

ORIGINAL ARTICLE

Challenges in evaluation of a simulation-based educational course for repair of obstetric anal sphincter injuries

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Abstract

Background: Failure to identify and repair anal sphincter injuries sustained during childbirth can lead to significant long-term morbidity. This paper describes the evaluation methods used to assess the efficacy of The All Wales Hands-on Third and Fourth Degree Perineal Tear Repair Course in reducing the long-term complications associated with obstetric anal sphincter injuries (OASIS). **Methods:** Formative evaluation was received from the learners between 2015 and 2021. The post-surgical outcome after OASIS repair in North East Wales was assessed using a postal questionnaire sent to general practitioners between 2012 and 2015. The survey was done 1 year after the last case of OASIS in 2015. **Results:** Feedback from all the learner delegates suggested a high satisfaction rate. Forty-five women were identified as needing repair of OASIS giving an OASIS incidence of only 0.6%. Of the 45 questionnaires, 35 (77.8%) were returned by the general practitioners. None of the 35 women had reported any residual symptoms of anal incontinence to their general practitioner. **Conclusion:** This review demonstrates high post-course satisfaction rates among attending delegates and very low reported long-term complication rates after OASIS repair in women giving birth in North Wales. The simulation-based education described appears highly effective in reducing the long-term complications associated with obstetric anal sphincter injuries, suggesting that the skills developed in the laboratory are being transferred to the real-life setting. However, designing a strategy to adequately evaluate a course of this nature is difficult and needs careful planning to overcome the challenges posed by this type of research.

Keywords: *obstetric anal sphincter injury; simulation-based education; evaluation of simulation-based education course*

Introduction

Specialty trainees in obstetrics and gynaecology are expected to achieve independent competence to identify and repair obstetric anal sphincter injuries (OASIS) by the end of specialty training year 4. Although there are risk factors associated with OASIS, most tears are unpredictable and occur in the acute setting, often out of hours. Trainees need to be able to both recognize and repair these tears independently. In the United Kingdom, the overall incidence of OASIS is 2.9%. The incidence has increased from 1.8% in 2000 to 5.9% in 2012.^{1,2} This increasing trend probably reflects the better recognition and reporting of OASIS rather than a deterioration in the quality of care during parturition.³ A recent survey among obstetricians identified a lack of satisfactory training in this area.^{4,5} Randomized trials report defective sphincter repair resulting in residual deficiency of the external anal sphincter in 19% to 36% women after surgical repair of OASIS.^{6–8} This can result in anal

incontinence, which may be life-long. Dedicated specialized training in the identification and repair of OASIS leads to a higher rate of identification and more effective repair.^{4,9,10}

The All Wales Hands-on Third and Fourth Degree Perineal Tear Repair Course has been running every year since 2008 at Wrexham Maelor Hospital, North Wales.

The delegate numbers limited to 12 in each course to provide one-to-one supervision for the practical learning exercise. This is a 1-day simulation-based education (SBE) course consisting of interactive sessions covering the theory of OASIS and briefing in preparation for the practical sessions. The theoretical part consists of presentations on pelvic and perineal anatomy, endoanal ultrasonography, long-term implications of a 3rd/4th degree tear, anal manometry and management of anal incontinence, counselling for women with this kind of tear, consent process before repair and follow-up after repair. A colorectal surgeon

participates in the theoretical session. The practical session is held in a dry laboratory on dedicated part task trainers (PTT) followed by SBE on cadaveric porcine perineum, where learners are required to identify the anal sphincter in a cadaver, create a 4th degree tear and then repair it using the technique that they would use in real life. Other models for SBE of OASIS repair have been described using goat's pelvis and porcine tongue and intestine.^{11,12}

Learning objectives of this course

Delegates for this SBE course include midwives, senior specialty trainees and new consultants who want to refresh their knowledge and technical skills. The learning objectives of this course are aligned to the Royal College of Obstetrician and Gynaecologists' (RCOG) core curriculum as follows:

- (i) Understand the anatomy and significance of anal sphincter injury and its consequences (theoretical knowledge)
- (ii) Inform women and obtain valid consent for repair of OASIS (theoretical knowledge)
- (iii) Identify and recognize the degree of tears of anal sphincters on the PTT and porcine perineum (briefing by video demonstration followed by simulation on PTT and porcine perineum)
- (iv) Achieve competence in satisfactory repair of anal mucosa and sphincters on the PTT and porcine perineum (briefing by video demonstration followed by simulation on PTT and porcine perineum)

The ultimate purpose of running this course is to reduce the morbidity associated with undiagnosed or inadequately repaired OASIS. This requires transfer of skills from the simulated setting of our course to real-life practice on the labour ward and the maternity operating theatre.

