Medicine and Society

Innovations to automate manual ventilation during Covid-19 pandemic and beyond

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ABSTRACT

Manual ventilation by compressing self-inflating bags is a life-saving option for respiratory support in many resource-limited settings. Previous efforts to automate manual ventilation using mechatronic systems were unsuccessful. The Covid-19 pandemic stimulated re-exploration of automating manual ventilation as an economically viable alternative to address the anticipated shortage of mechanical ventilators. Many devices have been developed and displayed in the lay press and social media platforms. However, most are unsuitable for clinical use for a variety of reasons. These include failure to understand the clinical needs, complex ventilatory requirements in Covid-19 patients, lack of technical specifications to guide innovators, technical challenges in delivering ventilation parameters in a physiological manner, absence of guidelines for bench testing of innovative devices and lack of clinical validation in patients. The insights gained during the design, development, laboratory testing and clinical validation of a novel device designated the 'Artificial Breathing Capability Device' are shared here to assist innovators in developing clinically usable devices. A detailed set of clinical requirements from such devices, technical specifications to meet these requirements and framework for bench testing are presented. In addition, regulatory and certification issues, as well as concerns related to the protection of intellectual property, are highlighted. These insights are designed to foster an innovation ecosystem whereby clinically useful automated manual ventilation devices can be developed and deployed to meet the needs associated with the Covid-19 pandemic and beyond.

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INTRODUCTION

Several patients with respiratory failure, who require mechanical ventilation, do not receive it due to lack of availability, accessibility or affordability. In such situations, manual ventilation is offered as an alternative.[1] Rhythmic manual compression of self-inflating bags (SIB) or bag–valve–masks (BVM) drive air (or air–oxygen mixture) into the lungs. Releasing the bag permits air to flow out passively, thereby simulating a respiratory cycle. Although manual ventilation can be life-saving, it is essentially an uncontrolled procedure and can be dangerous if performed by inexperienced personnel (which is often the case in resource-limited settings). In recent years, efforts to mechanize the process of manual ventilation met with limited success,[2–4] and no devices are available for clinical use. Since early 2016, I have been leading an interdisciplinary team, which designed, developed and bench-tested the 'Artificial Breathing Capability Device' (ABCD) as a cost-effective alternative to manual ventilation. The technical and clinical details of ABCD are described elsewhere.[5–8]

The Covid-19 pandemic, and the panic associated with anticipated shortage of mechanical ventilators in developed[9,10] as well as developing countries,[11] re-ignited interest in automating manual ventilation. In recent months, many such devices have been produced and widely publicised in the lay press and social media platforms.[12–20] However, for various reasons, most of these are unsuitable for clinical use in Covid-19 as well as other conditions. On the other hand, there is a need for devices automating manual ventilation to offer a life-saving option in clinical settings, even beyond the Covid pandemic. Besides enhanced safety and efficacy, automation has the potential to resolve the adverse humanitarian and ethical considerations associated with manual ventilation.[21,22] The following insights (based on my experience with the development of ABCD) are shared with inventors, innovators and imitators to help them develop appropriate devices that can meet clinical needs.

BOUQUETS

The effort by engineers/technologists and industry personnel, driven by altruism, at considerable personal cost, despite the shortage of workforce and material resources and disruption of conventional supply chains (during the prolonged lockdown), is indeed commendable. Faced with such challenges, it is remarkable that working models or prototypes could be developed within days to weeks. The media hype around these devices raised hope in frontline healthcare workers, policy-makers, healthcare administrators and the general public. Government and non-government organizations supported these initiatives with liberal disbursement of funds, fast-tracked project approvals and soft loans to industries interested in mass production.

However, the following considerations need attention.

