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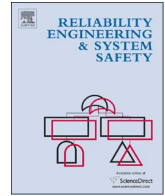
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How can health care organisations make and justify decisions about risk reduction? Lessons from a cross-industry review and a health care stakeholder consensus development process



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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.

Questions remain about which risks should be addressed and how much money should be spent.

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.

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

Table 1
Study participants.

Industry interviews		Health care consensus development process
Sector	Role	Role
Aviation	EU Regulations Impact Assessor Head of Air Transport System Operations Planning Unit (Air Traffic Management) Project Manager Safety (Regulator) Change and Safety Manager (Airport)	Chief Executive Clinical Director for Patient Safety Quality and Safety Manager Medical Director
Defence	Safety Engineer Safety Manager Safety Policy Manager Aircraft Design Standards Manager Safety Case Reviewer (Air Traffic Equipment)	Chief Nurse Head of Patient Safety Policy and Strategy Technical Claims Manager Senior Policy Advisor Director of Nursing
Nuclear	Design Authority Manager (Nuclear service provider) Lead Assessor (Regulator) Systems Engineer (Nuclear service provider) Independent Nuclear Safety Consultant	Clinical Improvement Network Director Senior Consultant Medical Director Consultant in Anaesthesia and Intensive Care Medicine
Process	Mechanical Engineer Process Safety (Consultant) Safety Superintendent (Oil refinery) Process Safety Manager (Chemicals manufacturing facility) Chemical Engineer (Regulator)	Director of Programmes Consultant in Acute Medicine Deputy Director of Risk, Governance and Patient Safety Consultant Paediatrician Director of Clinical Effectiveness
Rail and Road	Signalling Design Manager (Railway infrastructure provider) Head of Evaluations (Railway) Head of Road Economics	Lead Nurse in Acute Care Executive Clinical Director

working in these industries, and (b) safety assessments and corresponding trade-offs between risk reduction and cost are particularly relevant in safety-critical industries.

The consensus development process was not limited to any specific health care setting, but aimed to include views from a diverse range of health care stakeholders.

2.2. Semi-structured interviews

Industry stakeholder perceptions were elicited through semi-structured interviews. Interviews were conducted with a purposive sample of 21 participants during July – October 2014. Participants were sampled based on the industry they work in to ensure roughly equal spread across industries, and based on their involvement with safety or finance. Table 1 provides an overview of interview participants by industry and job role.

Participants received a participant information leaflet, and provided written consent prior to their involvement. Participation was voluntary, and participants were free to withdraw at any time. Interviews lasted between 30 and 50 min, and were carried out by different members of the research team who are experts in the respective industry. Interviews were audio recorded if the participant provided consent to this. Audio recordings were then transcribed verbatim. Any identifiers were removed to preserve anonymity.

The interviews explored the topics from the interview template shown in Table 2. The interview template was developed by reviewing the literature, and by discussing key findings from the review within the research team. The interview template, therefore, represents the main themes identified from the literature. The literature review focused on published regulatory guidance on making and justifying decisions about risk reduction, official reports, as well as literature evaluating the effectiveness of recommended approaches, such as quantitative Cost-Benefit Analysis.

Using the main themes identified from the literature as represented in the interview template as the overarching organising structure, interview transcripts were analysed inductively and iteratively using Thematic Analysis [38]. Transcripts were read and coded using Open Coding [39]. An analytic memo was kept as each transcript was coded to keep track of thoughts and ideas, and to reflect on the coding process. Themes within each interview topic were identified through clustering of similar or related codes in project meetings. While the initial thematic structure was provided by the literature review, the

analysis remained open to the possibility of new themes being identified by constantly comparing themes with the data. The coding was supported by the NVivo 10 software package.

This approach to qualitative analysis introduces the possibility of analyst bias and might reduce the validity of the findings. The main strategy adopted to ensure adequate quality and validity of the qualitative analysis process was to subject the emerging findings of the analysis to constant review and scrutiny by the wider research team. No additional respondent validation was undertaken at this stage, as the “reality check” for these findings was scheduled for the subsequent stakeholder consensus development process.

2.3. Consensus development process

The findings of the interview study with industry participants provided the starting point for a consensus development process with health care stakeholders. The rationale for this was that a group of health care stakeholders with a diverse range of backgrounds might be well placed to appraise the industry findings, and to generate lessons and priorities that might be acceptable to their peers.

A three-step consensus development process based on the Nominal Group Technique [40] was undertaken with a purposive sample of 20 healthcare stakeholders to establish lessons that are applicable to the health service (with a UK focus). Table 1 provides an overview of the participants by job role. Participants were sampled to include a breadth of clinical, managerial, policy-making and regulatory roles. All participants have a stake in the management of risk and patient safety, either as a service provider or from the regulatory side. Six of the 20 participants have patient safety as the main focus of their job role. No details were recorded about the formal risk and safety management qualifications of the participants. All participants received a participant information leaflet, and participation was voluntary. No personal or otherwise identifiable data was collected from participants.

