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The effect of a proficiency-based progression simulation programme on clinical handover (ISBAR) performance compared to standard training. A randomised controlled trial

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ABSTRACT

Objective

To determine the effectiveness of a proficiency-based progression training approach to clinical handover (ISBAR) compared to standard training.

Design

A randomised controlled trial with three parallel arms.

Setting

A university setting in Ireland

Participants

45 third year nursing and 45 final year medical undergraduates scheduled to undertake interdisciplinary National Early Warning Score (NEWS) training over a three day period in September 2016.

Interventions

Participants were prospectively randomised to one of three groups before undertaking a performance assessment of an ISBAR communication relevant to a deteriorating patient in a high fidelity

simulation facility. The groups were as follows (i) HSE; the national Health Service Executive NEWS e-learning programme only, (ii) S; the national e-learning programme plus standard simulation, and (iii) PBP; the national e-learning programme plus proficiency-based progression simulation.

Main outcome measures

The primary outcome was the proportion in each group reaching a pre-defined proficiency benchmark comprising a series of pre-defined steps, errors and critical errors during the performance of a standardised, high fidelity simulation assessment case which was recorded and independently scored by two independent blinded assessors.

Results

6.9% (2/29) HSE group and 13% (3/23) of the S group demonstrated proficiency in comparison to 60% (15/25) of PBP group. The difference between the HSE and the S group was not statistically significant (Chi-Square = 0.55, 99%, CI =0.63-0.66, p= 0.63) but was significant for the difference between PBP group and the HSE group (Chi-Square = 22.25, CI=0.00-0.00, p < 0.000) and between the S group and the PBP group (Chi-Square = 11.04, CI=0.00-0.00, p = 0.001).

Conclusions

Proficiency-based progression is a more effective way to teach ISBAR communication than e-learning either alone or in combination with standard simulation.

Trial Registration

ClinicalTrials.gov Identifier: NCT02886754

STRENGTHS AND LIMITATIONS OF THE STUDY

- This is the first randomised controlled trial of a proficiency-based progression educational intervention for a non-technical skill (handover).
- The peformance outcomes are robust objective measurements which do not rely on subjective assessments or learner perceptions.
- Limitations are the single centre design and the future need for the impact of proficiency-based progression programmes on patient outcomes

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no

support from any organisation for the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical Approval: Institutional review board approval was obtained. Informed written consent was obtained from all participants.

Transparency: The lead author affirms that the manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects have been omitted; and that any discrepancies from the study as planned have been explained.

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Data sharing: Consent was not obtained for data sharing but the presented data are anonymised and risk of identification is low.

Introduction

Good clinical communication between health care workers is paramount to patient safety. Communication failures are a significant source of medical error and preventable adverse events equal if not greater than errors due lack of technical skill [1, 2, 3]. The need for high quality structured communication has become urgent as organisations and medical therapies become more complex, patients have a greater degree of comorbidity and physicians move towards shift patterns of work.

Communication in relation to the acutely deteriorating patient demands the most efficient, concise and accurate flow of information

amongst healthcare workers of different disciplines for the best outcome to be achieved. Many healthcare services and providers have adopted the structured communication tool ISBAR (Identify, Situation, Background, Assessment, Recommendation) for this purpose although several other models exist[4]. The widespread desire to use communication tools in clinical practice mandates the need for a valid, reliable education and outcomes-based training programme to ensure a proficient workforce.

Early Warning Scores facilitate early detection of deterioration by categorising a patient's severity of illness and prompting escalation of care at specific trigger points utilising a structured communication tool such as ISBAR. This enables a more timely response using a common language [5]. Ireland was one of the first countries to agree and implement a standardised Early Warning Score (The National Early Warning Score, NEWS) across the entire acute hospital sector. NEWS utilises the ISBAR tool as the recommended structured communication tool for the acutely deteriorating patient [5, 6]. The Health Service Executive (HSE) in Ireland recommends the National Early Warning Score (NEWS) e-learning education programme as part of a mandatory interdisciplinary education programme for all healthcare professionals working in acute services. The programme

teaches ISBAR as the recommended tool to escalate care in the context of NEWS and the acutely deteriorating patient.

Proficiency-based progression (PBP) training is a form of outcome based training that involves training individuals to a "proficiency benchmark." The benchmark is set as the mean performance of clinicians who undertake the procedure regularly in clinical practice. It has been shown to improve the performance of individuals undertaking technical procedures (7, 8 ,9, 10, 11, 12, 13). This approach has not previously been applied to simulation based training for non-technical skills such as communication.

Methods

Objective

The primary aim of the study was to determine the effectiveness on ISBAR performance of a proficiency-based progression (PBP) simulation programme when compared with the same simulation programme without the proficiency requirement and compared with the national e-learning programme alone.

Study design

A randomised controlled trial with three parallel arms.

Participants

Eligible participants were 109 third year nursing and 201 final year medical students who were scheduled to undertake interdisciplinary National Early Warning Score training in September 2016 as part of their undergraduate curriculum. This comprised the entire undergraduate nursing and medical classes except for 31 medical students who were scheduled to undertake this training at a later time in the curriculum (figure 1).

Interventions

All 3rd year nursing and final year medical students were emailed prior to training and instructed to undertake the National Early Warning Score e-learning programme. Written informed consent was obtained from all participants. On the day of training, participants were required to submit a certificate of successful completion of the e-learning programme. A 15-minute lecture on the ISBAR tool was delivered before participants undertook training as per their allocated groups. Students were not notified as to which study group they were allocated. The study flow is outlined in figure 2.

The three training groups were as follows:

(i) e-learning only group (HSE). Participants in this group proceeded directly to the high fidelity suite for performance

assessment. After outcome assessment was complete, participants undertook simulation training similar to the S group in order to ensure that all students were afforded the same training opportunity.

(ii) e-learning plus standard simulation group (S). Participants worked in pairs of a medical student and nursing student. If a participant did not have a partner, then a non-study peer student was asked to pair with that individual for the purposes of training. Data from the non-study student was not included in the analysis.

Training consisted of a series of simulated phone calls using four standardised paper cases for each discipline. Case materials included case notes, NEWS charts, and a blank ISBAR template indicating the categories and type of information that should be communicated. Each scenario had a deteriorating patient event that necessitated an ISBAR telephone communication. Participants alternated between making and receiving simulated phone calls. A standardised script was given to the recipient. Two facilitators conducted the simulation training. Both facilitators were experienced clinicians and educators who had previously undergone the "Train the Trainer NEWS programme" and regularly facilitate NEWS training and healthcare simulation. The facilitators offered support and feedback in line with standard NEWS training by listening to simulated phone calls and

offering feedback on the ISBAR framework and by answering questions as they arose. Participants were required to work through all four cases with their partner. Towards the end of the training session the participants presented to the facilitator to repeat a simulated phone call for either case 3 or 4. The training session was 3.5 hours in duration, participants were required to stay until the end of the training regardless of progress. If an individual had completed all the cases, they were asked to assist by continuing to be the recipient of phone calls for their partner or by continuing to practice by repeating the cases if required.

(iii) e-learning plus proficiency-based progression simulation group (PBP). Participants underwent a training programme of the same structure, duration, content and facilitator: student ratio as the S group. The same two facilitators facilitated both the S and PBP training. However in the PBP group, partners scored each other's phone calls during training against a series of pre-defined metrics (quantified as steps, errors and critical errors for each case) on a score sheet to ascertain if the proficiency benchmark for that case was reached. Partners shared the results of the metrics and proficiency scores with each other as feedback at the end of each simulated phone call. If proficiency was not achieved the case was

repeated before progressing to the next case. Participants were required to reach proficiency on all four cases with their partner before performing case 3 or 4 with the facilitator and demonstrating proficiency again. If proficiency was not achieved with the facilitator then the participant returned to repeat cases with their partner and present for reassessment to the facilitator until proficiency was demonstrated.

Outcomes

The primary outcome was the ability to reach the proficiency benchmark on the standardised high-fidelity simulation assessment case. The secondary outcomes were the number of successfully completed steps, errors and critical errors performed by each group.

Performance metrics were developed for the training cases and for the high fidelity simulation assessment case as part of a pilot study in the previous year. Each case presented a different but commonly encountered clinical scenario of an acutely deteriorating patient. The metrics were derived for each of the training and assessment cases according to the 5 components of the ISBAR tool were specific for each case.

The performance metrics were validated through a modified Delphi expert panel consisting of 9 senior nurses and 8 medical staff who regularly facilitate NEWS/ISBAR communication training. Delphi panel members reviewed the performance metric for each of the simulation cases and the high fidelity performance outcome case and metric units were included, excluded or modified by consensus. Each metric unit was then classified as a step, error or critical error by consensus. The majority of metrics were common to both medicine and nursing. The number of metrics per case ranged from 24-26.

The proficiency benchmark was set as the mean performance of qualified personnel from the respective disciplines on each case. Nine nursing and five medically qualified practitioners (who regularly escalate care in the acute healthcare setting and with a mean years of experience=3 years) underwent the high fidelity simulation case. The proficiency benchmark for the assessment case was set as the mean performance for each discipline as scored by two independent assessors.

Digital recordings of each participant's performance of the standardised case in the high fidelity assessment suite were reviewed and scored by two independent assessors (experienced acute care nurses) using the pre-defined metrics and proficiency

benchmark. The assessors underwent training on scoring the material using 10 recordings of the same case obtained from non-study participants. An inter-rater reliability of > 85% was achieved prior to commencing scoring study material. The assessors were not part of the investigator group, were blinded to the study group allocations and had no prior knowledge of any of the participants.

Sample size

Power calculation: the numbers needed in each arm was based on transfer of training (ToT) observed in previous studies of proficiency based progression simulation in surgery and cardiology, where ToT rates of 42-69% have been observed [7, 8, 9, 10, 11, 12]. In a pilot for the current study on 133 medical and nursing students in the previous academic year, the TOT was observed to be 16% for the proficiency based training group and 3% for the simulation. The pilot however was constrained by the existing curriculum, which only allowed for 90 minutes training time once the e-learning programme was complete. In the current study a longer training time (3.5 hours) and a more rigorous structure was facilitated. We therefore expected to observe an increase in ToT to >40% based on a 3 fold increase in objective, blind, assessment of proficiency when compared to the

control group (i.e. 9% for the HSE group vs. 49% for the PBP group). A two –tailed test, with n=20 trainees in each group with an alpha of 5% (which corresponds to a 95% confidence interval) would yield a statistical power of 89.9. Therefore 30 (15 medical and 15 nursing students) were randomised to each group to allow for drop out rates observed in the pilot due to students rescheduling to non-study training dates as a result of conflicting demands of their curriculum.

Randomisation and blinding

A de-identified list of nursing and medical student numbers was obtained from the School of Nursing and Midwifery and the School of Medicine. The lists comprised 109 third year nursing and 201 final year medical students scheduled to complete an interdisciplinary ISBAR training programme as part of the University undergraduate curriculum in September 2016. Randomisation was stratified by discipline and was conducted using a computer-generated programme (GraphPad) as a two-stage process (figure 1).

Firstly n=45 nursing and n=45 medical students were randomly selected using the programme. Secondly, participants were randomly allocated by discipline using the same computer programme to one of the three training groups: HSE, S, and PBP. Subjects were excluded from the study if: (i) a certificate of successful completion (within the

previous 4 weeks) of the National Early Warning Score (NEWS) e-learning education programme was not presented on the day of training, (ii) lack of consent.

Two independent assessors who undertook scoring of performance for the assessment case were blinded to student allocations. The assessors had no prior knowledge of the students. The participants were not informed of the training group to which they were allocated.

Statistical analysis

Statistical Analysis was performed with SPSS 22 (Armonk, New York). The Kruskal-Wallis test was used to determine if there was a statistical difference between groups in relation to the primary end point (the numbers reaching proficiency) and the secondary end points (the number of completed steps, errors and critical errors). The relationship of the three training programmes on proficiency was explored using logistic regression analysis.

Patient and Public Involvement

Patients were not involved in the design or conduct of the study.

Results

Baseline characteristics with respect to age, gender, discipline, nationality and first language of the participants in each group are

shown in table 1. Figure 3 shows percentages of participants in each group who demonstrated the proficiency benchmark following assessment in the high fidelity simulation suite. At the end of training, 6.9% (2/29) of the e-learning only (HSE) group and 13 % (3/23) of the standard simulation (S) group demonstrated proficiency. In comparison 60% (15/25) of proficiency-based progression simulation (PBP) group were proficient. The difference between the HSE and the S group was not statistically significant (Chi-Square = 0.55, 99%, CI =0.63-0.66, p= 0.63) but was significant for the difference between PBP Group and the HSE Group (Chi-Square = 22.25, CI=0.00-0.00, p < 0.000) and between the S group and the PBP group (Chi-Square = 11.04, CI=0.00-0.00, p = 0.001).

On logistic regression analysis (figure 4) it was found that in comparison to the HSE group, the S group were 2 times as likely to demonstrate proficiency, whereas the PBP group were more than 20 times as likely i.e. the difference between HSE and S groups was not statistically different (Ext (B) =2.04, 95% CI=0.31-13.28, p=0.46) but was statistically significant for the difference between the PBP and HSE groups (Ext (B) =20.25, 95% CI=3.91-105, p<0.000).

