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Improved oxygen systems in district hospitals in Lao PDR: a prospective field trial of the impact on outcomes for childhood pneumonia and equipment sustainability.

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Improved oxygen systems in district hospitals in Lao PDR: a prospective field trial of the impact on outcomes for childhood pneumonia and equipment sustainability.

Authors:
Amy Zigrida Gray (1,2,3)
Melinda Morpeth (1,2)
Trevor Duke (1,2,3)
David Peel (1,7)
Christian Winter (6)
Manivanh Satvady (4)
Kongkham Sisouk (5)
Bouasengnignom Prasithideth (5)
Khamsay Detleuxay (5)

1. Centre for International Child Health, Department of Paediatrics, The University of Melbourne, Australia
2. The Royal Children's Hospital, Melbourne Australia
3. Murdoch Childrens Research Institute, Melbourne, Australia
4. Department of Health Care, Ministry of Health, Lao PDR
5. Mahosot Hospital, Ministry of Health, Lao PDR
6. WHO Country Office Lao PDR
7. Ashdown Consultants, Hartfield, TN7 4ET ,UK.

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Competing interests

There no competing interests to declare.

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Abstract

Background

Hypoxaemia is a common and potentially fatal complication of many childhood, newborn and maternal conditions, but often not well recognized or managed in settings where resources are limited. Oxygen itself, is often inaccessible, due to cost or logistics. This paper describes implementation of oxygen systems in Lao district hospitals, clinical outcomes after 24 months, and equipment outcomes after 40 months post-implementation.

Methods

A prospective field trial was conducted in 20 district hospitals, including 10 intervention hospitals which received oxygen concentrators and 10 control hospitals. Equipment outcomes were evaluated at baseline, 12, 24 and 40 months. Clinical outcomes of children under five years of age with pneumonia were evaluated using a before-and-after controlled study design with information retrospectively collected from medical records.

Results

Fourteen (37%), seven (18%) and 12 (34%) of 38 concentrators required repair at 12, 24 and 40 months respectively. The proportion of children discharged well increased in intervention (641/712, 90% to 658/691, 95.2%) and control hospitals (621/713 87.1% to 588/606 92.1%). In intervention hospitals, case fatality rates for childhood pneumonia fell by two thirds, from 2.7% (95%CI 1.48-3.84) to 0.80 (95%CI 0.17-1.54) post-intervention, with no change in control hospitals (1.7% (95%CI 0.73-2.62), and 2.3%, (95%CI 1.04-3.3)).

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Conclusion

Medium term sustainability of oxygen concentrators in hospitals accompanied by improved outcomes for childhood pneumonia has been demonstrated in Lao PDR. Significant local engineering capacity to address multiple causes of equipment malfunction was critical. The ongoing requirements and fragile structures within the health system remain major risks to long-term sustainability.

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What is known about the subject

- Hypoxaemia is a potentially fatal complication of many common childhood, neonatal and adult health problems.
- Hypoxaemia is often not well recognised or treated in the many low-resource settings, and oxygen is often inaccessible.
- Systematic use of pulse oximetry for detecting hypoxaemia and availability of reliable oxygen sources can reduce death rates from pneumonia in children.

What this study adds

- This study represents one of the most comprehensive evaluations of implementation of oxygen concentrator systems in district hospitals to date.
- It demonstrates improved outcomes for childhood pneumonia in hospitals which received oxygen concentrator systems which included equipment, engineering and clinical training.
- It also demonstrates the potential maintenance and engineering burden of concentrators on already fragile health systems.

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Introduction

Hypoxaemia, or insufficient oxygen levels in the blood, is a potentially fatal complication of many common causes of mortality in children, newborns and adults.(1) It is estimated that at least 13% of children with WHO-defined pneumonia requiring hospitalization have hypoxaemia, with wide geographical variation. (2, 3) Despite its importance, hypoxaemia is often not well recognized or managed in settings where resources are limited. (4, 5) Evidence from previous studies suggests systematic use of pulse oximetry for detecting hypoxaemia and availability of reliable oxygen sources can reduce death rates from pneumonia in children by up to 35%. (6)

In low and middle income countries oxygen can represent a significant hospital expense. In countries with a user-pays health system oxygen may be available, but the cost to the patient can limit use or precipitate early discharge. High costs of oxygen partly reflect logistical difficulties in transporting oxygen which also lead to intermittent availability of oxygen cylinders. High costs to patients and lack of access to oxygen potentially undermine community confidence in hospitals, and are a major impediment to universal access to health care.

Oxygen concentrators – small machines that remove nitrogen from atmospheric air to generate 85 to 95% oxygen - are one potential solution. (7) They have been found to be feasible for delivery of oxygen in low income countries, although there is variability in performance.(8-10) For concentrator systems to be sustainable they require a continuous and reliable power supply, a system for monitoring, maintenance and repair, as well as clinical staff trained in their use. (7)

The Lao Oxygen Therapy Pilot Project was established in recognition of the complex issues, and multiple barriers, relating to oxygen supply in Lao PDR. The aims of the

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project were to implement an affordable oxygen system in district hospitals and to evaluate its feasibility, sustainability and impact on patient care and outcomes. This paper describes the implementation approach, clinical outcomes at 24 months, and equipment outcomes at 40 months post-implementation

Methods

Hospital selection

Intervention hospitals were selected based on criteria including availability of reliable electricity, absent or limited oxygen supply, remote geographical location and anticipated admission numbers. Two Northern and three Southern provinces were included for different climates and disease patterns. Randomisation was not feasible given the selection criteria however control hospitals were recruited and selected from the same provinces based on similarity to intervention hospitals. One provincial hospital was included as a control as it was equivalent to the larger district hospitals.

Implementation of oxygen systems

The Project consisted of four phases; a situational assessment, establishment of the oxygen team and partners, systematic implementation of the oxygen systems, and evaluation of clinical use of oxygen, equipment use and maintenance requirements, clinical outcomes and patient costs. (Figure 1) The Lao Oxygen team included staff from the Lao Ministry of Health, local adult and paediatric intensive care physicians, provincial paediatricians, international paediatricians, an international biomedical engineer, and staff from the Lao Country Office of the World Health Organization (WHO). An agreement was made that oxygen delivered from project concentrators would be free to patients, removing any financial impediments to access.

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Implementation of oxygen systems in selected hospitals occurred from September to November 2011. All ten intervention hospitals were visited by the installation team to check existing resources, install the oxygen system and provide biomedical engineering training on its use and maintenance. This was followed closely by the clinical training team, consisting of clinicians from the Lao Oxygen team.

Lao-specific training materials including videos, guidelines, and case-based teaching materials were used by the clinical training team. On completion of training each participant underwent an observational assessment based on recognition and treatment of hypoxia, as well as oximeter use. Control hospitals were given pulse oximeters but did not receive any training on their use.

Equipment

The Visionaire oxygen concentrator (Airsep Corporation, Buffalo, New York, USA) was chosen because of several unique features which were considered to be appropriate for Laos. (7) Unlike other concentrators the Visionaire has no external filter which typically require regular maintenance and replacement. Removing this maintenance step was felt to be advantageous. The concentrator was specified to deliver 5 L per minute of oxygen in the concentration range 82% to 95% at 21°C degrees and operate at temperatures between 5°C and 35°C degrees with relative humidity up to 95%. Oxygen analysers (Hudson RCI, http://hudsonrci.com/) were provided to monitor the performance of concentrators.

A mains-powered, table-top oximeter was chosen from a major German manufacturer (Bitmos). It was selected to minimise risk of equipment loss and because the software rejects movement signals facilitating accurate use in children.

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Oximeter sensors with a guaranteed life of 1 year were sourced from Carril Instruments, Barcelona.

Evaluation design

A prospective field trial was conducted in 20 district, including 10 intervention hospitals which received oxygen concentrator systems and 10 control hospitals. This included a before-and-after controlled study of the outcomes of children less than five years of age with an admission diagnosis of pneumonia.

Equipment outcomes

Prospective evaluation of equipment outcomes was undertaken with data drawn from a number of sources including the field notes from meetings and the installation of oxygen systems, hospital reports and site visits to both control and intervention hospitals at baseline, 3, 12 and 24 months. Hospital equipment checklists and surveys were completed at both intervention and control hospitals at each visit. Data collected at these times included routine hospital admission data, hours of oxygen use as read from the concentrator display, and the availability and function of equipment. An additional visit to intervention hospitals was conducted 40 months after implementation, more than one year after the formal project ended, to understand the sustainability beyond the project timeframe.

