Valuing safety in healthcare

Lotte Steuten and Martin Buxton

INTRODUCTION

For many years, patient safety was an issue of mainly academic concern [1-5]. The publication of the Institute of Medicine's (IoM) report *"To err is human: building a safer health system"* in 2000 [6], however, made patient safety a major concern of the general public and policymakers in the US as well as abroad. The IoM report highlighted the risks of medical care in the US and shocked the sensibilities of many people, in large part through its estimates of the magnitude of medical-error-related deaths (44,000 to 98,000 deaths per year) and other serious adverse events. It prompted a number of legislative and regulatory initiatives designed to document errors and begin the search for solutions [7]. Since then, huge amounts of resources have been allocated to monitoring and improving safety in healthcare [8].

In the UK, the publication of the Department of Health reports "An organisation with a memory" [9] and "Making Amends" [10], as well as the establishment of the National Patient Safety Agency (NPSA) has increased awareness of the issues surrounding medical errors and adverse events in healthcare. The NPSA is determined that UK health services should remain among the worlds best and safest. In order to achieve this goal in the most cost-effective way, a report setting out an economic approach to safety was produced by Gray in 2003 [11]. This report describes how the standard methods for economic evaluation can be applied in safety research. So far, however, it remains unclear to what extent standard methods of economic evaluation, using risk-neutral consequentialist analyses of costs and outcomes of healthcare incidents, appropriately reflect the value of improved safety, and in particular whether a methodology is required to estimate the extra-consequentialist value of avoiding iatrogenic harm and avoidable errors and accidents.

This paper first describes the magnitude of the patient safety issue, the current approach to valuing safety improvements and its limitations. Second, it proposes a research methodology to better understand how stakeholder groups value scenarios consisting of both health and non-health attributes of safety in different healthcare contexts. Finally, it suggests a way to link this 'extra-consequentialist' approach into the standard cost-benefit framework.

Incidence and costs of medical errors and adverse events

Several studies report the incidence of medical errors and adverse events in different, but mostly developed, countries. Literature shows that the overall medical error rate in hospital care is about 3.1% for surgical procedures in the US. The overall adverse event rate in hospitals is about 1.6% - 11.7% in the UK, 3.7% - 17.7% in the US, 5% - 16.6% in Australia and 12.9% in New Zealand [11].

The first report of the NPSA's Patient Safety Observatory estimated that between 500,000 and 600,000 patients admitted to NHS hospitals in England and Wales experience a patient safety incident. In a report of an expert group on learning from adverse events in the NHS, it is estimated that in the UK, 400 people die or are seriously injured in adverse events involving medical devices every year; nearly 10,000 people are reported to have experienced serious adverse reactions to drugs; nearly 28,000 written complaints are made about aspects of clinical treatment in hospitals [9].
The Australian Patient Safety Foundation found healthcare to be "a risky business". Simply being a patient in an acute care hospital in Australia carries, on average, "a 40-fold greater risk of dying from the care process than from participating in traffic, and a 400-fold greater risk than working in the chemical industry." At least 10% of admissions to acute-care hospitals in Australia are associated with a potentially preventable adverse event [12].
Evidence shows that medical errors and adverse events consume lots of health resources [13-17]. It has been reported that, in the UK, the NHS pays out around £400 million a year settlement of clinical negligence claims, and has a potential liability of around £2.4 billion for existing and expected claims; hospital acquired infections (around 15% of which may be avoidable) are estimated to cost the NHS nearly £1 billion [9]. In Australia, the direct medical costs of preventable adverse events exceeds AU$2 billion per year and the total life-time cost of such preventable injury may be twice that amount. There is also a heavy toll in human costs on both those who are harmed and those who care for them [12]. Although caution has to be taken in interpreting the above figures because the definition of medical errors and associated costs varies greatly across literature sources, it nevertheless illustrates the worldwide necessity to improve patient safety in an effective, but also efficient way.

Characteristics of safety

Yet, to consider how the value placed on safety improvements can be estimated, it is important to consider its characteristics. Most safety enhancement is concerned with reducing the probability or severity of errors or accidents. In the IoM's report, patient safety was defined as: (1) "freedom from accidental injury"; (2) medical practice consistent with current medical knowledge and best practice; and (3) responsiveness to customer-specific values, expectations and preferences [6]. Building on this report, the following refined definitions were proposed: "If safety can be defined as freedom from accidental injury, then an adverse event can be defined as an injury caused by medical management rather than by the underlying disease or medical condition of the patient, and a preventable adverse event can be defined as an adverse event attributable to error. Finally, a negligent adverse event can be defined as a subset of preventable adverse event that satisfies legal criteria used in determining negligence"[10]. Further, injury may not only be to patients, but also to healthcare providers or others. More important for the understanding of this paper, however, is to realise that safety is not necessarily synonymous to avoidance of adverse events. Where adverse events can be seen as a 'failure' of an individual or a system to provide an intended 'safe' treatment, healthcare safety rather refers to

policies or institutional practices that are decided to be implemented based on explicit risk assessments, but accepts a certain degree of risk associated with them. As such, an adverse event resulting from a medication error, for example giving the incorrect dose of morphine, is different from an adverse outcome that is the result of a planned treatment strategy that to a certain extent is inherently risky even if the procedure is carried out in accordance with the institutional safety policy, as for example transmitting a virus during a blood transfusion.

A taxonomy or classification of adverse events will help to ensure that we consider a relevant range of examples and circumstances influencing their value, while investigating methods to value safety. Furthermore, a classification system has the potential to facilitate global monitoring and reporting of errors and near misses, and facilitates to the understanding of these incidents through better information on their prevalence, type, cause, severity and consequences. Although there have been many studies about safety, and patient safety is now recognized as a priority for any healthcare system seeking to assure and improve quality of care, no internationally agreed classification system for patient safety data is in place [6]. The Australian Patient Safety Organisation, however, recently published an information and management system based on a universal patient safety classification that would allow the worldwide sharing of information and dissemination of tools and devices for the implementation of strategies that have been shown to work [18]. In this classification system, healthcare incidents are divided into types, such as incidents related to therapeutic agents, to equipment and infrastructure, to clinical management, investigation and documentation or to specialty incident types [18,19]. Although this seems a promising next step, the actual feasibility and effectiveness of the system in terms of safety improvement have yet to be assessed.