The PBP group completed significantly more steps, mean 8.5 (1.7) than either the HSE, mean 5.8 (1.6), p<0.000 or S, mean 6.3 (2.1), p<0.000 group. Similarly, combined errors and critical errors were significantly less in the PBP, mean 3.7 (1.6) than the HSE, mean 5.9 (2.1), p<0.000 or S, mean 5.2 (1.5), p<0.01 group. Inter-rater reliability of the two assessors was 97%.

Discussion

Our results shows that addition of a proficiency-based progression simulation programme to an e-learning module can deliver a superior set of skills for ISBAR communication than an e-learning module either alone or in combination with standard simulation. Furthermore this benefit is seen with the same resources i.e. materials, timeframe, and facilitators as standard simulation. The Irish health service like its international counterparts has prioritised clinical communication as a key part of the patient safety agenda [5, 6, 14, 15, 16]. Clinical communication is now viewed as an essential skill and training is recommended as mandatory for all health and social care professionals [6]. All participants were required to produce a recent certificate of successful completion of the e-learning programme but only 6.9% of the group who undertook the e-learning

module demonstrated the proficiency benchmark. The addition of standard simulation did not significantly improve performance with only 13% of the S group reaching the benchmark. It could be argued that exposure to metrics-based scoring in the practice cases resulted in better performance in the assessment case for the PBP group. However this is precisely the desired effect i.e. that trainees know what skills need to be achieved, practice to achieve them to an objective pre-defined standard and transfer that training to a dynamic scenario. The S and PBP groups differed in only two respects: (i) practice was "repeated" in the S cohort as opposed to "deliberate" in PBP cohort i.e. focused on pre-defined metrics and (ii) the PBP group was required to reach proficiency benchmarks to progress through simulation cases whereas the S group were not. [17]. Our results demonstrate that proficiency-based training can achieve skill acquisition rates of the order of 60%, similar to those seen with technical skills using this approach. In a study of similar experimental design, Angelo et al found that there were 56% fewer intraoperative errors and 69% fewer critical errors when compared to traditional training [8]. To our knowledge our study is the first randomised trial of proficiency-based progression training of a non-technical skill.

The main strength of the study is the use of robust methodology to determine the effectiveness of an educational intervention on objectively assessed performance outcomes. The study combines the rigour of a randomised controlled trial with that of an outcomes based- training approach (proficiency-based progression) to clinical handover. A significant body of evidence already exists in relation to the use of proficiency-based progression for technical skill acquisition [7, 8, 9, 10, 11, 12, 13]. Our results support the use of proficiency-based progression training for communication skills also. Weaknesses of the study include the single centre design and the application to the undergraduate population only although the training programme is designed for use by qualified nurses and doctors also.

The study was also limited by the restriction on training time. The duration of simulation training was extended to 3.5 hours from the initial pilot (1.5 hours), but was still restricted by the existing undergraduate curriculum rather than that which would ideally be required to train a fundamental skill. Furthermore skills consolidation is an important part of the learning process particularly for new skills [18]. In the study by Angelo et al. [8] trainees had a weekend in which to acquire, refine and consolidate their skills

before their proficiency assessment at the end of training. Another difficulty, which may have impinged on the effectiveness of training, was the disparity in fidelity between the paper-based training environment and the assessment undertaken in the high fidelity simulation environment. This disparity is challenging for those with limited clinical experience such as the undergraduate population. Van Sickle et al [9] and Gallagher et al [10] have commented on the detrimental impact that this disparity can have on proficiency demonstration by trainees.

It is now widely recognised that clinical communication skills underpin patient safety. Implementation of a training programme in relation to clinical handover has already been shown to reduce medical error and preventable adverse events [19]. There is a need for valid, reliable, cost efficient clinical handover training programmes to address this need and the impact on patient as well as healthcare provider outcomes.

Conclusion

Proficiency-based progression is a more effective way to teach ISBAR communication than e-learning either alone or in combination with standard simulation.

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Table 1. Demographic characteristics of the three study groups, HSE, S, PBP.

	National e-learning programme (HSE)	National e-learning programme plus, standard simulation training (S)	National e-learning programme plus proficiency based progression simulation training (PBP)	Total
	n=30	n=30	n=30	n=90
Age Group				
18-23 years (%)	21 (70.0%)	19 (63.3%)	20 (66.7%)	60 (66.7%)
24-29 years (%)	7 (23.3%)	8 (26.7%)	9 (30.0%)	24 (26.7%)
>30 years (%)	2 (6.7%)	3 (10.0%)	1 (3.3%)	6 (6.7%)
Gender				
Male (%)	6 (20.0%)	5 (16.7%)	6 (20.0%)	17 (18.9%)
Female (%)	24 (80.0%)	22 (83.3%)	24 (80.0%)	73 (81.1%)
Discipline				
Nursing (%)	15 (50.0%)	15 (50.0%)	15 (50.0%)	45 (50.0%)
Medicine (%)	15 (50.0%)	15 (50.0%)	15 (50.0%)	45 (50.0%)
Nationality				
Irish (%)	22 (73.3%)	24 (80.0%)	21 (70.0%)	67 (74.4%)
Non-Irish (%)	8 (26.7%)	6 (20.0%)	9 (30.0%)	23 (25.6%)
First Language				
English (%)	25 (83.3%)	22 (73.3%)	19 (63.3%)	66 (73.3%)
Other (%)	5 (16.7%)	4 (13.3%)	7 (23.3%)	16 (17.8%)
Not available (%)	-	4 (13.3%)	4 (13.3%)	8 (8.9%)

%= % within research group

Figure legends

Figure 1. Consort diagram outlining selection, allocation and follow up of undergraduate medical and nursing participants in a study

comparing the effect of e-learning, standard and proficiency-based progression simulation training for ISBAR performance.

Figure 2. Outline of experimental design and study flow indicating training interventions and assessment of the three study training groups of undergraduate medical and nursing participants HSE, S and PBP.

Figure 3. The percentages reaching the proficiency benchmark at the end of training of the three study training groups of undergraduate medical and nursing participants HSE, S and PBP.

Figure 4. Logistic regression analysis for the relative differences between the three study training groups of undergraduate medical and nursing participants HSE, S and PBP.

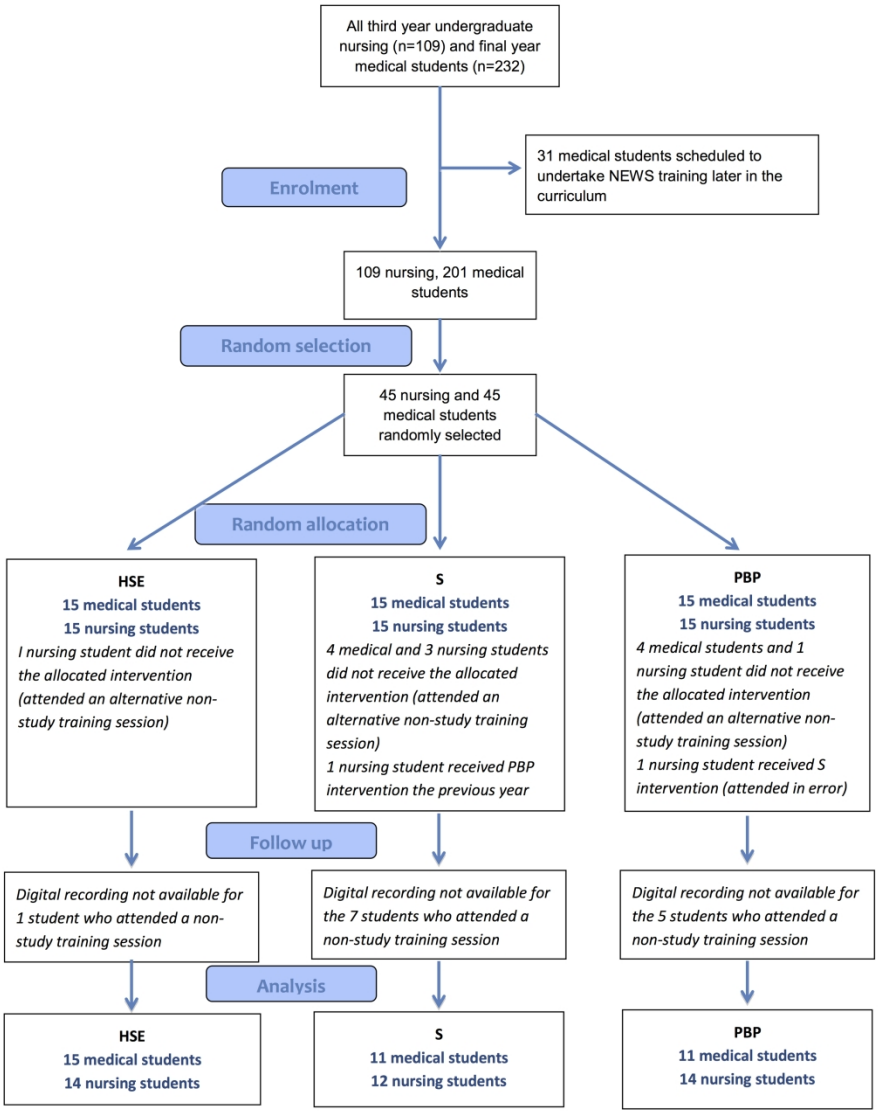

Figure 1. Consort diagram outlining selection, allocation and follow up of undergraduate medical and nursing participants in a study comparing the effect of e-learning, standard and proficiency-based progression simulation training for ISBAR performance.

279x361mm (300 x 300 DPI)

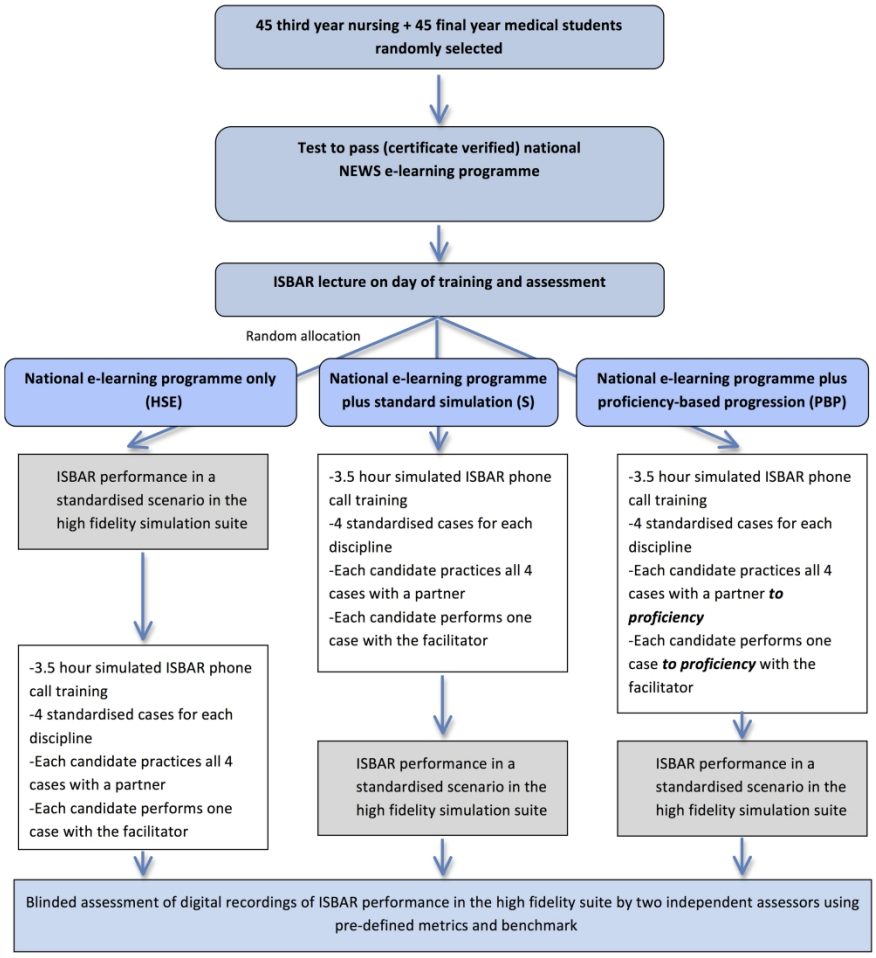

Figure 2. Outline of experimental design and study flow indicating training interventions and assessment of the three study training groups of undergraduate medical and nursing participants HSE, S and PBP.

279x361mm (300 x 300 DPI)

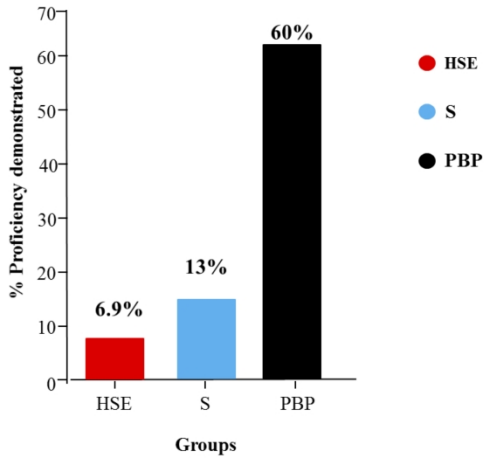

Figure 3. The percentages reaching the proficiency benchmark at the end of training of the three study training groups of undergraduate medical and nursing participants HSE, S and PBP.

