

The Politeoxygen splitter system (PSS) – a frugal LMIC oxygen delivery technology that expands the utility by up to 700%

Abstract

Background: Oxygen therapy is indispensable in neonatal care requiring prompt commencement when prescribed. This is often hampered by limited availability of oxygen cylinders or concentrators at busy SCBUs in Nigeria. Where available, these two items of oxygen sources overcrowd the SCBU creating movement barriers leading to injuries, neonatal infections from high traffic of dirty cylinders and noise pollution from many concentrators. This presents the urgent need for a low-cost technique that could help to make oxygen easily administered to as many neonates as the need arises simultaneously.

Aim: To describe an oxygen splitter system and compare outcomes of oxygen prescription in neonates pre and post-system installation.

Methods: Politeoxygen® Splitter System (PSS), a novel oxygen distribution system was designed to eliminate oxygen concentrator and cylinder adverse effects whilst enabling only one oxygen source to support up to eight neonates, simultaneously. Following ethical clearance from Research Ethics Committee of Niger State Ministry of Health, Nigeria, five sets of the device were installed and applied. Records of newborns who received oxygen therapy, pre-PSS installation and post-PSS were retrieved. Time delays to oxygen commencement following prescription were assessed in both groups. Incidences of cylinder falls and obstructions were noted.

Results: PSS supported multiple numbers of neonates using one oxygen-source with patient independent humidification and variable flowrates, sharing total flow up to 15 LPM amongst needy neonates as individually required. Six of 105 (6%) newborns received oxygen within 10minutes of prescription pre-PSS installation, whereas 96% (72/75) post-PSS. The median (range) time delay to commencing oxygen therapy post-PSS was 0(0–90) minutes whereas pre-PSS was 74(0–1110).

Conclusion: Unlike pre-PSS group, 100% of post-PSS neonates received oxygen as soon as this was prescribed, leading to prompt therapy initiation and many of them survived. It is author's opinion that the PSS is recommended to enhance prompt far-reaching oxygen to neonates in poor settings.

Keywords: oxygen therapy, neonate, politeoxygen splitter system, pss, hypoxemia

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Amadi HO

Department of Bioengineering, Imperial College London, United Kingdom

Correspondence: Professor Hippolite Amadi, Bioengineering department, Imperial College London, South Kensington Campus SW7 2AZ, United Kingdom, Tel +44 7984175083, Email h.amadi@imperial.ac.uk

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Background

Recent studies and reports have shown that oxygen support is frequently demanded by Nigerian neonates on admission but access to this in Nigerian hospitals is poor resulting in substantially higher mortality than normal.^{1,2} This has reflected in numerous attempts by the Nigerian government to actualise various programmes geared towards oxygen availability across hospital institutions.^{3,4} However, these efforts have yielded no sustainable result as recent communication has indicated that major deficiencies still exist in hospital oxygen systems.^{1,5} This has essentially left the problem of access to medical grade oxygen by needy patients as a largely unsolved one.

Introduction

Oxygen therapy is one of the most frequent interventions often given to newborn babies, especially premature neonates. There is no substitute gas for the need of oxygen for a needy patient anywhere, including at regions of poor settings around the world. However, oxygen has sadly remained an out-of-pocket expensive commodity at certain low-income settings and may have contributed to the deaths of millions of neonates at such settings.^{6,7} Nigeria records

high incidences of perinatal asphyxia, respiratory distress syndrome (RDS), and prematurity which exacerbates neonatal hypoxemia with high fatality rate. These complications are hard to resolve without mechanical administration of oxygen to the patient, either as a supplemental intervention via intranasal endotracheal tube or via outright mechanised breathing using a ventilator. The cases of severe RDS would require extreme interventions with invasive or non-invasive ventilators such as bubble continuous positive airway pressure (bCPAP) machines. All these devices require continuous flow of oxygen supply for effective support of the neonate. The mechanical ventilators are very expensive and often unaffordable to many caregivers at low- and middle-income countries (LMICs). However, the most frustrating deficiency-situation at many LMIC settings such as Nigeria is when oxygen therapy of any kind is prescribed for a high-risk patient to keep the neonate alive, but the patient would either not receive the therapy until death or this is delayed for many hours or days of waiting for the next available supply. Few centres exist where oxygen is centrally generated and distributed to the wards via piping network. However, such centres are often crippled soon after due to the sophistication of this technology which requires expensive maintenance costs beyond the warranty period. Hence, this becomes

unsustainable, and issues of readily affordable oxygen supply remains one of the greatest challenges of the LMIC neonatal care centres.

