Technical innovation in critical care in a world of constraints: lessons from the COVID-19 pandemic

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Despite their potentially devastating consequences, crises are a valuable source of learning for health organizations. Crises unveil weaknesses and pitfalls in the system and highlight what needs to be improved (1). The COVID-19 pandemic has subjected the health care system in general and the critical care community in particular to the highest stress ever encountered over the past decades. The outstanding difficulty of this crisis resides in the massive need for respiratory support, which has unfortunately not been satisfied globally. A condition that mimics to a large extent those which gave rise to critical care practice in the past. We herein intend to discuss the central role of constraints in the past and the present of critical care, and their importance in guiding the innovation process needed to face the future.

The role of constraints in the emergence of critical care

Although the art of resuscitation is very old (the Egyptians performed a tracheotomy-like procedure to treat upper airway obstruction around 1500 Before Common Era), the emergence of critical care as a standalone medical specialty was driven by constraints related to situations with massive surge of victims. During the Crimean war in the 1850's, the British nurse Florence Nightingale understood the importance of sorting out a massive influx of patients according to the severity of their conditions (placing the most seriously ill patients in the nearest beds to the nursing station to be watched more closely, i.e., invented the preliminary concept of a separate geographical area for the critically ill). One century after, during the great polio epidemic that raged in Europe, and in particular in Copenhagen in 1952, only six cuirass ventilators and one tank ventilator (negative pressure "iron lung", invented around 1928 by Drinker and Shaw in Boston, figure 1A) were available to treat the hundreds of patients suffering from respiratory palsy (2). That crisis incited the Danish physician Björn Ibsen to initiate positive pressure manual (bag) mechanical ventilation trough a tracheostomy (figure 1B) (2). Teams of "human ventilators" of about 200 medical students worked in shifts to maintain manual mechanical ventilation in these first intensive care units (ICUs) (2, 3).

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These images enter in resonance with those of units created for the current pandemic seven decades later (Figure 1C), with the notable detail that iron lungs have evolved into modern positive pressure ventilators and various non-invasive respiratory support devices.

Technological evolution of respiratory support

Since the emergence of the critical care modern era in the 50's, technological evolution of respiratory support has counted on tremendous long-term research and innovation process (4). The technology, performance, and ease of use of mechanical ventilators have considerably been optimized to obtain a more effective ventilation. Technological breakthroughs, such as the advent of ventilator screens displaying flow and airway pressure waveforms, have improved the understanding of pathophysiology and patient-ventilator interactions, boosted research, and allowed for better personalization of routine care. This innovative process has enabled health professionals to substantially improve outcome of hundreds of thousands of critically-ill patients worldwide each year. Basically, these technologies are developed in high-resource, low-constraint environments and have already achieved an acceptable level of performance in some basic specifications. However, most have moved towards the development of sophisticated, complex, and expensive solutions (4), at least in part motivated by desirability. Uzawa et al reported that the user interface simplicity or complexity influenced the rates of operational failures (5). For example, multiplying the modes and options of ICU ventilators (there are approximately 15 modes in the latest generation of the mostly used ICU ventilators in France) contrasts with the fact that only three major modes are used in nearly 80% of the mechanically ventilated patients (6). The presence of a myriad of options compromises the safe use of the ventilator, whereas fundamental tools needed to optimize ventilation delivery, like height measurement for predicted body weight calculation, are still largely empiric, manual, and underused (7). Modern ventilatory support developed in this way requires complex devices, demanding regular high-cost maintenance, a specific geographical location, and highly-trained and skilled healthcare professionals.