Patient safety research

Patient safety research initiatives can be divided in three stages, being (1) identification of risks and hazards; (2) design, implementation and evaluation of patient safety practices and devices, and (3) maintaining vigilance to ensure that a safe environment continues and patient safety cultures remain in place [20]. Clearly, different research methods and approaches are needed at each of these different stages.

So far, most patient safety research has focused on stage one, i.e. identification of risks and hazards. Moreover, research has mainly addressed adverse events with serious or catastrophic outcomes, obviously assuming that these also consume the most healthcare resources, but failing to investigate this empirically. In 2002, however, Runciman et al. showed that adverse events leading to ‘only’ minor disability generate 60% of the total additional hospital stay associated with all adverse events, versus 36% for adverse events leading to major disability and 4% for adverse events leading to death [21]. Since adverse events in general, and minor adverse events in particular, are underrepresented in randomised trials [21], and today’s safety improvement recommendations are prioritised “by the rigour with which safety interventions are studied but not by their cost-effectiveness” [8], we face a

situation in which a disproportionate amount of finite resources is probably allocated to the prevention of serious, but rare and relatively inexpensive adverse events. Thus, there is a need for economic evaluation in assessing the value of safety improvements across a variety of healthcare incidents, including those causing 'only' minor disability.

Economic evaluation of safety – need for a new approach?

In the economic analysis of healthcare incidents, in principle, the same costs and cost issues are at stake as in other economic evaluations. Costs have been classified into earning losses, lost household production and expected direct healthcare costs [14,17]. Since the emphasis on direct costs might distract the attention from important human costs, as pain and suffering of patients and/or loss of morale and frustration among healthcare providers, costs of healthcare incidents have also been classified in human costs, health system costs, tort system costs and lost opportunities [12]. The latter are also treated as a value of a medical intervention or device that reduces healthcare incidents.

As in all economic evaluations, the decision as to which cost to include in such analyses depends on the perspective taken. To this regard, whether or not to include medical-legal costs and compensation payments can be discussed. Following social welfare theory, medical-legal costs absorb available resources and should be included, but compensation payments should not be included as such since they do not absorb resources from society as a whole, but are merely a transfer of resources from one part of society to another. However, the care they enable the recipient to receive is a call on resources and should be included. From an NHS perspective, as would be adopted by NICE, compensation costs do need to be included, because expenditure used for compensation or settlement of legal claims has a direct opportunity cost in terms of the resources no longer available to the healthcare system.

Most importantly, however, is the challenge to appropriately include people's value judgement in the economic evaluation of a safety device or system [22]. For example, how should the avoidance of a needle stick injury or MRSA infection be valued? Would that simply depend on the consequences of that healthcare injury? Or would there also be nonhealth outcomes or process attributes at stake in the valuation of safety? Presumably, relatively intangible factors such as 'blame and shame', whether the incident has an iatrogenic cause or not, and the visibility of the consequences of the incident, affect the value placed on safety. Moreover, the extent to which a person can control the potential occurrence of an adverse event and the degree to which this person is risk averse (or risk seeking) will have an impact on their valuation. For example, most people deem it more safe to drive a car (that they can control) than to travel by airplane (which most of us do not control) and, as such, most of us probably place more value on increased air traffic safety than improved car safety, though the per-hour adverse event rate of the two is comparable. Similarly, if policy makers have to decide to spent scarce resources to either prevent a terrorist attack or to prevent people from eating fatty foods that cause heart attacks, what would they do? After all, terrorists are still more beyond our control than are

French fries, and dying as a result of a bomb attack is generally considered more dreadful than dying from heart disease, although the latter is far more likely in Western Europe.
The above illustrates a couple of issues that people might be considering when valuing safety. In the following paragraphs, the relationship between risk perception and the willingness to pay for safety improvements will be explored in more detail. Although safety systems are risk-neutral, individuals are generally risk averse to medical errors and it seems that risk perceptions and attitudes underlie many, if not all, of the before mentioned issues.

CONCEPTUAL FRAMEWORK

Conjoint analysis (CA) has been applied in health economics to determine how much benefit is derived from attributes beyond health outcomes itself, as process attributes or nonhealth attributes including for example risk and safety management strategies, reassurance, and prevention of healthcare incidents. Where cost is included as an attribute, conjoint analysis also allows for indirectly estimating willingness-to-pay (WTP) for improvements in individual attributes [23]. This is derived from Lancaster's theory of demand, which posits that a consumer values the quantity of product attributes at his disposal through the purchase of a commodity [24].
Because of its multi-attribute nature and its potential to explicitly include risk perception in the analyses, CA is considered as a means to overcome the principal limitations of current economic evaluation of safety improvement. The final attributes to value safety should therefore include both health and nonhealth outcomes and allow for the incorporation of risk attitudes into the conjoint analysis, whilst the inclusion of cost as an attribute additionally permits the estimation of individual WTP for changes in the level of attributes provided in the model as well as overall WTP for safety interventions with given attributes.

Risk perception and the value of safety

Basically, there are two crucial aspects of social responses to risk: public perception of hazards and social values for risk changes. Although these two research areas are closely related, and are major themes in much of the writing on societal responses to technological hazards [25-27], the potential relationship between them has received relatively little attention. Rather, the two areas have flourished as separate dimensions of risk management research. Economists and decision theorists have investigated the social value of health risk changes (i.e. the value of life) that should be employed in cost-benefit analysis of risk management options [28-29]. Normative economic analysis have emphasized the importance of an individual's wealth and base of initial level of risk as influences on willingness to pay (WTP) for reductions in risks [27,30,31]. At the same time, psychologists have investigated how people perceive and react to various hazards (27,32, 33). This research shows that diverse hazards can be understood in terms of their perceived underlying attributes, such as the extent of knowledge about a hazard, whether it is a source of dread, and the perceived exposure to the hazard.

