



Enablers and barriers to adopt the locally developed Masi mechanical ventilator amid COVID-19 pandemic in Peru

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ABSTRACT

Background: Limited supply of resources during the COVID-19 emergency encouraged the local development of the Masi mechanical ventilator (MV). Despite the efforts to promote Masi, adopting this innovation faced multiple obstacles, regardless of its performance. We explored the perceptions among healthcare personnel towards incorporating Masi to provide ventilatory support to COVID-19 patients during the second wave in Peru (January to June 2021).

Methods: We conducted twelve in-depth virtual interviews. Topics included experience when handling Masi, the impact of the training received, confidence in the device, barriers perceived, and enablers identified. All participants provided verbal informed consent.

Results: Most of the participants were male physicians. Participants belonged to seven hospitals that exhibited a wide range of healthcare capacities. Globally, the adoption of Masi MV was driven by the scarcity of ventilatory devices in the wards and reinforced by appropriate training and prompt technical support. Participants reported that Masi's structural and operational features played both advantages and disadvantages. Hospital infrastructure readiness, availability of commercial MVs, mistrust in its simple appearance, and resistance to change among healthcare personnel were perceived as barriers, while low-cost, prompt technical support and user-friendliness were valuable enablers. The first two enablers were observed in participants regardless of their attitude towards Masi. Despite the small number of participants for this qualitative study, it is important to note that the sample size was sufficient to reach saturation, as the topics discussed with participants became redundant and did not yield new information.

Conclusions: The perceptions among healthcare personnel to incorporate Masi as a mechanical ventilator for COVID-19 patients showed that communication, training and experience, and peer encouragement were essential to secure its use and sustainability of the technology. *A priori* judgments and perceptions unrelated to the performance of the novel device were observed, and its proper management may define its further implementation. Altogether our study suggests that

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along with strengthening local technological development, strategies to improve their adoption process must be considered as early as possible in medical innovations.

1. Introduction

SARS-CoV-2 infection can lead to a complex disease, COVID-19, which may progress to severe COVID-19 forms [1], including Acute Respiratory Distress Syndrome (ARDS). The evolution of the disease into ARDS may require prolonged mechanical ventilation [2]. In such stages, ventilatory support is vital.

Latin America suffered severely during the COVID-19 pandemic, devastating the already precarious health systems. In Peru, healthcare services were overcrowded even during low-demand periods [3]. The Peruvian healthcare system faced the COVID-19 pandemic with insufficient hospital space for inpatients, poor oxygen supply, lack of ventilatory devices, very limited intensive care unit (ICU) beds, and insufficient healthcare staff to assist the increasing number of patients [4,5].

Amid the pandemic, the Peruvian health care officers' intended to purchase mechanical ventilators (MV) abroad, since this type of medical equipment was not assembled in country [6]. However, stock was limited due to the high demand worldwide [7,8]. In this critical context -lack of resources and inability to import ventilatory devices-a multidisciplinary research group developed "Masi", a Peruvian MV [9].

Masi, which means "companion" in Quechua, is a low-cost MV which was approved for emergency use by the General Directorate of Medicines, Supplies, and Drugs of Peru (DIGEMID). The design is based on a manual resuscitator activated by two electronically controlled paddles. Masi operates on three basic ventilatory modes: volume control, pressure control, and pressure support, providing ventilatory support to patients with respiratory distress. Masi was the first MV produced locally and was deployed to healthcare facilities in the capital city of Lima and other urban areas through public and private intervention [9].

Developing, and especially implementing, novel biomedical technologies into everyday practice is a challenging process, from the initial design to the approval and final use and adoption. Moreover, the adoption of an innovation, and successful implementation face different cultural barriers [10–13]. Furthermore, innovations in critical areas such as ICUs and emergency wards deal with a continuous influx of medical technologies. Adoption of any new technology is guided by external factors such as technical support for the new technology, and internal factors like beliefs, attitudes, and knowledge about the applications of the new technology [12].

In Peru there have only been a handful of biomedical innovations that have been implemented in routine care. These have been led by the government and have focused on rapid diagnostic assays [14]. Therefore, the processes of development, approval and adoption of new technology are in its infancy in the country [6,15]. To understand the adoption of an innovation by like the Masi MV, this study aimed to explore the perceptions of health care personnel during the use of the equipment and identify facilitators and barriers when using the devices [16]. The information obtained in this study could help design better communication strategies, optimize training, and serve as baseline guidance for implementing and integrating Masi MV or other novel biomedical devices into clinical practice.