Clinical outcomes

Clinical data were collected in both intervention and control hospitals before and after the implementation. Admission books were retrospectively reviewed at each hospital pre-intervention (2011) and post-intervention (2014), to identify children under five years of age who were admitted with pneumonia or a lower respiratory tract infection. Data was collected by a paediatric resident or paediatrician familiar with WHO-

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classification of pneumonia and trained to identify signs or symptoms of pneumonia from records. Patients with diagnoses of “pneumonia”, “cough”, “respiratory distress”, “bronchitis”, “respiratory infection” and “bronchiolitis” were included in the initial identification of patients, but excluded later if 1) the medical record had been lost or 2) the clinical description in the medical record was inconsistent with the WHO-defined pneumonia.

Pre-intervention we aimed to identify 100 cases of pneumonia/lower respiratory tract infection from each hospital. If 100 cases were not found, data collection continued back to a maximum of five years (2007). Post-intervention data were collected for cases admitted between January 2012 and December 2013.

A standardized data abstraction form was used to collect patient demographics, diagnosis, pneumonia severity, documentation of SpO_2, oxygen therapy and patient outcome. Clinical signs and severity of pneumonia documented by the admitting doctor were reviewed by data collectors and investigators (MM/AG) and if clinical signs indicated a different severity then pneumonia severity was reclassified based on available data.

The primary outcome measure was the proportion of patients under five years of age with pneumonia who stayed in hospital to complete a course of treatment and were discharged well, with no signs of ongoing illness documented in the medical record. This was based on our hypothesis that improving access to oxygen would facilitate treatment completion and reduce early discharge.

Secondary outcomes included; the proportion of children under five years of age with pneumonia who were discharged unwell with ongoing signs of illness; the proportion

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of children who died; the proportion of children in whom SpO2 and oxygen therapy was documented.

Statistical analysis

The sample size calculation for clinical outcome data was based on estimates from our baseline assessment that 5% of children with pneumonia are discharged while still unwell, or die in hospital, and an expectation that the oxygen intervention might halve this proportion. A sample size of 906 cases was required in both the intervention and control arms. For other outcome measures, such as the proportion of patients monitored, this estimated sample size was likely to be conservative due to higher prevalence of the measured outcome or larger expected effect size.

Data were entered and stored securely in EpiData databases. Analysis was done using SPSS software. Descriptive analysis of quantitative data was performed with categorical variables described in terms of numbers and percentages and numerical variables described according to their median and range. Tests of proportions were performed on categorical variables pre-and post-intervention using chi-square.

Ethics

Ethical clearance was granted by the Lao National Ethics Committee for Health Research and the Human Research Ethics Committee of The University of Melbourne in 2011. Written consent was obtained from each participating hospital.

Results

Equipment outcomes

Control and intervention cohorts had similar bed and staff numbers as well as oxygen costs at baseline, while annual admission numbers varied. (Table 1) The median

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costs of provision of oxygen to a patient was approximately 200,000 Kip (25 USD) per cylinder.

In the first year following installation 37% (14/38) of concentrators experienced a fault, with a higher proportion in Southern compared to Northern provinces. (Table 2) Seven concentrators (18%) needed sieve beds replaced and four concentrators (11%) required a new compressor, with other repairs being relatively minor. Following repair 92% (35/38) of the concentrators were functional. The limiting factor was the quantity of spare parts rather than local engineering capacity. Given the equipment repair requirements at this time a request was made to the manufacturer to replace 10 concentrators with an updated model with improved airflow and compressors and to replenish spare parts. Nine were distributed to hospitals with concentrators requiring major repairs, or those in which problems were anticipated, with one kept in reserve in the central equipment stores.

At 24 months, 18% (7/38) of concentrators required repair including one new model machine, and all but one were repaired. Forty months post-implementation one third of concentrators (12/32) required repair of which 10 (83%) were original machines. (Table 2) It is useful to understand the cumulative failure rate of concentrators over time, however due to concentrators being replaced or removed from operation over time this was difficult. Instead cumulative failure rates can be expressed as a proportion of the number of "concentrator years of operation" (i.e. number of failed concentrators / total number of concentrators in field x number of years). For the original models the proportion of machines failing was 0.37, 0.30 and .28 at 12, 24 and 40 months respectively, compared to 0.11 and 0.14 for new model concentrators at 24 and 40 months respectively.

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Concentrators were used for 13,465 hours and 17,050 hours in the first and second years of the project respectively, with an overall total of around 30,000 hours. Accurate measurement of hours past 24 months was difficult due to movement of equipment between hospitals and concentrators taken out of service.

All oximeters and sensors were functional one year after implementation. After two years, nine of 10 oximeters were functioning and the majority of the sensors, with the exception of one hospital (H2P1). By 40 months 70% of oximeters remained functional, while the proportion of functional sensors varied widely between hospitals, from 100% (H2P3) to none (H1P2).

Clinical outcomes

A total of 2912 standardised data abstraction forms were collected from intervention and control hospitals, of which 2777 remained after excluding children greater than 5 years of age and 2722 after excluding other diagnoses. Table 3 outlines the characteristics of childhood pneumonia cases in the pre- and post-implementation era from control and intervention hospitals. Patient numbers, age, length of stay and pneumonia severity was similar between hospitals. There was variation in the proportion of patients contributed by different study hospitals pre- and post-intervention.

Pre-intervention, between group analysis demonstrated a small difference between control and intervention hospitals in the proportion of patients discharged well, with no difference in the proportion discharged with ongoing signs of illness, or who died in hospital, both overall (Table 4a) and in the most severe pneumonia cases. (Table 4b) Post-intervention the proportion of all pneumonia patients discharged home well improved in both the control and intervention hospitals. In patients with severe or

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very severe pneumonia, the proportional increase in patients discharged well was greater in the intervention compared to control hospital. (Table 4b)

There was a corresponding reduction in the proportion of pneumonia patients discharged home with documented signs of ongoing illness. (Table 4a&b) In the pre-intervention era approximately 70% of these patients had documentation of discharge against medical advice, and this fell to 25% of cases post-intervention accounting for most of change in patient numbers.

In intervention hospitals case fatality rates for all children with pneumonia fell by 70% from 2.7% (95%CI 1.48 to 3.84) pre-intervention to 0.8% (95%CI 0.17-1.54) post-intervention (p=0.01) (Table 4a). There was no significant change in case fatality rates in control hospitals (1.7% (95%CI 0.73-2.62) pre-intervention and 2.3% (95%CI 1.04-3.3) post-intervention (p = 0.41)). The same trends were seen for severe pneumonia (Table 4b).

Improved processes of care were seen in both intervention and control hospitals including increased documentation of SpO2 in medical records, with a larger proportional increase in intervention hospitals. (Figure 2a). In both cohorts SpO2 was more frequently documented in the more severe cases. Less improvement was seen in the proportion of children having oxygen therapy and/or oxygen flow rates documented, with minimal difference between hospitals. (Figure 2b)

Discussion

In 2010, the Lao Ministry of Health identified the lack of affordable oxygen therapy as a major health system challenge and responded with a pilot project to deliver affordable oxygen concentrator systems to district hospitals. The project built upon

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lessons learned in other settings and an increasing knowledge basis of the types of concentrators and equipment that may best suit different environments.(9, 10) There is evidence of its impact on care and outcomes, as well as ongoing challenges.

The project was embedded in the Ministry of Health and implementation decisions were made by a team supported by international partners. Lao clinicians and engineers received hands-on training aimed at building local. The local engineering capacity that was developed and sustained was evident by their ability to address substantial maintenance and repair requirements for concentrators. Despite this, many oxygen concentrators failed, and the impact of the maintenance requirements on feasibility and sustainability of concentrator systems should not be underestimated. Failure rates of the newer model replacement concentrators appeared to be less. Concentrator faults were reported either through the normal health system communication channels or through project evaluation activities. The majority of the equipment issues were only identified through the latter. In the absence of an “oxygen project” there remains a major risk that equipment falters and is abandoned.

Identifying reasons for equipment failure is essential. The high proportion of the original model concentrators requiring repair likely reflects poor suitability to the environmental conditions. The majority of major faults occurred in Southern provinces where temperatures of 40°C degrees are combined with humidity and dust. Laboratory testing of concentrators that occurred after the project began support our observations that the original machines do not function optimally in these conditions. Investigations demonstrated that the AirSep Visionaire was less reliable at high temperature and simultaneous high humidity than the earlier model AirSep

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Elite. (10) This was attributed to an inadequate internal cooling system in the Visionaire which leads to higher running temperatures and in turn failure of the compressor and sieve beds, as we saw in Laos. Despite modifications, the manufacturer no longer recommends the Visionaire for use in tropical conditions.