Objectives (i) to (iv) correspond to evaluation at Kirkpatrick levels 1 and 2 and possibly level 3, namely: (1) reaction of the learner; (2) learning by the learner; (3) behavioural change.¹³ These Kirkpatrick levels are similar to phase 1 of the evaluation strategy suggested in the Translational Science Research (TSR) method.¹⁴ Kirkpatrick's levels and the TSR framework are two practically useful frameworks for assessing the utility of SBE courses as follows:

- Kirkpatrick level 1: learner's reaction to the process of learning. There is no corresponding phase for this stage of learning in the TSR framework.

- Kirkpatrick level 2: degree or extent of enhancement of learner's knowledge and skills. TSR phase 1 corresponds to this level and is demonstrated by learning in a simulation course.
- Kirkpatrick level 3: skills transferred to capability to perform the practical procedure in a real-life job or in clinical practice. TSR phase 2 equates to this level.
- Kirkpatrick level 4: influence or effect of the SBE course on patient safety. TSR phase 3 is equivalent to this level and it is used to demonstrate whether there is any significant improvement in outcome for patients as a result of the skills acquired in the SBE course.

Need for evaluation and methods of evaluating

OASIS is a recognized indicator for the quality of maternity services.³ It is known that OASIS is under diagnosed and under reported and that symptoms of anal incontinence and faecal urgency are associated with defects in the anal sphincter.¹⁵ In the longer term, about 25% to 37% of women with OASIS experience anal incontinence and this can have an impact on their future obstetric choices.^{16,17} Johanson and Lafferty¹⁸ showed that only a third of people with anal incontinence reported it to their doctor because of a sense of embarrassment and presumed disgrace associated with this condition. The RCOG's core curriculum now includes the achievement of competence for identification and repair of OASIS as an essential requirement for training in obstetrics and gynaecology.¹⁹

Training on a simulator is important, both to teach the techniques and allow opportunities for repeated practice. This helps develop the skills needed to identify and adequately repair OASIS. In addition to justifying the effort, time and financial expenditure of running this course, it is morally and ethically necessary to evaluate the effectiveness of this course in achieving its objectives. The RCOG expects all trainees to attend simulation courses as part of their training in this subject.¹ It is accepted that well-designed training programmes are effective in maintaining a skilled workforce, but attention should be paid to how training is delivered and how the resulting competence is utilized in the workplace.²⁰ The authors state that designing and evaluating a training programme may be more difficult than implementing the programme, but both aspects are equally important. A study conducted in a low-resource setting demonstrated that knowledge and self-efficacy are positively correlated to setting of goal-oriented targets and factors related to available facilities for training.²¹

Because of the need for one-to-one supervision and tutoring, we have a maximum of 12 learners per course. At the end of the course, feedback is collected on prescribed forms (Appendix 1) from learners attending this course as a matter of the routine developmental process. Feedback from general practitioners (GPs) of patients is also normal practice, which we undertake to find out about the quality of our health care service. Hence, ethics approval was not believed to be necessary for reporting our findings.

Formative evaluation: helping evolution and development

During the early years, most of the feedback received was by hearsay or through verbal messages received after a trainee's Annual Review of Competence Progression (ARCP) by the Welsh Deanery. Such feedback risks being inaccurate and should be interpreted with caution. We also compared and learnt from more experienced SBE course providers in other parts of the United Kingdom and modified our course accordingly.

At present, feedback is sought from all attendees after the course (Appendix 1). The feedback form has evolved slightly over the years. This only assesses Kirkpatrick levels 1 and 2, which correspond to TSR phase 1. For most of the items or questions, learner's views are expressed on a Likert scale.

Summative evaluation of this course: are we there yet?

