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Table of Contents

AUGMENTING THE DRIVER AND AUTOMATING DRIVING – INVESTIGATIONS INTO THE CHANGING NATURE OF THE ROLE OF THE DRIVER WITH ADVANCED VEHICLE SYSTEMS

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Abstract

Over the past 20 years, Prof. Stanton has been involved in a variety of system design projects. He initially conducted research into driver performance with Adaptive Cruise Control with Jaguar – which was first vehicle manufacturer to market with the system. In subsequent years he has worked on other systems, including: vision enhancement, parking aids, queue assist, all-weather warnings, head-up displays, blind-spot monitoring, collision avoidance systems and various levels of vehicle automation. The route from research to production normally takes the course of analytical modelling, studies in driving simulators, test track studies and, finally, on-road trials. The selection and application of appropriate Human Factors and Ergonomics methods in each of these development phases is essential for successful design. In the course of the presentation, Prof. Stanton will present findings from some of his studies and insights into conducting applied driving research projects.

MANAGEMENT AND EVALUATION OF CHANGE

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General summary

A theory and model of change was developed at the beginning of the MASCA project as a framework to guide the development, support and evaluation of a set of actual change case studies. These case studies include the following:

- The introduction and use of Safety Performance Indicators in a Safety Management system as a way of identifying and driving improvements in a major airline.
- The gap between what our goals are and what we actually do: The introduction of a more holistic performance management approach in a small regional airport.
- The difficulties in aligning local goals for a more global objective: the CDM (Collaborative Decision Making) initiative (sharing of data across different stakeholders, Handling, Airport, Airline, ATM).

According to Dawson (1996) basic capabilities in managing change involve knowing what needs to change, having the consensus or power to make change possible and having control over the variables that need to be changed (while other aspects remain stable). While Dawson believed that this combination is rarely, if ever achieved, MASCA seeks to establish an enduring basis for achieving these criteria. The following summarises an initial formulation of the theoretical position.

1. It is proposed to incorporate change processes within a general theory of socio-technical systems that addresses the functionality of processes within the context of social relationships and knowledge and information flows. The functional dimension of this process theory relates to the major sources of uncertainty in the system. For routine operational processes, the sources of uncertainty can concern the supply of resources, the performance of tasks or the co-ordination of activity. For change, the major source of uncertainty concerns the outcome of the process. This implies, for a planned programme of change, that an iterative approach is often required, in which the initial actions may often be wrong but set the preconditions for the correct actions; and where the pre-requisites of successful change may not be fully apparent until after the change has been accomplished. However, the issue of sequence is important – there is a fundamental logic in the way in which planned change (as opposed to change which is purely spontaneous or emergent) happens. In order to understand the vagaries of what happens in everyday life a template of how it should happen, if all the circumstances are optimal, helps to show the consequences that may follow from the pragmatic decisions that are forced

by circumstances. Also as not every initiative requires the same attention to all elements, the template forces one to consider why this may be so.

2. Because the mechanisms and movement of the functional system are different from those of the socio-cultural system of relationships there is almost inevitably a 'décalage' or misalignment between them. The former is sequential, delivering transactional value in real time, subject to short-term change, while the latter is reciprocal delivering the social stability to deliver value over a longer time frame. This décalage sets the agenda for how the requirements of a future functional system need to be matched socio-culturally – in terms of the form of relationships, common understanding, values, learning, and cultural barriers.
3. There are two knowledge cycles whose potential role is to bridge the gap between the functional and socio-cultural systems. On the social side are the sequences of knowledge conversion between tacit to explicit to tacit knowledge. These operate both formally and informally and form the common currency of everyday relationships, as well as learning, and, most generally, culture. On the technical side is the use of functional knowledge to define and aggregate data to create information and subsequently knowledge about how the system is functioning. Knowledge about how the system works is potentially a key motivator in accepting (or not) change. Apart from physically changing the system through new technology (or material conditions), managing these two knowledge cycles provides the strongest opportunity for managing change in a proactive way, through understanding and engaging some of the emergent properties of change. The trajectory of these cycles is from local to global knowledge, with an optimal circular movement that provides feedback and validation of the knowledge.
4. One aspect that this analysis will focus on concerns what aspects of change management can be said to represent an enduring capacity; as opposed to the aspects that represent a 'service' delivered during the change process.

Trade-offs

The initial theory placed a heavy emphasis on the factors that maintain stability in organizations and which therefore often frustrate change. It was argued that, in order to understand change and how to support and facilitate it, it is necessary to understand the forces that make for stability. From then it was argued that for change to be successful it is necessary to create sufficient momentum to overcome these forces for stability. From this came the nine dimensions in the MASCA change management model. This model is a relatively weak model from a scientific point of view – it shows these nine dimensions in relation to each other, but provides limited information about their functionality – how they work, what are the causal dynamics between them. Moreover, the implications of the change model are that, for change to work, all of this activity, across the nine dimensions, needs to work at the same time. However change rarely occurs in an ideal situation. The normal constraints within which change operates – the 'exigencies of the situation' include the following, amongst others:

- Urgency
- Lack of resources
- Changing situation
- Management changes, lack of continuity

- Hard decisions need to be taken that are not popular – do more for less
- Insecurity.

The initial MASCA change model paid little regard to these practical considerations.

It follows that any theory of change that is useful needs not only to give guidance as to what needs to be done to overcome the inertial forces in organizations, but also how this can be done under these ‘normal exigencies of the situation’. It is also important to know, at this stage in the change cases, how well they are doing, in terms of an optimal understanding of change management under practical constraints, so that it may be possible to adjust either or both the trajectory of the cases themselves or the support they receive from the MASCA CMS. For this reason, it has been decided to thoroughly review and revise the theory and model, and, where appropriate, to suggest how to optimize the case studies and the CMS. This will require a more analytic focus on the mechanisms of change in order to deliver an improved basis for the design and development of interventions as well as evaluation *per se*.

Significance/Takeaway

A more dynamic change theory developed out of these principles will permit an improved understanding the dynamics of change in a way that is directly testable through evidence from the change case studies, providing a possibility of evaluating outcomes against process. Through this it will provide better guidance and support to change initiatives. It will do so by focusing on the following capabilities:

- Understanding the past, present and future in a rich functional model that addresses system mechanisms – how the system works and therefore how it can change. The data-information-knowledge cycle can inform about what the system is doing also enabling projections to the future. The tacit-explicit cycle can identify potential misalignment between the functional system in the real world now (and in the anticipated future) and the cultural configuration of the social system (values, meanings, expectations, practices, etc.), identifying what needs to change at a social and cultural level.
- Building consensus and managing different types of power in the social relationships that define how change can happen. The MASCA system is based on developing knowledge as a resource that can aid the appropriate exercise of power. This is not only through technical knowledge of how the system functions, but also through participation in the knowledge processes that help build new relationships and develop consensus.
- Understanding how to achieve control (leverage) over the key variables that need to change to influence the outcome. Of course, this implies having the technical and social/organizational capability both to redesign and to implement the new design.

CAPTURING HEARTS AND MINDS: PREPARING AN ORGANISATION FOR BEHAVIOUR BASED SAFETY

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Abstract

Many companies fail to successfully implement behaviour based safety (BBS) programmes within their organisation. Often failures are linked to the implementation strategy rather than the programmes themselves. BBS can be introduced without a clear rationale and can create fear of change and lack of trust, leading to low employee buy-in. ESB is Ireland's premier electricity utility and one of Europe's leading engineering and consultancy companies. This paper outlines the structure of a BBS framework at ESB which seeks to (i) facilitate employee involvement and (ii) build trust through leadership alignment. Combining best practice research from behavioural science and crew resource management, ESB's approach seeks to capture the hearts and minds for safety. Details of this approach are provided so as to enable leaders in high reliability industries to introduce BBS in a way that produces employee involvement and develops trust and leadership commitment.

Introduction

Behaviour based safety (BBS) is "a proactive approach to improving safety within organizations that utilizes behavior analysis principles" (Alvero & Austin, 2006, p. 61). Principally BBS focuses on safe behaviours that, when exhibited, proactively prevent injuries, rather than more traditional reactive strategies to safety. Behavioural issues are important to address, because behaviour turns systems and procedures into reality. It is not enough for an organisation to have good safety management systems, because safety performance is determined by how organisations actually 'live' or 'act out' their systems (Reason, 1997). Research evidence and practical experience show that significant improvements in safety performance can be achieved by implementing appropriate behaviour based safety programmes (Fleming & Lardner, 2000). For example, BBS interventions have resulted in improved safety behaviours such as personal protective equipment use (Streff et al.,1993), driving speed (Van Houten & Nau, 1983) and have successfully reduced recordable incidents in high reliability industries, (Hermann et al., 2010; Myers et al., 2010).

While substantial improvements can be achieved through BBS programmes, it is important to note that, at the implementation stage, there can often be mixed feedback; some companies report success whilst other companies using similar programmes have experienced more disappointing results. Often a major barrier to the effectiveness of BBS programmes is linked to the implementation strategy itself. Without having a clear view for the rationale and objectives of BBS, issues can arise such as a lack of employee "buy in" and participation, a lack of management commitment and a view that it is an approach designed to "blame" the front line worker for incidents that occur (Agnew & Ashworth, 2012). In plain terms, it is not enough to introduce a BBS intervention and expect successful outcomes for safe behaviour without giving due attention to the challenge of commitment, acceptance and buy in. If BBS interventions are resisted or are grudgingly accepted, then the positive effects of improving safety culture and increasing safe behaviour will either not occur or will be mitigated. Consequently, to effectively employ BBS techniques, safety professionals must prepare the organisation.

This paper describes a BBS framework which incorporates a number of tools and approaches relevant for behavioural safety that seek to capture hearts and minds, create buy in, participation and build trust and commitment to behavioural changes for safety. To achieve these goals, this framework focused on three key objectives: (1) build interpersonal trust and support, (2) create leadership alignment and (3) facilitate employee involvement (DePasquale & Geller 1999; Geller, 2008).

Building interpersonal trust

According to Geller, (1998), "interpersonal trust is what's missing in a culture deemed unready for behaviour-based safety" (p.14). Assertions that a lack of interpersonal trust can cause resistance to BBS interventions is supported in research by DePasquale and Geller (1999) who found that trust in management's abilities significantly predicted employees' involvement and participation with BBS programmes. If employees perceive a BBS programme to be a method for management to "blame" the front line worker for safety incidents or to monitor their behaviour, participation in BBS processes will be minimal (DePasquale & Geller, 1999).

Creating leadership alignment

In building trust, leadership alignment with regard to the central messages of a behaviour based safety programme as well as their visible commitment to the process is vital. The day-to-day activities and behaviours of leaders, is crucial to an organisation's success with behaviour based safety programmes (Geller, 2008). Managers at all levels of the organisation need to exemplify a shared vision of safety excellence and demonstrate safety leadership styles and practices that will drive behaviour based safety programmes, including fostering a sense of employee ownership of safety (Geller, 2008).

Facilitating employee involvement

Employee involvement and engagement is a critical success factor for BBS. According to research by Fleming (2000) on behaviour modification programmes in the oil and gas industry, no BBS interventions should be introduced without employee involvement. To encourage employee involvement with BBS, it is important that the BBS approach has a structure that allows for employees to be actively engaged (Geller et al., 2004).

Case study: Preparing Ireland's premier utility company for behaviour based safety

Setting

ESB is Ireland's premier utility company and employs over 5,000 people across power generation, distribution and customer supply. Their behaviour based safety programme is initially targeting the generation and wholesale market division of 2000 people. This division operates a portfolio of power stations across Ireland and the UK. Safe working is an integral part of how ESB plan and organise their business. During the past 15 years, large improvements in safety have been achieved through improved hardware and design, and through improved safety management systems and procedures. However, ESB's safety performance has levelled out with little significant change being achieved during the past two to three years. A different approach focused on behaviour change is required to encourage further improvement.

Background Measures

Safety culture assessments were conducted with 400 staff members in generation and wholesale markets over a 12 month period, assessing areas relevant to safety such as workforce involvement, trust, and leadership commitment. Facilitators knowledgeable in the areas of human factors and behaviour based safety also conducted participatory workforce and leadership workshops with 290 members of staff and management, in groups of 12-15 people, over a 15 month period. The information from the safety culture assessments and the participatory workshops were fed back through numerous communication forums within the business at both the local and organisational level with a view to ascertaining readiness for BBS, maturity of trust between management and staff and levels of commitment to action and behaviour change for safety.

Intervention

In preparing ESB for a behaviour based safety approach, this project initially focused on three pilot locations of approximately 120 staff members and the organisation's executive safety leadership team. The programme was then rolled out across a wider audience of 170 people within the Generation and Wholesale Market division. The approach included the following steps:

- Leadership Alignment
- Safety Culture Assessment
- Delivery of Non Technical Skills Programmes for employees and safety leaders

The aims of this particular approach were to:

- Create leadership alignment around the central messages of the BBS approach that best promoted employee buy in and participation;
- Capture employees' hearts and minds for safety;
- Assess and build levels of trust and leadership commitment;
- Lay the foundation in preparing ESB for participation in a BBS programme;
- Facilitate employee engagement with and ownership of BBS approaches, ideas and techniques.

Leadership Alignment

To ensure commonality in the messages that were communicated from leaders in the business about BBS, there were numerous leadership alignment workshops held at various levels in the organisation so as to create a common vision for the BBS project (O'Reilly et al., 2010).

Safety Culture Assessment
To ascertain readiness for BBS, as well as benchmark the maturity levels of trust, workforce involvement and leadership commitment , 400 staff members' (including supervisors and senior management) perceptions about safety culture were assessed on a location by location basis, using the psychometrically robust HSL survey tool (Sugden et al., 2009). The themes assessed in the assessment included: organisational commitment; peer group attitude; health and safety behaviours; engagement with health and safety.

Non-Technical Skills Workforce and Leadership Programmes
Non technical skills programmes were developed for staff and leadership groups with a view to facilitating workforce involvement in engaging with a BBS approach, to build interpersonal trust between management and staff and to instill leadership commitment for BBS. These programmes also aimed to impart skills for safety relevant to the thinking (e.g. attention), social (e.g. communication) and personal resource skills (e.g. fatigue management) that are needed to keep staff safe in high reliability settings, as well as to raise awareness and create change relating to health and safety leadership behaviour. The programmes were developed with input from employees, supervisors and managers as well as leading research in the field of human factors (Flin, O'Connor & Crichton, 2008), crew resource management (Flin, O'Connor, Gordon et al., 2000) and insights gained from industry programmes such as Shell's Hearts and Minds (Hudson, 2007).

Results
To date, there is mostly qualitative data to support the objectives of ESB's approach to BBS and measures of success have been achieved anecdotally by speaking to employees and leaders about the effects it has had for them for safety.

Creating Leadership Alignment and Assessing and Building Trust
The leadership alignment workshops were successful in ensuring that senior leaders, supervisors and managers were clear in delivering a consistent message about the purpose and rationale of BBS. Employees and leaders reported that these central messages for BBS successfully captured their hearts and minds for safety, in that they appealed to the personal and humanistic elements of safety. Leaders also stated that these workshops helped give them the confidence to "sell" the message for BBS at the local level, with other leadership groups in the business and in discussions at safety committees. The safety culture assessments were useful in ascertaining the maturity level of a location and its readiness for BBS as well as helping to identify areas that would require improvement (e.g., trust and greater leadership commitment) prior to introducing a BBS approach and pinpointing health and safety concerns (e.g., the tone of communications for safety; attitude to certain risk behaviours).

Capturing Employee's Hearts and Minds for Safety
The non-technical skills workforce programmes were very effective in terms of creating engagement and involvement from employees with BBS and in their objective to capture "hearts and minds". Example comments from the programmes included: "The workforce programme is a new way of looking at safety….I believe it promotes a better understanding of behaviour and attitudes towards safety for the benefit of all." Employees were enabled to give their views on safety and have their opinions and suggestions taken on board by management. Example comments from staff included: "it provided a space for me to have my say for safety".

Building Leadership Commitment to BBS
Leadership commitment to BBS and trust with employees was also created as a result of these workshops. Employees and managers were given a space to listen and talk with each other about safety concerns. Trust and commitment was also forged by leaders and managers acknowledging and implementing the feedback and suggestions from staff for safety in the workforce programmes. By tackling "quick wins" on site for safety, for example housekeeping and management of meetings, managers were able to create momentum with the BBS programmes, demonstrate commitment and create employee buy in to the process.

Laying the Foundation in preparing for BBS interventions
These workforce non-technical skills programme also helped to lay the foundation for participation in BBS programmes, providing a greater understanding of what a feedback and observation process involved and the rationale for such an approach. Most employees stated during the programmes that they would like to be involved with a BBS approach to safety. However, others did raise a concern about the manner in how it would be implemented on site and expressed apprehension about having confidence to deliver feedback, both positive and constructive. The leadership non-technical skills programmes were also effective in helping to lay the foundation for BBS. Example comments from the programme included: "Participation on the safety leadership programme has helped to give me a greater understanding of how I should behave to be a more effective safety leader."

Facilitating employee engagement with and ownership of BBS approaches ideas and techniques
Skills and behaviours that were learned through the non-technical skills programme were displayed post-training (e.g., increasing feedback), and management and staff reported positive changes to safety related behaviours. These programmes raised awareness about strength and development areas for supervisors and managers in relation to health and safety leadership behaviour. For example, management speaking personally with staff about safety and being more visible on the shop floor. They also resulted in behaviours and activities (e.g., challenging unsafe acts; recognising safe behaviours) being incorporated into staff's every day activities and work patterns, thus promoting ownership in putting BBS ideas and techniques into practice.

Conclusion

This paper outlined the importance of introducing a behaviour based safety approach that gives credence to assessing and creating interpersonal trust between management and staff, that ascertains and instills leadership commitment and alignment with a BBS approach and which ensures employee involvement and engagement throughout the process. It is within the plan of ESB over the next year, to re-administer the safety culture assessment post BBS intervention to ascertain improvements for safety in relation to areas such as: health and safety behaviours, organisational commitment and trust, communications for safety and employee engagement. At present, however it is difficult to assess this approach other than anecdotally. Yet what can be stated with much confidence is that this particular approach to BBS has been effective in helping to secure trust, involvement and commitment to the BBS process from all levels within ESB. The structure and strategy of this approach sets the scene for other high reliability industries to capture the hearts and minds for safety, to create employee buy in and to maximise the success factors critical to the implementation of a BBS approach.

Lessons Learned

There are lessons to be learned in terms of this approach. It is important from the outset to be explicit in managing expectations of both employees and management. BBS is a culture change approach, and culture change for safety takes time. With this approach there could often be expectations formed that behaviours and attitudes for safety would be changed "overnight." Expectations for what can be achieved and in what timeframe should be stated at the outset. It is also critical to ensure transparent and frequent communication with different stakeholders and to have time dedicated to communication within your plan for BBS. BBS can often be perceived as an approach designed to "change people" and when the term "behaviour" is used, it can cause people to be suspicious about its objectives. A big challenge with this approach was in pitching the message for BBS at the right level and in a way that would secure employee buy in, trust and leadership commitment.

While the leadership alignment workshops and other communication forums used within our approach have been effective, there are still challenges within our approach in fully ensuring that the right people involved in the process have a clear and transparent message for BBS and are confident in communicating the message. If employees know the rationale behind a BBS approach, if the message communicated for BBS evokes trust and is a message that leaders feel confident in expressing and demonstrating and if employees are involved in the process - then all of this helps to lay the foundation in preparing an organisation for implementing a BBS approach which will result in an improvement in safe behaviour in the workplace.

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ARE YOU READY FOR COMMUNITY BEHAVIOUR CHANGE?

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Abstract

The term community is most commonly associated with a population of people living in a particular area or place. Community can also, however, describe the collection of individuals within organisations. In the field of social marketing, community behavioural change is a growing area of interest (Edwards et al, 2000, Minkler et al, 2008) focusing on behavioural change in societal communities. In the field of ergonomics and human factors, much research is performed to develop safety programs through the behavioural change of individuals within organisational communities. It is apparent, therefore, that there are parallels between the goals of social marketers and ergonomists in promoting behavioural change. This paper seeks to introduce social marketing approaches to community behaviour change to the ergonomics and human factors profession, with a particular emphasis on the Community Readiness Model tool.

Introduction

Behaviour change in individuals is difficult to achieve, with community behavior change presenting further unique challenges. By nature, communities are fluid, ever changing, adapting and growing, a feature which impacts is significantly on community programmes, due to the diversity of each community; with widespread geographic, cultural and ethnic diversity. Communities can vary greatly in their interest and willingness to try new strategies, by both researchers and practitioners (Thurman et al, 2003, Bukoski & Amsel, 1994). Behaviour change at any level of a community is difficult, and if there is no community investment, then change will not occur (Thurman et al, 2003). The need for conducting community assessment prior to implementing community-based programmes is well recognised; best practice recommends identifying the need for community readiness towards potential programmes (Stith, 2006). Therefore, in order to ensure community-based programmes are successfully implemented and meet community needs, assessing community readiness is an essential component in the planning process (Selem, 2011).

Due to the diverse nature of communities, it is evident that there is *no one size fits all* approach to community change programmes which face significant challenges in requiring community behaviour change (Edwards et al, 2000). In order to overcome this challenge, it is essential that effective and appropriate strategies to address community behaviour change are developed, which must be inclusive of communities, ensuring that researchers, public health practitioners, policy makers and community organisers are equipped with rich data direct from the community to inform and shape evidence based strategies (Minkler et al, 2008).

In exploring behaviour change at community level, this paper identifies the dominant community social marketing models, following extensive review of the literature in this area. Furthermore, this paper describes the CRM and discusses its potential and the application of this innovative approach to community behaviour change. The paper further establishes, through modification and application of the CRM, the suitability of the model for wider community applications as a metric for gauging readiness This innovative approach will be outlined, along with information on the origins of the CRM and overview of how the Model has been modified and applied in the Irish context for the first time.

Community Behaviour Change

In the domain of social marketing, there is increasing recognition of the value of community led approaches (Bryant et al, 2007). This rise in community based efforts represents a move away from focusing on individual factors towards those of the overall health and social ecology of the community incorporating social and cultural contexts where behaviour occurs (Engstrom et al, 2002, Goodman et al, 1996). If social marketers are to fully engage with and empower communities, then levels of community readiness must first be assessed to facilitate engagement of community efforts to address local issues (Sprague Martinez et al, 2012).

However, change at the community level is difficult, due to the complexity of interrelated factors; such as sustaining citizen participation and empowerment, securing and maintaining funding (Scherer et al, 2001, Steckler & Goodman, 1989, Florin & Wandersman, 1990). Furthermore, resources also differ significantly in each community, as do strengths, challenges and political climates (Thurman et al 2003).

Community behaviour change programmes that overlook the need to assess community characteristics and needs have an increased possibility of unsuccessful and ineffective outcomes.

Dominant Community Behaviour Change Models

In light of such challenges, a potential solution lies in developing programmes and strategies through community engagement, which due to their comprehensive nature and profound understanding of community attitudes, are more inclined to result in successfully implemented approaches (Merzel & D'Afflitti, 2003). In recognition of the value of community led approaches in the area of social marketing, a review of the dominant community social marketing literature was conducted, identifying four dominant models community social marketing models, as outlined below.

Table 1: Dominant Community Social Marketing Models

	Community Prevention Social Marketing	Community Based Social Marketing	Community Led Social Marketing	Community Readiness Model
Description	Community directed framework where social marketers work with community partners.	Focuses upon the barriers to behavioural change the community level.	Based on the concept of the consumer as most important participant in the change process.	Model of community change for assessing levels of community readiness.
Key features	Community learning. Participation. Ownership. Empowerment.	Assessment of barriers and Benefits.	Audience insight. Consumer solution generation. Active community participation beyond consultation.	Readiness assessment. Cultural specific programme.
Previous application	Initiation of tobacco and alcohol use. Physical activity. Obesity prevention. Prevention of eye related injuries.	Environment. Pollution. Energy. Transportation. Agriculture. Conservation.	Health inequalities issues. Community health lifestyle project.	Drug/alcohol use. Domestic violence. Sexual violence. HIV/AIDS. Environmental issues.

Reference: FitzGerald, 2013 in Hastings & Domegan, Forthcoming.

