EXPLORATION, DESIGN AND APPLICATION OF

SIMULATION BASED TECHNOLOGY

IN

INTERVENTIONAL CARDIOLOGY



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ABSTRACT

Medical education is undergoing a vast change from the traditional apprenticeship model to technology driven delivery of training to meet the demands of the new generation of doctors.

With the reduction in the training hours of junior doctors, technology driven education can compensate for the time deficit in training. Each new technology arrives on a wave of great expectations; sometimes our expectations of true change are met and sometimes the new technology remains as a passing fashion only. The aim of the thesis is to explore, design and apply simulation based applications in interventional cardiology for educating the doctors and the public.

Chapters 1 and 2 present an overview of the current practice of education delivery and the evidence concerning simulation based education in interventional cardiology. Introduction of any new technology into an established system is often met with resistance. Hence Chapters 3 and 4 explore the attitudes and perceptions of consultants and trainees in cardiology towards the integration of a simulation based education into the cardiology curriculum.

Chapters 5 and 6 present the "i-health project," introduction of an electronic form for clinical information transfer from the ambulance crew to the hospital, enactment of case scenarios of myocardial infarction of varied levels of difficulty in a simulated environment and preliminary evaluation of the simulation. Chapter 7 focuses on educating the public in cardiovascular diseases and in coronary interventional procedures through simulation technology.

Finally, Chapter 8 presents an overview of my findings, limitations and the future research that needs to be conducted which will enable the successful adoption of simulation based education into the cardiology curriculum.

How many things are looked upon as quite impossible until they have been actually effected? Pliny the Elder

DEDICATION

I dedicate this work to my parents, husband and to my son

Individual	Mission statement
Mother	Knowledge is power
Father	Work is worship
Husband	Strive for perfection
Son	Always be the best – Number One

An investment in knowledge pays the best interest – Benjamin Franklin

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Project: Information driven optimisation of care pathways and procedures

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DECLARATION OF ORIGINALITY

I hereby certify that the work in this thesis was carried out in accordance with the requirements of the University Regulations and Code of Practice for Research Degree Programmes and that it has not been submitted for any other academic award. The work is the candidates own work. Work done in collaboration with, or with the assistance of others, is indicated as such. Any views expressed in the thesis are those of the author.

Signature:

Date:

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Signature:

Date:

The deepest sin against the human mind is to believe things without evidence Thomas H Huxley

LIST OF PEER REVIEWED PUBLICATIONS AND PRESENTATIONS

Scientific Papers

- Kesavan S, Malik I, Mayet J, Bello F, Sevdalis N, Kneebone R
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- Public education through simulation in cardiology
- Perception of consultants and junior doctors towards simulation based learning and training in cardiology

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- Factors affecting successful design and implementation of clinical information systems in healthcare
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- The Big Bang, NEC, Birmingham, March 15th 17th, 2012
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- The Imperial Festival, Imperial College London, South Kensington, London, 11th-12th May, 2012
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- Asia PCR / Sing Live, Singapore, 24th 27th January, 2013
- London Postgraduate School of Surgery: The EVAR Workshop 7th December, 2012
- Introduction to SPSS 2012
- Innovation and Entrepreneurship development 2012
- Research Skills Development Course Residential -2012
- Imperial College Finance Society Goldman Sachs 2012
- ASPiH Simulation Conference Oxford November, 2012
- Acute Cardiac Care Istanbul, Turkey October, 2012
- EuroPCR, Paris May, 2012
- Vascular and Endovascular update Charing Cross Symposium April, 2012
- Advanced Cardiovascular Interventions ACI Jan, 2012
- British Thoracic Society Winter Meeting 2011

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Chapter 1: Introduction

<u>1.1 Medical Education</u>

Medical education is an important aspect during the training and assessment of junior doctors. The approach to medical education has undergone a series of developments since inception, in parallel with the advancement of digital technology and communication. Traditional approaches to teaching medicine to medical students involved bedside teaching in the presence of the patient and didactic lectures. Any interventional procedure in medicine was learnt through apprenticeship – hence the culture of "See one, Do one, Teach one" has prevailed (1).

Modern approaches to medical education have involved case based learning, problem solving, multiple choice questions and on line learning (2). Interventional procedures can be visualized in high definition in two and three dimensional modes (3) by accessing the relevant websites (<u>www.youtube.com</u> – Interventional Cardiology – Minimally Invasive Procedures). Positive developments in the field of electronics and computing have led us into an age of simulation, where the representations of computer generated images are almost as accurate as the real ones. There is therefore an avenue for teaching and learning interventional procedures in cardiology by simulation, which could become a central part of medical education and accreditation.

The health care industry in the USA includes millions of practitioners who participate in on going education, training and certification in medicine (3). The aviation industry has incorporated flight simulator training and accreditation as a mandatory part of their

curriculum for many years (4). It helped them to review, reflect or rehearse their performance in a virtual world and made complex training - simpler, safer and cost effective. Difficult technological challenges have limited the use of virtual reality in medicine. Medical simulators use computer graphics and robotics technology to simulate real patients with anatomical and physiological features and complications. These systems provide an opportunity to assess both cognitive decision making skills and motor skills involved in interventional procedures (3).

Within healthcare, simulation is becoming an integral part of teaching, training, assessment and or accreditation in the following specialities in the UK – Anaesthetics (5 - 10), Interventional radiology (11 - 14), Neurosurgery (15 - 18) General Surgery / Endovascular surgery (19 – 25) and Otolaryngology (26 – 29).

Simulation is a technique to replace real patient experiences with guided experiences, artificially contrived, which evokes or replicates substantial aspects of real world in a fully interactive manner (30). It is a mechanism which enables predictions to be made about physical process, interaction or event in the real world: tools include defined clinical scenarios, bench top silicon models, virtual reality simulators, actors, animals, cadavers and computer-based virtual environments. Introduction of simulation based education in medicine creates opportunities for trainees and teams to learn skills through repetitive, constant, deliberate practice in a safe environment, remote from patients. Department of Health: A framework for technology enhanced learning document provides guidance to help commissioners and providers of health and social care deliver high quality, cost effective education and training (www.gov.uk).

Distributed Simulation (DS) and Sequential Simulation (SS) are well established. DS involves the simulation of small parts or units of the entire scenario whereas SS involves simulation of the entire sequence of the events or the entire scenario itself (31). Distributed simulation is an open standard for conducting real time platform level war scenarios across multiple host computers designed for training military personnel (32).

Currently, interventional cardiology trainees in the UK do not have adequate exposure to learning by simulation. This raises a potentially important concern due to changes in the working pattern of junior doctors. The competence of the doctor comes into question with the reduction in the hours of training during a stipulated time. Therefore, learning by simulation in cardiology could help interventional cardiologists to establish and maintain skills, effectively introduce new procedures and may provide a basis for evaluation of quality of care.

<u>1.2 Interventional Cardiology</u>

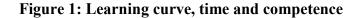
The European Society of Cardiology (ESC), in its core curriculum update 2008 acknowledged that simulation training promises to play an increasingly important role in technical skills training and will likely reduce the numbers of actual procedures to which a trainee must have direct exposure to achieve competence - (33). There are 3 levels of competencies defined by the ESC Levels 1, 2 and 3 (Table 1).

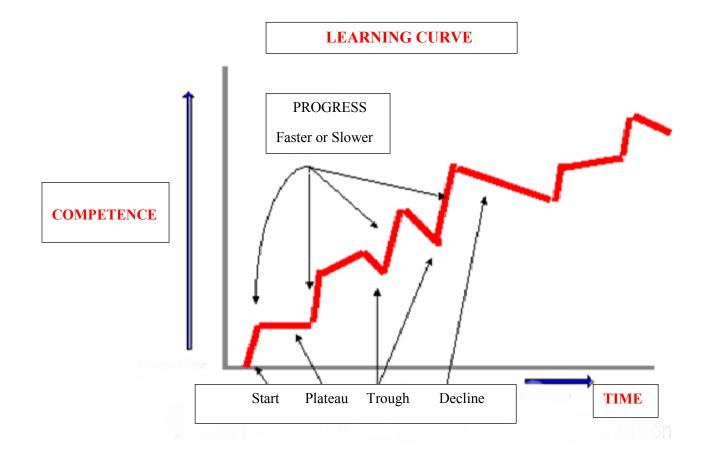
Table 1: Levels of competency

LEVELS	COMPETENCY			
	Experience of selecting the appropriate diagnostic modality and interpreting the results or choosing an appropriate treatment for which the patient should be			
Level 1 the results of choosing an appropriate treatment for which the patient show referred. This level of competency does not involve performing the technic				
	Practical experience but not as an independent operator and has assisted in or			
Level 2	performed a particular technique under the guidance of a supervisor,			
	Is able to independently perform the technique or procedure unaided. A trainee			
Level 3	should have performed 300 diagnostic cardiac catheterisation and 50			
	percutaneous coronary interventions during their training period.			

Completion of the cardiology training programme by a trainee will enable him or her to perform diagnostic cardiac catheterisation with Level 3 competence and percutaneous coronary interventions with Level 2 competences (33).

Training and competency are two different entities. A junior doctor can be trained but may not be competent enough to perform the procedure independently at a specific period of training. The difference is due to the heterogeneous nature of the "learning curve" of each individual and the "learning methodology" used by each individual to acquire knowledge and competency. A learning curve (34) is far from a straight progression (Figure 1).





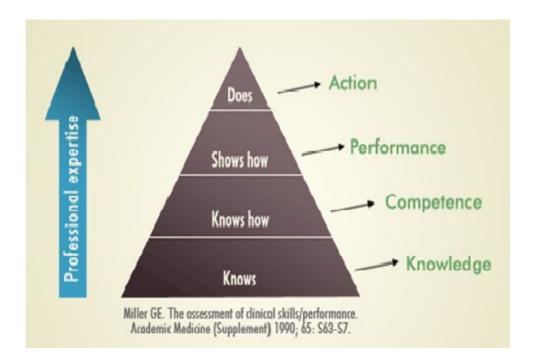
The Reynolds model (<u>www.learningandteaching.info</u>) of developing competence involves 6 stages – Help, Have a go, Hit and Miss, Sound, Relative Mastery and Second Nature. Linked to the Reynolds idea (1965) is the popular "progression of competence" model (Table 2).

 Table 2: Stages of competency

STAGES	COMPETENCE
Stage 1	Unconscious incompetence
Stage 2	Conscious incompetence
Stage 3	Conscious competence
Stage 4	Unconscious competence – the most desirable state

"Miller's Pyramid" (Figure 2) is a useful and a simple way of describing levels of competence. This describes the progress from 'Knows,' which reflects applied knowledge through to 'Knows How,' which requires more than just knowledge to 'Shows How,' which requires an ability to demonstrate a clinical competency through to 'Does' - which reflects what the doctor actually does in the workplace (35).

Figure 2: Millers Pyramid



The process of procedural skill acquisition in the present era of a changing clinical and regulatory environment is radically different from the residency programmes of the yester years (36). Trainees have to demonstrate proficiency in technical and non-technical skills (Communication, leadership, management and team work). Shortened training programmes, public scrutiny and greater accountability have resulted in a paradigm shift in the way doctors

are trained (37). Hence an evolving conclusion is that procedural training on a virtual reality simulator presents a viable adjunct to conventional training methods.

Virtual reality (VR) simulation is a powerful, effective and measurable approach to skills learning in complex tasks (38), as demonstrated by the aviation industry. It facilitates the trainee to rehearse, review and reflect on his/her performance in a risk free environment with a quantifiable, measurable outcome associated with a proximate feedback – these features make VR simulation a powerful and an effective tool in the process of learning procedural skills in medicine (39).

Commercial virtual reality (high and low fidelity) simulators are available in cardiovascular medicine (39) which may help us to develop a standardised, structured simulation training programme in partnership with the industry. Previous research conducted by the research group at Imperial College London has highlighted the importance of simulation based training in endovascular surgery and general surgery (40 - 45).

1.3 Research questions

The complexity involved in teaching methods, skills acquisition and the evolving technology in delivering training modules in interventional cardiology resulted in many broad questions. These are as follows:

- What are the best ways to integrate simulation based education and applications into interventional cardiology?
- What is the available evidence base on the above questions?

- What are cardiologists' views on simulation based education and applications in cardiology?
- What are the ways in which simulation and information technology can help in the care of patients with cardiovascular problems?
- How to use simulation for public education in cardiovascular diseases?

The answers to the above questions forms the basis of my thesis - which is a preliminary work exploring the field of simulation based education and applications in interventional cardiology.

1.4 Thesis: Aims and objectives

Based on the questions above, the aim of this thesis is to systematically explore the role and potential of simulation applications within the context of interventional cardiology. Specific aims are as follows:

- To analyse the background research conducted in the field of simulation training in interventional cardiology
- 2. To understand the views of senior consultant cardiologists and junior doctors concerning interventional training in cardiology by simulation
- 3. To explore the potential of simulation as a 'test-bed' for a newly developed computer assisted health care information transfer dashboard (electronic form) to be used by interventional cardiologists in handover situations
- 4. To develop viable teaching and training scenarios to be conducted in simulated environments

5. To develop clinical case scenarios integrating technology in cardiology to educate the public in cardiovascular diseases through simulation

1.5 Structure of the thesis

The thesis is structured into 8 chapters. Chapters 1 and 2 provides an introduction to medical education and focuses on the available evidence in various other specialities, including general surgery, endovascular surgery and interventional radiology. The current status of training in interventional cardiology is discussed with a suggestion of a framework for training by simulation. The paucity of literature concerning simulation based education in cardiology is highlighted. Chapters 3 and 4 involve qualitative (interviews) and quantitative (questionnaire survey) methods of analysis to understand the perception of consultants and trainees in cardiology towards a simulation based education.

Chapter 5 explores the need for the integration of technology into cardiology for swift transfer of critical, clinical information from the community to the cardiac catheterisation lab. Furthermore, the design, usefulness of an electronic form (e-form) and the electronic dashboard (iPad) are discussed.

Chapter 6 deals with the design and the development of five clinical scenarios of a patient with an acute myocardial infarction (a heart attack) and testing the pathways of care in a simulated clinical environment. The handover process between the ambulance team and the cardiology registrar on call is explored in detail in a simulated environment. Evaluation of the simulation, electronic form and the handover process are conducted. The evidence is further validated by interviewing the participants after the enactment of the case scenarios. A preliminary attempt at designing case scenarios dealing with complications and complexities during interventional procedures in the catheterisation lab is detailed in the final section of the chapter.

Chapter 7 provides an insight into an innovative way of educating the public about cardiovascular diseases through simulation. The focus is on the sequence of events following a chest pain, starting from the 999 call made by the simulated patient.

Finally, Chapter 8 is a summary of my work within this thesis, with focus on future research in the expanding field of simulation in cardiology.

Chapter 2: A literature review on simulation based education in cardiology

2.1 Chapter overview

In Chapter 2, I present a narrative review of the current evidence regarding simulation based education in cardiology, general surgery, vascular surgery and interventional radiology. The current status of training by simulation in interventional cardiology in the UK is discussed and a framework of training is proposed. The review will provide an unbiased view of the pros and cons of a simulation based education, enabling us to design a robust simulation based training programme in the future.

2.2 Introduction

Training in cardiology includes a period of general medical training, basic general cardiology training in peripheral hospitals and culminates in advanced training in the tertiary centres. During this period, trainees undertake a period of research leading to an academic degree and fellowship programmes in the UK or abroad to broaden their experience. Trainees need to acquire and demonstrate their skills in various aspects – academic, clinical, procedural, managerial and psychological competence to deal with a demanding profession of being a consultant cardiologist (46).

As explained in Chapter 1, the basic skill set and learning curves vary from an individual to individual. With such complexities involved, it is challenging for the educators and training programme directors to design a training programme which suits all the trainees. Combined with the pace of scientific advancement in cardiology with the reduction in training hours of the junior doctors, it is a daunting task to balance clinical and training commitments for the

trainer and the trainee. Hence, trainees need to utilise their training period productively and greater emphasis should be made on self-directed learning.

Learning by simulation bridges the gap between an apprenticeships based training and selfdirected learning. Simulation based education may remain as the second step in the learning process, followed by self-directed learning. This methodology of learning has been tested and adopted in many specialities in medicine and surgery. Trainees have been exposed to simulation based learning (www.limit.ac.uk) during their general medical core training period. Examples include - chest drain insertion (47) and ALS courses conducted by the Resuscitation Council, UK (www.resus.org.uk). This training methodology of simulation based learning should extend through their cardiology training programme (48).

The present chapter provides a narrative review of the current literature in interventional cardiology, interventional radiology and in surgical specialities (general surgery and endovascular surgery).

2.3 Aims

The aim of this chapter is to review the available evidence concerning training by simulation in interventional cardiology, general surgery, interventional radiology and endovascular surgery. Recommendations by the NICE (National Institute for Clinical Excellence), BCS (British Cardiac Society), BCIS (British Cardiac Interventional Society) and ESC (European Society of Cardiology) are reviewed. Commercial simulators in cardiology and state of the art simulation training centres in cardiology in Switzerland and Sweden are explained. A simulation based training framework is proposed and barriers towards implementation are discussed. Solutions are suggested which will enable a successful integration of simulation based learning in cardiology.

2.4 Methods

Literature search methodology

An electronic database search was conducted using Medical Subject Headings (MeSH) in MEDLINE, EMBASE, PubMed Central and the Cochrane database. The search was conducted using the key words – Simulation, Virtual Reality, Education, Interventional, Cardiology, General Surgery, Endovascular Surgery, Radiology, Learning and Training.

2.5 Results

Evidence from Interventional Cardiology

I found no literature concerning clinical trials, methodological studies, technological assessment and economic evaluation or Cochrane groups concerning training by simulation in interventional cardiology (IC) in the Cochrane database (Table 3).

	Interventional Cardiology	Endovascular surgery	General Surgery	Interventional Radiology
Cochrane Database	0	3	5	1
PubMed Central	18	20	290	33
Ovid MEDLINE (EMBASE, EMBASE Classic)	7	51	378	45

Table 3:	Citations	in the	database
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Author	Type of publication	Focus of the article	Design of the study	Key Findings	Conclusions	Journal
Yambe et al (1998) Tohoku University, Japan	Article	PTCA Simulator system –as an Educational Tool	Research – Technical Report	3D coronary anatomy + virtual PTCA simulator	Simulators provide a complementary learning tool in cardiology	Artificial Organs
Wang et al (1998) Kent Ridge Digital Labs, Singapore	Article	Simulator – Educational Tool – I Card (Interventional Cardiology Simulation System)	Research – Technical Report	Useful for training, designing and for pre procedural planning	Software provides 3D human vasculature Real time catheter / guide wire navigation system	Computer Aided Surgery
Dawson et al (2000) Massachusetts Gen Hospital, Boston, USA	Review	Design a simulator for interventional cardiology training	Research - First report - Review	Geometric / physical modelling, Haptic and rendering	PC based simulator + synthetic fluoroscopy with real time 3D and interactive anatomic display	Cath & Cardiovscular Interventions
Cotin et al (2000) Virtual Inc Boston, USA	Article	Interventional Cardiology Training System (ICTS)	Research – Technical Report	Fluid flow with haemodynamic model + 3D anatomy	Computer simulation of interventional cardiac catheterisation (including a beating heart and animated lungs)	Studies in Health Technologies & Informatics

Table 4: Citations related to Interventional Cardiology

Shaffer et al (2001) Massachusetts Gen Hospital, Boston, USA	Review	Design Principles - use of simulation – as an aid in interventional cardiology training	Review – Simulation Engine, Curriculum and system analysed	Recreation, replication, reconfiguration, reference, review, reflection of simulation	Successful training tool – real time graphic interactivity with haptic response Designing simulation with technical and pedagogical fidelity	Min Invas Ther & Allied Tech
Winder et al (2004) University of Ulster, Northern Ireland, UK	Article	VIST – Face Validity (Vascular Interventional Training System, Mentice)	Research – real time image data from patients. 20 image settings tested	Calibration curves determined accurate VIST image setting	Real image data compared with VIST image data VIST – a validated tool for simulation	Studies in Health Technologies & Informatics
Lake et al (2005) Verifi Technologies, PA	Narrative Review	Simulation in Cardiology, cardiothoracic and vascular surgery	Narrative review of surgical simulation technology	Learning by simulation – is only a part of the training	Review of available cardiac surgical simulation technology Issues with validation and general acceptance discussed.	Seminars in Cardiothoracic & Vascular anaesthesia
Dangas et al (2008) Columbia University Medical Center, New York, USA	Article	Recertification in Interventional Cardiology	Philosophy and steps to recertification - a narrative	Home study modules PIM – Practice Improvement Modules Assessment – goes beyond manual dexterity	Knowledge based examinations discussed Quality improving activities - re - certification issues are not clearly defined.	JACC: Cardiovascular Interventions

Schuetz et al (2008) University of Mainz, Germany	Article - Technical Report	High degree realism - combination of VR trainer and patient simulators	4 case scenarios – 143 participants Method A – Hardware Method B - Software	Method A and B synchronisation – resulted in a close reality situation	2 methods of heart beat synchronisation between 2 simulator devices tested. CATHI system – more realistic	Simulation in HealthCare
Makoto et al (2011) Kokura Memorial Hospital, Japan	Article - Conference Abstract	Efficacy - new simulation system – PCI training and evaluation Scoring system – CVIT - Cardiovascular Intervention and Therapeutics	8 residents and 4 interventional cardiologists - Group A, B, C. Scoring by an interventional cardiologists - blinded to groups	Group C (experienced interventionists) better than Group A (Lecture only) and B (Lecture + simulator training)	Whole body irrigatable PCI simulating vascular model – an useful tool for training and evaluation of PCI techniques	Journal of American College of Cardiology
Voelker et al (2011) Universitat Sklinikum, Germany	Article	Simulators & Criteria for quality improvement in VR for coronary diagnostic interventions	Conditions required for an implementation of a validated simulator based training programme	Learning objectives, curriculum, dedicated teachers, feedback and guidance - essential	High and low fidelity simulators are necessary Simple Mechanical Model – for puncture training VR simulator + mannequin – for team training, crisis	Herz (German)

Lipner et al (2010) (American Board of Internal Medicine)	Assessment of technical and cognitive skills - non randomised, voluntary participation study	115 physicians in 10 US HealthCare Institutions 6 test scenarios - SimSuite	90% subjects – cases were well simulated Scoring – by clinical nurse specialists.	P < 0.001 Able to differentiate between a novice, skilled and an expert	Simulation in HealthCare
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25 articles were retrieved in total from PubMed, PubMed Central and from Medline. 12 articles with varied focus in interventional cardiology were identified (Table 4) from the 25 articles. 6 articles were duplicate and the rest focused on carotid and peripheral artery stenting performed by vascular surgeons.

A review article by Dawson et al (49) and Shaffer et al (50) stress the importance of design principles and designing a structured training programme for interventional cardiologists. An ideal simulator device should enable the transference of skills from the virtual to the real. The device should enhance the motor skills and should influence the perceptual, analytical and judicial skills of the operator.

2 citations from Boston reported on ICTS (Interventional Cardiology Training System) devised by Virtual Presence, Inc, MA, USA (51). The system consists of a simulated fluoroscope, a physics model of a catheter, a haptic interface, a fluid flow simulation combined with a hemodynamic model and a learning system integrated in a user interface. MENTICE acquired the system and developed the VIST.

The cardiology team from Singapore suggests the introduction of the ICARD (Interactive Interventional Cardiology Simulation) system which provides a three-dimensional view of the blood vessels and fluoroscopic images for real-time visualization of the catheter position. ICARD can be used for training, design of equipment for pre-treatment planning for interventional cardiology (52). Articles from Germany focused on assessing technical and non-technical skills of the operator (53, 54). The team from Belfast tested the appropriateness of image quality settings during cardiac catheterisation in simulation, thereby altering the radiation dosage to the patient. The five angiographic views were simulated on a virtual interventional training system (VIST, Mentice Medical Simulation AB, Gothenburg, Sweden) (55).

The Ovid Medline search extracted the papers described above and also articles with emphasis on carotid artery / peripheral artery stenting. Patel et al (56) analysed interventional

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cardiologists (n = 20) participating in the Emory Neuro-Anatomy Carotid Training program who underwent an instructional course on carotid angiography and performed five serial simulated carotid angiograms on the Vascular Interventional System Trainer (VIST) VR simulator. Procedure time (PT), fluoroscopy time (FT), contrast volume, and composite catheter handling errors (CE) were recorded by the simulator. An improvement was noted in PT, contrast volume, FT, and CE when comparing the subjects' first and last simulations (all p < 0.05). Test-retest reliability was high for CE (r = 0.9, p = 0.0001).

Simulated scenarios in cardiac arrest situations were analysed by Hoyer et al (57). Participants were physicians (n=46) from internal medicine departments. An ambulance was used with a manikin mimicking an acute coronary syndrome-patient developing ventricular fibrillation. Participants were randomized in three groups: 1) control, 2) guidelines, and 3) checklist. Mean time to request the driver's assistance in the patient's compartment was 154 seconds (guidelines), 86 seconds (control), and 31 seconds (checklist, P = 0.021). Hands on-fraction was higher if the driver was requested (n = 39, median 60%), than if not (n = 7, median 49%, P = 0.0428). Requesting the driver within 90 seconds related to delegation of tasks to the ambulance crew, as chest compressions and ventilations were then performed exclusively by the ambulance crew (79% and 96% of cases, respectively). Not requesting assistance made the physician perform chest compressions or ventilations exclusively by himself throughout the resuscitation attempt (29% and 43% of cases, respectively - P < 0.001). A brief discussion with the ambulance crew lead to an increase in the use of resources (assistance from the driver) and the hands on-ratio during the resuscitation attempt, as well tasks (chest compressions and ventilation) being delegated to the ambulance crew. Rehearsal

of resuscitation guidelines delayed requesting for help significantly. Increased focus on training and rehearsing communication and team skills between professionals is needed.

Technical and cognitive skills evaluation of performance in interventional cardiology procedures using medical simulation was evaluated by Lipner et al at the American Board of Internal Medicine (ABIM) (58).Clinical case scenarios were developed by a committee of experts, who defined key decision nodes, such as stent positioning, and introduced unanticipated complications, such as coronary perforation. Subjects were 115 physicians from 10 U.S. healthcare institutions at 3 levels of expertise: novice, skilled, or expert. Subjects completed a questionnaire, one practice case and six test cases on a SimSuite simulator (Medical Simulation Corporation, Denver, CO), and an opinion survey. Clinical nurse specialists rated subjects' procedural skills. The study enabled to differentiate between a novice, skilled and an expert operator (p<0.001). The expertise of the various clinical nurse specialists remains unknown.

The ABIM concluded that the use of a high fidelity simulator incorporating multiple case scenarios of different levels of difficulty with immediate feedback would complement the results of traditional assessment methods of physician ability in interventional cardiology. In 2005, the Society of Cardiovascular Angiography and Interventions (SCAI) and the American College of Cardiology were the first to include into clinical guidelines the suggestion that a metric based VR simulation training may be an acceptable training pathway for a new procedure (59).

The paucity of literature and the varied focus of different studies precludes a meta-analysis or a systematic review concerning simulation based learning and training in interventional

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cardiology. Hence, it becomes extremely important to analyse the published guidelines and recommendations by the professional and advisory bodies in the UK and Europe concerning simulation based learning in cardiology, which are discussed in the following section.

BCS, NICE, ESC and BCIS recommendations

BCS -Working group report on simulation:

The British Cardiac Society (BCS) – (www.bcs.com) has published a comprehensive report on simulation based training in cardiology in August, 2011 (www.bcs.com/pages/news) and has put forward 15 key recommendations. The main focus was on trainees acquiring competence in technical and non-technical skills, protected time for trainees and trainers, availability of suitable equipment across deaneries and on using simulation for selection, accreditation and revalidation. The BCS endorses the necessity for simulation based learning for trainees and supports the activities directed towards the delivery of training.

NICE recommendations:

The National Institute for Health and Clinical Excellence (NICE) – (www.nice.org.uk) Interventional Procedures Programme produces guidance on the efficacy and safety of new interventional procedures. The evidence used to produce guidance includes published papers on the procedures and advice from clinical specialists (Specialist Advisers), which includes specific questions about training.

Specialist Advisers state that a procedure requires particular skills and/or special training. Based on their recommendations, comments about training are often included in NICE Interventional Procedures guidance. There has been extensive debate about the nature and format of training recommendations in the independent committee which considers the evidence and advises NICE. No guidelines exist on how to stipulate training needs for accredited specialists who want to embark on new procedures. The precise types and elements of training are beyond the remit of NICE and must depend on specialist committees to define and set standards. A formal system of training for accredited specialists is likely to be necessary to satisfy the demands of governance and revalidation.Simulation will play a major role in retraining, revalidating and accrediting interventional cardiologists, embarking on new invasive procedures in cardiology (http://guidance.nice.org.uk).

ESC:

The European Society of Cardiology (ESC) – (www.escardio.org) - core curriculum update 2008 states that "Simulation training promises to play an increasingly important role in technical skills training and will likely reduce the numbers of actual procedures to which a trainee must have direct exposure to achieve competence" (60). "With advances in technology, the use of simulators will play an increasing part in the training of practical procedures" – as mentioned in the specialty training curriculum for cardiologists in training in the United Kingdom (46, 48).

BCIS:

The British Cardiac Interventional Society (BCIS) – has defined 3 phases of training in (http://www.bcis.org.uk/pages/default.asp) interventional cardiology – Phase 1 (First 6 months) – understanding the principles of cardiac catheterisation, pre assessment, intraoperative and post procedure care, explanation of the findings of the angiogram, Phase 2 (Second 6 months) – Progression to working as a primary operator under close supervision and Phase 3 (Second year) – works as a sole operator with supervision available when required (www.bcis.org.uk). At each training stage (early, intermediate and advanced), the trainee is expected to be competent in a variety of technical and non-technical skills. Introducing a structured simulation curriculum may complement training.

Evidence from General Surgery:

Within general surgery, examples of evidence for simulation based learning include skills in: Colonoscopy (61) and laparoscopic surgery (62). The literature search retrieved 673 articles. Only selected studies, courses run by the RCS, The Wolfson Surgical Centre and the wellestablished laparoscopic curriculum are mentioned below to illustrate the key aspects of the evidence base.

A recent study showed that surgical trainees who received simulation-based training demonstrated superior intraoperative performance of a highly complex surgical skill (60). The current evidence base, outside cardiology, does suggest that a simulation helps trainees acquire key technical skills compared to those trainees who do not take part in simulation-based training (63). A unique multi-professional simulation-based educational programme was designed by the RCS (Royal College of Surgeons) England: Patient Safety in Theatre Teams (PSTT) course. It demonstrates the importance of human factors, non-technical skills and effective teamwork (64) in the operating theatre. The small group workshop teaching emphasises exemplars of leadership, situational awareness, communication skills and decision making for all team members and reinforces their significance to safe, professional practice (65).

The £ 3 million Wolfson Surgical Skills Centre (<u>www.rcseng.ac.uk</u> > Surgeons &Trainees > RCS Education) is the largest cadaveric (66) operative simulation facility in the UK. The centre has 9 specially designed operating style dissecting tables which incorporates state-of-

the-art audio-visual facilities with each dissecting table equipped with 2 video screens for close-up viewing of procedures. A large single screen video wall is linked directly to hospital operating theatres and lecture rooms to ensure live transmission to local and regional centres. 36 participants can be accommodated in one session. The centre provides a structured, surgical training programme in virtual reality which benefits the trainees in general surgery (67, 68).

The virtual reality (VR) laparoscopic colorectal curriculum (using LAP Mentor – www.simbionix.com/simulators/lap-mentor/) is a unique and an innovative learning opportunity for surgical trainees. The curriculum equips the trainee with the technical skills to perform a VR laparoscopic sigmoid colectomy independently to objectively defined benchmarks calculated from surgeons who have completed over 100 laparoscopic colorectal resections (69).

General surgeons have pioneered the technique of simulation based learning (Figure 3) and its integration to the mainstream curriculum. The next section provides the available evidence from endovascular surgery, which can be adapted to the cardiology training programme.





Figure 3: These pictures were taken by me while attending the "Current concepts in joint replacements" $5^{th} - 9^{th}$ December, 2012 – Orlando Florida.

The surgeons have pioneered the technique of mobile simulation surgical training.

The vehicles are selfcontained, 1100 sq ft, expandable trailers with the state of the art operating room space.

www.mobilesti.com

Evidence from Endovascular surgery:

Endovascular surgeons have explored the effectiveness of simulation-based learning and have conducted validated studies which could form a basis for formulating a structured, training programme in interventional cardiology for individual learning, team training and assessment. The literature search retrieved 74 articles and selected studies involving catheter based interventions alone are discussed below.

Results of a small randomised controlled study (n=20) concluded that simulation is a valid tool for instructing surgical residents and fellows in endovascular training programmes. The study reiterated that simulation can be used for retraining and refining catheter based interventions (70). A 4 year experience of Vascular surgery fellows' participation in simulation training at regional centres provided a lower cost alternative for providing highfidelity simulation training, compared with acquiring and operating an endovascular procedure simulator at their individual institutions (71). Dawson et al concluded that training with a simulator, incorporated into an individual or small group learning session, offers a means to learn and realistically practice endovascular procedures without direct risk to patients, with measurable improvements in key performance metrics (72).

Team training and evaluation of complex whole procedure simulations in the endovascular suite were demonstrated by Nestel et al (73). Willaert et al concluded that a simulated procedure rehearsal is more effective than a preoperative generic warm-up for endovascular procedures (74). "Virtual reality (VR) simulation is a useful tool enabling objective demonstration of improved skills performance both in simulated performance and in subsequent in-vivo performance" - quoted by Neequaye et al (44).

The evidence above shows that the endovascular surgeons have validated the different aspects of training involved in catheter based interventions. The next section explores the experience of interventional radiologists, who are the latest entrants to the field of simulation based learning.

Evidence from Interventional Radiology:

Interventional radiology is a sub specialty in radiology which require manual dexterity in handling catheters, balloons and guide wires, similar to interventional cardiology. In the 21st century, these group of specialties are termed as "procedural medicine". The literature search extracted 79 articles and selected studies concerning opinions from the experts and professional bodies are discussed below.

Gould (13, 75 - 77) suggests that with emerging, advancing technology simulation is a feasible option to train in procedural medicine. Lindsell (78) stresses the importance of combining traditional training methods in radiology with evolving, emerging simulation based methods. Learning process in interventional radiology has become increasingly difficult due to fewer "straightforward" procedures and growing concerns for patient safety. Computer-based simulation has the potential to allow an operator to realistically perform a virtual procedure with feedback about performance, which could at least reduce some of the patient's role during the learning process (79).