2. Materials and methods

2.1. Design and participant recruitment

We conducted a qualitative study to understand the perceptions of healthcare personnel after their experience with the Masi MV in patients needing ventilatory support. Masi MV was approved for emergency use in June 2020 by DIGEMID under authorization N°3134-2020/DIGEMID/DDMP/UFDM/MINSA [17]. Since then, the Masi MV has been included in a technological surveillance program to notify safety and adverse events during use.

Masi MVs were distributed to 13 Peruvian hospitals for emergency use during the COVID-19 pandemic during the second wave of the pandemic in the country (January–June 2021). Hospitals in Metropolitan Lima and Callao (the capital city) and cities in other locations like Iquitos (in the Amazon basin), Huacho, Lambayeque (both in the coastal area), and Puno (in the highlands) received between two and 14 Masi MVs.

The team conducting technological surveillance on Masi MVs provided personal contact information from eligible participants. We contacted potential participants directly by telephone or invited them to participate through their peers who had already been interviewed. We contacted 21 potential participants, but nine refused to participate due to lack of interest or availability.

Recruitment of participants was conducted after verbal informed consent was provided. We conducted twelve in-depth interviews between August and September 2021. The sample provided enough information to reach saturation, once the topics discussed with participants were redundant and did not provide new information. Saturation was discussed and assessed by the research group at weekly meetings after coding and analyzing new interview transcriptions. The consolidated criteria for reporting qualitative research (COREQ) checklist are shown in Additional file 1.

2.2. Study population

Healthcare personnel who had received training and used a Masi MV were invited to participate in the study. Participating healthcare personnel belonged to seven public hospitals with different healthcare levels. The level of healthcare for facilities in Peru are detailed in technical guidelines of the Ministry of Health [18]. Healthcare facilities categorized as low complexity provide

outpatient services for primary level healthcare. Higher or secondary complexity healthcare level facilities also offer surgery, emergency care, imaging, hemotherapy, and pathology services. Additionally, health care facilities at the highest or tertiary complexity level provide ICU, hemodialysis, radiotherapy, nuclear medicine, and transplantation services. [Table 1](#) portrays information about healthcare facilities where participants worked.

2.3. Data collection

Due to the pandemic, in-depth interviews were conducted through an online meeting platform. Interviews were in Spanish and lasted between 35 and 50 min. We requested the participants to secure a private area at their workplaces to conduct the interview. Only researchers and participants were present during the interviews. We conducted in-depth interviews following a semi-structured guideline (Additional file 2) that included questions regarding 1) general knowledge of Masi MV and conventional MVs, 2) experience using Masi: first time using the device, time to adaptation, ease, difficulties, technical support and impact of the device, 3) quality, quantity and structure of the training and 4) current reliance in Masi, perceptions pre and post use, barriers identified, strategies to improve adoption of Masi and future use. We validated the topics discussed in the guidelines with the Masi technological surveillance team that oversaw contacting end-users and retrieving suggestions and complaints regarding the distribution and use of the equipment. Piloting was not feasible because the target population had limited time availability, and even contacting and securing the interviews remained challenging. Interviews were videorecorded for transcription and to document the consent process. All recordings were saved in the institutional cloud server to ensure data protection. We conducted verbatim transcription and double-checking for quality control purposes.

2.4. Data analysis

Transcriptions were uploaded to Dedoose v.9.0.17 [19], a web application for qualitative analyses. With a content analysis approach [20], principal themes identified during the interviews were resumed *a priori* in a codebook, which was expanded *a posteriori*, if needed, when themes arose during the coding process. We generated twenty-five codes; the coding tree reflects the structure (Additional file 3). All transcriptions were double-coded, and discrepancies were resolved to prevent biases.

2.5. Ethics

The study protocol was approved by the Research Ethics Committee for Social Sciences of the Pontificia Universidad Catolica del Peru, approval N° 033-2021-CEI-CCSSHAA/PUCP. All participants provided verbal informed consent for study participation and video recording. Consent was given before the beginning of the interview in accordance with approved procedures. Verbal consent process and interviews were videorecorded. A checklist was used to help go through all the procedures with each participant.

3. Results

3.1. Population characteristics

Between August and September 2021, we contacted healthcare personnel from various healthcare facilities where Masi MV had been deployed in the ICU or emergency wards. We interviewed twelve participants. The average age among participants was 38 (min 27, max 68); notably, only one of the participants was a woman. Most participants were attending physicians in healthcare facilities in Lima, but three were from outside the capital city. Almost half of the participants also had management responsibilities. The participants had a wide range of experience, from one to 23 years, since graduating from medical school (see [Table 2](#)).