The Community Readiness Model

If researchers are to fully engage with and empower communities, then levels of community readiness must first be assessed to facilitate engagement of community efforts to address local issues (Sprague Martinez et al, 2012). The concept of community readiness evolves from the idea that if an approach or strategy is to be successful, then an understanding of the community and strategy formulation to increase community readiness must be investigated (Donnermeyer et al, 1997).

The Community Readiness Model (CRM) can be described as a map and a repair kit, which directs a community to where they are behaviourally and what they need to do to get moving again (Oetting et al, 2001). The CRM provides a practical tool that can be used by communities to focus their efforts towards a desired goal, making the most of the community resources and reducing the risk of failure, creating an approach to community behaviour change which is both sustainable and motivating (Thurman et al, 2003).

The CRM is designed to assess a community’s levels of readiness to address an issue or implement a programme and is based upon the participation of several community sectors, utilising resources and strengths from within the community, acting as a catalyst and facilitator for behaviour change (Scherer et al, 2001, Plested et al, 1998). The CRM provides an approach for working with communities in a practical way by identifying effective mobilisation strategies depending on community readiness levels. Through application of the CRM, communities are provided with a practical tool to focus their efforts towards a desired goal, making the most of community resources and reducing risk of failure. This results in the creation of a sustainable and empowering approach to community behaviour change (Thurman et al, 2003).

The CRM is a theory based, community directed method, consisting of nine stages of readiness ranging from “no awareness” to “high level of community ownership”. The readiness stages are assessed by conducting key informant interviews covering six dimensions; “Existing efforts, Community knowledge, Leadership, Community Climate, Knowledge and Resources” (Oetting et al, 2001). Once understood, these dimensions are used in strategy formulation, implementation and evaluation to address social issues.

The CRM has previously been applied to areas of health, nutrition and the environment (Lawsin et al, 2007) where it provided valuable insights into community beliefs and norms, identifying community members perceptions of important local issues, while providing policy makers with a reliable measurement tool to assist with planning, implementation and evaluation of community based intervention programmes (Scherer et al, 2001).

Conclusion

The CRM possesses a unique ability to assess specific stages of readiness and help mobilise change in a diverse range of communities. The model facilitates positive social change with efficacy, social significance and cost effectiveness (NICWA, 2012). Through engaging and interacting with key stakeholders in the community, this study incorporates the key concepts of community engagement, providing direct community input, which is essential in bringing about successful and sustainable behaviour change. This collaborative community model can, be used as a guide for change in areas of community life requiring change; health, social justice, transport and energy sustainability.

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HUMAN BEHAVIOUR AND PERFORMANCE: UNDERSTANDING MEMORY AND THOUGHT PROCESSING

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Abstract

Ergonomics' by necessity has moved away from unitary problems of singular task analysis to remain relevant in a more complex world where the boundaries between work and play are blurred with interaction opportunities facilitated by inter-connecting systems and technologies. In today's world a broad, holistic approach to ergonomics is more relevant than ever. It is the interactions between system elements such as humans, equipment and environment that are the future focus of ergonomics rather than the artefacts themselves. This is a very interesting distinction; in an increasingly complex world it is our memory, perception and thought process that is the future focus of ergonomics. As ergonomists the area of cognitive psychology and its current thinking on memory and thought processing have never been so important in our goal of understanding human behaviour and performance.

Introduction

In today's world the value and strength of ergonomics is its very systems perspective and holistic nature, (Wilson, 2000). Wilson also puts forward the view that it is the interactions between system elements such as humans, equipment and environment that are the future focus of ergonomics rather than the artefacts themselves. In an increasingly complex world where the artefact is often just the means to access multiple networks and systems, it is the transitions between technologies and the human that becomes important. Modern day tasks increasingly depend on human cognition as a basic requirement in terms of selecting options and making decisions. In these scenario's gaps between systems components are bridged by human cognition, gaps between perception and understanding are narrowed and bridged by human thought processing. Narrowing these gaps depends on human perception and thought processing to evaluate and act on a decision. Both perception and thought processing are dependent on our cognitive ability which effects performance and behaviour. Of course user motivation, strategy and ability are important considerations, as is the circumstances of the use environment, but the focus of this discussion will be the cognitive aspect.

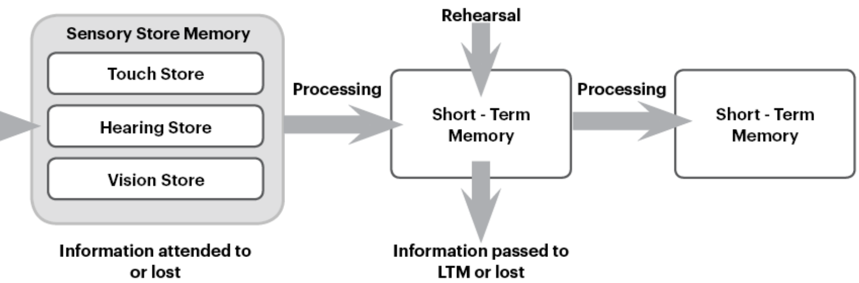
Context and background

At a basic level we perform every time we try to complete a goal orientated activity. The philosopher Marcuse (1955) described this value system or urge as *the performance principal*. Similarly, motivation theory has established the idea of a drive for behavioural competence which fuels our urge to perform, (McClelland, 1961; Murray, 1938). Performance and cognitive psychology seek to understand behaviours motivated by these performance goals. Understanding how information is processed, maintained and retrieved from memory is fundamental to understanding behaviour and performance. Our thinking and understanding is closely related to past experience, which in turn is related to memory and more importantly working memory (WM) and long term memory (LTM). Human cognition is information processing, (Eysenck & Keane, 1995; Lachman et al 1979) In the processing approach cognition is described as the number of stages through which imformation must pass. This begins with input or stimulus recieved through the senses being transformed into a internal repersentation which in turn is transformed into a responce. The theory of human performance is primarily derived from cognitive psychology, which in turn is based on the computational metaphor for performance, the brain is considered to function like a computer (Mathews et al, 2000). The Computer Metaphor although broadly correct may be unhelpful because of the diversity of computational systems. Also computers are governed by logic, humans are not. The biggest issue with this metaphor is that computers run programs initiated by an external agent. This is passive and in contrast with people pursuing goals activity and flexibly in the context of complex environments. The computer metaphor is useful but limited and not broad enough to consider performance in a real world context where people's performance is shaped by their strategies and personal goals. In this regard a specific focus is the breakdown and failure of performance. With this in mind let us critically assess current cognitive psychology theory in the area of human memory and how useful that understanding is to in everyday situations

Current cognitive psychology theory

Modelling is fundamental to cognitive psychology theory; models are proposed and then tested against empirical data facilitating the fundamental step in theory development (Matthews, et al, 2000). Modern day understanding of memory begins with an influential period in the 1960's when the concept of memory as a unitary faculty began to be challenged. A substantial amount of research at this time sought to understand and distinguish memory based on duration of memory storage and processing code. Conrad (1964) showed that recall error for example could be based on acoustic confusions where the letter "B" could be recalled instead of the similar sounding letter "V", suggesting that short term memory (STM) is an acoustic or Phonological code, while LTM is thought to be a semantic or meaning based code. The multi-store or modal model (Atkinson & Shiffrin, 1968), sought to distinguish memory based on duration of memory storage. The model outlines three types of memory store: sensory store, STM and LTM. Through the three type's memory capacity increases, sensory being the smallest and LTM is the largest. The stores are thought to work sequentially where information is first received into a sensory store; from here a selective attention mechanism transfers some information into STM. In the multi-store model STM is thought to be of limited capacity, information is quickly lost unless a person begins a process of rehearsal or repetition. This causes the memory to transfer to unlimited capacity LTM where it can be retrieved at a later date. The multi-store model developed to include three types of sensory store to deal with visual auditory and tactile senses, see Fig.1. Sensory store information was assumed to be a uniform verbal format. Therefore any visual information stored in STM is translated from visual into a verbal code. Responses to stimuli depends on accessing STM and as such STM acts like a bottle neck to long term learning because unless information remains in STM long enough it will not pass on to LTM. There is general agreement to the existence of a sensory store but its relevance to cognition is small as cognition is more concerned with items that have been attended to and what happens to them. STM has a larger duration and size than the sensory store; research suggests two seconds duration (Baddeley, 1997). To support this model of memory various experimental techniques were carried out focused on the different stores. One such experiment for example was based on a subject recalling a list of 20 words. It was found that the early words were easier to recall, this is known as the *Primacy effect*. The last words in the list were also easier to recall, this is known as the *Recency effect*, while words in the middle were muddled. Rehearsal & retrieval within STM control what is transferred in and out of LTM. Information in LTM is permanent. Capacity and duration of storage is unlimited and is held in a uniform format, information is thought to be stored as a *semantic* code; storage in terms of meaning.

Fig.1
Developed Multi-Store Model



The multi-store model of course inspired debate and proved to be the catalyst for much research, some supporting aspects of the model but most research highlighted fundamental issues and short coming in the models detail and structure. The first issue is illustrated in research by Milner (1996) on brain damaged patients and Baddeley and Warrington, (1970) on amnesiacs, this work highlight that the multi-store model may be too simplistic in that the bottle neck effect of STM being the only method of storing and retrieving information is misconceived. Also it seems too simplistic to assume that STM and LTM are unitary. The second issue related to dual tasks. Studies showed that when one task should have expended STM the second task could still be performed although more slowly, suggesting that STM and LTM are not uniform stores. In relation to LTM differences have been shown in *episodic* and *semantic* memory, Tulving (1992), *implicit* (low cognitive load) and *explicit* memory (high cognitive load), Graf & Schachter, 1985, also *declarative* and *procedural*, Anderson, 1993. The multi-store model also proposed that the STM was a verbal memory store only. However Paivio, 1969 and 1972 showed evidence that there were separate visual & spatial elements within STM. The third issue in the multi store model was that of rehearsal being thought of as the main method for progressing items from STM into LTM. While initial studies seemed to support this Craik and Lockhart (1972) showed evidence that it was how information was rehearsed that mattered most, this is referred to as *depth of processing* and is concerned with how information is *encoded*. Later research by Baddeley (1990), showed that recall of *recency effect* items were sensitive to different experimental manipulations in that *pre-recency* items were more difficult to recall if the rate at which they were presented to a test subject increased, but recency items were unaffected. With the addition of a 30 second task in the test before recall of the last word, recency was eliminated, however pre-recency remained unaffected meaning that the recency effect was associated with a sensitive, easy disrupted STM, whereas recall of pre-recency depended on LTM, (Matthews, et al, 2000). Baddeley (1990) shows forgetting from STM is caused by displacement, new memories replacing older ones, and that forgetting from LTM is primarily from interference and retrieval failure. Other studies show that context plays a part in information encoding and retrieval if cues map with memory trace, this effect is known as *context dependant memory* and is supported by Tulving and Thompsons's (1973) *Encoding*

Specificity Principle. The final problem with the multi-store model was the word length effect where participants can recall fewer long than short words. Miller (1996) found that there was not a limit on the number of items that could be recalled but rather the number of chunks. Miller's work would suggest that each word regardless of length is an information chuck as it is familiar. This problem raised by Baddeley, Thomson & Buchanan (1975) suggests that there is an issue in the classification of a chuck, or there being a set amount of chucks.

In recent years, theorists have argued that the entire multi-store concept is misguided and should be replaced by a unitary-store model. Unitary-store models assume that, STM consists of temporary activations of LTM. Evidence based on amnesic patient's research does not support this; however research in this area is quite new and has only recently begun in earnest. To date the working memory (WM) model put forward by Baddeley and Hitch (1974) shown in Fig.2 is the most supported by research and addresses the limitations of the multi-store model.

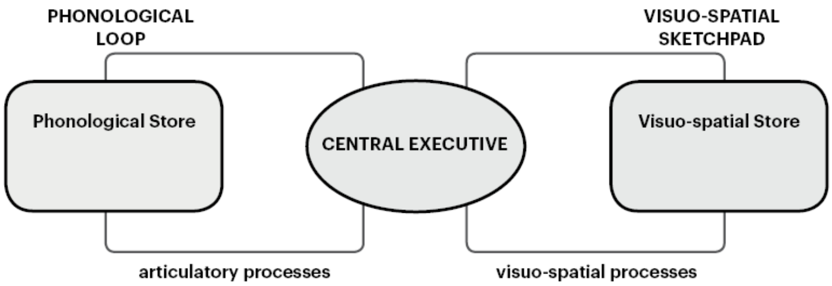


Fig.2 , Baddeley & Hitch (1974) Working Memory Model

In the WM model, *the central executive* controls attention and deals with cognitively demanding tasks in WM. The visuo-spatial sketch pad and phonological loop are slave components used for specific purpose by the central executive. The visuo-spatial sketch pad manipulates spatial and visual information, while the phonological loop maintains the order in which words are presented. The two components and central executive have limited capacity and are relatively independent of each other. If this is correct it is based on two assumptions. First, if two tasks utilise the same component, they will be difficult to perform together. Second, if two tasks utilise different components it should be possible to perform both well. Many dual task studies have been carried out to test these assumptions. One such study found that selecting chess moves involved the central executive and the visuo-spatial sketchpad but not the phonological loop. The effects of various additional dual tasks where similar on strong and weak players suggesting both groups used WM in the same way (Robbins, et al., 1996). The WM phonological loop component accounts for the word-length effects described as being problematic for the multi-store model. It also accounts for the effects of articulatory suppression, rapid repetition of simple sounds which uses the articulatory control process of the phonological loop. Evidence from brain damaged patients compared to neuro-imaging studies with healthy subjects supports the existence of the phonological store as well as an articulatory control process. The visuo-spatial sketchpad used for temporary storage and manipulation of spatial and visual information is used in many everyday situations. Logie (1989) carried out a study involving complex manoeuvrability. Early in training performance was drastically reduced when participants were required to carry out a secondary visuo-spatial task. After 25 hours training this impact was greatly reduced. Thus, the visuo-spatial sketchpad was used throughout training but its involvement decreased with practice. Neuro-imaging and research work with brain-damaged patients support this view. Also Klauer & Zhao (2004) showed little interference between visual and spatial multi-tasking.

Baddeley (2000) added an additional component to the WM model called the *episodic buffer*, see Fig.3. The buffer is used to integrate and store briefly information from the phonological loop, the visuo-spatial sketchpad and LTM. In view of the processing demands involved it is suggested that there would be close links between the episodic duffer and the central executive, (Eysenck & Keane, 2010). The reasoning behind adding the episodic buffer is that the original WM model was limited in that components were separate. Various studies show a combining of visual and spatial coding from phonological and visuo-spatial components. It is accepted that these components are separate; combining has to take place elsewhere, bringing the episodic buffer concept into play. The idea of an episodic buffer is useful as it provides an area where LTM can be combined with the components of WM. Research by Baddeley & Wilson (2002) with amnesic patients supports the concept of an episodic buffer and it being used in this way.

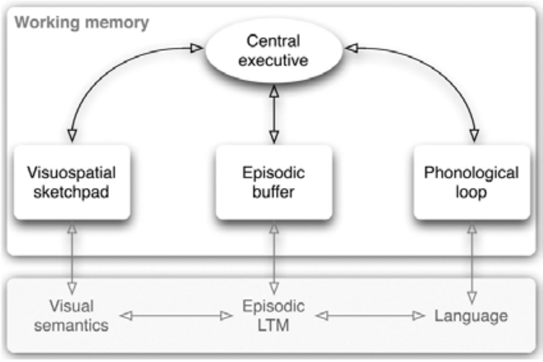


Fig. 3

The multi store model is valuable in that it introduced a number of concepts in exploring cognitive architecture and memory understanding. It has strengths in that it distinguishes between three types of memory store. However research has found the multi-store model to be simplistic and lacking in detail. Replacing STM with the developed version of WM including the episodic buffer addresses most of these issues, see Fig.4. At this stage our understanding the episodic buffer is basic, it being a place holder to explain code combining. Also, just as understanding of WM has developed into a multi-component concept, it seems certain that our understanding of LTM is evolving in the same direction. According to Baddeley (2004) the initial suggestion, that LTM is a single type of memory, now seems improbable.

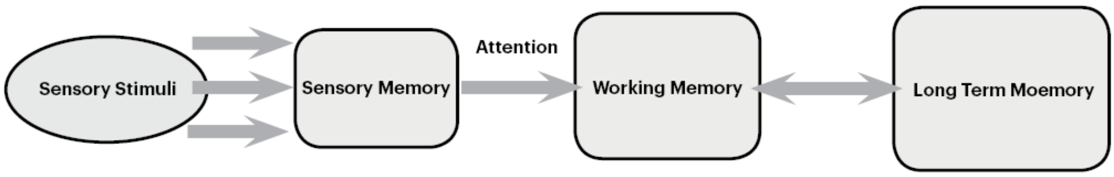


Fig.4 , Working Memory has replaced the STM of the Multi-Store Model

How useful is current cognitive psychology theory

Investigating the complex nature of memory based on producing precise testable models is best pursed in the laboratory. However it is legitimate to question its usefulness in understanding performance and behaviour in everyday life. A model that can predict responses in laboratory conditions may be of use, but unless it can be generalized to more ambitious questions, it is unlikely to advance the study of memory. Similarly observing interesting phenomena is equally unlikely to generate evidence based scientific theory, (Baddeley, Kopelman, & Wilson, 2004). Constructive responses to this cognitive versus performance psychology dilemma are underway with attempts to generalize laboratory findings to real world situations, another approach being to identify phenomena in everyday life not addressed by current models, examples being Barbara Wilsons Rivermead Behavioural Memory test (RMBT) and the Behavioural Assessment of the Dysexecutive Syndrome Test (Wilson et al., 1996). Our knowledge of human behaviour and performance under highly stressful situations has often come at the cost of human life where post event investigation reveal the cause of the problem and corrective measures are researched, and put in place. One such example is *situational awaerness.* Laboratory based research demonstrates that a test subject can become overly focused on a componet part of a problem, rather than considering the bigger picture. This focused concentration results in high cognative load to such an extent that other aspects are not attended too. Loss of situational awareness to the point of performance failure has long been understood in emergency services and aviation. Research has helped to understand the cognative process and formulate preventative tools and systems, a simple example being the use of *check lists* in civil aviation where basic and emergency procedures are subject to check lists. This type of system is also being employed in other professions. The need for this was recently highlighted in a situation at a UK hospital where a surgical team, having tried unsuccesfully to intubate a patients blocked airway were joined by additional surgical staff, who overlooking other possibilities continued with this unsuccessful course of action for 25 minutes. The surgical team lost situational awareness which resulted in a fatality. Interestingly, the resulting investigation also revealed that a nurse had suggested a tracheostomy procedure, this potentially life saving option was over looked and the nurse did not feel it was their place to press for the procedure highlighting issues with team dynamics effecting behaviour and performance. Based on this case the World Health Organisation put in place a number of check list systems to prevent loss of situational awareness. In this trail, involving 30 hospitals worldwide deaths were reduced by 40% and complications by 30% (BBC, Horizon, 26 March 2013).

In conclusion, there is a great deal of agreement as to what constitutes the psychology of memory, (Baddeley, et al, 2004). Our understanding has developed massively from when memory was considered to be a unitary faculty. The WM model and supporting research has addressed many of the problems with the multi-store model, greatly enhancing our understanding. However, more research is needed in the area of the episodic buffer. Research on LTM also suggests that a more complex model needs to be developed. Other disciplines and technologies such as Neuro-imaging will play an important role as will the continued study of patients with memory deficits. Research in the area of *prospective memory* is also of interest combining performance psychology methods with laboratory methods. It seems a twin approach of laboratory methods to establish theory combined with understanding of real-life behaviour, based on empirically testable performance psychology is a powerful combination in promoting understanding but also in making it useful in answering ambitious everyday performance questions. The value and strength of ergonomics is applying this understanding to human interaction and this application is at its most powerful when taking a broad systems perspective that is holistic in nature. There is no doubt that our understanding of human cognition is an increasingly important aspect of this endeavour.

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USER CENTERED DESIGN IN THE MEDICAL DEVICE INDUSTRY

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Abstract

Contemporary organisations must design innovative products using breakthrough technologies to gain competitive advantage in turbulent and dynamic environments. According to Saunders et al (2009) an innovative product '*changes, or has the potential to change the nature of the marketplace by satisfying a new (or latent) need or by satisfying customer needs in a significantly new way*'. Clearly the ability to identify and define customers' needs is essential to the design and development of innovative products. However the identification of customers' needs, wants and expectations is not easy. Customers have difficulty articulating needs and defining the intangible aspects of products that please them. Ulwick (2002) states simply that '*customers do not know what they want. Customers only know what they have experienced. They cannot imagine what they don't know about emergent technologies, new materials and the like*'. Consequently many organisations do not listen to the voice of the customer too closely since it is believed the information they can provide is vague, inaccurate and incomplete. Cooper (2008) asserts that '*upfront homework*' is not done and the front end of the new product development process is absent of structure and layout. However organisations that neglect this process can end up an adopters rather than innovators. Ultimately they will lag behind the market because they fail to identify winning next generation ideas that delight the customer and differentiate their products.

In recent years, many researchers have written about the fuzzy front end of the product innovation process. Whilst some researchers have focused on models and processes to capture the voice of the customer (see de Brentani and Reid, 2012; Griffin and Hauser, 1996) others have attempted to understand effective methods to identify and evaluate customer needs (see Martinsuo and Poskela, 2011; Van Kleef et al, 2004; Holt 1987). Many of these researchers advocate that organisations adopt a user centred perspective to the design and development of their products. There is also a growing recognition by some researchers that the physical environment plays a significant role in this process. Consequently some researchers have emphasised the need to engage with customers in their own environment. McQuarrie (1993) describes how a friend once said to him: '*a desk is a dangerous place from which to do business*'. He advises people to take a tour and observe – '*get out of the conference room*'. Cooper and Kleinscmidt (2007) also outline how people need to '*camp out*' with the customer in order to understand user needs and wants. User centred design is an approach that has

received some attention in recent years. It is lauded to effectively capture the voice of the customer so that specific and latent needs can be defined and infused into the product development process. Our research focuses on optimising the front end of the product development process in order to design and develop innovative products that meet the needs and expectations of customers and end users. We have studied the area of user centred design as a means of improving this space.

We note that user centred design has been studied from many different perspectives in the literature. For example, some authors have looked at empathic design strategies (e.g. McDonagh, 2011); others have examined the design process (e.g. Leonard and Rayport, 1997) and other studies have focused on benefits and outcomes of building sustainable relationships (e.g. Niinimäki and Koskinen, 2011). Despite this, we notice a dearth of studies that focus on the application of user centred design in specific industrial sectors. Our work attempts to bridge that gap. Therefore the goal of this study is twofold (a) to identify whether user centred design methods are applied in the medical device industry in Ireland and (b) to identify the challenges faced by designers when implementing tools and techniques in this space. The research aims to inform designers, engineers and those contemplating using user centred design techniques about the experiences of those who have navigated the process. This presentation focuses on the fundamental issues involved in user centred design such as; the drivers, rationale, stakeholders and the critical stages in the process. We also present findings from an exploratory study that synthesises the state of play in the industry and critical challenges faced by designers when implementing user centred design in the medical device industry in Ireland.

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A SURVEY OF SMARTPHONE USE BY JUNIOR DOCTORS: WHAT ARE THE IMPLICATIONS?

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Abstract

Smartphone use among healthcare professionals has become widespread and will continue to grow in the coming years. A survey was carried out of how junior doctors in two of the national intern training networks in the Republic of Ireland used smartphones to carry out their clinical work. It was found that out of 108 interns (47.0% response rate), 94.4% owned a smartphone. Of those respondents who owned a smartphone, on at least a daily basis for the purposes of work, 83.3% made or received phone calls, 87.2% sent or received texts, and 41.2% sent or received emails on their smartphone. A total of 52.9% had used their smartphone to take a work related picture. The most commonly used app was the British National Formulary (used daily by 29.4% of respondents with a smartphone), and the most commonly used website was Wikipedia (accessed at least weekly by 38.2% of respondents with a smartphone). Smartphones have the potential to facilitate effective communication, and positively impact patient care. However, if not used judiciously, smartphones can also be a distraction, negatively impact professionalism, lead to breaches in patient confidentiality, and result in treatment errors based upon inaccurate information. It is recommended that just as there are regulations and training in the use of other healthcare technologies, the same should be the case for smartphones.