Environmental conditions will not be the sole explanation for equipment failures. Hospital differences are apparent, even in geographically similar locations. The marked discrepancies in functioning oximeter sensors in some hospitals compared to others, suggests local factors such as attention to maintenance and loss are also important. Further exploration of high and low-performing case examples may provide insight into hospital-level influences on the effectiveness of oxygen concentrator systems and medical equipment in general.

The total of 30,000 hours over the first two years of the project represented only 5% of the potential 665,760 hours the machines were available for use during this time. This in part will be due to relatively low admission numbers of Lao district hospitals. It is may also reflect underuse of oxygen in cases in which it may have been indicated, or equipment downtime from faults.

Despite these problems, this study provides evidence of improved oxygen use and clinical outcomes for children under 5 years of age with pneumonia. Improvements in clinical outcomes were seen in all hospitals. In control hospitals this may reflect increased awareness of the importance of oxygen therapy, access to oximetry to determine completion of treatment, or other secular trends such as improved financial circumstances of the community. Although the numbers are small a significant reduction in pneumonia case fatality was observed in intervention hospitals, while rates in control hospitals demonstrated a non-significant increase -

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suggesting the change is likely to be explained by the oxygen system as seen in previous studies of oxygen implementation.(6) Improvements in documentation of SpO2 and oxygen delivery were also seen with a greater degree of improvement in the intervention group. For pulse oximetry, this may reflect improved availability of oximeters to control hospitals, compared to more intense training in their use at intervention hospitals. Perceived relevance of documenting SpO2 is also likely to be a factor as suggested by higher levels of documentation in more severe cases. Gaps remain between actual and ideal practice. A range of other contextual factors are likely to contribute, including the lack of a specific location on monitoring charts to document oximetry and oxygen, and established hospital practices for patient monitoring which require a broader cultural change.

There are limitations in the study design. The inclusion of a control group of hospitals improves on previous assessments of oxygen systems. However the inability to allocate oxygen systems using an experimental design still limits interpretations of outcomes. Improved clinical outcomes and mortality rates may have been due to confounding factors but we are unaware of other interventions which may have affected hospitals differentially. The accuracy and detail of medical records limited our ability to accurately determine pneumonia severity or patient outcomes in some instances. Medical records represented those we could locate; we cannot be sure how many children were admitted with pneumonia in the 20 hospitals in each of the two time periods. Variation between hospitals is evident and, similar to equipment outcomes, changes in clinical practice may be influenced by hospital characteristics which we were not able to explore in detail. For some hospitals the project provided the first reliable source of hospital oxygen, for others, it only removed the financial barrier.

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Delivery of an affordable, feasible and sustainable oxygen system to prevent hypoxaemia and reduce mortality is a critical intervention in resource-limited settings. It requires a multi-faceted approach including robust oxygen equipment, well supported local clinical and engineering capacity and ongoing support for the clinical use of oxygen. However, oxygen concentrator systems can create significant ongoing maintenance demands which already fragile health systems in low resource settings must be able to support to achieve long term sustainability, unless more robust equipment solutions can be found. There would be clear benefit from a more detailed understanding of contextual factors influencing equipment longevity and clinical outcomes, in order for future oxygen programs to have maximal impact.

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Figure 1: Graphical representation of study design and timepoints

Timepoint	Intervention	Control
Situational assessment	A	
Hospital recruitment (n=20)	B	B
Delivery of intervention and baseline evaluation	C D E F G H	D F G H
12 month post intervention follow up	F G H	F G H
Delivery of updated equipment	I	
24 month post intervention follow up	F G H	F G H
40 month post intervention follow up	G	

Key:

A	Baseline situational assessment of hypoxaemia prevalence, oxygen availability and use in Lao district hospitals (2010-2011)
B	Hospital recruitment. Selection of hospitals to receive the intervention was based on criteria proposed by the oxygen team, provincial and district hospital staff including current availability of a sufficiently reliable electricity supply, current absence or limited oxygen supply or difficulties in oxygen delivery, remote areas with poor populations and anticipated admission numbers with respiratory illness. Control hospitals were selected from the same or neighbouring provinces for comparison.
C	Delivery of oxygen system equipment and engineering training. The installation team delivered hands-on training to local hospital staff on equipment use, maintenance and repair.
D	Delivery of pulse oximeters. A mains-powered, table-top oximeter was delivered to each intervention hospital (Bitmos) Control hospital received hand held oximeters (Lifebox)
E	Clinical training on oxygen use. Clinical training over two-days via interactive workshops to all available hospital staff based on material from the WHO and included video, case-based teaching and practical sessions on hospital wards
F	Evaluation of clinical use of oxygen and costs. Data was collected during site visits and included cost and the availability and function of oxygen equipment. Once installed, hours of oxygen use was read from the concentrator displays.
G	Evaluation of equipment use and maintenance requirements. Data was drawn from a number of sources including installation data, hospital reports, and site visits to complete hospital equipment checklists.

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H	Evaluation of clinical outcomes. Data collected from medical records, using a standardized form, included patient gender and age, diagnosis, pneumonia severity, documentation of SpO2, oxygen therapy and patient outcome. Medical records were identified from admission books based on diagnosis recorded and later excluded if the medical record was lost or the clinical features were not consistent with a diagnosis of pneumonia.
I	Delivery of new oxygen concentrators. In the first year following installation 37% (14/38) of concentrators experienced a fault that required repair or maintenance. Concentrators were replaced with an updated model with improved airflow and compressors

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Table 1 Characteristics of study hospitals in 10 intervention and 10 control hospitals in the Lao Oxygen Project at baseline

	Hospital cohort	
	Control Median (Range)	**Intervention** Median (Range)
Inpatient beds	16 (10-35)	19 (10-30)
Admissions in 2010		
Total	610 (442-4573)	1236 (270-6194)
Adult admissions	383 (350-2042)	1354 (221-3284)
Paediatric admissions	225 (59-2531)	189 (49-2910)
Cost per oxygen cylinder (USD)	23 (14-64)	29 (14-64)
Total staff numbers		
Doctors	2 (1-27)	2 (0-6)
Medical assistants	3 (0-20)	2 (0-20)
Nurses	9 (3-44)	9 (4-24)

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Table 2 Concentrator repair and maintenance at 12, 24 and 40 months post-implementation of oxygen systems in 10 intervention hospitals, and hours of concentrator use in each time interval.

Hospital	Machines supplied, n	Concentrator repair and maintenance needs						
		12 months			24 months		40 months	
		Number needing repair, n(%)	Working after repair n (%)	Machines replaced n(%)	Number needing repair, n(%)	Working after repair n (%)	Number needing repair, n(%)	Working after repair n (%)
Northern provinces								
H1P2	2	1 (50)	2	0	1	2	1	1
H2P2	3	0 (0)	3	2	0	3	0	3
H1P3	4	2 (50)	4	0	1	4	2	2
H2P3	4	1 (25)	4	0	1	3	1	3
Subtotal	13	4 (31)	13 (100)	2 (15)	3 (23)	12 (92)	4 (31)	9 (69)
Southern provinces								
H1P1	4	2 (50)	3	2	1	4	2	2
H2P1	3	1 (33)	3	1	2	3	0	3
H1P4	4	4 (100)	3	2	1	4	2	2
H2P4	6	2 (33)	6	1	0	6	2	6
H1P5	4	1 (25)	3	1	0	4	2	3
H2P5	4	0 (0)	4	0	0	4	0	4
Subtotal	25	10 (40)	22 (88)	7 (28)	4 (16)	25 (100)	8 (32)	20 (80)
Total	**38**	**14 (37)**	**35 (92)**	**9 (24)**	**7 (18)**	**37 (97)**	**12 (32)**	**29 (76)**
Hours of use		13465 (data available from 37/38 machines)			17050 (38/38 machines)		17839 (35/38 machines)	

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Table 3 Admission numbers and characteristics of children under 5 years of age with pneumonia whose medical records were reviewed in pre- and post-implementation of oxygen systems in Lao district hospitals.