3.2. Qualitative findings

We organized the findings based on several topics that were discussed in the interviews, such as user experience, training for use, opinions about the reliability of the equipment, contrast with other mechanical ventilators and current and future role for Masi MV ([Table 3](#)). Moreover, the disadvantages and advantages reported for Masi MV are summarized in [Table 4](#).

Table 1
Hospital characteristics of participating healthcare personnel.

Hospital code	Region	Level of healthcare facilities	# Intensive and Intermediate care unit beds	#Inpatient beds
A	Metropolitan Lima and Callao	Secondary	<10	<20
B	Metropolitan Lima and Callao	Secondary	<10	20–40
C	Other location	Secondary	<10	>40
D	Metropolitan Lima and Callao	Tertiary	<10	>40
E	Other location	Tertiary	10–20	>40
F	Metropolitan Lima and Callao	Tertiary	10–20	20–40
G	Metropolitan Lima and Callao	Tertiary	>20	>40

Table 2
Characteristics of participating healthcare personnel.

#	Hospital complexity level	Region	Healthcare training	Time since graduation (years)	Area or ward	Position
1	Low	Metropolitan Lima and Callao	Specialist physician	18	ICU	Head
2	Low	Metropolitan Lima and Callao	General physician	9	ICU	Staff
3	Low	Metropolitan Lima and Callao	Specialist nurse	3	ICU	Staff
4	Low	Metropolitan Lima and Callao	General physician	3	ICU	Staff
5	Low	Metropolitan Lima and Callao	General physician	1	ICU	Staff
6	Low	Metropolitan Lima and Callao	Specialist physician	5	Critical care	Staff
7	Low	Other location	General physician	11	ICU	Head
8	High	Other location	Specialist physician	5	ICU	Head
9	High	Other location	General physician	1	ICU	Staff
10	High	Metropolitan Lima and Callao	Specialist physician	13	Pneumology	Head
11	High	Metropolitan Lima and Callao	General physician	18	Critical care	Staff
12	High	Metropolitan Lima and Callao	Specialist physician	23	Critical care	Head

Table 3
Themes analyzed from in-depth interviews.

1.	Impact of user experience
2.	Training
3.	Barriers identified during Masi use Disadvantages
4.	Enablers to adopt Masi Advantages
5.	Reliability and expectations on the novel technology
6.	Future perceived positive value Non-invasive ventilation Current and future use

3.2.1. Impact of user experience

Participants reported varied experiences with Masi MV. The biomedical equipment was accepted and adopted in some healthcare facilities, while in others, it was briefly tested, but was not incorporated in regular use. Participants from the latter reported how they had relied on conventional equipment to which they had access.

“We did not use it much, it only helped us to get out of trouble at that moment, and once the ventilators were released, we could use the other [commercial] ventilators.” Specialist physician, secondary healthcare level

Facilities that incorporated and adopted Masi MV referred to the needs they had and the scarcity of equipment to provide care for patients.

“It allowed us, at least in my hospital, to expand and give more opportunities to many more people, suddenly three more [ventilators], ... at that time, it was something very valuable.” Generalist physician, secondary healthcare level

Although adoption was not consistent across all healthcare facilities and participants, no serious incidents, such as a failure of the device to provide life support, were identified by participants in the study.

3.2.2. Training

The training's structure, content, and sufficiency depended on many factors. For some participants (5/12), a general overview was enough to operate the equipment, usually among specialist physicians trained for using intensive care devices. Participants also suggested some strategies to improve the training for healthcare personnel, such as receiving training directly with personnel who had used Masi MV before or being able to train with the equipment while in use with the patients.

Table 4
Advantages and disadvantages identified when using Masi MV.

	Advantages	Disadvantages
Structural	Low oxygen requirement	Limit to inspiratory pressure applied
Operational	Ease of use Portability	Manual PEEP valve Noisy alarms
Suitability	Low cost Prompt technical support	Hospital infrastructure readiness
Perception	User-friendliness	Equipment appearance Resistance to change

“Training inside ICU, ..., to be able to observe in real-time the use of Masi on the patient is very valuable ...” General physician, secondary healthcare level

“It was also useful receiving training from a person already using it, from a physician who had already used it ...” General physician, secondary healthcare level

Moreover, the pandemic provided a unique environment to conduct empirical training with biomedical devices. Training with commercial MV was more observational and usually hands-on only during medical residency. However, since the beginning of COVID-19, ICU services were overcrowded, allowing some physicians to experience hands-on with Masi MV from the first patient.