COVID-19 pandemic, ventilatory support and oxygen supply

During the COVID-19 pandemic, the massive influx of patients with viral pneumonia requiring respiratory support largely overwhelmed the usual ICU capacity even in high income countries. Very quickly, the fear of a shortage of mechanical ventilators arose and was widely reported in the media. To remedy that indenting issue, numerous initiatives came from engineers working all around the world to manufacture mechanical ventilators from commercially available spare parts or 3D printed parts. Most of these solutions failed to meet their objectives due to a lack of performance, reliability, and the impossibility of large-scale industrialization. Not to mention, these initiatives did not address the core need (8). The delivery of ventilatory support does not depend exclusively on the availability of a mechanical ventilator but on a rather more complex chain. Proper ventilation requires oxygen supply, a ventilation device with an appropriate power source, the right disposables, a staff trained on its functionalities, and an adequate monitoring system. Taking certain logistical impediments (e.g., regular power cuts) into account, it may be often safer for patients not to be put on invasive life support (e.g., invasive mechanical ventilation with sedation) compared to providing non-invasive support which leaves the patient with spontaneous breathing, even during power cuts.

The pandemic cruelly unveiled that a continuous oxygen supply, which is usually granted in low-constraint environments, can in fact be very difficult to maintain facing a surge in demand (9–12). The use of high-oxygen consumption devices (such as high-flow oxygen therapy), has exacerbated the risk of shortage by increasing oxygen demand to previously unseen levels. The imbalance between oxygen needs and supply has largely been underestimated and poorly anticipated in several geographical areas. For example, the demand for oxygen rose by more than 14 times in India’s largest cities and resulted in an unacceptable number of deaths due to significant supply shortage. In this unprecedented context, some caregivers tested the efficacy of manually occluding the oxygen tubing during exhalation (“oxygen pinching”) to make oxygen cylinders last longer (13). Obviously, such manual approach is hazardous and carries numerous drawbacks including additional work strain necessitating shorter shifts of caregivers, irregularity of respiratory rate, tubing leak at the crimping site, etc. This shows to what extent the conventional methods of oxygen production, delivery, and usage are not resilient. Already existing technological solutions for better oxygen management must now be systematically considered when developing new medical devices to ensure an optimal balance between oxygen consumption and the delivered fraction of inspired oxygen. Aside from the World Health Organization (WHO) injunction to increase oxygen production in order to match unusual demands by combining different oxygen on-site and off-site production sources, the development of judicious practices and new medical devices designed to limit oxygen waste is crucial for the future.

Critical care and crisis management

Current ICUs are very well structured and fitted to take care of few patients at the top of the economic pyramid, using sophisticated devices and highly trained personnel. This makes critical care capacity geographically limited: often physically restricted to ICUs in high-level hospitals, present in high income countries, which gives the impression of an “ivory tower”. Organized as such, critical care represents nowadays the most expensive branch of medicine in high-income countries, given the comprehensive, intensive, and advanced technology it requires to achieve its objectives. In the United States, daily ICU costs per bed increased between 2000 and 2010 from $2,669 to 4,300, and the annual cost of critical care medicine nearly doubled during the same period (from 56 to 108 billion dollars); a sum that represents around 0.72% of gross domestic product, 4% of national health expenditure, and 13% of hospital budget (14). This system however, is unsustainable for the majority of people on earth. In fact, there is a significant association between the global national income, current ICU organization, and the risk of death of the critically-ill (15). Universal healthcare is not yet the rule (16), and a study also showed that the disposable income of patients with sepsis influences their mortality when they have no health insurance or universal health coverage (17).

The failure of our modern ICUs to fully contain the massive surge of patients during the COVID-19 health crisis despite their high cost and immense technological evolution created an enormous cascade of complexities within and beyond the healthcare system. The increase in the demand for critical care has forced hospitals to extend critical care work beyond ICU walls (18). Forced adjustments resulted in major alterations in terms of the care provided to COVID-19 and non-COVID-19 critically-ill patients, and the suspension of almost all elective medical (19) and surgical (20) procedures and activities in order to free staff and resources (21). This resulted in enormous immediate and delayed impact on public health. For instance, testing for Human Immunodeficiency Virus fell by 22% and the number of individuals tested and treated for tuberculosis fell by 18%, amounting to about one million people left unchecked (22). Additionally, differing healthcare of non-COVID-19 patients raised major ethical issues (23).