Other studies on risk perception also demonstrated that people have a broad conception of risk, which is qualitative and complex and brings considerations such as uncertainty, dread, catastrophic potential, controllability, voluntariness, equity, risk to future generations, and so forth, into the equation [34,35]. This 'contextualist conception' of risk and safety places probabilities and consequences on the list of relevant attributes along with the before mentioned contextual parameters and assumes that risk and safety are characterised by some combination of these attributes [32-36].
Psychological research suggests that attributes of interest for the non-market good 'safety' could include the characteristics of hazards as perceived by consumers [24,27,34]. Taking Lancaster's theory of demand as a starting point, the perceived characteristics of hazards could enter into consumer utility functions when evaluating safety trade-offs and become partial determinants of the WTP for safety, next to the more traditional socioeconomic variables as emphasized in the normative literature.

Measuring willingness to pay for risk reduction

Estimates of WTP for risk reduction are of great importance for health policy because they permit individual preferences to be expressed in the non-market domain. As such, they can be used to provide guidelines for structuring the NHS budget. Traditionally, the means for improving healthcare safety, while affecting health, have come from sources that are not necessarily incorporated in the health budget. Thus, a first use of estimates of WTP for risk reduction is to improve the allocation of the budget between health and non-health components. Second, within the health domain, one (e.g. health insurers or procurement agencies) may want to trade off attributes against each other. For example, the potential preventive benefits of a particular medical device may be traded-off against curative benefits of another. However, since consumers cannot be forced to take advantage of preventive devices made available by industry or else, considerations of relative effectiveness need to be complemented by WTP estimates indicating whether individuals at risk value these devices to a sufficient degree as to actually take advantage of them.

METHODS

A way to use conjoint analysis for the economic evaluation of safety will be illustrated here from the contexts 'general health care', 'engineered sharps injury protections' (as an exemplar of staff safety) and 'interventions to reduce the incidence of MRSA infection' (exemplar for patient safety). This research explicitly focuses on healthcare professionals that have experience with budgeting and decision-making in healthcare, which will have consequences for the selection and definition of attributes. A further developed, fine-tuned version of the methodology is foreseen to be applied on patient groups in the future, but is currently beyond the scope of this paper.

Establishing attributes and their levels

An initial literature review was undertaken to identify key attributes of safety. Subsequently, a series of semi-structured one-to-one interviews with healthcare professionals were performed with the aim to determine and prioritise attributes of safety in a general healthcare context as well as in the contexts of needle stick injuries [22,37] and MRSA infections [38,39]. The study sample consisted of ten safety managers associated with the NPSA, all involved with budgeting at various levels but from different professional backgrounds (e.g. public health, nursing, governance – See Table 1 for study sample characteristics). Potential participants were informed about the purpose and procedures of the interview and a meeting was scheduled after written informed consent had been obtained. Interviews included one exercise [40] were respondents had to allocate a fixed budget of 100 points over a predefined set of attributes and another exercise [40] where they had to prioritise the six most important attributes, including attributes that were not part of the literature-based set provided for exercise one, but that were considered highly relevant by the respondent in each of the contexts. To standardise the framework for each context, respondents were given some background facts and figures on the likelihood of healthcare incident(s); their consequences, associated costs and ways to prevent the incident(s) and/or treat the health consequences [41-44]. All interviews were recorded and transcribed.

After identifying the six most prioritised attributes for each context, the levels for each attribute were carefully chosen by the research team to reflect plausible ranges, using suggestions of the interviewees, and include realistic levels that are sensible to respondents and are capable of being traded off against each other. Trade-offs arise where respondents are prepared to substitute a deterioration in one attribute for an improvement in another attribute within a discrete choice experimental design [23].

The selection of attributes and levels that emerged from this qualitative study will serve as the basis for a subsequent large-scale written questionnaire survey, in the format of a discrete choice experiment, to gain insight in the relative weight of the attributes.

Linking conjoint analysis to the standard-cost benefit framework

Assuming that the health consequences of a healthcare incident will be identified as one of the six most important attributes of safety, we propose to express the levels attached to this attribute in terms of QALYs. From a health economic perspective, ideally, one would like respondents to trade off QALYs directly, e.g. 0.6 QALY in scenario A versus 0.8 QALY in scenario B. However, a prerequisite for these trade-offs to be reasonably made and generate valid outcomes of the CA, is that respondents understand the QALY concept. Although this might be feasible for some stakeholder groups, it is likely to be too challenging for others. Alternatively, one could present scenario's including descriptions of health states reflecting potential health outcomes, which could subsequently be mapped on the associated EQ5D tariffs, in first instance by using existing literature.

Regardless the alternative that will be chosen, this approach would allow 1) producing the standard ICER in terms of cost/QALY, where 'cost' is effectively the financial consequences of one healthcare incident to society (in case a societal perspective is adopted for the analysis) and 2) to estimate marginal WTP for a level change in QALYs (i.e. purely based on health outcomes) in addition to total WTP for the scenario as a whole, i.e. including the nonhealth and process factors, which are perceived as most important for a given context.

RESULTS

Literature review

From published scientific literature on healthcare and environmental safety the following attributes of safety emerged [32-36]:

- likelihood of the healthcare incident;
- financial consequences;
- health consequences;
- timing of occurrence of the consequences (direct or delayed);
- voluntariness of being in the 'risky' situation;
- preventability of the healthcare incident;
- dreadfulness of the incident and its consequences;
- controllability of the healthcare incident and its consequences;
- trust in the safety systems / devices to manage the risk;
- equity of the risk for a particular healthcare incident among the total population.

Allocation exercise

Of the ten predefined attributes, preventability and likelihood of the incident are considered to be most important, with median scores as obtained from the allocation exercise of 35 and 15 points respectively. All other attributes scored five points, except the attributes 'voluntariness' and 'timing', which returned medians of zero points (See Table 2).

Completeness and prioritisation of attributes by context

General healthcare context

Fifty percent of respondents regarded the predefined set of attributes to be complete for application to a general healthcare context. Attributes suggested to be added or substitute some of the predefined attributes include: 'cost of preventing the incident to happen', 'perceived risk for the incident to happen', 'adverse effects on individual staff involved in the occurrence of an incident' and 'adverse effects on the profession as a whole and professional values of staff'.