296x419mm (300 x 300 DPI)

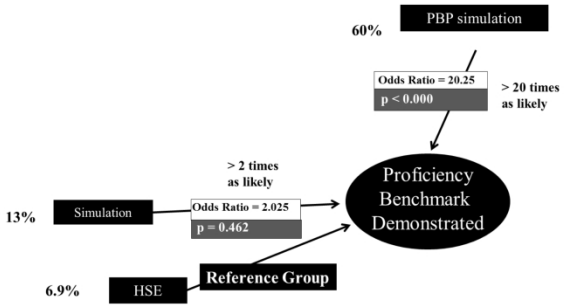

Figure 4. Logistic regression analysis for the relative differences between the three study training groups of undergraduate medical and nursing participants HSE, S and PBP.

296x419mm (300 x 300 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8/9/10/11 Figure 2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11 and 5 protocol
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	13
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	14
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	14
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	14
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	2/3 protocol
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	14, 15

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	8/9/10/11
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	15,16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	15,16
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15/16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
Other information			
Registration	23	Registration number and name of trial registry	ClinicalTrials.govNCT02886754
Protocol	24	Where the full trial protocol can be accessed, if available	Attached,Clinical trials.gov,

			and attached
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	none

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

The effect of a proficiency-based progression simulation programme on clinical communication for the deteriorating patient: A randomised controlled trial.

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The effect of a proficiency-based progression simulation programme on clinical communication for the deteriorating patient: A randomised controlled trial.

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The effect of a proficiency-based progression simulation programme on clinical communication for the deteriorating patient: A randomised controlled trial.

ABSTRACT

Objective

To determine the effectiveness of a proficiency-based progression training approach to clinical communication in the context of a clinically deteriorating patient.

Design

A randomised controlled trial with three parallel arms.

Setting

A university setting in Ireland

Participants

45 third year nursing and 45 final year medical undergraduates scheduled to undertake interdisciplinary National Early Warning Score (NEWS) training over a three day period in September 2016.

Interventions

Participants were prospectively randomised to one of three groups before undertaking a performance assessment of the ISBAR communication tool (Identification, Situation, Background,

Assessment, Recommendation) relevant to a deteriorating patient in a high fidelity simulation facility. The groups were as follows (i) E; the Irish Health Service national NEWS e-learning programme only, (ii) E+S; the national e-learning programme plus standard simulation, and (iii) E+PBP; the national e-learning programme plus proficiency-based progression simulation.

Main outcome measures

The primary outcome was the proportion in each group reaching a pre-defined proficiency benchmark comprising a series of pre-defined steps, errors and critical errors during the performance of a standardised, high fidelity simulation assessment case which was recorded and independently scored by two independent blinded assessors.

Results

6.9% (2/29) of the E group and 13% (3/23) of the E+S group demonstrated proficiency in comparison to 60% (15/25) of the E+PBP group. The difference between the E and the E+S groups was not statistically significant (Chi-Square = 0.55, 99%, CI =0.63-0.66, p= 0.63) but was significant for the difference between the E and the E +PBP groups (Chi-Square = 22.25, CI=0.00-0.00, p < 0.000) and

between the E+S and the E+PBP groups (Chi-Square = 11.04, CI=0.00-0.00, p = 0.001).

Conclusions

Proficiency-based progression is a more effective way to teach clinical communication in the context of the deteriorating patient than e-learning either alone or in combination with standard simulation.

Trial Registration

ClinicalTrials.gov Identifier: NCT02886754

STRENGTHS AND LIMITATIONS OF THE STUDY

- This is the first randomised controlled trial of a proficiency-based progression educational intervention for a non-technical skill.
- The peformance outcomes are robust objective measurements which do not rely on subjective assessments or learner perceptions.
- Limitations are the single centre design and the future need for the impact of proficiency-based progression programmes on patient outcomes.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical Approval: Institutional review board approval was obtained. Informed written consent was obtained from all participants.

Transparency: The lead author affirms that the manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects have been omitted; and that any discrepancies from the study as planned have been explained.

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All authors listed below met ICMJE criteria for contributorship as outlined below.

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Data Sharing: Deidentified individual participant data that underlie the results published in this article as well as study protocol, statistical analysis plan and analytical code will be made available on request beginning three months and ending 5 years after publication to researchers who provide a methodologically sound proposal. Please direct requests to the corresponding author. Data accessors will need to sign a data access agreement. The data from the pilot

study and from this study in relation to learner perceptions is undergoing analysis and will be available following publication.

Introduction

Simulation-based training is being increasingly deployed for both technical and non-technical skill acquisition in healthcare with the aim of reducing medical error and patient harm. There is a need for an evidence-based approach to such training to ensure that the resources utilised can reliably deliver a quantifiable improved skill set rather than just an enhanced educational experience. Proficiency-based progression (PBP) training is a form of outcomes-based training that involves training individuals to a "proficiency benchmark." Trainees undertake deliberate (rather than repeated) practice to demonstrate a pre-defined set of metrics. The proficiency benchmark is set as the mean performance of clinicians who undertake the procedure regularly in clinical practice. It has been shown to improve the performance of individuals undertaking technical procedures [1, 2, 3, 4, 5, 6, 7]. Metrics are operationally defined to facilitate objective scoring. For example in the study by Cates et al demonstrating improved performance of carotid angiography, pre-defined metric errors include "number of diagnostic catheters used

to obtain diagnostic pictures" and "catheter advancing without a guide-wire in front of it"[6]. Despite these results, PBP methodology has not previously been applied to simulation-based training for non-technical skills yet communication failures are a significant source of medical error and preventable adverse events equal if not greater than errors due to lack of technical skill [8, 9, 10]. Escalation of care for an acutely deteriorating patient demands the most efficient, concise and accurate flow of information amongst healthcare workers of different disciplines for the best outcome to be achieved.

Early Warning Scores facilitate early detection of deterioration by categorising a patient's severity of illness and prompting escalation of care at specific trigger points utilising a structured communication tool such as ISBAR (Identification, Situation, Background, Assessment, Recommendation). This enables a more timely response using a common language [11]. Ireland was one of the first countries to agree and implement a standardised Early Warning Score (The National Early Warning Score, NEWS) across the entire acute hospital sector. NEWS utilises the ISBAR tool as the recommended structured communication tool for the acutely deteriorating patient [12, 13]. The National Early Warning Score (NEWS) e-learning education programme is recommended as the national interdisciplinary

education programme for all healthcare professionals working in acute services. The programme teaches ISBAR as the standardised tool to escalate care in the context of the acutely deteriorating patient.

The primary aim of this study was to determine if the addition of a proficiency-based progression simulation training programme to the national NEWS e-learning module results in better performance of clinical communication of a deteriorating patient than either the e-learning module alone or in combination with standard simulation.

Methods

Study design

A randomised controlled trial with three parallel arms.

Participants

Eligible participants were 109 third year nursing and 201 final year medical students who were scheduled to undertake interdisciplinary National Early Warning Score training in September 2016 as part of their undergraduate curriculum. This comprised the entire undergraduate nursing and medical classes except for 31 medical students who were scheduled to undertake this training at a later time in the curriculum (figure 1).

Interventions

All 3rd year nursing and final year medical students were emailed prior to training and instructed to undertake the National Early Warning Score e-learning programme. Written informed consent was obtained from all participants. On the day of training, participants were required to submit a certificate of successful completion of the e-learning programme. A 15-minute lecture on the ISBAR tool was delivered before participants undertook training as per their allocated groups. Students were not notified as to which study group they were allocated. The study flow is outlined in figure 2.

The three training groups were as follows:

(i) e-learning only group (E). Participants in this group proceeded immediately following the 15-minute lecture to the high fidelity suite for performance assessment. After outcome assessment was complete, participants undertook simulation training similar to the E+S group as outlined below in order to ensure that all students were afforded the same training opportunity from a curriculum perspective.

(ii) e-learning plus standard simulation group (E+S). Participants worked in pairs of a medical student and nursing student. If a

participant did not have a partner, then a non-study peer student was asked to pair with that individual for the purposes of training. Data from the non-study student was not included in the analysis.

Training consisted of a series of simulated phone calls using four standardised paper cases for each discipline. Case materials included case notes, NEWS charts, and a blank ISBAR template indicating the categories and type of information that should be communicated. Each scenario had a deteriorating patient event that necessitated an ISBAR telephone communication. Participants alternated between making and receiving simulated phone calls. A standardised script was given to the recipient. Two facilitators conducted the simulation training. Both facilitators were experienced clinicians and educators who had previously undergone the "Train the Trainer NEWS programme" and regularly facilitate NEWS training and healthcare simulation. The facilitators offered support and feedback in line with standard NEWS training by listening to simulated phone calls and offering feedback on the ISBAR framework and by answering questions as they arose. Participants were required to work through all four cases with their partner. Towards the end of the training session the participants presented to the facilitator to repeat a simulated phone call for either case 3 or 4. The training session was

3.5 hours in duration, participants were required to stay until the end of the training regardless of progress. If an individual had completed all the cases, they were asked to assist by continuing to be the recipient of phone calls for their partner or by continuing to practice by repeating the cases if required.

(iii) e-learning plus proficiency-based progression simulation group (E+PBP). Participants underwent a training programme of the same structure, duration (3.5 hours), content and facilitator: student ratio as the E+S group. The same two facilitators facilitated both the E+S and E+PBP training. However in the E+PBP group, partners scored each other's phone calls during training against a series of pre-defined metrics (quantified as steps, errors and critical errors for each case) on a score sheet to ascertain if the proficiency benchmark for that case was reached. Partners shared the results of the metrics and proficiency scores with each other as feedback at the end of each simulated phone call. If proficiency was not achieved the case was repeated before progressing to the next case. Participants were required to reach proficiency on all four cases with their partner before performing case 3 or 4 with the facilitator and demonstrating proficiency again. If proficiency was not achieved with the facilitator then the participant returned to repeat cases with their

partner and present for reassessment to the facilitator until proficiency was demonstrated. The training session was 3.5 hours in duration, participants were required to stay until the end of the training regardless of progress. If an individual had completed all the cases, they were asked to assist by continuing to be the recipient of phone calls for their partner or by continuing to practice by repeating the cases if required.

Outcomes

The primary outcome was the ability to reach the proficiency benchmark on the standardised high-fidelity simulation assessment case. The secondary outcomes were the number of successfully completed steps, errors and critical errors performed by each group.

Performance metrics were developed for the training cases and for the high fidelity simulation assessment case as part of a pilot study in the previous year. Each case presented a different but commonly encountered clinical scenario of an acutely deteriorating patient. As an example, the outline of the nursing component of the high fidelity simulation assessment case is shown in figure 3.

The metrics were derived for each of the training and assessment cases according to the 5 components of the ISBAR tool and were specific to each case.

The performance metrics were validated through a modified Delphi expert panel consisting of 9 senior nurses and 8 medical staff who regularly facilitate NEWS/ISBAR communication training. Delphi panel members reviewed the performance metric for each of the simulation cases and the high fidelity performance outcome case and metric units were included, excluded or modified by consensus. Each metric unit was then classified as a step, error or critical error by consensus. The majority of metrics were common to both medicine and nursing. The number of metrics per case ranged from 24-26.

The proficiency benchmark was set as the mean performance of qualified personnel from the respective disciplines on each case. Nine nursing and five medically qualified practitioners (who regularly escalate care in the acute healthcare setting and with a mean years of experience=3 years) underwent the high fidelity simulation case. The proficiency benchmark for the assessment case was set as the mean performance for each discipline as scored by two independent assessors using the pre-defined metrics. An extract from the metric

scoring sheet and proficiency benchmark for the high fidelity simulation assessment case is shown in figure 4.

Digital recordings of each participant's performance of the standardised case in the high fidelity assessment suite were reviewed and scored by two independent assessors (experienced acute care nurses) using the pre-defined metrics and proficiency benchmark.

The assessors underwent training on scoring the material using 10 recordings of the same case obtained from non-study participants. Assessment of the digital recordings was undertaken within 2 months of study participation. An inter-rater reliability of > 85% was achieved prior to commencing scoring study material. The assessors were not part of the investigator group, were blinded to the study group allocations and had no prior knowledge of any of the participants.

Sample size

Power calculation: the numbers needed in each arm was based on transfer of training (the degree to which trainees transfer the knowledge and skills acquired from one learning situation to another setting) observed in previous studies of proficiency based

progression simulation in surgery and cardiology, where transfer of training rates of 42-69% have been observed [1, 2, 3, 4, 5, 6]. In a pilot for the current study on 133 medical and nursing students in the previous academic year, the transfer of training rate was observed to be 16% for the proficiency based training group and 3% for the standard simulation group. The pilot however was constrained by the existing curriculum, which only allowed for 90 minutes training time once the e-learning programme was complete. In the current study a longer training time (3.5 hours) and a more rigorous structure was facilitated. We therefore expected to observe an increase in transfer of training to >40% based on a 3 fold increase in objective, blind, assessment of proficiency when compared to the control group (i.e. 9% for the E group vs. 49% for the E+PBP group). A two –tailed test, with n=20 trainees in each group with an alpha of 5% (which corresponds to a 95% confidence interval) would yield a statistical power of 89.9. Therefore 30 (15 medical and 15 nursing students) were randomised to each group to allow for drop out rates observed in the pilot due to students rescheduling to non-study training dates as a result of conflicting demands of their curriculum.

