A Comprehensive Description of the Competencies Required for the Performance of an Ultrasound-guided Axillary Brachial Plexus Blockade

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A thesis submitted to the National University of Ireland, Cork for the degree of Doctor of Philosophy in the Department of Anaesthesia & Intensive Care Medicine, School of Medicine.

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Glossary

ABA	American Board of Anesthesiology
AMEE	Association for Medical Education in Europe
ASA	American Society of Anesthesiologists
ACGME	Accreditation Council for Graduate Medical Education
ASRA	American Society of Regional Anesthesia
BEME	Best Evidence in Medical Education
CbKST	Competency-based knowledge space theory
CI	Criticality index
CoA	College of Anaesthetists
CT	Computed tomography
CUH	Cork University Hospital
DQ	Detailed questionnaire
ESRA	European Society of Regional Anaesthesia
EWTD	European Working Time Directive (2000/34/EC amending Directive 93/104/EC)
FMECA	Failure modes, effects, and criticality analysis
GRS	Global rating scale
HTA	Hierarchical Task Analysis

MOCA	Maintenance of Certification in Anesthesiology
MRI	Magnetic resonance imaging
PFG	Preliminary focus group
PNB	Peripheral nerve blockade
PNS	Peripheral nerve stimulation
PQ	Preliminary questionnaire
SHERPA	Systematic Human Error Reduction and Prediction Approach
SSI	Semi-structured interview
TFG	Trainee focus group
UGRA	Ultrasound guided regional anaesthesia
USgABPB	Ultrasound-guided axillary brachial plexus blockade
USgPNB	Ultrasound-guided Peripheral Nerve Blockade
VR	Virtual Reality

Declaration

The author hereby declares that that this thesis has not been submitted as an exercise for a degree at this or any other University. The work, upon which this thesis is based, was carried out in collaboration with a team of researchers and supervisors who are duly acknowledged in the text of the thesis. The Library may lend or copy this thesis upon request.

Signed: Date:

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Finally, I want to aknowledge the friendship and support of the other PhD students in the department, Farjad and Szilard.

Dedication

I dedicate this work to my family which has grown over the last four years, as I have pursued the work presented here. To Caroline, I thank you for your love and her understanding (particularly when I didn't make it home on time, again!). To my children, Rachel and Mark, you make me proud every single day.

Publications/presentations arising from or associated with this work

Presentations

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Sultan SF, O'Sullivan O, Szucs S, O'Donnell B, Iohom G, Shorten GD. An Easily Reproducible, Effective and Economical Model for Training in Ultrasound Guidance for Regional Anaesthesia. Poster Presentation at the European Society of Regional Anaesthesia Annual Meeting (Sept 2010).

O'Sullivan O, Aboulafia A, Shorten GD. Determinants of Learning Ultrasound-guided Axillary Brachial Plexus Blockade. Best oral presentation, Irish Society of Regional Anaesthesia Annual General Meeting (May 2010).

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Chapter 1 - Introduction

Original Application

The following application for MD degree by Thesis in Anaesthesia was approved by the Faculty of Medicine at University College Cork in October 2009.

Title:

A Comprehensive Description of the Competencies required for the performance of an Ultrasound-guided Axillary Brachial Plexus Blockade (USgABPB).

Location:

This study will be based at the Department of Anaesthesia and Intensive Care, Cork University Hospital. It will also utilize the expertise at a number of other locations, namely South Infirmary Victoria University Hospital and the Department of Anatomy, University College Cork.

Supervisors:

Prof George Shorten, Professor of Anaesthesia and Intensive Care Medicine, University College Cork / Cork University Hospital

Dr Gabrielle Iohom, Consultant Anaesthetist and Lecturer in Anaesthesia and Intensive Care Medicine, University College Cork / Cork University Hospital

Dr Brian O'Donnell, Consultant Anaesthetist, South Infirmary and Victoria University Hospital

Background and Significance:

Axillary Brachial Plexus Blockade is a commonly performed medical procedure which enables surgery of the upper limb be performed without the risks associated with general anaesthesia or as an adjuvant to general anaesthesia, providing high-quality post operative analgesia.[1] Recently ultrasound has established itself as a valuable tool in the performance of this, and other peripheral nerve blocks.[2] The competent performance of the procedure involves a complex interaction between at least three active and simultaneous processes. These are (i) active management of the patient, (ii) the acquisition and (ii) interpretation of ultrasound images, and the placement of a needle in close proximity to specific nerves to deposit local anaesthetic. This complex procedure is one of the most commonly performed ultrasound-guided regional anaesthetic techniques,[3] an area soon to be a core competency in the training of anaesthetists.

The Accreditation Council for Graduate Medical Education (ACGME) asserts there are six domains of clinical medical competence; patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice.[4] Part 11 of the Medical Practitioners Act, 2007 deals with the maintenance of professional competence, and

specifically identifies the duty of the Medical Council to satisfy itself as to the ongoing maintenance of professional competence of registered medical practitioners. Section 88(4) of the same act deals with the Councils requirement to specify and publish standards for training and experience required for granting a specialist medical qualification.

Currently, medical trainees are taught manual techniques using an apprenticeship approach (in which patients are necessarily exposed to inexperienced practitioners) and by trainers with little expertise in education.[5] Most programmes currently provide training in ultrasound-guided regional anaesthesia in phases using both didactic teaching and "apprenticeship". Firstly, the trainees acquire an adequate theoretical knowledge of the relevant anatomy, physiology and pharmacology regarding regional anaesthesia, and understand the principles of ultrasound. Then they are routinely taught by demonstration or through direct supervision, guiding them through the steps as it is performed. It requires intensive trainer-trainee interaction and there is a significant learning curve in understanding the process and in reaching a high level a competency.[6] The learning process involves adapting existing patient management skills, acquiring ultrasound knowledge and proficiency, accurate needle positioning, and crucially integrating all these processes so that they can be performed simultaneously. This current model of teaching is further complicated by the implementation of the European Working Time Directive (EWTD)

(2000/34/EC amending Directive 93/104/EC). It states that "a 48 hour average working week is due to be introduced from 1st August 2009." This implementation plan, although clearly problematic, indicates that the decrease in clinical training opportunities is underway and progressing. This will particularly impair training in procedural skills such as peripheral nerve blockade. A survey carried out in the UK, during the staged introduction of the EWTD, found over 70% of trainee anaesthetists believed the implementation of the directive had a deleterious effect on their training.[7]

Overall Objectives:

This proposed work will define the learning objectives, and determinants of learning for those training in USgABPB. A formal hierarchical task analysis (HTA) will be performed to identify potential sources of error in the practice and learning of the procedure and to optimize its ergonomic performance. This information will inform the design of an innovative training simulator; I anticipate that usability testing of an early form of this simulator will also comprise part of my thesis.

Specific Aims:

(i) To define the determinants of learning of USgABPB.

(ii) To perform an hierarchical task analysis and an ergonomic study of the performance of USgABPB.

(iii) To report usability testing of an early prototype of a training /assessment simulator for USgABPB. This simulator will be developed as part of the 'Haystack' project.

Study Design:

This Study will be based at Cork University Hospital (CUH). It will utilise the wealth of experience in the Department of Anaesthesia & Intensive Care Medicine at this institute. This includes that of the anaesthetic staff (both trainers and trainees) and the patients of the CUH.

Individual aims will be met as follows:-

(i) Qualitative analysis of the teaching of this procedure will define the determinants of learning of USgABPB. This will involve literature reviews, focus groups, questionnaires, and semi-formal interviews

(ii) The performance of the procedure will initially be analysed using a technique known as Hierarchical Task Analysis (HTA). This ergonomic technique involves describing both the actions and the cognitive processes which make up a particular work activity. The Process begins with the definition of a task goal. It then decomposes the steps needed to achieve this goal into subgoals, which are subsequently broken down further. This process generates a hierarchy of task steps (behaviours that need to be performed in the conduct of a task). Once completed the HTA

can be used to analyse the performance of USgABPB, as a framework for promoting good practice and highlight areas of concern.

(iii) Competent performance of USgABPB relies on proficiency in a number of discrete tasks and integrating all these processes so that they can be performed simultaneously. One component of this performance relates to the ability to appropriately insert the block needle and appropriately interpret the sensations felt as the needle is advanced. Through collaboration with the National Digital Research Centre a prototype simulator will be tested to reproduce this component. This 'haptic device' will allow trainee anaesthetist to be taught the technique of inserting the needle and appreciate the sensation of moving the needle through different tissues (skin, muscle, etc), avoiding learning this step on real patients, as is the typical practice at present.

Feasibility:

This body of work will contribute to the ongoing research in the teaching and learning of anaesthetic procedures,[8] and ultrasound regional anaesthetic techniques[9,10] at Cork University Hospital. I plan to fully utilize these resources to successfully complete the work involved in this research.

Deviations from original application

The work carried out differed from that described in the original application in the following ways:

In August 2010, my application to change from MD to PhD was approved.

Two additional task analysis methods were applied to the results of the the Hierarchical Task Analysis (HTA). These were (i) Systematic Human Error Reduction and Prediction Approach (SHERPA), and (ii) Failure modes, effects, and criticality analysis (FMECA).

The usability testing of an early prototype of a training /assessment simulator for USgABPB was modified. It was not limited to testing the tactile sensations which the simulator could reproduce.

In addition to the studies outlined in the approved application, one further study was a carried out. This was a pilot randomised control trial assessing the effectiveness of a USgABPB simulator during its development.

The reasons for the changes:

The body of work I had the opportunity to undertake was considerably greater than initially anticipated. With the support of my supervisors, the opportunity arose to apply for a change from MD to PhD by thesis. This application was approved by the Faculty of Medicine at University College Cork.

In order to identify potential sources of error in the practice and learning of the procedure, our task analyis evolved to include two components not originally specified. SHERPA, a recognised extension of HTA,[11] was applied to the results of the HTA in order to characterise potential errors. FMECA[12] generated a hierarchy to these errors, identifying errors with potential to have greater significance and impact.

The third project was modified because it became clear, based on the findings of the first two studies, that visual cues were of much greater importance than haptic components during the performance of USgABPB. The study therefore included the testing of both visual and haptic elements which the prototype simulator was capable of rendering.

The opportunity arose to assess the ability of training on a prototype simulator to improve trainee performance of USgABPB in the clinical setting. Thus, a pilot "transfer" study (i.e one examining the extent to which learning in a simulated environment influenced clinical performance) was carried out.

The Problem

As evidence of its efficacy and safety increases, ultrasound-guided peripheral nerve blockade (USgPNB) has become more widely practiced. The evidence indicates that USgPNB is associated with improved block success,[13,14] faster block performance,[15] and earlier block onset[14] when compared to PNB guided by peripheral nerve stimulation (PNS). A recent survey of American Society of Regional Anesthesia (ASRA) members demonstrated that 67% (of 583 respondents) utilize USgPNB.[16] The use of ultrasound may soon be the gold standard for regional anaesthesia.[17] USgPNB comprises a set of complex procedures, involving acquisition and interpretation of ultrasound images, placement of a needle tip close to specific nerves, while simultaneously actively managing the patient. In novice hands, some errors are very common.[6,18] This introduction describes some of the currently available training models for USgPNB and suggests how simulation-based training could address certain of the current training deficiencies.

State of the Art / Current Training

The Accreditation Council for Graduate Medical Education (ACGME) has shifted the emphasis of medical education from process to outcomes of education.[19] The transition is evident in the way that USgPNB is currently taught. In the United States of America, the Anesthesiology Residency Review Committee of the ACGME have specified a minimum number of 40 patients in whom peripheral nerve blocks are used as part of the anaesthetic technique or perioperative analgesic as part of their core curriculum.[20] This represents the "process" approach. However, in one observational study, even after performing 60 ultrasound guided blocks, trainees were still making on average 2.8 errors per procedure.[6] ASRA and European Society of Regional Anaesthesia (ESRA) joint committee recommendations for education and training in ultrasound-guided regional anaesthesia[21] offer a number of useful resources; a list of 10 important tasks in performing USgPNB, suggested training routes, a description of the core competencies (mapped to the ACGME six domains), a recommended curriculum for training in ultrasound, and recommended scanning techniques.

The competency-based education model is not universally accepted.[22,23] A recent survey of 4,600 doctors in the UK found the majority of them did not aspire to be merely competent.[24] The elements which constitute expertise are ill-defined.[25] One key element is tacit knowledge.[26] This is known to be acquired by

example and practice, often without being explicitly discussed. It relates to matters of judgment, such as when to apply a learned set of rules. Such judgment differentiates the clinician from the technician. Complex procedures such as USgPNB may be more effectively taught if decomposed into component parts and sequentially learned prior to assimilating them into seamless performance of the complete procedure.[27] But the focus of training should be to enable competent behaviour not just the ability to do certain tasks.

Currently USgPNB is taught through "apprenticeship" and using various forms of simulation including tofu-based,[28] tissue phantoms (animal models such as turkey breasts),[29] and live anaesthetized pigs[30,31] (though limited by expense, ethical issues, and anatomical accuracy). In 2004, ASRA endorsed a set of initial guidelines for regional anaesthesia fellowship training.[32] However these contain limited reference to ultrasound guided regional anaesthesia and do not cover modular training programs for standard or “non-fellowship” trainees. Recently these deficits were addressed when an example of a single centre’s experience of a learner-centred regional anaesthesia curriculum was published.[33] The institution of dedicated regional anaesthesia rotation has been associated with an increase in the number of blocks performed by residents.[34] Another study demonstrated participation in a 4-week regional anaesthesia rotation increased trainees’ ability to identify anatomical structures on ultrasound.[35] ASRA/ESRA guidelines provide a route by which

residents and practitioners can become educated in ultrasound-guided regional anaesthesia.[21] The existence of guidelines does not necessarily imply they will be followed. A survey of colonoscopists in the UK found that only 17.0% had received supervised training for their first 100 colonoscopies, and that only 39.3% had attended a training course.[36]

Formal ultrasonography training is available from organizations such as Consortium for the Accreditation of Sonographic Education (www.case-uk.org). However, these full or part-time courses last a minimum of 12 months, typically, and are impractical for widespread training of anaesthetists. The Royal College of Radiologists in the UK has published recommendations for the training of ultrasound to medical and surgical specialties.[37] These recommendations cover a number of specific areas. These include vascular ultrasound, intensive care ultrasound and focused emergency ultrasound. There are no specific recommendations relating to the training of USgPNB.

Simulation based training

A systematic review by Issenberg et al[38] identified key features of simulation training associated with effective learning (Table 1 below). It is in improved patient outcomes by transfer of these skills into the clinical environment which will likely project simulation into the lives of every practicing clinician.[39,40] Transfer is the extent that newly acquired knowledge, skills and attitudes are applied "on the job".[41] The level at which new skills are generalized and how they are maintained are also important. Significant skill decay occurs if there is a delay between training and on the job performance.[42]

1.	**provide feedback** during learning
2.	Allow users to engage in **repetitive practice**
3.	**Integrate** simulation training into the **curriculum**
4.	Allow user practice scenarios with a **range of difficulty level**
5.	Have the ability to adapt to **multiple learning strategies**
6.	Scenarios should **capture clinical variation**
7.	Provide a **controlled environment**
8.	Allow **individualized learning**
9.	Clearly **defined outcomes**
10.	Proven **simulator validity**

Table 1. The features most closely associated with effective learning. Adapted from Med Teach 2005; 27(1): 10-28

Feedback is a behavioural correction intended to maintain and focus the learner's attention, provide goals and guidance, initiate practice, draw on learned knowledge, and provide informative, contextual, and objective information.[43] Some form of assessment is required in order to inform the content of feedback (formative assessment – see below). The main purpose of feedback, as described by Hattie, is to reduce discrepancies between current understandings and performance and a goal.[44] Feedback relies on the trainee having a level of knowledge. If this does not exist, instruction is the appropriate educational intervention. Evidence indicates that providing the learner with feedback during their performance may be associated with poor skill acquisition when compared to delivering feedback on completion of the task.[45] It is likely that this is due to adding additional demands to the attention capacity of the trainee. Overreliance on feedback may occur; if feedback is given too frequently, poor performance can result when it is not available.[46]

It should be understood that simulators are merely tools. To be effective, they must be incorporated into a structured curriculum from which they draw content. Simulated scenarios should be relevant to the learning goals and allow the trainee sufficient opportunity to manage the simulated case. A set of scenarios may allow a range of skills to be developed. Using variability in scenario design may increase long-term skill transfer and may also promote the application of skills in novel settings,[47] such as may frequently occur in clinical practice. The effectiveness of simulation training can

be enhanced by setting target proficiency goals which users must meet.[48,49] However it is important that the goals set are at an appropriate level, particularly in the early stages when a difficult task may overwhelm the novice.[43] Such goals can be based on replicating expert performance, although this introduces subjectivity to the process. These performance based goals contrast with those based on time or amount of practice (i.e. process) which take no account of individual learning curves or whether learning has actually occurred.

In terms of patient safety, one of the most attractive features of simulation-based training is the potential to optimize the competency level of trainees before performing their first clinical procedure, transferring the steep portion of the learning curve to the simulation lab. This is particularly relevant to complex procedures such as USgPNB. Errors can be made in a safe, non-judgmental environment. Gallagher et al[50] illustrated the benefits of "pre-training" in a simulated environment on the attentional capacity of novice surgeons performing laparoscopic procedures (Figure 1 below). With practice and experience, complex tasks can become automatized, thus freeing up cognitive reserve. The novice who might otherwise be overwhelmed is capable of making fuller use of the educational opportunity presented by enhancing psychomotor performance and visuospatial judgments in pre-training. The master surgeon can use surplus attentional resources to do a secondary task, such as teach the novice. Investigators have used this knowledge to establish the degree of attentional reserve available, measuring performance of a

primary task after the introduction of a secondary task.[51] Such methods should allow true expertise to be identified even when the primary assessment tool does not have the capacity to make that differentiation. While simulation's role in early training appears obvious it has a definite role at later stages in training. Simulation is a valuable tool in enhancing the retention of proficiency levels[52] and will also be invaluable for retraining of experienced individuals following extended periods of skill decay, for example following parental leave or sabbaticals. To date most studies which examine the effectiveness of simulation training involve small numbers of participants, often having a single educational intervention, the effect of which is typically assessed by means of a single performance with few studies assessing retention or decay of acquired skills.[53]

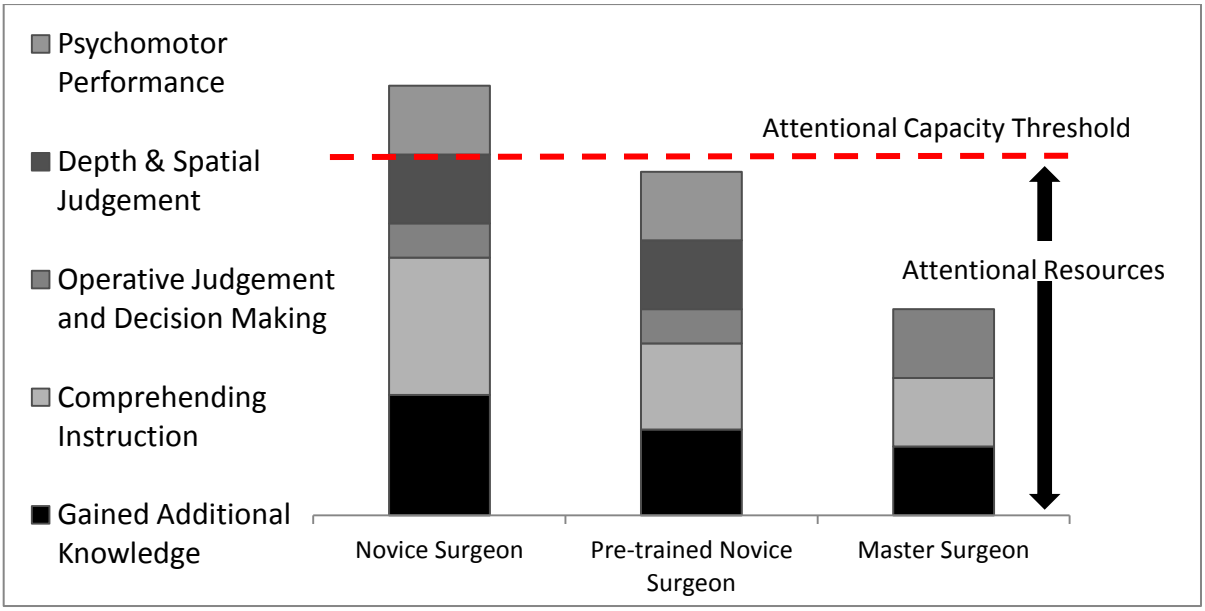

Figure 1. Theoretical benefit of simulation on the attentional resources of a trainee.

Adapted from Ann Surg 2005; 241(2): 364 (Permission Pending)

Practice is not just simple repetition.[41] Deliberate practice is key in acquiring procedural skills,[54] where frequent repetition of the task is refined through feedback (Table 2 below).[55] A number of studies[56-58] based at Northwestern University Feinberg School of Medicine (Chicago) have demonstrated the effectiveness of combining simulation and mastery learning/deliberate practice in the learning of a number of procedural skills. The group also produced a costing which estimated a net annual saving of $700,000, associated with a significantly decreased incidence of catheter related blood stream infections when a simulation programme was introduce to train ultrasound guided insertion of central venous cannulae.[59]

1. **Highly motivated learners with good concentration**
2. **Engagement with a well-defined learning objective or task**
3. **Appropriate level of difficulty**
4. **Focused, repetitive practice**
5. **Rigorous, precise measurements**
6. **Informative feedback from educational sources (e.g. simulators or teachers)**
7. **Monitoring, correction of errors, and more deliberate practice**
8. **Evaluation to reach a mastery standard, and**
9. **Advancement to another task or unit**

Table 2. Description of a framework for deliberate practice.

Adapted from Ann Surg 2005; 241(2): 364

Niazi et al[60] described the application of a physical model incorporating multiple target nerves, differing materials representing subcutaneous and muscular tissue, and blood vessels. Altering fluid velocity in the simulated artery allows trainees identify that structure using Doppler. The application of a small electrical current through the needle and simulated nerves allows an objective measure of contact between these structures, via a buzzer or light. A curved design to the model limits the ability to advance a needle below a linear ultrasound probe and also needle insertion caused a track to

develop, thus limiting the life span of this and similar rendered models. Pollard[28] has described a low cost tofu-based model for USgPNB training and gelatine-based models have been described for ultrasound guided biopsy in radiological literature.[61] Limitations of these physical models include a lack of variability and the requirement for a supervising individual to manually power simulated arteries. To date, no formal analysis of efficacy has been reported using these models. Tissue phantoms, utilizing materials such as lamb's legs[29] and turkey breasts[18] are an alternative which more closely match the tactile elements of clinical performance and also tend to better tolerate multiple exposures to needle insertion. Using an olive buried inside a turkey breast Sites[18] demonstrated could rapidly improve their performance in a simulated environment. Such tissue phantoms are limited by their inability to mimic human anatomy; they also have a short shelf life, are not easily standardized, may require significant preparation before each use, and the use of raw meat is inappropriate in the clinical environment and many non-clinical teaching areas.

Virtual Reality (VR) allows procedures to be simulated in a computer generated environment without the requirement for a physical model. The advantages of this type of simulation include the ability to use a variety of predefined scenarios involving multiple anatomical variations without risk of the models degrading due to repeated needle insertion. Basing virtual models on actual human anatomy (via MRI, CT or ultrasound derived data) allows realistic

representations to be presented. If multiple models are included, normal variation of a single anatomical site or the inclusion of multiple anatomical sites (thus different types of blocks) is possible. While VR simulators have been reported for PNS-guided regional anaesthesia,[62,63] as yet there is no published report of their application to USgPNB.

"*What we measure we tend to improve*" - Dr David Leach[64]

(Director ACGME)

The measurements that inform an assessment, or metrics, should be clinically relevant. They should be transparent, believable, and reflect the ability of the examinee. The fact that an anaesthetist can perform a block quicker than anyone else, tells us very little about their overall competency. Traditionally formal objective assessment was largely limited to tests of knowledge, by means of written and (less objective) oral examinations. In contrast, assessment of trainee performance has regularly been limited to in-training evaluations, often by means of a number of global ratings at the end of a rotation "I know it when I see it."[65] Certainly, this type of assessment is not consistent with the characteristics of an ideal system. Van der Vleuten[66] describes five essential elements of a useful assessment method: reliability, validity, impact on future learning and practice, acceptability, and cost effect.

The assessment of procedural skills is most frequently associated with subjective assessment by means of direct observation. These

frequently take place at the end of a training period, tending to be based on trainer recall of distant events, often with little or no training in how to assess. Trainee logbooks, used to assess trainee performance over time, are usually limited to a measure of participation (quantity of cases), without looking at quality measures (e.g. patient outcome measures), even though numbers of procedure performed does not necessarily imply competence.[67] Procedural skills may also be assessed by direct observation of individual procedures using checklists or global rating scales (GRS). This type of assessment may be impeded by the Hawthorne effect, where individuals alter their performance when being observed.

Simulation has frequently been used to assess the technical aspects of various procedures.[68-70] Simulations allow assessments that are standardized, controlled, and reviewable. Simulation based assessment incorporating objective metrics allow this data to be recorded. Thus individual learning curves may be generated, especially where assessment is recurrent. The details of the individual metrics may allow more meaningful formative feedback. For instance, informing the distance a needle was advanced while the tip was not in view, during a simulated in-plane USgPNB procedure. A more detailed description of a trainee's proficiency level can be generated where these metrics are aligned with specific competencies. This is the basis of competency-based knowledge space theory (CbKST) an innovate approach to procedural assessment.[71]

Future of Simulation Based Training

Simulation will certainly have a role in the future training of USgPNB. We envisage that simulation will offer a variety of platforms for this training to occur. Low fidelity and affordable simulators could be utilized by trainees at home, allowing continuous deliberate practice in a suitably motivated individual. It is likely such models would train components of the procedure, whereas a high fidelity (more expensive) version might be available at an institutional level. Such a simulator would allow the entire procedure to be performed. The creation of a virtual clinical environment[72] more representative of clinical practice allows the trainee become immersed in the scenario and also be exposed to realistic distractions, such as simulated alarms, distracting conversations, etc. If simulators are linked to learning management systems (LMS), learning curves can be constructed using continuous assessment. Computer based algorithms can analyze previous performances on a simulator and choose appropriately challenging scenarios for each individual learner. The generation of a large case library, ideally in collaborative process with multiple training centres, will help create sufficient variability to challenge more advanced learners. Simulation must also keep abreast of alterations in clinical practice, including advances in technology. For example, the future use of three-dimensional ultrasound for USgPNB may improve spatial awareness and allow a better appreciation of both anatomy and needle.[73]

Reflecting on what we know to date, aided in particular by the work of Issenberg et al,[38] we present our "wish list" of features we would like to see in an USgPNB simulator (Table 3 below). Such simulators should be developed in collaboration with clinicians. Simulation-based procedural training is developing rapidly, including in the areas of telesimulation, patient-specific rehearsal and warm-up. Telesimulation involves trainers teaching procedural skills and correcting errors, in real-time to individuals at remote locations.[74] Rehearsal involves using CT, MRI or similar data from a patient to allow, in VR, elements of the procedure to be recreated, practiced, and potential difficulties identified prior to performing the clinical procedure.[75] Pre-procedural warm-up involves simulated practice of related skills prior to performing a procedure. Kahol et al[76] demonstrated improved performance during a simulated procedure following a warm-up period. Significantly the improvement occurred at all levels of proficiency, including experts. Recently the transfer of the warm-up effect has been demonstrated in the clinical performance of laparoscopic cholecystectomys.[77] This may particularly interest medical malpractice insurers, who have already noted the benefit of simulation training, sponsored simulation programmes[78] or reduced-premium incentives.[79]

Allows the measurement of objective and clinically relevant metrics including the identification of clinically significant errors
When errors occur appropriate remediation is suggested (capable of formative assessment)
Allows users to attempt remediation immediately (deliberate practice)
Generates summative assessment scores robust enough to support high stakes decision
Informed by, and integrated into, established curriculum
Incorporates varying scenarios with differing degrees of difficulty
Allows users complete all tasks relevant to USgPNB (both in isolation and as an entire procedure)
Reflective of typical anatomical variation
Displays realistic response of simulated tissues to probe, needle and injectate, while allowing realistic representation of arterial flow on simulated Doppler
Proven short and long term transfer of skills to the clinical environment
Appropriate reliability and validity levels which are understood by faculty
Flexible to allow different types of block to be performed
Appropriately costed
Adapts easily to technological advances
Sound ergonomical design

Table 3. Suggested desirable features of the ideal USgPNB simulator.