END-USER PERSPECTIVE

Most innovators focused on technology solutions to manual ventilation, concentrating efforts to mechanize the compression of SIB/BVM.[12–20] Limited attention was paid to clinical needs or perspectives of the end-users, namely physicians using the devices and the patients for whom the devices are intended. Many innovation teams did not even include any medical personnel. Thus, most of these devices merely automate SIB/BVM compression at adjustable rates. Some offer additional features such as adjustable volume, variable inspiration time, capping of peak inspiratory pressure (PIP), insertion of positive end-expiratory pressure (PEEP) valve, display screens showing

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TABLE I. End-user requirements from devices automating manual ventilation

Efficacy features
Controlled cyclic compression of self-inflating bag/bag–valve–mask by mechanical, mechatronic or electro-mechanical systems
Control over peak inspiratory pressure and/or tidal volume (V_T)
Control over ventilation rate (VR)
Control over inspiratory time (Ti) and ratio of inspiratory:expiratory time (I:E)
Availability of pre-set or controllable positive end-expiratory pressure (PEEP)
Real-time display of delivered ventilation parameters with each breath
Safety features
Detection of patient cough during inspiration phase of ventilation, with auto cut-off and auto-resumption
Detection of (and alarms for) events such as endotracheal tube blockage, endotracheal tube displacement, ventilation circuit leak, self inflating bag displacement
Self-regulatory checks to prevent users from entering non-physiological ventilation parameters
User-friendliness
Feasibility of placing the device at the patient's bedside, without interference with clinical observations or procedures
The connection between the device and endotracheal tube should be such that there is no risk of re-breathing exhaled air
Light weight but sturdy, easy to handle and safe to transport
Operable with electricity as well as battery
Low maintenance
Low(er) cost

delivered parameters and audio/visual alarms when these parameters cross pre-set limits. In theory, these features appear appealing compared to completely uncontrolled manual ventilation. However, in practice, there are many gaps making them unsuitable for clinical use in patients. Table I summarizes the end-user requirements from devices automating manual ventilation. Attention to these perspectives will enhance the development of innovative devices.

VENTILATION NEEDS IN COVID-19 PATIENTS

The ventilation needs of patients with Covid lung injury are complex. These include high oxygen demand, type I as well as type II respiratory failure, decreased lung compliance, acute respiratory distress syndrome, etc.[23,24] The situation is more complex when cardiac injury is also involved. In these situations, manual ventilation is unlikely to be efficacious or safe. Therefore, devices that mechanize the process cannot meet the challenge. This is particularly true of devices whose technical capabilities for ventilation (in terms of pressure, volume, rate, inspiratory time and I:E ratio) are limited to supporting normal lungs.

TECHNICAL SPECIFICATIONS TO GUIDE INNOVATORS

At present, in India, there are no well-defined technical specifications to guide innovators developing devices for automating manual ventilation. This is one of the reasons for a slew of products that compress SIB/BVM but fail to meet the clinical need. A limited set of six criteria designated as 'essential technical features for ventilators for Covid-19' was prepared by the Defence Research and Development Organization at the end of March 2020 and readily accepted by the Ministry of Health and Family Welfare.[25]

However, these specifications are difficult to interpret. One of the six criteria[25] emphasizes that the device should be capable of providing invasive ventilation, non-invasive ventilation, and continuous positive airway pressure ventilation. However, no details were provided. Other criteria[25] demand the display of 'lung mechanics' and monitoring of 'lung mechanics/inverse ratio (I:E)' without clarifying what these mean. There is also the somewhat strange criterion of 'continuous working capability for 4–5 days',[25] without mentioning how patients with Covid-19 would be managed beyond this limit. Thus, these specifications are inadequate to guide innovators to develop devices automating manual ventilation. In contrast, the United Kingdom Government Medicines and Healthcare Products Regulatory Agency lately published a detailed set of technical specifications expected from rapidly manufactured ventilator systems.[26] Similar but non-regulatory specifications were shared by a prestigious American university as well.[27] Around mid-May 2020, detailed technical specifications were laid down for the development of intensive care unit (ICU) ventilators in India,[28] but there was no guidance for devices automating manual ventilation. Based on a detailed understanding of the clinical needs (described above), I propose a reasonable set of technical specifications shown in Table II.