Randomisation and blinding

A de-identified numbered list of nursing and medical student numbers was obtained from the School of Nursing and Midwifery and the School of Medicine. The lists comprised 109 third year nursing and 201 final year medical students scheduled to complete an interdisciplinary ISBAR training programme as part of the University undergraduate curriculum in September 2016. Randomisation was stratified by discipline and was conducted using a computer-generated programme (GraphPad QuickCals software package, www.graphpad.com/quickcalcs/) as a two-stage process (figure 1). Firstly n=45 nursing and n=45 medical students were randomly selected using the programme. These 90 students were then randomly allocated by discipline using the same computer programme to one of the three training groups: E, E+S, and E+PBP. Subjects were excluded from the study if: (i) a certificate of successful completion (within the previous 4 weeks) of the National Early Warning Score (NEWS) e-learning education programme was not presented on the day of training, (ii) lack of consent.

Statistical analysis

Statistical Analysis was performed with SPSS 22 (Armonk, New York). The Kruskal-Wallis test was used to determine if there was a

statistical difference between groups in relation to the primary end point (the numbers reaching proficiency) and the secondary end points (the number of completed steps, errors and critical errors). The relationship of the three training programmes on proficiency was explored using logistic regression analysis.

Patient and Public Involvement

Patients were not involved in the design or conduct of the study.

Results

Baseline characteristics with respect to age, gender, discipline, nationality and first language of the participants in each group are shown in table 1.

Table1

Study Group		E [a]	E+S [b]	E+PBP [c]	Total	
		n=30	n=30	n=30	n=90	prob. level[#]
Discipline	Nursing (%)	15 (50.0%)	15 (50.0%)	15 (50.0%)	45 (50.0%)	
	Medicine (%)	15 (50.0%)	15 (50.0%)	15 (50.0%)	45 (50.0%)	
Age Group	18-23 years (%)	21 (70.0%)	19 (63.3%)	20 (66.7%)	60 (66.7%)	
	24-29 years (%)	7 (23.3%)	8 (26.7%)	9 (30.0%)	24 (26.7%)	p = 0.853
	>30 years (%)	2 (6.7%)	3 (10.0%)	1 (3.3%)	6 (6.7%)	
Gender	Male (%)	6 (20.0%)	5 (16.7%)	6 (20.0%)	17 (18.9%)	
	Female (%)	24 (80.0%)	22 (83.3%)	24 (80.0%)	73 (81.1%)	p = 0.919
Nationality	Irish (%)	22 (73.3%)	24 (80.0%)	21 (70.0%)	67 (74.4%)	
	Non-Irish (%)	8 (26.7%)	6 (20.0%)	9 (30.0%)	23 (25.6%)	p = 0.664
First Language	English (%)	25 (83.3%)	22 (73.3%)	19 (63.3%)	66 (73.3%)	
	Other (%)	5 (16.7%)	4 (13.3%)	7 (23.3%)	16 (17.8%)	p = 0.223
	Not available (%)	-	4 (13.3%)	4 (13.3%)	8 (8.9%)	

Figure 5 shows percentages of participants in each group who demonstrated the proficiency benchmark following assessment in the high fidelity simulation suite. At the end of training, 6.9% (2/29) of the e-learning only (E) group and 13 % (3/23) of the standard simulation (E+S) group demonstrated proficiency. In comparison 60% (15/25) of proficiency-based progression simulation (E+PBP) group were proficient. The difference between the E group and the E+S group was not statistically significant (Chi-Square = 0.55, 99%, CI =0.63-0.66, p= 0.63) but was significant for the difference between E group and the E +PBP group (Chi-Square = 22.25, CI=0.00-0.00, p < 0.000) and between the S group and the E+PBP group (Chi-Square = 11.04, CI=0.00-0.00, p = 0.001).

On logistic regression analysis (figure 6) it was found that in comparison to the E group, the E+S group were 2 times as likely to demonstrate proficiency (Ext (B) =2.04, 95% CI=0.31-13.28, p=0.46). This difference was in the direction of improved performance but the effect was not statistically significant probably because of the sample size used in this study. In contrast the PBP trained group were more than 20 times as likely to demonstrate proficiency in comparison to

the E trained group and the difference was statistically significant (Ext (B) =20.25, 95% CI=3.91-105, p<0.000).

The E+PBP group completed significantly more steps, mean 8.5 (1.7) than either the E, mean 5.8 (1.6), p<0.000 or E+S groups, mean 6.3 (2.1), p<0.000 group. Similarly, combined errors and critical errors were significantly less in the E+PBP, mean 3.7 (1.6) than either the E, mean 5.9 (2.1), p<0.000 or the E+S groups, mean 5.2 (1.5), p<0.01 group. Inter-rater reliability of the two assessors was 97%.

Discussion

Our results show that addition of a proficiency-based progression simulation programme to an e-learning module can deliver a superior set of skills for ISBAR communication in relation to a deteriorating patient than an e-learning module either alone or in combination with standard simulation. Furthermore this benefit is seen within the same resources i.e. materials, timeframe, and facilitators as standard simulation. The Irish health service like its international counterparts has prioritised clinical communication as a key part of the patient safety agenda [12, 13, 14, 15, 16]. Clinical communication is now viewed as an essential skill and training is recommended as mandatory for all health and social care

professionals [13]. All participants were required to produce a recent certificate of successful completion of the e-learning programme but only 6.9% of the group who undertook the e-learning module only demonstrated the proficiency benchmark. The addition of standard simulation did not significantly improve performance with only 13% of the E+S group reaching the benchmark. It could be argued that exposure to metrics-based scoring in the practice cases resulted in better performance in the assessment case for the E+PBP group. However this is precisely the desired effect i.e. that trainees know what skills need to be achieved, practice to achieve them to an objective pre-defined standard and transfer that training to a dynamic scenario. The E+S and E+PBP groups differed in only two respects: (i) practice was "repeated" in the E+S cohort as opposed to "deliberate" in E+PBP cohort i.e. focused on pre-defined metrics and (ii) the E+PBP group was required to reach proficiency benchmarks to progress through simulation cases whereas the E+S group were not. Our results demonstrate that proficiency-based training can achieve skill acquisition rates of the order of 60%, similar to those seen with technical skills using this approach. In a study of similar experimental design, Angelo et al found that there were 56% fewer intraoperative errors and 69% fewer critical errors when compared

to traditional training [2]. To our knowledge our study is the first randomised trial of proficiency-based progression training of a non-technical skill.

The main strength of the study is the use of robust methodology to determine the effectiveness of an educational intervention on objectively assessed performance outcomes. The study combines the rigour of a randomised controlled trial with that of an outcomes based- training approach (proficiency-based progression) to clinical communication. A significant body of evidence already exists in relation to the use of proficiency-based progression for technical skill acquisition [7, 8, 9, 10, 11, 12, 13]. Our results support the use of proficiency-based progression training for communication skills also. This study indicates that the impact of a PBP training methodology appears to be >40% for non-technical as well as technical skills.

Weaknesses of the study include the single centre design and the application to the undergraduate population only, although the training programme was designed for qualified nurses and doctors also. Since the completion of study, the programme has been applied successfully to both nursing and medical undergraduate programmes in the university setting and to doctors in training in the hospital setting. There is a need for further robust evaluation of this

application of the programme and extension to other sites and clinical settings.

The study was limited by the restriction on training time. The duration of simulation training for both E+S and the E+PBP groups was extended to 3.5 hours from the initial pilot (1.5 hours), but was still restricted by the existing undergraduate curriculum rather than that which would ideally be required to train a fundamental skill. Skills consolidation is an important part of the learning process particularly for new skills [17]. In the study by Angelo et al. [2] trainees had a weekend in which to acquire, refine and consolidate their skills before their proficiency assessment at the end of training. Another difficulty, which may have impinged on the effectiveness of training, was the disparity in fidelity between the paper-based training environment and the assessment undertaken in the high fidelity simulation environment. This disparity is challenging for those with limited clinical experience such as the undergraduate population. Van Sickle et al [3] and Gallagher et al [4] have commented on the detrimental impact that this disparity can have on proficiency demonstration by trainees.

It is now widely recognised that clinical communication skills underpin patient safety. Implementation of a training programme in

relation to clinical communication has already been shown to reduce medical error and preventable adverse events [18]. There is a need for valid, reliable, cost efficient clinical communication training programmes to address this need and the impact on patient as well as healthcare provider outcomes.

In summary, our study shows that proficiency-based progression is a more effective way to teach clinical communication for the deteriorating patient than e-learning either alone or in combination with standard simulation.

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Legends

Table 1. Demographic characteristics of the three study groups: e-learning alone (E), e-learning plus standard simulation (E+S) and e-learning plus proficiency-based progression simulation (E+PBP) .

Figure 1. Consort diagram outlining selection, allocation and follow up of undergraduate medical and nursing participants in a study comparing the effect of e-learning alone (E), e-learning plus standard simulation (E+S) and e-learning plus proficiency-based progression simulation (E+PBP) on clinical communication.

Figure 2. Outline of experimental design and study flow indicating training interventions and assessment of the three study training groups (E, E+S, E+PBP) of undergraduate medical and nursing participants.

Figure 3. Outline of the high fidelity simulation performance assessment case for nursing undergraduates

Figure 4. Extract from the nursing metric scoring sheet illustrating some of the metrics and the proficiency benchmark for the high fidelity simulation assessment case.

Figure 5. The percentages reaching the proficiency benchmark at the end of training of the three study training groups; e-learning alone

(E), e-learning plus standard simulation training (E+S) and e-learning plus proficiency-based progression simulation training (E+PBP).

Figure 6. Logistic regression analysis for the relative differences between the three study training groups of undergraduate medical and nursing participants; E, E+S and E+PBP.

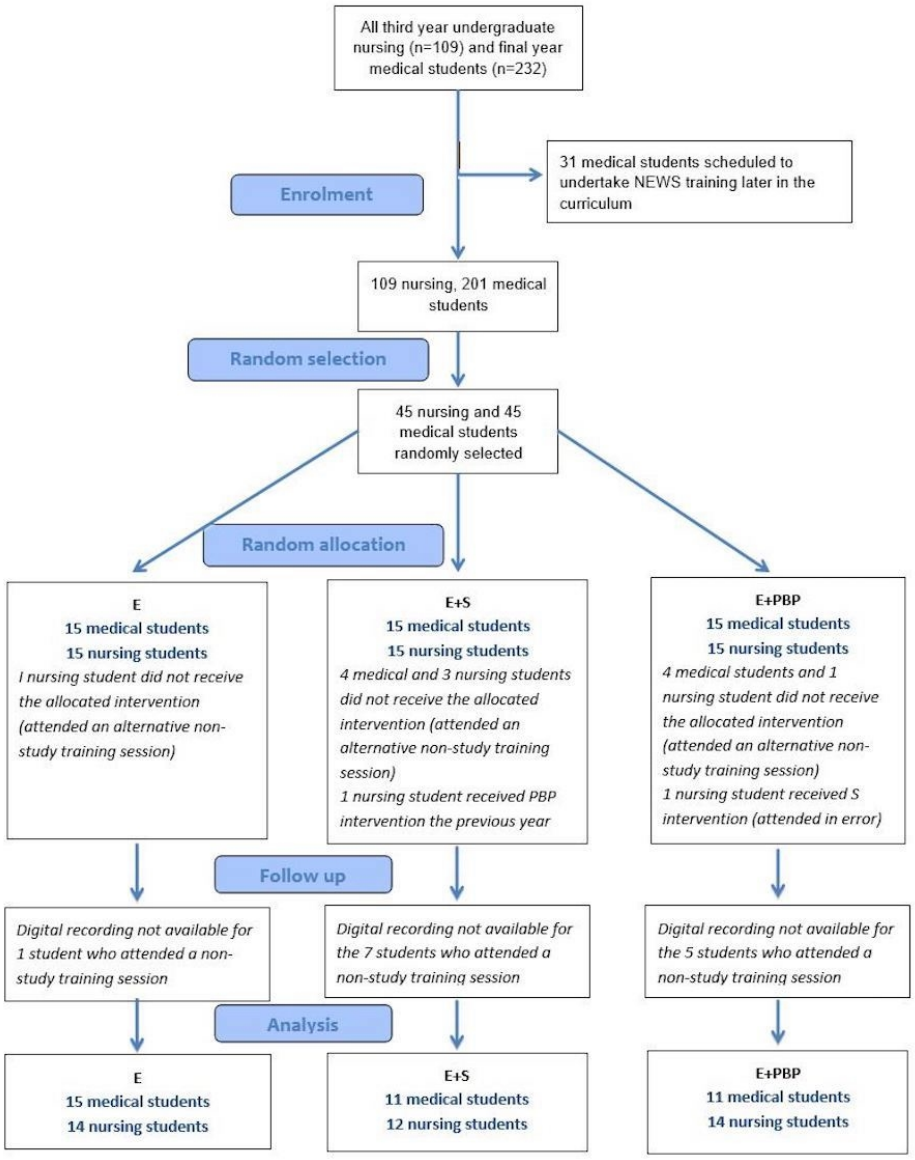


Figure 1. Consort diagram outlining selection, allocation and follow up of undergraduate medical and nursing participants in a study comparing the effect of e-learning alone (E), e-learning plus standard simulation (E+S) and e-learning plus proficiency-based progression simulation (E+PBP) on clinical communication.