The Intention

Simulation will play an increasingly important role in the acquisition of procedural skills; learning by trial and error on patients is no longer acceptable. The increasingly widespread practice of USgPNB means that it is, or soon will be, a core competence for all anaesthetists. This need is largely unmet by current training models. It is likely that well designed simulators can be used as one component of effective training in the necessary skills.

The purpose of this body of work is to inform the development of such a novel simulator. We do not aim to comprehensively address all facets of designing a simulation tool to train and assess USgABPB. This would be too ambitious an undertaking. Rather, we carried out a number of specific studies which would make this ultimate goal more readily achievable.

These were:

(i) We identified the key determinants of learning USgABPB, based on user perceptions, utilizing a structured, prospective, qualitative analysis. This involved, focus groups, semi-structured interviews and a series of questionnaires. Such determinants could serve to inform the design of training programmes and simulators.

(ii) Task analysis techniques, such as hierarchical task analysis (HTA), can inform the design of the simulator. It delivers an

understanding of the components tasks required for successful performance of the entire procedure. The application of systematic human error reduction and prevention analysis (SHERPA)[80] to USgPNB is a related method which allows clinical relevant errors to be characterized. In order to develop and automate a feedback process, a hierarchy of errors can be estimated using proactive hazards and risk analysis. Failure modes, effects, and criticality analysis (FMECA)[12] is an example of such an approach by which expert derived opinions of probability, criticality and detectability of potential errors produce a criticality index (CI). Errors of high CI may be prioritised during simulator development. Real-world issues trainees are exposed to in existing procedural training should be accounted for.[8] This approach ensures that the metrics selected for rendering and capture by a simulator have "real world" meaning (e.g. common or serious errors). We carried out an HTA, SHERPA and FMECA of USgABPB.

(iii) By maximizing a simulator's usability before it is used for training, it is possible to minimize or eliminate system-related artefacts that otherwise would negatively influence a trainee's learning. We set out to determine usability of serial prototypes of a UGRA simulator using quantitative and qualitative methods. We hypothesize that serial prototypes of a simulator for UGRA have limitations which are amenable

to improvement. To this end, we performed a prospective observational qualitative investigation based on end-user feedback.

(iv) We carried out a pilot prospective, single blind, randomized control trial to test the hypothesis that VR-based training offers an additional learning benefit over standard training (using cadaveric dissection and human volunteers) in preparing novice anaesthetists to perform their first USgABPB in the clinical setting.

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Chapter 2 - Determinants of learning ultrasound-guided axillary brachial plexus blockade

Abstract

Background: Training in medical procedural skills is currently undergoing important change. We set out to identify those factors, perceived by trainers and trainees, to be important determinants of learning of ultrasound guided axillary brachial plexus blockade.

Methods: We performed a structured, prospective, qualitative analysis of these determinants using a design-based approach. We collected data using focus groups, semi-structured interviews, and questionnaires.

Results: Based on 113 responses to a detailed questionnaire, the most important determinants of learning of ultrasound guided axillary brachial plexus blockade were access to and frequency of clinical learning opportunities in the presence of an appropriate trainer. Focus groups determined that meaningful learning opportunity required coexistence of appropriate patient, trainee, trainer, and environment. Trainers and trainees perceived that consistent provision of such opportunities required a formal structured training programme.

Conclusions: Optimum training in USgABPB requires a formal structured training programme. We propose that these findings can be used to optimize design of the curriculum, training programme and assessment for the procedure.

Co-investigators for this study

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2. Prof. George D Shorten. PhD. Department of Anaesthesia and Intensive Care Medicine, Cork University Hospital, Wilton, Cork, Ireland, and University College Cork, Cork, Ireland.

Background

Ultrasound guided axillary brachial plexus blockade (USgABPB) is a commonly performed medical procedure which enables the performance of surgery on the upper limb without general anaesthesia. Its competent performance entails complex, simultaneous interactions between the active management of a patient, acquisition and interpretation of ultrasound images, and the placement of a needle tip close to specific nerves to facilitate deposition of local anaesthetic. According to a 2002 survey, axillary brachial plexus blockade (ABPB) is the peripheral nerve block most frequently performed by members of the Society of Ambulatory Anesthesia.[1] Currently, the procedure is most frequently taught using two-dimensional drawings, cadaveric specimens, videos, 3D animations, live demonstrations, phantoms and/or supervised clinical practice.

Training in medical procedural skills is currently undergoing important change. Factors including altered patient expectations and the European Working Time Directive (2000/34/EC amending Directive 93/104/EC) have and will limit the number of clinical learning opportunities available to trainees. The traditional Halstedian apprenticeship model of medical training is being challenged.[2] “See one, do one” is no longer an appropriate method for teaching procedural skills.[3] In this setting patients are necessarily exposed to inexperienced practitioners. These changes will decrease the number of opportunities for trainees to learn and practice

procedural skills in a clinical setting. The National Institute for Clinical Excellence in the UK has produced guidelines stating "clinicians wishing to perform this procedure should be experienced in the administration of regional nerve blocks and trained in ultrasound guidance techniques."[4] Currently, most anaesthetists have little formal and verifiable training in ultrasound guided peripheral nerve blockade (USgPNB).

Thus it has become important and relatively urgent to design training programmes for USgPNB which (i) adhere to sound educational principles and (ii) take account of "real world" factors which influence learning. The objective of this study is to identify determinants of learning a specific form of USgPNB, USgABPB, based on user perceptions. Such determinants would serve to inform the design of training programmes (across diverse clinical settings) and simulators. We performed a structured, prospective, qualitative analysis of these determinants.

Methods

With institutional ethical approval, participants' opinions, behaviours and experiences were elicited using focus groups, semi-structured interviews, and questionnaires (See Figure 2 below). The study was carried out in a tertiary referral university-affiliated teaching hospital in Ireland.

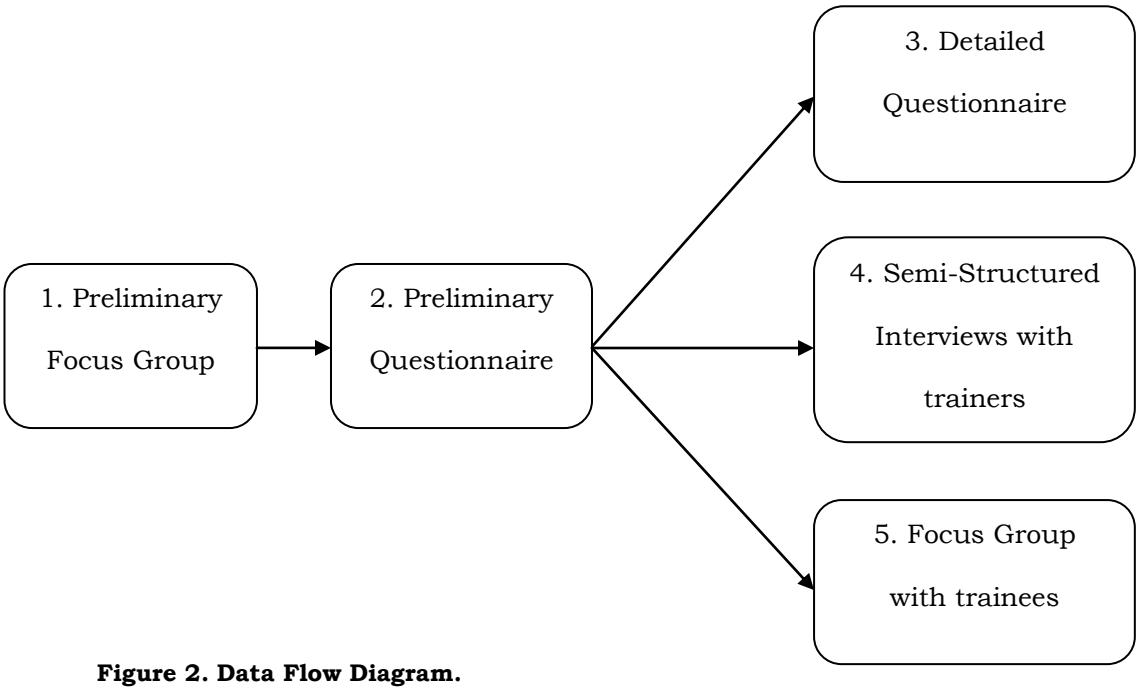

Figure 2. Data Flow Diagram.

Of the 5 discrete tools used, the first two informed the development of the subsequent 3 tools. A preliminary focus group (PFG) was used to define the broad themes for, and establish the scope of the subsequent study. The themes identified from the initial focus group formed the basis for a preliminary questionnaire (PQ). The output of the PQ was a number of proposed determinants which informed the design and content of a detailed questionnaire (DQ), a series of semi-

structured interviews (SSIs), and a focus group with trainees (TFG). The data acquired using these latter tools were analyzed independently.

1. **Preliminary Focus Group** (PFG)

Participants in the PFG were recruited locally and consisted of; two trainers, who teach USgABPB regularly, three trainees (whose experience in anaesthesia ranged from consultant to novice) and one patient who had previously undergone an USgABPB. The group was facilitated using a dual moderator technique, with one moderator ensuring the session progressed towards its objectives efficiently (a psychologist, experienced in facilitating focus groups), and the other (a clinician) ensuring that the relevant content was addressed. PFG lasted 90 minutes and was audio recorded with the participants' consent. Recordings were subsequently transcribed and their content analyzed for dominant or recurrent themes.

2. **Preliminary Questionnaire** (PQ)

The themes identified from the PFG formed the basis for a preliminary questionnaire (PQ). PQ was distributed by both e-mail and a mailed hard copy to 31 anaesthetists in the region known to participate regularly in teaching or learning USgPNB. One reminder e-mail was sent four weeks later. Each question was posed in an open format with a "no limits" free text response option available. Responses were collated and common responses identified. The data acquired from PQ were summarized and tabulated by two of the authors (OOS, AA). If three or more respondents gave a similar

response, it was included in further elements of the study, as a proposed determinant.

The output of PQ was a number of proposed determinants which informed the design and content of a detailed questionnaire (DQ), a series of semi-structured interviews (SSIs), and a focus group with trainees (TFGs). Using these different tools in concert minimized the intrinsic deficiencies of each when used alone [e.g. lack of generalizability (SSIs, FGs), limited depth (PQ, DQ)].

3. **Detailed Questionnaire** (DQ)

Determinants proposed in PQ formed the basis for questions in a DQ which was distributed nationally through the Irish College of Anaesthetists (CoA). This was done using an online survey tool (www.surveymonkey.com). Anaesthetists were invited to complete the questionnaire via an e-mailed invitation with a link directed to the survey. In November 2009 the CoA distributed the e-mail to all consultant and trainee anaesthetist on their database (907). One reminder e-mail was sent after three weeks, with a blank subject line (previously associated with greater response rates[5]). The survey closed one month after initial distribution. Anaesthetists were asked to provide information on their experience in medicine and of USgPNB. Questions were grouped into the themes based on the initial focus group output and formulated as statements e.g. “The main challenges to the performance of USgABPB for the first time are: …” The anaesthetists were asked if they agreed or disagreed with the proposed determinants using a five point Likert scale. In order to

distinguish between determinants with similar Likert-responses, participants were asked to nominate the most important determinant (of those stated) under each theme. All questions were in a closed format, with additional comments permissible only once (at the end of the questionnaire).

4. **Semi-structured interviews** (SSI)

Four anaesthetists who frequently (once per week or more frequently) teach the procedure were interviewed separately. Each was familiar with the study having participated in the PQ and given consent to be contacted. A number of predefined questions (interview guide) were asked of all four anaesthetists. The interviews (SSI-1 to SSI-4) were audio-recorded with the interviewees' consent and subsequently transcribed for analysis. The output of this analysis was a series of items not reported in previous tools. Items were deemed suitable for inclusion if they were consistently mentioned by all four trainers. Points deemed to be novel or otherwise overlooked, though raised by fewer than four trainers, were also included.

5. **Focus Group with Trainees** (TFG)

A group of six trainees (TFG-1 to TFG-6) were recruited based on: (i) variation in experience of training in peripheral nerve blockade and (ii) variation in setting in which this took place (Ireland, France, Portugal, and Hungary). The dual moderator approach as described above (same individuals) was used. This discussion was audio-recorded, with consent, and transcribed for subsequent analysis. The

output of this analysis was again a series of items of common agreement or interesting points brought up by individual trainees.

Results

1. Preliminary Focus Group (PFG)

Analysis of the preliminary focus group transcript identified three broad themes relevant to the learning of USgABPB.

(i) Learning follows a predictable pathway

(ii) Environmental factors are important determinants of learning

(iii) The specific characteristics of both trainer and trainee are important.

2. Preliminary Questionnaire (PQ)

Twenty nine (94%) respondents returned PQ within five weeks, 26/31 (84%) had completed it in full. Within each main theme, a number of specific determinants of learning were identified by grouping similar responses. To address the potential that significant determinants may not readily fall into one of these themes we also asked respondents their opinion of (i) the most important features leading to effective learning of USgABPB and (ii) important impediments to that process. PQ respondents estimated that 20 (median; range 7-50) block performances were necessary to achieve competence. Of the 29 responses to this question, only six respondents qualified their response (e.g. “depending on time interval between”, “needs to be on a regular basis”, “depending on person”).

3. Subsequent Tools

We present the key findings of the final three tools (DQ, SSIs, and FGT) together below. Where possible, we present this data arranged according to the themes generated in our PFG. Where this is not possible or appropriate, tool specific data is displayed separately.

Thirty four of the addresses on the College of Anaesthetists of Ireland e-mail database (907) were found to be invalid or defunct. Of the remaining 873, 113 responded to the invitation (12.9%) and 93 completed the questionnaire in full. The characteristics of respondents to DQ are summarized in Table 4 (below). Of note, nine of the 24 respondents (37.5%) who teach USgABPB did not describe themselves as either competent or expert. Of those who best describe themselves as likely to have difficulty becoming competent in the future, five (5/18, 28%) were in the first five years of training in anaesthesia. Of all proposed determinants in DQ, only two did not receive agreement of >70% of respondents. These were the use of lectures as an appropriate environment to learn the procedure and the fact that the complexity of the procedure may impede learning (41/101 (40.6%) and 33/95 (34.8%) respectively agreed/strongly agreed). Analysis of the responses to the free text opportunity did not identify an additional theme or determinant.

The four interviews (SSI-1 to SSI-4) lasted between 26 and 55 minutes. Specific items raised by trainers are listed below according to the themes identified in the PFG. The TFG lasted 77 minutes. In

comparison with the SSIs, trainees appeared more likely than trainers to speak of their frustrations in attempting to learn.

Years of anaesthesia experience	
<2 years	11/111 (9.9%)
2-5 years	24/111 (21.6%)
5-10 years	35/111 (31.5%)
10-20 years	23/111 (20.7%)
>20 years	18/111 (16.2%)
Estimated number of USgABPB performed ever	
0 blocks	33/112 (29.5%)
1-5 blocks	34/112 (30.4%)
5-20 blocks	25/112 (22.3%)
20-50 blocks	13/112 (11.6%)
50-200 blocks	6/112 (5.4%)
>200 blocks	1/112 (0.9%)
Best describes your current level of competence	
I am expert at performing USgABPB	2/102 (2.0%)
I am competent at performing USgABPB	18/102 (17.6%)
I will become competent in the future	64/102 (62.7%)
I will have difficulty becoming competent	18/102 (17.6%)

Formal teaching qualifications of teachers

	Qualification	*No qualification*	*Total*
Teaches USgABPB	4/110 (3.6%)	22/110 (20%)	24/102 (23.6%)
Does not teach USgABPB	9/110 (8.2%)	75/110 (68.2%)	78/102 (76.5%)

Self defined level of competency in teachers of USgABPB

	Competent/Expert	*Non-competent*	*Total*
Teaches USgABPB	15/102 (14.7%)	9/102 (8.8%)	24/102 (23.5%)
Does not teach USgABPB	5/102 (4.9%)	73/102 (71.6%)	78/102 (76.5%)

Table 4. Characteristics of respondents to DQ.

i. Determinants as a function of the learning pathway

a. Prerequisites

Eighty four of 106 DQ respondents (79%) agreed/strongly agreed that it would be beneficial to undergo assessment of the prerequisites before performing the block on a patient for the first time. Trainee requirements before beginning the learning process and means of meeting prerequisites, based on the responses to DQ, are detailed in Table 5 (below) and Table 6 (below).

Proposed Determinant (Output of Preliminary Questionnaire)	Strongly Agree / Agree	Most important prerequisite
Knowledge of relevant anatomy	107/107 (100%)	81/108 (75.0%)
Knowledge of indications/ contraindications of the block	107/107 (100%)	10/108 (9.3%)
Knowledge of ultrasound (physics, function and interpretation)	92/107 (86%)	9/108 (8.3%)
Knowledge of pharmacology of relevant agents	107/107 (100%)	3/108 (2.8%)
Knowledge of complications of the procedure	106/106 (100%)	3/108 (2.8%)
Knowledge of generic general anaesthesia care	99/107 (92.5%)	2/108 (1.9%)

Table 5. Trainee requirements before beginning the learning process.

Proposed Determinant	Strongly Agree / Agree	Most important means to meeting prerequisites
1:1 tutorials	100/107 (93.5%)	41.7% (45/108)
Observing the procedure in the clinical setting	103/106 (97.2%)	40.7% (44/108)
Attending courses	95/107 (88.7%)	13.9% (15/108)
Reading textbooks	91/106 (85.8%)	2.8% (3/108)
Attending lectures	95/107 (88.7%)	0.9% (1/108)

Table 6. Means of meeting prerequisites.

Points raised by trainers (SSIs):

- Currently self directed learning is important, in particular the use of existing on-line and paper based resources (including animations and video clips).
- The learning of prerequisites should be reinforced during and after the achievement of clinical competence.
- One interviewee emphasized the overlap in knowledge and skills with ultrasound guided vascular access.

b. Initial performance of USgABPB in the clinical setting

Challenges before performing first block and important means for preparing to perform first USgABPB ("narrow the gap"), based on the responses to DQ, are detailed in Table 7 (below) and Table 8 (below).

Proposed Determinant	Strongly Agree / Agree	Most important challenge
Exposure to an appropriate trainer	94/102 (92.1%)	43/98 (43.9%)
Sufficient opportunity to perform block	97/102 (95.1%)	16/98 (16.3%)
Ability to visualize structures	93/102 (91.2%)	16/98 (16.3%)
Ability to coordinate hands appropriately	83/102 (81.3%)	8/98 (8.2%)
Lack of support from institution / colleagues	77/102 (75.5%)	7/98 (7.1%)
Sufficient time to perform block	92/102 (90.2%)	4/98 (4.1%)
Trainee motivation / confidence	79/102 (77.5%)	4/98 (4.1%)

Table 7. Challenges before performing first block.

Proposed Determinant	Strongly Agree / Agree	Most important means
Exposure to an appropriate trainer	99/102 (97%)	50/99 (50.5%)
Participation in a structured training programme / module	93/102 (91.2%)	23/99 (23.2%)
Practice in the use of ultrasound	96/102 (94.1%)	21/99 (21.2%)
Use of simulators	73/102 (71.6%)	5/99 (5.1%)

Table 8. Important means for preparing to perform first USgABPB "narrow the gap."

Points raised by trainers (SSIs):

- Timing is often important during this transition and prerequisites "should be learnt in the general time [frame] that you are doing the block. (SSI-2)"
- Appropriate clinical exposure, while meeting the prerequisites, will allow trainees to contextualize the information in a real life situation thus enhancing retention.

- In order to prepare a trainee for performance his/her of their first clinical block, the use of a step-by-step approach was advocated by all interviewees. One such approach might entail a period of observation, self-directed learning, attendance at an intensive "hands on" course, and non-clinical practice (e.g. use of a turkey leg model).
- In the future, evolution of ultrasound technology will result in structures being easier to appreciate (e.g. enhanced ultrasound machines, echogenic needles).

<u>Points raised by trainees (TFG):</u>

- According to TFG-2 opportunity requires the concurrent presence of a number of factors, without which the learning experience will likely either be ineffective or negative. "Opportunity means having a teacher, a patient, a physical space, a desire, a relaxed environment in a module."
- If one or more of these elements is missing, the training opportunity will be lost. For example, the situation where a trainer "… is either elsewhere supervising or alternatively there is no nurse to assist you. (TFG-2)"

c. The acquisition of competence

Challenges to achieving competence and appropriate means to attain competency ("narrow the gap"), based on the responses to DQ, are detailed in Table 9 (below) and Table 10 (below).

Proposed Determinant	Strongly Agree / Agree	Most important challenge
Opportunity for clinical practice	97/99 (98%)	63/98 (64.3%)
Sufficient exposure to trainers	94/99 (94.9%)	19/98 (19.4%)
Ability to coordinate probe and needle	77/98 (78.5%)	8/98 (8.2%)
Lack of support from institution / colleagues	72/99 (72.7%)	5/98 (5.1%)
Confidence to perform the block	71/99 (71.7%)	3/98 (3.1%)

Table 9. Challenges to achieving competence.

Proposed Determinant	Strongly Agree / Agree	Most important means
Practice of the procedure	102/102 (100%)	47/101 (46.5%)
Exposure to appropriate trainers	101/102 (99%)	22/101 (21.8%)
Sufficient number of blocks over short period of time	92/102 (90.2%)	21/101 (20.8%)
Structured training programme / module	92/100 (92%)	7/101 (6.9%)
Creating a supportive environment	92/102 (90.2%)	3/101 (3.0%)
High quality feedback	89/101 (88.1%)	1/101 (1.0%)
Simulated practice	78/102 (76.2%)	0/101 (0%)

Table 10. Appropriate means to attain competency "narrow the gap."

Points raised by trainers (SSIs):

- The use of graduated independence was described as an important element of progression to competence. "They have to see a few. They have to do the phantom stuff, very closely supervised. The first 10 blocks, are supervised. Hands on, head over shoulder supervised. …they start to pull away after a while. (SSI-3)" "Lots of them over a short period of time… focus and repetitive practice"

Points raised by trainees (TFG):

- A number of trainees felt that the lack of specific learning objectives and an agreed definition of competency are frustrating and an obstacle to learning. The alternative of time-based assumptions on levels of competence was also viewed as unsatisfactory by trainees.
- TFG-2 expressed the need for both supervision and feedback – "[I can perform] the same block over and over again and have no idea if I am making a mistake unless someone is standing over my shoulder."

ii. Determinants related to environmental factors

Appropriate environments to teach USgABPB, based on the responses to DQ, are detailed in Table 11 (below).

Proposed Determinant	Strongly Agree / Agree	Most appropriate location
In a dedicated block room	95/101 (94%)	71/100 (71%)
In a quite / relaxed environment	92/101 (91%)	13/100 (13%)
In an operating theatre	73/100 (73%)	12/100 (12%)
On a course	79/101 (78.3%)	4/100 (4%)
At a lecture	41/101 (40.6%)	0/100 (0%)

Table 11. Appropriate environments to teach USgABPB.

Points raised by trainers (SSIs):

- All interviewees agreed the availability of a "block room", a dedicated space with all the resources to perform USgPNB safely, provides the optimal setting for effective learning of USgABPB, by delivering a controlled environment free of many of the stresses seen in the theatre.
- All interviewees emphasized the importance of managing operating lists so that patients' arrive in theatre at an appropriate time, thus maximizing the limited time that exists in a typically busy operating theatre.
- All interviewees described limitations of learning the procedure at short, intensive courses. Learning the block in such an environment results in very limited "skill transfer (SSI-4)"and "you still need to have on-the-job training, teaching and experience (SSI-2)."

- The availability of a suitable teaching space with equipment such as; ultrasound machines, gel phantoms and simulators, facilitate both formal instruction and self directed learning.

Points raised by trainees (TFG):

- TFG-3 aimed to follow the "practice pathway recommendations" of recent ESRA guidelines.
- Most trainees tended to learn the procedure "in the stressful, noisy environment of the theatre (TFG-6)"

iii. Determinants related to characteristics of the trainer and trainee

Appropriate qualities in a trainer of USgABPB, based on the responses to DQ, are detailed in Table 12 (below).

Proposed Determinant	Strongly Agree / Agree	Most important quality
Knowledge and experience (of USgABPB)	100/101 (99%)	34/99 (34.3%)
Ability to give constructive feedback	99/101 (98%)	17/99 (17.2%)
Patience	97/101 (96%)	17/99 (17.2%)
Desire and interest (in USgABPB)	98/101 (97%)	14/99 (14.1%)
Good communication skills	98/101 (97%)	12/99 (12.1%)
Relaxed	88/101 (87.1%)	5/99 (5.1%)

Table 12. Appropriate qualities in a trainer of USgABPB.

Points raised by trainers (SSIs):

Trainer characteristics

- All interviewees agreed that trainers should receive instruction and training in medical education, although not necessarily a higher education qualification.
- If trainees are exposed to more than one trainer of USgPNB, those trainers should "all be on the same wavelength and teaching the same thing. (SS1-3)" This may result in the restrictions in the number of teachers (a faculty) in order to deliver a consistent learning experience. "Dedicated nominated trainers, who will deliver a set curriculum. (SSI-4)"
- One interviewee emphasized the importance of finding time to give feedback to trainees. "If, in yourself, you don't know where you are...relative to your peers, relative to what is desired of you, then you can feel as if you are floundering. (SSI-4)"
- Trainers should have their teaching appraised by trainees in order to enhance these skills, "feedback can go both ways. (SSI-3)"
- Ideally trainers will adapt their teaching style in response to the needs of individual learners. "Sometimes you get individuals that are like chalk and cheese and the interaction will be the problem not the individuals. (SSI-4)"

Trainee characteristics

- All interviewees described the large variability in the capacity of trainees to attain adequate skill levels and their motivation to do so. Also, "not everybody wants to be a regional expert (SSI-1)".
- According to one trainer, experienced anaesthetists (learning the procedure as a new technique) tend not to listen to the trainer as much as junior trainees. Another trainer described specific characteristics which affect the learning process of such individuals; "personal motivation, bias, perceived inability to deal with new technology, and coping mechanisms – 'this is the way I do it, this is the way I have always done it.' (SSI-4)"

<u>Points raised by trainees (TFG):</u>

- In making best use of the training opportunities that arise, two of the trainees stated that effort should be made to attain the required knowledge before clinical exposure "because the expert's time is very limited. (TFG-1)" "Don't expect to be taught unless you have some background knowledge. (TFG-2)"
- There was also recognition that some trainers were not competent at performing the procedure. "You need to know what the person teaching you (is) qualified to teach you? What do they have in terms of expertise? (TFG-6)" The see one, do one, teach one "days are pretty much over now. (FGT-2)"

iv. Training Structure

In discussions with both trainers (SSIs) and trainees (TFG) it was evident that the point which was emphasized and recurred most was the importance of training structure in determining the effective learning of USgABPB.

