

Infection Control Measures, *in situ* Simulation, and Failure Modes and Effect Analysis to Fine-Tune Change Management during COVID-19

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Abstract

Coronavirus disease 2019 (COVID-19) was an impetus for a multitude of transformations – from the ever-changing clinical practice frameworks, to changes in our execution of education and research. It called for our decisiveness, innovativeness, creativity, and adaptability in many circumstances. Even as care for our patients was always top priority, we tried to integrate, where possible, educational and research activities in order to ensure these areas continue to be harnessed and developed. COVID-19 provided a platform that stretched our ingenuity in all these domains.

One of the mnemonics we use at SingHealth in responding to crisis is PACERS:

P: Preparedness (in responding to any crisis, this is critical)

A: Adaptability (needed especially with the ever-changing situation)

C: Communications (the cornerstone in handling any crisis)

E: Education (must continue, irrespective of what)

R: Research (new opportunities to share and learn)

S: Support (both physical and psychological).

This article shares our experience integrating the concept of simulation-based training, quality improvement, and failure mode analysis.

Keywords: Coronavirus disease 2019, Failure Modes and Effect Analysis, *in situ* simulation

INTRODUCTION: CHANGES SINCE SEVERE ACUTE RESPIRATORY SYNDROME

Since the severe acute respiratory syndrome (SARS) outbreak in 2003, the emergency department (ED) at Singapore General Hospital (SGH) has undergone changes in both its infection control infrastructure and workflow processes.^[1,2] These are critical and essential elements in our preparedness for handling any crisis, mass casualty incidents, infectious disease (ID) outbreaks, or pandemics. They have now become part and parcel of our day-to-day practice. What is important is that these practices are

very dynamic and their pattern is regularly updated and renewed at strategic intervals, including the need for the incorporation of critical new information as it becomes available and response to new outbreaks or other, directly relevant new developments.

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During the early phases of the coronavirus disease 2019 (COVID-19) pandemic, there was rapid evolution of, and dynamic changes to, this critical institutional workflow. At the peak of the pandemic, new information required incorporation into the existing paradigms as often as 3–4 times/day. This came about as new findings and evidence were being shared across the globe and case definitions continued to be refined.^[3,4] In practical terms, the above translated into important changes in terms of patient volumes, staffing needs, and evolving resource requirements. Thus, the key question emerged, “how quickly and efficiently can the ED cope?” In response, some of the enhanced practices have been introduced, including the following:

Risk-screening/pretriage

This describes the location and process where all ED patients have to complete a screening questionnaire to declare high-risk travel history and known contacts with ill persons, as well as undergo a body temperature measurement.^[5] The travel history screening is dynamic, customized, and updated regularly to include countries and regions with ongoing outbreaks. Examples of these would include adding the Middle-East countries during the MERS coronavirus outbreak or the African nations during the Ebola outbreak.^[6-8] The questionnaire should also incorporate the updated case definitions for operational optimization. If patients respond positively to any of the questions, they would be triaged to a “fever area (FA)” (see below). The pretriage area is strategically located outside the ED, just before the triage area, which had previously been taken as the first point of contact for patients presenting to ED. Risk screening now represents the first level of filtering patients who may represent higher risk of transmitting the infection. Segregating them from the usually crowded ED waiting room is an initial step in ID control and management. In addition to the “FA,” there is also a designated COVID-19 info tent/clinic where “walk-in” patients with a history of international travel/travel from a known “hotzone” would be evaluated and if indicated, a swab will be taken with the use of a bio-safety barrier counter.