“The first training [with commercial MV] ... was applied indirectly because ICU was never that crowded; it usually used operation manuals or indirectly. When you were with the patient, there was usually no opportunity to experience how the ventilator is set-up in a new patient.” General physician, secondary healthcare level

3.2.3. Enablers to adopt Masi

3.2.3.1. Low oxygen requirement. Users referred to several advantages they had identified while using Masi MV. One of the most important features was the possibility of using a biomedical device with low oxygen flow. Indeed, the equipment could be connected to oxygen tanks and consumed much less oxygen than conventional devices. In addition, during the first and second pandemic waves in Peru, there were oxygen shortages across the country. Therefore, the possibility of a device that made very efficient use of this resource was highly valued and recognized by most of the participants (8/12).

“We realized that commercial ventilators apparently could not continue to ventilate in optimal conditions due to this pressure drop generated by the oxygen generator, but we realized that patients with Masi did not have this problem So, if the Masi can work with low oxygen pressures, even with an oxygen tank, and consumes very little oxygen, it is what we need, given this crisis we had, and since then, given those circumstances and how easy it is to handle, many of us chose to use it in a more daily basis.” Specialist physician, secondary healthcare level

“Because an advantage that the Masi has is that it does not consume as much oxygen as other devices and when oxygen is scarce, Masi seemed an exciting option because it does not consume much oxygen ... that is a great advantage of the device.” Specialist physician, tertiary healthcare level

3.2.3.2. Ease of use and user-friendliness. When asked about the advantages of using the Masi MV, most participants (10/12) also mentioned the device’s simplicity. In addition, it was also considered an advantage to understand the workings of the equipment and handling settings for patient use.

“Masi is very, very understandable [easy to use]. For instance, the parameters are quite simple; any physician can [handle the equipment], and with training, we can understand it.” Specialist physician, secondary healthcare level

“It is easy to handle [the equipment], setting it is didactic, you do not get lost like with other ventilators. Everything is well organized in Masi, and modifications are simple [to set]. With basic training, [Masi MV] is easy to handle.” Specialist nurse, secondary healthcare level

Most participants (8/12) reported how simple and intuitive the use of Masi MV was, especially among intensive care physicians (specialists) who were familiar with handling other mechanical ventilators. Even if they did not receive formal training from the Masi MV team, they received instructions from peers and reported using the equipment without inconvenience.

“... in general, the ventilator is very user-friendly to anyone; there is no need to have great competence to use it; it is effortless.” Specialist physician, tertiary healthcare level

3.2.3.3. Portability. The capability of using Masi MVs with oxygen tanks also made it possible for users to operate the ventilators as portable devices. Portability allowed moving the patients around the hospital as required. This feature was handy when some hospitals faced oxygen scarcity.

“... maneuvering Masi was very useful, disconnecting it [from the general oxygen source outlet] and using it as a transport device because the ICU ran out of oxygen.” General physician, secondary healthcare level

3.2.3.4. Low cost. Participants commented that conventional MVs manufactured abroad were expensive, required training and engaging an effective maintenance program. However, such programs have not been consistently adopted. In other cases, they had delays when replacement parts were not available in-country. Therefore, using local, less-expensive technology presented an accessible solution and prompt technical service. The latter is discussed further in the next section.

“Because requesting a [ventilator brand] or another better equipment means a huge amount of money, and as they [medical staff] may not handle it properly, there is a possibility it will deteriorate, moreover with that same amount we can acquire similar or improved equipment [like Masi MV] manufactured [locally].” Specialist physician, tertiary healthcare level

3.2.3.5. Prompt technical support. As mentioned above, timely technical support was very valuable for healthcare personnel. Throughout the interviews, disregarding the positive or negative disposition of participants towards Masi MV, the prompt response from the technical support team was commonly mentioned (9/12). Requests for support ranged from adjusting proper settings to reporting malfunctioning equipment. The latter, as shown below, generated an improvement in the device, which might be one of the most critical enablers for using Masi MV.

“We did not have many commercial ventilators; unfortunately, the ones we did have were not modern, they already had many years of use, they had not been properly maintained, and they were breaking down, and it took a long time to fix them. Neglected maintenance has not happened to us with the Masi ventilator; maybe they get out of calibration there, but contacting the engineering team could quickly solve the issue.” General physician, secondary healthcare level

Indeed, a malfunctioning of the mechanical blades of the device occurred twice. This event originated from a safety feature within the electrical components that was triggered due to the lack of ground connection.

