

# Applying the principles of health technology assessments to intubation boxes for patients with COVID-19

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## INTRODUCTION

While global efforts are underway to reduce transmission of COVID-19 infection with a shortage of personal protective equipment (PPE), intubation boxes have become a popular new equipment for airway management.<sup>1</sup> Intubation boxes are essentially barrier enclosures composed of transparent components meant to contain the droplet and aerosols during intubation and prevent them from being dispersed to the environment and healthcare worker (HCW).<sup>1</sup>

Preliminary reports have shown intubation boxes to be effective in reducing droplets, more than aerosol exposure, to the HCW during laryngoscopy.<sup>1-3</sup> Consequently, these intubation boxes are being mass produced and implemented in both academic and community hospitals worldwide.

With the introduction of new equipment, such as intubation boxes, safety cannot be overemphasised. As Mytton *et al* discuss, new technology can be a sensitive process with the potential for unforeseen dangers.<sup>4</sup> Before new devices are introduced into a hospital, they undergo a series of stages including research and development, clinical trials, simulation, and finally, a formal review certifying that it is safe to be used.<sup>4-6</sup> Ideally, new devices, such as intubation boxes, would undergo a formal health technology assessment (HTA) which is a systematic and robust evaluation of technology.<sup>7-10</sup>

Central to the HTA that is typically done when a medical device is introduced is understanding the implementation (how should we apply it here?), appropriateness (can we apply it safely?), effectiveness (is it safe under real world conditions?), efficacy (is it safe under experimental conditions?) and performance (are there safety concerns?).<sup>2,8-10</sup>

In the emergency pandemic situation, traditional means to evaluate new equipment such as intubation boxes may not be timely or feasible. However, the safety concerns of

introducing new equipment should also not be disregarded. As such, rather than conducting a study on intubation boxes, we developed an evidence-based approach to evaluating the safety of intubation boxes using the components of a formal HTA.

## Multidisciplinary evaluation

Prior to mass introduction of intubation boxes, involvement of key stakeholders must be solicited. A multidisciplinary team including infection control and prevention (IPAC) representatives, nursing, respiratory therapists, anaesthesiologists and engineers are instrumental in evaluating new intubation boxes.<sup>2,5,8</sup>

Members from the IPAC department can provide critical feedback for safely using and removing intubation boxes. Studies evaluating infection processes post-severe acute respiratory syndrome emphasised that the time when most errors occurred, and thus most potential for contamination, is in the doffing of PPE.<sup>6</sup> While preliminary studies discussed how to place an intubation box for laryngoscopy, to our knowledge, there is little evidence on how to safely remove these boxes. Potential contamination at removal of the intubation box is of great concern, and guidance from members of the IPAC department is essential.

Clinical engineers are specialised in implementing technology and are key in understanding environmental infection processes.<sup>4</sup> For example, clinical engineers can provide information on air exchanges required to simulate a negative pressure environment, and thus reduce aerosolisation. This skill set is valuable in evaluating intubation boxes, as studies have shown that intubation boxes may reduce droplet contamination on the HCW but not necessarily aerosols.<sup>1</sup>

It is also important to recognise the dynamic nature of airway management when implementing devices. Insights from front-line workers, such as anaesthesiologists, respiratory therapists and nurses, are critical



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in understanding potential sources of error when using an intubation box, especially during emergencies.<sup>3</sup> They have first-hand knowledge specific to airway management and their input cannot be overemphasised.

### Simulation

Simulation affords HCWs the opportunity to practice using intubation boxes in a low-risk environment, and evaluate if the proposed new device is effective and safe.<sup>2,8,9</sup> A study by Begley *et al* used simulation to test intubation boxes and found the time to intubate with them was significantly higher than intubating without them, potentially leading to hypoxia in the patient with COVID-19.<sup>2</sup> Moreover, by using intubation boxes, there were breaches in PPE, raising safety concerns for the HCWs.<sup>2</sup> The authors stressed through simulations, they learnt intubation boxes served as an adjunct rather than a replacement for PPE.<sup>2</sup> Therefore, simulation is a useful tool in assessing a new device in real time for safety and effectiveness.

### Pilot study

Following simulations, a pilot study is a critical component in evaluating an intubation box.<sup>2,8,9</sup> Pilot studies can identify potential problem areas and safety concerns in the clinical setting that may have been missed during the initial stages of planning. Despite extensive planning, literature demonstrates pilot studies usually highlight issues that have not been considered.<sup>8,9</sup>

Piloting intubation boxes will allow for a greater sample size in evaluating new medical devices. It will also account for testing the intubation box with a diverse population (eg, obese patients, frail patients, etc.). A recent study trialled an intubation box in their anaesthetic and critical care units.<sup>3</sup> By conducting a pilot study, the authors were able to make appropriate modifications to their intubation box.<sup>3</sup> This further demonstrates the value of pilot studies as part of an HTA.

### Surveillance

Evaluating the safety of a new medical device is important, as it may capture the potential harm of using the device.<sup>2,8,9</sup> Reporting concerns with the intubation boxes must be a user-friendly process in order to truly capture incidents. The data collected from the reporting processes needs to be analysed and addressed in a timely fashion and is clinically meaningful to the HCW.<sup>2,8,9</sup>

### SUMMARY

Intubation boxes are a new medical device that can potentially prevent transmission of COVID-19 to HCWs.

Intubation boxes should not be used as a replacement for PPE, but rather an added device to reduce harm and promote safety for HCWs.<sup>2,3</sup> In the absence of large clinical trials or a formal HTA, we propose an evidence-based approach for evaluating intubation boxes. Through involvement of stakeholders, simulation, pilot studies and surveillance, the risk of harm from a new medical device can potentially be mitigated. The potential of a new device causing more harm with inadequate evaluation may override the benefit of introducing it. That is not to say that intubation boxes should not be used, but a methodological approach should be taken prior to mass implementation by HCWs.

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