TECHNICAL CHALLENGES IN DEVELOPING DEVICES TO AUTOMATE MANUAL VENTILATION

The respiratory cycle in mechanical ventilators involves a rapid rise in inspiratory pressure until the PIP is achieved, a pressure plateau for the duration of inspiration, followed by a fall to the pre-set PEEP level. PEEP is required to prevent the alveoli from collapsing. Mechanical ventilators allow all these components to be adjusted as per the clinical needs. On the other hand, manual ventilation is associated with a rapid rise in pressure and rapid fall to a zero level, without maintaining a plateau pressure during inspiration and without maintaining PEEP during expiration. This causes alveoli to collapse during expiration, necessitating higher opening pressure in the next breath. It is well documented that manual ventilation is associated with the delivery of far higher pressure (and the risk of barotrauma) compared to mechanical ventilators.[29] Unfortunately, most devices that mechanize SIB/BVM merely replicate this non-physiological pattern. Hence, there is a steep but transient rise in pressure (to the pre-set PIP) when the bag is compressed, followed by a rapid fall to the baseline, even if the bag remains compressed. In this situation, the true inspiratory time lasts for only 10%–15% of the set inspiratory time, and the remainder effectively contributes to the expiratory time. Figure 1 highlights this concept comparing the pressure profile delivered by one of the recently developed automated devices to the pressure profile delivered by ABCD.

Manual ventilation is performed by directly connecting the

TABLE II. Minimum technical specifications for devices automating manual ventilation

Efficacy specifications
The device should provide either pressure-controlled ventilation or volume-controlled ventilation, or both. Devices that merely compress SIB/BVM without measuring and controlling either pressure or volume should not be developed
Pressure-controlled device (for adults) should allow users to input desired PIP in the range 10–40 cm H_2O
Volume-controlled device should allow users to input desired V_T in the range 200–800 ml for adult patients, and 50–300 ml for infants/children
Device should allow users to input desired VR in the range 10–30/minute for adults and 15–50/minute for infants and children
Device should allow users to input desired Ti in the range 0.4–3.0 seconds for adults and 0.25–3.0 seconds for infants and children. The ratio of inspiration time to expiration time (I:E) should be in the range 0.25–1.0
Device should allow delivery of PEEP in the range 5–15 cm H_2O, using either pre-set valves or controlled by the device
Device should deliver parameters set by users without lag (i.e. within the first two breaths delivered)
Device should permit users to change desired ventilation parameters without switching off and restarting the system
Devices designed for adults as well as children should cover the specifications of both
Device should permit connection with an air–oxygen blender so that variable FiO_2 can be provided as per clinical need
Safety specifications
Compliance with established safety norms for electrical equipment, medical devices, ventilatory support equipment, anaesthetic equipment and biosafety
Self-regulatory checks for device mechanical integrity, electronic integrity, ventilation circuit integrity and prevention of inputting non-physiological ventilation parameters
Auto cut-off of ventilation if the patient coughs during the inspiration phase, followed by auto-resumption of ventilation with the original settings
Real-time display of ventilation parameters delivered with each breath
Audio and visual alarms if any ventilation parameter is delivered outside a safety margin of ±10% of the desired value
Audio and visual alarms (of different tones and appearance) in the event of ventilation circuit disconnection, endotracheal tube blockage, SIB displacement
Battery charging status and available battery life display
Internal cooling system to prevent over-heating of parts and fire hazard
For devices designed to be used in Covid-19 patients, exhaled air should be vented out safely without risk of environmental contamination
Medical environment specifications
Weight <10 kg
Low footprint enabling device to be placed at the patient's bedside, but permitting access to the patient for monitoring, procedures, etc.
Low centre of gravity, preventing tipping over
Parts requiring minimal maintenance (such as greasing, cleaning, replacement, etc.)
Non-interference with other devices in a clinical environment (especially patient monitors)

PIP peak inspiratory pressure V_T tidal volume VR ventilation rate Ti inspiratory time PEEP positive end-expiratory pressure SIB self-inflating bag BVM bag–valve–mask