The “fever area”

Existing triage areas in EDs are often designed with balanced focus on patient flow and satisfaction. All-too-often, the consideration for health-care worker (HCW) safety and protection is secondary. Because indoor air currents may transport infections via aerosolization, patients who are deemed to be infectious must be separated from others as early as practically possible. The importance of this principle has been illustrated during both the SARS outbreak and now the COVID-19 pandemic.^[9-11]

Due to the above considerations, the FA in the ED had undergone structural re-engineering and upgrading of the ventilation system. If there are any design flaws, turbulence in ventilation across patient access areas will enable the flow of aerosolized gases between the different areas and individual patient rooms. Thus, consideration of design, equipment, and ventilation is important.^[10,12] Incorporating negative-pressure

rooms/areas into health-care facility designs, whether natural or mechanical, serves to dilute droplet nuclei in the air. This seems to be the single-most important engineering control for the successful reduction of airborne infection transmission. In the FA, all the consultation rooms, the ante-rooms, and clinical areas should be equipped with negative-pressure ventilation. What this means is that the exhaust rate in these rooms must exceed the air supply rate by a generous margin. Infected air from patients in this area is prevented from circulating in the corridor and mixing with indoor air, by an exhaust system that filters it to the outside environment. During the construction phase, ventilation engineers must be consulted with regard to the sufficient amount of flow while considering how to avoid excessive turbulence or uncomfortable air pressure buildup. The positive pressure gradient between the isolation cubicles/rooms and the remaining contiguous areas (e.g., the corridors) is approximately 15 Pa.^[11] Negative-pressure rooms have windows which do not open and have ante-rooms which will help reduce the escape of droplet nuclei during opening and closing of doors.^[9,13] This area of our ED has been in regular use to manage and isolate patients deemed to be infectious (e.g., those with suspected measles, tuberculosis, varicella, herpes zoster, and other common IDs).

It is well established that the SARS-CoV-2 virus is transmitted primarily by bio-aerosol droplets or direct, close personal contact.^[1,10,14] When onsite measurement of bio-aerosol dispersion was performed during the previous SARS outbreak, the distribution of viral spread was generally in agreement with the expected spatial infection pattern.^[1,15] This information proved important in our strategic planning and COVID-19 pandemic management at the FA at SGH.

The coronavirus disease 2019 info tent coronavirus disease 2019 triage clinic

A distinct and separate designated area in pretriage is the COVID-19 Info Tent where walk-in patients with a history of travel but triaged out of the FA would be directed. These individuals would then undergo testing, as determined by the protocol which is based on the response to patient questionnaire. Testing is performed using a walk-in bio-safety barrier device, where the HCW is protected by the barrier device in addition to standard personal protective equipment (PPE). If not indicated, disposition plan bypassing the ED would be activated. With the overall increase in cases, such walk-in kiosks were gradually introduced into the pretriage area/zone, as exemplified by some recent experiences in India.^[16]

Hand hygiene and infection control training

Hand hygiene and fundamentals of infection control are compulsory topics for all clinical staff at our institution. Mandatory education includes an e-learning component and practical refresher courses (with self-assessment) every 6 months. It covers topics such as the “WHO 7 Steps” in hand hygiene, the appropriateness of alcohol- versus nonalcohol-based agents in infection control, as well as other directly related topics such as compliance.^[17-20] Scenario-based

learning is actively used during our assessments. Refresher training sessions on donning and doffing for HCWs were also initiated by the infection control team.

Updated vaccination records

Clinical staff must be up to date with their required, regular vaccinations (e.g., the annual influenza inoculation).^[21] Other vaccinations/immunizations should also be monitored, updated, and tracked within a specialized database for HCWs.^[22-24] This may also serve as a platform for contact tracing, especially when cases involving novel IDs are encountered.

THE CORONAVIRUS DISEASE 2019 PANDEMIC

With COVID-19, the number of patients who need to be managed in the FA has increased markedly. The clinical acuity level of these patients was higher than expected, as some patients required critical care management and intubation. Prior to COVID-19, when the number of patients requiring critical care management was smaller, higher acuity patients were customarily sent to the resuscitation room (RR), where Priority 1 (P1, e.g., highest acuity) patients are managed. In the RR, consisting of eight isolated patient cubicles/spaces, there are four end-cubicles, with lead doors (e.g., to facilitate portable radiography which is performed *in situ* in the RR). We have the ability to convert these four isolated spaces into negative-pressure rooms, which is our approach outside of outbreak or pandemic settings.

