COMMENTARY

Using simulation for interventional radiology training

D GOULD, MB, ChB, FRCP, FRCR

Department of Radiology, Royal Liverpool University and Broadgreen NHS Trust, Prescot Street, Liverpool L7 8XP, UK

ABSTRACT. Debate on the existence of innate skills has all but evaporated in the light of evidence that it is only the hours spent in deliberate practice that correlate with even the most elite levels of expertise. A range of simple to advanced technologies stands to address some of the many challenges to effective training of 21st century, procedural medicine. Simulation could train and assess behaviours remotely from patients, in complete safety, reducing the risks of inexperienced trainees learning critical tasks in patients while contributing to certification and revalidation. Understanding the strengths and limitations of these devices, determining and improving their effectiveness and identifying their roles, as well as those of individuals and teams, represents a cornerstone of successful adoption into the interventional radiology curriculum. This requires a simulation strategy that includes standards for simulator documentation.

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Skills training

Planning and implementing complex medical interventions within a constellation of human conditions is amongst the most demanding tasks performed by man, with the notable exception of the aerospace industry. Credentialling and revalidation by statutory bodies aims to reassure patients and passengers that an appropriate level of proficiency has been attained, and is maintained, by those charged with their care and safety.

Yet, errors still abound in medicine. In 1999, the Institute of Medicine published evidence of an annual toll of 44 000 to 98 000 deaths in American hospitals owing to preventable medical errors including “failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim”, errors performing an operation, procedure or test, as well as systems errors including communication [1]. Autopsy studies confirm diagnostic error rates of 10–20%, whereas one-third of known adverse events involve errors of execution in the management of correctly diagnosed patients [2].

The safety benefits of using procedural checklists in aviation have now also been shown for surgery. Haynes et al [3] used a simple pre-operative checklist of 19 tasks (including patient identity, operation site and nature, venous access and team introductions) to promote communication and teamwork, reducing post-operative mortality by 45%. That even expert and experienced teams can benefit from such simple measures is as salutary in medicine as it is in aviation. Teamwork is one element of a practitioner’s “toolbox” of basic to advanced behaviours that include knowledge,

judgement, attitudes, professionalism and cognitive and technical skills. Various combinations of these behaviours, together with appropriate context and identified standards, form key components of the training objectives of medical curricula. The fundamental elements of even the most challenging skill sets of highly complex tasks should lie within this hierarchy of skills.

From the earliest days of medicine to the procedural complexities of today, essential technical skills have been acquired during deliberate practice in patients. This apprenticeship is expensive [4]: cases not only take longer, but require an expert mentor who provides teaching, formative feedback and vigilance for trainee errors. It has been estimated that 10 000 h of such practice are needed to attain an elite level of expertise: indeed even amongst elite operators, assessed amounts of deliberate practice are closely related to differences in performance [5]. Paradoxically, the shift patterns that result from working time directives might have compromised this educational experience, as well as patient safety, during surgical training [6, 7].

An additional challenge to the apprenticeship training of interventional radiology (IR) lies in a revolution in diagnostic imaging that has largely removed the need for purely diagnostic, invasive procedures (*e.g.* diagnostic angiography, percutaneous cholangiography) that were previously used to meet IR core skills training objectives. There is, further, an unpredictable case mix across centres, pressure for other specialties to learn IR and infrequent exposure to rare and critical events. In addition, even experienced operators must maintain skills that are rarely used in order to sustain a general IR out-of-hours rota. This limited opportunity for learning across a range of training objectives represents an outstanding opportunity for novel and emerging learning methods.

Address correspondence to: Derek Gould, MB, ChB, FRCP, FRCR, Consultant Interventional Radiologist, Department of Radiology, Royal Liverpool University and Broadgreen NHS Trust, Prescot Street, Liverpool L7 8XP. E-mail: dgould@liv.ac.uk

What is simulation?