The Executive Councils of the Society of Interventional Radiology (SIR), Radiological Society of North America (RSNA), and Cardiovascular and Interventional Radiological Society of Europe (CIRSE) have charged their Medical Simulation Task Forces and Work Groups in 2007 to cooperate to achieve excellence and safety in interventional radiology patient care by jointly recommending and guiding implementation of a robust infrastructure and process to support Interventional Radiology (IR) simulation development, assessment, validation, application and dissemination (80). The two stage strategy (81) is outlined below - stage 1 focuses on curriculum development and organizational objectives whereas the core objectives of stage 2 are training standards, professional education, practice building research, economics and public education (Table 5).

Table 5: Strategy – Stage 1

Steps	Aims
	• Defines the role of simulation within a structured, training program including how, where, and when simulator training takes place.
Curriculum development	• Review assessment methodologies for establishing competence including traditional techniques, novel automatic assessment based on simulator-derived performance data, and observer-based methods.
	• Outlines the role of credentialing organizations to oversee accreditation and revalidation.
	• Methods to utilize simulator models to improve the performance of IR training and of health care institutions.
Organizational objectives	• Adoption of "Human Factors" for simulation, including identification of metrics and agreement on standards for the validity and efficacy of simulator models.
	• Criteria for evaluating simulators in relation to learning, training and performance feedback
	• Support for the task force will be enlisted from the industry, funding organizations, and the government.

Recommendations will be made regarding the use of simulation by simulator and medical device companies for education, when operating outside curricula (82).

Stage 2 - It is intended that this strategy will provide guidance regarding milestones, Gantt charts, specifications, costing, personnel, research, publication and dissemination of information concerning simulation based education.

Interventional radiologists have provided a structured outline for the development of a simulation based training programme. In collaboration with endovascular surgeons and interventional radiologists, the cardiology team can develop a robust simulation training programme benefitting all the trainees in these 3 specialties.

2.6 Simulation in interventional cardiology – current status

Evidence from general surgery and endovascular surgery provides a historical perspective and the progress made by the respective training boards towards a simulation based education. The cardiology team can draw the experience from the above societies and specialties to develop a robust, concise simulation based training programme. In this section, I focus on the currently available commercial cardiac simulators, state of the art simulation centres and the present status of simulation based education in interventional cardiology. Simulation is often perceived as "hi-tech" but actually encompasses a wide range of activities from simple to complex (37, 39). Teaching, training, assessment of technical and non-technical skills, such as communication, clinical decision making and effective team working can be promoted using carefully crafted scenarios, role-play exercises followed by a structured feedback to the individual (83 - 85).

Higher levels of training require an increased fidelity of simulation and hence animal and donated human cadavers are employed. The Human Tissue Act (2006 - UK) permitted for the first time, the use of cadavers for procedural simulation rather than solely for anatomical dissection (66). Electronic simulation is improving but is hampered by poor feedback of "touch and feel" sensation, known as "Haptics". 3D video technology forms an integral part of robotic surgery. Sir Liam Donaldson (Chief Medical Officer for England, 2009) has highlighted the importance of simulation in reducing medical errors and improving clinical performance (67, 68).

Interventional cardiology is amenable to simulation based training for the following reasons. It is a minimally invasive procedure. Cardiologists use a set of co-axial tools (diagnostic catheters, guide wire, balloon catheters) which provides minimal haptic feedback. The images are viewed in a fluoroscopic screen (visual feedback) in a two dimensional format unlike the surgeons who visualise anatomical structures in three dimensions. Hence a low fidelity simulation should suffice to provide adequate technical training. Despite these advantages, creating a simulation based training and curriculum for interventional cardiologists remains a challenge due to financial and logistic issues.

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In what follows, I provide an overview of the different types of commercial cardiac simulators currently in use, simulation centres in Europe, types of simulation training and the pilot courses conducted by the British Cardiac Society in the UK.

Simulators for coronary intervention:

VIST (Mentice AB, Gothenburg, Sweden) – www.mentice.com

The most validated VR simulator in cardiovascular medicine is the vascular intervention simulation trainer (VIST) system by Mentice AB. The simulation model is devised from real patient anatomy (extracted from computed tomography or magnetic resonance angiography) and can deliver assessments on a trainee's performance on a second by second basis using the full physics characteristics of the catheter–vessel wall interactions. Algebraic approximations of the catheter-vessel wall collision are detected faster enabling accurate feedback to the operator about his performance.

VIST is programmed to detect the properties of the devices (resistance, friction, stiffness) by force transmission motion, thereby providing an excellent haptic feedback to the operator in real time. The metric based, full physics high fidelity simulation allows trainees to receive immediate proximate feedback on their performance.

Accurate rendering of high fidelity, real patient anatomy enables meticulous pre procedural planning ("procedure rehearsal") like device approximation, guide wire selection and catheter manipulation in complex cardiovascular procedures. Experiencing problems in the simulator helps the operator to avoid those complications during live in vivo case.

Simantha (Medical Simulation Corporation, USA - www.medsimulation.com

The system offers simulations for coronary intervention, endovascular abdominal aortic aneurysm repair (EVAR) and Trans catheter aortic valve implantation (TAVI). The coronary intervention modules are currently used by the American Board of Internal Medicine (ABIM) in Interventional Cardiology Board recertification. Due to the lack of full physics capability, the haptic feedback is limited. Nevertheless, the system is well suited for team training and for the assessment of non-technical skills. Validation studies are limited.

Angiomentor (Simbionix, USA) - www.simbionix.com

The full procedural simulator offers VR simulations for coronary intervention, peripheral vascular intervention, TAVI and intra cerebral aneurysm interventions like coil embolisations. The AngioMentor system can measure procedural time, fluoroscopy time, amount of contrast used, the order of the devices used and percentage of lesion covered by the stents. However, it does not provide the contextual metric-based operator – device related performance assessments. Validation studies using this system are limited.

Biosensors International (Singapore)

Dedicated simulators for specific type of coronary anatomy and pathology have evolved. For example, coronary stent deployment at a bifurcation lesion is challenging. The bio-mechanics of stent, the vessel (main branch versus side branch) and the complexity of the lesion should be taken into account during stent deployment. Dedicated bifurcation coronary stents are available. Biosensors has a dedicated simulator to teach interventional cardiologists about coronary bifurcation stenting only (Figure 4).

Figure 4: Bifurcation stenting: Implantation sequence



The simulators are displayed by the company at national and international meetings where each interventional cardiologist has access to the simulator sessions for 30 - 45 minutes. There are no validated, metric based assessment studies authenticating the transfer of the skill acquired on the simulator to the real world.

The above simulators described focus on coronary intervention only. Commercial companies offer a variety of simulators for various sub specialties (Cardiac electrophysiology, congenital heart disease and cardiac Imaging) of cardiology. Current simulators in cardiology offer low and high fidelity simulation. For simulators to be incorporated into the mainstream education curriculum, they need to satisfy 3 important requirements – content validity, construct validity and face validity (86).

Content validity is said to be present when a simulation content (steps and behaviours that constitutes the simulated task) is appropriate to the desired training objective. Construct validity is present when assessments in the simulation are robust enough to form a judgement about the performance of the operator. Face validity is when the simulation appears sufficiently realistic to convey a sense of "realism" to the operator. There is a pressing need to assess the validity of these simulators on content, construct and face validity. A metric based performance assessment on a validated simulator will ensure that the skills are transferable from the virtual to the real world.

Simulation Training Centres:

State of the art simulation centres are available throughout the world, especially in the USA and Canada. They are expensive, labour intensive and a dedicated team of faculty are essential for conducting a successful simulation training programme. I had the opportunity to visit and train at one such centre in Europe at Tolochenaz, Switzerland, which is explained in detail below.

Medtronic International (Tolochenaz, Switzerland)

The Medtronic Training and Education Centre, Europe and Central Asia, conducts simulation training courses in cardiology throughout the year. At least 4 courses are conducted per week in different sub specialties / procedures of cardiology – coronary intervention, permanent pacemaker insertion, biventricular device implantation, TAVI. A dedicated team of trained faculty act as mentors to the trainee. The mentors are professors and consultants working in the European Union with a diverse clinical experience.

The number of participants in each course is kept to a minimum of 6 - 8 only, so that one to one teaching can be maintained. Each course lasts for 2 days. The course structure involves didactic lectures coupled with interactive case based teaching sessions. The next step involves hands on experience on the bench top simulators and silicon models followed by practising the entire procedure in the virtual catheterisation laboratory with the experts.

The bench top silicon model (Figure 5) helps the trainee to understand the mechanical properties of the catheters, guide wires, guide catheters and pacing wires during manipulation. The transparent silicon model helps the trainee to gauge the operator–device interaction during catheter or guide wire manipulation. The sequence of equipment intended for use can be practised many times in a safe, risk free environment with a mentor.

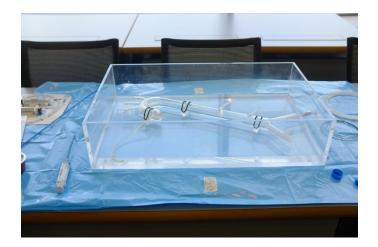


Figure 5: Silicon model: Aorta

The next step involves practising the procedure in a virtual reality environment (Figure 6) in the catheterisation lab. Working in a real catheterisation lab for the first time is a daunting experience for a junior doctor. The Medtronic training facility helps to allay those fears and ensures that trainees understand the expectations of the senior team whilst in the lab. The virtual cath lab provides a realistic environment for the trainees. A team of technical, electrical, electronic and mechanical engineers have ensured that the trainees have an excellent haptic feedback during device manipulation.



Figure 6: Simulated cardiac catheterisation lab

Ward scenarios and follow up of patients can also be practised in the virtual hospital at the training centre. Trainees have the opportunity to understand about the growth of the company from the museum situated opposite to the training facility (Figure 7). Adjacent to the museum, is the manufacturing section for developing the pulse generator units of the pacemakers. Trainees have a glimpse into the world of product design, manufacturing, quality control and the logistics involved in permanent pacemaker production.

"The Medtronic Cube" (Figure 8) is a mobile, transparent, virtual cath lab facility which is displayed at international meetings – EuroPCR, where trainees can book sessions. The facility allows training a wider audience in a short span of time. I was immensely thrilled to visit such a state of the art simulation training centre and am grateful to the Medtronic team.

Figure 7: Simulated environment and training faculty: Professor. Jean Marco



Figure 8: "The Medtronic Cube" at EuroPCR, Paris, 2012



Orzone AB (Gothenburg, Sweden)

The Swedish company has developed a state-of-the-art training facility (OR camp) which simulates the operating room, controls and interactive video monitors. The virtual reality simulator is embedded in the manikin in the hybrid operating room. It is an excellent environment for team training particularly for new team members working together in complex cardiovascular procedures. The similarity between the high fidelity environment and in vivo operating room is of high standard providing a fully immersive simulated environment for the operators.

Simulation training centres provided by other companies

GE Healthcare, Biotronik, Berlin, Germany and Crossroads Institute, Abbott Vascular, Belgium provides simulation based training in cardiology for dedicated procedures only. Simulators are expensive and companies have developed a keen interest to promote simulation based learning for many reasons. Interventional cardiologists are keen to adapt to evolving technologies and hence simulation is intuitively attractive. The companies are able to promote their dedicated products, technology and device innovations to the clinicians.

Feedback forms are collected from the trainees from each training session but no validation or metrics exist for the above systems. No published literature or cardiology specialty training boards have validated the use of the above training centres Nevertheless, trainees should make use of the advanced technology and every opportunity to learn cardiology from an expert, international faculty.

Types of simulation training in cardiology in the UK:

A fundamental function of any medical educational and training curriculum is to facilitate the attainment of proficiency by the transition of the trainee from one skill level to the next. A series of "anchor statements" are provided to act as a formative guide to the trainee and the trainer by the specialty training board <u>www.jcrptb.org.uk</u> (46).

For the procedural skills assessments, they are:

Level 1 – able to perform the procedure under direct supervision/assistance

Level 2 – able to perform the procedure with limited supervision/assistance

Level 3 – competent to perform the procedure unsupervised and deal with complications

On completion of their training period, a trainee should achieve level 3 competence.

A cardiology trainee need to master technical and non-technical skills (human factors) in a defined time frame to become a competent and a confident cardiologist. Current traditional training methods coupled with the modern changes (reduction) in training hours have resulted in trainees having inadequate experience at the end of the stipulated, fixed training period. Hence simulation based education seems to be a viable option to supplant the lost training hours in cardiology. The new cardiology education pathway involving simulation may complement existing training methods and enhance the learning curve of the trainees, equipping them towards a faster acquisition of skills in a safe environment.

Technical skills: Virtual Reality (VR) simulators in cardiology

The Royal College of Physicians (ST3 Recruitment Website) (46) states the characteristics of a cardiology trainee – "Cardiology will particularly suit trainees who are: motivated, hard-working, able to develop procedural skills and keen to engage in clinical research". Mastery

of technical skills is an important component in cardiology training. Simulation based training provides an excellent opportunity to acquire technical skills.

VR simulators provide an introduction to the complexity of technical skill acquisition in cardiology to the trainee. It helps the trainee to familiarise with the technical equipment and the order in which each device / guide wire or catheter is used. The trainees can review, reflect and rehearse the procedure many times during the training session. Close interaction between the mentor and trainee in a risk free situation provides an ideal environment for acquiring technical skill competency. VR simulators can be attached to an actor (a simulated patient) to provide the essential content of a real procedure, providing a "hybrid simulation".

Simulation based education has been shown to be as effective for the acquisition of technical skills as apprenticeship training models in a few invasive procedures which have been well validated (87 - 92). Two randomised trials in surgery (VR to OR) and in vascular surgery (STRIVE) (92) have demonstrated significantly reduced procedural errors (>50% reduction in VR trained groups) in trainees learning laparoscopic cholecystectomy (89) and in attending clinicians learning carotid angiographic procedures (92).

There are no validated studies in interventional cardiology to prove that the technical skills acquired during the training session are directly transferable to the real world. No metric based performance assessment for each trainee is performed at national or international meetings in cardiology. There is no consensus metric based performance assessment for each interventional procedure in cardiology. Moreover, "Human Factors" cannot be taught with

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the help of a VR simulator alone, without a simulated environment. As participation is voluntary, not every trainee undergo simulation based training. The above are the limitations of the current VR simulators only - based education.

Non-technical skills: - Team training in cardiology

Teamwork, leadership, communication, managerial skills, operator confidence, task prioritisation, decision making under pressure, conflict solving, managing uncertainty, coping with fatigue, situational awareness, co-operation and interpersonal skills (93) are prerequisites for a smooth functioning of a cardiovascular team in a busy catheterisation lab environment and in a dynamic patient care setting. Introduction of specific team training modules and the assessment of the trainees for non-technical skills (94) has been challenging. Whilst procedural skills can be mastered in the cath lab in real life situations, mastery of nontechnical skills is abstract and complex in nature (58).

Introduction of team training sessions at the BCS annual conference have taken place with mixed response from the trainees (Chapter 3). These distributed simulated sessions were introduced for the first time in 2012 without a simulated cath lab environment. No sequential simulation were involved. Informal interview with the trainees attending the conference suggested that it did not replicate a real life situation.

There are inherent limitations in the assessment of non-technical skills – Human observers / assessors have their own inherent characteristics introducing bias and limitations. Only certain aspects of the behaviour can be assessed in any particular scenario, as it is complex to

incorporate and capture every aspect of psychological trait and behaviour in an individual (95).

The above methods of training (VR simulators and team training) with robust validated assessment metrics will provide a comprehensive method of simulation based education which can complement the current training methods. The BCS Simulation working group have understood the necessity of such a training and have taken the initial steps to deliver simulation based training in a structured, standardised way.

BCS - Annual Conference - www.bcs.com/ace

Training by simulation is currently voluntary. The British Cardiac Society provides a range of virtual reality simulators (coronary interventions, pacing, trans-thoracic echocardiography and trans-oesophageal echocardiography) during the annual conference. The Boston Scientific, CAE Healthcare, Cordis, HeartWorks, Medtronic, Mentice and Terumo are the companies which provide a range of simulators. The various VR simulators are arranged in series on each table. Commercially available virtual reality simulators provide sophisticated consoles with graphical user interface and an excellent haptic feedback. These simulators are made available at national and international meetings. The company team for each simulator are available to answer any queries and to address technical problems.

Trainees sign up to these sessions beforehand (months in advance) to secure a training session (www.bcs.com/simulatorbookingform). Each trainee has a dedicated mentor (consultant cardiologist) explaining about the pros and cons of the procedure. Each trainee can practice on different type of simulators depending on their subspecialty interest. A training session lasts for 45 minutes. An immediate feedback is provided to the trainee. Trainees are provided with a certificate of completion of simulation training for the particular procedure by the designated mentor.

Training design is a systematic process that enables dissemination of technical and nontechnical skills required to improve and enhance the performance of the trainee. A systematic approach to a training development programme will pay off in the long run in terms of quality and relevance of the training (58). The British Cardiac Society (BCS) have run 2 pilot courses addressing the training needs of junior doctors in cardiology, which are discussed in the section below.

BCS Simulation courses - Pilot (2012, 2013)

Following the recommendations of the BCS Simulation working group report, the committee has piloted 2 simulation courses in cardiology – Birmingham (2012) and in London (14th & 15th January, 2013: Course Directors: Dr David Wald, Dr Andrew Wragg). The duration of the course is for 2 days. The course is directed towards ST3 trainees in cardiology who have passed the MRCP examinations. ST3 trainees are the junior most trainee doctors in cardiology and have completed their core general medical training. 17 ST3 trainees and 18 ST3 trainees attended the Birmingham and the London courses respectively.

The course structure focuses on acquiring technical skills from VR simulators and on nontechnical skills by taking part in a simulated cath lab scenario. The participants are divided into 2 groups – Technical and non-technical group. Participants completed a pre course, general questionnaire, a questionnaire for each training procedure (before and after), team training questionnaire (before and after) and a post course evaluation questionnaire.

The technical group attend didactic lecture concerning the intended interventional procedure for 20 minutes followed by individual sessions on the desk top simulator with a designated mentor for the next 45 minutes. The procedure is repeated until all interventional procedures are covered. Then, the technical group switches to the non-technical group and vice versa to complete the rest of the training modules.

The non-technical group are briefed on a clinical scenario in a lecture room with a video transmission of the proceedings from the simulated cath lab, located adjacent to the lecture room in the education centre. One of the trainee doctor consents to do the invasive procedure in the cath lab on the manikin, which covers the sophisticated coronary angiogram simulator with haptic feedback. The proceedings are relayed live to the other trainees in the lecture room.

The doctor is briefed on the clinical scenario by a consultant cardiologist. Assessments are carried by 2 consultant cardiologists and a consultant anaesthetist with a vast experience in simulation based assessments. The cath lab team is provided by a consultant cardiologist, who is the radiographer, cath lab nurse – is a sister involved with patient safety, the scrub nurse is a training doctor in cardiology. Responses by the patient are provided by a senior nurse who manages the controls displaying the haemo-dynamics and coronary angiograms. Varying levels of difficulty are introduced during the session and the scenario is stopped after

a pre designed, defined end point. The assessment team have discussions about the performance of the trainee.

Several behaviour rating systems are described which are used for assessment, feedback and for auditing – NOTECHS (Non- Technical Skills) – used by airlines (96) (crm.aviatraining.net), NOTSS (Non-Technical Skills for Surgeons) by the surgeons and ANTS – by the anaesthetists (www.abdn.ac.uk/iprc/notss). The ANTS (Anaesthetists Non-Technical Skills) behavioural rating system (97) was adopted for assessing the participants in the non-technical group at the BCS course (Table 6).

Categories	Elements	Observations	Element rating	Debriefing notes and category rating
Task	Planning & preparing			
Management	Prioritising			
	Providing & maintaining			
	standards			
	Identifying and utilising			
	resources			
Team	Co-ordinating activities with			
Working	the team			
	Exchanging information			
	Using authority and			
	assertiveness			
	Assessing capabilities			
	Supporting others			

Table 6: ANTS – Observation & Rating System

Situation	Gathering information
Awareness	Recognising & understanding
	Anticipating
Decision	Identifying options
Making	Balancing risks & selecting
	options
	Re-evaluating

The trainee and the rest of the delegates are met in the lecture room by the panel of experts. Individual opinion of the delegates about the trainee's performance is sought, followed by the opinion of the experts. Interaction between the delegates and the expert panel is encouraged and a final summary is provided to the trainee. Human factors are stressed during the discussion and the trainee is provided with ways to improve his performance in the cath lab.

The next trainee volunteers and the process begin again. It is important to note that as each non-technical training session lasts for more than an hour, only 3 or 4 trainees have the chance to be in a simulated cath lab in one morning or afternoon session. Team training sessions are time consuming and labour intensive.

The above course offers training in technical and non-technical skills for trainees in cardiology. Currently, no validated metrics are in use to assess the performance of the technical group. Specific behavioural training assessment tools tailored to cardiology team training are lacking. Despite the limitations, the BCS Simulation group have made an attempt to inculcate the culture of training in technical and non-technical skills in cardiology. Results from the completed questionnaires by the trainees and the faculty members are awaited, which may help the faculty members to develop the training programme further, to suit the needs of the trainee.

2.7 A proposed framework of simulation based training in cardiology

Cardiology is one of the varied medical specialities, comprising a wide range of subspecialities including electrophysiology, device therapy, interventional cardiology, imaging and specialist heart failure management. Cardiovascular problems account for a large proportion of the general medical workload and cardiologists can make a real difference to patients. Within cardiology, physicians can develop a wide range of careers encompassing cardiovascular research, interventional cardiology, electrophysiology & device implantation, specialised heart failure management, advanced cardiac imaging and several smaller subspecialities. The needs of patients with cardiovascular disease continue to grow and therefore, cardiology remains a growing speciality.

Public awareness of cardiovascular diseases and public scrutiny has made the medical profession equally demanding. Hence proficiency and competency of the doctor should be of the highest standard. Future trainees should adapt and adopt new training methodologies and assessment of performance to maintain their professional standards.

The American Board of Internal Medicine (ABIM) has adopted simulation as a part of its maintenance of certification (58). Development of a metric based simulation curriculum and adoption of proficiency benchmarking definitions are essential to provide a simulation based training (21). A proposed framework, stages of simulation learning cycle and future initiatives to deliver simulation based training in cardiology in UK are discussed.

My proposed framework

In the United Kingdom, higher specialist medical training (Figure 9) has been reduced in real terms from 30,000 hours to less than 8000 hours, which has deprived trainees of vital clinical learning opportunities (84). To maintain a high standard of clinical practice, novel, innovative, high impact and effective clinical teaching methods need to be developed to compensate for the deficiency in total clinical exposure. High fidelity immersive simulation of basic and complex case scenarios with facilitated debriefing and mentoring provides an effective way of delivering training to the next generation of junior doctors.

Trainees undergo the following assessments during the various stages of Higher Specialist Training (Figure 9) in cardiology (ST3 to CCT) – KBA (Knowledge based assessment), WPBA (workplace based assessment), DOPS (Direct Observation of procedural skills), Mini CEX (Clinical Evaluation Exercise), CBD (Case based discussion), ACAT (Acute Care Assessment Tool), AA (Audit Assessment), TO (Teaching Observation), MSF (Multisource Feedback) and patient survey (PS) (46, 60). ARCP (Annual Review of Competence Progression) is undertaken to scrutinise and assess the career progression of the trainee in the above assessments. On satisfactory completion, a certificate is issued so that trainee can continue in the training programme with defined goals.

Learning by simulation involves 4 key stages (Figure 10) - Simulator plan, Simulation, Debriefing and Transference (83). Effective planning and delivery of the first 3 stages may result in transference of skills from simulation to real life. Successful completion of a simulator based programme should be endorsed by a qualified trainer with formal feedback and debrief to the trainee (84). Simulators based learning can be incorporated in a structured training programme (41) in cardiology to deliver high quality education (Table 7).

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Figure 9: Stages of Higher Specialist Medical Training in the UK

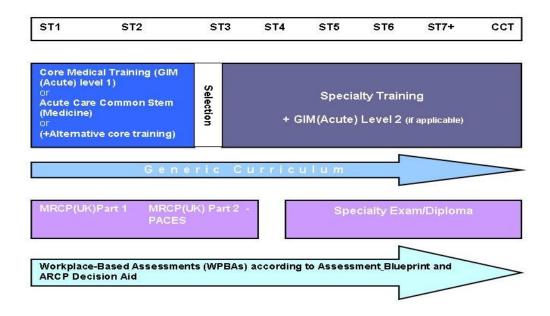


Figure 10: Simulation Learning Stages

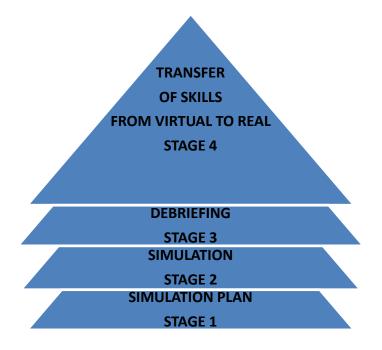


Table 7:	Framework	of training ir	simulation	in cardiology
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Skills	Early – ST3	Intermediate – ST4, ST5	Advanced – ST6, ST7
Technical	Skills: Diagnostic coronary angiography (radial & femoral)	Skills: Percutaneous coronary intervention – Elective and Emergency Procedures, vascular closure devices	Skills: Expert operator – Elective and Emergency Procedures - PPCI
	Transthoracic Echocardiography Basic surgical skills –	Familiarity with the IVUS, FFR,OCT, IABP insertion, Rotablation and equipment set up	Complex Procedures – Bifurcation, CTO, Mutli vessel disease – LMS, Crisis Management
	Incision, suture techniques and post - operative care	Familiarity with emergencies in the cath lab and their management	Expert use of IVUS, Pressure wire, OCT, Rotablation, IABP
	Pericardiocentesis, Cardioversion, Cardiac Monitoring Analysis, Cardiac MRI, Myocardial perfusion scan imaging	Trans-oesophageal echocardiography, Stress echocardiography, Cardiac MRI - stress, Myocardial perfusion scan imaging	Familiarity with trans septal puncture, TAVI, Aortic stent implantation, septal and left atrial appendage occluder devices, Balloon valvuloplasty, Lead extraction
	Permanent pacemaker insertion Pulse generator change, ILR implantation	ICD implantation, device programming, CRT lead placement Manangement of emergencies / complications in the lab	Manangement of emergencies / complications in the lab
	Simulators: Bench top models Virtual Reality Operating Room HeartWorks (Echo) ViMedix – (Echo)	Simulators: Virtual Reality Operating Room AngioMentor - SYMBIONIX MENTICE	Simulators: Virtual Reality Operating Room
	Assessment: WPBA, DOPS, MSF, Mini CEX, CBD	Assessment: KBA, Simulator Metrics, Faculty Assessment Procedural Checklist, Video based assessment and debrief,	Assessment: Video based assessment and debrief

		Teaching: Trainees to understand the methodology of teaching via simulation	Teaching: Trainees to teach in simulation courses - local, regional, national and at international meetings
Non-	Skills:	Skills:	Skills:
Technical	Decision Making Communication Situational Awareness	Leadership Stress Management Team work / Team training Interdisciplinary collaboration – with cardiac / vascular surgeons, radiologists, anaesthetists and sub specialty colleagues	Decision making under pressure Interdisciplinary discussion – with cardiac / vascular surgeons, radiologists, anaesthetists And sub specialty colleagues
	Simulators: Simulated Patients Clinical Scenarios	Simulators: Sequential Simulation Distributed Simulation	Simulators: Virtual reality cardiac catheterisation lab
	Assessment: MSF, Patient Survey	Assessment: Video based assessment and feedback, Teamwork assessment, Non-technical skills scales – NOTECHS, MSF, Patient Survey	Assessment: Video based assessment and feedback Global Rating Scale – NOTECHS, MSF, Patient Survey

Challenges and solutions regarding simulation based education in cardiology:

Adopting novel training methodologies and performance assessment tools into an established curriculum (42) requires careful consideration of several factors: the curriculum's training objectives that would represent the best use of simulations and the simulators; the behaviours (technical and non-technical skills) that are to be trained and assessed; the metrics to be used for performance assessments; the prerequisite skills (core skills) and knowledge required; and where, how and by whom this form of training should take place (43). In the United Kingdom, the Postgraduate Medical Education and Training Board (PMETB) has defined eight standards for curricula: the rationale, the learning content, the model of learning, the

learning experiences, supervision and feedback, the management of curriculum implementation, the process of curriculum review, and update and conformity of the curriculum with equality and diversity legislation (www.gmc-uk.org) (77).

Learning outcomes for each stage of the training should be defined before the commencement of the training programme. The efficacy of the training programme should be assessed by Donald Kirkpatricks Four Level Evaluation Model –

- Reaction How well did the trainees like the learning process
- Learning What did the trainees learn? (The extent to which trainees gain knowledge and skills)
- **Behaviour** What changes in the work performance resulted from the learning process? (capacity to perform newly acquired skills)
- **Results** What are the results of the learning process in terms of cost, quality, productivity and efficiency?

Demonstrating the impact of learning is important and is a key concept. It provides an excellent guidance to effective planning and delivering education.

The conceptual framework of training suggested above is an initial step towards a defined simulation based training curriculum / programme in cardiology. Nevertheless, significant challenges remain. Some of the key challenges and solutions are reviewed below.

Technical and non-technical skills:

Technical skills training has made significant progress with the availability of high and low fidelity simulators provided at major national and international meetings. The human factor aspects (training in non-technical skills) of care delivery remain under-researched (90). The lack of focus on behavioural aspects of cardiology training may be a result of the

misconception of simulation as being a tool developed exclusively for training technical procedures. Simulation based training involves much more than purchasing of virtual reality models. It involves a robust training curriculum, reliable and valid assessment metrics, expert and a well-trained faculty.

Time and an immersive environment:

Junior doctors and trainers should have protected time to practise on simulators and take part in simulated scenarios (elective, emergency and crisis management). Trainers should ensure that the simulation is adequately modelled to provide an authentic experience of a real life scenario. Models for providing faculty training ("Train the Trainers") supported by the deanery should be investigated – simulation training boot-camp followed by regular updating of skills at selected centres. General training of trainers is offered through a range of courses run by London Deanery (http://simulation.londondeanery.ac.uk/faculty-development). The key challenge is to recreate an authentic, immersive experience, without creating unmanageable levels of difficulty or cost.

Location of training centres:

Centralization at a few accessible sites to provide high fidelity training (team training and complex skills) might prove cost-effective. Less expensive, portable, desk top simulators and web-based solutions can be more widely dispersed across various deaneries. Deaneries can share equipment, technology and faculty to deliver a high quality simulation training.

Technology:

Simulators with different levels of fidelity (high and low) and realism can be introduced during the various stages of the training programme. Mastery of basic (core) skills can be achieved by desk top models in a virtual reality lab, where a full team will ensure that the simulation exercise feels realistic for the trainee.

Assessment of learning tools:

Validated, systematic, standardised and structured assessment tools (for technical and nontechnical skills) should be used for summative assessment, debrief and feedback (98). A structured curriculum should guide the trainee and the trainer so that explicitly defined learning outcomes are achieved.

Research:

A database needs to be developed to assess the effectiveness and validity of the available simulators, simulations and assessment metrics .Studies need to be conducted to determine the transfer of skills from the virtual to the real world. Cost effectiveness of the training programme needs to be estimated.

The above review provides an insight and highlights the paucity of literature concerning simulation based learning in interventional cardiology. Advancement in digital technology along with the changed working pattern of the junior doctors has stimulated a greater demand for simulated training in cardiology in the United Kingdom. Learning by simulation will complement and should not replace current training methods. There is a pressing need for structured, randomised studies to validate the enhanced clinical performance of the operators after training by simulation in cardiology.

Department of Health: NHS Simulation Provision and Use Study provides key recommendations to integrate technology into the training curriculum in a cost effective way.

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The Specialty Training Committee for Cardiology in the UK and the European Society of Cardiology do approve of training by simulation in cardiology. The surgeons have made the transition from the traditional approach and have embraced learning by simulation with great enthusiasm. With emerging evidence of strengths and limitations of a simulation based education from other specialties, the time is right for a measured introduction into the cardiology curriculum, alongside other training methods that remain essential to comprehensive learning. Training by simulation (validated, structured, standardised programme) should form an integral part of the cardiology curriculum in the future.

2.8 Discussion

Chapter 2 provides a detailed summary of the available evidence concerning simulation based education in interventional cardiology. Limited number of published evidence precludes conducting a meta-analysis or a systematic review. The articles were diverse in nature with different focal themes. The types of the articles were varied too – technical report, conference presentation, expert opinion, narrative review and non-randomised studies only. There is a lack of peer reviewed literature regarding randomised trials which constitutes a Level 1 evidence.

A detailed summary of the studies in interventional radiology, general surgery and endovascular surgery is not provided, as the main focus is on interventional cardiology. Nevertheless, relevant studies in the inter-disciplinary fields which will influence the shaping of the simulation training programme in cardiology are discussed. Numerous commercial simulators are available and their efficacy in providing training or transfer of skills from the VR to the real world have not been validated. Similarly, simulation centres and their training programmes are not standardised or validated.

The BCS has taken the initiative by forming a simulation working group and by conducting 2 pilot courses with emphasis on technical and non-technical skills. Analysis and results of the study are awaited. The current training scheme in cardiology is fixed and hence trainees need to utilise their training period effectively. The proposed training framework is an initial attempt in defining a structured simulation based training curriculum in cardiology.

Commencing a simulation programme is expensive, time consuming and labour intensive. Nevertheless, general surgeons, endovascular surgeons, anaesthetists and interventional radiologists have provided a blue print of a simulation training programme which could be adapted towards cardiology simulation training. As cardiovascular interventional procedures are more complex and involves a multi-disciplinary team, it is important to involve various inter-related disciplines while designing a structured, standardised training programme.

Delivering a clinical training programme along with a simulation training curriculum will be a challenging, uphill task for training programme directors in cardiology. Barriers towards implementation and possible solutions to each issues were explained. Despite the limitations, I feel the initial steps have been taken. After all, every journey begins with the first step.

