

Failure modes and effects analysis to assess COVID-19 protocols in the management of obstetric emergencies

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Received 28 July 2020
Revised 17 October 2020
Accepted 4 November 2020
Published Online First 17
November 2020

ABSTRACT

The Royal Free Hospital is one of four High Consequence Infectious Disease centres in England and as of the end of May 2020, seven women were confirmed COVID-19 peri-delivery. We developed a standard operating procedure (SOP) for suspected and confirmed COVID-19 women undergoing operative delivery. This was revised in response to our ongoing clinical experience and changes in guidance from medical and public health organisations. Following 10 weeks of clinical practice, we formally tested the SOP using point-of-care simulation to enable optimisation for a potential second surge. Our high-fidelity simulation of a COVID-19-positive parturient requiring an emergency caesarean was facilitated by the simulation team in our obstetric unit. It was designed to test the performance and safety of our SOP as well as staff performance. We used the Failure Modes and Effect Analysis tool (a systematic, prospective method of process mapping) to identify how a complex task might fail and assess the relative impact of different failures. The decision-to-delivery was 17 minutes, which we considered to be successful. However, a number of operational deficiencies were identified. The main failures related to lack of situational awareness, ill-fitting personal protective equipment and difficulties communicating between theatre and the neonatal teams located outside, posing serious potential risks to safe neonatal care. Subsequently, we have modified our SOP to include a communication check, implemented communication training for the neonatal team and organised further simulation training for theatre staff unfamiliar with COVID-19 considerations.

INTRODUCTION

The COVID-19 pandemic places a huge burden on healthcare delivery and novel risks to patients and staff.¹ Its evolution required the rapid formation of institutional pathways based on expert opinion and emerging scientific evidence.^{2,3} In situ simulation is a technique that can inform the development and testing of such pathways in a safe manner, especially when facing novel clinical challenges.² Simulation-based training has been identified as an important training modality to improve healthcare delivery in high-pressure situations.³⁻⁵ Whilst it demands the coordination of many healthcare providers and resources, it can significantly improve patient care and safety.^{6,7} Its potential uses in the COVID-19 pandemic include:

- ▶ Supporting organisational response to the current crisis

- ▶ Evaluating new or temporary care settings;
- ▶ Supporting and training staff to practise new skills
- ▶ Modifying policies and procedures
- ▶ Facilitating individual and organisational learning

The Royal Free Hospital is one of four High Consequence Infectious Disease centres in England.⁸ Our obstetric department performs approximately 3000 deliveries a year. As of the end of May 2020, seven women were confirmed with COVID-19 peri-delivery. Here, we share our experience in the use of in situ simulation to ensure safe provision of obstetric services during the COVID-19 pandemic.

A standard operating procedure (SOP) for suspected and confirmed COVID-19 women undergoing operative delivery at our hospital was formulated for the obstetric multidisciplinary team. A COVID-19 simulation team was formed, consisting of consultant anaesthetists and fellows in simulation. The team was assembled specifically for the COVID-19 surge and ran a series of dedicated simulations on emergency intubation and personal protective equipment for all obstetric staff.² In addition, they undertook a point-of-care simulation for the transfer of an obstetric patient with COVID-19 from isolation to theatre using the failure modes and effects analysis (FMEA) tool to guide safety.⁹

The SOP was modified in response to our clinical experience and changes in guidance from Public Health England, the Obstetric Anaesthetists Association and the Royal College of Obstetrics and Gynaecology.¹⁰⁻¹² A key development at the time was the decision to treat all delivering women as suspected COVID-19 due to lack of available testing.¹¹ Training was then required to educate labour ward staff on the appropriate use of personal protective equipment depending on the stage of labour and type of delivery.

The reorganisation of obstetric theatres into clean and dirty areas presented a number of issues, which included restricting access to theatre and reallocating equipment and drugs away from contaminated areas. The combination of donning personal protective equipment and these modifications posed risks to delays in delivery time. In order to increase efficiency and safety, we created standardised colour-coded drug containers for general and regional anaesthesia and standardised intubation crates containing all the equipment required to intubate patients with COVID-19. A runner was allocated outside theatre to provide any extra



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To cite: Curtis S, Flower R, Emanuel-Kole L, et al. *BMJ Simul Technol Enhanc Learn* 2021;**7**:259–261.

equipment or drugs needed and communication was conducted using two-way radios.

Following 10 weeks of clinical experience, we sought to formally reassess our SOP and departmental systems to optimise ongoing care for patients with confirmed COVID-19.

METHODS

Due to the lack of patient involvement, our research and development department stated that ethical approval was not required. Written, informed consent was obtained from all participants.