MEDICAL DEVICE USABILITY TESTING METHODS FOR REDUCING MEDICAL ERROR IN HEALTHCARE

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Abstract

Medical devices have been associated with medical errors in two ways: through failure of the device (Dhillon, 2000), and through user misuse of the device (Cooper et al., 1984, Ludbrook et al., 1993, Money et al., 2011). While traditionally manufacturers, regulators and healthcare facilities interest has focused on the former, in recent years there has been a formalisation of regulatory requirements concerning the need to identify and mitigate use error risks. Regulatory guidance promotes the field of usability engineering as a methodology for meeting this need.

Usability engineering is most effective during the design and development phases of medical devices, when the device can be modified to accommodate any identified risks. For this reason usability engineering standards and guidance have been developed specifically for medical device manufacturers and focus on the design and development phases. However, usability engineering should also be incorporated into a healthcare facilities decision to acquire a new medical device. Murff et al. (2001) recommend that device purchasers should strongly consider institution-specific usability testing.

This paper seeks to address this recommendation though an analysis of the existing usability engineering standards to extract methods and guidance most suited to the needs of healthcare facilities.

Introduction

The issue of preventable medical error in healthcare has seen much debate, analysis and research since the Institute of Medicine (IOM) report “To Err Is Human”. In this report the IOM attributed adverse health care events with up to 98,000 deaths and 1.3 million injuries per year in the US alone (Kohn et al., 1999). The ‘Engineering a Learning Healthcare System’ report, jointly published by the Institute of Medicine and the National Academy of Engineering, highlights the role of medical equipment within the health care system. The report states that despite the potential of new technologies to improve the quality of care and outcomes, the limited systematic integration of healthcare technologies, including IT, laboratory / radiology systems, and monitoring equipment has led to their misuse and overuse (Grossmann et al., 2011).

(Amoore and Ingram, 2002) in analysing adverse incidents involving medical equipment found that although adverse incidents are often ascribed to human factors, including users' inexperience, they are typically multifactorial in origin, with latent factors, faults, errors, and mistakes aligning together in the manner of the Swiss Cheese Model (Reason et al., 2006) .

Latent factors, which predispose threat or error, in particular have been identified as contributing significantly to patient safety incidents (Leape et al., 1998) .

It is evident therefore that processes to counter both active and latent risk factors in patient safety incidents are desirable. Many researchers have proposed methodologies to meet this need, for example (Chadwick and Fallon, 2012) addressed human reliability, (Challis, 1999) focussed on medical education and (Calland et al., 2002) proposed a systems approach to surgical safety. There is also a significant body of literature highlighting the role of medical device design in preventing (or facilitating) adverse events (Fairbanks and Wears, 2008). Usability engineering standards are typically employed for evaluating and improving aspects of medical device design which involve interaction with the user, these standards can also be useful in giving guidance on the identification of latent risk factors in medical devices prior to use in specific healthcare settings.

Medical Device Usability Standards

The discipline of usability is believed to have started with the work of John Whiteside at Digital Equipment Corporation and John Bennett at IBM (Dumas, 2007). During the late 1980s, Whiteside and Bennett published a number of chapters and papers on the topic of usability engineering (Whiteside et al., 1988). In 1993 usability engineering was formally introduced to the medical device domain when the Association of Medical Instrumentation (AAMI) in the USA launched 'Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices' (HE48, 1993). Other standards followed, including IEC 60601-1-6 Medical Electrical Equipment - General requirements for basic safety and essential performance - Collateral standard: Usability (IEC, 1998) and ANSI/AAMI HE-74 The human factors design process for medical devices (AAMI, 2001). These earlier standards have been superseded by, and incorporated into two current standards; ISO/IEC 62366:2007 Medical Devices – Application of Usability Engineering to Medical Devices (ISO, 2007) and ANSI/AAMI HE75:2009 Human factors engineering – Design of medical devices (ANSI/AAMI, 2009). In the following sections both of these standards will be examined to establish how usability engineering methods presented can be utilised by healthcare facilities.

ISO/IEC 62366 Medical Devices – Application of Usability Engineering to Medical Devices

ISO/IEC 62366 is a process-based standard which aims to help manufacturers of medical devices 'design in' usability and 'design out' use errors. The ISO medical device usability standard IEC 62366:2007 defines usability as a 'characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction'. It further defines usability engineering as the 'application of knowledge about human behaviour, abilities, limitations, and other characteristics related to the design of tools, devices, systems, tasks, jobs, and environments to achieve adequate usability'. The standard specifies a process for a manufacturer to analyse, specify, design, verify and validate usability, as it relates to safety of a medical device. This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors (ISO, 2007). In support of the usability engineering process ISO/IEC 62366 presents a number of methods and techniques for the usability engineering process. Table 1 describes and assesses advantages and limitations of each tool as presented in the standard.

Table 1: ISO/IEC 62366 Usability Techniques: Advantages & Limitations

Technique	Advantages	Limitations
Cognitive walk-through	Permits evaluation of different design concept.	None identified.
Contextual inquiry and observation	Observing and working with users in their normal environment, permits a better understanding of the relevant tasks and workflow.	This technique generally does not reveal cognitive processes, attitudes, or opinions.
Design audits	Design audits are relatively quick and cost-effective.	Often yield only a superficial understanding of user interface issues.
Medical device comparisons and functional analysis	Such comparisons can be useful for understanding which design approach best meets user needs.	None identified.
Expert reviews	Many serious design flaws can be detected early and without incurring user testing costs.	If used in isolation, this technique is unlikely to detect all of the design flaws.
Functional analysis	This type of analysis is used to determine the appropriate allocation of functions to humans versus machines.	None identified.
Heuristic analysis	It is particularly useful early in the design process for discovering problematic aspects of the user interface. This method is usually quick and inexpensive.	Generally, it is not applied in the actual use environment, and typical users are usually not involved in the evaluation.
Interviews	Structured interviews are useful in circumstances in which the goal is to uncover answers to specific questions, often when designers are fairly well along in the design process. Unstructured interviews are useful for gaining initial insights about designs under conditions in which the designer wants to avoid biasing the interviewee.	None identified.
Participatory design	None identified.	None identified.
Prototyping	None identified.	None identified.
Simulated clinical environments and field-testing	High-fidelity simulation allows the test team to evaluate dynamic interactions among multiple medical devices, personnel, and task constraints.	Usability issues raised at this time can adversely affect commercial success
Task Analysis – General Task Analysis	Task analysis can yield information about the knowledge, skills, abilities, and hazardous situations associated with the completion of relevant tasks.	Can be time-consuming, and the large amounts of data that can be generated are sometimes difficult to analyse and interpret.
Task Analysis – Time-and-motion studies	The technique can be used to discover interferences and opportunities for streamlining, to determine if actions can be completed within established time constraints, or to examine the effect of a medical device's use on processes and procedures	None identified.
Task Analysis – Cognitive task analysis	Cognitive task analysis can also be used to evaluate how the medical device implementation changes how users think	None identified.

	about the processes involved.	
Task Analysis – Usability testing	Usability testing, especially when conducted in the field, can detect use errors.	As the subject populations are small, low probability errors cannot be detected.
Task Analysis – Use error analysis	None identified.	None identified.
Task Analysis – Workload assessment	Workload assessment helps to evaluate or predict the worker's cognitive capacity for additional tasks.	Workload assessment methods generally need to be validated and can be technically complex and difficult to analyse.
Human Reliability Methods[1]	Quantifies human error potential Analyses performance shaping factors	High level of training and experience required Limited applications to date in healthcare

[1] Human Reliability methods do not feature in ISO/IEC 62366.

ANSI/AAMI HE75:2009 Human factors engineering – Design of medical devices

The human factors standard, ANSI/AAMI HE75:2009—Human factors engineering–Design of Medical Devices, is a comprehensive compendium of user interface considerations for medical device developers, but it also benefits clinical and bioengineering teams in institutional care settings as well as designers of electronic medical records and healthcare information technology systems (North and Patterson, 2010).

ANSI/AAMI HE75 categorises usability tests as either *formative* or *summative.* Formative usability testing is performed early, using simulations and early working prototypes; it is intended to explore whether usability objectives are attainable, but does not have strict acceptance criteria (ANSI/AAMI, 2009). Summative usability testing is performed late in design as part of a formal verification and validation (ANSI/AAMI, 2009). It is evident therefore that the scope of summative testing most appropriately reflects the usability evaluation needs of healthcare providers.

ANSI/AAMI HE75 states that in usability tests, representatives of the intended user population interact with one or more device models, prototypes, or production units to assess ease of learning, ease of use, effectiveness and efficiency of use, memorability, safety, and/or user appeal. Based on this generic view of usability testing the ANSI/AAMI HE75 standard gives guidance on good usability testing design. Specific usability testing techniques are incorporated into this guidance.

Central to this guidance is the recommendations for the content of the usability test plan. ANSI/AAMI HE75 states that the usability test plan should describe the following:

i. Purpose of the usability test
ii. The setting for the test; e.g. laboratory, clinical setting etc.
iii. Participants; should be representative of the users most likely to use the device.
iv. Prototypes and simulations

v. Methodology or test protocol; the method description in a usability testing plan, its actual protocol, and the subsequent report are much like the methodology section of any scientific report. The usability test plan should describe the usability study methodology and related test protocols in enough detail that another researcher or designer could replicate the study.
vi. Tasks; the usability test plan should describe the tasks that subjects will be asked to perform and should specify the order in which the tasks will be presented.
    a. Task-analysis studies should be performed to identify the usability-test tasks. Task analysis is done by means of contextual inquiry techniques of systematic observation and data collection to create task flows, use cases, and typical usage scenarios, among many other outcomes.
    b. The tasks selected for usability testing should include the most critical safety-related tasks. Analytical usability inspection methods such as cognitive walk-throughs are recommended for comprehensively evaluating all user tasks.
vii. Usability Objectives; The main reason for specifying usability objectives (also known as usability requirements, usability goals, performance goals, or human factors requirements) is to define metrics that can be applied during usability testing to provide quantitative test acceptance criteria.
viii. Data Collection; Data collection can take many forms, from simple paper-based logging forms and stopwatches, to computer logging software and video recording, to systems that track dynamic eye movements. The form of data collection depends on the stage of development, the criticality of the device, and the development project's budget and schedule constraints.
ix. Data Analysis; Data Analysis should be mostly quantitative for summative usability testing against usability objectives with quantitative acceptance criteria.
x. Reporting; Usability testing results should be reported according to accepted practices for writing scientific reports, especially in the case of summative usability tests with formal acceptance criteria

ANSI/AAMI HE75 also refers to usability inspection methods; i.e. analytical methods that are complementary to empirical measures of usability. These methods are:

i. Cognitive Walk-throughs
   Cognitive walk-throughs involve a structured review of user requirements for the performance of a sequence of predefined tasks.
ii. Expert Reviews
   Expert reviews are evaluations of device usability by HFE specialists to identify design strengths and weaknesses and to recommend improvements.
iii. Heuristic Reviews
   In a heuristic review, clinical or HFE experts evaluate a device or system by assessing how it conforms to well established user-interface design rules or heuristic guidelines. A heuristic review is a more formal process than an expert review and requires multiple experts who develop a consensus opinion about design characteristics.

Conclusion

ISO/IEC 62366 is a process-based standard that specifies a process for a manufacturer to analyse, specify, design, verify and validate usability, as it relates to safety of a medical device

(ISO, 2007). ANSI/AAMI HE75, on the other hand, is a set of design principles rather than a pure process standard that must be followed every step of the way. ANSI/AAMI HE75 is seen a useful resource for both human factors professionals and for engineers who might know only a little about human factors engineering as it gives specific advice on design principles. Rather than scouring the HFE literature, engineers can look up the design principles in ANSI/AAMI HE75 (Patterson et al., 2010).

In terms of extracting guidance on which usability engineering methods can be employed by healthcare facilities it is evident that the scope of ISO/IEC 62366 is more aligned with formative usability testing, presenting named techniques within formal requirements for manufacturers while ANSI/AAMI HE75 gives more detail and guidance in conducting summative usability tests. ANSI/AAMI HE75, therefore, may be seen as the 'go to' reference guide for clinical engineers in developing and executing summative usability tests both prior to purchase and upon installation of medical equipment.

Healthcare facilities should also be cognisant of the importance of sample sizes in addressing the probability of identifying low rate use errors. ANSI/AAMI HE75 recommends that summative testing is performed with at least 15 to 20 participants per distinct user group (Each distinct user group—e.g., physicians, nurses, patients—has a different user profile). This level of testing, however, will often be cost and resource inhibitive for healthcare providers. It is imperative, therefore, that all usability testing performed by the healthcare facility is supported by pre-emptive risk management techniques such as FMEA, HAZOP and FTA and that suitable risk analysis methods are employed to examine the residual risk associated with any and all task failures observed in the summative usability test.

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THEORETICAL COMPLEMENTARITY BETWEEN HUMAN FACTORS/ERGONOMICS AND COGNITIVE ENGINEERING

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Abstract

Human Factors/Ergonomics (HFE) and Cognitive Engineering (CE) have much to offer by addressing major business and societal challenges regarding work and product/service systems. The potential of both, however, seems to be under-explored. This study synthesizes the complementary theoretical contributions of HFE and CE for the performance of work systems. These were presented emphasizing the perspectives of the main authors investigated and the fundamental characteristics of HFE (systems approach, design driven, and performance and well-being goals) and of CE (application of cognitive psychology to the design and construction of machines or human-machines systems). The proposed method was effective to show how to optimize the complementarity between HFE and CE, thereby indicating potential paths for the improvement of the design/operation of human–machine systems and of the environment appropriateness to the human.

Keywords: Human factors/ergonomics; cognitive engineering; theoretical complementarity; values; performance of work systems.

Introduction

The relationship between Human factors/Ergonomics (HFE) and Cognitive Engineering (CE) is an issue that appears to not yet be well explored in literature. The definition of HFE and HFE specialists (adopted by the IEA, International Ergonomics Association, in 2000) reflects the interactions between humans and their environment, and methodologies for analysing and designing systems over the past 50+ years, as follows (IEA, 2000): *'Ergonomics (or human factors) is the scientific discipline concerned with the understanding of the interactions among humans and other elements of a system, and the profession that applies theoretical principles, data and methods to design in order to optimize well-being and overall performance'*; focusing the application of human science and psychology to human–machine system design with the intent of improving system performance (Wilson *et al.*, 2013). CE 'is an applied cognitive science that is based on the knowledge and techniques of cognitive psychology and related disciplines to provide the foundation for principle-driven design of person-machine systems' (Woods and Roth, 1988), which focuses on the application of cognitive psychology to the design and construction of machines or human–machine systems (Norman, 1986). However, while some advocate that CE should be considered as simply another dimension of the field of

HFE (e.g. applied psychology or engineering psychology), assuming that CE is completely in line with psychology and human factors as a whole; another group understand CE as being new and revolutionary (Wilson *et al.*, 2013).

The system can be a work system (where the human is a worker and the environment is the work environment) or a product/service system (where the human is a product user or person who receives a service and the environment is the environment where the product is used or where the service is received) (Bruder, 2000). Despite these possibilities, in this study we will emphasize the work systems.

The starting point of this paper is that successful complementarity between HFE and CE has great potential to ensure the improvement of the environment appropriate to the human and of the design/operation of human-machine systems, respectively. When HFE and CE do not play a role in system design, this can lead to sub-optimal systems with quality deficits, reduced efficiency, illness, dissatisfaction, etc. The complementarity between HFE and CE can provide solutions to these problems; however, the potential of both seems to be under-explored. At least four reasons can be identified (Dul *et al.*, 2012; Wilson *et al.*, 2013): (i) many stakeholders involved in the design, management and use of artefacts (e.g. customers, workers, managers, other professionals, society at large) are not aware of the values of HFE and CE and as a consequence, do not exhibit a strong demand for both; (ii) in certain situations where there is a demand for HFE and CE (e.g. 'ergonomic products' in product marketing, 'ergonomic systems' in safety critical industries such as defence, transport, oil, and healthcare), there is not enough high-quality values in the design process because both are lacking or its applications are too limited in scope, resulting in sub-optimal solutions; (iii) the field is very small in comparison to established disciplines involved in designing artefacts like engineering and psychology, and is often incorporated within these disciplines without explicit references to the HFE and CE disciplines; and (iv) the very strength of HFE and CE, its multi-disciplinary bases, are also a potential weakness; a diversity of topics, views and practices exist within the HFE and CE communities, resulting in unclear communication to the external world.

In order to synthesize the complementary theoretical contributions of the HFE and CE approaches for the performance of work systems, the starting point is the description of the scope and the strategies of each one of the fundamental characteristics of the HFE and CE in Section 2. Then, these contributions in terms of values in the context of the perspectives of the main stakeholder groups related to HFE and of the frameworks within the approaches to CE, are harmonised with the view of the main authors, are presented in Section 3. Finally, it is proposed that this theoretical complementarity can be optimised by the synergy between the values of four tabulated contexts (within 'Fundamental characteristics versus Perspectives'), thereby helping to achieve a prosperous future for integration of HFE and CE.

The fundamental characteristics of HFE and CE

The scope and the strategies of each one of the fundamental characteristics of HFE (systems approach, design driven, and performance and well-being goals) and of CE (application of cognitive psychology to the design and construction of machines or human-machines systems) are shown in the following paragraphs. These characteristics are derived from their own definitions presented in the introduction of this paper.

System approach (or 'holistic approach'), design driven, and focuses on related outcomes of performance and well-being

HFE focuses on goal-oriented and purposefully designed systems consisting of humans and their environment (Helander, 1997; Schlick, 2009), which can be any human-made artefact e.g.

workplace, tool, product, technical processes, service, software, built environment, task, organisational design, etc. as well as other humans (Wilson, 2000). When defining problems and formulating solutions, system boundaries are defined, and the focus of HFE can be on considering different aspects of the person (physical, physiological, psychological (affective and cognitive), and social), different aspects of the environment (physical, social, informational, etc.), or address issues on various system levels from micro-level (e.g. humans using tools or performing single tasks) to meso-level (e.g. humans as part of technical processes or organisations) to macro level (e.g. humans as part of networks of organisations, regions, countries, or the world); but the broader context of the human within the environment is always taken into consideration (Rasmussen, 2000).

HFE seeks to improve performance and well-being through systems design (analysing and evaluating result in recommendations and actions), and can be involved in all stages of planning, design, implementation, evaluation, maintenance, redesign and continuous improvement of systems (Woods and Dekker, 2000; Japan Ergonomics Society, 2006). These stages are not necessarily sequential; they are recursive, interdependent, dynamic, but design is at the heart of them. HFE specialists can be active participants in design processes, and a particular feature of HFE is that those who will be part of the system being designed, are often brought into the development process as participants (Noro and Imada, 1991; Noy, 1995; Rasmussen, 2000).

HFE recognises that any system always produces two intertwined and strongly connected outcomes (Pot and Koningsveld, 2009): performance (e.g. productivity, efficiency, effectiveness, quality, innovativeness, flexibility, (systems) safety and security, reliability, sustainability) and well-being (e.g. health and safety, satisfaction, pleasure, learning, personal development), where performance can influence well-being, and well-being can influence performance, both in the short and the long-term. By fitting the environment to the human capabilities and aspirations, HFE can contribute to optimising these joint outcomes (Neumann and Dul, 2010). These Ergonomics and other outcomes are balanced by HFE specialists, managing practical, as well as ethical trade-offs within systems (Wilson *et al.*, 2009).

The main stakeholder groups (individuals and their representing organisations at company, national and international level) related to HFE can be defined as (Dul *et al.*, 2012):

- System Actors (SA) - This stakeholder group can be divided into actors of work systems (employees), and actors of product/service systems (product users, service receivers).
- System Experts (SE) - This stakeholder group consists of a variety of professionals from the technical and social sciences that can be involved in the design of systems, e.g. (industrial) engineering, information technology/computer sciences, psychology, management consultancy, design, facility management, operations management, human resource management, interior design, architecture. These professionals aim to design a system that performs well according to the standards of their respective professions, and to the requirements of system decision makers.
- System Decision Makers (SDM) - This stakeholder group consists of decision makers (e.g. managers, purchasers) that decide about the design (e.g. requirements, final design) of work systems and product/service systems.
- System Influencers (SI) - System influencers have a general public interest in work and product/service systems, in particular regarding their outcomes.

Application of cognitive psychology to the design and construction of machines or human-machines systems

Considering the origins of experimental psychology itself in issues with respect to the design of human-machine systems, CE is a core (or fundamental) discipline within academic psychology (Wilson *et al.*, 2013). Essentially, psychology has always been CE (Helton and Kemp, 2011).

A sociotechnical system describe the interaction between people and technology, bearing in mind that the term technology can refer to not only machinery but procedures and knowledge as well, in which humans provide essential functionality related to deciding, planning for, collaborating with, and managing the system. The study of macrocognition, or the cognition of skilled operators working in actual sociotechnical systems (Baxter and Sommerville, 2011), examine the emergent properties that become evident when the human cognitive system is situated in a larger system as described immediately above; is distinguished from the study of microcognition that often focuses on the subcomponents of cognition of individuals considered in isolation. Macrocognitive constructs are generally broad in nature (e.g., mental simulation and situational awareness), whereas microcognitive constructs are narrower in focus (e.g., sustained attention and working memory). As depicted in Figure 1, the distinction between macrocognition and microcognition is an unique ontological distinction, though correlated, with the choice of epistemological method, 'Experimentation versus Observation' (Wilson *et al.*, 2013).

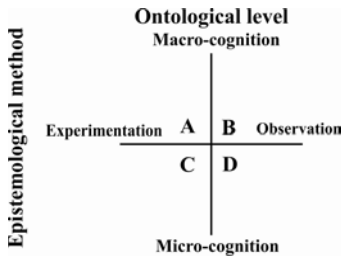

Figure 1: The quadrants of cognitive engineering (adapted from Wilson *et al.*, 2013)

The three frameworks within CE that are often considered to be more recent or 'newer' additions are (Wilson *et al.*, 2013): (i) Cognitive Systems Engineering (CSE) - emphasizes the study of macrocognition, while advocates of CSE may be found more often in quadrant B, performing observational research on macrocognition, and cognitive psychologists in quadrant C, performing controlled laboratory studies of microcognition, research in quadrants A and D is important and should not be neglected; (ii) Naturalistic Decision Making (NDM) - also concerns macrocognition; and (iii) Ecological Interface Design (EID) - focuses on the affordances which the work domain offers the human operator. All three share in common an approach that focuses heavily on the interplay of sociotechnical systems, and thus macrocognition. Some, however, consider NDM and EID to be frameworks within CSE itself. All focus more on fieldwork than laboratory work, perhaps, distinguishing the new CE from the more traditional approach to CE; researchers in the newer approaches of CSE and NDM tend to be found in quadrant B (but not exclusively). Klein *et al.* (2003) suggest that a focus on macrocognition in CSE and NDM is beneficial, because it allows an assessment of human performance in context (which is critical to understanding system performance).

The three research topics within CE that might be considered to represent the more traditional approach to CE (Sanders and McCormick, 1993) are: (i) Vigilance (V), (ii) Skill Learning and Expertise (SLE), and (iii) Visual Displays and Iconic Cues (VDIC). These topics make extensive use of what new CE advocates would call microcognition and experimentation, especially in controlled laboratory settings (Figure 1, quadrant C).

Theoretical contributions of HFE and CE for the performance of work systems

The implementation of the strategies of the fundamental characteristics of HFE and CE described above reveal some of its theoretical contributions for the performance of work systems. In this section, these contributions were synthesized in terms of *values* in the context of the following perspectives (harmonized with the view of the main authors investigated):

- The main stakeholder groups related to HFE – SA, SE, SDM, and SI – listed in Table 1.
- The frameworks within the approaches to CE – CSE, NDM, EID, V, SLE, and VDIC – mentioned in Table 2.