Point raised by trainers (SSIs):

- All interviewees indicated the training of USgABPB should be as part of a structured training programme [e.g. a 2-3 month module or a fellowship (1 year plus)], in which the prerequisites, the procedure-specific skills, and the other components of providing patient care are incorporated.
- In the absence of structured training, it was universally agreed that competence is not readily achievable.
- All interviewees supported the view that training in USgABPB should incorporate goal directed learning, with a defined curriculum, based on "What exactly you want to teach (SSI-3)" As a result, trainees would know what is expected of them and know what they are setting out to achieve.
- If such a structure does not exist "it (competence) requires a very significant investment by the individual". However, trainee motivation can serve as a means to create the opportunity to learn ("struggle and you will find… (SSI-1)"). The ability of a trainee to "just go to where the blocks are (SSI-2)" may also hampered by service provision requirements.

- As access to clinical training opportunities decreases, the importance of formal structured training will increase further.

Points raised by trainees (TFG):

- Trainees expressed a desire for a clearly defined learning path. Thus each trainee might embark on a well established programme with defined milestones to direct progress. “If you plan to teach both the anatomy and the block (in one session)…. you’ll end up not knowing very much. (TFG-6)”
- TFG-4 felt that structure also aids trainee confidence, a confident system reflecting on the trainees.
- Frustrations were expressed. “In any institution I’ve worked in, I would say the method of training and teaching is so ad hoc to make competency not readily achievable (TFG-6)”.

v. Important features and impediments to learning

The questionnaire format allowed us to establish the respondent’s opinions as to the overall weighting of proposed determinants across all aspects of learning USgABPB. This also allowed opportunity to uncover any significant determinant which did not neatly fit into the themes established in the PFG. Important features leading to effective learning of the block, based on the responses to DQ, are detailed in Table 13 (below). Important impediments to effective learning of the block, based on the responses to DQ, are detailed in Table 14 (below).

Proposed Determinant	Strongly Agree / Agree	Most important determinant
Sufficient opportunity	93/94 (98.9%)	29/94 (30.9%)
High quality trainer	91/93 (97.8%)	18/94 (19.1%)
Frequent practice	92/94 (97.9%)	17/94 (18.1%)
Desire to learn	91/93 (97.8%)	7/94 (7.4%)
Modular training programme	80/94 (85.1%)	6/94 (6.4%)
Patient trainer	91/94 (96.8%)	5/94 (5.3%)
Availability of equipment and space	92/93 (98.9%)	4/94 (4.3%)
Good knowledge of relevant anatomy	93/94 (98.9%)	4/94 (4.3%)
Lack of time constraints	84/94 (89.3%)	4/94 (4.3%)
Relaxed environment	87/94 (92.5%)	0/94 (0%)

Table 13. Determinants of learning of USgABPB.

Proposed Determinant	Strongly Agree / Agree	Most important impediment
Insufficient opportunity or time	88/95 (92.6%)	39/94 (41.5%)
Limited experienced trainers	88/95 (92.7%)	21/94 (22.3%)
Lack of ethos amongst colleagues for USgPNB	82/95 (86.3%)	11/94 (11.7%)
Lack of a structured training programme	76/95 (80%)	11/94 (11.7%)
Lack of equipment and physical space	83/95 (87.3%)	9/94 (9.6%)
Inadequate trainee preparation	70/95 (75.2%)	3/94 (3.2%)
Complexity of the procedure	33/95 (34.8%)	0/94 (0%)

Table 14. Important impediments to effective learning of the USgABPB.

Discussion

We found the most important determinants of learning of ultrasound guided axillary brachial plexus blockade are:

(i) Access to a formal structured training programme

(ii) Frequent exposure to clinical learning opportunity in an appropriate setting

(iii) An appropriate patient, trainee and teacher being present at the same time, in an appropriate environment.

Only 17.6% of respondents to DQ described themselves as competent with a further 2.0% reporting expertise in performing the procedure. Thirty seven point five percent of those claiming to teach USgABPB do not describe themselves as competent or expert. This likely reflects a concerning prevalence of the "see one, do one, teach one" approach to procedural training. However, this may be exaggerated by the lack of experienced teachers of this particular procedure, as was indicated in DQ responses.

Our findings are consistent with those of previous works which examined the learning of spinal anaesthesia.[6,7] Data acquired suggests that the majority of anaesthetists in Ireland cannot perform USgABPB competently. A comparable deficit has been identified in advanced airway skills of final year trainees in the UK, where 60% failed to meet their own definition of competence.[8]

Our findings are not consistent with all elements of a previous study which looked to characterize the features of expertise in the

performance of regional anaesthesia.[9] That study found aspects of the non-technical or affective domain to be particularly important (technical fluency, handling the patient, and recognizing the limits of safe practice). This may be attributed to; (i) our limited subject (a single procedural skill carried out in a non-urgent setting) and (ii) we focused on competent performance of USgABPB, and not features which differentiate “expertise” from “competence”. This study also found trainees may initially find the variety of different methods practiced by experts to be confusing. Our discussions with trainers also emphasized the importance of the consistency of the training experience even if this means limiting the number of trainers.

Certain limitations apply to this study. Much of the data collected was elicited from individuals currently working at a single institution, although many of these had experience of training in ultrasound guided regional anaesthesia elsewhere, nationally and internationally. A response rate of 12.9% (113/873) is low but it is similar to that obtained in another large survey on this subject.[10] The use of closed questions in DQ, though informed by the open responses of PQ, was criticized by one respondent as being proscriptive.

In the absence of formal structured training it may be very difficult for a given trainee, seeking to learn this procedural skill, to get sufficient exposure to learning opportunities of suitable quality (appropriate patient, teacher, etc). Repetitive opportunities are essential to reinforce learning and acquire procedural skills, as part

of a deliberate practice model.[11] In 1994, while Kapral[12] et al published some of the seminal work in the area of ultrasound guided regional anaesthesia; our surgical colleagues were dealing with a somewhat similar situation in the training for laparoscopic surgery. In that year a call went out for training guidelines for the training and accreditation for such procedures.[13] In 2014, the anaesthetic community is fortunate in that much of this work has already been done for ultrasound guided regional anaesthesia. The onus now most certainly is on us to implement structured training based on these and future work. These determinants can be used to address the design of training programmes, curricula and learning environments for USgABPB.

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Appendices

Appendix 2.1 – Preliminary Questionaire for Anaesthetists

How many years experience in anaesthesia do you have? _____

Approximately how many of the following have you performed (i. ever, ii. over the past year)?

Procedure	i. Ever	ii. Past Year
Peripheral Nerve Block (PNB) (*excluding spinal/epidural*)		
Ultrasound-guided Peripheral Nerve Block (USgPNB)		
Ultrasound-guided Axillary Brachial Plexus Blockade (USgABPB)	>200	>100

Do you teach the procedure of USgABPB?_____

How often do you teach it?_____

How many USgABPB do you think it takes to become competent at performing the block?

_____

How many USgABPB do you think it takes to become expert at performing the block?

_____

Before beginning to learn about USgPNB, what kind of knowledge/experience should a trainee have?

_____
_____
_____
_____
_____

What is the main challenge between beginning to learn about USgPNB and performing the block for the first time?

_____
_____
_____
_____

How could the gap between these points be minimised?

_____
_____
_____
_____
_____

What is the main challenge between performing USgPNB on a patient for the first time and performing it competently?

_____
_____
_____
_____
_____

How could this gap be minimised?

_____

_____

_____

_____

_____

In what environment is this procedure best taught? Why?

_____

_____

_____

_____

_____

During your training, how many anaesthetists have set out to teach you how to perform:-

i. a peripheral nerve block?

   _____

ii. an USg peripheral nerve block?_____

iii. an USgABPB?

   _____

Which qualities are desirable in a clinical teacher?

_____

_____

_____

_____

Which qualities are desirable in a teacher of USgPNB?

_____

_____

_____

_____

List the three most important factors which favourably influence teaching or learning USgPNB.

_____

_____

_____

List the three most important impediments to learning USgPNB in the present system of training.

_____

_____

_____

_____

THANK YOU

May we contact you to arrange a brief (30 min) interview at your convenience on this topic? _____

If yes, how would you prefer to be contacted to make an appointment?

_____

____(e-mail address or phone number)

_____

Please make any additional comments on this page.

_____

_____

_____

_____

_____

_____

Appendix 2.2 - Data

Data relating to Chapter 2 are provided in folder labelled Chapter 2 in the Supplementary Digital Content accompanying this thesis. Data are presented as follows:

1. Transcript of Initial Focus Group 21 July 2009 *(.doc)*
2. Collated Responses to Preliminary Questionnaire *(.xlsx)*

   Individual replies to PQ are provided in a separate folder (handwritten replies have been digitized (PDFs))
3. Collated Responses to Detailed Questionnaire *(.xlsx)*
4. PowerPoint Presentation for Trainee Focus Group (TFG) and Semi-Structured Interviews with trainers (SSIs) *(.ppt)*

   A PowerPoint presentation, based on the output of the Initial Focus Groups and the Preliminary Questionnaire response, provided an broad structure to both Trainee Focus Group (TFG) and Semi-Structured Interviews with trainers (SSIs).
5. Transcript of Focus Group with Trainees 20th October 2009 *(.doc)*
6. Transcript of Semi-Structured Interviews
   i. SSI-1 *(.docx)*
   ii. SSI-2 *(.docx)*
   iii. SSI-3 *(.docx)*
   iv. SSI-4 *(.docx)*

Chapter 3 - Proactive error analysis of ultrasound-guided axillary brachial plexus block performance

Abstract

Background: Detailed description of the tasks anaesthetists undertake during the performance of a complex procedure, such as ultrasound-guided peripheral nerve blockade, allows elements that are vulnerable to human error to be identified. We have applied 3 task analysis tools to one such procedure, namely ultrasound-guided axillary brachial plexus blockade, with the intention that the results may form a basis to enhance training and performance of the procedure.

Methods: A Hierarchical Task Analysis (HTA) of the procedure was performed with subsequent analysis using Systematic Human Error Reduction and Prediction Approach (SHERPA). Failure Modes, Effects and Criticality Analysis (FMECA) was applied to the output of our SHERPA analysis to provide a definitive hierarchy to the error analysis.

Results: Hierarchical Task Analysis identified 256 tasks associated with the performance of ultrasound-guided axillary brachial plexus blockade. Two hundred and twelve proposed errors were analyzed using the Systematic Human Error Reduction and Prediction Approach. Failure Modes, Effects and Criticality Analysis methodology was applied to the output of the Systematic Human

Error Reduction and Prediction Approach analysis to prioritize 20 errors.

Conclusions: This study presents a formal analysis of (i) the specific tasks that might be associated with the safe and effective performance of the procedure and (ii) the most critical errors likely to occur as trainees learn to perform the procedure. Potential applications of this data include curricular development and the design of tools to teach and assess block performance.

Co-investigators for this study

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4. Prof. George D Shorten. PhD. Department of Anaesthesia and Intensive Care Medicine, Cork University Hospital, Wilton, Cork, Ireland, and University College Cork, Cork, Ireland.

Background

Ultrasound guided regional anaesthesia (UGRA) involves a reliable nerve localization technique which may facilitate faster onset, improved quality of peripheral nerve blockade[1] and administration of smaller doses of local anaesthetic[2] than with traditional nerve stimulation technique. In 1994 Kapral and colleagues[3] described how ultrasound can be used, in real time, to guide nerve blockade. By 2009, a survey of American Society of Regional Anesthesia and Pain Medicine members demonstrated that 67% (of 583 respondents) utilize UGRA.[4] This dissemination has created a requirement to teach and learn a series of new and complex procedures, involving acquisition and interpretation of ultrasound images and the placement of a needle tip close to specific nerves, while simultaneously actively managing the patient. Changes in the landscape of medical education are likely to decrease the number of opportunities for trainees to learn and practice procedural skills in a clinical setting, in part, due to the curtailment of working hours.[5,6] "See one, do one" is no longer the sole method for teaching procedural skills.[7]

These circumstances have created a need to address the quality of training. Procedures such as UGRA may be more effectively taught if addressed initially as its component parts, each subsequently mastered and then assimilated into seamless performance of the complete procedure.[8] Simulation-based training is likely to be important in delivering effective safe training in this new

environment.[9] Simulation facilitates the acquisition of necessary skills at a point removed from the patient, thus allowing learner errors to occur without adverse clinical effects.

In clinical practice, the attainment of a successful procedural endpoint does not ensure error-free procedure performance. In one study, even after performing 60 ultrasound-guided blocks as part of regional anaesthesia rotation, trainees were still making on average 2.8 errors per procedure.[10] Design of future training programs and tools should/could be guided by identifying important errors that occur during procedural performance. Our principal objective was to identify and rank for priority those errors most likely to occur during trainee performance of one UGRA procedure, ultrasound-guided axillary brachial plexus blockade (USgABPB). We believe that this information would be useful in informed development of training and assessment programs for UGRA. Furthermore, we believe that the methodological approach we adopted might have applicability to a wide range of procedural skills. In order to achieve this, we utilized a number of task analysis tools. The tools were chosen based on their ability to characterize the procedure and provide qualitative and quantitative information about the errors which may occur during trainee performance. In order to characterize specific errors using these tools it was necessary to select a single UGRA procedure, as each block will have a different error profile. We selected to analyze USgABPB for a number of reasons; (i) it is a commonly performed block in our institution and elsewhere,[11,12] (ii) it involves multiple nerve targets in close proximity to vascular structures, (iii) the block

has less site specific complications associated with it than others (e.g. pneumothoraces, hemidiaphragmatic paresis, unintentional neuraxial blockade).

Methods

Having received approval from the Clinical Research Ethics Committee of the Cork Teaching Hospitals, and the expressed consent of all participants, data were collected in a tertiary referral university-affiliated teaching hospital in Ireland during the period September 14th 2009 to April 30th 2010. Five experts currently and regularly teaching UGRA to resident and non-expert staff anaesthetists were recruited locally. Each expert had performed a minimum of 200 ultrasound-guided nerve blocks during the preceding year. The study involved the following components:

1. Hierarchical Task Analysis (HTA) was used to describe goals and sub-goals of the procedure in detail by decomposing the complex procedure into a hierarchy of operations and suboperations.[13,14] The HTA followed a well described framework[14] and entailed two analysts, a clinician (OOS) and an educational psychologist (AA), reviewing a variety of educational resources[15-20] to generate an initial description of the procedure. This was followed by a series of one to one semi-structured interviews with each of three experts. Task decomposition entailed experts describing tasks (including cognitive tasks), in detail, which would be carried out by an anaesthetist in performing an USgABPB during the interval commencing with (i) positioning of the patient and equipment (pre-block) and ending at (ii) completion of the initial assessment of block efficacy. Tasks specific to the use of

peripheral nerve stimulation were excluded. The purpose and methodology of the study were explained to the experts during an initial group session. During a one month period, each expert was interviewed on two occasions, lasting 60-90 minutes each.

2. Systematic Human Error Reduction and Prediction Approach (SHERPA)[14] was applied to the results of the HTA to predict potential errors. Using SHERPA taxonomy,[21] OOS and AA reviewed the output of the HTA and identified and compiled a list of credible errors that could occur during trainee performance of the procedure. This list was used to create a questionnaire that was distributed electronically (www.surveymonkey.com) to five experts (including those three who participated in the HTA). We chose to increase the number of experts involved to account for the variety of taught and performed practice of the procedure. Opinions of the probability of a trainee making each error and the criticality of the situation should that error occur were elicited. Experts were asked to consider the occurrence of each error during trainee performance of the procedure and select a probability and criticality rating for each from predefined options for both variables (Table 15 below). A free text box was associated with each error to allow experts to suggest possible remedial or recovery steps. At nine distinct points, experts were asked to indicate if any significant error had been omitted.

Probability	Criticality
• Extremely common >50% • Very common >10% • Common >1% • Uncommon >0.1% • Very uncommon <0.1%	• Safety (Patient) - High (a potentially life-threatening or permanent effect) • Safety - Medium (a potentially noticeable but transient effect) • Safety - Low (a barely noticeable effect) but block failure high • Safety - Low and block failure low • Safety – Nil but block failure high • This is not an error

Table 15. Probability and criticality options available to experts.

3. In order to readily allow important errors in performance to be distinguished from errors of lesser significance we utilized Failure Modes, Effects, and Criticality Analysis (FMECA) methodology to convert the semi-quantitative SHERPA output to quantitative data. Adapting previously utilized scales[22,23] we converted the Criticality and Probability estimates from SHERPA into Severity and Probability ratings (Table 16 below). Having applied these ratings to the SHERPA responses, the product of probability and severity ratings [P x S] of each error was calculated for each expert. An initial ranking of errors was generated by ordering errors occurring to decreasing mean [P x S] value. In order to generate a criticality index (CI) for each error a detectability rating was required. This process was limited to the 20 errors with greatest mean [P x S] value i.e. those likely to be of greatest clinical significance. The same five experts estimated the "detectability" [D] for each i.e. how easily an unsupervised trainee learning the procedure might detect

that an error had occurred, using a 10 point scale, from least (1 - an error easy to detect) to greatest (10 - an error likely to go unnoticed). The CI for these 20 errors was calculated as P x S x D. Rearranging these errors according to their CI values allowed a final ranking of errors to be determined.

		Rating
Occurrence		
"Very uncommon"	<0.1%	2
"Uncommon"	>0.1%	4
"Common"	>1%	6
"Very Common"	>10%	8
"Extremely Common"	>50%	10
Severity		
This is not an error		0
Safety – Nil but block failure high		2
Safety - Low (a barely noticeable effect) and block failure low		3
Safety - Low but block failure high		5
Safety - Medium (a potentially noticeable but transient effect)		8
Safety - High (a potentially life-threatening or permanent effect)		10

Table 16. Probability and severity ratings applied to output of SHERPA.

Statistical Methods

Inter-rater reliability was assessed using Cohen's Kappa.

Results

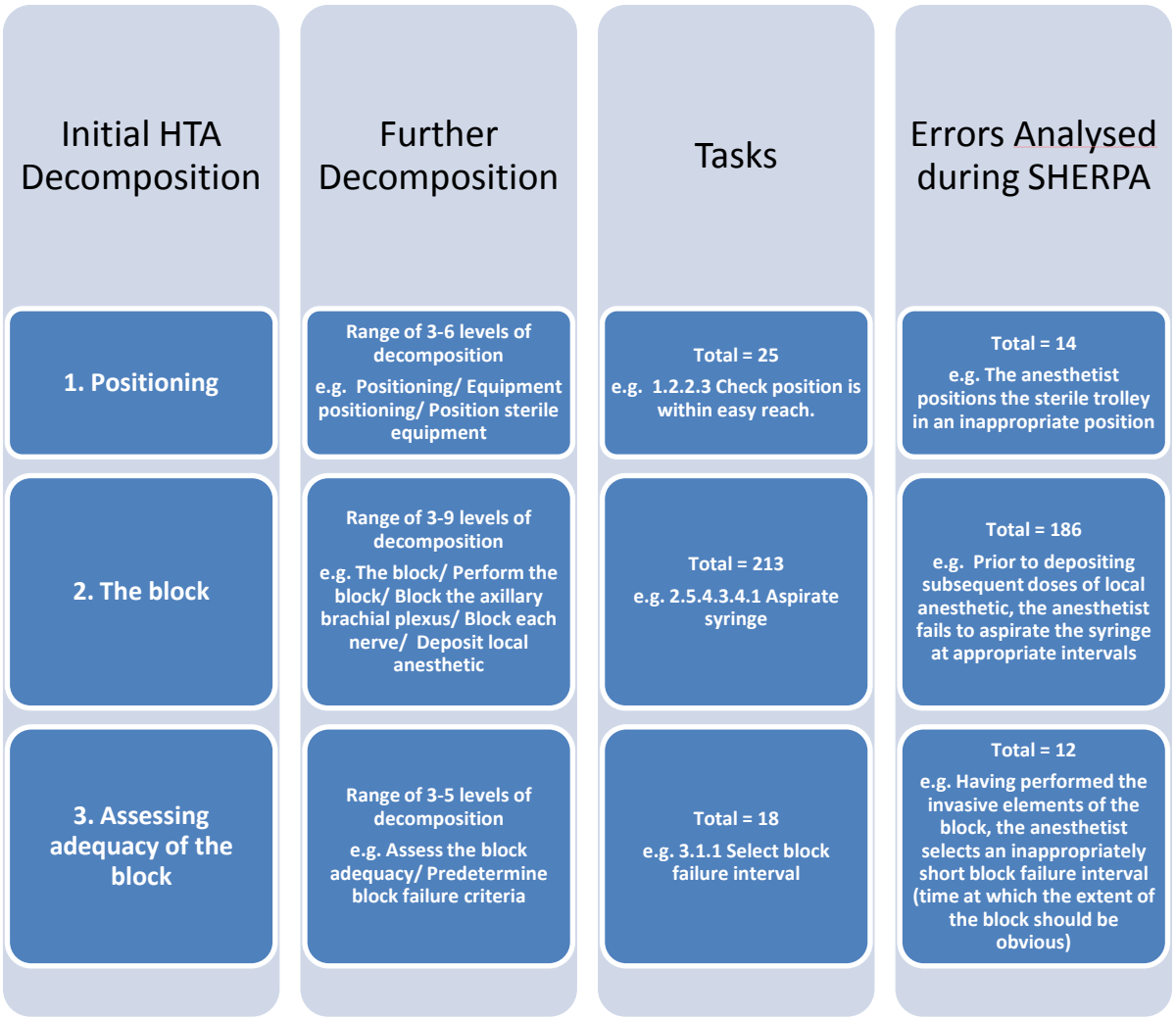

Figure 3. An overview of the output of the Hierarchical Task Analysis and Systematic Human Error Reduction and Prediction Approach.

The decomposition of USgABPB resulted in 256 specific tasks being identified (See Figure 3 above). Twenty five tasks identified relate to "positioning of patient /equipment" (1), a further 213 to “Performance of the block” (2), and 18 to "Block assessment" (3). An example of the decomposition is provided in Table 17 (below). The complete HTA is provided in the supplementary digital content accompanying this thesis. From these, the two investigator analysts identified 212 credible errors (See Figure 3 above) which were subsequently

reviewed by the five experts. No proposed error was considered “not an error” by all five experts. No additional errors were suggested by the participating experts.

As an example, Figure 4 (below) describes the process by which the Criticality Index (CI) of an error was generated by tracking its "journey" through the task and error analyses. The final error ranking table is shown in Table 18 (below). Eleven of the 20 errors shown have a similar identifying notation (right hand column Table 18; beginning 2.5.4.3.3) indicating they arise from a specific and limited part of the procedure. An illustration of how this HTA numbering is generated is available in supplementary digital content. Five of the twenty errors with greatest [P x S] relate to “Advance Needle” (HTA numbering = 2.5.4.3.3.1) and its subordinate tasks. A further six relate to errors made in confirming the needle is at the target (2.5.4.3.3.2). More than one error can arise from a single task; in the case of the twenty errors ranked, this occurred three times. The CI serves to differentiate between errors arising from a single task in terms of overall clinical importance. For example, "if in advancing the needle under ultrasound guidance, the anaesthetist *believes* the needle tip is visible when in fact it is not” (HTA task 2.5.4.3.3.1.1; CI = 460.8), is judged to be an error of greater overall clinical importance than "*failure to check* that the entire length of the needle (including the tip) is visible” (HTA 2.5.4.3.3.1.1; CI = 268.6).

Do in order 1-3 *(plan)*

1. Positioning *(operation)*

- Position the patient and the equipment appropriately *(goal)*

2. The block

- After completing final preparations, safely perform the axillary brachial plexus block under ultrasound guidance

Do in order 1-5

2.1. Scout Scan *(suboperation)*

- Perform an initial survey ultrasound scan of the axilla and arm to identify relevant anatomy

2.2. Confirm patient comfort

- Before proceeding with scrubbing for the procedure, ensure the patient remains comfortable

2.3. 'Scrub' for procedure

- Perform final preparations to maximize sterility during the performance of the block

2.4. Perform final preparations

- Perform final preparations, which required the handling of sterile equipment

2.5. Perform the block

- Perform the ultrasound guided axillary brachial plexus blockade

Do in order 1-6

2.5.1. Note patient vital signs

- Prior to performing the block take note of the patient's vital signs so that they be later recorded and also so that as a point of reference for any subsequent variation

2.5.2. Position Ultrasound Probe

- Relocate the best location to perform the block and stabilize the probe at this location

2.5.3. Infiltrate local anaesthetic subcutaneously

- Infiltrate local anaesthetic at an appropriate location subcutaneously prior to introducing the block needle

2.5.4. Block the axillary brachial plexus

- Under ultrasound guidance, deposit sufficient local anaesthetic around the 4 relevant nerves using the prepared block needle, maintaining a sterile technique

Do in order 1-6

2.5.4.1. Plan order

- Select a systematic order of which the nerves will be blocked, blocking the nearest nerve first so as maximize its mobility and minimize the risk of skewering it when passing the needle beyond it

2.5.4.2. Insert Block needle

- Insert Block needle with LA attached to administration port and flushed though needle

2.5.4.3. Block each nerve

- Maintaining the predetermined plan block each of the 4 relevant nerves

Do 1, then repeat in order 2-4 until all 4 nerves blocked

2.5.4.3.1. Ensure probe is immobilized

- Check the probe is in a stable position which can be maintained for the duration of the block

2.5.4.3.2. Select target

- Choose a target nerve according to the predetermined order (2.5.4.1)

2.5.4.3.3. Position needle at target

- Manipulate the needle tip towards the target and confirm it is in an appropriate location prior to depositing local anaesthetic solution

Do in any order 1-2, then do 3 if preferred, then do 4

2.5.4.3.3.1. Aspirate syringe

- Gently aspirate the syringe and examine for the presence of blood in the extension tubing, indicating an inadvertent vascular puncture

2.5.4.3.3.2. Confirm needle on screen

- Examine the ultrasound image to confirm needle tip can be identified in close proximity to the target nerve

2.5.4.3.3.3. Consider using PNS

- Consider gaining additional confirmation with through the use of peripheral nerve stimulation

2.5.4.3.3.4. Inject test dose

- Having confirm the tip is in close proximity to the target nerve and with a no blood on aspiration observe the ultrasonic appearance to the injection of a small volume of local anaesthetic, which will confirm the position of the needle tip

2.5.4.3.4. Deposit local anaesthetic

- Once the tip is located adjacent to the target nerve deposit sufficient local anaesthetic solution

2.5.4.4. Remove block needle

- Remove the block needle and dispose of it appropriately

2.5.4.5. Apply dressing

- Apply a sterile dressing to the puncture site

2.5.4.6. Place the arm in an appropriate position

- Place the arm in a comfortable position which will protect it from injury once anaesthesia established

2.5.5. Vigilant for signs of systemic toxicity

- Following injection of local anaesthetic solution be vigilant for any symptoms reported by or elicited from the patient which could signify systemic local anaesthetic toxicity

2.5.6. Dispose of equipment

- Following completion of the block dispose of all sharps and biomedical waste in the appropriate fashion

3. Assess the adequacy of the block

- Assess the effects of the block to provide anaesthesia and analgesia at appropriate intervals following the performance of the block

Table 17. An example of task decomposition illustrating a sample output generated by the Hierarchical Task Analysis.

The procedure is decomposed into a discrete number of operations. These are subsequently decomposed into suboperations, which themselves may be decomposed further into constituent suboperations. The process continues until the procedure can be described in terms of

simple finite tasks. Each operation is associated with a goal and a plan which describes the relationship between its suboperations (consecutive, concurrent, unordered, etc.). Individual operations and tasks are identifiable by a unique HTA number (e.g. 2.5.4.3.3.2.2).