2.9 Limitations

The main focus of the chapter is directed towards interventional cardiology. Other sub specialities like cardiac imaging and cardiac electrophysiology needs further exploration and analysis. The proposed training framework is a suggestion and may not be practical to implement. Although the training curriculum remains the same throughout the UK, the delivery of training by the individual deaneries are entirely different. Funders, educators, institutions, national / international bodies, NICE and policy makers need to arrive at a consensus opinion.

2.10 Conclusion

This chapter enabled me to understand the complexities involved in designing and introducing a new training methodology into an established curriculum. Any new intervention goes through five developmental stages of acceptance – awareness, curiosity, visualisation, try out and adoption (www.gov.uk/defence). Cardiology is in the fourth phase.

The cardiology community has the benefit of understanding, adapting and adopting the principles from endovascular surgery and interventional radiology. A step wise structured approach will result in the development of a robust curriculum. At every stage of development, research needs to be conducted to validate the findings to record and reflect on the views expressed by the end users.

The next chapter is a qualitative interview study which explores the perceptions of consultants and trainees in cardiology regarding simulation based education and its application in the specialty.

Chapter 3: Consultants and trainees views of simulation based training and applications in cardiology: A qualitative interview study

3.1 Chapter overview

In this chapter, I analyse the views of the consultants and trainees in cardiology concerning simulation based education with a semi - structured interview.

3.2 Introduction

Simulation based training is an integral part of the core medical curriculum (BLS – Basic Life Support, ALS – Advanced Life Support) in the UK. Nevertheless, there is a lack of a validated, structured simulation based training programmes in interventional cardiology with a paucity of literature concerning cardiologists perceptions of simulation based education in cardiology.

Currently, bench top simulators in cardiovascular procedures provide low fidelity simulation and are made available at national (www.bcs.com) and international meetings (ESC, EuroPCR) for cardiology trainees to familiarise with the technique and the equipment. Companies like Medtronic provide a virtual cath lab (The Glass Cube) environment with high fidelity simulation to practise cardiac catheterisation, device implantations, complex interventional cardiac procedures with advanced haptics and interactive software. Trainees attending these meetings benefit from simulation based education from a designated mentor for a brief period of time. Hence access to simple and complex simulators are limited and trainees do not spend adequate number of hours training on simulators to achieve competence to perform as an independent operator in real life.

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Simulators are expensive and to train a team of dedicated simulation faculty members / mentors is labour intensive. Logistic issues and financial constraints likely suppress the progression of a simulation based education in cardiology. However, with increasing focus on patient safety and with the reduction in the working hours of junior doctors in cardiology, it has become evident that simulation based education (www.adlnet.gov – Transfer of training from simulations in civilian and military workforces) is a necessity to achieve competence in cardiology.

<u>3.3 Aims</u>

The aim of this study is to understand and explore in depth the perceptions of consultant cardiologists and junior doctors in cardiology towards a simulation based education in cardiology. Ultimately, such an understanding can contribute to the formulation of a structured simulation based training programme in cardiology.

3.4 Methods

Study design:

A qualitative approach involving a semi structured interview methodology, based on theory led topic guide was chosen to explore and to understand the pros and cons of a simulation based education in cardiology in the UK.

The interview was divided into 2 parts – The first part focused on the clinical experience, qualification and familiarity with simulation. The second part focused on the participant's general views towards simulation based education, assessment of technical and non-technical

skills in elective and emergency cases, barriers towards implementation of a simulation based education, and finally introduction of novel techniques and device technology through simulation. Interviews were performed, audiotaped and analysed by the primary researcher (S.K). Emergent themes were identified and coded by the primary and by an independent researcher with advanced background in psychology and expertise in qualitative methods (Dr. Stella Mavroveli) at Imperial College, London.

Data collection:

The study participants for the interviews were from 3 deaneries in the UK – Severn, Oxford and the North West London deanery. The interviews were conducted at the Bristol Heart Institute, Bristol, John Radcliffe Hospital, Oxford and at Hammersmith Hospital, London, between November 2011 and March, 2012. A total of 13 consultants and 11 trainees in cardiology were interviewed from the above deaneries.

Consecutive participants were recruited from both genders and from a range of seniority levels and sub specialities (Interventional cardiology, Non-invasive cardiology and Electrophysiology) in cardiology. The mean duration of an interview was 21 minutes (Range - 13 to 44 minutes).

Participation was voluntary and consent was obtained for conducting the interviews. The study was approved by the Joint Research Compliance Office (North Western London). Confidentiality and anonymity was ensured.

Data analysis:

Preliminary analysis of all interviews was performed by the interviewing researcher (S.K). Emergent themes were coded and compared across the entire dataset. A blinded analysis for a sub set of interviews was performed by a second member of the research team with a background in psychology (Dr. Stella Mavroveli), to ensure accuracy in coding. Emergent themes were discussed and areas of agreement formed the basis of our finalised thematic structure. Thematic analysis aided the recruitment process and continued until theoretical saturation (repetitive and consistent findings across the interviews) was achieved.

3.5 Results

Demographics, clinical experience and familiarity of the participants with simulation in cardiology are summarised (Table 8, 9 and Table 10).

No	Place of work	Tenure as Consultant (years)	Academic position	Fixed training session - juniors	Clinical / Educational Supervisor / Both	Member – ARCP Panel	No of interventional procedures / Week
1	Tertiary	2	Honorary Contract	No	Clinical supervisor	No	10
2	Tertiary	22	Honorary Contract	No	Clinical Supervisor	No	8
3	Tertiary	1	Honorary Contract	No	Clinical Supervisor	No	8
4	Tertiary	10	No	No	Clinical Supervisor	No	9
5	DGH	6	No	4 hours / week	Clinical Supervisor	No	12
6	DGH	11	Clinical Lecturer	4 hours / week	Both	Yes	4
7	DGH	3	Honorary Contract	4 hours / week	Both	No	4
8	Tertiary	1	No	4 hours / week	Clinical Supervisor	No	10

 Table 8: Interview study: Demographics: Consultants

9	DGH	6	No	4 hours	Clinical	No	5
				/ week	Supervisor		
10	Tertiary	6	Honorary	No	Clinical	No	6
			Contract		Supervisor		
11	Tertiary	12	Professor	No	Both	Yes	6
			Cardiology				
12	Tertiary	10	Professor	No	Both	No	5
			Cardiology				
13	Tertiary	20	Professor	No	Clinical	No	5
	-		Cardiology		Supervisor		

5 consultants hold an honorary contract with the university and 4 of them do not hold any academic position with the university. The 3 professors who were interviewed were from the London deanery. 4 consultants are clinical and educational supervisors and also hold academic position with the university.

No	Place of work	Area of research	Academic training	Grade of training	Number of years in training (cardiology)	Academic Qualifications	No of interventional procedures / Week
1	Tertiary	Nil	Nil	ST3	1	Nil	3
2	DGH	CRT	Nil	ST4	5	MD	5
3	Tertiary	Imaging	Nil	ST5	4	Nil	4
4	Tertiary	Imaging	Academic Training	ST4	3	Nil	6
5	Tertiary	Nil	Nil	Fellow	6	Nil	20
6	Tertiary	Imaging	Nil	ST6	6	MD	5
7	Tertiary	Nil	Nil	ST5	12	Nil	15
8	Tertiary	Nil	Nil	ST3	2	Nil	2
9	Tertiary	Imaging	Hon Clin. Teacher	ST3	5	Nil	3
10	DGH	Basic Science	Nil	ST5	3	Nil	5

Table 9: Interview study: Demographics: Trainees in cardiology

11	Tertiary	Basic	Nil	ST6	11	MD	10
		Science					

Table 10: Demographics: Summary: Consultants and Trainees in cardiology

	Consultants (n =13)	Trainees (n = 11)
Number – working in a tertiary centre	9 (69.23%)	9 (81.81%)
Tenure as a consultant (Median – in years)	6	NA
Academic Position	4 (30.76%)	NA
Fixed training session for juniors – 4 hours / week	5 (38.46%)	NA
Clinical Supervisor only	9 (69.23%)	NA
Member of the ARCP panel	2 (15.38%)	NA
No of interventional procedures performed per	6	5
week (Median)		
Area of research interest (Basic Science)	NA	2
Academic Training post	NA	2
Grade of training - ST3, ST4, ST5, ST6, Fellow	NA	3, 2, 3, 2, 1
Number of years in training in cardiology	NA	5
Academic qualifications (MD) recently obtained	NA	3 (27.27%)

Detailed analysis of the interviews enabled me to identify the emergent themes and the sub themes from the participant's transcripts which are presented in the table below (Table 11). Verbatim quotes from the study participants are quoted to illustrate each one of them.

Themes	Subthemes	Verbatim Quotes
Role of simulation based education in cardiology	Bridging step, good stepping stone Complements training and not a replacement Enhances the training of junior doctors Safe, risk free, no pressure Simulations look easy, not in real life Difficult to genuinely simulate stressful situations	 " lots of practice in a small period of time, an alternative to practice" "I wish I had simulator training before I did on real patients"
Simulation based training	Elective and emergency cases training is useful Training curriculum for each stage of the training period Mentoring is important Earlier the better One to one teaching is essential	"Not only you are learning from the simulator, but from the consultant too"
Technical and non-technical skills	Able to assess psychomotor skills Establishes familiarity of the equipment Assessment of team work, leadership and management skills Decision making under pressure Authoritative, prioritise things	" Priority of tasks in a complex scenario is essential"
Accreditation / ARCP / Revalidation	Provides a standardised form of assessment No validated data yet Not for experienced operators Very useful and less time consuming	"reproducible, consistent in the case scenarios between every trainee" "DOPS is a better assessment tool"
Barriers and limitations	Currently under-utilised No validated structured programme as a benchmark Cost issues – expensive Protected time for trainers / trainees Simulators – primitive, but getting better	"Technology not advanced enough to mimic complex case scenarios" "can mimic each stages, not as a continual sequence of complex events" "Selection of centres is important – using it in many

	Access to simulators	centres versus selected centres"
Future Applications - Novel technologies, TAVI, MV repair	Extremely useful Gives an idea about the new technique and technology	"technically difficult procedures can be tested first" " new technologies can be
Simulators / Simulation Courses	Desk top models alone – not so useful Simulated environment is necessary BCS courses Medtronic Courses – Switzerland 3 companies have simulators	tested – a good idea" "They say they will make it difficult – but actually it is easy on simulators" "Simulators are harsh – In real life – you have to be gentle" "Models – never quite the same. It has put me off"
Simulation based education framework	Validated, structured, defined training programme Centralised training curriculum Basic and complex scenario simulation training programme Tailored to different stages of the training period	

Consultants and trainees expressed that simulation can only complement training and cannot compensate for the experience gained by treating patients in the hospital. The point was stressed many times during an interview too. They were uniform in the decision that simulation in cardiology has not reached the finesse or the fidelity to be used for accreditation, revalidation or for selection of trainees. Partnership with the industry is essential to offset the cost of running a simulation based training programme – as simulators are expensive.

A dedicated "Simulation Department" with a trained faculty supported by "simulation fellows" or "education fellows" is essential for running a robust programme throughout the

year. Consultants felt that simulation plays a vital role in educating operators learning advanced, complex, new and novel procedures. Consultants stressed that a centralised, validated, structured simulation curriculum and a training programme is essential before simulation based education is introduced into mainstream cardiology curriculum.

3.6 Discussion

This qualitative study reveals an overall positive attitude towards embracing a simulation based training programme in cardiology among consultants and trainees in cardiology. Consultants discussed the pros and cons of simulation and the challenges that will be faced during the assimilation of the new technology into the existing training curriculum. Interdisciplinary collaboration (Endo-vascular and Interventional radiology) with allied fields is essential to arrive at a consensus opinion. Lessons can be learnt from simulation training programmes in cardiology from Europe, USA and Canada – so as to adapt and adopt to the UK curriculum.

Trainees voiced their opinion about their likes and dislikes concerning such a training programme and have also explained in detail about the simulation courses currently available in the UK and in Europe. Most trainees expressed their concern regarding securing bleep free time off from busy service commitments to undergo simulation training.

Only 38% of the consultants had a fixed training session of 4 hours per week. The type of training methods offered during these training sessions varies between individual consultants. The focus is on didactic lectures delivered by experts in the field to a group of trainees, rather

than interactive teaching sessions with an individual trainee. Hence, the method of delivering training has to change to meet the demands of a trainee in an ever-changing work place environment.

The BCS have taken the initial step and have run two pilot cardiology simulation courses in collaboration with the industry, following the Simulation Working Group Report, August, 2012 (www.bcs.com). 35 ST3 trainees in cardiology from different deaneries took part in the course which will enable us to understand the efficacy and feasibility of running such a training programme. Data is awaited from the BCS.

3.7 Limitations

Majority of the consultants and the junior doctors are from tertiary centres. Occasionally, the interview was interrupted by urgent calls to the clinicians which may affect the thought process of the concerned individual. The overall sample size is limited in number, although representative of a qualitative study of this type. There is an element of self-selection as consultants and trainees interested in simulation took part in the study.

Inherent limitations are there where participants may not practise what they preach or vice versa. However, the analysis provides a basis to devise a structured framework towards the development of a simulation based education in cardiology.

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3.8 Conclusion

The views of the consultants and trainees in cardiology is vital to arrive at a consensus opinion which will enable to formulate a structured simulation based training programme in cardiology. In this way, the concerns raised can be addressed and the problems can be ironed out at an earlier stage to avoid unnecessary delays towards adoption of a new educational methodology.

The interview analysis provided an overview which I subsequently aimed to validate further using a structured, quantitative survey at a larger scale, which is the focus of the next chapter.

Chapter 4: Consultants and trainees views of simulation based education and applications in cardiology: A quantitative survey study using a national sample

4.1 Chapter overview

In the present chapter, I have summarised the responses of consultants and trainees in cardiology with the help of a structured questionnaire.

4.2 Introduction

Previous chapter provided an in-depth analysis of perceptions of seniors and trainees in cardiology towards a simulation based education in 3 centres only. Simulation for training, accreditation, recertification, revalidation, simple case scenario training, complex case scenario training, complications, interventional procedural training, logistics and the barriers towards implementation of a simulation based training were discussed in great detail.

The present chapter involves analysis of a structured questionnaire survey conducted at a national level, so as to arrive at a validated, consensus opinion. Simulation-based testing to demonstrate competence with new procedures is already required by the US Food and Drug Administration for angiographically-placed devices, and it is likely that simulation-based credentialing for procedures will be increasingly prevalent. Hence, it is important to validate the perceptions of the end users (consultants and trainees in cardiology) towards a simulation based education by quantitative analysis.

<u>4.3 Aims</u>

The present study explores the perceptions of consultants and junior doctors (Specialty trainees) in cardiology regarding simulation based education in interventional cardiology and the potential applications of simulation technology by a questionnaire survey.

4.4 Methods

Study Design:

A structured questionnaire (quantitative method), based on the previously elicited themes from the interviews reported in Chapter 3 was designed. A survey was conducted to quantify responses at a larger scale using Likert scales.

The structured questionnaire was in 2 parts. The first part obtained information about the demographic profile of the participants, their work experience, exposure to simulation based education and attendance at courses concerning simulation. The second part involved a 21 item structured questionnaire (Figure 11 and 12) which was designed based on the emergent themes from the interviews. The emergent themes from the interviews were grouped into 5 categories – general view towards simulation, training in simulation, accreditation / selection, barriers towards implementation and using simulation for testing novel techniques and devices. The questionnaire was designed in collaboration with a psychologist (Dr. Tanika Kelay) with extensive experience in qualitative and quantitative methods.

Figure 11: Questionnaire Survey: Consultants

		ON BASED LE				NG	
)r Sujatha Kesavan, Res upervisor: Dr Iqbal Malił arch Associate: Dr Tanil	k, Consulta	ant Cardio	logist	Cardiology	
	Simulation is an important part of tra questionnaire is designed to unders interventional cardiology.						This
	Place of Work District General Hospital Tertiary Centre Hospital 	Number of years working cardiology	-	ultant in		nder	
	Do you hold an academic position at a university? Yes No	Do you have a fixed session for education and training juniors?	Are you a	cal or	AR	you a men CP Panel? Yes	nber of the
		No	Supervise				
	How many interventional cardiology 31-40 □ 41-50 □ >50	procedures do you perfo	rm per wee	k? □ <1(0 🗌 11	-20 🗆 21	-30 🗆
	Do you have any prior experience in	n simulation training in Inte	erventional	Cardiology	?		
	Have you visited any institute, meet	-	imulation tr	aining in Ir	nterventior	nal Cardiolo	ogy?
	If Yes, please name the Institute, m	ooting or					
	course	•					
	course	-	ach statem	ent by cir	cling a n	umber on t	he right.
	•	-	ach statem Strongly Disagree	i ent by cir Slightly Disagree	cling a nu Neutral	umber on t Slightly Agree	he right. Strongly Agree
1	course	agree or disagree with ea	Strongly	Slightly	-	Slightly	Strongly
1	Course Please indicate how much you a Cardiology trainees should train on si	agree or disagree with ea	Strongly Disagree	Slightly Disagree	Neutral	Slightly Agree	Strongly Agree
2	Course Please indicate how much you a Cardiology trainees should train on si performing procedures on patients Simulation should be introduced early e.g. at ST3 level Simulation should be introduced durin e.g. at ST5 level	agree or disagree with ea mulators before r in cardiologists' training, ng sub-speciality training,	Strongly Disagree 1	Slightly Disagree 2	Neutral 3 3 3	Slightly Agree 4	Strongly Agree 5
2 3 4	Course Please indicate how much you a Cardiology trainees should train on si performing procedures on patients Simulation should be introduced early e.g. at ST3 level Simulation should be introduced durir e.g. at ST5 level Simulation-based learning is less time 'shadowing' and watching real cases	agree or disagree with ea mulators before r in cardiologists' training, ng sub-speciality training, e-consuming than	Strongly Disagree 1 1 1 1 1	Slightly Disagree 2 2 2 2 2 2	Neutral 3 3 3 3 3	Slightly Agree 4 4 4 4 4	Strongly Agree 5 5 5 5 5
2 3 4 5	Course Please indicate how much you a Cardiology trainees should train on si performing procedures on patients Simulation should be introduced early e.g. at ST3 level Simulation should be introduced durin e.g. at ST5 level Simulation-based learning is less time 'shadowing' and watching real cases Simulation can complement training, I clinical experience	agree or disagree with ea mulators before r in cardiologists' training, ng sub-speciality training, e-consuming than but cannot fully replace	Strongly Disagree 1 1 1 1 1 1	Slightly Disagree 2 2 2 2 2 2 2 2	Neutral 3 3 3 3 3 3 3	Slightly Agree 4 4 4 4 4 4 4	Strongly Agree 5 5 5 5 5 5 5
2 3 4 5 6	Course Please indicate how much you a Cardiology trainees should train on si performing procedures on patients Simulation should be introduced early e.g. at ST3 level Simulation should be introduced durin e.g. at ST5 level Simulation-based learning is less time 'shadowing' and watching real cases Simulation can complement training, I	agree or disagree with ea mulators before r in cardiologists' training, ag sub-speciality training, e-consuming than but cannot fully replace aining environment for	Strongly Disagree 1 1 1 1 1	Slightly Disagree 2 2 2 2 2 2	Neutral 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	Slightly Agree 4 4 4 4 4	Strongly Agree 5 5 5 5 5 5 5 5
2 3 4 5 6 7	Course Please indicate how much you a Cardiology trainees should train on si performing procedures on patients Simulation should be introduced early e.g. at ST3 level Simulation should be introduced durin e.g. at ST5 level Simulation-based learning is less time 'shadowing' and watching real cases Simulation can complement training, I clinical experience Simulation provides an appropriate tra developing technical skills (e.g. cather Simulation provides an appropriate trat developing team skills (e.g. community multi-tasking)	agree or disagree with ear mulators before r in cardiologists' training, ag sub-speciality training, e-consuming than but cannot fully replace aining environment for terisation) aining environment for cation, leadership and	Strongly Disagree 1 1 1 1 1 1 1 1 1	Slightly Disagree 2 2 2 2 2 2 2 2 2 2 2 2	Neutral 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	Slightly Agree 4 4 4 4 4 4 4 4 4	Strongly Agree 5 5 5 5 5 5 5 5 5 5
2 3 4 5 6 7 8	Course Please indicate how much you a Cardiology trainees should train on si performing procedures on patients Simulation should be introduced early e.g. at ST3 level Simulation should be introduced durin e.g. at ST5 level Simulation-based learning is less time 'shadowing' and watching real cases Simulation can complement training, I clinical experience Simulation provides an appropriate tra developing technical skills (e.g. cather Simulation provides an appropriate tra developing team skills (e.g. communic multi-tasking) Simulation provides an appropriate tra learning what to do 'when things go w management skills)	agree or disagree with ear mulators before r in cardiologists' training, ag sub-speciality training, e-consuming than but cannot fully replace aining environment for terisation) aining environment for cation, leadership and aining environment for rong' (i.e. crisis	Strongly Disagree 1 1 1 1 1 1 1 1 1	Slightly Disagree 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Neutral 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	Slightly Agree 4 4 4 4 4 4 4 4	Strongly Agree 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5
2 3 4 5 6 7	Course Please indicate how much you a Cardiology trainees should train on si performing procedures on patients Simulation should be introduced early e.g. at ST3 level Simulation should be introduced durin e.g. at ST5 level Simulation-based learning is less time 'shadowing' and watching real cases Simulation can complement training, I clinical experience Simulation provides an appropriate tra developing technical skills (e.g. cather Simulation provides an appropriate tra developing team skills (e.g. communic multi-tasking) Simulation provides an appropriate tra learning what to do 'when things go w	agree or disagree with ear mulators before r in cardiologists' training, ag sub-speciality training, e-consuming than but cannot fully replace aining environment for terisation) aining environment for cation, leadership and aining environment for rrong' (i.e. crisis routinely offered to entire am of cardiologists,	Strongly Disagree 1 1 1 1 1 1 1 1 1	Slightly Disagree 2 2 2 2 2 2 2 2 2 2 2 2	Neutral 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	Slightly Agree 4 4 4 4 4 4 4 4 4	Strongly Agree 5 5 5 5 5 5 5 5 5 5

11	Simulation has a role for both junior and senior cardiologists	1	2	3	4	5		
12	Simulation is useful for selection of trainees prior to them embarking on a career in cardiology	1	2	3	4	5		
13	Simulation can be used for re-validation/recertification of experienced/expert cardiologists	1	2	3	4	5		
14	Simulation can be used for accreditation purposes (i.e. to judge competence of junior doctors during ARCP)	1	2	3	4	5		
15	Simulation is currently under-utilised due to financial barriers in the NHS	1	2	3	4	5		
16	Simulation is currently under-utilised due to logistical issues, as simulators are not accessible to all trainees across Deaneries	1	2	3	4	5		
17	Simulation is currently under-utilised due to lack of educational resources (including validated training programmes and faculty)	1	2	3	4	5		
18	Current simulators lack high fidelity to replicate the range of complications during real interventional procedures	1	2	3	4	5		
19	Simulation allows learning of novel, complex interventional procedures in a safe environment (e.g. TAVI, LAA)	1	2	3	4	5		
20	Simulation is useful in testing new devices or novel equipment (e.g. bifurcation stents)	1	2	3	4	5		
21	Simulation is useful in testing innovations to be subsequently applied to cardiac care pathways (e.g. technology-supported handovers)	1	2	3	4	5		
	Thank you for taking time to complete this survey							

Figure 12: Questionnaire Survey: Trainees in cardiology

SIMULATION BASED LEARNING & TRAINING IN INTERVENTIONAL CARDIOLOGY Principal Investigator: Dr Sujatha Kesavan, Research Fellow, Interventional Cardiology Clinical Supervisor: Dr Iqbal Malik, Consultant Cardiologist										
Res	Research Associate: Dr Tanika Kelay, Psychology									
	Simulation is an important part of training in other fields i.e. the Aviation industry and Formula 1 racing. This questionnaire is designed to understand the views of junior doctors concerning learning by simulation in interventional cardiology.									
Place of Work	Medical School Attended		Gender	·						
 District General Hospital Tertiary Centre Hospital 	UK Abroad Year of Graduation		Age							
Do you have a fixed, protected session for education and training every week?	Are you in an academic training programme in cardiology? Yes No	Grade of traini	☐ ST6 □ ST7	Other						
		ST5								
How many interventional cardiolog 31-40 □ 41-50 □ >50	y procedures do you perforr	n per week?] <10 🛛 11-20	□ 21-30 □						

	Have you visited any institute, meeting or course that offers sir	nulation tra	aining in Int	erventiona	I Cardiolo	av?
	□ Yes □ No		J		,	
	If Yes, please name the Institute, meeting or					
	course					
	Please indicate how much you agree or disagree with each	ch stateme	ent by circ	ling a nur	nber on th	e right.
		Strongly Disagree	Slightly Disagree	Neutral	Slightly Agree	Strongly Agree
1	Cardiology trainees should train on simulators before performing procedures on patients	1	2	3	4	5
2	Simulation should be introduced early in cardiologists' training, e.g. at ST3 level	1	2	3	4	5
3	Simulation should be introduced during sub-speciality training, e.g. at ST5 level	1	2	3	4	5
4	Simulation-based learning is less time-consuming than 'shadowing' and watching real cases	1	2	3	4	5
5	Simulation can complement training, but cannot fully replace clinical experience	1	2	3	4	5
6	Simulation provides an appropriate training environment for developing technical skills (e.g. catheterisation)	1	2	3	4	5
7	Simulation provides an appropriate training environment for developing team skills (e.g. communication, leadership and multi-tasking)	1	2	3	4	5
8	Simulation provides an appropriate training environment for learning what to do 'when things go wrong' (i.e. crisis management skills)	1	2	3	4	5
9	Team training in simulation should be routinely offered to entire cardiac care teams (e.g. Cath-Lab team of cardiologists, nurses and radiographers)	1	2	3	4	5
0	Simulation-based learning transfers to real clinical environments (e.g. Cath-Lab)	1	2	3	4	5
1	Simulation has a role for both junior and senior cardiologists	1	2	3	4	5
2	Simulation is useful for selection of trainees prior to them embarking on a career in cardiology	1	2	3	4	5
3	Simulation can be used for re-validation/recertification of experienced/expert cardiologists	1	2	3	4	5
4	Simulation can be used for accreditation purposes (i.e. to judge competence of junior doctors during ARCP)	1	2	3	4	5
5	Simulation is currently under-utilised due to financial barriers in the NHS	1	2	3	4	5
6	Simulation is currently under-utilised due to logistical issues, as simulators are not accessible to all trainees across Deaneries	1	2	3	4	5
7	Simulation is currently under-utilised due to lack of educational resources (including validated training programmes and faculty)	1	2	3	4	5
8	Current simulators lack high fidelity to replicate the range of complications during real interventional procedures	1	2	3	4	5
9	Simulation allows learning of novel, complex interventional procedures in a safe environment (e.g. TAVI LAA)	1	2	3	4	5
20	Simulation is useful in testing new devices or novel equipment (e.g. bifurcation stents)	1	2	3	4	5
!1	Simulation is useful in testing innovations to be subsequently applied to cardiac care pathways (e.g. technology-supported handovers)	1	2	3	4	5

Data Collection:

Delegates attending the Advanced Cardiovascular Interventions (ACI) 2012 meeting in London, UK completed the questionnaire survey. Completion of a questionnaire was voluntary. A Likert scale (1 -5) for each question enabled the participants to record their views independently.

Data analysis:

Data entry of the completed questionnaires was performed on IBM SPSS statistics 19. Response for every question was coded from a value of 1 to 5 (Strongly disagree, slightly disagree, neutral, slightly agree to strongly agree). Mann Whitney U test was used to analyse the difference in responses for each question between the consultant cardiologists and the cardiology trainees.

4.5 Results

Demographics

55 (93%) consultant cardiologists were male (age – range- 35 - 65 years). 36 (61%) consultants worked in a tertiary centre. 52 (88%) consultants performed at least 20 interventional procedures per week. 38 (64%) consultants had prior experience in simulation training and 35 (59%) consultants have attended courses concerning simulation based training (Table 12).

	Consultants (n = 59)	Trainees in cardiology (n = 61)
Gender (Male)	55 (93.22%)	45 (73.77%)

Table 12: Questionnaire survey: Demographics

Age (Median in years)	44.5	34
Working in a tertiary centre	36 (61.01%)	42 (68.85%)
Academic Position	19 (32.20%)	NA
Fixed teaching session to train	33 (55.93%)	33 (54.09%) – Fixed teaching
juniors each week		session each week
Educational and clinical supervisor	29 (49.15%)	NA
Member of ARCP panel	12 (20.33%)	NA
No of years working as a consultant (Median)	7	NA
Experience in simulation training	38 (64.40%)	27 (44.26%)
Simulation based courses attendance	35 (59.32%)	26 (42.62%)
No of interventional	11	10
procedures per week (Median)		
Medical school (UK)	NA	41 (67.21%)
Academic Training	NA	10 (16.39%)
Programme		

45 (73%) junior doctors were male (age – range- 28 - 41 years). 42 (68%) junior doctors worked in a tertiary centre. 19 (31%) junior doctors graduated abroad in medicine. 52 (85%) junior doctors performed at least 10-20 interventional procedures per week. 27 (44%) junior doctors had prior experience in simulation training and have attended courses concerning simulation (Table 12).

Survey responses: Descriptive and comparative analysis between the consultants and the trainees

There were no statistically significant difference between the perceptions of consultants and junior doctors regarding simulation as a training tool, effectiveness of simulation in team training or in testing novel techniques in simulation (Table 13.1 and 13.2). The main barrier to the introduction of simulation as a training tool was financial and logistic issues (access to simulators, time constraints, availability of trainers and mentors).

Table 13.1: Questionnaire: Data: Perception of simulation based education in cardiology

	Consultants		Trainees		Independent Sample	Mann W U test Mean Rank		Asym sig – 2 tailed	
Questions	Mean Median	SD	Mean Median	SD	Median Test value	Cons	Trainees	Distribution	
Trainees should train on simulators first before	3.881	0.872	3.639	1.07	0.596	64.16	56.96	0.234	
performing on patients	4		4						
Simulation – at ST3 level	4.152 4	0.943	4.266 4	0.686	0.975	59.60	61.37	0.763	
Simulation – at ST5 level	3.389 4	1.114	2.833 3	1.164	0.029	67.89	53.35	0.018	
Simulation based learning is less time consuming	3.084 3	1.163	3.2 3	0.98	0.891	59.31	61.66	0.700	
Simulation - complements training	4.576 5	0.855	4.65 5	0.636	0.932	61.02	60.00	0.839	
Simulation – technical skills	3.949 4	0.936	3.633	0.964	0.149	66.10	55.08	0.059	
Simulation – team skills	3.322	1.237	3.45 4	1.104	0.937	58.56	62.38	0.530	
Simulation – for crisis management skills	3.627	1.065	3.7	1.066	0.553	58.86	62.15	0.574	
Team training – entire cardiac teams	3.898 4	0.864	3.866 4	0.797	0.596	60.79	60.22	0.924	
Simulation – skills transferable to real life	3.745 4	0.862	3.633 4	0.876	0.937	62.76	58.31	0.452	
Simulation – role for junior and senior cardiologists	3.966 4	0.909	3.916 4	0.801	0.339	62.03	59.02	0.604	
Simulation – for trainee selection	3.203	0.924	2.783	1.363	0.740	66.08	55.10	0.075	
Simulation – for revalidation/recertification	2.966 3	1.098	2.766 3	1.292	0.895	63.18	57.91	0.393	
Simulation – for accreditation –ARCP	3.118	1.051	2.7 2	1.24	0.371	66.32	54.87	0.062	
Simulation – underutilised – financial barriers in NHS	3.796 4	0.886	3.916 4	0.899	0.923	57.68	63.21	0.359	
Simulation – underutilised – Logistic issues	4.016	0.819	4.083	0.714	0.604	59.10	61.85	0.638	
Simulation – underutilised – Lack of training programmes	4.067	0.715	4.0	0.774	0.752	61.46	59.57	0.745	
Simulators – lack fidelity	3.491 4	1.165	3.783	0.945	0.908	56.14	64.71	0.160	
Simulators – to learn novel techniques (TAVI, LAA)	4.016	0.798	3.966 4	0.893	0.914	60.97	60.05	0.872	
Simulators – useful in testing new devices	3.847 4	0.925	3.883 4	0.914	0.925	59.73	61.25	0.790	
Simulators – help in technology aided handovers	3.745 4	0.733	3.683	0.786	0.827	62.03	59.02	0.599	

Questions	Mean	Standard	25 th	50 th	75 th percentile	
		Deviation	percentile	percentile		
Trainees should train on simulators	3.75	0.952	3	4	4	
first before performing on patients						
Simulation – at ST3 level	4.21	0.821	4	4	5	
Simulation – at ST5 level	3.14	1.161	2	3	4	
Simulation based learning is less time consuming	3.14	1.071	2	3	4	
Simulation - complements training	4.60	0.749	4	5	5	
Simulation – technical skills	3.80	0.959	3	4	4	
Simulation – team skills	3.40	1.169	2.25	4	4	
Simulation – for crisis management skills	3.67	1.06	3	4	4	
Team training – entire cardiac teams	3.89	0.82	3	4	4	
Simulation – skills transferable to real life	3.69	0.86	3	4	4	
Simulation – role for junior and senior cardiologists	3.94	0.85	4	4	4	
Simulation – for trainee selection	3.00	1.18	2	3	4	
Simulation – for revalidation/recertification	2.80	1.19	2	3	4	
Simulation – for accreditation – ARCP	2.91	1.16	2	3	4	
Simulation – underutilised – financial barriers in NHS	3.85	0.891	3	4	5	
Simulation – underutilised – Logistic issues	4.05	0.765	4	4	5	
Simulation – underutilised – Lack of training programmes	4.03	0.743	4	4	5	
Simulators – lack fidelity	3.65	1.06	3	4	4	
Simulators – to learn novel techniques (TAVI, LAA)	3.99	0.845	4	4	5	
Simulators – useful in testing new devices	3.86	0.916	4	4	4	
Simulators – help in technology aided handovers	3.71	0.757	3	4	4	

Table 13.2: Questionnaire (n = 120): Descriptive Statistics and Percentiles

Junior doctors preferred simulation based training to be introduced at an earlier stage of their training (ST3) whereas consultants preferred training to be introduced at a later stage (ST5) (p = 0.018). Junior doctors were not in favour of using simulation as a selection tool (p = 0.075) or for accreditation (p = 0.062) during Annual Review of Competence Progression (ARCP).