	Pre intervention n=1425 (2007-2011)		**Post-intervention** n=1297 (2012-2013)	
	Control	Intervention	Control	Intervention
Patient numbers, n	713	712	606	691
Patient numbers by province n (%)				
Champasack	62 (8.7)	161 (22.6)	83 (13.7)	41 (5.9)
Luang Namtha	146 (20.5)	69 (9.7)	112 (18.5)	78 (11.3)
Oudomxay	170 (23.8)	139 (19.5)	81 (13.4)	211 (30.5)
Savannakhet	235 (33.0)	144 (20.2)	250 (41.3)	216 (31.3)
Sekong	100 (14.0)	199 (27.9)	80 (13.2)	145 (21.0)
Age in months, median (IQR)	12 (6-24)	12 (6-24)	15 (7-24)	12 (7-25)
Length of stay, median (IQR)	2 (2-4)	2 (1-4)	3 (2-4)	2 (1-3)
Pneumonia severity n (%) Non severe pneumonia Severe/very severe pneumonia	 372 (52.2) 341 (47.8)	 412 (57.9) 300 (42.1)	 396 (65.3) 210 (34.7)	 423 (62.2) 261 (37.8)

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Table 4a Recorded outcome of all children under 5 years of age admitted with pneumonia of any severity to study hospitals pre- and post-implementation of oxygen systems.

	Pre-intervention		**Post-intervention**	
Admissions	N		N	
Control	713		606	
Intervention	712		691	
Well at discharge	n (%)	Between group analysis	n (%)	Pre - post comparison
Control	621 (87.1)	P <0.001	588 (92.1)	p=0.003
Intervention	641 (90.0)		658 (95.2)	p<0.001
Died				
Control	12 (1.7)	p=0.20	14 (2.3)	p=0.41
Intervention	19 (2.7)		6 (0.8)	p=0.011
Discharged unwell/with signs of illness				
Control	58 (8.1)	p=0.15	20 (3.3)	p<0.001
Intervention	44 (6.2)		13 (1.9)	p<0.001

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Table 4b Recorded outcome of all children under 5 years of age admitted with severe or very severe pneumonia to study hospitals pre- and post-implementation of oxygen systems.

	Pre-intervention		**Post-intervention**	
Admissions	N		N	
Control	341		210	
Intervention	300		261	
Well at discharge	n (%)	Between group analysis	n (%)	Pre - post comparison
Control	261 (76.5)	p=0.17	179 (85.2)	p=0.013
Intervention	243 (81.0)		244 (93.5)	p=0.28
Died				
Control	12 (3.5)	p=0.097	14 (6.7)	p=0.09
Intervention	19 (6.3)		6 (2.3)	p=0.021
Discharged unwell/with signs of illness				
Control	48 (14.1)	p=0.15	9 (4.3)	p<0.001
Intervention	31 (10.3)		6 (2.3)	p<0.001

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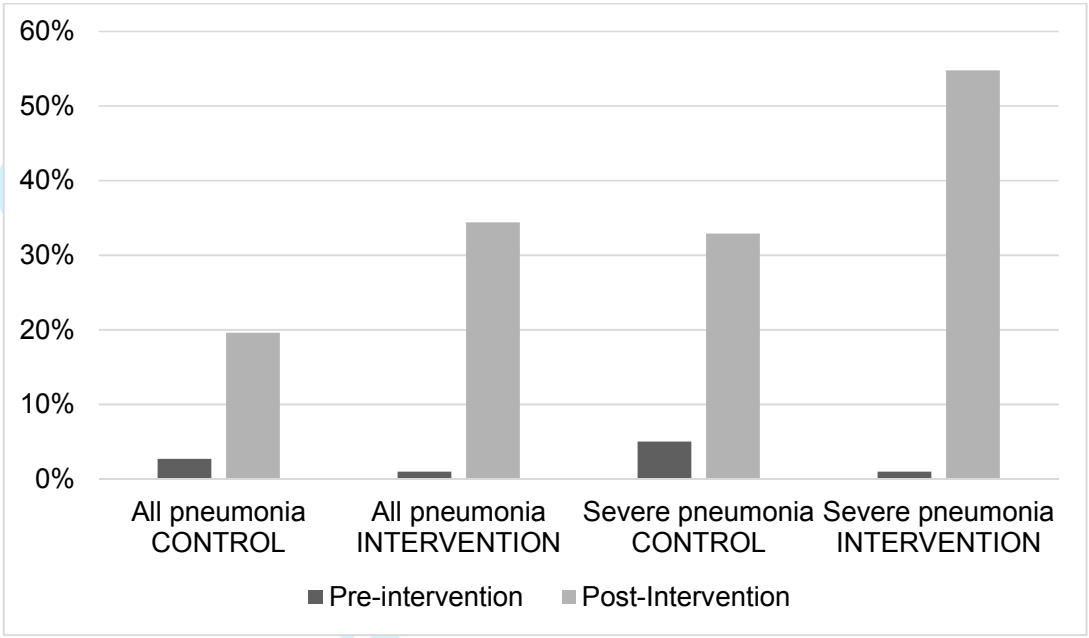

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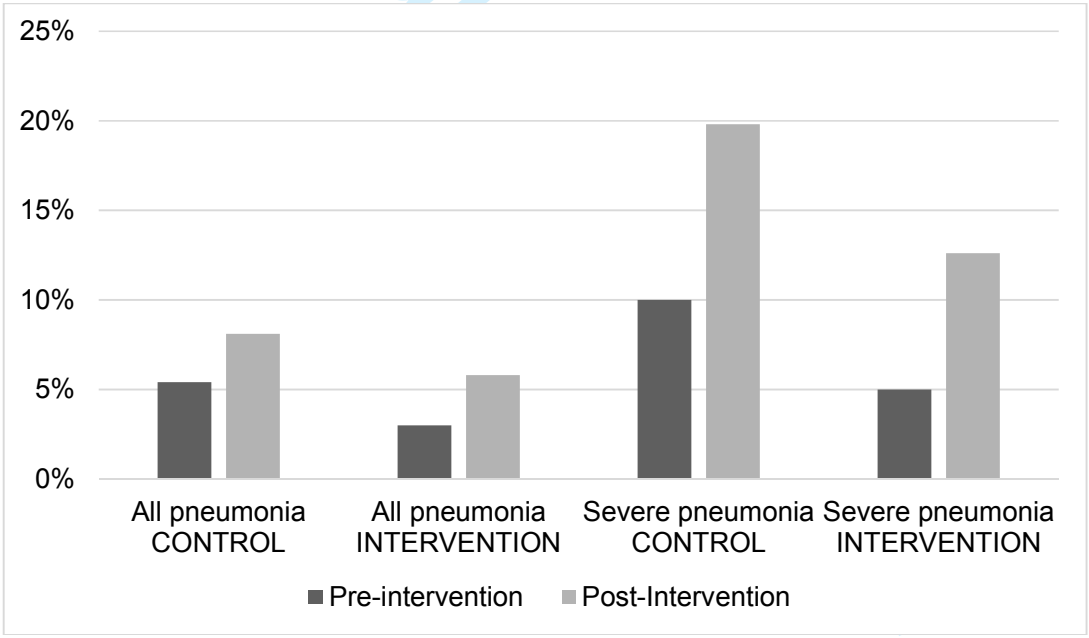

b

Figure 2 Percentage of cases of pneumonia in children less than five years of age in control and intervention hospitals in which a) SpO2 and b) oxygen therapy were documented in the medical records, pre- and post-intervention.

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Author contributions

AG contributed to study design, developed the clinical training materials, assisted with the implementation of oxygen systems, supervised data collection and training of data collectors, analysed the data and was responsible for the first draft of the manuscript.

MM contributed to supervision of data collection in the post-implementation era, entered, cleaned and analysed data and contributed to both the first draft and subsequent revisions of the manuscript.

TD contributed to study design, planning of implementation and contributed to interpretation of results and revision of the manuscript.

DP contributed to study design, provided technical expertise into the engineering aspects of the program, supervised implementation of equipment and contributed to revision of the manuscript.

CW contributed to study design, equipment procurement and implementation of oxygen systems as well as revision of the manuscript.

MS contributed to study design, in particular hospital selection and liaison, implementation of oxygen systems, monitoring of equipment in the field and reviewed the manuscript.

KS contributed to study design, clinical training in oxygen use, data collection from medical records and supervised other data collectors and reviewed the manuscript.

BP contributed to study design, clinical training in oxygen use, data collection from medical records and supervised other data collectors and reviewed the manuscript.

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KD contributed to study design, clinical training in oxygen use and supervision of data collectors and reviewed the manuscript.

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Improved oxygen systems in district hospitals in Lao PDR: a prospective field trial of the impact on outcomes for childhood pneumonia and equipment sustainability.