HTA NUMBER	DESCRIPTION	CI
2.5.4.3.3.1.4	In the event that the needle is poorly or not visualized while advancing it towards the target, the anaesthetist continues to advance the needle	490
2.5.4.3.3.1.1	In advancing the needle under ultrasound guidance, the anaesthetist believes the needle tip is visible when in fact it is not	461
2.5.4.3.3.2.4.2	In using a small bolus of local anaesthetic to confirm the needle tip is in an appropriate location, the anaesthetist incorrectly identifies visual cues as appropriate when they are not	437
2.5.4.3.3.2.2	Prior to depositing a bolus of local anaesthetic, the anaesthetist believes the needle tip is visible when in fact it is not	432
2.1.6.2.2	In finding the best needle trajectory to perform the block, the anaesthetist fails to check the risk of the possible trajectory to cause neural/other injury or vascular puncture	404
2.5.4.3.3.2.4.3	In using a small bolus of local anaesthetic to confirm the needle tip is in an appropriate location, the anaesthetist checks for the presence of inappropriate visual cues but fails to recognize them when they occur	403
2.5.4.3.3.1.6	In attempting to optimize the image of a needle which is poor/lost, the anaesthetist moves needle rather than the probe	394
2.5.4.3.3.1.5	In attempting to manipulate the ultrasound probe to optimize the image of a needle which is poor/lost, the anaesthetist fails to note the cues provided by examining the orientation of probe and needle at the skin surface	382
2.5.4.3.3.2.2	Prior to depositing a bolus of local anaesthetic, the anaesthetist fails to confirm the needle tip is visualized	374
2.1.5.1.3	In confirming the anatomy of the vessels in the axilla, the anaesthetist fails to identify all veins	336
2.5.5.1	Having deposited what is believed to be sufficient local anaesthetic, the anaesthetist fails to be vigilant of signs of CNS toxicity	269
2.5.4.3.3.1.1	In advancing the needle under ultrasound guidance, the anaesthetist fails to check that entire length of the needle (including the tip) is visible	269
2.5.4.3.4.1	Prior to depositing subsequent doses of local anaesthetic, the anaesthetist fails to aspirate the syringe at appropriate intervals	246
2.5.4.3.3.2.4.1	Prior to depositing local anaesthetic around the target nerve, the anaesthetist fails to administer a small test bolus to confirm the needle tip is in an appropriate location	234
2.1.6.1.3	In finding the best location to perform the block, the anaesthetist checks for the ability to visualize the blood vessels in the area but fails to identify all of the significant vessels	227
2.5.4.2.6.1	In attempting to advance the needle towards the target nerve, the anaesthetist is markedly inaccurate	222
2.1.6.3	In finding the best needle trajectory to perform the block, the anaesthetist fails to scan proposed needle trajectory with colour Doppler to identify unsuspected blood vessels	187
2.5.4.2.5	Prior to advancing the block needle, the anaesthetist misaligns the needle trajectory and the scanning plane of the ultrasound probe	180
2.1.5.1.3	In confirming the anatomy of the vessels in the axilla, the anaesthetist fails to identify any veins	163
2.5.4.3.3.2.1	Prior to depositing a bolus of local anaesthetic, the anaesthetist fails to aspirate the syringe	112

Table 18. Errors likely to occur during trainee performance of Ultrasound guided axillary brachial plexus blockade in order of "Criticality Index (CI)"

Errors are associated with a specific task, each with a HTA (Hierarchical Task Analysis) number.

The data provided by the experts on “Recovery potential / Remedial strategy” was substantially incomplete and inconsistent. While many recovery and remedial steps were suggested many others, obvious to analysts, were not. Several of the responses were generic e.g. “education” or lacked sufficient detail to be useful e.g. “should raise alarm bells”. To address this one expert was selected, based on the quality and detail of her original responses, and interviewed to complete the “Recovery potential / Remedial strategy” dataset. Therefore the authors analysed the responses given, chose the expert who had most comprehensively completed this section, and interviewed that individual to complete any missing data. The recovery potential/remedial strategy analysis was limited to the top twenty errors (see Table 19 below).

Number	Description	Recovery Potential	Remedial Strategy
2.1.5.1.3	In confirming the anatomy of the vessels in the axilla, the anaesthetist fails to identify all veins	2.1.5.1.4 Alternate probe pressure 2.1.6.3 Check colour Doppler 2.5.4.3.3.2.4.2 Inappropriate cues absent (On test dose injection)	Automatic visual or audio cue provided by ultrasound machine (to check for all veins with a reminder that there is likely multiple veins)
2.1.5.1.3	In confirming the anatomy of the vessels in the axilla, the anaesthetist fails to identify any veins	2.1.5.1.4 Alternate probe pressure 2.1.6.3 Check colour Doppler 2.5.4.3.3.2.4.2 Inappropriate cues absent (On test dose injection)	Automatic visual or audio cue provided by ultrasound machine
2.1.6.1.3	In finding the best location to perform the block, the anaesthetist checks for the ability to visualise the blood vessels in the area but fails to identify all of the significant vessels	2.1.6.3 Check colour Doppler 2.5.4.3.3.2.4.2 Inappropriate cues absent (On test dose injection)	None offered
2.1.6.2.2	In finding the best needle trajectory to perform the block, the anaesthetist fails to check the risk of the possible trajectory to cause neural/other damage or vascular puncture	2.1.6.3 Check colour Doppler 2.5.4.3.3.2.4.2 Inappropriate cues absent (On test dose injection)	Ask anaesthetist to identify on the ultrasound screen the intended path – which will promote consideration for all structures on or near that path
2.1.6.3	In finding the best needle trajectory to perform the block, the anaesthetist fails to scan proposed needle trajectory with colour Doppler to identify unsuspected blood vessels	2.5.4.3.3.2.4.2 Inappropriate cues absent (On test dose injection)	Automatic visual or audio cue provided by ultrasound machine
2.5.4.2.5	Prior to advancing the block needle, the anaesthetist misaligns the needle trajectory and the scanning plane of the ultrasound probe	Immediate 2.5.4.2.6.2 Identify needle (on the ultrasound image) 2.5.4.3.3.1.5 Note position of hands	Use of needle insertion guide Use of echogenic needle
2.5.4.2.6.1	In advancing the block needle towards the target nerve, the anaesthetist misses the target significantly	Immediate 2.5.4.2.6.2 Identify needle (on the ultrasound image) 2.5.4.3.3.2.4 Inject test dose 2.5.4.3.3.3.2. Redirection needle 2.5.4.3.3.1.7.3 Withdraw needle to subcut. tissue and begin again	None offered
2.5.4.3.3.1.1	In advancing the needle under ultrasound guidance, the anaesthetist believes the needle tip is visible when in fact it is not	2.5.4.3.3.1.7.1 Oscillate needle 2.5.4.3.3.2.4.2 Appropriate visual cues present (On test dose injection)	Use of echogenic needle
2.5.4.3.3.1.1	In advancing the needle under ultrasound guidance, the anaesthetist fails to check that entire length of the needle (including the tip) is visible	2.5.4.3.3.1.7.1 Oscillate needle 2.5.4.3.3.2.4.2 Appropriate visual cues present (On test dose injection)	Use of echogenic needle Automatic visual or audio cue provided by ultrasound machine
2.5.4.3.3.1.4	In the event that the needle is poorly visualised or lost while advancing it towards the target, the anaesthetist continues the advance the needle without visualising it appropriately	2.5.4.3.3.1.6 Reorientate ultrasound probe	New ultrasound technology with tracking capability Use of echogenic needle
2.5.4.3.3.1.5	In attempting to manipulate the ultrasound probe to optimize the image of a needle which is poor/lost, the anaesthetist fails to note the cues provided by	Immediate 2.5.4.3.3.1.7.3 Withdraw needle to subcutaneous tissue and begin again	New ultrasound technology with tracking capability

	examining the relative position of his/her hands		
2.5.4.3.3.1.6	In attempting to optimize the image of a needle which is poor/lost, the anaesthetist moves needle rather than the probe	2.5.4.3.3.1.7.3 Withdraw needle to subcutaneous tissue and begin again	New ultrasound technology with tracking capability
2.5.4.3.3.2.1	Prior to depositing a bolus of local anaesthetic, the anaesthetist fails to aspirate the syringe	2.5.4.3.3.2.4.2 Appropriate visual cues present (On test dose injection) 2.5.4.3.3.2.4.3 Inappropriate cues absent (On test dose injection)	Novel syringe which is locked until aspiration occurs
2.5.4.3.3.2.2	Prior to depositing a bolus of local anaesthetic, the anaesthetist believes the needle tip is visible when in fact it is not	2.5.4.3.3.1.7.1 Oscillate needle 2.5.4.3.3.2.4.2 Appropriate visual cues present (On test dose injection)	Use of echogenic needle
2.5.4.3.3.2.2	Prior to depositing a bolus of local anaesthetic, the anaesthetist fails to confirm the needle tip is visualised	2.5.4.3.3.1.7.1 Oscillate needle 2.5.4.3.3.2.4.2 Appropriate visual cues present (On test dose injection)	Use of echogenic needle Automatic visual or audio cue provided by ultrasound machine
2.5.4.3.3.2.4.1	Prior to depositing local anaesthetic around the target nerve, the anaesthetist fails to administer a small test bolus to confirm the needle tip is in an appropriate location	2.5.4.3.4.3.1 Collection adjacent to target 2.5.4.3.4.3.2 Collection continues to enlarge	(? Novel technology) Use syringe which requires incremental aspiration Automatic visual or audio cue provided by ultrasound machine
2.5.4.3.3.2.4.2	In using a small test bolus of local anaesthetic to confirm the needle tip is in an appropriate location, the anaesthetist incorrectly identifies visual cues as appropriate when they are not	2.5.4.3.4.3.1 Collection adjacent to target 2.5.4.3.4.3.2 Collection continues to enlarge	Ensure patient is not overly sedated and can report discomfort / paraesthesia (if intraneural injection)
2.5.4.3.3.2.4.3	In using a small test bolus of local anaesthetic to confirm the needle tip is in an appropriate location, the anaesthetist checks for the presence of inappropriate visual cues but fails to recognise them when they occur	2.5.4.3.4.3.1 Collection adjacent to target 2.5.4.3.4.3.2 Collection continues to enlarge	Ensure patient is not overly sedated and can report discomfort / paraesthesia (if intraneural injection)
2.5.4.3.4.1	Prior to depositing subsequent doses of local anaesthetic, the anaesthetist fails to aspirate the syringe at appropriate intervals	2.5.4.3.4.3.1 Collection adjacent to target 2.5.4.3.4.3.2 Collection continues to enlarge	(? Novel technology) Use syringe which requires incremental aspiration Automatic visual or audio cue provided by ultrasound machine
2.5.5.1	Having deposited what is believed to be sufficient local anaesthetic, the anaesthetist fails to be vigilant of signs of CNS toxicity	1.1.5.3.3.2 Maintain voice contact	Require documentation that symptoms of CNS were checked

Table 19. Recovery potential and remedial strategy analysis of the top twenty errors.

Expert agreement (Cohen's Kappa) for probability and criticality were k = 0.01 (p=0.26) and k = 0.11 (p=0.00) respectively, indicating at best only slight agreement between experts.[24]

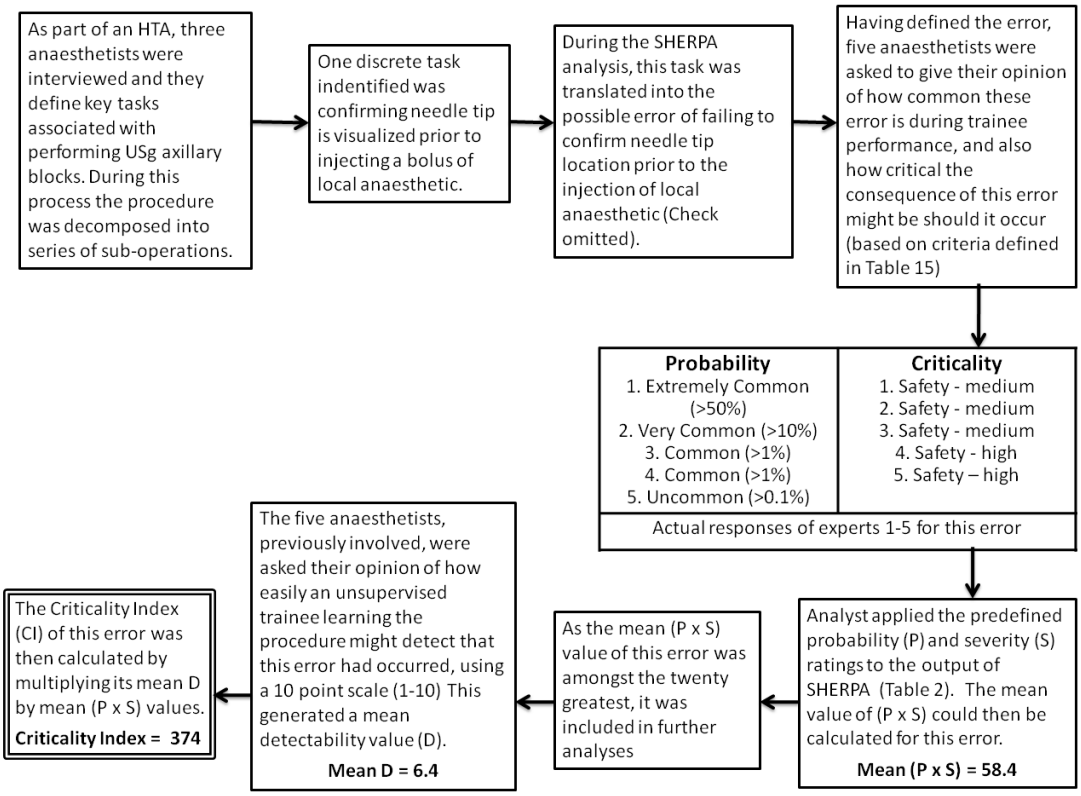

Figure 4. Example of how the Criticality Index (CI) was calculated for one error.

This figure illustrates how the CI of a single error was generated through the sequential application of Hierarchical Task Analysis (HTA), Systematic Human Error Reduction and Prediction Approach (SHERPA), and Failure Modes, Effects, and Criticality Analysis (FMECA).

Discussion

This study reports the results of an expert opinion-based analysis of the tasks involved in the performance of ultrasound guided axillary block and the errors most likely to be encountered during trainee's performance of the block. In their landmark study of the effect of human factors in the practice of anaesthesia, Cooper and colleagues[25] analyzed anaesthesia-related critical incidents retrospectively. They demonstrated that most preventable incidents involved human error. Sites and colleagues[10] analyzed errors and quality-compromising patterns by observing novice performance prospectively. Failure to visualize the needle before advancement was identified as a significant error. Although this is consistent with the findings of our study, other errors are not similarly prioritized. One of the quality compromising behaviours identified by Sites was fatigue (defined by the need to switch hands holding the probe, the need to use both hands to hold the probe, or tremors). Through the use of HTA/SHERPA/FMECA, errors associated with fatigue, such as difficulty maintaining probe immobility, can be identified but not attributed to a specific cause. Our study differs from that of Sites and colleagues in three important aspects. (i) Our data were obtained by expert opinion rather than observing clinical events. (ii) We addressed cognitive events as well as observable behaviours. (iii) Our prioritization of errors was based on frequency, criticality and detectability, rather than on likelihood of occurrence alone.

The five regional anaesthesia experts who participated in the study represent great diversity in training and practice of UGRA (having undergone higher subspecialty training in regional anaesthesia in Ireland, UK, France, Canada, and Hungary). This diversity was important in ascertaining the essential components and procedural steps to be performed consistently by a trainee, independent of the individual practice of the supervising anaesthetist. By allowing experts a relatively comprehensive choice of options for probability and severity, the output of SHERPA presents data in a form suitable for application of FMECA. The additional options that were available did, however, decrease the likelihood of getting high inter-expert agreement. SHERPA provides a more structured basis for FMECA. Ordinarily the errors analyzed in FMECA are limited to those selected through a "brain-storming" session. HTA and SHERPA have previously been applied to a number of medical procedures including the induction, maintenance and emergence from general anaesthesia.[26] FMECA has previously been utilized in analyzing errors that may occur during administration of medication[22] or during the production of parenteral nutrition.[23] To our knowledge, this is the first application of SHERPA and FMECA in combination. It should be noted that SHERPA and FMECA terminologies differ. "Criticality" as applied in SHERPA is equivalent to "Severity" as used in FMECA in which the criticality index incorporates severity, probability and detectability.

This study is subject to a number of limitations. The process we employed does not necessarily attribute cause to the errors identified

(e.g. lack of knowledge, technical imprecision, fatigue, etc.). There is also a large degree of subjectivity in the processes of task and error analysis. We do not regard this subjectivity itself as a limitation; rather we believe that the appropriate use of these qualitative methods enabled us to acquire data which quantitative methods alone would not have accessed. However the use of subjective findings to calculate CI and a final ranking raises a question over the reliability of our results. This is especially the case as inter-expert agreement was poor. Previously published SHERPA analyses of medical procedures have not reported inter-expert reliability. Phipps, in reporting finding of extended HTA to analyze cognitive tasks during the planning and delivery of anaesthesia, described inter-rater agreement which is similarly poor.[27] It is possible the results would be different if five different experts were selected, or if the expert panel was expanded to 50 members. As the list of credible errors was complied by non UGRA-experts significant errors may have been overlooked. Indeed, no proposed error was unanimously considered "not an error" by all five experts. Change in best practice is inevitable given rapidly evolving technology in the field and wider practice of UGRA. One example of this is the, yet to be defined, visual endpoint for adequate local anaesthetic spread around the target nerve.[28] Limiting the estimation of detectability to 20 errors may result in an error, which is likely to go unnoticed (detectability rating approaching 10) but with a P x S value outside the top 20, being omitted from the final top 20 errors though its final composite value may have warranted inclusion.

The tools used to establish expert opinion required that questions relating to a specific procedure are asked. It is likely, but it is not our contention, that the results of this study can be applied to other nerve blocks. We do not intend to make any claims of translational validity. Further studies will be required to establish real world correlation of the output of this study.

We carried out a detailed non-clinical analysis of (i) tasks possibly carried out during the performance of USgABPB and (ii) errors anaesthetists learning the procedure could make. Error analysis methods utilized were proactive, attempting to identify potential errors and allow safety issues to be addressed before errors actually occur. We have described the novel application of HTA, SHERPA and FMECA in combination to determine the clinically important errors which a trainee might make in learning to perform the procedure. We propose that this combination of analytic tools might be useful to the teaching, learning and assessment of procedures such as USgABPB. However, this proposition remains to be tested and validated in a clinical scenario.

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Appendices

Appendix 3.1 - Summary of Terms Used

Criticality (SHERPA) – The ordinal risk to patient safety and/or block success should the error occur. See Table 15 (above).

Criticality Index (FMECA) – Generated from the product of estimated ratings for each of these features Severity x Probability x Detectability. In this study Severity and Probability ratings were derived directly from the Criticality and Probability output of SHERPA, see Table 16 (above). Detectability was defined as "how easily an unsupervised trainee learning the procedure would detect that an error had occurred." It was rated by the experts using a 10 point scale, from least (1) to greatest (10).

HTA framework - Stanton[14] suggested the following framework for conduction HTA:

(i) Define the purpose of the analysis

(ii) Define the boundaries of the system description

(iii) Access a variety of sources of information about the system to be analyzed

(iv) Describe the system goals and sub-goals

(v) Try to keep the number of immediate sub-goals under any super-ordinate goal to a small number (i.e., between 3 and 10)

(vi) Link goals to sub-goals, and describe the conditions under which sub-goals are triggered

(vii) Stop re-describing the sub-goals when you judge the analysis is fit-for-purpose

(viii) Try to verify the analysis with subject-matter experts

(ix) Be prepared to revise the analysis

Probability (SHERPA) - The ordinal probability of the error occurring during trainee performance. See Table 15 (above).

SHERPA taxonomy - The starting point of SHERPA is an HTA. The bottom level sub-operation tasks are each classified according to the following taxonomy; (i) an action, (ii) a retrieval (of information), (iii) a check, (iv) an information communication, (v) a selection. Predefined "error modes" are then systematically applied, such as action mistimed, wrong information retrieved, or check omitted.

Appendix 3.2 - Data

Data relating to Chapter 3 are provided in folder labelled Chapter 3 in the Supplementary Digital Content accompanying this thesis. Data are presented as follows:

1. The HTA (*.pptx*)

   The entire Hierarchical Task analysis is presented as a Powerpoint presentation. In slideshow. Each operation associated with a goal and a plan - describes the relationship between its suboperations (consecutive, concurrent, unordered, etc). A hierarchy of operations and suboperations Is used to describe goals and sub-goals of USgABPB in detail. Individual operations and tasks are identifiable by a unique HTA number (Where HTA numbering for suboperations is long the final 4-5 digits are presented in red font). The bottom level sub-operation tasks are each classified according to the following taxonomy; (i) (A) an action, (ii) (R) a retrieval (of information), (iii) (C) a check, (iv) (I) an information communication, (v) (S) a selection. The letter associated which each of these tasks is presented in the Powerpoint.

   Where an operation is decomposed into suboperations, it is presented as a hyperlink. Clicking on the hyperlink will bring the user to the subordinate operations. A hyperlink in the lower left corner will bring the user back to the immediate higher level operation.

2. 212 Credible errors with Mean expert values for (i) probability, (ii) severity, and (iii) PxS. *(.xlsx)*
3. Original SHERPA data from Surveymonkey

i. Part 1 *(.xlsx)*

ii. Part 2 *(.xlsx)*

iii. Part 3 *(.xlsx)*

4. Conversion of Surveymonkey data into numerical scores (using Table 16 above)

   i. Part 1 *(.xlsx)*

   ii. Part 2 *(.xlsx)*

   iii. Part 3 *(.xlsx)*

5. Expert SHERPA collated responses to probability, criticality, recovery potential, remedial strategy. *(.xlsx)*
6. Top 20 mean expert P x S Values. *(.xlsx)*
7. Expert Estimation of Detectability of Top Twenty Errors. *(.xlsx)*
8. Top 20 errors according to CI. *(.xlsx)*

Chapter 4 - Usability of a novel ultrasound-guided regional anaesthesia simulator.

Abstract

Background: Simulation-based training and assessment is an increasingly important component of procedural healthcare. We sought to evaluate the usability of a novel ultrasound-guided regional anaesthesia simulator during its design and development. We hypothesized that serial prototypes of a simulator for UGRA have limitations which are amenable to improvement during its development. To this end, we performed a prospective observational qualitative investigation to elicit end-user feedback.

Methods: All trainees commencing Higher Specialist Training in anaesthesia in Ireland on July 1st 2010 were invited to participate in this study. Participants were presented with a prototype on three successive occasions and asked to complete a number of discrete tasks using the available prototype which related to performance of ultrasound-guided regional anaesthesia. Development of the simulator between sessions was intended to improve content, realism and usability. Observations and comments made by participants relating to usability were recorded. Participants were also asked to record written comments and complete a Likert questionnaire after each session. Data were collated and subsequently reviewed by investigators and key themes were identified.

Results: Analysis of the datasets (observer notes, participants' comments and questionnaire responses) rendered five Categories of topics and 21 specific items deemed to be relevant to simulator usability, design and future development. Several of the items identified in the first and second session influenced the design of the prototype simulator presented in subsequent sessions. Participants indicated following both the second and third sessions that certain of their previous comments had been specifically addressed.

Conclusions: We describe a methodology for eliciting end-user input in the evaluation of a novel simulator during its development. This input has and will continue to inform the development of the simulator. It is likely that data generated in this study may be relevant to the development of other visuo-haptic simulators for medical procedures.

Co-investigators for this study

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2. Dr. Annette Aboulafia. PhD. Interaction Design Centre, University of Limerick, Ireland.
3. Prof. George D Shorten. PhD. Department of Anaesthesia and Intensive Care Medicine, Cork University Hospital, Wilton, Cork, Ireland, and University College Cork, Cork, Ireland.

Background

In the development of medical devices, the nature and extent of end user input varies substantially and may be sought at any or all of the concept, design, testing and trials, and deployment stages.[1] Although there is general agreement on the need to involve end users, there is great variability in the timing (i.e. stage of development) and the methodologies used to elicit that input (e.g. usability tests, interviews and questionnaire surveys). Clinical simulation has been used to enhance the value of user input, for example in the development of a decision support system.[2] However, to date, there is very limited information available of usability testing and user input to the development of simulation devices themselves. Most medical simulation devices are developed based on some form of input from expert clinicians. Kneebone has emphasized the importance of involving learners, an important cohort of end users of such devices, in this process.[3] Many early/intermediate learners will be younger than their trainers; it is likely that technology has played a greater role throughout their lives, with significant exposure to technology enhanced learning during education up to and beyond undergraduate training in medicine.[4]

Ultrasound-guided regional anaesthesia (UGRA) involves the use of ultrasound technology to guide, in real time, the placement of a needle adjacent to a target nerve structure. The American Society of Regional Anesthesia and Pain Medicine (ASRA) and European Society of Regional Anaesthesia and Pain Medicine (ESRA) jointly issued

guidelines for the training of UGRA which included the use of simulators.[5] There is currently a lack of commercially available UGRA simulators. We are currently attempting to address this unmet need by developing a virtual reality visuo-haptic simulator to train UGRA procedures. The simulator attempts to provide a real-time and adaptive rendering of the haptic (related to tactile and proprioceptive) sensations normally felt during manipulation of both needle and ultrasound probe. At the same time a visual interface is provided to present a realistic representation of the clinical situation including ultrasound imagery.

It is likely, in the future, that much greater emphasis will be placed on simulation-based training of health professionals.[6] We believe that a need exists to examine methodologies for testing usability of new simulators based on end user input. By maximizing a simulator's usability before it is used for training, it is possible to minimize or eliminate system-related artefacts that otherwise would negatively influence a trainee's learning. The objective of this study is to determine usability of serial prototypes of a UGRA simulator using quantitative and qualitative methods. We hypothesize that serial prototypes of a simulator for UGRA have limitations which are amenable to improvement. To this end, we performed a prospective observational qualitative investigation based on end-user feedback.

Methods

With the approval of the Clinical Research Ethics Committee of the Cork Teaching Hospitals, and having obtained written informed consent of each, participants were presented with the current simulator prototype on three successive occasions. All trainees (n=11) commencing Higher Specialist Training in anaesthesia in Ireland on July 1st 2010 (annual training commencement date) were invited to participate in this study. The content and configuration of the simulator version presented to trainees were the same during each session. Development of the simulator between sessions was intended to improve content, realism and usability. Sessions were carried out between 16th August 2010 and 13th June 2011.

At the beginning of each evaluation session, one of the investigators (OOS) presented a short explanation of and orientation to the simulator. During each session, participants were asked to complete a number of discrete tasks relating to the performance of ultrasound guided axillary brachial plexus blockade. Participants were asked to perform 2-5 procedure-specific tasks following orientation (Table 20 below). These included identification and scanning of simulated anatomy and advancement of a needle towards a target using an "in-plane" approach. Non-technical aspects were incorporated into the final session. Each session lasted approximately 45 minutes (excluding the orientation). One of the investigators was available to address queries throughout. A technician was also in attendance to note and, when possible, resolve technical problems. Participants

were encouraged to “think aloud”, a recognized technique to elicit the strategies individuals use to understand a novel device and its use. An observer with expertise in usability testing (EL or AA) manually recorded comments made by participants (utterances) and noted participant behaviours and characteristics of the participant-prototype interactions (observations). These were documented as field notes. Immediately after each session, participants were asked to complete a Likert based questionnaire on their perceptions of (i) the realism of the simulator, and (ii) the acceptability of the device. Participants were asked to respond to presented stems according to the following structure; 1 – strongly disagree, 2 – disagree, 3 – neutral, 4 – agree, 5 – strongly agree. Participants were also asked to record in writing the best and worst features of the simulator and to record other impressions as free text. Participants were not permitted to observe each other using the system and were not aware of feedback provided by others.