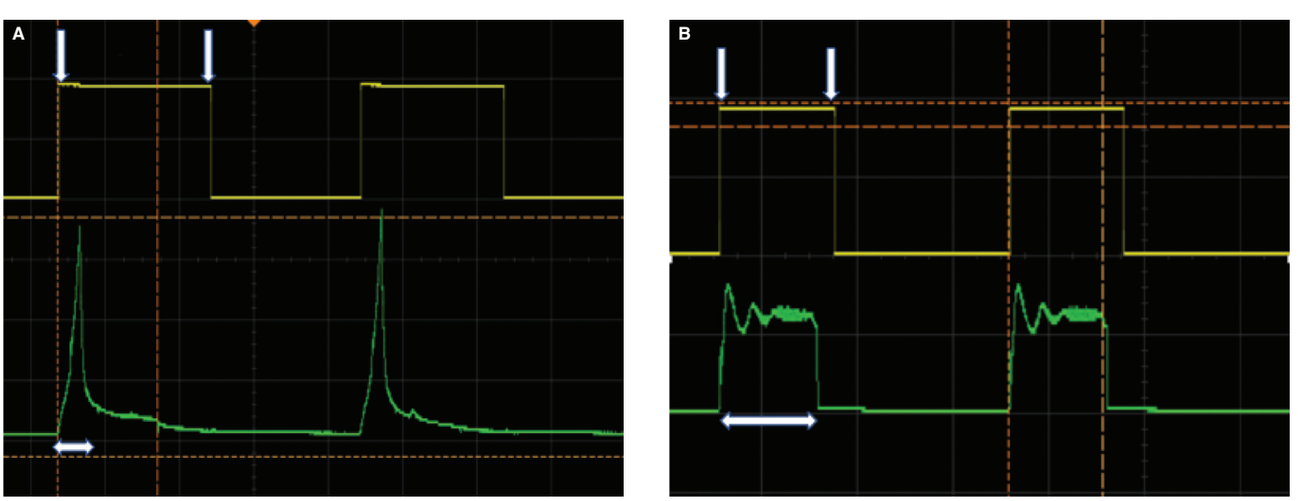

FIG 1. Pressure profile delivered by an automated manual ventilation device (A) compared to Artificial Breathing Capability Device (B). The interval between the downward pointing white arrows represents inspiratory time of 1 second. The green tracing represents the pressure profile. The horizontal white arrows represent the effective inspiratory time

SIB/BVM to the endotracheal tube and placing it next to the patient's head. This is not possible with a mechanical device, which has to be placed at some distance from the patent's head. This necessitates the use of a long ventilation tube (usually at least 100 cm in length). If a single tube is used to connect the device to the endotracheal tube, exhaled air may get released into the tube and re-breathed in the next cycle. If separate inspiratory and expiratory tubings are used, an additional valve

TABLE III. Laboratory testing of innovative devices automating manual ventilation

Parameter	Specifications
Efficacy	Pressure-controlled devices should test combinations that encompass the entire range of PIP (in increments of at most 5 cm H_2O), PEEP (in increments of at most 3 cm H_2O), VR (in increments of at most 5/minute), and I:E ratio (in increments of 0.25). This translates to 560 user combinations for a device designed for adults Volume-controlled devices should test combinations encompassing the entire range of V_T (in increments of at most 25 ml), VR (in increments of at most 5/minute), and I:E ratio (in increments of 0.25). This translates to 500 user combinations for a device designed for adults Each combination of settings should be tested for at least 120 continuous minutes
Safety	All alarms should be tested for accuracy and timeliness, multiple times Audio and visual alarms should be tested separately Functionality in an environment simulating a busy hospital setting should be tested
Robustness	Ability of the device to work in a variety of ambient conditions including ambient temperature ranging from 5 to 40 °C, ambient relative humidity ranging from 0% to 70%, ambient air current speeds generated by ceiling or wall-mounted fans working at maximal speed, and ambient condition where other electrical, mechanical, electromagnetic, wireless or radiofrequency controlled systems are in operation (as would be expected in a hospital environment) For devices designed to work during patient transport, testing should be done simulating travel in an ambulance as well as movement in a patient trolley
Reliability	Ability of the device to work without mechanical, electronic or electrical failure(s) over the following escalating periods of continuous usage: 6 hours, 12 hours, 24 hours, 72 hours, 7 days, 15 days, 30 days and 60 days
Precision	Fidelity of the system to deliver the pre-set parameters without drift during escalating periods of continuous usage over 6 hours, 12 hours, 24 hours, 72 hours, 7 days, 15 days, 30 days and 60 days