In the first round of the consensus development process, participants were invited individually to describe in writing scenarios where trade-offs between risk reduction and the associated costs might have to be taken and justified. The second round consisted of a workshop held at the Health Foundation office. Prior to the workshop, participants were sent a summary of the findings from the analysis of industry stakeholder perceptions. The summary included a description of the ALARP concept. It is reasonable to assume that the majority of participants will have been unfamiliar with the ALARP concept. The

Table 2
Topics explored during the industry interviews.

Topic	Prompts
Role	Could you please describe your current role within your organisation and how many years of experience you have in this role?
Scenarios and examples of trade-offs between risk reduction and cost	Could you please describe through examples the type and range of situations where trade-offs between risk reduction and cost are made? What are typical types of projects (large scale/small scale)? Is there a focus on engineering projects or does it include general organisational changes (e.g. risks of shift handover)? What types of decisions are supported through this trade-off?
Motivations for making the trade-off between risk reduction and cost explicit	What is the influence of regulatory requirements? What role have previous major accidents in the industry played? What is the role of safety benefits (risk reduction) within the company's business case?
Making ALARP judgements in practice	Is there a formal process for managing the trade-off? What does it look like? What kinds of methods are used? Are explicit values placed on human life? What other factors are considered, e.g. ethical issues, business impacts, technical feasibility, regulatory considerations)? How are decisions recorded? How much effort is involved in making such decisions in practice?
Communicating decisions	How are decisions about risk reduction and cost communicated? Who gets to see the analysis and decisions? What kinds of communication processes exist with the regulator? How explicit is the communication (e.g. safety case)? What gets challenged in practice?
Practical challenges	What are the obstacles and challenges in practice when managing these trade-offs? How are these challenges dealt with in practice? What are possible suggestions for improving the practice of managing the trade-off?

Table 3
Stakeholder proposed scenarios used during the consensus development workshop.

Scenario	Description
Moving services into the community	To reduce the burden on hospitals, and to provide more patient-centred care, the introduction of a new community intravenous antibiotic service is considered. However, this novel type of service might entail new forms of patient safety risk, such as elderly patients being unable to cope at home, and less opportunity for healthcare professionals to monitor patients at home.
Purchase of an IT system	Prescribing errors are a recognised threat to patient safety. The literature provides evidence that with the introduction of electronic prescribing, error rates may be reduced significantly. However, the literature also suggests that the introduction of electronic support systems, such as electronic prescribing, can lead to unanticipated consequences and novel patient safety risks.
National patient safety alert notice	National bodies, such as formerly the National Patient Safety Agency (NPSA), issue guidance on how to deal with recognised patient safety risks. An example might be the health IT requirements specification established by the NPSA to minimise the possibility of prescribing overdoses of oral methotrexate. The specification introduced the following safety features: <ul style="list-style-type: none"> ● Picking list with drug form and strength pre-populated ● Alerts at point of drug selection to remind the practitioner that this is a high risk process ● Alerts to warn of the danger of dual therapy ● Links to clinical audit and monitoring. Consider this case from the point of view of the national body (how do they arrive at this set of recommendations for reducing risk?), as well as from the point of view of the healthcare organisation implementing this process (how do they make decisions about whether or not the risks in their context have been adequately controlled).
Changing staffing levels	Certain patient safety risks might be reduced through increased staffing levels. For example, extra pharmacy staff to cover weekends might contribute to reducing delays and stress-related human error. On the other hand, sometimes it may be desirable to reduce the number of staff for economic reasons. However, this might contribute to increased levels of risk.

purpose of providing participants with a description of ALARP was to sensitise them for the presentation of the findings that would take place during the workshop. The description of ALARP provided was not intended to thoroughly educate participants. On the day, the workshop consisted of: (a) presentations by the research team about key findings to date including an overview and discussion of ALARP to ensure all participants had a basic understanding of the concept and the rationale for adopting it in UK industries, (b) group work, where participants discussed aspects of managing the trade-off between risk reduction and cost using a sub-set of the scenarios identified in the first round, structured by a discussion template, and (c) a facilitated plenary discussion, where participants attempted to draw out key lessons and open issues from the day. The list of scenarios used during the

workshop is shown in Table 3, and the discussion template is shown in Table 4. The completed scenario templates from the workshop, and the notes from the plenary session were used to develop an online survey for the final, third round of the consensus development process. The survey was split into two parts: the first part served as validation of key findings from the workshop, and the second part was for establishing consensus around lessons and priorities for health care. Participants filled in the survey individually. For the purpose of this study, consensus was defined as agreement by at least two thirds of participants. Some questions were worded in such a way that disagreement by at least two thirds of study participants was regarded as consensus. The survey statements are shown in Table 5.

Table 4
Scenario template with prompts for discussion.

