

Clinton Health Access Initiative, Inc.

Request for Proposal

Request for Proposals (RFP) for the installation of autoclave for the Vicente Corral Moscoso Hospital in the city of Cuenca and Martin Icaza Hospital in the city of Babahoyo, Ecuador

April 8, 2022



Summary of terms

Release of Request for Proposals: April 8, 2022

Proposal expiration / last proposal submission date: April 17, 2022
5pm EST

Clinton Health Access Initiative (CHAI) invites interested and capable organizations to submit proposals to install an autoclave with a chamber capacity of 100 - 140 liters for the Vicente Corral Moscoso Hospital in Cuenca and Martin Icaza Hospital in Babahoyo, Ecuador.

Completed Request for Proposals (RFP) should be submitted electronically to Rodrigo Valencia, COVID-19 Associate, South America, at rvalencia.ic@clintonhealthaccess.org before 5pm (EST) on Sunday, April 17, 2022.

Questions regarding the RFP should be addressed to Rodrigo Valencia to the email mentioned above.

Background

A. Clinton Health Access Initiative (CHAI)

Clinton Health Access Initiative, Inc. (CHAI) is a global health organization committed to saving lives and reducing the burden of disease in low- and middle-income countries, while strengthening the capacities of governments and the private sector in those countries. to create and maintain high-quality health systems that can succeed without our help. For more information visit:

www.clintonhealthaccess.org

B. The program: oxygen technical assistance

The first case of SARS-CoV-2 was registered in Latin America on February 26, 2020, when Brazil confirmed the presence of the virus in Sao Paulo. Since then, more than 46 million cases have been registered in the region. According to statistics from the World Health Organization (WHO), in 2020, Latin America and the Caribbean had the highest number of confirmed cases worldwide, representing a quarter of all cases globally.

Latin America continues to bear one of the highest burdens of COVID-19 in the world and its health systems are among the hardest hit by the pandemic. Despite initial progress in preparing for an emergency response, many countries in the region continue to experience difficulties in providing quality and timely care to patients. Documented gaps included limited testing capacity, difficulty in connecting the patient care pathway with a single information system, limited ability to implement oxygen therapy, medication shortages, intensive care unit (ICU) saturation, and delays in the implementation of a vaccination strategy or limited access to vaccines.

Since July 2021, CHAI began supporting Ecuador and Guatemala with a new program focused on strengthening the technical oxygen capacity of those two countries. Under the new Oxygen Technical Assistance Program, funded by UNITAID, CHAI is working with the ministries of health in prioritizing five

to six hospitals, in different departments of the aforementioned countries, where COVID-19 cases are higher, as well as the gaps to provide adequate therapy to patients. Program interventions will include: a) improvement of hospital infrastructure, b) training in clinical aspects of oxygen therapy and also in O2 prognosis and related products, and c) development of preventive and corrective maintenance programs for each of the prioritized hospitals.

C. Technical assistance at Vicente Corral Moscoso Hospital

The Vicente Corral Moscoso Hospital in the city of Cuenca in Ecuador was officially opened in 1977 with an installed capacity of 290 beds. Over the last few years, several remodeling works have been carried out that have not been completed from a technical and functional point of view due to budget constraints.

It is the only hospital with the greatest technical and resolution capacity in the Service Network of the Ministry of Public Health (MSP) in the south of the country, and therefore, the greatest demand for services from the population. It receives referrals from the health units of the MSP in zones six and seven, as well as from the units of the Comprehensive Public Health Network, especially the Hospital José Carrasco Arteaga of the IESS, Hospital Militar de Cuenca and the Private Complementary Network, which do not have sufficient resolution capacity -an aspect that saturates all services and causes slowness or repression in care.

In March 2020, the Vicente Corral Moscoso was declared a sentinel hospital for the hospitalization and treatment of suspected and confirmed patients with the COVID-19 virus. Since then, the entire emergency area has been designated for the care of positive patients with COVID-19, and redesigned to meet biosafety regulations, including the restriction of access to prevent possible infections. The area houses 24 ICU patients (ventilated with high flow), in addition to ICU patients from the pediatric, neonatology, operating rooms, delivery rooms, and adult ICUs (not COVID-19).

The project requires strengthening of the medical gas distribution system, which will allow the hospital to expand its capacity to care for patients, especially those suffering from COVID-19.

D. Technical assistance at Martin Icaza Hospital

Due to the damage of the sterilizers and therefore, limited availability of sterile surgical instruments in the operating room area, compliance with elective surgeries has been affected forcing the hospital to prioritize emergencies, and delay scheduled surgeries.

Before the COVID-19 pandemic, the hospital performed approximately 300 surgeries per month, which reduced dramatically after the spread of the virus. By the end of 2021, surgeries had resumed to normal and have been rising since, making it difficult to meet with 100 percent of the scheduled operations and medical safety standards due to the difficulty in sterilizing the instruments.

Scope of work

The purpose of this Request for Proposals (RFP) is to request competitive bids for the installation of a steam sterilizer, in Ecuador.

