Proposal

Irish Centre for Patient Safety

P. O’Connor
E. Fallon
W. van der Putten
I. Keogh
D. O’Keeffe

College of Engineering and Informatics,
College of Science,
College of Medicine, Nursing and Health Sciences
National University of Ireland, Galway

and

Galway and Roscommon University Hospitals Group
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>3</td>
</tr>
<tr>
<td>1. Organisational and project objectives</td>
<td>4</td>
</tr>
<tr>
<td>2. Rationale for the Centre</td>
<td>5</td>
</tr>
<tr>
<td>3. Intended outcomes</td>
<td>8</td>
</tr>
<tr>
<td>4. Activities and work programme</td>
<td>9</td>
</tr>
<tr>
<td>- Education and training</td>
<td></td>
</tr>
<tr>
<td>- Service Provision</td>
<td></td>
</tr>
<tr>
<td>- Research</td>
<td></td>
</tr>
<tr>
<td>- Information support</td>
<td></td>
</tr>
<tr>
<td>5. Organisational details</td>
<td>12</td>
</tr>
<tr>
<td>6. Project risks and barriers</td>
<td>13</td>
</tr>
<tr>
<td>7. Evaluation</td>
<td>14</td>
</tr>
<tr>
<td>8. Leverage, Sustainability and Communication</td>
<td>14</td>
</tr>
<tr>
<td>Conclusion</td>
<td>15</td>
</tr>
<tr>
<td>Bibliography</td>
<td>16</td>
</tr>
<tr>
<td>Appendix I. Research in patient safety in NUI Galway</td>
<td>17</td>
</tr>
</tbody>
</table>
A Proposal for the Establishment of a Centre for Patient Safety at NUI, Galway and Galway and Roscommon University Hospitals Group

Introduction

Safety can be defined in a number of different ways: “Safety is freedom from accidents or losses.” (Leveson, 1995), “Safety can be defined as the judgement of risk acceptability for the system.” (Ayyub, 2003). Ayyub’s definition implies that safety has a relative aspect to it. The International Electrotechnical Commission (IEC) defines safety in its broadest and most absolute sense as; “Safety is the freedom from unacceptable risk (IEC, 1998).” Irrespective of the definition used, the safety of a system is dependent on the environment in which it is operating and how it is being used.

The concept of system safety was developed as a result of the large numbers if aircraft lost due to pilot error during World War II and problems with safety in the Apollo space program. As the use of complex-technology and software increased in safety-critical projects, guidelines were drafted to ensure the continued safety of personnel and equipment, e.g. MIL-STD-882D (1987). The initiative was taken first by the U.S military, but over time these approaches have been adopted by other high-risk industries (e.g. nuclear power, chemical processing, offshore oil and gas exploration) and used as a basis for developing their own, industry specific, policies.

The introduction of technology to replace and support manual tasks in systems has increased productivity and system performance. However, technology has the potential to raise levels of risk due to the fact that it allows an increased number of activities to be carried out in parallel and at greater speed. Safety systems design is concerned with the identification, evaluation, elimination, and control of hazards and risks through analysis, design and management practices. The core principles of safety systems are:

- emphasis on designed-in safety, not just added as after-thought;
- analysis of the system as a whole as opposed to subsystems or constituent elements;
- taking a larger view of hazards than just failures, including the prospective analysis of systems to facilitate a culture of continuous improvement;
- emphasis on analysis instead of exclusively relying on past experience; and
- emphasis on qualitative techniques as opposed to quantitative techniques (Leveson, 1995).

“A hazard is a situation in which there is actual or potential danger to people or to the environment.” (Storey, 1996) Hazard identification and analysis enables designers to tackle the cause of potential failures and improve a system’s safety, reliability and performance. For every hazard there is an associated risk. Risk is defined as: “Risk is a combination of the frequency or probability of a specified hazardous event, and its consequence.” (Storey, 1996) Risk analysis must consider society’s attitude to the risk in question. Balancing society’s perception of risk against the value that it places
on human life requires experience and a thorough knowledge of the environment and operating conditions in which the system functions.

The watershed moment in terms of a systems safety approach to After publication of the seminal report “To Err is Human” (Kohn et al., 1999) there has been a significant increase in research into medical errors and patient safety using Human Factors engineering techniques. Root Cause Analysis (RCA) (a retrospective tool for analysing errors and near misses) and Failure Modes and Effects Analysis (FMEA) (a proactive risk assessment tool) feature prominently in healthcare guidelines (Habraken et al., 2009; Latino, 2004). RCA was mandated for use in the investigation of clinical errors in 1997 for hospitals accredited by the US Joint Commission on Health Care Safety (Iedema et al., 2006). FMEA was recommended for use by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as part of risk analysis of hospital systems (Habraken et al., 2009). However to date outside the United States, few healthcare organisations and services have adopted these recommended tools.

The report of the Irish Commission on Patient Safety and Quality entitled ‘Building a Culture of Patient Safety’ and published in 2008 identified a need for “an active research programme on patient safety and quality issues in healthcare for Ireland” (p. 24). Following a review of the published literature, searching the websites of Irish Universities, talking to and visiting researchers across Ireland who might be expected to have an interest in patient safety (e.g. Royal College of Surgeons Ireland) it is clear that, despite a recognised need, an active Centre for Patient Safety does not exist within Ireland. The Centre for Patient Safety, NUI Galway, has been established to fill this void.