Topic	Prompts
Scenario overview	A description of a healthcare scenario will be provided, but participants might wish to add to/clarify the scenario.
Current practice	Participants reflect on how decisions about risk reduction and cost are made in the scenario including: <ul style="list-style-type: none"> ● Types of risk reduction/cost decisions that are made ● Criteria that are used ● How costs and benefits are compared ● Who gets to make the decisions ● What is the role of the regulator
Future practice	Participants reflect on possible improvements to current practice using the prompts above and lessons from industry (e.g. is ALARP a suitable criterion, should the regulator set a framework etc.).
Expected benefits	Participants discuss the benefits they expect from potentially more systematic approaches to making decisions about risk reduction and cost, including: <ul style="list-style-type: none"> ● What are the benefits? ● Who will see these benefits?
Enablers and facilitators	Participants reflect on the proposed approach by considering the current organisational and regulatory environment: <ul style="list-style-type: none"> ● Will the application of a more formal approach to making decisions about risk reduction and cost rely on other existing regulations/ systems/ developments? ● Are there factors that may facilitate the application of this formal approach to the selected scenario?
Constraints and barriers	Participants reflect on the proposed approach by considering the current organisational and regulatory environment: <ul style="list-style-type: none"> ● What potential obstacles or constraints are there? ● How could these be overcome?
Ethical considerations	Participants reflect on the ethical underpinnings of making decisions about risk reduction and cost, e.g.: <ul style="list-style-type: none"> ● Should all risks be reduced as far as possible as a moral duty? ● Is there a case for the application of the principle of “reasonable practicability”? ● Should affordability override the moral duty to reduce risks?
Any other issue	Please list and describe here any other issue relevant to the discussion.

Table 5
Consensus statements and results.

A. Validation of workshop discussion	Participants in agreement (%)
1. New services are implemented (or new models of services) and changes to existing services are undertaken if this feels like “the right thing” to do, when it is politically supported and desirable, and when it is perceived to be financially beneficial.	92
2. Systems-based and organisational safety risks are not considered formally in the design or at the outset of the change.	67
3. The concept of safety risk and the measurement of risk are poorly developed.	75
4. Safety risk management practices are reactive focusing on harm, not risk.	83
5. There is a lack of understanding of and transparency about how cost-benefit decisions in safety assessments are made.	100
6. There is a lack of published literature on how to make decisions about risk reduction and cost in healthcare.	83
7. The regulators are not involved in the planning of new services or changes to existing services.	67
8. The regulators do not have a notion of acceptable levels of risk.	58
9. The regulators do not incentivise risk reduction.	83
B. Lessons and priorities for the health service	
1. The regulator should become actively involved in the design of novel services and significant changes to existing services.	25
2. The regulator should incentivise organisations to reduce risk.	92
3. The regulator should mandate an explicit account of organisational patient safety risks in the form of a safety case.	58
4. The regulator should provide best practice guidance on standardised risk reductions interventions.	67
5. Organisations should develop an explicit account of patient safety risks in the form of a safety case (even if not mandated) in order to complement the finance focus of their business cases.	83
6. The NHS should adopt as a regulatory requirement the As Low as Reasonable Practicable (ALARP) principle, which the Health & Safety Executive requires from operators of safety-critical systems.	50
7. The NHS should adopt the ALARP principle as guidance, but should not set it as a regulatory requirement.	50
8. The NHS should develop and adopt a healthcare specific notion of acceptable levels of risk (rather than adopt ALARP).	83
9. The NHS should not adopt a common notion of acceptable levels of risk because the NHS is not in a position to price-in risk reduction interventions.	0
10. The NHS should adopt a structured process for making cost-benefit decisions in safety assessments (this can be qualitative).	83
11. The complexity of healthcare makes the adoption of a quantitative cost-Benefit Analysis (CBA) impractical.	8
12. A cost book, which provides guidance figures for costs associated with risks, should be developed to facilitate a quantitative CBA.	58

3. Perceptions about risk reduction and cost in five UK industries

The findings of the qualitative analysis are reported based on the themes identified from the literature, focusing on motivations for making the trade-off between risk reduction and cost explicit, the use of ALARP in practice, the role of quantitative Cost-Benefit Analysis (CBA), the communication of decisions about risk reduction, and practical problems that participants have experienced. Furthermore, the role of quantitative CBA was identified as an important additional theme during the analysis.

3.1. Motivations for making the trade-off between risk reduction and cost explicit

Each industry is regulated by standards that are expressions of the ALARP principle in some form. Therefore, being able to justify to the regulatory authority that risks have been reduced ALARP is an overarching motivation.

There are also ethical and societal concerns that act as motivations for making well reasoned and appropriately documented decisions about risk reduction. There can be genuine concern for employees and the public, who should be protected from risk. In addition to such ethical drivers, there can also be the recognition that risks to reputation

and the resulting business risks might be more significant than purely the safety risks. Organisations might wish to be seen to be acting ethically and not as making unsound decisions about safety. In some cases, this might compel organisations to make greater financial investments in safety than would be required from a regulatory perspective alone.