The high-fidelity point-of-care simulation was developed and facilitated by the simulation team and carried out on 21 May 2020 in our obstetric unit. Participants involved in the simulation were briefed and consented to participate on the morning of the exercise. The scenario was designed to test the safety of our COVID-19 SOP, institutional processes and participants' behaviour, teamwork and communication. We used the FMEA tool, a systematic, prospective method of process-mapping to identify how a complex task might fail and to assess the relative impact of different failures.^{13 14} The simulation team consisted of anaesthetic consultants with specialist interest in simulation and simulation fellows. They prospectively identified failure modes and hazards following analysis of the SOP. They also highlighted any failures in systems processes, communication and teamwork.

To test the full scope of the SOP, the following scenario was devised. A confirmed COVID-19 labouring woman required emergency caesarean section under general anaesthesia due to severe fetal distress. Following delivery, the neonate would require 5 min of resuscitation before the scenario was terminated following an improvement in the Apgar score. The objective was timely and safe delivery of the neonate while protecting staff from risks of exposure to COVID-19.

To best represent a real-life scenario, the simulation was conducted during a normal working hours, using anaesthetists, obstetricians and theatre staff rostered to work on the obstetric unit that day. A high-fidelity Laerdal 3G SimMan (Laerdal Medical, Orpington, UK) and 'neonatal sim model' were used to represent mother and baby. Participants were instructed to call on any additional clinical staff as appropriate.

The participants were briefed that a labouring 36-week patient with confirmed COVID-19 is on labour ward in an isolation room. Shortly following the briefing, signs of severe fetal distress developed with prolonged bradycardia on the CTG. Participants were then assessed on decision-to-delivery time, conduct of general anaesthesia and surgery and management of neonatal resuscitation.

Failure modes were recorded separately by two members of the simulation team and a structured debrief was performed on all participants.

RESULTS

The scenario was concluded at 25 minutes and the time interval for decision-to-delivery was 17 minutes. A number of operational deficiencies were identified. The active failures and latent threats recorded and subsequent organisational responses are summarised in table 1.

Feedback from the participants was broadly positive in terms of experience and confidence following the simulation. Participants did, however, report difficulties with non-verbal communication due to the use of personal protective equipment and heightened anxiety due to additional COVID-19 considerations.

DISCUSSION

Our simulation was broadly positive in affirming the progress we have made in the last 10 weeks in terms of staff training and

Table 1 Summary of the active failures and latent threats identified, with the subsequent organisational response.

Breach	Issue	Effect (outcome from failure)	Organisational response
Active failure			
Situational awareness	Failure to be mindful of surroundings and patient's condition	The mother was left unattended in the theatre while the team donned personal protective equipment. Participants attended to the mother without adequate personal protective equipment in the side room.	Structured debrief and written feedback to obstetric/anaesthetic staff regarding sim results. Clearer posters alerting staff to personal protective equipment requirements.
Communication	Failure to use closed loop communication	Staff failed to state their role, location and use standardised radio terminology. Neonatal team could not operate two-way radio correctly which delayed the arrival of resuscitation equipment. Hand signals between the operating room and staff outside were misinterpreted. Impaired communication due to FFP3 mask and visor. Failure to establish method of communication between theatre and 'runners' outside.	Training for all obstetric and neonatal staff on correct two-way radio operation and terminology, conducted via our communications team. Neonatal teams issued their own dedicated two-way radios to be carried by their resuscitation team. Additional step added to labour ward theatre time out—'Communication with outside theatre established?'
Shared mental model	Lack of common understanding of the plan/situation	There was a delay in the neonatal team entering theatre, despite the scenario suggesting the neonate would be at high risk of requiring respiratory support. The ODP had not assisted in a COVID-19 intubation before.	Clarification regarding neonatal protocol distributed to staff via email. Learning point established that neonates in these cases are at high risk of requiring support. Training for all ODPs on airway management in COVID-19 cases. Redistribution of COVID-19 protocols.
Latent condition			
Policy or protocol	Policy or protocol not followed ► COVID-19 intubation checklist ► COVID-19 caesarean section protocol	Sodium citrate was not administered, and the Oxford HELP was not used to assist intubation. There was confusion regarding attendance of the neonatal team in the theatre prior to delivery which delayed their assistance in neonatal life support.	COVID-19 intubation protocol amended to include sodium citrate and Oxford HELP cushion. Increased number and improved sizing of intubation posters in theatre. Additional step in 'sign in' procedure to clarify whether neonatal team should be donned and in theatre prior to commencement of surgery.
Equipment/environment	Technical, equipment or environmental failure or not available	Personal protective gowns available did not fit all staff members. This delayed donning of the anaesthetic team. Following intubation, staff members entered theatre directly rather than via the anteroom thus posing an infection hazard to staff.	Acquisition of gowns that fit taller members of staff. Further donning and doffing procedure training. Warning signs erected on entrance to theatre.
Systems issue	System process failure	The speakerphone in the theatre did not have an extension number displayed for staff to contact the runners on.	Speakerphone in theatre now has laminated instructions for use and important contacts clearly displayed.