“There was no ground connection for the emergency area [electrical] current, and some ventilators failed due to this kind of electrical fluctuation, and what was wrong? The mechanical movement of the blades that pressed the resuscitator failed.” Specialist physician, secondary healthcare level

Both times, the patients were immediately transferred to another Masi MV and had no further problems. In addition, once the issue was identified and corrected, there were no other problems with the functioning of the biomedical device. Participants from hospitals located outside Metropolitan Lima and Callao reported a slightly less efficient response compared with those in the capital city.

3.2.3.6. Special context. The lack of sufficient equipment in some Peruvian healthcare facilities during the pandemic determined the use of Masi MV. The motivation to try the biomedical device was clearly in response to a critical situation.

“... however, in the context of a pandemic, any device is welcome; you must try it. If it had not been a pandemic and would we have accepted, it? I do not think so.” Specialist physician, tertiary healthcare level

3.2.4. Barriers identified during the use of Masi MV

3.2.4.1. Limit to inspiratory pressure applied. This issue is probably the main concern mentioned by the users and is part of the limitations of the equipment design. Since the main operation is based on a manual resuscitator, the biomedical device is not designed to exceed an inspiratory pressure of 45 cmH₂O or an end-expiratory pressure of 20 cmH₂O [9]. The users specifically addressed this barrier, commenting on the requirements of higher pressure for some patients:

“With Masi, there is not much force [pressure]; therefore, you have to be careful in what type of patient you are going to use; it should not be too compromised.” Specialist physician, secondary healthcare level

“Some colleagues [were] reluctant because of the issue of alveolar recruitment that one can do in these patients with COVID ... the Masi MV did not generate very high pressures, if I am not mistaken, it only gave a peak pressure up to 40 [cmH₂O], then all the alarms sounded and so on.” Generalist physician, secondary healthcare level

3.2.4.2. Manual PEEP valve and alarms. The hand-operated PEEP valve adjustment became especially problematic when moving patients, triggering the alarms. Regular handling or movements of the patients easily activated the signals.

“... we were not so confident since the ventilator was buildable, its alarms were also very sensitive, they rang all the time, that stopped us a bit to use it on a patient from the beginning.” Generalist physician, tertiary healthcare level

“For example ... the technical staff bathes [the patients], the nursing staff does certain procedures, that is, in the slightest movements sometimes they move the handle of the PEEP, and that also makes the ventilator sound, and the PEEP in those small movements does not move one or two units, large units were moving, and that was also a difficulty that we had with the Masi”. Generalist physician, Secondary healthcare level

However, even the loud buzzers were not completely identified as a disadvantage but more of an inconvenience, making the ventilator more demanding in terms of supervision.

“Sure, but that is difficult for the staff but not for the patient. Because the patient is with the correct parameters and the weaning process is the same as another conventional ventilator. Nevertheless, it was more inconvenient for the staff because you had to be constantly graduating it so it would stop ringing.” Specialist nurse, secondary healthcare level

3.2.4.3. Hospital infrastructure readiness. High-complexity hospitals had more inpatient and ICU beds during the first COVID-19 wave. These were the first to acquire the conventional MV purchased abroad. Masi MV adoption was not accomplished in some facilities because some healthcare personnel felt there was no more need for the equipment. The capacity available on these sites included conventional MV and there were no more personnel or space to expand patient care.

“I cannot say: ‘Look, we can also use these [Masi] ventilators’ ...; indeed, more volumetric ventilators arrived, and we concluded the use of Masi ventilators, neither as first choice nor as a rescue option, we do not use them anymore.” Specialist physician, secondary healthcare level

In this context, two hospitals redirected Masi MV use to non-invasive ventilatory wards.

“Yes, fundamentally we used [Masi MV] for non-invasive [ventilation] ... when [the Masi team] proposed me to use Masi, I showed them all the [conventional] ventilators that we had ... that is why I decided [not to use it] because the ICU was complete with ventilators.” Specialist physician, tertiary healthcare level

3.2.4.4. Equipment appearance. The simple design and structure of Masi MV with a manual resuscitator (ambu bag) generated major mistrust at the beginning for several participants (5/12). In some cases, this feeling was diluted as the user experience progressed, between one to four weeks, according to participants’ reports. However, for a few others, this *a priori* judgment remained and defined the adoption of the device.

