

A Low-Pressure Oxygen Storage System for Oxygen Supply in Low-Resource Settings

Roger P Rassool PhD, Bryn A Sobott PhD, David J Peake PhD, Bagayana S Mutetire, Peter P Moschovis MD MPH, and Jim FP Black MBBS PhD MCommH

BACKGROUND: Widespread access to medical oxygen would reduce global pneumonia mortality. Oxygen concentrators are one proposed solution, but they have limitations, in particular vulnerability to electricity fluctuations and failure during blackouts. The low-pressure oxygen storage system addresses these limitations in low-resource settings. This study reports testing of the system in Melbourne, Australia, and nonclinical field testing in Mbarara, Uganda. **METHODS:** The system included a power-conditioning unit, a standard oxygen concentrator, and an oxygen store. In Melbourne, pressure and flows were monitored during cycles of filling/emptying, with forced voltage fluctuations. The bladders were tested by increasing pressure until they ruptured. In Mbarara, the system was tested by accelerated cycles of filling/emptying and then run on grid power for 30 d. **RESULTS:** The low-pressure oxygen storage system performed well, including sustaining a pressure approximately twice the standard working pressure before rupture of the outer bag. Flow of 1.2 L/min was continuously maintained to a simulated patient during 30 d on grid power, despite power failures totaling 2.9% of the total time, with durations of 1–176 min (mean 36.2, median 18.5). **CONCLUSIONS:** The low-pressure oxygen storage system was robust and durable, with accelerated testing equivalent to at least 2 y of operation revealing no visible signs of imminent failure. Despite power cuts, the system continuously provided oxygen, equivalent to the treatment of one child, for 30 d under typical power conditions for sub-Saharan Africa. The low-pressure oxygen storage system is ready for clinical field trials. *Key words:* pneumonia; hypoxia; LMIC; oxygen concentrator; infant; child; preschool. [Respir Care 2017;62(12):1582–1587. © 2017 Daedalus Enterprises]

Introduction

International effort to address the Millennium Development Goals has driven a dramatic decrease in under-five

mortality globally.¹ Despite these efforts, in sub-Saharan Africa, large numbers of children < 5 y old continue to die from preventable and treatable diseases, such as pneumonia and diarrhea.²

Drs Rassool, Sobott, Peake, and Black are affiliated with the FReO₂ Foundation Australia, Melbourne, Australia. Drs Rassool and Sobott are also affiliated with the School of Physics, University of Melbourne, Melbourne, Australia. Ms Bagayana Mutetire is affiliated with the Mbarara Regional Referral Hospital, Mbarara, Uganda. Dr Moschovis is affiliated with Massachusetts General Hospital, Boston, Massachusetts. Dr Black is affiliated with the Nossal Institute for Global Health, University of Melbourne, Melbourne, Australia.

This study was funded by a Grand Challenges Explorations grant from the Bill and Melinda Gates Foundation. Dr Moschovis has received research funding from the National Institutes of Health (Grant 5F32HL124951), the Thrasher Research Fund Early Career Award, and a KL2/Catalyst Medical Research Investigator Training award (an appointed KL2 award) from Harvard Catalyst: The Harvard Clinical and Translational Science Center (National Center for Research Resources

and the National Center for Advancing Translational Sciences, National Institutes of Health Grant KL2 TR001100). The content is solely the responsibility of the authors and does not necessarily represent the official views of Harvard Catalyst, Harvard University and its affiliated academic health-care centers, or the National Institutes of Health. Drs Peake, Sobott, Black, and Rassool are members and/or directors of FReO₂ Foundation Australia, which is a not-for-profit organization based in Melbourne, Australia. Drs Black and Peake are directors of FReO₂ Pty Ltd, which controls the associated intellectual property. The other authors have disclosed no conflicts of interest.

Correspondence: Jim Black MBBS PhD MCommH, 8 French Avenue, Northcote, Victoria 3070, Australia. E-mail: jim@freo2.org.