Literature has declared that prematurity is responsible for high volume of neonatal mortality at LMICs, and that this accounts for a quarter of neonatal deaths in Nigeria.^{8–10} Perinatal asphyxia and RDS are other morbidities frequently blamed for high rates of neonatal mortality in Nigeria and around LMICs whilst discussing interventions of bubble continuous positive airways pressure (bCPAP) for blended oxygen delivery.^{11–14} These suggest that treatment of these high-risk morbidities would be unsuccessful without ready availability of oxygen, which goes to suggest that lack of oxygen could be argued as the significant contributor to final cause of death. Observably, documented causes of death at the Nigerian special care baby units (SCBU) setting are often identified with the diagnosed conditions without the mention of its intervention failures. Therefore, lack of readily deployable oxygen to a needy neonate in Nigeria and other similar LMICs could be a significant contributor to high neonatal mortality due to prematurity, asphyxia, and RDS. I hypothesise that the use of any LMIC-affordable technology that could allow easy accessibility of oxygen to the teeming population of needy neonates would considerably lower neonatal mortality owing to these conditions.

A lot of neonates have lost their lives whilst waiting for too long for a refilled oxygen cylinder or oxygen concentrator to become available for such a neonate. They died because they ‘could not breathe’ and could not be given oxygen owing to insufficiency or unavailability. The possibility of having as many as 10 neonates or more in need of oxygen at the same time in a big Nigerian SCBU would often set-off the high traffic of frenzy movements of available items of oxygen cylinders and concentrators across units, corridors, workshops, plant houses, and from outside the hospital premises, all into the already busy practice space of the SCBU. This presents adverse problems such as:

- (A) Deafening noise pollution from many oxygen concentrators running simultaneously in the same small room.
- (B) Uncontrollable radiant heat generation from the oxygen concentrators affecting neonatal thermoneutral control, often overwarming neonates in cots, hence, instigating another undesirable complication.
- (C) High power consumption incurred in running up to seven or eight concentrators to produce a total oxygen flowrate that could easily be produced by only one concentrator, hence increasing operational cost. A hospital standard oxygen concentrator can generate up to 10 LPM flowrate of pure oxygen, and some neonates’ need for lifesaving therapy may be as little as 1 LPM flowrate of breathable oxygen.
- (D) Relatively higher cost on overhead is incurred due to the maintenance of unavoidably more devices that run simultaneously to cover workload.
- (E) There is high congestion of available free space within the SCBU wards due to multiple numbers of cylinders and O₂ concentrators as required, obstructing easy movement and workflow. Hence, too many cylinders in the way of movement become hazards as nurses and doctors could accidentally bump into these causing injuries, especially when this involves falling tall cylinders.
- (F) Oxygen replacement from the works department often comes with high infection risks as both cylinders and those bringing them are highly contagious transmitters of killer microbes that infect the neonates, leading to the death of many.

Prior to this project, the Nigerian practice could only deliver oxygen in the ratio of one oxygen-cylinder to one neonate, or one oxygen-concentrator to one neonate. The aim of this project was to devise an LMIC-affordable technology that could boost the reach of any deployable oxygen source to more than one neonate simultaneously to decongest the SCBU but at the same time serving more needy neonates. Design would be such that the oxygen source could be left outside of the nursery room or building to minimise the negative impact of heat generation and noise pollution from oxygen-concentrators and reduce infection due to the high traffic of dirty oxygen cylinders in and out of the SCBU.

Materials and methods

A pressure-sensitive airflow channel with one input port and four exit ports was designed such that the system could automatically deliver unrestricted equal volume flow at all exits simultaneously. This was developed into a prototype and tested at the Amina-neonatal-centre of the General Hospital Minna, Niger State Nigeria (Figure 1). The prototype was a simple construct whereby multiple bifurcation plastic T-pieces and food grade silicon tubing were assembled to build a circuit of multiple delivery flow exits from one input tube.