Consultants and trainees in cardiology have a positive attitude towards simulation based education - which is evident in the various categories from figure 13 to figure 17.

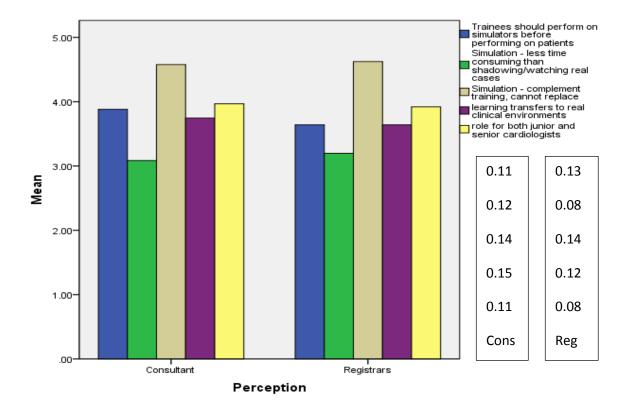


Figure 13: General Perception towards simulation

The numbers in the text boxes represent the standard error

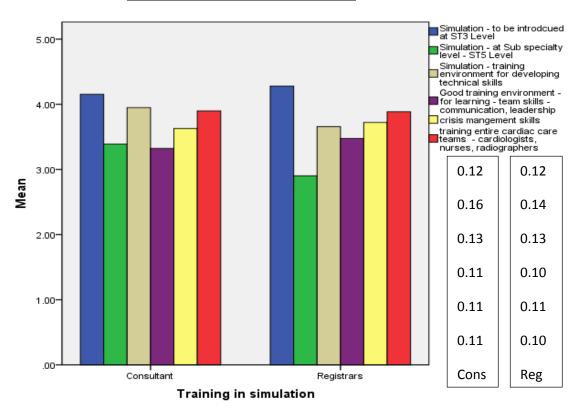
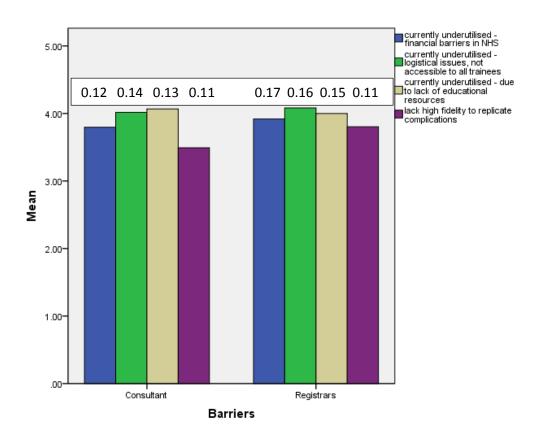




Figure 15: Barriers towards implementation



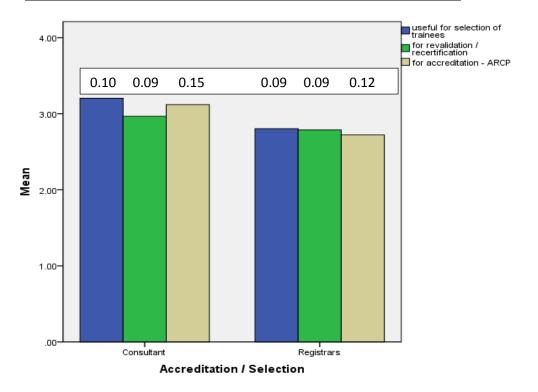
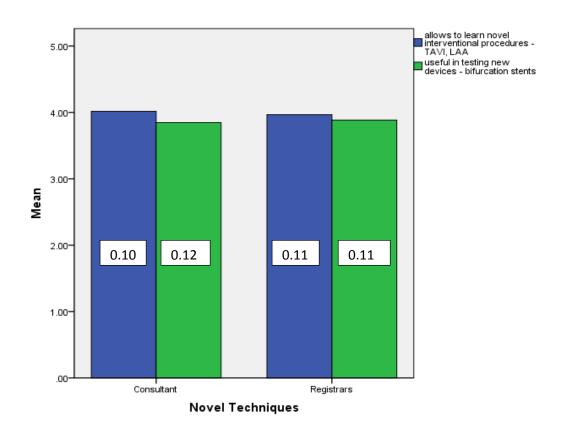


Figure 16: Simulation for accreditation and selection of trainees

Figure 17: Simulation for testing novel devices and for learning new techniques



4.6 Discussion

There is a paucity of literature concerning simulation based education in cardiology – which was illustrated by my review in Chapter 2. This study makes a novel contribution by systematically analysing the views of consultants and juniors in cardiology in the UK regarding simulation based training. The interviews of Chapter 3 have provided an in depth analysis of the topic which will help the educators to devise a training curriculum to suit the educational needs of the trainee. Trainees prefer low and a high fidelity simulation which can capture the "realism" of the simulation as accurately as possible. Regular training sessions involving one to one teaching with an enthusiastic, dedicated mentor was considered an essential component for the success of the programme. Protected time, easy access to simulators and a centralised, standardised training programme are essential.

The questionnaire survey was aimed as an extension of the interviews, to provide further evidence from a large number of consultants and trainees in cardiology in the UK. The study revealed that there are financial constraints; logistic issues and the availability of a trained faculty throughout the year require smart planning and management. The consensus was that simulation can complement training and cannot replace the existing teaching methods currently in use. The earlier the introduction of simulation training, the steeper the learning curves. Sequential high fidelity simulation is not currently available and hence the cardiology community felt that it is unsuitable for trainee selection or accreditation at this stage. Moreover, performance based validated metrics for each simulator, for every type of interventional procedure is lacking, which precludes the use of simulation as a selection, accreditation, recertification or a revalidation tool.

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My results provide an insight into the attributes necessary to design a successful, simulation training programme. The views represent the consensus opinion of experts and juniors in cardiology. The issues raised need to be addressed for the successful outcome of the training programme. Feedback, audit, research and evaluation are necessary for continued professional development and robustness of the simulation training programme.

4.7 Limitations

Training grades from ST3 to ST7 and fellows completed the questionnaire survey and the individual sample size for each grade of training are small in number. However, the study provides the first comparative analysis of views between consultants and juniors in cardiology towards a simulation based education.

The study participants involved delegates attending the ACI Conference, 2012 in London. Hence, there is a chance that the consultants and junior doctors from the London deanery predominantly completed the questionnaire. Hence, the study may reflect the views of doctors working in the tertiary centre only. The interview study was conducted considering these factors into account, which has provided an in depth analysis of the views of doctors practising in district general hospitals and tertiary centres. There is an element of selfselection as those who were not interested (in simulation) did not complete the questionnaire and the participation in the study was voluntary.

Further, the study is based on self-reported data, which should be complemented by actual simulation based education and evaluation of its impact on skills (technical and non-

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technical) and patient safety within the speciality. On the positive side, a multi-method multistage approach as taken to ensure content validity and relevance of the themes that were explored to the participants

4.8 Conclusion

Based on the questionnaire survey study reported in this chapter, along with the interview analysis in the preceding chapter, I conclude that consultants and junior doctors in cardiology are positive about simulation based training and learning. Junior doctors preferred introduction of simulation during the early stages (ST3) of their training period compared to consultants, who preferred simulation to be introduced at a later stage (ST5) of the training programme. Junior doctors do not prefer simulation based assessment for trainee selection or for accreditation.

Junior doctors lack exposure to a structured, validated, simulation based education and hence there is an unmet need to design a standardised, structured simulation based training programmes in cardiology.

The next chapter deals with the design and application of technology in cardiology (The "ihealth project") and its integration into simulation based education in cardiology. Chapter 5: Integration of technology in cardiology: A new challenge for simulation based applications

5.1 Chapter overview

Consultants and trainees in cardiology have embraced the idea of integration of simulation and technology in cardiology (Chapters 3 and 4). The present chapter focuses on the "i-health project" with the main aim of optimising care pathways in the context of an acute myocardial infarction with the introduction of an electronic form for critical information transfer from the community to the hospital.

5.2 Introduction

The Technology in the NHS report outlined a vision to transform care and interaction in the NHS through technology in 2008. A further review made promotion of innovation a legal duty for health authorities (99). "Engaging patients in their health" concluded that the use of technology is "underdeveloped and poorly deployed" in the NHS (100). A 2007 Nuffield Trust Report (101) on Electronic Personal Health Records (ePHRs) stated that ePHRs have the potential to improve communication between the providers and patients by sharing information, to enhance the quality of records by highlighting inaccuracies, and to reduce the burden of care by engaging patients in managing their own health and illness.

In the US, Kaiser Permanente's "My Health Manager" (102) states that "Implementation of necessary technology is highly context dependent and research is essential to inform strategic decision making" (103). In the UK, The EMIS Access (104) and Renal Patient View (105, 106) allow transmission of clinical data from primary and secondary care respectively.

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My Diabetes My Way (107) is an example of a diabetes focused personal record functioning in NHS Scotland. The "i-health project" is the first attempt in integrating technology in cardiology enabling data transfer from the community to the cath lab in the setting of an acute MI.

5.3The "i-health project"

The "i-health" is an EPRSC-funded project (Figure 18) that aims to design and develop tools focusing on the next generation of clinical information systems and physical simulators to help optimise exemplar-care pathways. "i-Health" is a multi-disciplinary collaboration between the Faculty of Engineering – Imperial College London (Department of Bioengineering, Department of Computing) and the Faculty of Medicine – Imperial College London (Division of Surgery, Oncology, Reproductive Biology and Anaesthetics, Department of Primary Care and Social Medicine).

The present chapter involves the steps involved in designing an electronic form (e-form) for critical, clinical information transfer from the community by the ambulance team in the context of an acute MI. Qualitative analysis (interviews) was undertaken to analyse the views of consultants and trainees in cardiology towards the integration of the e-form into mainstream clinical practice in cardiology.

5.4 Electronic transmission of data from the community to the cardiology team

Acute myocardial infarction (MI) is a medical emergency. Prompt diagnosis and treatment



Figure 18: Imperial i-Health Project: Home Care to Tele Care

are essential, which determines the long term prognosis of the patient. Hence accurate clinical information capture and data transfer is crucial, especially during the early stages of admission. Accurate recording and timely transfer of patient information across the MI care pathway between clinical teams has been highlighted as a key feature of safe and effective healthcare systems (108). Failures in information transfer, incorrect or incomplete information, or delays in obtaining relevant information have been implicated in increased risk of adverse events and near misses across a range of healthcare specialties (109 - 111). With the increasing importance assigned to effective communication in healthcare, a number of interventions to enhance these processes have emerged – including team training (111 - 113) , checklists (114, 115) , and team briefings/debriefings to ensure that all members of a team have an accurate and shared "mental model" of their patients and respective tasks (112, 115 - 118).

In addition to these solutions, modern information and communication technologies (ICT) are being increasingly introduced into healthcare settings to record, store, and manage information. These tools include the patient record (increasingly electronic), electronic prescribing, various electronic pro-formas, and a range of other ICT-based management and administration systems. A key premise of such information systems is that they streamline information transfer. They function as depositories of information that are always available, cross-searchable, and immune to "human factors" failures, like lapses in attention or memory (119). Despite their documented benefits (120, 121) such systems are often met with apathy or even hostility from frontline healthcare personnel – resulting in either low uptake or large scale failures to effectively implement such systems into everyday clinical practice (122).

Hammersmith Hospital - Current Status

Acute cardiac care was chosen as the setting for the study as it represents an example of a treatment pathway in which real time information plays a key role. Patients experiencing acute cardiac related chest pain require immediate treatment, with time-related endpoints (e.g., time to treatment not exceeding 90 minutes, coronary blood flow restoration time). CCUs are acute, stressful, medical environments with fast paced, diverse clinical activity and emergency admissions.

Ensuring that accurate information is available on time and efficient handovers of information between clinical teams contribute directly to the smooth handling of patients, safer care provision and efficient workflow within a CCU. Information availability and accuracy can have significant implications for the quality of care that patients receive, as well as for the efficiency of clinical teams (108). Disruptions to the flow of information at any stage in the MI care pathway may have direct and serious consequences for the level of care patients receive – and at the very least may render the clinical process less efficient, with clinical and nursing personnel browsing through multiple forms, away from direct patient contact (119).

Previous pilot analysis by our group revealed a total of 13 discrete systems utilised across the various stages of the MI care pathway. In order to gain a complete set of patient information, healthcare staff had to access an average of six of these systems. CCU staff accessed an increasing number of different systems as the patient progressed through the pathway from admission through to discharge. Information deemed vital for decision making was, on average, stored across 3 discrete systems with some information duplicated across as many as 10 systems.

Although there are certainly historical and technical reasons why a number of different systems ought to be in place in an environment like the CCU, we believe numerous systems suggest fragmentation of information. Fragmented information systems represent a significant barrier to information provision leading to delays in accessing information, frustration and potentially poorer, delayed clinical decisions. User-centred design and user involvement at early stages of the implementation of a new system with the view to integrate old and new systems (rather than just add) are recommendations that could reduce some of the duplication and address this problem.

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Patient handover has previously been highlighted as a key area where communication of patient information may be lost (123). It follows that subsequent improvements in data capture may be relevant and feasible at this stage of the pathway. Detailed observation and analysis of local clinical circumstances, utilisation, and need could be a first step in a larger programme of designing and implementing novel data capture, storage and management systems within what is often a pressurised, acute clinical environment. Future research should focus on user involvement at the early stages of the design followed up with user involvement when a system is piloted within the clinical workplace – to ensure that the system is truly relevant and useful to its users prior to implementation.

Based on our findings, we suggest that integrated ICT based data capture and information transfer systems would facilitate efficient communication between different clinical teams and would ensure higher standards of patient safety and patient care. Our pilot study highlighted the various clinical information systems that physicians, medical and paramedical personnel need to access to gain sufficient information about a single patient, which is prone to medical errors and can compromise patient safety and care along the MI care pathway. On the basis of these findings, we have the developed an electronic form for data capture by the ambulance team during the admission stage of the PPCI pathway (i.e., when the patient first gets transferred from the ambulance team to the CCU personnel) with direct clinical and nursing input and is aimed at streamlining information capture and transfer across this highly-pressurised clinical environment.

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5.5 Design of the electronic form

The healthcare industry is growing in complexity due in part to the fragmented nature of healthcare and the drive to improve quality of care. Ever larger and more complex volumes of data are being generated and need to be stored, accessed, shared and analysed. The limitations of paper based information are intuitively apparent. Crucially, however, only a subset of the available information is required at any step of the patient care. This supports the need for an information technology management system (124, 125).

The electronic form (e-form) supports the use of ICT to support decision-making and improve patient care in emergency cardiac care. More specifically, it aims at assessing the usefulness of an electronic dashboard that allows the swift transfer of critical information of a patient suffering from a heart attack from their first point of contact with an ambulance team to treatment by a cardiology team in the hospital.

The Life Net Log Sheet Form - John Radcliffe Hospital, Oxford

The first phase was to understand the Life Net Log sheet system (Figure 19), followed at the John Radcliffe Hospital, Oxford, which provided an insight into the design of an electronic form.

The paper form is kept in a folder in the coronary care unit (CCU) at the John Radcliffe Hospital, Oxford. The CCU nurse picks up the PPCI call from the community and completes the above form and waits for the electronic transmission of the ECG alone from the ambulance to the CCU. The ambulance team in the Oxford deanery uses the Life Pack system to transmit the ECG to the hospital. Next, the information is passed on to the cardiology team / trainee and the on call consultant cardiologist. Any paper based clinical information transfer has inherent limitations. It is prone to delay, medical errors and information lost in transit. The above system highlighted the pros and cons of a paper based system and allowed us to perfect the development of an electronic form (e-form) at Imperial College London, London, UK.

Date: DoB / Age:	Call Taker: Crew No:
Name of the patient:	Time of ECG: Time of call:
Chest pain assessment OLDCART	Observations:
	BP HR RR
	Spo2 BM AVPU
12 Lead ECG – PPCI Criteria Met Y / N	Risk factors (Please Circle)
ECG Interpretation:	FH DM HTN CHOL SMOKING
Comments:	PPCI ACTIVATION: YES / NO
	PPCI ACTIVATION TIME:
	PATIENT ETA:
	CREW ASKED TO GIVE 10 MIN ETA CALL
	YES / NO

Figure 19: The Life Net Log Sheet Form

The Electronic Form (e-form) – Imperial College, London

The second phase involved the development of an e-form in collaboration with the experts in cardiology (126) and the bio-engineering team. An electronic form (Figures 20 and 21) was

designed to convey key information about the patient with a heart attack.

Figures 20 and 21	represent the electronic form with colour of	codes

		M	01-J 19	Jan CAD Number: 56789 56 NHS Number: 12345 Since onset of Chest Pain
	Age: Weight: Height: Patient Add 210, Anorymou		Complaint	Onset of Pain: 09:00 Duration: 25 min Call for Help: 09:15 Ambulance at Scene: 10:15 Clinical Impression: Stother pain (cardiac in origin) Other chest pain (cardiac in origin) ST DEPRESSION IN 2,3 AVF NSTEM Palpitations Sweaty Asymptomatic Sweaty Asymptomatic
à	BA1 XYZ, Ba Contact:	ath UK 01225-856701	e S	
Scores	Pulse: BP: O2 Sats: GCS:	100 bpm 120 / 87 100 % 15	Patient ECG	A set of the set

Go	O1-Jan CAD Number: 56789 1956 NHS Number: 12345	323 mins since onset of Chest Pain
Smoker Standard Standard Stan	Renal Dysfunction Bleeding Disorders Future Surgery	Cardiac History Previous MI Previous PCI Previous CABG
G Family Hx of CAD S Diabetes ✓ Hypertension	Codeline	Drugs Given in Ambulance Aspirin Dose: 300 mg Clopidogrel Dose: 600 mg Morphine Dose: 10 mg
Digital Concella Lik	Drug History Warfarin Dose: Occasional cannabis user Paracetamol regular for back pain	escription
² alsolarming Business and Social		

The e-form uses colour codes to emphasise critical information and a streamlined layout for the initial phase of care. The data come from two sources: the patient's record for background information and information completed and transferred by the ambulance crew. The third phase focused on the evaluation of the e-form by the end users (Consultants and trainees in cardiology) using a semi structured interview study.

5.6 Preliminary user-based testing of the e-form: Interviews with consultants and trainees in cardiology

Study design:

A semi-structured interview was designed to understand the views of consultants and trainees in cardiology about the design, simplicity and the usefulness of the e - form. Specific questions concerning the e-form formed the last section of the main interview concerning simulation based education in cardiology (which I have reported in Chapter 3).

Data collection:

Consultants and Trainees in cardiology were interviewed from 3 deaneries (Severn, Oxford and London) – Bristol Heart Institute, Bristol, John Radcliffe Hospital, Oxford and at Hammersmith / St Marys Hospital, London, UK between November 2011 and March, 2012. Consecutive participants were recruited from both genders and from a range of seniority levels and sub specialities (Interventional cardiology, Non-invasive cardiology and Electrophysiology) in cardiology. Participation was voluntary and consent was obtained for conducting the interviews. Confidentiality and anonymity was ensured. Data analysis:

Preliminary analysis of all interviews was performed by the interviewing researcher (S.K). Emergent themes were coded and compared across the entire dataset. A blinded analysis for a sub set of interviews was performed by a second member of the research team with a background in psychology, to ensure accuracy in coding. Emergent themes were discussed and areas of agreement formed the basis of our finalised thematic structure. Thematic analysis aided the recruitment process and continued until theoretical saturation (repetitive and consistent findings across the interviews) was achieved.

Results:

13 consultants and 11 trainees in cardiology were interviewed. Demographics and clinical experience of the participants are explained in tables 8, 9 and 10 (Chapter 3). The following were the emergent themes from the analysis of the interviews (Table 14).

Themes	Verbatim Quotes						
	" clever and a nice idea"						
Design	"Good and a brilliant idea"						
	"concise one page information with critical data						
Simplicity	entry is extremely useful"						
	"great to have a helpful checklist"						
	"colour coding is very useful"						

Table 14: Electronic Form – Interview Analysis

Usefulness	"It's certainly got some positive value" "It's useful, Yes, it's good" "Don't have to go through questions many times" "ECG is the important information that we need"
Concerns / Comments	"Time spent in filling forms can be directed towards patient care" "Who are the personnel to complete the forms?" "I won't fully rely on the form. I will ask questions again to get first-hand information from the patient" "It does not replace clinical assessment and judgement"

The consultants expressed their intention to use the e-form as a means of support only. An electronic form does not replace clinical assessment and judgement. Completion of the e - form should not introduce a delay into the procedure. The form can also be tailored to different scenarios according to the clinical presentation of the patient.

The trainees were enthusiastic and are keen to adopt the technology as it provides a concise checklist. Remote monitoring, tele-medicine / tele-health is the future and will ensure better patient care. All agreed that clinical information transfer will be fast with the electronic form.

Some of the participants were also keen to integrate video transmission of the patients profile en route to the hospital.

5.7 Discussion:

Time is of essence while treating a patient with a heart attack. The sooner the information becomes available, the quicker the decision making. Hence it is aspired that the above electronic form of information transfer will be a useful tool in daily cardiology clinical practice. Unnecessary admissions to tertiary centres for invasive procedures can be avoided by reviewing the ECG online.

Directing the ambulance team to divert the patient to the nearest hospital providing the necessary care is an extremely cost effective way of utilising the health services. Expert advice can be provided to the general practitioners and the surgery so that they can streamline and triage patient care effectively. Discussions between the clinical teams during information transfer via an electronic form helps to educate the various teams in the latest advancements in cardiovascular medicine, thereby improving patient care.

Video transmission of a patients profile is being relayed to the hospital team in a few centres in India, Bangladesh and Nepal (127). In France, the doctor is in the ambulance with the patient which facilitates the video transmission and the clinical information transfer to the hospital. In the UK, the transfer of a patient with a MI is managed by the para-medical team (2 para-medics) only. One para-medic is a driver and the other para-medic cares for the patient during transfer. Currently, deaneries have a diverse range of information transfer systems from the community (ambulance team) to the cardiology team, when a patient develops a MI. It starts from verbal information only, verbal and faxing the ECG to accident and emergency department only, verbal and faxing the ECG to tertiary centre CCU from a nearest hospital. The described methods result in undue delay in accessing the correct treatment for the patient. The electronic form transfer from the community to cath lab, CCU and to the cardiology team can provide a solution to the above problems.

Data sharing through technology needs to be grounded in good information governance to protect patients and minimise security risks. The Caldicott principles (128) define basic information standards for all, but organisations need to carefully consider the implications of any new data sharing project. Technology development in healthcare has been hampered by concerns around security and lack of expertise. Digital health will play an increasingly important role over the coming decades and mainstream health providers need to find innovative ways to overcome the barriers and work with commercial, governmental and non-governmental partners to achieve the best care for their patients.

5.8 Limitations:

Only one consultant from Oxford was interviewed about the newly designed e-form, although all the consultants at Oxford are familiar with the Life Net Log Sheet Form. Clinical commitments limited the scheduling of interview of other consultants in Oxford - specifically the consultant who designed the Life Net Log Sheet form. The participants could not test the newly designed e-form in real situations as the ambulance teams in London, Oxford and Bristol were not trained to use the new electronic form.

5.9 Conclusions:

The electronic form appears to be an acceptable and a helpful clinical tool providing essential information about the patient during the most critical period (i.e. the early stages of a heart attack). It may assist in accurate information transfer between different clinical teams within the care pathway, thereby reducing medical errors and ensuring patient safety.

5.10 Future Direction:

Future research will focus on the implementation of the electronic form in realistic clinical settings and the assessment of its impact on clinical workflow. The aim is to integrate the transmission of the electronic form from the community to CCU, cath lab and to mobile platforms (eg - iPhone, tablets) used by the consultants and the junior doctors in cardiology for swift information transfer.

Simulations scenarios depicting a heart attack sequence are being carried out in collaboration with the cardiologists to assess the usefulness of the electronic form as well as establishing the limits of its functionality, which is the aim of the following chapter.

Chapter 6: Simulation in Cardiology - Pilot study

6.1 Chapter overview

In this chapter, the electronic form is tested in a simulated environment in a pilot study in collaboration with the specialty trainees in cardiology (London Deanery). Evaluation of simulation and the electronic form (e-form) are conducted on clinical case scenarios designed following a PPCI call. Development of case scenarios and assessment metrics for the virtual cath lab study is in progress and a preliminary attempt has been made to outline the development of a training programme.

6.2 Introduction

The two methods (interview and the questionnaire survey) of qualitative analysis explained in Chapters 3 and 4 have explored the perceptions of consultants and trainees regarding a simulation based education and the response has been positive towards such a training methodology. Whilst the trainees are competent enough to address general medical problems, it is a daunting task for a ST3 trainee in cardiology to manage a patient with an acute myocardial infarction (MI) following a primary PCI call from the community, during his / her first shift on call – especially at night and out-of-hours (weekends). Due to shorter training schemes, trainees are not exposed enough to handling emergencies arising in the catheterisation lab following coronary intervention.

The present chapter focuses on the pilot study – PPCI call study and the virtual reality lab study. The PPCI call study is explained in detail and an attempt has been made to design case scenarios suitable for testing the competence of the trainee in cath lab emergencies. Once tested and validated in a simulated environment, these scenarios, e-form and the assessment metrics can be integrated into the deanery training programme in cardiology in the future.

6.3 PPCI Call study – A prospective, small scale, pilot study

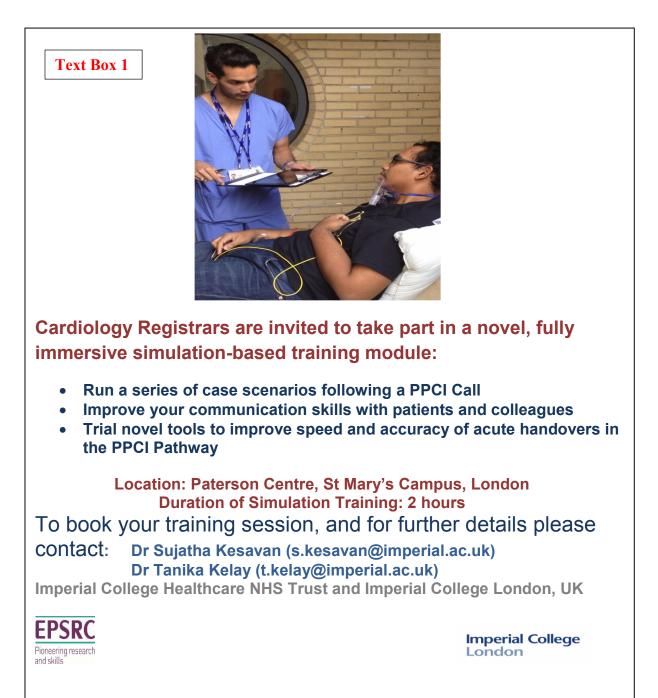
6.3.1 Aims

The aim of this study is to design case scenarios centred on a PPCI call and to test the electronic form in a simulated environment. Post scenario evaluation of the simulated scenarios and the e-form will test the feasibility of adoption of the technology to deliver training in cardiology.

6.3.2 Methods

Study design:

The first step was to design a poster (Text Box 1) conveying the key messages to generate interest among the specialty trainees in cardiology. The posters were displayed in the cardiac catheterisation labs and were also individually distributed to cardiology registrars during weekly departmental meetings. An invitation letter was sent to all the specialty trainees in cardiology in the London deanery electronically.



Prof Roger Kneebone / Dr. Nick Sevdalis / Dr. Fernando Bello / Prof Richard Kitney / Prof Jamil Mayet / Dr Iqbal Malik

Department of Simulation / Bioengineering / Department of Cardiology

<u>i-Health</u>: i-Health is an EPRSC-funded project that aims to design and develop the tools for this vision, including the next generation of clinical information systems as well as physical simulators to help optimise exemplar-care pathways.

<u>i-Health</u> is a multi-disciplinary collaboration between the Faculty of Engineering – Imperial College London (Department of Bioengineering, Department of Computing) and the Faculty of Medicine – Imperial College London (Division of Surgery, Oncology, Reproductive Biology and Anaesthetics, Department of Primary Care and Social Medicine). The next step was to develop clinical case scenarios depicting a patient with a MI and to test it in a simulated environment with the electronic form at the Skills Lab, Level 2, Paterson Centre, St Marys Hospital, London. The case scenarios (n = 5) were scripted with varying levels of difficulty testing communication, information transfer and management.

The first scenario was a "dummy run" (Text Box 2), allowing the participant to familiarise with the simulated environment and the electronic form. It enabled us to clarify any doubts that arose from the participants.

<u>Case Scenario – Dummy Run</u>

Text Box 2

Scene 1 – Introduction

A 40 year old, with a history of COPD, Hiatus Hernia and a strong family history of coronary artery disease experienced chest pain. Patient called the GP, who has examined the patient and has called for the ambulance - 999 call.

The ECG performed by the ambulance team is completely normal. Oxygen, Aspirin 300 mg and Diamorphine was given to the patient and but he still has chest pain.

On arrival, patient is haemodynamically stable with mild chest pain and abdominal pain, located in the epigastrium and moving up the chest

Scene 2 - Nurse to the doctor on call

Ambulance call

40 year old man with chest pain and abdominal pain

ETA: 5 minutes

Scene 3 – verbal handover from the ambulance team to the doctor

The doctor at the ED starts asking questions to the ambulance team and the patient.

The doctor introduces himself to the ambulance team and the patient

A 40 year old, with a history of COPD, Hiatus Hernia and a strong family history of coronary artery disease experienced chest pain. Patient called the GP, who has examined the patient and has called for the ambulance - 999 call.

The ECG performed by the ambulance team is completely normal. Oxygen, Aspirin 300 mg and Diamorphine was given to the patient and but he still has chest pain.

On arrival, patient is haemodynamically stable with mild chest pain, located in the epigastrium and moving up the chest

Scene 4 - Questions to the ambulance team from the doctor

What time did the chest pain start? How long did it last? Location of the pain?

Chest pain started 2 hours ago, it comes and goes. Each time, it lasts for 10 minutes or so

Is the chest pain associated with SOB, Palpitations? Is it worse on breathing?

Patient says there is a fluttery feeling in the chest and occasionally it is worse on breathing

Is it worse in certain positions?

Sometimes worse when lying on the side or on my back

What are the drugs given? Aspirin, Diamorphine

Is he allergic to any medication? Cephalosporins, another medication – not sure

Any risk factors?

Father had a heart problem – underwent an operation. Not sure – what it is.

Past medical history? Any previous cardiac history?

COPD, Hiatus Hernia. Previously investigated for chest pain – but the doctors said that everything was normal. That happened in 2009.

Examination findings? Pulse rate – 76 / minute, regular, Blood Pressure – 100 / 76 mm

Oxygen -- sats -- 98% on air, GCS -- 15 / 15

<u>Scene 5 – Questions to the patient from the doctor</u>

Do you have chest pain now? If there is chest pain, please let us know. We can give you more medications to ease the pain. It is mild now.

Have you had chest pain in the past? Many years ago. But the doctors said that everything was alright.

Are you taking any tablets for the heart? Not at the moment

Any other medicines? No, only my inhalers for the breathing problem.

Any previous history of heart problem or other medical problems? No

Then the doctor proceeds to examine the patient, will explain the diagnosis. Currently the diagnosis is uncertain as the patient is free of chest pain. The doctor explains about cardiac bio-markers and serial ECGs which will help in the diagnosis. Further investigations need to be done – like chest X ray, ETT. The treatment strategy will be discussed depending on the results of the investigations.

Diagnosis: Non cardiac chest pain

Each scenario (Text Box 2) was scripted in detail which facilitated the training of the faculty involved in the simulation. The simulation faculty members (Ambulance team, Nurse, Actor, Bio-engineering team and myself) were aware of the entire case scenario.

The study participant acquires information only from the nurse in the coronary care unit (Scene 2) which will be the first point of information exchange about the patient. The initial exchange of information is kept to the minimum to ensure standardisation across all the case scenarios. Additional information about the patient was obtained from the ambulance team (Scene 3 ad 4) and from the patient (Scene 5) on arrival to the simulated heart centre (Second Floor, Paterson Centre).

In scenes 3, 4 and 5, free flow of information exchange was encouraged to ensure that the simulation sequences represents an authentic, realistic experience to the participant.

<u> Clinical Scenario 1 - Mr. Gordon Smith – NSTEMI</u>

55 year old man, with a history of hypertension had chest pain and was reviewed by the ambulance team, following a 999 call.

The ambulance team have given the initial treatment - Aspirin 300 mg, diamorphine, maxolon, GTN spray and have obtained an ECG. ECG shows **Non STEMI** and the patient is transferred to the Emergency Department at Hammersmith Hospital.

<u>Clinical Scenario 2 - Mr. Peter Wood – Acute Anterior STEMI</u>

A 62 year old man, with a previous history of CABG - 2000, PCI - 2005, Atrial fibrillation - since 2008 has central chest pain, radiating down the left arm for the last few days. The pain is worse on exertion and is associated with SOB and palpitations. It has been troublesome for the last few days.

He is taking warfarin, aspirin, beta blocker, ACE – I, Statin, GTN spray. Today, the GTN spray did not relieve the chest pain and hence he called the ambulance. The ambulance team have given him diamorphine and 300 mg of Aspirin. Patient has mild chest pain now – similar to the chest pain in 2000. ECG in the ambulance confirms **STEMI in V2 – V6** (Acute Anterior MI)

<u>Clinical Scenario 3 - Mr. Jason Bourne – Acute Inferior STEMI</u>

A 50 year old man (smoker, obese, with a history of chronic alcohol intake, Hypercholesterolaemia) experiences chest pain at 9.00am. It was a central crushing chest pain, unbearable and hence he dialled 999. He felt dizzy at home and has injured his head. There is a scalp wound which is bleeding.

The ambulance team have done an ECG – which shows **acute inferior MI**. They have forwarded the details to CCU - Hammersmith and the cath lab team are waiting for the patient's arrival. The team have given him aspirin 300 mg, clopidogrel 600 mg, Diamorphine, Maxolon, GTN spray. The scalp wound is superficial and he has a dressing. GCS - 15 / 15.

Clinical Scenario 4 - Mr. Alex Stewart – Acute Anterior STEMI

A 40 year old, with a history of COPD, Hiatus Hernia and a strong family history of coronary artery disease experiences central, crushing, chest pain. Patient called the GP, who has examined the patient and has called for the ambulance - a 999 call.Patient is sweaty and pale.

GP gave Aspirin 300 mg, Diamorphine, maxolon to the patient.