Beyond the healthcare system, a number of restrictive governmental measures colloquially known as lockdowns (ranging from limiting gathering sizes and closing businesses or educational institutions to stay-at-home orders) have been implemented worldwide during the pandemic. Imposing these national and international restrictions was at least in part driven by the inability of ICUs to contain the massive influx. In other words, policymakers relied on the number of ICU beds occupied by COVID-19 patients (24) as a capacity bottleneck and a threshold not be exceed in order to maintain the healthcare system working (25). By April 2020, about half of the humanity (more than 3.9 billion people in more than 90 countries) were under lockdown (26). These restrictions have had major short-term and long-term health, social, and economic impacts worldwide (27).

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Altogether, these facts highlight that a non-negligible part of the burden imposed on the healthcare system by the pandemic was driven by the constraints faced by ICUs to manage the massive surge of patients. Understanding the role of these constraints is essential.

We can no longer ignore constraints

According to the theory of constraint (an overall management philosophy), the rate of goal achievement by an organization (i.e., the system's throughput) is limited by at least one constraint; the latter being anything that prevents the system from achieving its goal (28). The theory adopts the common idiom "a chain is no stronger than its weakest link" (29). The constraints can be cyclical (e.g., during the pandemic) or structural (e.g., when caring for the critically-ill outside the ICU or in low-income countries).

During the COVID-19 pandemic, these constraints were managed by unsatisfying solutions. For instance, applying a strict patient selection using stringent triage (30) raised complex ethical issues (e.g., a lottery system was proposed to allocate medical resources) (31–33). Even more, improvised and medically questionable solutions were also tested, like uncertified ventilators or one ventilator for two patients (21, 34). In any case, simply transposing traditional approaches to constrained environments is certainly non-perennial, often useless or even detrimental. Their implementation is largely limited by the shortage of properly trained staff (35) and generally leads to misuse and early breakdowns (36). The WHO highlighted the inequity between the complex high-tech products designed and made available primarily to be used in classical “unconstrained” care, and the relative paucity of medical devices specifically designed for use in constrained situations and environments (37). Although the pandemic has boosted the development of critical care medicine in many low and middle income countries, his development requires a specific approach to guaranty his sustainability. The global trends in the burden of critical care and the prospective of next pandemics suggest the amplification of constraints in the future (38).

Frugal approach

All of the aforementioned constraints are often conceived as barriers, but they could be transformed into an opportunity for frugal innovation (Figure 2) (36). A frugal solution is defined as being refined to its maximum to precisely meet needs without concession on quality, whilst maintaining optimized performance and concentrating on core functionalities, without superfluous addition (36, 39). The goal of the frugal approach is to produce essential, high value and quality, rugged, adaptable, simple, user-friendly, and easy to use solutions. The primary aim is not to reduce the cost by simply stripping off certain features or options. Instead, frugal innovations are meant to find high-performing technology that meets end-user needs, and takes into account the characteristics of the operational environment and associated constraints (36). Such innovations developed to manage constrained situations or environments may be particularly effective and cost competitive even in unconstrained situations, which represents the basis of the reverse innovation concept. An example of this concept is mobile banking, a modal that was initially built for markets in Sub-Saharan Africa and is now being reinvested in Western countries (Europe and the USA).

Frugal innovation can also be disruptive, i.e., that eventually troubles an existing paradigm, or displaces established medical approaches. Among the five most cited disruptive innovations in healthcare, “mobile health applications” stands aside as typically frugal (40). There is also a huge potential for cross-fertilization. For example, the difficulties to provide critically-ill patients with oxygen and ventilatory support outside the ICU, during transportation, in case of a massive surge, in humanitarian medicine, or in low-income countries simulate to a large extent those encountered in very different environments like high altitude exploration, civil and military aviation, or spatial exploration. In all those situations, the scarcity of the resource, the criticality of the situation, and the high level of expected result require to focus on the core need. Some innovation pathways may be offered to better assist the critically-ill in respiratory distress by tuning pulse oxygen therapy (developed in civil aviation), on board oxygen generating systems (routinely used in military aviation) or next generation oxygen production devices (developed for Mars exploration). This cross-fertilization model had already proven to be beneficial in the past, when the masks of fighter pilots inspired engineers to develop the face masks for non-invasive ventilation (41).