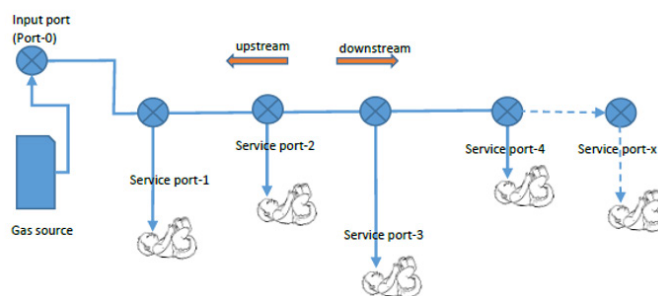


Figure 1 The politeoxygen splitter system (PSS) concept.

Tubing length in-between the T-pieces was made to be equal to one-quarter of the perimeter of the main nursery hall of the neonatal unit. An oxygen concentrator was used to deliver 8 LPM flow of gas to confirm there were no significant pressure-drop throughout the circuit, and equal output flow of 2 LPM from each of the four ports. The prototype passed all tests; hence the project was progressed to implementation stage which involves surface installation of the piping sleeve around the ward walls and installation of independent flowmeters for the control of the input flow and respective humidification and control of each output flow port (Figure 2).

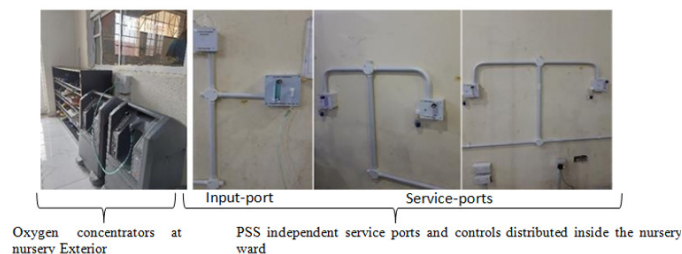


Figure 2 Piping sleeving and individual flow control.

An approval was obtained from the Niger State Research Ethics Committee for the permission to carry out the clinical characterisation of the new installations of respiratory support devices at the Amina-centre and any other collaborating centre within the country. Trialling commenced and continued for three months from January 2019 with excellent preliminary outcome at the Amina-centre Minna. A second collaborating centre, the Special Care Baby Unit (SCBU) of Alex-

Ekwueme Federal Teaching Hospital Abakaliki (AFTH), joined in the trialling and accepted the installation of two sets of the device with a capacity of six neonates per PSS set. Hence, the PSS at AFTH enabled two oxygen cylinders or two oxygen concentrators to deliver oxygen to up to 12 neonates simultaneously. The two hospital centres continued usage of the technology for additional nine months as the systems were observed and tweaked for improvements. All relevant data for every initiated therapy was recorded, including time lapse between prescription and commencement of therapy. The data was analysed and presented at the 51st National Conference of the Paediatrics Association of Nigeria in 2020.¹⁵

The AFTH Abakaliki SCBU data that related to initiation of oxygen therapy for the period of three months prior to the use of PSS (pre-PSS data) was extracted and analysed. This provided a measure for the SCBU's pre-PSS characteristic time-delays before therapy commencement. A total of 105 previous cases were identified from patients records. This was applied in a comparative analysis against the Unit's post-PSS installation for up to January 2020. The Amina neonatal centre Minna was originally equipped with a hi-tech central oxygen piped system with some components from Greece (G-Samaras, Greece) and installed at a cost of 17.5 million naira (about \$68,000) by Supreme Meditech Ltd, Abuja Nigeria. The system had a source chamber of six tall cylinders (dimensions: 23 cm x 146 cm; 85 kg weight, 11300 L volume) that supplied a total of 36 service ports in the Labour ward, delivery room, theatre, and the neonatal wing of the complex. Eighteen of the 36 oxygen service ports were installed across the different sections of the neonatal unit (the Amina-centre). Within the first 12 months of its installation, the centre could no longer afford the cost of its maintenance through the meagre out-of-pocket payments from neonate carers, hence, many more neonates began to suffer the consequences of irregular oxygen availability. Therefore, a decision was taken by the Amina-centre and readily oxygen supply to the neonates was restored by the installation of three sets of the PSS, each of which was powered by one oxygen concentrator and distributed to six independent service ports. The oxygen concentrators – a total of eight at the centre – were regularly serviced and made to run in shifts of 8 hours, covering the daily workload. The total cost of the installation of the 18-outlet-ports PSS was one million naira (\$4,000). Other alternative power installations at the Amina-centre made it possible to operate the centre without interruption of power supply, making the oxygen concentrator option reliable, sustainable, and readily available. This relieved the Centre from the burden of high cost of commercial cylinder deliverable oxygen and made oxygen always available to all needy neonates at a very cheap rate for their meagre out-of-pocket payments. The Amina-centre's comparative assessment was carried out using their pre-PSS average cost of oxygen delivery to a neonate as against what this became post-PSS installation, covering the period January 2019 to January 2020.