1. Organisational and Project Objectives

The mission of the proposed Centre for Patient Safety is to develop and stimulate research on patient safety in Ireland, with a view to promoting the safe and effective use of complex and increasingly scarce resources. The Centre will also offer research expertise, educational and training activities as well as direct practical support to public, private and voluntary agencies involved in the delivery of health care. It will do this in collaboration with colleagues, both nationally and internationally. The Centre has five main objectives:

- to promote the use of systems safety, human factors and other safety and risk methods and techniques in healthcare, in order to ensure the delivery of safe and effective services to patients;
- to conduct, report and disseminate research and information on patient safety in close collaboration with a large academic teaching hospital;
- to facilitate the provision of patient safety services in the Irish health care system through the coordination of work, the facilitation of linkages and interaction amongst practitioners, hospital managers and researchers in the field in Ireland;
- to coordinate undergraduate and post-graduate educational and training activities in patient safety in collaboration with local and national health service providers and professional bodies; and
- be a vehicle to coordinate any future approaches to grant-aiding bodies.
The proposed role of the Centre fits with the view of the University as a resource for the community at large. The Centre will be a central reference point for all health service providers related to the application of patient safety. By providing a central service, the proposed Centre will become an expert reference point for public and private health care providers as well as local and national government. The University is uniquely placed to provide a both formal and informal linkages and strategic alliances with a diverse range of groups in these categories. Through consolidation of the expertise available in the University, the Centre Patient Safety will be a valuable resource to the Irish health care community.

2. Rationale for the Centre

The increasing interest and requirements to ensure safe patient care in an environment with reduced costs implies that there is a need for effective and efficient risk assessment tools within the health care environment as well as a substantial number of individuals who are trained in techniques of risk assessment, failure mode investigation and techniques of accident and incident investigations such as Root Cause Analysis and others.

2.1 Training and Education

A key role of the proposed Centre would be to provide and coordinate training and education at professional, and both postgraduate and undergraduate level. The report of the Commission on Patient Safety and Quality Assurance, Government of Ireland (2008), recommended that there should be a strong emphasis on patient safety, quality, and human factors in the undergraduate and post-graduate education programmes of all healthcare professionals. It also called for the integration of patient safety education and training modules into healthcare professionals’ continuing education and training programmes and Competence Assurance Schemes.

The Centre for Patient Safety would be in a strong position to develop courses and modules to support these recommendations. NUI Galway has developed significant educational competencies in the general areas of Health & Safety and Systems Safety through its involvement in the M.Sc / Grad. Dip. Occupational Health & Safety and B.Sc Health & Safety Systems, over a twenty year period. Over the past four years, aspects of Systems Safety, Human Factors Engineering, and Human Reliability have been taught to postgraduates in Medical Physics and Surgery. Members have also provided a series of courses and seminars in, for example: Cork University Maternity Hospital (2009), University of Minho (2009), Conference in London (2011), Conference in Dublin (2011)

An example of a highly successful course which has been running for the last seven years is a course on Risk and Safety management. The program of this course (2010 edition) is attached. Lecturers on this course have been members of staff of NUI Galway, University Hospital Galway, State Claims Agency and international speakers from National Patient Safety Agency, Lund University Sweden and Eindhoven University of Technology, Netherlands. The Centre would also be ideally placed to provide custom made training courses to Hospital management, Risk Advisors,
Outline Program Risk and Safety Course