In the setting of critical care, the frugal solutions should prioritize bedside approaches, increase the healthcare worker autonomy, and alleviate work burden.

Frugal innovation for oxygen access and ventilatory support

There is a crucial and urgent need to develop new cost-effective, energy-efficient, oxygen generation devices with minimal maintenance. Different avenues, not mutually exclusive, could be explored, such as optimizing the existing pressure-swing adsorption systems (e.g., using new materials such as Metal Organic Frameworks), developing a new oxygen generation technology (42), or minimizing oxygen consumption via continuous oxygen recycling. It is paramount to work with oxygen manufacturers to better forecast needs, and perhaps to combine various on-site and off-site solutions on a case-by-case basis according to the different geographical areas and healthcare organizations.

Already existing non-invasive frugal solutions like continuous positive airway pressure devices working as virtual valves have successfully been used in the early management of moderate acute hypoxemic respiratory failure to avoid ICU admission during the COVID-19 pandemic (43). These devices are meant to be easy-to-use in the pre-ICU stage (e.g., at home, during transportation, in the emergency room, or in hospital wards). Efforts should be directed to optimize the efficiency of these virtual valves, i.e., delivered oxygen – generated pressure coupling, to make them usable in low oxygen flow conditions. Innovation should also be directed towards designing new non-invasive support devices with very high oxygen saving properties, using the principles of reservoir and/or rebreathing. While waiting for these innovations, simple measures in our daily practice may reduce oxygen waste, such as tailored SpO_2 targets, avoiding leaks during non-invasive ventilation and using of non-rebreathing masks.

Applying the frugal innovation concept to the invasive ventilatory support implies that the sole characteristic to consider is the safe delivery of ventilation. Likewise, the ventilatory modes selection should rely only on what is clinically relevant and needed, and discard superfluous or redundant add-ons. Some mechanical ventilators for anesthesia (e.g., Glostavent® and Helix® Diamedica, UK) were successfully conceived with a frugal approach, but their safe use in critically-ill patients with altered respiratory mechanics warrants a formal evaluation (44).

Further innovation work is also needed for the monitoring systems. Field experience has shown that simplifying and harmonizing what the monitors display on their screens ensures better safety of mechanical ventilation and allows it to be customized to the patient's needs. The design of innovative universal stand-alone monitors could offer the possibility of turning every ventilatory device into a precision care device. Dedicated innovative flow and pressure sensors could be inserted on the ventilator circuit with agnostic connectivity between the standalone monitors and ventilators to achieve full interoperability and have full access to data/waveforms from any manufacturer. Such groundbreaking monitoring system could also incorporate diagnostic and decision support tools and even make ventilatory support systems usable by non-expert caregivers if needed

It is paramount that the innovated devices have robust structure and are internally designed to work in constrained environments (extreme temperatures, dusty environment, unstable power supply, and power failure). Frugal innovation also concerns the device consumables since the intention is to provide non-captive and if possible, re-usable products. Concerning the maintenance, a simplified design and technology should facilitate maintenance and incite end-users to undertake part of it, especially of key components like the battery, the filter, or even the turbine.

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Lastly, broadening ventilation expertise by developing end-user training programs in ventilatory assistance is also a priority. For this purpose, the devices should be user friendly, incorporating tutorials and decision-support solutions, and easily operated by health staff (intensivists, nurses) or even family members when those can be engaged as caregiver (with advice from a remote professional) due to shortage of resources in some settings.

The frugal innovation approach in and outside the ICU

Other aspects of critical care may benefit from a frugal innovation approach. In the setting of sepsis management and antimicrobial stewardship, the simple and affordable β-LACTA™ test technology for resistant strains (45) could be perfected for direct examination at bedside. For hemodynamics, clinically-meaningful skin derived perfusion indices like capillary refill time (46) could be automated to improve their reproducibility. For monitoring, frugal ultraportable ultrasound machines (47) have the potential to revolutionize bedside hemodynamics if coupled with an adequate training.

