are generally set by the combined lingering effects of multiple immediate factors. These factors should be extracted from the workspace descriptions previously registered. If, for instance, the description indicates that "half of the ventilators are more than 10 years old", then "obsolete equipment" might be considered an immediate risk factor associated with triggers involving such ventilators.

A possible method to select the factors involved in each trigger is to try to answer the question: *"Could this characteristic affect the performance of this element in such a way that it would contribute to that trigger?"* (for negative characteristics) – or, conversely, the question *"Could the absence of this characteristic affect the performance of this element in such a way that it would contribute to that trigger?"* (for positive characteristics). This way, only the pertinent characteristics included in the element's description should be identified as *Immediate Risk Factors*.

Because it might be difficult for analysts to decide whether some characteristics are pertinent or not, the prudent approach is to classify all the dubious characteristics as immediate risk factors during this step, because irrelevant factors included in the map at this point may be dismissed later, but relevant factors ignored here will most likely remain ignored.

Given the somewhat subjective nature of selecting element characteristics from descriptions and translating them into risk factors, some practical considerations must be made about this step in the mapping method.

First, some characteristics might seem neutral if individually assessed – "there are multiple infusion pump models being currently used in the institution" –, but they can combine with other workspace characteristics – "operational training for infusion pumps is only given regularly for model A" – and increase the likelihood to set a certain trigger – "misuse of infusion pumps in the institution is more likely to occur due to the lack of device standardization and to deficiencies in the device operation training program".

Second, because multiple elements are generally connected to each trigger, it is important to focus on their characteristics more closely related to the mechanisms behind the triggers. Suppose, for example, a *slip* trigger (e.g., "picking the wrong drug on a shelf"): human error theory indicates that slips are caused by attention failures (Reason, 1990), so the factors related to perception and concentration (e.g., noise and lighting levels, drug label similarities, pharmacist's workload and interruptions from coworkers) will have greater influence on this kind of trigger.

Third, analysts might occasionally identify important flaws in the system that are clearly unrelated to the critical incident currently under analysis (e.g., a certain medical device is subject to interference from one of the elements in the *Risk Factors Map*). Such factors should be reported to the risk management committee of the organization so they can take the necessary measures.

Finally, factors related to areas outside of the health care organization (e.g., energy quality) might be identified as closely related to some triggers. As noted in the previous chapters, multiple socio-technical systems intersect in health care, so this kind of occurrence is expected. Because it is also expected that analysts might not have the expertise to evaluate some factors, it is recommended such factors be not further analyzed (and that the scope is adjusted) or that experts from outside of the analysts' team are consulted for these particular factors.

All of the *Immediate Risk Factors* must be placed at the *Workspace* level of the *Risk Factors Map* and connected to their respective triggers. The *Immediate Risk Factors Form* (Appendix E) may be used to document the relations between triggers and immediate risk factors in a tabulated format.

4.7 IDENTIFY REMOTE RISK FACTORS

After identifying the *Immediate Risk Factors*, the next step is to find out the acts or omissions in decisory levels that caused them to appear and remain at the workspace level of the socio-technical health care system, i.e., the *Remote Risk Factors* (section 3.6).

As indicated by Dien and coauthors (2012), analysts implicitly halt analyses during incident investigations when they reach the causes to which they cannot propose corrective measures. In this method, analyses should consider the whole socio-technical system, because even if analysts are not in a position to recommend changes to certain hierarchical

levels (especially outside of the organization), the knowledge of factors in those levels might help to devise strategies to minimize their negative effects within the organization.

These factors may be identified by looking for actions or decisions in higher hierarchical levels of the system that induced or failed to prevent the emergence of undesirable characteristics in the elements forming the workspace. Based on the dichotomous development/operations socio-technical system control structure proposed by Leveson (2004) (presented in Fig. 5), two simple pairs of questions may be used to identify the remote risk factors associated with the immediate ones:

1. Is such Immediate Risk Factor associated with either the behavior or the operational instructions of workspace elements? If so, how are operational practices and protocols defined?
2. Is such Immediate Risk Factor associated with the design or other intrinsic characteristics of the workspace elements? If so, how are the design and specifications of the workspace elements defined?

The control mechanisms that answer each pair of questions are the remote factors more directly related to the immediate risk factors in the workspace. These factors will not necessarily be located at the managerial level right above the workspace, since some decisions made at regulatory levels, for example, are instructions directly aimed at specific practices or devices.

The *Remote Risk Factors* might be chained to other factors, generally in higher levels of the socio-technical control hierarchy. Since decisory mechanisms are more complex than workspace elements, it is not possible to apply the same design/operations classification to drive the identification of the remote factors chained above them. Instead, analysts should look for rules, laws, standards and other control mechanisms related to each specific remote factor.

Chains of *Remote Risk Factors* climb up the socio-technical hierarchy until it reaches a factor in a level where competent authorities have autonomy to control it, or until it reaches a factor that is not subject to any authority in the hierarchy (e.g., public opinion).

Similarly to the *Immediate Risk Factors*, multiple remote factors might concurrently influence factors in lower levels.

The factors identified in this step and their connections must be placed at the *Organizational* and *External* levels of the *Risk Factors Map*.

The list of remote factors and their relations should also be registered in a tabular form such as the *Remote Risk Factors Form* present in Appendix F.

4.8 CLASSIFY MAP FACTORS

The final step in the mapping process is to classify the triggers and risk factors included in the *Risk Factors Map*, i.e., to recommend some map elements for further analyses and remove unimportant ones.

Even with multiple scope adjustments during analysis, the described method might produce cluttered maps with no indication of which factors should be marked for future corrections. To avoid the unnecessary expenditure of resources, analysts must try to dismiss irrelevant factors that might have made it to the factors map and highlight those deemed more relevant to the critical incident.

Since the nature of some risk factors might be more or less objective than others (e.g., water quality and distractions), the analysis team might require multiple tools to assess the relevance of different risk factors.

We recommend analysts not to worry about ranking risk factors at this point. Instead, they should only sort factors (or triggers) into three groups: *confirmed*, *dismissed*, and *reasonable* factors.

Confirmed factors are those whose influence on the potential critical incident is confirmed by objective data on previous incidents or by expert opinion. *Dismissed* factors are those whose influence is dismissed by objective data or expert opinion – e.g., because there are effective countermeasures for them. Finally, *reasonable* factors are those whose influence cannot be traced to a specific previous incident but neither can be dismissed because they seem plausible enough to be kept on the map.

Analysts should clearly define the criteria for each class, according to the selected tools. For quantitative methods, such as Likert scales, hazard scores, and objective measurements, analysts should indicate thresholds for relevance classes. For more subjective tools, such as interviews with experts, analyses of previous incident reports, and observations, analysts might need to prepare a list of criteria for each class.

After classifying the factors – and, possibly, triggers and conditions – analysts might want to prepare two versions of the *Risk Factor Map*: a *documentation version* and a *highlights version*.

The *documentation version* must include all the elements considered during analysis and might serve as a reference for future analyses. In this version, *confirmed* factors must be indicated by grey textboxes; *dismissed* factors, by strikethrough text; and *reasonable* ones, by regular text boxes.

The *highlights version* of the Risk Factors Map is a simplified diagram aimed at managers and other stakeholders unfamiliar with the method presented here. This version presents no *dismissed* factors and the *confirmed* ones are highlighted by grey textboxes and bigger font. For clarity purposes, analysts might choose to also remove some *reasonable* factors from this version if they seem unlikely to receive attention from its intended public.

The *Classification Form* in Appendix G can be used to register the relevance of risk factors and other workspace elements, as well as the justification for each classification.

A final analysis report should include all the data gathered during analysis, but also provide a simplified description of the topic and its motivations, the analysis limitations and methods, the main findings, and both a *documentation* and a *highlights* version of the *Risk Factors Map*. The simplified data on the final report will be aimed at stakeholders not familiar with the method, thus it should be placed at the beginning.

Appendix H, *Guidelines for Mapping*, presents some guidelines for the mapping process; and Appendix I, *Guidelines for Reporting*, some guidelines for composing a final report.

5 RESULTS

This chapter presents three case studies aimed at testing the method with a variety of objectives and scopes.

In the first case, the critical incident is related to a key part of the medical instruments sterilization process: the cleaning. The core data was obtained from the final report of a risk assessment made with a different risk management tool.

In the second case, the critical incident is related to the medical devices market entry process and the analysis is mainly based on regulations and open reports from the regulatory agency.

In the final case, a generic critical incident associated with infusion pumps was selected and the analysis was based on the literature on infusion pumps.

The diagrams were drawn with the Microsoft Visio software and the forms were made with the Microsoft Excel software.

5.1 FIRST CASE: THE SURGICAL INSTRUMENT CLEANING PROCESS

This case study is focused on a small yet fundamental health care process: the instrument cleaning before disinfection or sterilization.

This topic was selected due to the necessity of testing the proposed method with data from a specific workspace and to the author's familiarity with the HFMEA report (Sousa, 2014) where such data were readily available.

The original study was conducted by a graduate student as part of her master's degree. After selecting a hospital's sterilization plant and the cleaning process as the topic to apply the HFMEA method – as described by DeRosier et al., 2002 –,a multidisciplinary team was gathered and adopted the following steps during multiple meetings: describe the process; identify the failure modes and potential causes; rate severity and probability for each potential cause; and propose corrective actions.

Following the proposed method here, the first step for a Risk Factors Map was to select a critical incident associated with the process analyzed in the report, i.e., instrument cleaning. Since the objective of the cleaning process – which includes rinsing and drying (Acosta-Gnass & Stempliuk, 2010) – is "the removal of the visible soil" (Rutala and Weber,

2008) the critical incident had to be associated with the instruments' final state after the process.

Considering the instrument must be both clean and dry (Sousa, 2014), the critical incident was defined as "Dirty or moist instrument leaves cleaning area". It indicates a situation where, despite passing through the cleaning process, the instrument is not thoroughly cleaned or dried, but validation fails to prevent it from proceeding to sterilization or disinfection – thus jeopardizing the effectiveness of those processes. The critical incident was placed at the bottom of the *Incident Conditions* level of the Risk Factors Map (Fig. 13).

The second step was to gather data. The main data source for this case was the aforementioned HFMEA report (Sousa, 2014). The other main sources, necessary to better understand the cleaning procedure, were guidelines for sterilization and disinfection (Rutala and Weber, 2008; Acosta-Gnass & Stempliuk, 2010), and a national regulation on good medical device processing practices (Brasil, 2012).

The third step was to identify the fundamental conditions for the critical incident. Three fundamental conditions were extracted from the critical incident description: "instrument is dirty" (C1); "instrument is moist" (C2); and "instrument proceeds to other processing stages" (C3).

Restrictions of the scope were mainly based on the processes, failure modes, potential causes, and workspace characteristics identified in the original report: "only immediate risk factors related to the cleaning area"; "only sub-processes related to the instrument cleaning phase"; and "only non-automated processes".

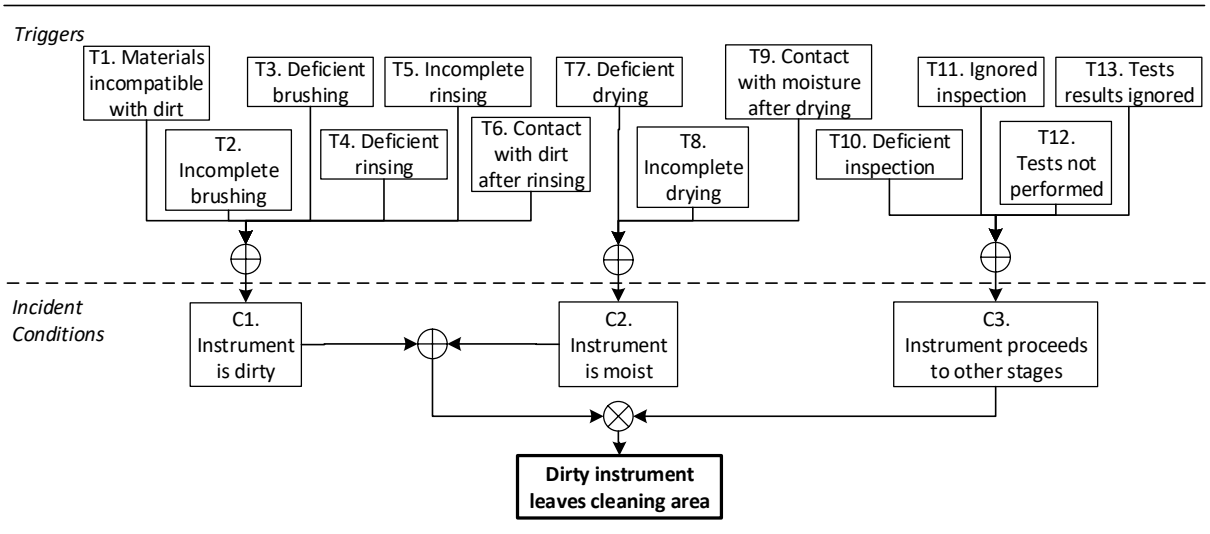

Fig. 13: Connections between fundamental conditions and triggers in the first case study.

The fourth step was to draft a simplified processes diagram based on the references. Four subprocesses (brushing, rinsing, drying, and validation) as well as the tasks and workspace elements, such as the sinks, brushes, detergents, and professionals associated with the *brushing* sub-process, were identified. The process diagram is presented in Fig. 14.

The twelve workspace elements identified were then placed in a table and their descriptions were extracted from the failure modes and potential causes of the HFMEA report.

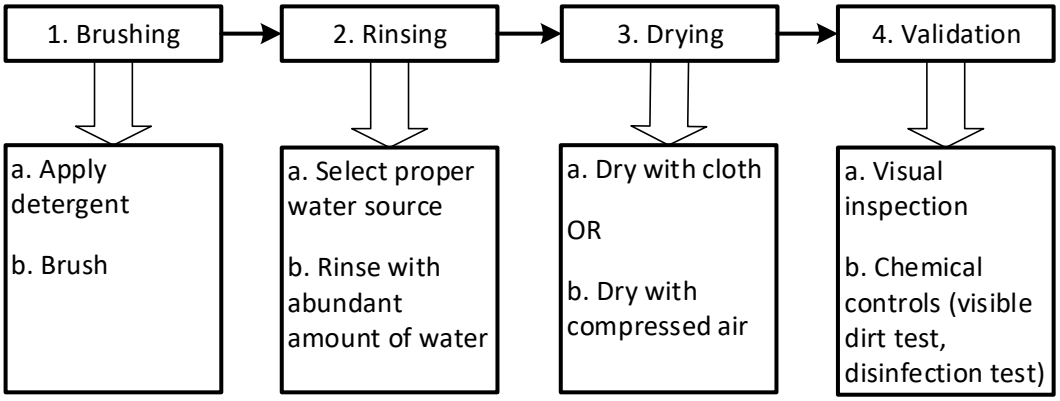

Fig. 14: Process diagram for surgical instrument cleaning

The fifth step was to identify the triggers associated with the fundamental conditions. The combinations between fundamental conditions and subprocesses were assessed with the framework of the *Classes of Triggers* (Table 2) and the triggers associated with each condition were identified and registered at the *Table of Triggers Form*. As an example, the trigger "Materials incompatible with dirt" (T1) was identified at the "Brushing" sub-process as a potential trigger for the "Instrument is dirty" (C1) fundamental condition. A total of thirteen triggers were associated with the three fundamental conditions. They were placed at the *Triggers* level of the *Risk Factors Map*, as presented in Fig. 13.

The sixth step was to identify the *Immediate Risk Factors*. The descriptions of workspace elements associated with each one of the thirteen triggers were analyzed and the element characteristics that were considered influential to the triggers were extracted as immediate risk factors ("Inadequate brushes" (I2), for example, was associated with three triggers: "Materials incompatible with dirt" (T1), "Incomplete brushing" (T2), and "Deficient brushing" |(T3). A total of seventeen immediate risk factors were extracted from the descriptions and registered in the *Immediate Risk Factors Form*. The seventeen factors were placed at the *Workspace* level of the Risk Factors Map and connected to their respective triggers. Because some factors influence multiple triggers, the connections between them totaled 44.

The *Risk Factors Map* excerpt in Fig. 15 shows the immediate factors associated only with the three aforementioned triggers.

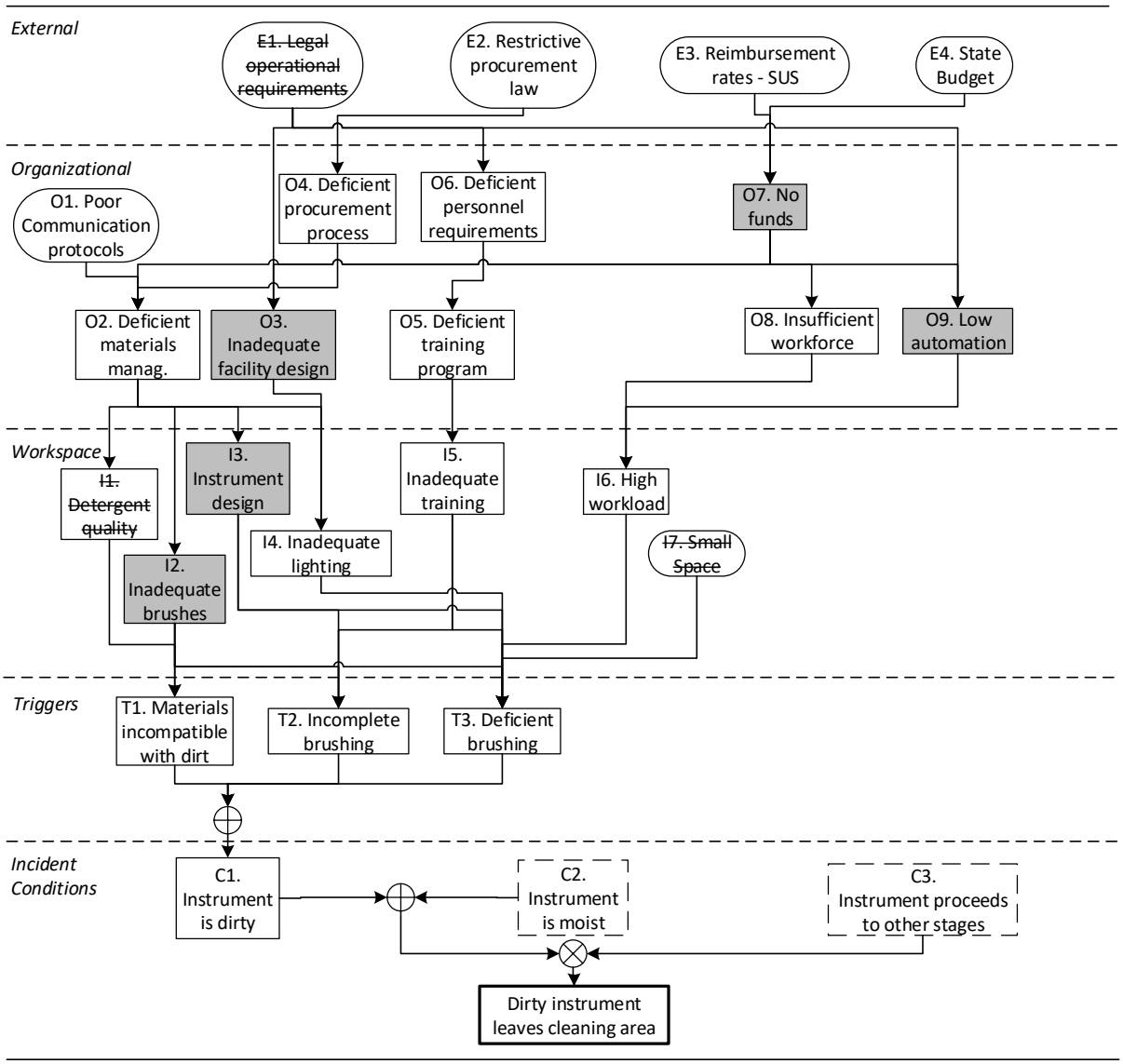

Fig. 15: Excerpt from the Risk Factors Map – factors related to the brushing sub-process

The seventh step was to identify the *remote risk factors* that might be the reason for the *immediate risk factors* just identified. Operational and design causes for each immediate factor were considered: although some were directly based on the failure modes causes present in the original analysis, part of the remote factors was derived from them. The "inadequate brushes" immediate factor, for example, was considered to be influenced by "deficient materials management". Seventeen connections were directly made between the seventeen immediate risk factors and seven remote risk factors, but while some immediate factors had

no connections due to scope restrictions (indicated by rounded edges in Fig. 15), others were connected to multiple remote factors.