Table 1: Synthesis of the theoretical contributions of the HFE for the performance of work systems by the perspective of its fundamental characteristics and of the main stakeholder groups (SA, SE, SDM, SI)

Stakeholder groups	Theoretical contributions of the **Human Factors/Ergonomics [HFE]** (Dul *et al.*, 2012) *System approach, design driven, and performance and well-being goals*
SA	* Employees can benefit in terms of: Improved physical, psychological and social well-being (health and safety) through optimisation of work environments; Higher motivation, growth and job satisfaction, through freedom to act and room to grow and learn; and Improved performance leading to intrinsic or extrinsic reward. Product users/service receivers can benefit in terms of: Better experience; Shorter time of familiarisation; Better fitting of products/services to individual characteristics/needs; Fewer mistakes; Greater efficiency. As HFE commonly takes participatory design approaches, another value of HFE is that it ensures that SA can influence system design.
SE	* HFE can help to reach the SE because HFE contributions help to ensure: Better users' acceptance of designed systems; Better performance; Better fit with (legal) standards (e.g. health and safety, accessibility, professional ethics); Improved development process through more efficient user consultation.
SDM	* SDM about work systems can benefit from HFE as it ensures performance in terms of: Better productivity by reduced time for performing work procedures through optimisation of work equipment, work flow or worker qualifications; Better quality and reliability of production processes and produced goods and services through optimisation of work equipment, operating instructions or worker qualifications; Lower operating costs due to lower levels of health problems, motivational deficits, accidents, absenteeism, and related productivity loss through better working conditions; More innovation by increased employee creativity through creativity stimulating work environments; Better reputation for hiring and retention of talented employees through attractive work, and positive worker and consumer associations with the firm and its products/services (employee well-being, sustainability, corporate social responsibility, end user well-being); Better decision-making through improved information about the effects of system design on employees. SDM about product/service systems can benefit from HFE design as it ensures product/service performance in terms of: Better market performance through due to unique characteristics such as ease of use; Greater profitability; Less re-design due to interaction problems after market introduction; Better decision-making by improved information about effects of system design on product/service users.
SI	* HFE can contribute simultaneously to two general goals: Social wealth of individuals and society at large through the well-being outcome of HFE system design; Economic wealth of individuals and society at large through the performance outcome of HFE system design.

Table 2: Synthesis of the theoretical contributions of the CE for the performance of work systems by the perspective of its fundamental characteristics and of the frameworks within of the approaches to CE (CSE, NDM, EID, V, SLE, VDIC)

Frameworks within of the approaches to CE	Theoretical contributions of the **Cognitive Engineering [CE]** (Davies and Parasuraman, 1982[1]; Warm, 1984[2]; Logan, 1985[3]; Vicente and Rasmussen, 1992[4]; Warm, 1993[5]; Procter and Dutta, 1995[6]; See *et al.* , 1995[7]; Chun and Jiang, 1998[8]; Matthews *et al.* , 2000[9]; Baars, 2002[10]; Bebko *et al.* , 2003[11]; Woods and Hollnagel, 2006[12]; Helton, 2007[13]; Helton and Warm, 2008[14]; Helton, 2009[15]; Helton and Russel, 2012[16]; Wilson *et al.* , 2013[17])
	Application of cognitive psychology to the design and construction of machines or human-machine systems
CSE	* Observation, where practitioners observe work being done to understand how workers do what they do and adapt within their environenment[12]; Abstraction, which involves retrieving information and patterns from the various situations and settings[12]; Discovery and innovation, whereby the information garnered from the first two processes is utilized to create improved concepts and procedures[12].
NDM	* Decision-making strategies that are engaged in field settings are often distinct from the strategies that are evident in relatively impoverished laboratory environenments[17]; Understanding how experts operate in naturalistic settings by addressing a number of areas previously neglected in psychological research and by introducing new models and methods of psychological inquiry[17]; More forcefully advocating rigorous qualitative data analysis[17].
EID	* Attempting to completely eliminate errors is futile, but instead, efforts should be directed toward their control and management[17]; Abstraction hierarchies to describe constraints within an environenment in such a way that it aids potential coping methods[4]; The skills, rules, and knowledge taxonomy to elucidate the cognitive processess involved in decision making in these settings[4]; Presentation the information in forms, usually visual, that enable the categorization of information, the antecipation of changes that are likely to occur, and the consequences of intended actions[17].
V	* Vigilance decrement is marked by either a decline in signal detections with time-on-task or an increase in response latencies with time-on-task, and the intriguing aspect is that the loss of performance occurs even though critical signals are perceptible when observers are fore-warned about them[17]; Vigilance tasks require the detection of perceptible changes that are not compelling changes in the operating environenment, and these critical stimuli appear unpredictably with a relatively low probability of occurrence and the observer hasn't control over when they appear[1, 2, 5, 7, 9, 14, 16]; An understanding of the factors that influencing the vigilance decrement may help system designers develop better systems to mantain operator vigilance[17]; Peripheral and central physiological markers can also be used to gauge the amount of cognitive resources that a human operator is expending[17]; The future of vigilance research will take a neuroergonomic perspective in an attempt to prevent vigilance decrement via system intervention when the human operator is in an unvigilant state[17].
SLE	* Developmental transition in skill from active control to automaticity, frees up attention for other concurrent tasks and operations[3, 6, 13, 15]; Skills become more automated and less attention demanding with practice[11]; Contextual regularities that affect performance can be acquired independent of conscious awareness, and the human participant must actively attend to the display for the sequences to be learned[8, 10]; Determining who is actually expert at the task is one challenge for research involving the acquisition of complex skills[17].
VDIC	* Disengagement from a primary task inevitably results in a situation where the acquisition, integration, and interpretation of information associated with a change in the system state must be completed within a shorter period of time than might be the case if the operator was fully engaged in system operator[17]; Fore more experienced operators, the process of information acquisition will quickly become more refined to a point where the pattern is recognized and the diagnosis is resolved[17]; Iconic cues are tools that have the capacity to highlight a change in the system state, direct the attention of the operator to key features that will enable a more rapid and a more accurate diagnosis and response to the change in the system state[17].

Theoretical complementarity between HFE and CE

In order to contribute to future work system design, HFE must demonstrate its values more successfully to the main stakeholders of system design, helping to ensure that people do not get injured at work or while using products or receiving services, that work systems and product/service systems are profitable for companies and for society at large, and that work systems and product/service systems are accessible for people with a variety of capacities and aspirations. HFE already has a strong value proposition (mainly well-being) and interactivity with the stakeholder group of SA. However, the value proposition (mainly performance) and relationships with the stakeholder groups of SE, and SDM, who have a strong power to influence system design, need to be developed (Dul *et al.*, 2012).

The overall perspective of the CE approaches is that studying the person in the actual working system is radically different from studying the person in isolation of the entire working system (Shanteau, 1992). Wilson *et al.* (2013) demonstrates the complementary nature of laboratory research or traditional human factors with the concerns and techniques being developed by the new CE. Both CE approaches can be integrated effectively and the field, to be effective, needs to cover all quadrants in Figure 1, highlighting the continued relevance of tightly controlled laboratory study to CE.

By analyzing Tables 1 and 2, it is possible to conclude that the theoretical complementarity between HFE and CE can be optimized by the synergy between the values of the tabulated contexts ('Fundamental characteristics versus Perspectives'): (i) 'System approach, design driven, and performance and well-being goals versus Frameworks within of the approaches to CE'; (ii) 'Application of cognitive psychology to the design and construction of machines or human-machine systems versus Stakeholder groups'; (iii) context of the Table 1; and (iv) context of the Table 2. The results of (i) and (ii) shall be further prospected in future studies. This synergy represents the possible paths for improvement of the design/operation of human-machine systems and of the environment appropriateness to the human (Dul et al., 2012; Wilson et al., 2013).

Conclusions

This review synthesized the complementary theoretical contributions, in terms of values, of the HFE and CE for the performance of work systems. These contributions were considered as being a consequence of the implementation of strategies of the fundamental characteristics of HFE and CE. The presentation of these contributions emphasized the view of the main authors investigated regarding the perspective of the main stakeholder groups related to HFE (Table 1, where the performance and relationships with the stakeholder groups of SE, and SDM, need to be developed) and of the frameworks within the approaches to CE (Table 2, where both CE approaches can be integrated effectively and the field needs to cover all quadrants in Figure 1).

The proposed method was effective to reveal how to optimise the theoretical complementarity between HFE and CE by the synergy between the results of the following presented relationships ('Fundamental characteristics versus Perspectives'): (i) 'System approach, design driven, and performance and well-being goals versus Frameworks within of the approaches to CE'; (ii) 'Application of cognitive psychology to the design and construction of machines or human-machine systems versus Stakeholder groups'; (iii) context of the Table 1; (iv) context of the Table 2. The results of (i) and (ii) shall be further prospected in future studies. This synergy represents the potential paths for improvement of the design/operation of human-machine systems and of the environment appropriateness to the human (Dul *et al.*, 2012; Wilson *et al.*, 2013).

In the future development of these potential paths, the following aspects should be additionally considered with related to theoretical values of HFE and CE: (i) limitations, (ii) applications and evidences, (iii) explanations, (iv) associative analysis, (v) alternative perspectives and methods, and (vi) view of others authors.

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PREVALENCE OF LOW BACK PAIN IN BRICKLAYERS AND WORK RELATED UPPER LIMB DISORDERS IN CARPENTERS CORRESPONDS TO THE VARIATION IN PHYSICAL EXPOSURE

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Abstract

The Construction Industry is the oldest and most conservative industry of mankind where work is still physically straining and work organisation and work methods are very traditional (Koningsveld and Van der Molen, 1997). Construction work is hard work, often involving working in difficult weather conditions and consequently construction workers feel the results. They accept that the work is punishing to the body, but continue with it because it pays the bills. Construction workers believe that getting hurt and working with pain are part of the job, that it's just the nature of the business (Ringen et al 1995). Despite its size the proportion of occupational health and safety research (including ergonomics) in the construction industry has been rather poor compared to other industries, which are relatively controlled and organised environments within which studies can take place. At only a few places in the world, institutions or centres have been active in this field over a long period of time (Koningsveld and Van der Molen, 1997).

Introduction

Some of the most common construction injuries are the result of job demands that push the human body beyond its natural limits. Very few studies exist that provide detailed risk assessment and intervention development to improve well-being at an individual level and population level across these trades in a variety of work environments in this industry. Bricklayers and carpenters are two trades which are seen as high risk for non traumatic soft tissue disorders of the upper extremity, neck and back. Jobs or working conditions presenting multiple risk factors will have a higher probability of causing musculoskeletal problems and the level of risk depends on the intensity, frequency and duration of the exposure to these conditions and the individual's capacity to meet the force or other job demands that might be involved (Punnet and Wegman, 2004).

Site observations of bricklayers showed a variety of problems, especially concerned with handling of heavy materials, variation in working height, performing repetitive tasks and bending and twisting (Spielholz et al 2001). The most common block built in Ireland weighs 20 kg. Bricklayers in Ireland lay on average 225 blocks per day resulting in a total weight over an 8 hour working day of 4500kg.

Site observations of carpenters showed that tasks can vary widely and is divided into many sub-trades (Schneider et al 1994). These studies have shown that working as a carpenter requires the use of different body parts and depending on the task may require forceful use of the back and upper and lower limbs. Such work often entails the handling of power tools, or forceful repetitive gripping, twisting, reaching or moving actions. Carpenters can spend up to 9.8% of their working time in a kneeling or squatting position and 9.5% of their time working with their hands in an over head position and above shoulder level (Hartmann and Fleischer 2005).

Methodology

This study was based on Quantitative research methods using a cross sectional survey and on literature review**.** Because of the limited time, resources and small budget available to the researcher study participants were recruited on a convenience basis. The questionnaire consisted of three parts, personal information, physical risk factors and musculoskeletal disorders symptoms. The questionnaires or modified versions used in this research are widely used in epidemiological literature with well established validity and reliability.

Results

Sample Demographics

A total of 99 respondents participated in this survey with approximately equal numbers of bricklayers (number=48, 48.5%) and carpenters (number=51, 51.5%).

The results revealed similar characteristics for the two trades in terms of age, weight, experience, type of employment, length of employment and smoking which are seen as potential confounders for musculoskeletal symptoms. This would suggest that differences in musculoskeletal symptoms between both trades cannot be accounted (or only be accounted to a small degree) to differences in the sample.

Prevalence of low back pain and upper limb disorders

The results seems to suggest that there is an association between low back pain and occupation with both the bricklayers (66.7%) and carpenters (37.7%) reporting symptoms of LBP in the last twelve months. There is a lot of evidence to suggest that low back pain is associated with heavy physical work. It could also be seen from the results that bricklayers were more likely to report having had trouble with their wrist/hands (54.2%) compared to carpenters (33.3%). The tendons in your wrist can be strained if you frequently exert strong force with your hand or repeat the same wrist movements over and over. The results also showed that carpenters were much more likely to report having had trouble with their elbows in the last 12 months (41.7%) compared to bricklayers (18.0%). Frequently use hand-held vibrating power tools and forceful operation of screw guns and hammers are common causes of forearm sprains and elbow pain because of overexertion.

Manual Handling and Lifting

There seemed to be a strong association between occupation and the frequency with which the respondents report carrying or lifting materials with both hands with 95% of the bricklayers reporting this activity compared to 62.7% of carpenters. Carpenters were more likely (54.9%) to report sometimes carrying, lifting or moving with one hand than bricklayers (38.3%). The results also demonstrated that the majority of bricklayers (87.5%) report that they always perform repetitive tasks which compared to only 20.0% of carpenters. Disorders caused by manual handling and lifting include low-back muscle strains and inter-vertebral disc lesions.

Using Power Tools
There seemed to be a strong association between use of power tools and occupation with almost half of the carpenters (49.0%) having indicated that they always use power tools compared to only one of the bricklayers (2.1%)). Using power drills and hammers are common cause of forearm sprains and elbow pain because of overexertion.

Working Posture
Using Peasons Chi Square Test there was no distinct variation between the two trades when it came to what they saw as perceived exposure to working posture. The results were quite similar with regard to how often both trades spent kneeling, bending and twisting, working in confined spaces and working with their hands over their shoulders for long periods.

Discussion

There is wide scope for action to reduce the risks of musculoskeletal disorder among carpenters because of their large numbers and the wide range of tasks they perform. There should be more detailed study of carpenters, subdividing them into specialties, and using task analysis to examine the musculoskeletal loading factors in each specialty (Reid et al, 2001). Studies have recommended that ergonomic awareness programs be integrated into apprenticeships for trades (Alberts et al, 1997) encouraging them to make more use of the solutions that already exist to the problems of manual handling. Examination of the current generation of handheld power tools (Reid et al, 2001) and non powered tools to identify poor design features (Dabebneh, et al, 2004).

The physical nature of masonry work has limited the types of administrative and engineering interventions that are possible to reduce musculoskeletal stress. There is scope for action to ensure that block sizes and weights are chosen with due regard to the problems of manually handling them into position. Encourage the Construction industry to develop new types of block that are easier to handle, e.g., smaller, lighter, less dense, hollow, or with handholds (Schneider et al, 2004). Indeed, studies have found an increase in productivity when using lighter weight blocks. Encourage designers, structural engineers and architects who influence the building materials specified to consider the manual handling problems created by the method of construction specified. In particular, designers and architects should specify the minimum weight block necessary for the intended use particularly the effect of the weight of the block (Reid et al, 2001). Also a more detailed analysis of trowel sizes to evaluate the relationship between trowel length and biomechanical stresses on the wrist joint and an evaluation of the relationship between trowel size and mortar spreading time (Vi et al, 2002).

Conclusion

This study seems to show that it is possible to rank different construction tasks with respect to physical exposure. There are ergonomic solutions to the problem and there have been improvements certainly in safety, but much remains to be done about the continuing poor occupational health of the industry‘s employees. Indeed most of the literature on occupational health and safety in the construction industry is still at the stage of descriptive epidemiology and is shot through with expressions of concern and frustration that the very nature of the industry and the people who work in it militate against improvements**.** It is hoped that this study will increase awareness and understanding of the risk from physical exposure to both of these trades and may be of benefit to larger studies carried out in the future.

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PLASTERING ACTIVITIES IN IRELAND: ARE PLASTERES AT RISK OF DEVELOPING WORK RELATED MUSCULOSKELETAL DISORDERS (WRMSDS)?

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Abstract

The construction industry plays a vital role in the provision of infrastructure to support and protect populations. However, when compared to other industries, high levels of accidents, injuries and ill health are reported by its workforce on an annual basis. Work Related Musculoskeletal Disorders (WRMSDs) is one of the top causes of workplace absenteeism and early retirement. Plasters are one of the trades who experience high prevalence rates of the disorders when compared with other trades within the industry. The incidence of the disorders is believed to be attributed to risk factors that are an intrinsic part of their daily activities. High levels of absenteeism and early retirement is attributed to WRMSDs. Additionally, employees with WRMSDs, their employer and the economy experience a significant financial burden because of lost income, treatment, compensation, and insurance costs.

An ergonomic study of the plastering activity was carried out to evaluate if plasterers working in Ireland were at an increased risk of developing WRMSDs because of their tasks and working conditions. The methods used in this study were selected based on their suitability to evaluate WRMSD risk. Visual Analogue Discomfort Scales (VADS) was used to evaluate psychophysical stress; Heart Rate Analysis (HRA) was used to evaluate physiological stress, and Electromyography (EMG) was used to evaluate biomechanical stress.

The VADS survey was used to establish details about plaster's working activities, and their working times and break-taking behaviours. The method was also used to establish temporal pattern of perceived discomfort, and to determine if their daily activities and their work and break patterns influenced discomfort intensities. Eighteen plasterers working on active construction sites participated in the VADS study over a five day work week.

Simulated workstations were set up in an apprentice training centre to represent real-life working conditions. This enabled a more detailed analysis of conditions that occur on active sites. These included: standing surfaces (e.g. ground, stilts, trestle, and hop-up), plastering surfaces (e.g. wall and ceiling), plastering tasks (e.g. Mix Plaster, Load Mortarboard, Load Hawk, Load Trowel and Plaster), and mortarboard stand heights (e.g. 775mm and 1270mm).

Heart Rate Analysis (HRA) was used to evaluate and compare plasterer's physiological response when they carried out a wet-plastering task the assessment

workstations. Electromyography (EMG) was used to simultaneously evaluate the plasterers' biomechanical response for the same task. Ten plasterers were assessed in the simulated working environment.

The results indicate that plastering activities and working conditions increase plasterers' risk of developing WRMSDs. Overall plasterers experienced increasing levels of perceived discomfort intensity levels over five consecutive workdays. A decline in intensity levels was observed after a period of rest i.e. lunch break or overnight break. EMG and HRA results indicate that plasterers experience higher levels of stress when working on a ceiling while standing on a trestle and using a low mortarboard stand

The findings from the data analysis were used to provide recommendations for control interventions to minimise the adverse effects that the plastering task and working conditions has on the musculoskeletal system and decrease the probability of plasterers developing WRMSDs.

LEADERSHIP AND TEAM SITUATION AWARENESS DURING DAILY ROUNDS IN THE INTENSIVE CARE UNIT

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Abstract

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CAN COMPLEX MEDICAL PROCESSES SUCH AS PROSTATE SEED BRACHYTHERAPY BE MORE EFFECTIVELY THOUGHT? COMPARISONS WITH AVIATION

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Abstract

In recent years, the introduction of new technologies has greatly improved the outcomes for prostate cancer patients. The implantation of radioactive seeds into the prostate gland as a method of curing prostate cancer involves a multi-disciplinary team of between 5-7 personnel. The introduction of these new technologies has influenced the composition of the team, how the team members work together, and how they are trained.

In the public health service in Ireland, prostate seed brachytherpay was only performed in one centre, University College Hospital, Galway (UCHG). As part of the development of a national cancer strategy, it was decided to expand the service to other radiotherapy centres in the country. During the process of developing a teaching programme to transfer the skills and competencies from the experienced personnel at UCHG to the other facilities it became apparent that the process required to achieve a high calibre of care delivery was not dissimilar to the process use to train pilots. Aviation, like most other "high reliability" industries, has a number of pertinent characteristics that are relevant to the prostate seed brachytherapy treatment process:

- Limit the discretion of workers;
- Reduced autonomy;
- Transition from a craftsmanship mindset to that of equivalent actors;
- Developed system-level (senior leadership) arbitration to optimize safety strategies;
- Simplification of processes.

The above characteristics are at odds with the traditional values of clinical independence and autonomy, creativity, academic expression and the exercise of professional judgement.

Patient outcomes have been shown to improve when experienced 'high volume' teams perform the procedure, independent of what the actual procedure is. Therefore, there is a need to shorten the 'learning curve' and develop expert performance sooner rather than later when medical procedures are being taught. Patient's lives are at stake, literally.

The authors compare the training required to achieve competence in prostate seed brachytherapy implantation with aviator training. The implications of the lessons drawn from this are manifold and should be of interest and applicable across a wide spectrum of health care.

CHALLENGES OF APPLYING NASA-TLX TO BRACHYTHERAPY

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Abstract

This paper examines the challenges of applying NASA-TLX to brachytherapy. The background to NASA-TLX, prostate brachytherapy treatment, and the important challenges in data collection using the tool are presented. The lessons learned from the direct observation of individual brachytherapy team members while carrying out their work and the application of NASA-TLX to each are reported. The field work supporting this paper was performed during February and March 2013 at the Radiotherapy Department at Galway University Hospitals as part of the Radiation Oncology Systems Safety Analysis (ROSSA) project.

Introduction

Brachytherapy

Brachytherapy is a form of cancer treatment, where small radioactive seeds (usually Iodine-125) are permanently implanted into the patient's prostate gland. The procedure requires a team of experts, including a physician, medical physics team, oncology nursing team, and anaesthesia team to work together to successfully carry out the treatment. This requires strict protocols and has to be performed while the patient is anesthetised.

Applying NASA-TLX to brachytherapy

NASA-TLX (Task Load Index) is a subjective workload tool which measures the perceived workload of the person performing the task. It was developed in 1988 (Hart, S. G. & Staveland, L. E., 1988), and has been successfully applied to a number of industrial sectors, including aviation, aerospace, healthcare, automotive, and nuclear power.

The format can be paper- or computer- based. For the convenience of this research, the paper-based format consisting of a single worksheet of paper was used. The term "worksheet" refers to the "NASA-TLX worksheet". It is split into two parts. The first part consists of a scale with the values raging from 0 to 100 of the six featured dimensions: Mental Demand (MD), Physical Demand (PD), Temporal Demand (TD), Performance (PE), Effort (EF), and Frustration (FR). The second part consists of 15 pair-wise comparison tiles, where the six dimensions are paired together and compared against each other. One option has to be chosen over another in each tile. The pair-wise compared tiles contribute to the depth of the analysis of each dimension. They give an overall perceived workload value, while the scales give the overall perceived workload level of each dimension. An example of administered worksheet to a physician measuring

Table 1: An example of an administered worksheet to a physician

	Weight	Raw rating	Product
MD	5	88	440
PH	0	3	0
TD	2	70	140
PE	4	3	12
EF	3	98	294
FR	1	15	15
Sum	15		901

Weighted rating = Product / Weight sum = 901 / 15 = 60.06

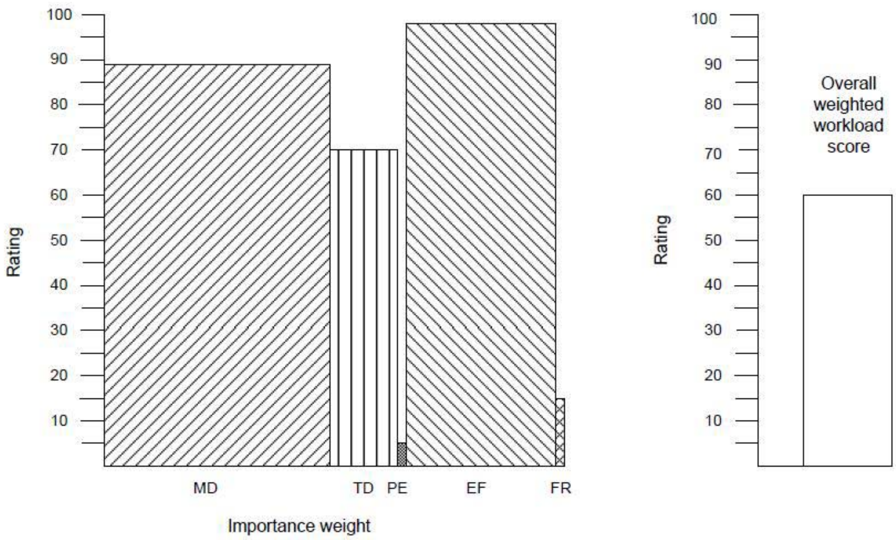

Figure 1: Graphic example of the weighted NASA-TLX score

overall perceived workload is presented in Table 1. Graphic example of the composition of the weighted score is presented in Figure 1.