Session	***Session 1***	***Session 2***	***Session 3***
Orientation	*Duration approximately 20 minutes* • Standardized scripted explanation plus Q+A • Hands-on familiarization session with simulator • Two 2D displays (One for ultrasound image + one displaying virtual arm)	*Duration approximately 10 minutes* • Brief orientation • Free practice session • Single 2D display (ultrasound image displayed on same screen as virtual scene), cartoon ultrasound, probe and needle haptic devices	*Duration approximately 5 minutes* • Brief orientation
Task 1	**Nerve Identification + Nerve Tracking (ID Anatomy)** • 2D display, cartoon ultrasound, probe haptic device • e.g. "Identify the median nerve and follow it to the elbow and back, keeping the nerve in the centre of the screen" • Automated (limited) and observer feedback • Repeat tasks 2-4 occasions, as time allows	**Nerve Identification + Nerve tracking (ID Anatomy 2D)** • Single 2D display (ultrasound image displayed on same screen as virtual scene), cartoon ultrasound, probe haptic device • Automated graphical and numerical feedback (clarified by trainer if required) • Repeat tasks 2-4 occasions, as time allows	**Enabling Skill 1 (ES1) – Align probe with Static Needle** • 3D display, cartoon ultrasound, probe haptic device • Simplistic non-anatomical virtual scene (a box) • Automated graphical and numerical feedback (clarified by trainer if required) • Repeat tasks 2-4 occasions, as time allows
Task 2	**Needle in plane advancement towards a target (Perform block)** • 2D display, cartoon ultrasound, probe and needle haptic devices	**Needle in plane advancement towards a target (Perform block 2D)** • 2D display, cartoon ultrasound, probe and needle haptic devices	**ES2 – Advance needle towards target (keeping tip in plane at all times)** • 3D display, cartoon ultrasound, probe and needle haptic devices

	• e.g. "Advance the needle towards the target structure, keeping the shaft and tip of the needle in view at all times, indicate when you are ready to inject local anaesthetic" • Automated and observer feedback • Repeat tasks 2-4 occasions, as time allows	• Additional real-time 'picture-in-picture' image giving secondary overhead view of needle insertion • Automated graphical and numerical feedback (clarified by trainer if required) • Repeat tasks 2-4 occasions, as time allows	• Simplistic non-anatomical virtual scene. • Automated graphical and numerical feedback (clarified by trainer if required) • Repeat tasks 2-4 occasions, as time allows
Task 3	None	**Nerve Identification + Nerve tracking (ID Anatomy 3D)** • as per task 1, but using 3D display	**ES3 – Inject near target (keeping tip in plane, inject near but not within the target)** • 3D display, cartoon ultrasound, probe and needle haptic devices • Simplistic non-anatomical virtual scene. • Automated numerical feedback (clarified by trainer if required) • Repeat tasks 2-4 occasions, as time allows

Task 4	None	**Needle in plane advancement towards a target (Perform block 3D)** • as per task 1, but using 3D display	**Nerve identification (ID Anatomy)** • 3D display, realistic ultrasound, probe haptic device, 2nd haptic device used as pointer to identify features • Virtual arm visible from shoulder to wrist • Asked to scan virtual arm and identify named structure at two locations (in the axilla and near the elbow) • Graphical feedback given.
Task 5	None	**Realistic Ultrasound Scanning (US Scan)** • 3D display, realistic ultrasound, probe haptic device • Limited to simple exposure of participant to realistic ultrasound (no specific task requirements) • No feedback provided (automated/trainer)	**Virtual Patient Scenario (VP)** • 2D display of text data. The pre-operative course of a virtual patient's management is controlled by the participant. • Computer mouse used to select an appropriate management option from those available. • On completion of text scenario, 3D virtual scene launched with display of heart rate of virtual patient. A "well" managed patient will have a normal heart rate. A poorly managed

			patient will be uncomfortable and will have an increased heart rate.
	Questionnaire – feedback	Questionnaire – feedback	Questionnaire – feedback

Table 20. Tasks Presented to Participants.

Text based data (observations and statements/utterances recorded by the observers, as well as written points noted by participants in the questionnaires) were collated and subsequently reviewed by investigators (OOS, EL) and key themes were identified. An initial review of approximately 50% of data was undertaken to identify recurrent themes or topics (*Categories*). Within each category specific items were identified as identical, recurrent or of particular importance (i.e. likely to influence future design) (*Items*). Having defined Categories and Items, the same investigators returned to the complete collated dataset and coded each entry to a single Item. The investigators subsequently reviewed the Categories and Items initially selected to ensure that the entire dataset was accurately and comprehensively represented. Finally, the entire dataset was coded according to this revised set of Categories and Items.

Results

A total of eleven individuals commenced Higher Specialist Training in anaesthesia in Ireland on July 1, 2010. With the agreement of the College of Anaesthetists of Ireland, with institutional ethical approval and having obtained written informed consent from each, nine participated in the study. Of the nine trainees recruited, eight participated in all three sessions (one participant did not complete the third session because it was not possible for the individual to attend during the required interval). Participant characteristics are summarized in Table 21 (below). The interval between the 1st and 2nd evaluations was 77 days (77-93 days) (median; range), and that between the 2nd and 3rd was 182 days (142-220 days) (median; range). All participants completed the first session in the simulation centre of the College of Anaesthetists of Ireland. Subsequent sessions either took place at this location or at a site more convenient to participants.

Years of experience as anaesthetic trainee	3 years (median) 2-7 years (range)
Previous direct experience of virtual reality simulators	2/9 (22.2%)
Current frequency of video game usage	0 hours/week (median) 0-5 hours/week (range)
Maximum past frequency of video game usage	0 hours/week (median) 0-20 hours/week (range)

Experience of peripheral nerve blockade (PNB) – using solely peripheral nerve stimulation

0 Blocks	1-5 blocks	5-10 blocks	10-50 blocks	50-100 blocks	>100 blocks
2/9 (22.2%)	3/9 (33.3%)	2/9 (22.2%)	1/9 (11.1%)	1/9 (11.1%)	0/9 (0%)

Experience of ultrasound-guided PNB

0 Blocks	1-5 blocks	5-10 blocks	10-50 blocks	50-100 blocks	>100 blocks
1/9 (11.1%)	3/9 (33.3%)	2/9 (22.2%)	2/9 (22.2%)	0/9 (0%)	1/9 (11.1%)

Experience of ultrasound-guided axillary brachial plexus blockade

0 Blocks	1-5 blocks	5-10 blocks	10-50 blocks	50-100 blocks	>100 blocks
3/9 (33.3%)	4/9 (44.4%)	0/9 (0%)	1/9 (11.1%)	1/9 (11.1%)	0/9 (0%)

Table 21. Participant characteristics.

Table 22 (below) provides a description of the components of the technical specification of prototypes used during each session.

Figure 5 (below) shows task 5 of session 2 being attempted (for illustrative purposes the screen is displaying images in 2D rather than 3D).

Session	*Session 1*	*Session 2*	*Session 3*
PC specifications	Intel Core 2 Duo E8500 3.16Ghz, 3.5 GB ram, NVIDIA Quadro FX 3700	Intel Core 2 Duo E8500 3.16Ghz, 3.5 GB ram, NVIDIA Quadro FX 3700	Intel Core 2 Duo E8500 3.16Ghz, 3.5 GB ram, NVIDIA Quadro FX 3700
Screen and 3D solution	Samsung SynMaster 2233, NVIDIA 3D Vision (active stereo)	Samsung SynMaster 2233, NVIDIA 3D Vision (active stereo)	Samsung SynMaster 2233, NVIDIA 3D Vision (active stereo)
Haptic Devices	2 x Sensable Phantom Premium 1.0	2 x Sensable Phantom Premium 1.0	2 x Sensable Phantom Omni
Software	Windows XP 32-bit SP3, H3D API 2.0, VHTK	Windows XP 32-bit SP3, H3D API 2.0, VHTK	Windows XP 32-bit SP3, H3D API 2.0, VHTK

Table 22. Technical specification of prototypes used during each session.

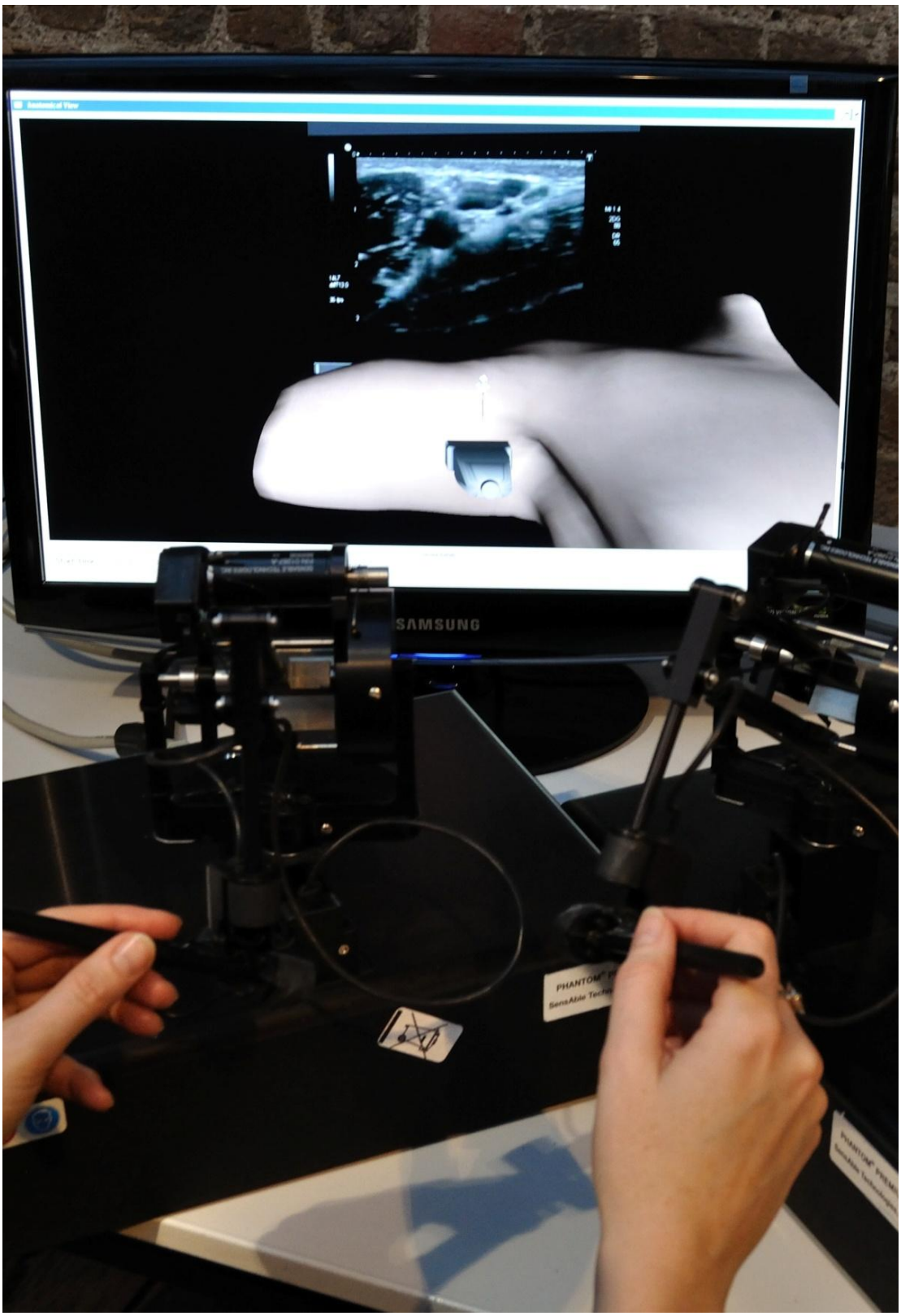

Figure 5. Task 5 of session 2.

The collated dataset contained (i) 74 points noted by participants as written responses to the questionnaires, (ii) 314 items were observations noted in field notes, and (iii) 119 items were statements/utterances the participants made during sessions which were recorded in writing by the observers. Analysis of all 507 entries rendered five Categories of comment and 21 specific Items (Table 23 below) deemed to be relevant to simulator usability, design and future development. All data were coded to a single Item with a number of exceptions. Firstly, 13 entries were not specific enough to be coded to a specific Item. These could be attributed to a Category (10 related to "Task Comprehension", 2 related to "Task Performance", and 1 related to "Ergonomics"). Secondly, all entries relating to the Category "Task Interruptions" were coded to both dichotomous Items. The items were not mutually exclusive. Indeed all "Task Interruptions" were either anticipated or not, and either occurred during the task performance or between tasks.

Category	Item	Example
Task * Comprehension	• Active search for information / clarification	"How do you inject?" Participant asked *after* reading instructions. (ES2) (COA3.1 – stated)
	• Intervention by trainer	Score, graph and graph scaling clarified by instructor. (ES1) (COA3.2 – observed)
	• Incorrect participant response / unintended participant behaviour	Didn't notice the change in the on-screen instruction. "I was clicking on many nerves [rather than following the instructions]". (ID Anatomy) (COA3.6 – stated)
Task* Performance	• 3D spatial experience	
	I. Virtual environment	ES box model was moved to clarify relative positions of needle and box. (ES1) (COA3.7 – observed)
	II. Hardware (incl. screen)	*Asked if 3D solution better than 2D* - "Probably, my scores are better". (*Learning or 3D?)* – (Perform block 3D) (COA2.5 - stated)
	III. Virtual interaction/orientation	"I feel very clumsy" - expressed she found the virtual procedure more difficult than in reality (ES3) (COA3.3 – stated)
	IV. Dynamic interaction between virtual tools	"Orientation of the needle in relation to the probe could be tricky - at one stage my needle appeared to be piercing the probe" (COA1.8 – noted)
	• Task Fidelity	
	I. Needle appearance & behaviour	Subject would like to be able to take his hand off the needle. (*Not possible with 3 DOF feedback haptic device used)* (COA2.9 –stated)
	II. Ultrasound image appearance & behaviour	"Adjusting the depth by applying more or less pressure I found unrealistic" (COA1.5 – noted)
	III. Model fidelity/artefact	Participant positioned the needle inside of the probe on three occasions (*physically not possible in reality*). (ES3) (COA3.9 – observed)
	IV. Lack of physical contact	Participant would like a mannequin. Will stop him from applying too much pressure with probe. Will act as a reference for position and orientation. (COA2.9 - stated)

	V. Task triggering	Struggled to find the inject button - "In real life you have a second person [who you ask to inject]" (ES2) (COA3.1 – stated)
Task Interruptions	• Expected (participant pre-warned or observed on previous attempts) and unexpected (random or new interruption)	As expected, the virtual scene had to be rotated on start. (ID Anatomy) (COA3.9 – observed) US volume was not loaded properly after re-start (system error) – (ID Anatomy 2D) (COA2.7 - observed)
	• During tasks versus between tasks	Six "crashes" in total while scanning. (ID Anatomy) (COA3.2 – observed)
Ergonomics	• User positioning and comfort	Participant used the arm rests on the chair – appeared to have a comfortable working position. (ES2) (COA3.6 – observed)
	• Interactions with hardware	Participant held needle as a pen. (COA3.8 – observed)
	• Handedness	"I found the needle difficult to control with my right hand - as I am left handed. Also, finding the needle position relative to the probe was a bit difficult too." (COA1.7 – noted)
Integration into training programme	• Pre-training conditions	Participant used to performing femoral nerve blocks and seemed slightly confused with the task in this context. (ES2) (COA3.3 – observed)
	• Perceived "value" of the simulator	"It's very cool, cooler every time I see it" – (US Scan) (COA2.3 - stated)
	• Change with practice	
	I. Procedural training	"Good 1st task with a gradual increase in expectation per task" (Best features – 3 of 3)(COA3.2 – noted)
	II. System learning	"I find it hard [the task]", "I need to get used to the system", "Too long since the last time" – (ID Anatomy 2D) (COA2.7 -stated)

Table 23. Participant derived input - design relevant categories and items.

Table 23 Legend. * Task: refers to task /tasks which a participant was asked to undertake (see Methods). Where appropriate, examples are attributed to specific tasks (e.g. ES1: Enabling Skill 1 (see Table 20)).

Examples are also attributed to a specific evaluation session *x* (i.e. 1, 2, or 3) and a specific participant *y* (1-9) according to (COA*x.y*). Examples may be (i) written responses of participants to the questionnaires ('noted'), (ii) observations recorded as a filed note ('observed'), or (iii) statements/utterances made the participants made during sessions, recorded in writing by the observers ('stated').

Finally, 29 entries were coded to "Change with practice" but could not be further classified to "Procedural Training" or "System Learning". These related to objective or subjective changes in performance during and between sessions which could be partially related to both items.

The two most frequently recurring items were (i) "*intervention by trainer*" (55 of 507 entries, 10.8%) and (ii) "*Ultrasound image appearance & behaviour* (task fidelity)" (46 entries, 9.1%). The items most frequently associated with the best feature of the simulator, as noted by participants, were – (i) "*Perceived 'value' of the simulator*" and (ii) *"Ultrasound image appearance & behaviour"*. The latter item was also most frequently associated with the worst features of the simulator, as noted by participants. No specific reference was made to the lack of specified learning outcomes during the sessions. There was also little or no emphasis on the fact that there was discordance between the relative positions of the tools as animated (virtually) and the actual position of the participant's hands holding the end effectors of the haptic devices.

Several of the items identified during the 1st and 2nd session influenced the design of the prototype simulator presented in

subsequent sessions. For example, one participant found the text-based instructions displayed during task performance in session 1 to be distracting and impossible to keep track of. He suggested using verbal instructions instead of text instructions on-screen. He said this would be a lot clearer than text, as that is how training generally happens in reality. In the 2nd and 3rd sessions enhanced instructions were presented prior to a task and all potentially distracting text displayed during the task was removed. With interval progression in the design of the simulator, a number of design issues were resolved, some persisted, and other new issues came to light. Table 24 (below) details some of the interval changes between the first and second prototypes.

	Category	Item	Issue
Design Issues - Persisting	Task Performance	Task Fidelity – Lack of physical contact	Participants look to contact surface of virtual patient's arm with their hands, which is not possible
	Task Performance	Task Fidelity – Task triggering	Participant has difficulty with inject button
	Ergonomics	Interactions with hardware	Device height is too low relative to participant position
	Ergonomics	Interactions with hardware	The end effector shape on the haptic devices (probe/needle) are markedly different from the shape of a real ultrasound probe and block needle
Design Issues - Potentially Resolved	Task Comprehension	Incorrect participant response / unintended participant behaviour	Distracting on-screen text instructions during task performance were removed
	Task Performance	3D spatial experience - Virtual interaction / orientation	The exaggerated response of the virtual probe to subtle movements of the haptic device is no longer an issue
	Task Performance	3D spatial experience - Virtual interaction / orientation	Participants have less of an issue judging depth, in particular, where to insert needle on the virtual model
	Task Performance	Task Fidelity – Ultrasound image appearance & behaviour	Anatomical features on ultrasound are not too easy to make out
	Task Performance	Task Fidelity – Ultrasound image appearance & behaviour	Needle tip appearance is not highlighted too much
	Task Performance	Task Fidelity – Needle appearance & behaviour	The response to needle redirection is less unrealistic
Design Issues – New issues not previously appreciated / emphasized	Task Comprehension	Active search for information	Additional explanation to automated feedback (graph) sought by participants

	Task Comprehension	Active search for information	Instructions (text) to scout scan task is unclear
	Task Comprehension	Intervention by trainer	Additional explanation to automated feedback (graph) provided by trainer
	Task Performance	Task Fidelity - Model fidelity/artefact	The lack of haptic surface to probe allows the needle to move through the virtual probe freely without haptic feedback
	Task Performance	Task Fidelity – Ultrasound image appearance & behaviour	There is a lack of pulsatility to arteries and compressibility of vascular structures

Table 24. Interval change in designs issues observed between session 1 and session 2.

Likert data are summarized in Table 25 (below). None of the stems identified consistent or strong signals either supportive or critical of the prototype function. Median values other than 3, 3.5 or 4 were elicited in 13 of a possible 98 questions. Participants indicated after both session 2 & 3 that they did not need to learn a lot about ultrasound guided regional anaesthesia before using the system independently. Following session 1, the participants strongly agreed that the prototype was useful to train hand-eye co-ordination and also that further practice on the simulator would be beneficial as part of their training. The responses to similar questions following sessions 2 and session 3 were not as positive (median values < 5). Participants indicated across all sessions that the simulated tasks were not too difficult. Participants disagreed that the simulator generated scores during session 3 were generous. Participants also disagreed that the movement of the virtual instruments during session 3 were realistic. However session 3 was the only session

during which the arrangement of the components of the simulator was not found to be awkward. During session 2 (but not session 1 or 3) participants disagreed with the statement that controlling the virtual probe with a haptic device was easy. Participants indicated following both session 2 (median value = 4) and session 3 (median value = 4) that their previous comments had been specifically addressed.

	Session 1	Session 2	Session 3
I found it easy to use the simulator	3 (2-4)	4 (2-4)	4 (2-4)
I would imagine that most people would learn to use this system quickly	Not Asked	4 (3-4)	4 (3-4)
I would not be able to use this system without the support of a trainer/technical person	Not Asked	3 (2-5)	4 (2-5)
I would like to use the system frequently	Not Asked	4 (3-5)	4 (2-5)
I need to learn a lot about ultrasound guided regional anaesthesia before I could use this system independently	Not Asked	2 (2-4)	2 (1-3)
This is a better simulator than previous version	Not Applicable	4 (2-5)	4 (3-5)
The simulator could become a useful tool in teaching the block	4 (3-5)	4 (3-5)	4 (2-5)
The orientation session was adequate	4 (2-5)	Not Applicable	Not Applicable
Task instructions were clear	Not Asked	4 (3-5)	4 (3-5)
The simulator was helpful for training scanning of nerves (2D/Better than previous/3D/Better than previous)	4 (3-5)	4 (3-4)	No 2D
		4 (3-4)	No 2D
	No 3D	4 (4-5)	4 (2-5)
		4 (3-5)	4 (3-5)
The simulator was helpful for training needle in plane technique of needle insertion (2D/Better than previous/3D/Better than previous)	4 (2-5)	4 (2-4)	No 2D
		4 (2-4)	No 2D
	No 3D	4 (2-5)	4 (3-5)
		4 (3-5)	4 (3-5)
The simulator was useful to train hand-eye coordination	5 (3-5)	4 (2-4)	No 2D
		3 (3-4)	No 2D

(2D/Better than previous/3D/Better than previous)	No 3D	4 (4-5)	4 (3-5)
		4 (2-5)	4 (3-5)
Further practice on the simulator would be beneficial as part of my own training of the procedure (2D/3D)	5 (3-5)	4 (3-4)	No 2D
	No 3D	4 (3-5)	4 (3-5)
The simulated tasks were too difficult (2D/3D)	2 (1-3)	2 (1-2)	No 2D
	No 3D	2 (1-2)	2 (1-3)
I felt the simulator generated scores were generous	3 (2-4)	3 (1-4)	2 (2-3)
The virtual arm was realistic (2D/3D)	4 (2-5)	3 (3-4)	No 2D
	No 3D	4 (3-5)	4 (2-4)
The simulator's ultrasound representation was adequate for my training of the procedure (Using Cartoon)	3 (2-5)	3 (2-4)	N/A
The simulator's ultrasound representation was adequate for my training of the procedure (Using Volume)	N/A	3.5 (2-5)	4 (2-4)
The simulator's haptic (tactile) sensations were adequate for my training of the procedure	4 (2-5)	3 (2-4)	3 (2-5)
The movement of the virtual instruments were realistic (2D/3D)	3 (1-5)	3 (2-4)	No 2D
	No 3D	3.5 (1-5)	2 (2-4)
The functions of the virtual ultrasound were realistic	4 (3-5)	3 (2-5)	4 (2-5)
The feedback from the simulator/instructor was helpful for my training of the procedure	4 (2-5)	Not Asked – See Below	Not Asked – See Below
The text feedback was easy to relate to my performance of the procedure during today's	3 (1-5)	3 (1-5)	4 (1-5)

training session			
The graphical feedback from the simulator was helpful for my training of the procedure	Not Applicable	4 (3-5)	4 (2-4)
Controlling the virtual probe with a haptic device was easy (2D/3D)	3 (2-4)	2 (2-4)	No 2D
	No 3D	2.5 (2-4)	3 (2-5)
Controlling the virtual needle with a haptic device was easy (2D/3D)	3 (2-5)	4 (1-4)	No 2D
	No 3D	4 (1-4)	4 (2-5)
The arrangement of the different components of the simulator was awkward	3 (1-4)	3 (1-5)	2 (1-4)
I felt comfortable using the simulator (2D/3D)	Not Asked	3 (2-4)	No 2D
		3 (2-4)	4 (2-5)
The overall realism of the simulator was adequate (2D/Better than previous/3D/Better than previous)	4 (2-4)	3 (2-4)	No 2D
		4 (2-4)	No 2D
	No 3D	4 (2-5)	4 (2-4)
		4 (2-5)	4 (3-5)
My comments and concerns about the previous version have been accounted for	Not Applicable	4 (2-4)	4 (3-4)

Table 25. Collated responses to Likert questions.

Reported as median (range), where 1=strongly disagree, 2=disagree, 3=neither agree or disagree, 4=agree, and 5=strongly agree

Discussion

We have described in some detail a methodology for eliciting end-user input in the evaluation of a novel simulator during (and contributing to) its development. Our results indicate that these methods are feasible and valuable (i.e. capable of generating relevant, useful information). We believe that the results may also be generalizable to other simulators of medical procedural skills. Participant-derived input has, and will continue to, inform the development of this UGRA simulator. It is likely that the design relevant Categories and Items generated in this study may be relevant to the development of other simulators, especially visuo-haptic devices training image guided needle based interventions such as ultrasound-guided interventional pain procedures.[7]

Shah et al[8] described the importance of involving end users at all stages of development and redevelopment of medical devices, not just at inception or final product testing. Our study describes a possible means of achieving this end, specifically applied to simulators of procedural skills. A recent Finnish study found that physicians were highly critical of the information technologies systems they used; many of these physicians were willing to contribute to the development of such systems but lacked a means of participating in such a process.[9] Methodological frameworks have been described for the usability testing of health information systems[10] and immersive medical visualization virtual environments.[11] Such frameworks aid in the heuristic evaluation of such devices. However, where such

guidelines do not exist, one option is to utilize a formative evaluation process. This involves the iterative exposure of representative end-users to representative tasks.[11] This was the approach we followed in this study.

Our study has a number of strengths. We invited a complete national cohort of motivated participants (all trainees commencing the national training programme). They represent a single but highly relevant group (i.e. very likely to use a simulator for training). We acquired data from a number of sources using different techniques, namely observations of behaviour, recorded participant verbal comments during sessions, comments noted by participants on questionnaire, and responses to Likert questionnaires. In qualitative research, the combination of two or more methods is commonly applied to increase the validity of empirical data, referred to as *triangulation*. A conscious effort was made by the moderator to allow participants use the system without prompting, as much as possible. The intent was to acquire as "true" a measure as possible of the system's usability. We have utilized cross-disciplinary investigators (engineering, education, clinical, psychology, qualitative researchers) in the development and application of the methodology described. We have recently highlighted the use of such an approach in developing virtual-reality based medical training devices.[12]

This study is subject to a number of limitations. The sample size is small. However 9 of 11 eligible individuals participated in this study. One of the participants was unable to attend the 2nd evaluation

session. The interval between sessions, particularly the 2nd and 3rd sessions, may have been excessive. Any such evaluative approach needs to balance the currency of experience of the participants of the system with the extent to which developers can respond to the usability deficits identified. Thus the intervals between sessions may have seemed short to the development team and may account for the limited technical developments achieved between sessions. This provides one explanation for the persistence of some design issues across testing sessions (Table 24 above). The duration of the testing sessions themselves were limited. An exhaustive testing of all available aspects of usability and functionality during each session may not have been possible. It is arguable that one should define an ideal "basic system functionality" before usability testing commences. This contrasts with the approach described here in which additional functionality was developed in parallel with refinements in usability. The prototypes tested are limited to currently available commercial haptic devices the limitations of which have been described by Kahol et al.[13] Participants did not notice the (at times) significant discordance between relative position of their own hands and the position of the virtual objects. This may be explained by the fact that visual cues are trusted more when there is a perceptual conflict between vision and proprioception.[14] Factors impacting on participant's appreciation of the 3d versions of the simulator includes; (i) his/her innate ability to perceive 3 dimensional images using a stereoscopic display and active liquid crystal shutter glasses,

(ii) the hardware (e.g. screen, shutter glasses), (iii) the design and configuration of the virtual 3d environment (including lighting, colouring and surface textures), (iv) the task required of the participants (e.g. gross versus fine movements, angle of movement relative to the participants view).