Beyond 2020, the three parallel and two parallel sets of the PSS at Amina-centre Minna and AFTH Abakaliki, respectively, continued in use till date. Hence, the centres were requested to provide a qualitative operational service assessment of 4-years of PSS usage based on observational reliability and estimated total number of neonates that the systems have been used to readily deliver their emergency oxygen need for survival.

Results

The real size PSS installations at the two Special Care Baby Units replicated the expected outputs from all the service ports as earlier observed from the prototype. No leakages were observed from all the independent humidifiers as all the system's output flowrates from the service ports added up to the total input flowrate at port-0 as demonstrated in Figure 3.

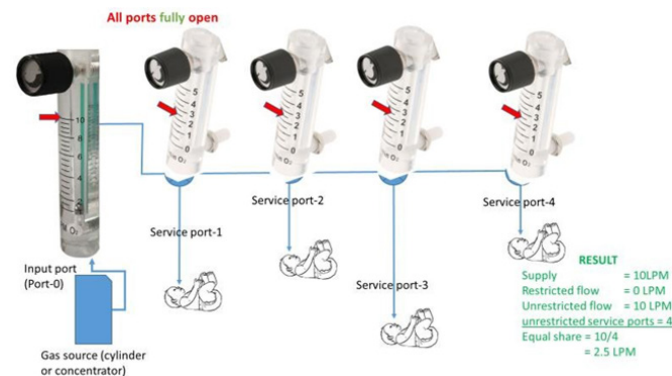


Figure 3 System outcomes in all ports unrestricted situation.

System operational characteristics

When all input and output ports' flowmeters were fully opened, any specific amount of total oxygen delivery into the system was easily selected – provided the source delivery flowmeter (oxygen cylinder or concentrator flow gauges) was set at such delivery value, for example, 10 LPM. The system's input port (Port-0) responded by confirming the actual flowrate being delivered. However, in situations of inaccurate amount being delivered, perhaps due to faulty source gauge, then port-0 control was used to adjust the input to the specific required value.

- When oxygen input flowrate into the system was restricted to a total of 10 LPM with all service port flowmeters fully opened, the system automatically shared the input flow equally among all the service ports (Figure 3).
- From a state of system settings as in condition (a): when the output flow through a service port, such as port-1, was restricted by any amount. The system automatically subtracts this amount from the total input, and then shares the remaining amount of input equally across the rest of the fully open service ports as shown in Figure 4.
- Pressurised oxygen input situation occurred when the total sum of service port demands falls far below the input flowrate such as demonstrated in Figure 5. The excess (or restricted gas) in the system resulted in build-up of internal tube wall pressure leading to a possible forceful disengagement of the source supply tube. We called this 'the busting pressure'. Busting pressure could be eliminated (depressurising) by appropriately reducing the source flowrate. The system was modified by the addition of a 'safety point', located along the tubing line between the oxygen source and port-0 (Figure 5). The safety-point makes a 'pop' sound to notify a user that input flowrate was far more than the demands from the service ports.