Ambulance arrives. ECG shows **STEMI V2 to V6 (Anterior).** Clopidogrel 600mg is given. While in transit to the hospital, patient develops **ventricular tachycardia (VT).** DC shock is delivered by the ambulance once and he is in sinus rhythm with ST elevation from V2 – V6. Patient is in severe pain. The 4 scenarios (Text Box 3) described were utilised for data collection and data analysis. Each scenario was tested with and without the electronic form (displayed on the ipad) resulting in 8 clinical scenarios.

Assessment tools:

After the enactment of every scenario, the following post scenario evaluation forms were completed:

- STAI State Trait Anxiety Inventory Self Evaluation Form
- NASA TLX Scale NASA Task Load Index
- Manser Handover Rating Evaluation of the handover process

STAI: State Trait Anxiety Inventory

STAI is a self-evaluation questionnaire, designed by Charles D Spielberger in 1968 to measure the types of anxiety (129). It enables to differentiate between the 2 types of anxiety state anxiety (a temporary condition experienced in specific situations) and trait anxiety (a general tendency to perceive situations as threatening). It is a psychological inventory based on a 4 point Likert scale. A complete assessment involves 40 questions incorporated into Form Y -1 (20 questions) and Form Y- 2 (20 questions). The set of questions used in our study are the 6 questions from Form Y – 1 (Short STAI Evaluation - Table 15) measuring state anxiety (description of how subjects feel at the present time), as depicted below

Table 15: Short STAI evaluation form

Please read each statement and select the appropriate response to indicate how you felt during the handover you have just completed. Please state the answer which seems to describe your present feelings best.

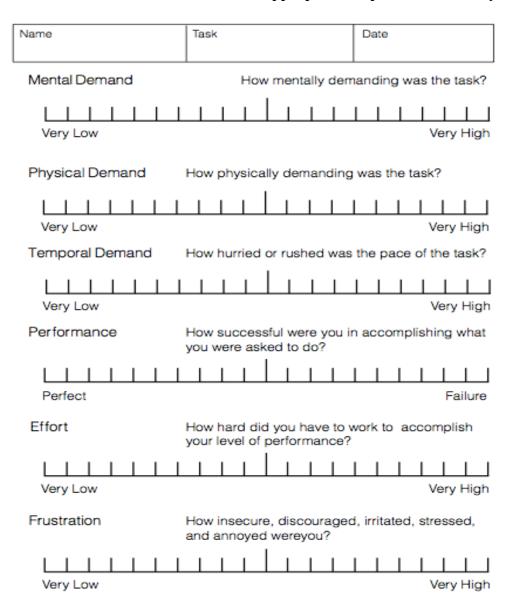
	Not at all	Somewhat	Moderately so	Very much so
I feel calm	1	2	3	4
I feel tense	1	2	3	4
I feel upset	1	2	3	4
I am relaxed	1	2	3	4
I am content	1	2	3	4
I am worried	1	2	3	4

NASA TLX Scale:

The NASA Task Load Index (NASA-TLX) is a subjective, multidimensional assessment tool that rates perceived workload (130), in order to assess a task, system, or team's effectiveness or other aspects of performance (Figure 22). It was developed by the Human Performance Group at NASA Ames Research Centre over a three year development cycle that included more than 40 laboratory simulations. The total workload is divided into 6 categories (131, 132).

Figure 22: NASA TLX Scale

Please read each statement and select the appropriate response to indicate your opinion



Manser Handover Rating:

Effective handover practices are critical to ensure continuity of care and patient safety. Many adverse events can be traced back to "inadequate handover" (133). Manser and her team have designed the 19 questions (Figure 23) concerning handovers with special focus on the characteristics, quality and the circumstances of the handover (134).

Figure 23: Manser Handover Rating

Please read each statement and select the appropriate response to indicate your opinion

	Not at all				Very much
Handover followed a logical structure	1	2	3	4	5
Person handing over the patient continuously used the available documentation to structure the handover					
Not enough time was allowed for the handover					
In case of interruptions during handover, attempts were made to minimise them					
All relevant information was selected and communicated					
Priorities for further treatment were addressed					
Person handing over the patient communicated her/his assessment of the patient clearly					
Possible risks and complications were discussed					
It was easy to establish good contact at the beginning of the handover					
There were tensions within the team during the handover					
Questions and ambiguities were resolved (active enquiry by the person taking on responsibility for the patient)					
Team jointly ensured that the handover was complete					
Documentation was complete					
There was too much information given					
Too much information was asked for					
The patient's experience was considered carefully during the handover (respect)					
Overall, the quality of the handover was very high					
Person handing over the patient was under time pressure					
Person taking on responsibility for the patient was under time pressure					

After completion of all the scenarios, the participant completed the following 2 forms

- Evaluation of the usefulness of the electronic form (Figure 24)
- Evaluation of the simulation (Figure 25)

Figure 24: Electronic Form evaluation

Please read each statement and select the appropriate response to indicate your opinion

	Strongly Disagree	Slightly Disagree	Neutral	Slightly Agree	Strongly Agree
The information presented on the dashboard is clear and understandable	1	2	3	4	5
The dashboard is easy to use	1	2	3	4	5
The dashboard covers important aspects of patient care	1	2	3	4	5
The dashboard is relevant to my job	1	2	3	4	5
I have no problem with the quality of the dashboard's output	1	2	3	4	5
I have the knowledge necessary to use the dashboard	1	2	3	4	5
I consider myself computer literate – i.e. I have no difficulty using computers	1	2	3	4	5
I would consult the dashboard in my patient care and management	1	2	3	4	5
I would consult the dashboard regularly	1	2	3	4	5
My colleagues will think that it is important to consult the dashboard	1	2	3	4	5
The benefits of using the dashboard are apparent to me	1	2	3	4	5
The dashboard improves patient outcomes	1	2	3	4	5
The dashboard improves my	1	2	3	4	5

productivity					
Using the dashboard is beneficial to my patient care and management	1	2	3	4	5
Using the dashboard enhances my effectiveness in the job	1	2	3	4	5
The dashboard provides useful feedback on how a unit department is delivering service	1	2	3	4	5
The dashboard improves transfer of information	1	2	3	4	5
The dashboard increases awareness of patient safety	1	2	3	4	5
The dashboard is a useful tool to increase staff's engagement with information about clinical practice	1	2	3	4	5
The dashboard allows transparent information sharing across the Trust's departments/units	1	2	3	4	5
The dashboard is useful in providing real-time information on service delivery	1	2	3	4	5

Figure 25: Simulation scenario evaluation

Please read each statement and select the appropriate response to indicate your opinion

	Strongly Disagree	Slightly Disagree	Neutral	Slightly Agree	Strongly Agree
The scenario in the simulation is close to what happens in the workplace	1	2	3	4	5
The simulated pathway is a realistic representation	1	2	3	4	5
The simulated environment is a realistic representation of the real clinical environment	1	2	3	4	5
The interaction with the clinical team / simulated patient is realistic	1	2	3	4	5
The equipment used in the simulation	1	2	3	4	5

is realistic					
I was fully immersed in the simulation	1	2	3	4	5
I performed as I do in the real workplace	1	2	3	4	5
I behaved in the same way as I do in the workplace	1	2	3	4	5
The simulation allows me to adequately demonstrate my skills	1	2	3	4	5
The scenario allows me to adequately demonstrate my clinical knowledge	1	2	3	4	5
The simulation allows me to adequately demonstrate my human factor skills (eg. Communication, Team work	1	2	3	4	5
The simulation allows me to adequately demonstrate my professionalism	1	2	3	4	5
The simulation is able to highlight strengths and weaknesses in my workplace performance	1	2	3	4	5
Overall, the simulation is an accurate judge of my overall competence at work	1	2	3	4	5

Finally, a semi-structured brief interview (Text box 4) was conducted in the end for the exchange of information between the participants and the simulation faculty. The focus was on the electronic form and the cardiac simulation scenarios (Text box 4). The process enabled me to understand the pros and cons of running a simulation sequence, enabling us to design sequential simulation scenarios in cardiology tailored to the needs of the trainees.

Study participants

The participants were specialty trainee doctors in cardiology of varying grades of seniority. All the participants worked in the London deanery. An invitation letter was sent to all the trainees in the London deanery. A participant information sheet was provided.

Interview Protocol

Text Box 4

Questions - Cardiology

- Scenarios: Level of difficulty? Standardisation? Comparison between other simulation courses scenarios?
- Training: Useful or not? Simple versus complex procedural training?
- Assessment: Conventional versus simulation? Robust method?
- Electronic versus Paper documentation: Pros and cons
 - Information transfer to CCU, Cath lab, your iPhone
 - Static versus dynamic dashboard
 - ? Bigger display monitor
 - Doctor versus ambulance form
- Simulators: Access site simulators versus other simulators
 - Models / companies preferred
- Suggestions for improvement: (if time permits)

Questions - Electronic form

- Are you familiar with using tablets? Do you own a tablet?
- Physical Tablet: Would handling the tablet interfere with patient care? Are you comfortable carrying it around when on call? Could you suggest a practical way of carrying tablet?
 - Information Content Is the information displayed sufficient? Did you spot anything missing? Did you have enough time to go through info on dashboard before handover? Importance of information-hierarchy
- Layout: Two pages sufficient? Any problems navigating? Colours used-warning scheme
- Errors & discrepancies: (If time permits)

END

Participation in the study was voluntary and consent was obtained. Strict confidentiality and

anonymity was maintained. Participants were provided with scrubs, stethoscope, consent

form and stationery to maintain the authenticity of the scenes.

Procedure:

Enactment of each scenario comprises of introduction of the faculty to the participant, walk around the department, initial briefing about the PPCI call, logistics, evaluation, completion of questionnaires and debriefing about the scenario. The Bio-engineering team (Dr.M. Bultelle) provided explanation about the lay-out, colour codes and the schematic representation of the electronic form to the participant, prior to the simulation of the "dummy run - case scenario". A programme sheet (Text box 5) was given to the participant on arrival. The entire sequence of events concludes in 2 hours.

The participant was blinded to the sequence (with or without the electronic form) of the scenarios and the programme sheet provided a rough guide only. The order of scenarios were changed from one participant to the other to avoid "familiarity fatigue" between the simulation faculties.

PROGRAMME	E	Text Box: 5
Welcome: Dr. Sujatha Kesavan	2 minutes	
Introduction: Dr. Sujatha Kesavan	10 minutes	
Electronic Form (iPad): Dr. Matthieu Bultelle	5 minutes	
Dummy Run Scenario	15 minutes	
Scenario 1	15 minutes	
Scenario 2	15 minutes	
Scenario 3	15 minutes	
Scenario 4	15 minutes	
Interview: Dr.Sujatha Kesavan / Dr.Matthieu Bultelle	10 minutes	
Team Debriefing:	10 minutes	

Data collection

Each scenario (with and without the e - form) concluded with the completion of 3 assessment forms concerning the handover process between the ambulance team and the participant – STAI, NASA TLX Scale and Manser Handover Rating. The sequential simulation following a PPCI call was video recorded to be analysed later and coded with a pre procedure checklist. An informal interview to understand the perception of the trainees concerning the e-form and simulation scenarios was conducted and recorded, after conclusion of all the scenarios. An evaluation form regarding the simulation and the electronic form was completed by each participant after the interview, with permission to use free text to express their views.

Training of faculty

The faculty involved 4 groups – The ambulance team, actor, nurse and the Bio-engineering team. Private ambulance services (Mr. Arnall and team) were involved and they are familiar with the transfer of patients with an acute myocardial infarction. They were presented a folder with all the scenarios enclosed for their perusal. Instructions were given to them to adhere to the script - nevertheless free exchange of information was encouraged between the ambulance crew, simulated patient and the doctor.

The actor was played by 2 research students (Mr.Hafiz Harun and Mr.Przemyslaw Korzieswki) with a background in computer graphics and haptic. The role of the actors were randomised to avoid familiarity between the participant and the simulated patient. The dummy run and the clinical scenarios were scripted in detail (verbatim) and I conducted many sessions to teach him about cardiac anatomy, blood supply, coronary artery disease, acute myocardial infarction, arrhythmias, defibrillation, ECG, medications, coronary angioplasty, coronary stent, CABG and cardiac rehabilitation.

The nurse in the coronary care unit was played by Dr.Tanika Kelay (Psychologist) and a list of bleep numbers of the specialty trainees was provided to her, along with the case scenarios to enact scene 2.The Bio-engineering team involved Dr.Matthieu Bultelle, with whom I have spent many hours designing the electronic form for the case scenarios.

Data analysis

Collected data from the evaluation forms were recorded and coded in EXCEL. Basic descriptive statistics were computed but no further statistical analysis was performed as the study sample size is small in number. The interviews were transcribed by a professional agency. Emergent themes were identified and coded by the primary researcher. Verbatim quotes were highlighted.

6.3.3 Results

Participants:

3 specialty trainees in cardiology have taken part in the study. The first participant took part in 8 scenarios (4 with the e-form and 4 without the e-form). The second and the third participants took part in 6 scenarios each (3 with e-form and 3 without e form). It was identified that consecutive 8 scenarios were very exhaustive for the entire team and hence further studies were conducted with 6 scenarios only. In total, 20 scenarios were enacted (10 with the e-form and 10 without the e- form). The demographics of the study population is described in the table below (Table 16).

	Participant 1	Participant 2	Participant 3
Age	32	32	33
Gender	Male	Male	Male
Hospital	Tertiary centre	Tertiary centre	Tertiary centre
Grade of training	ST5 - Academic	ST6 - Academic	ST5 - Academic
Number of interventional Procedures / week	< 10	21 - 30	< 10
Experience in simulation based training in cardiology	No	No	No

Table16: Demographics

All the participants were in the academic training period and hence were able to attend the simulation sessions. None of the participants underwent any form of simulation based training in cardiology

Evaluation of simulation and the electronic form:

Table 17: Simulation scenario evaluation - Median score

Statements	Median Score
The scenario in the simulation is close to what happens in the workplace	3
The simulated pathway is a realistic representation	4
The simulated environment is a realistic representation of the real clinical environment	2
The interaction with the clinical team / simulated patient is realistic	4

The equipment used in the simulation is realistic	4
I was fully immersed in the simulation	5
I performed as I do in the real workplace	5
I behaved in the same way as I do in the workplace	4
The simulation allows me to adequately demonstrate my skills	4
The scenario allows me to adequately demonstrate my clinical knowledge	5
The simulation allows me to adequately demonstrate my human factor skills (eg. Communication, Team work	5
The simulation allows me to adequately demonstrate my professionalism	5
The simulation is able to highlight strengths and weaknesses in my workplace performance	5
Overall, the simulation is an accurate judge of my overall competence at work	4

A score of 2 on the Likert scale represents that the participants "slightly disagree" with the statement (Table 17). Rest of the statements commanded a score of 3 to 5 (3 - Neutral, 4 - Slightly agree, 5 – strongly agree), favouring simulation. Comment in the free text – "The first one could be a walk-through of a non-complicated case to familiarise / ask questions regarding practical issues".

	Table 18:	Electronic	form	evaluation -	- Median score
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Statements	Median Score
The information presented on the dashboard is clear and understandable	5
The dashboard is easy to use	5
The dashboard covers important aspects of patient care	5
The dashboard is relevant to my job	5

I have no problem with the quality of the dashboard's output	4
I have the knowledge necessary to use the dashboard	5
I consider myself computer literate – i.e. I have no difficulty using computers	5
I would consult the dashboard in my patient care and management	5
I would consult the dashboard regularly	4
My colleagues will think that it is important to consult the dashboard	4
The benefits of using the dashboard are apparent to me	5
The dashboard improves patient outcomes	3
The dashboard improves my productivity	4
Using the dashboard is beneficial to my patient care and management	4
Using the dashboard enhances my effectiveness in the job	4
The dashboard provides useful feedback on how a unit department is delivering service	5
The dashboard improves transfer of information	5
The dashboard increases awareness of patient safety	5
The dashboard is a useful tool to increase staff's engagement with information about clinical practice	3
The dashboard allows transparent information sharing across the Trust's departments/units	4
The dashboard is useful in providing real-time information on service delivery	3

The scores 4 and 5 on the Likert scale for the evaluation of the e-form demonstrates participant's positive views towards the integration of the electronic form in a clinical setting. A score of 3 denotes a neutral opinion (Table 18). The following are the comments from the free text –

- "Pen and paper is better can't always trust technology"
- "The dashboard will only be as good as the person reporting the data"

 "Relevant clinical details – like head injury, alcohol in one patient, are not clear enough".

Evaluation of anxiety, work load and handover:

Table 19: State Trait Anxiety Inventory – STAI – Median and total score

Statements	E - Form - Yes		E- Form – No	
	Median	Total score	Median	Total Score
I feel calm	3	10	2	9
I feel tense	2	8	2	8
I feel upset	1	4	1	4
I am relaxed	2	8	2	9
I am content	3	10	3	12
I am worried	1	7	2	8

(Aggregate data)

Score 1: Not at all Score 2: Somewhat Score 3: Moderately so Score 4: Very much so The median and the total scores for all the 4 case scenarios with and without the e -form is summarised in table 19. There is no significant difference in the scores for all cases with and without the electronic form. The participants experienced the same level of anxiety and attitude towards scenarios of varying difficulty with and without the electronic form, which is well represented in the median scores.

<u>Table 20: NASA Task Load Index Scale – 4 case scenarios with & without the E-Form</u>

(Aggregate	data)
------------	-------

Statements	E - Form - Yes		E- I	Form – No
	Median	Total score	Median	Total Score
Mental Demand	8.5	33.5	8	31

Physical Demand	7	25	4	15
Temporal Demand	9	31.5	7.5	25
Performance	4.5	15.5	5	19.5
Effort	6.5	22	7.5	29.5
Frustration	6	19.5	3.5	17.5

Mental, physical, temporal demand, effort and frustration: Score 1 to 10 (very low to very high)

Performance: Score 1 to 10 (perfect to failure)

Mental, physical and temporal demand was high with the e-form while performance was better without the e –form. Frustration level was high with the e-form (Table 20). It is important to note that case scenario 4 was enacted by only one participant (First Participant) – which may skew the results. Case scenario 4 was complicated too.

The above data provides an insight into the suitability of the e-form in various case scenarios. The e-form may be suitable and valid for simple cases and not for complex, complicated case scenarios. Inference from the current data should be of a cautious approach as the sample size is small. Analysis with Manser handover rating follows.

Table 21: MANSER HANDOVER RATING - 4 scenarios - with & without the E-Form

Score 1: Not at allScore 5: Very Much

The median and the total scores for all the 4 case scenarios with and without the e -form is

summarised below. Case 4 was enacted by the first participant only.

	E-F	orm - Yes	E-Fo	rm – No
Statements	Median	Total score	Median	Total Score
Handover followed a logical structure	4	14	4	12
Person handing over the patient, continuously used the available documentation to structure the handover	4	15	3	10
Not enough time was allowed for the handover	3	11	3	10
In case of interruptions during handover, attempts were made to minimise them	4	16	4	15
All relevant information was selected and communicated	4	18	4	15
Priorities for further treatment were addressed	4	17	4	17
Person handing over the patient communicated her / his assessment of the patient clearly	4	16	4	12
Possible risks and complications were discussed	3	13	4	14
It was easy to establish good contact at the beginning of the handover	4	15	5	17
There were tensions within the team during the handover	1	6	1	4
Questions and ambiguities were resolved (active enquiry by the person taking on responsibility for the patient)	4	14	4	12
Team jointly ensured that the handover was complete	5	18	5	15
Documentation was complete	5	19	4	17
There was too much information given	2	8	2	7
Too much information was asked for	2	8	1	5
The patients experience was considered carefully during the handover	4	18	4	13
Overall, the quality of handover was very high	5	18	3	12
Person handing over the patient was under time pressure	5	19	4	13

Person taking on responsibility for the	5	19	4	13
patient was under time pressure				

Although the total scores varies, the median scores remain nearly identical between the 2 groups (with and without e-form). The e-form did demonstrate that the quality of handover was excellent and the documentation was complete (Table 21). Nevertheless, a significant difference between the 2 groups could not be demonstrated.

Evaluation of the interviews:

Participant 2 and 3 were interviewed and the analysis below are the excerpts from the interview. Participant 1 was not interviewed as the format of the interview was still in the design phase. The views expressed by the participants are summarised below (Table 22).

Evaluation - Themes	Verbatim Quotes
	"They were good – fairly close to realistic"
Simulation	"In real life, it's never quick as that. So everything takes much longer"
Sinuation	"I think it is very good for training" – especially trainees who are starting.
	"Not necessarily a bad thing – as well as to refresh. As I said, its two and half years - I have been in research, so that's good"
	"I like it. It's quite attractive - the way you have laid out"
	"It's got all the key things that we would be interested in as people who are about to perform a procedure"

Electronic Form	"It's very helpful because it means all the mundane things that I would forget – time of arrival, onset of chest pain etc are there"
	"Psychologically for me, as it is here – I tend to believe more. That may or may not be a good thing"
	"Any information is better than no information. I still like a verbal communication. I wanted everything clarified"
	"In the heat of the moment, it's very easy to tick the wrong boxes"
	"The expected time of arrival of the patient is more than 5 minutes in real life. Normally its 20 minutes or so. Hence ETA in simulation can be longer"
Suggestions	"Echo machine – a mobile phone toy. They look just like flip phones"
	"The first scenario – make it a straightforward case, nothing complicated, just to get into the flow of it"
	"The documentation by the paramedics should be permanent. Then, we should be able to go to the doctors page with a four finger swipe"
	"The live ECG transmission would be definitely be useful"
	"Live transmission of haemodynamics with 4G and Ethernet, you can actually see the BP, Stats"

6.3.4 Discussion:

Participants favoured a simulation based education in cardiology and were keen to integrate technology into cardiology to assist clinical information transfer. There was no evident differences in anxiety scores, which could mean a smooth introduction of the electronic form into regular clinical practice. Nevertheless, further research is mandatory to validate my preliminary findings. The electronic form was considered to provide complementary information only, so that the clinicians can check the information verbally from the patient on arrival.

The simulation scenarios were realistic but the simulated environment was not authentic enough to create the atmosphere. It is one of limitation of simulation of emergency clinical scenarios – as the participants are aware that it is "simulation" from the beginning. There is no surprise when a PPCI call is received and the participants are not interrupted with other distractions (Bleep, Telephone ringing in the ward, Personal telephone ringing, a patient waiting to speak to the doctor while answering a call, another emergency in the ward, junior doctor waiting to discuss a case with the registrar and many more). The suggestions provided in the interviews can be incorporated into the study so as to provide an authentic experience to the trainee.

The study is limited by the sample size (small in number). Hence any conclusion drawn from the present pilot study is "hypothesis generating" than "hypothesis testing". All the participants were academic registrars and hence there is no diversity in their clinical expertise. Assessments were not performed across all the training grades - from ST3 to ST7.

The first participant enacted all the 4 scenarios with and without the dashboard. The second and the third participants enacted 3 scenarios only, with and without the dashboard. Nevertheless, the pilot study gave me and the rest of the team an insight into running a sequential simulation scenarios for trainees in cardiology and the hurdles that one has to encounter in running such a training programme for the deanery.

6.3.5 Conclusion:

The pilot study has provided a framework for simulation scenario enactment and assessment of the participants concerning simulation based education in cardiology. The electronic form is a novel, innovative approach to the handover process in the context of an acute myocardial infarction. The effectiveness of the electronic form in simple and complex cases (cardiac arrest) need to be tested with rigour. Effectiveness and integration of the electronic form in the clinical care pathway can only be achieved after confirmatory evidence from randomised, robust clinical studies.

The above pilot study focused on the initial stages of the MI pathway from the community to the cath lab / ward. The next section deals with the design and development of clinical case scenarios concerning emergencies and complications that can arise during interventional procedures in the cath lab.

6.4 Virtual reality cath lab study - Development of clinical scenarios and checklist

6.4.1 Introduction

Teamwork, leadership, communication, managerial skills, operator confidence, task prioritisation, decision making under pressure, conflict solving, managing uncertainty, coping with fatigue, situational awareness, co-operation and interpersonal skills are prerequisites for a smooth functioning of a cardiovascular team in a busy catheterisation lab environment and in a dynamic patient care setting. Human error cannot be eliminated, but efforts to identify, minimise and mitigate errors can be done by ensuring that the individuals have appropriate technical / non-technical skills to cope with the risks and demands of their work. Nontechnical skills are the cognitive and social skills that complement workers' technical skills (5, 93, 94, 96, 97) - Table 23.

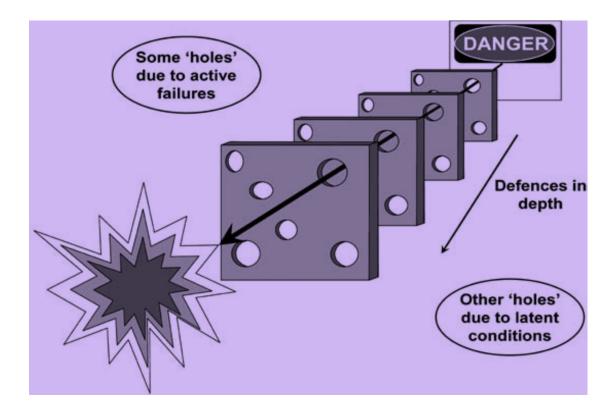
Category	Elements
Situational Awareness	Gathering and interpreting information Anticipating future states
Decision Making	Defining problem and considering options Selecting and implementing option Outcome review
Communication	Sending information clearly and concisely Including context and intent during information exchange Receiving information, especially by listening Identifying and addressing barriers to Communication
Team Working	Supporting others and solving conflicts Exchanging information Co-ordinating activities
Leadership	Using authority and maintaining standards Planning and prioritising Managing workload and resources
Managing Stress	Identifying symptoms of stress Recognising effects of stress Implementing coping strategies
Coping with fatigue	Identifying symptoms of fatigue Recognising effects of fatigue Implementing coping strategies

Table 23: Main categories and elements of non-technical skills - Flin et al

Accidents are usually caused by a sequence of flaws in an organisation's defences (Figure 26). These can be attributed to a combination of errors and violations by the operational staff (active failures) and the latent, repetitive, unsafe working practices (passive failures) in the

working environment due to external and internal factors. Technical expertise alone does not provide adequate protection from human error (9).

Figure 26: "Swiss Cheese Model" – An accident trajectory passing through the corresponding holes in the layers of organisational defences (Reason, 1997)



Introduction of specific team training modules and the assessment of the trainees for technical and non-technical skills has been challenging. Whilst procedural skills can be mastered in the cath lab in real life situations, mastery of non-technical skills is abstract and complex in nature. Checklists are essential to mitigate errors. Case scenarios, described in the previous section dealt with the initial stages of the MI care pathway. The next step was to develop case scenarios and assessment metrics involving interventional procedures in the cath lab.

<u>6.4.2 Aim:</u>

The aim of the work reported in this chapter was to design clinical scenarios in collaboration with the interventional cardiologists (Hammersmith Hospital) and cardiac electrophysiologists (Harefield NHS Trust), with guidance from the programme training director of the London deanery, Professor. Jamil Mayet.

6.4.3 Clinical scenario development:

<u>Case scenarios – Interventional Cardiology:</u>

The case scenarios were developed following discussions with Dr.Iqbal Malik, Director, Cardiac Catheterisation Lab, Hammersmith Hospital, London, UK. The focus was on 3 complications – Hypotension, bradycardia, pulmonary oedema (Text Box 6, 7 and 8). These clinical situations are not encountered in the lab on a daily basis and it was deemed important for trainees to understand, assess and manage these complex situations in a dynamic environment.

Each scenario was divided into 2 sections - a ward (CCU) scenario and a cath lab scenario. A pre-procedure comprehensive assessment is vital in these situations and the decision to transfer the patient for further intervention / management should be made by the trainee. The 3 case scenarios, venue for the ward and the cath lab scenario are described in the text boxes and in the figures that follow.

Text Box: 6

HYPOTENSION

Case 1 – Mr. Edmond

A 55 year old man, with a past history of hypertension and hypercholesterolaemia, underwent PPCI (Primary Percutaneous Coronary Intervention) to LAD (Left Anterior Descending Coronary artery), following an acute anterior myocardial infarction. 2 drug eluting stents were deployed and the procedure was uneventful (via femoral approach). There is a family history of Ehlers Danlos Syndrome. The patient was transferred to coronary care unit for further care.

30 minutes after the procedure, the patient is unwell and looks pale. Mild Chest pain. Heart rate -108 / minute, regular, sinus rhythm. BP -90 / 60 mm of Hg.

Differential Diagnosis:

Acute Stent Thrombosis, Retroperitoneal bleed, cardiogenic shock, pulmonary oedema, post MI VSD,

? Aortic dissection

WARD SCENARIO: Skills Centre - Paterson

Patient is in the coronary care unit after PPCI to LAD

Age: 55 years

PMH: Hypertension, Hypercholesterolaemia

Family History: Ehlers Danlos Syndrome

Diagnosis: Acute Anterior MI on ECG

Procedure: PPCI to LAD, 2 DES deployed

Complication; Sudden onset hypotension

Assessment by the doctor: History taking, examination, Decision making, management

CATH LAB SCENARIO: VR lab with VIST simulator

Management of Hypotension in the cath lab

ECG changes – ST elevation, cardiogenic shock

END

BRADYCARDIA

Case 2 – Mr. Adam

A 62 year old lady, with a past history of COPD (Chronic Obstructive Pulmonary Disease) is undergoing a PCCI (Primary Percutaneous Coronary Intervention) to RCA (Right Coronary Artery) in the cath lab, following an acute inferior myocardial infarction. It is a long lesion in the RCA and the first stent has been deployed. TIMI 3 flow was established and the second stent is being prepared for deployment. The ST segments were settling to the baseline on the monitor. The procedure was being done via the right radial approach.

Patient feels unwell, dizzy and has mild chest pain. Heart rate has dropped from 68 / minute to 22 / minute on the monitor. ST elevation was noted on the monitor. BP has dropped from 152 / 80 to 120 / 69 mm of Hg. 300 mcg of atropine did not produce any significant improvement.

Diagnosis:

Bradycardia -requiring atropine and temporary pacing wire, Extension of the infarct – RV infarction

WARD SCENARIO: Skills centre – Paterson Centre

Patient is in the patient bay outside the cath lab for PPCI

Age: 62 years

PMH: COPD

ECG: Acute Inferior Myocardial Infarction

Assessment by the doctor: History taking, Consent, Examination, Management, decision making

CATH LAB SCENARIO: VR lab with the VIST Simulator

Patient is in the cath lab

Right radial approach

Bradycardia - 22, Mild Chest pain

Management of bradycardia in the cath lab

END

Text Box: 7

ACUTE PULMONARY OEDEMA

Case 3 – Mr. Joseph

A 45 year old obese man with a history of hypertension and NIDDM (Non- Insulin Dependent Diabetes Mellitus) was admitted with NSTEMI. He is a heavy smoker with peripheral arterial disease. Past History includes CABG – 2005 and a brief episode of NSAID induced renal impairment.

He is undergoing cardiac catheterisation via the femoral approach. The first puncture was unsuccessful. The second puncture was successful, after some difficulty as there was some resistance. There is difficulty advancing the J wire. The J wire is removed and femoral / iliac angiograms are performed. Decision is made to use the TERUMO wire. Angiograms of native coronary arteries were obtained. There are 4 grafts to be identified. The 2 vein grafts were identified. There was difficulty in identifying the 3rd vein graft. Hence the operator decided to identify the LIMA (Left Internal Mammary Artery). The catheter has just engaged into the ostium of the LIMA partially. Patient develops sudden SOB (shortness of breath) in the cath lab and is unable to lie flat. Monitor shows VT (Ventricular Tachycardia).

Diagnosis:

Acute Pulmonary Oedema - Contrast induced nephropathy

WARD SCENARIO: Skills Lab – Paterson Centre

Patient is in the cardiac ward

Age: 45 years, obese, heavy smoker

PMH: NIDDM, Peripheral arterial disease, CABG – 2005, NSAID induced renal impairment. Number of grafts - unsure – 4 or 5

Diagnosis: NSTEMI. Awaiting cardiac catheterisation

Assessment by the doctor: History taking, consent, decision making, management

CATH LAB SCENARIO: VR lab with the VIST Simulator

Patient is in the cath lab

Difficult puncture. 4 grafts to be identified. 2 vein grafts were identified. 3rd graft - unable to identify despite many attempts. LIMA engaged

Sudden onset of SOB, ECG: VT

Management of pulmonary oedema and ventricular tachycardia in the cath lab

END

Text Box: 8

Ward scenario:

The ward scenario can be simulated at the Paterson Centre, Second Floor, St Marys Hospital Paddington (Figure 27). The mobile panels can be arranged into consecutive bays mimicking the setting of a coronary care unit.





Figure 27: Paterson's Centre

The two pictures depict the Skills Lab Centre at Paterson's Centre, which is equipped with state of the art facilities – The room can be converted into various formats to suit the needs of the educators, trainees and the trainers. It can be transformed from a lecture room to a complete ward facility in 30 minutes, by rearranging the panels and equipment to provide an authentic experience for the trainee.

Catheterisation lab scenario:

The cath lab scenario can be simulated and enacted independently or in sequence with the ward scenario. Depending on the design of the simulation, the appropriate venue can be chosen. The 2 venues chosen are the virtual reality lab at the Paterson's centre and the operating theatre, 10th Floor, QEQM Building, St Marys Hospital, Paddington, London.



Figure 28: QEQM Building, 10th Floor, Virtual Reality Operating Theatre

The facility at the QEQM building (Figure 28) offers a separate control room, which mimics the real life scenario. The caveat is the lack of C-arm in the suite. The facility at the Paterson's centre offers a C-arm with no separate control room. In an immersive simulation, the realism of the simulated environment within the enclosed area of the participant is vital compared to the facilities in the periphery of the participant. Hence, Paterson's centre is the ideal choice (albeit with minor modifications) for a sequential simulation with ward and cath lab scenario.

6.4.4 Assessment instrument development:

The next step is to design a pre-procedure assessment checklist (Figure 29), which was modelled on the assessment checklist approved by the PCR Seminars group – ESC.