However, with COVID-19, the circumstances of the pandemic forced us to manage critical patients in the FA rather than sending them to the RR. Relevant equipment and staff were re-allocated to the FA in order to ensure that appropriate level of care can

be provided. With this, we noticed certain areas of opportunity, especially during the early stages of process implementation. For example, we noted lack of HCW familiarity in terms of critical logistics, such as the knowledge of the placement of equipment and drugs. Because of a number of human factors identified during the above process, we devised a plan to use *in situ* simulation (ISS) to help us recognize and remedy various latent threats and issues. This would also help streamline and enhance the care we provide for critical patients, allowing us to approximate the original RR level of care.

Because all routine research and training activities, inclusive of the simulation training center, had been suspended due to the COVID-19 pandemic, we decided to bring our teams and simulation training directly into the clinical areas, essentially implementing “point-of-care” (POC) education.^[25,26] In the redesign of our workflow, we had to bear in mind our capabilities and limitations. Containment measures were classified and grouped according to the Hierarchy of Controls (HoC) approach [Figure 1].^[27] This approach is often used to manage and control exposures to workplace hazards, including in the health-care setting. The three principles of HoC relevant to our management of the pandemic response are: (a) elimination and control of the “hazard” is the most effective option; (b) errors due to human factors can occur and thus we must use techniques and approaches to reduce and mitigate these errors; and (c) management of risks due to human behavior is very challenging.^[27] With the COVID-19 pandemic, faced with a primarily respiratory pathogen, the attainment of process control can be achieved via innovation/engineering, administrative measures, and PPE (inclusive of other nonpharmaceutical approaches).

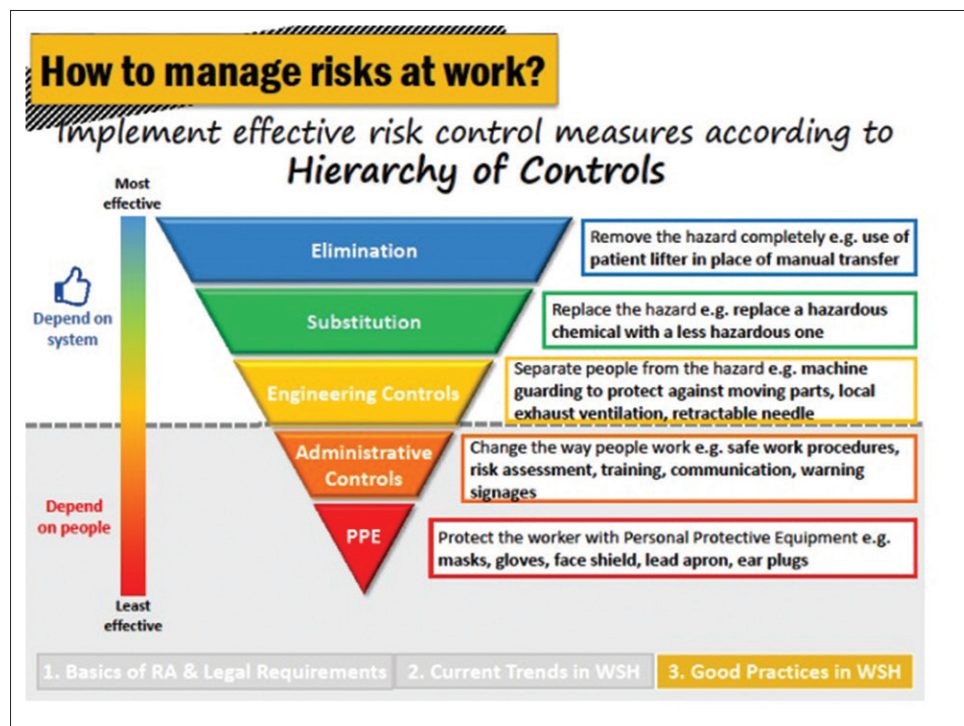


Figure 1: Hierarchy of control model as our reference in planning



Figure 2: Photo 1: Simulation team preparation in full gear to enhance the realism: with personal protective equipment and powered air-purifying respirator

Other institutions have designated a separate patient flow pathway whereby critically ill COVID-19 patients requiring airway intervention are transferred to the COVID intubation zone. Within such designated area, airway management is carried out with a locally developed bio-safety barrier device which isolates the patient trolley from the surrounding environment. In resource-constrained settings where a negative-pressure isolation room for aerosol-generating procedures is not available, a zone outside the ED and open to the external environment, with the additional use of a barrier device for intubation, provides better protection than doing the same in the conventional RR. To ensure smooth transition to such new workflow pattern, simulation-based preparatory work including the newly incorporated barrier device is of critical importance.

