

Editorial

Thinking outside the (acrylic) box: a framework for the local use of custom-made medical devices

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Before the COVID-19 pandemic, clinicians were already adept at creating workarounds for day-to-day shortages of equipment, inventively cobbling substitute gadgets together to fulfil a clinical need. This is colloquially known as 'jury-rigging' or 'MacGyvering', the latter taken from the eponymous 1980s television series of a problem-solving crime fighter who could seemingly manufacture anything from a few paperclips and some chewing gum [1].

Arguably, the COVID-19 pandemic has intensified the impetus for 'MacGyvering' or creating 'Heath-Robinson' devices. The need to simultaneously protect one's own health while managing surges of patients with possible COVID-19 disease during a world pandemic would have been unthinkable 4 months ago. Added to this is the actual or threatened scarcity of personal protective equipment (PPE), ventilators and hand sanitiser [2]. Concerns for healthcare provider infection may be justified in many centres as standard supply channels become overburdened or disrupted, and pre-pandemic stockpiles may be insufficient alongside a lack of shared resource accounting [3]. Coupled with a potential loss of trust in authority [4], this has resulted in the situation where front-line healthcare providers understandably scramble to create self-made alternatives [5].

Is there a problem?

MacGyvering is not inherently wrong. Clinicians often have a clear understanding of a problem and its potential

solutions, and the COVID-19 pandemic is no exception. Examples include the invention of the Macintosh laryngoscope blade by Sir Robert Macintosh [6] and the laryngeal mask airway by Sir Archie Brain [7]. However, adverse consequences may occur when a well-intentioned product is introduced into a highly complex healthcare system without stepwise testing. The risk of introducing a new piece of equipment, protocol or operating system must be balanced by its proven (or at least plausible) effectiveness. The makers of such hastily produced equipment may pride themselves in their handiwork, overstating benefits and underappreciating risks of their homemade device despite a lack of evidence; this has been termed the 'MacGyver bias' [8].

To illustrate this bias and how to guard against it, we shall use the example of the 'intubation box'. Intubation boxes have been proposed to serve as a physical barrier between the patient with potential COVID-19 disease and the airway team performing tracheal intubation, a high-risk aerosol-generating procedure [9]. Extensive promulgation of several designs has occurred on various social media platforms, with the tacit legitimacy afforded by recent publication of one design in a high-impact journal [10].

Rejecting any innovation that has not received full regulatory approval could potentially overlook an advancement in safety. Is there a way to evaluate new

devices to minimise potential risks before widespread introduction? The following seven considerations (Box 1) are not intended in any way to serve as a replacement for the rigorous regulatory and legal frameworks regarding medical device development. We provide these questions to serve as a framework for the clinician-inventor to assess their proposed MacGyvered solutions in a logical manner. There is a high degree of variability of custom device legislation between jurisdictions and countries. Regulatory and legal frameworks should always be consulted and complied with if mandated, and appropriate legal advice should always be obtained; to do otherwise may result in litigation.

Define the problem that needs to be addressed

A clinician-inventor should be clear about the problem that their device is intended to solve, in this case minimising exposure to an airborne pathogen.

Several society-endorsed guidelines have addressed the risks of airway management during the COVID-19 pandemic [11-13]. All have recommended tracheal intubation with dense neuromuscular blockade, an experienced airway team and a clinician most likely to have the highest first-pass tracheal intubation success rate [13]. Arguably, we do not need an intubation box per se, we need adequate, trustworthy protection during tracheal intubation [14,15,16].

Box 1 Proposed framework for the safer adoption of a MacGyvered device

- 1 Define the problem and rule out existing solutions.
- 2 List benchmark safety indices for the device.
- 3 Seek broader feedback from all stakeholders on the design's utility and potential pitfalls.
- 4 Perform laboratory-based and in situ simulations.
- 5 Introduce into low-risk clinical settings after local due process and patient consent.
- 6 Introduce into higher-risk clinical settings with a discrete group of trained 'super-users'.
- 7 Encourage an iterative cycle of feedback, review, re-design and improvement.

Do not: adopt, publish, endorse or disseminate via social media a MacGyvered device without data to support safety.

Define benchmarks by listing important safety indices for the device

Safety indices come in many forms, generally discoverable by literature review and discussion with content experts. Performance requirements can be sought from manufacturing standards (such as those published by the International Organization for Standardization), clinical guidelines and medical device regulatory frameworks underpinned by legislation.

An often overlooked first step is to make a list of optimum safety goals. During the SARS epidemic in 2003, healthcare providers involved in tracheal intubation were six times more likely to become infected compared with similar healthcare providers who were not involved [9]. Avoiding repeated tracheal intubation attempts is one of the basic tenets of airway management during the SARS-CoV-2 pandemic [11-13].

An intubation box may prolong intubation attempts and reduce first-pass success by forcing the airway team to perform tracheal intubation in an ergonomically awkward manner while still wearing often uncomfortable PPE including facemasks (known to hinder verbal communication) and visors (that may impede vision). Therefore, reasonable safety indices would include use of the intubation box associated with a similar first-pass success rate and time to intubation compared with tracheal intubation without its use. Benchmark safety indices should not be limited solely to the time to tracheal intubation. Safety indices encompass the entire intubation box 'life cycle' including: the safe removal, decontamination and quality control of dirty intubation boxes; and the transport, storage and retrieval of clean intubation boxes.