76x98mm (300 x 300 DPI)

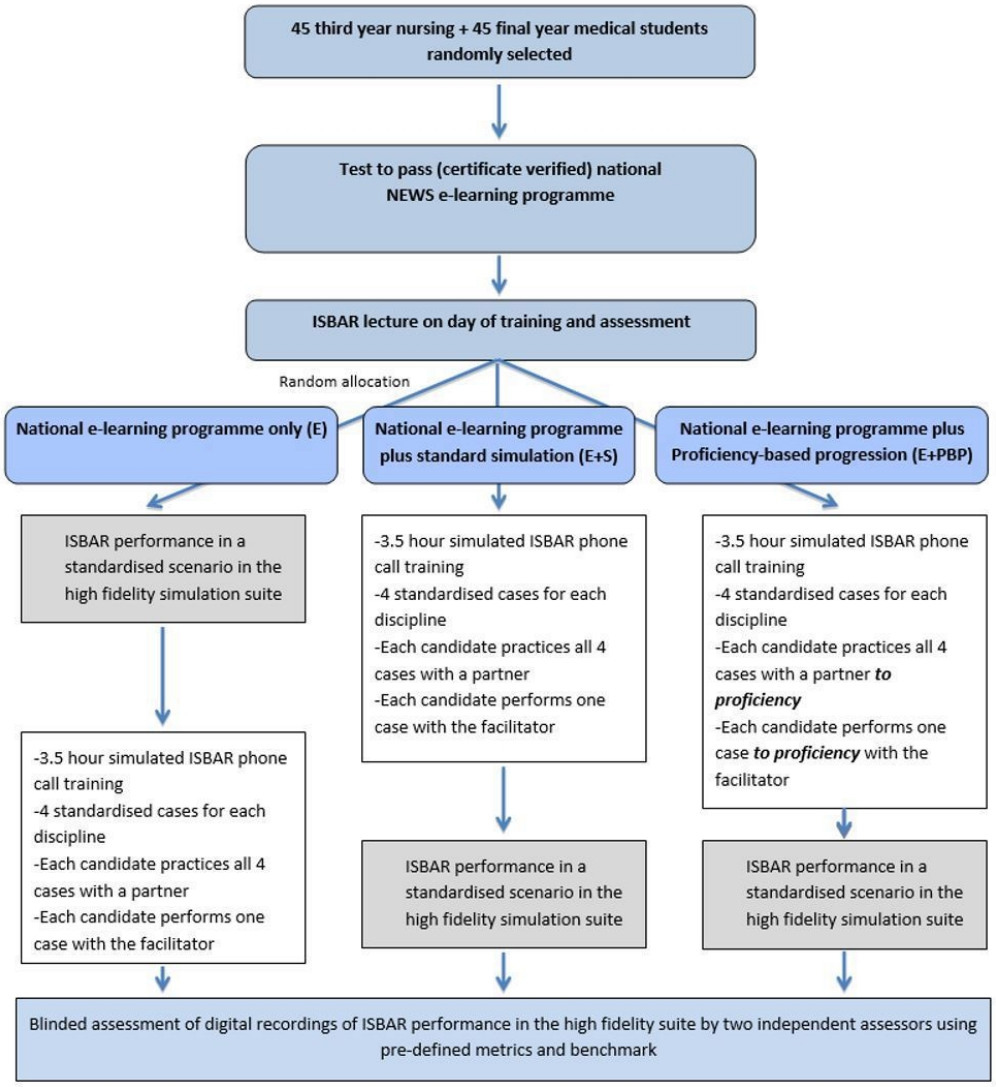


Figure 2. Outline of experimental design and study flow indicating training interventions and assessment of the three study training groups (E, E+S, E+PBP) of undergraduate medical and nursing participants.

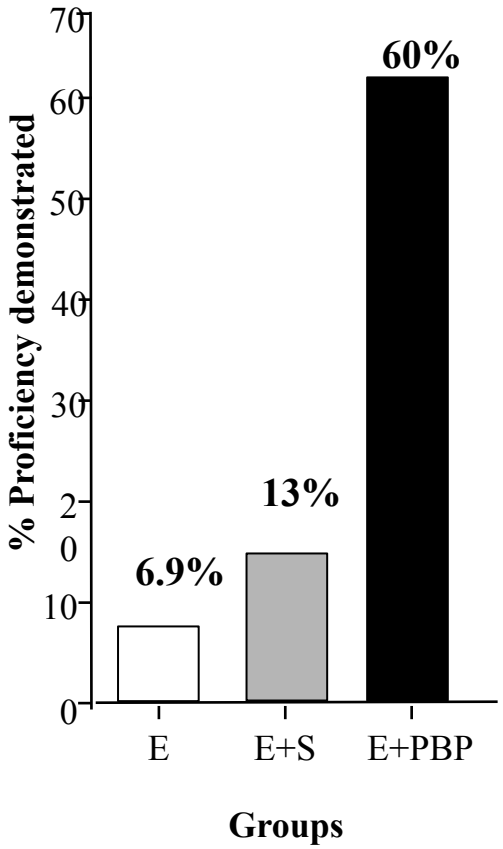
82x90mm (300 x 300 DPI)

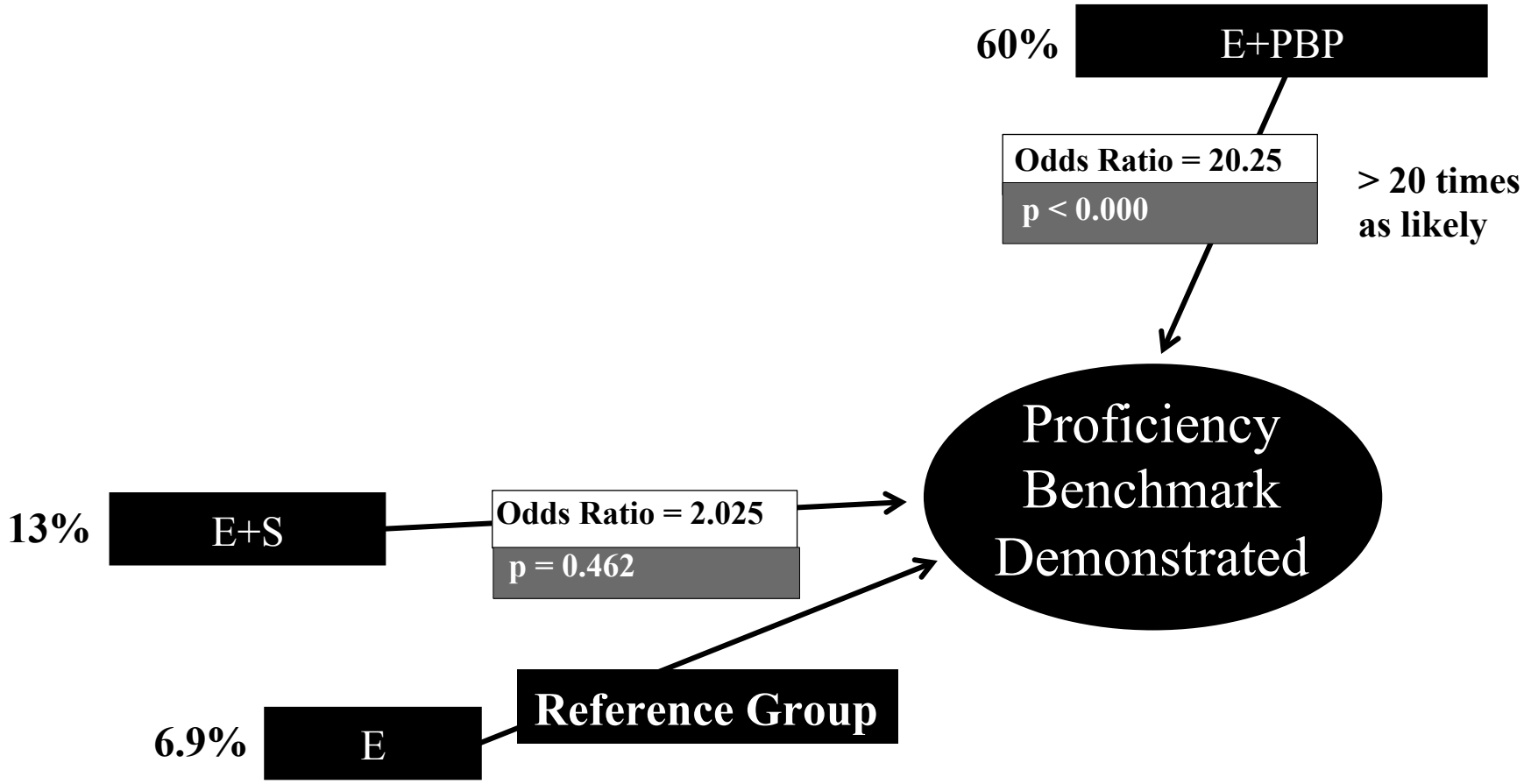
N-EWS simulation 10 mins in total							CSSRC Clinical Skills Simulation Resource Centre		
You are a registered nurse on the surgical ward. It is 0800hrs and you have come on duty, you have received the below handover and are going in to meet your patient and to do her post-op observations									
HANDOVER: **Rebecca Murphy 47,** has a past medical history of crohn's disease & a fractured humerous - 2 years ago									
She is **DAY 2** post laparotomy and formation of an ileostomy for poorly controlled crohn's disease.									
Rebecca's pain is well controlled with PCA. She required breakthrough analgesia twice over night									
She remains NPO with IV fluids in progress. She continues on hourly urine monitoring with an adequate output recorded overnight									
Routine bloods were taken this morning									
	Simulator Parameters			**Roleplayer vocals**			**Escalation Call**		
2	**RR**	21		2 days post laparotomy					
3	**SpO_2**	96%		you feel **very tired and weak**			**If after 7mins** there has been no escalation call, facilitator to say		
4	**oxygen**	Room Air		you think you should be feeling better than you are			**"please phone the doctor and seek medical assistance now"**		
5	**BP**	92/58					Do not ask any questions or provide any information throughout this phone-call except to answer the below questions		
6	**HR**	98		you thought you would be improving at this stage			**Possible questions**	**Responses**	
7	**AVPU**	Alert		if asked you feel your pain is less controlled than yesterday			If asked "is this *name* ?"	"yes, speaking"	
8	**Temp**	36.7		you are still nil by mouth			If asked who you are?	"this is Dr. Dara O'Leary"	
9	**EWS**	5		you now have a temporary ileostomy and are a quite upset about this, but know it will hopefully be reversed in the future			If asked to confirm role - Information provided should match that in simulation room	Intern: Chris Hatfield	
10	**Cardiac monitor**	Sinus tachycardia (if attached to CM)						SHO: Dara O'Leary	
11	**Cap refill**	less than 2sec						REG: Jo Kelly	
12	**skin**	pink, warm, dry						Consultant: Prof Healy	
13	**Urinary output (0.5ml/kg/hr)**	20mls last hour					If recipient name not confirmed, and you are asked "is this the intern/SHO/reg?"	"yes"	
14	**IV site**	VIP = 0 [visual infusion phlebitis score]					If asked for any recommendation	"Please commence a 500ml bolus of IV Hartmans"	
15	**IV hydration**	125mls/hr					If told "I think she is bleeding/needs review/has sepsis"	"OK"	
16	**Pain**	**Student to assess** if asked for PCA - 32mls in syringe; 35 demands, 18 successful]					If asked "Will you review her?"	"I will"	
17	**Bowel sounds**	**Student to assess** absent					If asked "When will you review her?"	"as soon as I can"	
18	**Abdomen**	**wound** - assess independently **drain** assess independently **ileostomy:** assess independently **distension** yes abdomen is distended					If told "Her EWS is (3-7), so you must review her in 30mins"	"OK"	
19	**Blood Loss**	**If students enquire requiring volume in drain/ileostomy** - say "you may assess independently" If students pick up a jug to empty either give them the relevant volume "**there are 250mls in the drain**" **"there are 100mls in the ileostomy"**					If asked "Will you review her in 30 minutes/straight away?"	"I will"	
20	**Chest sounds**	normal							
21	**Cap blood sugar**	5.8mmol/L							

Extract from Nursing Simulation Metric

			Tick if present	Tick if present	Tick if present
16	S	States the situation ***There is 100-300mls of blood in drain or if not exact volume qualifies with (a lot, significant amount, unusual amount, quite a bit) AND/OR states blood in ileostomy bag no qualification needed.***			
17	S	States the situation ***Her urinary output 20mls/hr***			
18	S	States the situation **States patient is on IV fluids**			
19	B	Background information ***States she has history of Crohn's disease states history***			
20	B	Background information ***States she is two days post laparotomy/ileostomy/bowel resection***			
21	B	Irrelevant background ***States fractured humerus two years ago***			
22	A	Assessment *Gives relevant **case specific** assessment*			
23	A	Assessment ***I think she is bleeding*** +/- patient is hypovolemic			
24	R	Seeks a recommendation from recipient ***Do you want me to do anything else/what else would you recommend?***			
25	R	Omits to "repeat back" ***You would like me to give her a fluid bolus of 500mls and the time frame agreed for review*** *[eg: straight away/ in 30 minutes]*			
26	R	Uses own notes and/or an ISBAR sticker to aid phone call			
27		Length of call [seconds]			secs
			no. of steps = no. of boxes checked	no. of errors = no. of boxes checked	no. of critical errors = no. of boxes **NOT** checked
		TOTALS			

Proficiency Benchmark	**Proficiency Demonstrated** [tick box]	**Observer's Initial**
• **Steps ≥ 6** • **No more than 4 Errors, 3 of which may be critical**	**YES** **NO**	


70
60
50
40
30
2
0
10
0
% Proficiency demonstrated
60%
13%
6.9%
E
E+S
E+PBP
Groups


60%
E+PBP
Odds Ratio = 20.25
p < 0.000
> 20 times as likely
Proficiency Benchmark Demonstrated
13%
E+S
Odds Ratio = 2.025
p = 0.462
Reference Group
6.9%
E

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8/9/10/11 Figure 2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11 and 5 protocol
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	13
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	14
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	14
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	14
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	2/3 protocol
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	14, 15

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	8/9/10/11
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	15,16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	15,16
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15/16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
Other information			
Registration	23	Registration number and name of trial registry	ClinicalTrials.govNCT02886754
Protocol	24	Where the full trial protocol can be accessed, if available	Attached,Clinical trials.gov,

			and attached
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	none

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

The effect of a proficiency-based progression simulation programme on clinical communication for the deteriorating patient: A randomised controlled trial.