Simulation uses a model to enable predictions to be made about some physical process, interaction or event in the real world: techniques include scenarios, fixed models, actors, animals, cadavers and computer-based virtual environments. Today's aviation safety record is predicated, in no small part, on 80 years of development of curricula that today embrace training of pilots and crew using accredited, commercial simulations that are subject to a wide range of standards [8]. The step from aviation simulation (*e.g.* Figure 1) to medicine and patient safety, therefore, seems a logical one. The comparatively recent introduction of simulation into medicine creates opportunities for trainees and teams to learn skills through deliberate practice in safety, remote from patients; assessment of proficiency can be performed by an observer or, in certain cases, by using the simulation itself. Once proficiency in prerequisite core skills is shown, mentored training of more complex tasks can commence in simulations or in patients [9].

Anatomical models can provide simple solutions to training certain core competencies, and could be more widely implemented in IR training today. To emulate catheter and guide-wire exchange *in vitro* does not require a high-fidelity (faithfulness of replication) computer simulation and can be taught by a mentor in a simple scenario on the bench. Fixed models can be inexpensive, even home made, yet highly effective: they can even be attached to an actor (a simulated or standardised patient) to provide the essential context of a real procedure [10]. More sophisticated anatomical models can, however, be considerably more costly, particularly where there is a need to vary their anatomy and "pathology". In addition, models cannot authentically replicate physiological processes (tissue deformation, flow, pulsation, respiration, and so on), and manipulations such as repeated needle puncture will ultimately lead to the model's destruction. Although anaesthetised animals naturally provide correct representation of physiology and have been widely used for skills training, they lack pathology and there are political issues that limit their use, particularly in the UK and USA.

Figure 1. Heliflight-R, aviation simulation. Acknowledgment: Dr Mark D White, Department of Engineering, University of Liverpool.

Over the past decade, computer-based simulations have developed a groundswell of interest, in part fuelled by technology developments in the games industry. The techniques used aim to generate recognisable and appropriate visual and tactile ("haptics" = touch) cues, while providing an environment wherein an operator can choose to respond with whatever action(s) he/she considers appropriate. A computer-generated three-dimensional, virtual environment (VE) replicates patient anatomy and the effects of virtual instruments, in some cases augmented by models or mannequins (augmented reality; Figure 2) [11, 12].

The VE might be patient specific, created from actual patients' imaging data. Key anatomical structures are manually or semi-automatically segmented using proprietary or novel software; for added effect, these can be touched up by a medical illustrator. Segmented anatomy is then converted into a VE based on voxels or adjoining polygons that form a mesh. Algorithms to calculate the response of tissues and instruments to stress are incorporated within the VE as a "three-dimensional database" that calculates the simulation's appearances, physical processes (collisions, deformations, instrumentation, physiological motion) and "feel" (force feedback or haptics). The feel of using an instrument, such as a guidewire, in the simulation is provided by a human-computer interface or haptics device. These hardware items can be derived from the games industry at surprisingly low cost, although high-end systems can be £10 000 or more. Financial costs aside, the computational expense of performing such complexity in real time brings challenges for computing hardware, although these will potentially be resolved through technical advances over time [13].

Many simulation techniques have a role in IR training, although computer-based simulation has a unique potential to replicate complex, real-world, medical interventions in patients. The fidelity that would need to be attained for a given simulated task might be

Figure 2. ImaGiNe-S mannequin/VR simulation: an operator uses the mannequin (on the left-hand side of the picture) to determine an access site to perform ultrasound-guided needle biopsy of a target lesion. The actual targeted biopsy is performed in an immersive, three-dimensional virtual environment (on the right-hand side of the picture). CRaIVE collaboration, www.craive.org.uk.

determined, with subject matter experts (SME), by considering the nature and content of the training objective and the real world task. For example, simulating straightforward positioning of balloons and stents in unchallenging anatomy might be acceptable using low fidelity. Yet, there are some clinical situations where high fidelity is needed to replicate the very delicate manipulations required to avoid complications (*e.g.* carotid and intragenicular vessels).

Despite these aspirations, limits are imposed on the fidelity of computer simulations by the resolution of interface hardware currently available, a dearth of data on physical properties of instruments and by the unpredictable, non-linear behaviours of human tissues. The real-world response of tissues to stress depends on hydration, disease, age and pathology; exact simulation in the face of such variability is currently impossible, although improvements can be obtained using empirical data from studies of tissues and medical instruments in the laboratory and *in vivo* [14–18].