Authors:
Amy Zigrida Gray (1,2,3)*
Melinda Morpeth (1,2)
Trevor Duke (1,2,3)
David Peel (1,7)
Christian Winter (6)
Manivanh Satvady (4)
Kongkham Sisouk (5)
Bouasengnignom Prasithideth (5)
Khamsay Detleuxay (5)

1. Centre for International Child Health, Department of Paediatrics, The University of Melbourne, Australia
2. The Royal Children's Hospital, Melbourne Australia
3. Murdoch Childrens Research Institute, Melbourne, Australia
4. Department of Health Care, Ministry of Health, Vientiane, Lao PDR
5. Mahosot Hospital, Ministry of Health, Vientiane, Lao PDR
6. WHO Country Office, Vientiane, Lao PDR
7. Ashdown Consultants, Hartfield, TN7 4ET, UK.

* Corresponding author: Department of Paediatrics, The University of Melbourne, Royal Children's Hospital, Flemington Rd, Parkville, Victoria, Australia 3052.
Email: amy.gray@rch.org.au
Phone: +61 (3) 93454647
Fax: +61 (3) 93456667

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Competing interests

There no competing interests to declare.

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Abstract

Background

Hypoxaemia is a common and potentially fatal complication of many childhood, newborn and maternal conditions, but often not well recognized or managed in settings where resources are limited. Oxygen itself is often inaccessible, due to cost or logistics. This paper describes implementation of oxygen systems in Lao district hospitals, clinical outcomes after 24 months, and equipment outcomes after 40 months post-implementation.

Methods

A prospective field trial was conducted in 20 district hospitals, including 10 intervention hospitals which received oxygen concentrators and 10 control hospitals. Equipment outcomes were evaluated at baseline, 12, 24 and 40 months. Clinical outcomes of children under five years of age with pneumonia were evaluated using a before-and-after controlled study design with information retrospectively collected from medical records.

Results

Fourteen (37%), seven (18%) and 12 (34%) of 38 concentrators required repair at 12, 24 and 40 months respectively. The proportion of children discharged well increased in intervention (90% (641/712), to 95.2% (658/691)) and control hospitals (87.1% (621/713) to 92.1% (588/606)). In intervention hospitals, case fatality rates for childhood pneumonia fell from 2.7% (19/712) pre-intervention to 0.80% (6/691) post-intervention with no change in control hospitals (1.7% (12/713) pre-intervention and 2.3% (14/606) post-intervention).

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Conclusion

Medium term sustainability of oxygen concentrators in hospitals accompanied by reduced case fatality for childhood pneumonia has been demonstrated in Lao PDR. Significant local engineering capacity to address multiple causes of equipment malfunction was critical. The ongoing requirements and fragile structures within the health system remain major risks to long-term sustainability.

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What is known about the subject

- Hypoxaemia is a potentially fatal complication of many common childhood, neonatal and adult health problems.
- Hypoxaemia is often not well recognised or treated in many low-resource settings, and oxygen is often inaccessible.
- Systematic use of pulse oximetry for detecting hypoxaemia and availability of reliable oxygen sources can reduce death rates from pneumonia in children.

What this study adds

- Represents one of the most comprehensive evaluations of implementation of oxygen concentrator systems in district hospitals.
- Improved outcomes for childhood pneumonia in hospitals which received oxygen concentrator systems which included equipment, engineering and clinical training.
- The potential maintenance and engineering burden of concentrators on already fragile health systems.

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Introduction

Hypoxaemia, or insufficient oxygen levels in the blood, is a potentially fatal complication of many common causes of mortality in children, newborns and adults.(1) It is estimated that at least 13% of children with WHO-defined pneumonia requiring hospitalization have hypoxaemia, with wide geographical variation. (2, 3) Despite its importance, hypoxaemia is often not well recognized or managed in settings where resources are limited. (4, 5) Evidence from previous studies suggests systematic use of pulse oximetry for detecting hypoxaemia and availability of reliable oxygen sources can reduce death rates from pneumonia in children by up to 35%. (6)

In low and middle income countries oxygen can represent a significant hospital expense. In countries with a user-pays health system oxygen may be available, but the cost to the patient can limit use or precipitate early discharge. High costs of oxygen partly reflect logistical difficulties in transporting oxygen which also lead to intermittent availability of oxygen cylinders. High costs to patients and lack of access to oxygen potentially undermine community confidence in hospitals, and are a major impediment to universal access to health care.

Oxygen concentrators – small machines that remove nitrogen from atmospheric air to generate 85 to 95% oxygen - are one potential solution. (7) They have been found to be feasible for delivery of oxygen in low income countries, although there is variability in performance.(8-10) For concentrator systems to be sustainable they require a continuous and reliable power supply, a system for monitoring, maintenance and repair, as well as clinical staff trained in their use. (7)

The Lao Oxygen Therapy Pilot Project was established in recognition of the complex issues, and multiple barriers, relating to oxygen supply in Lao PDR. The aims of the

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project were to implement an affordable oxygen system in district hospitals and to evaluate its feasibility, sustainability and impact on patient care and outcomes. This paper describes the implementation approach, clinical outcomes at 24 months, and equipment outcomes at 40 months post-implementation

Methods

Hospital selection

Intervention hospitals were selected based on criteria including availability of reliable electricity, absent or limited oxygen supply, remote geographical location and anticipated admission numbers. Two Northern and three Southern provinces were included for different climates and disease patterns. Randomisation was not feasible given the selection criteria however control hospitals were recruited and selected from the same provinces based on similarity to intervention hospitals. One provincial hospital was included as a control as it was equivalent to the larger district hospitals.

Implementation of oxygen systems

The Project consisted of four phases; a situational assessment, establishment of the oxygen team and partners, systematic implementation of the oxygen systems, and evaluation of clinical use of oxygen, equipment use and maintenance requirements, clinical outcomes and patient costs. (Figure 1) The Lao Oxygen team included staff from the Lao Ministry of Health, local adult and paediatric intensive care physicians, provincial paediatricians, international paediatricians, an international biomedical engineer, and staff from the Lao Country Office of the World Health Organization (WHO). An agreement was made that oxygen delivered from project concentrators would be free to patients, removing any financial impediments to access.

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Implementation of oxygen systems in selected hospitals occurred from September to November 2011. All ten intervention hospitals were visited by the installation team to check existing resources, install the oxygen system and provide biomedical engineering training on its use and maintenance. This was followed closely by the clinical training team, consisting of clinicians from the Lao Oxygen team.

Lao-specific training materials including videos, guidelines, and case-based teaching materials were used by the clinical training team. On completion of training each participant underwent an observational assessment based on recognition and treatment of hypoxia, as well as oximeter use. Control hospitals were given pulse oximeters but did not receive any training on their use.

Equipment

The Visionaire oxygen concentrator (Airsep Corporation, Buffalo, New York, USA) was chosen because of several unique features which were considered to be appropriate for Laos. (7) Unlike other concentrators the Visionaire has no external filter which typically require regular maintenance and replacement. Removing this maintenance step was felt to be advantageous. The concentrator was specified to deliver 5 L per minute of oxygen in the concentration range 82% to 95% at 21°C degrees and operate at temperatures between 5°C and 35°C degrees with relative humidity up to 95%. Oxygen analysers (Hudson RCI, http://hudsonrci.com/) were provided to monitor the performance of concentrators.

A mains-powered, table-top oximeter was chosen from a major German manufacturer (Bitmos). It was selected to minimise risk of equipment loss and because the software rejects movement signals facilitating accurate use in children.

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Oximeter sensors with a guaranteed life of 1 year were sourced from Carril Instruments, Barcelona.

Evaluation design

A prospective field trial was conducted in 20 district hospitals, including 10 intervention hospitals which received oxygen concentrator systems and 10 control hospitals. This included a before-and-after controlled study of the outcomes of children less than five years of age with an admission diagnosis of pneumonia.

Equipment outcomes

Prospective evaluation of equipment outcomes was undertaken with data drawn from a number of sources including the field notes from meetings and the installation of oxygen systems, hospital reports and site visits to both control and intervention hospitals at baseline, 3, 12 and 24 months. Hospital equipment checklists and surveys were completed at both intervention and control hospitals at each visit. Data collected at these times included routine hospital admission data, hours of oxygen use as read from the concentrator display, and the availability and function of equipment. An additional visit to intervention hospitals was conducted 40 months after implementation, more than one year after the formal project ended, to understand the sustainability beyond the project timeframe.

