

Mechanical ventilator purchases in Latin-American countries: did we make the correct decisions during the COVID-19 pandemic?

Compra de ventiladores mecánicos en países de América Latina:
¿Tomamos las decisiones correctas durante la pandemia de COVID-19?

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RESUMEN

Objective To establish the purchase price, authorization strategies, availability of health registrations and technical specifications for the purchase of mechanical ventilators in Latin America during the COVID-19 pandemic.

Methods A health technology assessment was conducted by searching for technical specifications, health registrations and safety information on mechanical ventilators purchased by nine Latin-American countries including Colombia, Guatemala, Mexico, Argentina, Uruguay, Costa Rica, Brazil, Paraguay, and Peru. Based on the information of 129 tenders and contracts, technical information was obtained from the websites of 32 suppliers and manufacturers, covering 55 different models of mechanical ventilators. This information was compared to the World Health Organization's technical specifications for mechanical ventilators. Information on the availability of health registrations and safety of ventilators was obtained from searching the websites of the sanitary agencies of the nine countries. Information was recorded in a form designed by the researchers.

Results In the purchase of mechanical ventilators, significant differences were found in prices, depending on the date of acquisition. Several devices were identified as being non-compliant with some of the technical criteria established by the World Health Organization.

Conclusions Access to information on contracts for the purchase of mechanical ventilators is limited, both in terms of access and public consultation. Complete technical information must be required from manufacturers and suppliers and information gaps should be avoided, especially for public purchasing processes.

Key Words: Ventilators; mechanical; coronavirus infections; COVID-19; disease outbreaks; price list; Latin America (*source; MeSH, NLM*).

ABSTRACT

Objetivo Establecer el precio de compra, estrategias de autorización, disponibilidad de registros sanitarios y especificaciones técnicas para la compra de ventiladores mecánicos en América Latina durante la pandemia por COVID-19.

Métodos Se realizó una evaluación de tecnologías sanitarias mediante la búsqueda de especificaciones técnicas, registros sanitarios e información de seguridad de los ventiladores mecánicos adquiridos por nueve países de América Latina (Colombia, Guatemala, México, Argentina, Uruguay, Costa Rica, Brasil, Paraguay y Perú). Con base en la información de 129 licitaciones y contratos, se realizó una búsqueda de información técnica en los sitios web de los proveedores y fabricantes de 32 marcas y 55 modelos diferentes. Esta información se comparó con las especificaciones técnicas de la Organización Mundial de la Salud para estos dispositivos. La información sobre

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la disponibilidad de registros sanitarios y la seguridad de los ventiladores se obtuvo de la búsqueda en sitios web de las agencias sanitarias de los nueve países. La información se registró en un formulario diseñado por los investigadores. Resultados En la compra de ventiladores mecánicos se encontraron diferencias significativas en los precios, según la fecha de adquisición. Se identificaron varios dispositivos que no cumplían con algunos de los criterios técnicos mínimos establecidos por la Organización Mundial de la Salud.

Conclusiones El acceso público y la información sobre los contratos realizados para la compra de ventiladores mecánicos son limitados. Se debe exigir información técnica completa a los fabricantes y proveedores y se deben evitar los vacíos de información, especialmente para los procesos de compras públicas.

Palabras Clave: Ventiladores mecánicos; infecciones por coronavirus; brotes de enfermedades; lista de precios; América Latina (*fuentes: DeCS, BIREME*).

Of the infection by the new coronavirus, we know that the clinical presentation ranges from an absence of symptoms up to the presence of mild to severe symptoms. In the most severe stages, type-2 acute respiratory syndrome (SARS-CoV-2) is present, which requires care in an intensive care unit and respiratory support (1). Acute respiratory failure is a clinical syndrome characterized by the respiratory system's failure to provide proper arterial oxygenation and elimination of carbon dioxide (CO₂). This syndrome is a common final consequence of a great variety of specific conditions. These conditions are not only of respiratory origin but can also be of cardiac, neurologic, toxic, infectious, and traumatic origin (2). It is one of the most common medical problems in emergency wards, as well as one of the most common causes for admission into intensive care units (1).