The predefined attributes 'voluntariness' and 'timing' were considered to be redundant by ≥50% of respondents, and are most likely to be sacrificed for the new attributes mentioned above.

Ninety percent of respondents rank the attribute 'preventability' at place one, versus one respondent who ranks 'adverse effects on the profession as a whole and professional values of staff' highest. Rankings two to six show a more heterogeneous pattern and are presented in Table 3. The six attributes with the most top 6 ranks are: preventability (n=9), likelihood of the incident (n=8), health consequences (n=8), dreadfulness (n=6), controllability (n=6) and trust (n=6).

MRSA context

Fifty percent of respondents consider the predefined attributes to be complete for the MRSA context. The same new attributes have been suggested for this context as for the general healthcare context. However, they appear in the top six ranking more often, again at the cost of the attributes 'timing' and 'voluntariness'.

Preventability again dominates the rankings, being considered the most important attribute of safety by 70% of respondents. Further, the attributes 'health consequences', 'financial consequences' and 'adverse effects on individual staff', received a number one rank each. The top six of attributes is formed by preventability (n=10), controllability (n=9), likelihood of the incident (n=8), health consequences (n=7), financial consequences (n=7) and trust (n=6) (see Table 3).

Sharps injuries context

Forty percent of respondents regard the predefined set of attributes to be complete for the sharps injuries context. Except for the attribute 'perceived risk of the incident to happen', the same new attributes have been suggested. In this context, however, the new attributes were suggested to replace timing and dreadfulness, while voluntariness gets relatively more weight. Nevertheless, preventability receives the most number one ranks, and the top six includes to a large extent the same attributes as found for the general healthcare and MRSA contexts (see Table 3), being: preventability (n=8), health consequences (n=8), trust in safety systems / devices (n=8), financial consequences (n=7), controllability (n=6) and a shared sixth position for voluntariness and likelihood of the incident (both n=5).

Selection of attributes and associated levels

The final selection of attributes is based on the results of the interviews, and theoretical and methodological requirements to allowing estimation of WTP, account for risk attitudes and linking the results of the planned discrete choice experiment to the standard cost-benefit framework.

Given the above, the following attributes are selected for each context: preventability, likelihood of the incident to happen, average health consequences, financial consequences, cost to you as an individual healthcare professional in case of an adverse event, and trust in safety systems / devices. In addition, two context specific attributes have been selected based on the combined results of the ranking and

allocation exercises, being 'dreadfulness' for the general health context; and 'controllability' for the MRSA and the sharps injuries contexts.

Levels are to be context-specific, but mapping the health consequences to EQ5D tariffs or trading off QALYs directly, would allow comparison of QALYs across a range of safety improvements in different contexts. One can calculate the cost per QALY, by dividing the difference in financial consequences over the difference in QALYs generated in each scenario, but when comparing the costs/QALY estimates over a variety of contexts, the financial consequences should reflect the same perspective (e.g. societal) in every context. Levels for the selected attributes in each context are suggested in Tables 4A-C, including both the direct as well as the indirect QALY levels. Examples of two possible scenarios for each context to be traded-off against each other is provided below:

Example: General health care context

Choice X	**Scenario A**	**Scenario B**
Likelihood of the healthcare incident to happen to you	10%	5%
Average health consequences of the healthcare incident	Loss of 0.5 QALYs *OR* "Moderate impact on general health"	Loss of 0.75 QALYs *OR* "Severe impact on general health"
Total financial consequences of the healthcare incident to society	£500	£10,000
Cost to you as an individual healthcare professional	£500	£1000
Extent to which the healthcare incident can be prevented	Preventable in circa 80% of cases	Preventable in circa 10% of cases
Amount of trust that can be placed on safety systems and devices to reasonably prevent and/or manage healthcare incidents	Limited amount of trust	Limited amount of trust
Perceived dreadfulness if the healthcare incident would happen to you	Very dreadful	A little dreadful

Example: MRSA context

Choice X	**Scenario A**	**Scenario B**
Likelihood of an MRSA infection to happen to you	25%	1%
Health consequences of the MRSA infection	Loss of 0.15 0QALYs *OR* "Asymptomatic infection"	Loss of 0.48 QALYs *OR* "Symptomatic infection leading to permanent impairment"
Total financial consequences of MRSA infections to society	£10,000	£5000
Cost to you	£3000	£500
Extent to which MRSA infections can be prevented	Preventable in circa 80% of cases	Preventable in circa 10% of cases
Controllability of MRSA infections (once detected) Amount of trust that can be placed on safety systems and devices to reasonably prevent and/or manage MRSA infections	Hardly controllable Limited amount of trust	Usually controllable Substantial amount of trust

Example: Sharps injuries context

Choice X	**Scenario A**	**Scenario B**
Likelihood of a sharps injury to happen to you	10%	25%
Health consequences of a sharps injury	Loss of 0.64 QALYs for a maximum of two weeks, no QALY loss afterwards *OR* "Acute symptomatic hepatitis, leading to general ill-health for up to two weeks, but full recovery afterwards"	Loss of 0.15 QALYs *OR* "No health consequences due to post-exposure prophylactic treatment "
Total financial consequences of sharps injuries to society	£10,000	£5000
Cost to you	£1000	£500
Extent to which sharps injuries can be prevented	Preventable in circa 10% of cases	Preventable in circa 80% of cases
Controllability of MRSA infections (once detected in a hospital)	Hardly controllable	Usually controllable
Amount of trust that can be placed on safety systems and devices to reasonably prevent and/or manage MRSA infections	Substantial amount of trust	Limited amount of trust

Linking the outcomes to the standard cost-benefit framework (hypothetical example)