Clinical outcomes

Clinical data were collected in both intervention and control hospitals before and after the implementation. Admission books were retrospectively reviewed at each hospital pre-intervention (2011) and post-intervention (2014), to identify children under five years of age who were admitted with pneumonia or a lower respiratory tract infection. Data was collected by a paediatric resident or paediatrician familiar

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with WHO-classification of pneumonia and trained to identify signs or symptoms of pneumonia from records. Patients with diagnoses of “pneumonia”, “cough”, “respiratory distress”, “bronchitis”, “respiratory infection” and “bronchiolitis” were included in the initial identification of patients, but excluded later if 1) the medical record had been lost or 2) the clinical description in the medical record was inconsistent with the WHO-defined pneumonia.

Pre-intervention we aimed to identify 100 cases of pneumonia/lower respiratory tract infection from each hospital. If 100 cases were not found, data collection continued back to a maximum of five years (2007). Post-intervention data were collected for cases admitted between January 2012 and December 2013.

A standardized data abstraction form was used to collect patient demographics, diagnosis, pneumonia severity, documentation of SpO_2, oxygen therapy and patient outcome. Clinical signs and severity of pneumonia documented by the admitting doctor were reviewed by data collectors and investigators (MM/AG) and if clinical signs indicated a different severity then pneumonia severity was reclassified based on available data.

The primary outcome measure was the proportion of patients under five years of age with pneumonia who stayed in hospital to complete a course of treatment and were discharged well, with no signs of ongoing illness documented in the medical record. This was based on our hypothesis that improving access to oxygen would facilitate treatment completion and reduce early discharge.

Secondary outcomes included; the proportion of children under five years of age with pneumonia who were discharged unwell with ongoing signs of illness; the proportion

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of children who died; the proportion of children in whom SpO2 and oxygen therapy was documented.

Statistical analysis

The sample size calculation for clinical outcome data was based on estimates from our baseline assessment that 5% of children with pneumonia are discharged while still unwell, or die in hospital, and an expectation that the oxygen intervention might halve this proportion. A sample size of 906 cases was required in both the intervention and control arms. For other outcome measures, such as the proportion of patients monitored, this estimated sample size was likely to be conservative due to higher prevalence of the measured outcome or larger expected effect size.

Data were entered and stored securely in EpiData databases. Analysis was done using SPSS software. Descriptive analysis of quantitative data was performed with categorical variables described in terms of numbers and percentages and numerical variables described according to their median and range. Tests of proportions were performed on categorical variables pre-and post-intervention using chi-square.

Ethics

Ethical clearance was granted by the Lao National Ethics Committee for Health Research and the Human Research Ethics Committee of The University of Melbourne in 2011. Written consent was obtained from each participating hospital.

Results

Equipment outcomes

Control and intervention cohorts had similar bed and staff numbers as well as oxygen costs at baseline, while annual admission numbers varied. (Table 1) The

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median costs of provision of oxygen to a patient was approximately 200,000 Kip (25 USD) per cylinder.

In the first year following installation 37% (14/38) of concentrators experienced a fault, with a higher proportion in Southern compared to Northern provinces. (Table 2) Seven concentrators (18%) needed sieve beds replaced and four concentrators (11%) required a new compressor, with other repairs being relatively minor. Following repair 92% (35/38) of the concentrators were functional. The limiting factor was the quantity of spare parts rather than local engineering capacity. Given the equipment repair requirements at this time a request was made to the manufacturer to replace 10 concentrators with an updated model with improved airflow and compressors and to replenish spare parts. Nine were distributed to hospitals with concentrators requiring major repairs, or those in which problems were anticipated, with one kept in reserve in the central equipment stores.

At 24 months, 18% (7/38) of concentrators required repair including one new model machine, and all but one were repaired. Forty months post-implementation one third of concentrators (12/32) required repair of which 10 (83%) were original machines. (Table 2) It is useful to understand the cumulative failure rate of concentrators over time, however due to concentrators being replaced or removed from operation over time this was difficult. Instead cumulative failure rates can be expressed as a proportion of the number of “concentrator years of operation” (i.e. number of failed concentrators / total number of concentrators in field x number of years). For the original models the proportion of machines failing was 0.37, 0.30 and .28 at 12, 24 and 40 months respectively, compared to 0.11 and 0.14 for new model concentrators at 24 and 40 months respectively.

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Concentrators were used for 13,465 hours and 17,050 hours in the first and second years of the project respectively, with an overall total of around 30,000 hours. Accurate measurement of hours past 24 months was difficult due to movement of equipment between hospitals and concentrators taken out of service. There were no adverse incidents, such as a fire, from the use of concentrators during the study period.

All oximeters and sensors were functional one year after implementation. After two years, nine of 10 oximeters were functioning and the majority of the sensors, with the exception of one hospital (H2P1). By 40 months 70% of oximeters remained functional, while the proportion of functional sensors varied widely between hospitals, from 100% (H2P3) to none (H1P2).

Clinical outcomes

A total of 2912 standardised data abstraction forms were collected from intervention and control hospitals, of which 2777 remained after excluding children greater than 5 years of age and 2722 after excluding other diagnoses. Table 3 outlines the characteristics of childhood pneumonia cases in the pre- and post-implementation era from control and intervention hospitals. Patient numbers, age, length of stay and pneumonia severity was similar between hospital cohorts both pre- and post-intervention. There was variation in the proportion of patients contributed by different study hospitals pre- and post-intervention. There was a reduction in the proportion of severe/very-severe pneumonia cases in the post-intervention era, but the proportions were comparable between intervention and control hospital cohorts.

Pre-intervention, between group analysis demonstrated a small difference between control and intervention hospitals in the proportion of patients discharged well, with

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no difference in the proportion discharged with ongoing signs of illness, or who died in hospital, both overall and in the most severe pneumonia cases. (Table 4) Post-intervention the proportion of all pneumonia patients discharged home well improved in both the control and intervention hospitals. In patients with severe or very severe pneumonia, the proportional increase in patients discharged well was greater in the intervention compared to control hospital. (Table 4)

There was a corresponding reduction in the proportion of pneumonia patients discharged home unwell with documented signs of ongoing illness in both control (8.1% (58/713) pre-intervention and 3.3% (20/606) post-intervention, RR 0.41 (95%CI 0.25-0.67)) and intervention hospitals (6.2% (44/712) pre-intervention and 1.9% (13/691) post-intervention, RR 0.30 (95%CI 0.16-0.56)). (Table 4) In the pre-intervention era approximately 70% of these patients had documentation of discharge against medical advice, and this fell to 25% of cases post-intervention accounting for most of change in patient numbers.

In intervention hospitals, case fatality rates for childhood pneumonia fell from 2.7% (19/712) pre-intervention to 0.80% (6/691) post-intervention (RR 0.33, 95%CI 0.13-0.81) with no change in control hospitals (1.7% (12/713), and 2.3% (14/606), RR 1.37, 95%CI 0.64-2.95). (Table 4) The same trend was seen for the most severe pneumonia cases (Table 4).

Improved processes of care were seen in both intervention and control hospitals including increased documentation of SpO2 in medical records, with a larger proportional increase in intervention hospitals. (Figure 2a). In both cohorts SpO2 was more frequently documented in the more severe cases. Less improvement was seen

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in the proportion of children having oxygen therapy and/or oxygen flow rates documented, with minimal difference between hospitals. (Figure 2b)

Discussion

In 2010, the Lao Ministry of Health identified the lack of affordable oxygen therapy as a major health system challenge and responded with a pilot project to deliver affordable oxygen concentrator systems to district hospitals. The project built upon lessons learned in other settings and an increasing knowledge basis of the types of concentrators and equipment that may best suit different environments.(9, 10) There is evidence of its impact on care and outcomes, with a reduction in case fatality rates for childhood pneumonia in intervention, but not control hospitals. However there are also ongoing challenges, and the engineering investment and health system support required to achieve these outcomes must be recognised.

The project was embedded in the Ministry of Health and implementation decisions were made by a team supported by international partners. Lao clinicians and engineers received hands-on training aimed at building local. The local engineering capacity that was developed and sustained was evident by their ability to address substantial maintenance and repair requirements for concentrators. Despite this, many oxygen concentrators failed, and the impact of the maintenance requirements on feasibility and sustainability of concentrator systems should not be underestimated. Failure rates of the newer model replacement concentrators appeared to be less. Concentrator faults were reported either through the normal health system communication channels or through project evaluation activities. The majority of the equipment issues were only identified through the latter. In the

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absence of an “oxygen project” there remains a major risk that equipment falters and is abandoned.

