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How can health care organisations make and justify decisions about risk reduction? Lessons from a cross-industry review and a health care stakeholder consensus development process

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ABSTRACT

Interventions to reduce risk often have an associated cost. In UK industries decisions about risk reduction are made and justified within a shared regulatory framework that requires that risk be reduced as low as reasonably practicable. In health care no such regulatory framework exists, and the practice of making decisions about risk reduction is varied and lacks transparency. Can health care organisations learn from relevant industry experiences about making and justifying risk reduction decisions? This paper presents lessons from a qualitative study undertaken with 21 participants from five industries about how such decisions are made and justified in UK industry. Recommendations were developed based on a consensus development exercise undertaken with 20 health care stakeholders. The paper argues that there is a need in health care to develop a regulatory framework and an agreed process for managing explicitly the trade-off between risk reduction and cost. The framework should include guidance about a health care specific notion of acceptable levels of risk, guidance about standardised risk reduction interventions, it should include regulatory incentives for health care organisations to reduce risk, and it should encourage the adoption of an approach for documenting explicitly an organisation's risk position.

1. Introduction

For the past 15 years improving patient safety has been a national priority in many countries [1,2], while well publicised scandals such as the failings at Mid Staffordshire NHS Foundation Trust [3] and previously at Bristol Royal Infirmary [4] have contributed to increasing the public concern about the safety and quality of health care provision. Many of the frequently suggested patient safety improvements and risk reduction interventions carry an associated cost, such as increasing the number of nursing staff or the introduction of electronic prescribing systems [5]. National health care systems, such as the National Health Service (NHS) in England, are operating in an extremely difficult financial climate [6]. Therefore, health care organisations need to make decisions about whether or not to invest effort and resource in understanding and reducing risks to patient safety, i.e. organisations need to manage – implicitly or explicitly – the trade-off between risk reduction and the associated costs.

At present, health care regulators and health care organisations lack clear guiding principles for how such trade-offs should be managed, and how decisions about patient safety improvements and risk reduction interventions should be taken and justified [7]. Decisions about whether to invest in risk reduction are often taken implicitly, and practice is, therefore, variable and dependent on individuals or local patient safety improvement teams [8]. Box 1 provides a brief real-world vignette from the Safer Clinical Systems programme [8].

In UK safety-critical industries, such as the petrochemical and nuclear industries, decision-makers are faced with similar problems of having to manage the trade-off between risk reduction and associated cost [9]. However, in these industries decision-making about risk reduction is embedded in a strong regulatory framework [10]. Trade-

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Box 1.Cost-Safety Trade-Offs in a Renal Surgery Safety Improvement Example.

Ninety-nine risks were identified for shared care of patients undergoing surgery on a renal unit.	A hospital aimed to improve the safety of shared care arrangements between the renal medicine team and the surgical team for patients with Established Renal Failure. The local improvement team used Failure Mode, Effects and Criticality Analysis (FMECA) to understand the vulnerabilities of their current process. The team identified 99 hazards and associated risks. These included, for example, absence of medical review by a senior doctor pre-operatively, no documented surgical plan pre-operatively, and documented surgical review not provided post-operatively. The improvement team decided to work on the six highest-ranking risks.
Questions remain about which risks should be addressed and how much money should be spent.	This decision was taken based on practicality: the resources and time available, and the control the local team had over the proposed improvements. However, the team did not have guidance available for important questions such as: What level of risk is acceptable and how would the team determine such a level? Is there an ethical duty to reduce all identified risks or is it appropriate to focus only on a sub-set? How much money should be spent on risk reduction and how would this be determined?

offs between reducing risk and the associated costs are made explicitly within the context of the concept of "reasonable practicability" [11]. This concept is used to demonstrate that risks have been controlled effectively to a point where the cost of further risk reduction would be grossly disproportionate to the expected benefits (As low as reasonable practicable – ALARP) [12]. Affordability of risk reduction interventions is not a consideration in the ALARP justification. The trade-offs and justifications are documented in a safety case, which can be reviewed and challenged by the regulator [7].

In practice, making such decisions can be difficult, and practical problems with the ALARP concept have been highlighted [13–15]. More generally, the concept of risk has been framed and discussed from different perspectives in the literature, and there is no single or agreed definition of risk [16]. Detailed theoretical discussions of the risk concept are provided, for example, in [16–19]. While risk has often been regarded as something calculable or as an objective reality, there are other views that emphasise the dynamic and social dimension of risk [20–22]. In health care the unique perspective of the patient should also be considered, and it has been suggested that in this context risk might best be understood as something personal that needs to be discussed and negotiated between the patient and health care professionals [23]. Therefore, the question of whether a system or a health care service is safe enough, should not be decided based on the, usually, probabilistic analysis of risk alone, but rather through a process that takes into account both the scientific evidence as well as other value judgements [15,24].

Health care organisations and national health systems have been encouraged to learn lessons from other industries in order to improve their safety management systems and safety performance [25], for example through the introduction of incident reporting systems [26], the use of proactive hazard identification methods [27], or the adoption of aviation-style checklists to manage safety-critical tasks [28]. Learning from industry is a reasonable suggestion [29], but the successful transfer of lessons from industry to health care often proves to be challenging in practice [7,30]. For example, there is a wealth of literature discussing the perceived failures of incident reporting systems in health care [31–34] and the practical problems associated with the implementation of checklists [35,36]. Owing to the different organisational, institutional and cultural context in health care lessons from industry need to be transferred with caution, and tools and methods have to be adapted appropriately [8]. Failure to understand properly the underpinnings, benefits and limitations of tools and methods within their original industrial context might limit their utility in health care [37] or even contribute to increasing risk to patients [30].

In order to facilitate learning and the transfer of lessons from industry about how decisions about risk reduction and the associated costs are made and justified, it is important, therefore, to study how such trade-offs are made in practice in different industries, and to reflect on how corresponding tools, methods and frameworks might be adapted within a health care context. The paper describes stakeholder views on the practice of managing the trade-off between risk reduction and cost in five UK industries. The analysis of these industry perspectives provided the starting point for a consensus development process with health care stakeholders about potential lessons for health care. Based on this consensus development process the paper argues that there is a need in health care to develop a regulatory framework and an agreed process for managing explicitly the trade-off between risk reduction and cost. Such a framework should include guidance about a health care specific notion of acceptable levels of risk and standardised risk reduction interventions. It should also provide regulatory incentives for health care organisations to reduce risk. In order to complement and integrate with existing business cases, this framework should encourage the adoption of an approach for documenting explicitly an organisation's risk position, for example through the use of safety cases.

The paper is organised as follows: Section 2 describes the research design, and the methods for data collection and data analysis. Section 3 presents key themes from the analysis of interviews with industry stakeholders. Section 4 outlines the lessons from the health care stakeholder consensus development. Section 5 discusses the findings of the study with a view to the existing literature. Implications for policy and practice are provided in the concluding Section 6.

2. Methods

The study included two main components: a qualitative analysis of UK industry stakeholder perceptions on how decisions about risk reduction and the associated costs are made in practice, and a consensus development process with health care stakeholders to identify lessons for health care.

2.1. Setting

The five safety-critical UK industries included in the study were: aviation, defence, nuclear, petrochemical and transportation (rail and road). These industries were selected because (a) the research team had pre-existing links to stakeholders as well as personal experience of