The importance of corporate risk and reputation is highlighted by the quotation below. The participant suggests that there has been a change in attitude, and that companies are now more aware of the potentially negative impact of poor safety performance on the reputation and business of a company.

“Yes, over the last ten years that [corporate responsibility] has become really much more significant. It was not really there at all some time ago, you know, ten, fifteen years ago. But now that’s seen as one of the primary drivers that the business wants its reputation to be high, and it wants to show that it’s ethical and not making any unsound decisions regarding safety and over ethical issues as well.” (Safety Engineer/Defence)

3.2. Making ALARP judgements in practice

Trade-offs between risk reduction and costs are made in the context of ALARP judgements. Determining whether risks are ALARP can be required in different kinds of situations, ranging from assessing new designs for a nuclear power plant to everyday operational risk management, such as determining whether to install additional safety valves in a petrochemical plant.

Participants suggested that a systematic risk analysis usually forms the basis for ALARP demonstrations. Trade-offs between risk reduction and cost can be identified and described qualitatively first, by estimating the number of fatalities, and by assigning coarse estimates to the cost of possible risk reduction (order of magnitude). The risk analysis and the qualitative approach to estimating the potential benefits of risk reduction and the associated cost can be informed to a large extent by engineering judgement and gut feeling. This level of qualitative analysis typically is considered sufficient in cases where the analysis indicates that no significant costs will be involved. If, on the other hand, the analysis points to significant impacts (either in terms of costs or risk) or high levels of uncertainty in the analysis, then a more detailed impact assessment might be undertaken. A quantitative CBA might also be involved at this stage, but the level of this analysis would usually be proportionate to the risk and the costs involved.

The ALARP judgements are based on a broad range of factors that can go beyond the simple cost of the proposed risk reduction intervention and the potential benefits in terms of prevented fatalities. Participants provided examples that include business or production benefits other than improved safety, and ethical considerations. In the military context there might be considerations of operational capability in situations where equipment such as aircraft would have to be taken out of service for implementing risk-reducing modifications.

Ethical as well as business considerations might lead to higher investments in risk reduction than required by regulatory guidance. Corporate responsibility is a consideration, and whether one could stand up in a court of law and argue that one truly believed (“*hand on heart*”) that risk reduction was adequate. In the quotation below a participant from the petrochemical industry describes that in situations where the operational site management (i.e. the petrochemical processing facility) feels that investment in particular risk reduction interventions was the best thing to do, even if not required from an ALARP perspective, they might look for other ways of justifying the expenditure to the budget holders.

“With some issues, even if we don’t have to do them from a cost-benefit reason, we would still say, well actually it’s still the best thing to do. Is there any other way we can justify doing it? So it’s

almost if it’s something the site wants to do, it doesn’t necessarily just stop at its not cost effective if it’s what the site believes should be done. We will try and progress that through the business.” (Process Safety Manager/Petrochemical)

3.3. The role of quantitative CBA in practice

The extent to which quantitative CBA is used varies across the industries. However, participants suggested that reference to good practice often means that there might not be a need for detailed quantitative analysis. Quantitative CBA builds on the qualitative analysis, and is used predominantly in situations that are characterised by high risk (close to the unacceptable region in ALARP), where the expenditure required is perceived as significant, and where the findings from the qualitative analysis were inconclusive. The risk reduction interventions that might be analysed using CBA tend to be engineering solutions rather than organisational changes, since costs for the former are thought to be more readily available.

Reasons for adopting a quantitative analysis of safety benefits and associated costs include further data requirements following the qualitative analysis, ensuring that safety-cost trade-off decisions stand up in court, and providing more convincing arguments for safety investments to management. A participant from the petrochemical industry explained that CBA might be used as a tool to convince Board members to spend money, rather than as a justification for gross disproportionality. Quantitative results from a CBA might be perceived as a better communication tool with high-level management than the simple observation that a site might be made safer as a result.

A key consideration in the application of CBA is the determination of how to monetise human life and suffering. Across the industries an estimated value of preventing a statistical fatality (VPF) based on figures provided by the Department of Transport, and suggested by the Health & Safety Executive, is adopted (around £1m). However, this figure is frequently taken only as a basis, and modifications might be applied. Organisations might also choose to increase the suggested amount to err on the side of caution, for ethical reasons or to protect business and reputational interest.

Results from the quantitative CBA are usually not the only determinants for making decisions about risk reduction and cost trade-offs. In the quotation below, the participant uses the example of risk transfer to suggest that there are factors that are not normally considered in CBA, but that would feed into the final decision.