In a recent study, self-regulated learning (unsupervised) of lumbar puncture skills using simulation led to retention of skills at three months, whereas instructor-regulated learning was not.[15] In developing a simulator, we aim to produce a device which is usable in a self-training situation. With such a personalized training approach (as one component of an overall structured training programme), learning benefits could be achieved without the need for a trainer to observe practice directly and to provide feedback. In this setting, formative feedback could be provided to the trainee using accurate personal data derived from his/her performances on the simulator. Such automated feedback could facilitate a deliberate practice model of procedural training.[16] For a device to be effective in aiding deliberate practice it should be attractive to engage with the device repeatedly over a period of time. If this is to be achieved, usability in context (i.e. by an individual un-supported learner) is all important and must be as fundamental a component of the design as fidelity or content. Usability is likely to be hampered by devices which are, for example, overly complex to operate, require continuous technical or academic supervision, and are awkward or uncomfortable to operate. This study describes the value of involving prototypal testing by end-

users throughout the development of an effective simulator. The approach we have described is feasible but labour intensive. Although not specifically addressed by this study, we believe that it is likely that an integrated team of developers should work with end users throughout the development cycle. We suggest that utilizing a truly design-based approach will benefit the development of medical simulators.

Future work should include the establishment of social acceptability of this device. For example, how do trainees and trainers see it as an integral and "embedded" component of procedural training (e.g. where, when, how often) and what barriers might exist to implement training and assessment using such a device (e.g. cultural, financial, technical). McGaghie et al[17] highlighted the many cultural issues, impeding widespread adoption of simulation based education, which exist amongst the medical profession. Ultimately, it is essential that training on such devices transfers to improved outcomes for patients (transfer validity). This study provides important information to inform the design of one simulator (for UGRA) and also lays out a methodolgy with relevance to the design/development of many types of medical simulator.

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Appendices

Appendix 4.1 - Baseline Participant Characteristics Questionnaire

Participant Number _____

Years Experience of Anaesthesia _____

Experience of peripheral nerve blockade (PNB) – using solely peripheral nerve stimulation (tick the appropriate box)

No Blocks	1-5 blocks	5-10 blocks	10-50 blocks	50-100 blocks	>100 blocks

Experience of ultrasound guided PNB

No Blocks	1-5 blocks	5-10 blocks	10-50 blocks	50-100 blocks	>100 blocks

Experience of ultrasound guided axillary brachial plexus blockade

No Blocks	1-5 blocks	5-10 blocks	10-50 blocks	50-100 blocks	>100 blocks

Previous use of virtual reality simulators

Yes	
No	

Video game usage (pick one most appropriate response)

	Number of hours per week
Current level of video game usage	
Peak usage in past	

Appendix 4.2 - Script and Plan for Session 1

Participant completes baseline questionnaire

5 minute introduction

"We plan to use a novel computer based simulator to assess your ability to perform tasks associated with the competent performance of ultrasound guided axillary brachial plexus blockade. In a moment we will show you the simulator and explain how it is controlled. We will then give you a short period of time to familiarise yourself with the simulator. Following this we will run through two scenarios. The first involves identifying relevant structures on a virtual ultrasound and follow their course in the virtual arm. The second involves inserting a virtual needle into the virtual environment and advance it using an in-plane technique towards a target structure. *(Clarify in-plane technique is understood).* During each session you will be given some on screen instructions to follow. On completion of the task you will be given a computer generated score. You will also be given some informal feedback from the facilitators. Following this you will be given an opportunity to repeat the task on a number of occasions. Along with the computer generated scores we will record specific difficulties you may have encountered during the session.

On completion of both scenarios we will ask you to complete a short questionnaire."

Introduction to Simulator (max 5 min)

Explain each component individually;

Screen and 2D/3D screen

3D environment

Haptic devices

Virtual ultrasound machine

Allow participant opportunity to become accustomed to 3D screen and haptic device using a 3 dimensional cube and pointer (or similar)

Introduction to scene

Demonstrate how the devices are now ultrasound probe and needle. Demonstrate how to orientate probe.

Allow participant 5 minutes to move around scene (Free practice – no on screen instructions). Participant should be able to establish boundaries of the scene and movements of the ultrasound probe.

Participant then inputs user identification.

Scout Scan (15-20min)

The student would be allowed as many full attempts at the Scout Scan scenario as he/she can complete. Participant follows on screen instructions to complete task. Once scenario is complete automated onscreen feedback (metric) augmented by advice from the facilitators. Deliberate practice will be encouraged. If possible scores can be tracked over each attempted and the trend displayed.

"Perform block" (15-20min)

ditto

Feedback questionnaire completed.

Appendix 4.3 - Feedback Questionnaire (Session 1)

Participant Number:-

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1. I found it easy to use the simulator	1	2	3	4	5
2. The orientation session was adequate	1	2	3	4	5
3. The simulator was helpful for training scanning of nerves	1	2	3	4	5
4. The simulator was helpful for training needle in plane	1	2	3	4	5
5. The simulator was useful to train hand-eye coordination	1	2	3	4	5
6. Further practice on the simulator would be beneficial as part of my own training of the procedure	1	2	3	4	5
7. The simulated tasks were too difficult	1	2	3	4	5
8. The simulator could become a useful tool in teaching the block	1	2	3	4	5
9. The virtual arm was realistic	1	2	3	4	5
10. The simulator's ultrasound representation was adequate for my training of the procedure	1	2	3	4	5
11. The simulator's haptic (tactile) sensations were adequate for my training of the procedure	1	2	3	4	5

12. The movement of the virtual instruments were realistic	1	2	3	4	5
13. The functions of the virtual ultrasound were realistic	1	2	3	4	5
14. The feedback from the simulator/instructor was helpful for my training of the procedure	1	2	3	4	5
15. The text feedback was easy to relate to my performance of the procedure during today's training session on the simulator	1	2	3	4	5
16. I felt the simulator generated scores were generous	1	2	3	4	5
17. Controlling the virtual probe with a haptic device was easy	1	2	3	4	5
18. Controlling the virtual needle with a haptic device was easy	1	2	3	4	5
19. The arrangement of the different components of the simulator was awkward	1	2	3	4	5
20. The overall realism of the simulator was adequate	1	2	3	4	5

Comments

Appendix 4.4 - Feedback Questionnaire (Session 2)

Participant Number:-

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1. I found it easy to use the simulator	1	2	3	4	5
2. Task instructions were clear	1	2	3	4	5
3. The simulator could become a useful tool in teaching the block	1	2	3	4	5
4. The simulator's haptic (tactile) sensations were adequate for my training of the procedure	1	2	3	4	5
5. The functions of the virtual ultrasound were realistic	1	2	3	4	5
6. The graphical feedback from the simulator was helpful for my training of the procedure	1	2	3	4	5
7. The text feedback was easy to relate to my performance of the procedure	1	2	3	4	5
8. I felt the simulator generated scores were generous	1	2	3	4	5
9. I would imagine that most people would learn to use this system quickly	1	2	3	4	5
10. I think that I would not be able to use this system without the support of a trainer/technical person.	1	2	3	4	5
11. I think I would like to use this system frequently	1	2	3	4	5

12. The arrangement of the different components of the simulator was awkward	1	2	3	4	5
The following questions address the "2D" and "3D" versions, you have used today, separately					
13. The "**2D**" version of the simulator was helpful for training scanning of nerves	1	2	3	4	5
14. Better than version 1 (August 2010)	1	2	3	4	5
15. The "**3D**" version of the simulator was helpful for training scanning of nerves	1	2	3	4	5
16. Better than version 1 (August 2010)	1	2	3	4	5
17. The "**2D**" version of the simulator was helpful for training needle in plane technique of needle insertion	1	2	3	4	5
18. Better than version 1 (August 2010)	1	2	3	4	5
19. The "**3D**" version of the simulator was helpful for training needle in plane technique of needle insertion	1	2	3	4	5
20. Better than version 1 (August 2010)	1	2	3	4	5
21. The "**2D**" version of the simulator was useful to train hand-eye coordination	1	2	3	4	5
22. Better than version 1 (August 2010)	1	2	3	4	5
23. The "**3D**" version of the simulator was useful to train hand-eye coordination	1	2	3	4	5
24. Better than version 1 (August 2010)	1	2	3	4	5
25. Further practice on the "**2D**" version of the simulator would be beneficial as part of my own training of the procedure	1	2	3	4	5
26. Further practice on the "**3D**" version of the simulator would be beneficial as part of my own training of the procedure	1	2	3	4	5
27. The simulated tasks in the "**2D**" version of the simulator were too difficult	1	2	3	4	5
28. The simulated tasks in the "**3D**" version of the simulator	1	2	3	4	5

were too difficult					
29. The virtual arm in the "**2D**" version of the simulator was realistic	1	2	3	4	5
30. The virtual arm in the "**3D**" version of the simulator was realistic	1	2	3	4	5
31. The movement of the virtual instruments in the "**2D**" version of the simulator were realistic	1	2	3	4	5
32. The movement of the virtual instruments in the "**3D**" version of the simulator were realistic	1	2	3	4	5
33. Controlling the virtual probe with a haptic device in the "**2D**" version of the simulator was easy	1	2	3	4	5
34. Controlling the virtual probe with a haptic device in the "**3D**" version of the simulator was easy	1	2	3	4	5
35. Controlling the virtual needle with a haptic device in the "**2D**" version of the simulator was easy	1	2	3	4	5
36. Controlling the virtual needle with a haptic device in the "**3D**" version of the simulator was easy	1	2	3	4	5
37. The overall realism of the "**2D**" version of the simulator was adequate	1	2	3	4	5
38. Better than version 1 (August 2010)	1	2	3	4	5
39. The overall realism of the "**3D**" version of the simulator was adequate	1	2	3	4	5
40. Better than version 1 (August 2010)	1	2	3	4	5
41. The simulator's ultrasound representation in the "**2D/3D**" versions were adequate for my training of the procedure	1	2	3	4	5
42. The simulator's ultrasound representation in the final prototype was adequate for my training of the procedure	1	2	3	4	5
Final few questions and comments					
43. I need to learn a lot about ultrasound guided regional anaesthesia before I could use this system independently	1	2	3	4	5

44. I feel this is a better simulator than version 1 (August 2010)	1	2	3	4	5
45. I feel my comments and concerns about the previous version (August 2010) have been accounted for	1	2	3	4	5
46. I felt comfortable using the "**2D**" version of the simulator	1	2	3	4	5
47. I felt comfortable using the "**3D**" version of the simulator	1	2	3	4	5

Best thing/feature of the current simulator

_____

_____

_____

Worst thing/feature of the current simulator

_____

_____

_____

Comments

_____

_____

_____

Appendix 4.5 - Feedback Questionnaire (Session 3)

Participant Number:-

		Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1.	I found it easy to use the simulator	1	2	3	4	5
2.	Task instructions were clear	1	2	3	4	5
3.	The simulator could become a useful tool in teaching the block	1	2	3	4	5
4.	The simulator's haptic (tactile) sensations were adequate for my training of the procedure	1	2	3	4	5
5.	The functions of the virtual ultrasound were realistic	1	2	3	4	5
6.	The graphical feedback from the simulator was helpful for my training of the procedure	1	2	3	4	5
7.	The text feedback was easy to relate to my performance of the procedure	1	2	3	4	5
8.	I felt the simulator generated scores were generous	1	2	3	4	5
9.	I would imagine that most people would learn to use this system quickly	1	2	3	4	5
10.	I think that I would not be able to use this system without the support of a trainer/technical person.	1	2	3	4	5
11.	I think I would like to use this system frequently	1	2	3	4	5

12. The arrangement of the different components of the simulator was awkward	1	2	3	4	5
13. This version of the simulator was helpful for training scanning of nerves	1	2	3	4	5
14. Better than previous versions	1	2	3	4	5
15. This version of the simulator was helpful for training needle in plane technique of needle insertion	1	2	3	4	5
16. Better than previous versions	1	2	3	4	5
17. This version of the simulator was useful to train hand-eye coordination	1	2	3	4	5
18. Better than previous versions	1	2	3	4	5
19. Further practice on this version of the simulator would be beneficial as part of my own training of the procedure	1	2	3	4	5
20. The simulated tasks in this version of the simulator were too difficult	1	2	3	4	5
21. The virtual arm in the this version of the simulator was realistic (ID anatomy)	1	2	3	4	5
22. The movement of the virtual instruments in this version of the simulator were realistic	1	2	3	4	5
23. Controlling the virtual probe with a haptic device in the this version of the simulator was easy	1	2	3	4	5
24. Controlling the virtual needle with a haptic device in the this version of the simulator was easy	1	2	3	4	5
25. The overall realism of this version of the simulator was adequate	1	2	3	4	5
26. Better than previous versions	1	2	3	4	5
27. The simulator's ultrasound representation in the this version was adequate for my training of the procedure	1	2	3	4	5
28. I need to learn a lot about ultrasound guided regional anaesthesia before I could use this system independently	1	2	3	4	5

29. I feel this is a better simulator than previous versions	1	2	3	4	5
30. I feel my comments and concerns about the previous versions have been accounted for	1	2	3	4	5
31. I felt comfortable using the this version of the simulator	1	2	3	4	5

Best thing/feature of the current simulator

_____

_____

_____

Worst thing/feature of the current simulator

_____

_____

_____

Comments

_____

_____

_____

_____

Appendix 4.6 - Data

Data relating to Chapter 4 are provided in folder labelled Chapter 4 in the Supplementary Digital Content accompanying this thesis. Data are presented as follows:

1. Collated Responses to Likert questionnaires following sessions 1,2 and 3. *(.xlsx)*

   Presented with 4 tabs; session 1, session 2, session 3, and comparing 1-2-3.

2. Collated coded dataset with categories and items *(.xlsx)*

   Each data point is presented with; (i) a participant identifier, (ii) which session the datum relates to, (iii) the simulation task it relates to, (iv) the type of data (stated, noted or observed) and (v) whether it relates to a Best/Worse feature as noted on the questionnaire.

Chapter 5 - The effect of simulation-based training on initial performance of ultrasound-guided axillary brachial plexus blockade in a clinical setting – a pilot study.

Abstract

Background: There is increasing acceptance that simulation has a role to play in the training and assessment of procedural skills. To date, simulation in ultrasound-guided regional anaesthesia has largely been limited to tissue (e.g. turkey breasts or cadavers) and non-tissue (e.g. gelatine or tofu) phantoms. We hypothesized that computer based virtual reality simulation-based training offers an additional learning benefit over standard training in preparing novice anaesthetists to perform their first ultrasound-guided axillary brachial plexus blockade in the clinical setting. We carried out pilot testing of this hypothesis using a prospective, single blind, randomized control trial.

Methods: We planned to recruit 20 College of Anaesthetists of Ireland affiliated trainees who had no experience of performing ultrasound-guided regional anaesthesia. Initial stanardized training, reflecting current best available practice was provided to all participating trainees. Trainees were then randomised into one of two groups; to undertake additional simulation-based training or no further training. On completion of their assigned training, trainees

attempted their first ultrasound-guided axillary brachial plexus blockade in the clinical setting which was video-recorded for subsequent assessment. Two experts, blinded to the trainees group allocation, assessed the performance of trainees using validated checklist and global rating scale (GRS) tools.

Results: This study was discontinued following a planned interim analysis. Recruitment was discontinued, having recruited 10 trainees, because functionality of the available simulator was insufficient to meet our training requirements. We found no statistically significant difference in clinical performance, as assessed using the sum of the GRS and checklist scores, between simulation-based training [mean 32.9 (std. dev. 11.1)] and control trainees [mean 31.5 (std dev 4.2)] ($p = 0.885$).

Conclusions: We have described a randomised control trial assessing the effectiveness of an USgABPB simulator during its development. We failed to demonstrate a statistically significant improvement in trainee performance. We believe that the learning acquired will be useful if performing future trials on learning efficacy associated with simulation based training in procedural skills.

Co-investigators for this study

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Background

As patient safety has become a more fundamental element of clinical practice,[1] the traditional Halstedian models of training are being replaced. Several factors limit a trainee's, in particular a novice trainee's, opportunity to learn a procedural skill. These include shorter duration of training programmes, fewer training opportunities and lesser acceptance of the perception that trainees 'practice' on patients. We have demonstrated that anaesthetists in Ireland perceive a lack of opportunity as being the most important impediment to learning ultrasound-guided axillary brachial plexus blockade (USgABPB).[2]

There is increasing acceptance that simulation has a role to play in the training and assessment of procedural skills.[3] Simulation offers trainees an opportunity to attain skills in risk free environment. Training bodies are attempting to move from traditional time-based training programmes to competency-based training.[4] Simulation is being incorporated into competency based curricula and also has a role in the assessment of competence.[5] Since January 2010, the American Board of Anesthesiology (ABA) has included simulation based training as a mandatory component of Maintenance of Certification in Anesthesiology (MOCA).[6] A recent meta-analysis demonstrated that (technology-enhanced) simulation based training is associated with large positive effects on knowledge, skills, and behaviours, and moderate effects on patient based outcomes.[7] In a

further meta-analysis, the same group demonstrated that simulation-based laparoscopic surgery training achieves large benefits when compared with no intervention and is moderately more effective than non-simulation methods.[8] Grottke et al[9] have previously described the development of a virtual reality (VR) simulator for regional anaesthesia guided by peripheral nerve stimulation. Previous work at our institution reported the development of a similar device simulating spinal anaesthesia.[10]

The American Society of Regional Anesthesia and Pain Medicine (ASRA) and European Society of Regional Anaesthesia and Pain Medicine (ESRA) issued joint recommendations on the education and training of ultrasound-guided regional anaesthesia (UGRA) which included the use of simulation, specifically for practice of needle insertion techniques.[11] To date, simulation in UGRA has largely been limited to tissue (e.g. turkey breasts or cadavers) and non-tissue (e.g. gelatine or tofu) phantoms.[12,13] Computer based VR simulation has been utilized effectively in training a number of procedural domains, e.g. laparoscopic surgery[14] and colonoscopy.[15] VR simulation offers a number of advantages over other alternatives; (i) variety of predefined standardised scenarios, (ii) multiple anatomical variations, (iii) models do not degrade with repeated needle insertion, (iv) realistic representations of anatomy acquired via MRI, CT or ultrasound derived data, (v) normal variation of a single anatomical site can be represented, and (iv) multiple anatomical sites (thus different types of

blocks) can be represented in a single simulator.[16] Despite the large number of simulation studies published in anaesthesia journals, there remains a lack of studies addressing the transfer of "anaesthetic" skills from the simulated environment into the clinical environment.[17] We have participated in developing a VR visuo-haptic simulator to train USgABPB, as part of a collaborate project with the National Digital Research Centre (www.ndrc,ie). We set out to assess the effect of training USgABPB utilizing a novel prototype simulator, during its development, on skill transfer.

We hypothesized that VR-based training offers an additional learning benefit over standard training (using cadaveric dissection and human volunteers) in preparing novice anaesthetists to perform their first USgABPB in the clinical setting. We carried out pilot testing of this hypothesis using a prospective, single blind, randomized control trial.

Methods

This prospective, randomized control trial was conducted at Cork University Hospital and St Mary's Orthopaedic Hospital (Cork, Ireland). The Clinical Research Ethics Committee of the Cork Teaching Hospitals approved the study and the study was registered with ClinicalTrials.gov (NCT01965314). All subjects, patients and anaesthetists, provided written informed consent. We planned to recruit 20 College of Anaesthetists of Ireland affiliated trainees who had no experience of performing ultrasound guided regional anaesthesia. The sample size was based on previous studies indicating the effectiveness of VR simulation-based teaching procedural skills to novices.[14] Subjects provided baseline personal data; experience in practice of anaesthesia (years in training) and handedness. Each was asked to categorise his/her (i) previous experience of peripheral nerve blockade with peripheral nerve stimulation [0=0 blocks, 1=1-5 blocks, 2=5-10 blocks, 3=10-50 blocks, 4=50-100 blocks, 5≥100 blocks] (ii) previous experience of ultrasound-guided vascular access [0=0 procedures, 1=1-5 procedures, 2=5-10 procedures, 3=10-50 procedures, 4=50-100 procedures, 5≥100 procedures] (iii) previous attendance at a peripheral nerve blockade course (incorporating ultrasound-guided techniques) [0=never, 1=≤half day course, 2=full day course, 3=≥2 day course, 4=multiple courses]. Baseline visuo-spatial ability was assessed using the card rotation, shape memory, and snowy picture

tests (Educational Testing Service).[18] Psychomotor ability was assessed using a grooved pegboard (Lafayette Instruments, Lafayette, IN). Subjects were randomly allocated (non-stratified) into 1 of 2 groups, (i) the control group (CG) or (ii) the simulator trained group (SG) using random number tables.

Common Training

All participating anaesthetists received standardized training. These educational sessions took place in the Department of Anatomy, University College Cork. Between 4 and 6 trainees attended the educational sessions. A single anaesthetist (BO'D) with expertise in both teaching and performing the procedure delivered all sessions and supervised the trainees during the hands-on sessions. Each session involved a number of components, namely; (i) a didactic session, (ii) a hands on session with appropriately prepared cadaveric specimens, (iii) ultrasound scanning of a volunteer, and (iv) a needling skills session with tissue phantoms. The didactic session encompassed relevant anatomy, ultrasound (physics, function and interpretation), pharmacology of relevant agents, indications/contraindications of the block and complications of the procedure (30-40 minute lecture). This was followed by a demonstration of the gross anatomy of the axillary brachial plexus and its relationship to surrounding structures, using a number of pre-existing cadaveric specimens (20-30 minutes). Using a live human volunteer, subjects were given a 10-15 minute demonstration on how to perform an ultrasound examination (scout scan) of the

nerves and structures relevant to USgABPB. Subjects were shown how to track relevant structures distally towards to elbow, in order to aid differentiate the structures. Each subject then had a 5-7 minute supervised hands-on session during which they identified the relevant anatomy. Finally, each subject had a supervised hands-on needling skills session where they practiced advancing needles towards target structures in tissue phantom models (turkey breasts). Subjects were taught to perform USgABPB using a technique as described in Appendix IV and V of 'The American Society of Regional Anesthesia and Pain Medicine and the European Society of Regional Anaesthesia and Pain Therapy Joint Committee Recommendations for Education and Training in Ultrasound-Guided Regional Anesthesia'.[11] This technique uses a transverse (or short-axis) view, on ultrasound imaging, of the axillary brachial plexus and axillary blood vessels. The needle is inserted in a sterile fashion using an 'in-plane' approach, that is, the needle shaft and tip remains visible on ultrasound view throughout its course towards the relevant nerves. All ultrasound examinations performed on volunteers or on patients entailed the use of a Sonosite M Turbo (or similar device) with a 7-12 MHz 38mm linear probe. Following the educational intervention all subjects were asked to give written feedback, by means of a standard form, on the content and delivery of the session.

On completion of the common training the CG received no further training. The SG went on to complete a proficiency based training period using a prototype simulator.

Simulator training

The simulator was comprised of two PHANTOM Desktop devices (www.sensable.com), a desktop computer (Hewlett-Packard, www.hp.com), a liquid crystal display (LCD) monitor (Samsung Sync master 2233) capable of rendering 120 frames per second synchronised with a pair of 3D stereoscopic glasses (www.nvidia.co.uk), and the H3D API (www.sensegraphics.se). The SG subjects were asked to scan and perform procedure specific tasks on a virtual arm. The model of the arm was informed using a 1.5 Tesla MRI DICOM datasets which generated skin and bone surfaces. A number of computer generated structures were added to this model based on typical anatomical positioning (The Science Picture Company, www.sciencepicturecompany.com). These were the axillary artery and three nerves (representing median, ulnar and radial nerves). The resultant image was thus a computer generated "animation".

Before subjects began simulation based training, 3 experts (each of whom had undertaken structured higher subspecialty training in regional anaesthesia and maintained proficiency by performing at least 100 USgPNB procedures during the previous year) performed each task under similar conditions on 3 consecutive occasions. The

mean values of their performances went on to set a proficiency level against which subsequent trainee performance was benchmarked. SG subjects were required to meet these proficiency levels on two consecutive attempts before passing each task. In order to complete simulation training the SG subjects had to pass all 4 tasks.

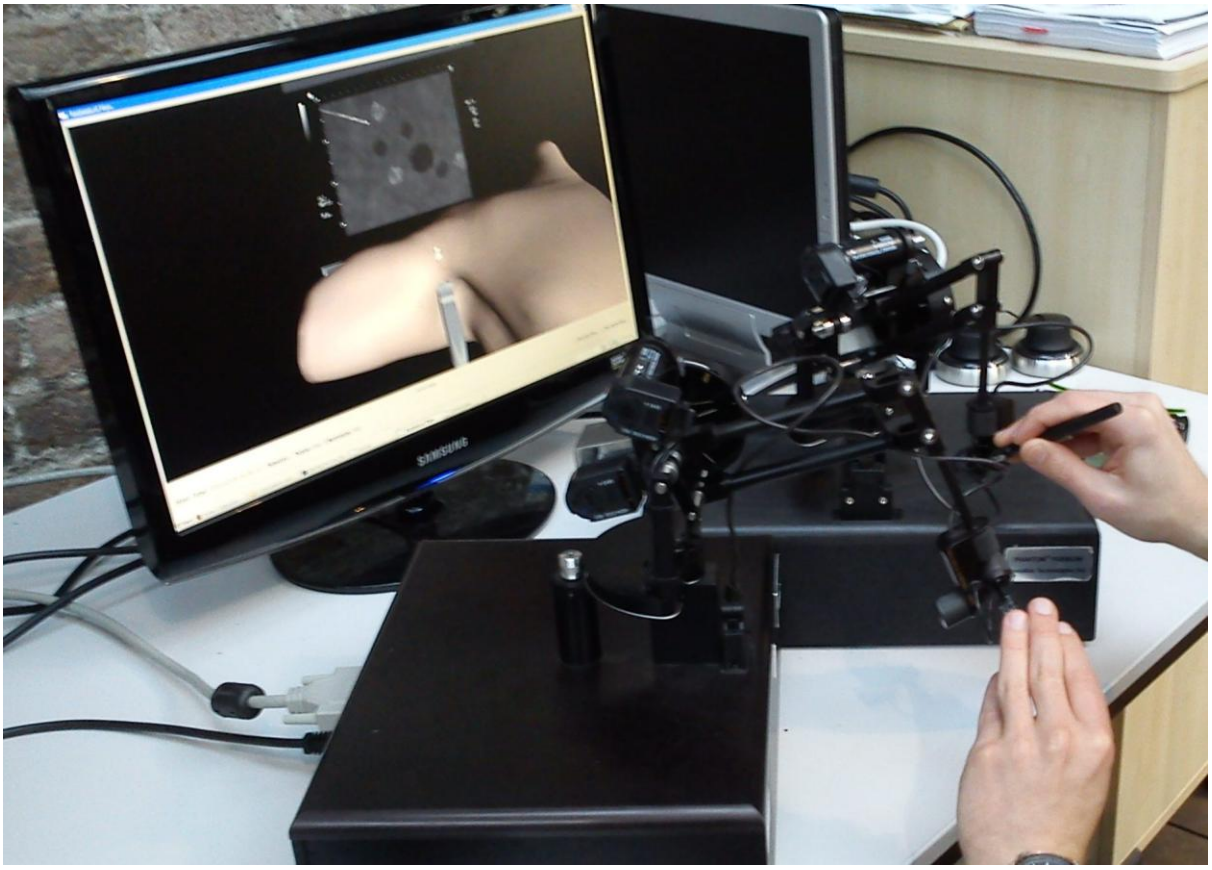

Figure 6. Configuration of simulator similar to that during trial.