Respiratory failure is diagnosed based on the oxygen saturation curve, specifically when arterial oxygen pressures are below 60 mmHg and the fraction of inspired oxygen (F_IO₂) at rest and at sea level is 21 % (2). Within the main clinical manifestations, one can observe mental alterations (agitation, somnolence), an increased work of breathing, tachypnoea, mucosal membrane cyanosis, tachycardia, hypertension, among others (1). Treatment for patients with respiratory failure consists of a rapid administration of procedures that contribute an additional provision of oxygen. In some cases, the use of early respiratory support is needed, whether invasive or non-invasive, to avoid irreversible respiratory failure¹. Mechanical ventilation is a vital support technique that has greatly contributed to improve the health of patients who suffer from acute respiratory failure by allowing the altered gas exchange and minimizing work of breathing (3).

A mechanical ventilator or respirator is a medical device that works by creating a positive pressure which allows the provision of air to the respiratory tract, so the patient receives an adequate volume of air per minute to fulfill its basic respiratory needs (3). There are several types of ventilators. Some work with negative pressures and others with positive pressures. The latter can be classified in terms

of how invasive they are: invasive and non-invasive. When the device is placed in the trachea, it is considered invasive; when an interface that is external to the respiratory tract is used, it is considered non-invasive (3). Selection of an invasive or non-invasive ventilator to treat a patient with acute respiratory failure will depend on the patient's characteristics and clinical state. Traditionally, invasive methods are used, however, when considering the complications derived from prolonged use, and if the patient's conditions allow it, using non-invasive methods is also possible (3).

Invasive ventilators require qualified medical staff to perform the intubation, manage pressure controls and set alarms. The air supply must also be adjusted in terms of infrastructure, air sources, room temperature and humidity. These ventilators also require qualified staff to be responsible of solving issues with the equipment, provide maintenance, and perform decontamination procedures. These types of ventilators are classified into two categories: ventilators for patients in ICU wards and ventilators to transport/care for mass victims (3).

Non-invasive ventilators use interfaces, like masks, to provide respiratory support. This provides some benefits in terms of a lower need for sedation and the reduction of lesions in the respiratory tract that are usually caused by invasive ventilation (4). The use of non-invasive ventilation is justified in patients that do not require urgent intubation, that do not have contraindications for its use and who's pathology is likely to improve with its assistance. Cooperative young patients with less serious symptoms and a good level of consciousness usually respond better to this alternative (5).

In the context of the COVID-19 pandemic, between 5 % and 15 % of diagnosed patients require care in intensive care units and respiratory support (5). The Latin American region has widely mobilized resources and initiatives to make public purchases of enough mechanical ventilators so that the increased demand for these devices in intensive care units and health centers is met. Ideally, these mechanical ventilators should be low-cost, accessible, and quick to manufacture so that they can be used in COVID-19

patients with medium to severe symptoms, that reside in medium or low-income countries (6). Reports from independent consultants suggest that the mechanical ventilator market has grown, even since before the pandemic, due to the adoption of these devices in the treatment of chronic illnesses such as asthma, chronic obstructive pulmonary disease, bronchitis, lung cancer, and due to an increase in the number of intensive care units (7,8). This market is expected to keep growing in the context of the pandemic due to the need of having these devices available to treat patients in a critical state caused by the SARS-CoV-2 infection (8).

Given the wide variety of mechanical ventilators available in the market, it is necessary to have independent sources of comparative information on the necessary aspects needed to guide decision-making based on trustworthy information. These sources of information are also necessary for future negotiations related to the purchase of these devices, especially those involving public resources. However, the existing information on the availability of mechanical ventilators, their market, prices, existence of patents, and other relevant facts to be considered is not available in full, and mostly, is not publicly available or easy to access.

On June 30th, 2020, the Centro Latinoamericano de Investigación Periodística (Latin American Center of Investigative Journalism) (El Clip), published an investigation detailing the investments made by nine Latin American countries to equip their hospitals' intensive care units with mechanical ventilators to treat severe patients with COVID-19; this, to meet the demand as contagion reaches its highest peaks or new waves of infection take place (9). As a follow-up to this journalistic work, the objective of this study was to establish the purchase prices, the authorization strategies, the requirements and availability of health registrations, and the technical specifications for the purchase of mechanical ventilators made in Latin America in the context of the COVID-19 pandemic.