After identifying those seven remote risk factors, the same operational and design considerations were applied to them and remote factors at higher levels were identified. The process was then repeated to the chained factors that were still not out of scope until no more factors could still be considered within the scope. The "deficient materials management" remote factor, for example, was chained to "poor communication protocols", "no funds", and "deficient procurement process", all at the *Organizational* level of the *Risk Factors Map*, as observed in Fig. 15. The last two remote factors were chained, respectively, to "state budget" and "reimbursement rates", and to "restrictive procurement law", all at the *External* level of the map.

A total of nine remote factors were chained – directly or indirectly – to the first seven ones and the connections between then totaled fifteen. Most remote factors were from the organizational level of the socio-technical system.

Some of the remote risk factors, such as "restrictive procurement law", were extracted directly from the original report, but others, like "deficient procurement process" were included for analytical purposes because they were implicitly indicated elsewhere. The connections with and among *remote risk factors* were registered in the *Remote Risk Factors Form*.

The final step was to classify the map factors as *dismissed*, *confirmed* or *reasonable*. In this case, the author took advantage of the HFMEA structure applied to the original analysis and used the probability ratings already present there as the classification criteria for the *Risk Factors Map*: risk factors associated with failure modes with "remote" probabilities were classified as *dismissed*; "frequent" ones, as confirmed; and the others – "occasional" and "rare" – as *reasonable*. Fig. 15 presents a complete branch of the risk factors map, with *confirmed* factors indicated by grey textboxes; *dismissed* factors, by strikethrough text; and *reasonable* factors, by regular text boxes. The complete classification data were registered in the *Classification Form*.

The complete forms and maps related to this case are included in Appendix J.

5.2 SECOND CASE: MEDICAL DEVICES REGULATIONS

This case study is aimed at the regulatory level of the Brazilian health care system – more specifically at the medical devices premarket approval regulations.

The topic selection was motivated by an interest in verifying if the tool would allow analyses to depart from hierarchical levels above the workspace.

The first step was to select the critical incident and, considering the focus on regulations, the most direct failure that could occur in the regulatory system was selected: "A hazardous medical device legally reaches healthcare in Brazil". It was placed at the bottom of the *Incident Conditions* level of the *Risk Factors Map* as "Unsafe medical device reaches healthcare"

Since the focus was not on an ordinary workspace, but on the regulatory system, the second step, data gathering, was mainly focused on the body of regulations issued by the Brazilian Health Surveillance Agency (ANVISA), but other sources such as international medical device standards, official medical device incident reports, ANVISA's operational reports and publications related to regulations were also used.

All the regulations related to the premarket approval process of medical devices – more specifically, of medical equipment – up to 02/23/2016 were examined and notes on requirements and on process particularities were taken. In this step, special attention was given to regulations that determined or changed the requirements for the various parts of the medical device premarket review process.

The third step was to identify the fundamental conditions and two pairs of conditions were extracted from the critical incident description. The first pair is related to the inherent risk associated with specific technologies: "device has an inherently high risk" and "clinical reports are not reproved". The second pair is related to design and manufacturing – "device has faulty parts or design" and "technical report is not reproved". Either pair of conditions is enough to provoke the critical incident, so logical operators were used in the *Risk Factors Map* to explain their relations (Fig. 16).

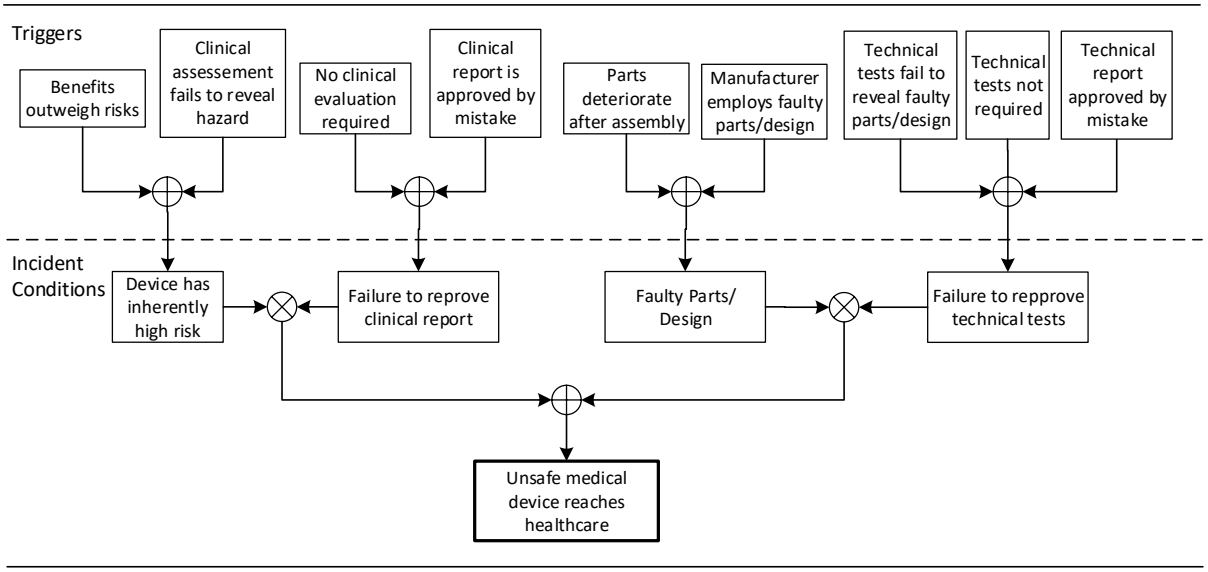

Fig. 16: Connections between fundamental conditions and triggers in the second case study.

Since the fundamental conditions point at multiple directions, *workspace* represents the aggregation of four different workspaces in this case: the clinical investigation facilities where trials are made; the plants where devices are manufactured; the metrology laboratories where devices are tested for technical safety requirements; and the regulators' offices where clinical and technical assessment reports are evaluated by regulatory agents.

Because the focus of this study is on regulations, specific conditions of the multiple workspaces (e.g., the training of technical laboratory personnel) were mostly left out of the scope, except when deemed necessary to represent the systemic effects of regulatory flaws (e.g., the academic background of GMP inspectors). Potential criminal acts, such as bribery and clinical data fabrication, were also ignored in order to keep the focus on the regulations.

The fourth step was to describe the medical device market approval process. Since there was no interest in workspace details, the process was just roughly drafted. Four main subprocesses were identified: "Manufacturing", "Device Certification", "Clinical Assessment", and "Report Evaluation". Only eight workspace elements were associated with the subprocesses, but some of them were actually formed by multiple smaller elements that were too specific to remain in the scope but had analytical value as a group ("device certification system", for example, included protocols, personnel, laboratories, etc.). The process description and simplified diagram were registered at the *Process Description Form*.

The eight workspace element descriptions were succinct and they were mainly based on the references, but some professional judgment was necessary to fill some gaps. They were registered at the *Workspace Description Form*.

The fifth step was to assess the combinations between fundamental conditions and subprocesses (using Table 2 – *Classes of Triggers*) and identify the triggers. As an example, the trigger "No clinical evaluation required" was identified at the "Report evaluation" process as a potential trigger to the fundamental condition "Failure to reprove clinical report". Fig. 16 shows the nine triggers identified for this case and their connections to their respective fundamental conditions. The triggers were registered at the *Triggers Form* and placed at the *Triggers* level of the *Risk Factors Map*.

The sixth step was to identify the *Immediate Risk Factors*. Since the focus of this case was on regulations, details on workspace elements were mostly unimportant to this analysis and the immediate risk factors were only indications of their potential imperfections (e.g., "poor quality control" and "inadequate GMP inspectors"). A total of only eight immediate factors were associated with the nine triggers: they were registered at the *Immediate Risk Factors Form* and placed at the *Workspace* level of the *Risk Factors Map*. Fig. 17 shows an excerpt of the map with the two triggers and three immediate factors associated with the "Faulty parts/design" fundamental condition.

The seventh step was to identify the *remote risk factors*. Unlike the pattern presented in this accident causation model, i.e., *triggers* are connected to *immediate risk factors* and *immediate risk factors* are connected to *remote risk factors*, this case has three *triggers* ("Benefits outweigh risks", "No clinical evaluation required", and "Technical tests not required") directly connected to *remote risk factors* at the *External* level of the system (respectively, "Permitted by regulations", "Inadequate clinical assessment requirements", and "Inadequate technical testing requirements"). These connections are related to regulatory exemptions from certain process requirements that directly affect the workspace processes associated with those specific triggers.

A total of twenty remote risk factors was directly or indirectly connected to the eight *immediate risk factors* (and to three of the *triggers*) in a total of 35 connections, including those between chained remote factors. The *remote risk factors* were registered at the *Remote Risk Factors Form* and placed at the *Organizational* and *External* levels of the *Risk Factors Map*. The excerpt in Fig. 17 shows three remote factors at the *Organizational* level and three more at the *External* level.

Most remote factors were extracted from the references and adjusted for analytical purposes. The need for adjustments, in this case, is observable in the *triggers* related to report evaluations – "clinical report is approved by mistake" and "technical report is approved by mistake": although these are regulatory activities (thus normally related to the *External* level),

some remote risk factors were placed at the *Organizational* level on the map. The reason for that was to keep the institutional rules and protocols that shape the regulatory office activities close to the *Workspace* level on the map.

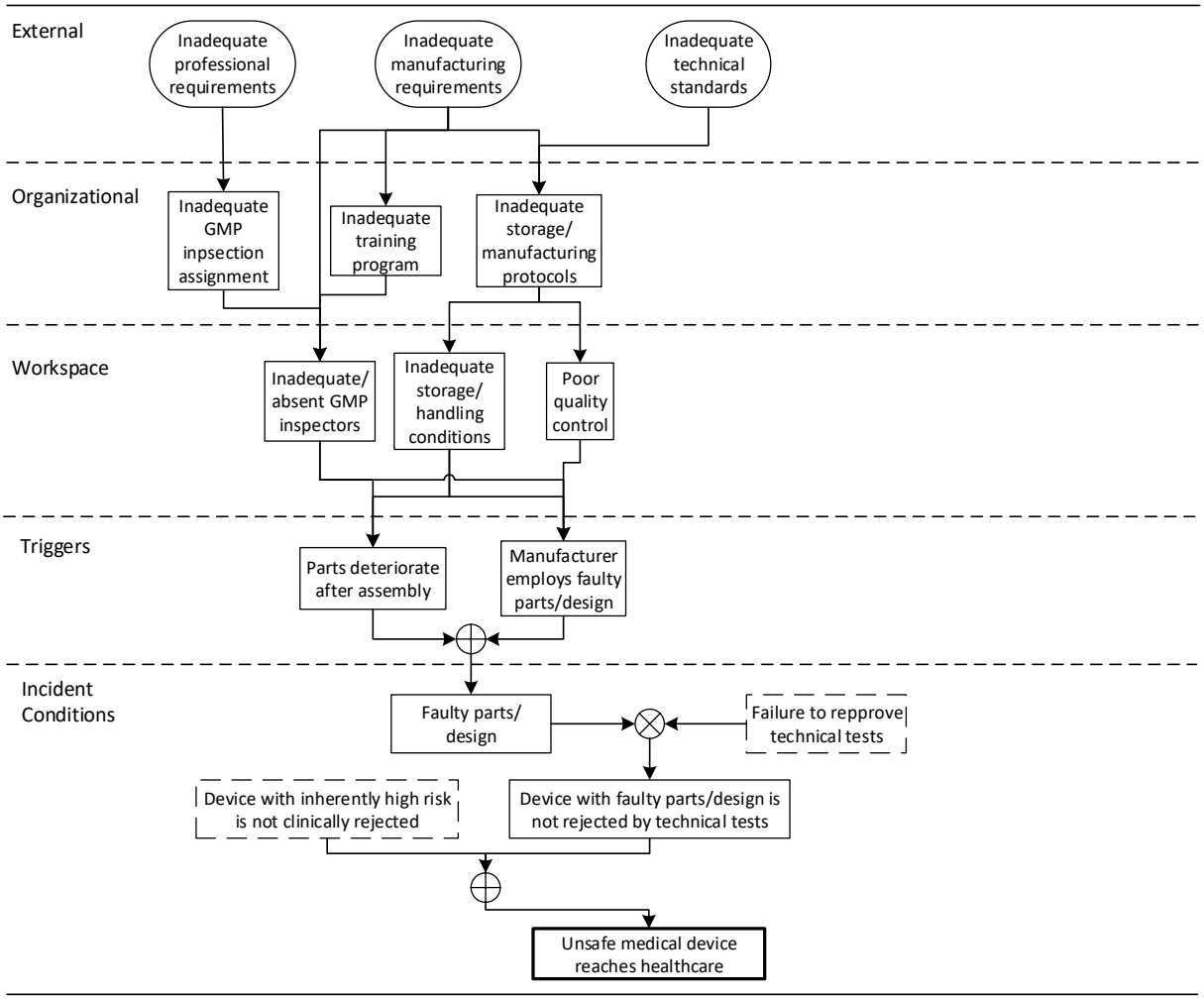

Fig. 17: Excerpt from the Risk Factors Map – factors related to the "Faulty parts/design" condition.

The last step was to classify the map factors. In this case, only two classification criteria were determined: evidence among the references indicating the influence of the factor on the system provided a *confirmed* classification; evidence negating the influence of the factor, e.g., through countermeasures, provided a *dismissed* classification. All the other factors – for which no positive or negative evidence could be found – were classified as *reasonable*. The primary source for this kind of evidence was the public information provided by the regulatory agency, especially the regulations, but guidelines and public reports were also considered. In a total of 36 risk factors (immediate or remote), two remote risk factors were classified as *confirmed* (indicated by grey textboxes) and two as *dismissed* (indicated by strikethrough text). The classification data were registered in the *Classification Form*.

Appendix K presents the complete forms and maps related to this case study.

5.3 THIRD CASE: INFUSION PUMPS

The objective of this case study was to verify if the tool can adequately be used to build a *generic Risk Factors Map* – a comprehensive representation of the risk factors associated with a generic critical incident, i.e., a critical incident not related to a specific setting – similar to Svedung's and Rasmussen's (2002) *generic AcciMap*.

Infusion pumps were selected as the topic for this case study because they are ubiquitous in healthcare and because of their repeated appearance on ECRI's *Top 10 Health Technology Hazards* series.

The first step was to select a critical incident. Given the topic and the intention of producing a generic risk factors map, the selected critical incident had to be associated with the device's fundamental function – i.e., delivering drugs to patients at a specific pattern – and it was formulated as "Inadequate drug dose delivered to the patient by infusion pump".

The second step was to gather data. References for this case study included a biomedical engineering handbook, an international technical standard on infusion pumps, guidelines for medication administration and patient safety, a report from an infusion device summit, an infusion pump life cycle guidance aimed at industry and regulators, and online instructional resources on setting up infusion pumps.

The third step was to identify the *fundamental conditions*. After analyzing the references, three conditions were derived from the critical incident description: "Reduced dose/No delivery", "Increased dose", and "Rate variation". The conditions were registered in the *Analysis Information Form* and connected to the *critical incident* at the *Incident Conditions* level of the *Risk Factors Map* (Fig. 18).

Because it is a generic map, certain restrictions were necessary to keep the scope manageable: patient's abnormal sensitivities to drugs were ignored, as were drug-related problems not associated with the operation of the device; smart pump technology was also ignored, because it is only widespread in affluent healthcare institutions and it would bring a whole different set of risk factors to the study; finally, "wrong drug" cases were only considered when associated with IV-line mix-ups.

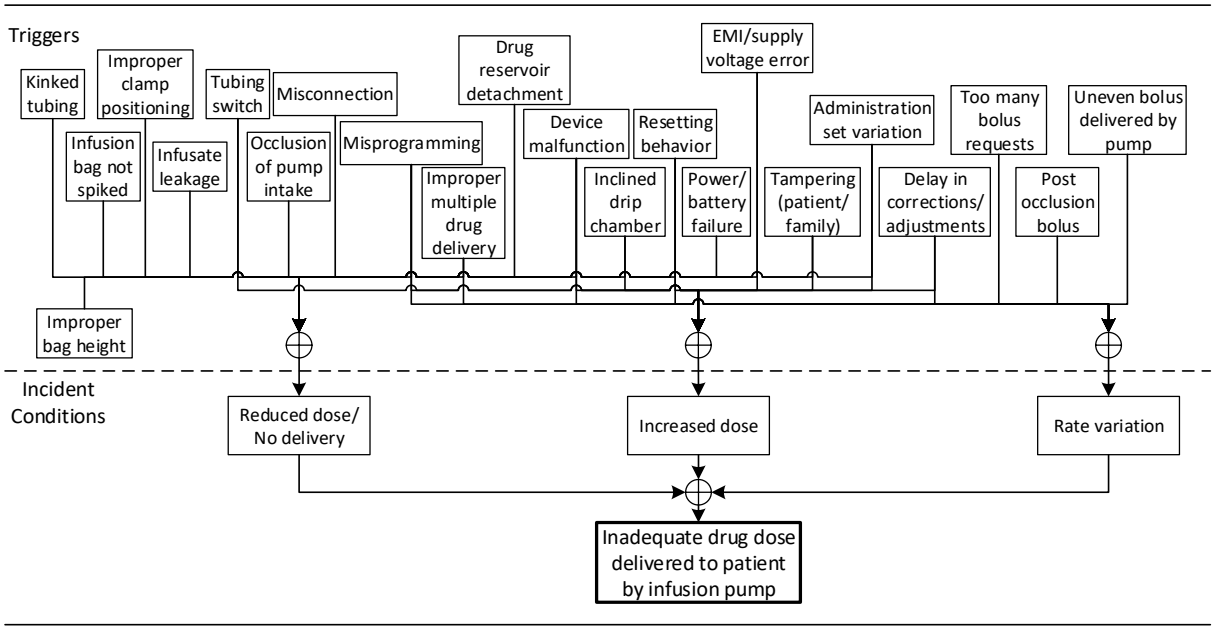

Fig. 18: Connections between fundamental conditions and triggers in the third case study.