The worksheet should be applied straight after the task is performed. However, applying it directly is challenging due to a number of reasons outlined below.

Challenges

The clinical environment

The brachytherapy clinical environment is an environment where the patient is anesthetised, and the physician and oncology nurse are gowned-up and wear surgical gloves. Consequently, it would be difficult, if not impossible for them to directly fill out the worksheet immediately after they perform their respective tasks which require high attention and focus. The same also applies to the other team members who are not gowned up. Any interruptions during the procedure could compromise their performance.

The best time to administer the worksheets to the staff is immediately after the brachytherapy procedure has been completed. However, the questions that arise with this are: How much time should pass between task completion and filling out the worksheet before the tool's validity is called into question? How is this influenced by scheduling treatments sequentially?

The time between the completion of tasks and filling out the worksheet should be minimised. If there are a number of treatments planned per day, the best time would be to fill out the worksheets immediately one after another. If they are filled out after all scheduled treatments are completed, their validity might be compromised, as team members' perceptions might vary due to the new tasks involved, new challenges that arose, or they just might not be able to relate to their performance very clearly due to the time lag involved.

What is measured: Team workload, or individual workload in a team?
It would be very challenging to measure team workload as a whole, as there are many parameters that would need to be taken into consideration. The concept of team workload is discussed by Funke et al. (2012). Since NASA-TLX was designed to measure an individual's workload, "individual workload" is therefore measured within a team. That is, team interaction is part of the workload measure, but it is not isolated.

The worksheets have to be prepared beforehand, and administered to measure an individual's workload at different stages of their performance. When the tasks in their performance overlap, the individual members of a team naturally share their workload with other team members. The perception of shared workload is different for each team member due to their respective roles during the treatment process.

Weighted or unweighted scores?
The original NASA-TLX paper (Hart, S. G. & Staveland, L. E., 1988) explains the background and the reasons for using this method. The worksheet includes the scale for 6 dimensions (MD, PD, TD, PE, EF, FR), and 15 tiles with pair-wise comparison of these 6 dimensions. However, some researchers state that "the weighting procedure of TLX is superfluous and can be omitted without compromising the measure" (Young, M.S. & Stanton, A.N., 2004). This would change the original method of calculating the average workload to a simple calculation of an arithmetic mean of the obtained scores (Young, M.S. & Stanton, A.N., 2004).

Another reason why the pair-wise comparison procedure could be ignored is that this only adds the depth to the scale, and nothing else. Although, as described above, these 15 pair-wise tiles do contribute to the *overall* workload score called *weighted rating score* which is calculated as a product of the weighted scores and raw rating scores, by simply dividing the weighted scores and raw rating scores by 15. If the overall score was calculated strictly on the basis of the average score (sum of everything divided by the number of items, the average result would be different). For this reason, the original method of calculating the overall perceived workload was selected using the 15 pair-wise tiles as part of the administered worksheet.

The cut-off point for high workload scores
The cut-off point for workload between low and medium, and medium, and high workload are not clearly defined. What defines a workload to be low, medium, or high? How are cut-off points divided? Is it the nature, or category of the task, or is it the perceived workload values?

After the workload levels are collected, they are marked on a scale between 0 and 100. If this scale is divided into three equal parts, then the cut-off points for low-medium and medium-high values will be 33.33 and 66.66 respectively. However, these threshold values would need to be related to the perceived values obtained from the users and a particular point in time. Relating the values to the perceived values would require additional analysis, since every work environment is unique, especially when it comes to brachytherapy treatment.

Team availability and missing data
The team consists of highly trained professionals with different educational backgrounds, different professional experience, and different training in brachtyherapy. The treatment can only be successfully performed if the team works effectively together. If any of the team members are missing or unavailable, the treatment cannot proceed.

It is similar with data collection. If the worksheet is incorrectly filled out, it loses its validity. At the same time, when data is missing from one team member, all of the data collected at that time is invalid. For the data to be valid, the whole team has to individually complete the worksheets.

Time availability in filling out the worksheet
When staff members are in a hurry due to other job obligations and they have to fill out the worksheets, do they fill them out correctly? Aren't things done in a hurry done less precisely? It would be interesting to compare the answers when the staff members have enough time available to fill out the worksheets (5-10 minutes), versus when they have a very limited time available (2-3 minutes).

Filling out worksheets at a later stage
If the worksheet is filled out at a later stage, are the results still valid? Sometimes the staff members do not fill out the worksheet simply because they have other job obligations to fulfil, for example, they could be working on different projects, or there could be emergency cases they have to respond to. In each of these cases, how much time can pass before the worksheet values become invalid? How accurately can a staff member fill out the worksheet a number of hours or days after brachytherapy treatment? Is the data collected still valid if the staff member fills out the worksheet a week after completing the brachytherapy?

Familiarity with the worksheet
Do staff members who are familiar with the worksheet fill it out differently to staff members who are not familiar with it? When the team members become familiar with the worksheets, do they fill them out individually one at the time, or automatically one after another because they are familiar with the worksheet format? Is it possible that they would memorise the answers? Do the given answers really cover personal perception based on the tasks performed?

The staff members have to be familiar with the worksheet, and comfortable enough to fill it out individually. Additional introductory meetings may be needed beforehand to use time effectively after the treatment.

The change of an individual's perception with time
How does an individual's perception of the worksheet change with time? Do team members perceive their workload in the same way when first filling out the worksheets as they do when doing it at later stage, e.g. after a couple of months? It is currently not known how team members' perception of the filled out worksheets changes with time.

Errors
One of the factors that can contribute to the perceived workload, are errors that occur during the bracytherapy treatment. Examples include:

- Human errors e.g. incorrect identification of implanted seeds, incorrect reading of the needle positioning, incorrect seed count, poor ultrasound positioning, inexperienced staff, etc.
- Technological errors e.g. disconnected cable between the machines, poor visual feedback due to improper ultrasound positioning, etc.

For this reason it is important that the researcher is present in the room during the brachytherapy treatment to record such events. Precise notes have to be written down as any small error during treatment can influence the perceived workload of any individual team member. Other data the researcher has to record are personal patient characteristics: The size of the prostate gland, the shape of the gland, the number of radioactive seeds inserted, the number of needles inserted, the radioactivity of the seeds, years of training/experience, limited time available to perform the treatment, etc. These are all performance shaping factors that can also contribute to each staff member's workload.

Conclusions

Based on the observations performed during February and March 2013 at the Radiotherapy Department at Galway University Hospitals, the points outlined above were noted. It is important that the worksheet is administered correctly immediately after the treatment procedure to all team members otherwise it will result in missing data thus rendering the study invalid. Further research challenges also lie in applying workload analysis to automation and automated equipment used in brachytherapy, and what impact these factors have on treatment safety.

Acknowledgements

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STUDYING PATTERNS OF LAPAROSCOPIC SURGERY INSTRUMENT USE IN LONG DURATION COLORECTAL SURGICAL PROCEDURES

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Abstract

Background: There are little data in the literature on the frequency and duration of use for different types of laparoscopic surgical instruments during long duration colorectal surgical procedures. The aims of this study are twofold: firstly to pilot a method of categorising surgical instrument use during long duration laparoscopic procedures, and secondly to pilot the method to study the operators hand actions during a case study procedure.

Method: A case study was performed on a single high definition recording of the laparoscopic portion of a sigmoid colectomy. The Observer XT V9.0 software package was programmed to study specific instrument usage, the actions associated with each instrument, idle behaviour time and instrument changeover times.

The Observer XT software was an effective method of categorising the actions during the procedure. The data from the case study indicated that for this specific right handed operator, the right hand led the procedure, using the most instruments and separate actions. The left hand provided support through actions such as grasping and manoeuvring only. The most used instrument was the suction/irrigation instrument, followed by the bowel grasping instruments. Key operations such as stapling/dissecting occupied the least amount of time. More time was spent manoeuvring the internal anatomy than performing operations on the colon.

Introduction

Common laparoscopic abdominal surgery procedures include cholecystectomy, appendectomy, reflux surgery, gastric bypass surgery, ventral hernia repair, and colectomy. Laparoscopic surgery has many proven benefits over open procedures (Xiao, Jakimowicz et al. 2012). Laparoscopic surgery is characterised by reduced risk of infection, reduced surgical invasiveness, shorter recovery times, smaller scars, better visualisation of internal anatomy for surgeons, and better postoperative clinical outcomes for the patient. It has been shown that abdominal surgical procedures can be performed using laparoscopic surgical techniques, and the list of compatible procedures is expanding (Tiwari, Reynoso et al. 2011).

Laparoscopic surgery requires the surgeon to perform complex operative procedures, utilising a relatively small set of standardised tools, including surgical laparoscopic instruments and laparoscopes, which are inserted into the patient through port sites in the abdomen (Trejo, Doné et al. 2006). Previous studies on the human factors of laparoscopic surgery have focused heavily on training, perception and musculoskeletal disorders (Stomberg, Tronstad et al. 2010).

Laparoscopic surgery has many benefits for the patient over open surgery but the remote nature of the procedures involves inherent human factors challenges which can impact on clinical outcome for the patient. These issues are compounded by the long duration of many abdominal laparoscopic surgeries. For example, while performing laparoscopic procedures, surgeons must often maintain non-neutral limb postures while using repetitive precision grips with static shoulder postures. Instrument design is a key factor influencing upper limb posture (van Veelen, Jakimowicz et al. 2004) and fatigue for the surgeon (Berguer, Gerber et al. 1998).

The purpose of this research is to explore opportunities to improve clinical outcome in laparoscopic abdominal surgery using human factors methods to identify specific design needs. As part of the primary research work it became evident that there were little data available on the fine actions of the lead surgeon's hands during specific laparoscopic procedures. As such, the aim of this research was to firstly develop a method to study the hand actions and surgical equipment use during long duration surgical procedures at a fine level of detail (i.e. at a resolution of 0.5 seconds). A secondary aim of the research was to apply the method to a case study of the laparoscopic portion of a sigmoid colectomy.

Method

Procedure Case Study

A high definition video recording from a laparoscope camera during a laparoscopic-assisted sigmoid colectomy was used for the study. Permission was obtained from the local Research Ethic Committee to use of the video recordings in the university for educational purposes.

A sigmoid colectomy involves the removal of the sigmoid colon, located on the left side of the colon and upper rectum. The procedure involves separating the blood vessels and lymph nodes to that part of the bowel, followed by removal of the left side of the colon and then end to end colon anastomosis (joining).

Table 1: Behaviours programmed into The Observer XT

Dorsey Intestinal Forceps (Left Hand)	
	Manoeuvring
	Grasping
	Idle
Dolphin Tip Sealer/Cutter (Right Hand)	
	Manoeuvring
	Sealing/Cutting
Suction/Irrigation Instrument (Right Hand)	
	Manoeuvring
	Suction/Irrigation
Universal Stapler (Right Hand)	
	Manoeuvring
	Stapling/Dissecting
Trocar	
	Manoeuvring
Bowel Grasping Forceps (Right Hand)	
	Manoeuvring
	Grasping
Dorsey Intestinal Forceps (Right Hand)	
	Manoeuvring
	Grasping
	Idle

Task Analysis of Laparoscopic-Assisted Sigmoid Colectomy

A Hierarchical Task Analysis (HTA) was performed on the full laparoscopic-assisted sigmoid colectomy procedure, the details of which are given in Figure 1. The tasks highlighted in grey indicate the laparoscopic portion of the procedure examined in this case study.

Video analysis software

Observer XT software V9.0 (Noldus 2009) has been used to collect and analyse data from either live video feed or video recordings of psychological, human factors, animal behaviour and observation studies. Behaviours such as movement, activities, posture, interaction and position, can be recorded simultaneously. These event based behavioural activities can be analysed within the software. Each activity is marked through use of coidentification between the video and a list of relevant behavioural criteria. The software was previously used by Browne and O'Sullivan (2012) to integrate wrist joint and EMG data with video recordings for simulated testing of endoscope needle biopsy deployment designs (Browne and O'Sullivan 2012).

Once the coding scheme is fully programmed, the analysis of the video commences. The video is played slowly, and each behaviour is flagged every time it occurs during the procedure, creating a timeline of each activity. An example of data analysis and extraction is presented in Figure 2. The event log at the bottom of the screen image illustrates the events or behaviours as they occurred during the surgical procedure. The coding scheme is displayed on the right side of software window. Figure 3 illustrates the software interface of the codified data. There are no overlapping durations for each individual behaviour group.

Before conducting the study, the video was edited to remove segments at the beginning and end which were unrelated to the procedure. The video quality was reduced so that there would be no lag or performance issues between the video and the analysis software. The Observer XT Software package was used to conduct this case study. Within the program, subjects, who are those performing the actions in the video, are input manually. The actions that subjects perform are called behaviours. Subjects and behaviours (Table 1) to be studied were then programmed into the software. For this case study, the key subjects involved were the right hand, left hand, transanal entry, and placement with other instruments. The subjects and behaviours were subsequently coded over the video timeline in the software, manually. These behaviours can be point events or have a set duration. In order to determine which behaviours to program, the video recording must be watched multiple times to ensure that all instruments and actions are programmed. Once the coding scheme is fully programmed, the analysis of the video commences.

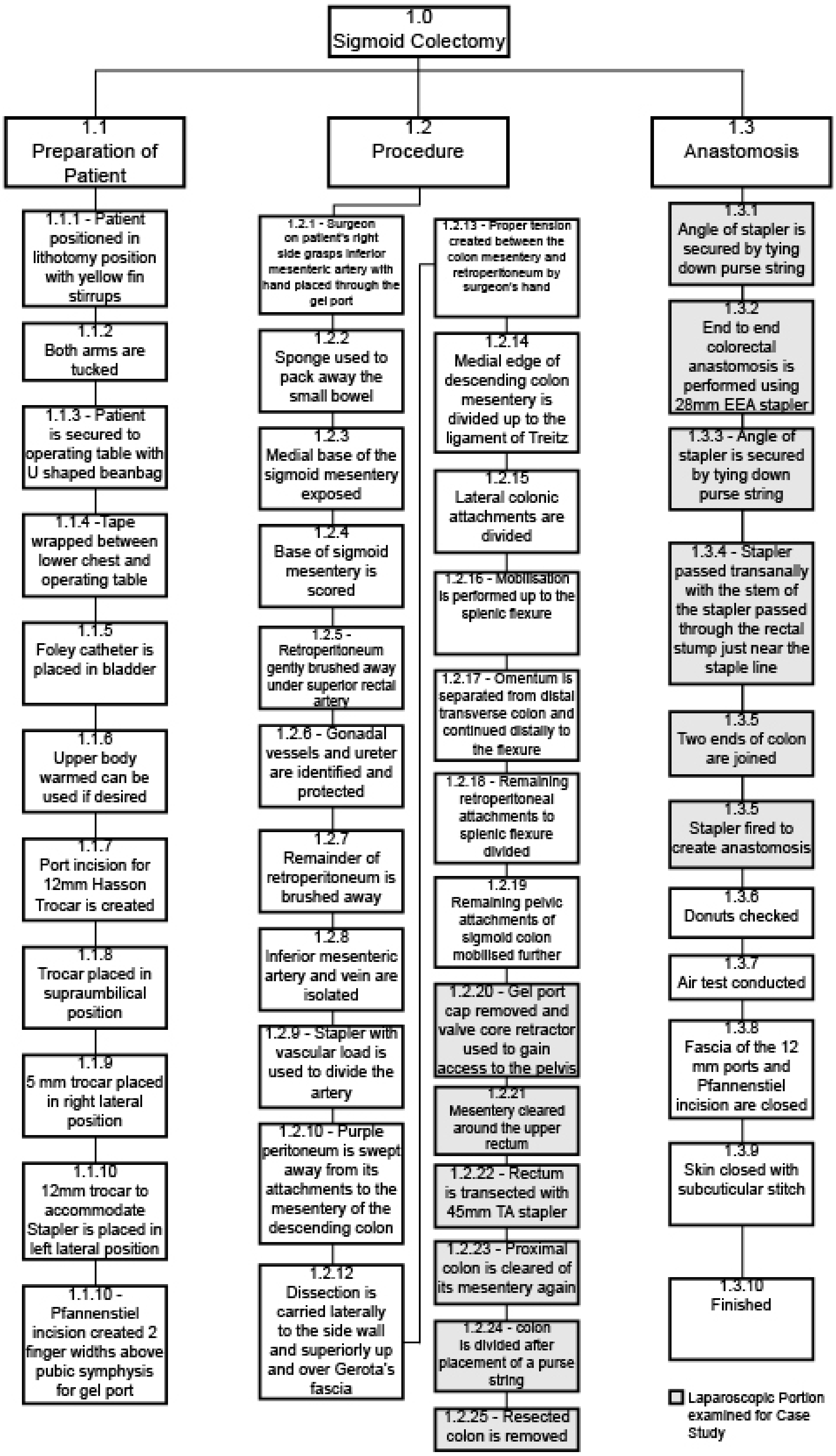

Figure 1: Hierarchical Task Analysis of full Laparoscopic-assisted Sigmoid Colectomy procedure

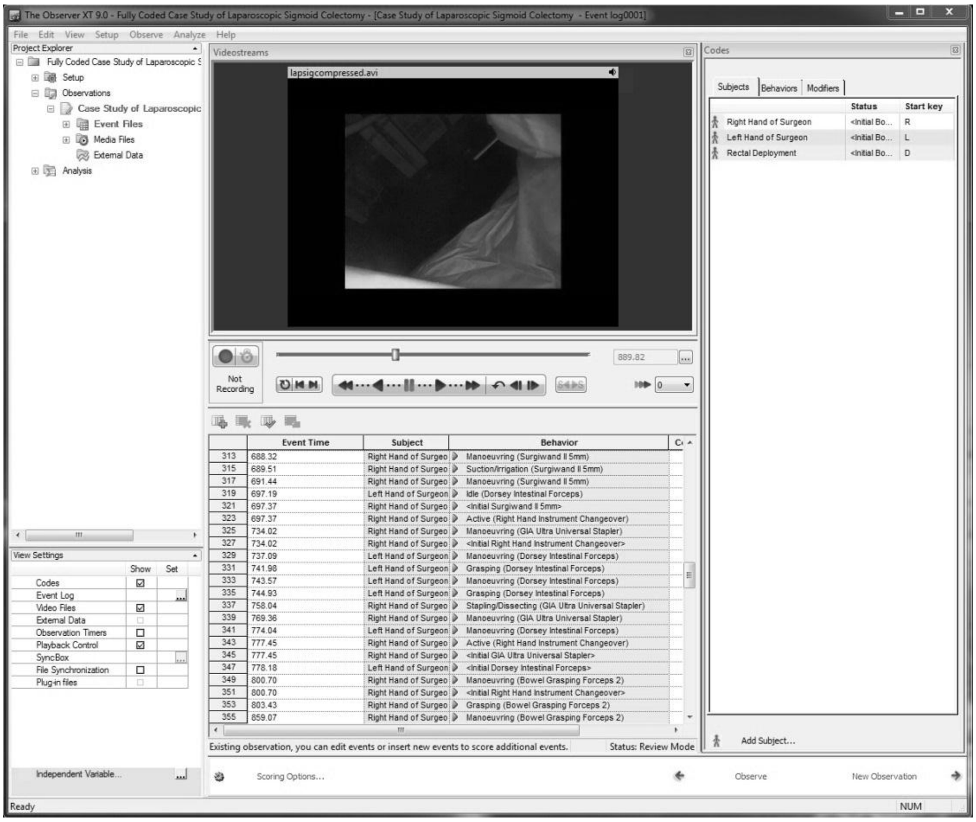

Figure 2: Analysis of Video using The Observer XT V9.0

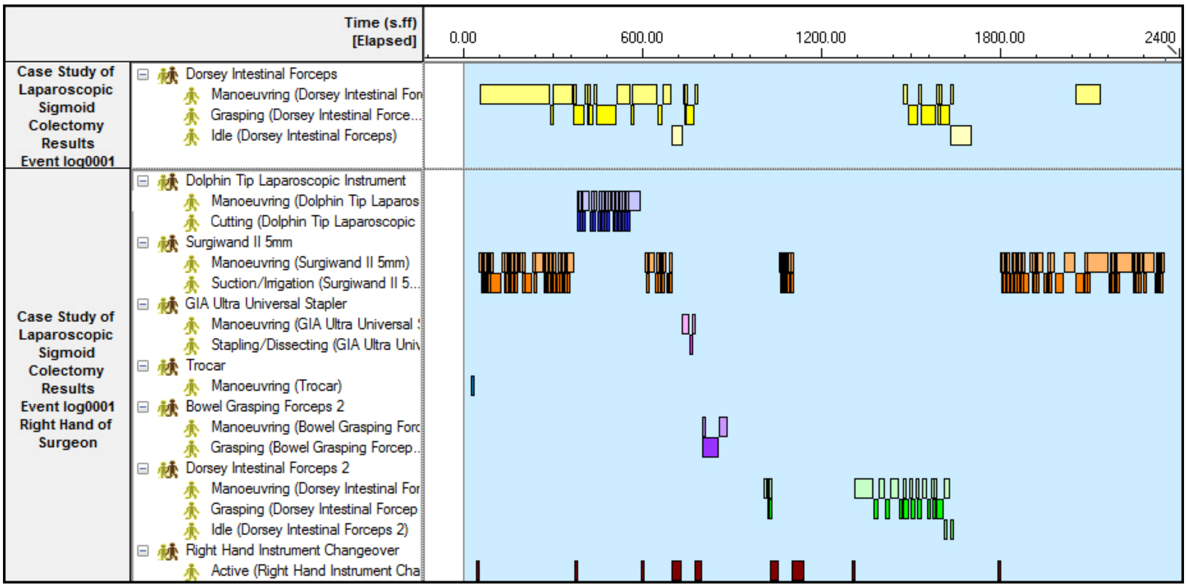

Figure 3: Timeline of Behaviours performed by Subjects

Results

The laparoscopic instruments used, including the handle types and grip type utilised during both grasping and operating, are summarised in Table 2. A summary of the main activities of the left and right hands, grouped by surgical instrument used and activity, are summarised in Table 3.

The top three behaviours for the right hand were manoeuvring using the suction/irrigation instrument (611 seconds), suction/irrigation using the suction/irrigation instrument (389 seconds), and manoeuvring using the Dorsey Intestinal forceps (192 seconds). The left hand performed only three types of activities: manoeuvring using the intestinal forceps (622 seconds), grasping using the intestinal forceps (309 seconds) and the hand idle holding the intestinal forceps (110 seconds).

The percentage of time in which instruments were used does not total 100% (Table 4). During the laparoscopic portion of the procedure some of the procedure was either downtime or actions were performed outside the view of the laparoscope camera for both the right and left hand. During the period of video between 885.5 and 1007 seconds, the laparoscope was removed from the patient. No usable data were available during this time so the data were not included in the overall analysis of the hand actions.