METHODS

Design

Health technology assessment. This study aimed to assess the available information on purchase prices, technical specifications, and approval strategies for mechanical ventilators acquired during 2020 in the context of the COVID-19 pandemic.

Scope of the health technology assessment

This health technology assessment encompasses:

- Condition: patients with acute respiratory failure.
- Intervention: invasive mechanical ventilators.
- Context: Latin American countries during the COVID-19 pandemic.

Aspects to be evaluated:

- Technology domain: technical specifications
- Safety domain: adverse events
- Economic implications domain: purchase of ventilators in different countries, including comparative prices whenever possible.
- Legal aspects domain: regulations within the region for emergency purchases of mechanical ventilators.

Sources of information

To obtain the necessary information for each one of these established domains, details were extracted from the web pages of manufacturers, providers, and innovator companies when data on the brand and model of the ventilator was available. Moreover, the minimum recommended criteria suggested by the World Health Organization (WHO), for the purchase of mechanical ventilators in the context of the COVID-19 pandemic were identified and compared (10). To identify the different prices of ventilators, a database with the reports of tenders and contracts provided by El Clip was used. This information contained reports of purchases of mechanical ventilators made between the months of March and June of 2020 for nine countries in Latin America (Colombia, Guatemala, Mexico, Argentina, Uruguay, Costa Rica, Brazil, Paraguay, and Peru). With the objective of giving continuity to the information provided by El Clip, a search for information on the web pages of each country's sanitary authority was performed to identify the approval mechanisms and safety alerts on the mechanical ventilators involved.

Lastly, to select the variables to be studied, two expert clinicians were consulted and based on their experience in the area of critical care and respiratory therapy, they recommended and selected the variables to analyze.

Data extraction

An Excel database was created containing the information on national public purchases made in the context of the pandemic. This information was gathered from searching the web pages of the sanitary authorities and government agencies of Colombia, Brazil, Argentina, Chile, Peru, and Mexico. The data was extracted by the authors in an independent manner.

Qualitative variables measured

- General characteristics of the contracts: country, date of contract, country of origin.
- Technical specifications: brand, model, description of the required devices according to the WHO: portable or non-portable, invasive or non-invasive ventilation, ventilator volume, ventilator pressure, ventilation modes, support pressure, presence of alarms, numerical and

graphical monitoring by scalars and loops. Availability of devices by experts: bilevel, dual modes, ventilatory tools, weaning parameters, automated ventilatory weaning methods, sensibility/triggers, leak compensation, APA filters, pulmonary mechanics.

- Economical aspects: provider, quantity of ventilators purchased, cost per unit in local currency and USD, total amount of purchase in dollars. The exchange rate assigned is that of June 30th of 2020 for each of the nine countries studied.
- Legal aspects: authorization strategies: requirements and availability of health registrations.
- Safety: techno-vigilance and adverse event reports by searching in all the official web pages of the included countries' sanitary agencies.

When no information was found, it was registered in the database as “no information”.

Analysis

The information was summarized descriptively for each one of the established domains. The technical characteristics of the mechanical ventilators, cost of purchase, health registrations, and the techno-vigilance information available was compared. In order to facilitate the analysis of the technical specifications, a classification was made based on the level of complexity between those devices used to transport and move patients and those used in hospitals in intensive care units. Given the nature of the information and the study's objectives, no statistical analyses were contemplated.

RESULTS

The database that was built includes information on 129 contracts reported for the nine Latin American countries selected. The ventilators purchased match 32 brands, including the most frequent CareFusion (Vyaire) (USA), Puritan Bennet (USA and Ireland), Philips Respironics (USA and The Netherlands) and Dräger (Germany) Mindary (China). The ventilators of Latin American origin were of the brands Weg and Magnamed from Brazil, Tecme from Argentina, Medica D and IDEM from México, Leistung from Argentina and Leistung from Brazil. These were distributed mainly for local purchases in each country. The identified purchases were made between January and September of 2020.

Technical specifications

With the available information on the 129 contracts reported by El Clip, it was possible to conduct an assessment of the technical specifications for 55 models of mechanical ventilators.

Following the WHO suggested classification for invasive ventilators, based on the intended use, out of the 55 models of ventilators evaluated, 40 were identified as being for hospital use in Intensive Care Units (ICU) and 15 for use in transportation of patients.