Identifying reasons for equipment failure is essential. The high proportion of the original model concentrators requiring repair likely reflects poor suitability to the environmental conditions. The majority of major faults occurred in Southern provinces where temperatures of 40°C degrees are combined with humidity and dust. Laboratory testing of concentrators that occurred after the project began support our observations that the original machines do not function optimally in these conditions. Investigations demonstrated that the AirSep Visionaire was less reliable at high temperature and simultaneous high humidity than the earlier model AirSep Elite. (10) This was attributed to an inadequate internal cooling system in the Visionaire which leads to higher running temperatures and in turn failure of the compressor and sieve beds, as we saw in Laos. Despite modifications, the manufacturer no longer recommends the Visionaire for use in tropical conditions.

Environmental conditions will not be the sole explanation for equipment failures. Hospital differences are apparent, even in geographically similar locations. The marked discrepancies in functioning oximeter sensors in some hospitals compared to others, suggests local factors such as attention to maintenance and loss are also important. Further exploration of high and low-performing case examples may provide insight into hospital-level influences on the effectiveness of oxygen concentrator systems and medical equipment in general.

The total of 30,000 hours over the first two years of the project represented only 5% of the potential 665,760 hours the machines were available for use during this time. This in part will be due to relatively low admission numbers of Lao district hospitals. It

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is may also reflect underuse of oxygen in cases in which it may have been indicated, or equipment downtime from faults.

Despite these problems, this study provides evidence of improved oxygen use and clinical outcomes for children under 5 years of age with pneumonia. Reduction in the proportion of children with pneumonia who were discharged unwell before completing treatment was seen in both intervention and control hospitals, with a corresponding increase in the proportion discharged well. In control hospitals this may reflect a number of factors including a Hawthorn effect from participation in the study, with increased awareness of the importance of oxygen therapy. It may also reflect access to oximetry to determine completion of treatment, or other secular trends such as improved financial circumstances of the community. Finally case severity impacts on outcomes, and in both the control and intervention groups there was a reduced proportion of severe and very severe pneumonia in the post-intervention era. However these changes were comparable between control and intervention hospitals - they do not explain the reduction in the proportion of patients discharged unwell which was observed among the most severe pneumonia cases, nor do they explain the reduction in case fatality observed only in intervention hospitals. Therefore, although there are many confounding factors to consider, the reduction in pneumonia case fatality documented in intervention hospitals seems likely to be explained, at least in part, by access to improved oxygen systems as seen in previous studies of oxygen implementation.(6)

Improvements in documentation of SpO2 and oxygen delivery were also seen with a greater degree of improvement in the intervention group. For pulse oximetry, this may reflect improved availability of oximeters to control hospitals, compared to more

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intense training in their use at intervention hospitals. Perceived relevance of documenting SpO2 is also likely to be a factor as suggested by higher levels of documentation in more severe cases. Gaps remain between actual and ideal practice. A range of other contextual factors are likely to contribute, including the lack of a specific location on monitoring charts to document oximetry and oxygen, and established hospital practices for patient monitoring which require a broader cultural change.

There are limitations in the study design. The inclusion of a control group of hospitals improves on previous assessments of oxygen systems. However the inability to allocate oxygen systems using an experimental design still limits interpretations of outcomes. Improved clinical outcomes and mortality rates may have been due to confounding factors, as discussed previously, but we are unaware of other interventions which may have affected hospitals differentially. The accuracy and detail of medical records limited our ability to accurately determine pneumonia severity or patient outcomes in some instances. Medical records represented those we could locate; we cannot be sure how many children were admitted with pneumonia in the 20 hospitals in each of the two time periods. Variation between hospitals is evident and, similar to equipment outcomes, changes in clinical practice may be influenced by hospital characteristics which we were not able to explore in detail. For some hospitals the project provided the first reliable source of hospital oxygen, for others, it only removed the financial barrier.

Delivery of an affordable, feasible and sustainable oxygen system to prevent hypoxaemia and reduce mortality is a critical intervention in resource-limited settings. It requires a multi-faceted approach including robust oxygen equipment, well

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supported local clinical and engineering capacity and ongoing support for the clinical use of oxygen. However, oxygen concentrator systems can create significant ongoing maintenance demands which already fragile health systems in low resource settings must be able to support to achieve long term sustainability, unless more robust equipment solutions can be found. There would be clear benefit from a more detailed understanding of contextual factors influencing equipment longevity and clinical outcomes, in order for future oxygen programs to have maximal impact.

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Table 1 Characteristics of study hospitals in 10 intervention and 10 control hospitals in the Lao Oxygen Project at baseline

	Hospital cohort	
	Control Median (Range)	**Intervention** Median (Range)
Inpatient beds	16 (10-35)	19 (10-30)
Admissions in 2010		
Total	610 (442-4573)	1236 (270-6194)
Adult admissions	383 (350-2042)	1354 (221-3284)
Paediatric admissions	225 (59-2531)	189 (49-2910)
Cost per oxygen cylinder (USD)	23 (14-64)	29 (14-64)
Total staff numbers		
Doctors	2 (1-27)	2 (0-6)
Medical assistants	3 (0-20)	2 (0-20)
Nurses	9 (3-44)	9 (4-24)

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Table 2 Concentrator repair and maintenance at 12, 24 and 40 months post-implementation of oxygen systems in 10 intervention hospitals, and hours of concentrator use in each time interval.

Hospital	Machines supplied, n	Concentrator repair and maintenance needs						
		12 months			24 months		40 months	
		Number needing repair, n(%)	Working after repair n (%)	Machines replaced n(%)	Number needing repair, n(%)	Working after repair n (%)	Number needing repair, n(%)	Working after repair n (%)
Northern provinces								
H1P2	2	1 (50)	2	0	1	2	1	1
H2P2	3	0 (0)	3	2	0	3	0	3
H1P3	4	2 (50)	4	0	1	4	2	2
H2P3	4	1 (25)	4	0	1	3	1	3
Subtotal	13	4 (31)	13 (100)	2 (15)	3 (23)	12 (92)	4 (31)	9 (69)
Southern provinces								
H1P1	4	2 (50)	3	2	1	4	2	2
H2P1	3	1 (33)	3	1	2	3	0	3
H1P4	4	4 (100)	3	2	1	4	2	2
H2P4	6	2 (33)	6	1	0	6	2	6
H1P5	4	1 (25)	3	1	0	4	2	3
H2P5	4	0 (0)	4	0	0	4	0	4
Subtotal	25	10 (40)	22 (88)	7 (28)	4 (16)	25 (100)	8 (32)	20 (80)
Total	**38**	**14 (37)**	**35 (92)**	**9 (24)**	**7 (18)**	**37 (97)**	**12 (32)**	**29 (76)**
Hours of use		13465 (data available from 37/38 machines)			17050 (38/38 machines)		17839 (35/38 machines)	

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Table 3 Admission numbers and characteristics of children under 5 years of age with pneumonia whose medical records were reviewed in pre- and post-implementation of oxygen systems in Lao district hospitals.

	Control hospitals n=1319		**Intervention hospitals** n=1403	
	Pre*	Post**	Pre*	Post**
Patient numbers, n	713	606	712	691
Patient numbers by province n (%)				
Champasack	62 (8.7)	83 (13.7)	161 (22.6)	41 (5.9)
Luang Namtha	146 (20.5)	112 (18.5)	69 (9.7)	78 (11.3)
Oudomxay	170 (23.8)	81 (13.4)	139 (19.5)	211 (30.5)
Savannakhet	235 (33.0)	250 (41.3)	144 (20.2)	216 (31.3)
Sekong	100 (14.0)	80 (13.2)	199 (27.9)	145 (21.0)
Age in months, median (IQR)	12 (6-24)	15 (7-24)	12 (6-24)	12 (7-25)
Length of stay, median (IQR)	2 (2-4)	3 (2-4)	2 (1-4)	2 (1-3)
Pneumonia severity n (%) Non severe pneumonia Severe/very severe pneumonia	 372 (52.2) 341 (47.8)	 396 (65.3) 210 (34.7)	 412 (57.9) 300 (42.1)	 423 (62.2) 261 (37.8)

* Refers to the pre-intervention era with medical records collected between 2007 and 2011. Data collection in hospitals in 2011 stopped once oxygen systems had been installed.
** Refers to the post-intervention era with medical records collected between 2012 and 2013

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Table 4 Recorded outcomes of children under 5 years of age admitted with pneumonia to study hospitals pre- and post-implementation of oxygen systems.