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The effect of a proficiency-based progression simulation programme on clinical communication for the deteriorating patient: A randomised controlled trial.

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1

The effect of a proficiency-based progression simulation programme on clinical communication for the deteriorating patient: A randomised controlled trial.

ABSTRACT

Objective

To determine the effectiveness of a proficiency-based progression training approach to clinical communication in the context of a clinically deteriorating patient.

Design

A randomised controlled trial with three parallel arms.

Setting

A university setting in Ireland

Participants

45 third year nursing and 45 final year medical undergraduates scheduled to undertake interdisciplinary National Early Warning Score (NEWS) training over a three day period in September 2016.

Interventions

Participants were prospectively randomised to one of three groups before undertaking a performance assessment of the ISBAR communication tool (Identification, Situation, Background,

Assessment, Recommendation) relevant to a deteriorating patient in a high fidelity simulation facility. The groups were as follows (i) E; the Irish Health Service national NEWS e-learning programme only, (ii) E+S; the national e-learning programme plus standard simulation, and (iii) E+PBP; the national e-learning programme plus proficiency-based progression simulation.

Main outcome measures

The primary outcome was the proportion in each group reaching a pre-defined proficiency benchmark comprising a series of pre-defined steps, errors and critical errors during the performance of a standardised, high fidelity simulation assessment case which was recorded and scored by two independent blinded assessors.

Results

6.9% (2/29) of the E group and 13% (3/23) of the E+S group demonstrated proficiency in comparison to 60% (15/25) of the E+PBP group. The difference between the E and the E+S groups was not statistically significant (Chi-Square = 0.55, 99%, CI =0.63-0.66, p= 0.63) but was significant for the difference between the E and the E +PBP groups (Chi-Square = 22.25, CI=0.00-0.00, p < 0.000) and between the E+S and the E+PBP groups (Chi-Square = 11.04, CI=0.00-0.00, p = 0.001).

Conclusions

Proficiency-based progression is a more effective way to teach clinical communication in the context of the deteriorating patient than e-learning either alone or in combination with standard simulation.

Trial Registration

ClinicalTrials.gov Identifier: NCT02886754

STRENGTHS AND LIMITATIONS OF THE STUDY

- This is the first randomised controlled trial of a proficiency-based progression educational intervention for a non-technical skill.
- The peformance outcomes are robust objective measurements which do not rely on subjective assessments or learner perceptions.
- Limitations are the single centre design and the future need for the impact of proficiency-based progression programmes on patient outcomes.

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Competing interests: All authors have completed the ICMJE uniform

disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical Approval: Institutional review board approval was obtained. Informed written consent was obtained from all participants.

Transparency: The lead author affirms that the manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects have been omitted; and that any discrepancies from the study as planned have been explained.

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All authors listed below met ICMJE criteria for contributorship as outlined below.

Dr Dorothy Breen

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2. Drafting the work, revising the work critically for important intellectual content AND

3. Drafting the final version to be published; AND

4. Agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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4. Agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Data Sharing: Deidentified individual participant data that underlie the results published in this article as well as study protocol, statistical analysis plan and analytical code will be made available on request beginning three months and ending 5 years after publication to researchers who provide a methodologically sound proposal. Please direct requests to the corresponding author. Data accessors will need to sign a data access agreement. The data from the pilot study and from this study in relation to learner perceptions is undergoing analysis and will be available following publication.

Introduction

Simulation-based training is being increasingly deployed for both technical and non-technical skill acquisition in healthcare with the aim of reducing medical error and patient harm. There is a need for an evidence-based approach to such training to ensure that the resources utilised can reliably deliver a quantifiable improved skill set rather than just an enhanced educational experience. Proficiency-based progression (PBP) training is a form of outcomes-based training that involves training individuals to achieve a proficiency benchmark. The process involves "deliberate" practice against a set of clearly defined objective metrics. The proficiency benchmark is set as the mean performance of clinicians who undertake the procedure regularly in clinical practice. It has been shown to improve the performance of individuals undertaking technical procedures [1, 2, 3, 4, 5, 6, 7]. Metrics are operationally defined to facilitate objective scoring. For example in the study by Cates et al demonstrating improved performance of carotid angiography, pre-defined metric errors include "number of diagnostic catheters used to obtain diagnostic pictures" and "catheter advancing without a guide-wire in front of it"[6]. Despite these results, PBP methodology has not previously been

applied to simulation-based training for non-technical skills yet communication failures are a significant source of medical error and preventable adverse events equal if not greater than errors due to lack of technical skill [8, 9, 10]. Escalation of care for an acutely deteriorating patient demands the most efficient, concise and accurate flow of information amongst healthcare workers of different disciplines for the best outcome to be achieved.

Early Warning Scores facilitate early detection of deterioration by categorising a patient's severity of illness and prompting escalation of care at specific trigger points utilising a structured communication tool such as ISBAR (Identification, Situation, Background, Assessment, Recommendation). This enables a more timely response using a common language [11]. Ireland was one of the first countries to agree and implement a standardised Early Warning Score (The National Early Warning Score, NEWS) across the entire acute hospital sector. NEWS utilises the ISBAR tool as the recommended structured communication tool for the acutely deteriorating patient [12, 13]. The National Early Warning Score (NEWS) e-learning education programme is recommended as the national interdisciplinary education programme for all healthcare professionals working in acute services. The programme teaches ISBAR as the standardised

tool to escalate care in the context of the acutely deteriorating patient.

The primary aim of this study was to determine if the addition of a proficiency-based progression simulation training programme to the national NEWS e-learning module results in better performance of clinical communication of a deteriorating patient than either the e-learning module alone or in combination with standard simulation.

Methods

Study design

A randomised controlled trial with three parallel arms.

Participants

Eligible participants were 109 third year nursing and 201 final year medical students who were scheduled to undertake interdisciplinary National Early Warning Score training in September 2016 as part of their undergraduate curriculum. This comprised the entire undergraduate nursing and medical classes except for 31 medical students who were scheduled to undertake this training at a later time in the curriculum (figure 1).

Interventions

All 3rd year nursing and final year medical students were emailed prior to training and instructed to undertake the National Early Warning Score e-learning programme. Written informed consent was obtained from all participants. On the day of training, participants were required to submit a certificate of successful completion of the e-learning programme. A 15-minute lecture on the ISBAR tool was delivered before participants undertook training as per their allocated groups. Students were not notified as to which study group they were allocated. The study flow is outlined in figure 2.

The three training groups were as follows:

(i) e-learning only group (E). Participants in this group proceeded immediately following the 15-minute lecture to the high fidelity suite for performance assessment. After outcome assessment was complete, participants undertook simulation training similar to the E+S group as outlined below in order to ensure that all students were afforded the same training opportunity from a curriculum perspective.

(ii) e-learning plus standard simulation group (E+S). Participants worked in pairs of a medical student and nursing student. If a participant did not have a partner, then a non-study peer student was

asked to pair with that individual for the purposes of training. Data from the non-study student was not included in the analysis.

Training consisted of a series of simulated phone calls using four standardised paper cases for each discipline. Case materials included case notes, NEWS charts, and a blank ISBAR template indicating the categories and type of information that should be communicated. Each scenario had a deteriorating patient event that necessitated an ISBAR telephone communication. Participants alternated between making and receiving simulated phone calls. A standardised script was given to the recipient. Two facilitators conducted the simulation training. Both facilitators were experienced clinicians and educators who had previously undergone the "Train the Trainer NEWS programme" and regularly facilitate NEWS training and healthcare simulation. The facilitators offered support and feedback in line with standard NEWS training by listening to simulated phone calls and offering guidance on the ISBAR framework and by answering questions as they arose. Participants were required to work through all four cases with their partner. Towards the end of the training session the participants presented to the facilitator to repeat a simulated phone call for either case 3 or 4. The training session was 3.5 hours in duration, participants were required to stay until the end

of the training regardless of progress. If an individual had completed all the cases, they were asked to assist by continuing to be the recipient of phone calls for their partner or by continuing to practice by repeating the cases if required.

(iii) e-learning plus proficiency-based progression simulation group (E+PBP). Participants underwent a training programme of the same structure, duration (3.5 hours), content and facilitator: student ratio as the E+S group. The same two facilitators facilitated both the E+S and E+PBP training. However in the E+PBP group, partners scored each other's phone calls during training against a series of pre-defined metrics (quantified as steps, errors and critical errors for each case) on a score sheet to ascertain if the proficiency benchmark for that case was reached. Partners shared the results of the metrics and proficiency scores with each other as feedback at the end of each simulated phone call. If proficiency was not achieved the case was repeated before progressing to the next case. Participants were required to reach proficiency on all four cases with their partner before performing case 3 or 4 with the facilitator and demonstrating proficiency again. If proficiency was not achieved with the facilitator then the participant returned to repeat cases with their partner and present for reassessment to the facilitator until

proficiency was demonstrated. The training session was 3.5 hours in duration, participants were required to stay until the end of the training regardless of progress. If an individual had completed all the cases, they were asked to assist by continuing to be the recipient of phone calls for their partner or by continuing to practice by repeating the cases if required.

Outcomes

The primary outcome was the ability to reach the proficiency benchmark on the standardised high-fidelity simulation assessment case. The secondary outcomes were the number of successfully completed steps, errors and critical errors performed by each group.

Performance metrics were developed for the training cases and for the high fidelity simulation assessment case as part of a pilot study in the previous year. Each case presented a different but commonly encountered clinical scenario of an acutely deteriorating patient. As an example, the outline of the nursing component of the high fidelity simulation assessment case is shown in figure 3.

The metrics were derived for each of the training and assessment cases according to the 5 components of the ISBAR tool and were specific to each case.

The performance metrics were validated through a modified Delphi expert panel consisting of 9 senior nurses and 8 medical staff who regularly facilitate NEWS/ISBAR communication training. Delphi panel members reviewed the performance metric for each of the simulation cases and the high fidelity performance outcome case and metric units were included, excluded or modified by consensus. Each metric unit was then classified as a step, error or critical error by consensus. The majority of metrics were common to both medicine and nursing. The number of metrics per case ranged from 24-26.

The proficiency benchmark was set as the mean performance of qualified personnel from the respective disciplines on each case. Nine nursing and five medically qualified practitioners (who regularly escalate care in the acute healthcare setting and with a mean years of experience=3 years) underwent the high fidelity simulation case. The proficiency benchmark for the assessment case was set as the mean performance for each discipline as scored by two independent assessors using the pre-defined metrics. An extract from the metric

scoring sheet and proficiency benchmark for the high fidelity simulation assessment case is shown in figure 4.

Digital recordings of each participant's performance of the standardised case in the high fidelity assessment suite were reviewed and scored by two independent assessors (experienced acute care nurses) using the pre-defined metrics and proficiency benchmark.

The assessors underwent training on scoring the material using 10 recordings of the same case obtained from non-study participants. Assessment of the digital recordings was undertaken within 2 months of study participation. An inter-rater reliability of > 85% was achieved prior to commencing scoring study material. The assessors were not part of the investigator group, were blinded to the study group allocations and had no prior knowledge of any of the participants.

Sample size

Power calculation: the numbers needed in each arm was based on transfer of training (the degree to which trainees transfer the knowledge and skills acquired from one learning situation to another setting) observed in previous studies of proficiency based

progression simulation in surgery and cardiology, where transfer of training rates of 42-69% have been observed [1, 2, 3, 4, 5, 6]. In a pilot for the current study on 133 medical and nursing students in the previous academic year, the transfer of training rate was observed to be 16% for the proficiency based training group and 3% for the standard simulation group. The pilot however was constrained by the existing curriculum, which only allowed for 90 minutes training time once the e-learning programme was complete. In the current study a longer training time (3.5 hours) and a more rigorous structure was facilitated. We therefore expected to observe an increase in transfer of training to >40% based on a 3 fold increase in objective, blind, assessment of proficiency when compared to the control group (i.e. 9% for the E group vs. 49% for the E+PBP group). A two –tailed test, with n=20 trainees in each group with an alpha of 5% (which corresponds to a 95% confidence interval) would yield a statistical power of 89.9. Therefore 30 (15 medical and 15 nursing students) were randomised to each group to allow for drop out rates observed in the pilot due to students rescheduling to non-study training dates as a result of conflicting demands of their curriculum.

Randomisation and blinding

A de-identified numbered list of nursing and medical student numbers was obtained from the School of Nursing and Midwifery and the School of Medicine. The lists comprised 109 third year nursing and 201 final year medical students scheduled to complete an interdisciplinary ISBAR training programme as part of the University undergraduate curriculum in September 2016. Randomisation was stratified by discipline and was conducted using a computer-generated programme (GraphPad QuickCals software package, www.graphpad.com/quickcalcs/) as a two-stage process (figure 1). Firstly n=45 nursing and n=45 medical students were randomly selected using the programme. These 90 students were then randomly allocated by discipline using the same computer programme to one of the three training groups: E, E+S, and E+PBP. Subjects were excluded from the study if: (i) a certificate of successful completion (within the previous 4 weeks) of the National Early Warning Score (NEWS) e-learning education programme was not presented on the day of training, (ii) lack of consent.