A. Technical and quality information

The following are the technical specifications that the supplier must meet and provide associated documentation for the installation, materials, and devices:

TO. Technical specifications for steam sterilizer

Spec category:

Specifications adapted from WHO 2014

Description:

A mains electricity (AC-powered) device designed for total elimination and/or inactivation of microorganisms from medical devices and related products, not placed in sterilization wraps/packaging, using pressurized steam (i.e., moist heat) as the sterilizing agent; it is used for products non-sensitive to high temperature, water, or steam. It typically includes a treatment chamber with shelves for device placement, usually after cleaning of gross debris; a means to introduce the steam into the chamber; and controls to regulate the time and/or temperature of the procedure. The device is available in a variety of shapes and sizes, including stand-alone (bulk) and tabletop units.

- Uses pressurized steam to kill microorganisms on medical devices and products
- Allows the user to control time and temperature of procedure
- Allows easy access to chamber
- Generates heat using integral electric heater
- Micro-processor control
- Overheat shutoff and overpressure safety valve to be incorporated
- Vacuum air removal facility is not required, gravity removal valve is sufficient
- Pressure lock to be incorporated to prevent door opening at pressure
- Temperature range to include at least 100 to 132 °C
- Chamber capacity to be at least 100 to 140 liters
- Required water level to be clearly indicated.
- External surfaces to remain at safe temperatures even when in use
- Internal steam electrical generator.
- At least the following cycles available:
 - Solids
 - Glassware materials
 - Liquids
 - Vacuum test
 - Bowie-Dick Test
- Adjustable temperature working range not smaller than from 115 °C up to at least 121 °C
- Temperature measure precision not greater than +/- 3%
- Vacuum pump and vacuum sustainability diagnostic system
- Safety systems, at least: Thermostat, Pressure switch, Valves
- Protection system for high pressure risks
- Filters for air intake system

- Automatic block in high- and low-pressure conditions
- Display:
 - Temperature
 - Pressure
 - Working Time
 - Equipment status and alarms
 - Alarms for at least:
 - Power failure
 - Low water
 - Door not closed
 - Pressure and/or Temperature out-limits
 - Sterilization cycle failure
 - End of sterilization cycle
- User-resettable time elapsed indicator to be incorporated
- All metal parts to be constructed of stainless steel
- Power supply:
 - Requires continuous AC power source to operate (e.g. mains with generator, UPS or battery)
 - Electrical power input requirements: 120VAC/60Hz with $\pm 10\%$ allowance in voltage fluctuations
 - Plug style as per local supply
 - Power cable to have length ≥ 3 m
 - Electrical protection by resettable circuit breakers or replaceable fuses, fitted in both neutral and live lines.
- Accessories:
 - Stainless steel stand designed to support the autoclave.
 - At least n. 2 system compatible baskets for different sterilization applications
 - Printer to document sterilization information
- Spares:
 - Two sets of spare fuses (if non-resettable fuses used)
 - Replacement door gasket
 - Replacement heating element
 - 1 x air intake spare filter
 - 2 x sets of compatible printing paper (if integrated printer provided)
 - 2 x complete Bovie-Dick test kits for daily monitoring
 - 4 x testing complete sets for standard cycles control/tests
- Environmental:
 - Storage: capable of being stored continuously in ambient temperature from 0-40 °C, relative humidity from 15-95%, preferably simultaneously
 - Operations: capable of supplying the specified oxygen concentration continuously in ambient temperature from 10-40 °C, relative humidity from 15-95%, preferably simultaneously
- Documentation:
 - 1 x set user and maintenance manuals, hard and soft copies, in local language, or in agreed other language if local is not available. English version must also be available
 - 1 x certificate of calibration and inspection
 - 1 x list of equipment and procedures required for local cleaning, disinfection, troubleshooting, calibration, and routine maintenance
 - 1 x list of all spares and replacement parts, with part numbers, cost, anticipated need for 5 years of operations.

Installation, testing, and commissioning

- Pre-shipment: Certificate of quality, calibration, and inspection

- On-site:
 - Installation to include training on start-up, use, and maintenance
 - Inspection, testing, and commission should be done before handover.
- If possible, conformity of installation shall be verified by a certified third party. Otherwise, alternative verification process to be agreed upon between vendor and owner.

Warranty

- 2 years minimum

QMS

- ISO 13485 (medical device QMS)

Regulatory

- SRA approval (e.g., FDA or CE)

Product performance & safety standards

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-1 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 61010-2-040 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Requirements for sterilizers and washer-disinfectors used to treat medical materials

Packaging

- Name and/or trademark and address of the manufacturer.
- Product name.
- Product reference.
- Type of product and main characteristics.
- Performance testing information against the mentioned standards.
- Lot number prefixed by the word "LOT" (or equivalent harmonized symbol).
- Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol), if applicable.
- Information for handling, if applicable (or equivalent harmonized symbol).
- If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
- Gross Weight.
- Cubic Measurement.
- All indicated at least in English.