More generally, the frugal innovation is a concept that may allow to do more, with less, for more patients (48). It may turn critical care into a more inclusive practice with which health professionals are enabled to provide care for the critically-ill patients irrespective of the context and constraints, inside or outside ICU walls, in high- or low-income settings. Critical care should also focus on the prevention of critical illness, for example in the emergency department where patients with unstable vital and/or organ functions can be detected early and simple non-invasive interventions can prevent progression to organ failure and development of critical illness. The role of non-invasive approaches in lessening the nosocomial burden is fundamental (49).

The frugal approach is also more sober, globally sustainable, and ensures societal, economic, and environmental fairness (50). Another role for frugal innovation will be to generalize research in critical care so as to help release more consistent international recommendations. To date, most critical care recommendations have been driven from studies conducted in low-constraint environments. This could make such recommendations inefficient or even deleterious if applied to high-constraint environments (36). A good example on that is when sepsis protocols using fluid boluses were implemented in Sub-Saharan Africa and resulted in worse outcomes possibly because of the scarcity of ventilator support (or other intensive care resources), and/or the burden of some tropical pathologies (51–53).

The frugal approach intrinsically increases equity and may also facilitate the achievement of Essential Emergency and Critical Care (EECC) for all patients. This concept, defined as “the care that should be provided to all critically-ill patients of all ages in all hospitals in the world” (54), has recently been specified in a global consensus (55) covering 40 clinical processes, from the identification of critical illness to oxygen therapy, intravenous fluids and patient positioning to maintain a free airway. EECC can be seen as a frugal approach on which the health services are redesigned to provide the most basic, life-saving treatments to those who need them. Many may see such basic care as a right that is always granted. Unfortunately, this is not currently the case for most humans on earth. In Malawian hospitals before the pandemic, only one-in-ten hypoxemic patients and one-in-ten hypotensive patients received oxygen and intravenous fluids, respectively, and half of the unconscious patients received no actions to maintain their airways patent (56). Even in high-income countries, basic life-saving care can be missed, especially in non-specialized general wards, leading to the widespread introduction of early warning scores, and intervention of rapid response teams.

Eventually, the frugal approach may improve the resilience of the critical care system. This resilience is a sine qua non condition to face the next pandemic and disaster challenges. The frequency and severity of spillover infectious diseases – directly from wildlife host to humans – are steadily increasing (38). The current pandemic should not be conceived as a black swan event, but rather as a dress rehearsal for the next pandemic, which could come at any time, and could be even more profoundly damaging to human safety (38). Solidarity, equity, and sustainable development, are considered as crucial pillars to guide preparedness for future pandemics (57) and the capacity of the government to rapidly react to a pandemic (58). The number of climate-related disasters has tripled in 30 years and the world is becoming less peaceful. A rise in the scale and frequency of humanitarian crises, conflicts, and natural disasters is expected over the next decades. In these situations, the accumulation of constraints is troublesome. A massive and unpredictable influx of patients may occur in structures often not resilient beforehand and directly weakened by destruction or insecurity. The degraded living conditions may also generate a second hit (e.g., cholera epidemics following major floods). In all, conventional solutions may be counterproductive. For example, having several models of complex respirators, although generously supplied, often makes it much more difficult to supervise and train novice staff. The frugal approach therefore makes sense here, because it is guided by a pragmatic analysis of the needs, taking into account the various constraints on the ground.

Conclusion

The current pandemic revealed weaknesses in the current critical care model upon facing constraints. These pitfalls have already been detected when caring for the critically-ill outside the ICU or in low-income countries. The innovation process should incorporate constraints as a *prima materia*, and focus on the core needs in the field. This frugal innovation approach may give rise to a more resilient, inclusive, and equitable critical care system. This paradigm shift is essential for the current and future challenges of the specialty as it is for the global health issues.