“Well, there’s certainly the risk transfer issue. So, you could provide further risk reduction that reduces the safety risk, but maybe transfers the risk to the environment, or it reduces the risk to one group of people and increases it to another group of people, and I’ve never seen that addressed in a quantitative way, but sort of qualitative arguments are quite often presented for that sort of thing.” (Chemical Engineer/Petrochemical)

3.4. Communication of risk reduction decisions

Trade-offs between risk reduction and cost are normally documented formally as part of the justification that risks have been reduced ALARP. The ALARP justification forms a key part of the safety case or safety report, which is required by the regulator.

The regulator might challenge or question the justifications provided in the safety case. These queries tend to relate to the qualitative risk assessment rather than the quantitative CBA. A reason for this is that CBA might be perceived as a “number crunching” exercise, which is determined by the assumptions made during the qualitative risk assessment.

Organisations might not wish to publicise their management of safety-cost trade-offs for fear of being perceived as acting unethically,

unless they have to. In the quotation below, a participant suggests that, similarly, individuals might not wish to disclose the specifics of their analysis, which in turn reduces transparency and prevents learning.

“People are always quite reticent to publicise what they’ve got, not possibly because it’s intellectual property, but because what if what they say then doesn’t agree with what someone else is saying. You keep your cards close to your chest within your business area and as long as your business area is happy, then there’s no need to publicise further.” (Safety Policy Manager/Defence)

3.5. Practical challenges

Participants identified a large number of practical challenges to managing and justifying trade-offs between risk reduction and cost. These challenges are concerned with the complexity of systems, the difficulty of performing a quantitative analysis, and the use of the analysis results.

3.5.1. Complexity

The complexity and scale of industrial systems poses a challenge to the risk analysis and the estimation of benefits. Setting the boundary for the analysis might be difficult because the consequences of certain events might propagate throughout the system in unforeseen or even unpredictable ways.

Participants suggested it was important to involve all relevant stakeholders. In large-scale systems with many different roles and even different organisations involved, getting the right people together for risk analysis, and accessing data from different organisations can be challenging. In addition, in such multi-stakeholder environments the costs and the benefits might not be evenly distributed between the different stakeholders, i.e. there might be “winners and losers”. Reaching agreement in such situations might be practically challenging.

3.5.2. Quantification

Performing a quantitative CBA can be challenging because the numbers that go into the analysis are based on estimates, and the error associated with these estimates might scale up during the calculations to the extent that there is little confidence in the overall result. This problem is exacerbated for novel systems, where the costs and the way of use have not been properly established. CBA is often used for high consequence accident scenarios (e.g. explosion on a petrochemical processing facility, mid-air collision between two aircraft etc.), but the likelihood of, and hence the confidence in the estimates about such events might be very low.

Quantification of the safety benefit might be challenging for a number of reasons: due to the complexity of systems alluded to above, it might be difficult to identify the precise contribution to global system safety of an intervention at the local level; and considerations such as impact on consumer confidence and business reputation might be hard to foresee and express in monetary terms with confidence.

3.5.3. Use

In order to understand and use the output of any analysis appropriately, decision makers need to be provided with an appreciation of the range of factors that were considered or excluded, and the uncertainty associated with the analysis. There is a risk that with the use of CBA the focus shifts from a thorough understanding of the risks towards the mechanics of the method. If the sensitivity of the analysis is left unexplained the results might be deceiving to those who need to base their decisions on them. In the extreme case, the application of CBA might be perceived as generating an answer that is desirable by adjusting assumptions and figures accordingly.

4. Lessons and priorities for health care – stakeholder consensus development

The industry stakeholder perceptions described in the previous section served as input for the consensus development process with health care stakeholders (as described in Section 2).

4.1. Consensus on how the trade-off between risk reduction and cost is currently managed

Nine validation statements about the current practice in health care were presented to participant, see Table 5 (A. Validation of Workshop Discussion). Participants reached consensus on eight of these. Participants perceive the current approach to managing the trade-off between risk reduction interventions and cost as not transparent. Risk management is perceived as being reactive, and as lacking in understanding of systems and organisational issues. The concept of risk and the measurement of risk are perceived as poorly understood in health care. The role of the regulator is viewed critically, with regulators perceived as not incentivising risk reduction. While the majority of participants agreed that the regulator does not operate with a well-defined notion of what constitutes acceptable levels of risk, there was no consensus reached on this aspect.

4.2. Lessons and priorities

The discussions around the scenarios and the plenary discussion of the workshop were summarised in twelve consensus statements, see Table 5 (B. Lessons and priorities). Participants reached consensus on six of these (including one reversely worded consensus statement 9). The consensus can be expressed in terms of five key recommendations for health care.

4.2.1. Recommendation 1: There should be regulatory incentives for organisations to reduce risk

There is a perceived lack of institutional driver for, and absence of regulatory guidance on systematically reducing risk. While organisations and individuals are engaged in developing and implementing risk reduction interventions, these are often not carried out systematically and depend on individual initiative. Without institutional drivers and regulatory guidance there might not be sufficient traction to promote proactive consideration of patient safety risk. The recommendation is, therefore, that regulatory incentives should be established for organisations to reduce risk.

