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Failure modes and effect analysis to develop transfer protocols in the management of COVID-19 patients

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Editor—The severe acute respiratory syndrome caused by SARS-CoV-2 has created a need for innovative approaches to novel and complex issues surrounding patient care. Emergency physicians, intensivists, and anaesthetists play an early and vital role in the management of these high-risk patients, requiring cooperation and information sharing. All NHS organisations are required to test and refine their pandemic planning.[1] However, the 'real time' organisational preparedness for these resource-exhaustive scenarios is challenging and reactive policies will be necessary to deal with new rapidly evolving scenarios. It is of paramount importance that all new guidance developed is locally adapted and tested. Failure to do so may expose both patients and staff to medical errors and harm. A system engineering approach to pathway design is necessary.

As a group of anaesthetists from Royal Free Hospital, one of the four High Consequence Infectious Disease centres in England,[2] we have considerable experience in using *in situ* simulation in conjunction with a modified failure modes and effect analysis (FMEA) tool in order to test processes and detect latent risks (system-based threats to safety) and active threats (an unsafe act that has damaging immediate consequences).[3] We propose a pragmatic and effective approach to develop and test protocols iteratively using prospective risk analysis through FMEA and repeated simulation.

FMEA is a systematic, prospective method of process mapping to identify where and how a complex task might fail, and to assess the relative impact of different failures in order to identify which corrective interventions are needed most. The first step in the FMEA process is to split a large complex goal into small simpler ones. In this case the complex goal was to transfer a coronavirus disease 2019 (COVID-19) patient from one part of the hospital to another. The ability to create a list of what tasks are necessary to complete this challenge requires a list of subgoals that need to be achieved to complete the 'how'. Examples of subgoals in the process of transferring the patient include donning personal protective equipment (PPE), allocation of staff, and appropriate equipment. These subgoals then require a set of tasks to ensure they are completed. In the case of equipment, the tasks may be to collect the transfer trolley, check oxygen cylinders, and ensure that the ventilator is available and checked. By dividing the process into smaller goals and tasks required to achieve these goals, we could then identify the possible failure modes that could impact our ability to complete the complex goal, of transferring the patient safely. This process helped our team to identify and prioritise risks in order to find ways to eliminate or mitigate their impact.[4] This is shown in Supplementary File 1.

Our team used this tool in conjunction with *in situ* simulation to perform a comprehensive hazard analysis of processes required for the transfer of COVID-19 patients. The findings of the simulation were used to generate a transfer policy, thus refining it and ensuring its safe operational suitability.

We performed two high-fidelity transfer scenarios during a full day of training. Scenario A was an urgent transfer of COVID-19 patient from ward to theatre. Scenario B was a COVID-19 patient in labour transferred to theatre for an emergency Caesarean section.

The scenarios were facilitated by experts in simulation. FMEA-generated process mapping and a structured debrief was performed on all participants.

Careful consideration was given to both operational challenges, technical and non-technical issues such as situational awareness, role allocation, communication, and cognitive load.

Multiple hazards and areas for improvement were identified. They are summarised in Table 1.

Participant feedback highlighted difficulty in communication owing to lack of non-verbal cues and muffled speech.

Table 1 Multiple hazards and areas for improvement. CTG, cardiotocography; PPE, personal protective equipment.