19-23 April 2010, National University of Ireland, Galway

<table>
<thead>
<tr>
<th>Monday 19 April</th>
<th>Tuesday, 20 April</th>
<th>Wednesday, 21 April</th>
<th>Thursday, 22 April</th>
<th>Friday, 23 April</th>
</tr>
</thead>
<tbody>
<tr>
<td>09.00 Registration</td>
<td>09.30 Introduction</td>
<td>09.30 Introduction to Health and Safety</td>
<td>09.30 Introduction to Networks</td>
<td>09.00 Finish Workshop</td>
</tr>
<tr>
<td>10.00 Setting the Scene</td>
<td>10.00 Setting the Scene</td>
<td>10.00 Setting the Scene</td>
<td>10.00 Setting the Scene</td>
<td>10.00 Setting the Scene</td>
</tr>
<tr>
<td>10.30 Wil van der Putten</td>
<td>10.30 Wil van der Putten</td>
<td>10.30 Wil van der Putten</td>
<td>10.30 Wil van der Putten</td>
<td>10.30 Wil van der Putten</td>
</tr>
<tr>
<td>11.00 Coffee</td>
<td>11.00 Coffee</td>
<td>11.00 Coffee</td>
<td>11.00 Coffee</td>
<td>11.00 Coffee</td>
</tr>
<tr>
<td>11.30 Safety and Health at Work Act</td>
<td>11.30 Safety and Health at Work Act</td>
<td>11.30 Safety and Health at Work Act</td>
<td>11.30 Safety and Health at Work Act</td>
<td>11.30 Safety and Health at Work Act</td>
</tr>
<tr>
<td>12.15 Keith Sheerin</td>
<td>12.15 Keith Sheerin</td>
<td>12.15 Keith Sheerin</td>
<td>12.15 Keith Sheerin</td>
<td>12.15 Keith Sheerin</td>
</tr>
<tr>
<td>12.15 Hospital safety HSE/IOQA</td>
<td>12.15 Hospital safety HSE/IOQA</td>
<td>12.15 Hospital safety HSE/IOQA</td>
<td>12.15 Hospital safety HSE/IOQA</td>
<td>12.15 Hospital safety HSE/IOQA</td>
</tr>
<tr>
<td>12.15 Carmel Higgins</td>
<td>12.15 Carmel Higgins</td>
<td>12.15 Carmel Higgins</td>
<td>12.15 Carmel Higgins</td>
<td>12.15 Carmel Higgins</td>
</tr>
<tr>
<td>13.00 Lunch</td>
<td>13.00 Lunch</td>
<td>13.00 Lunch</td>
<td>13.00 Lunch</td>
<td>13.00 Lunch</td>
</tr>
<tr>
<td>14.00 Medical Device Legislation and Regulation; Role of Irish Medicines Board</td>
<td>14.00 Medical Device Legislation and Regulation; Role of Irish Medicines Board</td>
<td>14.00 Medical Device Legislation and Regulation; Role of Irish Medicines Board</td>
<td>14.00 Medical Device Legislation and Regulation; Role of Irish Medicines Board</td>
<td>14.00 Medical Device Legislation and Regulation; Role of Irish Medicines Board</td>
</tr>
<tr>
<td>14.00 Cathal Brennan</td>
<td>14.00 Cathal Brennan</td>
<td>14.00 Cathal Brennan</td>
<td>14.00 Cathal Brennan</td>
<td>14.00 Cathal Brennan</td>
</tr>
<tr>
<td>15.30 STARSWEB Reporting</td>
<td>15.30 STARSWEB Reporting</td>
<td>15.30 STARSWEB Reporting</td>
<td>15.30 STARSWEB Reporting</td>
<td>15.30 STARSWEB Reporting</td>
</tr>
<tr>
<td>16.00 Dr. Allish Quinton</td>
<td>16.00 Dr. Allish Quinton</td>
<td>16.00 Dr. Allish Quinton</td>
<td>16.00 Dr. Allish Quinton</td>
<td>16.00 Dr. Allish Quinton</td>
</tr>
<tr>
<td>16.30 Hazard Management in UHG</td>
<td>16.30 Hazard Management in UHG</td>
<td>16.30 Hazard Management in UHG</td>
<td>16.30 Hazard Management in UHG</td>
<td>16.30 Hazard Management in UHG</td>
</tr>
<tr>
<td>17.00 Frank Kirrane</td>
<td>17.00 Frank Kirrane</td>
<td>17.00 Frank Kirrane</td>
<td>17.00 Frank Kirrane</td>
<td>17.00 Frank Kirrane</td>
</tr>
</tbody>
</table>
technology staff as well as clinical staff, all of whom require a grounding in Risk and Safety management.

2.2 Research

Research in the area of patient safety has intensified throughout the developed world since the publication of “To Err is Human: Building a Safer Health System”, (Institute of Medicine 2000), which estimated that between 44,000 and 98,000 people die in hospitals in the U.S. each year as a result of preventable medical errors that could have been prevented. In the U.S and other countries significant resources have been allocated to research in the areas of event reporting systems, computerised patient records, computerised physician ordering systems, systems thinking in technology and service delivery and risk assessment and management. The report of the Commission on Patient Safety and Quality Assurance, Government of Ireland (2008), identifies the need for an active research programme in patient safety and quality in Ireland. The need for research in the areas of systems thinking, high reliability design, human factors design and safety sciences in health care is clearly identified in the report. These activities require a multidisciplinary approach with inputs from disciplines as diverse as medicine, nursing, medical physics, psychology, human factors, IT and clinical engineering.

Quality of research has been shown to be significantly enhanced when an interdisciplinary approach to research is taken. The Centre will actively promote and support inter-disciplinary research involving medical physics, human factors and safety engineering, clinical engineering, other technology disciplines, basic medical sciences and clinical medicine. The proposers have extensive experience in developing such links and collaborating in such research.

Examples of current and successfully completed research include:

- Development of a Systems Engineering & Error Analysis Methodology for Health Care: Systems and Error Analysis Bundle for Health Care (SEABH).
- A Systems Safety Approach to the Management of Medical Equipment
- Radiation Oncology System Safety Analysis (ROSSA)
- A Human Factors Analysis of Two Common Robotic Surgery Procedures
- Levels of Automation in Radiotherapy
- A comparison of the teamwork attitudes and knowledge of Irish surgeons and U.S Naval aviators.
- An evaluation of the effectiveness of a pre-internship training programme
- A Comparison of Performance of Medical Students on Surgical Robotics and Laparoscopic Training Drills
- An evaluation of levels of stress of Irish medical students and interns
- Human Factors Training For Interns
The new Centre will seek to expand and further develop existing research links at NUI, Galway among these fields of medical physics, bioengineering, medicine, safety, economics, psychology, and human factors. It will also further develop existing links with universities in Ireland and abroad and medical facilities. Currently links exist with University College Dublin, University College Cork, Queen’s University Belfast, the Open University, Milton Keynes UK Eindhoven University of Technology, Netherlands and the Galway Clinic. The Centre will also provide the appropriate leadership and support for multi-disciplinary teams engaged in research in the broad field of patient safety medical in Ireland.

2.3 Collaboration in Public-Private partnerships.

There are a number of institutions in Galway and the surrounding area which use the services of Patient Safety professionals, but have difficulty accessing specialist knowledge available locally. The proposed centre would be an ideal vehicle for the collaboration between staff in public and private health care facilities in Galway. The Centre would facilitate the collaboration of staff in different health care facilities in a collegial and supportive way. The use of the Centre based in NUI Galway would avoid potential conflicts of interest and would help to support high quality medical care in the Galway region, irrespective of the type of health care facility.