The fourth step was to describe the processes and workspace.

The infusion pump setup process was split into five sub-processes: “Gather Materials”, “Prepare Infusion Bag”, “Prepare Administration Set”, “Prepare Infusion Pump”, and “Start Infusion”, each of them was composed of multiple tasks, as observed in Fig. 19. These data were registered in the *Process Description Form*, along with the workspace elements involved in each sub-process.

A total of eight workspace elements were associated with these sub-processes: professionals, drip stand, medication bag, administration set, infusion pump, prescription, patient, and facility. Element descriptions included multiple characteristics that may appear in their respective classes and they were mainly based on the references (e.g., “medication bag” was described as three potential characteristics: “label legibility, multiple medication bags, inadequate infusion portal”). The workspace elements descriptions were registered in the *Workspace Description Form*.

The fifth step was to identify the *triggers* for this case. The combinations between three fundamental conditions and four subprocesses provided 22 different triggers (the “Gather Materials” sub-process was ignored because triggers related to this sub-process can be associated with the other four with no loss to the study). The triggers and their relations to the sub-processes and *fundamental conditions* were registered in the *Triggers Form*.

Fig. 18 (above) shows how the *fundamental conditions* and *triggers* are connected in this case. It should be noted the elevated number of triggers in the figure required them to

be disposed at the *Triggers* level of the *Risk Factors Map* in such a way that they would fit a single figure, but the actual map had to be split into multiple parts.

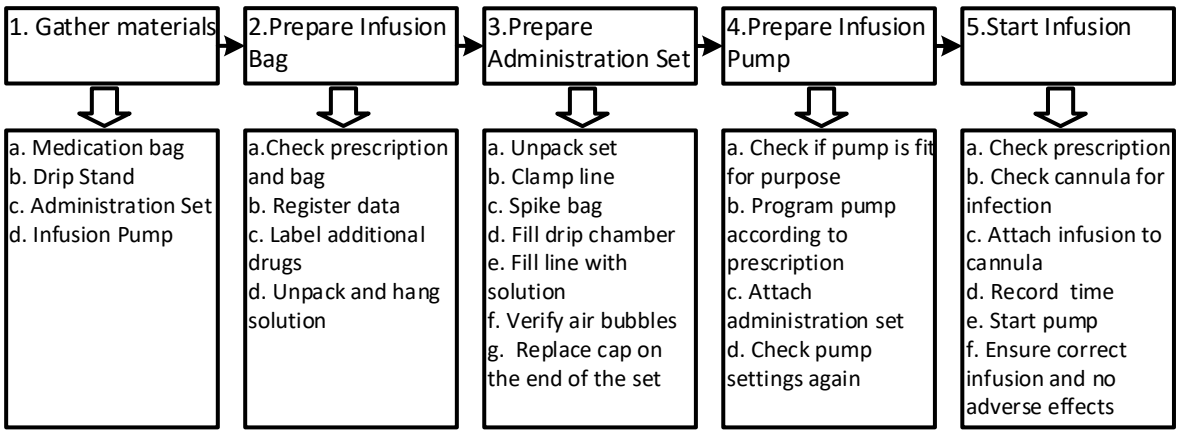

Fig. 19: Process diagram for infusion

The sixth step was to identify the *immediate risk factors*. The descriptions of the workspace elements were associated with the 22 *triggers* and 28 *immediate risk factors* were identified. The total of connections between *triggers* and immediate factors was 98, the minimum being two immediate factors for some triggers (e.g., the "Improper bag height" trigger was associated with "drip stand height" and "training"), and the maximum being thirteen immediate factors for "Misprogramming" (e.g., "display legibility", "lack of safety features", and "poor pump usability"). The immediate factors were placed at the *Workspace* level of the *Risk Factors Map*, as presented in the excerpt associated with the "Device malfunction" trigger in Fig. 20. The connections between *triggers* and *immediate risk factors* were registered in the *Immediate Risk Factors Form*.

The seventh step was to identify the *remote risk factors*. After considering potential operational and design causes for each immediate risk factor and then for the chained remote factors, a total of 36 *remote risk factors* were identified, mostly based on the references: 25 at the organizational level of the socio-technical system (e.g., "maintenance protocols" and "technical specifications") and 11 at the external level (e.g., "Technical requirements" and "quality standards"). Direct connections between immediate and remote factors totaled 52; indirect ones (chained remote connections) totaled 29. The *remote risk factors* and their connections were registered in the *Remote Risk Factors Form* and placed at the top levels of the *Risk Factors Map*. Fig. 20 presents the fourteen *remote risk factors* associated with the "Device malfunction" trigger.

The last step, *Classification*, was simplified: because this case presents a generic map based on the literature and other references, all factors were considered *reasonable*. The only classification criterion was that factors with no reference to their influence on the health care system would be classified as *dismissed*, but there was no such case. Factors at the external level were classified as *reasonable* without classification checks because analyses of legislation and standards were out of scope. The *Classification Form* shows the references that indicate the influence of each risk factor in the system.

The complete forms and maps related to this case are presented in Appendix L.

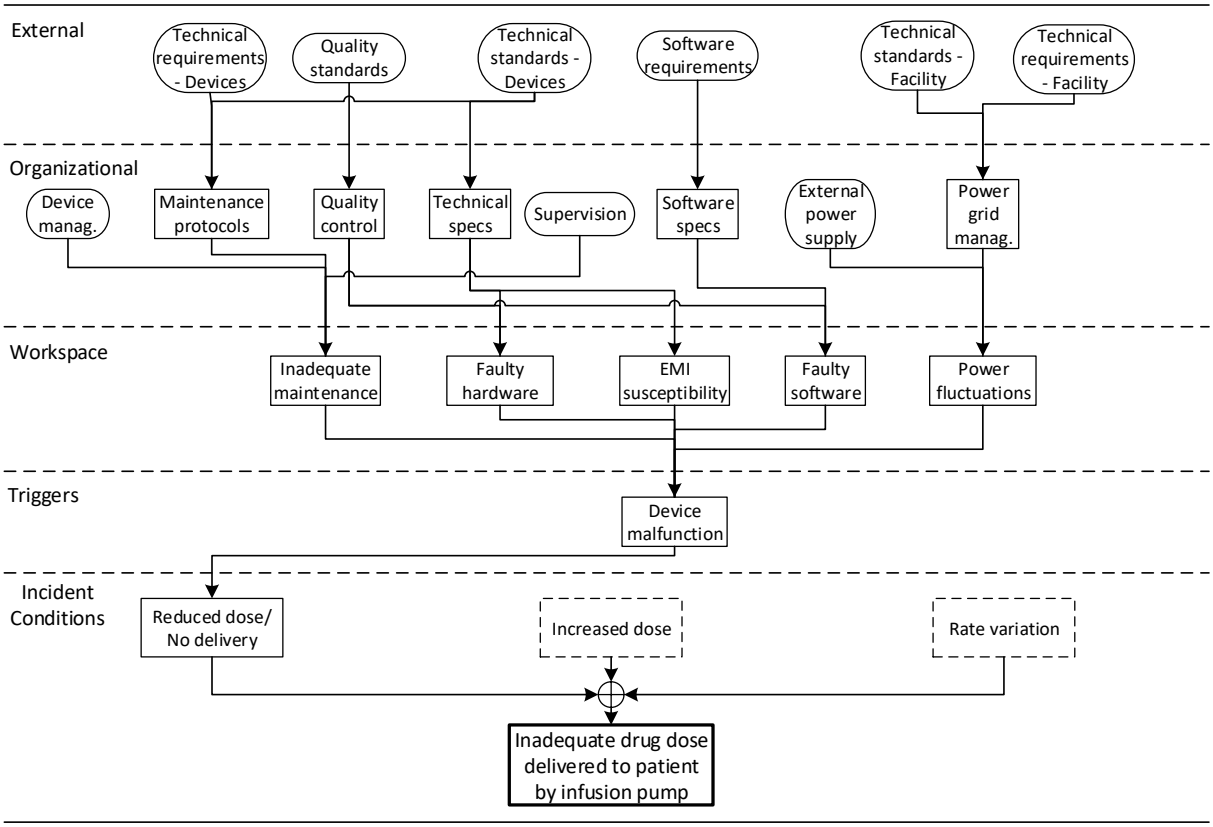

Fig. 20: Excerpt from the Risk Factors Map – factors related to the “Device malfunction” trigger.

6 DISCUSSION AND CONCLUSIONS

The aim of this research has been to develop a prospective method for mapping risk factors at different levels of the health care system based on key concepts of accident causation in complex socio-technical systems and to test it with case studies.

This chapter is divided into three sections: in the first section, cases studies are compared and the findings, difficulties, and limitations in their execution and consistency issues among them are considered; in the next section, the accident causation model and the risk factors mapping method are examined in light of the results and compared with other models and tools present in the literature; in the last section, study limitations, possible applications, and future research topics are discussed and a concluding statement is given.

6.1 THE CASE STUDIES

The original purpose of this thesis was to develop a prospective method for mapping risk factors in the socio-technical health care system. Secondary – and necessary – objectives of the thesis were to merge multiple accident causation concepts into a single model and to test the developed method on multiple case studies.

Three cases were devised for that purpose, each one focused on a different aspect of the health care system: the first one was based on a potential failure at a specific instrument processing environment; the second, on a regulatory critical incident associated with medical devices; and the third, on a specific type of medical device. The results for each case were presented in the previous chapter, but they require some consideration before the method itself and the model upon which it was based can be properly discussed.

The instrument-cleaning case study, being the more closely structured according to the original purpose of the method, was arguably the most hindered by the availability of data since no onsite data were collected specifically for this study.

Although the main data source was a thorough risk analysis built by a multidisciplinary team in the course of several meetings, it was still secondhand data: the workspace information presented there was overall rich enough to provide an adequate picture of the *Immediate Health Care System*, but the original tool was not focused on higher-level factors. The result of that was a somewhat generic description of the chains of factors at the *Remote*

Health Care System – at both the organizational and external levels. Certain workspace element descriptions were also found lacking and had to be completed with generic characteristics commonly associated with their kind.

On the other hand, the resulting risk factors maps were completed with only a few adaptations and inclusions. This points out to the value of previous risk analyses as additions to data collected on site – or even as the sole references to risk factors maps when combined with a team of experts. Accident reports associated with similar critical incidents would probably have been less useful since they are generally focused on specific elements that played a major role in their incidents, although they could still have provided valuable information about the triggers associated with them.

Due to the relative completeness of the tool used for the report upon which the first case was based (HFMEA), the application of this method could be considered a structured graphical representation of a specific potential problem in that specific system. The additional data was only necessary to fill some gaps in the new, focused, perspective.

The other cases, being less specific by nature, did not suffer from the use of premade reports, but they presented some difficulties of their own.

In the second case, related to the medical devices premarket approval process, some concepts related to the socio-technical system hierarchy seemed to have been applied more loosely, namely the presence of immediate risk factors associated with regulatory offices, which are generally part of the *External* level. The contradiction in the method is only apparent and instead of weakening the model, it confirms the Immediate Health Care System includes multiple workspaces; it is, however, a warning for the need to adjust the model definitions when atypical settings are considered – as is the case when the critical incident under analysis occurs at the regulatory level.

Another effect of changing the level at which the critical incident occurs is creating direct connections between triggers and remote factors at the *External* level because some of the former are requirements directly regulated by some of the latter. It makes certain branches of the risk factors maps look like regulatory loophole maps, evoking the aligned holes in the accident causation model, but they only apply to a small subset of the potential medical devices market entry scenarios.

Since the third case was a generic risk factors map, it did not present structural challenges to the model or data limitations due to restrictive reference selection, but it required the most caution when defining the scope of analysis, especially due to its generic nature. Good data sources made it simple to develop generic descriptions of the infusion process

and the workspace elements, but certain trends had to be ignored due to scope restrictions and to the dissimilar nature of some problems associated with them – smart pump technology, for example, is currently a very popular topic, but it brings IT issues, such as interoperability and library management, to the table.

The case studies, as a whole, seemed to show the *Risk Factors Map* proposed in this thesis as an adequate way to display risk factors information pertaining to different levels – and angles – of the health care socio-technical system. The fact that no specific incident report was used as the basis for any of the case studies indicates that prospective data can be used to develop risk factors maps in a socio-technical framework.

The most obvious limitation of the case studies was their execution by a single individual instead of a team – contrarily to what is recommended by the method. This limitation was mitigated by the use of a multidisciplinary report in the first case; by the absence of a specific workspace in the second; and by the generic nature of the map in the third – although health care personnel expertise would certainly have improved the analyses, especially during process and workspace descriptions.

Besides case limitations, there were also inconsistencies in their execution. The aforementioned "workspace" definition adjustment for the medical devices regulations case is one of them.

There is also certain inconsistency in the distribution of risk factors in their respective forms among the different cases: in the first and second cases, the triggers in the *Immediate Risk Factors* forms follow the same sequence they appeared in the *Table of Triggers*, but they are ordered alphabetically in the third case; the *Remote Risk Factors* forms are also organized inconsistently, with factors distributed in order of distance from workspace in the first and third cases – i.e., first all immediate risk factors, then direct remote factors connected to them, then the chained remote factors – and separated in two forms associated with the Fundamental Conditions in the second case.

Although such inconsistencies might suggest insufficient or flawed instructions for filling the forms, they might as well just indicate that the data distributions in the forms mirror, to a certain extent, their respective case structures: the alphabetical order for the immediate factors in the third case might thus be caused by the impossibility of separating the triggers by fundamental condition, since many of those are connected to more than one of these; similarly, the separation of remote risk factors in two forms in the second case was only made possible by the reduced number of factors for the case and by the relative independence of factors between the two main fundamental condition branches.

Considering all these variations in structure, it might be helpful for analysts to write down explicit descriptions of what is included in each hierarchical level of the map.

6.2 THE MODEL AND THE METHOD

The application of the method to diverse situations suggest the proposed accident causation model offers an adequate mental framework for the prospective identification of risk factors in health care because, despite the need for adjusting the workspace definition to include regulatory offices, the analyses followed the same basic pattern: critical incident requires certain conditions that are provided by triggering events at the workspace due (mainly) to imperfections in the workspace elements and those imperfections are there due to problems at the levels where decisions are made.

Although the model integrates elements from different systems and tools, certain care was taken to avoid the use of conflicting concepts: Reason's Swiss Cheese model (Reason, 1990) is reinterpreted as a series of barriers not formed by multiple hierarchical levels, but shaped by them; the socio-technical framework (Rasmussen, 1997; Leveson, 2004) explains how the barriers are shaped by higher hierarchical levels; and the workspace level dynamics, not detailed by the other models, is described in terms of human error (Reason, 1990) and other system failures – especially associated with HFMEA (DeRosier et al., 2002) and *Shepherd's System* (Shepherd, 1998).

To the best of the author`s knowledge, the risk factors-mapping method designed after this model is the first attempt to provide instructions for the prospective risk analysis of socio-technical systems.

Besides the benefit of mitigating the culture of blame by focusing on hypothetical events instead of investigating actual accidents, the method's structure also shifts the focus of analysis from a linear perspective – which generally departs from a single identifiable error associated with a health care professional – to a more systemic approach that considers accidents to be the result of complex interactions provided by multiple factors at different levels of the socio-technical system.

By highlighting the fact that certain conditions are necessary for a critical incident to happen and showing that multiple triggers – even routine actions – may provide them, the method confirms that "error-free delivery of health care is a utopia" (Cuschieri, 2006) and it

makes potential errors more visible, presenting them as signals that may "indicate incubating accidents in the system" (Dien et al., 2012).

As indicated by Nieva and Sorra (2003), who discussed RCA and HFMEA, being prospective does not completely eliminate staff resistance to expose weaknesses in the processes under their responsibility, partly due to "fear of challenging the institutional hierarchy", and that's why the involvement of senior management is necessary before collecting workspace data. For this method, specifically, management cooperation is even more critical later, when collecting data at the organizational level.

Because the *Risk Factors Map* takes *AcciMap* as its main reference, it may have similar problems: first, it might require some formal training before people are able to use it properly – which Sklet (2004) classifies as an 'expert' level; second, it has some reliability and validity issues (Branford, 2007; Goode et al., 2017; Waterson et al., 2017; Gonçalves Filho et al., 2019) that, although do not recommend against the use of the tool, do require the subjectivity and judgment applied during analysis to be considered when basing practical decisions on its results. The method also shares some of AcciMap's advantages, such as "the capacity to take the big picture into account, identifying factors from within the organization(s) involved as well as other interrelated bodies" and the ability to distil "large quantities of information about the contributing factors and their interrelationships into a single diagram" (Branford, 2011).

Due to its prospective nature and the influence of multiple risk analysis and incident investigation tools, there are some differences between the *Risk Factors Map* and other AcciMap approaches (Svedung & Rasmussen, 2002; Branford et al., 2009): first, it is not aimed at providing recommendations for correcting the system, only at diagnosing system problems by analyzing hypothetical failures; second, it does not consider causal connection between risk factors and triggers, only potential influence – which leaves causal strength threshold criteria entirely to analysts' judgment; and third, while AcciMaps are focused on describing complex chains of events leading to a critical incident, the *Risk Factors Map* is focused on providing multiple scenarios for it.

It should be finally noted that the systemic approach enforced by the method should not be considered a complete dismissal of the individual approach: proficiency in execution is fundamental to health care (Cuschieri, 2005) and accountability tells the public that the system does not favor the professionals over the patients (Walton, 2004). Systemic analyses should thus be inserted in a "Just Culture" (Sculli & Hemphill, 2013), where fair proce-

dures are used to “draw the line between conduct deserving of discipline and conduct for which discipline is neither appropriate nor helpful.”

6.3 CONCLUSIONS

Although the accident causation model developed for this study comprehends the whole socio-technical health care system and merges solid elements from the Risk Management and Safety domain, certain concepts might seem odd to those used to more traditional models. The concept of “barrier” used here is associated with the absence of flaws in the workspace elements – in contrast to its more traditional definition related to specific safety mechanisms or processes intended to prevent the propagation of error.

Since the method was built upon the identification of systemic flaws at multiple hierarchical levels, it is eminently diagnostic, and, thus, does not provide certain desirable features, such as rating risks or proposing corrections.

The method, however, might have useful applications, such as planning critical incident scenarios for high fidelity simulations, assessing the current system’s resistance to a particular type of incident, and revealing systemic flaws that might require further investigation.

Since the method suffers from the lack of taxonomies of contributing factors, as occurs with the AcciMap (Goode et al., 2017; Waterson et al., 2017; Grant et al., 2018), future studies might add specific error taxonomies for the *Organizational* and *External* system levels (similar to the *Classes of Triggers* table). Comparisons between *Risk Factors Maps* for similar critical incidents in different types of health care organizations might be helpful to evaluate validity and reliability.

The addition of a structured quantitative analysis stage might provide more robust capabilities for prioritizing which risk factors demand a closer look. It would require experts to evaluate the contributory factors, as has been tried with AcciMap (Wang et al., 2018), or incident report systems to feed the analyses with plentiful and accurate risk factors data (which is a challenge in itself).

Considering the differences among the three case studies and the comprehensiveness of the accident causation model developed for this study, it seems the risk factors mapping method is suitable for prospective analyses of the healthcare socio-technical system.