Subjects logged into the system with a unique username and password. Following initial familiarization with the simulator, lasting 50 – 60 minutes, SG subjects were asked to complete 4 procedure specific tasks to a predefined proficiency level, 2 relating to ultrasound scanning (utilizing a single haptic device) and 2 relating

to needle advancement under ultrasound guidance (concurrently controlling two haptic devices – see Figure 6 above). Computer generated feedback was given to the subject after each attempted performance of each task. The tasks were specifically chosen to cover both the pre-procedural scout scan and the needling component of USgABPB, and also to capture behaviours likely to lead to significant clinical errors.[19] Table 26 (below) outlines each task, the feedback given and the proficiency level which had to be met. There was no time limitations set to meet these requirements. Subjects were free to control the frequency and duration of use of the simulator. Following initial orientation, training on the simulator in this study was largely unsupervised. An individual was immediately available to address any technical issues which may have arisen.

	Task	Feedback	Proficiency Level
1	Identify the 4 relevant structures represented at a point in the axilla	Number of structures correctly identified	All four structures identified
2	Follow the course of two of these structures (median and ulnar nerves) from axilla towards the elbow, while keeping the structures in the centre of the virtual ultrasound screen	The amount (%) of the structure represented in the middle of the virtual ultrasound as a proportion of the total length of the structure (from axilla to elbow) (out of 100%)	Mean expert performance
3	Advance a virtual needle towards a specified target (median nerve) keeping the needle in plane during advancement	The proportion (%) of needle advancement which occurred "in plane" as a proportion of the total distance the needle tip advanced in the virtual arm	Mean expert performance
4	Trigger a virtual injectate at an appropriate distance from the target.	The distance from the needle tip to the target structure when injection triggered	Injection at a distance not less than the mean expert minimum distance and not more than the mean expert maximum distance. Needle tip must also be visualised at the time of triggering.

Table 26. Task, the feedback given and the proficiency level to be met.

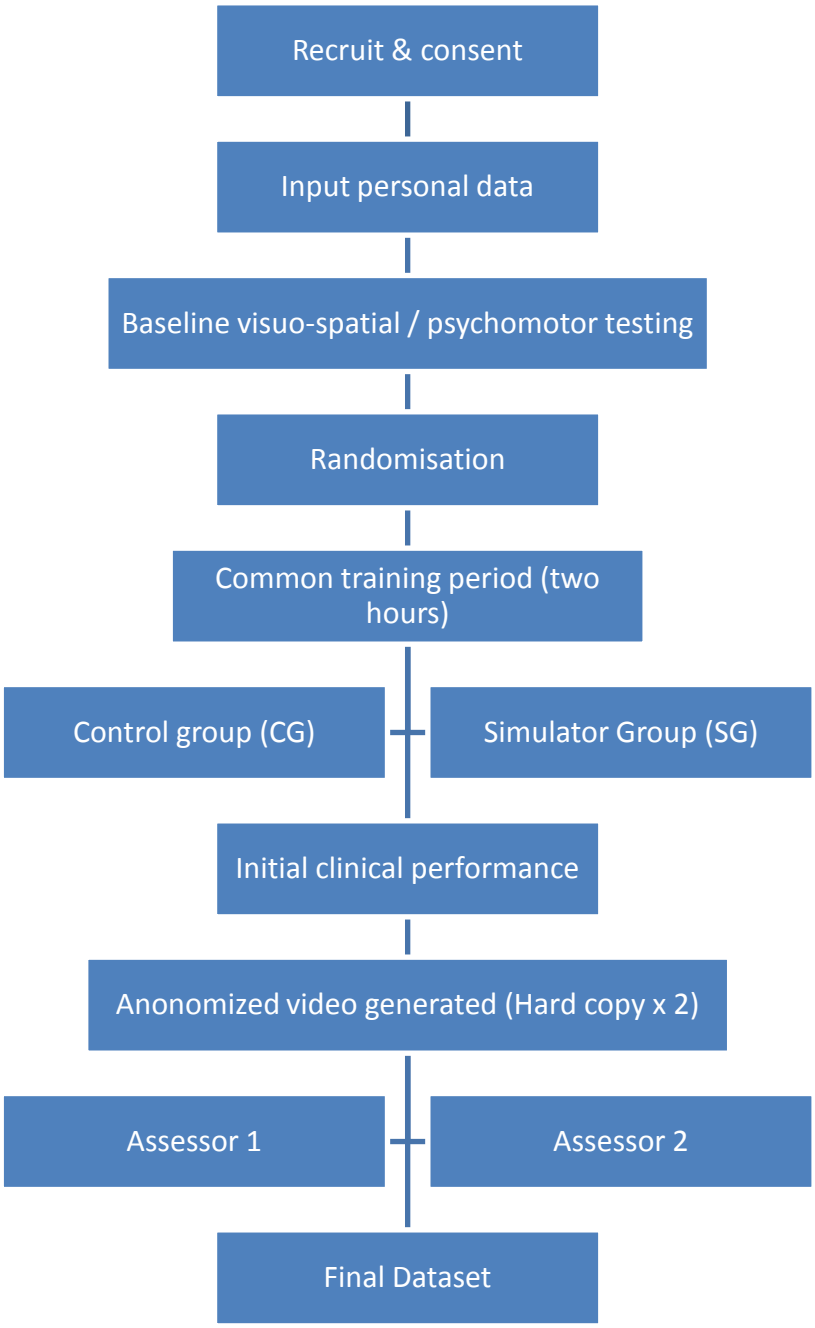

Figure 7. Study flowchart.

Assessment

We aimed to assess the subjects' performance within two weeks of the completion of their educational interventions. All subjects' first clinical performance of an ultrasound guided nerve block, specifically an ultrasound guided axillary brachial plexus blockade, was video

recorded for subsequent analysis by two experts (see definition above) in UGRA. Patients recruited required anaesthesia for forearm/wrist/hand surgery where USgABPB would ordinarily be offered as standard care. Intravenous sedation was administered as clinically indicated (midazolam up to a maximum of 0.05mg/kg). Subsequent care of the patient may have included general anaesthesia, as clinically indicated. *Patient inclusion and exclusion criteria were:*

Inclusion criteria	Exclusion criteria
ASA grades I and II	Parameters outside inclusion criteria
Age 18-80 years	Contraindication to regional anaesthesia
Capacity to consent	Language barrier
Already consented for USgABPB	Psychiatric history
Body Mass index 20 – 26 kg/m^2	Pregnancy

Subjects were asked to perform the procedure, using an in-plane approach and short-axis view, in the presence of a supervising trainer, blinded to training group, who was available to intervene if required, for patient safety, or requested by the subjects themselves. Patients were also blinded to subject allocation. Using a handheld video recording device (Flip Ultra, www.theflip.com) the performance of a "clinician-indicated" USgABPB for a scheduled operation was recorded. Video recording was directed to capture performance of the procedure at either Cork University Hospital or St Mary's Orthopaedic Hospital. The recording proceeded in a manner aimed to conceal the identity of the patient and maintain confidentiality. All efforts were taken to ensure the recording did not include images of the patients face. For the purpose of blinding, a similar effort was made conceal the identity of the anaesthetists performing the block. The recording included a pan shot of the setup of the room in which the block was performed. The acquired ultrasound images were recorded concurrently. After expert assessment of the performance and resulting dataset input, all recorded video was destroyed. As specified in our submission for ethical approval, this was carried out in order to maximise confidentiality. It was explained to all participants (patients and clinicians) and formed part of the written informed consent documentation.

For the purpose of the study the subjects were given the following instructions.

1. Position the patient and equipment appropriately.

2. Perform a pre-procedure ultrasonic survey of the relevant area, specifically identifying the four relevant nerves (musculocutaneous, radial, median, and ulnar).

3. Perform a sterile four nerve ultrasound-guided axillary brachial plexus block, utilizing a single skin entry point (where possible), short axis view of the brachial plexus, and needle in-plane approach.

4. Demonstrate the effectiveness of the blockade.

Following the recorded performance of the procedure the subjects were asked to complete a written questionnaire indicating their confidence in performing the procedure and their perception of the influence of external stressors (including the presence of a camera).

Outcome Measures

The subject's performances were assessed retrospectively based on a task specific, dichotomous, checklist and a behaviourally anchored 5-point global rating scale previously validated for this procedure (See Appendices).[20] Two experts, experienced with this form of evaluation, carried out these assessments. The experts were blinded to the training status of the subjects. The interval of this assessment was from patient and equipment positioning to assessment of effectiveness of blockade. The primary outcome measure was the average value of the sum of (i) global rating scale (GRS) scores and (ii)

total of procedural checklist items as assessed by the two blinded experts. Secondary outcome measures were (i) GRS scores, (ii) checklist scores, (iii) procedural times (from patient and equipment positioning to assessment of adequacy of block), (iv) number of needle passes, (v) block success (as defined by sensory & motor blockade in the distribution of all four relevant nerves demonstrated within 15 minutes of USgABPB), (vi) block failure (as defined by an unanticipated need for an additional peripheral nerve block or an unplanned conversion to general anaesthesia), (vii) participating anaesthetist confidence levels (measured on a ten point verbal rating scale, on completion of assessment of the block – "How confident were you in performing the block?") following performance of the USgABPB, and (viii) patient satisfaction measure (measured on a ten point verbal rating scale, on discharge from recovery "How satisfied were you with the block?").

SPSS version 17.0.2 software (SPSS, Inc., Chicago, IL, USA) was used for data analysis. Data were analysed using Mann–Whitney's U-test for continuous variables. A p value of <0.05 was considered significant. Inter-rater levels of agreement were estimated using Cohen's Kappa and percentage inter-rater reliability, defined as agreements / (agreements + disagreements) times 100.[14]

Results

Having originally planned to recruit 20 trainees, this study was discontinued following a planned interim analysis. Ten trainee anaesthetists were recruited from a university affiliated teaching hospital (Cork University Hospital) in July 2010, 4 to the Simulation group and 6 to the Control group. Our a priori minimum sample size was 10/group. Recruitment was discontinued because functionality of the available simulator was insufficient to meet our training requirements. Baseline participant data are summarised in Table 27 (above). The results of visuo-spatial testing using Snowy Picture, Shape Memory and Card Rotation Tests and psychomotor assessment using the Perdue Pegboard are summarised in Table 28 (below). Trainees in the SG did score significantly better in the Shape Memory Test than those in the CG, a measure of visual memory (23.3 (4.6) vs. 12.3 (4.6), $p = 0.010$). The differences in other visuo-spatial and psychomotor tests were not statistically significant.

Video data corruption occurred during the recording of 2 participant's ultrasound guided axillary brachial plexus blockade, rendering assessment impossible (both in CG). A comparison of primary and secondary outcome measures is shown in Table 29 (below). There was no statistically significant difference in clinical performance between each group, as assessed using the sum of the GRS and CHECKLIST scores. There was also no difference in the secondary outcomes measured. No participant completed the

performance of the block independently. Data relating to procedural times, number of needle passes and block success/failure were therefore not available. All candidates in both groups were adjudged by expert consensus to have "failed" in their performance of the block.

Participant assessment of content and delivery of the Traditional training portion is shown in Table 30 (below). Trainees in the SG rated elements of traditional training higher than CG participants. However, the magnitude of the differences tended to be low.

There was a trend towards a greater interval from commencement of training (traditional training session) to block performance in the Simulation group compared to that in the Control group, however this was not statistically significant [24.5 (16.1) [mean (std dev)], 6.5 (6.0) respectively, p=0.054].

The inter-rater reliability of the assessment of trainee performance by review of video was 89.3% (Range 83.7-93.9%) for checklist scores and 27.8% (Range 0-66.7%) for GRS scores. The Kappa for checklist scores was 0.749 ($p<0.01$) indicating a good level of agreement,[21] while the Kappa for GRS scores was not statistically significant (Kappa=0.037, p=0.628), indicating poor inter-rater reliability.[21] Table 4 compares i) sum of global rating scale plus checklist scores, ii) global rating scale scores, and iii) checklist scores between the two groups. Participant confidence did not differ statistically between the

group 2 (2.45), and 2.83 (2.64) [mean (std dev)] in the Simulation and Control Groups respectively (p=0.587).

	Simulation Group (n=4)	**Control Group (n=6)**
Male : Female	2 : 2	5 : 1
Years Experience in practice of anaesthesia [*Median(Range)*]	5(0-12)	4.5(0-22)
Previous Experience of Peripheral Nerve blockade with peripheral nerve stimulation	0.5(0-4)	1.5(0-3)
Previous Experience of Ultrasound-Guided Vascular Access	2(0-4)	1(0-5)
Previous Attendance at a Peripheral Nerve Blockade course (incorporating Ultrasound-Guided techniques)	0.5(0-2)	0(0-3)
Handedness	3 Right + 1 Ambidextrous	6 Right

Table 27. Baseline participant data.

	Simulation Group (n=4)	**Control Group (n=6)**	**Mann–Whitney's U-tests**
Snowy Pictures [mean(std dev)]	13.3 (5.6)	10 (4.8)	p = 0.285
Shape Memory Test	23.3 (4.6)	12.3 (4.6)	p = 0.010*
Card Rotation Test	21 (15.3)	6.67 (10.7)	p = 0.165
Pegboard - Sum Averages Right + Left + Both Hands	45.1 (8.0)	43.1 (5.3)	p = 0.522
Pegboard – Assembly	35.6 (7.8)	32.3 (5.7)	p=0.240

Table 28. Visuo-spatial and psychomotor testing.

Visuo-spatial testing using Snowy Picture, Shape Memory and Card Rotation Tests (Educational Testing Service) and psychomotor assessment using the Grooved Pegboard (Lafayette Instruments)

	Simulation Group (n=4)	Control Group (n=4)	Mann–Whitney's U-tests
GRS+CHECKLIST [mean (std dev)]	32.9 (11.1)	31.5 (4.2)	p = 0.885
GRS	18.4 (5.8)	15.8 (1.7)	p = 0.561
CHECKLIST	14.5 (5.4)	15.8 (4.6)	p = 0.564

Table 29. Primary and secondary outcome measures.

		Simulation Group (n=4)	Control Group (n=6)	Mann – Whitney's U-tests
Lecture	*Quality of Speaker [median(range)]*	10 (10-10)	10 (8-10)	p = 0.224
	Quality of Slides	10 (10-10)	8 (8-9)	p = 0.005*
	Potential to Learn	10 (10-10)	8 (8-9)	p = 0.005*
Cadaveric Anatomy	*Delivery of information*	10 (9-10)	8 (8-10)	p = 0.040*
	Hands on Experience	8 (7-10)	8 (6-10)	p = 0.904
US Scanning of Volunteer	*Delivery of information*	10 (10-10)	10 (9-10)	p = 0.221
	Hands on Experience	10 (9-10)	9 (5-10)	p = 0.069
Tissue Phantom	*Delivery of Information*	10 (10-10)	10 (9-10)	p = 0.414
	Hands on Experience	10 (10-10)	9.5 (3-10)	p = 0.114

Table 30. Participant assessment of content and delivery of the Traditional training.

Discussion

We have described a randomised control trial assessing the effectiveness of an USgABPB simulator during its development. We failed to demonstrate a statistically significant improvement in trainee performance. This may have been due to a Type 2 error. The study was discontinued as the prototype simulator used rendered approximations of ultrasound images which were insufficient in quality. Simulated sono-anatomy was subject to a number of limitations (e.g. clinically relevant muscles/tendons/fat were not modelled), resulting in relevant structures being presented against a relevantly homogenous background. There are two main reasons for this; 1. The technical requirements to generate simulated structures, such as biceps or coracobrachialis muscles/tendons, would be significant and were beyond the resources of our team, and 2. The computational requirements to render these secondary structures accurately in real-time, as the user scanned the virtual arm, would be beyond the capacity of the available computer processing units. As a result, it is likely that the simulator allowed for identification of structures in an unrealistic fashion (i.e. lacked fidelity). Indeed, one participant in the SG commented that she would have preferred to attempt to perform the block at an interval closer to the traditional training session, where she had practiced scanning a real human volunteer. It is likely the simulator had a negative impact in teaching trainees sono-anatomy relevant to USgABPB. It is possible that this

diminished any potential improvement in ultrasound guided needle advancement.

The recent Association for Medical Education in Europe (AMEE) Best Evidence in Medical Education (BEME) guide,[22] highlighted outcome measures of education as one of the key areas requiring further research. This is the first study to look at the transfer of skills from VR simulation based training to clinical practice, for an UGRA procedure. In their analysis of VR based training for laparoscopic surgery, Sinitsky et al[23] acknowledged that the science of setting proficiency levels is still ill defined, describing it as "the most pressing issue." We chose to set proficiency levels based on a limited number of attempts by our group of experts (mean of first three attempts following initial familiarisation). Sinitsky et al[23] also recommended that laparoscopic procedural skills are best learnt through distributed not massed practice. A one day intensive hands-on course on UGRA is an example of massed practice, whereas distributed practice is spread over a greater period of time (shorter practice sessions with long intervals between sessions). In more general studies of the effectiveness of technology-enhanced learning on medical education, Cook[7,24] also suggests distributed practice is more effective than massed practice. The same authors also found an association between individualised learning and better non-time based skills outcomes.[24] Following the initial familiarisation session, trainee's use of the simulator in this study was self regulated. As a

result, participants could train at a rate which best suited them and was distributed across a number of sessions over a number of days. Inter-rater reliability between experts was poor for GRS scores. This is likely due to the relatively subjective nature of GRS assessment. This may have been improved by enhanced training on using the assessment tools. While inter-rater reliability was good for checklist scores, such tools are subject to a number of limitations. In a systematic review and qualitative analysis of published clinical procedural skills assessment checklists, McKinley et al[25] found the assessment of the key competencies 'Infection control' and 'safety' were lacking in up to 50% of the tools analysed. A recent study involving the assessment of central venous catheter placement by 34 first year medical residents, using a landmark technique in a simulated environment compared the use of checklist and global ratings scales.[26] Using a passing score of 80% for checklist assessment, 11 of 13 deemed incompetent by expert assessors passed. These individuals all made serious errors with significant patient safety implications (lack of sterility, loss of control of guidewire, unsafe number of attempts). However, these errors were poorly captured on checklist assessment. It is possible that an assessment tool which specifically captures clinically relevant errors would be more useful in assessing procedural skills. Such a tool would be particularly useful in providing formative feedback. In the absence of such a validated tool, we choose our primary outcome measure as a combination of GRS and checklist scores.

Our study design incorporated the training of SG participants to a proficiency level derived from expert performance. Having attempted a task, the participant was given immediate computer generated feedback on their performance allowing them the opportunity to repeat the task with aim of meeting the proficiency level. There is increasing recognition that deliberate practice is essential to develop expertise.[27] Simulators can facilitate the generation of environment where deliberate practice can occur. A recent meta-analysis compared the effectiveness of simulation based medical education combined with deliberate practice with traditional training methods on clinical skills acquisition.[28] It was found that the former is associated with a large effect size. We know that current training models can provide trainees with insufficient opportunity to practice USgABPB.[2] Simulators such as the prototype used in this study can give trainees with multiple opportunities to practice. Training on the simulator also incorporated at least 6 of 9 key elements of deliberate practice; (i) engagement with a well-defined learning objective or task, (ii) focused, repetitive practice (iii) rigorous, precise measurements, (iv) Informative feedback, (v) monitoring, correction of errors, and more deliberate practice, (vi) evaluation to reach a mastery standard.[29]

Our study is subject to a number of limitations. Firstly the prototype simulator used was insufficient to meet the training requirements for teaching novice anaesthetists USgABPB. Our study sample was small

and technical issues with video-recording decreased the size of the dataset acquired further. The poor inter-rater reliability of the GRS component raises questions over the validity of our results. There was a difference in training time between the two groups. This difference related to the additional time it took participants in the simulation group to complete simulation training to the predefined proficiency level. It is possible that an improvement in performance in the SG could have been partially attributed to the increased training time, had this occurred. It is also possible that, in this novice population, elements of the traditional training were more important than those enhanced by the simulator training. In particular, when compared to the simulator generated images, novices appeared over-whelmed by the amount of information they had to interpret in reality. The trend towards an increased interval from the traditional training to block performance in the SG may have had a negative impact on their performance. A number of elements of the traditional training session were rated lower by CG participants than by SG participants. This study does not look at cost of training.[30] The simulator described utilizes haptic devices which are costly. Comparisons of haptic and non-haptic based in VR simulation has questioned the need for such devices when training laparoscopic surgical skills.[31] Future studies will need to address this question in training UGRA. Our study utilised a prototype simulator during its development. Indeed, the results of this study have informed the iterative development of the simulator. Ultrasound imagery in future

prototypes will likely be based on real acquired ultrasound data[32] from which the simulator will be capable of rendering a real-time image.

With increasing computational capacity and reduced cost, it is likely that simulation will move to a more personal environment where supervision is no longer a necessary component to the experience.[33] This may facilitate an individual gaining expertise through self regulated deliberate practice. However establishing validity of such devices would be essential. The potential for a trainee to learn incorrect or dangerous techniques in an unsupervised environment, could have catastrophic results if transferred into the clinical domain.[33] To date, publications of simulation based training in UGRA have largely been limited to descriptive pieces with few addressing transfer of skills into a clinical setting. Here, we attempt to partially address this deficit. Miller classically described a framework for clinical assessment.[34] At the base of Miller's pyramid is "knowledge" (knows), above this is "competence" (knows how), above this is "performance" shows, and on top of the pyramid is "action" (does). Isolated clinical assessment may only demonstrate that a clinician is capable of a certain level of "performance." It is not necessarily capable of predicting what a clinician actually "does" on a routine basis. It is largely this highest level of assessment that is required to ensure that simulation based training will lead to improved patient based outcomes.[35]

In conclusion, we were not able to answer the research question posed at the outset. We believe that the learning acquired will be useful if performing future trials on learning efficacy associated with simulation based training in procedural skills. In particular, confirmation of a degree of fidelity in the challenges rendered by a simulator is a pre-requisite to carrying out such a study. We believe that failure to do so, could result in spurious results due to factors other than the training or educational value of the simulation based programme.

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Appendices

Appendix 5.1 – Task Specific Checklist

Task Specific Checklist for Ultrasound Guided Axillary Brachial Plexus Block

CLEARLY IDENTIFIED OBSERVABLE BEHAVIOR

i.e. can be identified if seen by assessor on videotape

Yes/No

Positioning

1. Exposure of the axilla ☐☐
   - The subjects dignity should be maintained
   - The arm should be out of the sleeve
   - Axilla and shoulder should be completely exposed
2. Positioning of arm ☐☐
   a. Abduction - 90° at the shoulder
   b. Flexion – flexion of arm at the elbow
   c. External rotation – external rotation of arm
3. Patient comfort following positioning ☐☐
4. Positioning of Equipment
   a. Ultrasound Screen ☐☐
      - Ultrasound machine screen should be in the same field of vision as the ultrasound probe
   b. Sterile Trolley ☐☐
      - Sterile trolley should be within in arms distance and within the same field of vision as the ultrasound machine screen and the ultrasound probe

Preparation

5. Preparation of needle
   a. 22G gauge, 50mm Stimuplex needle (Standardized)
   b. Needle flushed ☐☐
6. Preparation of Ultrasound Probe
   a. Protection of probe ☐☐

- Probe should be covered with either a sheath or a protective covering

b. Application of gel ☐☐
   - Gel can be applied to either axilla or ultrasound probe

Block

7. Preparation of Axilla
   a) Antiseptic solution should be applied in the axilla ☐☐
8. Application of Ultrasound Probe
   a. Orientation of probe ☐☐
   b. Probe placed perpendicular to the arm in upper axilla ☐☐
   c. Stabilizes transducer hand by resting gently on the patient ☐☐

9. Identification of Anatomical Structures
   - The participant will at this stage point at the ultrasound screen and identify the individual anatomical structures

   a. Axillary Artery ☐☐
   b. Axillary Vein/s ☐☐
      - The Axillary artery and vein should be identified via colour flow analysis

   c. Coracobrachialis muscle ☐☐
   d. Musculocutaneous Nerve ☐☐
   e. Median Nerve ☐☐
   f. Ulnar Nerve ☐☐
   g. Radial Nerve ☐☐

10. If using long axis approach maintain the needle in plane keeping whole needle in view at all times ☐☐

11. Deposition of Local Anaesthetic
    - For each nerve **(v) further dose injection** – the spread of Injectate should be visible on ultrasound screen

    a. Nerve 1_____
       i. Needle tip is identified ☐☐
       ii. Aspiration ☐☐
       iii. Test Dose (spread of injectate identified) ☐☐
       iv. Patient comfort on injection ☐☐
       v. Further dose injection ☐☐
    b. Nerve 2_____
       i. Needle tip is identified ☐☐
       ii. Aspiration ☐☐
       iii. Test Dose (spread of injectate identified) ☐☐

iv. Patient comfort on injection ☐☐
v. Further dose injection ☐☐

c. Nerve 3 _____
   i. Needle tip is identified ☐☐
   ii. Aspiration ☐☐
   iii. Test Dose (spread of injectate identified) ☐☐
   iv. Patient comfort on injection ☐☐
   v. Further dose injection ☐☐

d. Nerve 4 _____
   i. Needle tip is identified ☐☐
   ii. Aspiration ☐☐
   iii. Test dose (spread of injectate identified) ☐☐
   iv. Patient comfort on injection ☐☐
   v. Further dose injection ☐☐

Assessment

12. Wound stabilization device removed ☐☐
    - Dressing/ cast should be removed before assessment
      Patient should be asked about pain before removing device

13. Musculocutaneous Nerve
    a. Sensory ☐☐
       - Lateral aspect of forearm should be checked for cold sensation
    b. Motor ☐☐
       - Forearm Flexion

14. Radial Nerve
    a. Sensory ☐☐
       - Posterior forearm, dorsum of hand, thumb, index and middle finger should be checked for cold sensation
    b. Motor ☐☐
       - Wrist and finger Extension

15. Median Nerve
    a. Sensory ☐☐
       - Anterior and medial aspect of forearm, thumb, index, middle and half of ring finger should be checked for cold sensation
    b. Motor ☐☐
       - Flexion of lateral two fingers

16. Ulnar Nerve
    a. Sensory ☐☐

- Medial aspect of hand on the hypo-thenar eminence, little, ring and middle finger should be checked for cold sensation

b. Motor ☐☐

- Thumb opposition or finger abduction

NOTE:

Regarding 10.