3. Intended Outcomes

The intended outcomes for the project can be separated into short-term, medium and long-term:

**Short-term outcomes**
- The establishment of the first Centre for Patient Safety in Ireland
- The facilitation of dedicated research in areas of patient safety and quality of patient care in within a truly multi-disciplinary setting;
- The development of a research, education and information strategy for the integration of patient safety within health care in Ireland;
- Research reports and publications in the field of Patient Safety;
- Develop and coordinate Masters and PhD programmes in Patient Safety
- Develop diploma courses for post-graduate, professional training;

**Medium-term outcomes**
- The Centre will be the coordinator and focal point for research in Ireland;
- The Centre will initiate and develop a national post-graduate School in Patient Safety
- The Centre will a recognised as a self-sustaining, independent, Centre of Expertise in education and training in Patient Safety, both nationally and internationally;
- The Centre will be regarded as a model for the development and assessment of safe high technology medicine and will become a focal point and Centre of Expertise for all health care institutions seeking guidance and help with the introduction of such technology in their organizations.
**Longer-term outcomes**
- The Centre will have closely integrated the academic research carried out in the University setting and the Clinical work in the hospital.
- The Irish Health Care sector will have been enriched by the work of the Centre
- The Centre will have nurtured and trained a core of leaders in Patient Safety Management in the country
- A Cadre of Expertise will exist in the Centre and will be recognised nationally and internationally as leaders in Patient Safety Education and Research.

4. Activities and Work Programme

The work programme of the new Centre will focus on applications of Patient Safety in Health Care and can be broken-down into the following areas:

- Education and training
- Service provision
- Research
- Information support

The details of the work programme in the longer-term will depend, to some extent at least, on the new opportunities arising from increased public and private investment in the health care system in Ireland and the interests of stakeholders in particular research themes.

New funding will facilitate the hiring of additional researchers in each of the fields as outlined below. Funding will also support the dissemination of information through short courses, seminars, conferences and the development of a website which is intended to be hosted through the Centre.

4.1 Education and Training

The key planned outputs under education and training are as follows:

- Coordination of the existing programs in patient safety within NUI Galway
- Develop Modules for post-graduate programmes in specific areas of Patient safety. Examples could be Post-graduate diplomas in Medical Device Risk assessment, training courses in Root Cause analysis, incident investigation etc.
- Provision of a Masters programme in Patient Safety at the National University of Ireland, Galway within 2 year timeframe;
- The provision of research training through the provision of Ph.D. programmes and the interaction through Graduate Schools;
- Participation in National and International Training programmes in Patient Safety and risk management;
- Provision of Skills courses for health professionals and practitioners in the field in Ireland. Examples are Radiation Safety, Laser Safety, Optical Safety, Electrical Safety and others;
4.2 Service Provision

The Centre will act as a “clearing house” in the provision of Patient Safety services for local health care institutions in the Western seaboard region. It will do this by coordinating service providers, the development of service level agreements with customers and the organization of the service delivery such as incident investigation and specific tailored service improvement programs. The University is ideally placed for the development of this service and it can be envisaged that at a later date this could be “spun off” as a commercial entity. It is envisaged that this has the possibility of acting as a Revenue source for the Centre. The Centre will liaise with service users and other stakeholders such as HSE and State Claims Agency.

4.3 Research

Four research themes will be explored in the first five years of the new Centre:

**Theme 1: Risk in Radiotherapy**

*Planned Activity:* The research activity will focus on the evaluation and optimization of image quality in digital radiology. Digital radiology allows for the uncoupling of image quality and patient dose and allows for an examination where the image quality and patient dose are tailored and appropriate for the examination.

*Planned Output/Deliverable:* development of a Toolbox and instruments which should allow clinical users to evaluate complex clinical information systems. Initially applied to radiotherapy.

*Collaborators:* NUI Galway internal (HRB funded)

**Theme 2: Allocation of Functions**

*Planned Activity:* The current research is focused on the application and development of Levels of Automation (LOAs) models for radiotherapy; that is, how users (usually staff working with computers and hi-spec machines, such as CT machine, Linear Accelerator, etc.) interact with automated systems. With applying LOAs at the task level, it should be possible to identify how users’ and automated systems’ tasks are allocated, and what kind of impact LOA has on working processes, i.e. work organisation, working roles, levels of responsibility etc. (Fallon, Chadwick and van der Putten 2010). It will also enable the identification of new potential errors that could occur when automation systems (or parts of) are changed or upgraded and also help to develop error reduction strategies. Different LOA models have been developed in the last 3-15 years for the military, aerospace, and manufacturing domains. However, currently there are no LOA models that are directly applicable to the radiotherapy domain or healthcare in general.

*Planned Output/Deliverable:* The main deliverable will be the development of a framework which will enable healthcare systems developers and operators to evaluate the impact of automation on the way health services are delivered. In particular it will enable decision makers to establish the impact of automation on how work is organised and also vice versa, i.e. lean systems. Initially the LOA will be applied to
Radiotherapy but will also be extended to other areas where significant automation and technology is employed.