While modelling of human tissues and physiology remain frontiers in attaining appropriate fidelity in medical simulation, similar limitations replicating air-flow and turbulence in aviation simulation have not prevented the latter from occupying a defined role in aviation training curricula [8]. Evidence for effectiveness now supports using simulation in medical curricula for anaesthesia, laparoscopic surgery, colonoscopy and life support [19–22]. Similar evidence for the best use of IR simulations is still accumulating.

Identifying effectiveness in simulations

Evaluation, or validation, of a simulation supports claims that the simulation in question can be used to train and assess skills as a component of a well-constructed curriculum. Validation explores whether the simulation is fit for the intended purpose, including whether skills acquired will transfer to procedures performed in patients (transfer of training) and whether they will be maintained over time (skills maintenance). Such effectiveness is more likely where three criteria are met: content validity, face validity and construct validity.

Content validity

Content validity is said to be present when a simulation's content (steps and behaviours that constitute the simulated task) is appropriate to the desired training objective.

For this to be the case it should be possible to authentically reproduce all correct and, indeed, incorrect steps of the target procedure; relevant cues should be recognisable and key psychomotor actions correctly replicated.

Iterative content validation is an invaluable tool during simulator development, where feedback to simulator developers acts as a basis for continual revision and improvement of content and, where appropriate, fidelity. Once content is shown to adequately mirror the steps of the real-world task, a search

for evidence of skills transfer to patients is much more likely to be fruitful. This can be evaluated within the target curriculum by randomising trainees to simulator-based training or conventional curriculum-based training (control group), followed by procedural assessments in patients.

Face validity

Face validity is when the simulation, including its instruments, imaging and any context, appears sufficiently realistic to convey a sense of "presence" to the operator.

Face validity, content validity and fidelity are key factors determining the likelihood of skills transfer. Procedure steps that are lacking in these qualities are less likely to provide correct training and assessments and, in turn, less likely to transfer these specific behaviours to procedures in patients.

Construct validity

Construct validity is present when assessments in the simulation are sufficiently robust to form the basis of judgements made about operator performance [23].

Using metrics in a simulation as a basis for major decisions, such as medical certification, constitutes a high-stakes assessment. For such meaningful formative (and, ultimately, summative) assessments, a simulation must use metrics that correctly evaluate operator behaviours during steps that are of critical importance to safe completion of the target procedure in a patient. For relevance to a curriculum it is therefore essential that critical performance steps (CPS) are first identified or ratified by SMEs in close collaboration with, and reflecting any standards set by, the Credentiaing organisation concerned. For outcomes that are reproducible and repeatable, there should be content validity for these CPS.

Arguably, the most investigated medical computer-based simulation to date has been the virtual reality (VR) Minimally Invasive Surgical Trainer (MIST-VR, Mentice, Gothenberg, Sweden) (Figure 3). Its development and content was based on a detailed task analysis of the target procedure, replicating eight key skills that were common to a number of laparoscopic tasks. Skills transfer to laparoscopic procedures in patients was shown by Seymour et al [19] and, more recently, by others [20]. Similar effectiveness of training has been shown for colonoscopy skills, with reduced pain scores in patients following simulator training compared with an apprenticeship-trained group [21].

Such validity evidence has, however, been slow to accrue for endovascular simulations. A 2006 study evaluating content in carotid, renal and iliac interventions using both the Vascular Interventional Surgical Trainer (VIST VR, Mentice, Gothenburg, Sweden) and Angio-Mentor (Simbionix Ltd, Lod, Israel; Figure 4) endovascular simulations concluded that these were suitable to train cognitive steps, which are of great importance to safe completion of complex procedural tasks. Fidelity, however, appeared as yet, insufficient to train fine motor

Figure 3. The virtual reality (VR) Minimally Invasive Surgery Trainer: MIST-VR. An operator performs specific psychomotor actions in a task-primitive environment to train laparoscopic surgery skills. Acknowledgment: Mentice, Gothenburg, Sweden.

actions and other means (*e.g.* apprenticeship in patients) were required to train these skills [24].