Assume the following equation would have been estimated for each of the contexts:

$$\Delta \text{ Benefits} = \alpha_1 \text{LIKELIHOOD} + \alpha_2 \text{HEALTH} + \alpha 3 \text{FINANCIAL} + \alpha_4 \text{COST} + \alpha_5 \text{PREVENT} + \alpha_6 \text{TRUST} + \alpha_7 \text{`Context-Specific'} + e + u$$

where Δ Benefits is the change in utility in moving from one safety scenario to another, for example as a result of a new safety device, LIKELIHOOD is the probability for a certain healthcare to happen within a certain time period, HEALTH are the average health consequences (physical and mental) that result from the healthcare incident, FINANCIAL are the total costs associated with one healthcare incident from a certain perspective, COST are the 'cost to you' in terms of the money you have to spent, in case of an adverse event, from the institutional budget that is allocated to you as an individual healthcare professional, PREVENT is the extent to which a particular healthcare incident can be prevented from happening, and TRUST is the amount of trust that is placed on the current available safety systems and devices to reasonably prevent and/or manage healthcare incidents. For a general healthcare context the 'Context specific' parameter is the perceived dreadfulness of the incident and its consequences; in the MRSA and sharps injury contexts it refers to the extent to which infections can be controlled once detected. The unobservable error terms are represented by e and u, where e is the error term due to differences among observations and u is the error term due to differences among respondents [23]. A constant term will be 'suppressed' by asking subjects to assume that all aspects of health care, other than those specified in the questionnaire, are identical for all presented scenarios [23]. The relative importance of the different attributes can then be given by α_j (j= 1,2,3,4,5,6,7) [23]. The ratio of the parameters would show the trade-offs between the attributes with α_j/α_4 being an estimate of the WTP for levels of the individual attributes [23]. Consequently, α_2/α_4 estimates the marginal WTP for an improvement in health outcomes, which can be directly or indirectly derived QALYs, between two scenarios. The difference between this estimate and the estimated WTP for the total marginal benefit of the difference between two scenarios as a whole would show the potential discrepancy between the 'value' of safety as purely based on health outcomes (which is the current standard) versus the 'value' of safety from a contingent perspective. Further, α_1/α_4 and α_5/α_4 can be viewed as an indication of the extent to which people are risk averse (or risk seeking), since these ratios are estimates of the WTP for a reduction in the likelihood of the incident to happen and increase in extent to which the incident can be prevented, respectively. The proposed approach is illustrated below with an example based on hypothetical estimates.

Example: Hypothetical output from a conjoint analysis study

Attribute	Coefficient	Marginal WTP (£)	Current	Proposed	Difference	Benefit marginal utility	Benefit marginal WTP
Likelihood (%)	−0.455	14.68	10	5	−5	2.28	73.39
Health consequences 0 = none (0 QALYs), 1 = mild (-0.25 QALYs) 2 = moderate (-0.5 QALYs) 3 = severe (-0.75QALYs) 4 = death (-1.0 QALYs)	−0.586	18.90	2	0	−2	1.17	37.81
Financial consequences (£)	−0.012	0.39	£5000	£500	−£4500	£54	£1741.94
Cost to you (£)	−0.031	N/A	£500	£100	−£4000	£12.40	N/A
Preventability 0 = hardly preventable, 1 = preventable in the majority of cases	0.176	5.68	0	1	1	0.18	5.68
Trust 0 = limited, 1 = substantial	0.153	4.94	0	1	1	0.15	4.94
Dreadfulness 0 = somewhat dreadful, 1 = very dreadful	−0.418	13.48	1	0	−1	0.42	13.48
Total (£)						**70.59**	**1877.23**

For the purpose of this example we assume that all coefficients have the expected sign and are statistically significant at the 1% level. The positive signs on the attributes preventability and trust indicate that the higher these attributes are in the proposed scenario relative to the current scenario, the more likely the individual is to choose the proposed scenario over the current. Similarly, negative signs on likelihood, financial consequences, cost and dreadfulness indicate that the lower these attributes are in the proposed scenario as compared to the current scenario, the more likely an individual is to choose the proposed scenario.

This output would indicate, for example, that a one pound reduction in the 'cost to you' would result in less benefit than a 1% fall in likelihood of the incident, since the effect size −0.031< −0.455. Substantial trust in the system would be more important than a 10 pound decrease in cost of one incident to society (0.153 > [10*0.012]), but preventability would be more important than trust (0.176 > 0.153). Further, an individual healthcare professional would accept a 1.28% increase in the likelihood of an incident to happen for a one level reduction in severity of its health outcomes. Finally, professionals would be willing to pay from their allocated budget: £14.68 for 1% reduction in likelihood, £18.90 for a one level decrease in health consequences, £0.39 for one pound decrease in total cost to society, £5.68 for improved preventability, £4.94 for improved trust, and £13.48 for one level reduction in perceived dreadfulness of the incident.

As regards linking the outcomes of the CA to the standard cost-utility and cost-benefit framework, the following is suggested: assume the output presented above to be collected in a general healthcare context and the associated EQ5D tariff for health outcome level '2' to be 'loss of 0.5 QALYs' and 'no QALY loss' for outcome level '0'. Undiscounted, this would indicate the current scenario to generate −0.5 QALYs and the proposed scenario 0 QALYs, thus choosing the proposed scenario over the current would lead to an increase of 0.5 QALYs. Given a difference in 'total financial consequences to society' of −£4500 for the proposed scenario relative to the current, the resulting ICER would be: −£4500/0.5 = −£9000 QALY. Further, the marginal WTP for a one level change in health outcome would be £18.90, resulting in benefit marginal WTP of £37.81 for the difference in health outcomes between the two scenario. This is only a fraction of the total WTP of £1877.23 and even when the benefit marginal WTP for 'financial consequences' would be ignored for a moment, because of its dominance in this hypothetical example, the fraction of WTP for health outcomes would be ≤50% of the remaining total WTP of £135.29. This approach may thus provide an indication of the direction and magnitude of the discrepancy between (in this case: underestimation of) the total marginal 'value' of a change in safety from a contingent versus a purely health focused perspective.