Collaborators: Mechanical and Biomedical Engineering (Industrial Engineering), School of Physics (Medical Physics) NUI Galway, University Hospital Galway (Radiotherapy)

Theme 3: Human Factors

Planned Activity: To build upon the human factors training being provided to interns and surgical trainees. The goal will be to develop a curriculum of evidence-based human factors education for undergraduate and postgraduate health care professionals across the School of Health Sciences at NUI Galway. The education programme will be tailored to each speciality, with the purpose of improving patient safety and quality of care through an improved understanding of human factors by healthcare professionals.

Explore the utility of adopting techniques used in other high-risk domains (e.g. checklists and standardisation, behavioural markers, leading and lagging indicators of safety performance) to improve patient safety and quality of care in Irish hospitals. It is intended that funding for this work will be sought from the Health Research Board and European funding sources such as FP7 and Marie Currie.


Collaborators: Royal College of Surgeons in Ireland, London School of Economics, University of Aberdeen, Harvard University, State Claims Agency, Health Services Executive.

Theme 4: Risk Assessment of Medical Devices and Systems

Planned Activity: A major strand of research will be the systematic examination of the Risk Assessment of Medical Devices. Also examined will be studies of risk assessment of the networks and systems of which medical devices increasingly form part. This will be done from the perspective of the clinical user with as aim to gain a better understanding of the risk of medical technology and of ways to manage these risks.

Planned Output/Deliverable: The outcome will be methods to aid in Risk assessment of Medical Devices and Systems in the Irish health care system. The research will feed back into the annual Seminars on Risk Assessment in Medical Technology which are held as part of the M.Sc. in Medical Physics (and will be part of the proposed M.Sc./M.Eng in Clinical Instrumentation)
Collaborators: Mechanical and Biomedical Engineering (Industrial Engineering) NUI Galway, National Standards Authority of Ireland, Eindhoven University of Technology, Netherlands.

4.4 Information Support

The key planned outputs under information support will include:

- The development of an information repository for best practice in the field of patient safety in Ireland within 1 year.
- The provision of an information service on national and international policy reports on issues affecting the areas of interest.
- The provision of information on developments at European level and information on best practice in member states of the European Union within 1 year.
- The development of a website to provide comprehensive information on patient safety with links to appropriate and relevant organisations within 1 year.

5. Organisational Details

Organizational Aspects
It is envisaged that the Centre will be a “virtual” centre for the initial few years of operation. Administrative support will be provided from within existing resources. Should additional work be undertaken, it is envisaged that some limited administrative support will be required. This will be costed as part of the proposed work.

Membership of the Centre
The range of personnel within the Centre for Patient Safety will reflect the multi-disciplinary nature of the work. Physical scientists will combine with colleagues from engineering and clinical sciences such as psychology to provide the essential multi-disciplinary approach to patient safety. The new Centre will include members drawn from the following disciplines: Physics, Mechanical and Biomedical Engineering (Industrial Engineering), Psychology, Nursing, Midwifery and Medicine. Key people have been identified in each of these disciplines for collaboration on various projects and programmes. No attempt will be made to impose artificial relationships across the various researchers and strands of research that make up the Centre. The Centre will, however, provide the identity, framework and the flexibility for people to work together on various projects related to Patient Safety. It is envisaged that this includes the collaborative projects throughout Ireland.

Members will be supported in the research tendering process and the Centre will support and co-ordinate research applications for small and large research projects, as well as providing administrative assistance during the course of all research projects. All research applications and outputs will display the corporate identity of the Centre.

The Director
The role of Director of the new Centre will be to lead, co-ordinate and integrate the multi-disciplinary research activity within the Centre. The Director will have
responsibility for generating new business and for developing research career structures within the Centre to facilitate a significant expansion of all projected activities in the area. It is proposed that the first Director of the new Centre will be for an initial tenure of five years.

**Governance**

The Centre will have its own internal management structure centred on the pivotal roles of the director and the Management Committee, and supported by an Advisory Board. The Director of the Centre will be advised primarily by the Management Committee which will develop the Centre’s research, training and education priorities and assist with fund raising. It will consist of five members as follows:

- The Director of the Centre
- One member appointed by the University Management Team
- Three members drawn from core collaborating departments

The functions of the Advisory Board are to provide strategic guidance to the Centre going forward, to assist with fundraising initiatives and to help raise the Centre’s profile nationally and internationally. The Advisory Board will consist of a number of members as follows:

- Several members drawn from the senior staff of the University and working in fields that are germane to Patient Safety;
- Individuals with considerable experience and eminence related to patient Safety from outside the University and representing a range of constituencies such as the public sector (HSE), the private sector and other research centres with which the Centre may develop strategic alliances;
- The Director of the Centre;
- A representative from the University Management Team who will act as Chairperson of the Advisory Board.

The exact size of the Advisory Board is still to be decided.

**6. Project Risks and Barriers**

The project is building on the already substantial achievements of the key individuals and the interest of the clinical partner. The Centre is likely to secure funding through the coordination of service work within the Private and Public sector, both locally within the Western region and further. The Centre will be ideally placed to participate in future funding. The networks and relationships necessary to carry out such collaborative work already exist within NUI, Galway, and the new Centre will provide the focus for greater multi-disciplinary output within the larger area of Technology within the Irish health care system.

The fact that the new Centre will have a significant focus on the clinical aspects of Medical Technology will complement existing developments elsewhere such as those of the National Centre for BioEngineering Science in NUI Galway. Up to now, there has been no research group or agency focusing specifically on the role of Medical
Technology in Health Care. Consequently, research and developments from the new Centre will be new and innovative for Ireland.