“Yes, I have heard several physicians say the fact of seeing the ventilator, or how it works manually, or how simple it is internally, does not give them that confidence.” Specialist physician, secondary healthcare level

“As ICU specialists, we know what a MV is, what is the technology it has, so seeing that this ventilator [Masi MV] had an ambu bag and that was the support, ... personally, it generated mistrust.” Specialist physician, secondary healthcare level

3.2.4.5. Resistance to change. Hesitancy to use Masi MV is a complex multifactorial construct exhibited both before and after the use of the device. Some practitioners commented that using Masi required frequent surveillance of the patient. Being used to commercial ventilators functioning for several years could be challenging when adapting to a novel, more demanding technology.

“Sometimes [people] do not agree with change ... we are used to a commercial MV, to introduce ourselves to a new one and have the experience of a new beginning, this may produce rootedness, they do not want to let go of their [commercial] MV.” Generalist physician, secondary healthcare level

3.2.5. Reliability and expectations of the novel technology

Participant experience was better among those who used the Masi MV more extensively, became familiar with its operation, and witnessed positive results. Therefore, a major barrier to technology adoption requires experience to become familiar with the equipment.

“In the end, we did not get to use them because of that fear of basically theoretical foundations, not based on experience. As I said, fear could be lost if it were favorably used in other contexts; I think it could be produced.” General physician, tertiary healthcare level

“The expertise for handling Masi during this time has allowed us to know the ventilator.” Specialist physician, secondary healthcare level

Participants with high expectations of the device (3/12) later became disappointed with the equipment, feeling that the design limitations on expiratory and inspiratory pressure may lead to failure. Thus, it did not generate enough confidence among some users:

“... so seeing a device that has low flow, there is this fear that we are going to use it and that we are going to waste valuable time in the management of these patients ...” General physician, tertiary healthcare level

Other participants (5/12) were initially hesitant and were later satisfied with the equipment’s performance.

“At the beginning, like anyone ... with fear, perhaps fear, for the unknown or perhaps just learning to use a new equipment or a different equipment.” Other healthcare worker, secondary healthcare level

Interestingly, as has been commented before, participants who used the device more also became more confident with it, but this required overcoming initial fear or mistrust of an unfamiliar and novel device. Experience handling ventilatory devices can be as crucial as strong team support and a positive attitude towards innovation.

“Yes, experience has a lot to do with it; I think that as much as the experience is the person’s disposition.” Specialist physician, tertiary healthcare level

3.2.6. Future perceived positive value

3.2.6.1. Non-invasive use. Although the Masi MV was created for invasive ventilatory support for patients with low COVID-19, the device exhibited convenient versatility that was not initially considered by the developing team but was explored in hospital wards. The lack of ventilatory devices forced healthcare personnel to adapt Masi MV to non-invasive ventilation. While adaptable, not including this use from the design led to difficulties, such as the device signals going off constantly.

“As the device has not been designed to be non-invasive at the time the mask is put on, as it is not direct to the airway, there are leaks, and the device detects that leak and sounds an alarm that is very noisy, which is typical of the device ...” Specialist physician, tertiary healthcare level

“What happens is that I am a specialist, and I have used mechanical ventilators for non-invasive ventilation, and we do observe differences with the Masi because the Masi has not been designed for that.” Specialist physician, tertiary healthcare level

3.2.6.2. Current and future use of Masi. We asked participants to discuss the future role that Masi MV could have in healthcare facilities. Most (8/12) healthcare personnel believed the equipment fulfilled its function, but it could be insufficient for an acute pathology such as ARDS. However, it is essential to note that the Masi MV operating manual specifies that the equipment is not designed for these cases.

“For example, if they ask me if I feel safe using Masi, I would answer that yes, I could put a Masi on that patient with Guillain-Barré, I would feel very safe; but, to place a Masi on a patient with ARDS in COVID, I do not feel safe.” General physician, tertiary healthcare level

Also, while the Masi MV may be replaced by conventional MVs in higher healthcare level facilities, the use of the device could be feasible in primary and secondary healthcare settings with limited availability of biomedical devices and oxygen supply.

“It could be useful in peripheral places; I even believe that it could be useful in health posts, even in primary healthcare facilities, since conventional mechanical ventilators are obviously not available, which are much more expensive. However, it is often necessary to start with ventilatory support in the periphery or primary healthcare facilities to safeguard the patient’s life.” General physician, tertiary healthcare level

Finally, it is important to highlight that the participants’ overall experience was positive with Masi MV. Some participants (6/12) were completely satisfied, and others decided not to use them anymore because of other equipment available, but they had no severe adverse incidents reported.