Active failure An unsafe act that has damaging immediate consequences	**Issue**	**Behaviour**
Situational awareness	Failure to recognise time required for donning PPE. Failure to limit staff exposure. Failure to recognise time required to co-ordinate transfer. Failure to manage documentation required for theatre.	Donning of PPE took 4–8 min. Unnecessary team members entering isolation room. Touching face after patient contact. Participants did not wear third pair of gloves to examine patient. Failure to convert facemask oxygen to nasal cannula. Failure to place FFP3 mask on patient.
Communication	Failure to establish reliable communication with team outside isolation room. Failure to use closed-loop communication.	Incorrect use of speaker phone by holding handset to face, thereby contaminating user. Incorrect use of walkie-talkies. Failure to hear other team members because of muffled speech.
Shared mental model	Lack of team understanding in how to execute tasks efficiently and safely. Failure to recognise transfer poses risk to staff and members of the public. Failure to decide plan if deterioration occurred *en route*. Failure of anaesthetic team to prepare to receive patient in theatre correctly	Unsure who should facilitate the transfer. Unsure destination of transfer. Attempt to enter anaesthetic room instead of theatre directly. Scenario B – anaesthetist donned PPE on isolation ward, delaying transfer.
Latent hazards System-based threats to safety		
Policy or protocol	Current transfer checklist inappropriate for COVID-19 patient. PPE posters unavailable.	Participants failed to stop face mask oxygen therapy for transfer. Failed to check FFP3 mask on patient. Failed to don and doff PPE correctly. Lack of COVID specific transfer protocol.
Equipment	Non-essential equipment brought on patient transfer. Non-essential documentation contaminated on transfer. Inadequate equipment for transfer. Transfer pathway obstructed. Lack of priority access cards to lifts. Glasses hindered doffing.	Failure to bring only required consent form and theatre care pathway in theatre. Failure to disconnect CTG monitor for transfer. Unnecessary infusions brought on transfer and fell of the bed. No swipe card available for transfer team. Lift opened inadvertently at two other levels exposing members of the public without PPE. Staff were contaminating each other during doffing.
Staff	Lack of staff to supervise donning and doffing.	Difficulty finding PPE-trained staff – delaying transfer
Environment	Temperature in PPE. Noise.	Obstetrician fatigued following transfer.
Systems issue	Phone in isolation room did not work properly. Failure to have designated radio channel for walkie-talkies.	Interruption on radio channel from other areas in the Trust.

They found it difficult to identify other team members. All participants found the temperature in PPE was unpleasant, and this impacted upon their comfort significantly. Candidates also experience heightened anxiety because of the risk of potential clinical exposure to COVID-19, even in a simulated scenario.

Reports from Italian clinicians involved in the care of these patients suggest the number of cases requiring advanced respiratory support double every 4–5 days, with some regional variations.[5] The team response to a transfer call has to be swift and proportionate. The systems we put in place must protect staff and patients, and be effective and adapted to local conditions. Ideally, they should ensure maximal protection of staff for the minimal level of complexity.

We showed that all these steps required to manage patients take a significant amount of time. The donning and doffing take a few minutes each and mandate the presence of a buddy on a one-to-one basis. As the case burden increases, we foresee that this will become a real issue that needs careful analysis and a pragmatic approach. Doffing carries the highest risk of contamination for staff so particular attention should be paid there.[6] Because of the availability of buddies, there might be the need to do sequential donning and doffing, which will add a substantial time to the process. Streamlining the local protocols to ensure safety within simplicity is key to avoid operational compromise.

Another important consideration is communication. In full PPE, staff cannot hear or recognise each other easily. Communication with the runner outside the contaminated clinical area is risk prone. In our scenarios, staff used both phones and walkie-talkies. Phones should only be used on speaker mode to avoid risk of contamination. When walkie-talkies were introduced into simulations, we realised the need for closed-loop communication using the SBAR (situation, background, assessment, recommendation) approach and the need for appropriate training. Clinicians who were not used to talking through them found them difficult to operate. There are limited amounts of channels and sometimes multiple teams share the same channel. In a situation with increased cognitive and emotional load, there is the potential for error.

We cannot stress enough the importance of a team brief prior to commencing of any task. This allows team members to share a mental model. Task allocation is vital to avoid confusion and unnecessary duplication.

Our team designed and streamlined a transfer checklist that sets out clear roles for all team members. It also highlights key interventions to increase safety. This is a key intervention, because as the burden of cases increases it may be required to allocate staff with less experience.

We strongly recommend using a checklist that is tested and adapted to meet local conditions.

Transition of care is a risk-prone process. Multiple studies have shown a correlation between the number of transfers of command and error.[7,8] Essential information may be missed leading to harm. In the event of multiple patients requiring advanced respiratory support, there will be an inevitable overspill of patients from the ICU to other clinical areas for which an effective transfer of information and command becomes vital.

Non-essential equipment and infusions were brought on transfer and multiple encounters with other staff and public occurred due to an inadequate cordon set-up and problems with priority-access cards to theatre. The logistics of a transfer of this nature require careful consideration at the local level.

All participants reported heightened anxiety during the scenario because of the confirmed COVID-19 status regarding exposure of themselves and uncertainty on how to manage the process. All reported this would be further heightened in a real-life scenario.

We want to share our experience and learning on how simulation in conjunction with a simplified FMEA tool can provide an effective way to iteratively design guidelines and pathways.

Secondly, we would like to raise awareness of the possible hazards surrounding the transfer and intubation of COVID-19 patients.

Our simulation findings are backed up by real experience of the authors with managing these patients.

Declarations of interest

The authors declare that they have no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bja.2020.04.055.

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