Figure 29: LONDON DEANERY TRAINING PROGRAMME

INTERVENTIONAL CARDIOLOGY

Information About the patient	From Ambulance Team, Ward Staff, Case Notes	Confirmation by Doctor (case notes, obs chart)	Observations ECG, Echo, previous angio
1. Patient Information (Name, Gender, Date of Birth)			
2. Patient Status (Stable / unstable)			
3. ECG - STEMI / NSTEMI / Angina / Normal / Abnormal			
4. Time since onset of pain, description of the chest pain, exacerbating and relieving factors (if known)			
5. Drugs administered by ambulance team / Ward staff CCU – (Name of drug, dosage, time of administration?)			
6.Observations - Heart Rate, Blood Pressure, Oxygen SATS, GCS			
7. Past Medical History (if known) – DM, Stroke, TIA, MI, CAD, GI – Ulcer, Bleeding, CABG, PCI, PVD, Carotid Disease			

Pre-procedure assessment and optimization checklist

8. Drugs and Drug Allergies (if known) – esp Warfarin, GP 2B inhibitors		
9. Family History / Personal History		
10. Examination of the patient		
11. Medications to be given by the doctor - (Clopidogrel or prasugrel, morphine, IV fluids)		
12. Diagnosis		
13. Plan management strategy - Explain to the patient		
14. Check peripheral pulses and plan access		
15. Check FBC, urea , electrolytes, Troponin, other investigations – Echo, previous angiograms		
16. Explain procedure to the patient (Risks and Benefits)		
17. Consent to be obtained		

The assessment checklists for hypotension, bradycardia and pulmonary oedema in the cath lab are yet to be designed. The endovascular team and the interventional radiology team have explored the field of assessment during interventional procedures in the lab, as explained in Chapter 2. Collaboration with the interdisciplinary teams to arrive at a consensus assessment protocols is mandatory and is beneficial for all the specialties. A consensus statement is yet to be achieved. Meanwhile, case scenarios for cardiac electrophysiology were designed, which are explained further in this chapter.

Case scenarios - Cardiac Electrophysiology

The case scenarios were designed in collaboration with Dr.Mark Mason and Dr.Rebecca Lane – Consultant Cardiologists – Harefield NHS Trust, London. 2 case scenarios (Text boxes 9 and 10) in relation to permanent pacemaker insertion (Figure 30) were designed.

Design of an assessment metric for technical and non-technical skills in the cath lab is in progress.

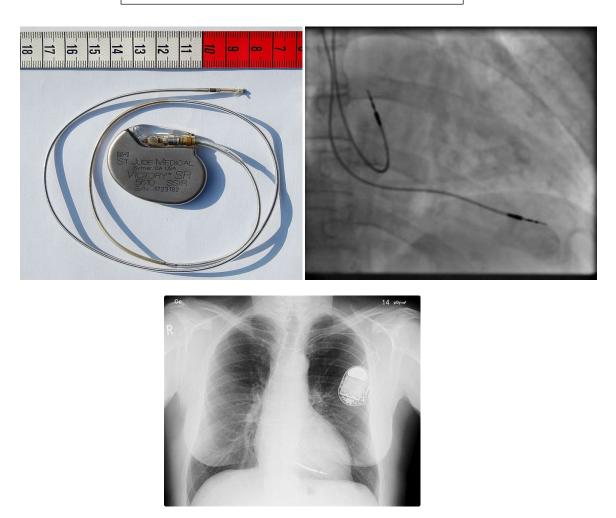


Figure 30: PERMANENT PACEMAKER

Courtesy: Wikimedia Commons (freely licensed media file repository)

PERMANENT PACEMAKER INSERTION

Text Box: 9

Case 1

An 87 year old female is admitted for a pacemaker. She has been found to have 2:1 heart block with intermittent complete heart block. She has a history of a metallic aortic valve replacement in 2007, and so is on warfarin therapy.

Issues:

- Do we perform the procedure on warfarin? What are the alternative strategies?
- Do we plan for 'active' or 'passive' atrial and ventricular leads, and why?

Select active A lead, passive V lead

• When attempting to position the V lead, no stable position can be found.

What next? - select active V lead

There is now no underlying rhythm- can pace through the passive fixation V lead but clearly this is not a satisfactory permanent solution.

What next?

Leave the passive fixation lead in place for the moment whilst gaining access and positioning an active fixation V lead, then remove the passive fixation V lead.

END

- A atrium
- V ventricle
- ERI Elective Replacement Indicator
- PSA Pacing System Analyzer
- DDDR Dual chamber pacing, dual chamber sensing, dual function (trigger or inhibit), rate responsive

PULSE GENERATOR CHANGE

Text Box: 10

Case 2

A 73 year old man arrives in the lab for a pacemaker generator change. The device was implanted at another centre in 1997 and the old records have not yet come to your centre. All you know is that it is a DDDR system.

Issues:

- What should the operator wish to establish (the device is at ERI and cancellation is not an option)?
- What are the lead parameters?

A lead threshold 0.6V at 0.4ms, impedance 564 ohms, 'P wave' 3.1mV; V lead threshold 0.4V at 0.4 ms, impedance 633 ohms, 'R wave' is 8.5mV. Is either lead known to be unipolar?

No Is the patient pacing 'dependent'?

The measurable 'R wave' should tell us the answer is no!

The case commences and the generator dissected out. It is disconnected from the leads and the V impedance is now 200 ohms

• Is this acceptable, and if not what are the possible explanations?

Not acceptable, and likely due to insulation break during dissection.

• What next? Implant a new V lead

The new lead is placed and the old lead disconnected from the 'PSA'. There is no underlying ventricular activity now.

• What next? Back on the PSA. Initially onto the old lead as was still pacing.

Now need to check the new lead, what are the options?

- Either move the black connector to the tip of the new lead leaving the red connector connected to the ring of the old lead, then move the red connector from the ring of the old lead to that of the new (this stepwise manoeuvre takes much of the stress out of the process by minimising the time for the patient to be without a cardiac output)
- Get a second PSA!

The new lead has satisfactory parameters. It must now be inserted into the new generator. The patient still appears to be pacing dependent.

• What are the options?

Leave a PSA connected to the old lead whilst inserting the new lead into the new generator

This is done, but on disconnecting the old V lead from the PSA there is loss of V pacing with loss of cardiac output.

• What are the possible explanations (the new V lead is now connected to the new generator)?

Most likely is that the device is programmed unipolar. This is not uncommonly regarded as the safe way of shipping the devices to prevent problems when connecting a unipolar lead to the generator, but creates problems as relatively few unipolar leads are still attached to generators! On arrival in a pacing department, all devices should be checked for their shipping parameters and reprogrammed where appropriate.

END

Overall conclusion:

This chapter explored the integration of technology in cardiology with the help of the electronic form and the effectiveness of simulation scenarios / electronic form following a PPCI call were analysed. Case scenarios for interventional cardiology and cardiac electrophysiology are in place. Assessment checklists for each scenario in the cath lab are yet to be designed. A consensus opinion between cardiologists, endovascular team and interventional radiology team is required to design robust assessment metrics, which will benefit the trainees of interdisciplinary specialties.

The previous chapters 1 to 6 dealt with medical education, integration of technology and application of simulation to educate doctors. The next chapter introduces a new concept to educate the public in cardiovascular diseases with the help of technology.

Chapter 7: Public education through simulation in cardiology

7.1 Chapter overview

The concept of educating the junior doctors in medicine in a simulated risk free environment is well accepted. The present chapter focuses on educating the public in cardiovascular diseases (eg Acute Myocardial Infarction) through simulation scenarios enacted in the community.

7.2 Introduction

Heart and circulatory disease is the biggest killer in the world. Every year, 124,000 patients are diagnosed with an acute myocardial infarction (AMI) in the UK. Significant advances over the last 15 years have enhanced its treatment and has reduced mortality >30%. The greatest benefit are seen in patients treated very early in the MI course. However, there are millions of people who fail to recognise the early signs of an acute myocardial infarction (135 - 137).

Delays in treatment—both pre-hospital and in-hospital—contribute significantly to patient mortality and morbidity (138, 139). Pre-hospital delay, accounting for some 65% of the interval between symptom onset and initiation of treatment, can stem from patient misperception about the severity of chest pain justifying emergency presentation (140 - 142). Community education programmes seeking to increase public awareness of the signs and symptoms of acute chest pain hold promise for reducing pre-hospital delay and encouraging appropriate use of emergency transport systems (143 - 147).

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Learning through simulation is an integral part of the medical curriculum as all physicians know. Similarly, educating the public through a simulated sequence of events provides a simple method to deliver complex information to the community. Tang et al (148) have published a series of articles relating to the concept of public engagement and education through a shared immersive simulation. Prof Roger Kneebone, Dr.Sujatha Kesavan and Dr.Fernando Bello at Imperial College, London in collaboration with the Bioengineering Department (Prof. Richard Kitney) have developed sequential simulation clinical scenarios concerning an acute myocardial infarction, diagnostic coronary angiogram, coronary angioplasty and stent insertion to interact with and teach the public.

Traditionally, role play, drama and theatre have been used to educate the public since medieval times. There is a paucity of literature regarding the benefits of public education in cardiovascular diseases in the digital age. Simulation incorporating an inflatable operating theatre to provide a "realistic" simulated environment to educate the public in treating cardiovascular diseases has never been done before. The novel, innovative approach to public education in cardiovascular diseases is explained in this chapter in great detail.

<u>7.3 Aim</u>

The main focus of the chapter is to understand the perception of public towards a simulation based education in cardiovascular disease (Example: Acute Myocardial Infarction) through a qualitative analysis (Interviews). The aim was to assess the impact of public education in cardiovascular diseases through simulations performed during the public engagement events.

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7.4 Methods

The process involved 3 stages – design of the clinical case scenario, development of a semistructured interview and the enactment of the scenario to the general public. A clinical case scenario (Text box 11) with a patient developing chest pain, whilst at home was designed. The scenario is divided into 3 main stages which corresponds to the 3 stations on display during the sequential simulation.

Case scenario for simulation – Acute Myocardial Infarction

Text Box: 11

Patient: History

Mrs. Smith, aged 58 years: Sudden onset central, crushing chest pain, radiating down the left arm. Felt cold and clammy, difficulty in breathing. Chest pain – one hour ago, unbearable – hence called 999

<u>Past Medical History:</u> Hypertension (10 years), High cholesterol – for the last 2 years, Exsmoker, Diabetes Mellitus – diet controlled

<u>Family History:</u> Father died at the age of 50 - due to MI (Heart Attack), Sister aged 52 - angina, underwent PCI and stent insertion

Medication: Amlodipine 5 mg once daily, Cod Liver oil one capsule per day

Drug Allergy: Nil

Station1:

The patient (played by a professional actor or actress) develops chest pain while at home

doing her daily chores. The simulated home is created by using mobile, flat panels with the

ambience of a home. The patient dials 999 and is promptly picked up by the ambulance crew

(Figure 31). They confirm the diagnosis of an acute myocardial infarction and the PPCI call

is activated (Text box 12).



Figure 31: Patient experiencing chest pain & is being examined by the ambulance crew



Figure 32: The cardiology registrar on call examines the patient

Station 1: Ambulance: Admission

Text Box: 12

<u>ECG:</u> ST elevation in 2, 3, avf. An acute inferior MI is diagnosed. PPCI call activated. Venflon inserted. Team have given Aspirin 300 mg, GTN spray, Morphine 7.5 mg, Maxolon 10 mg IV, Oxygen therapy

Continuous monitoring in place and the patient still has chest pain.

Handover from the ambulance team to the cath lab team, Sujatha examines the patient and takes history. Procedure and necessity of coronary angioplasty explained to the patient. Consent obtained. Risks explained. A hand held echo (V Scan) is performed which reveals good LV function. No valvular abnormality noted.

Prasugrel 60 mg is administered. Further Morphine 5 mg administered

Station 2: Cath lab procedure: Coronary angioplasty and stent insertion

<u>Primary Operator</u>: Dr. Sujatha Kesavan performs the procedure through a right femoral artery approach.

Drugs administered: heparin, bivalirudin.

Right coronary artery lesion is identified. It is explained to the patient. Coronary angioplasty is performed first and then a coronary stent (drug eluting) is deployed.

The procedure concludes without any complications. Patient is discharged after a 3 day stay in hospital.

<u>Medication:</u> Aspirin 75 mg once daily, Bisoprolol 2.5 mg once daily, Ramipril 5 mg once daily, Atorvastatin 80 mg once daily. Prasugrel 10 mg once daily – for 12 months, GTN spray.

Letter to the GP sent. Follow up in the PPCI clinic in 6 weeks' time arranged.

Station 3: Consultation with GP: Cardiac Rehabilitation

GP performs a general examination, Checks BP, Pulse rate. Chest and CVS examination are normal.

Risk factor modification is addressed – Control of BP, Cholesterol, Blood Sugar, Smoking cessation. Life style modification suggested.

Compliance with medication – absolutely important Risk of further MI and future cardiac events – discussed.

END

The crew relay the history, diagnosis and the clinical condition to the cardiology registrar on call at the tertiary centre (Figure 32).

Station 2:

The interventional cardiologists are ready to receive the patient in the cath lab – which is an inflatable room / theatre with 3 display monitors and a simulated, portable C arm. Coronary angioplasty and stent insertion is performed (Figure 33). The procedure is performed on a polystyrene model with the professional actor (patient) lying flat, covered in blue drapes.

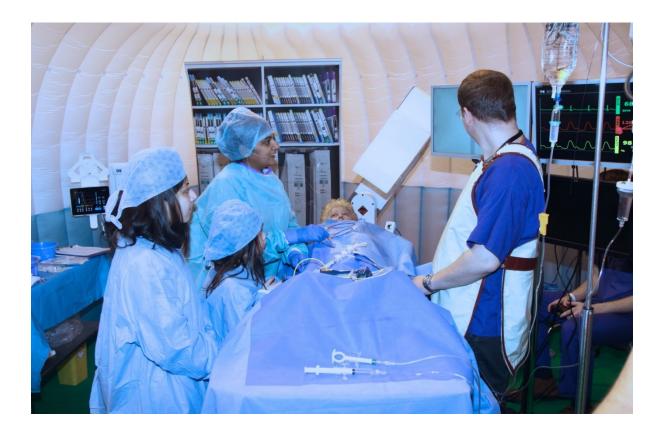


Figure 33: Coronary angioplasty and stent insertion performed

Station 3:

The patient is reviewed by the GP (Figure 34) in a few weeks' time. The follow up consultation involves addressing the risk factors concerning coronary artery disease providing

advice on secondary prevention, life-style changes and modification (Text box 12). Enactment of the entire clinical scenario concludes in 20 minutes.



Figure 34: A simulated patient (actress) with her General Practitioner

Technology integrated within the simulation:

The portable, low cost, inflatable room / theatre were designed by a team of doctors, designers and engineers - Matt Harrison (MEng Mechanical Engineering) and Cian Plumbe (DIC Mechanical Engineering). It provides an overall impression of performing the procedure in the cardiac cath lab with backdrops (posters) mimicking a typical scenario of the cath lab (Figure 35). A joy stick helps to control the movements of the light weight simulated C arm. The display monitors are connected to iPads with heart rate, BP, oxygen saturation monitoring and pressure tracing.

Figure 35: A simulated cardiac catheterisation lab



Computer graphics with haptic technology providing tactile feedback facilitates the display of the procedure of coronary angioplasty and stent insertion. The above, portable set up can be installed in 30 minutes.

The importance of prompt transfer of patient to the cath lab for primary PCI is emphasized followed by the demonstration of coronary angioplasty and stent insertion to the culprit lesion to the public (Figures 36 & 37). The above "realistic simulation" teach members of the public to understand the importance of early recognition of the warning signs and symptoms of an acute myocardial infarction. The various scenarios provide an opportunity to experience the

sequence of events following an acute MI. The public have the chance to do the procedure, feel the wires / catheters and inspect coronary stents and the technology behind the design. Distribution of educational material in the form of posters, books and leaflets are followed by the interaction of the public with the experts in interventional cardiology.



Figure 36: School children learning about PTCA balloons and coronary stents.



Figure 37: Members of the public learning from the public education team.

A new addition is the dissection of a porcine heart (Figure 38) to teach the coronary anatomy to the public. School children are able to pass guide wires via guide catheters after engaging

the coronary artery through a linear incision in the aorta. Excitement and a sense of triumph follow during the inflation of the PTCA balloon in the relevant coronary artery.



Figure 38: Surgeon demonstrating the dissection of the aorta and cholesterol plaques

Interview:

Study design:

A qualitative analysis using a semi-structured interview was designed (Text box 13). Participation in the interview was voluntary. A verbal consent was obtained. Strict anonymity and confidentiality was maintained. Ethical approval to interview the public during public engagement events was obtained. The interview was guided by a set of questions designed in collaboration with a psychologist.

HEART ATTACK SCENARIO EVALUATION FORM

Text Box: 13

Age	Male	Female
\leq 25 years		
26 - 45 years		
46 years +		
Occupation		

Can I start with your overall impressions of the exhibition in general?

What brought you here?

Can I just ask you about that station you were looking at there? Could you tell me what were you being shown there?

And what attracted you to that station to have a look?

And what might people be learning from that, if anything?

Is there anything there that wasn't clear to you?

If you were going to meet up with your friends and describe what you saw there, what would be the key thing you would say about it?

Scale for learning experience: (1-10) what would it take to make it - 9 or a 10?

Just one last question: how would you rate it as an engaging experience?

And what would it take to make it a bit more engaging? Thank you so much.

END

Data collection:

Our team have demonstrated the simulations to school children, parents, teachers, educators and the public at the Big Bang Fair, Science Museum, Science Communication Conference and the Cheltenham Literature Festival, which are summarised in table 24. A detailed description of each event is explained in section 7.9.

The public attending the Science Museum – LATES, 2012 and the Cheltenham Literature Festival, 2012 were interviewed for the purpose of the study. The interviews were conducted immediately after the event, at the venue

Events	Venue and date	Target audience	Attendance
			number
BBC World – Health	A church, London	General Public	28 million viewers
Show	14 th January, 2012		
Science Museum –	The Flight Gallery	Public – aged above	5400 people
LATES, London	29 th February, 2012	18 years of age	
		Students, Teachers,	
The Cheltenham	Cheltenham College	Educators and	School Students -
Literature Festival	13 th October, 2012	members of the public.	500
	"The Heart Zone"	General public, school	
The Big Bang Fair	NEC, Birmingham	students, teachers,	64000 people
	March $14^{\text{th}} - 17^{\text{th}}$,	educators,	
	2012	professionals	
		Educators, teachers,	
Science	Kings Place, London	science	Focus group – 200
Communication	15 th May, 2012	communicators,	delegates
Conference		education and health	
		policy makers	
	South Kensington,		
The Imperial Festival	London	General Public	6000 people
	$11^{\text{th}} - 12^{\text{th}}$ May, 2012		
NIHR Biomedical	Hammersmith	Researchers,	
Research Day	Hospital, London	Sponsors, NIHR	
		Faculty, Research	
		council members,	
		Lecturers, Professors,	
		Media, Science	250 people
		Journalists and	
		prospective medical	
		students.	

Table 24: Public education events in the UK

Duration: 3 hours (6.00 – 9.00pm)

Dr. Iqbal Malik and Dr. Justin Davies were the lead consultant cardiologists performing cardiac catheterisation and the public had the chance to interact with the experts in the field of interventional cardiology. The balcony in the flight gallery presented an excellent overview of the proceedings to the public. The display monitor provided accurate images of the manipulation of the guide wires, guide catheters and coronary stent deployment. I had the chance to explain to patients the pros and cons of percutaneous coronary angioplasty and stent insertion. My explanation to the patients allayed their fears as they were due to undergo the procedure in a few weeks' time.

The Cheltenham Literature Festival, 13th October 2012

The Cheltenham Literature Festival encompasses a wide range of disciplines – from journalism to drama to science. Our focus was to educate the students undertaking GCSE, A levels and AS levels.

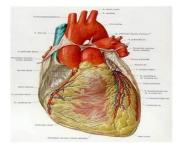


Figure 39: Coronary arteries and the major blood vessels of the heart

The aim was to create awareness about the coronary anatomy, signs and symptoms of a heart attack (Figures 39 and 40), recent advances in cardiovascular medicine and the advanced

technology involved in treating coronary artery disease.



The students were accompanied by their teachers. After the conclusion of the scenario enactment, they had the chance to visit each station (Figure 41) which provided hands on experience (Figure 42). Interactive question and answer sessions followed which was entertaining. The students had the opportunity to hear about the personal experiences of patients who had survived a previous cardiac arrest and heart attack.



Figure 40: Patient with severe chest pain (courtesy: www.healthhype.com)



Figure 41: Students learning from the 3 stations – ambulance station, cath lab station & the GP station

Data analysis:

The interviews were initially transcribed by the primary researcher (Sujatha Kesavan) and the emergent themes were identified. An independent researcher performed the analysis and the themes were coded after repetitive saturation was achieved.

7.5 Results

12 interviews were conducted. The mean duration of the interview was 6 minutes. None of the participants were employed at the Imperial College, London or were employed by the Imperial College HealthCare NHS Trust. None of the participants have seen the demonstration and the enactment of the heart attack scenario by our team before. The demographic profile of the participants (Table 25) and the perception of the public towards education in cardiovascular diseases through simulation are summarised (Table 26).



Figure 42: Students learning the anatomy of the heart from the surgeon

Table 25: Demographics

Number of participants	12
Age in years (Mean)	51
Gender	Male = 5 Female = 7
Occupation and the profile of the participants	Physics Teacher -1 Deputy Head Teacher (Biology) – 1 School Teacher (Juniors) - 1 Snow Consultant – 1 Doctor – 1 Student – 3 (1 - Kings College, London) Science Museum Member – 1 Regular visitor to science events – 2 Retired - 1

Table 26: Public perception towards education through simulation

Themes	Verbatim Quotes
General Experience	 "Fantastic" "Excellent. Well done" "enjoyed the cardiology reconstruction scenario" "Very good" "The experience has been positive" "Everything is surprising and interesting" "Good role play and to see how technology was involved", "Very impressive", "Very visual" "Very clear and well explained", "Good audio too" "Simulation is good" "pretty comprehensive" "different, nice, new opportunity and its great"
Rating of Public Education Experience	"I did learn many things new" – comments from a doctor (anaesthetist).
(Mean = 8.4, Median = 8)	"New for the students today, which will add onto their knowledge" - comments from a teacher
Rating of Public Engagement Experience (Mean = 9, Median = 9)	"Very engaging. People were enjoying" "It's just brilliant. Hands-on experience" "Great opportunity to actually feel the stents, balloons and the size of the little wires and tubes that they use"
	"It was interesting to know that a balloon treatment can treat heart attacks" "May be, I will become conscious about my health" "It helps to raise the general awareness and also tells

Take Home Messages	you what to do when someone has a chest pain" "I will tell my friends to make the important one call" "Heart disease is dangerous and we have to be careful" "It's new to me. I did not know that the procedure can be done through the groin and the wrist"
Suggestions and Comments	 "Showing it in central London is fine. What about other areas? Many organisations will welcome such demonstrations" "GP consultation could be made better – to focus on specific type of exercises, specific diet etc" "I think we can include CPR" "The groups are a little too large. May be 5 in group"

7.6 Discussion

Simulation provides an excellent medium of communication to convey complex information in a simple way to the audience. The previous chapters dealt with education of doctors through simulation and the present chapter has extended the applications of simulation based education through technology. Simulation based learning need not be restricted to hospital premises alone and has a wider role in transferring knowledge to the patients and the public.

Our sequential simulation scenarios depicting the journey of a patient with a heart attack was well received by the public (Figure 43). The British Heart Foundation (BHF) booklets distributed after each event further enhances their knowledge concerning the burden of cardiovascular disease. The public had the chance to interact with the experts in the field, in an out of hospital setting - which is an unusual experience for them. Students shared an enhanced learning and interactive experience, which enabled them to decide about future career pathways.



Figure 43: The concept of balloon inflation being explained to the public

Teachers have endorsed the complementary method of education which makes learning an enjoyable experience for the student and the teacher. An out of class room experience is vital for the generation of new ideas and provides a template for innovation. Teachers have expressed the importance of various learning methodologies to acquire knowledge, especially for those students focusing on the STEM subjects. The public demonstrations have created an interest in interventional cardiology and prospective medical students have undergone work experience programmes at our esteemed department.

A community education campaign can significantly increase the effective use of pre-hospital emergency medical service resources and may increase the number of patients presenting with acute chest pain symptoms, including MI -The Wabasha Heart Attack Team project (149). A short duration education campaign may increase knowledge about AMI. Feedback from the public are analysed by our research team (Sujatha Kesavan, Jessica Tang, Jason Maroothynaden) after every event to provide a short summary to the event organisers.

7.7 Limitations

A prospective analysis of the views of the public prior to the enactment of the scenario was not performed. Hence we are not aware of the baseline knowledge of individual participants. Comparison of a pre and post scenario enactment questionnaire and an interview analysis would have provided a validated result of an enhanced learning experience through simulation. The interviews were conducted at the exhibition stand itself where the participants are prone to many distractions (interruptions and views of spouse, partner or colleagues). This may have influenced and could have limited the free expression of thoughts of the participants. Despite the limitation, the public have provided valuable comments and suggestions which will enable us to fine tune our work for future public engagement events.

7.8 Conclusions

The Heart Attack Sequential Simulation depicts the sequence of events that a patient with chest pain would encounter when 999 is dialled. The general public benefitted from the simulation scenario and are keen to log on to the BHF website (www.bhf.org.uk) for more information. The events have created an interest and awareness about cardiovascular disease and its consequences, which will enable a generation to work towards a healthier society.

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7.9 Public education events in the UK

Public education through simulation helps to raise the awareness of cardiovascular diseases in the community, thereby enabling a generation to be better equipped to tackle the burden of cardiovascular disease. Here I provide details on a number of public education events that I took part in and contribute to as part of my thesis:

BBC World – Health Show (Bill and Melinda Gates Foundation)

The above project is supported by the Bill and Melinda Gates Foundation and is a weekly, half an hour health show programme aired throughout the world. The focus is on 6 divergent themes on health issues, each with a duration of 5 minutes. Our programme was titled "The Inflatable Operating Theatre" where I had the chance to demonstrate to the public the concept of coronary artery disease and its treatment. The benefits of learning in a safe, risk free environment was demonstrated by teaching a junior doctor in training.

http://www.rockhopper.tv/the-health-show/programmes.aspx?programmeid=756

Science Museum - LATES & the Cheltenham Literature Festival

These 2 events were explained in detail and formed the basis for the interview analysis, reported earlier in this chapter.

The Big Bang Fair, NEC, Birmingham

Duration: 9.00 am - 6.00 pm (every day for 4 days) - 16 shows were conducted.

The "heart zone" was part of the science fair. The first two days of the programme focused on school groups only (Figure 44). Each group of 15 school children of various grades were supervised by their respective science teacher. The children were chosen on a competitive basis from their schools for achieving excellent grades in their STEM subjects. The demonstration for the next 2 days were for the general public. Two school students from the audience volunteered to help me perform the procedure of coronary angioplasty (Figure 45).

Figure: 44: School children with their teachers



Each day, the clinical scenario was enacted 4 times and the public had ample time to interact with the medical students, ambulance team, GP, experts in the field of cardiology and general medicine. Our team was one of the three chosen teams for a special demonstration for the sponsors, which was a prestigious moment.



Figure 45: School children performing coronary angioplasty

Science Communication Conference, Kings Place, London

Duration: 45 minutes

Distributed simulation with focus on the cath lab scene with the inflatable operating theatre alone was on display. There was a change in the clinical scenario with the actor developing chest pain while delivering a speech in the conference. It was a powerful message to the audience to call 999 when a person develops a sudden onset severe central chest pain (Figure 31). Focus group interviews and analysis were performed to assess the impact of public education in cardiovascular diseases through simulation.

The Imperial Festival, South Kensington, London

Duration: 9.00am - 6.00 pm.

The Imperial Festival was the first of its kind (Figure 46), mainly designed to show case the work performed by the various scientific departments and their respective research teams to

the general public. It was a privilege to demonstrate our work to the President and the Rector, Sir Keith O Nions, Professor Lord Robert Winston, lecturers, students and professors of other inter-related and non-related specialties. I had the chance to meet patients who have undergone the procedure before, who marvelled at the technological progress made since their primary cardiac event.



Figure 46: The first - Imperial Festival - 11th – 12th May, 2012

NIHR Bio-medical Research day, Hammersmith Hospital, London

Duration: 9.00 am – 2.00 pm.

The demonstration was conducted in collaboration with the computing (Dr. Fernando Bello) and the bio-engineering team (Dr. Robert Dickinson). The focus was on the technical aspects of simulation, haptic response while manipulating the guide wires / guide catheters and on the electronic form for transfer of critical clinical information from the community to the lab. The delegates had an insight into the sequence of events following a heart attack and the benefits of integration of technology into cardiology.



Figure 47: The cath lab team

The above picture features Mr. M. Harrison (sitting), who had the idea and designed the low cost, portable, inflatable operating theatre (The Igloo). Mr. P. Korzeniowski (standing in the background) is in charge of the computer simulations and graphics regarding coronary angioplasty and stent insertion (Figure 47).

The seven public education events portray a diverse range of audience from pre-school children, patients, professors and the public. The heart attack scenario was enacted more than 30 times during these events. There is a varied nature of assimilation of information by

different age groups by different methods (audio, visual, practical, experimental, interactive and combinations of these). Hence to develop future enactments tailored to the demands of a diverse audience, we need to perform assessments on our public education events.

7.10 Future directions

A prospective study of patients with coronary artery disease should be undertaken to compare the impact of simulation based education prior to the intended invasive elective coronary procedure.

It is also important to understand the career choices made by the school students following a simulation based education.

A study of the medical, para medical team, students and the actor taking part in the simulation scenarios need to be conducted to assess the validity and the impact of simulation based educational programmes in the community.

Chapter 8: General discussion, conclusions and future directions

8.1 Overview of thesis findings

The present thesis reports a series of studies which explores the field of simulation and the integration of technology in interventional cardiology. I started with a narrative review of the literature concerning the field of simulation in interventional cardiology (Chapter 2). Qualitative analysis in the form of interview (Chapter 3) and questionnaire survey (Chapter 4) highlighted the positive response among consultants and trainees in cardiology towards a simulation based education. In Chapter 5, the electronic form was tested in simple and complex case scenarios and the feasibility of integration of the e-form was assessed. In Chapter 6, the focus is on designing case scenarios and assessment checklist for interventional procedures in the catheterisation lab. The suitability of running a simulation programme in cardiology at the Paterson's Centre is highlighted. Chapter 7 focuses on the integration of simulation technology to educate the public in cardiovascular diseases.

8.2 Thesis findings by aim

Aim 1: To analyse the background research conducted in the field of simulation training in interventional cardiology

A literature review concerning simulation and medical specialties highlighted the paucity of literature concerning simulation in cardiology in Chapter 2. There are no studies in cardiology registered in the Cochrane database. The general surgical team, endovascular team and the interventional radiologists have explored the present field in greater detail and have provided robust evidence regarding the benefits of a simulation based education during training. Cardiologists can benefit from a robust evidence base from these specialties to design a structured, validated training programme in cardiology. The BCS, Simulation

Working Group - UK, ESC and the NICE recommends the integration of simulation based training in cardiology to educate, refresh and to learn new procedural skills.

The only validated simulator is the VIST, which can be utilised for assessments in the cath lab. There are no validated and accredited simulation centres in cardiology in the UK or Europe. The British Cardiac Society have run 2 pilot simulation training programmes and data are awaited. The focus is on the effectiveness of running a simulation programme only. Robustness of the simulators, a structured, validated, technical and non-technical assessments of all the trainees were not conducted. Hence, it is a limited pilot study testing the feasibility of running a simulation training programme.

A structured conceptual framework is suggested to integrate a simulation based education, tailored to each stages of the training period in cardiology. The framework provides a guidance for further studies to be conducted at every stage of the training period to understand the robustness of such a training programme.

Aim 2: To understand the views of the senior consultant cardiologists and junior doctors concerning interventional training in cardiology by simulation

Qualitative studies presented in Chapters 3 and 4 revealed the attitudes of consultants and trainees in cardiology towards a simulation based education. Overall, the response was positive. Trainees preferred a simulation based education during the early stages of their training period, which is understandable. Trainees are used to a simulation based education

during their core medical training and hence continuation of a simulation based education is necessary, especially with the reduction of training hours due to EWTD.

Simulation in cardiology is labour intensive, time consuming and expensive. Hence delivery of a programme should be standardised and validated in selected centres only. The programme should be delivered in 2 parts – Simple simulation sequences can be enacted and trained at a local level, while complex and new procedural skills can be learnt at select centres only with the guidance of a trained faculty / proctor to maintain the quality of the programme. Deaneries should share the equipment, faculty and the varied expertise of the trainers for the programme to be cost-effective. Certification of the trainees after the completion of a validated, robust training programme is mandatory – similar to the ALS accreditation. Consensus was reached that simulation cannot be used as a tool for accreditation, revalidation and recertification or for ARCP at the present stage due to the lack of available evidence in cardiology.

Aim 3: To explore the potential of simulation as a 'test-bed' for a newly developed computer assisted health care information transfer dashboard (electronic form) to be used by interventional cardiologists in handover situations

Acute Myocardial Infarction is a medical emergency and hence accurate information transfer swiftly to the hospital, to make key decisions is vital. An electronic form, designed in collaboration with the Bio-engineering team and cardiologists was designed and tested in a simulated environment. The pros and cons of introduction of an electronic form were analysed in Chapter 5. It is a pilot study with a small sample size. Nevertheless, it provides an insight into the possible integration of such a technology into daily clinical practice in the future. 4 clinical case scenarios were tested with and without the e-form. Evaluation forms were completed and the information was validated further with interview analysis. It was deemed extremely useful for simple case scenarios. Effectiveness of the e-form in complex case scenarios need to be tested further. Participants' ratings of 4 and 5 on the Likert scale was reassuring. The lay out, colour coded schemes and real time calculation from the onset of chest pain appealed to the doctors. The simplicity of the form was well appreciated and was validated by the interview analysis.

Aim 4: To develop viable teaching and training scenarios to be conducted in simulated environments

Chapter 6 describes the 5 case scenarios which were tested in a simulated environment with focus on the handover between the ambulance team and the cardiology registrar on call, which is the first step in the MI care pathway. The case scenarios were "realistic" and hence could be adopted for further testing in a larger sample size population. Evaluation forms were completed and the views expressed by the participants were further validated by an informal interview in the end. Free text was permitted and participants aired their views without any coercion. Overall, it was a positive response. The issues raised by the participants can be addressed in future simulation sequences to provide an authentic experience to benefit the trainee. The simulated environment can be made more "realistic enough" by introducing distractions in the sequence of events. The Paterson's centre was deemed suitable for running the handover study.