***In-situ* SIMULATION IN COMBINATION WITH FAILURE MODES AND EFFECTS ANALYSIS**

ISS is defined as POC simulation taking place in the actual clinical environment during the work day. It can be used to test overall preparedness and seamlessness within a particular workflow and/or a process. It promotes experiential learning which is closely aligned to the actual work experiences.^[28,29] This type of experiential simulation requires the institution to set aside specific times during regular shifts/working hours so as to minimize any encroachment into otherwise allocated staff time.

ISS enables the institution to address a number of aspects related to health-care operations, organizational efficiency, and operational safety, including the identification of latent hazards, knowledge gaps, unmet equipment needs, space and environmental constraints, as well as a plethora of human factor issues. If executed properly, ISS provides an opportunity to supplement overworked staff and offset temporary losses due to sick leave or quarantine. This is especially important in high-risk clinical scenarios and in time-pressured environments. Moreover, ISS-based training helps improve the

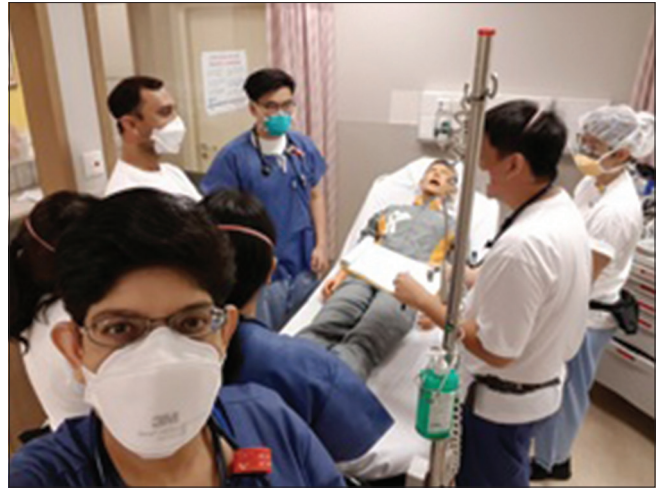


Figure 3: Photo 2: Debrief of the *in situ* simulation scenario in the fever area

reliability and safety in our high-risk and high-stress areas. At times, unexpected issues may appear during the simulation, not infrequently representing potential opportunities which may have been overlooked in the initial planning and setup phases. One benefit from such dynamic learning process is that we can quickly learn from the experience and implement any required mitigation measures without delays.

ISS embodies and promotes the combined principles of adult learning, experiential learning, repetitive learning to reach mastery, as well as reflective self-assessment. ISS can also help strengthen and nurture team cohesiveness, resulting in both stronger leadership and team performance.^[30] Finally, ISS provides unique opportunities to develop effective communication and systems-based practice within the institution.^[31,32] The combination of a low- and medium-level fidelity simulation is usually utilized in order to meet the objectives of the various scenarios created specifically for COVID-19 preparation.

The Failure Modes and Effects Analysis (FMEA) model in health care is a quality improvement tool which usually involves an interprofessional team assembled to identify systemic risks, using the steps as shown in Table 1.^[33,34] FMEA is used prospectively to identify systemic failures which need to be addressed, with the overall system made more robust as a result. The FMEA focuses on processes and not on a specific event.^[35,36] FMEA helps to pinpoint failure modes derived from expert opinion and statistical estimates, as opposed to an evaluation of a specific process under actual operating conditions.^[37-39] Thus, our plan to combine both ISS with FMEA was based on our goal of making the experience as practically oriented as possible.