Using a catheter-based endovascular simulator model (VIST-VR) Hsu et al [25] measured time to perform a carotid stent procedure, along with a series of other objective measures, although time was the only significant discriminator. Although time might be a surrogate measure of technical ability, it cannot alone be a discriminator of quality. Indeed, without clearly proven content validity for CPS, or evidence for skills transfer,

such performance in a simulation has little relevance to actual procedures in patients.

Another study evaluated experts and novices using the VIST-VR simulation as a training aid for carotid artery stenting [26]. The researchers reported a significant improvement in performance of both novices and experts after a period of training for 30–60 min. Indeed, the novices rapidly achieved scores close to those of the experts, although it seems implausible that years of practical skill and knowledge can be acquired in just a few hours. Clearly, using simulations to train skills without understanding whether the content of key procedural steps is correctly replicated will lower the credentialing “bar” unless these skills are confirmed in mentored patient procedures.

The same research group went on to investigate skills transfer to patients following training of a contralateral iliac angioplasty/stent procedure using VIST-VR [27]. Transfer was shown for a number of cognitive and motor behaviours, although there were limitations of the study that included unmatched mentorship teaching (simulation-trained group only), use of an unvalidated assessment tool and limited assessment of procedure steps involving dexterity.

Another validation study of interventional vascular simulation has claimed to have demonstrated skills transfer using the VIST-VR [28]. This, however, related to skills transfer between iliac and renal tasks within the same simulation, which is of limited relevance to procedures in patients [29].

Automated, simulator-based metrics could provide valuable, IR objective assessments, although there is scant evidence of construct validity for high-stakes testing using existing commercial vascular IR simulations. Some claims of construct validity for simulator-generated assessments have used metrics based, for example, on idiosyncratic opinion (*e.g.* “catheter dragging” in the aortic arch) or high-level events (procedure/fluoroscopy time, contrast volume, end product) [25–27], although other workers dispute the relevance of such metrics [30, 31]. Observer-based assessments could overcome technical shortcomings in using computational metrics within simulations, although adopting even validated surgical assessment tools might lose relevance when applied to simulated IR tasks. Some workers have, however, shown construct validity for proficiency

Figure 4. AngioMentor simulation with virtual fluoroscopy visualisation of catheter and guidewire manipulations in a range of virtual vascular environments. Acknowledgement: Simbionix Ltd, Lod, Israel.

assessments in an endovascular simulation, using an observer-based global rating scale [32]; at the same time, there was no demonstrable construct validity for the simulation's inbuilt, objective, automated metrics. Hence, there is a pressing need to develop valid, evidence-based metrics for objective assessment of known CPS in IR simulations; this key, but unrealised, strength of virtual simulations is a fertile area for ongoing investigation [33].

When considering using simulations for assessment, it is important that construct validity is determined in the context of the target curriculum for high-stakes testing. For training purposes, limited content validity for fine motor actions in current, high-end, virtual IR simulations restricts their use for curriculum training objectives that require replication of real-world dexterity: other methods (apprenticeship in patients) must therefore be used for such training. For these reasons it seems important that credentialling organisations consider standards, such as exist within aviation [8], for medical simulations that are to be used within their credentialling programmes.

It is clear that the accumulating evidence identifies not only limitations, but also potential benefits of using existing simulation methods. Focusing on known strengths, such as training procedural sequencing, cognitive and communication skills, gross motor behaviours and teamwork within context, represent opportunities to use simulation as a component of a recognised IR curriculum [30, 34–36].

Strategies for implementing simulation into an IR curriculum

Adopting novel training methodologies and performance assessment tools into an established curriculum requires careful consideration of several factors: the curriculum's training objectives that would represent best use of simulations; the behaviours that are to be trained and assessed; the metrics to be used for performance assessments; the prerequisite skills and knowledge required; which simulations to use; and where, how and by whom this form of training should take place [37].

Which curriculum training objectives would represent best use of simulation?