“... it has been used in four patients; all four have worked well.” Specialist physician, tertiary healthcare level

“But speaking of the Masi equipment or the Masi machine, whether it has helped us enough, there are people who are alive thanks to having used the Masi equipment, at the right time.” Specialist physician, secondary healthcare level

4. Discussion

The COVID-19 pandemic in Peru led to several structural changes within healthcare provision, such as the collaboration between public and private health systems, expansion of critical care services, acquisition of biomedical devices, and hiring specialized healthcare personnel at a national scale to care for COVID-19 patients [17,21–24]. However, similar to other low and middle-income countries, the vulnerability of the Peruvian response during epidemic waves was enhanced due to the unavailability of devices worldwide and restrictions over international trade [7]. In this context, the development of the Masi MV was urged by the high demand for devices for ventilatory support and public guidelines that called for support to local biomedical initiatives and technological innovations [25].

Innovations in healthcare are challenging to disseminate, despite their broad scientific base and intensive investment in novel solutions [26]. The theory of Diffusion of Innovations, which was comprehensively developed by Rogers et al. [27] and presented by Berwick [26], describes the adoption process starting with the identification of the three clusters of influence: a) perceptions of the innovation, b) characteristics of adopters and non-adopters and c) context. The adoption process could be enabled if the innovation is considered an asset to be adopted or a specific benefit should be gained with its use. Using any medical device in a clinical setting requires knowledge, training, and experience. Also, the innovation must be compatible with the population’s beliefs, the level of complexity must be in accordance with what can be managed, and the innovation has to be tested and observed. As can be seen from the case of Masi MV, healthcare personnel involved in this study tested and tried the equipment or observed its use by other colleagues. Some participants ventured with the equipment and gained more proficiency in its use than others, which can be related to the other characteristics, mainly the relative advantage to its use and compatibility.

The relative benefit is likely related to the needs in some healthcare facilities where Masi MV was used more frequently, which had lower healthcare level complexity. These facilities demanded were in demand of MVs, and the relative benefit of having the Masi MV with its inherent limitations was evident. In contrast, within higher healthcare level facilities, where conventional MVs were available, the relative benefit of using a MV with known limitations like Masi was not a desired option. This equipment was tested less in such

situations, and its benefits were observed less frequently. A similar situation can be identified with telemedicine, where successful adoption worldwide has been driven by the need to provide healthcare and monitoring during the COVID-19 pandemic due to restrictions at [28]. Although telemedicine is an innovation readily accepted because of its safety and effectiveness, it was only because of the COVID-19 pandemic that telemedicine was widely adopted [28]. Likewise, the Masi MV had better acceptance within healthcare facilities that were not supplied with sufficient ventilatory devices.

On the other hand, compatibility, which “is the degree to which an innovation is perceived as being consistent with the existing values, past experiences, and needs of potential adopters” [27], was contested. Masi has known limitations, mainly the inability to reach peak pressures for lung tissue with low compliance [9]. This situation contradicts what was expected and participant’s previous experiences with conventional MV. Likewise, the PEEP valves were manual and needed constant surveillance, an undesirable feature within critical care personnel who prefer to be focused on the patient rather than handling any device [29]. The influence of personal preferences is also a limitation since healthcare personnel tend to develop predilection for those devices they use more frequently [30]. This trend also explains the greater acceptance of participants who used the Masi MV more extensively.

In contrast to the innovative feature of compatibility, complexity did not seem to be an issue identified by the participants. Even healthcare personnel who had used the equipment briefly and were not entirely convinced of its usefulness in their facilities, agreed that it was simple and easy to use. Despite the shortage of intensive care personnel and the challenges when training new human resources [5], general practitioners and specialist physicians reported that Masi MV presented a friendly interface for the user, which facilitated learning for recently graduated medical doctors. Previous studies have also identified ease of use, technical support, and innovation’s relative benefits as enablers in introducing novel technologies [12].

The users highly appreciated prompt technical support and emphasized that this is rare for other biomedical devices. Unfortunately, this situation is pervasive and underscores the need for better biomedical device management throughout the healthcare system [31] and is a barrier worth addressing when considering the implementation of novel technologies [32]. In another study about implementing new technology, the lack of proper feedback every time an issue arose, and an inadequate training program were perceived as critical barriers to adopt the technology [33]. In our research, technical support was provided to healthcare facilities in and outside the capital city. However, participants reported that remote interaction was slightly less efficient.