Hopefully, the *Risk Factors Map* will be used as a diagnostic tool for revealing flaws in specific workspaces and the associated system – or at least the ideas explored in this study will encourage researchers and risk management teams to move the focus of their efforts from incident investigations to prospective analyses and from workspace issues to systemic factors.

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APPENDICES

APPENDIX A - ANALYSIS INFORMATION FORM

Critical Incident (Short name for the Critical Incident – section 4.1)**:**

Description (Brief description of the Critical Incident – section 4.1)**:**

Analysis Team (Names of the analysis team members – section 4.1)

Keywords (List of keywords for topics associated with the Critical Incident – section 4.2)

References (Main initial references to the topics associated with the Keywords – section 4.2)**:**

Fundamental Conditions (List of Fundamental Conditions for the Critical Incident – section 4.3)**:**

(Draw logical relations here)

Scope (List of restrictions to the analysis – section 4.3)**:**

Notes

APPENDIX B – PROCESS DESCRIPTION FORM

Process Name (name of process potentially associated with the critical incident – section 4.4)**:**

Description (general description of the process – section 4.4)**:**

Subprocess (part of the process)	**Elements Involved** (list the elements involved in each subprocess: consider device, facility, patient, team, supply, and environment components):

(Draft process here)

Notes

APPENDIX C – WORKSPACE DESCRIPTION FORM

1. List elements involved in the subprocesses in the *Element* column. Place a new element after the previous description (section 4.4).
2. Write a general description of the kind of element in the *Description* column. Use as many rows as necessary (section 4.4).

Element	**Description**

Notes

APPENDIX D – TRIGGERS FORM

[Based on section 4.5]
1. List Fundamental Conditions in the *Fundamental Condition* column (one per row);
2. List processes where the fundamental condition might emerge in the *Process* column (one per row);
3. List potential triggers that might occur at the specific process in the *Trigger* column (one per row).

Fundamental Condition	Process	Trigger

Notes:

APPENDIX E – IMMEDIATE RISK FACTORS FORM

[Based on section 4.6]
1. List Trigger in the *Trigger* column (one per row);
2. List Immediate Risk Factors associated with each trigger in the *Immediate Risk Factors* column.

Trigger	**Immediate Risk Factors**

Notes:

APPENDIX F – REMOTE RISK FACTORS FORM

[Based on section 4.7]
1. List immediate risk factors in the *Lower Factor* column (one per row);
2. List remote risk factors directly associated with them in the *Higher Factor* column (one per row);
3. Copy the remote risk factors to the left column (one per row);
4. List the chained remote factors in higher levels in the right column (one per row);
5. Repeat steps 3 and 4 until there are no more new chained remote factors in higher levels.

Lower Factor	**Higher Factor**

Notes:

APPENDIX G – CLASSIFICATION FORM

[Based on section 4.8]
1. List map elements (condition/trigger, factor) in the *Map Element* column (one per row);
2. Check "C" for *Confirmed* factors, "R" for *Reasonable* factors, and "D" for Dismissed factors;
3. List references to back up the selected status in the *Evidence* column.

Status			Map Element	Evidence
C	R	D		

Notes:

APPENDIX H – GUIDELINES FOR MAPPING

Risk Factors Maps tend to become very complex due to the number of elements (conditions, triggers, immediate risk factors, and remote risk factors) and the connections between them. The brief guidelines below might be useful for improving the readability of Risk Factor Maps.

Element names in textboxes should be as short as possible to keep the boxes small. Lower box width is more important than lower box height in order to allow for a higher density of textboxes per map without compromising clarity too much. The middle section of map elements should not be obstructed by other elements above or below them if they are connected to other map elements in those directions. Common words might be abbreviated, but boxes should be wide enough to prevent words from being broken into multiple lines. Text fonts shouldn't be lower than 8 (the usual limit for figures).

Connectors between map elements should follow a pattern: straight down from the higher element, then turn horizontally towards the lower element, and then finally turn straight down to the lower element. Multiple connectors from the same higher element must be aligned at the horizontal level. There must be enough blank space between map levels to prevent horizontal lines of different higher factors from aligning. Connectors should always start at the lower midsection of the higher level element and end with an arrow at the upper midsection of the higher element.

Logical operators (AND/OR) should only be used to describe relations between conditions and the critical incident and between triggers and conditions.

Even with careful positioning of textboxes and connectors, it may be necessary to split a Risk factors map into multiple parts to make them fit into the selected page sizes. The priority for splitting maps must be bottom up, using operators as connection references between maps: start by splitting the branches related to different conditions into different maps; if the maps associated with certain conditions still won't fit in the page, split the map into two groups of triggers (perhaps just separating a specific trigger connected to the larger number of risk factors). Due to the complexity of interactions between system levels, it might be necessary to try different arrangements before finding one where all maps fit in their pages.

APPENDIX I – GUIDELINES FOR REPORTING

After finishing the analysis, the analysts should make a thorough report on what they found in their study.

The report should not require deep knowledge of the method presented in the thesis to understand the main findings but should present all the necessary information for those who might wish to verify the premises upon which the study was done.

We suggest the final document to be composed by a Brief Report and multiple appendices with the data.

The Brief Report should be composed of four main sections: Introduction, Methodology, Results, and Summary and Recommendations.

The aim of the Introduction is to answer what the analysis is about. It should start by presenting the general topic of the analysis and then proceed to indicate the motivation to assess risk factors associated with the topic. This should be followed by a very brief description of the method and of the critical incident (e.g., “Prospectively map the risk factors associated with critical incident X”). Finally, a brief description of main scope limitations and the list of analysts involved (possibly, only their professional background – e.g., “The analysis team was composed by a pathologist, a clinical engineer, and a human factors specialist”).

The Methodology section indicates how the analysis was done. It should first present the criteria for selecting the analysis team members and a brief description of the main references used in the analysis. After that, it should present the reasoning for the Fundamental Conditions identified. Following the conditions, all the processes considered during analysis should be indicated. A brief – and generic – description of the other steps should also be included, with practical considerations on how triggers and risk factors were identified. A more detailed account of the study limitations should also be provided in this section. Finally, the criteria for determining the relevance of map elements should be explained.

The Results section should present the issues – and also the particularly positive system characteristics – found during analysis. The confirmed Risk Factors and other map elements should be highlighted and a simplified Risk Factors Map should be included.

The Summary and Recommendations section should present a brief description of the main findings in the risk factors analysis and a list of issues in order of priority – the most relevant and manageable, i.e., controllable by the organization, should be placed higher on the list.

APPENDIX J – CASE 1 DATA

Forms:

-Analysis Information Form

-Process Description Form

-Workspace Description Form

-Triggers Form

-Immediate Risk Factors Form 1

-Immediate Risk Factors Form 2

-Remote Risk Factors Form 1

-Remote Risk Factors Form 2

-Classification Form

-References

Maps:

-Map 1

-Map 2

-Map 3

ANALYSIS INFORMATION FORM

Critical Incident (Short name for the Critical Incident)**:**

Dirty or moist instrument leaves cleaning area

Description (Brief description of the Critical Incident)**:**

Instrument passes through the cleaning area, but it is not properly cleaned and dried.

Analysis Team

Only the PhD Candidate

Keywords (List of keywords for topics associated with the Critical Incident)

Sterilization; cleaning materials; medical device processing

References (Main initial references to the topics associated with the Keywords)**:**

HFMEA report from dissertation (Almeida, 2014);

Sterilization Manual for Health Centers (Acosta-Gnass & Stempliuk, 2010)

RDC 15/2012 - requisitos de boas práticas para o processamento de produtos para saúde (ANVISA, 2012)

Guideline for Disinfection and Sterilization in Healthcare Facilities (Rutala & Weber, 2008)

Fundamental Conditions (List of Fundamental Conditions for the Critical Incident)**:**

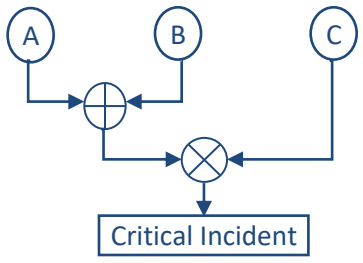
(A) Instrument is dirty;

(B) Instrument is moist;

(C) Instrument proceeds to other processing stages

(Draw logical relations here)

(A+B).C



Scope (List of restrictions to the analysis)**:**

Only factors related to the cleaning area of a specific hospital

Only processes related to instrument cleaning

Only non-automated processes

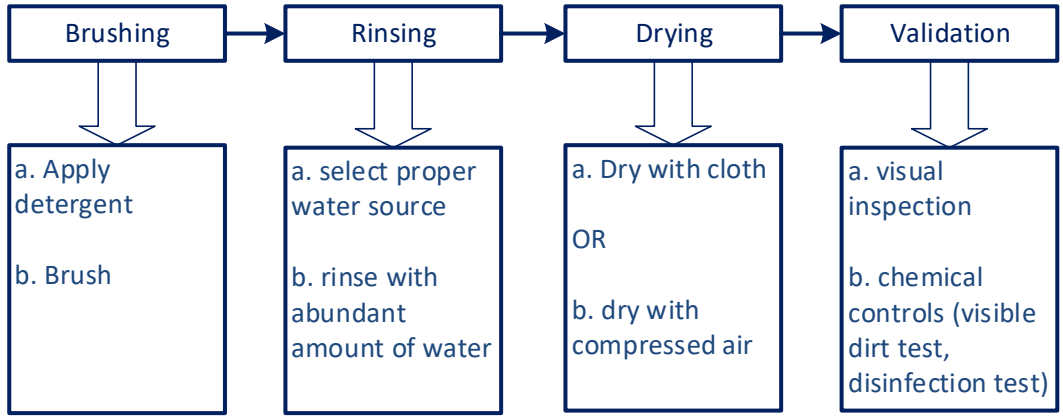
Notes

PROCESS DESCRIPTION FORM

Process Name (name of process potentially associated with the critical incident):
Manual cleaning of surgical instruments

Description (general description of the process)**:**
Dirty instrument is received at the cleaning area. Then, it is brushed with water and detergents, rinsed and dried with towels or compressed air

Subprocess (part of the process)	**Elements Involved** (list the elements involved in each subprocess: consider device, facility, patient, team, supply, and environment components):
brushing	bench, sinks, brushes, detergents, professionals, lighting, PPEs, water,
	instruments
rinsing	bench, sinks, professionals, water (variable quality), PPEs, lighting, instru-ments
drying	bench, professionals, cloths, compressed air terminal, lighting, instruments
validation	bench, professionals, lighting, instruments, test kits



(Draft process here)

Notes

WORKSPACE DESCRIPTION FORM

1. List elements involved in the subprocesses in the *Element* column.

2. Write a general description of the kind of element in the *Description* column. Use as many rows as necessary.

Element	Description
water	there's not enough reverse osmosis water, reverse osmosis system is
	broken, poor supply planning, low quality piped water, filters 'saturated' due
	to the poor maintenance schedule
working area	the area is not large enough; there's no air conditioning; excessive noise;
	waste accumulation (in bins); dust accumulation on furniture; presence of
	insects in the room
cloths	no data on report*
compressed air	there are too few terminals and they are not always working
carts	inadequate dimensions; inadequate usage protocols; insufficient/inadequate
	metal boxes for instruments
brushes	too low quantity; not enough diameter variety
validation tests	tests not available (no funds).
detergents	dilution procedures are ignored; team forgets adequate quantity
lighting	inadequate/insufficient
energy	there's no emergency power supply to the cleaning area
instruments	low-quality material; abused during procedures (damage); not regularly
	replaced; bad design prevents cleaning and internal inspection; disassembly
	and precleaning protocols are ignored; manual checklist
team	insufficient training; deficient supervision; deficient communication; high
	workload; stress; lack of qualified personnel; high turnover; low morale/
	commitment; deficient protocols; alcohol abuse; distraction; occasionally,
	omit certain activities (e.g., inspections)

Notes

*assume there are no immediate risk factors associated

TRIGGERS FORM

1. List Fundamental Conditions in the *Fundamental Condition* column (one per row);
2. List processes where the fundamental condition might emerge in the *Process* column (one per row);
3. List potential triggers that might occur at the specific process in the *Trigger* column (one per row).

Fundamental Condition	Process	Trigger
Dirty instrument	Brushing	Deficient brushing
		Incomplete brushing
		Materials incompatible with dirt
	Rinsing	Deficient rinsing
		Incomplete rinsing
		Contact with dirt after rinsing
Moist instrument	Drying	Deficient drying
		Incomplete drying
		Contact with moisture after drying
Instrument is approved	Validation	Improper inspection
		Ignored inspection
		Tests not performed
		Test results ignored

Notes:

IMMEDIATE RISK FACTORS FORM

1. List Trigger in the *Trigger* column (one per row);
2. List Immediate Risk Factors associated with each trigger in the *Immediate Risk Factors* column.

Trigger	Immediate Risk Factor
Deficient brushing	small space
	instrument design
	inadequate training
	inadequate brushes
	workload
	inadequate lighting
Incomplete brushing	inadequate brushes
	inadequate training
	instrument design
Materials incompatible with the type of dirt	detergent quality
	inadequate brushes
Deficient rinsing	inadequate water quality
	instrument design
	inadequate training
	inadequate lighting
	insufficient reverse osmosis water
incomplete rinsing	instrument design
	insufficient reverse osmosis water
Contact with dirt after rinsing	small space
	dirt accumulation
	presence of insects
	distracted
Deficient drying	instrument design
	inadequate training
	workload
	inadequate lighting
	unavailable air terminal
Incomplete drying	inadequate training
	instrument design

Notes:

(1 of 2)

IMMEDIATE RISK FACTORS FORM

1. List Trigger in the *Trigger* column (one per row);
2. List Immediate Risk Factors associated with each trigger in the *Immediate Risk Factors* column.

Trigger	Immediate Risk Factor
Contact with moisture after drying	distracted
	inadequate space
Deficient inspection	workload
	distracted
	inadequate lighting
Ignored inspection	inadequate training
	low morale
	workload
	inadequate supervision
Tests not performed	inadequate training
	workload
	no test kits
	low morale
Test results are ignored	workload
	inadequate training

Notes:

(2 of 2)

REMOTE RISK FACTORS FORM

1. List immediate risk factors in the *Lower Factor* column (one per row);
2. List remote risk factors directly associated with them in the *Higher Factor* column (one per row);
3. Copy the remote risk factors to the left column (one per row);
4. List the chained remote factors in higher levels in the right column (one per row);
5. Repeat steps 3 and 4 until there are no more new chained remote factors in higher levels.

Lower Factor	Higher Factor
detergent quality	deficient materials management*
distracted	out of scope
dirt accumulation	inadequate facility management
high workload	insufficient workforce
	low automation
inadequate brushes	deficient materials management*
inadequate lighting	inadequate facility design
	deficient materials management*
inadequate supervision	insufficient workforce
	inadequate task assignment
inadequate water quality	inadequate facility management*
instrument design	deficient materials management*
insufficient reverse osmosis water	deficient materials management*
low morale	out of scope
no test kits	deficient materials management*
presence of insects	inadequate facility design
small space	out of scope
inadequate training	deficient training program
unavailable air terminal	deficient materials management*
room not climatized	inadequate facility design

Notes:

*Not explicitly indicated in the study. Derived from other factors.

REMOTE RISK FACTORS FORM

1. List immediate risk factors in the *Lower Factor* column (one per row);
2. List remote risk factors directly associated with them in the *Higher Factor* column (one per row);
3. Copy the remote risk factors to the left column (one per row);
4. List the chained remote factors in higher levels in the right column (one per row);
5. Repeat steps 3 and 4 until there are no more new chained remote factors in higher levels.

Lower Factor	Higher Factor
deficient materials management*	poor communication protocols*
	no funds
	deficient procurement process*
deficient training program	deficient personnel requirements*
inadequate task assignment	deficient personnel requirements*
inadequate facility design	legal operational requirements*
	no funds
inadequate facility management	legal operational requirements*
insufficient workforce	no funds
low automation	no funds
	legal operational requirements*
no funds	state budget
	reimbursement rates - SUS
deficient personnel requirements*	legal operational requirements*
deficient procurement process*	restrictive procurement law
legal operational requirements*	out of scope
poor communication protocols*	out of scope
restrictive procurement law	out of scope
state budget	out of scope
reimbursement rates - SUS	out of scope

Notes:

*Not explicitly indicated in the study. Derived from other factors.

(2 of 2)

CLASSIFICATION FORM

1. List map elements (condition/trigger, factor) in the *Map Element* column (one per row);
2. Check "C" for *Confirmed* factors, "R" for *Reasonable* factors, and "D" for Dismissed factors;
3. Indicate data to back up the selected status in the *Justification* column.

Status			Map Element	Justification
C	R	D		
		X	detergent quality	Probability 1
X			dirt accumulation	Probability 4
X			distracted	Probability 4
	X		high workload	Probability 3
X			inadequate brushes	Probability 4
	X		inadequate lighting	Probability 3*
		X	inadequate supervision	Probability 1
	X		inadequate training	Probability 2
	X		inadequate water quality	Probability 2
X			instrument design	Probability 4
X			insufficient reverse osmosis water	Probability 4
	X		low morale	Probability 3
X			no test kits	Probability 4
	X		presence of insects	Probability 3
X			room not climatized	Probability 4
		X	small space	Probability 1
X			unavailable air terminal	Probability 4*
	X		deficient materials management	Probability 3*
	X		deficient training program	Probability 2**
X			inadequate facility design	Probability 4
	X		inadequate facility management	Probability 2
	X		insufficient workforce	Probability 3
X			low automation	Probability 4
X			no funds	Probability 4
	X		inadequate professional requirements	Probability 2**
	X		deficient procurement process	Probability 2**
		X	legal operational requirements	***
	X		poor communication protocols	***
	X		restrictive procurement law	Probability 2**
	X		state budget	***
	X		reimbursement rates - SUS	***

Notes:

-Classification based on probability ratings defined by the multidisciplinary team in the HFMEA study

-Confirmed factors are those with probability scores of 4;

-Dismissed factors are those with probability scores of 1;

-The remaining factors are considered Relevant (those with probability scores 2 or 3).

*Related probabilities vary.