7. Evaluation

Evaluation by peer review, involving internationally renowned experts, will be undertaken at five-year intervals. Initial performance will be measured against the objectives outlined in this proposal. The continued appropriateness of the work programme to meet these objectives and to attaining the Centre’s mission will be thoroughly assessed. The extent by which the Centre will meet it’s will represent the bottom line in the evaluation.

Key outputs or benchmarks in the evaluative process will include:

- Publication output by the Centre;
- Existence of under-graduate and post-graduate programmes in Patient Safety;
- Volume of contract research and rate of increase in contract income;
- Outreach activity and feedback from stakeholders such as public and private health care providers;
- Development of comprehensive information networks and dissemination processes;
- Invited conference papers

Programme evaluation will be organised by the Dean of Research in consultation with the Advisory Board of the Centre. The evaluation will be paid for mainly out of contract research income generated by the Centre. The Review Group will be comprised of external academic examiners along with professional practitioners in the field and will report to the President of the University.

The Director of the Centre will be responsible for data collection for the evaluation process. This will necessitate the collection of qualitative and quantitative data relating to the performance and activities of the Centre. The Centre will publish an annual report which will be incorporated into the President’s Report for NUI, Galway. The benchmarks for evaluation will be elaborated upon in the Strategic Plan for the Centre which will be published by the Director in the first 3 months of his tenure.

The Management Committee of the Centre for Patient Safety will be notified of the evaluator’s judgements and will implement any corrective action or adjustment which may result from the evaluative process.

8. Leverage, Sustainability and Communication

Funding for projects carried out by the founding members of the Centre has in the past has come from a wide variety of agencies including the Health Research Board, the HSE and Enterprise Ireland. Individual researchers across the various relevant disciplines at NUI Galway have also succeeded in the past in raising both small and large grants in a time of fewer opportunities for research, which positions them well to capture an increased share of any additional funding available. Through the
concentration and integration of existing research strengths, the new Centre will enable researchers in the clinical physics and engineering area in the University to compete even more successfully for funding in the highly competitive national and international research arenas.

Members of the Centre who have existing research links will be encouraged to develop these relationships further within the framework of the new entity. Potential members of the new Centre may already be active participants in other units or centres within NUI Galway and elsewhere. There will be no difficulty in maintaining or extending involvement in other centres and individuals will be free to develop their own research strategies as appropriate, while continuing to play a role in the development of the Centre for Patient Safety.

A number of formal cross-border links will be explored in the context of developing competitive inter-institutional strategies for the maximisation of research opportunities and funding for the Centre on the island of Ireland. The Centre will also encourage and accommodate visiting scholars from abroad and will actively and strategically encourage their involvement in research activities within the University and the country.

The Centre for Patient Safety will act as an information repository for best practice in the field. The Centre will develop a website which will be used to promote the new Centre and to provide information on publications and seminars. The Centre will also produce regular and accessible electronic research and information bulletins addressing relevant ageing issues in a timely and contemporaneous manner.

**Conclusion**

The establishment of the Centre for Patient Safety at NUI Galway provides a timely opportunity to develop and nurture services and research in Patient Safety in Ireland. The establishment of this integrated unit, with interdisciplinary research teams, will enhance the potential and development of patient safety in the country, thereby making an important contribution to the development of high quality and safe patient care for the 21st Century. The Centre will act to underpin the pre-eminence of Galway as a centre for high technology medicine.
Bibliography


Appendix I. Current Research Projects by members of Centre in areas of Patient Safety

Development of a Systems Engineering & Error Analysis Methodology for Health Care: Systems and Error Analysis Bundle for Health Care (SEABH).

Current Status: Successfully Completed
Investigators: Dr. Liam Chadwick (NUI Galway), Mr. Enda Fallon (NUI Galway)

In this research project the use of tools and techniques from safety-related systems engineering in the analysis of health care treatment processes was investigated. The research aim was to establish an integrated set of tools that could be used by healthcare stakeholders to proactively and systematically analyse existing and developing treatment processes for potential system failures and human errors. The tools would provide greater supporting information, be more efficient and of higher quality than existing tools or methods. The resulting ‘SEABH’ methodology includes a flowchart which guides the analysis, taxonomies of human error and related potential causes and a detailed healthcare specific risk assessment tool. The method supports the identification of error related Performance-Shaping Factors (PSFs) and Psychological Error Mechanisms. It directly links the identified human errors to potential causes and supports the determination of appropriate control measures. The validation of the methodology has been supported by two application cases: The first was a Low Dose Rate prostate brachytherapy using real time planning and the other was a prescription administration process in a cardiothoracic unit.

A list of publications associated with the project is contained below.

A Systems Safety Approach to the Management of Medical Equipment

Current status: Ongoing
Investigators: Dermot Hale (PhD Researcher), Mr. Enda Fallon (NUI Galway)

This research examines the management of medical equipment in healthcare using programs, tools and techniques of systems engineering, human factors engineering, risk management, quality management, environmental management and Lean Six Sigma. The research aim is to develop an original standard that can be used by healthcare stakeholders to systematically and efficiently manage medical equipment from procurement to end-of-life disposal. The developed standard will be designed to serve the financial and patient safety needs of healthcare providers. Currently the tools, techniques and concepts underpinning standards related to safety, quality, risk, efficiency and the environment are being analysed in detail. Subsequently, conventional safety-related systems and equipment management programmes of other safety critical industries such as aviation, offshore and power generation will be studied. The first stage of the research fieldwork will involve unstructured brainstorming meetings with subject matter experts and with current stakeholders of the medical equipment management process in healthcare. These meetings, together with the literature review, will identify critical considerations and potential techniques for use in the proposed standard. Development of the standard will involve on-going consultation with identified experts through the use of the Delphi method or expert review methods.
Upon completion, the standard will be validated by using the Validation Square, a prescriptive tool for the validation of new methods, and tested using case studies; most likely in applying the standard to the management of radiotherapy equipment in University College Hospital, Galway.