Statistical analysis

Statistical Analysis was performed with SPSS 22 (Armonk, New York). The Kruskal-Wallis test was used to determine if there was a

statistical difference between groups in relation to the primary end point (the numbers reaching proficiency) and the secondary end points (the number of completed steps, errors and critical errors). The relationship of the three training programmes on proficiency was explored using logistic regression analysis.

Patient and Public Involvement

Patients were not involved in the design or conduct of the study.

Results

Baseline characteristics with respect to age, gender, discipline, nationality and first language of the participants in each group are shown in table 1.

Table1

Study Group		E	E+S	E+PBP	Total
		n=30	n=30	n=30	n=90
Discipline	Nursing (%)	15 (50.0%)	15 (50.0%)	15 (50.0%)	45 (50.0%)
	Medicine (%)	15 (50.0%)	15 (50.0%)	15 (50.0%)	45 (50.0%)
Age Group	18-23 years (%)	21 (70.0%)	19 (63.3%)	20 (66.7%)	60 (66.7%)
	24-29 years (%)	7 (23.3%)	8 (26.7%)	9 (30.0%)	24 (26.7%)
	>30 years (%)	2 (6.7%)	3 (10.0%)	1 (3.3%)	6 (6.7%)
Gender	Male (%)	6 (20.0%)	5 (16.7%)	6 (20.0%)	17 (18.9%)
	Female (%)	24 (80.0%)	22 (83.3%)	24 (80.0%)	73 (81.1%)
Nationality	Irish (%)	22 (73.3%)	24 (80.0%)	21 (70.0%)	67 (74.4%)
	Non-Irish (%)	8 (26.7%)	6 (20.0%)	9 (30.0%)	23 (25.6%)
First Language	English (%)	25 (83.3%)	22 (73.3%)	19 (63.3%)	66 (73.3%)
	Other (%)	5 (16.7%)	4 (13.3%)	7 (23.3%)	16 (17.8%)
	Not available (%)	-	4 (13.3%)	4 (13.3%)	8 (8.9%)

Figure 5 shows percentages of participants in each group who demonstrated the proficiency benchmark following assessment in

the high fidelity simulation suite. At the end of training, 6.9% (2/29) of the e-learning only (E) group and 13 % (3/23) of the standard simulation (E+S) group demonstrated proficiency. In comparison 60% (15/25) of proficiency-based progression simulation (E+PBP) group were proficient. The difference between the E group and the E+S group was not statistically significant (Chi-Square = 0.55, 99%, CI =0.63-0.66, p= 0.63) but was significant for the difference between E group and the E +PBP group (Chi-Square = 22.25, CI=0.00-0.00, p < 0.000) and between the E+S group and the E+PBP group (Chi-Square = 11.04, CI=0.00-0.00, p = 0.001).

On logistic regression analysis (figure 6) it was found that in comparison to the E group, the E+PBP trained group were more than 20 times as likely to demonstrate proficiency and the difference was statistically significant (Ext (B) =20.25, 95% CI=3.91-105, p<0.000).

The E+PBP group completed significantly more steps, mean 8.5 (1.7) than either the E, mean 5.8 (1.6), p<0.000 or E+S groups, mean 6.3 (2.1), p<0.000 group. Similarly, combined errors and critical errors were significantly less in the E+PBP, mean 3.7 (1.6) than either the E, mean 5.9 (2.1), p<0.000 or the E+S groups, mean 5.2 (1.5), p<0.01 group. Inter-rater reliability of the two assessors was 97%.

Discussion

Our results show that addition of a proficiency-based progression simulation programme to an e-learning module can deliver a superior set of skills for ISBAR communication in relation to a deteriorating patient than an e-learning module either alone or in combination with standard simulation. Furthermore this benefit is seen within the same resources i.e. materials, timeframe, and facilitators as standard simulation. The Irish health service like its international counterparts has prioritised clinical communication as a key part of the patient safety agenda [12, 13, 14, 15, 16]. Clinical communication is now viewed as an essential skill and training is recommended as mandatory for all health and social care professionals [13]. All participants were required to produce a recent certificate of successful completion of the e-learning programme but only 6.9% of the group who undertook the e-learning module only demonstrated the proficiency benchmark. The addition of standard simulation did not significantly improve performance with only 13% of the E+S group reaching the benchmark.

It could be argued that exposure to metrics-based scoring in the practice cases resulted in better performance in the assessment case

for the E+PBP group. However this is precisely the desired effect i.e. that trainees know what skills need to be achieved, practice to achieve them to an objective pre-defined standard and transfer that training to a dynamic scenario. The E+S and E+PBP groups differed in only two respects: (i) practice was "repeated" in the E+S cohort as opposed to "deliberate" in E+PBP cohort i.e. focused on pre-defined metrics and (ii) the E+PBP group was required to reach proficiency benchmarks to progress through simulation cases whereas the E+S group were not. Our results demonstrate that proficiency-based training can achieve skill acquisition rates of the order of 60%, similar to those seen with technical skills using this approach. In a study of similar experimental design, Angelo et al found that there were 56% fewer intraoperative errors and 69% fewer critical errors when compared to traditional training [2]. To our knowledge our study is the first randomised trial of proficiency-based progression training of a non-technical skill.

The main strength of the study is the use of robust methodology to determine the effectiveness of an educational intervention on objectively assessed performance outcomes. The study combines the rigour of a randomised controlled trial with that of an outcomes based- training approach (proficiency-based progression) to clinical

communication. A significant body of evidence already exists in relation to the use of proficiency-based progression for technical skill acquisition [7, 8, 9, 10, 11, 12, 13]. Our results support the use of proficiency-based progression training for communication skills also.

Weaknesses of the study include the single centre design and the application to the undergraduate population only, although the training programme was designed for qualified nurses and doctors also. Since the completion of study, the programme has been applied successfully to both nursing and medical undergraduate programmes in the university setting and to doctors in training in the hospital setting. There is a need for future research on the application of the programme in different clinical settings and its impact on patient outcomes.

The study was limited by the restriction on training time. The duration of simulation training for both E+S and the E+PBP groups was extended to 3.5 hours from the initial pilot (1.5 hours), but was still restricted by the existing undergraduate curriculum rather than that which would ideally be required to train a fundamental skill. Skills consolidation is an important part of the learning process particularly for new skills [17]. In the study by Angelo et al. [2] trainees had a weekend in which to acquire, refine and consolidate their skills

before their proficiency assessment at the end of training. Another difficulty, which may have impinged on the effectiveness of training, was the disparity in fidelity between the paper-based training environment and the assessment undertaken in the high fidelity simulation environment. This disparity is challenging for those with limited clinical experience such as the undergraduate population. Van Sickle et al [3] and Gallagher et al [4] have commented on the detrimental impact that this disparity can have on proficiency demonstration by trainees.

It is now widely recognised that clinical communication skills underpin patient safety. Implementation of a training programme in relation to clinical communication has already been shown to reduce medical error and preventable adverse events [18]. There is a need for valid, reliable, cost efficient clinical communication training programmes to address this need and the impact on patient as well as healthcare provider outcomes.

In summary, our study shows that proficiency-based progression is a more effective way to teach clinical communication for the deteriorating patient than e-learning either alone or in combination with standard simulation. Furthermore, improved performance with proficiency-based progression simulation was achieved with the

same training time and facilitator/student ratio as standard simulation.

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Legends

Table 1. Demographic characteristics of the three study groups: e-learning alone (E), e-learning plus standard simulation (E+S) and e-learning plus proficiency-based progression simulation (E+PBP) .

Figure 1. Consort diagram outlining selection, allocation and follow up of undergraduate medical and nursing participants in a study comparing the effect of e-learning alone (E), e-learning plus standard simulation (E+S) and e-learning plus proficiency-based progression simulation (E+PBP) on clinical communication.

Figure 2. Outline of experimental design and study flow indicating training interventions and assessment of the three study training

groups (E, E+S, E+PBP) of undergraduate medical and nursing participants.

Figure 3. Outline of the high fidelity simulation performance assessment case for nursing undergraduates

Figure 4. Extract from the nursing metric scoring sheet illustrating some of the metrics and the proficiency benchmark for the high fidelity simulation assessment case.

Figure 5. The percentages reaching the proficiency benchmark at the end of training of the three study training groups; e-learning alone (E), e-learning plus standard simulation training (E+S) and e-learning plus proficiency-based progression simulation training (E+PBP).

Figure 6. Logistic regression analysis for the relative differences between the three study training groups of undergraduate medical and nursing participants; E, E+S and E+PBP.

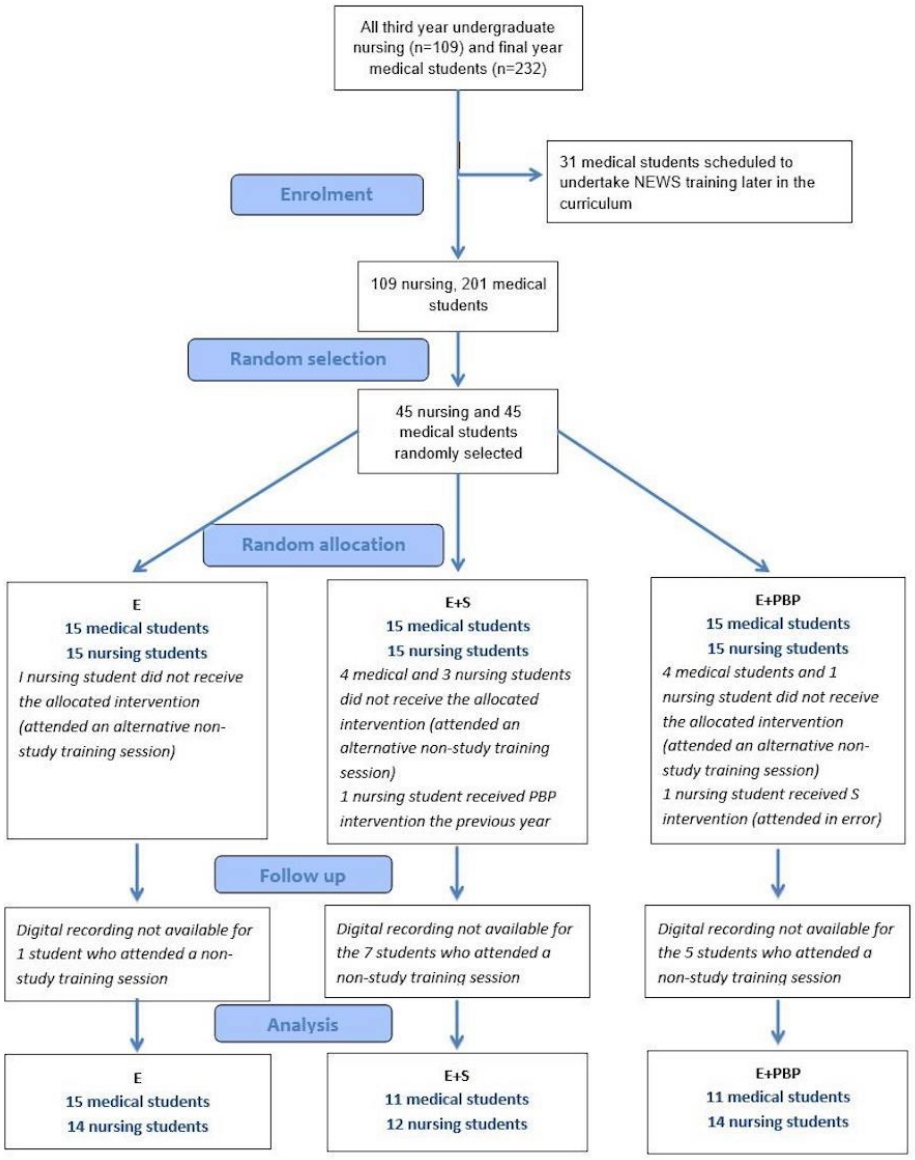


Figure 1. Consort diagram outlining selection, allocation and follow up of undergraduate medical and nursing participants in a study comparing the effect of e-learning alone (E), e-learning plus standard simulation (E+S) and e-learning plus proficiency-based progression simulation (E+PBP) on clinical communication.