Table 2: Instruments and Grip Type

Instrument	Handle Type	Grip Type	Manipulation Needed (grasp)	Additional Manipulation
Bowel Grasping Forceps	Insulated Sheath & Standard Non-Ratchet Handle with Monopolar HF Port	Pinch Grip	Pinching Force on Thumb and Fingers	Thumb Rotation
Dorsey Intestinal Forceps	Insulated Sheath & Standard Non-Ratchet Handle with Monopolar HF Port	Pinch Grip	Pinching Force on Thumb and Fingers	Thumb Rotation
Universal Stapler	Standard Handle	Pinch Grip with Power Component	Compression Power Grip	Push using non-dominant hand
Suction/Irrigation Instrument	Standard Handle	Power grip with a precision component (thumb)	Compression Power Grip	Thumb used as precision component to perform suction or irrigation
Dolphin Tip Sealer/Cutter	Standard Handle	Pinch Grip	Pinching Force on Thumb and Fingers	
Anastomosis Stapler (male component)	Standard Handle	Power grip with a precision component (thumb)	Power Grip	Compression
Anastomosis Stapler (female component)	Standard Handle	N/A	Manipulated with other instruments	

Table 3: Behaviours observed during surgery

	Mean (s)		Total duration (s)		Rate per min		Total number		Percentage %	
	Left hand	Right hand	Left hand	Right hand	Left hand	Right hand	Left hand	Right hand	Left hand	Right hand
Grasping Instruments:										
Dorsey Intestinal Forceps										
Manoeuvring	34.5	13.7	622	192	0.46	0.36	18	14	26.42	8.17
Grasping	22.1	12.7	309	153	0.36	0.31	14	12	13.16	6.51
Idle	55.0	6.7	110	13.5	0.05	0.05	2	2	4.68	0.57
Bowel Grasping Forceps								Total %	44.26	15.25
Manoeuvring	-	14.5	-	29.1	-	0.05	-	2	-	1.24
Grasping	-	55.6	-	55.6	-	0.03	-	1	-	2.36
								Total %		3.60
Suction/Irrigation Instruments:					Total for Instrument Group %					18.85
Suction/Irrigation Instrument										
Manoeuvring	-	6.4	-	611	-	2.42	-	95	-	25.97
Suction/Irrigation	-	4.2	-	389	-	2.32	-	91	-	16.54
Stapling and Cutting Instruments:								Total %		42.51
Universal Stapler										
Manoeuvring	-	16.0	-	32.1	-	0.05	-	2	-	1.36
Stapling/Dissecting	-	11.3	-	11.3	-	0.03	-	1	-	0.48
Dolphin Tip Sealer/Cutter								Total %		1.84
Manoeuvring	-	8.4	-	151.3	-	0.46	-	18	-	6.43
Cutting	-	4.3	-	64.9	-	0.38	-	15	-	2.76
								Total %		9.19
					Total for Instrument Group %					11.03
Manoeuvring (Trocar)	-	14.4	-	14.4	-	0.03	-	1	-	0.62
								Total %		0.62
Right Hand Instrument Changeover Time	-	19.5	-	176	-	0.23	-	9	-	7.48
								Total %		7.48

Table 4: Percentage of time for hand usage during procedure

	Active	Inactive
Right Hand	85.6%	14.4%
Left Hand	49.4%	50.6%

Five separate instruments were used by the right hand, not including trocar placement. There were a total of nine instrument changeovers. The right hand performed specific actions - such as cutting, stapling/dissecting and suction/irrigation - unique to that hand (Figure 4). The left hand used one surgical instrument, mainly providing support through actions such as grasping and manoeuvring (Figure 5). There were no instrument changeovers for the left hand.

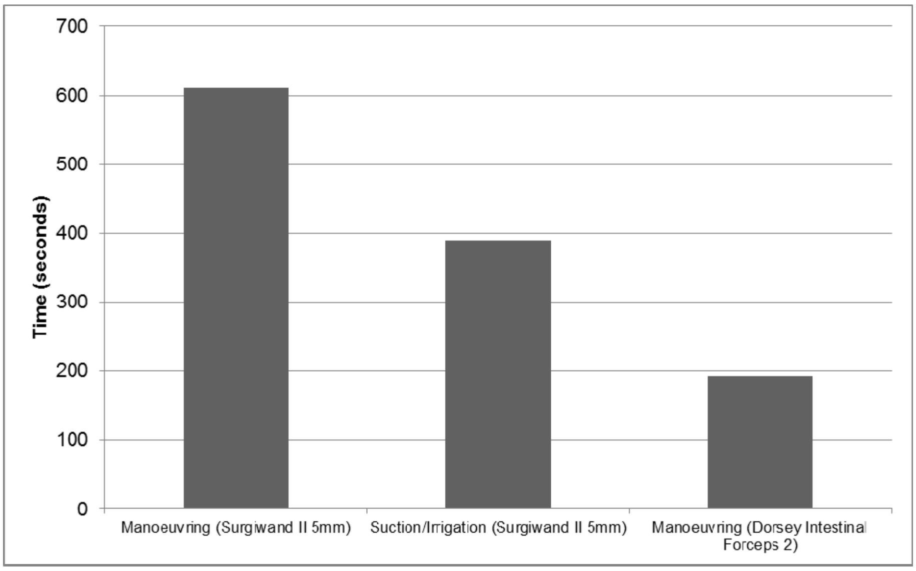

Figure 4: Total duration of top three actions performed by the right hand during surgery

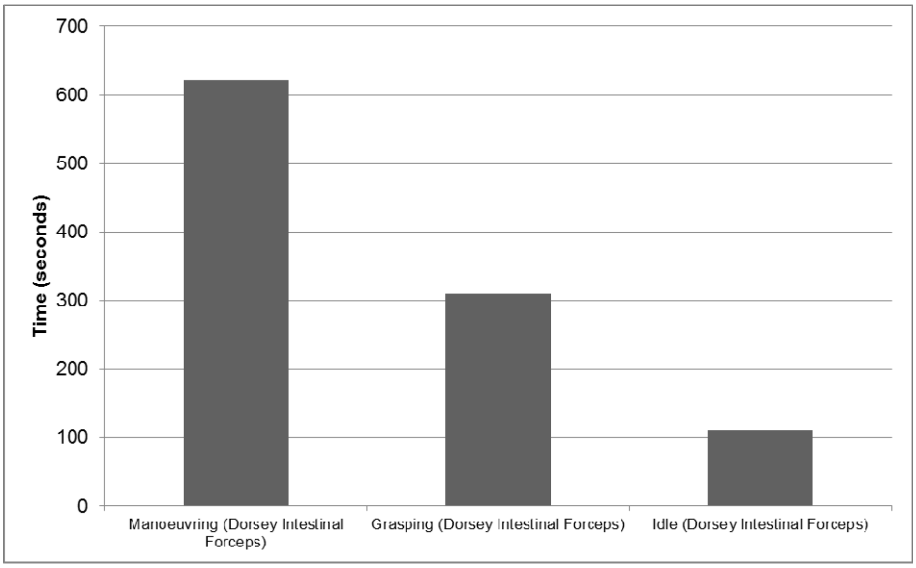

Figure 5: Total duration of actions performed by the left hand during surgery

Dorsey intestinal forceps: The Dorsey Intestinal forceps was the only instrument used by both hands during the procedure. For the purpose of this study, two separate Dorsey intestinal forceps were programmed into The Observer XT so data for both hands could be obtained. This was the sole instrument used by the left hand during the laparoscopic portion of the sigmoid colectomy procedure. Comparing usage times of this instrument between both hands showed that the right hand used this instrument more efficiently than the left hand, but used it for just 15.2% of the total procedure duration. The left hand used this instrument for 44.2% of the total procedure duration.

Bowel grasping forceps: The bowel grasping forceps was used by the right hand only. It performed two actions, manoeuvring and grasping, which accounts for 3.6% of the total procedure activity.

Dolphin tip sealer/cutter: The Dolphin tip sealer/cutter was used by the right hand only. It was involved in two actions; manoeuvring and cutting. It was found that this instruments spent more time manoeuvring bowel sections than separating tissue. But the entire duration of this instrument's use was only 9.1% of the total procedure.

Suction/irrigation instrument: The suction/irrigation instrument was used by the right hand only. It was involved in three actions; manoeuvring, suction and irrigation. Throughout the laparoscopic portion of this procedure, the suction/irrigation instrument was used the most (42.5% of total duration). Due to the difficulty in differentiating between both suction and irrigation (as the head of the instrument was submerged at certain points when being used) both suction and irrigation were amalgamated into a single behaviour.

Universal stapler: The universal stapler was used by the right hand only. It was involved in three actions; manoeuvring, stapling and dissecting. Both stapling and dissection occurred simultaneously, therefore for this case study they were also amalgamated into a single behaviour. Although an important instrument used during this procedure, it was the least used after trocar placement.

Trocar placement: Before recording of the video began, the port incision for the 12mm Hasson Trocar was created in order for the first trocar to be placed in the supraumbilical position. This was not included in the video recording. However the second trocar was placed during the video recording. It took 14.48 seconds, accounting for 0.62% of the procedure.

Instrument changeover: Instrument changeover for the right hand occurred nine times, accounting for 176 seconds (7.5 % of total procedure). There was no change over for the left hand.

Discussion

The Observer XT V9.0 software package is mainly associated with collecting and analysing data from either live video feed or video recordings taken during psychological, human factors, animal behaviour and observation studies. It was found to be an effective process to categorise instrument use during the procedure. This process may also be applied to open surgeries of laparoscopic surgeries that take place outside the abdominal area. The next phase of this work necessitates the application of this process across different laparoscopic procedures and to broaden the depth of analysis performed, especially in relation to studying the simultaneous actions of both hands where applicable.

Regarding the results from the analysis over the entire duration of the video, it was clear that the right hand performed many more activities than the left hand, which is not surprising. The right hand made use of five separate instruments. The left hand was used for support at infrequent times, spending more time manoeuvring tissue, clearing the path in which the right hand operated. The left hand was idle for 50.6% of the procedure whereas the right hand was idle for 14.4% of the procedure.

The main outcome for this analysis is that the majority of the procedure duration involved manipulation and grasping, with a relatively small portion of time cutting, removing and joining (anastomosis) of the colon. Elements of human factors and product design could be applied to instruments such as the suction/irrigation instrument and Dorsey Intestinal forceps as these instruments were used and operated most frequently during this procedure. This could lead to a reduction in surgical procedure duration, mental fatigue (Miller, Benden et al. 2012) and lead to an improved clinical outcome (Xiao, Jakimowicz et al. 2012). An alternative is to design new, innovative approaches to laparoscopic colorectal surgical procedures involving a step change in the methods currently in use.

Limitations

This was a case study of one laparoscopic procedure performed by one surgeon. More case studies performed by more surgeons are necessary in order to capture the variation between A. patients anatomies and severity of disease states, and B. between surgeons surgical preferences.

This case study focused on the actions of the right and left hand while performing the laparoscopic portion of this procedure. However, the anastomosis was omitted due to difficulty in identifying which member of the surgical team operated the circular stapler. Anastomosis is a critically important step in colectomy procedures as, if not performed successfully, internal bowel leakage can occur resulting in sepsis.

Conclusions

The Observer XT software package was suitable to codify the hand actions and instrument use during long recordings of this surgical procedure using video recordings from the laparoscope.

In this single case study a high percentage of the procedure was spent navigating in order to gain access to a specific part of the bowel. More time was spent navigating to the surgery site than performing the actual colon resection and anastomosis. There would appear to be a previously unmet clinical need to innovate new approaches to this type of surgery to shorten the duration of the surgery while preserving or improving the clinical outcome for the patient. More case studies are needed to confirm this.

Acknowledgements

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MODELLING THE EFFECTS OF ERROR PRODUCING CONDITIONS ON ADVERSE EVENTS DURING TRANSCATHETER AORTIC VALVE IMPLANTATION

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Abstract

A number of studies over the last fifteen years have indicated that approximately 10% of hospitalised patients suffer an adverse event as a result of the care provided, with approximately 1% of patients in the USA suffering permanent disability or death. Surgical procedures account for 48% of all adverse events, with 54% of these deemed preventable. A review of the literature demonstrates divergent views on the causes of these adverse events in surgery; from the individual (surgeon) to the team, and/or the collective hospital system. Recent guidelines in the US and in Europe emphasises the importance of applying human factors and usability during medical device design in order to help mediate adverse events during surgery and patient treatment. The purpose of this study was to apply the Human Error Assessment and Reduction Technique (HEART) to Transcatheter Aortic Valve Implantation (TAVI) to model the key contributing areas from error producing conditions and performance shaping factors that could negatively affect clinical outcome during the procedure.

Introduction

Over 575,000 preventable deaths occurred as a direct result of 2.5 million patient safety incidents in U.S. hospitals over a two year period from 2000 to 2002 (HealthGrades 2004). During the past two decades the medical field has become increasingly aware of the need to understand the human factors in adverse events during surgery (Carthey et al. 2001). Research that takes a systems approach to identify the organizational, team, and human pressures that lead to adverse events is of particular importance (Ummenhofer et al. 2001). Performing highly skilled surgical tasks involves a cascade of complex cognitive processes for the surgeon (Hall et al. 2003), however there are numerous external factors that can influence the quality of clinical outcome.

Usability & Human Factors in medical device design

Increased awareness of the role of Human Factors Engineering (HFE) and Usability Engineering (UE) in medical device design has led to the proposed adoption of various standards aimed at decreasing error through better device design. Table 1 outlines the main standards applicable to HFE/UE as per the draft guidelines *'Applying Human Factors and Usability Engineering to Optimize Medical Device Design'* currently in consultation (FDA 2011). In the European Union the CE mark process for medical devices has required a HFE/UE evaluation as part of the approval process for several years. Currently the Food and Drug Administration (FDA) is recommending that any device requiring full pre-market approval (class III devices) should submit a comprehensive HFE/UE evaluation, while class I, IIa and IIb do not require a HFE/UE evaluation as part of the approval process.

Table 1: HFE/UE standards for medical devices

Standard	Title	Main Purpose
AAMI/ANSI HE75:2009	*Human Factors Engineering – Design of Medical Devices*	Comprehensive reference that includes general principles, usability testing, design elements, integrated solutions
ISO/IEC 62366:2007	*Medical devices – Application of usability engineering to medical devices*	HFE/UE process applied to all medical devices, with emphasis on risk management
ANSI/AAMI/ISO 14971:2007	*Medical Devices – Application of risk management to medical devices*	Risk management process for medical devices
IEC 60601-1-8:2006	*Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*	HFE/UE process applied to alarm systems for medical electrical equipment and systems

Human Error Assessment & Reduction Technique: HEART

HEART (Williams 1986) was developed as a quick and efficient method to quantify risk of human error in tasks. HEART is a method that is applicable to any situation or sector where human reliability is of critical importance (Bell 2009). The method can shed light on the key points of task vulnerability and can be subsequently used to identify areas for improvement (Williams 1992). The method compromises nine Generic Task Types (GTTs), each with an associated nominal Human Error Probability (HEP), with a further 38 Error Producing Conditions (EPCs) that may affect task reliability, each with a maximum amount by which the nominal HEP can be multiplied (Bell 2009). The method includes error reduction strategies or remedial measures linked to the error producing conditions, such that once an assessment is completed, the predicted contribution to error can be anticipated both in terms of EPCs and HEPs (Williams 1992).

Ward (2013) applied HEART in a study of guide wire loss in the body during the placement of a central line in the venous system. They found that the predicted error rate was within one order of magnitude of reported rates nationally. They also indicated that HEART may be suitable for use in the study of human error in other areas of healthcare with minor alterations to the method. The revised method they propose is HEARTH – HEART for Healthcare (Ward 2013).

The HEART method is based on a number of assumptions:

- Basic human reliability is dependent upon the nature of the task to be performed (Generic Task Types).
- In 'ideal' conditions, this level of reliability will tend to be achieved consistently within probabilistic limits.
- Given that these 'ideal' conditions do not exist in all circumstances, the human reliability predicted may degrade as a multiple of identified Error Producing Conditions (EPCs) that might apply.

The key elements to performing the HEART method are:

- Classify the task into one of the GTTs and assign the nominal HEP to the task.
- Decide which EPCs may affect task reliability.
- Consider the Assessed Proportion Of Affect (APOA) for each EPC. Then calculate the task HEP with the equation: $(\alpha\text{-}1)\times\beta+1=\Omega^1$ (*where α –HEP Value, & β –APOA Value within the range: 0.1-1)*
- Calculate overall probability with the equation: $GTT\times\Omega^1\times\Omega^2\ldots\Omega^n$

Performance Shaping Factors

Humans deal with situations requiring actions with a response based not only on their ability and training, but also on the surrounding conditions. While not directly responsible for how well a person performs a task, these other conditions influence what the person does and are therefore referred to as Performance Shaping Factors (PSFs) (Carayon 2011). PSFs are an active area of research in the healthcare system as the focus on patient safety and avoidable errors increases. Notable examples include the effects of stress on surgical performance (Wetzel et al. 2006) and surgical performance, human error and patient safety (Undre et al. 2009). A review of over 200 error taxonomies by Kim and Jung (2003), detailed how PSFs taxonomies and HRA taxonomies were combined to developed a 'complete' set of PSFs divided into 4 main groups (*Human, System, Task, & Environment)* with 13 sub-groups (Kim and Jung 2003).

Transcatheter Aortic Valve Implantation

Aortic stenosis is the most common form of valvular heart disease in patients over the age of 65. It predominantly affects those who are high risk candidates for surgical aortic valve replacement, which is still considered as the gold standard treatment. The alternative percutaneous approaches to the management of symptomatic aortic stenosis in high-risk patients have become more an attractive alternative to open heart surgery in recent years (Grimaldi et al. 2012). Transcatheter Aortic Valve Implantation (TAVI) has become a widely recognised procedure for high risk patients with native or bio-prosthetic aortic valve stenosis. TAVI involves passing a bio-prosthetic aortic valve mounted on a stent frame through a catheter and deploying in the heart without the need for open surgery, thus reducing risk and recovery times associated with traditional surgery. Transfemoral and transapical implantation techniques have been well described (Clarke et al. 2013). Table 2 gives the published reported complication rates from two leading TAVI providers. Rates of adverse event during TAVI have ranged from 2.9-10% for critical adverse events including stroke, to 5.9-22% for less critical adverse events including pacemaker implantation (Bosmans et al. 2011, Forbes 2011, Zajarias and Cribier 2009).

Table 2: Adverse events in TAVI

Procedure	Report	Adverse events	Rates
TAVI *(Edwards Sapien)*	PARTNER (Forbes, 2011)	Major Vascular Complications	7.4-11.3%
	SOURCE (Zajarias and Cribier, 2009)	Stroke	2.9-6.8%
		New permanent pacemaker Implantation	5.9%
TAVI *(Medtronic Corevalve)*	Belgian registry (Bosmans et al. 2011)	New permanent pacemaker Implantation	9.3-22%
		Renal failure	7%
		Stroke	4-10%

(Bosmans et al. 2011, Zajarias and Cribier 2009, Forbes 2011)

Aim of this study

The purpose of this study was to apply the HEART method to model factors potentially contributing to human error and adverse events during TAVI procedures. The study details EPCs and PSFs possibly related to human error in TAVI adverse events based on the review of human error taxonomies by Kim and Jung (2003).

Method

HEART modelling of adverse events in TAVI

The GTT score selected for this evaluation is based upon the assumption of a highly skilled operator, i.e. the surgeon. The GTT selected was "G: Completely familiar, well-designed, highly practised, routine task occurring several times per hour, performed to the highest possible standards by highly-motivated, highly trained and experienced person totally aware of implications of failure, with time to correct potential error, but without the benefit of significant job aids" (Williams 1992). The nominal human error rate is 4×10^{-4}, with the 5th to 95th percentile bounds 8×10^{-5} to 7×10^{-3} respectively.

The standard 38 EPCs from HEART were divided into the 4 subgroups as per the human error taxonomy review by Kim and Jung (2003). This framed the EPCs & PSFs into groups that could be applied to observations of deficiencies. Using live recordings of TAVI cases, as well as field observation of endovascular procedures, a list of deficiencies were drawn up and its contents collated into appropriate subgroups. These were then further broken down inside each group to assign specific EPCs and PSFs to each one. An APOA was assigned to each of the modified EPCs. APOA weightings were assigned by human factors specialists.

Results

Using direct and recorded observation alongside expert opinion, a theoretical HEART model for TAVI was created. Table 3 lists the observed EPCs deemed applicable and grouped according to the PSFs system as per Kim and Jung (2003) (i.e. *system, human, task,* and *environment*). A description of observed and reported deficiencies during TAVI procedures was provided to classify the EPCs in context. The table allows for the identification of the key contributing areas for error during TAVI.

Using the HEART calculations, a nominal 50th percentile predicted error rate of 19.5% was derived. At the 5th percentile boundary the predicted rate was 3.9%. As the level of training of the operator increases, the human error potential decreases (from 50th percentile: 4×10^{-4} to 5th percentile: 8×10^{-5} respectively). At the 95th percentile the figure was above the threshold of 1 (100% probability).

Discussion

System

EPCs grouped under 'system' were identified as the leading contributor to error during TAVI (49%). Specific deficiencies under system include fluoroscope resolution, critical parameter monitor alarm/failure (ECK, blood pressure, SpO_2, etc.) and any other equipment or medical devices used by the operator during the procedure. As an example, an 'alarm avalanche' caused by a patient's condition deteriorating rapidly can result in a situation where various alarms are indistinguishable from one and other or where silencing a series of 'non critical' alarms may lead to inadvertently ignoring a critical one. System error in TAVI is particularly important during the imaging of the native valve and implantation of the prosthetic valve. 'Low signal to noise ratio' was identified as the single largest individual factor (Ω=3.7) referring to the difficulties associated with fluoroscopy, particularly with older, lower resolution systems. Table 4 lists some of the potential system PSFs that could lead to human error during TAVI. Medical device usability was not specifically listed as a PSF by Kim and Jung (2003) so it was added by the current authors.

Table 3: Generic task type, human error potential & assessed proportion of affect

GTT	*Observation (Error producing condition)*	*HEP (α)*	*APOA (β)*	(α-1)×β+1 (Ω)	*Overall (%)*
System					
2	Emergency situation with limited time detect and correct cause	11	0.1	2	49%
3	Lack of clarity from fluoroscope or other imaging methods	10	0.3	3.7	
4	Unintentional ignoring of alarms/warnings	9	0.1	1.8	
8	'Alarm avalanche' (several critical parameters change simultaneously)	6	0.1	1.5	
13	Compromised system feedback (pressure/heart rate/blood loss etc.)	4	0.1	1.3	
14	Delay between action and response of equipment or devices	3	0.1	1.2	
Human					
7	No obvious solution to a slip or lapse	8	0.1	1.7	30%
10	Transfer of critical knowledge (patient data) from task to task	5.5	0.2	1.9	
12	Perceived risk less than actual risk	4	0.1	1.3	
18	A conflict between short term & long term goals	2.5	0.1	1.15	
29	High emotional stress	1.3	0.1	1.03	
Task					
36	Interruptions by others not related to current task	1.06	0.1	1.006	16%
1	Emergency 'once off' unforeseen situation	17	0.1	2.6	
Environment					
16	Impoverished information due to poor communication	3	0.1	1.2	5%

GTT – Generic Task Type, HEP – Human Error Potential, APOA – Assessed Proportion of Affect.

Table 4: System PSFs

Related system performance shaping factors adapted from Kim and Jung (2003)

Phenomenological characteristics	*Man Machine Interface*
Physical characteristics –rate of change of critical parameters –trend of critical parameters –value of critical parameters –number of dynamic changing variables –degree of alarm avalanche	**System states** –stuck instrument –conflicting signals/cues **Panel/Screen layout** –visibility –reachability
Operational characteristics –suddenness of onset –overlap with previous tasks –time available for operator performance –time pressure (time required vs. time available) –existence of preceding information on scenario	**Support Systems** –availability/adequacy of special equipment, tools and supplies. **Medical Device Usability*** –intuitiveness of controls –force required to operate –visualisation

*Proposed additional PSF to capture issues arising specifically from device usability

Human

EPCs grouped under 'Human' were identified as the second largest contributor to adverse event occurrence with 30% of the overall HEP (Table 5). The human is assumed to be a highly skilled individual with adequate training; however the primary additional contributor to errors in this category were due to high levels of cognitive loading. The Wicken's human information processing model illustrates one explanation on how cognitive processes relate to attention resources (Hollands and Wickens 1999). Ultimately high cognitive loading can compromise the operators' ability to transfer knowledge from task to task without loss (such as patient specific data), as well as impair decision making abilities. EPCs and PSFs, especially in this context of surgical procedures, can impact on attention resources leading to a 'lapse' or 'mistake'. It is important to note the overlap of PSFs between human and task (Table 6) even though human accounts for a larger contribution to overall HEP.

Table 5: Human PSFs

Related human performance shaping factors adapted from Kim and Jung (2003)

Cognitive characteristics	*Physical and psychological characteristics*	*Personal and social characteristics*
Cognitive states		**Personal**
–attention	**Physical states**	–attitude
–intelligence	–gender/age	–morale/motivation
–skill level	–motor skills	–risk taking
–knowledge	–fatigue/pain	–self-esteem and self-confidence
–experience	–discomfort	–sense of responsibility
–training	–hunger/thirst	–sensation seeking
		–leadership ability
Temporal cognitive states	**Psychological states**	–sociability
–memory of recent actions	–emotion/feeling	–personality
–operator diagnosis	–confusion/perplexity	–anticipation
–perceived importance	–task burden	
–perceived consequences	–fear of failure/consequences	**Social**
–operator expectations	– high jeopardy risk	–status
–confidence in diagnosis		–role/responsibility
–memory of previous actions and accident history		–norms

Task

Task describes the demands of the individual case at hand for the operator. Task accounted responsible for 16% of the HEP during the procedure. While this is a much smaller value than for system and human combined (79%) it is still an important contributing factor. The difficulties and nuances of individual scenarios, particularly in medicine, require the ability of the operator to adapt dynamically at short notice. The PSFs under Task (Table 6) a lot completely with the PSFs of the human with the onus being on the human to master the skills required to carry out the task.