**Probability not explicitly indicated in the study. It was based on related factors' ratings.

*** Probability was not indicated in the report. Status based on literature.

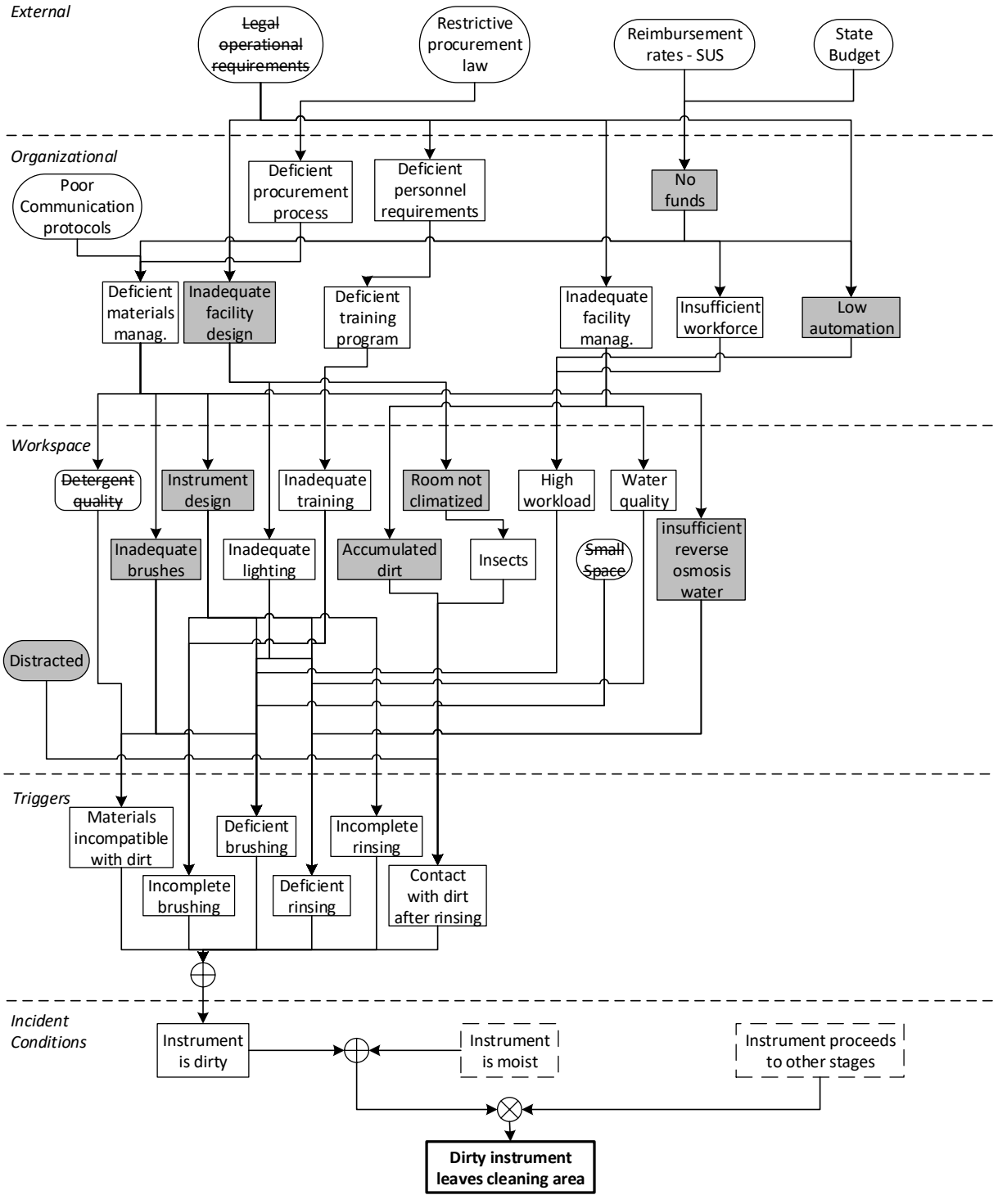
REFERENCES

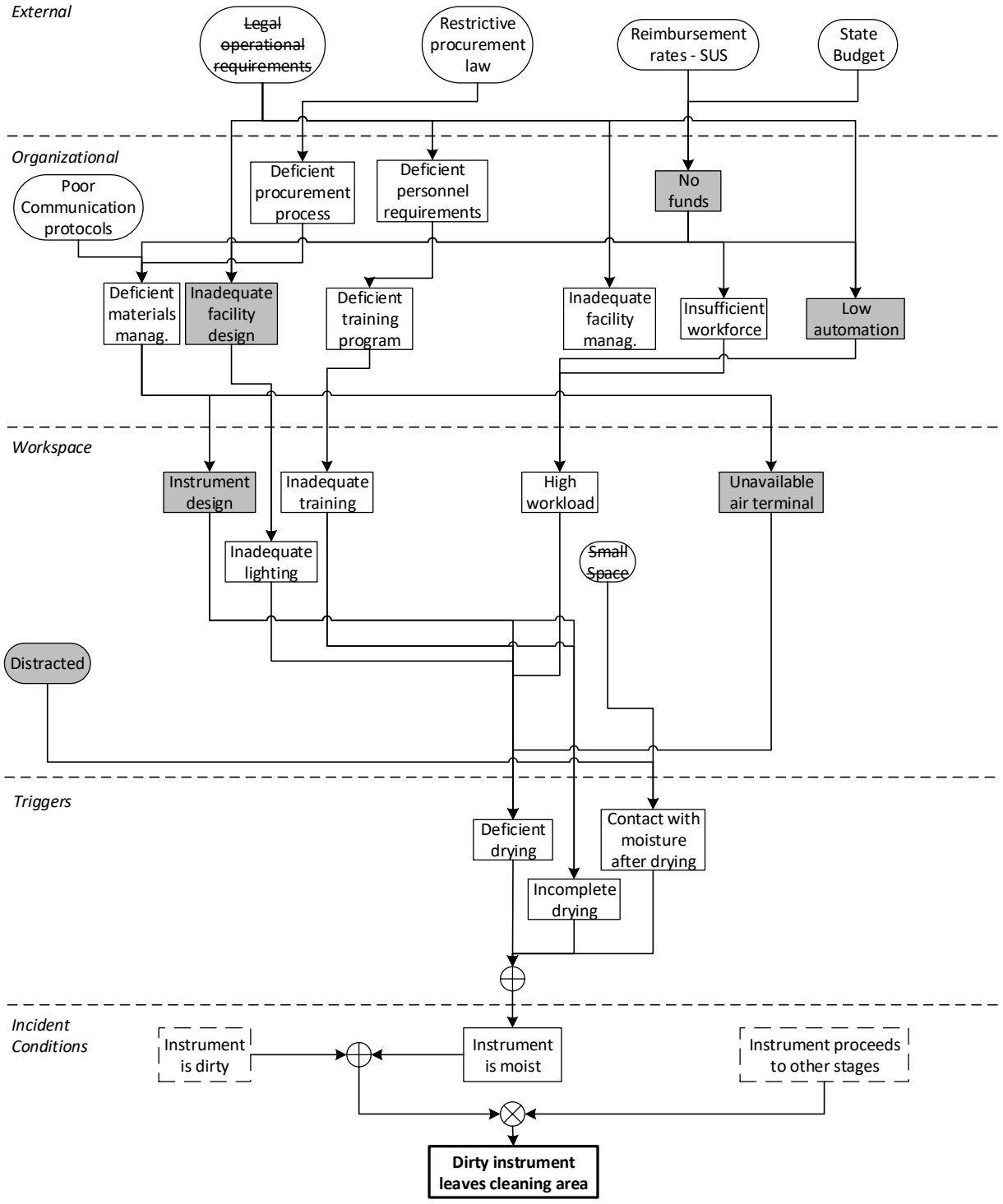
ACOSTA-GNASS, Silvia I.; STEMPLIUK, Valeska De Andrade. **Sterilization manual for health centers**. Pan American Health Organization, 2009.

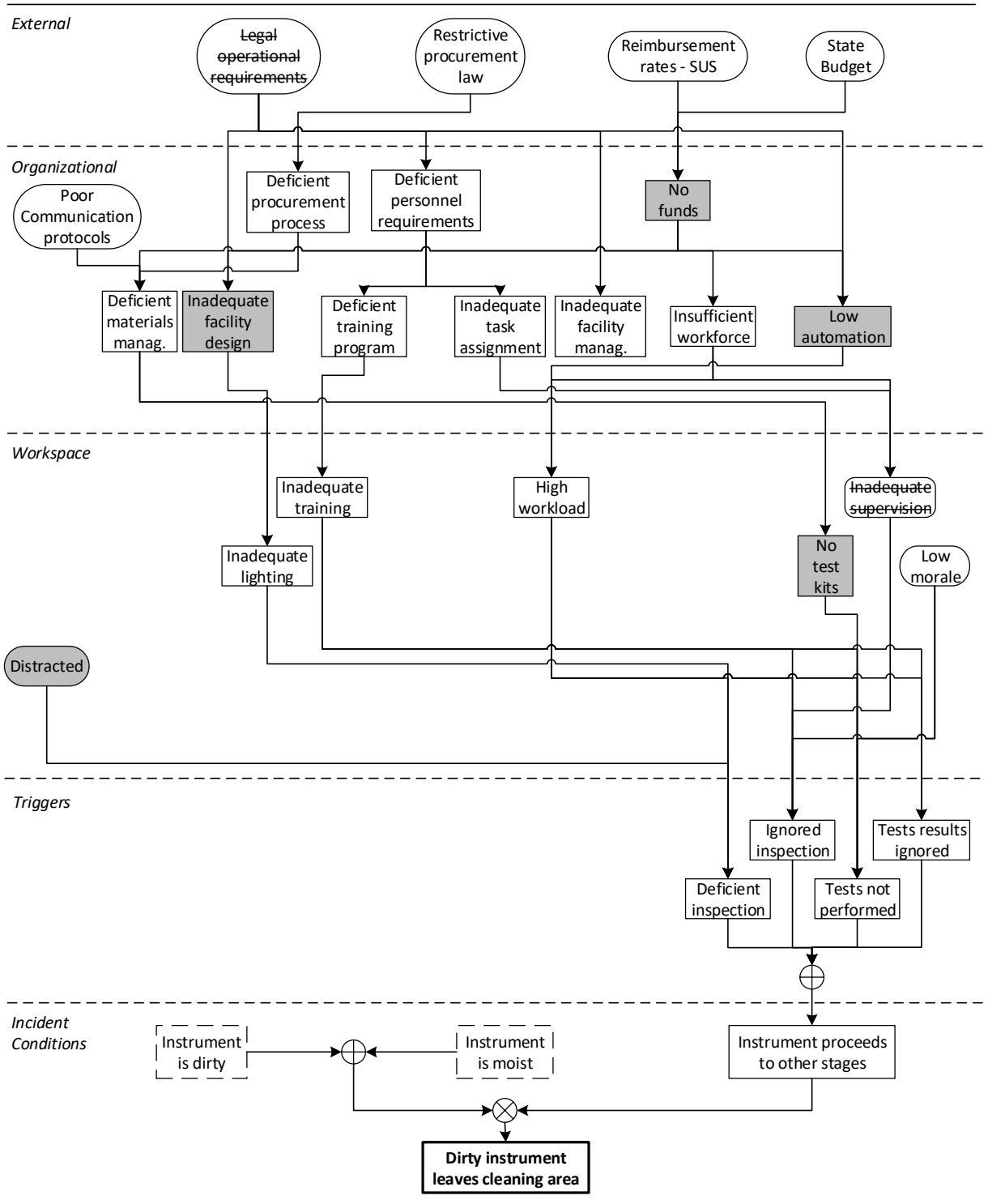
BRASIL. RDC nº 15, de 15 de Março de 2012. Dispõe sobre requisitos de boas práticas para o processamento de produtos para saúde e dá outras providências. **Diário Oficial da União** 2012, 15 Mar.

RUTALA, W. A.; WEBER, D. J. **Guideline for Disinfection and Sterilization in Healthcare Facilities**, CDC 2008.

SOUSA, Michele Cristina Almeida et al. **Aplicação da ferramenta de gerenciamento de risco HFMEA no setor de expurgo do centro de material e esterilização**. 2014.


External
~~Legal operational requirements~~
Restrictive procurement law
Reimbursement rates - SUS
State Budget
Organizational
Poor Communication protocols
Deficient procurement process
Deficient personnel requirements
No funds
Deficient materials manag.
Inadequate facility design
Deficient training program
Inadequate facility manag.
Insufficient workforce
Low automation
Workspace
~~Detergent quality~~
Instrument design
Inadequate training
Room not climatized
High workload
Water quality
Inadequate brushes
Inadequate lighting
Accumulated dirt
Insects
~~Small Space~~
insufficient reverse osmosis water
Distracted
Triggers
Materials incompatible with dirt
Deficient brushing
Incomplete rinsing
Incomplete brushing
Deficient rinsing
Contact with dirt after rinsing
Incident Conditions
Instrument is dirty
Instrument is moist
Instrument proceeds to other stages
Dirty instrument leaves cleaning area


External
~~Legal operational requirements~~
Restrictive procurement law
Reimbursement rates - SUS
State Budget
Organizational
Poor Communication protocols
Deficient procurement process
Deficient personnel requirements
No funds
Deficient materials manag.
Inadequate facility design
Deficient training program
Inadequate facility manag.
Insufficient workforce
Low automation
Workspace
Instrument design
Inadequate training
High workload
Unavailable air terminal
Inadequate lighting
~~Small Space~~
Distracted
Triggers
Deficient drying
Contact with moisture after drying
Incomplete drying
Incident Conditions
Instrument is dirty
Instrument is moist
Instrument proceeds to other stages
Dirty instrument leaves cleaning area


External
~~Legal operational requirements~~
Restrictive procurement law
Reimbursement rates - SUS
State Budget
Organizational
Poor Communication protocols
Deficient procurement process
Deficient personnel requirements
No funds
Deficient materials manag.
Inadequate facility design
Deficient training program
Inadequate task assignment
Inadequate facility manag.
Insufficient workforce
Low automation
Workspace
Inadequate training
High workload
~~Inadequate supervision~~
Inadequate lighting
No test kits
Low morale
Distracted
Triggers
Ignored inspection
Tests results ignored
Deficient inspection
Tests not performed
Incident Conditions
Instrument is dirty
Instrument is moist
Instrument proceeds to other stages
Dirty instrument leaves cleaning area

APPENDIX K – CASE 2 DATA

Forms:

-Analysis Information Form

-Process Description Form

-Workspace Description Form

- Triggers Form

-Immediate Risk Factors Form

-Remote Risk Factors Form 1

-Remote Risk Factors Form 2

-Classification Form 1

-Classification Form 2

-References

Maps:

-Map 1

-Map 2

ANALYSIS INFORMATION FORM

Critical Incident (Short name for the Critical Incident):

A hazardous medical device legally reaches healthcare in Brazil.

Description (Brief description of the Critical Incident):

A medical device is hazardous but the regulatory system does not prevent it from reaching the market.

Analysis Team

Only the PhD Candidate

Keywords (List of keywords for topics associated with the Critical Incident)

Premarket approval; medical devices; Good Manufacturing Practices; Medical Device Regulations; medical device incidents; risk management

References (Main initial references to the topics associated with the Keywords):

-National regulations on medical devices;

-International Medical Device Standards;

-Official medical device incident reports (MAUDE and ANVISA);

-Publications from manufacturers, service companies, and consultants involved with regulations;

-Academic papers on medical devices' regulatory issues;

-Operational reports and staff selection requirements published by ANVISA.

Fundamental Conditions (List of Fundamental Conditions for the Critical Incident):

A - Device has inherently high risk

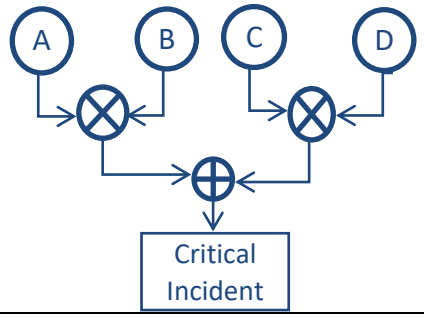
B - Clinical reports are not reproved

C - Device has faulty parts or design

D - Technical report is not reproved

(Draw logical relations here)

(A.B)+(C.D)



Scope (List of restrictions to the analysis):

-Ignore specific conditions of manufacturing plants, metrology laboratories, and regulator's offices, except when they represent the effects of regulatory flaws in the system;

-The focus is on regulations, thus, potential criminal acts (e.g., bribery and clinical data fabrication) were ignored.

Notes

PROCESS DESCRIPTION FORM

Process Name (name of process potentially associated with the critical incident)**:**

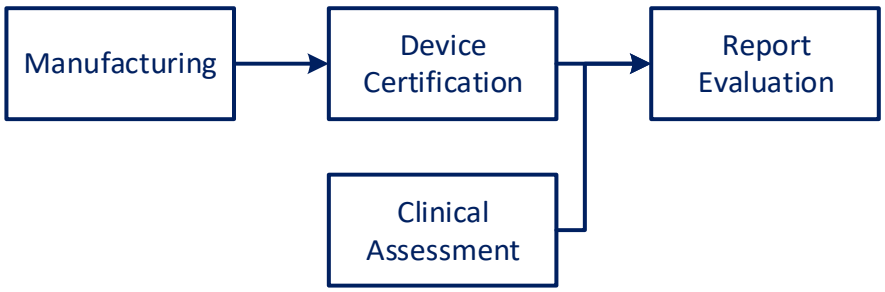
Medical Device market approval process

Description (general description of the process)**:**

Clinical safety is assessed by manufacturers and report is sent to regulators for approval

Manufactured device is sent to testing laboratories for certification and report is sent to regulators for approval.

Subprocess (part of the process)	**Elements Involved** (list the elements involved in each subprocess: consider device, facility, patient, team, supply, and environment components):
Clinical assessment	clinical assessment system (personnel, resources, protocols), GCP inspectors
Device Report	clinical evaluators, technical evaluators (regulators)
Evaluation	
Manufacturing	Storage/handling system (facilities, personnel, supplies), quality control,
	GMP inspectors
Certification	Device certification system (protocols, personnel, resources)



(Draft process here)

Notes

WORKSPACE DESCRIPTION FORM

1. List elements involved in the subprocesses in the *Element* column. Place new element after the previous description.
2. Write a general description of the kind of element in the *Description* column. Use as many rows as necessary.

Element	Description
Clinical assessment	Performance might be affected by personnel and available resources.
system	Also by clinical assessment protocols. Specific laboratory conditions ignored.
	Protocols harmonized with international standards, consider adequate.
GCP inspectors	Performance might be affected by training and inadequate task assignment.
Clinical report	Evaluators' performance might be influenced by training, clinical evaluation
evaluators	protocols, and inadequate task assignment. There are no guidelines for
	systematic risk/benefit analyses. Some areas at ANVISA seem to have a
	potentially insufficient number of professionals, especially those with
	background in STEM areas.
GMP inspectors	Performance might be influenced by training and inadequate task assignment
	GMP inspections do not consider types of devices, only risk classes (and not all of them).
	Lack of inspectors, especially for medical devices.
Storage/handling	Influenced by protocols and GMP inspections. Storage and handling
resources	requirements seem comprehensive.
Quality control	Influenced by protocols and GMP inspections. GMP requirements seem
	comprehensive.
Device certification	Influenced by personnel, resources, and protocols. Only explicitly indicated
system	standards are mandatory. There are not national standards for every type of
	medical devices.
Technical report	Performance might be influenced by training, technical evaluation
evaluators	protocols, and inadequate task assignment. Low number of professionals
	with STEM background. No guidelines for systematic technology evaluations.

Notes

TRIGGERS FORM

1. List Fundamental Conditions in the *Fundamental Condition* column (one per row);
2. List processes where the fundamental condition might emerge in the *Process* column (one per row);
3. List potential triggers that might occur at the specific process in the *Trigger* column (one per row).

Fundamental Condition	**Process**	**Trigger**
Device has inherently high risk	Clinical	Benefits outweigh risks
	Assessment	Clinical assessment fails to reveal hazards
Failure to reprove clinical report	Clinical Report	No clinical evaluation required
	Evaluation	Clinical report is approved by mistake
Device has faulty parts or design	Manufacturing	Manufacturer employs faulty parts or design
		Parts deteriorate after device is assembled
Failure to reprove technical	Certification	Technical tests fail to reveal faulty parts/
report		design
	Technical report	Technical tests are not required
	evaluation	Technical report is approved by mistake

Notes:

IMMEDIATE RISK FACTORS FORM

1. List Trigger in the *Trigger* column (one per row);
2. List Immediate Risk Factors associated with each trigger in the *Immediate Risk Factors* column.