DOI: 10.4187/respcare.05532

In a well-resourced setting, the standard of care assumes the availability of therapeutic oxygen. However, despite the World Health Organization listing oxygen as an essential medicine, it remains in limited supply in most low- and middle-income countries, especially in remote settings.³

Timely and uninterrupted oxygen therapy is important in reducing childhood mortality, especially from pneumonia, currently the leading infectious killer of children < 5 y old according to UNICEF (<https://data.unicef.org/topic/child-health/pneumonia/>, Accessed March 10, 2017). Reliable oxygen supplies are scarce in the settings with the highest mortality,³ and to reduce mortality, many more health facilities will need access to oxygen.

Currently, two options exist for the delivery of oxygen in low- and middle-income countries: high-pressure compressed-oxygen cylinders and oxygen concentrators. Many health workers rely on their familiarity with cylinders, citing their ease of use, ability to provide oxygen for extended periods, and lack of need for maintenance.⁴ However, in remote or low resource settings, replenishing oxygen cylinders is often impossible and/or cost-prohibitive.

For reasons of practicality and cost, the use of electrically powered oxygen concentrators has been proposed.^{5,6} These devices are one way to bring oxygen to smaller and more remote health facilities. The use of even the most robust models is limited by (1) interruptions in power supply, (2) fluctuations in voltage levels and voltage spikes that occur as the grid or generator power is restored after a failure, and (3) variable performance in the combination of high temperature and humidity common in low-resource settings.⁷ Many pioneers of oxygen therapy have reported that standard concentrators exhibit a lower life expectancy than anticipated, regrettably in the places where they are most needed.^{8,9}

The Low-Pressure Oxygen Storage System

The low-pressure oxygen storage system directly addresses several of the factors limiting the usefulness of concentrators where the power supply is unreliable and intermittent. At the core of the system is any oxygen concentrator delivering between 5 and 10 L/min oxygen at 90% purity. To protect the concentrator, low-pressure oxygen storage conditions and manages the electrical power delivered to it. This electrical protection (FREO₂ PROTECT) unit includes surge protection, solid-state voltage stabilization, and an intelligent power-fail relay. The oxygen produced by the concentrator is stored in the low-pressure oxygen storage vessel, which allows for simultaneous delivery while the unit is being filled. When electricity is interrupted, previously stored oxygen is delivered automatically without electricity. Thus,

QUICK LOOK

Current knowledge

Oxygen concentrators provide a useful option for treatment of childhood pneumonia in low- and middle-income countries. However, power cuts interrupt the flow of oxygen, and voltage fluctuations shorten the working life of these machines.

What this paper contributes to our knowledge

The low-pressure oxygen storage system is a relatively low-cost and simple way to protect concentrators and maintain oxygen supply during power cuts. It showed no signs of wear after simulated prolonged use and maintained oxygen flow equivalent to one child patient in an African hospital setting despite power cuts and voltage fluctuation.

during a power outage, the low-pressure oxygen storage system maintains oxygen flow to a patient without user intervention.

At the heart of the storage system are 2 interconnected storage vessels arranged as in Figure 1. The lower vessel incorporates 2 internal chambers, which allow for the concurrent storage of a liquid and a gas. The liquid section of the lower reservoir is filled to maximum capacity with water. A 25-mm-diameter hose links this section to the empty upper reservoir, which is positioned at a predefined height above. The operation of the low-pressure oxygen storage system relies on the movement of water between the lower and upper reservoir.

During operation, the oxygen concentrator is configured to deliver its maximum output, and priority is given to providing oxygen to the patient. Oxygen that exceeds patient demand is automatically diverted into the low-pressure oxygen storage. As oxygen enters the gas section of the lower reservoir, it forces the water in the liquid section into the upper reservoir. The oxygen never comes into contact with the water, and no water is lost to evaporation.