SIMULATION DURING CORONAVIRUS DISEASE 2019

When preparing and responding to the first wave of COVID-19 infections, we utilized simulation modeling and training to assess and strengthen the following aspects of organizational functioning and preparedness:

Table 1: Combining *in situ* simulation and health-care Failure Modes and Effects Analysis

Phases	<i>In situ</i> simulation	FMEA
Identification of processes	Identify critical and time-dependent processes and tasks in new areas, for example, intubation with PAPR in the FA	Breakdown of processes and tasks into small or component steps
Allocation of teams	Simulation team performers: from our modular teams to prevent cross-interaction and mixing	Team made up of senior faculty, nursing managers, modular team leaders, senior resident physician, and senior staff nurse. They will make observations from the simulation and identify gaps, lapses, and failure modes needing corrective action and follow-up
Description of processes	Process mapping of management in detail, with time considerations	Testing of efficiency and adequacy of algorithms and flowcharts. Also what changes need to be implemented postevent
List of observations	Gaps, lapses, etc., needing change and corrective action identified. Also collected from debrief session after the simulation	List all failure modes (based on the experiences of the team members)
RCA	The RCA is a common session with health-care FMEA	
Implementation and follow-up action	Change and update algorithm and work processes/ensure implementation of these changes and updates. Also to communicate these to the whole department in a timely fashion (e-mail blast, private chat groups, flyers, and charts put up in the department and work areas)	

FMEA: Failure Modes and Effects Analysis, RCA: Root cause analysis, PAPR: Powered air-purifying respirator, FA: Fever area

- a. Department and institution readiness
 - b. Health-care staff readiness
 - c. Systems-based practice and referral system readiness
 - d. Establishing and refining standards of care.
- ISS modeling also enabled us to test out our systems dynamics, care protocols, and pathways during the current pandemic. We found this simulation modeling especially useful because:
- a. It enabled us to flexibly meet up with the rapidly changing demands, workflow, and processes as new evidence were generated, at strategic intervals
 - b. It also provided an avenue for real-time testing of various control measures.
- Our ISS-based goals and objectives were accomplished collaboratively between the department of emergency medicine, infection control department, division of IDs, and the emergency preparedness department. However, the initiative was not restricted to only these departments and their staff. Engagement of the other departments and staff within the institution was both crucial and highly encouraged, as the regularly updated workflows and pathways were shared and communicated throughout our health-care system. Uploading of the regularly updated documents, policies, and procedures onto the institutional Intranet helped raise awareness and made this critical knowledge readily accessible by all stakeholders.
- The following represents the list of activities and scenarios whereby simulation was utilized under the simulation paradigm outlined above:
1. Donning and doffing of PPE: This was useful as a refresher for new trainees. At any point in time, any staff member could request to have the training if they felt unsure regarding any aspect of the established procedure or standard issue equipment.
 2. Donning and doffing of powered air-purifying respirator (PAPR)
 3. Procedural training while donning PPE ± PAPR:
 - a. Endotracheal intubation, inclusive of suctioning
 - b. Toilet and suture
 - c. Chest tube insertion
 - d. Central line insertion (ultrasound guided)
 - e. Practice of physical examination on potentially infected patients (note that with PAPR it was not possible to auscultate or use a stethoscope on a patient).
 4. Workflow and work process training:
 1. Full-scale resuscitation exercise
 2. Trauma team activation exercise
 3. Stroke team activation exercise
 4. ST-elevation acute myocardial infarction management, inclusive of cardiac catheterization laboratory team activation.
 5. Other common resuscitation scenarios included:
 - i. Pregnant COVID-19-positive patients with cardiac arrest or in labor
 - ii. Respiratory distress
 - iii. Septic shock
 - iv. Ventilator connection and disconnection
 - v. Use of noninvasive ventilation and metered dose inhalation (MDI)
 - vi. Ventilator dys-synchrony.
 6. Transport and transfers, with the following common examples:
 - i. Which route should be taken to send COVID-19 patient to the isolation ward
 - ii. What PPE is required for the staff accompanying the patient.
 5. Working effectively in negative-pressure environment.