76x98mm (300 x 300 DPI)

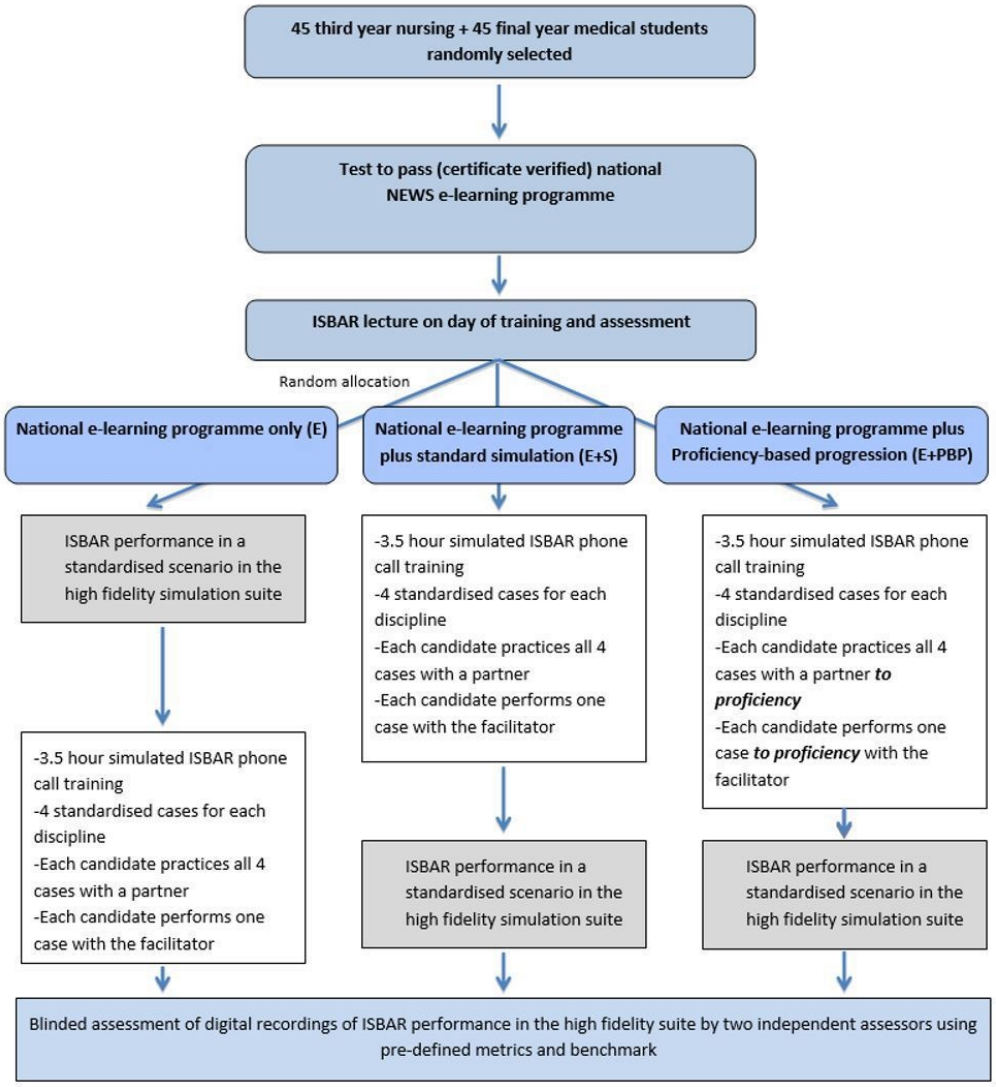


Figure 2. Outline of experimental design and study flow indicating training interventions and assessment of the three study training groups (E, E+S, E+PBP) of undergraduate medical and nursing participants.

82x90mm (300 x 300 DPI)

N-EWS simulation 10 mins in total

CSSRC
Clinical Skills Simulation Resource Centre

You are a registered nurse on the surgical ward.
It is 0800hrs and you have come on duty, you have received the below handover and are going in to meet your patient and to do her post-op observations

HANDOVER: **Rebecca Murphy 47,** has a past medical history of crohn's disease & a fractured humerous - 2 years ago

She is **DAY 2** post laparotomy and formation of an ileostomy for poorly controlled crohn's disease.

Rebecca's pain is well controlled with PCA. She required breakthrough analgesia twice over night

She remains NPO with IV fluids in progress. She continues on hourly urine monitoring with an adequate output recorded overnight

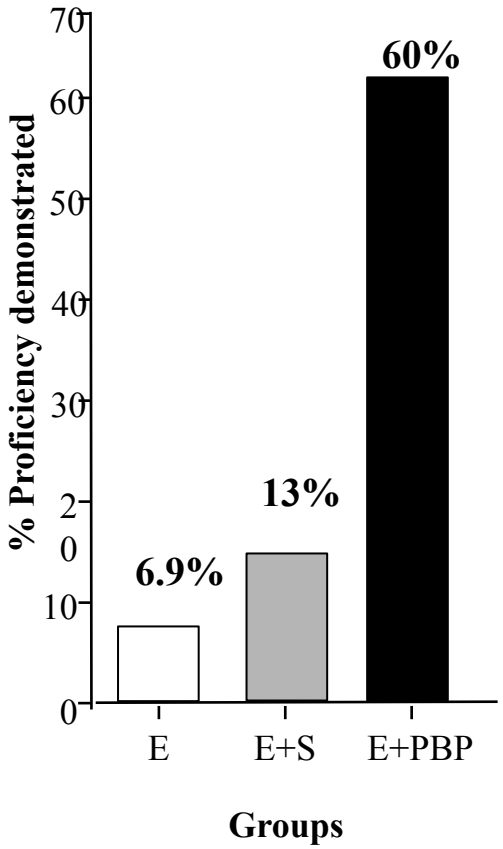
Routine bloods were taken this morning

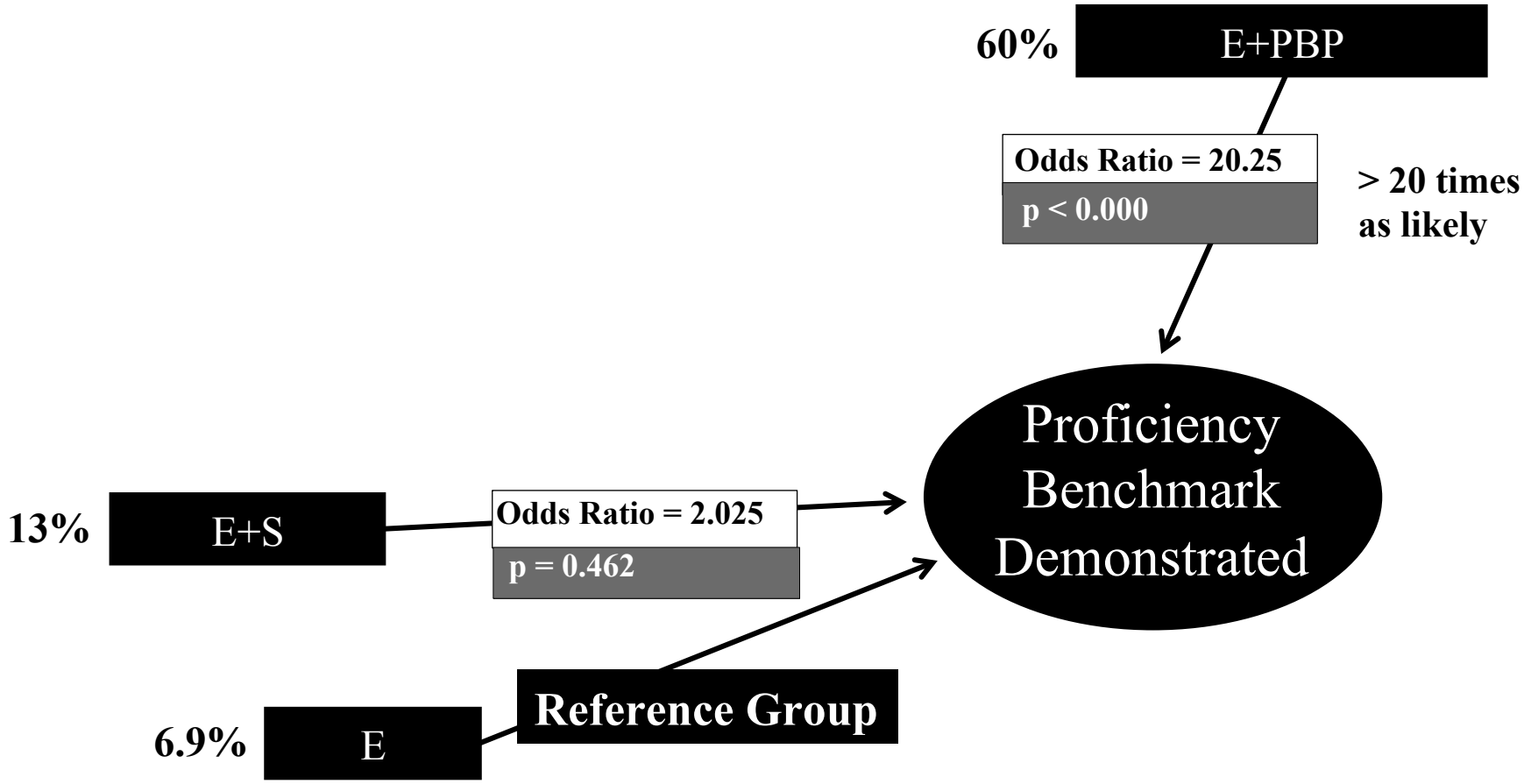
	Simulator Parameters		Roleplayer vocals	Escalation Call	
2	**RR**	21	2 days post laparotomy		
3	**SpO_2**	96%	you feel **very tired and weak**	**If after 7mins** there has been no escalation call, facilitator to say	
4	**oxygen**	Room Air	you think you should be feeling better than you are	**"please phone the doctor and seek medical assistance now"**	
5	**BP**	92/58		Do not ask any questions or provide any information throughout this phone-call except to answer the below questions	
6	**HR**	98	you thought you would be improving at this stage	**Possible questions**	**Responses**
7	**AVPU**	Alert	if asked you feel your pain is less controlled than yesterday	If asked "is this *name* ?"	"yes, speaking"
8	**Temp**	36.7	you are still nil by mouth	If asked who you are?	"this is Dr. Dara O'Leary"
9	**EWS**	5	you now have a temporary ileostomy and are a quite upset about this, but know it will hopefully be reversed in the future	If asked to confirm role - Information provided should match that in simulation room	Intern: Chris Hatfield
10	**Cardiac monitor**	Sinus tachycardia (if attached to CM)			SHO: Dara O'Leary
11	**Cap refill**	less than 2sec			REG: Jo Kelly
12	**skin**	pink, warm, dry			Consultant: Prof Healy
13	**Urinary output (0.5ml/kg/hr)**	20mls last hour		If recipient name not confirmed, and you are asked "is this the intern/SHO/reg?"	"yes"
14	**IV site**	VIP = 0 [visual infusion phlebitis score]		If asked for any recommendation	"Please commence a 500ml bolus of IV Hartmans"
15	**IV hydration**	125mls/hr		If told "I think she is bleeding/needs review/has sepsis"	"OK"
16	**Pain**	**Student to assess** if asked for PCA - 32mls in syringe; 35 demands, 18 successful]		If asked "Will you review her?"	"I will"
17	**Bowel sounds**	**Student to assess** absent		If asked "When will you review her?"	"as soon as I can"
18	**Abdomen**	**wound** - assess independently **drain** assess independently **ileostomy:** assess independently **distension** yes abdomen is distended		If told "Her EWS is (3-7), so you must review her in 30mins"	"OK"
19	**Blood Loss**	**If students enquire requiring volume in drain/ileostomy** - say "you may assess independently" If students pick up a jug to empty either give them the relevant volume "**there are 250mls in the drain**" **"there are 100mls in the ileostomy"**		If asked "Will you review her in 30 minutes/straight away?"	"I will"
20	**Chest sounds**	normal			
21	**Cap blood sugar**	5.8mmol/L			

Extract from Nursing Simulation Metric

			Tick if present	Tick if present	Tick if present
16	S	States the situation ***There is 100-300mls of blood in drain or if not exact volume qualifies with (a lot, significant amount, unusual amount, quite a bit) AND/OR states blood in ileostomy bag no qualification needed.***			
17	S	States the situation ***Her urinary output 20mls/hr***			
18	S	States the situation **States patient is on IV fluids**			
19	B	Background information ***States she has history of Crohn's disease states history***			
20	B	Background information ***States she is two days post laparotomy/ileostomy/bowel resection***			
21	B	Irrelevant background ***States fractured humerus two years ago***			
22	A	Assessment *Gives relevant **case specific** assessment*			
23	A	Assessment ***I think she is bleeding*** +/- patient is hypovolemic			
24	R	Seeks a recommendation from recipient ***Do you want me to do anything else/what else would you recommend?***			
25	R	Omits to "repeat back" ***You would like me to give her a fluid bolus of 500mls and the time frame agreed for review*** *[eg: straight away/ in 30 minutes]*			
26	R	Uses own notes and/or an ISBAR sticker to aid phone call			
27		Length of call [seconds]			secs
			no. of steps = no. of boxes checked	no. of errors = no. of boxes checked	no. of critical errors = no. of boxes **NOT** checked
		TOTALS			

Proficiency Benchmark	**Proficiency Demonstrated** [tick box]	**Observer's Initial**
• **Steps ≥ 6** • **No more than 4 Errors, 3 of which may be critical**	**YES** **NO**	


70
60
50
40
30
2
0
10
0
% Proficiency demonstrated
60%
13%
6.9%
E
E+S
E+PBP
Groups


60%
E+PBP
Odds Ratio = 20.25
p < 0.000
> 20 times as likely
Proficiency Benchmark Demonstrated
13%
E+S
Odds Ratio = 2.025
p = 0.462
Reference Group
6.9%
E

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8/9/10/11 Figure 2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11 and 5 protocol
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	13
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	14
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	14
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	14
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	2/3 protocol
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	14, 15

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	8/9/10/11
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	15,16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	15,16
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15/16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
Other information			
Registration	23	Registration number and name of trial registry	ClinicalTrials.govNCT02886754
Protocol	24	Where the full trial protocol can be accessed, if available	Attached,Clinical trials.gov,

			and attached
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	none

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.