Environment

In our evaluation of TAVI, the environment was estimated to have a very low contributing factor to overall error (5%), with only a possible breakdown or error in communication identified as contributing to an adverse event. By contrast, there is a comprehensive list of PSFs from Table 7 that impact on the cognitive abilities of the operator and compromise clinical outcome. This highlights the shortcomings of a generalised HEART evaluation in such a specific context.

Table 6: Task PSFs

Related task performance shaping factors adapted from Kim and Jung (2003)	
Task characteristics	–multiple sensory requirements
Task type	–perceptual requirements
–dynamic vs. step-by-step activities	–task criticality
Task attribute/requirement	–physical requirements
–amount of required information	–degree of manual operation
–amount of necessary information to be memorized	–motor requirements
–information load	–muscular power
–task difficulty–>multiple attempts	–speed
–task novelty	–dexterity
–task consequences	–precision
–frequency and familiarity of task	–calculation requirement
–degree of discrepancy with familiar tasks	–anticipatory requirement
–number of simultaneous goals/tasks	–requirement on and type of feedback
–concurrent activities and interruptions	–degree of reference to other materials
–interruption from other personnel	–communication requirement
–discrepancy between training and reality	–team cooperation requirement
–necessity of auxiliary tools	–necessity of decision making from higher organization
–appropriateness of required tools	

Table 7: Environment PSFs

Related environmental performance shaping factors adapted from Kim and Jung (2003)	
Physical working conditions	*Team and organization factors*
Physical constraints	**Team-related factors**
–physical inconvenience from protective clothing	–clearness in job description or role definition
–temperature/humidity/pressure/illumination	–clearness in responsibilities/communication line
–interference in communication	–adequacy of distributed workload
–noise and vibration	–intra/inter-team cooperation
–air pressure/quality/ ventilation	–ability/leadership/authority of team leader
–movement constriction	
–moving distance	**Training**
–narrow work space or obstacles	–simulation/scope of simulator
–dangerous work space	–fidelity of simulation scenario
–accessibility of components	–frequency and training time
–architectural features	–time period between training sessions
–order and cleanliness	
	Management and policy
Timing aspects	–shift organization and shift rotation
–time on duty	–supporting team
–time into scenario	–hospital policy
	–maintenance

Limitations

The generic HEART model does not have a sufficient resolution to pinpoint specific deficiencies within a specific EPC group. It was therefore not possible to estimate the EPCs specifically due to usability of device design and how error due to poor usability might be mediated by PSFs. As such the results are estimates associated with the implantation of heart valves transcatheter generally as a surgical procedure rather than being specific to any individual TAVI device on the market. Further work is required to create a more detailed HEART model applicable to TAVI and other endovascular devices to more accurately estimate rates of human error including those related especially to the design usability of the devices.

Conclusions

The major adverse events in TAVI comprise of stroke (2.9-10%), vascular complications (7.4-11.3%), and new permanent pacemaker implantation (5.9-22%) resulting from conduction arrhythmias after valve implantation (Munoz-Garcia et al. 2012). Applying HEART to TAVI sheds light on the factors that can augment inexperience and potentially lead to adverse events. The study estimated a human error rate of 3.9- 19.5% (nominal) during TAVI, compared to actual reported rates of 2.9-22% from published registries. EPCs ground under 'system' were the largest contributor to estimated error, followed by EPC grouped under human. This study proposes including medical device usability as an EPC under 'system' for this application. The evolution of both EC and FDA regulations of medical device safety, specifically medical device usability, clearly reflects the changing attitudes towards the importance of human factors and usability engineering in medical device design to lower the risk of human errors in adverse events. The translation of generic EPCs to TAVI and other endovascular surgical procedures specific EPCs are challenging and require careful attention. Research is needed to develop more accurate methods to estimate human error rates due to poor medical device design for TAVI and other endovascular surgery procedures.

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ENHANCING SYSTEMS ANALYSIS IN HEALTHCARE INCIDENT INVESTIGATION: A WORK IN PROGRESS

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Abstract

This paper describes the evolution of incident management policy, practice and terminology in the HSE and the consultation and research processes underpinning it. The HSE published a toolkit of documentation to support incident management in the HSE in March 2009 (HSE 2009). The investigation methodology used in this publication was based on the systems analysis methodology outlined in the *"London Protocol for the Systems Analysis of Clinical Incidents"* (Taylor-Adams and Vincent, 2004). Following this, it emerged that there was a need to enhance the guidance in this toolkit particularly in relation to the definitions of *"care delivery problems"* and *"service delivery problems"* and to clarify the need for each problem to be analysed to find contributory factors to enable investigators to focus on specific incident causes and remedies as far as this was possible. In response to this, an updated draft HSE Investigation Procedure was developed by an Investigation Process Working Group (IPWG) in 2010. This proposed replacing the two terms *"care delivery problems"* and *"service delivery problems"* with a single term *"deviation from safe/acceptable practice"* which was defined as:

"Issues that arise in the process of delivering and managing health services, usually actions or omissions by members of staff".

Deviations from safe/acceptable practice were further described as having one essential feature, namely:

"The deviation had a direct effect on the eventual adverse outcome for the individual(s) harmed".

In addition, enhanced guidance on communications to those affected and involved; incidental findings; writing investigation reports; factual accuracy checking, due process, natural and constitutional justice, and writing apologies was included in the IPWG's updated draft HSE Investigation Procedure in 2010.

Nine consultation and engagement workshops with over 320 HSE employees and service users took place across the HSE in May and June 2010. Questionnaires and focus groups were used to collect participants' feedback. Analysis of questionnaires indicated that 83% of participants were satisfied or very satisfied with the proposed investigation procedure and 73.4% believed the procedure to be an improvement on existing procedures. The IPWG amended the procedure based on feedback from this consultation.

A pilot project in relation to the new draft procedure commenced in 2011 when 30 trainees - including existing HSE investigators and volunteer external investigators nominated by service user representative agencies - were trained in the new draft investigation procedure. Further consultation and engagement with these trainees at this time, and with a technical reference group (TRG) culminated in further changes to the definition of *"Deviation from safe/acceptable practice"* to the following:

"Deviations from safe/acceptable practise are defined as issues that arise in the process of delivering and managing health services where the deviation(s) had an effect on the eventual adverse outcome".

The rational for the changes was as follows:

- The pilot project trainees highlighted a difficulty with the reference in the existing definition to *"Acts or omissions by members of staff"*. They indicated that this might put and unhelpful emphasis on the "individual" factors that might contribute to incidents and an under emphasis on other factors which might contribute to incidents. They highlighted that this in turn could contribute to a problem of an organisational tendency to unfairly blame individuals rather than considering incidents very impartially, methodically and systematically. Pilot project trainees highlighted that the entire framework of contributory factors should be used in any incident investigation and a definition that focused on only one element of this framework (i.e. individual factors only) might be unhelpful.
- Members of the IPWG Technical Reference Group (TRG) highlighted a difficulty with the following reference in the existing definition *"The deviation had a direct effect on the eventual adverse outcome for the individual(s) harmed".* Specifically, the IPWG TRG highlighted that there could be deviations that could have an effect, albeit not necessarily a *"direct"* effect on the eventual adverse outcome - which would be important to be able to include in investigations, hence the recommendation to delete the word *"direct"* in the definition.

- The IPWG TRG identified that the allusion to *"individuals harmed"* could be an obstacle to applying the investigation methodology to incidents that do not result in clear/direct harm to people such as a PPARS (Human Resource System) incident; data protection incidents etc. Hence, this allusion was removed from the definition.

Further consultation and engagement on the updated draft guidelines occurred in May/June 2012. This consultation and engagement included internal and external stakeholders including general and professional regulators; employee and service user representatives; and external independent patient safety experts and general safety experts. Feedback from this was considered in finalising the document which was published as the *"Guidelines for Systems Analysis Investigation of Incidents and Complaints"* (HSE 2012). Changes based on feedback included enhanced guidance on communications to those affected and involved; incidental findings; writing investigation reports; factual accuracy checking, due process, natural and constitutional justice, and writing apologies. In relation to the terminology and definitions, changes in the new guidelines included new terminology including replacing the term *"deviation from safe/acceptable practice"* with the term *"key causal factor"* which was defined as:

"Issues that arose in the process of delivering and managing health services which had an effect on an eventual adverse outcome".

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FACTORS IN DETERMINING THE LEVEL OF CAUSAL ANALYSIS IN HEALTHCARE INCIDENT INVESTIGATIONS

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Abstract

Some literature and agencies advocate risk rating incidents in healthcare to decide likelihood of recurrence and the level of investigation that should be applied (Department of Health (UK) (2001); National Patient Safety Agency (UK) (2008 and 2009); Clinical Indemnity Scheme (2009 and2011); Veterans Health Administration Centre for Patient Safety). Consequently, the practice of risk rating incidents is widespread in healthcare. This involves an assessment of the incident before a detailed investigation of the incident occurs to determine the likelihood of future similar incidents reoccurring; and the probable severity of harm that might result from such future incidents. These findings are combined to determine a risk rating for a particular incident as high, medium or low. This risk rating then informs the level of causal analysis that is required and decisions about the requirement to report incidents to external agencies. This paper asserts that this strategy needs to be considered for a number of reasons. The validity of the risk rating process itself is questionable for critical cognitive and logistical reasons. The process takes significant resources to implement which need to be justified in terms of evidence of enhanced system safety. Indeed the approach is based on the assumption that what an incident may tell us about system safety can be judged prior to a thorough investigation. This paper proposes considering that, in the first instance, the level of investigation be determined by severity of the consequence since the level of death and serious harm incidents in health care is high and thorough investigation of all these incidents is already required and sufficiently time-consuming to stretch investigation resources. There needs to be continuous investment in and improvement of the quality of incident data collected and available to investigation decision makers, together with critical examination of the factors used to determine the level of causal analysis to ensure that the data and the decision making factors contribute to optimum investigation decision making; optimum investigation resource utilisation; and optimum safety improvement.

Risk rating to predict incident occurrence in the proactive hazard identification and risk assessment process

The objective of the proactive hazard identification and risk assessment process as set out in the international literature and standards (Standards Australia / New Zealand (2004), AIRMIC (2002)), is to identify the hazards and assess their associated risks. Hazards are anything that can cause harm, and the associated *risk* is the *chance* that the hazard will actually result in harm. These hazards can be identified by a number of means including but not limited to:

- Using prompts / checklists / brainstorming to identify the latent factors in the environment that may cause harm (Standards Australia / New Zealand 2004);
- Identifying the contributory factors of incidents / near-misses that have arisen. (Taylor-Adams and Vincent 2004). Contributory factors are by definition the "causes of harm / hazards" in the incidents being investigated (WHO 2009).

The literature and standards advocate that the risk associated with each of the identified hazards is determined on the one hand by assessing the *likelihood / probability / frequency* that harm will arise as a consequence of the identified hazard – and on the other hand by determining the *severity / impact* / *consequences* of the harm that may arise. These two variables (i.e. frequency and severity) are plotted on the x and y axis of a graph (risk matrix) to determine the level of risk (high, medium, low etc). It is based on the assumption that *Risk = Frequency x Severity* (Cox 2008).

A *risk matrix* is a table that has several levels of "probability" for its rows (or columns) and several categories of "severity", "impact", or "consequences" for its columns (or rows, respectively). It associates a recommended level of risk, urgency, priority, or management action with each row-column pair, that is, with each cell, (Cox, 2008).

Figure 1 shows an example of a 5 x 5 matrix used in a 2007 Federal Aviation Administration (FAA) Advisory Circular (AC) introducing the concept of a safety management system for airport operators. The accompanying explanation states: *"Hazards are ranked according to the severity and the likelihood of their risk, which is illustrated by where they fall on the risk matrix. Hazards with high risk receive higher priority for treatment and mitigation"* Federal Aviation Administration (2007).

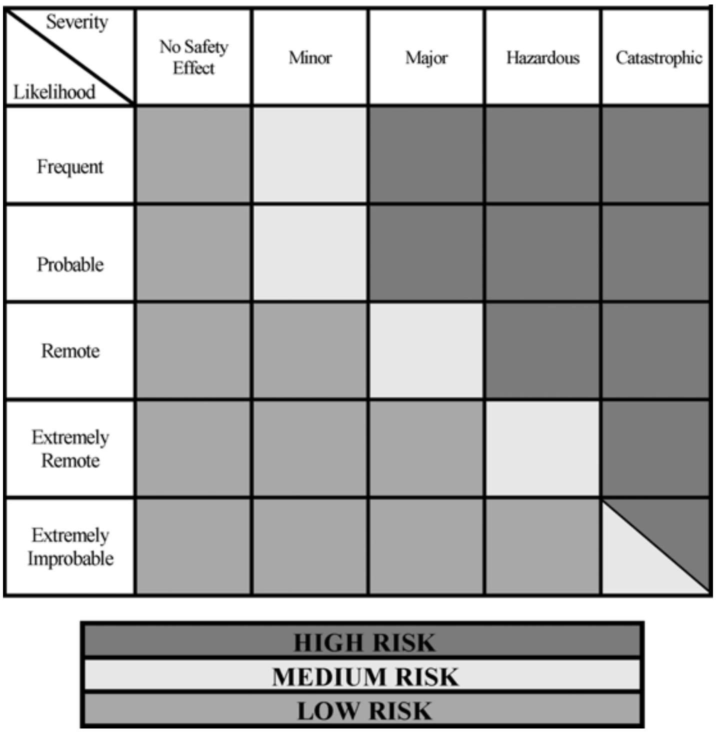

Figure 1: Example of a Predictive Risk Matrix for the Federal Aviation Administration (USA). (*Source:* Federal Aviation Administration, 2007 www.faa.gov/airportsairtraffic/airports/resources/advisorycirculars/media/150-520037/150 5200 37.doc)

Cox (2008) highlights that risk matrices have been widely praised and adopted as simple, effective approaches to risk management. Cox (2008) further highlights that risk matrices provide a clear framework for systematic review of individual risks and portfolios of risks. They are convenient documentation for the rationale of risk rankings and priority setting. They facilitate opportunities for many stakeholders to participate in customizing category definitions and action levels. Finally, Cox (2008) states that risk matrices facilitate opportunities for consultants to train different parts of organisations on "risk culture" concepts at different levels of detail, from simply positioning different hazards within a predefined matrix to helping thought leaders try to define risk categories and express "risk appetite" preferences in the colour coding of the cells. As many risk matrix practitioners and advocates have pointed out, constructing, using, and socialising risk matrices within an organisation requires no special expertise in quantitative risk assessment methods or data analysis. Yet, despite these advantages and their wide acceptance and use, there has been very little rigorous empirical or theoretical study of how well risk matrices succeed in actually leading to improved risk management decisions. Very little prior technical literature specifically addresses logical and mathematical limitations of risk matrices. See Cox et al (2005), in relation to some limitations in qualitative risk rating systems.

Cox et al (2008) demonstrated the following mathematical and logical limitations of risk matrices for determining the level of risk associated with hazards identified by proactive hazard identification work:

a. *Poor Resolution.* Typical risk matrices can correctly and unambiguously compare only a small fraction (e.g. less than 10%) of randomly selected pairs of hazards. They can assign identical ratings to quantitatively very different risks ("range compression").

b. *Errors.* Risk matrices can mistakenly assign higher qualitative ratings to quantitatively smaller risks. For risks with negatively correlated frequencies and severities, they can be "worse than useless", leading than worse-than-random decisions.

c. *Sub-optimal Resource Allocation:* Effective allocation of resources to risk-reducing countermeasures cannot be based on the categories provided by risk matrices.

d. *Ambiguous inputs and outputs:* Categorisation of severity cannot be made objectively for uncertain consequences. Input to risk matrices (e.g. frequency and severity categorisations) and resulting outputs (e.g. risk ratings) require subjective interpretation, and different users may obtain opposite ratings of the same quantitative risks.

Cox (2008) concluded that these limitations suggest that risk matrices should be used with caution for proactive risk assessment, and only with careful explanations of embedded judgements.

Risk rating incidents to determine the predictability of incident reoccurrence

If the use of risk matrices to rate the risk associated with specific hazards identified proactively is problematic, their use to risk rate incidents in terms of the predictability of recurrence may be even more problematic given that an incident is not a hazard, but is usually rather a culmination of numerous contributory factors or hazards. The notion of risk rating incidents is advocated in Department of Health (UK) and National Patient Safety Agency, (2001) and elsewhere including guidance from the Veterans Health Administration National Centre for Patient Safety, United States of America (See Figure 2 below).

		SEVERITY			
		Catastrophic	Major	Moderate	Minor
PROBABILITY	Frequent	16	12	8	4
	Occasional	12	9	6	3
	Uncommon	8	6	4	2
	Remote	4	3	2	1

Figure 2: Safety Assessment Code (SAC) Matrix used by the Veterans Health Administration National Centre for Patient Safety, United States of America

In this literature, risk rating incidents is recommended to establish:

- The level of local investigation and causal analysis that should be carried out and
- The reporting requirements in relation to the National Patient Safety Agency and the Department of Health (UK).

These publications recommend that designated persons should risk rate incidents using the above methodology prior to their investigation.

More recent publications from the National Patient Safety Agency do not advocate risk rating incidents (National Patient Safety Agency (UK), 2009).

Toft and Reynolds (2005) describe how any assessors' perception of the likelihood that an incident will recur will be affected to a lesser or greater extent by the '*Availability Heuristic*'. They go on to state that:

> *"Psychological research has shown that when human beings are asked to make judgement about risks where no statistical data is available we make inferences regarding the risk by drawing upon what we have heard or seen. The rules of thumb that are used to draw such inference are known as heuristics and are designed to reduce what is essentially a complex cognitive problem into a much simpler one. Unfortunately, while heuristics are helpful on many occasions they can lead to large and persistent biases with serious implications for risk assessment."*

Rolfe (1977) suggests that:

> "*The human observer sees the world in relation to his past experience. In consequence, what he perceives is partly determined by what he expects to see…An individual, therefore, has expectations regarding what is likely to happen in a frequently encountered situation.*"

Following on from this, Toft and Reynolds (2005) argue that when organisations carry out assessments of the risks that face them and what guides their choice of what to address will be their knowledge of what has happened in the past. They go on to suggest that tentative support for this observation can be drawn from a series of experiments undertaken by Tversky and Kahneman (1981) where they asked subjects to judge the arithmetic probability of a number of different risks taking place. In the course of the research, they found that the probabilities for the risks that the subjects arrived at were affected by factors unrelated to the actual frequency of the events. In the Tversky and Kahneman (1981) experiments they observed that:

> *"…any incident that makes the occurrence of an event easy to imagine or to recall is likely to enhance its perceived frequency*."

Toft and Reynolds (2005) go on to suggest that the easier it was for the subjects to recall a particular risk the more likely it was that the subject would perceive the frequency of its occurrence to be greater than it actually was. The two factors that appear to create this effect were emotional ties to a risk or how recently a subject has had a particular risk brought to their attention. For example, if the relative or friend of a subject in the experiment had died of cancer the subject would rate the frequency with which the disease struck significantly greater than a subject who had not had that experience. Similarly, if a subject had been asked to judge the frequency of a risk that had recently been highlighted in the media then once again the subject's assessment of that risk was higher than the actual reported frequency.

Finally, Toft and Reynolds (2005) conclude that:

> *"…the availability heuristic has profound implications for the assessment of risks for this psychological bias operates without a person being aware of it. Hence, when asked to identify the risks associated with a particular operation a person could unknowing be*

captured by there own biases. As a consequence it is possible for organisations to be deceived into believing they should address risks that in reality may not require the first call on their resources."

This demonstrates the importance of ensuring that those involved in decision making about investigations are aware of the factors that may bias their sense of the risks involved. It also demonstrates the importance of ensuring that decision makers have the best possible data available to them and are aware of its limitations.

Other considerations in decision making about the level of investigation required

The National Patient Safety Authority (NPSA 2008) advocate that the *"investigation should be conducted at a level appropriate and proportionate to the incident, claim, complaint or concern under review"*. They further advocate three levels of investigation depending on the severity of harm as follows:

Level 1 – "Concise investigation"
Used for incidents, claims, complaints or concerns that resulted in no, low or moderate harm to the patient; This commonly involves completion of a summary one page structured template; Includes the essentials of a thorough and credible investigation in the briefest terms and involves a select number of Root Cause Analysis (e.g. 5 why's, contributory factors framework).

Level 2 – "Comprehensive investigation"
Used for actual or potential "severe harm or death" outcomes. This is conducted to a high level of detail including all elements of a thorough and credible investigation. This includes use of analytical tools (e.g. tabular timeline, contributory factors framework, change analysis, barrier analysis). Normally conducted by a multidisciplinary team or involved experts/expert opinion/independent advice of specialist investigator(s)

Level 3 – "Independent investigation"
Used for incidents associated with high public interest or attracting media attention.

This guidance does not require that the incidents be formally risk rated, but it does advocate investigation level 2 investigation of "potential severe harm or death" events.

Issues arising with these considerations to determine the level of investigation required

The following issues arise for this decision making about levels of investigation to apply to incidents:

Isomorphism
The National Patient Safety Agency (2008) guidance for decision making about incident investigation is based on the type and severity of the incident. Toft and Reynolds ((2005) describe the phenomenon of "Isomorphism" whereby similar types of incidents can have very different causes, and different types of incidents can have very similar causes. While analysis of types of incident can be helpful, isomorphism highlights the limitations of such analysis and

the importance of thorough investigation to identify underlying causes that are not apparent prior to investigation.

Justification of resources required to decide level of investigation
There are no metrics of the resources required to develop and implement procedures supporting the application of this level 1, 2 and 3 investigation decision-making. Resources are used in developing the procedures; training staff in using them; and checking that they are being applied properly. Information needs to be gathered to make the decision about the level of investigation required and people need to be consulted about it. While the National Patient Safety Agency no longer advocates risk rating incidents, other agencies such as the Veterans Health Administration National Centre for Patient Safety still do, and the issues with this approach are highlighted above. There is no documented evidence that these procedures for deciding the level of investigation to apply enhance incident management and safety improvement. It is necessary to test whether applying different levels of investigation to different types of incidents, with or without risk rating - contributes to enhanced incident investigation and patient safety improvement and how it compares to other methods of decision making about the level of investigation required.

Our obligation to investigate all death and serious harm events
A very high level of death and serious harm events occurs in healthcare (Scrivens (2005), Kohn et al (2000) and Hogan et al, (2012)). There is a duty to investigate these thoroughly for the following reasons:

→ There is a duty to make a full and open disclosure about incidents to those harmed and/or their families. Inherent in this notion of full and open disclosure is the idea of communicating to those affected that there will be an investigation to find causes, that the causes will be addressed and that the findings of investigations will be shared with those harmed.
→ There is a legal requirement under the Safety, Health and Welfare at Work Act (Office of the Attorney General (2005)), and it is good safety management practice to identify hazards, assess associated risks and put in place control measures to satisfactorily address these. When an incident occurs, it is necessary to investigate it satisfactorily in order to identify the underlying contributory factors/hazards.

The fact that the rate of death and serious harm events is so high in healthcare poses a significant investigation burden on the organisation. Therefore, in the current juncture, the primary criterion for investigation should prioritise severity – death or serious injury - seeking to focus resources on investigating these incidents thoroughly as they arise and implementing the lessons learned to prevent or reduce the risk of future harm arising. As the quantity of incident data accumulates and quality improves, it will become more possible to infer risk of potential harm in cases where such harm has not occurred. Accumulated evidence about causal and contributory factors is critical here. This will enable the development of an effective policy to allocate scarce investigation resources where the risks are rated highest on the basis of objective evidence.

The complexity or simplicity of an incident and the consequent complexity or simplicity of an investigation required has little to do with the severity of an incident
The amount of time and energy required to investigate has less to do with how serious or not the incident is - and has more to do with how complex or simple the incident is. The complexity of an incident may not be apparent prior to investigation – but may only unfold as an investigation

progresses. A very serious death event, while tragic - could be a simple event from the investigative perspective and therefore very simple to investigate requiring relatively little investigation resource; while a less serious incident could be very complex requiring relatively large investigation resource.