Some of the variables established as minimal criteria by the WHO could not be identified in the data sources or did not comply with the suggested requirements. These variables are described in Table 1.

Table 1. WHO variables not reported in data sheets

Variable	Number of models	Brand and models
Volume-controlled ventilation modes	5,0	BMC Medical RESmart GII BPAP, Philips Respironics V60, Philips Respironics E30, WEG WL3, Löwenstein Prisma Vent
Pressure Support Ventilation	10,0	MEK-ICS MV2000, Hamilton Medical T1, Philips Respironics T100, ResMed Astral, Philips Respironics V60, Philips Respironics E30, Intermed iX5, Magnamed Oxymag, WEG WL3, ResMed Astral 150
Non-Invasive ventilation capability	12,0	Puritan Bennett 560, Puritan Bennett 740, IDEM Ventilamex, KTK Microtak, Leistung Luft3, WEG WL3, Northern Meditec Limited Crius V6, Prunus Boaray 5000D, Dräger Evita V300, Löwenstein Prisma Vent, ResMed Astral 150, GE Healthcare Carestation 650
Displayed Parameters (For ventilators meant to be used in Intensive Care Units)	10,0 models with only scalar monitoring	Dräger XL Evita, Puritan Bennett 560, Zoll Medical Corporation EMV+, Covidien Plus HT70, BMC Medical RESmart GII BPAP, Puritan Bennett 760, Puritan Bennett 740, Philips Respironics T100, ResMed Astral, Philips Respironics V60, IDEM Ventilamex, Leistung Pr4-g, Löwenstein Prisma Vent, ResMed Astral 150
	2,0 models with only loop displays	Prunus Boaray 5000D, Dräger Evita V300
	6,0 without graphic monitoring	ResMed Astral 100, Philips Respironics E30, KTK Carmel, KTK Microtak, WEG WL3, Newport HT70

Source: Self-elaboration.

Following the recommendations made by the experts, three differentiating variables were identified in terms of the technical characteristics of mechanical ventilators. These findings are summarized in Table 2.

The results for the variables suggested by the experts are described below:

- Two out of the 15 models intended for transportation and 20 out of the 40 models identified for hospital use

had information on weaning modes. In terms of automated weaning methods, only 5 of the models had this characteristic: Dräger XL Evita, Dräger Babylog VN500, Prunus Boaray 5000D, Dräger Evita V300, and Dräger Evita Infinity v500.

- In terms of the availability of Airway pressure release ventilation (APRV) or bilevel ventilatory modes, these features were found in 13 out of the 15 transport

Table 2. Findings in the selected variables in terms of how useful and relevant they are, according to experts

Parameter	Description	Advantages	Findings
Weaning parameters	They seek to reduce the patient's ventilatory support once the root cause that determined the connection to mechanical ventilation is controlled. It facilitates achieving a successful extubation*.	Reduced costs, shorter stays in the ICU, infections and other complications that arise from mechanical ventilation ¹³ .	22 models with these characteristics were identified.
Automated weaning methods	They are automated strategies incorporated into 4th generation devices onward.	They make the extubation process easier.	Five models with this characteristic were identified.
APRV and BiLevel ventilatory modes		They provide advantages over conventional ventilation by improving the oxygenation process, preserving spontaneous ventilation, improving the hemodynamic state, and reducing potential adverse effects from mechanical ventilation.	Five models had no information on whether they had these modes, nine models included an APRV mode, 21 a BiLevel mode, and 20 both APRV and BiLevel modes.

* World Health Organization. Technical specifications for invasive and non-invasive ventilators for COVID-19: Interim guidance. World Health Organization. 2020:10. <https://apps.who.int/iris/handle/10665/331792>; Montes MA, Rodríguez J, Villalobos J, Franco J. Modalidades de destete: Ventilación con presión soporte, presión positiva bifásica y liberación de presión de la vía aérea. *Rev Asociación Mexicana Médica*. 2008; 22(4): 260-27; García-Prieto, E., et al. Monitorización de la Mecánica Respiratoria en el Paciente Ventilado. *Medicina Intensiva*. 2014; 38: 49–55. <http://dx.doi.org/10.1016/j.medin.2013.09.003>. APRV: Airway pressure release ventilation. Source: Self-elaboration.

ventilators and in 37 of the hospital-use ventilators. Regarding the existence of ventilatory tools, information was found for 9 out of the 15 transportation devices and for 24 out of the 40 hospital devices.