Radiation Oncology System Safety Analysis (Rossa)

Current Status: Ongoing
Investigators: Mr. Gordon Sands (PhD Researcher), Mr. Matjas Galicic (PhD Researcher), Prof. W.J. van der Putten (Galway University Hospitals and NUI Galway), Mr. Enda Fallon (NUI Galway)

Although Radiotherapy is a safe way to deliver very effective treatment of cancer, the potential for errors and mishaps has been well recognised and is of real concern as recent media reports have shown. Radiotherapy is currently going through a rapid technological change with for example the introduction of Intensity Modulated Radio Therapy and Image Guided radiotherapy. This allows for more accurate treatment delivery but also increases the potential for errors. The aim of ROSSA is to develop a set of workable tools for use within a radiotherapy department which allow the users of such a department to analyse risks and hazards in a systematic manner and taking account of the actual patient and data flow. This will result not only in safer and more accurate radiotherapy but will also be of benefit not just to the patient itself but also to society at large due to improved treatments and outcome. The methodology reported here will also be of benefit to a large number of other areas in health care as ROSSA can be adapted to such diverse clinical information systems as Radiology (PACS), Clinical information Systems in ICU and Cardiology. The overall benefit of ROSSA would be a Risk assessment system in health care which will be based on standards formed in industry where safety and risk assessment has been considerably more developed such as the Nuclear, petro-chemical as well as the Aviation industry.

A Human Factors Analysis of Two Common Robotic Surgery Procedures

Current Status: Ongoing
Investigators: Mr. Enda Fallon (NUI Galway)

The purpose of this study is to identify and analyse the steps taken by a surgeon to conduct two procedures: a prostatectomy and oophorectomy using the DaVinci robotic surgery system. These results of this task analyses will then be used to identify the potential for error, and the risk associated with these errors at each step of the two surgical procedures. The external error modes used in the Observational Clinical Human Reliability Assessment (OCHRA; Tang et al, 2004) will be used for this purpose. OCHRA was developed to capture observable errors in laparoscopic surgery and should be applicable to robotic surgery. The OCHRA method has ten generic external error mode types. The first six correspond to the ability of the surgeon to execute the component steps in the correct order and, hence, these are collectively grouped as “procedural error modes”. In contrast, external error modes 7 through 10 reflect manipulations with the robot arms instruments by the surgeon to execute a specific component step of the operation and are categorized as “execution error modes.” This distinction is of practical importance because it determines the nature of
the prescriptive error-reduction system specific to the operation. Execution errors can be reduced by better training of operative skills and by improving instrument design; whereas, procedural errors can be minimized by improving the knowledge that ensures the correct choreography of execution, that is, the surgeon performs the component tasks (Tang et al, 2004). Once the potential errors have been identified, the surgeons will then categorise each error on the basis of the severity and probability of the error.

This study will provide a detailed understanding of the two procedures analysed and identify the potential risk associated with each step. It is suggested that this information is valuable when training to carry out the procedures, and in particular identifying high risk steps in the procedure.


A Comparison of Performance of Medical Students on Surgical Robotics and Laparoscopic Training Drills

Current Status: On-going

Investigators: Dr. Marion Hartmann (NUIG surgical trainee), Dr. Paul O’Connor (NUI Galway), Mr. David Bouchier-Hayes (urology, Galway Clinic), Mr. Mo’iad Al-Azzam (gynaecology, Galway Clinic)

The attributes of robotics, such as motion scaling, three-dimensions visualisation, and articulated instrumentation, provides a surgeon with more dexterity in carrying out a procedure than traditional laparoscopy. With only four of six degrees of freedom in laparoscopic surgery, the acquisition of the skills is time consuming and difficult, and in some cases may never be mastered. In contrast, a small number studies, with low numbers of participants, suggest that robotic surgery allows surgeons to acquire the skills necessary to carry out reconstructive procedures much more easily than is the case for laparoscopic surgery. Robotic technology allows the surgeon six degrees of freedom and the ability to throw and tie a laparoscopic knot with the same dexterity as the human hand. This study will evaluate the performance of medical students carrying out the training drills with laparoscopic instruments and the DaVinci robotic surgery system.

Levels of Automation in Radiotherapy

Current Status: Ongoing, PhD Researcher appointed

Investigators: Mr. Enda Fallon (NUI Galway)

Radiotherapy is a discipline that is changing rapidly, primarily as a result of developments in technology. For example, vision systems such as Computerised Tomography (CT) and Magnetic Resonance Imaging (MRI) have improved diagnostic capabilities and Intensity Modulated Radiotherapy (IMRT) and Image Guidance Radiotherapy (IGRT) have enabled more accurate treatment planning and delivery of treatment doses. However, the development of new technologies means that new possibilities for errors can occur. Adverse events can be attributed to errors by human
operators, system technology, or by the interaction between the two at different work organisation levels and at different stages of the working process. Errors or failures in radiotherapy do not occur frequently, however, when they do occur, the consequences for the patient can be significant. It is very important to develop and to apply appropriate tools that can help to identify errors prior to the design of and during the operation of radiotherapy systems. It is also important to look at the whole process from the standpoint of systems safety engineering, that is, to look at it as a system as a whole, and to apply appropriate tools, methods and techniques to it – especially Human Factors techniques.