For organizers, the ultimate aim would be to demonstrate that this course makes a positive clinical difference in the management of OASIS. In an attempt to evaluate the impact of our course on OASIS and its repair, the outcome for all women who underwent repair of OASIS in North East Wales was assessed. A short questionnaire (Appendix 2)

was sent to the GPs of women who underwent OASIS repair during the 3-year period between 2012 and 2015.

Results

The learner survey form evolved over the years, and the questions asked changed slightly due to better understanding of requirements from the course. In practice, not all the questions in the survey form were answered by the learners. Because the survey was anonymous, it was not possible to identify the defaulter learners to ask them to fill in the missing answers. The maximum score on the Likert scale varied. In 2015, each question had a maximum score of 5 and for other years, it was 10. Results of feedback from learners from 2015 to 2021 are shown in Table 1. Due to Covid pandemic restrictions and because of the nature of this course, we could not hold the course in 2020. The total number of learners who attended during this period was 55.

For the survey of GPs, a total of 45 women were identified from the operating theatre computerized information system. There were approximately 7500 births during this period, giving an OASIS incidence of 0.6%. This is significantly lower than recently published data.²² Thirty-five of the 45 (77.8%) questionnaires were returned. This survey was undertaken in 2016, 1 year after the last case of OASIS in 2015. None of the 35 women whose questionnaires were returned had reported any residual symptoms of anal incontinence to their GP.

Discussion

The GPs' responses suggest attainment of Kirkpatrick levels 3 (behaviour) and 4 (outcome). The education imparted in our course had not only carried over to the actual patient care setting (TSR phase 2) but also led to improved outcomes in the health care of women (TSR phase 3) affected

Table 1 Feedback score from learners (updated following our last course in 2021)

Question	Total number of responses	Score obtained/maximum score	Percentage score obtained	Number who did not respond
Q1: Did this course enhance your knowledge about recognition of 3rd and 4th degree perineal tears?	45	360/405	89	10
Q2: Was the video demonstration useful?	47	400/425	94	8
Q3: Was the hands-on experience useful?	47	408/425	96	8
Q4: Would you recommend this course to colleagues and friends?	55	500/505	99	0
Q5: Did this course enhance your skills in repairing 3rd and 4th degree perineal tears	36	341/380	90	19
Q6: Overall assessment of course	27	255/270	94	28

by OASIS. Although this may be true, there are a number of problems in the way the data were collected that may have influenced the results.

The number of learners is relatively small and not all of those learners responded to all the survey questions. As mentioned earlier, a significant proportion of women do not report symptoms of faecal incontinence because of embarrassment and therefore may not have sought help from the GP, leading to under reporting of complications. Another deficiency of this study is the lack information on a significant number of women.¹⁰ Also, there is no way for us to know whether all cases of OASIS were correctly identified during the study period and what number were missed during that time. This survey only included those women in whom OASIS was identified and repaired. It is acknowledged that OASIS is under diagnosed and many cases remain unidentified at clinical examination.^{23–25}

As elucidated in the Centre for Disease Control (CDC) Program Operations Guidelines, it is also uncertain whether there are any confounding effects (external influences) on our apparent excellent outcome. Recent publication of a host of guidelines and publicity on this subject might have increased awareness about OASIS and its long-term ill effects. In the same document, the CDC refers to ‘outcome evaluation’, which was the purpose of obtaining feedback from GPs.²⁶

‘Impact evaluation’, as defined by the CDC, is a different level of evaluation that describes how the impact on the population of a simulation course such as ours can be assessed. We are wary of the fact that in recent times there has been a steady increase in caesarean delivery rates coupled with a decrease in the rate of instrumental vaginal delivery.²⁷ Instrumental vaginal delivery is known to be associated with an increased incidence of OASIS. It may be that the learning and enhanced awareness of this after our simulation-based course has inadvertently led to an avoidance of instrumental delivery.

Economic evaluation and sustainability

To reduce the cost of running this course, some of the consumable items are donated by our operating theatre, and food and drinks are funded by named sponsors. Supervision and teaching is done voluntarily by willing clinicians during their free time. The rooms used in the local medical institute come free of cost.

The economic benefits are therefore much more difficult or perhaps impossible to calculate. Although important, the course is not aimed at reducing the incidence of OASIS, but at identifying and correctly repairing the obstetric

injury with a view to reducing the complications and the on-going distress experienced by women affected by OASIS.