- Regarding the pulmonary mechanics variables (pulmonary compliance or resistance), 31 models did not report or have information. In terms of the existence of APA filters, no information was found for 45 models.

Authorization strategies, requirements, and availability of health registrations

Different strategies used in countries within the region to approve and increase access to health technologies, such as mechanical ventilators, were identified.

Two strategies to authorize mechanical ventilators in the context of the pandemic were found. The first one consists in authorizing the devices through general regulations, which implies that no health registration is emitted for a specific model of ventilator but that for the approval of a marketing authorization, it is only necessary to meet the established technical directives. This case was observed in Uruguay (11).

On the other hand, the second strategy was found in countries such as Brazil, Colombia, Peru, and Argentina, who issued health registrations for medical devices for specific

models (Brazil) or for a group of devices that shared specific technical characteristics (Colombia, Argentina, and Peru).

In Colombia, 24 health registrations covering a total of 54 models of ventilators were found. In Argentina, 6 health registrations were found that authorize 22 models of ventilators. In the case of Brazil, 17 health registrations for a total of 46 models were found, and for Peru, 8 health registrations covered 28 models.

Based on the analyzed information (129 purchases of mechanical ventilators), Colombia and Brazil stand out as the countries with the highest percentages of approved health registrations for these types of devices (36 % and 18 %, respectively).

At the time of data extraction for the present study, it was not possible to access the health registration information for mechanical ventilators in Guatemala, Costa Rica, Mexico, and Paraguay.

Prices and purchases

The price per unit for mechanical ventilators oscillated between 28,000 and 34,000 USD. Between countries, price differences were identified for purchases of the same models and among models with similar technical specifications. The cases identified are described in Table 3.

Table 3. Purchase price differences for mechanical ventilators by country and date of purchase

Model	Country	Month of purchase	Quantity	Unit price
Mindray SV300	Costa Rica	March	40,0	28,000 USD
	Mexico	April	1,0	41,790 USD
Maquet Servo Air	Costa Rica	March	30,0	32,000 USD
	Peru	March	35,0	50,028 USD
	Colombia	May	29,0	18,700 USD
Dräger Evita v300	Mexico	May	10,0	50,306 USD
	Peru	April	3,0	48,529 USD
	Paraguay	April	2,0	25,781 USD
Carefusion (Vyair) Avea	Mexico	April	1,0	52,500 USD
	Mexico	May	2,0	23,730 USD
	Paraguay	April	31,0	41,000 USD

Source: Self-elaboration.

Techno vigilance and adverse event reports

There was only one safety alert found during the safety review of mechanical ventilators acquired for the regulatory institutions of the nine countries in the region. This safety alert was issued on September 9, 2020, by the Instituto Nacional de Vigilancia de Medicamentos y Alimentos de Colombia (National Institute for the Surveillance of Drugs and Food) (INVIMA). The document announces a suspension of import and commercialization of mechanical ventilators from the Chinese brand Eternity, specifically model SH-300, since cycle failures were identified, the devices would turn themselves off, and would provide altered data on the controlled ventilatory parameters (12).

No additional reports were found in the web pages of the other sanitary agencies for this, or other models of mechanical ventilators studied.

The reports only mention one purchase made in Mexico for devices of this brand, however, the model is not disclosed. Public purchases in the region made at a later date, for these devices, are not ruled out.

The highest paid prices per unit correspond to two purchases of mechanical ventilators made by Guatemala belonging to the Dräger brand, for which approximately \$100,000 USD per unit were paid during the month of April. In other purchase reports for the same brand of mechanical ventilators, in countries such as Mexico, Peru, and Uruguay, the prices oscillated between 30,000 and 50,000 USD. However, the model acquired in these cases was not disclosed, which limits the price comparison.

Prices were also found to be different for devices with similar specifications, across brands and models. For example, in the case of the device Carescape R860 from General Electrics and the device Bellavista from IMT Medical, even though they had no important differences in terms of technical specifications, the former had a unit cost of 28,000 USD and the latter of 51,000 USD.