PEEP positive end-expiratory pressure PIP peak inspiratory pressure V_T tidal volume VR ventilation rate

is required to prevent air flowing from the device (during inspiration) from blowing off through the expiratory limb (without reaching the patient). This problem can be overcome by detaching the flap membrane valve of the SIB and placing it in a separate casing just outside the endotracheal tube, thus preventing re-breathing of exhaled air.

Some automated devices require several breaths for the desired ventilation parameters to be delivered. This lag (up to 45 seconds in some devices) is unacceptable in clinical settings because the patients remain hypo-ventilated during the lag time.

BALANCING EFFICACY AND SAFETY

Most innovative breathing devices focus on efficacy (i.e. compressing the SIB/BVM effectively), without a concomitant emphasis on patient safety. This is partly because innovators approach the problem from a technological, rather than clinical angle. Manual ventilation poses risks to patient safety by hypo-ventilation, hyper-ventilation, barotrauma or volutrauma, dys-synchrony with patient events, especially cough, endotracheal tube block, etc. In such situations, manual ventilation is not only ineffective but can be dangerous. Therefore, mere mechanization of the process carries the same risks. It can pose additional risks since the personnel performing manual ventilation intuitively adjust their hand movements when faced with such situations, whereas a machine cannot. Thus, a life-saving device can become life-threatening. These problems can be resolved by meticulous consideration of the clinical needs and designing devices to be fail-safe.

LABORATORY TESTING

Needless to mention, novel respiratory support devices require rigorous laboratory testing to ensure robustness, reliability and precision. This necessitates a laboratory environment to test the device in a variety of simulated clinical conditions, hi-tech data acquisition systems for continuous processing of data during the testing phase, and dedicated workforce to conduct the tests. Although there are specific standards for bench validation of such devices,[30] there are no guidelines for laboratory testing. Most innovators have conducted rudimentary tests on their prototypes, focusing on delivering set ventilation parameters for short periods. Based on the bench-testing of ABCD, a set of laboratory validation criteria are summarized in Table III. Testing may be done on a standard test lung (with the facility to vary compliance) or a clinical simulator. Testing should be done inputting various permutations and combinations of the parameters that can be set in the device.

CLINICAL VALIDATION

The guiding principle of *primum non nocere* (first do no harm) in healthcare delivery has been forgotten or ignored by innovators of many respiratory devices. Therefore, most of these devices have been showcased (in the lay press and social media platforms) without clinical validation. Some of these devices have even been put to clinical use with disastrous results.[31–33] Clinical validation is complex, expensive and time-consuming, because it involves meticulous patient management, with continuous clinical as well as electronic monitoring to ensure patient safety during the testing phase. Although all innovators appear to appreciate this, most believe that it is outside the scope of their work (expecting someone else to do it). Many mistakenly believe that the Covid emergency situation justifies bypassing this step in the eagerness to do something rather than nothing. For a life-saving device that can be potentially life-threatening, clinical validation may require a step-wise approach starting with testing in terminally ill patients, followed by carefully selected salvageable patients, followed by pragmatic trials in unfiltered patients.