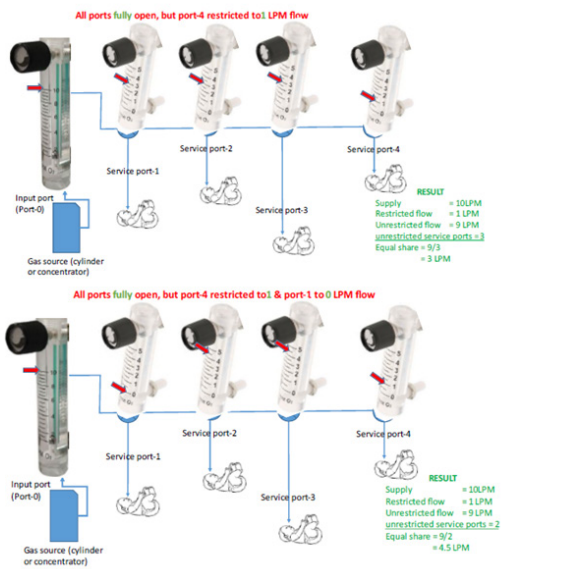


Figure 4 System outcomes in all ports restricted situation.

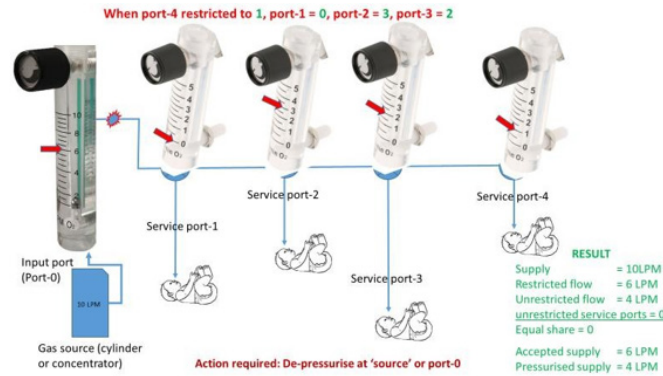


Figure 5 System outcomes in busting pressure situation.

System operational guidelines

Following the outcomes of the operational characteristics of the PSS, a set of operational guidelines was developed as part of the usage manual as shown in Figures 6A & 6B.

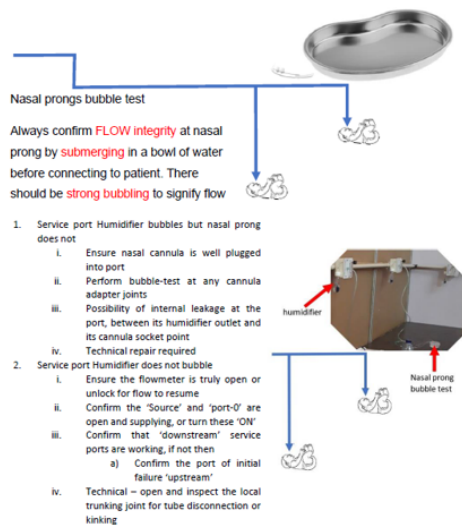


Figure 6A Operational guideline.

- No flow at 'upstream' port (e.g. port-2) but flow at 'downstream' port (e.g. port-3 or port-4)
 - Problem is local to port-2 or along the "upstream" supply line
 - If flow exists at 'upstream' service ports, then
 - Open port-2 junction box to re-fix its supply tube if detached
 - Open service port-2 to find and fix the any tube kink or leakage
- No flow at service port-3 & beyond
 - Open up the junction box at port-3 to fix a possibly kinked tube or re-attach separated supply tube at the junction
 - If no problem identified at port-3 junction, then the preceding port junction box should be opened to re-attach the connecting tube
- No flow at all service ports
 - Ensure 'source' supply is 'ON' and delivering
 - Ensure port-0 is open and gauge indicating a flow
 - Search and fix a possibly kinked or detached tube between service port-1 junction box and port-0
- Water in nasal cannula tube
 - Disconnect cannula from patient
 - Ensure water level in the service port humidifier is below 'maximum' (hold depression point)
 - Hold down the nasal prongs below the service port height and open the gas flow to push off trapped water
- Water aspiration via service port humidifier
 - Keep humidifier water level below 'maximum' mark (i.e. at midway the finger-hold depression point)
 - Disengage nasal prongs from baby and hold this below service port height
 - Fully open gas flow to push-off trapped water
- Water aspiration via 'source' humidifier
 - Reduce water below the 'maximum' mark on the humidifier
 - Ensure that all service-ports and port-0 are open
 - Fully open 'Source' supply to push all trapped water into their nearest service port humidifiers
- Pressurised pipeline
 - De-pressurise at port-0 by turning knob anticlockwise until gauge ball is about to drop

Figure 6B Operational guideline continuation.