The next focus was to develop scenarios for the catheterisation lab – interventional cardiology and cardiac electrophysiology. 3 case scenarios for interventional cardiology and 2 case scenarios for cardiac electrophysiology were developed in collaboration with Prof. Jamil Mayet, Dr.Iqbal Malik, Dr.Mark Mason and Dr.Rebecca Lane. The focus was on complications arising in the catheterisation lab as it was felt that routine procedures can be learnt in the lab on a daily basis by the trainee, by regular attendance. Complications arise occasionally in the lab and the trainee should have the capacity to cope with stressful situations and should rehearse these scenarios in a safe, risk free simulated environment. Hypotension, bradycardia, pulmonary oedema, difficulties encountered during PPM insertion and complications during pulse generator change were considered important and 5 case scenarios were designed with the above themes.

The 5 case scenarios focusing on complications can be enacted in 2 stages – a ward scenario and a cath lab scenario. The ward scenario sets the preamble to the cath lab scenario. Proper pre-procedure assessment, decision making, planning a strategy and anticipating possible complications prevents adverse events in the cath lab. Hence a ward scenario, prior to the cath lab scenario is equally important. Pre-procedure checklist for interventional cardiology was designed after reviewing the checklist endorsed by the PCR Seminars Group, chaired by Prof. Jean Marco. I had the opportunity to attend a course on PCR Seminars at Tolochenaz, Switzerland and had the chance to discuss about standardised checklists with the experts in the field of interventional cardiology.

Checklists for cath lab procedures are more complex. The checklist should focus on 3 issues
Assessment of technical skills, assessment of non-technical skills and the assessment of

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competence of the trainee in the management of complications in a changing dynamic environment. Cardiologists, Endovascular teams and Interventional Radiologists should work in collaboration to design structured, standardised checklists and assessment metrics which is applicable across all the 3 disciplines. The expertise across various disciplines should be tapped and co-ordinated to devise a validated, structured simulation interventional training programme which will benefit trainees in the future.

Aim 5: To develop clinical case scenarios integrating technology in cardiology to educate the public in cardiovascular diseases through simulation

Whilst simulation is used in medical education, it remains underutilised in public education in cardiovascular diseases, which is the main theme of Chapter 7. In this chapter, I have explored the possibility of public education through simulation, targeting various groups – parents, teachers, educators, science communicators, social workers, health policy directors, lecturers of various scientific disciplines, pre-school children, school children and the general public.

A case scenario depicting a patient with an inferior MI was enacted, where she underwent angioplasty and coronary stent insertion to the right coronary artery. A short, semi structured interview was conducted in two of the public events. The positive response has been astounding and encouraging. The scenario was enacted more than 25 times at various venues across the UK to highlight the burden of coronary artery disease. The highlight was the filming by the BBC Health Show – sponsored by Bill and Melinda Gates Foundation, which enabled us to reach an audience of over 25 million.

<u>8.3 Limitations of the thesis</u>

There are several limitations in the evidence base for simulation in interventional cardiology due to the paucity of literature. It precludes a systematic review or a meta-analysis and hence a narrative review is presented in the thesis.

The main limitation of the thesis is that the participants in the studies (questionnaire and interview) are predominantly from tertiary centres only. Although the questionnaire survey was conducted at a national meeting, more than 60% of the participants were from tertiary centres only. The clinical case scenarios were enacted by the academic trainees in the London deanery only. The trainees were in ST5 and ST6 and have wide experience in managing patients with MI many times. Every grade of trainee should be tested with special focus on ST3 trainees.

The electronic form was used by the private ambulance services and has never been tested by the NHS Ambulance Services Team. Hence, the e-form was tested only in a simulated environment and not in the real world (eg in the community or in the cath lab). The thesis focused only on the preliminary testing of the e-form.

The public education events should also be used to influence career choices of school students and hence targeted engagement with schools is necessary. Robust evaluation and validated assessment tools are essential to assess the impact of public education in cardiovascular diseases.

8.4 Discussion and future direction

The number of implications that have emerged from the results of the thesis require further discussion. The thesis has opened the world of simulation in cardiology, which can be utilised for medical education, public education and patient education. It has highlighted the feasibility and the importance of integration and embracing technology in healthcare for improving quality of services and patient care. The thesis is a preliminary step which explored simulation and technological applications in cardiology. Data from the pilot study conducted in a simulated environment will enable the research team to design robust studies in the future to be tested in the real world - electronic form in the community, case scenarios in the cardiac catheterisation lab at Hammersmith Hospital.

Consultants and trainees in cardiology work in a demanding atmosphere faced with constant emergencies in cardiology. Hence, the sample is small in most of the studies conducted - as I appreciate their time. 2 other centres - Oxford and Bristol – were involved to avoid bias into the study and also to arrive at a consensus opinion. The BCS – Simulator Pilot Course provided an insight into future simulation training programmes in cardiology. The industry is flooded with a variety of simulators and caution should be exercised in choosing the appropriate, validated simulator for the particular training programme. State of the art simulation centres are functioning in Europe, which can provide a guidance and supervision for the development of such a centre in the UK.

There are lessons to be learnt from the endovascular and the interventional radiology teams so that cardiologists can avoid those pitfalls and work towards designing a structured,

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validated, robust simulation training programme in cardiology. Qualitative and quantitative research needs to be conducted in the field of simulation in cardiology directed towards medical education, patient education and public education.

Future research should focus on designing a structured, standardised, simulation training curriculum for each stage of the training period in cardiology, which addresses the core and advanced skills necessary to become a competent cardiologist. The next step would be to conduct randomised studies to understand the validity of the training programme and to assess the "realism" provided by the currently available simulators for each sub-specialty in cardiology.

8.5 Personal reflections

It has been a great journey. Consultants and trainees in cardiology at Bristol were ambivalent about me embarking on a research post in interventional cardiology (for 12 months only) which is neither basic science nor clinical cardiology. Personally, I considered it as a challenge to conduct research on my colleagues and consultant cardiologists. The idea was novel, innovative and exciting.

It was prestigious to be enrolled as a student (ID:319851) of the Imperial College London. To be funded by the EPSRC – Engineering and Physical Sciences Research Council was a privilege. I am extremely grateful to Prof. Richard Kitney, the grant holder of the project for providing me a chance to work with the esteemed faculty in the bioengineering team (Dr. Robert Dickinson, Dr.Matthieu Bultelle). The initial funding for my post was for a period of 12 months only. Extension of the grant for a further few months enabled the submission of the present thesis to the College. Hence, I always owe a debt of gratitude to Prof. Richard Kitney for his generosity and for introducing me to the world of bio-engineering. I taught cardiology and the bioengineers reciprocated by educating me in technology. The partnership was mutually beneficial and paved the way for innovative discussions, allowing me to complete this work.

My daily train journey from Bath to London provided an ample opportunity for reading books on qualitative, quantitative and social research. On my return journey, I focused on the history of medicine, which was fascinating.

I made myself comfortable in a corner at the Research Fellows Office, Second Floor, Paterson's Centre, St Marys Hospital, London. I was surrounded by 3 post-doctoral fellows in education (Dr. Stella Mavroveli, Dr. Jessica Tang and Dr.Jason Maroothynaden), 1 consultant surgeon (Dr. Anne Yeh) and 2 PhD surgical fellows (Mr.Alexander Harris, Dr.Alexandra Cope). I benefitted a great deal from the expertise that the elite group provided me in the office. Heated discussions ensued in the afternoon regarding appropriate statistical tests and its validity. Doubts were clarified and feedback from the group was prompt. Constructive criticism was actively encouraged and new ideas were welcomed. At present, Jessica lives in Hong Kong, Jason works in Singapore and Anne is in Taiwan – nevertheless, technology has enabled me to keep in touch with them and has made distances seem shorter. My primary academic supervisor was Dr.Nick Sevdalis. With no experience in qualitative research, I met him with trepidation. I appreciate his patience for listening to my questions and for providing answers. I cannot find apt words to thank him for providing guidance, support, education and encouragement in my academic activities.

Although the study did not require an ethics approval, an R & D application and IRAS forms had to be submitted as I was working towards a NIHR Portfolio adoption. Many trips to Charing Cross hospital to meet Miss Selvy Raju ensued. It was a different exercise compared to the IRAS application system and made me aware of the eligibility, procedures and protocols necessary for submission. The study was deemed eligible for adoption and we have been allocated a CRN support framework and the study is registered in the NIHR Portfolio Database (Reference No: 99624: Developing and evaluating simulation applications for cardiologists).

The opportunity to work at Imperial College enabled me to meet and work with experts in cardiology – Prof. Jamil Mayet, Dr.Iqbal Malik, Dr.Justin Davies, Dr.Mark Mason and Dr.Rebecca Lane, Dr.David Wald, Dr.Andrew Wragg. Regular trips to Hammersmith Hospital, Harefield Hospital and the London Chest Hospital followed. Education centres / facilities were visited and education fellows were met. I understood the difficulties faced by the consultants in delivering education to the juniors whilst managing an active clinical cardiology commitments.

The computer graphics team, supervised by Dr.Fernando Bello, were an interesting group working on polystyrene models to understand the haptics. They worked with many specialties in the medical field – Obstetrics, Stroke Medicine. They branched into cardiology and I was all the more delighted to contribute to their work. I took part in questionnaire surveys conducted by Mr.Hafiz Harun and in experiments concerning force transmission movements while manipulating a cardiac catheter or a guide wire. In return, Mr.Harun and Mr.Korzeniowski acted as simulated patients in our MI scenarios and experienced more than 5 heart attacks a day.

Public education in cardiology was an entirely new field and it enabled me to think laterally regarding education in cardiology through simulation. Now, I think in 3 aspects – education for doctors, patients and the public. This was possible due to the pioneering work done by Prof. Roger Kneebone in the field of public education in surgery. Extensive work has been done in the field of surgery and I had the privilege to work with him in the field of cardiology. I considered it as a part of my charity work by educating the public in cardiovascular diseases and have distributed the BHF booklets to thousands of people explaining about the burden of coronary artery disease and the benefits of a healthy lifestyle.

My significant contribution to 2 grant applications to STELI (Simulation and Technology enhanced Learning Initiative), London Deanery have been successful, which will enable the purchase of access site simulators and cardiac pacing stimulators. Dr.Iqbal Malik is the grant holder and the amount (£ 107,328) granted will help to conduct studies in the virtual catheterisation lab. The clinical case scenarios and the checklists which I have designed are

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approved by the training programme director, Prof. J.Mayet, which will benefit future trainees in cardiology.

The Endovascular team, under the leadership of Prof. N.Cheshire have performed pioneering work in the field of simulation in interventional procedures. Prof. Cheshire is the principal investigator of the EVEREST Team and the work is complemented by Dr.Isabelle Van Herzeele, Consultant Vascular Surgeon, University of Ghent, Belgium. They are actively involved in the Charing Cross Symposium and teach about pre-procedural planning and procedural rehearsal to the interventional trainees every year. I am extremely fortunate to have been educated by the expert faculty and had the opportunity to attend EVAR Simulation courses with the endovascular team, presided by Mr. Colin Bicknell, Consultant Vascular Surgeon, Imperial College Healthcare NHS Trust, London. The expertise across various disciplines should be tapped and co-ordinated to devise structured checklists and validated assessment metrics for interventional procedures, which will materialise in the future.

2012 was an important year in the British history. I was a volunteer for the Olympics and the Paralympics and met champions who worked against all odds to excel in their field. It taught me a great lesson - to persevere in our goal, despite the hurdles that one may face. Competitive athletes taught me the key mental qualities required for success – "The Four Cs"- Concentration, Confidence, Commitment and Control. The road to success is hard, hence one has to maintain focus and the results will be delivered in due course. It was a special moment when I received a letter of recognition of service to the nation from the Rt Hon David Cameron MP, Prime Minister and Minister for the Civil Service and First Lord of the Treasury. With such a diverse experience provided by the Imperial College London, I am pleased to report that peer reviewed publications and presentations followed. The studies were presented at international meetings in cardiology and simulation. I became a reviewer of the journal - EuroIntervention and voiced my opinion to Prof. Patrick Serruys and Dr.Cummins. The experience has honed me well in the foundation and the principles of research which will enable me to conduct further research and complete my clinical training in interventional cardiology.

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Appendices

10.1 Project proposal

Developing, implementing and evaluating simulation applications for interventional cardiologists

Version 2.0, 05/12/2011

Introduction

Medical education is an important aspect during the training and assessment of a junior doctor. The approach to medical education has undergone a series of developments since inception, in parallel with the advancement of electronics and communication.

The traditional approach to teaching medicine to medical students involved bedside teaching in the presence of the patient and didactic lectures in lecture rooms. Any interventional procedure in medicine was learnt through apprenticeship – by observing the seniors performing the procedures many times. Hence the culture of "See one, Do one, Teach one" has prevailed (1).

A more modern approach to medical education has involved case based learning, problem solving, multiple choice questions and on line learning (2). Interventional procedures can be visualized in high definition in three dimensional modes by accessing the relevant website. Nevertheless, the interventional procedures cannot be practised in real time off line, as there are no tools and techniques which supplant the real with the virtual.

The positive developments in the field of electronics and computing have led us into an age of simulation, where the representation of computer generated images precedes the literal. The future is learning by simulation for interventional procedures, which has the potential to become a central part of medical education and accreditation (2).

Background

The HealthCare industry in the USA includes millions of practitioners who participate in on going education, training and certification in medicine (3). The Aviation industry has incorporated flight simulator training as a part of their curriculum for many years. Difficult technological challenges have limited the use of virtual reality in medicine.

Medical simulators use computer graphics and robotics technology to simulate real patients with anatomical and physiological features and complications. These systems provide an opportunity to assess both cognitive skills and motor skills involved in interventional procedures (4). The use of these technologies in cardiology can help interventional cardiologists to establish and maintain skills, effectively introduce new procedures and will provide a basis for evaluation of quality of care.

Simulation has been an integral part of teaching, training, assessment or accreditation in the following specialities – Anaesthetics, Intensive care and Surgery (including Endovascular surgery, which is technically similar to interventional cardiology). There are only a few centres in the world which can provide a comprehensive package of curriculum in simulation training to their trainees.

Simulation training promises to play an increasingly important role in technical skills training and will likely reduce the numbers of actual procedures to which a trainee must have direct exposure to achieve competence - quoted by the ESC core curriculum update 2008 (5).

Currently, Interventional trainees in cardiology do not have adequate exposure to learning by simulation. This raises an important concern due to change in the working pattern of the junior doctors. The competence of the doctor comes into question with the reduction in hours of training during a stipulated time. Hence learning by simulation becomes an integral part of medical education during the training period.

The present thesis aims to identify the necessity for training by simulation in interventional cardiology in the UK, to assess the cognitive and psychomotor skills of the operator and also to devise a structured training programme in simulation in interventional cardiology in the UK

Aims

The overall aim of this thesis is to systematically explore the role and potential of simulation applications within the context of interventional cardiology. More specifically, my aims include

- To analyse the background research conducted in the field of simulation training in interventional cardiology
- To understand the views of the senior consultant cardiologists concerning interventional training by simulation
- To understand the views of junior doctors in cardiology concerning learning by simulation in interventional cardiology
- To develop tools that allow assessment of the technical and non-technical skills of junior and senior interventional cardiologists within the simulation contexts
- (a) To develop computer assisted health care information transfer by formulating an electronic database of patient information and testing it within a simulated environment and (b) To develop reliable, valid teaching and training scenarios to be conducted in the AngioSim suite / OR camp at Imperial College, London and in other tertiary centres / district general hospitals using available mobile OR camp facility

Methods and Studies

1. Systematic Review

There is a paucity of literature concerning the training by simulation in interventional cardiology. Nevertheless, training by simulation has been incorporated in many endovascular procedures like carotid artery stenting. A systematic review analysing the methodology and outcomes of all the studies will be synthesized. A literature search will be conducted through the Cochrane Library, MEDLINE, PubMed, Google scholar and other databases. The review will provide current available evidence concerning the field of training by simulation.

2. Interview study

A semi-structured interview pro-forma will investigate the participant's views and concerns towards learning by simulation. The pro-forma will be scripted based on the systematic review and initial piloting study.

Procedure:

Participation in the study is voluntary and suitable subjects will be contacted by me. I intend to interview doctors and consultants working in the district general and teaching hospitals in London and Bristol. Volunteers will be given a written instruction and a brief introduction by me about the purpose of the study. Suitable participants can also be identified in national conferences – British Cardiac Society annual conference, Advanced Cardiovascular Intervention – annual meeting (January 2012). The study participants will be anonymised and confidentiality will be maintained. The interviews will be conducted in the presence of Dr.Tanika Kelay, Psychologist, Imperial College, London

Closed and open ended questions will be incorporated which will enable the participant to express his views without any inhibitions. Each interview will last 15 minutes and 20 interviews (junior doctors in cardiology – 10, Consultants in cardiology – 10) will be conducted. Interviews will be audiotaped, transcribed verbatim and analysed. Transcripts will be cross checked with the original recordings to ensure accuracy. All interviews will be analysed for content to identify emergent themes. The emergent themes from all the interviews will be reviewed by me and Dr.Kelay.

3. Survey study

Although training by simulation is used by the endovascular team and surgeons, it has never been a part of the accredited training programme in vascular surgery or general surgery. In the field of interventional cardiology, there is no structured training programme for learning by simulation. Hence a survey (11) will be conducted to assess the need of the trainees and the views of consultants practising interventional cardiology.

Procedure:

The preliminary questionnaire survey (protocol enclosed) will provide an insight into the interest shown towards training by simulation by cardiologists. It is envisaged that a total of 50 junior doctors and 50 interventional cardiologists, working in a district general hospital and/ or in tertiary centres will complete the questionnaire. As in the previous study, suitable subjects can also be identified in national conferences – British Cardiac Society annual conference, Advanced Cardiovascular Intervention – annual meeting (January 2012).

The survey will be conducted by me by meeting the doctors individually in the hospital. The first 5 questions will assess the participant's clinical expertise in cardiology, followed by 10 questions which will be directed towards training, assessment and accreditation by simulation in interventional cardiology. Data accrued from this study will help me explore the views of junior and senior interventional cardiologists regarding potential applications of simulation in the setting of this speciality.

4. Developing and testing assessment systems for technical and nontechnical skills

Observational study

Based on the interviews conducted, the key elements necessary for assessment during training to be an interventional cardiologist can be identified.

Procedure:

Participants can be classified into novice, skilled or an expert based on the level of training and the number of interventional procedures performed. Novice – ST3, ST4, ST5 trainee who has not performed the relevant number of interventional procedures as defined by the cardiology curriculum, Skilled – ST6, ST7 trainee who has performed the relevant number of procedures as dictated by the cardiology curriculum and an expert is defined as one who has performed more than 1000 interventional procedures.

There are 3 levels of competencies defined by the European Society of Cardiology (Levels 1, 2 and 3), Core Curriculum update, 2008 (5). Level 1 – experience of selecting the appropriate diagnostic modality and interpreting the results or choosing an appropriate treatment for which the patient should be referred. This level of competency does not involve performing the technique, Level 2 – Practical experience but not as an independent operator (has assisted in or performed a particular technique under the guidance of a supervisor, Level 3 – is able to independently perform the technique or procedure unaided. A trainee should have performed 300 diagnostic cardiac catheterisation and 50 percutaneous coronary interventions during their training period. Completion of the cardiology training programme by a trainee will enable him or her to perform diagnostic cardiac catheterisation with level 3 competence and percutaneous coronary interventions with level 2 competences.

A scoring / grading system will be devised to score the performance of the operators. Technical skills and nontechnical skills will be assessed. Nontechnical skills will focus on communication, team work, leadership, management and decision making in complex case scenarios. The study will enable us to test the integration of information technology into healthcare for efficient transfer of information between medical and para-medical personnel.

5. High-fidelity, simulation-based testing of training scenarios: Development of a training programme

The above observational studies, questionnaires and interviews will help us to develop a structured training programme for interventional trainees in cardiology with the guidance of the experts. Previous research (6-11) conducted by the research group at Imperial College, London has highlighted the importance of simulation based training in endovascular surgery and general surgery. Case based scenarios (simple and complex) will help us to assess, train, validate and accredit an individual trainee with high fidelity simulation. It offers benefits to novices learning invasive procedural skills, especially in a climate of decreasing clinical exposure.

Simulation device:

The virtual reality simulator (VIST) is a device consists of a personal computer-based software interface (Procedius, Mentice AB, Gothenburg, Sweden) and a two flat-panel monitors coupled to a mechanical interface device (Haptics Unit) that allows the user to manipulate wires, catheters, balloons and stents (10). User interface functions includes table movement, fluoroscopic C-arm positioning, cine-loop recording and road mapping. The interface device is designed to be the virtual patient with a simulated groin. The participant starts the procedure by selecting the specific tools to be used for the simulation. A

fluoroscopic image is displayed along with the virtual tool that has been selected by activating a foot pedal.

Further approaches to simulation research and training:

Two novel types of simulation have been developed by the wider research group – Distributed Simulation (DS) and Sequential Simulation (SS). Distributed simulation involves the simulation of small parts or units of the entire scenario whereas sequential simulation involves simulation of the entire sequence of the events or the entire scenario itself (12). Distributed simulation is an open standard for conducting real time platform level war scenarios across multiple host computers designed for training military personnel (13). In the context of primary percutaneous coronary intervention (PPCI) for a patient with an acute myocardial infarction, the distributed simulation will involve simulation of various units (the initial hand over process from the ambulance team to the doctor, instructions by the doctor to the rest of the team, assessment of the patient, procedure of cardiac catheterisation and the aftercare of the patient) in individual modules.

Sequential simulation involves the simulation of the entire scenario. In the context of PPCI, the simulation begins from the handover process from the ambulance team and ends after the patient is transferred to the ward.

Distributed and Sequential simulation will provide a virtual reality of the journey of a patient with an acute myocardial infarction. Both technical and non-technical skills of the operator can be tested. Moreover, the "Haptics" – "The touch and feel "of the simulator device can be assessed to provide a realistic model which could replace the literal.

The programme will enable us to train future interventional cardiologists in a safe environment where they can record, review and reflect on their performance. Interventional training by simulation will ensure patient safety and will avoid medical errors.

10.2 Ethical approval, Funding and NIHR Portfolio adoption

Ethical approval and sponsorship letter

Raju, Selvy <Selvy.Raju@imperial.nhs.uk>

Hi Sujatha,

I can confirm, that your study does not require Research Ethics Committee approval, but still needs NHS R&D Trust clearance, before your study can commence on ICHNT site, if you want this in a letter format, I can send this to you as soon as possible.

Please note I have still not heard back from the portfolio team, but as your study involves staff only, it may be worthwhile to not proceed any further with portfolio adoption, although there is a possibility, you may be eligible for adoption, I will leave this up to you.

In the meantime, please send me the corrected, revised, documents, so that I can proceed with sponsorship approval.

Regards

Selvy

Selvy Raju , Research Facilitator , Joint Research Compliance Office (JRCO)

Imperial College London and Imperial College Healthcare NHS Trust

Room 501, 5th Floor, Lab Block, Charing Cross Hospital, Fulham Place Road, London, W6 8RF

T: 0203 311 0210, F: 0203 311 0203, E: <u>selvy.raju@imperial.nhs.uk</u>

Dear All,

Thank you Sujatha, for your prompt response with the revised documents, having looked at the provided documentation, please see below:

Re: Developing, implementing and evaluating simulation applications and technologies for interventional cardiologists

JRCO Insurance Reference Number: CRO2004

After review of the R&D application and supporting documentation for the above study, I am pleased confirm that Imperial College London will act as Sponsor for this project. I will send the formal letter of sponsorship approval. The letter will be signed by either by Ms Lucy Parker, Research Governance Manager, JRCO or myself on the behalf of Lucy. Also the original copy of the letter will be sent via the post to Professor Kneebone, as the Chief Investigator (the letter will also be scanned to you all as well), I have attached the insurance certificate for your information.

I can also confirm that, on the basis of information supplied in the returned insurance questionnaire, the above research will be covered by the College's Arthur J. Gallagher International negligent (public liability) and non-negligent harm (no fault) policy: number B1262FI0103012.

Please note that Imperial College Sponsorship is conditional on all local, regulatory and Clinical Programme Managers approvals being in place prior to the start of the research

Please do not hesitate to contact me should you require any further information.

UNDER D2 declaration by the sponsor's representative and you can request an electronic authorisation from the representative please add my details, once you are ready to submit and have added in the main details, and obtained all the necessary signatures (I will sign the D2 section of the form, electronically my email address is as provided): <u>selvy.raju@imperial.nhs.uk</u>

Please could you forward the current versions of all documents to me, as soon as possible.

Kind regards,

Selvy

Selvy Raju Research Facilitator, AHSC, Joint Research Compliance Office Imperial College London and Imperial College Healthcare NHS Trust Room 501 5th Floor, Lab Block, Charing Cross Hospital, Fulham Place Road, London, W6 8RF T: 0203 311 0210 F: 0203 311 0203 E: selvy.raju@imperial.nhs.uk

Email: portfolio.applications@nihr.ac.uk

Dear Dr Kesavan,

Your study, entitled **Developing and Evaluating Simulation Applications for Cardiologists (IRAS 99624)**, has progressed through the NIHR Coordinated System for Gaining NHS Permission (CSP) and is ready to be added to the NIHR CRN Portfolio.

To ensure that the information we enter is as accurate as possible, I would be most grateful if you would fully complete the attached form and **return it to us within 10 working days to ensure there is no delay in adding your study to the Portfolio database**. Once this has been done we will inform you of your study's UKCRN ID number.

To assist you in the allocation of the RDC (Recruitment Data Contact) and SC (Study Coordinator) roles, there is a brief description of the responsibilities and access rights associated with each role below.

I appreciate your help and look forward to hearing from you soon.

Kind regards,

Davina

Davina Hemmings, Portfolio Support Assistant, Comprehensive Clinical Research Network

Comprehensive Clinical Research Network Coordinating Centre (CCRN CC)

16 Clarendon Place, Leeds, LS2 9JY, Telephone: 0113 343 0345

E-mail: davina.hemmings@nihr.ac.uk Web: www.crncc.nihr.ac.uk/about_us/ccrn

Imperial College London

Imperial College Healthcare

NHS Trust

Joint Research Compliance Office Academic Health Science Centre Imperial College London and Imperial College Healthcare NHS Trust Room 5L10A, 5th Floor, Lab Block Charing Cross Hospital Fulham Palace Road London W6 8RF Tel: +44 (0)20 3311 0206 Fax: +44 (0)20 3311 0206 Jucy parker@imperial.ac.uk/

> Lucy Parker Research Governance Manager

15/01/2013

Dr Sujatha Kesavan Research Fellow – Interventional Cardiology Imperial College London Department of Surgery and Cancer Second Floor Paterson Centre St Mary's Hospital 20 South Wharf Road London W2 1PD

Dear Sujatha,

RE: JRCO Study Approval

Project Title: Developing implementing and evaluating simulation applications and technologies for interventional cardiologists

Short Title: Developing and evaluating simulation applications for cardiologists

Joint Research Compliance Office Reference number: JRCOSM0401

Ethics reference number: n/a – study involving staff only Principal Investigator: Dr Sujatha Kesavan

CSP reference number: 99624

I confirm that this project has now been approved by the Joint Research Compliance Office. The project may now start at Imperial College Healthcare NHS Trust sites. Please note that the start date of the project is the date of this letter and the duration is the same as that provided in your application form.

The list of documents reviewed and approved by the Joint Research Compliance Office under requirements of the Research Governance Framework are as follows:

Document	Version	Date
NHS NRES IRAS R&D application form, version 3.4	99624/385770/14/874	03rd October 2012
NHS NRES IRAS Site Specific Information (SSI) application form, version 3.4	99624/382291/6/615/176586/258219	09 th November 2012
MD Study Research Protocol		
Chief Investigators CV: Professor Roger Kneebone		
Principal Investigators CV: Dr Sujatha Kesavan		

Imperial College London

 Participant Research Interview and Assessment Consent Form
 Version 2
 07th November 2011

 Participant Research Informed Consent Form
 Version 2
 07th November 2011

 Simulation based learning/training in interventional cardiology – Question sheet
 06th November 2012

 Letter confirming staff honorary contract
 06th November 2012

 Funding educational grant award letter from novo nordisk
 Schedule 1

 Study Research Poster Advert
 06th November

Before you commence your research, please note that you must be aware of your obligations to comply with the minimum requirements for compliance with the Research Governance indicators 17 (Data Protection); 25 (Health and Safety) and 22 (Financial Probity). Details of the requirements to be met can be found in the Research Governance Framework available on <u>www.dh.gov.uk</u>.

Under the Research Governance regulations, Serious Adverse Event Reports, and amendments to the protocol or other supporting documents must be forwarded to the Joint Research Compliance Office. In accordance with the Research Governance Framework, research projects carried out in the Trust may be randomly chosen by the Joint Research Compliance Office for auditing.

I wish you well in your research.

Yours sincerely,

PP <u>Serjas</u> (cuttorised to sign on bakely of): Ms Lucy Parker Research Governance Manager

Funding

Engineering and Physical Sciences Research Council

Polaris House, North Star Avenue Swindon, Wiltshire, United Kingdom, SN2 1ET Telephone +44 (0) 1793 444000 Internet http://www.epsrc.ac.uk

Research Office Imperial College London, Level 3, Faculty Building Exhibition Road, South Kensington, London, SW7 2AZ Direct line 01793 444088 Local fax 01793 E-mail sue.johnston@epsrc.ac.uk

24/09/2009 Our Ref: EP/H019804/1

Dear Contracts Administration Manager

EPSRC GRANT OFFER LETTER: Standard Research, EP/H019804/1

The EPSRC is offering a grant towards the cost of the above project, subject to the terms and conditions set out overleaf.

Return of the 'Offer Acceptance' will be taken as acceptance of the grant on the terms stated. If you are unable to accept the grant you should return a 'Decline' confirmation as soon as possible. Upon receipt of the 'Offer Acceptance' a 'Start Confirmation' request will be issued.

EPSRC grants are cash-limited and expenditure against the grant must not exceed the value awarded. The funds awarded include a sum to take account of expected inflation and pay awards over the period of the grant.

Please note copies of this letter have not been sent to the individual(s) named overleaf. It is the Responsibility of the lead Research Organisation to distribute copies as necessary. Yours faithfully Mrs Sue Johnston Grants Processing Team enc.

OFFER LETTER - EP/H019804/1 24/09/2009

NX0273v1 Page 2 of 15 **Organisation:** Imperial College London **Principal Investigator:** Professor R Kitney, Imperial College London, Bioengineering **Grant Title:** Information Driven Optimisation of Care Pathways and Procedures

Starts: 01/10/2009 Ends: 30/09/2012

Co-Investigator(s):

Dr N SEVDALIS, Imperial College London, Division of Surgery and Oncology Dr B Cox, Imperial College London, Imperial College Business School Professor Y Guo, Imperial College London, Computing Dr F Bello, Imperial College London, Division of Surgery, Oncology and Reproductive Biology Dr R Kneebone, Imperial College London, Division of Surgery, Anaesthetics and Intensive Care Dr RJ Dickinson, Imperial College London, Bioengineering

GRANT VALUE

Funds Awarded - Authorised FEC - (£) RC Contribution (£) net cash limit Total % FEC Directly Incurred

Staff 858647 28434 686918 22748 709665 80 Travel and Subsistence 10000 225 8000 180 8180 80 Other Costs 195025 4388 156020 3510 159530 80

Directly Allocated

Investigators 162226 3655 129781 2924 132704 80 Estates Costs 332994 7492 266395 5994 272389 80 Other Directly Allocated 25790 580 20632 464 21096 80 Indirect Costs

Indirect Costs 977007 21983 781606 17586 799192 80 Total 2561689 66757 2049351 53406 2102757

STAFF Summary Authorised FECnet, RC Contribution net - Number of Months - Number of Posts Post - Doctoral 858647 686918 246.00 10 Investigator 162226 129781 252.00 7 Total 1020873 816698 498.00 17 OFFER LETTER - EP/H019804/1 24/09/2009

NIHR portfolio adoption

Dear Sujatha Kesavan,

Re: 99624 - Developing and evaluating simulation applications for cardiologists

Thank you for submitting your Portfolio Application Form.

Your study has been registered on CSP and you are now able to make your completed R&D Submission (forms plus documents) via IRAS. Your R&D submission will be reviewed and, if the required information is present, your study will begin processing through CSP.

If your study is to be considered for Clinical Research Network support, we will email you within 30 working days of receiving your R&D submission to confirm whether your study is eligible. If your study is not funded by the NIHR, other area of central government or an NIHR non-commercial Partner, you will be contacted by the appropriate Research Network, who will arrange for your study to be assessed for access to CRN support.

We look forward to receiving your R&D submissions so we can continue to progress this study. The Lead CLRN will contact you in a few days to offer assistance in compiling the documentation to support your R&D application.

Kind regards

Portfolio Applications Team, NIHR Clinical Research Network

Email: portfolio.applications@nihr.ac.uk

Dear Sujatha Kesavan,

Re: 99624 - Developing and evaluating simulation applications for cardiologists

I am pleased to inform you that your study is eligible to receive CRN support.

Further information about *Eligibility for Studies to receive CRN support,* is available on our web site at:

http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/p_eligibility/

Your study will continue through NIHR CSP, and you will receive further communications as your study moves through the process of gaining NHS permission.

Please note your study has provisionally been assigned to **Comprehensive Clinical Research Network (CCRN).** A member of the network portfolio team will be in touch to collect any additional information required for inclusion of your study on the Portfolio Database. However if you have any queries please don't hesitate to contact CCRN directly at: <u>ccrn.portfolio@nihr.ac.uk</u>

Kind regards

Portfolio Applications Team, NIHR Clinical Research Network

10.3 Participant Information Sheet



Department of Surgery and Cancer Division of Surgery Imperial College London

2nd Floor, Paterson Centre St Mary's Campus Norfolk Place, Paddington, London W2 1NY Tel: +44 (0)20 7594 9726 Fax: +44 (0) 020 7594 3127

s.kesavan@imperial.ac.uk www.imperial.ac.uk

Research Information Sheet

Assessment of technical skills, non-technical skills and technologies by virtual reality simulation in percutaneous coronary procedures

Chief Investigator: Dr.Sujatha Kesavan, Research Fellow in Interventional Cardiology

Consultant Cardiologist: Dr.Iqbal Malik

Research Team: Dr.T.Kelay, Dr.N.Sevdalis, Dr. F. Bello, Prof. R.Kneebone

Invitation

You are being invited to take part in a research study. Before you decide to take part in this study it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Take time to decide whether or not you wish to take part. Thank you for reading the document.