Application to the project

Based on the national COVID-19 response, through the Oxygen Technical Assistance Program, CHAI assessed priority facilities and determined where new equipment and services could be placed. The evaluations have included an assessment of the current infrastructure, the types of care provided, and the capacity of staff. Considerations for oxygen availability, such as network design and optimization for oxygen supply, have been incorporated into this stage.

To apply for this RFP, applicants must provide (1) a completed application form (Sections 1 and 2); (2) a complete budget template (collectively “Materials”), (3) technical and regulatory and quality documentation outlined in the scope of work (if regulatory or quality certificates are within 6 months of expiry, please include details regarding status of renewing these certificates). Candidates should send questions by April 12 and submit their proposals by April 17, 2022. The winners will be announced on April 19. From April 20, the winners will have two months to finalize their proposed budgets, which must not exceed USD \$ 65,000. Quotations will remain valid for 30 days from the closing date of this RFP.

Section 1: Beneficiary information

1. Name of the beneficiary organization:
2. Contact information (include contact name, address, phone number and email):
3. Total budget requested:
4. Commercial references:
5. Provide a brief description of the organization.
6. Provide information on experiences related to the work area.

Section 2: Project information

1. Description of the project and deliverables
2. Top activities with due dates and deliverables schedule (make sure the activities shown here match the activities shown in the budget template):

Activity (s) / Deliverables	Description	Estimated date of completion

3. How will this project contribute to the optimization of oxygen delivery to patients in the country or to what extent will it contribute to improving it?
4. How will you carry out the project within the indicated timeframe? If the project is urgent (for example, funding must be ready before the XX date to achieve the proposed results), indicate it here.

Eligibility and qualification of offers

Eligibility:

Suppliers will agree to establish a temporary project team structure that includes CHAI staff. Suppliers also agree to organize regular meetings (in person or via telecommunications) and on site when necessary.

Offer rating:

Qualification criteria of the tender:

- a. The determination of the qualifications for the selection of the winning bid will be made according to the criteria described in the following table:

CRITERION	POINTS
Delivery Time	10
Technical Support	20
Warranty	30
Price	40

Delivery time:

The offer that presents the shortest delivery time in business days for Installation and delivery of accessories, you will automatically get ten (10) points; the other offers will have a rating inversely proportional to the first, depending on the value of your offer. For which the following formula must be taken:

$$\frac{\text{Shortest delivery time offered} \times 10}{N \text{ value}}$$

N value = Delivery term of the offers to qualify (in business days).

Technical support:

Documents that certify the technical skills of the personnel who will execute the installation, binding certifications, including CVs, photocopies of diplomas, certificates and / or certifications that guarantee competence in this type of service, in the last 10 years to the date of presentation. of the offers.

For the qualification, the BOARD will assign twenty (20) points according to the documents that endorse the competence of the technicians presented by the BIDDER, according to the following formula:

$$\frac{\text{Value} \times 20}{\text{Increased number of records}}$$

N value = Evidence to qualify.

Warranty:

The offer that presents the highest guarantee will automatically obtain thirty (30) points; the other offers will have a rating inversely proportional to the first, depending on the value of your offer. For which the following formula must be taken:

$$\frac{\text{Lowest Price Offered X 30}}{\text{N value}}$$

N value = Offer price to qualify.

Price:

The offer that presents the lowest price will automatically obtain forty (40) points; the other offers will have a rating inversely proportional to the first, depending on the value of your offer. For which the following formula must be taken:

$$\frac{\text{Lowest price offered X 40}}{\text{N value}}$$

Value N = Offer price to qualify.

Other information

Failure to provide all the information required by the RFP or submitting an offer that does not respond to the RFP in all respects will be the responsibility of the bidder and may result in the rejection or disqualification of the offer.

CHAI shall have the right to seek any additional information or document from the bidder in the manner it deems appropriate in its sole and absolute discretion.

The offer prepared by the bidder, as well as all correspondence and documents related to the offer exchanged by the bidder and CHAI will be drawn up in Spanish only. However, in case the bidder chooses to attach certain supporting documents in any language other than Spanish, the bidder must also attach certified / authentic translated copies thereof in English. Any document that is not translated into Spanish will not be considered and the offer will be considered incomplete and therefore, subject to disqualification.

All prices quoted in the offer will be quoted in United States dollars.

CHAI will examine the offers to determine if they are complete, if they comply with all the conditions of the RFP and if the documents have been duly signed and the offers are in general order. If there is a discrepancy between words and figures, the quantity in figures can be used as the prevailing quantity.

Disclaimer

Distribution of this document does not mean that CHAI is committing to award a contract or fund an applicant.

CHAI will not reimburse or assume any costs associated with this RFP regardless of whether an organization is selected to supply.

Please note that no fee is required for the submission of these applications.

CHAI makes no representations or warranties and will not incur any liability under any law as to the accuracy, reliability, or completeness of the information contained in the RFP.

Confidentiality

The information that the respondent considers proprietary must be clearly marked as such. All such information will be treated confidentially and used by the CHAI team for evaluation purposes only.