When undertaking cost analysis, the unit of measure would be (a) the number of women with OASIS who were identified and remained asymptomatic after repair of OASIS and (b) the number of women for whom OASIS remained undiagnosed at the time of injury and the cost of restoring normal quality of life. When the unit cost is determined, then a comparison can take place between the cost of running the SBE course and cost of one unit as stated above. In this scenario, calculation of a cost-utility analysis is more suitable as the woman’s ailment after a missed diagnosis or an inadequate repair may be assessed by quality-adjusted life years (QALY). For a detailed discussion on other methods of economic evaluation, we refer readers to the CDC Program Operations Guidelines.²⁷

It is tempting to think that the ideal way to evaluate economic gains may be through a double-blind randomized controlled trial, but as Forrest and Mckimm²⁸ suggest, it is not clear that this kind of trial is possible in SBE because the participants cannot be blinded.

We have to bear in mind factors beyond Kirkpatrick levels and TSR phases and evaluate the sustainability of this course. The above-mentioned logistics and resource implications make it clear how we have been able to sustain and run this annual course since 2008.²⁹

Evaluation by high stakes assessment: is this SBE stage appropriate?

This SBE course is not appropriate for high stakes (summative) assessment because OASIS in real-life practice is different from an anal sphincter injury identified and repaired in a cadaveric porcine perineum. Echoing the sentiment of Khan and Ramachandran,³⁰ the learning objectives of this course will help learners to improve their competence where ‘competence’ is a quality or characteristic possessed or achieved by the learner. On the path to achieving the expected level of performance, competence is a station. By implication, increasing competence should lead to an enhanced or a higher level of performance. As Khan and Ramachandran point out,³⁰ transforming competence to performance needs intellectual capability, meta-cognition and as suggested by Donald Schon,³¹ reflection, both in action and on action. To this list of necessities, we should also add repeated practice in SBE courses and then in real life. Khan and Ramachandran³⁰ state that many environmental influences affect performance and that ideally, performance should be assessed when the learner or performer is unaware that they are being assessed.

Implementation of high stakes assessment may give rise to fear of reprimand or failure and as a result, dissuade learners from enrolling on a course like this to learn and practice freely to improve their skills. This phenomenon is evident from the pilot study by McClenny³² and the review by Nichols.³³ McClenny also states that some students felt that high stakes testing can potentially hamper transfer of skills to real-life practice.

Formative assessment of competence: its role in evaluation

This SBE course aims to provide a friendly, tension-free environment in which to learn, where the learner is not worried about making mistakes or being reprimanded. The aim is to provide formative assessment through constructive feedback and dialogic debriefing throughout the hands-on part of the course in both in the dry and wet laboratory. As Rudolf and colleagues suggest,^{34,35} we follow the same four steps in closing the performance gap in learners. These steps consist of (1) determination of the objectives, (2) feedback to describe any existing gap, (3) reflect and assess reasons for the gap, and (4) facilitate closure of the performance gap through focussed and targeted instruction.

Once the objectives of the course have been achieved, the learner should then manage the appropriate number of cases of OASIS under the direct supervision of a qualified supervisor. As shown in the systematic review by Boet and colleagues,³⁶ this kind of transfer of skill from SBE to real patient is possible and is something we would expect after this course.

The number of real cases required before trainees graduate to independent practice will vary according to individual circumstances. Until the learner achieves the stated objectives of this course, we would encourage them to repeat this type of SBE course to allow them the time and resources needed to rehearse and practice before transferring to the acute situation. As discussed by Aluko and Shonubi,³⁷ the ability of the learner to transfer the acquired skills from SBE to real-life practice also depends on the culture and environment in the workplace and the behaviour of managers and supervisors.

Other evaluation techniques have been described in the context of nursing education to evaluate progression or development of the learner through stages of learning; for example, the Quint Levelled Clinical Competency Tool (QLCCT)³⁸ and the Lasater Clinical Judgement Rubric.³⁹ However, these are more suitable for a training programme that takes place over a period of time rather than a 1-day course where there is no substantial scope for assessing the

learner's progression from a novice to a mature state. Ochylski and Aebersold⁴⁰ described use of video in assessing performance progression. We feel that such measures can give rise to apprehension in the learner, and anxiety and a feeling of lack of freedom to enquire about their doubts.