Currently, there are already incentives to reduce harm (based on outcome measures, e.g. number of pressure ulcers) and to comply with best practice (based on process measures, e.g. timely administration of antibiotics to reduce the likelihood of severe sepsis). These might be extended to include incentives for reducing risk. Ideally, the systematic reduction of risk would be promoted throughout regulatory and quality assurance bodies.

There is a need for inspectors and guidance developers to have a thorough understanding of patient safety risk and proactive risk management approaches. This might require targeted education that enables, for example, inspectors to ask the right questions, and assessors to look for adequate arguments and corresponding evidence. In addition, a suitable communication tool to facilitate the interaction between regulators and healthcare organisations around risk is required.

4.2.2. Recommendation 2: A regulatory framework should be established, which provides best practice guidance on standardised risk reduction interventions

There is a perceived lack of guidance on how to develop, implement and demonstrate the impact of standardised risk reduction interventions. While there are many mandatory practices (e.g. mandatory risk

assessments and screenings for patients at risk of falls, infections etc.), there is a perceived emphasis on meeting regulatory targets rather than on reducing risk. The recommendation is that regulators provide more practical guidance on specific risk reduction interventions and on how to demonstrate that risk has been reduced.

Regulatory bodies aim to be drivers for improvement, and they define quality standards and specify targets as indicators of quality of care. These might be accompanied further by guidance on how to implement risk reduction interventions that fulfil these quality aims. In addition, further guidance is required on how to demonstrate, in a consistent way, that the implementation of the recommended interventions have contributed to a reduction in risk.

4.2.3. Recommendation 3: Organisations should develop an explicit account of patient safety risks in the form of a safety case (even if not mandated) in order to complement the finance focus of their business cases

The focus of quality and safety improvement in many healthcare organisations is provided by the investigation into serious adverse events, the occurrence of never events, and by external targets (such as reduction in the number of patient falls). Such learning and drivers are based on observed outcomes, i.e. they are reactive, and they do not provide a proactive, systems-based focus on the risks that are present in the care processes. The recommendation is that organisations should adopt an appropriately tailored safety case concept to develop an explicit account of patient safety risks.

4.2.4. Recommendation 4: Health systems should adopt a health care specific notion of acceptable levels of risk

When organisations start to develop an understanding of the risks present in the system, they are confronted with a large number of potential threats to patient safety. At present, healthcare organisations do not possess systematic processes or criteria that enable them to determine in a consistent and transparent way whether risks should be reduced further and how the trade-off between cost and risk reduction should be managed. As a result, the way risks are approached varies significantly and relies often on individual judgement. The recommendation is that the NHS as a whole should reason about possible common notions of acceptable levels of risk, or frameworks for determining these, that can be used in the decision-making process.

The NHS faces different challenges than other safety-critical industries, and there is a duty to provide care to an aging population with increasingly complex health needs while at the same time reducing the burden on the taxpayer. It might be argued that a strict principle, such as ALARP, cannot be implemented within the financial climate of the NHS. However, it should be possible to start a dialogue and build a common framework around how the NHS as a whole would like to treat patient safety risk and corresponding trade-offs between cost and risk reduction in a consistent way.

A main prerequisite for starting such a process is a better understanding of risk in the NHS. Further education is required to provide a more proactive mindset that shifts from the consideration of outcomes only towards a risk-based perspective. One way to get this started is by developing explicit accounts of the risks that are present in the system.

4.2.5. Recommendation 5: Health systems should adopt a structured process for managing trade-offs between risk reduction and cost

Care processes and pathways can be complex, and the effects of changes and risk reduction interventions might be difficult to anticipate to their full extent, in particular when services are provided across organisational boundaries. However, the extent to which risks are assessed proactively, and the criteria that are used to manage potential trade-offs between risk reduction and cost depend largely on individual initiative and judgement. The recommendation is for the NHS as a whole (and for other health systems) to consider the development of a structured framework for managing such trade-offs to ensure consistency and transparency across the NHS.

and transparency across the NHS.

The learning from other industries provides evidence of the utility of a structured approach to managing trade-offs between risk reduction and cost. In particular in situations that are complex and where the assessment of risk and the estimation of costs and benefits are difficult, the use of a structured process might be very valuable to facilitate justification and assessment of decisions taken.

This will require a dialogue among the different stakeholders in the NHS. Learning from other industries about the use of ALARP and safety cases could provide helpful insights, but it is likely that the health sector needs to come up with solutions that are tailored specifically to the needs of healthcare. Greater awareness of the notion of risk in patient safety and the current level of risk in care processes might represent a useful and necessary first step.