In the event of a power failure, the weight of the water previously displaced into the upper reservoir provides the force to drive the stored oxygen to the patient, without the need of a pump. A release valve prevents overfilling of the oxygen store, and a regulator ensures uniform delivery pressure to the patient. A provisional patent application based on this method has been filed.¹⁰ This paper describes proof-of-concept laboratory bench testing and the first 30 d of nonclinical field trials of the low-pressure oxygen storage system in Mbarara, Uganda.



Fig. 1. Low-pressure oxygen storage system installed in Mbarara, Uganda. The lower bag is inflated with stored oxygen, whereas the upper bag is holding the water ballast.

Methods

Bench Testing

A test system was established at the University of Melbourne Physics Laboratory in July 2015. For the lower reservoir, two 200-L polyethylene bladders were placed inside a custom-made 200-L bag constructed from a knitted fabric made of UV-stabilized high density polyethylene. The upper reservoir comprised a single polyethylene bladder placed in an identical external bag. This arrangement provided a physical separation between the stored oxygen and the working liquid. The performance of the low-pressure oxygen storage system was quantified by measuring flows and pressures with sensors placed at strategic points in the pneumatic circuit.

Proof-of-concept testing of the system was undertaken using a 5-L/min concentrator (NewLife Elite, AirSep Corp., Buffalo, New York) as the source of oxygen. A mock patient oxygen delivery system was assembled to recreate the anticipated use-case of delivering oxygen to 6 beds. This included 40 m of delivery pipe, individual volumetric flow controllers for each patient, and nasal prongs immersed in 8 cm of water.

For accelerated fatigue testing, the concentrator was replaced with an air compressor (model 607CD22-1948, Thomas Industries, Milwaukee, Wisconsin), which pro-

vided air instead of oxygen, at a much higher high flow and therefore significantly reduced cycle time. Power failures and voltage fluctuations from 170 to 260 V were introduced into the electrical supply to the air compressor by a computer-controlled electrical relay.

Pressure in the oxygen reservoir was monitored using a pressure sensor (MPX4250, Freescale, Austin, Texas), and the oxygen flows from the concentrator, into and out of the low-pressure oxygen storage store, and to the patient were monitored using flow meters (SFM3000, Sensirion, Staefa, Switzerland). Oxygen concentration was monitored with an oxygen analyzer (JAY-120, Longfian Scitech, Baoding, China). Each of these sensors was calibrated against laboratory standards. During the tests, the sensors were linked into a daisy chain by an RS-485 bus, which was polled at 1.25 Hz by a specialized data acquisition system, and the data were routinely logged to solid-state drives. The bags were filled at a peak rate of approximately 25 L/min, and a pressure relief valve was used to prevent overpressure. The robustness of the reservoir construction was further tested by inflating at measured increasing pressures until structural failure (ie, rupture of any of the bags).

Field Testing

A duplicate low-pressure oxygen storage system was shipped in July 2016 to the Mbarara Regional Referral Hospital (Mbarara, Uganda). The steel frame on which the reservoirs reside was constructed locally in Mbarara. The design for this frame included a platform to accommodate the concentrator, a 10-L/min oxygen concentrator (NewLife Elite, AirSep Corp.), and the FREQ₂ PROTECT unit on a shelf between the upper and lower reservoirs.

Figure 1 shows the system in a fully charged state with the lower oxygen reservoir filled with oxygen. Also on the mid-level shelf is a suitcase housing the dedicated data acquisition system described above and an Africell 3G modem data link. In the field system, we also included a battery backup facility for the data acquisition system to allow logging during power interruptions. Every 20 min, the logged data were compressed and transmitted to the Melbourne laboratory for analysis.

Before the long-term test began, the Mbarara system was first submitted to an accelerated testing cycle using a mechanical timer switch (model D810SLIM, HPM Legrand, Prestons, Australia). This was placed between the grid power source and the FREQ₂ PROTECT unit and set to cycles of 60 min of electrical power on and 60 min of electrical power off. The concentrator's flow meter was used to set its production rate to 4.5 L/min, and a volumetric oxygen flow meter at the "patient" end was set to a constant 1.2 L/min (similar to the level required for the treatment of a young child with pneumonia).