DISCUSSION

The principal limitation of methods for assessing the value of improved safety is perceived to be their failure to take risk attitudes into account and their neglect of important aspects of safety other than the direct medical health outcomes and costs associated with an adverse event. The aim of this paper was therefore to describe the development of a research methodology for understanding how stakeholder groups value scenarios consisting of both health and non-health attributes of safety improvements in different healthcare contexts and to link this 'extra-consequentialist' approach into the standard cost-benefit framework. To achieve this, a literature search was carried out to identify all potentially relevant attributes of safety, followed by a series of semi-structured interviews to select the most important ones. Finally, a methodological exercise based on hypothetical CA-results was performed to illustrate how data generated by a conjoint analysis could potentially be linked into a standard cost-utility or cost-benefit framework.

The literature review yielded 10 potential attributes of safety and showed that in addition to probabilities and health consequences, factors as uncertainty, dread, controllability and voluntariness are likely to have an impact on the value of improved safety and WTP for that. Although only half of the respondents regarded this predefined set of attributes to be complete, and other attributes were suggested, these 'new' attributes did eventually not reach enough top 6 rankings to be included in the final set of attributes. The results from the interviews indicated that 'likelihood of the incident to happen',' health consequences', 'financial consequences', 'preventability of the healthcare incidents' and 'trust in safety systems / devices', were regarded of major importance in a general healthcare context, a patients safety (i.e. MRSA) context as well as a staff safety (i.e. sharps injuries) context. Furthermore, two context specific attributes were identified, being 'dreadfulness' for a general healthcare context and 'controllability' for the MRSA and sharps injuries contexts. This suggests that prioritisation of attributes may vary depending on the type of safety context that is investigated. The fact that for both the MRSA and sharps injuries contexts the additional attribute 'controllability' was selected, is most likely due to the fact that both consider infections. Although the selection of context specific attributes might improve the accuracy of WTP estimates for particular safety attributes within one context, it may hinder the comparability of results across contexts. As such, the question remains if one should aim to decide on one set of safety attributes to be applied across all contexts, or if future studies may first want to identify the most important attributes in a pilot study, given the particular context that will be investigated, before conducting a larger scale CA.

Furthermore, since this study is very much 'work in progress', so far only safety managers associated with the NPSA have been interviewed. Although they come from a variety of professional backgrounds, the sample size of n=10 was considered too small to derive

conclusions regarding variations between stakeholders groups in valuing safety. However, the method used to prioritise attributes, which was based on a previously validated method [40], has proved to be feasible and informative. It will be applied in further interviews with medical managers and front-line staff (e.g. physicians and head nurses) to test the hypothesis that, keeping all else equal, the relative weight of safety attributes will vary significantly between stakeholder groups as well as the total WTP for a particular safety improvement.

Another aspect of the proposed methodology that needs careful consideration is the levels that have been attached to the attributes. As previously described in the health economic literature, the indirect estimation of WTP in conjoint analysis via a cost attribute, faces many methodological challenges, most of which are associated with determining the appropriate range and magnitude of the cost levels [45-47]. Whilst acknowledging that these issues undiminished apply to this study, we would like to focus this discussion on the levels that have been proposed for the attribute health outcome.

Directly trading off the health outcomes associated with an adverse event in terms of QALY losses, combined with the WTP estimates derived from the CA, would be a useful vehicle to link the results of the CA into the standard cost-utility framework. However, in many respondent groups, the approach of directly trading off QALYs is likely to challenge an important prerequisite for any conjoint analysis, i.e. that levels should be "plausible, actionable, and capable of being traded" [23] and could therefore lead to invalid results. When targeting individuals that have substantial experience in medical decision-making, such as medical managers, this limitation could potentially be overcome by explaining the QALY concept beforehand, for example by means of a one page information sheet or in person. For others, however, with no previous experience in medical decision-making or who never before had to think (let alone decide) in terms of QALYs, this might be a bridge too far. In that case, one could apply an indirect estimation of QALYs by describing the health outcomes in a general clinical way, and map these onto EQ5D tariffs. The advantages of this approach would most likely be a higher response rate as well as increased validity and reliability of the results. A major disadvantage of the approach would be that the researcher does not know to what extent the EQ5D tariffs that are mapped onto each potential health outcome, actually reflect the loss in quality of life as perceived by the respondent for the described health outcome. As this remains an open ended question so far, further research into the validity and reliability of CA results generated by either directly or indirectly trading-off QALYs within a discrete choice experiment, is needed to decide on the best way forward. Suggestions to this regard, as well as pertaining to the definition and levels of the other attributes, are very much welcomed.

Finally, the use of conjoint analysis for assessing multiple dimensions of healthcare innovations, thus allowing for a more meaningful comparison with other healthcare

interventions in the pursuit of efficient allocation of resources, is increasingly suggested as an alternative to the standard economic evaluations that are based on one single measure of health outcome. Conjoint analyses in the field of risk assessment and diagnostics, for example, have shown that both physicians and the general public attached significant utility to aspects of diagnostics other than their pure clinical value [48,49,50], and thus indicate that results comparable to the hypothetical outcomes showed in this paper, might actually arise from future studies and have an impact on healthcare policy making. At this moment, however, the challenge remains to further develop a research methodology that adequately deals with difficulties in eliciting valid cost and utility estimates, is applicable across different healthcare interventions and contexts, while accounting for risk attitudes and preferences of the (different) stakeholder groups involved.