With these scenarios, we were able to “stress” the staff and also test the system. We created challenges embedded within the scenarios, such as unexpected equipment failure or lack of availability in the FA, intentional errors, lack of information, as well as the arrival of a second or third critical patient (Figure 2 and 3). Moreover, we incorporated various cultural and communications challenges into our simulated scenarios. Finally, we also had to bear in mind our pandemic workflow. One such example would be the use of PAPR with high-risk infectious patients:

1. Challenges with using the PAPR:
 - a. Inability to auscultate and listen to lung sounds
 - b. Communication challenges
 - c. Patient’s apprehension and anxiety
 - d. Proper training required: to don, to doff, and to care for
 - e. The filters are disposable and cannot be reused.

EVIDENCE-BASED EFFECTIVENESS

We intentionally chose a low-fidelity training approach with relevant skills trainers, to allow for crisis resource management and real-time testing of workflow. Drugs and equipment that were requested would have to be physically obtained by participants in the simulation. All equipment used was decontaminated after simulation. Participants were asked to wear appropriate PPE so as to enforce safety culture when caring for patients with ID and to account for time and environmental factors in gaining access to patients. To ensure that care is not compromised for actual patients, each SSI event was held during less active periods in the department. The participants were informed of the simulation schedule and took turns participating to allow for continuity of care of actual patients.

RESULTS AND OUTCOMES

The overall results of this simulation experience are provided in Table 1. In aggregate, the aim of this exercise was to achieve the following tangible outcomes:

1. To achieve individual team member technical proficiency
2. To establish and foster desirable team behaviors [Table 2]
3. To identify any active and latent systems issues, opportunities, and threats.

Combining ISS and FMEA enabled us to become more aware of the complexities that exist within our system. The

Table 2: Behavioral markers observed during the simulation

Team function: relationship between team members, decision-making, coordination
Leadership: execution of role, leading the team, instruction delivery, sharing mental model with team
Situational awareness
Closed loop communications
Shared mental model and its execution

entire exercise served as a catalyst for positive change in our institutional clinical care system and environment. The use of both SSI and FMEA created an important synergy and helped us realize the benefits of the rapid cycle improvement, helping to improve and better refine each consecutive ISS session. Simulated scenarios utilized lessons learned from previous sentinel events, as appropriate. Inputs from all stakeholders were shared in a transparent, honest, and nonpunitive environment, whether they were participants in the ISS, the facilitators/faculty, or the expert observers. This approach made everyone more engaged and empowered. The organizers of the simulation exercise stressed the principle of “safe practice in a safe environment” and as in all simulations, repetitive practice was both applicable and encouraged. The ISS enabled us to perform real-time observations of various possible failure modes and lapses, including their possible impact. Unlike FMEA, we utilized the principle of simulation whereby immediate debriefing was conducted and facilitated after the exercise. This enabled us to investigate and perform interventions more quickly, in most cases immediately after each respective training session.

Combining ISS and FMEA also enabled us to study both latent threats and active failures simultaneously.^[40] In addition, it allowed us to perform concurrent audit of team performance and our internal communications processes. Validating FMEA through ISS during this pandemic facilitated the performance of “stress testing” of the system to help initiate and fine-tune critical change processes [Table 1].

CONCLUSION

The use of ISS in identifying gaps in patient care and operational team performance is not a new concept. With the ongoing COVID-19 pandemic and a surge in need for emergency and critical care services, EDs across the world must be able to adapt quickly, train new staff dynamically, and design workflows that are both efficient and sustainable. Institutions also need to be prepared to open new clinical areas when necessary, and that entails significant preparations in terms of staffing, training, and other logistics. We found that our simulation experience was effective in identifying gaps in workflow and knowledge of the newly evolved teams. Postsimulation huddles and debriefing, combined with application of the health-care FMEA, proved critical in ensuring adequate preparation and seamless workflow. The lessons learned and observations made during SSI provided very useful guidance for fine-tuning our operations, logistics, and work processes. Finally, the exercise also contributed positively to high levels of our staff motivation, both as a result of enhanced training and a downstream effect of a better functioning workplace.

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Conflicts of interest

There are no conflicts of interest.

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