A LOW-PRESSURE OXYGEN STORAGE SYSTEM

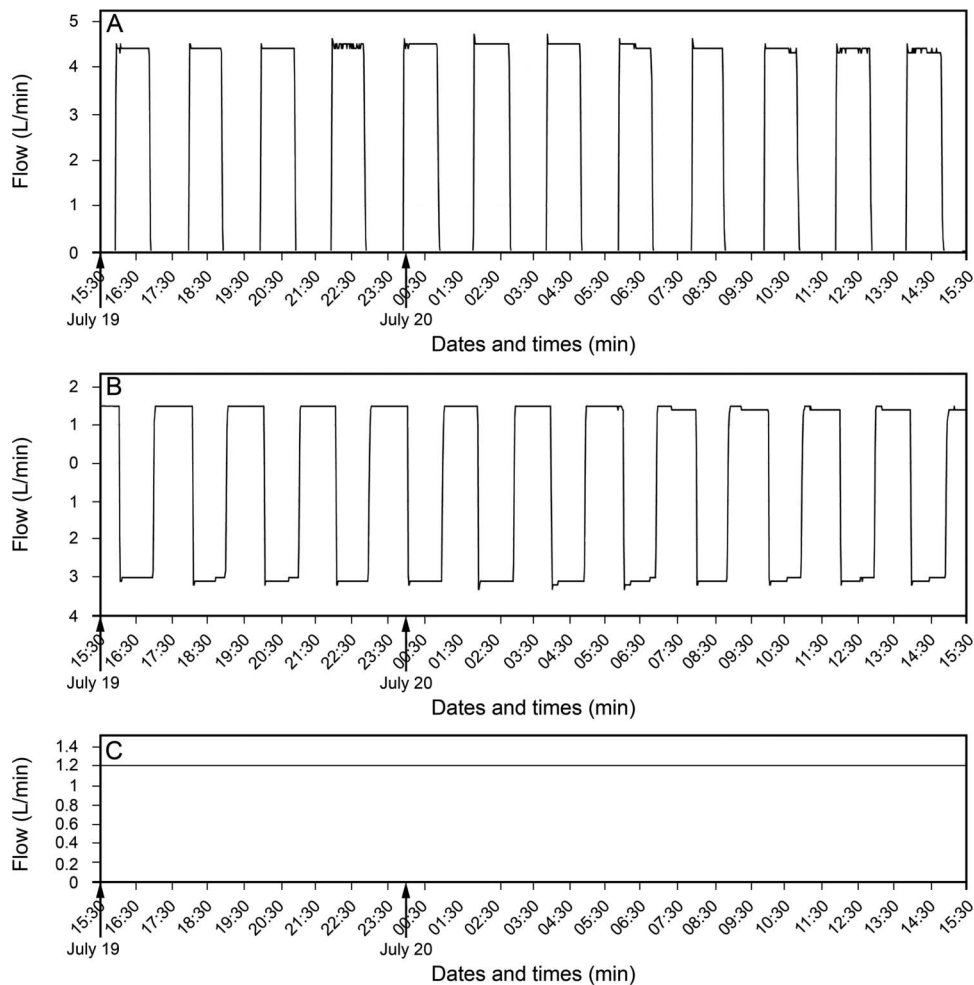


Fig. 2. Plots of oxygen flows in each component of the system during testing. A: Concentrator flow. B: Low-pressure oxygen system store flow. C: Flow to simulated patient.

After completing the accelerated testing, the concentrator was reconnected to grid power through the FREQO₂ PROTECT unit, with the concentrator again set to produce 4.5 L/min and the patient flow set to 1.2 L/min. Because the equipment was at an unproven stage, no oxygen was delivered to patients. Instead, this flow was directed through an additional 10 m of the 12-mm tubing and released to atmosphere. No ethics approval was sought because the study did not involve any human participants.

Results

Bench Testing

In the proof-of-concept testing, the height of the upper reservoir was set to 1.2 m to provide sufficient pressure to overcome the losses of the delivery system and therefore enable automatic constant supply of oxygen to the nasal prongs. Seven hundred forty-eight cycles of filling and

emptying were performed on the test system, simulating approximately 2 y of operation (assuming a setting in which power is interrupted daily). No signs of severe wear or imminent failure were observed in any of the components when inspected after the test was completed. The upper and lower bladders were dismantled and visually inspected for any signs of wear or failure, such as localized thinning or stretching. No such signs were observed. In the pressure test, the bladders sustained a pressure of 247 mm Hg (33 kPa), twice the standard working pressure, before rupture of the outer bag.

Field Testing

Twenty-one 2-h test cycles were performed on the Mbarara test system, beginning at 2:30 PM on July 19, 2016. Figure 2 shows the oxygen flows in the component parts of the system during a representative 24-h period during the test. In each plot, positive values represent flows to-

A LOW-PRESSURE OXYGEN STORAGE SYSTEM

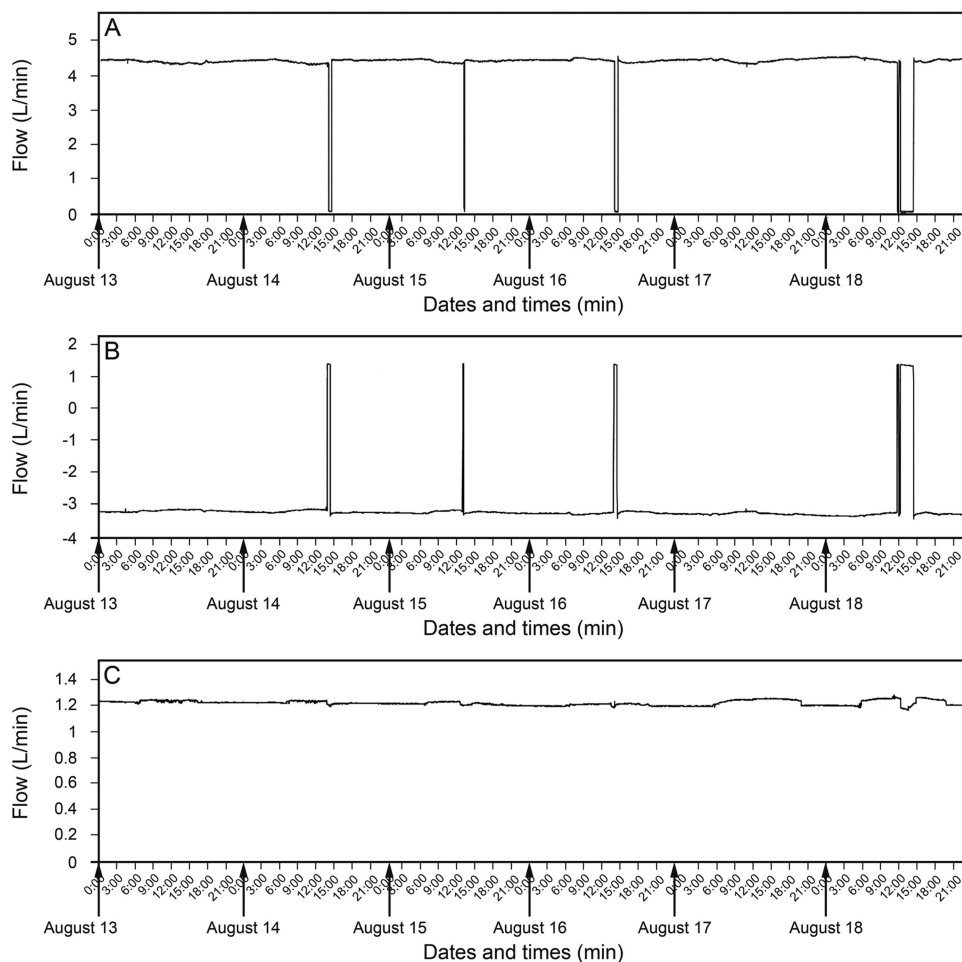


Fig. 3. Illustrative responses to grid power cuts over 5 d. For flows, positive values represent flow toward the simulated patient.

ward the patient. Patient flow was maintained at a constant 1.2 L/min throughout the entire test, regardless of concentrator output.

Testing on grid electricity began at 10:55 AM on August 12, 2016. During the first 30 d of continuous operation, the patient flow continued uninterrupted at an average \pm SD of 1.2 ± 0.02 L/min. Twenty-four power cuts interrupted the concentrator function for ≥ 1 min each, accounting for 2.9% of the total testing time. These cuts had durations between 1 and 176 min, with a mean of 36.2 min and median of 18.5 min. The interval between cuts ranged from 25 min to 4.6 d, with a mean of 1,203 min and median of 829 min, or 20.05 and 13.8 h, respectively. Figure 3 shows flows during a typical 6-d period from the test, showing the effects of three of the power cuts.

Costs

The total bill of materials for the low-pressure oxygen storage system, excluding the concentrator, was less than AUD \$600 (USD \$460). In complete clinical implemen-

tations, there may also be costs for piping oxygen to the specified beds in the ward and for a weather-proof housing for the device outside the ward. We found the power consumption of the concentrator to be very similar across various flows, so that the use of low-pressure oxygen storage system generated minimal extra electricity cost.

Discussion

The prototype low-pressure oxygen storage system performed well in both accelerated fatigue testing and in continuous (nonclinical) operation in a typical African health facility. Despite power interruptions, the flow of oxygen to a simulated patient was maintained without interruption for 30 d. Accelerated fatigue testing equivalent to > 2 y of operation yielded minimal signs of wear and tear. During power outages, the system operates automatically with no need either for another source of electricity or for user intervention. Preliminary testing indicates that the multi-layer bladder system is rugged, long-lasting, and low-cost

and offers the possibility of easy servicing by local technicians.

The low-pressure oxygen storage approach thus seems able to resolve some of the key problems restricting the use of oxygen concentrators in low-resource settings. The 200-L prototype would provide >200 min of supply at a demand of 1 L/min, >67 min at 3 L/min, or >40 min at 5 L/min. (The storage pressure of around 120 mm Hg [16 kPa] means that a 200-L bag contains the equivalent of about 232 L at atmospheric pressure.) The cost of materials for the prototype was less than one third the cost of the concentrator. With a suitable outdoor housing, the cost of a low-pressure oxygen storage system should still be less than the price of a concentrator. Simply increasing the working life of the concentrator could justify the cost, even without the benefit of uninterrupted oxygen supply.

There are other advantages to this approach. Compressing gas is necessarily energy-intensive, and by operating at pressures supplied by oxygen concentrators, low-pressure oxygen storage avoids the capital and maintenance costs associated with oxygen compressors. Second, low-pressure oxygen storage allows filling of a reservoir at any flow; when patient demand is low, the majority of oxygen will be diverted to the reservoir, and when patient demand increases, any excess oxygen is utilized. This improves concentrator utilization, minimizes disruption to workflow, and allows for energy saving by automatic duty-cycling of the concentrator. These features may be particularly relevant to clinics dependent on solar power. At times where the demand is greater than the maximum output of the concentrator, previously stored oxygen from the low-pressure oxygen storage system can be used to supplement the production capacity of the concentrator.

A consequence of this approach is that space requirements grow proportionally with volume. It is therefore anticipated that the low-pressure oxygen storage system will be housed outside the ward, with preliminary measurements indicating a viable oxygen delivery range of > 60 m.

Much work, however, remains to be done. Clinical trials will be needed, to assess the impact on relevant clinical outcomes and estimate the cost-effectiveness of the system. As others have noted with concentrators,^{11,12} Low-pressure oxygen storage will need to be introduced as part of an integrated package including maintenance of the concentrator, introduction and use of pulse oximetry, training of health workers, and resupply of consumables for the concentrator.

The likely lifetime of the system will be a function of the oxygen requirement and the reliability of electricity.

To inform this decision, we have deployed power-loggers in 3 East African countries to monitor the voltage and availability of electricity.

The low-pressure oxygen storage system is now ready for clinical trials. If successful, we believe it raises the possibility of oxygen supply for every health facility that cares for in-patients and has access to some electricity.

ACKNOWLEDGMENTS

We are grateful for the generous support of the Mbarara Regional Referral Hospital, especially the director, Dr Celestine Barigye, and Mr Reuben Mwesigye of the Biomedical Engineering Department.

REFERENCES

1. United Nations. The Millennium Development Goals Report 2015. New York: United Nations; 2015. [http://www.un.org/millenniumgoals/2015_MDG_Report/pdf/MDG%202015%20rev%20\(July%201\).pdf](http://www.un.org/millenniumgoals/2015_MDG_Report/pdf/MDG%202015%20rev%20(July%201).pdf). Accessed June 5, 2017.
2. United Nations Inter-agency Group for Child Mortality Estimation. Levels and trends in child mortality: report 2015. New York: United Nations; 2015. http://www.childmortality.org/files_v20/download/igme%20report%202015%20child%20mortality%20final.pdf. Accessed June 5, 2017.
3. Duke T, Cheema B. Paediatric emergency and acute care in resource poor settings. *J Paediatr Child Health* 2016;52(2):221-226.
4. Duke T, Peel D, Wandt F, Subhi R, Sa'avu M, Matai S. Oxygen supplies for hospitals in Papua New Guinea: a comparison of the feasibility and cost-effectiveness of methods for different settings. *P N G Med J* 2010;53(3):126-138.
5. La Vincente SF, Peel D, Carai S, Weber MW, Enarson P, Maganga V, et al. The functioning of oxygen concentrators in resource-limited settings: a situation assessment in two countries. *Int J Tuberc Lung Dis* 2011;15(5):693-699.
6. Bradley BD, Light JD, Ebonyi AO, N'Jai PC, Ideh RC, Ebruke BE, et al. Implementation and 8-year follow-up of an uninterrupted oxygen supply system in a hospital in The Gambia. *Int J Tuberc Lung Dis* 2016;20(8):1130-1134.
7. Peel D, Neighbour R, Eltringham R. Evaluation of oxygen concentrators for use in countries with limited resources. *Anaesthesia* 2013; 68(7):706-712.
8. Duke T, Mgone J, Frank D. Hypoxaemia in children with severe pneumonia in Papua New Guinea. *Int J Tuberc Lung Dis* 2001;5(6):511-519.
9. Hill SE, Njie O, Sanneh M, Jallow M, Peel D, Njie M, et al. Oxygen for treatment of severe pneumonia in The Gambia, West Africa: a situational analysis. *Int J Tuberc Lung Dis* 2009;13(5):587-593.
10. Sobott B, Black J, Peake D, Rassool R, inventors. FReO₂ Pty Ltd, assignee. Systems and methods for delivering a therapeutic gas. Australian Patent Application 2016903912; 2016.
11. Enarson P, La Vincente S, Gie R, Maganga E, Chokani C. Implementation of an oxygen concentrator system in district hospital paediatric wards throughout Malawi. *Bull World Health Organ* 2008; 86(5):344-348.
12. Perrelet A, Zellweger JP, Talla I, Ndiaye Y, Gautier E, Gehri M. The oxygen concentrator: an appropriate technology for treating hypoxic children in developing countries. *Int J Tuberc Lung Dis* 2004; 8(9):1138-1141.