Literature

1. Shimmel EM. The hazards of hospitalization. Ann Intern Med. 1964;60:100-1.
2. Ogilvie RI, Ruedy J. Adverse drug reactions during hospitalization. Can Med Assoc J. 1967;97(24):1450-7.
3. Ogilvie RI, Ruedy J. Adverse reactions during hospitalization. Can Med Assoc J. 1967;97(24):1445-50.
4. Steel K, Gertman PM, et al. Iatrogenic illness on a general medical service at a university hospital. N Engl J Med. 1981;304(11):638-42.
5. Brennan TA, Leape LL, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. NEJM 1991;324(6):370-6.
6. Kohn L, Corrigan J, et al. To Err Is Human: Building a Safer Health System. Washington, DC: Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, 2000.
7. Shojania KG, Duncan BW, et al. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence report/Technology Assessment No. 43 (Prepared by the University of California at San Francisco–Stanford Evidence-Based Practice Center under Contract No. 290-97-0013). AHRQ Publication No. 01-E058. Rockville, MD: Agency for Healthcare Research and Quality, 2001.
8. Warburton RN. Patient safety-how much is enough? Health Policy 2005;71(2): 223-32.
9. Department of Health, UK. An organisation with a memory: report of an expert group on learning from adverse events in the NHS. DoH, London: The Stationery Office, 2000.
10. Department of Health, UK. Making Amends: a consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS. DoH, London, 2003.
11. Gray A. Adverse events and the National Health Service: an economic perspective. Report to the National Patient Safety Agency. Oxford: University of Oxford, Health Economics Research Centre, Department of Public Health, 2003.
12. Runciman WB, Moller J. Iatrogenic injury in Australia. Adelaide: Australian Patient Safety Foundation, 2001. http://www.apsf.net.au/dbfiles/Iatrogenic_Injury.pdf
13. Couch NP, Tilney NL, et al. The high cost of low-frequency events: the anatomy and economics of surgical mishaps. NEJM 1981;**304**(11):634-7.
14. JohnsonWG, Brennan TA, et al. The economic consequences of medical injuries. Implications for a no-fault insurance plan. JAMA 1992;**267**(18):2487-92.
15. Kalish RL, Daley J, et al. Costs of potential complications of care for major surgery patients. Am J Med Qual 1995;**10**(1):48-54.
16. Schneider PJ, Gift MG, et al. Cost of medication-related problems at a university hospital. Am J Health Syst Pharm 1995;**52**(21):2415-8.

17. Thomas EJ, Studdert DM, et al. Costs of medical injuries in Utah and Colorado. Inquiry 1999;**36**(3):255-64.
18. Runciman WB, Williamson JAH, Deakin A, Benveniste KA, Bannon K, Hibbert PD. An integrated framework for safety, quality and risk management: an in information and incident management system based on a universal patient safety classification. Qual Saf Health Care 2006;**15**(Suppl 1):i82-i90.
19. Rasmussen J. Information processing and human-machine interaction: an approach to cognitive engineering. System Science and Engineering Series, vol. 12. New York: Elsevier, 1986.
20. Battles JB, Lilford RJ. Organising patient safety research to identify risks and hazards. Qual Saf Health Care 2006;**12**(Suppl 2):ii2-ii7.
21. Runciman WB, Edmonds MJ, Pradhan M. Setting priorities for patient safety. Qual Saf Health Care 2002;**11**:224-9.
22. Fisman DN, Mittleman MA, et al. Willingness to pay to avoid sharps-related injuries: a study in injured health care workers. Am J Infect Control 2002;**30**(5):283-7.
23. Ryan M. A role for conjoint analysis in technology assessment in health care? Int J Technol Assess Health Care 1999;**15**(3):443-457.
24. Lancaster K. A new approach to consumer theory. J Pol Econ 1966;**74**:132-57.
25. Fischhoff B, et al. Acceptable Risk. Cambridge: Cambridge University Press, 1981.
26. Morgan MG. Choosing and managing technology-induced risk. IEEE Spectrum 1981; December:53-60.
27. McDaniels TL, Kamlet MS, Fischer GW. Risk perception and the value of safety. Risk Analysis 1992;**12**(4):495-503.
28. Linnerooth J. The value of human life: a review of the models. Economic Inquiry 1979;**17**:52-74.
29. Weinstein MC, Shepard DS, Pliskin JS. The economic value of changing mortality probabilities: a decision theoretic approach. Quarterly J Econ 1980;**94**:373-96.
30. Jones-Lee MW. The value of life: an economic analysis. Chicago: University of Chicago Press, 1976.
31. Howard RA. On making life and death decisions. In: Schwing R and Albert W, Jr. (eds.), Societal Risk Assessment: how safe is safe enough? New York: Plenum Press, 1980, pp 89-107.
32. Slovic P, Finucane ML, Peters E, MacGregor DG. Risk as analysis and risk as feelings: some thoughts about affect, reason, risk, and rationality. Risk Analysis 2004;**24**(4):311-322.
33. Peters E, Slovic P, Hibbard JH, Tusler M. Why worry? Worry, risk perceptions, and willingness to act to reduce medical errors. Health Psychology 2006;**25**(2):144-52.
34. Slovic P. Perception of risk. Science 1987;**236**:280-6.
35. Slovic P. The risk game. J Hazard Mater 2001;**86**:17-24.
36. Sjöberg L. Attitudes tpwrads technology and risk: going beyond what is immediately given. Policy Sciences 2002;**35**:379-400.
37. Leigh JP, et al. Costs of needlestick injuries and subsequent hepatitis and HIV infection. Curr Med Res Opin 2007; epub ahead of print.
38. Nixon M, Jackson B, Verghese P, Jenkins D, Taylor G. Methicillin-resistant Staphylococcus aureus on orthopaedic wards: incidence, spread, mortality, cost and control. J Bone Joint Surg (Br) 2006;**88-B**:812-7.
39. Lodise Jr TP, McKinnon PS. Burden of Methicillin-Resistant *Staphylococcus aureas*: focus on clinical and economic outcomes. Pharmacotherapy 2007;**27**(7):1001-12.
40. Ryan M, Scott DA, reeves C, Bate A, van Teijlingen ER, Russell EM, et al. Eliciting public preferences for healthcare: a systematic review of techniques. Health Technol Assess 2001;5(5).
41. Department of Health, UK. Safety First: A report for patients, clinicians and healthcare managers. DoH: London, 2006.
42. National Institute for Clinical Excellence, UK. Infection Control: prevention of healthcare-associated infection in primary and community care. NICE: London, 2003.