Trigger	**Immediate Risk Factors**
Benefits outweigh risks	None.*
Clinical assessment fails to reveal hazards	Inadequate GCP inspectors
	Inadequate clinical assessment system****
No clinical evaluation required	None**
Clinical report is approved by mistake	Inadequate clinical report evaluators
Manufacturer employs faulty parts or design	Poor quality control
	Inadequate storage/handling conditions
	Inadequate GMP inspectors
Parts deteriorate after device is assembled	Inadequate storage/handling conditions
	Inadequate GMP inspectors
Tests fail to reveal faulty parts/design	Inadequate technical testing system*****
Technical tests are not required	None***
Technical report is approved by mistake	Inadequate technical report evaluators

Notes:

*Remote factor: RDC 56/2001 indicates some risks might be acceptable in relation to expected bene-

** Remote factor: Inadequate Clinical Assessment Requirements

*** Remote factor: Inadequate technical testing requirements

**** Includes clinical personnel and resources, which are out of the scope

***** Includes technical personnel and resources, which are out of the scope

REMOTE RISK FACTORS FORM

1. List immediate risk factors in the *Lower Factor* column (one per row);
2. List remote risk factors directly associated with them in the *Higher Factor* column (one per row);
3. Copy the remote risk factors to the left column (one per row);
4. List the chained remote factors in higher levels in the right column (one per row);
5. Repeat steps 3 and 4 until there are no more new chained remote factors in higher levels.

Lower Factor	**Higher Factor**
Inadequate GCP inspectors	Inadequate GCP task assignment
	Inadequate GCP training program
Inadequate clinical assessment system	Inadequate assessment protocols
Inadequate GCP inspection assignment	Inadequate professional requirements
Inadequate GCP training program	Inadequate inspection protocols
Inadequate clinical assessment protocols	Inadequate GCP requirements
Inadequate inspection protocols	Inadequate GCP requirements
Inadequate clinical report evaluators	Inadequate report evaluation assignment
	Inadequate training program
Inadequate task assignment	Inadequate professional requirements
Inadequate training program	Inadequate report evaluation protocols
Inadequate report evaluation protocols	Inadequate clinical report eval. requirements
None*	Permitted by regulations
None**	Inadequate clinical assessment requirements
Permitted by regulations	Out of scope
Inadequate professional requirements	Out of scope
Inadequate GCP requirements	Out of scope
Inadequate clinical assessment requirements	Out of scope
Inadequate clinical report eval. requirements	Out of scope

Notes:

-Only the factors associated with clinical assessment

* From trigger: Benefits outweigh risks

** From trigger: No clinical evaluation required

REMOTE RISK FACTORS FORM

1. List immediate risk factors in the *Lower Factor* column (one per row);
2. List remote risk factors directly associated with them in the *Higher Factor* column (one per row);
3. Copy the remote risk factors to the left column (one per row);
4. List the chained remote factors in higher levels in the right column (one per row);
5. Repeat steps 3 and 4 until there are no more new chained remote factors in higher levels.

Lower Factor	Higher Factor
Poor quality control	Inadequate storage/manufacturing protocols
Inadequate storage/handling conditions	Inadequate storage/manufacturing protocols
Inadequate/absent GMP inspectors	Inadequate GMP inspection assignment
	Inadequate training program
	Inadequate manufacturing requirements
Inadequate storage/manufacturing protocols	Inadequate manufacturing requirements
	Inadequate technical standards
Inadequate GMP inspection assignment	Inadequate professional requirements
Inadequate training program	Inadequate manufacturing requirements
Inadequate technical testing system	Inadequate test protocols
Inadequate test protocols	Inadequate technical standards
	Inadequate technical testing requirements
Inadequate technical report evaluators	Inadequate report evaluation assignment
	Inadequate training program
Inadequate report evaluation assignment	Inadequate professional requirements
Inadequate training program	Inadequate evaluation protocols
Inadequate evaluation protocols	Inadequate technical evaluation requirements
None*	Inadequate technical testing requirements
Inadequate technical standards	Out of scope
Inadequate professional requirements	Out of scope
Inadequate manufacturing requirements	Out of scope
Inadequate technical testing requirements	Out of scope
Inadequate professional requirements	Out of scope
Inadequate technical evaluation requirements	Out of scope

Notes:

-Only factors associated with technical assessment

*From trigger: Technical tests not required.

CLASSIFICATION FORM

1. List map elements (condition/trigger, factor) in the *Map Element* column (one per row);
2. Check "C" for *Confirmed* factors, "R" for *Reasonable* factors, and "D" for Dismissed factors;
3. List references to back up the selected status in the *Evidence* column.

Status			Map Element	Evidence
C	R	D		
			(Clinical Assessment)	
	X		Inadequate GCP inspectors	
	X		Inadeq. clinical assessment system	
	X		Inadequate personnel or resources	
	X		Inadequate task assignment	
	X		Inadequate training program	
	X		Inadequate assessment protocols	
	X		Inadeq. professional requirements	
		X	Inadeq. GCP requirements	RDC10/2015: GCP must comply with international standards
X			Benefits outweigh risks (trigger)	RDC 56/2001 admits acceptable risks in relation to benefits
X			Permitted by regulations	As above.
			(Clinical Report Evaluation)	
	X		Inadeq. clinical report evaluators	
	X		Inadequate task assignment	
	X		Inadequate training program	
	X		Inadeq. report evaluation protocols	
	X		Inadeq. professional requirements	
	X		Inadeq. clin. report eval. requirem.	
		X	Inad. clinical assessment requirem.	RDC 56/2001: safety requirements compliance must be
				backed by scientific literature or data from clinical
				investigations
		X	No clinical eval. required (trigger)	As above.

Notes:

Classification criteria:

-'Confirmed' if regulation text supports map element or if other data show instances of the element influencing the system;

-'Dismissed' if regulations seem to prevent the influence of the map element

-'Reasonable' if no data have been found to confirm or dismiss the influence of the element

CLASSIFICATION FORM

1. List map elements (condition/trigger, factor) in the *Map Element* column (one per row);
2. Check "C" for *Confirmed* factors, "R" for *Reasonable* factors, and "D" for Dismissed factors;
3. List references to back up the selected status in the *Evidence* column.

Status			Map Element	Evidence
C	R	D		
	X		(Manufacturing)	
	X		Poor quality control	
	X		Inadeq. storage/handling conditions	
	X		Inadequate GMP inspectors	
	X		Inadeq. storage/manufact. protocols	
	X		Inadequate task assignment	
	X		Inadequate training program	
	X		Inad. professional requirements	
	X		Inad. manufact. requirements	
			(Testing and report evaluation)	
	X		Inadeq. technical testing system	
	X		Inadequate test protocols	
	X		Inadequate technical standards	
	X		Inadeq. personnel or resources	
X			Inad. tech. testing requirements	RDC 27/2011: some requirements might be dismissed
				due to deficiencies in the national testing system
X			Tech. tests not required (trigger)	As above
	X		Inad. technical report evaluators	
	X		Inadequate task assignment	
	X		Inadequate training program	
	X		Inadequate evaluation protocols	
	X		Inad. professional requirements	
	X		Inad. tech. evaluation requirements	

Notes:

Classification criteria:

-'Confirmed' if the regulation text supports map element or if other data show instances of the element influencing the system;

-'Dismissed' if regulations seem to prevent the influence of the map element

-'Reasonable' if no data have been found to confirm or dismiss the influence of the element

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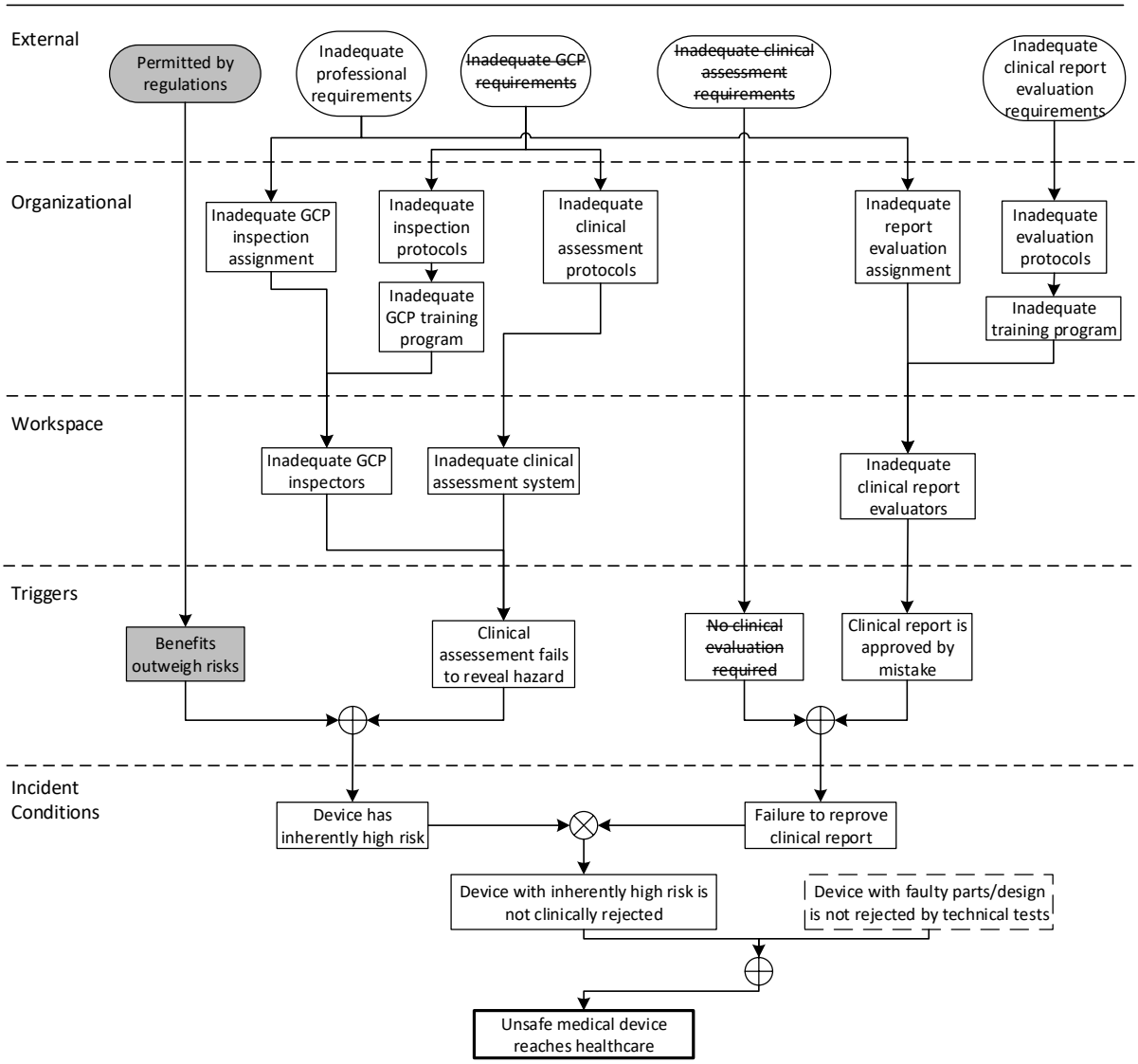
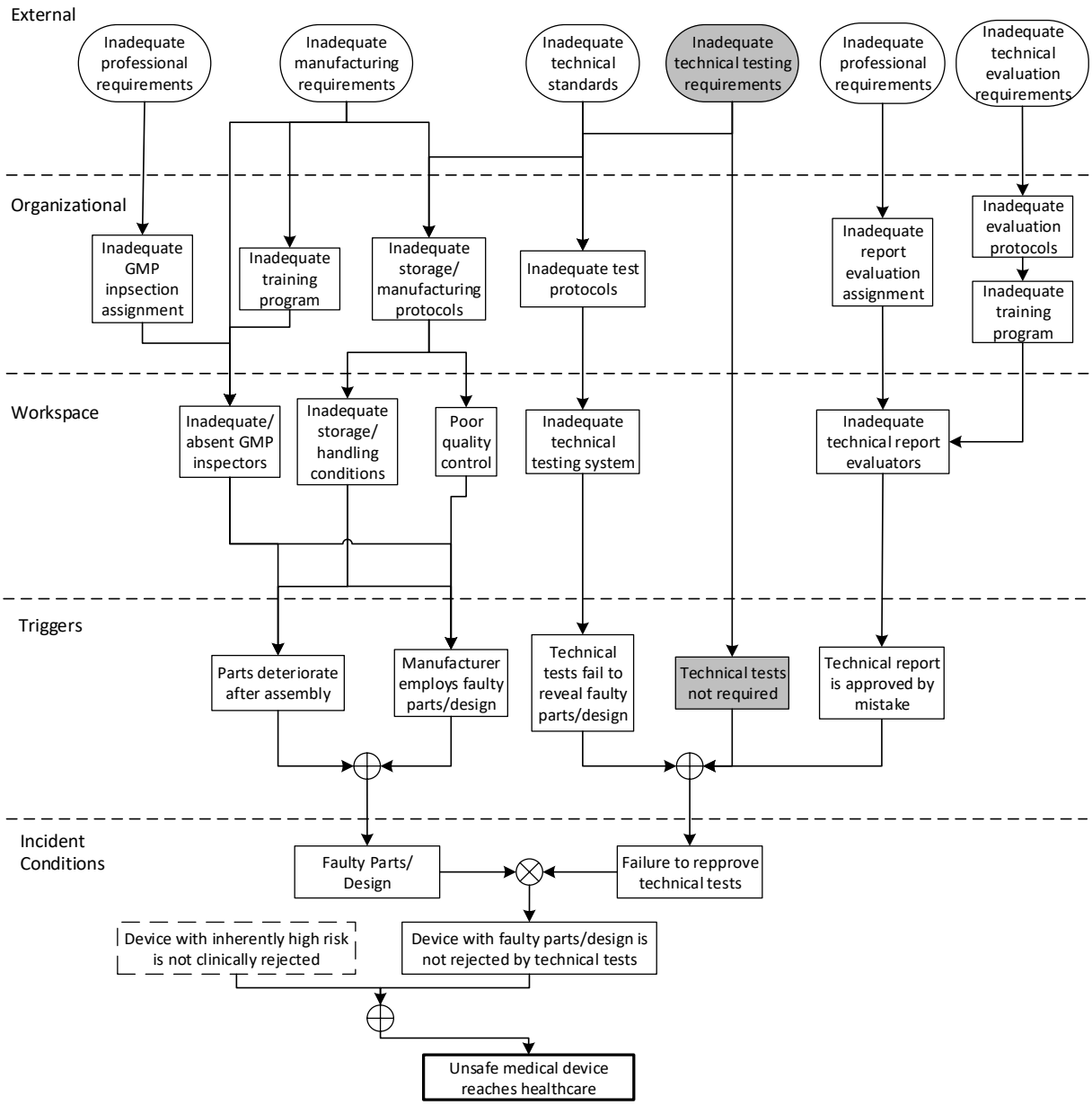

External
Permitted by regulations
Inadequate professional requirements
~~Inadequate GCP requirements~~
~~Inadequate clinical assessment requirements~~
Inadequate clinical report evaluation requirements
Organizational
Inadequate GCP inspection assignment
Inadequate inspection protocols
Inadequate clinical assessment protocols
Inadequate report evaluation assignment
Inadequate evaluation protocols
Inadequate GCP training program
Inadequate training program
Workspace
Inadequate GCP inspectors
Inadequate clinical assessment system
Inadequate clinical report evaluators
Triggers
Benefits outweigh risks
Clinical assessement fails to reveal hazard
~~No clinical evaluation required~~
Clinical report is approved by mistake
Incident Conditions
Device has inherently high risk
Failure to reprove clinical report
Device with inherently high risk is not clinically rejected
Device with faulty parts/design is not rejected by technical tests
Unsafe medical device reaches healthcare


External
Inadequate professional requirements
Inadequate manufacturing requirements
Inadequate technical standards
Inadequate technical testing requirements
Inadequate professional requirements
Inadequate technical evaluation requirements
Organizational
Inadequate GMP inpsection assignment
Inadequate training program
Inadequate storage/ manufacturing protocols
Inadequate test protocols
Inadequate report evaluation assignment
Inadequate evaluation protocols
Inadequate training program
Workspace
Inadequate/ absent GMP inspectors
Inadequate storage/ handling conditions
Poor quality control
Inadequate technical testing system
Inadequate technical report evaluators
Triggers
Parts deteriorate after assembly
Manufacturer employs faulty parts/design
Technical tests fail to reveal faulty parts/design
Technical tests not required
Technical report is approved by mistake
Incident Conditions
Faulty Parts/ Design
Failure to repprove technical tests
Device with inherently high risk is not clinically rejected
Device with faulty parts/design is not rejected by technical tests
Unsafe medical device reaches healthcare

APPENDIX L – CASE 3 DATA

Forms:

-Analysis Information Form

-Process Description Form

-Workspace Description Form

-Triggers Form 1

-Triggers Form 2

-Immediate Risk Factors Form 1

-Immediate Risk Factors Form 2

-Immediate Risk Factors Form 3

-Remote Risk Factors Form 1

-Remote Risk Factors Form 2

-Remote Risk Factors Form 3

-Classification Form 1

-Classification Form 2

-References

Maps:

-Map 1.1

-Map 1.2

-Map 2.1

-Map 2.2

-Map 3

ANALYSIS INFORMATION FORM

Critical Incident (Short name for the Critical Incident):

Inadequate infusion pump delivery

Description (Brief description of the Critical Incident):

Inadequate drug dose delivered to patient by infusion pump.

Analysis Team

Only the PhD candidate.

Keywords (List of keywords for topics associated with the Critical Incident)

inadequate drug dose; patient; infusion pump

References (Main initial references to the topics associated with the Keywords):

Biomedical Engineering Handbooks

International Standards

Academic reviews on smart pump technology

Adverse event reports related to smart pumps

Instructional resources online

Fundamental Conditions (List of Fundamental Conditions for the Critical Incident):

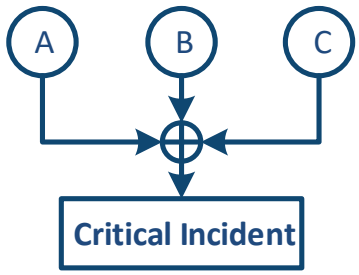
(A) Reduced dose/ No delivery

(B) Increased dose

(C) Rate variation

(Draw logical relations here)

(A+B+C)



Scope (List of restrictions to the analysis):

-Since the focus is on the pumps, patient's allergies, sensitivities or tolerance to drugs will be ignored. Also exclude drug-related problems not associated with device operation (e.g., pharmacy problems);

-Focus on peristaltic infusion pumps, which are much more common than smart pumps.