5. Discussion

The results of this study suggest that health care stakeholders perceive a need for better understanding and for greater transparency of how decisions about risk reduction and the associated costs are made. While there are differences between safety-critical industries and health care, study participants identified lessons for health care based on the learning from other industries. These lessons are addressed to health care organisations, the regulators, and health systems as a whole. Study participants recommended that the concept of risk should be integrated better into safety management and regulatory practices as a prerequisite for making and justifying decisions about risk reduction and cost. Health care organisations should identify and document their current levels of risk in a safety case, suitably tailored for use in health care. A regulatory framework that incentivises risk reduction and provides best practice guidance should be established. Study participants also recommended that health systems should engage in discussions about what constitutes acceptable levels of risk, and what an appropriate process and framework for making decisions about risk reduction and cost should look like.

Study participants from the health sector suggested that the concepts of risk (in relation to patient safety) and of risk management are poorly understood. This is hardly surprising, considering also the ongoing debate about the nature of risk in the scientific literature [15,16,41]. While detailed discussion of issues such as uncertainty [18], emerging risk [42], and Black Swans [43,44] is beyond the scope of this paper, there are practical considerations in the literature, which have a direct relevance for the results reported in this study. The health care stakeholders recommended that health systems develop a health-care specific notion of acceptable levels of risk. The UK industry stakeholders perceived the ALARP concept as a reasonable framework for making and justifying decisions about risk reduction interventions and the associated costs. However, the analysis of the interviews demonstrated that making judgements about risk reduction in practice does not appear to rely on the ALARP concept in a simplistic and deterministic way. Decisions about risk reduction and about whether a system is regarded as safe enough are influenced by broader considerations of corporate responsibility, ethical reasoning, other potential business benefits and impacts, and, at times, whether it was “a good thing” to do. In the literature similar views have been expressed. It has been pointed out that relying on the ALARP concept in isolation might create considerable practical, philosophical and ethical problems [11,12,45,46]. In addition, it has been suggested that risk analysis and managerial decisions about risk should be regarded as two distinct phases [24]. Decisions about risk reduction could be considered risk-informed rather than risk-based [15], because they are based on not only the scientific evidence produced during the risk analysis, but also on social discourse and other value judgements [11,22,43]. ALARP has also been criticised for not addressing how the views of the public might be integrated [11]. These practical considerations appear particularly relevant in a health care context, where patients are at

the centre of the service, and where risk perceptions can be shaped significantly by personal experience and social interactions [23].

A second practical problem identified by interview participants as well as the literature pertains to the use of quantitative CBA to inform decisions about risk reduction. Industry participants suggested that quantification of costs and benefits was challenging due to the complexity of many systems, which can lead to oversimplification and a focus on those aspects that can be quantified more readily. Participants also suggested that application of CBA was challenging due to the uncertainty associated with high severity, low probability events, which can have a significant effect on the validity of CBA calculations. Similarly, in the literature the use of expected values in CBA has been criticised when used as the basis for safety management [47–49]. This use of expected values does not take into account that different scenarios with the same expected value might be perceived differently by society. The term societal risk has been coined to refer to events with multiple fatalities. It has been suggested that for such high-consequence events risk aversion among the public might be greater, and this is not considered when using CBA based on expected values [47–49]. The recent interest in the concept of Black Swan events [50] within the risk and safety communities also highlights the problem of using probabilistic modelling for such high severity, low probability events [43,44]. It has been suggested that risk management approaches should, therefore, be explicit about the uncertainty associated with assumptions made, and that they should be appropriately adaptive to include not only risk-based strategies but also precautionary strategies and sensitivity to weak signals [42,47–49]. Of particular interest in a health care context is the complexity of systems. ALARP decisions have been criticised for focusing too much on the local context, while failing to consider the wider impact on the system [51]. National health systems typically have a duty of care to the whole population while the budget is determined and fixed by a government department. Well-intentioned risk reduction in one area might preclude investment in the development and provision of services in another area, thus creating a further trade-off to consider in the decision-making process.

Current safety management practices in health care are often not informed by a detailed risk analysis. Practice is largely reactive, and is frequently driven by the investigation of serious untoward incidents and by the counting of past harms [52,53]. Safety improvement efforts are then directed at preventing similar incidents from occurring again, and at reducing certain harms to meet regulatory targets. However, one might question whether the use of such pre-defined criteria and targets provides a good enough driver for continuous improvement [54]. It has been frequently suggested that health care organisations are lacking the capacity to learn and to improve sustainably and transparently [52,55–58]. Lessons from industry, as well as from the present study, suggest that organisations should aim to understand their risks proactively, and then generate improvement alternatives and weigh the associated burdens and benefits in a systematic manner [48,54,59]. A key recommendation for industry following from the Nimrod Review was that organisations should document and make explicit their current risk position, rather than to argue that a system is safe [13]. This proposed shift from safety cases to risk cases might also be a good starting point for health care organisations for incorporating a risk-based approach into their safety management practices [7]. This view is supported by the recommendations generated by the health care stakeholders reported in this paper. There has been criticism of the safety case concept for regulatory purposes [46,60], but as a practical improvement tool for documenting that risks have been understood a suitably tailored safe case approach might provide health care organisations with structure and direction for embedding the risk concept in their safety management practice [8,61].