What is the purpose of the study?

Simulation training promises to play an increasingly important role in technical skills training and will likely reduce the numbers of actual procedures to which a trainee must have direct exposure to achieve competence - European Society of Cardiology core curriculum update 2008. "With advances in technology, the use of simulators will play an increasing part in the training of practical procedures" – as mentioned in the specialty training curriculum for cardiologists in training in the United Kingdom.

There is a paucity of literature concerning the role of training by simulation in interventional cardiology. The purpose of the study is to investigate the impact of simulation in improving the technical and the non-technical skills of the operator performing percutaneous coronary interventions. The study is a part of a MD project, registered in Imperial College London, United Kingdom.

The steps involved are enactment of simulation scenarios following a PPCI call, followed by an interview / questionnaire concerning your views on simulation scenarios / handovers which will be conducted today.

Why have I been chosen?

Training by simulation is an emerging field in interventional cardiology. You have been chosen as you have the expertise in the field of interventional cardiology. We hope to recruit 20 participants - 10 cardiology trainees, 10 consultant cardiologists (Interventional cardiology)

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

If you decide to take part in the study you will be asked to complete the following:

- 1. A questionnaire or interview about your demographics 2 minutes
- 2. A questionnaire or interview exploring your perspective of learning by simulation in interventional cardiology 5 minutes
- 3. Assessment of simulation based handovers / procedures in the virtual reality skills lab, Paterson Centre, St Marys Hospital, London

The study will also involve the presence of members of the research team. The interview will be recorded in an anonymised way and no part of the interview will be used to broadcast or to communicate with the members of the public. The content of the interview will be analysed only by Dr.Sujatha Kesavan and Dr.Tanika Kelay. The questionnaire and assessment are anonymised and confidentiality is maintained.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks as a result of participating in the study.

What are the possible benefits of taking part?

The questionnaire and the interview will help us to understand learning by simulation in interventional cardiology. This will be the first part of the study, which we aim to perform today. The information gathered will help us to understand the training needs of the trainees and the views of the Consultants. The data will allow us to design a structured, simulation-based training programme and learning by simulation for the trainees in the future.

What if something goes wrong?

We do not foresee anything going wrong. However if there are any problems, you are free to terminate your participation in the study at any time.

Will my taking part in this study be kept confidential?

Information that is collected from you during the course of the research will be kept strictly confidential. Anything you say will be anonymous when reported. The data will be kept securely.

What will happen to the results of the research study?

The results of the research will be written up as a research report and as a MD thesis. It may be published in a research journal and presented at conferences. You will not be personally identifiable in any report/publication.

Who is organising and funding the research?

The study is funded by the Engineering and Physical Sciences Research Council (EPSRC) and organised by the Centre for Patient Safety and Service quality (CPSSQ) within the Department of Surgery & Cancer based at St Mary's Hospital, Imperial College London.

Insurance and indemnity

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator Dr.Sujatha Kesavan (s.kesavan@imperial.ac.uk)

The normal National Health Service complaint complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Office.

Who has reviewed the study?

The Joint Research Compliance Office at Imperial College, London has approved the study.

Contact for Further Information

If you would like further information about this study please contact -

Dr.Sujatha Kesavan, MBBS, MRCP s.kesavan@imperial.ac.uk

You will be given a copy of the research information sheet and a signed consent form to keep, if you wish.

END

10.4 General Consent Form

Imperial College London 100 years of Uvings Department of Surgery and Cancer Division of Surgery Imperial College London

Level 2, Paterson Centre St Mary's Campus Norfolk Place, Paddington, London W2 1NY Tel: +44 (0)20 7594 9726 Fax: +44 (0) 020 7594 3127

skesavan@imperial.ac.uk www.imperial.ac.uk

Research Consent Form

Assessment of technical skills, non-technical skills and technologies by virtual reality simulation in percutaneous coronary procedures

Chief Investigator: Dr. Sujatha Kesavan Consultant cardiologist: Dr.Iqbal Malik

(Research Information Sheet must accompany this form)

Names of Researchers: Dr.Sujatha Kesavan, Dr.Tanika Kelay, Dr Nick Sevdalis,

Dr.Fernando Bello, Dr.Iqbal Malik, Prof Roger Kneebone

- 1. I confirm that I have read and understood the research information sheet for the above study and have had the opportunity to ask questions which have been answered fully.
- 2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my legal rights being affected.
- 3. I understand that my anonymised evaluations may be looked at by responsible individuals from our research team at Imperial College, London and that my data will be collated with other participants so that I cannot be identified individually.
- 4. I agree to take part in the above study.

Date

Name of Participant

Signature

Dr. Sujatha Kesavan Name of Person taking consent (if different from researcher) Signature

Date

Imperial College London

Department of Surgery and Cancer Division of Surgery Imperial College London Level 2, Paterson Centre St Mary's Campus Norfolk Place, Paddington, London W2 1NY Tel: +44 (0)20 7594 9726 Fax: +44 (0) 020 7594 3127

skesavan@imperial.ac.uk www.imperial.ac.uk

Research Interview and Assessment Consent Form

Assessment of technical skills, non-technical skills and technologies by virtual reality simulation in percutaneous coronary procedures

Chief Investigator: Dr Sujatha Kesavan Consultant Cardiologist: Dr.Iqbal Malik

Research Team: Dr.T.Kelay, Dr.N.Sevdalis, Dr.F.Bello, Prof. R.Kneebone

- 5. I confirm that I have read and understood the research information sheet dated 07.11.2011 version 2 for the above study and have had the opportunity to ask questions which have been answered fully.
- 6. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my legal rights being affected.
- 7. I understand that anonymised data from the interview will be used by researchers sections of my research and by responsible individuals from Imperial College, London. I give permission to these individuals and researchers to access my anonymised data that are relevant to this research.
- 8. I understand that there are no compensation arrangements.
- 9. I give consent for this interview to be recorded and later transcribed. The transcript will then be anonymised for the purposes of analysis. No personally identifiable information will be reported from this study. Findings will be based on the collective contributions of participants, which may include anonymous representative quotes taken from the interviews.
- 10. I agree to take part in the above study.

Name of Participant	Signature	Date
Jame of Person taking consent	Signature	Date
Name of Person taking consent	Signature	

Please initial box









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Cardiac Simulator Training Course – BCS

Day 1. The Left Heart

- 08.30 Registration and pre-course questionnaire
- 08.50 Introduction lecture
- **09.00** Indications, patient preparation for a coronary angiogram and cath lab set up
- 09.15 Arterial access for Coronary Angiography and Intervention: Radial vs Femoral

09.30 Simulator Workshop 1 (Manifold Stations)

- 10.15 Coffee
- 10.30 Catheter selection and manipulation for coronary angiography and graft cases
- 10.45 Coronary anatomy: Standard Angiographic views and coronary angiogram
- 11.00 Simulator Workshop 2
- 11.45 Simulator Workshop 3
- 12.30 Simulator Workshop 4
- 13.15 Lunch
- 13.45 Complications and their management
- 14.15 Radiation and contrast
- 14.30 Simulator Workshop 5
- 15.15 Coffee
- 15.30 Simulator Workshop 6
- 16.15 Simulator Workshop 7
- 17.00 Close

Day 2. The Right Heart and Emergency Cardiology

- 08.30 Registration
- 08.50 Welcome to Day 2
- 09.00 Right heart catheters: Who, how and what does the data mean?
- 09.30 Simulator Workshop
- 10.00 Temporary pacing: Who and how?
- 10.30 Simulator Workshop
- 11.00 Coffee
- 11.15 Percardiocentesis: Who and how?
- 11.45 Simulator Workshop
- 12.30 Lunch
- 13.00 Cath Lab team training afternoon (Faculty)
- 16.30 Close and feedback forms

END

	1. Establish ID of the person
Introduction	2. Introduce yourself.
	3. Introduce the project
	4. Seek permission to tape the interview
	1. Reduction in junior doctors hours –
	interventional experience is less
	2. CPR technique is practised on manikins
Present System	and the attendance / training is
	accredited. In a similar fashion, Learning
	by Simulation can be introduced.3. I would like to talk to you about the use
	of simulation in interventional cardiology
	1. I would value your views on assessing technical skills by simulation
Technical skills - Simulation	2. Cases – where the approach could be
	2. Cases – where the approach could be beneficial
	1. I would value your views on assessing
Nontechnical skills -Team work	non-technical skills (team work) via
Nontechnical skills - I eam work	simulation.
	2. Cases - examples
	1. I would value your views on assessing
Communication	communication skills via simulation.
Communication	2. Cases - examples
	- curre thanking
	1. I would value your views on assessing
Leadership	leadership skills via simulation.
Leadership	2. Cases - examples
	r r r r r
	1. I would value your views on assessing
	crisis management scenarios via
Crisis Management - Scenarios	simulation.
Crisis Management - Scenarios	2. Cases - examples
Simulation – a training / teaching tool	1. I would value your views on simulation
Simulation a training / teaching tool	techniques as a training / teaching tool
Simulation – for accreditation	1. I would value your views on simulation
	as a method for accreditation
Simulation – for revalidation	1. I would value your views on simulation
	as a method for revalidation
Simulation Training – for cardiology	1. I would value your views on simulation being a part of the core cardiology
curriculum	being a part of the core cardiology curriculum
Questions – Barriers / Challenges	1. Do you have any questions?
Suggestions	1. Do you have any suggestions?
	1 Variations when
ICT in HealthCare	1. Your views, please

<u>10.8 Example transcript from the interview study – Simulation in cardiology</u></u>

- Interviewer Okay, just a few general questions, Number of years you're working as a consultant cardiologist, please?
- Respondent: Okay, so I've been a consultant since 2001 and I've been in my current post since 2007.
- Interviewer: And I would like to know whether you hold any specific academic position within the university.
- Respondent: No, I'm an NHS consultant.
- Interviewer: And do you have any fixed session for education and training for the juniors?
- Respondent: Not a fixed session, no. I just teach in the day to day running of my job.
- Interviewer: The clinical...?
- Respondent: Yeah.
- Interviewer: Are you an educational supervisor, clinical supervisor or both?
- Respondent: I'm a clinical supervisor but not an educational supervisor.
- Interviewer: And are you a member of the CP panel?

Respondent: No.

- Interviewer: Okay. And the number of interventional procedures that you perform per week?
- Respondent: Per week?
- Interviewer: Or per year.
- Respondent: I do about 200 angioplasties a year, about, I suppose, 100 angiograms, because the juniors do those. And I also do about 30 TAVI procedures a year.
- Interviewer: Okay. So the whole idea of the interview is about simulation based training in interventional cardiology. And, like you were saying, there is like a structured training programme for the surgeons and the surgeons are very into simulation based training in the cardiac role.
- Respondent: Yeah, absolutely.
- Interviewer: So I want to know what are your views about bringing simulation based learning in interventional cardiology?
- Well, I think it does have a role. I'm aware that the British Cardiac Society Respondent: have produced a discussion document on simulation based learning currently. I think there are two drivers for it. One is that the climate within which we work has changed, so that learning as you go along and learning by the mistakes you make on patients is maybe not the way that we can work in the modern era, in the way that maybe we did 20 years ago. And I think second is that, because of the contraction of junior doctors' hours and their number of hours training, they don't get as much exposure to actually doing things. So their experience is very curriculum based, a lot of it is quite theoretical. In my opinion there's a bit too much emphasis on the theoretical learning and not enough just getting on with doing the job, but that's maybe a personal point of view. My exposure to simulators has been positive. I've taught on some simulators for angioplasty and we also went to Germany to use the TAVI simulators before we started our TAVI programme. So I'm familiar with simulators. They're not real patients, of course, but they're a good start.

- Interviewer: So at what stage of the training do you think to introduce simulation learning would be appropriate?
- Respondent: I'm guessing about year three of the six year programme.
- Interviewer: Of the six year programme, before they start their speciality interest or anything?
- Respondent: Yeah, exactly. So get your basics done, all your general experience, decide what you might want to do as a sub speciality and then work on that before you actually start doing it. And then maybe revisit at a later stage the more complex procedures.
- Interviewer: Right. I mean, would you consider that your juniors should have like an accreditation in simulation prior to touching a real patient, before they perform their procedure or...?
- Respondent: I can see that might be the logical conclusion. I'm not sure that we need that right now but it might go that way.
- Interviewer: And how about using simulators for re-validation, re-certification, which is coming in 2012 as well.
- Respondent: Yes. I can see the attraction because it's reproducible. It's very difficult for any of us to come and inspect somebody else's practical skills, a, because there isn't enough time, and it's quite difficult to go and watch somebody do a procedure live, as it were, and give them a mark out of ten. So a structured way of doing it I can see would have some attractions.
- Interviewer: And what have been the barriers so far to introducing simulation based learning, do you think, in cardiology?

- Respondent: Well, I suppose, a, the simulators, until quite recently, have been fairly primitive, the technology. And secondly I suppose there's people giving enough time to sit down and just think about how you set it up, how you may create a programme.
- Interviewer: Sure. So, I mean, the technical skills are one aspect of understanding from your training (inaudible 0:04:53) on a simulator based learning. But what are the other things that you could look for in your trainee, do you think, not only technical? What are the non-technical skills you would look for in your trainee?
- Respondent: You mean generally or do you mean around procedures?
- Interviewer: Generally, even around procedures.
- Respondent: Okay. Well, I mean, you're looking for the qualities of a good doctor, so they have to be empathetic and able to listen and understand. So there's that patient based thing. There's also all the issues about communication and multitasking and organisation of your time. Then there's the issues about your ambition and where you want your career to go and how you pursue that. And then finally there's just the hand skills that are required. So, a, to do the procedure, but also, b, to look after the patient while you're doing the procedure. Some people are very good technically but they're rubbish with talking to the patient at the same time. And then of course in cardiology there's the whole issue about crisis management, i.e. dealing with things when things go wrong.
- Interviewer: Yeah. There's sort of a technical scenario which we all encounter and as a primary PCA case, like a (inaudible 0:06:09), bystander CPR, unconscious, intubated, shocked once. Then he comes to the (inaudible 0:06:17). And like you rightly said, in this situation the registrar has to demonstrate not only technical skills but communication, leadership, everything. Those are the things you would be looking for.

Respondent: Mm-hmm.

- Interviewer: Okay. Then how about future applications? I mean, you did mention about TAVI or even mitral valve repair.
- Respondent: Well, I think the issue with those is that they are technically difficult procedures. They're much more involved than angioplasty. Secondly, you don't get many... They're not high volume procedures, so you don't get the opportunity to do 100 in three months to really get to the heart of it. And the third is that the patients that we do them on are often quite frail and also the equipment that we're using is often a little bit novel. So there's buttons and knobs and wheels that you've not used before, whereas if you've done lots and lots of angioplasty it's wires and balloons and you're used to that. But when you're presented with a new box of equipment you need to know how it all fits together and what it looks like on the screen and all the rest of it.
- Interviewer: What about like future applications? Even research could be conducted on simulators first and then can be tested on the real patient once we have deemed it like a safe procedure to...
- Respondent: Yeah, potentially.
- Interviewer: So that has got a potential application?
- Respondent: Mm-hmm.
- Interviewer: Okay. Part of the programme also involves designing and introducing technology in cardiology and the transfer of information from the community to the hospital during a primary PCI. So right now ECGs are not transmitted from the community to us in the primary PCI. I don't know about Oxford.
- Respondent: They are here.
- Interviewer: They are here? Oh excellent, very good, okay. So that's interesting. So that's exactly what we have designed here, a baseline form and a checklist of questions that we would ask. And then an ECG transmission (inaudible

0:08:16) IPAP. So, yeah, but it's already in Oxford. So how does your system work then?

- Respondent: So we have that already. We have the ECGs transmitted directly to the CCU and also to the catheter lab at the same time. And we get a warning bell that one is coming through and then we all gather round and look at it.
- Interviewer: Okay. So is it only the ECG that gets transmitted or do you have like minimal information about previous cardiac...?
- Respondent: We don't have that. What happens is that we get a transmission and then the CC nurses can ring ambulance control and they can make direct contact with the paramedic by mobile if they're driving. So they can talk about the patient and the clinical scenario as the patient is moving to hospital.
- Interviewer: So how long have you had this ECG transmission for? I'm really curious.
- Respondent: Perhaps a year, 18 months.
- Interviewer: Oh excellent. Okay, that's good.
- Respondent: It seems to work.
- Interviewer: And what do you... I mean, in France, in Europe, some of them have actually continuous... Even a video transmission of the patient's profile. And do you think that would be useful? I mean, along with the ECG...
- Respondent: You would see the patient?
- Interviewer: Exactly, see the patient and then...

- Respondent: Yeah, I've heard about that. I mean, there have been some where you can even talk to the patient.
- Interviewer: Yes, of course. What do you think? I mean, is Oxford planning to go along those lines?
- Respondent: I'm not sure of any plans to be able to see the patient. I can see the attraction. What we are doing is researching a system, I can't think of the right phrase now, but a system for remote monitoring of all vital signs.
- Interviewer: Yes, telemonitoring and (overspeaking 0:09:53) monitoring.
- Respondent: Exactly, pulse, blood pressure, at least tells us things...
- Interviewer: Tele health based.
- Respondent: Exactly, as the patient is...
- Interviewer: En route to the hospital, yes.
- Respondent: Might be getting better, might be getting worse, you have this constant stream of information. So that's a project we're working on at the moment.
- Interviewer: Excellent, okay. That sort of marries with my project. Okay, thank you. So any questions or any other ideas concerning simulation you have? What do you think is the future of simulation?
- Respondent: Well, it's here and it's here to stay. I think it is a positive thing overall. I don't think it can substitute for real patients, because that's a bit like people going

and reading in books about how to manage hypertension rather than learning how to do it in the clinic. So I would always protect the need for hands on training, as it were. But for the reasons we've discussed I can see that simulators do offer advantages. They're not the same as patients.

Interviewer: Yes, but they can complement their training during their...

- Respondent: Yes, it's a complimentary training technique. I think my only call would be that if we're going to implement it, it needs to be standardised so that your simulation training in London is the same as your simulation training in Newcastle or Belfast or wherever it might be. So there's a uniform standard.
- Interviewer: Sure, okay. Thank you. Any other questions you want to ask?
- Respondent: No, no.
- Interviewer: Okay. That's all I want to know. Thank you very much.

END

m	perial College	SIMUL	ATION BASED LEARN	NING & TR	AINING	;	CD	SRC		
LO	ndon	and the second second second second	INTERVENTIONAL CA					ing researc		
		Clinical Investigat	or: Dr Sujatha Kesavan, Research	Follow Interve	ational Card	liology	and skil	ls		
		Inves	tigator: Dr Tanika Kelay, Research A	ssociate, Psych	ology	liology	(-1)		
		Clini	cal Supervisor: Dr Iqbal Malik, Con	sultant Cardiol	ogist		C	/		
		t part of training in ot	ther fields i.e. the Aviation industry and ing learning by simulation in intervention in intervention in the simulation in intervention in the simulation in the simulation in intervention in the simulation in the simulation in the simulation in intervention in the simulation in intervention in the simulation in the s	nd Formula 1 rac	ing. This que	estionnair	e is designed	l to		
	Place of Work		Number of years working as a c	consultant in card	liology	G	ender	1		
	 District General Hospit 	ital	<i>Γ1</i>				je			
	Tertiary Centre Hospit	lal	years			Ą	gel			
	Do you hold an academic	position at a	Do you have a fixed session for				e you a mem	ber of the		
	university? ☐ Yes □ No		education and training juniors?		Supervisor		ARCP Panel?			
		cardiology procedur	es do you perform per week?		ional Superv □ 21-30 □		□ 41-50			
			n training in Interventional Cardiolog	N	Sela Manager and State	A Yes				
L	Have you visited any institution	itute. meeting or cou	rse that offers simulation training in l	nterventional Ca		Yes				
	If Yes, please name the Ir	nstitute, meeting or c	course	?. ₇						
	Plaasa it	ndicate how much	you agree or disagree with each s	atement by cirr	ling a num	her on th	e right			
12 2	r icase ii	nuicate now much	you agree of disagree with each o	Strongly	Slightly		Slightly	Strongly		
			6 6 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Disagree	Disagree 2	Neutral 3	Agree 4	Agree		
1	55		efore performing procedures on patien	1	2	3	4	<u> </u>		
2		Simulation should be introduced early in cardiologists' training, e.g. at ST3 level					4	5		
4	Simulation should be introduced during sub-speciality training, e.g. at ST5 level Simulation-based learning is less time-consuming than 'shadowing' and watching real				2	3	4	5		
	cases			1	U			67		
5			fully replace clinical experience	1	2	3	4	(5)		
6	(e.g. catheterisation)		ronment for developing technical skills ronment for developing team skills (e.g		2	3	4	(5)		
	communication, leadership	and multi-tasking)		,.				4		
8	things go wrong' (i.e. crisis	management skills)	ronment for learning what to do 'when	1	2	3	4	(5)		
9	Team training in simulation Cath-Lab team of cardiolog		offered to entire cardiac care teams (e. ographers)	g. 1	2	3	4	(5)		
10			cal environments (e.g. Cath-Lab)	1	2	3	(4)	5		
					111			-		
11	Simulation has a role for bo	and the second se		1	2	3	4	5		
12	cardiology	action of trainees prio	r to them embarking on a career in	0	2	3	4	J		
13			cation of experienced/expert cardiolog		2	3	4	5		
14	Simulation can be used for doctors during ARCP)	accreditation purpos	es (i.e. to judge competence of junior	1	(2)	3	4	5		
15	Simulation is currently und	er-utilised due to fina	ncial barriers in the NHS	1	2	3	4	5		
16	Simulation is currently under accessible to all trainees and		stical issues, as simulators are not	1	2	3	4	(5)		
17		ler-utilised due to lack	of educational resources (including	1	2	3	4	(5)		
100			the range of complications during real	1	2	3	4	5		
18			erventional procedures in a safe	1	2	3	4	5		
18 19			ovel equipment (e.g. bifurcation stents)	1	2	3	4	(5) (5)		
	Simulation is useful in testi	ing new devices of ne	·····			3				

10.9 Example of a completed questionnaire – Simulation in cardiology

10.10 Invitation letter to the trainees – PPCI call study

Dear Cardiology Registrar,

Good Morning.

Here is a great opportunity to integrate the latest technology and cardiology. As cardiology registrars, we have the chance to shape the technology to suit our clinical needs.

We invite you to take part in testing the novel technology on 4 case scenarios, designed following a PPCI call. The cardiology team and the Bio-engineering department (Imperial College, London) would like to test a novel technology of clinical information transfer from the community to the doctor following a PPCI call.

Total duration: 2 hours. Venue: Paterson Centre, St Marys Hospital, London

We value your time and will adjust to your schedule (weekdays or weekends). Hence, I would be grateful if you could let us know of a suitable time and date.

Thank you very much for your participation and a certificate of attendance will be issued for your portfolio. We appreciate your views and comments.

Thanking you.

Yours sincerely,

Prof Roger Kneebone / Prof Richard Kitney / Prof Jamil Mayet / Dr Iqbal Malik

Department of Simulation / Bioengineering / Department of Cardiology

Contacts: Dr. Sujatha Kesavan, Research Fellow – Interventional Cardiology <u>s.kesavan@imperial.ac.uk</u>

i-Health: i-Health is an EPRSC-funded project that aims to design and develop the tools for this vision, including the next generation of clinical information systems as well as physical simulators to help optimise exemplar-care pathways.

i-Health is a multi-disciplinary collaboration between the Faculty of Engineering – Imperial College London (Department of Bioengineering, Department of Computing) and the Faculty of Medicine – Imperial College London (Division of Surgery, Oncology, Reproductive Biology and Anaesthetics, Department of Primary Care and Social Medicine).

10.11 Example transcript from the interview study – Electronic form

- Interviewer: Part of the research project involves also electronic transmission of information from the community to the cath lab and to CCU. Like, at present, we don't have ECG transfer from the community to the cath lab. Do you have it here, by any chance?
- Respondent: We do have ECGs being sent in, but at the moment they're sent in to the emergency department.
- Interviewer: Right, that is via a fax, but not electronically, not through an iPad or -
- Respondent: To be absolutely honest, I think it is a fax.
- Interviewer: It's a fax. Okay. This is a form that we have designed -
- Respondent: No, actually I'm not sure if it is, sorry. I haven't been down there for a while and seen what... It may actually be some sort of telemetry system.
- Interviewer: Okay, but only the ECG is transferred -
- Respondent: Only the ECG at this time, yes.
- Interviewer: But that is transferred to A&E and not the on-call cardiology team or the cath lab? I agree, you don't have time –
- Respondent: No, they're sent to A&E if an MI is suspected, and if they have ST elevation and a primary angioplasty, then the emergency department call us here and the patient comes straight up, so everyone at the lab is pre-prepared and alerted. So someone would come in for a primary angioplasty through that route.

Interviewer: But they come through the emergency route?

- Respondent: Yeah, but they don't stop there, they do come straight up, but yes, for other things, I'm not sure what you've got in mind, but if for instance a GP wants an opinion on ECG, they would fax that through to the cardiology department directly.
- Interviewer: Right. This is a form that we have designed, and basically it addresses the type of questions that we ask prior to perform a primary PCI, so I would like to have your views about this form. If you get this form directly to your iPhone or iPad in the cath lab for a primary PCI call, what are your views about this form? Do you think this form has sufficient enough information to proceed to primary PCI? I mean, that'll be an electronic transmission of the ECG as well. This form, and the ECG, you will have it on your cath lab computer or on your iPad, even before the patient comes to you in the cath lab, so what I want to know is would consider this information really useful to speed up?
- Respondent: It is useful, yes it's good. It seems to have most of the things there. I suppose the key thing for primary angioplasty is to ensure that completing an electronic form doesn't actually introduce a delay into the procedure. Obviously we want the door to balloon time to be very short, so of course you may get plenty of forewarning if the ambulance telemeters the ECG through and there's time to do all these things. But patients who present sort of *de novo* to the emergency department, what we usually have in that situation is a telephone call with a history over the telephone and an ECG to go with that. Undoubtedly, the form has got important information on. It's good. And I'm sure that could be adopted via some means. It's just a case of tailoring it to the different scenarios in terms of the patient's presentation.
- Interviewer: I mean the main point, I agree with you, the main thing you are interested in is the ECG, and the form actually can be, the details could be heard over the phone.
- Respondent: It's nice to have the checklist there. That's useful, and it's good to know what time the chest pains started, and when the call was put out, what drugs have been given in the ambulance and any bleeding disorders?

- Interviewer: Because we are asking the question again and again, and we thought if we had this form, even before the patient arrives, filled in, whether it would be useful for a cardiologist performing the PPCI. Okay.
- Respondent: Yeah, it's good. Is that the form in use at the moment, or not?
- Interviewer: No, it's not in use, but that's why this information gathering and interviews are being conducted, but I agree your point time shouldn't be spent on filling the form, but electronic transfer of ECG is vital and everything could be heard over the phone en route as well. Which we do right now. But if the form could also be transmitted via iPad from the ambulance, then we thought whether it would be useful.
- Respondent: Yeah, it potentially could.
- Interviewer: Then in France and in Europe they also have like a video camera fitted on the helmets of the ambulance people, and they are able to see the profile of the patient as well. Would you consider that useful? You have like a video transmission of the patient en route to hospital, you have the ECG at least, so you can actually see the profile of the patient en route to hospital.
- Respondent: When you say the profile, what do you mean?
- Interviewer: I mean if the patient is haemodynamically stable, I mean is he alert, well oriented. You can actually see the patient, like a Skype, like a video conferencing basically, with the ambulance team, the patient and yourself sitting in the cath lab while you're waiting for the patient to come through.
- Respondent: I'm not sure if I would actually, because I think the question would be, what's it going to alter? You're still going to take the patient no matter what, if they're having an ST elevation MI, and the key things really are the rhythm and the haemodynamics –

Interviewer: And the basic information –

- Respondent: ...and that can be given without having to see the patient themselves, so you can say the BP's 80 over 40, they've had some VT and so on, so that information's probably just as well transmitted verbally, I think.
- Interviewer: Okay. What other implications do you think has technology in cardiology? Like you've seen the surgeons have adopted it, especially laparoscopic surgery and robotic surgery, they are actually incorporated into the curriculum. The trainees are accredited for virtual reality laparoscopic surgery first, and then they go on to do laparoscopic surgery. So what are the future applications of technology in cardiology, do you think is available, or could be adopted (inaudible 00:18:05).

END

10.12 Example transcript from the interview study – Public education

We arrived at 7.00 pm. My son is a paramedic and he is here. He told us about it and hence I am here

Anything interesting: The whole thing is very interesting. There is a family history of heart disease and that's why we have decided to come to the heart zone.

At present, we have seen the heart attack scene. We are not sure what we will be seeing next. I will look into the list.

It takes away any fear about heart attacks. What is going to happen and what will be done was explained very well. I did not know that the procedure can be done through the groin. It is new to me.

In future, I will be careful about my heart in the future. The whole thing is very impressive.

It takes away part of my worry. Especially with my age, I suppose I am prone to heart attacks. Now today, everything was explained – what will happen, what can be done. It has given me a bit of confidence.

As a unit and a team, it was very efficient. From the moment the patient called – transfer by the ambulance team to the hospital – doctors examining her and doing the procedure – then the after care. Everything was good.

Anything to remember; Main thing is - not to fear. I was afraid of going into an operating theatre. It has taken that fear away. I was surprised that you are awake during the procedure but the doctor told me that medicines can be given to knock you off.

The whole thing was very clear and well explained.

I don't think anything is there to be improved. Showing it in central London is fine. What about other areas? Many organisations will welcome such demonstrations and teaching. They would welcome this talk and which would be nice.

I will tell my friends to make that important phone call – the routine is gone through and how you are taken care off.

Learning experience; 10 / 10. Very impressed. Everybody explained well.

Engaging Experience; 10 / 10. It was a good experience. You are allowed to follow the lady about what is happening. Very visual and good audio as well.

Main point: Take it on tour. Heart attacks are common. That is one big fear. The doctor during the consultation could have explained more about specific type of exercises to take and specific diet to follow after heart attack.

Ultimately, I think it was excellent - Well done.

Thank you very much for doing the interview. Thanks a lot.

10.13 STATE TRAIT ANXIETY INVENTORY – 4 cases – with & without the e-form

STATE TRAIT ANXIETY INVENTORY - STAI

4 CASE SCENARIOS - WITH AND WITHOUT THE E-FORM

Numbers represent the median scores of all the participants for the particular statement for the 3 case scenarios. Case 4 was enacted by the first participant only.

	Case 1	Cas	Case 2		Case 3		e 4
Statements	Yes - e-form - N	o Yes - e-	form - No	Yes-e-	- form- No	Yes-e	- form- No
I feel calm	3 3	3	2	3	2	1	2
I feel tense	1 2	2	2	2	3	3	1
I feel upset	1 1	1	1	1	1	1	1
I am relaxed	3 3	2	2	2	1	1	3
I am content	2 3	4	3	3	3	2	3
I am worried	1 2	1	2	1	2	4	2

Score 1: Not at all Score 2: Somewhat Score 3: Moderately so Score 4: Very much so

10.14 NASA Task Load Index Scale - 4 cases - with & without the e-form

NASA Task Load Index Scale - 4 case scenarios with and without the E-Form

Numbers represent the median scores of all the participants for the particular command for the 3 case scenarios. Case 4 was enacted by the first participant only.

	Case 1		Ca	Case 2		e 3	Case 4	
Statements	Yes e-form No		Yes e-form No		Yes e-form No		Yes e-form No	
Mental Demand	7.5	5.5	8.5	8	7.5	7.5	10	10
Physical Demand	5	1.5	7	4	3	2.5	10	7
Temporal Demand	5.5	7	9	5.5	7	7.5	10	5

Performance	3.5	4	2.5	3.5	4.5	5	5	7.5
Effort	6.5	6	5.5	6.5	5	7.5	10	9.5
Frustration	6	3	2	2	6	3.5	5.5	9

10.15 MANSER HANDOVER RATING - 4 cases - with & without the e-form

MANSER HANDOVER RATING - 4 scenarios - with and without the e-form (EF)

Numbers represent the median scores of all the participants for the particular statement for the 3 case scenarios. Case 4 was enacted by the first participant only.

	Case 1		Cas	e 2	Case 3		Cas	e 4
Statements	EF	No	EF	No	EF	No	EF	No
Handover followed a logical structure	3	4	3	3	4	4	4	1
Person handing over the patient, continuously used the available documentation to structure the handover	3	3	3	3	4	2	5	2
Not enough time was allowed for the handover	1	2	2	2	5	3	3	3
In case of interruptions during handover, attempts were made to minimise them	4	4	4	4	3	3	5	4
All relevant information was selected and communicated	4	4	5	3	4	4	5	4
Priorities for further treatment were addressed	4	4	5	4	3	4	5	5
Person handing over the patient communicated her / his assessment of the patient clearly	4	4	4	4	3	4	5	4
Possible risks and complications were discussed	2	2	3	4	3	4	5	5
It was easy to establish good contact at the beginning of the handover	3	3	4	5	4	4	4	5
There were tensions within the team during the handover	2	1	1	1	2	1	1	1
Questions and ambiguities were resolved	4	4	4	4	3	4	3	4

(active enquiry by the person taking on responsibility for the patient)								
Team jointly ensured that the handover was complete	5	5	4	2	4	3	5	5
Documentation was complete	4	4	5	4	5	4	5	5
There was too much information given	3	1	1	2	2	1	2	3
Too much information was asked for	2	1	1	2	3	1	2	1
The patients experience was considered carefully during the handover	2	4	4	4	4	3	4	3
Overall, the quality of handover was very high	5	3	5	3	3	4	5	2
Person handing over the patient was under time pressure	4	2	5	4	5	4	5	3
Person taking on responsibility for the patient was under time pressure	4	2	5	3	5	4	5	4

NEVER STOP LEARNING

Interventional Cardiology is one of those crafts that you ever fully master to the point where there is nothing left to learn. There is always a new technique to master, fresh skills to acquire, inspirational interventional cardiologists to encounter and all these things will have an impact on the work that we do and will take one to greater things. The goal posts will move and we need to keep pushing ourselves throughout our whole career to achieve the best and contribute to the world of interventional cardiology.

THE END