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Figure legends

Figure 1: Iron lungs at Rancho Los Amigos Hospital (California) in 1953 (panel A, reprinted with permission of the Polio Survivors Association from http://www.polioassociation.org/pictures.html), a young patient with poliomyelitis being manually ventilated by a medical student during the poliomyelitis epidemic in Copenhagen in 1953 (panel B, reprinted with permission of the American Thoracic Society from reference (59)), and patients in the emergency room of the Nossa Senhora da Conceicao hospital during the COVID-19 outbreak in Porto Alegre (Brazil) in 2021 (panel C, reprinted with permission; copyright REUTERS/Diego Vara).

Figure 2: Frugal innovation principles. Frugal innovation consists in transforming constraints into an opportunity to innovate, by focusing on the core need and removing all what is superfluous.

Figure 1

A

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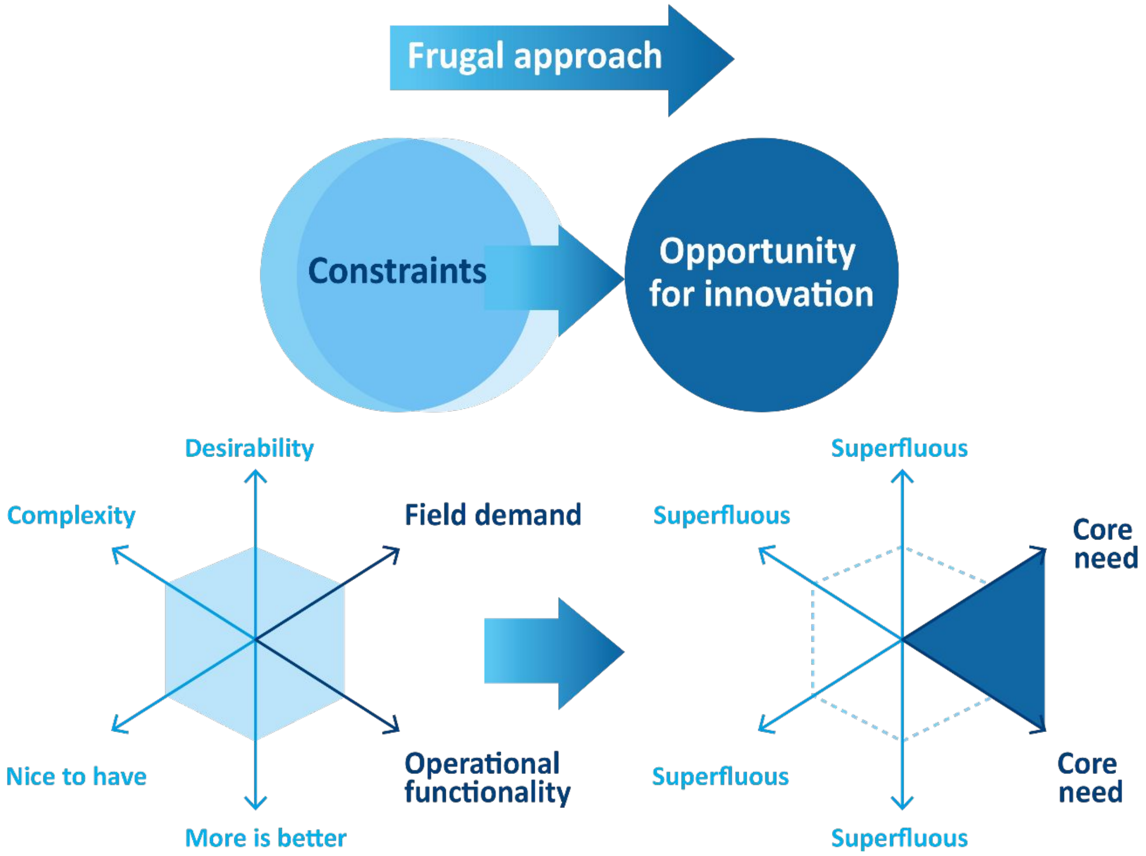
Figure 2



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