FFP3, Filtering Face Pieces class 3; HELP, Head Elevating Laryngoscopy Pillow; ODP, Operating department practitioner.

implementation of our protocols. The total time from decision-to-delivery of the fetus was 17 minutes, which we considered excellent when following full personal protective equipment guidance and protocol. Furthermore, participants were positive regarding the experience and reported less anxiety when faced with these cases than 8 weeks previously.

Based on findings from the simulation, the following changes have been implemented at our trust:

- ▶ Training for neonatal team on use of two-way radio and procedure for communicating in personal protective equipment
- ▶ Further simulation training for operating department practitioners (ODPs) and theatre staff unfamiliar with COVID-19 considerations
- ▶ Acquisition of protective gowns that fit all members of staff
- ▶ Modification of COVID-19 intubation checklist to include sodium citrate and oxford Head Elevating Laryngoscopy Pillow (HELP) pillow
- ▶ Additional step at 'time out' to establish method of communicating to outside the theatre suite and that the equipment is working
- ▶ Revision of local COVID-19 SOP to highlight neonatal teams' discretion in attending theatre immediately
- ▶ Signage on theatre doors to prevent incorrect entry in theatre suite and potential exposure of staff to COVID-19 after aerosol-generating procedures

CONCLUSION

In conclusion, we found that using a combination of point-of-care simulation and the FMEA tool led to the detection of safety hazards in local SOPs which have now been corrected.

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Acknowledgements We acknowledge the help of our obstetric teams, anaesthetic teams and midwives who aided in the running of the simulations and writing the SOPs. In particular, Dr Sally Harrison, Margaret Blott, Jennifer Woods and Dr Kate Sherratt.

Contributors SC, RF and LE-K devised and carried out the simulation. SC wrote the manuscript with support from PN, RF and LE-K. All authors devised the failure modes and effects analysis. PN conceived the original idea and supervised the project. All authors reviewed and authorised the final manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. Results from the simulation study and trust SOP are available from the supervising author.

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REFERENCES

- 1 WHO. Coronavirus disease 2019. *World Heal Organ* 2020;2633.
- 2 Ventre KM, Barry JS, Davis D, et al. Using in situ simulation to evaluate operational readiness of a children's hospital-based obstetrics unit. *Simul Healthc* 2014;9:102–11.
- 3 Aggarwal R, Mytton OT, Derbrew M, et al. Training and simulation for patient safety. *Qual Saf Health Care* 2010;19:i34–43.
- 4 Everett TC, Morgan PJ, Brydges R, et al. The impact of critical event checklists on medical management and teamwork during simulated crises in a surgical daycare facility. *Anaesthesia* 2017;72:350–8.
- 5 Schmidt E, Goldhaber-Fiebert SN, Ho LA, et al. Simulation exercises as a patient safety strategy: a systematic review. *Ann Intern Med* 2013;158:426–32.
- 6 Brazil V, Purdy EI, Bajaj K. Connecting simulation and quality improvement: how can healthcare simulation really improve patient care? *BMJ Qual Saf* 2019;28:862–5.
- 7 Brazil V. Translational simulation: not 'where?' but 'why?' A functional view of in situ simulation. *Adv Simul* 2017;2:1–5.
- 8 Gov.Uk. *High Consequence Infectious Diseases (HCID)*, 2018.
- 9 Sevastru S, Curtis S, Emanuel Kole L, et al. Failure modes and effect analysis to develop transfer protocols in the management of COVID-19 patients. *Br J Anaesth* 2020:19–21.
- 10 The Faculty of Intensive Care Medicine. *Updated advice regarding PPE to be worn when managing pregnant women with known or suspected COVID-19*, 2020.
- 11 Gov.Uk. *Covid-19 personal protective equipment for use in aerosol generating procedures*, 2020.
- 12 Royal College of Obstetricians and Gynaecologists. *Coronavirus (COVID-19), pregnancy and women's health* 2020.
- 13 Davis S, Riley W, Gurses AP, et al. Failure modes and effects analysis based on in situ simulations: a methodology to improve understanding of risks and failures. *Adv Patient Saf New Dir Altern Approaches* 2008.
- 14 Sharma KD, Srivastava S. Failure mode and effect analysis (FMEA) implementation: a literature review. *Coppr J Adv Res Aeronaut Sp Sci* 2018;5:2454–8669.