Regulatory bodies can play an important role in facilitating the adoption of consistent and transparent risk management approaches across an industry [7]. This is particularly important as there is an increasing recognition that many patient safety problems would

require sector-wide collaboration and coordination [62]. In the NHS, as well as in other health systems, there are many safety targets, e.g. so-called Never Events [63], and performance indicators for a range of well established harms (for example the NHS Safety Thermometer [64]). There are also instances, where regulatory standards set out requirements based on a risk analysis framework, for example for medical devices [65] or for selected high-risk processes [66]. However, there is no consistent approach across the health system for learning from past experience and for continuously improving practice [52,55], which would be a prerequisite for a transparent framework for reasoning about trade-offs between risk reductions and cost. Incentivising risk reduction, as suggested by the stakeholders in this study, might be a potential consideration for regulatory bodies in order to provide a greater drive for improvement. A potentially limiting factor might be the fact that there is no single body to provide centralised and coordinated oversight of patient safety [67]. It has been suggested that the presence of, currently, more than 20 regulatory bodies in health and social care in England has led to a lack of a coherent push towards improving patient safety [68]. Initiatives in the UK and the US suggested that the framework for regulating patient safety should be reconsidered [68], and recommended the introduction of a national patient safety oversight structure [67]. At least in the NHS it is hard to see this happening in the short to medium term, even more so with the abolishment of the National Patient Safety Agency in 2012. It is also worth noting that there would be a need for knowledge, effort and resource within any such regulatory body in order to make such an approach work effectively in practice [54,69].

Resolution of the above challenges is beyond the scope of this paper, and, as one reviewer of the manuscript pointed out, the devil will be in the detail. It is worth noting that health systems are very heterogeneous entities. Different parts of the health care system or different health care processes might require different risk management approaches, which might emphasise, for example, risk avoidance for well-understood processes and more adaptive strategies for novel and less tractable processes [42,70,71]. Highlighting the need for a dialogue among stakeholders about how health systems should treat patient safety risks in a consistent and transparent way, informed by experiences from other industries, might be a promising starting point.

5.1. Limitations

The study design used a qualitative research approach, which relies on views and opinions elicited from study participants. The participants typically will have had an interest in the study topic and in research more generally. Therefore, there is a risk of bias because study participants' views might not be representative of other people working in their domain. This is particularly true for the participants from the health care sector, who could be regarded as patient safety enthusiasts in their respective organisations.

Participants from health care all had a strong interest in patient safety, and for some managing risk and improving patient safety was their main job focus. However, one might assume that only a minority of the participants had any detailed prior knowledge of industrial risk management practices or the ALARP concept. Therefore, participants were confronted with new information during the consensus development process. The potential lack of in-depth understanding of these issues might lead to oversimplification in the formulation of recommendations. This source of bias should be acceptable, because participants' recommendations are intended as a starting point for debate rather than as concrete suggestions for immediate implementation.

It has been highlighted that health care is not like an industrial product that is manufactured, but rather a service that is co-created between the patient and the various health care professionals [72]. Including the views of the patient and the public is an important consideration in health services research. The consensus development process did not include patient and public representatives, and this should be considered a priority in further discussion and debate.

6. Conclusions

Learning from other industries suggests that it is possible to construct a facilitating regulatory framework, for example based on the concept of “reasonable practicability”, in order to support consistency and transparency in making and justifying trade-offs about risk reductions and the associated cost across industries. In practice, such a framework is not just about safety risks and costs, but can also include consideration of corporate responsibility, and ethical and societal concerns.

In health care, trade-offs about risk reductions and cost are often not managed consistently or transparently. Local teams might be enthusiastic about improving patient safety, but the lack of a shared framework might lead to varied practice and some frustration. Study participants from health care provided five recommendations aimed at health care organisations, regulatory bodies and health systems as a whole, in order to better manage trade-offs, as well as patient safety risks more generally. These recommendations need to be underpinned by education and greater awareness around the concept of risk and proactive risk management in health care. Progress could be made reasonably quickly in some instances, for example through the adoption of safety cases as a practical improvement tool to reason about risks in a structured way, and through the introduction of regulatory incentives for risk reduction.

Learning from other industries can provide valuable insights, but the health sector will have to develop frameworks that work in health. This might be particularly true when considering acceptable levels of risk and the ALARP framework. ALARP might or might not be applicable in health care, but the need for a shared framework for making and justifying risk reduction decisions has been clearly identified in this study. Stakeholders should engage in discussions, and develop a consensus about how health systems can manage risks to patient safety and the necessary trade-offs in a consistent and transparent way.

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