DISCUSSION

The present study shows that Latin American countries have a high degree of technological dependence in terms of the manufacturing of mechanical ventilators, mainly from industries located in the United States of America, China, Germany, among others. Only Brazil is able to meet its own internal demand, while Mexico, Argentina, and Uruguay do it in a partial manner.

On the other hand, the minimum technical specifications by the WHO and the consulted experts could not be properly identified and evaluated in 58 % of the purchases. Most of the information available is complete in terms of ventilation modes and graphical monitoring, while information on the required alarms, the parameters and

methods of weaning, type of pulmonary mechanics, and the existence of APA filters is scarcer.

The specific health registrations, or those for models of ventilators, are the most common strategy used during the pandemic. However, in Uruguay, they were acquired under normal regulations.

When a code or a health registration is issued, either for a specific model or group of models, it allows for more clarity on the information of the mechanical ventilators available and their basic technical characteristics. In countries where health registrations were provisional or were not granted in the context of the sanitary emergency, analysis of these aspects become difficult.

Major differences were found in terms of purchase prices for the same or similar models with comparable technical specifications. These differences could be explained by the degree of sophistication of the included devices, the negotiation capacity of the countries, the number of units acquired and the time (date) of purchase. This last aspect can be explained considering that, as the pandemic moved forward and the number of cases grew, the demand for mechanical ventilators became more evident.

A wide search for information was undertaken, however, the non-availability of information on the models was a limiting factor for the analysis of information on health registries, and especially for the process of verifying the technical specifications of these devices. This way, we were only able to identify information for 42 % of the mechanical ventilator models. Not having information on a model reflects a lack of transparency in the contracts, given that, when complete information is not provided, it goes against the principle of quality of information established in transparency laws.

It is important to highlight that for the 55 models studied, in some cases, the technical data sheets did not contain all the variables of the established technical specifications. In these cases, it was not possible to identify better sources of information. The variables suggested by the experts correspond to those that could indicate a level of sophistication in the mechanical ventilators that should be considered by the health providers. That level of sophistication represents a differential feature, so, those variables should be clearly mentioned in the technical information provided in brochures and manuals. The results of this study are only applicable to the countries where information was found.

One of the limitations of the present study is that it was not able to evaluate the quality of the identified documents since there are no tools to analyze this type of information. However, thanks to the participation of experts in intensive care and mechanical ventilation, priority variables of interest could be established. It is important that, for

contracts made with public resources, tools to verify the minimum required information in data sheets or brochures from manufacturers start to be generated.

The only information found on techno-vigilance and adverse events was found in Colombia. This situation highlights the need to continue techno-vigilance activities in case that other models present failures and unexpected adverse events.

There is a lack of available information in regional and international literature, and in general, about the evaluation of mechanical ventilators in terms of the areas described in this study. Some studies that compare the technical characteristics of adult and pediatric ventilators were identified (13). Either way, one must consider that this situation is highly atypical, in terms of the evaluation of medical devices, given the tension between the urgent need for devices and the adequate safety evaluation prior to authorizing their use in patients with respiratory failure due to SARS-CoV-2 (COVID-19). However, steps to ensure the benefits and safety of these devices cannot be skipped due to urgency (14).

To conclude, information on contracts to purchase robust health technologies, such as last-generation mechanical ventilators, is limited in terms of access and public consultation. Complete technical information must be demanded and centers for health technology assessment must exist at an institutional level, so compliance to international standards can be verified. These health technology assessment centers should provide information on the safety, effectiveness, and the ethical, economical, and organizational implications derived from the mass use of these devices which are involved in a high technology dependence.

Given pandemic situations like the current one, where the decisions to purchase devices could not be entirely guided by valid information, but by urgency and uncertainty, it is necessary that manufacturers and innovator companies provide decision makers with all of their models' technical specification information. It would also be important for decision makers to be advised by multidisciplinary teams that are able to perform health technology assessments in terms of health outcomes and the implications-of-use of said devices (15).

There is a need for contracts to contain more information on the acquired models and their technical specifications to guarantee transparency in the procurement processes. These contracts should be publicly accessible so that better social controls can take place.

Information on prices must be shared by the governments of the region to achieve better terms of negotiation. Pressures coming from innovator companies, based in high-income countries, to keep this information confidential should be limited. This, as a preparation for any future pandemics ♦

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