	All pneumonia cases			**Severe or very severe pneumonia cases**		
	Pre-intervention	**Post-intervention**		**Pre-intervention**	**Post-intervention**	
Admissions	N	N		N	N	
Control	713	606		341	210	
Intervention	712	691		300	261	
Well at discharge	n (%)	n (%)	Pre-post comparison**	n (%)	n (%)	Pre-post comparison**
Control, n (%)	621 (87.1)	588 (92.1)	p=0.003	261 (76.5)	179 (85.2)	p=0.013
Intervention, n (%)	641 (90.0)	658 (95.2)	p<0.001	243 (81.0)	244 (93.5)	p=0.28
Between group analysis*	p<0.001			p=0.17		
Died						
Control	12 (1.7)	14 (2.3)	p=0.41	12 (3.5)	14 (6.7)	p=0.09
Intervention	19 (2.7)	6 (0.8)	p=0.011	19 (6.3)	6 (2.3)	p=0.021
Between group analysis*	p=0.20			p=0.097		
Discharged unwell/with signs of illness						
Control	58 (8.1)	20 (3.3)	p<0.001	48 (14.1)	9 (4.3)	p<0.001
Intervention	44 (6.2)	13 (1.9)	p<0.001	31 (10.3)	6 (2.3)	p<0.001
Between group analysis*	p=0.15			p=0.15		

*Using Chi-square test of proportions for pre-intervention (baseline) data between control and intervention groups
*Using Chi-square test of proportions to compare pre-intervention and post- intervention data within the hospital cohort.

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Figure 1. Graphical representation of study design and time points.

Figure 2. Percentage of cases of pneumonia in children less than five years of age in control and intervention hospitals in which a) SpO2 and b) oxygen therapy were documented in the medical records, pre- and post-intervention.

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Author contributions

AG contributed to study design, developed the clinical training materials, assisted with the implementation of oxygen systems, supervised data collection and training of data collectors, analysed the data and was responsible for the first draft of the manuscript.

MM contributed to supervision of data collection in the post-implementation era, entered, cleaned and analysed data and contributed to both the first draft and subsequent revisions of the manuscript.

TD contributed to study design, planning of implementation and contributed to interpretation of results and revision of the manuscript.

DP contributed to study design, provided technical expertise into the engineering aspects of the program, supervised implementation of equipment and contributed to revision of the manuscript.

CW contributed to study design, equipment procurement and implementation of oxygen systems as well as revision of the manuscript.

MS contributed to study design, in particular hospital selection and liaison, implementation of oxygen systems, monitoring of equipment in the field and reviewed the manuscript.

KS contributed to study design, clinical training in oxygen use, data collection from medical records and supervised other data collectors and reviewed the manuscript.

BP contributed to study design, clinical training in oxygen use, data collection from medical records and supervised other data collectors and reviewed the manuscript.

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KD contributed to study design, clinical training in oxygen use and supervision of data collectors and reviewed the manuscript.

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Time point	Intervention	Control
Situational assessment	A	
Hospital recruitment (n=20)	B	B
Delivery of intervention and baseline evaluation	C D E F G H	D F G H
12 month post intervention follow up	F G H	F G H
Delivery of updated equipment	I	
24 month post intervention follow up	F G H	F G H
40 month post intervention follow up	G	

Key

A	Baseline situational assessment of hypoxaemia prevalence, oxygen availability and use in Lao district hospitals (2010-2011).
B	Hospital recruitment. Selection of intervention hospitals was based on criteria proposed by the oxygen team, provincial and district hospital staff including current availability of a sufficiently reliable electricity supply, current absence or limited oxygen supply or difficulties in oxygen delivery, remote areas with poor populations and anticipated admission numbers with respiratory illness. Control hospitals were selected from the same or neighbouring provinces for comparison.
C	Delivery of oxygen system equipment and engineering training. The installation team delivered hands-on training to local hospital staff on equipment use, maintenance and repair.
D	Delivery of pulse oximeters. Intervention hospitals received table-top oximeters (Bitmos). Control hospitals received handheld oximeters (Lifebox).
E	Clinical training on oxygen use. Clinical training over two-days via interactive workshops to all available hospital staff based on material from the WHO and included video, case-based teaching and practical sessions on hospital wards
F	Evaluation of clinical use of oxygen and costs. Data was collected during site visits and included cost and the availability and function of oxygen equipment. Hours of oxygen use was read from the concentrator displays.
G	Evaluation of equipment use and maintenance requirements. Data drawn from a number of sources including installation data, hospital reports, and site visits to complete hospital equipment checklists.
H	Evaluation of clinical outcomes. Data collected from medical records, using a standardized form, included patient gender and age, diagnosis, pneumonia severity, documentation of SpO2, oxygen therapy and patient outcome.
I	Delivery of new oxygen concentrators. In the first year following installation 37% (14/38) of concentrators experienced a fault that required repair or maintenance.

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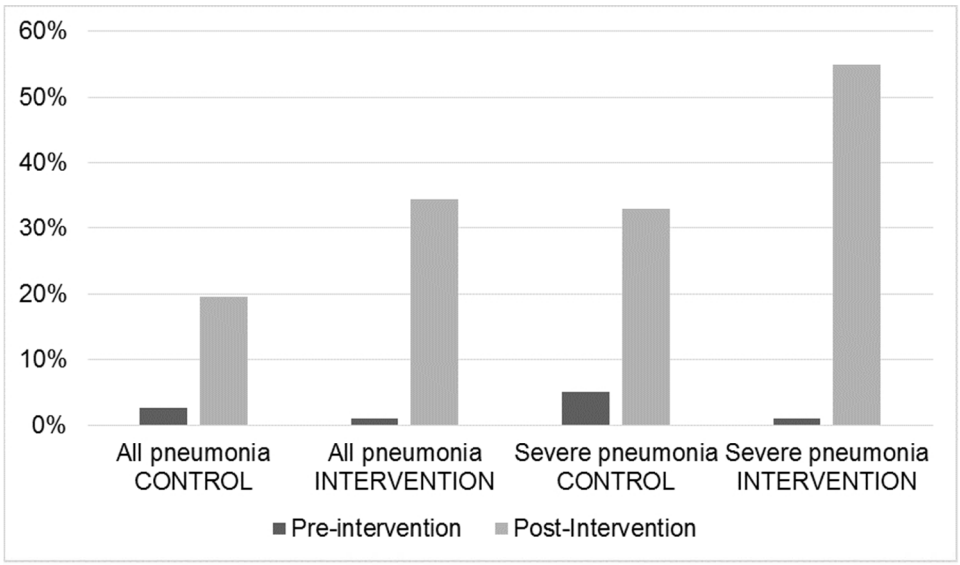

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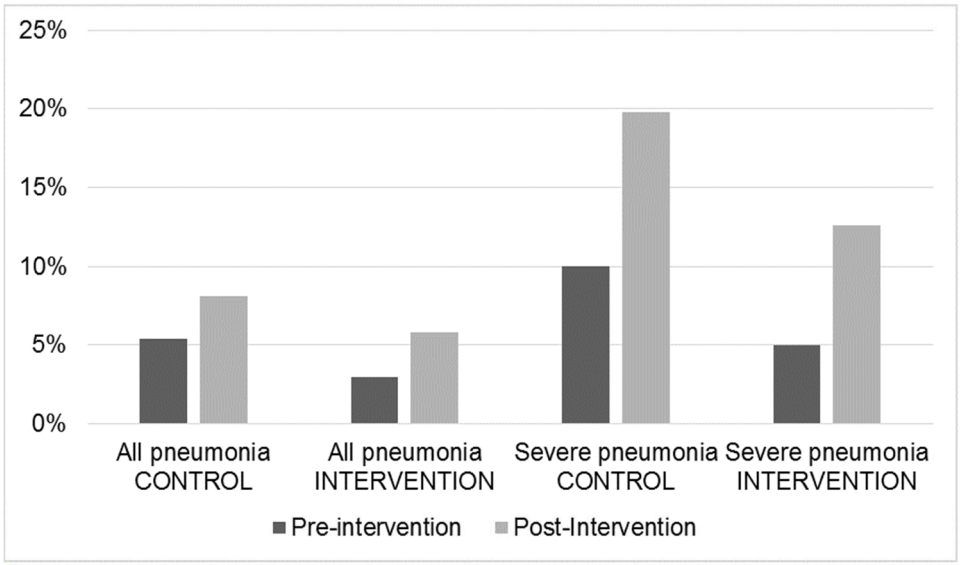

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