For each nerve (**v) further dose injection** – the spread of Injectate should be visible on ultrasound screen

Regarding 13a-16a (sensory assessment) Assessment at one of listed sites is sufficient

Appendix 5.2 - Generic Technical Skills Global Rating Scale

Respect for Tissue	**1**	**2**	**3**	**4**	**5**
	Frequently used un-necessary force on tissue or caused damage		Careful handling of tissue but occasionally caused inadvertent damage		Consistently handled tissue appropriately with minimal damage
Time and Motion	**1**	**2**	**3**	**4**	**5**
	Many un-necessary moves		Efficient time/motion but some un-necessary moves		Clear economy of movement and maximum efficiency
Instrument Handling	**1**	**2**	**3**	**4**	**5**
	Repeatedly makes tentative or awkward moves with instruments by inappropriate		Competent use of instruments but occasionally		Fluid moves with instruments and no awkwardness

	use of instruments		appeared stiff or awkward		
Knowledge of Instrument	**1**	**2**	**3**	**4**	**5**
	Frequently asked for wrong instruments or used inappropriate instrument		Knew names of most instruments and used appropriate instruments		Obviously familiar with the instruments and their names
Flow of Procedure	**1**	**2**	**3**	**4**	**5**
	Frequently stopped procedure and seemed unsure of next move		Demonstrated some forward planning with reasonable progression of procedure		Obviously planned course of procedure with effortless flow from one move to the next
Use of Assistants	**1**	**2**	**3**	**4**	**5**
	Consistently placed assistants poorly or failed to use		Appropriate use of assistants most of the times		Strategically used assistants to the best advantage at all times

Knowledge of Procedure	**1**	**2**	**3**	**4**	**5**
	Deficient knowledge		Knew all important steps of operation		Demonstrated familiarity with all aspects of operation/ procedure
Overall Performance	**1**	**2**	**3**	**4**	**5**
	Very poor		Competent		Clearly superior

Overall in this task, should the candidate ☐ Pass ☐ Fail?

Appendix 5.3 - Data

Data relating to Chapter 4 are provided in folder labelled Chapter 4 in the Supplementary Digital Content accompanying this thesis. Data are presented as follows:

1. Participant Randomisation *(.xlsx)*

2. Collated Baseline Characteristics *(.xlsx)*

3. Collated Feedback on quality of common training *(.xlsx)*

4. Collated; (i) GRS and (ii) checklist assessments with tabs (iii) trainee confidence and (iv) Interval from training commence to block performance *(.xlsx)*

5. Collated visuospatial and psychomotor testing *(.xlsx)*

Chapter 6 – Conclusions

Principal Findings

We addressed four research questions, each relating to the training and assessment of the competencies associated with the performance of ultrasound-guided axillary brachial plexus blockade. These were:

What are the most important determinants of learning of USgABPB?

We demonstrated that these were :

Access to a formal structured training programme

Frequent exposure to clinical learning opportunity in an appropriate setting

An appropriate patient, trainee and teacher being present at the same time, in an appropriate environment

What is USgABPB? What are the errors most likely to occur when trainees learn to perform this procedure?

We performed a formal task analysis of USgABPB, identifying

256 specific tasks associated with the safe and effective performance of the procedure

the 20 most critical errors likely to occur in this setting.

How should end-user input be applied to the development of a novel USgABPB simulator?

We described a methodology for this and collected data based on detailed, sequential evaluation of prototypes by trainees in anaesthesia.

Does structured simulation based training influence novice learning of the procedure positively?

We carried out a pilot randomised control trial assessing the effectiveness of a USgABPB simulator during its development. Our data did not enable us to draw a reliable conclusion to this question; the trail did provide important new learning (as a pilot) to inform future investigation of this question.

New Learning on How End-Users Inform the Design and Development of a Virtual Reality Simulator to Teach Ultrasound-Guided Axillary Brachial Plexus Blockade

Better training of USgABPB should lead to better performance of the procedure, which should lead to improved clinical outcome. We believe simulation-based training will prove a powerful vehicle for improved training, improved clinical performance and improved patient outcomes. Simulators which have integrated tools for assessment of performance provide a potentially powerful means of providing formative feedback to the trainee. However, this relies on the assessment itself being valid and the feedback providing a meaningful basis for improvement in subsequent attempts.[1]

Taken together our findings indicate the fundamental importance of a comprehensive description of *what the procedure is* to training, to assessment, to performance in a clinical setting and ultimately to patient benefit. Thus procedural characterisation is the cornerstone of any system which purports to enable a procedure (such as USgABPB) to deliver on its potential for health gain.

Figure 8 (below) provides a framework for this approach. Our work specifically addresses a number of aspects of this framework (in red font). In chapter 3, our task and error analysis characterised the procedure. Knowing the procedural steps and the errors likely to occur allows the design of appropriate assessment tools. We have specifically used this information to inform the design of a VR

simulator (and its integral automated assessment). The information could be utilized for other systems addressing procedural assessment, for example a paper based clinical assessment tool. Formative assessment will drive learning of procedural skills, particularly when integrated with deliberate practice or proficiency progression models. In chapter 2 we sought to discover other aspects which determine whether USgABPB is taught and learnt effectively. In chapter 4 we describe our methods of involving end-users in the development of tool which would allow performance of UsgABPB in a simulated setting. In Chapter 5 we sought to assess if training, to expert proficiency levels, utilizing a prototype simulator would result in improved clinical performance. The impact of clinical performance on clinical outcome is a poorly studied field and will require future work. Validated clinical assessment tools are required for such studies or audits. Our procedural characterisation could be utilized to design an assessment tool, for example a tool which aims to capture the occurrence of certain important errors (an error-based tool). Clinical practice is a dynamic entity. It is likely that USgABPB as practiced today will evolve over the coming years. One area which will likely drive such a change is the introduction of new technological devices or enhancements to existing devices. It is likely that evidence of improved clinical outcome will be required in order to introduce such devices into clinical practice. Technological enhancements may be aided by the provision of a virtual reality test bed, where designs might be refined rapidly in a risk free

environment. As the procedure evolves, out procedural characterisation will need to be adapted accordingly.

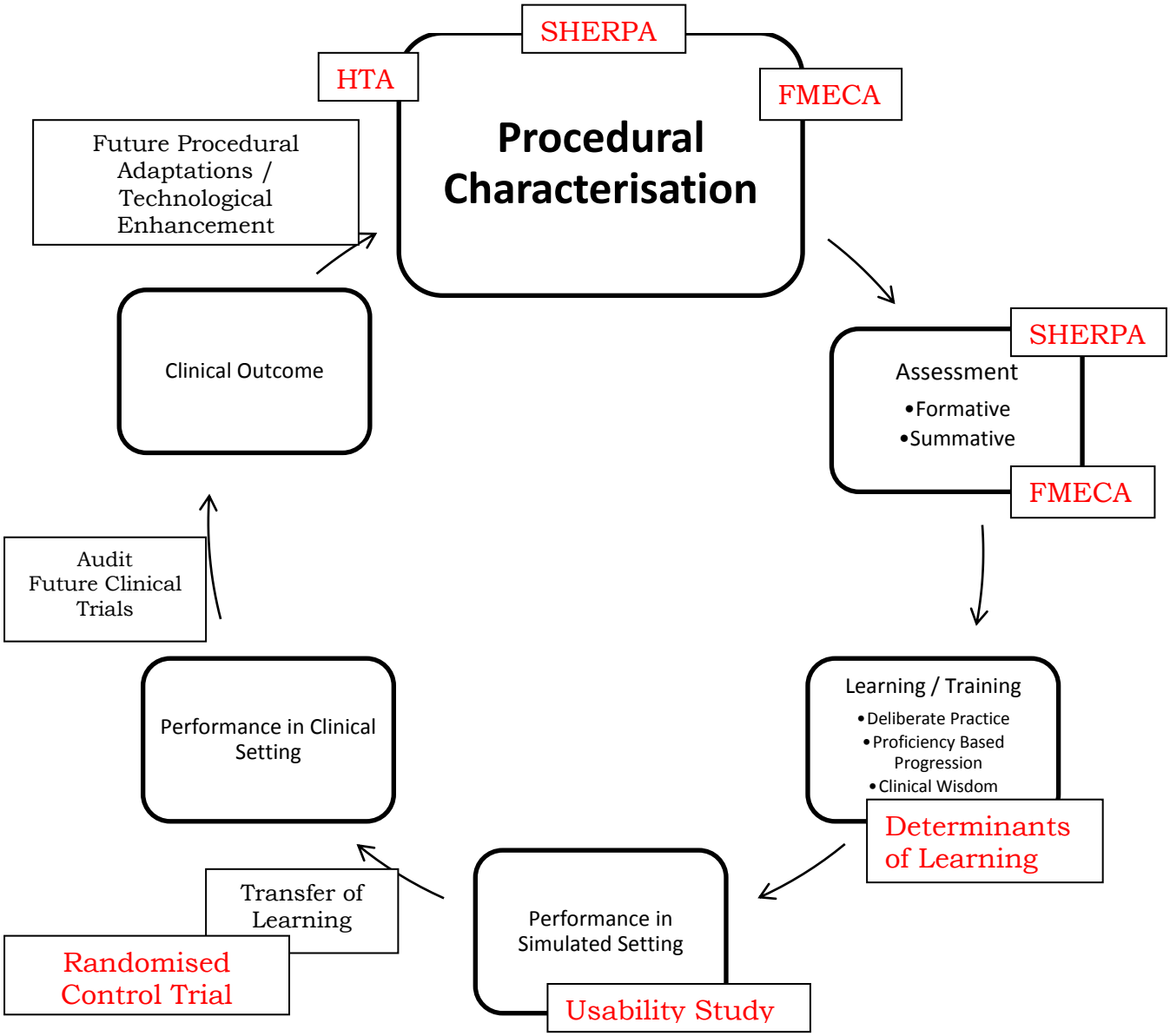

Figure 8. Procedural characterisation as a driver for improved clinical outcome through simulation-based training.

This body of work has addressed a number of these areas (labelled in red font).

Assessment

Our hierarchical task analysis allowed characterization of the components of USgABPB. Design of the virtual reality simulator was directed by the 256 task steps indentified in the HTA. Where possible, our virtual reality environment was designed to allow replication of each step. To date, the simulator has evolved to ask users complete a series of part-tasks (See Table 20 above and Table 26 above). The use of part-tasks has facilitated the development of a simulator which has been suitable for testing by clinicians during its development (chapter 4). Developers were given the task of replicate elements of the procedure in isolation rather than tackling replication of the entire procedure in the first instance. Combined, our error analyses (SHERPA & FMECA) gave us a list of critical errors which help direct the design of the part-tasks. Of the top twenty errors of highest Criticality Index, 5 relate to "Advance Needle" (HTA numbering = 2.5.4.3.3.1) and its subordinate tasks. A further six relate to errors made in confirming the needle is at the target (2.5.4.3.3.2). As a result, developers directed their attention towards these areas in particular.

Our error analysis also informed the design of performance measurements (metrics) within the simulators software. The top twenty errors gave priority to which metrics should be addressed. The characterization of the errors guided the software developers in designing the specific metrics which were developed.

For example:

- Error 1
    - "In the event that the needle is poorly visualised or lost while advancing it towards the target, the anaesthetist continues to advance the needle without visualising it appropriately"
    - **<u>ACTION</u>: Continues Needle Forward Motion**
        - *Either*
        - (i) Specified Distance
        - (ii) Specified time, after condition occurs
    - **<u>CONDITION</u>**: **Needle shaft not in view & needle tip not in view**
    - **<u>Feedback:</u> Distance needle tip travels in tissue where needle is adequately visualised as a proportion of total distance needle tip has travelled.**

In delivering such feedback, the trainee gets meaningful information on how they can improve their performance. In chapter 5, we used a proficiency level, based on expert performance, which trainees needed to meet. The addition of a proficiency level provides the trainee with a specific goal to aim for and context to the feedback of an objective numerical 'score'. Using such a system, the trainee can

strive to reach proficiency in a part-task before moving on to the next part task.

Learning / Training

In chapter 2, we learnt that the most important impediments to learning the procedure related to lack of clinical learning opportunities. We also found that a clinical learning opportunity requires appropriate *patient*, *trainee* and *trainer* being present at the same time, in an *appropriate environment*. Our results demonstrated that these elements often do not co-exist. Simulation has the potential to address some of these issues.

1. Issues relating to the learning **environment** can be addressed by placing the simulator in a quiet location, adjacent/convenient to clinical working environment.
2. Coupling the simulator with a means of addressing the prerequisites of learning the procedure (see Table 5) could ensure that the **trainee** is adequately prepared to learn how to perform USgABPB.
3. Replacing the **patient** in the learning opportunity relies on the simulation addressing appropriate content. It is unnecessary for a simulator to replicate all aspects of the patient/doctor experience. However it is most desirable that the simulator can replicate, to an appropriate level of exactness or fidelity, components of the procedure where errors are likely to occur. This could allow learners to hone their skills and rectifying

erroneous behaviours before attempting their first procedure in the clinical setting.

4. If the simulator were capable of monitoring performance and delivering appropriate formative feedback it is possible that a trainee could practice the procedure without the presence of a **trainer**.

Out task and error analysis allowed us to address points 3 and 4 above.

In chapter 2, we demonstrated that the majority of anaesthetists in Ireland do not consider themselves competent in the performance of USgABPB. It is therefore likely that a significant number of patients are not offered USgABPB as an anaesthetic option when undergoing upper limb surgery. We also found that 9 of the 24 respondents to our detailed questionnaire who teach USgABPB did not describe themselves as either competent or expert. This worrying sign of the prevalence of 'see one, do one, teach one' methods would indicate that not only are anaesthetists practicing the procedure on patients, but also many of the supervisors may not have sufficient proficiency to identify errors should they occur (the blind leading the blind). Simulation can potentially address these issues. It can move the early part of the learning curve away from the patient into an environment where a learner is free to make errors without negative consequence. The removal of the early part of the learning curve from practicing on patients to practicing on a simulator should benefit

patients both in terms of material performance (by an operator) and of perception (their confidence in the operator's competence).

Performance in the Simulated Setting

There could be an assumption made that simulated practice is inherently good. However we know that repetitive practice in itself is insufficient to gain competency. Sites et al demonstrated that even after performing 60 ultrasound guided blocks, trainees were still making on average 2.8 errors per procedure.[2] Despite this, an individual's level of competency carrying out a specific procedure is often measured in terms of the number of times they have previously carried out the procedure. In our preliminary questionnaire we asked respondents to estimate the number of block performances necessary to achieve competence. Of the 29 responses to this question, only six respondents qualified their response (e.g. "depending on time interval between", "needs to be on a regular basis", "depending on person"). According to these responses 20 (median; range 7-50) block performances were necessary to achieve competence.

In setting expert-based proficiency levels (chapter 5) we recruited a number of clinicians locally, each of whom had undergone subspecialty training in regional anaesthesia and who practice UGRA routinely (i.e. at least on a weekly basis). In our national survey (chapter 2) only 2 of 102 respondents defined themselves as an 'expert' in the performance of USgABPB. It is possible that some of the practitioners setting our proficiency level would not define

themselves an 'expert'. Deliberate practice is key in acquiring procedural skills and gaining expertise,[3] where frequent repetition of the task is refined through feedback (Table 2 above).[4]

We have developed our simulator with a deliberate practice model in mind. The trainee would learn the procedure through repetitive practice coupled with computer generated, clinically relevant, formative feedback. Tasks would initially be relatively simple and progress, on attainment of defined proficiency levels, to more complicated tasks. A simulator which is immediately available for self directed learning without the need for immediate supervision would increase the opportunity for deliberate practice. There is also increasing evidence that this type of distributed practice is more effective than massed practice (e.g. attending a UGRA course).[5,6]

An essential element to simulation based deliberate practice is that the learner will want to engage with repetitive practice using the device. We have placed emphasise on the usability of our simulator, particularly by trainees – the potential end users of the device (chapter 4). A simulator which has proven efficacy in preparing a trainee to perform USgABPB in the clinical setting would be of limited value if the trainee did not want to use the device because, for example, users frequently got a headache or the software was subject to crash frequently.

VR simulation-based training does not necessarily need a trainer to be present, thus allowing the trainee opportunity for self directed

learning. Participants in our usability study would have been presented with an image similar to Figure 9 (below) on logging into the simulator at session 3. Although not fully implemented, it gives an indication of what is possible in the future. The trainee begins by completing, to proficiency, a number of "enabling skills" (e.g. keeping a static needle aligned with the ultrasound probe). The trainee would then progress to perform a clinically relevant part of the procedure, a "part task" (e.g. identify the median nerve and follow its course to the elbow, keeping the nerve in the middle of the ultrasound screen). The fidelity of the task would peak in the "patient scenarios". By integrating a virtual patient player within the simulator, a trainee will be expected to complete not technical components relating to the care of a patient undergoing USgABPB (e.g. appropriately consenting the patient, choosing appropriate local anaesthetic agents, assessing adequacy of the block (post procedure)). The HTA and subsequent error analyses have been invaluable in directing with part-tasks and enabling skills to prioritize.

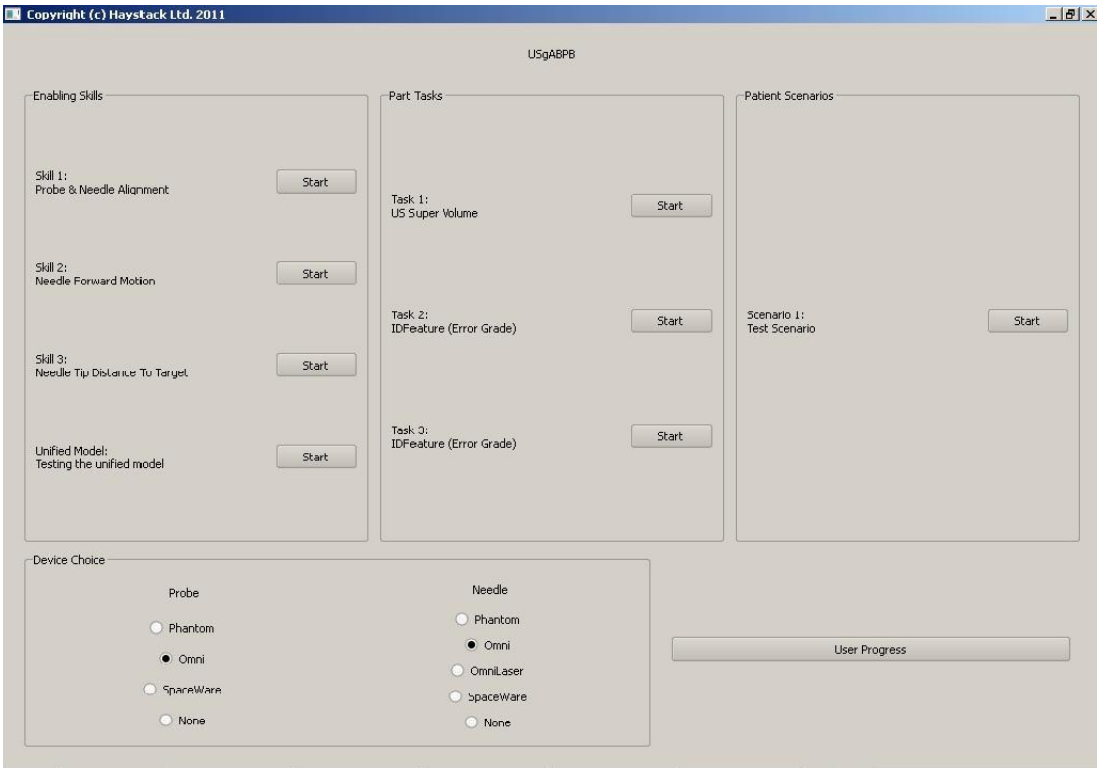

Figure 9. Simulator menu.

Performance in the Clinical Setting

Better training implies better performance. However, we cannot assume that simulation-based training transfers directly to the clinical setting, as improved performance. This 'transfer' validity needs to be established before such a claim can be made. Transfer of learning from the simulated setting to the clinical setting has been established for other procedures, for example, VR simulation-based training of laparoscopic skills.[7] The assessment of competency and expertise is, in reality, much more complicated than measuring how many procedures the practitioner has performed or for mow many years they have been practicing. To a patient, it is likely the most pertinent pieces of information are; (i) will the procedure work

(frequency of failure) and (ii) what are the potential complications (frequency of complications). A similar, patient-based approach needs to be taken when evaluating a simulation tool. It is the potential correction of errors and other aberrant behaviours that will ultimately benefit patients. In chapter 5, we address this issue. We attempted to establish *transfer validity* of one iteration of our simulator. That is, will a trainee who has learned the procedure using the simulator perform better when attempting the procedure on a real patient in the clinical setting? There is a lack of studies addressing the transfer of "anaesthetic" skills from the simulated environment into the clinical environment.[8] While our study is a negative study, we see the investigation of transfer validity as a key issue for simulation based UGRA training.[9]

We also see simulators having a role in enhancing the performance of the 'trained' anaesthetist. That is, the anaesthetist who is competently performing the procedure independently. Deliberate practice is critical to the development of expertise.[3] Simulation, with integrated rigorous means of assessment, has the potential to provide a motivated anaesthetist a powerful tool for deliberate practice.

Clinical Outcome

If simulation-based training were proven to improve performance in the clinical setting it is probable that patients will benefit. This may be, for example, in the form of a reduction in block failure complication rates. Another possible outcome may be increased

comfort due to a reduction in the rate and duration of needling. There is limited evidence linking clinical performance and clinical outcome. A recent study by Birkmeyer et al[10] is, perhaps, the first to provide evidence to support this link. This group demonstrated an association between greater technical skill of practicing bariatric surgeons and fewer postoperative complications, lower rates of reoperation, readmission, and visits to the emergency department following laparoscopic gastric bypass procedures. Attributing any change in patient outcome measures to simulation based training would have to be explicitly proven. A formal trial would be required to assess the predictive validity of completing proficiency based training using a simulator on patient based outcomes. A simulator could in time be used as a purely summative assessment tool. If the sensitivity and specificity of its predictive value were sufficient, a simulation-based assessment tool could be utilized as for high stakes decisions on trainee progression or licensing.

What Questions Remain?

We believe effective simulation-based training in UGRA will soon be a reality. However, there are a significant number of questions which need to be resolved and more which have yet to be addressed. In addressing the current deficit in this area, we did not set out to comprehensively address all problems. Using USgABPB as an index procedure, we believe this 'work' has furthered science in this field. At the time of writing, we believe the following questions need to be addressed.

What level of fidelity is required to be an effective USgPNB simulator?

Chapter 4 describes the evolution of a simulator to train novices USgABPB. During the development of the simulator, much effort was placed in enhancing and refining the simulated ultrasound imagery. The simulated tasks used in the intervention arm of our randomised control trial (RCT chapter 5) were similar to the tasks 3 & 4 of session 2 in chapter 4 (See Table 20). This simulator used ultrasound imagery which was 'cartoon' in nature. The ultrasound images were, we believe, insufficient to meet our needs (i.e. to train novices how to perform USgABPB). Subsequent simulator prototypes incorporated more realistic ultrasound imagery. This utilized the acquisition of ultrasound images of real human axilla (volunteers) and the concurrent recording of the relative position of the ultrasound probe in a manner similar to Cash et al.[11] It is possible that inadequacies which occurred in our RCT may have been addressed had we

sufficient resources available to refine this realistic ultrasound imagery (Figure 5 above) and use it in the place of the 'cartoon' imaged available to us (Figure 6 above). We believe defining the appropriate fidelity of the ultrasound imagery is one of the most significant questions to be addressed.

Examples of other specific questions, yet to be addressed, which involve simulator fidelity, are:

Is haptic feedback important in simulation-based training of UGRA?

In generating VR environments to train UGRA, is there an advantage in using a three dimensional stereoscopic display over a standard computer monitor (2D)?

> In navigating around a 3D environment, 2D images offer limited cues of depth (e.g. from shadows cast). 3D Stereoscopic displays create an illusion of depth. These displays typically require the user to wear specialised polarised glasses and the simulator to use a specialised computer monitor. What is not clear is the benefit of utilizing 3D stereoscopic techniques. The ability to perceive 3D using this technology (Stereoacuity) is subject to large individual differences. It is estimated that 8% of the population cannot fuse stereo pairs (image to right and left eye) at all.[12] It remains to be quantified, the difference in performance of VR simulated tasks relating to UGRA using (i) a standard (2D) display and (ii) a three dimensional

stereoscopic display. A study design investigating this subject would incorporate the standardisation of lighting conditions, viewing distance, and viewing direction. Of note a history of epilepsy is a specific contraindication of the use of 3D glasses (as specified by manufacturer www.nvidia.co.uk).

Is an error-based clinical assessment tool for UGRA reliable and valid?

In chapter 5, we choose our primary outcome measure as a combination of GRS and checklist scores. It is possible that an assessment tool which specifically captures clinically relevant errors would be more useful in assessing procedural skills. Such a tool would be particularly useful in providing formative feedback. The output of our error analysis in Chapter 3 (Table 18) could be utilized as a basis for the development of such a tool. Subsequently, a clinical trial would be required to establish reliability and validity of such a tool.

Is simulation based training of UGRA effective?

In chapter 5, we attempt to establish whether simulation-based training of USgABPB using a novel prototype VR-based simulator resulted in improved clinical performance. Our study investigated the impact of simulation-based training on the first performance of an USgABPB by a novice trainee. We failed to demonstrate 'transfer validity'. However we believe our work will benefit future attempts to address this question.

Future studies on the efficacy of simulation-based training will have to take a more long term, patient centred approach. For example; *is the benefit of training sustained? Does the completion of simulation based training have a positive impact on patient based outcomes? Is it possible to set an objective minimum competency level which a trainee would have to meet before attempting a clinical block / practicing independently?*

Are VR simulators to train UGRA socially acceptable?

Do trainees and trainers see it as an integral and "embedded" component of procedural training (e.g. where, when, how often) and what barriers might exist to implement training and assessment using such a device (e.g. cultural, financial, technical). McGaghie et al[417] highlighted the many cultural issues, impeding widespread adoption of simulation based education, which exist amongst the medical profession. The importance of social acceptability may become more significant. A public health dilemma could emerge if, for instance, transfer validity of a simulator/device was established but the potential health gain had not been realised because market forces did not support its commercialisation.

Is self-regulated learning and unsupervised practice of UGRA using simulation effective?

In developing a simulator, we aim to produce a device which is usable in a self-training situation. With such a personalized training approach (as one component of an overall structured training

programme), learning benefits could be achieved without the need for a trainer to observe practice directly and to provide feedback. In this setting, formative feedback could be provided to the trainee using accurate personal data derived from his/her performances on the simulator. Such automated feedback could facilitate a deliberate practice model of procedural training.[13]

Is patient-specific rehearsal of UGRA feasible? Does it result in improved patient outcomes?

Recently, evidence is emerging that clinical performance may be improved by means of two specific simulation-based interventions. These are (i) pre-procedural warm-up,[14] and (ii) pre-procedural rehearsal.[15] Warm-up is a period of practice immediately prior to clinical performance involving psychomotor and cognitive tasks related to the procedure. An analogy from sport would be a drill involving a soccer player dribbling a ball around a series of cones. Pre-procedural rehearsal is analogous to a soccer team working on a specific set piece in a training session (e.g. an attacking corner) with the intent of replicating it during a match. The procedure, or a portion thereof, is practiced in a simulated environment which incorporates features predicted to be specifically encountered during the subsequent clinical procedure.

In sessions 2 & 3 of chapter 4, the prototype simulator utilised ultrasound imagery acquired from a human volunteer. Had the ultrasound imagery been acquired from a patient, about to undergo

USgABPB, it may have been possible for the clinician performing the block to rehearse elements of the procedure in advance. We have not attempted to address this problem as part of this study. It is likely that simulator fidelity would have a significant impact on the usefulness of this approach. It is also unclear if patient-specific rehearsal of UGRA would result in improved patient outcomes, were it proven to be feasible.

Conclusions

The work described here provides a comprehensive characterisation of USgABPB. We have described factors likely to determine whether the procedure is learned effectively or not. We have described a methodology to engage end-users throughout the design of novel simulation tools so as to address current training deficits. Finally we carried out a trial to establish whether simulation-based training on a prototype device transferred to the clinical setting. We believe that the ultimate goal of designing effective simulation-based training and assessment of USgPNB is closer to realisation as a result of this work. It remains to be proven if this approach will have a positive impact on procedural performance, and more importantly improve patient outcomes.

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