The usefulness of investigating "potential" harm events

The National Patient Safety Authority (NPSA 2008) advocates level 2 – "comprehensive investigation" of "potential" severe harm or death events. This means events that did not result in death or severe harm - but which *could* have resulted in death or severe harm. This paper has already outlined the difficulty of reliably gauging the risk that an incident will result in harm and the severity of the harm that might arise, demonstrating that reliably determining "potential serious harm events" is challenging and needs to be done with caution, and only with careful explanations of embedded judgments (Cox 2008). The notion of identifying "potential" harm events (i.e. events that have not actually resulted in harm (i.e. near-misses)), which would be useful to be investigated for organizational safety learning purposes - arises from non-healthcare sectors where the rate of actual harm events is significantly lower than it is in healthcare. But these sectors do tend to thoroughly investigate all death and serious harm events. For example, all plane crashes are thoroughly investigated. The significant differences in the rates of actual death and serious harm events occurring in healthcare compared with these other sectors may render the application of this process of selecting non-harm events for investigation for organizational learning as less relevant in healthcare where the obligation to and the burden of efficiently investigating actual death and serious harm events is extremely high. Never-the-less, all reasonable opportunities for identifying safety problems and solutions need to be harnessed and this includes harnessing opportunities for safety improvement presented by "potential" harm events. However, it is important that those involved in decision making about investigations are aware of the factors that may bias their sense of the risks involved in "potential" harm events and that they have the best possible data available to them and that they are aware of any limitations of such data, in order to counter these biases and limitations as well as possible.

Internal versus external investigation of incidents

The NPSA (2008) level 3 investigation advocates independent external investigation of incidents that have high public interest and attract media attention. While it may be appropriate for there to be an external independent investigation of such incidents, it is generally appropriate to also conduct an internal investigation of such incidents for the following reasons:

Reasons for conducting external investigations

→ Factors outside the control of the health system may contribute to incidents of harm within the health system and carefully constructed external investigations may have a stronger remit to make recommendations to address these external factors. However, internal investigations should at a minimum identify these factors and communicate them to the relevant authorities/organisations

→ To deal with issues of conflict of interest and real or perceived bias that may occur in internal investigations. It should be noted that conflict of interest and bias may affect external investigations and well constructed investigations using good methods are necessary to counter the problem of conflicts of interest and bias in both internal and external investigations

→ External investigations may have better access to appropriate expertise for investigations. However, it is necessary to continuously improve measures to ensure better access by internal investigations to appropriate expertise.

Reasons for conducting internal investigations

- It is known that the factors that cause an incident - if unchecked - may give rise to future harm, so these must be identified and addressed to prevent future harm occurring or if this is impossible to reduce the risk as far as is reasonably practicable. External investigations may or may not take place, and in circumstances where they do take place, it may take time before they are commissioned and report. Furthermore, the objective of external investigations may be different to the objective of an internal safety investigation which must be to identify the safety problem causes and solutions to address these.
- The process of organizational constructive criticism by robust investigation of serious incidents brings much incidental process learning that is critical for the development and evolution of enhanced organisational safety culture and practice for effective safety improvement
- Good internal incident investigations should reveal all incident causes and all necessary effective solutions to address these. Comparison of the findings and recommendations of an internal investigation with the findings and recommendations of external investigations is in effect an opportunity to independently quality assure the internal investigation process.

Cromie et al (2004) state that:

"What an event tells us about a system is not obvious prior to an investigation"

The WHO Draft Guidelines for adverse event reporting and learning systems (WHO, 2005) emphasise that the ultimate aim of incident reporting is to lead to systems improvements by understanding the systems failures that caused the error or injury. At the organisational level, this requires investigation and interviews with involved parties to elicit contributing factors and underlying design failures.

This paper has highlighted the dilemmas in decision making about investigating incidents. It shows that thorough investigation is necessary to determine what learning there is to be derived from any incident, but that incidents should not be considered in isolation but rather in the context of continuously improving incident data leading to an enhanced picture of the health system risk. Significant resources are required initially for decision making about levels of investigations and subsequently for thorough investigations. Issues with investigating "potential" harm events and with the pre-assessment of incidents to determine the likelihood of recurrence or to determine levels of investigation have been highlighted. These need to be countered by investment in and the continuous improvement of the quality of incident data collected and available to investigation decision makers, together with critical examination of the factors used to determine the level of causal analysis. It is important to develop a robust evidence base that demonstrates that incident data and the decision making factors contribute to optimum investigation decision making; optimum investigation resource utilisation; and optimum safety improvement. Consideration of the maturity of any risk assessment process, the experience of the decision makers, and the quality of the information available to them are all important in mitigating the risks of risk assessments and decision making tools.

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HUMAN FACTORS CONSIDERATIONS FOR THE NEW 'NATIONAL EARLY WARNING SCORE' SYSTEM

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Abstract

The National Early Warning Score system is a new initiative to introduce processes that facilitate the identification of a patient's deterioration and prompt staff to escalate the care of the patient for an early medical review. It is similar to many existing Rapid-Response Systems that have existed for several years in a variety of countries. The efficacy of these systems has not been definitely proven, with several problems associated with the failure to escalate or up-tempo care beyond that of the primary care team. This paper highlights the human factors problems that have been identified by researchers examining this 'Failure To Rescue' problem, so that they may be considered from the outset of the new Irish system.

Introduction

The National Early Warning Score (NEWS) system is a new initiative backed by the Health Service Executive and launched in February (HSE, 2013). The system:

1. Facilitates early detection of patient deterioration by categorising the patient's severity of illness, based on the VitalPAC™ Early Warning System (EWS) (ViEWS) (Prytherch *et al.*, 2010)
2. Prompts staff to seek a medical review at specific trigger points, using a standardised observation chart (Royal College of Physicians, 2012)
3. Utilises a structured communication tool (ISBAR (Marshall *et al.*, 2009))
4. Provides a defined escalation plan.

This system is a modified version of existing care trigger and escalation protocols and Rapid Response Systems (RRS) than have been functioning for several years in a variety of countries such as Australia and New Zealand (Jones *et al.*, 2008), Sweden (Konrad *et al.*, 2010) and the US (Sharek *et al.*, 2007). These systems have been well researched and a number of problems with their use have been identified.

Rapid Response Systems

The findings of the first consensus conference on Medical Emergency Teams (MET) defined Rapid Response Systems (RRS) as the "*system* (and not just the individual components of the system) for providing a safety net for patients who suddenly become critically ill and have a mismatch of needs and resources" (DeVita *et al.*, 2006). A functioning RRS requires four components: the afferent limb, 'crisis detection' and triggering of the Rapid-Response Team (RRT) which is the focus of the NEWS; the efferent (responder) limb, the RRT itself; the quality improvement structures, provide data and feedback to the RRS; and the governance and administrative structures, coordinating the resources to facilitate improved care (DeVita *et al.*, 2006, Jones *et al.*, 2011).

The efficacy of RRS as a clinical intervention remains a somewhat contentious issue. The Medical Emergency Response and Intervention Trial [MERIT], a cluster-randomised controlled trial, reported a negative relationship between RRS-type activity and the incidence of cardiac arrest, unplanned ICU admissions, and unexpected death (Hillman *et al.*, 2005). However, 14 studies have since reported improved patient outcomes associated with the introduction of a RRT; 13 of which were based on a Physician-led MET (Jones *et al.*, 2009).

Time Opportunities for Care Escalation

Jones et al. (2009) highlighted that a low RRS utilisation is unlikely to improve patient outcomes, conversely increased RRS utilisation appears to be associated with a reduction in cardiac arrests, e.g. the introduction of a RRT with a multidisciplinary, multifaceted education system for clinical staff resulted in a 24% per year decrease in cardiac arrests (Buist *et al.*, 2007). It is clearly only possible to recover the rapidly escalating complexity of a deteriorating patient if their physiologic and cognitive decline is detected in time and escalated to the RRT, i.e. if there are to be efficient clinical interventions, the RRT activation must be sufficient (of urgency and cogency) given the risk exposure of the patient to be treated (Jones *et al.*, 2009).

This would suggest that there is a period of time in which the patient's vital signs indicate their deviation from their intended treatment plan, i.e. for an important subgroup of patients the care triggered by the primary care team must be timely and authoritative, or may be too little too late. The utilisation effect supports the basis of a time period wherein a subgroup of deteriorations could be prevented with an early escalation of care or an up-tempo secondary review to course correct the patient's decline (see Amalberti and Brami (2011) for a discussion of tempos in patient care).

Figure 6 shows a theoretical representation of this failure to escalate care in a timely manner to the RRS. It can be seen on the figure that there is typically:

1. A delay in the activation of the RRS (a recovery step), the far right phase
2. A significant time phase from which the patient has started to deteriorate (a coping phase) but in which the team fail to up-tempo the patient's care, the middle phase.
3. A time opportunity for proactive care (foresight) in which the patient's early indicators of non-response could be identified and acted upon to correct the patient's non-response to treatment, the initial time phase.

A relationship has been shown between the time of day and number of RRS escalations, e.g. at scheduled nursing activities and handovers (Galhotra *et al.*, 2006, Jones and Bellomo, 2006, Schmid, 2007). More recently, the MERIT group found the majority of RRS calls occurred between 06:00 and 12:00, i.e. during handovers and ward rounds, with the greatest cardiac arrest survival rate between 12:00 and 24:00 (Flabouris *et al.*, 2010), i.e. when units are closest to optimum staffing levels.

The documentation of vital signs in the period before adverse events is commonly incomplete, with a particular deficiency in the recording of the patient's respiratory rate (Chen *et al.*, 2009). Patient respiratory rate has subsequently been identified as the predominant indicator of patient deterioration accounting for up to 55% of RRS triggered events in one study (Jäderling *et al.*, 2011).

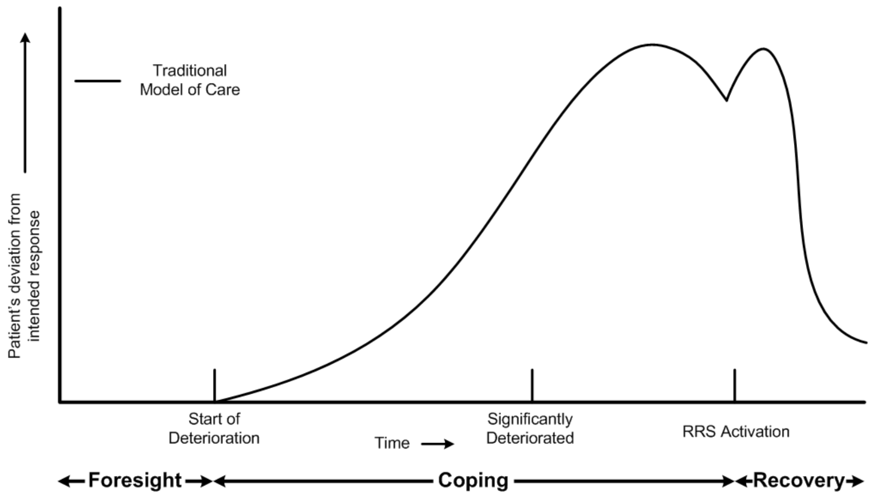

Figure 6: Patient decline versus time

Failure To Rescue

Silber *et al.* (1992) introduced the concept of "Failure To Rescue" (FTR), as an outcome measurement: a failure to react promptly or commensurately escalate patient care, which can result in a serious adverse event (Jones *et al.*, 2011). FTR constitutes an 'Afferent Limb Failure' (ALF) as defined by Trinkle and Flabouris (2011): *documented MET criteria in a general hospital ward, for which no MET call was triggered, in a time period of 15 minutes to 24 hours, prior to an in-hospital event.* FTR is influenced by the complex interactions and interdependencies of both static and dynamic patient- and system-level factors that can have synergistic effects on response complexity (Hravnak *et al.*, 2011).

The onset of a patients deterioration is most significantly influenced by patient characteristics, but once this has been recognised the hospital (infrastructure & organisation) and 'system' characteristics are more strongly correlated to recovery and positive patient outcomes (Silber *et al.*, 1992). For example, they identified FTR factors influenced by the level of technology utilisation, bed capacity, total number of physicians, nurse-to-patient ratio, nurse-to-bed ratio, whether anaesthesia care was provided by a board-certified anaesthesiologist and the level of registered nursing staff (Silber *et al.*, 1992).

Several additional influencing factors for FTR have been reported: 7% increase in the odds of FTR for each additional patient a nurse must monitor (Aiken *et al.*, 2002); communication breakdowns within the care team or with the patient and the care team, failure to recognize early signs of deterioration and incomplete assessments or inadequate treatments (Thomas *et al.*, 2007); perceived condescension and hostility from the RRT, the busyness of RRT members, fearful of appearing 'dumb', unsure of the process of escalation, calling the attending physician instead of the RRT (Astroth *et al.*, 2013).

Shearer *et al.* (2012) reported that nearly half of patients meeting set escalation criteria (42%) did not receive the appropriate clinical response from the staff, while most (69.2%) recognised that their patient did meet the physiological criteria, with 75.8% of the staff being ‘quite' or 'very’ concerned about the patient. The top four reasons behind these FTR included hospital, sociocultural and organisational factors:

1. Felt the situation was under control in the ward setting
2. ICU team already involved but no intensive care unit (ICU) bed was available
3. Team involved were experienced in this type of patient and felt RRS activation was not required
4. Poor communication/prioritisation by medical team

Delayed RRT activation and increased RRT utilisation should be priorities for hospitals operating RRS (Calzavacca et al., 2008). A survey by the Austin hospital of their own hospital ward nursing staff following the introduction of a ‘successful’ MET found that 72% of nurses would call the covering doctor before the MET, despite the presence of the hospital MET protocol and the patient corresponding to the established MET criteria (Jones *et al.*, 2006). This behavioural response and reluctance to escalate has not been thoroughly examined. There appears to be a frequent reluctance of staff to escalate care even though they understand the protocols, the patient's status and the correspondence of these key pieces of information.

Discussion

The introduction of a National Early Warning Score system is a positive step towards preventing patient's non-response to care and potential deterioration. The system being introduced in Ireland utilises strategically designed and developed tools to fit this purpose. However, for the system to be as successful as it can be, it is imperative that the human factors influencing the use of the system are actively managed.

Several groups implementing similar systems have identified a range of hospital, sociocultural and organisational factors that adversely affected the utilisation and efficacy of their systems. These range from concern about the availability of beds in the ICU, excessive belief in individual staff or ward team ability to care for increasingly complex patients, not wanting to look 'dumb', adhering to established 'lines of authority', lack of staff to monitor patients, hostility from the RRT and communication failures.

These human factors exist in other safety-critical fields, which have had significantly more time to understand, manage and overcome these problems, such as transportation systems, chemical industry and, energy generation and supply. These human factors are also increasingly being examined within the healthcare domain, e.g. Leonard *et al.* (2004), Cosby and Croskerry (2004) and (Marshall *et al.*, 2011).

It should not be forgotten that a time period remains that has predominantly failed to be capitalised on, the 'foresight' phase, in which active management of the patient by a care team can pre-emptively course correct the patient's non-response to treatment, i.e. before patient deterioration occurs. This was partly the subject of a recent NHS report on ward based multi-disciplinary ward rounds (Royal College of Physicians and Royal College of Nursing, 2012). The implementation of this form of ward rounding could potentially shift the focus of the patient's care from responding to their decline to modifying their treatment plan in a proactive manner and add another dimension to the care process.

Conclusion

Despite their extensive use, the efficacy of Rapid Response Systems remains somewhat contentious. This is influenced to a large degree by the problem of the 'Afferent Limb' in the form of 'Failure to Rescue', caused by the lack of escalation of care. The predominant factors related to failing to escalate care are human factors related, i.e. they are institutional, organisational, sociocultural, systems-level factors.

The efficacy of the new National Early Warning Score system must take account of these human factors if it is to be successful; staff must be adequately trained about the system, staff must be encouraged to continually use the system, senior staff should set good examples for junior staff to follow in using the system, documentation and checks must be completed as stated in the system, and team communication about the system should be unambiguous and explicit.

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EUROPEAN INNOVATION PARTNERSHIP ON ACTIVE AND HEALTHY AGEING IS A KEY DRIVER OF THE IRISH NATIONAL IMPLEMENTATION PLAN ON FALLS AND BONE HEALTH

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Introduction

The purpose of this study is to explore how the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) is a key driver in implementing the 'National Strategy for the Prevention of Falls and Fractures in Ireland's Ageing Population'(1).

Relevance
Falls are the dominant cause of injuries among older persons, accounting for approximately one-third of fatal injuries in persons aged 60 and over. Falls can often lead to long- term physical disability (e.g. loss of mobility), severe dependency and reduction in quality of life. The causes of falls in older persons are multi-factorial, many of which are modifiable and preventable. Falls prevention (A2) is the pilot initiative for EIP-AHA which aims to increase the average healthy life years (HLY) in the EU by 2 years by 2020, known as a "Triple Win" for Europe (2). This approach also offers cost containment and efficiency measures for health and social care systems, and coincides with the HSE /DOH decision to prioritise implementation of the National Strategy (Figure 1) in 2013.

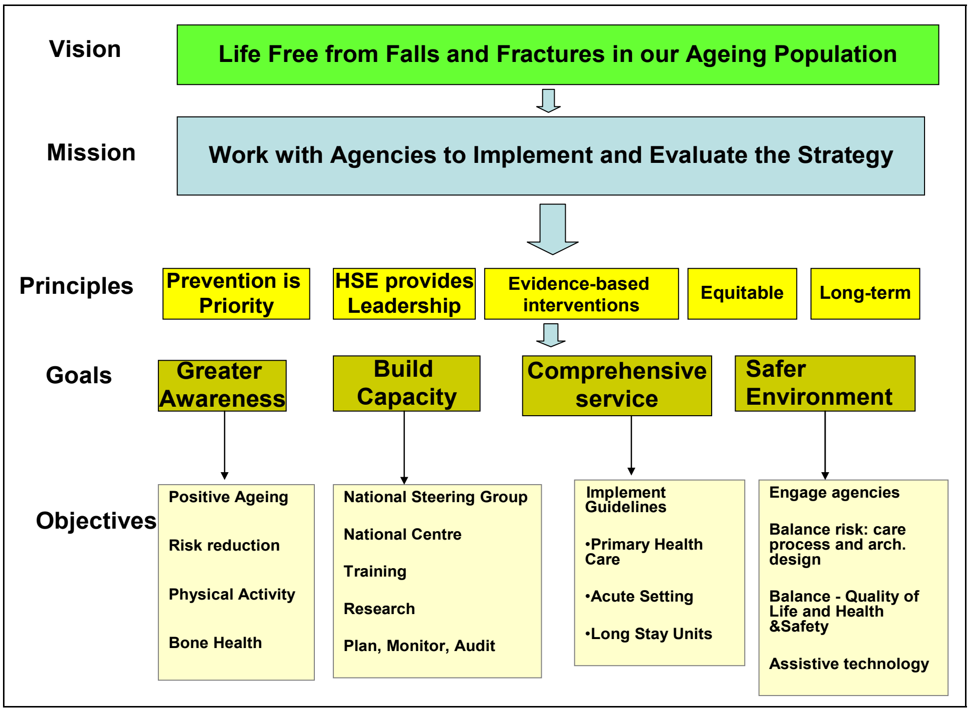

Figure 1: The Vision, Mission, High Level Principles, Goals and Objectives of the National Strategy for the Prevention of Falls and Fractures in Ireland's Ageing Population'

Participants

The European Strategic Implementation Plan (SIP) of which A2 is a part, will ensure Europe´s health and social care systems move *from* a reactive and curative approach to disease *to a* proactive care based on health promotion and disease prevention (3). This means involving (older) persons in their own care through shared decision-making and engaging people in community initiatives as co-producers of health and wellbeing. A2 has brought together over 30 commitments, representing over 150 partners and over 15 countries to date, from many different types of organisations and stakeholders. Stakeholders identified in the Irish commitment are also multi-sectoral /disciplinary/agency, and includes the DOH, HSE, SCA, TRIL, professional bodies and county councils.

Methods

Key policy documents, action plans and change management methodologies were reviewed to explore the relationship between the EIP-AHA and the Irish National Strategy. Study findings were informed by national data, HSE activity levels and internationally relevant comparative data.

Analysis

Preliminary analysis of related and relevant activities, for both the EIP-AHA project and the HSE was concerned with the creation of knowledge (through research), the diffusion and acquisition of knowledge (e.g. through organisational learning), and its exploitation in the form of new or improved products, processes or services.

Results

Critical change management success factors intrinsic to the EIP-AHA project are common to both the European and Irish projects. There is significant alignment between the A2 objectives, action areas and deliverables and the HSE Implementation Plans. The political, funding, legislative and organisational reforms and challenges happening within the Irish health and social care system resonate with the EIP-AHA strategy (Figure 2) in its desire for standardisation, collaborative working, scaling up of good practices and clarifying privacy restrictions for data sharing.

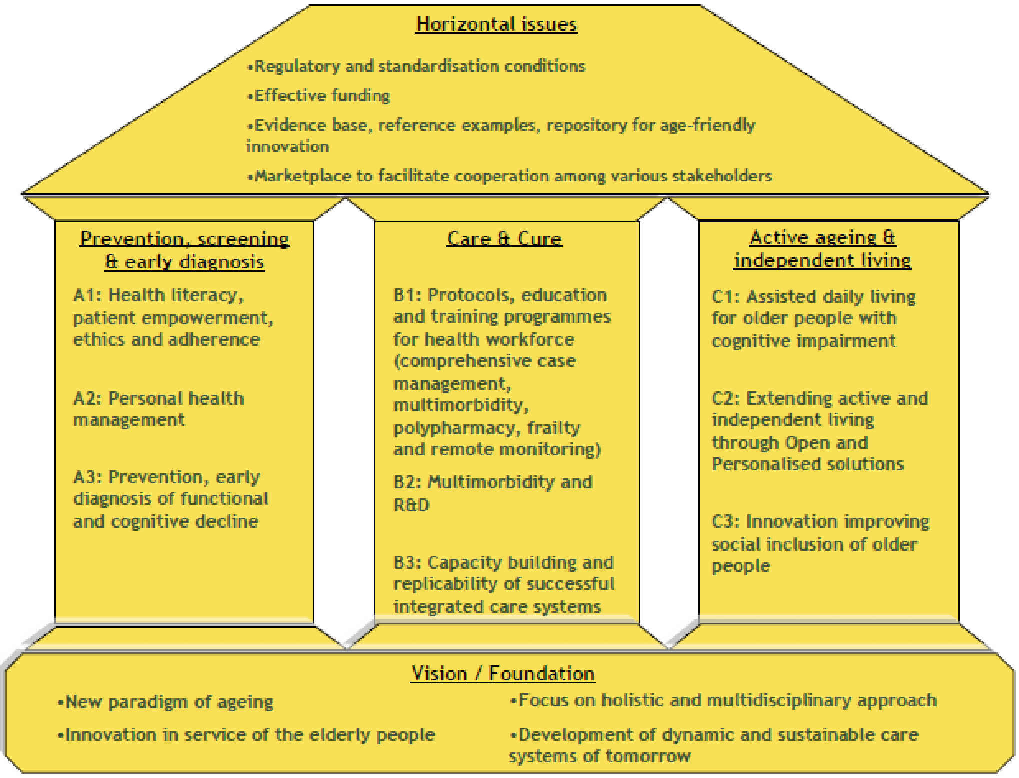

Figure 2: Strategic innovation priority action areas of the European Innovative Partnership on Active and Health Ageing (EIP-AHA) Strategic Framework

Discussion

Conclusions

Falls among older persons is a complex and costly problem, and is ideally addressed though an integrated approach with timely and targeted prevention, screening, intervention and monitoring, which requires a multi-disciplinary, multi-agency and multi-level approach. EIP-AHA will enable nations/regions to leverage the necessary resources, innovations and collaborations needed to affect safe, effective and sustainable outcomes.

Implications
Ireland will share in international best-practices, strengthen monitoring and service improvement measures, contribute to the alignment of data-registries and toolkits and learn how innovative technologies can be implemented as an integral part of integrated care pathway models. Technological innovations, industrial collaborations and continuous improvement models will drive sustainability and cost-effectiveness. A "whole system" approach implemented in Ireland will increase HLY and secure a "Triple Win" for Europe in collaboration with EU partners.

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