43. Pratt RJ, et al. Epic 2: National evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England. J Hosp Infect 2007;**655**:S1-S64.
44. Coia JE, et al., for the Joint Working Party of the British Society of Antimicrobial Chemotherapy, the Hospital Infection Society, and the Infection Control Nurses Association. J Hosp Infect 2007;**635**:S1-S44.
45. Ratcliffe J. The use of conjoint analysis to elicit willingness-to-pay values. Proceed with caution? Int J Technol Assess in Health Care 2000;16(1):270-90.
46. Stewart JM, O'Shea E, Donaldson C, Shackley P. Do ordering effects matter in willingness-to-pay studies of health care? J Health Econ 2002;21:585-99.
47. SlothuusSkjoldborg U, Gyrd-hansen D. Cinjoint analysis. The cost variable: an Achilles' heel? Health Econ 2003;12:479-91.
48. Berwick DM, Weinstein MC. What do patients value? Willingness to pay for ultrasound in normal pregnancy. Med Care 1985;23:881-93.
49. Mushlin AI, Mooney C, Grow V, Phelps CE. The value of diagnostic information to patients with suspected multiple sclerosis. Arch neurol 1994;51:67-72.
50. Sassi F, McDaid D, Ricciardi W. Conjoint analysis of preferences for cardiac risk assessment in primary care. Int J Technol Assess in Health Care 2005;21(2):211-8.

Table 1: Study sample characteristics

Variable	*Respondents (n=10)*
Age (years±sd)	46.4(±3.4)
Gender (m/f)	1/9
Experience with budgeting and/or decision-making in *healthcare in general* (years±sd)	9.5(±6.0)
Experience with budgeting and/or decision-making in *healthcare safety* (years±sd)	5.3(±3.9)
Professional/educational background:	
- RN / Midwife / Physiotherapist	6
- MSc (incl. Public Health / Epidemiology / Risk Management / Policy & Law)	5
- Risk management & Governance	2

[#] May not add up to 10 since individuals might have experience on more than one of the indicated levels.

Table 2: Allocation of a fixed 100-points budget over the ten predefined attributes

Attribute	*Median*	*1st quartile - 3rd quartile*
Likelihood	15	10 - 20
Financial consequences	5	0 - 5
Health consequences	5	4 - 10
Voluntariness	0	0 - 3
Timing consequences	0	0 - 2
Preventability	35	30 - 50
Dreadfulness	5	0 - 10
Controllability	5	0 - 10
Trust in safety systems / devices	5	0 - 10
Equity of the risk	5	0 - 8

Table 3: Overview of total number of top 6 rankings by context

Attribute	*Total number of top 6 rankings by context*		
	General healthcare	MRSA	Sharps injuries
Likelihood	***8***[*]	***8***	***5***[§]
Financial consequences	5	***7***	***7***
Health consequences	***8***	***7***	***8***
Voluntariness	0	0	***5***
Timing consequences	0	0	0
Preventability	***9***	***10***	***8***
Dreadfulness	***6***	4	3
Controllability	***6***	***9***	***6***
Trust in safety systems / devices	***6***	***6***	***8***
Equity of the risk	3	3	4
Cost of prevention	1	1	1
Perceived risk for the incident	1	2	0
Adverse effects on individual staff	2	1	1
Adverse effects on profession / professional values	3	2	2
Unspecified[#]	2	0	3

[#]Three respondents did not provide a top six, but limited their prioritisation to four or five attributes, leaving some ranks unspecified.

[*]Figures printed in bold italic font indicate that the attribute is part of the top 6 of highest ranked attributes for that context.

[§]The underlined figures indicate a shared 6th position, effectively leading to seven prioritised attributes instead of six.

Table 4A: Attributes and associated levels for a general healthcare context

Attribute	*Levels*
Likelihood of a healthcare incident to happen	5%
	10%
	25%
Health consequences of healthcare incidents	No health consequences (no QALY loss)
	Mild health consequences (-0.25 QALYs)
	Moderate health consequences (- 0.50 QALYs)
	Severe health consequences (-0.75 QALYs)
	Death (-1.0 QALY)
Total financial consequences of one healthcare incident to society	£500
	£5,000
	£10,000
Cost to you	£0
	£100
	£500
	£1,000
	£3,000
	£5,000
Preventability healthcare incidents	Preventable in circa 10% of cases
	Preventable in circa 80% of cases
Trust that safety systems / devices reasonably prevent and manage healthcare incidents	Limited amount of trust
	Substantial amount of trust
Perceived dreadfulness if the incident would happen to you	A little dreadful
	Very dreadful

Table 4B: Attributes and associated levels for a MRSA context

Attribute	*Levels*
Likelihood of a healthcare incident to happen	1%
	10%
	25%
Health consequences	No health consequences (no QALY loss)
	Asymptomatic infection (11112 => 0.848 => -0.15 QALYs)
	Symptomatic infection that is successfully treated (11122 => 0.725 => -0.27 QALYs)
	Symptomatic infection leading to permanent impairment (22222 => 0.516 => -0.48 QALYs)
	Death (0 => -1.0 QALY)
Total financial consequences of one MRSA infection to society[(Lodise2007)]	£1,250
	£15,000
	£50,000
Cost to you	£0
	£100
	£500
	£1,000
	£3,000
	£5,000
Preventability of health care incidents	Preventable in circa 10% of cases
	Preventable in circa 80% of cases
Controllability (once detected in a hospital)	Hardly controllable
	Usually controllable
Trust that safety systems / devices reasonably prevent and manage healthcare incidents	Limited amount of trust
	Substantial amount of trust

Table 4C: Attributes and associated levels for a sharps injury context

Attribute	*Levels*
Likelihood of a healthcare incident to happen	1% 10% 25%
Health consequences	No health consequences due to post-exposure prophylactic treatment (No QALY loss) Acute symptomatic hepatitis, leading to general ill-health for up to two weeks, but full recovery afterwards (21321=> 0.364 => -0.63 QALYs for two weeks; no QALY loss afterwards) Chronic asymptomatic hepatitis or HIV seropositive (11112 => 0.848 => -0.15 QALYs) Chronic symptomatic hepatitis (11222 => 0.689 => -0.31 QALYs) or AIDS (22222 => 0.516 => -0.48 QALYs) Death (0 => -1.0 QALY)
Total financial consequences of one sharps injury to society(Leigh 2007)	£75 £150 £300
Cost to you	£0 £100 £300
Preventability of health care incidents	Preventable in circa 10% of cases Preventable in circa 80% of cases
Controllability (once infection is detected)	Hardly controllable Usually controllable
Trust that safety systems / devices reasonably prevent and manage healthcare incidents	Limited amount of trust Substantial amount of trust