Training objectives that involve high-risk IR procedures in patients, or clinical cases that are rarely encountered within prevailing case mix, represent important areas for using some form of simulation. SMEs can analyse the curriculum to identify these "insertion sites", together with their context and standards for performance, closely collaborating with the Credentialling organisation. This might typically propose [38]:

- Fundamental (entry-level) skills/tasks, where the opportunity to train is diminishing because of decreased trainee duty hours; non-invasive diagnostic

imaging; other factors, such as competing disciplines. Examples include ultrasound needle guidance and Seldinger technique.

- High-risk tasks, where the traditional apprentice model poses an unacceptable risk to patients. Examples include stent placement and retrieval of a foreign body from the heart.
- Adverse, infrequent events due to error, risk and complications that might not be evenly experienced, even at the end of a defined programme of training. Examples include removal of a misplaced coil, recognition and management of vessel rupture after percutaneous transluminal angioplasty and contrast-induced anaphylactic reaction.

What are the behaviours that are to be trained and assessed?

For relevance to a particular curriculum insertion site, a simulated task must correctly reflect that task's performance in the real world. Getting this right during simulator development, and identifying metrics, requires performance task analysis (TA). The TA is developed specifically to identify the physical and cognitive behaviours that constitute real-world performance, as well as the conditions under which the task is performed [39, 40].

TA is initiated by trained psychologists who decompose video-recorded IR procedures performed on patients by SMEs, detailing the operator's perceived cues (visual, tactile, auditory, olfactory, and so on) and actions (conscious or subconscious/automatic; gross or fine motor actions). Cues might be specific to the task (the feel of a pulse, locating a dilated calyx) or may relate to the context of that task (a patient cries out, an oximeter alarms). Cues, cognitive behaviours (decision making, attitudinal, judgemental, and so on) and detailed actions can be respectively identified, inferred or explored during interviews with SMEs. The compiled TA then forms the basis of further SME reviews to identify CPS, using a scale (e.g. Likert) to grade each procedural step for its importance and risk.

Which metrics are to be used for performance assessments?

Using metrics in a computer simulation requires a collaboration of SMEs, credentialling organisations, psychologists and computer scientists to identify appropriate, measurable events (angular, dynamic, geometric, temporal, and so on) that reflect the CPS identified above. Methods are then devised to actually detect these events during simulated tasks. Ensuing construct validity will thus, in part, be dependent on aspects of the simulator model itself.

Some steps will be impossible to measure because of specific technical issues, such as a fine motor action that lies below the level of resolution of an interface device, or where limitations in developing the virtual environment have omitted essential anatomical data. Unobserved, perceptual and cognitive steps cannot themselves be

directly measured, and assessment of these is reliant on inferences drawn from the operator's ensuing actions.

For relevance for credentialling purposes, metrics must provide fair, accountable, defensible and blinded evidence that is compatible with evidence from other, established curriculum assessment tools. At the same time, assessments must also allow for the broad range of accepted IR practice within the standards that are set by the credentialling organisations [33].

What prerequisite skills and knowledge are needed?

Is proficiency in a lower level skill set recommended before starting to learn a given training objective in a particular (validated) simulation? Is this training objective itself a component of another (higher level) task [38]?

Such information can be derived during the curriculum analysis for insertion sites. Having identified the prerequisite skills required, their presence (or absence) could be inferred from a trainee's stage of training and his or her in-training assessments, ideally using validated, objective assessment tools. This information would be particularly important before progressing to mentored procedures in patients.

Which simulation to use?

Where possible, training should use validated elements of existing simulations that adequately reflect the behaviours and conditions of intended insertion sites. Unvalidated simulations that, nonetheless, have preliminary evidence of suitable content represent an opportunity to perform formal validation studies within the overarching curriculum. Some training objectives might, however, require development and validation of appropriate context, teamworking elements (e.g. Figure 5), new virtual environments, novel interface devices or completely new simulations.