REGULATORY AND CERTIFICATION ISSUES

In the absence of a functional Medical Devices Regulatory Authority, automated manual ventilation devices require to comply with the Bureau of Indian Standards and Central Drugs Standard Control Organization (CDSCO) guidelines. Citing the

exigency of the Covid-19 pandemic, the CDSCO permitted manufacturers to produce ventilator devices without requiring any licensing.[34]

INTELLECTUAL PROPERTY ISSUES

Against the backdrop of the Covid-19 emergency, many innovators have ignored or completely violated intellectual property (IP) rights in the interest of producing something to meet the challenge. Thus, many prototypes that are improvizations or imitations of existing designs for automated devices are falsely claimed as novel innovations or even inventions. Further, many developers of these devices, being fully aware that there is no scope of claiming IP, freely disclose their prototypes to the lay press. This creates a piquant situation wherein genuine inventors and innovators are unable to disclose their work (until IP is protected), whereas improvisers and imitators do so. This poses the additional risk that genuine innovations will never receive IP protection, as the imitated designs have been widely published. Innovators working in developed countries are fortunate to have systems for fast-tracked IP protection, which is lacking in most developing countries.

INNOVATION PARADIGM AND INNOVATION ECOSYSTEM

These insights are not intended to discourage innovation, but to develop a rational pathway that ultimately benefits all stakeholders (including healthcare consumers, providers, payers, policy-makers, etc.) and the healthcare system as a whole. The ideal paradigm of innovation (intended for clinical use) requires multiple steps starting from the bedside (to assess the clinical needs as mentioned previously), bench-work for development, followed by laboratory testing of prototypes, referring back to the bedside for clinical validation, followed by submission for regulatory approvals and certification. Only then should a product be commercialized and released in the market. Thereafter, ongoing post-marketing surveillance is essential to receive end-user feedback and identify issues affecting safety and efficacy. Thus, developing an innovative product resembles a journey more than a destination. Unfortunately, many innovators have short-circuited these logical steps.

It is impossible for a single individual or team to complete all the steps. This necessitates an innovation ecosystem that networks individuals and institutions with expertise in healthcare delivery, technology development, clinical validation supervised by ethics boards, IP protection, product realization, regulatory approval, commercialization, technology transfer, post-marketing surveillance and last (but not the least) securing funding for these activities. India is fortunate to have a national Biomedical Instruments and Devices Hub (*https://biomedhubpgichd.com*), which has been established to address many of these needs. This hub, based at the Post-graduate Institute of Medical Education and Research (PGIMER) Chandigarh, works in collaboration with multiple technology institutions, healthcare institutions, industry partners and individual experts across multiple disciplines to facilitate innovators to navigate the innovation paradigm, providing (individual and/or institutional) support for each of the components involved.

CURRENT STATUS OF INNOVATIVE RESPIRATORY SUPPORT DEVICES

At present, none of the innovative devices other than ABCD meets these standards.[35] However, the development of ABCD shows that it is achievable. In the interim, conventional ventilators that provide safety and efficacy should continue to be prioritized for development at low(er) cost.

THE LAST WORD

As an individual, I applaud the innovative spirit, motivation to work in the public interest, and generous contributions of innovators attempting to mitigate the problems posed by Covid. As a clinician with some experience and expertise in ventilation, I urge innovators to carefully consider the insights shared in this aticle. As a fellow innovator, I welcome collaboration across disciplines, following all steps of the innovation pathway, to build usable devices with potential for use during the Covid pandemic and beyond. As a Coordinator of the Biomedical Instruments and Devices Hub, I offer its facilities and services towards one or more steps of design, development, laboratory testing and clinical validation of innovative respiratory support devices.

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Obituaries

Many doctors in India practise medicine in difficult areas under trying circumstances and resist the attraction of better prospects in western countries and in the Middle East. They die without their contributions to our country being acknowledged.

The National Medical Journal of India wishes to recognize the efforts of these doctors. We invite short accounts of the life and work of a recently deceased colleague by a friend, student or relative. The account in about 500 to 1000 words should describe his or her education and training and highlight the achievements as well as disappointments. A photograph should accompany the obituary.

—Editor