-Ignore wrong drug cases, except if caused by IV line mix-up at the bed

Notes

Analysis of a generic risk factors map

Infusion pumps appeared in several of the latest ECRI's Top 10 Health Technology Hazards issues

PROCESS DESCRIPTION FORM

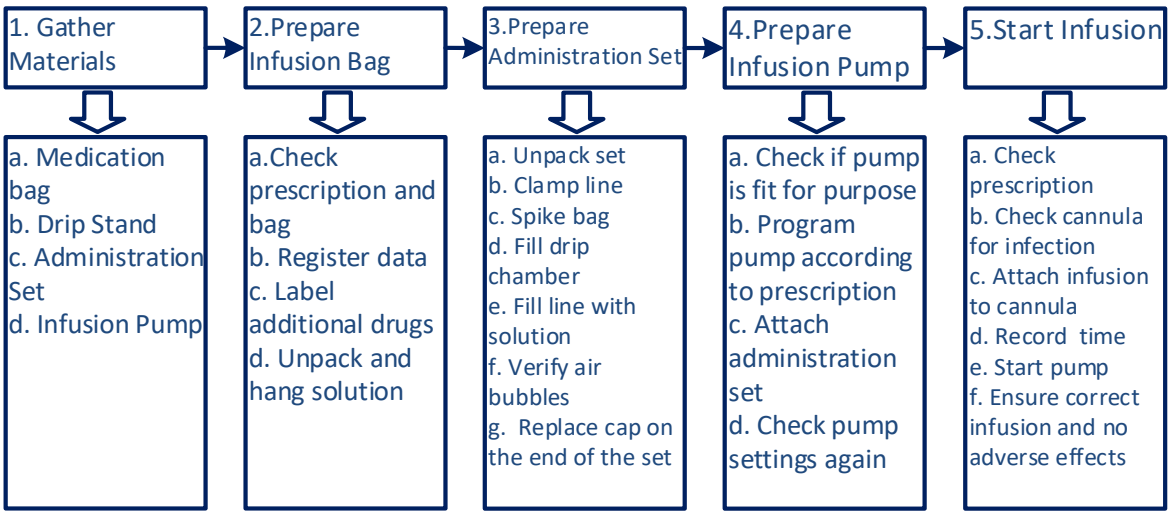
Process Name (name of process potentially associated with the critical incident)**:**

Set up an infusion with an infusion pump.

Description (general description of the process)**:**

Professionals gather the necessary elements for a medication infusion, prepare the infusion bag, the administration set, the infusion pump, and then start the infusion, making sure it started correctly.

Subprocess (part of the process)	**Elements Involved** (list the elements involved in each subprocess: consider device, facility, patient, team, supply, and environment components):
Gather Materials	professionals, drip stand, medication bag, administration set, infusion
	pump, facility, prescription, other drugs, patient
Prepare medication	professionals, drip stand, medication bag, facility, prescription, other drugs,
bag	patient
Prep. administration	professionals, administration set, medication bag, facility
set	
Prep. Infusion pump	professionals, administration set, infusion pump, prescription, power
	outlets, facility
Start infusion	prescription, cannula, administration set, infusion pump, patient, facility



(Draft process here)

Notes

WORKSPACE DESCRIPTION FORM

1. List elements involved in the subprocesses in the *Element* column. Place a new element after the previous description.
2. Write a general description of the kind of element in the *Description* column. Use as many rows as necessary.

Element	Description
professionals	high workload, distracted, improper training/experience, deficient
	communication, fatigue
drip stand	inadequate height, inadequate pump support
medication bag	label legibility, multiple medication bags, inadequate infusion portal
administration set	no differentiation (multiple sets), inadequate dimensions, material resistance,
	drip chamber inclination, inadequate inlet (spike), set design
infusion pump	poor usability, lack of safety features, inadequate accuracy, EMI
	susceptibility, absent/discharged battery, display legibility, complex menus,
	multiple pump models (standardization), resetting behavior, terminology,
	mounting stability, faulty software, faulty hardware/components,
	scarcity, alarm problems, lack of maintenance,
prescription	prescription legibility
patient	ability to comply, patient conditions
facility	noise, poor lighting, power fluctuations

Notes

TRIGGERS FORM

1. List Fundamental Conditions in the *Fundamental Condition* column (one per row);
2. List processes where the fundamental condition might emerge in the *Process* column (one per row);
3. List potential triggers that might occur at the specific process in the *Trigger* column (one per row).

Fundamental Condition	Process	Trigger
Reduced Dose/No Delivery	Prepare Inf. Bag	Infusion bag not spiked
		Improper bag height
	Prepare Adm. Set	Improper clamp positioning
		Kinked tubing
		Improper delivery of multiple drugs (single access)
		Infusate leakage
		Misconnection
		Inclined drip chamber
	Prepare Inf. Pump	Misprogramming
		Tubing switch
	Start Infusion	Occlusion of pump intake
		Tampering (patient/family)
		Device malfunction
		Resetting behavior
		EMI/supply voltage error
		Power/battery failure
		Drug reservoir detachment
		Administration set variation
Increased dose	Prepare Adm. Set	Inclined drip chamber
	Prepare Inf. Pump	Misprogramming
		Tubing switch
	Start Infusion	Administration set variation
		Tampering (patient/family)
		Device malfunction
		Delay in corrections/adjustments
		Too many bolus requests
		Resetting behavior
		EMI/supply voltage error

Notes:

(1 of 2)

TRIGGERS FORM

1. List Fundamental Conditions in the *Fundamental Condition* column (one per row);
2. List processes where the fundamental condition might emerge in the *Process* column (one per row);
3. List potential triggers that might occur at the specific process in the *Trigger* column (one per row).

Fundamental Condition	Process	Trigger
Right dose, wrong rate	Prepare adm. Set	Improper delivery of multiple drugs (single access)
	Prepare inf. Pump	Misprogramming
	Start infusion	Device malfunction
		Delay in corrections/adjustments
		Post-occlusion bolus
		Resetting behavior
		Uneven bolus delivery by the pump

Notes:

(2 of 2)

IMMEDIATE RISK FACTORS FORM

1. List triggers in the *Trigger* column (one per row);
2. List Immediate Risk Factors associated with each trigger in the *Immediate Risk Factors* column.

Trigger	Immediate Risk Factors
Delay in corrections/adjustments	deficient communication
Delay in corrections/adjustments	distracted
Delay in corrections/adjustments	noise
Delay in corrections/adjustments	workload
Device malfunction	EMI susceptibility
Device malfunction	faulty hardware
Device malfunction	faulty software
Device malfunction	inadequate maintenance
Device malfunction	power fluctuations
Drug reservoir detachment	ability to comply
Drug reservoir detachment	distracted
Drug reservoir detachment	inadequate infusion bag
Drug reservoir detachment	inadequate infusion set
EMI/supply voltage error	ability to comply
EMI/supply voltage error	distracted
EMI/supply voltage error	EMI susceptibility
EMI/supply voltage error	power fluctuations
EMI/supply voltage error	training
Improper bag height	drip stand height
Improper bag height	training
Improper clamp positioning	distracted
Improper clamp positioning	fatigue
Improper clamp positioning	inadequate infusion set
Improper clamp positioning	lighting
Improper clamp positioning	training
Improper multiple drug delivery	patient conditions
Improper multiple drug delivery	poor pump usability
Improper multiple drug delivery	scarcity
Improper multiple drug delivery	training
Improper multiple drug delivery	workload
Inclined drip chamber	drip stand height
Inclined drip chamber	inadequate pump support
Inclined drip chamber	training

Notes:

-"inadequate infusion set" is a combination of poor set design and materials

-"training" is a combination of experience and training in device operation and procedure protocols

-"poor pump usability" includes hardware and software usability problems (e.g., irresponsive controls and complex menus)

IMMEDIATE RISK FACTORS FORM

1. List Trigger in the *Trigger* column (one per row);
2. List Immediate Risk Factors associated with each trigger in the *Immediate Risk Factors* column.

Trigger	Immediate Risk Factors
Infusate leakage	ability to comply
Infusate leakage	inadequate infusion bag
Infusate leakage	inadequate infusion set
Infusate leakage	training
Infusion bag not spiked	distracted
Infusion bag not spiked	fatigue
Infusion bag not spiked	inadequate infusion bag
Infusion bag not spiked	inadequate infusion set
Infusion bag not spiked	workload
Infusion set variation	ability to comply
Infusion set variation	faulty hardware
Infusion set variation	inadequate infusion set
Infusion set variation	training
Infusion set variation	workload
Kinked tubing	ability to comply
Kinked tubing	drip stand height
Kinked tubing	inadequate pump support
Kinked tubing	training
Misconnection	ability to comply
Misconnection	distracted
Misconnection	fatigue
Misconnection	inadequate infusion set
Misconnection	training
Misconnection	workload
Misprogramming	ability to comply
Misprogramming	display legibility
Misprogramming	distracted
Misprogramming	fatigue
Misprogramming	label legibility
Misprogramming	lack of safety features
Misprogramming	lighting
Misprogramming	multiple pump models
Misprogramming	poor pump usability
Misprogramming	prescription legibility
Misprogramming	terminology
Misprogramming	training
Misprogramming	workload

Notes:

-"poor pump usability" includes hardware and software usability problems (e.g., irresponsive controls and complex menus)

IMMEDIATE RISK FACTORS FORM

1. List Trigger in the *Trigger* column (one per row);
2. List Immediate Risk Factors associated with each trigger in the *Immediate Risk Factors* column.

Trigger	Immediate Risk Factors
Occlusion of pump intake	inadequate infusion bag
Occlusion of pump intake	inadequate infusion set
Occlusion of pump intake	training
Post-occlusion bolus	distracted
Post-occlusion bolus	faulty hardware
Post-occlusion bolus	training
Power/battery failure	faulty/discharged battery
Power/battery failure	faulty hardware
Power/battery failure	inadequate maintenance
Power/battery failure	power fluctuations
Resetting behavior	faulty software
Resetting behavior	inadequate maintenance
Resetting behavior	training
Tampering (patient/family)	ability to comply
Tampering (patient/family)	deficient communication
Too many bolus requests	ability to comply
Too many bolus requests	deficient communication
Too many bolus requests	distracted
Too many bolus requests	training
Tubing switch	distracted
Tubing switch	fatigue
Tubing switch	inadequate infusion set
Tubing switch	lighting
Tubing switch	no set differences
Tubing switch	workload
Uneven bolus delivered by pump	EMI susceptibility
Uneven bolus delivered by pump	faulty hardware
Uneven bolus delivered by pump	faulty software

Notes:

(3 of 3)

REMOTE RISK FACTORS FORM

1. List immediate risk factors in the *Lower Factor* column (one per row);
2. List remote risk factors directly associated with them in the *Higher Factor* column (one per row);
3. Copy the remote risk factors to the left column (one per row);
4. List the chained remote factors in higher levels in the right column (one per row);
5. Repeat steps 3 and 4 until there are no more new chained remote factors in higher levels.

Lower Factor	Higher Factor
ability to comply	inadequate patient management protocols
faulty/discharged battery	inadequate maintenance protocols
faulty/discharged battery	inadequate supervision
deficient communication	communication protocols
display legibility	inadequate technical specifications
display legibility	inadequate quality control
distracted	not further evaluated
drip stand height	inadequate design specifications
drip stand height	inadequate acquisition assessment
EMI susceptibility	inadequate technical specifications
fatigue	not further evaluated
faulty hardware	inadequate quality control
faulty hardware	inadequate technical specifications
faulty software	inadequate quality control
faulty software	inadequate software specifications
inadequate infusion bag	inadequate design specifications
inadequate infusion bag	inadequate quality control
inadequate infusion bag	inadequate acquisition assessment
inadequate infusion set	inadequate quality control
inadequate infusion set	inadequate design specifications
inadequate infusion set	inadequate acquisition assessment
inadequate infusion set	inadequate device management
inadequate maintenance	inadequate maintenance protocols
inadequate maintenance	inadequate device management
inadequate maintenance	inadequate supervision
inadequate pump support	inadequate design specifications
inadequate pump support	inadequate acquisition assessment
inadequate pump support	inadequate maintenance protocols

Notes:

REMOTE RISK FACTORS FORM

1. List immediate risk factors in the *Lower Factor* column (one per row);
2. List remote risk factors directly associated with them in the *Higher Factor* column (one per row);
3. Copy the remote risk factors to the left column (one per row);
4. List the chained remote factors in higher levels in the right column (one per row);
5. Repeat steps 3 and 4 until there are no more new chained remote factors in higher levels.

Lower Factor	Higher Factor
label legibility	inadequate label templates
lack of safety features	inadequate safety specifications
lack of safety features	inadequate acquisition assessment
lighting	inadequate facility management
multiple pump models	lack of model standardization
no set differences	inadequate safety protocols
no set differences	inadequate acquisition assessment
noise	inadequate training protocols
noise	inadequate facility management
patient conditions	not further evaluated
poor pump usability	inadequate usability specifications
poor pump usability	inadequate acquisition assessment
power fluctuations	inadequate grid management
power fluctuations	inadequate power supply
prescription legibility	inadequate prescription templates
prescription legibility	inadequate device management
scarcity	inadequate device management
terminology	non standardized terminology
terminology	inadequate training protocols
training	inadequate training protocols
training	inadequate task assignment
training	inadequate training program
workload	insufficient professionals
workload	inadequate task assignment

Notes:

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REMOTE RISK FACTORS FORM

1. List immediate risk factors in the *Lower Factor* column (one per row);
2. List remote risk factors directly associated with them in the *Higher Factor* column (one per row);
3. Copy the remote risk factors to the left column (one per row);
4. List the chained remote factors in higher levels in the right column (one per row);
5. Repeat steps 3 and 4 until there are no more new chained remote factors in higher levels.

Lower Factor	Higher Factor
inadequate acquisition assessment	bidding legislation*
inadequate communication protocols	not further evaluated
inadequate design specifications	technical requirements - devices*
inadequate design specifications	technical standards - devices*
inadequate device management	not further evaluated
inadequate external power supply	not further evaluated
inadequate facility management	not further evaluated
inadequate grid management	technical requirements - facility*
inadequate grid management	technical standards - facility*
inadequate label templates	safety requirements*
inadequate maintenance protocols	technical requirements - devices*
inadequate maintenance protocols	technical standards - devices*
inadequate patient management protocols	safety requirements*
inadequate prescription templates	prescription standards*
inadequate quality control	quality standards*
inadequate safety protocols	safety requirements*
inadequate safety specifications	technical requirements - devices*
inadequate safety specifications	technical standards - devices*
inadequate software specifications	software requirements*
inadequate supervision	not further evaluated
inadequate task assignment	job requirements*
inadequate technical specifications	technical standards - devices*
inadequate training program	job requirements*
inadequate training protocols	not further evaluated
inadequate usability specifications	usability requirements*
insufficient professionals	not further evaluated
lack of model standardization	not further evaluated
non standardized terminology	technical standards - devices*
inadequate power supply	not further evaluated

Notes:

*End-of-chain factors are not further evaluated.

CLASSIFICATION FORM

1. List map elements (condition/trigger, factor) in the *Map Element* column (one per row);
2. Check "C" for *Confirmed* factors, "R" for *Reasonable* factors, and "D" for Dismissed factors;
3. List references to back up the selected status in the *Evidence* column.

Status			Map Element	Evidence
C	R	D		
	X		ability to comply	AAMI, 2010
	X		faulty/discharged battery	FDA, 2018
	X		deficient communication	McCabe, 2004
	X		display legibility	AAMI, 2010, p.23
	X		distracted	Beyea, 2007
	X		drip stand height	Voss & Butterfield, 2015
	X		EMI susceptibility	BS EN 60601-1-2 2007
	X		fatigue	Owens, 2007
	X		faulty hardware	FDA's *Medical Device Recalls*
	X		faulty software	FDA's *Medical Device Recalls*
	X		inadequate infusion bag	MAUDE - "Container, I.V."
	X		inadequate infusion set	Wollitz & Grissinger, 2014
	X		inadequate maintenance	Jamshidi et al., 2014
	X		inadequate pump support	Halls, 2010
	X		label legibility	Thimbleby, 2010
	X		lack of safety features	AAMI, 2010
	X		lighting	Figueiro et al., 2006
	X		multiple pump models	AAMI, 2010
	X		no set differences	Halls, 2010
	X		noise	Morrison, 2003
	X		patient conditions	AAMI, 2010
	X		poor pump usability	AAMI, 2010
	X		power fluctuations	BS EN 60601-1-2 2007
	X		prescription legibility	Thimbleby, 2010
	X		scarcity	Nunnally & Bitan, 2006
	X		terminology	AAMI, 2010
	X		training	AAMI, 2010
	X		workload	Christian et al., 2006

Notes:

Criteria: because it is a generic risk factors map based on the literature, all factors are considered *reasonable*. Factors would be classified as *dismissed* only if no reference to their influence on the socio-technical system could be found.

CLASSIFICATION FORM

1. List map elements (condition/trigger, factor) in the *Map Element* column (one per row);
2. Check "C" for *Confirmed* factors, "R" for *Reasonable* factors, and "D" for Dismissed factors;
3. List references to back up the selected status in the *Evidence* column.

Status			Map Element	Evidence
C	R	D		
	X		inadequate acquisition assessment	AAMI, 2010
	X		inadequate communication protocols	Donchin et al., 1995
	X		inadequate design specifications	Halls, 2010
	X		inadequate device management	Halls, 2010
	X		inadequate external power supply	Bendre et al., 2004
	X		inadequate facility management	Elias & Calil, 2014
	X		inad. internal power grid management	Hartungi & Jiang, 2010
	X		inadequate label templates	Thimbleby, 2010
	X		inadequate maintenance protocols	Jamshidi et al., 2014
	X		inadeq. patient management protocols	McCabe, 2004
	X		inadequate prescription templates	Thimbleby, 2010
	X		inadequate quality control	FDA's *Medical Device Recalls*
	X		inadequate safety protocols	AAMI, 2010
	X		inadequate safety specifications	FDA's *Medical Device Recalls*
	X		inadequate software specifications	FDA's *Medical Device Recalls*
	X		inadequate supervision	Gawande et al., 2003
	X		inadequate task assignment	Gawande et al., 2003
	X		inadequate technical specifications	FDA's Medical Device Recalls
	X		inadequate training program	AAMI, 2010
	X		inadequate training protocols	AAMI, 2010
	X		inadequate usability specifications	Halls, 2010
	X		insufficient professionals	Herout & Erstad, 2004
	X		lack of model standardization	AAMI, 2010
	X		non standardized terminology	AAMI, 2010
	X		bidding legislation	*
	X		job requirements	*
	X		prescription standards	*
	X		quality standards	*
	X		safety requirements	*
	X		software requirements	*
	X		technical requirements - devices	*
	X		technical requirements - facility	*
	X		technical standards - devices	*
	X		technical standards - facility	*
	X		usability requirements	*

Notes:

Criteria: because it is a generic risk factors map based on the literature, all factors are considered *reasonable.* Factors would be classified as *dismissed* only if no reference to their influence on the socio-technical system could be found.

*Remote factors at the *External* level are all classified as reasonable too because the analysis of legislation and standards is out of the scope of this study.