In addition to compatibility and beliefs for the adoption, the Masi MV exhibited novel, desirable features. First, the low amount of oxygen flow that the device needed to provide high FiO₂. Since several Peruvian settings suffered shortages of medical oxygen supply [34], this feature was naturally reported as very valuable among the participants. Second, the low cost of the Masi MV compared with conventional ones was a highly recognized feature. Conventional MV prices ranged between \$25,000 to \$50,000 when bought in the USA, plus additional handling, transport, and importation permit fees [35]. Indeed, the pandemic produced a shortage of ventilators worldwide and rising standard prices [36]. The Masi MV was designed to be a low-cost device. Therefore, designers and developers favored operational characteristics that allowed for an affordable manufacturing process, including relatively easy-to-locate components. As a result, the cost of producing a Masi MV ranged between USD\$5,000, considering components and parts, and USD\$15,000, including personnel time and quality control. Finally, a feature that produced mistrust among the study population was the visually simple design and self-inflating resuscitator bag inside the device which underscores the need to consider this visual appeal in the design of biomedical devices [37].

Despite the contribution of our study, some limitations must be considered when interpreting the results. First, the representativeness of the study population was not achieved. However, we contacted and invited most of the Masi MV users and managed to conduct the interviews. The overall limited use of the device restricted the source population and could have impacted the collection of different perceptions and experiences. The limited participation of non-physicians and healthcare workers from provinces was a concern, as well as the small sample size, though we did reach saturation on the topics discussed in the interviews. Although the pandemic triggered an opportunity to use the MV, its adaptation was also deployed in a problematic situation that challenged the correct introduction of the MV. Despite the limitations herein described, this is one of the first studies that addresses aspects related to the use of medical innovations in Peru, which are vital to establishing strategies to improve adoption and implementation approaches in regions that face similar challenges. It is also one of the few studies that have used this technology for mechanical ventilation in clinical settings [38–41].

Finally, although Masi was developed for patients exhibiting low ARDS due to COVID-19 within ICU services, the Masi MV may have proven a more flexible use. During the pandemic, healthcare workers using the Masi MV noticed its positive potential impact in primary healthcare level facilities, potentially in peri-urban or rural areas, mainly due to local manufacturing, ease of use, and low cost. In Peru, the number of healthcare workers and ICU beds were severely insufficient: 25% and 88%, respectively, lower than recommended [42–44]. The nationwide scarcity across low- and middle-income regions poses an opportunity to consider using Masi MV or other innovations generated to respond to the COVID-19 pandemic when the public health emergency is over. Masi MV could play a key role in emergency settings, in less-complex healthcare facilities, or for patients requiring MV but without ARDS, options that were suggested by some of the participants.

The development of innovations in low- and middle-income regions entails multilevel challenges. However, these initiatives are crucial due to the prevalent scarcity of biomedical equipment in limited-resource settings [30]. Moreover, local innovations are advantageous because they provide solutions that respond to local needs [45–47] and context. The results of our study should be handled with caution because the adoption of the MV was introduced under a unique context. Nevertheless, these lessons will remain and serve as precedent experiences that inform the adoption of innovations into clinical practice.

5. Conclusions

The perceptions among healthcare personnel to incorporate Masi MV for COVID-19 patients show that communication, training and experience, and peer encouragement were important enablers to secure its use and the sustainability of the technology. Participants recognized several benefits and advantages to using the device (ie. Low oxygen requirements, low cost, portability, prompt technical support). There were also several barriers to adoption. Participants had *a priori* judgments and perceptions unrelated to the performance of the novel device, were not confident in its response and had mistrust due to its simple design.

We expect that the future development of local health technologies will maximize strategies related to the enablers observed in the current study. Also, there is long-term work to improve the ecosystem to develop and adopt novel technology in low- and middle-income countries, including funding for local development, pre-clinical and safety evaluation, and appropriate guidelines and support by regulatory agencies.

Ethics

The study protocol was approved by the Research Ethics Committee for Social Sciences of the Pontificia Universidad Católica del Perú, approval N° 033-2021-CEI-CCSSHAA/PUCP. Each participant gave his/her verbal consent to participate in the study.

Author contribution statement

Stephanie Montero: Performed the experiments; Analyzed and interpreted the data; Wrote the paper. Gloria Morón: Analyzed and interpreted the data. Giuliana Arrunategui-Salas: Performed the experiments; Wrote the paper. Fanny L. Casado; Benjamin Castaneda: Conceived and designed the experiments. Gabriela Salmon-Mulanovich: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Wrote the paper.

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Data availability statement

Data will be made available on request.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Abbreviations

COVID-19	Coronavirus disease 2019
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
ARDS	Acute respiratory distress syndrome
ICU	Intensive care unit
MV	mechanical ventilator
LHC	Low complexity hospital
HCH	High complexity hospital
PEEP	Positive end-expiratory pressure

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.heliyon.2023.e19586>.

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