Seek broader feedback on the design's utility, potential pitfalls and identify if the problem has already been solved

To prevent wasting time and effort 're-inventing the wheel', one should ask if the problem been solved in another discipline or jurisdiction. It is worthwhile engaging other disciplines including biomedical engineering or even harnessing social media to 'crowd source' solutions that may already exist.

It is important to attempt to mitigate unanticipated adverse consequences and investigate potential dependencies including supply chain details; personnel; training; and manufacturing needs throughout the lifecycle of the device. Construction, use, maintenance and reprocessing all hold equal importance. All plausible

clinical environments and contexts for device use should be considered.

Complications could arise from the device that may place either the patient (e.g. the box collapsing) or a member of the healthcare team at risk (e.g. lacerating PPE due to sharp edges of arm holes in the intubation box) [17]. Other valuable insights can be gained from people outside the department (including those with and without content-expertise). Biomedical engineers may have suggestions regarding materials, be aware of existing solutions, or provide insight into issues not yet considered.

Perform laboratory-based and in-situ simulations

Simulation should include the use of the device in all plausible clinical environments and contexts (e.g. in the operating theatre and intensive care, emergency and elective procedures). The intubation box should be tested with the airway team in full PPE, including those of various heights and strengths, with the bed in different positions and simulating variations in patient anatomy and physiology. Clinically-relevant outcomes should be measured, such as first-pass success rate. A subjective assessment of the airway team's cognitive load during the process should be made and compared with intubation without the use of the box. A recently published simulation study demonstrated intubation boxes to be associated with both prolonged intubation attempts and decreased first-pass success [17].

Consideration should be given to 'ideal use' versus 'typical use'. For example, the intubating box may sit well horizontally, but what if the patient is unable to lie flat? Will the intubation box be used under less controlled circumstances such as tracheal intubation during cardiac arrest or major trauma? Finally, assessment of performance should not be limited only to those with anaesthetic training who have performed tracheal intubation on thousands of patients.

Tracheal intubation is a team effort and therefore team education and practice using an intubation box during simulated scenarios including with donned PPE is essential before patient use. Safety without additional harm must be demonstrated.

Introduce into a low-risk clinical setting

The decision to introduce any device into clinical practice requires the approval of appropriate institutional authorities, including local ethics and risk management, the peri-operative management committee, departmental head and equipment representative among others. A new

piece of equipment such as an intubation box should not be used in a clinical setting until discussed with all stakeholders with appropriate due process. It is vital that informed consent is obtained from the patient when discussing risks of anaesthesia, even as an informal or verbal consent including the potential for hypoxia and haemodynamic events.

Introduce into a higher-risk clinical setting with a discrete group of trained 'super-users'

Super-users are defined as those completing protocolised, mandatory training to ensure a standardised approach is used. Super-users should not be limited to those on the intubation box development team and should be observed by a neutral third party, who can note any difficulties or complications that may arise. Feedback should be obtained from both the super-users and all other team members on the functionality of the device. Given the potential complications of the device being used on high-risk patients, usual practice plans must be immediately available should the intubation box hinder performance or fail completely. Outcome parameters should be the same as those collected in the low-risk clinical situation.

Encourage an iterative cycle of feedback, review, re-design and improvement

As with the introduction of every unfamiliar piece of equipment into a clinical environment, it is important to continue to critically evaluate the performance of the MacGyvered device. Ongoing data collection to assess usefulness, safety and unintended complications is vital [17,18]. Discuss the use of the intubation box in inter-departmental meetings, with users of the device, as well as those observing its use. Without data, an iterative cycle of safety and performance cannot take place.

Social media

We must acknowledge the dramatic increase in homemade devices that has pervaded social media during the COVID-19 pandemic. Although the dissemination of MacGyvered device designs has always been present on social media (e.g. Twitter, Facebook, etc.) COVID-19 has presented healthcare providers with the unique situation of their own health and safety being dependent on their clinical skills and PPE. Faced with widespread perceived and real deficits in PPE, the tendency to view MacGyvered solutions as having only potential benefit without harm is understandable.

Posting on social media provides faster feedback than the iterative process we have outlined. Twitter 'likes' do not imply that an idea is safe or effective. Failure, abandonment of concept, or harms are less likely to be tweeted with the same exuberance. Invention is an iterative process for the tenacious achiever not afraid of repeated failure. Sir Archie Brain first conceptualised the laryngeal mask airway in 1981 only to finally settle on a device for commercial sale 6 years later [19]. Nevertheless, discussion via platforms such as Twitter may be incredibly valuable to vet ideas and should be viewed as part of the iterative process.

During the COVID-19 pandemic, many MacGyvered devices have and will continue to be presented on social media to solve a clinical question that may or may not exist. Every new invention will have unintended consequences in the complexities of healthcare provision. Without a stepwise approach to their use, including the prospective recording of impartial data, we place both ourselves and our patients at potential risk.

We encourage scrupulous consideration to whether regulatory and/or legal approval is required for the new device to avoid litigation and hope this sequence of steps provide a starting point for the inventor inside every clinician. Collaboration, tenacity and the ability to accept failure and change design are the hallmarks of profession-changing leaders. As healthcare providers we must balance our ability to identify and solve problems quickly with the due diligence that only comes from engaging others to assist us in making sustainable solutions.

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