Facilitation, supervision, instruction

In this course, the role of instructor, supervisor or facilitator is always taken up voluntarily by qualified consultant obstetricians. Before the start of the course, the faculty of instructors meet and discuss the requirements of the course and the model of expected clinical behaviour achieved by the learner at the end of the SBE course. In this way, we aim to provide skilled supervision and minimize bias in debriefing and assessment. We have deliberately stayed away from the use of checklists in the assessment because their interpretation may be subjective and learners may be prone to play act to the requirements of the checklist.⁴¹ Learning and achievement of objectives is multifactorial and depends on the ways and means of facilitation of the SBE course. As mentioned by Franklin and colleagues,⁴² we ensure that our facilitators are broad minded and flexible enough to accommodate the learners' individual differences in behaviour, attitude, knowledge, skill and culture.

Conclusion

Organizing an SBE course of this nature takes a significant amount of time and effort coupled with substantial financial expenditure. The expenditure needs to be justified by the outcome of the training course, not only for the organizers and trainers but also for the learners who make the time and effort to come and learn. Designing a strategy to evaluate a course of this nature is difficult and needs a deliberate and concerted effort to plan. Calculation of cost effectiveness, cost utility and cost benefit may be more complicated than they appear superficially. Even with the best of intentions, the outcomes of an evaluation strategy may be shrouded in uncertainty, contaminated by external influences, leaving results that are difficult to interpret.

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Conflict of interest

We have no conflict or vested interest in running this course or publishing this paper. The only declared interest is in educating and training tomorrow's doctors.

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Appendix 1: Feedback form for All Wales Regional Hands-on Course: 3rd and 4th Degree Perineal Tear Course

All Wales Regional Hands-on Course 3rd & 4th Degree Perineal Tear Course

FEEDBACK FORM

Scale of rating : 1= not at all ; 10 = Very much so.

1. Did this course enhance your knowledge about recognition of 3rd and /4th degree perineal tear ?
RATING :
2. Do you feel this course will enhance your skills in repairing 3rd & 4th degree perineal tear ? RATING :
3. Which lecture did you find most useful ? (circle ONE only):
Anatomy / RCOG guideline & consent / Colorectal view / Radiological lecture
4. Please provide a grade or rating for each of the following on a scale of 1 to 10
(1 = very poor; 10 = excellent)
Lectures on : Anatomy
RCOG guideline & consent
Colorectal view
Radiological lecture.....
5. Video demonstration.
RATING :
6. Hands-on experience with model & pig's perineum in skills lab useful ?
RATING :
7. Supervision and tutoring with hands-on repair on model and pig's perineum.
RATING :
8. Technical aspect of audio-visual presentations satisfactory ?
RATING :
9. Overall assessment of this course.
RATING :
10. Catering arrangements.
RATING :
11. Would you recommend this course to colleagues or friends?
(Circle ONE) Yes / No / Not sure.
12. Any additional comments on ways to improve or something you particularly liked or any other views.
(You may use space on the back of this page)

Appendix 2: Feedback form sent to GPs about women who underwent third or fourth degree perineal tear repair

FFEDBACK FROM GENERAL PRACTITIONER

Dear General Practitioner,

According to our departmental policy every patient who underwent the above mentioned tear should be offered an appointment in the Gynaecology clinic after 3 months for a post-operative review. From our computerised records, the above named patient does not appear to have attended any such follow up appointment and we hope all is well with her. Please excuse us if we have missed any record or that by accident she did not receive a follow-up appointment.

I will be grateful if you could kindly fill in the following for my information and records as part of a review about the repair of third and fourth degree perineal tear. Please return your response in the enclosed self addressed envelope.

Thank you

PLEASE ENCIRCLE OR STATE AS APPROPRIATE:

1. Are there any records with the General Practitioner to indicate any complaints in relation to the patient's perineal tear repair (e.g. incontinence of urine or stool, difficulty with sexual intercourse etc)
YES / NO
2. If answer to above statement was YES, then please state what the problem was.
3. Are there any ongoing issues with that complaint related to perineal tear repair :
YES / NO
4. If answer to item 3 is YES, then please state whether the patient is undergoing or has undergone any treatment for this.
5. Other relevant information: