Oxygen Therapy Pilot Project

Lao PDR, 2011-2012

Bringing affordable and life-saving oxygen to patients in district hospitals

Intermediate Technical Report
February 2012

World Health Organization

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Ministry of Health

The University of Melbourne

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1. Introduction

Globally pneumonia is the leading cause of death in children under 5 years of age, being responsible for at least 19% of all deaths in this age category globally.[1;2] However in many developing countries pneumonia causes far in excess of this, up to 50% in reliable studies.

Hypoxaemia (insufficient oxygen in the blood) is the major fatal complication of pneumonia, and greatly increases the risk of death. It is estimated that at least 13% of children with WHO-defined pneumonia requiring hospitalization have hypoxaemia,[3] but again the prevalence range for hypoxaemia among children admitted to hospitals is broad, with some of the highest prevalence rates reported from Asia.[3] Hypoxaemia is also common in other conditions of childhood, particularly in neonatal illnesses. These conditions include the common causes of neonatal deaths, including lung diseases of prematurity, birth asphyxia and neonatal sepsis.

In adults, many conditions are commonly associated with hypoxaemia, particularly chronic obstructive pulmonary disease, asthma, pneumonia, heart failure, major trauma and obstetric emergencies. All these conditions are commonly seen in district hospitals in developing countries. Despite its importance, hypoxaemia is often not well recognized or managed in settings where resources are limited.

In many countries where fees are charged for drugs and services, hospital utilization is low. The poorest people cannot afford the fees, so do not come to hospital, or if it becomes apparent that their child will require unspecified days of treatment with a certain drug, particularly oxygen, they will request to leave hospital. Despite knowing the risks, families often make a decision to forgo expensive treatment than to risk going further into poverty. This undermines community confidence with hospitals, and is a major impediment to supporting health and equity in their communities.

Effective management of hypoxaemia requires a reliable test for hypoxaemia and a reliable, affordable source of oxygen. Pulse oximetry is an accurate, non-invasive way to detect low oxygen levels in the blood which does not require any blood tests or needles. Oxygen concentrators are small machines that purify atmospheric air to generate 85-95% oxygen, and have been found to be sustainable in low income countries.[4]

1.1 Current situation in Laos

The mortality rate for children under the age of 5 years is 70 per 1000 live births.[5] Neonatal mortality in Laos is estimated to be 28.3 per 1000 live births, which is 40% of child deaths.[5]

The "National Health Statistic Report Fiscal Year 2009-2010", published by the Lao Ministry of Health, provides some estimates about the burden of respiratory diseases in the country.[6] Pneumo-bronchitis was ranked as being the third most frequent cause of hospital admission (6.6%) in Laos. Almost 4,000 times a severe pneumo-bronchitis was recorded as admission diagnosis for inpatients, which is approximately 0.6 admissions per 1,000 population. Most of these patients were children under 5 years resulting in 2.6 admissions per 1,000 population in this age group. In the same report, acute respiratory infection was ranked as the most frequent single cause of death. In total, 199 deaths were recorded, and 115 of theses deaths were in the under 5 years of age.[6]

This data is an underestimation of the real burden of respiratory diseases in Laos as only patients reaching health facilities were included. In Laos severely ill patients are often discharged from hospitals to die among their family either at home or in a Wat (Buddhist temple). These deaths are not recorded at the health facilities and do not appear in these hospital-based statistics.

Additional data about the burden of respiratory diseases and hypoxaemia was collected retrospectively from 2007-09 from medical records of three hospitals and prospectively in a survey of 5 hospitals. Results of the first study showed that almost 60% of respiratory diseases were found in children under 5-years of age.[7]

Before 2010, few hospitals had pulse oximetry, which was only available in some central and provincial hospitals, mostly in surgical operating theatres. Few general wards or children's wards had pulse oximetry and there were no guidelines on its use. In 2010, in response to the Pandemic H1N1 outbreak, pulse oximeters were distributed in all Lao hospitals (including two pulse oximeters for each district hospital).

Currently, most oxygen in Laos is provided by 7,000 L cylinders, which cost between 50,000 and 260,000 Kip (6-31 USD). There are several private manufacturers making oxygen and refilling cylinders. Some are in the main towns near provincial hospitals, but many district hospitals are remote from these. In a situational analysis doctors from district hospitals spoke of the difficulties of getting oxygen, and the high costs and logistics of transport.

Most hospitals in Laos pass on the costs of oxygen to patients or their families, the cost being between 50,000 Kip and 400,000 Kip per day, with the typical cost of 85,000 Kip per day (10.5 USD). Some hospitals charge by the hour if oxygen is only given for a short term, between 10,000 and 30,000 Kip per hour was the typical cost to patients. It has also been reported that many families cannot afford to pay the high costs, and many children and newborns are discharged early before an effective course of treatment can be given. In some cases, and only when patients have a certificate from their village head stating that they are poor, the hospital would cover the costs.

As in other countries with limited resources, the lack of live-saving appropriate oxygen therapy has been identified as a major health concern in Laos, where oxygen therapy is mainly available to patients in central and provincial hospitals.

1.2 Improved oxygen systems

There is strong evidence from district and provincial hospitals from other countries in the region that the systematic use of pulse oximetry for screening and monitoring for hypoxaemia and the availability of reliable oxygen sources can reduce death rates from pneumonia by up to 35%.[8]

Pulse oximeters measure the heart rate and the oxygen saturation in the blood. Using pulse oximeters has been found to correctly identify 20–30% more children with hypoxaemia than using clinical signs alone.[9-12]

Oxygen concentrators are an alternative and cheap way of delivering oxygen. Concentrators draw in atmospheric air and remove nitrogen, leaving 85-95% oxygen. They produce 5-10 L per minute depending on the model, and cost 570 USD for a

high quality 5 L per minute model which has been developed for tropical climates. With a 5 L per minute concentrator oxygen can be given to 1-5 patients at a time, depending on flow rates. Newly developed flow splitters that attach to the oxygen outlet enable flows to be divided and adjusted to the needs of the patients. This is suitable for neonatal care where flows are typically 0.1 to 0.5 L per minute through nasal prongs and for giving oxygen to older infants and children flows of 1-3 L per minute are used. In adults flows of 2-5 L per minute are adequate through nasal prongs.[13]

In recent years, district hospitals in Laos were connected to power supplies. This enables them to use oxygen concentrators that require continuous power.

Estimations for Laos showed that 7,000 L of oxygen would cost 2.39 USD if produced by concentrator compared to 6-30 USD if produced by cylinder. Data from Laos and assumptions based on oxygen therapy projects in other countries were used to do these estimations. For more detail see ANNEX. In Laos using concentrators to produce oxygen would be much cheaper and cost-effective than using cylinders. However, the real point about this oxygen program is NOT the cost saving but the change of mindset for hospital staff who should now freely treat ALL patients with oxygen who are in need of oxygen. There is no longer a need to ration oxygen. The change for the patient should be even greater, from a crippling cost to no cost.

1.3 Requirements for a successful oxygen program

Good clinical practice requires patients with hypoxaemic pneumonia to be quickly and correctly identified, admitted to hospital, given supplemental oxygen and then closely monitored.

Requirements for a successful oxygen program include equipment, personnel, training, maintenance and monitoring. This requires input from clinicians, engineers, administrators and trainers; a team of people who can act as a resource for participating hospitals. This has been shown to be feasible and effective in other countries, but requires a systematic and programmatic approach.[14]

Although much more cost-effective than oxygen cylinders, oxygen concentrators have requirements, including a continuous and reliable power supply, clinical staff

trained in their use and everyday maintenance, preventive maintenance, repairs, and a program of monitoring, reinforcement of training and replacement of equipment. If these are not in place then concentrators are not effective.

Unfortunately there are many examples of concentrators being donated in other developing countries without a program in place to ensure they are effective or properly maintained. This can undermine the confidence of health care workers in such technology, and undermine efforts to improve quality of care.

The World Health Organization has produced a manual called "The Clinical Use of Oxygen. Guidelines for health-care workers, hospital engineers and managers".[13] This manual outlines all the steps that need to be taken to develop and manage successful oxygen systems in hospitals with limited resources.

2. Oxygen Therapy Pilot Project

2.1 Initiation of the project

After attending the 2nd meeting of the "Regional Clinical Network on Emerging Infectious Diseases" in Manila, November 2010, members of the Lao Clinicians' Working Group became very interested in having an oxygen programme in Laos. During the meeting Prof. Trevor Duke had presented a report about a successful oxygen programme in Papua New Guinea.

The Lao Ministry of Health has requested the assistance of the World Health Organization (WHO) and the Centre for International Child Health (CICH, University of Melbourne, Australia) to trial an improved system of oxygen therapy in district hospitals in the country.

In February 2011, a one-week exploratory visit to Laos was conducted by the international consultants Prof. Trevor Duke, Dr. David Peel and Dr. Amy Gray. Consultation meetings with partners from the Lao Ministry of Health (incl. Vice Minister Dr. Bounkong Syhavong, Vice Director of the Health Care Department Dr. Chanphomma Vongsamphanh and Director of the Medical Products Supply Center Dr. Thanom Insal), clinicians from Mahosoth Hospital, WHO Country Office and the international consultants took place. The outline of the project and many other topics were discussed with all partners. The discussed ideas and the suggested involvement and responsibility of the different national partners in this project were included.

The team visited two hospitals in Savannakhet Province to better understand the situation in district and provincial hospitals in the country.

Finally, a workshop was held for staff from the Health Care Department of the MoH, central hospital clinicians and representatives and residents from each initially proposed district hospital to officially launch the project. There was widespread support for the project, universal recognition of the need, and agreement about the method of implementation and evaluation. It was agreed that one single model of oxygen concentrator should be used throughout the country to simplify maintenance requirements and stocking of spare parts.

2.2 Project aims and outline

The project aims to improve the quality of care for common illnesses associated with low oxygen levels, and reduce costs of hospitalisation through implementation of an improved and lower cost oxygen system in district hospitals in Laos, which will be free of charge to patients. Additionally, it will support the government of Laos in reaching the Millennium Development Goal 4 "Reduce by two thirds the mortality rate among children under five**".**

The project consists of these three main components:

1. Implementation of an improved oxygen system in 10 selected district hospitals in five provinces of Laos. The "oxygen system" includes supplying and installing oxygen concentrators and pulse oximeters with technical training in the use and maintenance of oxygen concentrators and the clinical use of oxygen based on signs of respiratory illness and hypoxaemia.
2. Building of local capacity in both clinical training and use of oxygen and biomedical engineering. This will occur though engagement of Lao clinicians from central, provincial and district hospitals and biomedical engineers from the Medical Products Supply Centre (MPSC) of the Ministry of Health in both the delivery and evaluation of the project. It includes the development of clinical and technical guidelines and training on the use of oxygen. This capacity will be crucial for future sustainability of the project and for expansion to other district hospitals in the future if the pilot project is successful.
3. Evaluation of the pilot trial in order to understand the feasibility and sustainability of this approach in Laos, as well as the effect on patient outcomes and cost of care.

This project will integrate with other programs to improve quality of care, including the introduction of the Lao Pocketbook of Hospital Care for Children. At some stage in the 2 year duration of the project, each hospital involved in this project (both intervention and control) will receive training on the use of the Pocketbook, a set of adapted WHO evidence-based guidelines that are being introduced by the Lao Ministry of Health. This project on oxygen systems is an appropriate technology

component of improving quality of care, and also tests whether making a commonly used expensive intervention affordable in a poor population will result in increased hospital utilization (increased access, care seeking and increased rates of treatment completion for serious illness).

Hospital utilization will be measured as the number of admissions for pneumonia, bronchiolitis, asthma and newborn conditions. This variable, like hospital length of stay is subject to confounding effects, disease outbreaks and secular trends. However, having contemporaneous control hospitals will reduce the problems of confounding and assist in determining if improving oxygen systems increases community demand and care seeking.

2.3 Involved partners

A Lao "National Oxygen Team" is responsible for the project. Members of this team include Ministry of Health administrators, senior clinicians, and biomedical engineers:

- Health Care Department, Ministry of Health: Dr. Manivanh Savatdy, Dr. Vanseng Sikhotchounlamaly, Dr. Chanphomma Vongsamphanh
- National clinicians: Dr. Kongkham Sisouk, Dr. Khamsay Detleuxay, Dr. Bouasengniyom Prasitthideth (Mahosoth Hospital)
- Medical Products Supply Center: Mr. Khamkhoun Bouppha, Mr. Khamtick Phanthalamixay, Mr. Thang Dylaphan, Mr. Sengdao Inthapatha, Dr. Thanom Insal

The National Oxygen Team is supported by provincial and district health staff, particularly the network of paediatricians, and by an international team from WHO and the Centre for International Child Health (CICH):

- WHO Country Office Lao PDR: Dr. Christian Winter, Dr. Sonesavanh Phimmasine, Dr. Reiko Tsuyuoka, administrative support team
- Centre for International Child Health: Prof. Trevor Duke, Dr. Amy Gray, Dr. Margie Fulton (University of Melbourne, Australia), Dr. David Peel (Ashdown Consultants, East Sussex, UK)

2.4 Selection of intervention and control hospitals

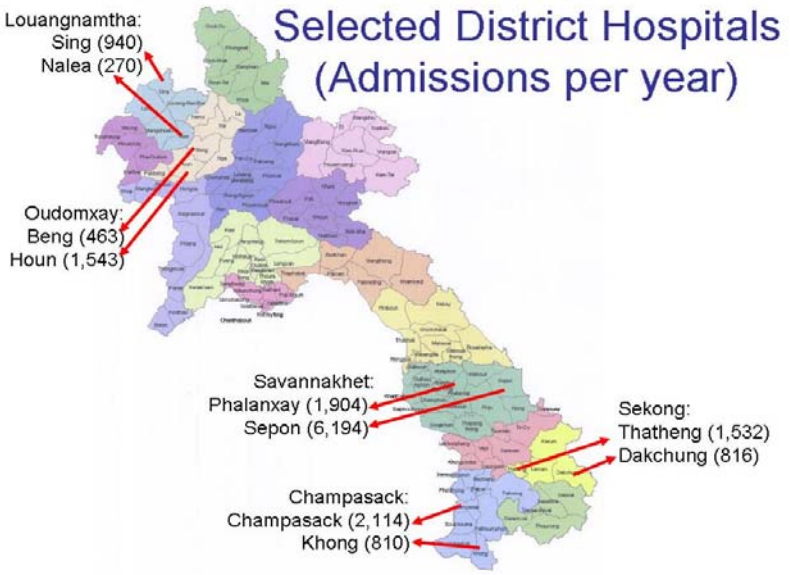
After initial discussion between the Ministry of Health and the international partners, it was decided to include 20 district hospitals (10 intervention and 10 control hospitals) from 5 selected provinces (Savannakhet, Sekong, Champasack, Oudomxay and Luang Namtha) in the project. Representatives from each of these provinces agreed to participate in the project and the evaluation design at a meeting in Vientiane Capital in February 2011.

The selection criteria for the 10 intervention hospitals, proposed by the National Oxygen Team and the provincial and district health staff, were hospitals that:

- Had no or poor oxygen supplies / difficulty getting oxygen
- Had a high number of admissions for respiratory disease
- Are in remote areas where the poorest people in Laos live

These following 10 intervention hospitals were selected to receive the "oxygen system":

- Sing and Nalea District Hospitals, Luang Namtha Province
- Houn and Beng District Hospitals, Oudomxay Province
- Thatheng and Dakchung District Hospitals, Sekong Province
- Phalanxay and Sepon District Hospitals, Savannakhet Province
- Champasack District and Khong District Hospitals, Champasack Province



The following 10 control hospitals were selected:

- Long and Viengphokham, Luang Namtha Province
- Pakbang and La, Oudomxay Province
- Atsaphanthong, Pin and Champhone, Savannakhet Province
- Sekong Provincial Hospital, Sekong Province
- Soukhouma and Mounlapamok, Champasack Province

If the pilot is successful, control hospitals will be prioritized when the project is expanded to other district hospitals. The project recognizes the breadth of problems that exist in district hospitals and believes that oxygen systems are only one part of a range of activities necessary to improve care in this setting. Therefore, both intervention and control hospitals will receive training in the use of the WHO Pocketbook of Hospital Care for children which is currently being implemented in Laos and provides guidelines for managing common childhood illnesses. It is also acknowledged that participation in this project may raise awareness and concerns about some of the current clinical practices. Providing the WHO Pocketbook training is seen as one way to provide needed clinical support and resources that may address some of these concerns in the control hospitals in the absence of the oxygen-specific intervention.

3. Preparations

3.1 Equipment

3.1.1 Equipment procurement

In summary, the following equipment was procured:

- 40 oxygen concentrator Airsep Visionaire
- 20 flow splitter Sureflow
- 10 pulse oximeters Bitmos SAT 805
- 120 SpO2 Sensors for neonates, children and adults
- 1 SpO2 performance analyzer Lightman and adaptors
- More than 4,000 pieces of tubing, nasal prongs, connectors, fire valves, surge protectors and pipe clips.

3.1.2 Choice of equipment

Oxygen concentrator

The Visionaire oxygen concentrator from Airsep is a new concentrator, introduced in the USA 2 years ago. It was chosen because it has several unique features which were considered to be appropriate for Laos. Unlike all other concentrators, it has no filter so that regular washing and replacement of a filter is not needed. It also has a 5 year guarantee for free replacement of parts and a comprehensive set of spare parts was stored at the MPSC in Vientiane Capital. In addition, there is a mechanism which prevents excess flow being delivered by the concentrator. This feature is an important method of avoiding damage to the concentrator.

The concentrator is specified to deliver 5 L per minute of oxygen in the concentration range 87 to 95% at 21°C degrees and will operate at temperatures between 5°C and 35°C degrees with relative humidity up to 95%.

Sureflow (flow splitter)

This device, made only by Airsep, splits the flow of 5L per min oxygen into five separately controlled streams in the range of 0 to 2 L per min. It is particularly useful for accurately controlling low flows to newborns and infants in the range of 0.1 to 0.5 L per min. The total flow of 5 L per min may be shared between 5 outlets. There is however the possibility of coupling 2 concentrators to 1 Sureflow if needed so that 5 patients could all have 2 L per min.

Pulse oximeter

A mains powered, table-top oximeter was chosen from a major German manufacturer (Bitmos). It is fitted with patented Masimo software which rejects signals caused by movement and therefore makes this oximeter particularly useful with newborns and infants who are a critical group of patients. The effectiveness of this software was clearly demonstrated during treatment of several patients in different hospitals during the project implementation.

Nasal prongs

The manufacturers of nasal prongs all mark these devices for single use only. At a cost of 4 USD each this unjustifiable specification would make the use of nasal prongs uneconomic in Laos. With the aid of the WHO consultant on Infection Control Mrs. Astrid Chojnacki a washing, disinfecting and drying procedure was defined which will allow the re-use of nasal prongs. This procedure has been translated into Lao language. One major advantage of using nasal prongs is that humidification is not needed since the prongs carry humid room air into the patient.

Oxygen analyser

This device measures the oxygen concentration produced by the concentrator at different flows. The Hudson oxygen analyser was chosen because it can easily be calibrated on room air to give an accuracy which is adequate for diagnosis of problems with the oxygen concentrator.

Pulse oximeter sensors

Three sensors were provided with each of the Bitmos oximeter, which have no guarantee on their life. Nine more sensors for each oximeter were purchased from a specialist manufacturer (Carril, Spain) who gives a guarantee of 1 year. Three types of Carril sensors were provided to suit patients of different ages: neonates, children and adults. It is confidently expected that this stock of sensors will last at least 5 years.

Lightman oximeter sensor tester

This is a new device which measures the intensity of the light beams in the pulse oximeter sensor. Fading of the lights occurs with age and leads to inaccurate SpO2 values and is a mode of sensor failure which can only be measured with this device. The usefulness of this device in Lao will be decided from the results obtained during the project.

3.1.3 Distribution and transport of procured equipment to district hospitals

The Medical Products Supply Center organized the transport of all the equipment to the 10 intervention hospitals in the week before the installation team (engineers, MoH and Dr. David Peel) began their work.

The quantities of the major items delivered to each hospital were decided on the basis of information provided by the hospitals on the annual total of inpatients:

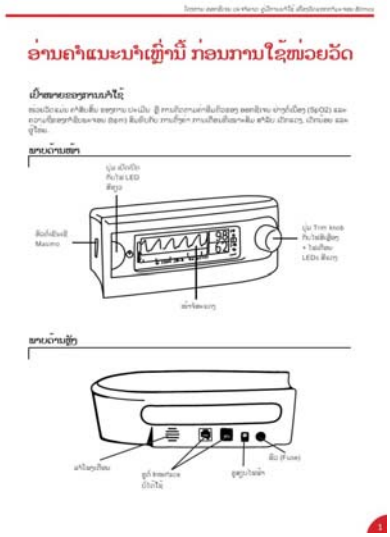
Hospital	Oxygen concentrators	Sureflow with 5 flow meters	Pulse oximeters	Total of Sensors
Phalanxay	4	2	1	12
Sepon	6	3	1	12
Champasack	4	2	1	12
Khong	3	2	1	12
Thatheng	4	2	1	12
Dakchung	4	2	1	12
Beng	4	2	1	12
Houn	4	2	1	12
Nalea	2	1	1	12
Sing	3	2	1	12

Appropriate quantities of all other items such as tubing, connectors and nasal prongs were supplied to each hospital. Two concentrators were delivered to the MPSC for training purposes and as a back-up if a concentrator in one of the participating hospitals needs replacement.

3.2 Development of guidance and training material

It was necessary to use only guidance and training material in Lao language. As part of this project and in preparation for the implementation phase, different Lao- and equipment specific guidance and training materials were developed and translated into Lao language between February and September 2011. The recent WHO publication "The Clinical Use of Oxygen: Guidelines for health-care workers, hospital engineers and managers." was translated into Lao language (1st photo below). This comprehensive guideline provides guidance for clinicians as well as biomedical engineers. A DVD was produced with the five parts on oxygen therapy of the WHO DVD for pediatric care dubbed into Lao language, so that it could be used for the

clinical trainings (2nd photo below). A simple manual for the pulse oximeter Bitmos SAT 805 (3rd photo below) was written during the project and translated into Lao language. Different laminated one-page documents were produced in Lao language to support the correct use of the oxygen equipment. Lao-specific training materials for the clinical and the engineering training workshops have been developed too.



4. Implementation

The implementation of oxygen systems included visiting all 10 intervention hospitals by the installation team (1 week per hospital) to check all equipment and install the oxygen system with training on its use (Sept. - Nov. 2011).

4.1. Installation

4.1.1 Summary of activities

At each intervention hospital, the following activities were done by the installation team:

- Looked at existing locations and planned the route for the piping
- Unpacked and checked the performance of the equipment
- Installed all equipment and tubing
- Checked concentrations and gas flows at all outlets
- Trained medical staff on usage of equipment
- Tested gas flow to patients
- Trained medical staff on recording of oxygen concentration for all concentrators

4.1.2 General description of installation

After the installation team (Dr. Manivanh, MPSC and provincial engineers and Dr. David Peel) had a meeting with the hospital management, they asked for the nomination of at least four persons to be responsible for the maintenance, recording and reporting on the use of the equipment in addition to training their colleagues to use the equipment.

Then the team looked at the layout of each hospital and agreed which beds would be provided with a controlled flow of up to 2 L per minute of oxygen. The engineers installed electrical sockets where needed and proceeded to install the Sureflow which distributes and controls the flow from one concentrator to 5 outlets.

At least one concentrator was not connected to fixed tubing or the Sureflow multi-flow meter so that it could remain portable, and be used to deliver up to 5 L per minute of oxygen to any patient at any location in the hospital.

Once the installation was complete the team tested the concentration and flow of oxygen delivered at each bed in the presence of the responsible persons from the hospital. A training session was then held at which the operation and use of the concentrators and pulse oximeter were explained to the responsible persons and other hospital staff. A demonstration of the effectiveness of the fire-breaks installed in the oxygen system was given at each hospital.


4.1.3 Technical training

Training sessions were conducted for engineers and technicians at central, provincial and district levels during the implementation phase. There were three aspects of training for this project, (1) training of engineers for installation and service of the equipment, (2) training of users and responsible persons in the hospitals and (3) training of responsible persons at a final course in Vientiane.



The engineers nominated by MPSC, Mr Khamkhoun Bouppha and Mr Thaeng quickly demonstrated their ability to install the oxygen tubing. They have been instructed

about how to test sensors. They have been shown how to change a compressor and sieve beds on the concentrator and the AirSep service manual clearly explains the other procedures to change failed components which are in fact unlikely to occur. Provincial engineers from Savannakhet, Champasack, Sekong, Oudomxay and Luang Namtha also participated effectively in the installation process. Very few hospitals had a resident engineer but where available, as in Nalea, they also assisted with the installation. The installation visits put emphasis on the training of users with several sessions in each hospital.

After close supervision provided by Dr. Peel, the installation work was successfully conducted by Mr Khamkhoun Bouppha and Dr Manivanh in two intervention hospitals in Sekong province.

4.1.4 Maintenance and repair workshop in Vientiane Capital

The 4-day training course in Vientiane went into much more detail than had been possible in half a day at the hospitals. Participants included district medical staff, two engineers from each province and the engineers from MPSC. The course was followed by a written examination on the theory of the equipment and fault diagnosis with possible actions to be taken locally. At the end of the course a concentrator with a faulty cooling fan was repaired by Mr. Khamkhoun Bouppha and Mr. Khamtick Phanthalamixay under the supervision of Dr. Peel using the free spare part provided by AirSep.

4.2 Clinical training

For this project a very interactive and hands-on training was developed by Dr. Kongkham Sisouk, Dr. Khamsay Detleuxay, and Dr. Bouasengniyom Prasitthideth from Mahosoth Hospital and Dr. Amy Gray, who all had gained extensive experience during the provision of the WHO Pocketbook trainings in Laos. Newly developed Lao-specific training materials such as videos, guidelines, lectures, and case-based teaching adapted from the WHO Pocketbook training were used. The practical sessions included using nasal prongs, oxygen masks and catheters with dummies and guided examinations of patients with respiratory diseases.

Altogether, clinical training was provided at each of the 10 intervention hospitals (Oct.-Nov. 2011) and during a 2-day training workshop in Vientiane Capital.

These training sessions included the following items:

- Introductory lecture to oxygen and importance of its appropriate use in reducing mortality
- O2 therapy video in 5 parts with chance to ask questions
    - Oxygen therapy
    - How to give oxygen
    - Delivering oxygen to a child
    - Common problems
    - Delivering oxygen to more than one child
- Practical session: using nasal prongs, O2 masks and catheters
- Use of oximetry
    - Case-based teaching adapted from WHO Pocketbook training
    - Participants should use the O2 therapy guideline to work through the case
    - Practice on ward afterwards
- Discussion time
    - Addressing many questions and clarifications that arise
    - Opportunity for nurses and doctors to ask about misconceptions and out-dated practices.

5. Evaluation

5.1 Organisation of the evaluation

The evaluation is being conducted as collaboration between the Lao Ministry of Health, WHO Country Office Lao PDR, the Centre for International Child Health, Lao clinicians based at Mahosoth Hospital in Vientiane and in provincial and district hospitals in target provinces, and provincial health offices. This collaborative approach is also important for keeping all participating hospitals informed of the evaluation plan and progress, and for providing communication channels for problems that may arise throughout the duration of the project.

Coordination of permissions to undertake the project and evaluation activities is being overseen by the Lao MoH and provincial health offices. In the initiation meetings it was agreed that the CICH is taking primary responsibility for the evaluation design and data handling and analysis. Data from medical records and general hospital data is collected by paediatricians and residents of the Lao paediatric training program who are being trained in data collection by members of the CICH research team and key Lao paediatricians. They have been involved in development and piloting of the data forms in a district hospital in Laos. While collecting this data at baseline they were also responsible for training hospital staff in completion of the prospective data forms for patients receiving oxygen. This data will be collected by local paediatricians at regular intervals throughout the duration of the project.

5.2 Evaluation methods

5.2.1 Study design

The evaluation will be conducted using a before-and-after controlled study design with each province having two intervention hospitals which receive the “oxygen system”. Control hospitals were selected from the same provinces except for Sekong province where a control was chosen from the neighbouring province of Savannakhet. More information is provided in above section "Selection of intervention and control hospitals".

5.2.2 Data collection and outcome measures

The following data is collected in intervention hospitals only:

1. A process evaluation will document the implementation of oxygen concentrators and pulse oximeters in district hospitals in Laos. This includes a description of the method of implementation, training, building of engineering capacity, and other technical aspects of installation. Monitoring of the programmatic and engineering aspects include the keeping of a log book by hospitals as well as regular reporting of concentrator use, functioning and maintenance requirements by hospitals to the National Oxygen Team.

The following data was collected in both intervention and control hospitals at baseline (August –November 2011) and will be collected again one year later:

2. Data on hospital utilization through collection of routine hospital data regarding the number of admissions, burden of diseases and, where this information is available, the number of patients who have received or have been transferred to another hospital to receive oxygen.
3. Prospective data on patients who receive oxygen therapy throughout the duration of the project. This includes their oxygen saturation before and after treatment, the cost of oxygen and hospital treatment and their outcome. This is done using data forms completed by staff at participating hospitals, when patients who have received oxygen are discharged home. The main outcome measures from this data collection will include the total number of patients who receive oxygen therapy and the cost of treatment.
4. Data on oxygen monitoring and clinical outcomes obtained from the medical records. Relatively low case fatality rates are found in district hospitals in Lao PDR. This is partly because families cannot afford the cost of care, so they often choose to leave hospital early, especially if started on oxygen and this (potential) death may not be recorded. Though information on case fatality is recorded, no change in this outcome measure is expected. The clinical outcome data will be collected from hospital medical records using

standardized data forms. The admission book will be used in each hospital to find the last 100 cases of severe/very severe pneumonia and 100 neonatal admissions. Data from medical records will be de-identified.

The main clinical outcome measures will be:

1. Proportion of patients with severe or very severe pneumonia who stay in hospital to complete a course of treatment and are discharged well
2. Proportion of neonates needing oxygen who stay in hospital to complete a course of treatment and are discharged well
3. The proportion of patients monitored with pulse oximetry
4. The proportion of patients with hypoxaemia (SpO_2<90%) who are documented to have received oxygen
5. The proportion of patients with severe or very severe pneumonia who are documented to have received oxygen

5.2.3 Sample size and data management

The sample size calculation for clinical outcome data is based on the estimation that 5% of children with pneumonia are discharged while they are still unwell, or die in hospital, and an expectation that the oxygen intervention might halve this proportion to 2.5%. This estimation compares well to previous data collected in Lao hospitals. In this scenario the necessary sample size is 906 cases in both the intervention and control arms. For other outcome measures, such as the proportion of patients monitored this estimated sample size is likely to be very conservative due to higher prevalence of the measured outcome or larger expected effect size.

Data will be stored securely in EpiData databases, with access only permitted by the Lao oxygen team. Analysis will be done using SPSS software. Tests of proportions will be performed on clinical outcome measures pre- and post-intervention.

6. Ethical considerations

Ethical clearance has been granted by the Human Research Ethics Committee of The University of Melbourne and the Lao National Ethics Committee for Health Research in 2011.

Verbal agreement will be used for obtaining consent from patients for information about the cost of treatment. Only two pieces of information will be required from patients for this purpose (overall treatment cost and oxygen cost). In this situation it was felt that verbal consent following a brief verbal explanation of the purpose of the project from hospital staff is the most appropriate method of obtaining consent from patients. This statement is intended to be brief and covers information that is deemed relevant and appropriate in the Lao context and according to the Lao ethics committee.

7. Project budget

7.1 Overall budget in 2011

In total, approximately 217,000 USD were spent for the pilot project in the first project year 2011. Please find more details in the following table:

Equipment and activities	USD
1. Situation assessment and project launching	7,762
2. Equipment incl. flight charges	83,968
3. International consultants	64,020
4. Development of training and guidance material	5,699
5. Implementation phase (excl. intern. consultants)	47,856
6. Evaluation	7,710
Total	**217,014**

7.2 Equipment and consumables expenses in detail

Almost 40 % of the project costs in 2011 have been related to the expenses of procuring equipment and consumables. In total, the equipment expenses reached 84,000 USD. More details of these costs can be found in the below table:

Equipment and consumables	USD
Oxygen concentrators 5 L/min (n=40)	22,800
Pulse oximeters (n=10)	7,951
Oximetry sensor probes (n=120)	21,488
Oxygen analyser (n=10)	5,558
Flow splitter (n=20)	9,000
SPO2 sensor performance analyzer Lightman + adapter connector (n=1)	6,825
Oxygen supply tubing	555
Prongs	6,460
Other consumables	53
Installation materials	2,679
Flight charge + custom clearance	600
Total	**83,968**

8. Sustainability

In 2010, the Ministry of Health has identified that the lack of affordable live-saving oxygen therapy is a major health concern in Laos. In most hospitals in Laos oxygen is provided via oxygen cylinders resulting in difficult logistics of transport and high costs to the patients in need. This pilot project trials an improved and affordable system of oxygen therapy in 10 district hospitals in the country.

From the beginning it was important that the Lao Ministry of Health took the lead in the project and that all the important decisions were made by the Lao National Oxygen Team supported by the international partners.

Lao clinicians and engineers/technicians from all different levels (central, provincial and district) were closely involved in both the delivery and the evaluation of the project. They received hands-on training in order to build local capacity in both clinical management and use of oxygen and biomedical engineering.

Lao-specific clinical and technical guidelines and training material on the use of oxygen were developed and translated into Lao language. These can be easily reprinted and used in other districts and provinces in the country, which will help facilitating future capacity building in oxygen therapy in Laos.

This project integrates with other programs to improve quality of care, including the introduction of the Lao Pocketbook of Hospital Care for Children. Each hospital involved in this project (both intervention and control) will receive training on the use of the Pocketbook, a set of adapted WHO evidence-based guidelines that are being introduced by the Lao Ministry of Health.

During the pilot project oxygen therapy is provided free of charge to the patients. It was discussed if hospitals could request minimum expenses from the patients or their relatives after the pilot project in order to compensate for ongoing smaller expenses (electricity, replenishment of prongs, maintenance and repair etc.). However, it needs to be clear that such expenses should be affordable to all patients in need and cannot be an income generating practice for the hospitals. This was strongly supported by the Lao Ministry of Health.

In the future, the costs of implementing these appropriate oxygen systems to other district and provincial hospitals will be lower. These lower costs are due to the fact that all the necessary training material has been developed already, the evaluation requirements will be less extensive and only limited involvement of international consultants will be required.

The long-term aim of the project is to build sufficient clinical and engineering capacity in the country so that the installation of oxygen systems can be expanded to additional hospitals in need if funding is available. Therefore, the Lao Ministry of Health in collaboration with WHO will look for additional funding. The Centre for International Child Health and WHO will continue to provide their technical expertise.

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ANNEX

Comparison of the oxygen costs produced by concentrators and by cylinders

The volume of oxygen produced in 1 day by a concentrator is 7,200 L (5 L x 60 min x 24 hours). This is close to the volume of 7,000 L which is the normal volume in a large cylinder. For the purposes of this estimate we shall assume that one, 24 hours concentrator day is equivalent to 1 cylinder, which we call "cylinder equivalent".

CONCENTRATOR COSTS

There are 3 cost elements for concentrators:

a) *Capital cost of the concentrator*

This can be written off over 5 years = 22,800 USD for 40 concentrators. The 38 concentrators at the intervention hospitals could produce as much oxygen as 69,350 cylinders in 5 years (365 days x 5 years x 38 cylinders). However, we know that a concentrator in a hospital runs for between 20 and 40% of the total time. This running time will be measured from the readings on the concentrators. If we estimate 30% then the total number of cylinder equivalents in 5 years would be 20,805 (0.3x 69,350). The average cost per cylinder equivalent is then 1.1 USD (22,800 USD /20,805 cylinder equivalents).

The concentrator is expected to run for more than 5 years and then the cost is only the cost of maintenance.

b) *Cost of electricity*

The power consumption of the Visionaire concentrator is 290 Watts so that in 24 hours it uses 6.96 kWh (24 x 0.29 kWh). We had great difficulty in finding out the cost of electricity in hospitals in Laos and the costs varied from hospital to hospital but were always well below the International cost of about 0.15 USD/kWh. It is safe to say that the cost per 7,000 L cylinder equivalent does not exceed 1.04 USD (6.96 kWh x 0.15 USD).

c) *Cost of maintenance for 5 years*

Spare parts are free for 5 years. However, costs for maintenance visits and transport of equipment from provincial to central level for more difficult repairs are estimated to be approximately 0.25 USD per cylinder equivalent.

d) The total cost per 1 cylinder equivalent during the first 5 years is 2.39 USD (1.1 USD + 1.04 USD + 0.25 USD). Thereafter the cost should reduce to about 1.5 USD.

CYLINDER COSTS

There are typically 4 cost elements for cylinders; a) cost of gas, b) rental cost of the cylinder, c) deposit on the cylinder and d) cost of transport.

a) Cost of gas has been quoted in the range of 6 to 30 USD

b) & c) Rental costs and deposit costs were not investigated during the installation phase but estimates of these costs from PNG were about 8% of the cost of the gas. A similar ratio could be assumed for Laos

d) Transport costs are the big unknown and we have no data on transport costs in Laos but evidence from elsewhere shows that these costs may exceed the cost of the gas.

Because of these unknown costs in b), c) and d) we may simply state that the total cost of oxygen from cylinders will exceed the range of 6 to 30 USD per cylinder and is likely to increase in the long term.