The current research is focused on the application and development of Levels of Automation (LOAs) models for radiotherapy (Sheridan and Verplank, 1978), (Parasuraman, Sheridan and Wickens, 2000); that is, how users (usually staff working with computers and hi-spec machines, such as CT machine, Linear Accelerator, etc.) interact with automated systems. With applying LOAs at the task level, it should be possible to identify how users’ and automated systems’ tasks are allocated, and what kind of impact LOA has on working processes, i.e. work organisation, working roles, levels of responsibility etc. (Fallon, Chadwick and van der Putten 2010). It will enable the identification of new potential errors that could occur when automation systems (or parts of) are changed or upgraded and also help to develop error reduction strategies.

Currently there are no LOA models that are directly applicable to the radiotherapy domain or healthcare in general. Different LOA models have been developed in the last 3-15 years for the military, aerospace, and manufacturing domains.


A comparison of the teamwork attitudes and knowledge of Irish surgeons and U.S Naval aviators.

Current Status: Complete
Investigators: Dr. Paul O’Connor (NUI Galway), Prof Ivan Keogh (ENT), Dr. Stephen Ryan (ENT)

Poor teamwork skills are contributors to poor performance and mishaps in high risk work settings, including the operating theatre. A questionnaire was used to assess the attitudes towards, and knowledge of, Irish surgeons (n=72) towards the human factors that contribute to mishaps and poor teamwork in high risk environments. The responses were compared to those obtained from U.S Naval aviators (n= 552 for the
attitude questions, and \( n = 172 \) for the knowledge test. U.S. Naval aviators were found to be significantly more knowledgeable, and held attitudes that were significantly more positive towards effective team working than the surgeons. Moreover, 78.9\% of Senior House Officers and Registrars stated that junior personnel were frequently afraid to speak-up (compared with 31.3\% of Consultants). Only 7.3\% of surgeons stated that an adequate pre-operative brief team brief was frequently conducted, and only 15\% stated that an adequate post-operative team brief was frequently conducted. It is suggested that although the human factors training provided to surgeons in Ireland is a very positive first step. However, there is a need to stress the importance of assertiveness in juniors, listening in seniors, and more reinforcement of good team working behaviours in the operating theatre.

**An evaluation of the effectiveness of a pre-internship training programme**

Current Status: Complete

Investigators: **Dr. Paul O’Connor (NUI Galway)**, Dr. Dara Bryne (HSE West Intern Coordinator), Sinead Lydon, Prof. Michael Kerin (Surgery)

Despite the need for a well prepared intern, a consistent finding in the literature is that new interns often do not possess the basic clinical skills required to perform their job effectively. Training designed to prepare newly graduated medical students for internship was developed and delivered to 106 students. The course was delivered over 19 days and the content of the training was based upon a survey of interns, the requirements of the Irish National Intern Training Programme curriculum, and the domains of good professional practice identified by the Medical Council of Ireland. The training was found to be positively received, with the students reporting higher levels of preparedness for internship after the training as compared to before the training. The largest effect size of the training was for the administration of medication. However, the participants desired less lectures and more opportunities to practice the clinical skills and procedures taught in the training. The findings also indicate a need for further training on clinical decision making and emergency management. It is suggested that this training course could serve as a model to address the unsatisfactory levels of preparedness for internship consistently reported by medical students from many different countries.

**An evaluation of levels of stress of Irish medical students and interns**

Current Status: On-going

Investigators: **Dr. Paul O’Connor (NUI Galway)**, Dr. Dara Bryne (HSE West Intern Coordinator), Dr. Camilla Murtagh, Sinead Lydon, Prof. Michael Kerin (Surgery)

Assessments of the level of stress in medical students and interns have consistently been found to be high. However, these studies have almost exclusively been carried out in the U.S., with few studies carried out in Europe, and none in Ireland. The purpose of the study is to assess levels of stress in medical students and interns. This project is pilot study for a larger HRB proposal to assess and mitigate stress in interns. Data was collected from 209 medical students (representing all years of undergraduate medical training) and 102 interns using the 12 item general health questionnaire (GHQ). This data will allow a comparison to be made with norms from
other populations and levels of stress reported by medical students and interns from other countries. It will also allow a comparison of levels of stress between students and interns in different levels of medical training at NUI Galway.

**Human Factors Training For Interns**

Current Status: On-going  
Investigators: Dr. Paul O'Connor (NUI Galway), Dr. Dara Byrne (HSE West Intern Coordinator), Prof Michael Kerin (Surgery)

The purpose of the training is to provide interns with a foundation of human factors knowledge and how it related to safety and quality of patient care. The aim is to educate the interns in the identification of threats, errors, and how to mitigate them. The goal is for the training to be interactive with a practical focus. The structure of the training will be based upon Helmreich and colleagues threat and error management model. This model was developed for aviation, but has been adapted to a healthcare environment. The model takes a systems approach to patient safety and considers the latent and immediate threats, strategies to manage these threats, and processes to manage error. Initially the training will be piloted with Interns in the Western Health Board. However, given the lack of human factors training available for intern, it may then be extended to train of interns in other health boards in Ireland.