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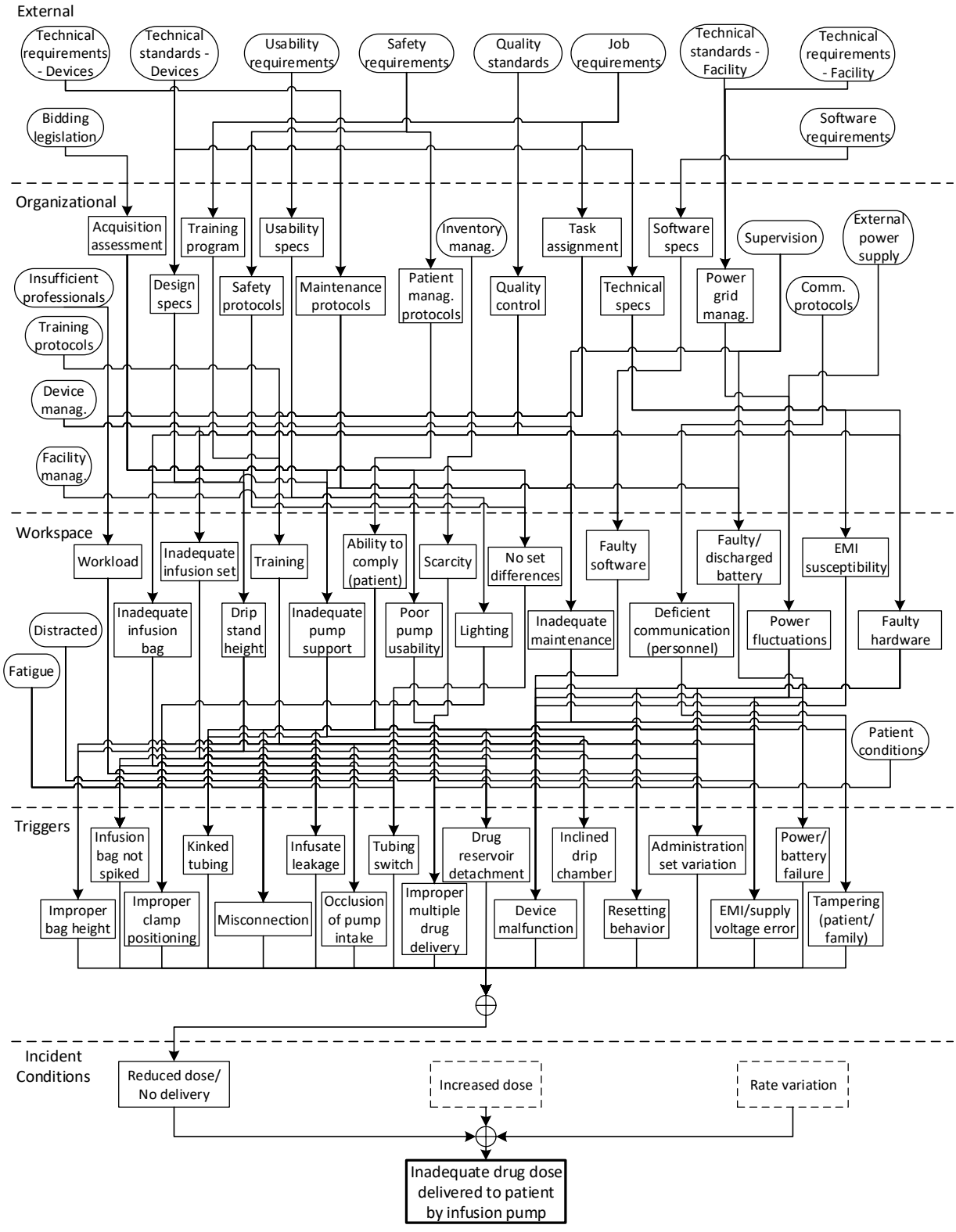
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Usability specs
Inventory manag.
Task assignment
Software specs
Supervision
External power supply
Insufficient professionals
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Maintenance protocols
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Facility manag.
Workspace
Workload
Inadequate infusion set
Training
Ability to comply (patient)
Scarcity
No set differences
Faulty software
Faulty/ discharged battery
EMI susceptibility
Distracted
Fatigue
Inadequate infusion bag
Drip stand height
Inadequate pump support
Poor pump usability
Lighting
Inadequate maintenance
Deficient communication (personnel)
Power fluctuations
Faulty hardware
Patient conditions
Triggers
Infusion bag not spiked
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Infusate leakage
Tubing switch
Drug reservoir detachment
Inclined drip chamber
Administration set variation
Power/ battery failure
Improper bag height
Improper clamp positioning
Misconnection
Occlusion of pump intake
Improper multiple drug delivery
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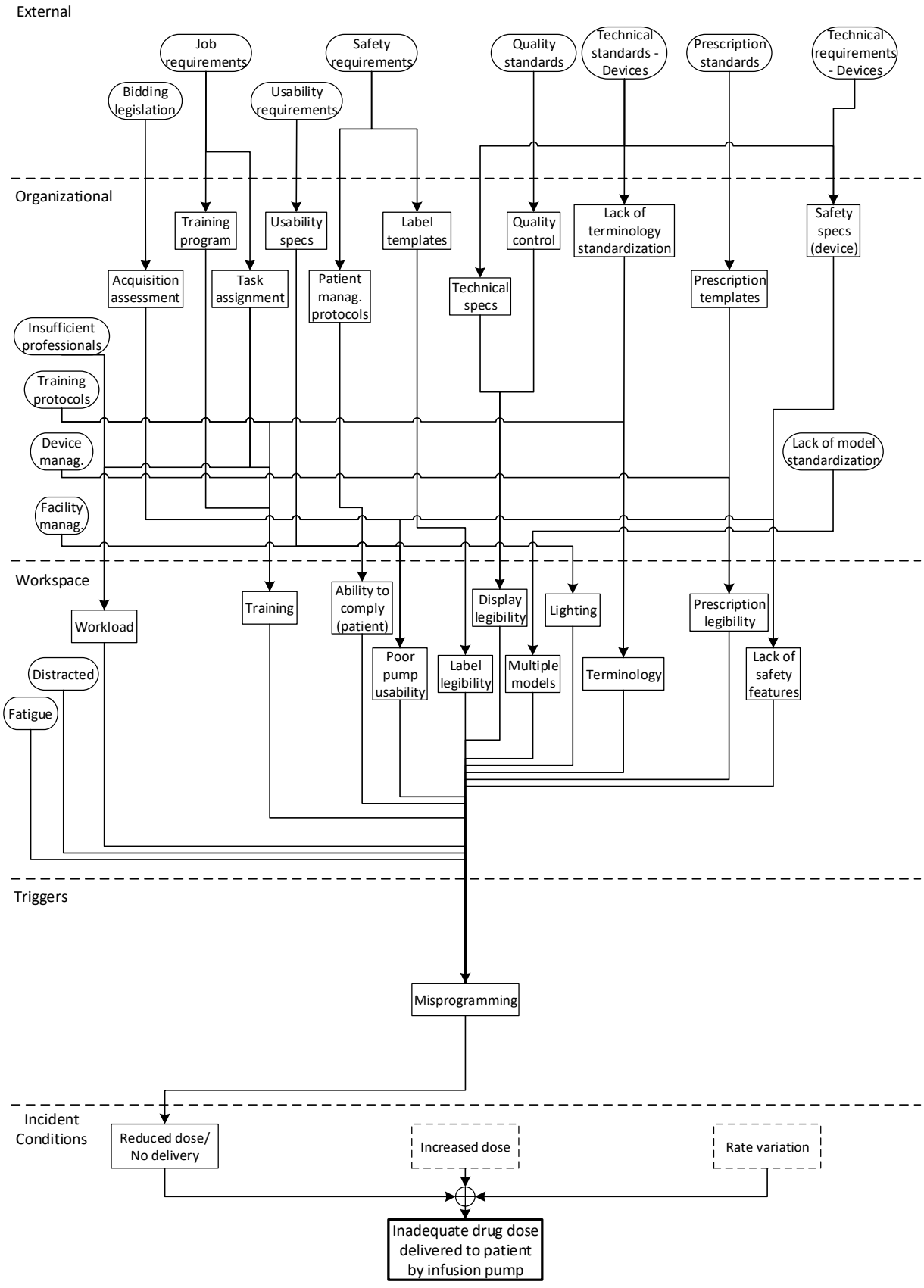
Reduced dose/ No delivery
Increased dose
Rate variation
Inadequate drug dose delivered to patient by infusion pump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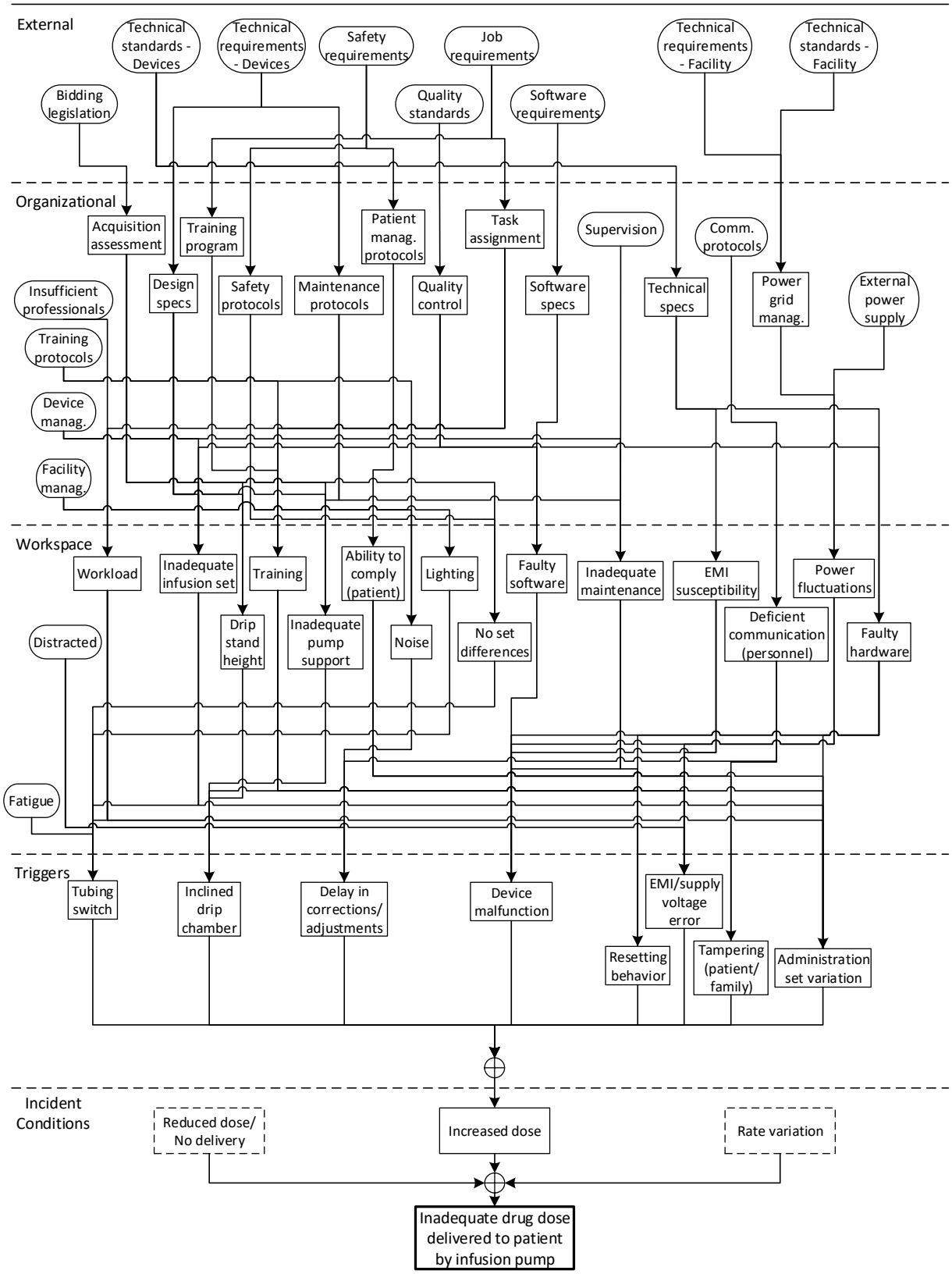
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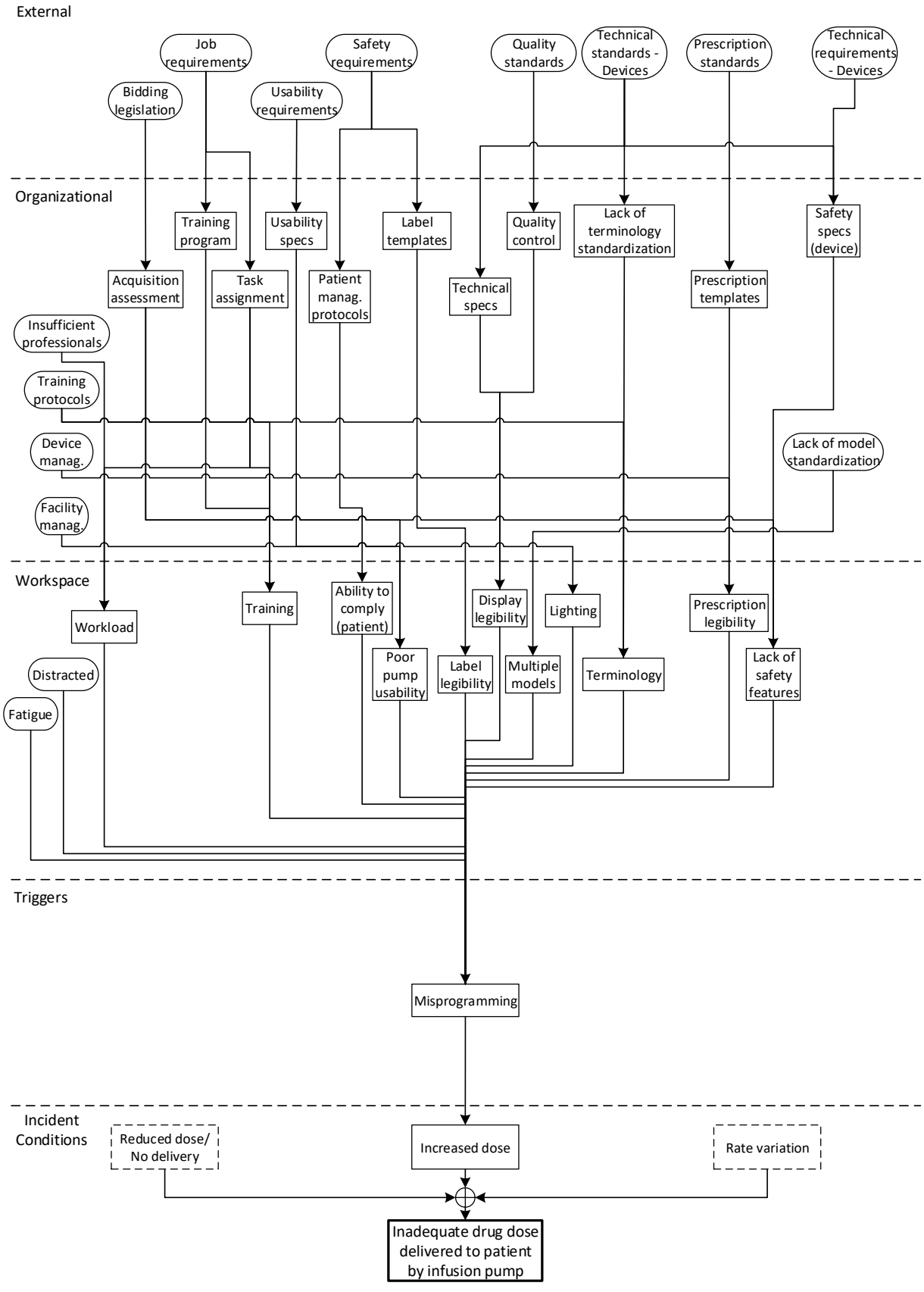
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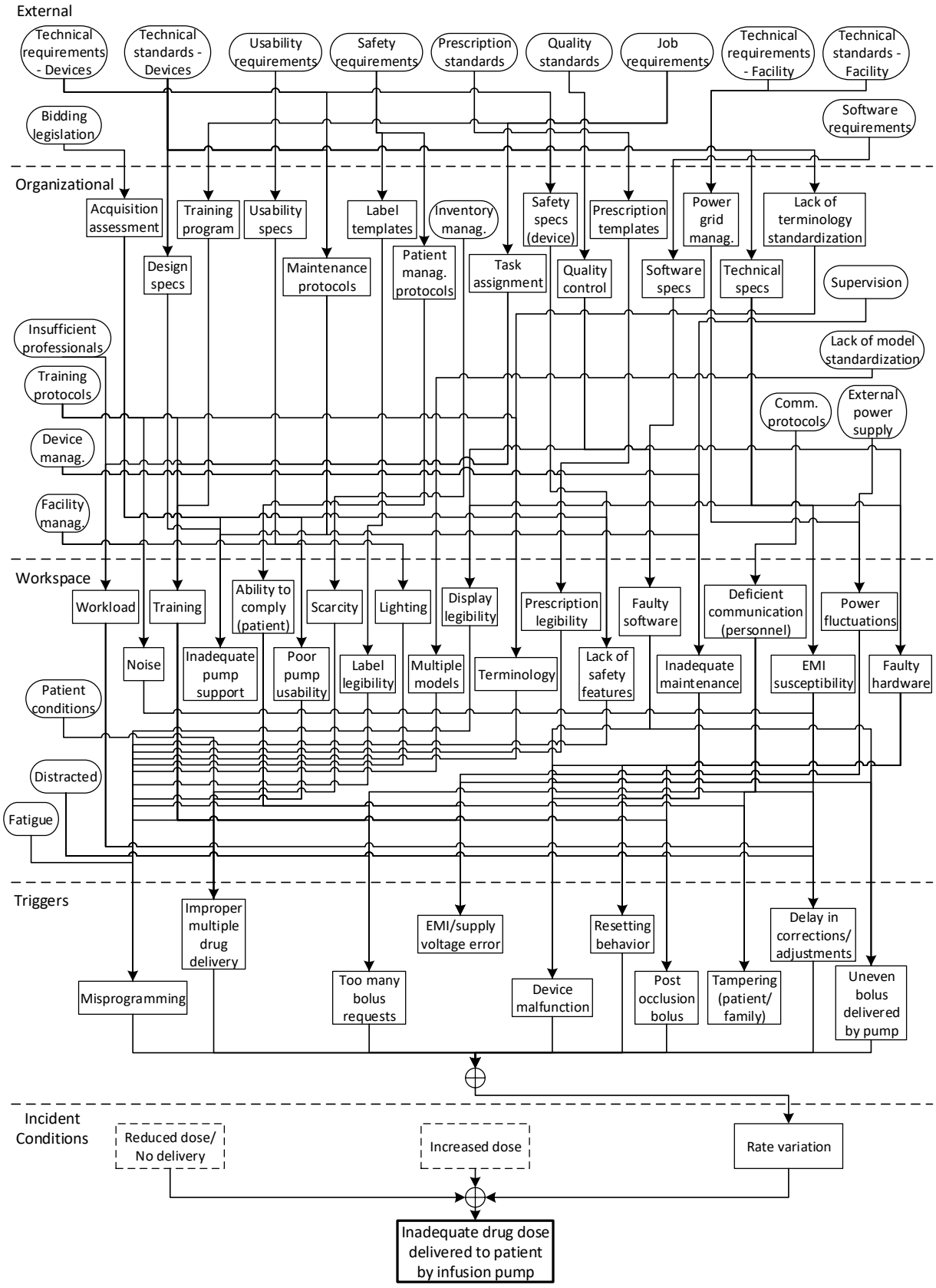
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Post occlusion bolus
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Rate variation
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