Purchasing or hiring a specific simulation to fit predetermined insertion sites should be informed by a tendering process led by credentialling and subspecialty training organisations. Information requested about the development history of a simulation should include the original, intended target curriculum; intended insertion sites within that curriculum; minimum prerequisite skill sets; task analysis and metrics data used in development; contributing SME advisors and their credentialling organisations; evidence (published and otherwise) from any validation studies performed; identification of content that is correct and, indeed, any elements that are known to not be correctly replicated; specific relevant technical details such as hardware specification; the available virtual environment data sets; and the resolution and fidelity of visual and haptics interfaces. Other considerations might be financial (e.g. lease hire), concessions (e.g. reduced costs in association with planned validation programmes) and bulk purchase (e.g. to supply a nationwide curriculum).

Where, how, by whom?

Formal training, using validated simulations, should comprise a mentorship within a curriculum for acquiring knowledge, skills and professionalism [38]. Where training is to use expensive models and/or computed-based simulations, centralisation at a few accessible sites (e.g. close to a rail hub) might prove cost-effective. Less expensive and web-based solutions might be more widely dispersed.

The methodologies to be used will require consideration of several factors:

- creating the conditions under which the task is normally performed;
- facilitating training of entire procedural teams;
- developing, by training and education boards, new case and event scenarios;
- creating opportunities for experts to learn new, complex tasks and maintain old skills (revalidation); and
- introducing simulation into certification.

Figure 5. A contextualised simulation of interventional radiology encompassing key technical elements of an interventional theatre. Picture copyright: OR-Zone, Gothenburg, Sweden.

Trainers will need to understand the background to the training tools they will be using, including their strengths and limitations, and would require a short course to “train the trainers”. This could include the implications of an “apprenticeship without patients”: their continued role as mentor; the opportunities presented in the “safe” environment and the limitations; what can and cannot be trained in a particular simulation; the importance of training professionalism; and the cognitive, technical and communication skills that occur outside the simulation.

Trainees will also need to understand the background to the learning they will undergo, its strengths and limitations. Their future progression might well, in part, be determined by this technology.

What this means for IR, now and in the future

Current simulations, including models and virtual environments, are useful to train and assess procedural steps and sequencing, many gross motor skills, use of instruments and team training, such as the management of critical events [34]. Such experience is available, with mentors, in the simulator galleries of the annual meeting of the Cardiovascular and Interventional Society of Europe, although the more challenging task remains: actual adoption into an IR curriculum.

There remains a technology gap predicated on the level of fidelity that is currently achievable for replicating and detecting fine motor actions and related subtle visual and haptics cues. Solving these challenges will considerably enhance the potential of computer simulation to train dexterity, and the discriminating capability of procedural assessments of fine motor actions. Notwithstanding these technological limitations, simulation represents an opportunity to train many other aspects of interventional medicine today. Adopting protocols, or standards, such as have already been proposed [34, 37, 38] could allow best use of a particular simulation technology or method to be identified, introducing, developing, contextualising and validating simulations as a part of the existing IR curriculum.

Further, evidence-based development of content, metrics and fidelity will allow IR simulations to be chosen, or specifically developed, to fit a wide range of curriculum insertion sites, predicting and measuring procedural outcomes with sufficient accuracy to:

- enable novice operators to practice in a range of case scenarios, remote from patients;
- make up “lost hours” in the working time directive limited week;
- deliberately create and experience errors and their outcomes in complete safety;
- use metrics for objective assessment of relevant actions, providing validated formative feedback, and consistent proficiency standards;
- train to criteria rather than for a time period;
- enable experts to refresh/maintain old skills and learn new ones;
- provide evidence for Credentialling and revalidation;
- train the entire procedural team, with cross-site, web-based training experience;

- practise challenging procedures in a real patient’s imaging data set (mission rehearsal), predicting outcomes before performing the procedure for real; and
- test new medical devices “*in silico*” in a range of clinical case scenarios.

There seems little doubt as to the enormous benefit that simulations are poised to bring to interventional medicine. With emerging evidence for both their strengths and limitations, the time is right for measured introduction into an IR curriculum, alongside other training methods that remain essential to comprehensive learning. This includes mentored training in patients within an interventional apprenticeship, a process that is unlikely to ever be entirely replaced by simulation [41]. Indeed, simulation is not a substitute for curriculum-based training, or for participating in the actual care of real patients — it should be used in support of both [34–42].

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