End users results

In the first six months of usage, the PSS supported up to 347 neonates at the Abakaliki and Minna centres using one oxygen-cylinder or concentrator to supply up to six neonates as designed. Each patient independent humidification and variable flows functioned efficiently with the system sharing total flow of up to 15 LPM (for a cylinder source) and 10 LPM (for oxygen concentrator source) amongst needy neonates as individually required. There was a total of 105 needy neonates three months prior to the installation of the PSS at AFTH as identified from records and six (6%) of these neonates received oxygen within 10 minutes of therapy prescription. The median (range) time delay to commencing oxygen therapy pre-PSS was 74(0–1110) minutes. During the succeeding three months after the PSS usage was commenced, the AFTH-centre prospectively delivered emergency oxygen therapy, as prescribed, to a total of 75 neonates out of which 72 (96%) received oxygen via the PSS within 10 minutes of therapy prescription. The median (range) time delay to commencing oxygen therapy post-PSS was 0(0–90) minutes (Figure 7).

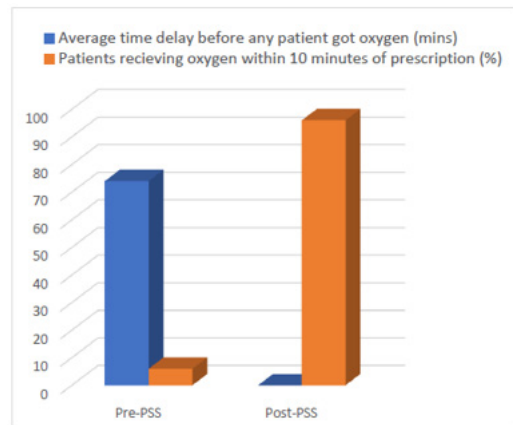


Figure 7 Treatment outcome comparisons before and after PSS.

None of the two centres reported any adverse clinical effects from the use of the systems. There was a total of three technical callouts during the initial three months. These were issues relating to intra-sleeve kinking of distribution tube. The common problem led to a redesign of the patterns of points of curvature within the distribution network; hence the problem was permanently resolved. Beyond the initial usage presentation by the AFTH Special Care Baby Unit

(SCBU) Abakaliki at the 2020 Nigerian Paediatrics Conference,¹⁵ two more Nigerian hospital centres took the advantage to implement the system. These were the Neoroom of the Calabar Women and Children Hospital, Calabar¹⁶ and the Special Care Baby Unit of the Federal Medical Centre Owerri.¹⁷

The observational qualitative reports of four years of usage at the Amina-centre Minna show that the centre did not record any clinical adverse effect till date. The high levels of noise pollution and heat generation from many oxygen concentrators have literally been eliminated and oxygen is delivered to neonates at little or no cost for most of the cases. The 4-years total of neonates who have benefitted from the PSS at the centre was reported to be 2,013.

Discussion

The specific number of Nigerian neonates who currently die for lack of prompt oxygen therapy may be empirically unknown because this cause of death is always swallowed up within other reasons such as respiratory distress syndrome (RDS), asphyxia, prematurity, hypoxemia, or some other treatable conditions that would also require simultaneous oxygen support whilst treatment lasts. Ironically, the Nigerian special care baby unit (SCBU) reporting technique for the end note of a deceased neonate is not structured to intentionally capture and report consumable failures, such as oxygen. By standard, end of life note essentially identifies the so-called ‘primary’ and ‘secondary’ causes of death which are often morbidities and pathologies. However, material and technology support failures are never mentioned by name to brazenly expose the lack of these simple materials and tools that could have saved the neonate. This interventional inadequacy leading to death remained powerful and only known in the shadows and in the minds of the clinical and nursing staff, whereas these neonates might have survived the morbidities if they received prompt oxygen therapy as prescribed.

The havoc of regular oxygen deficiency leading to neonatal deaths was endemic in Nigeria as was personally observed by this author, who served as visiting consultant at over 80% of Nigeria’s tertiary hospitals. Lack of readily available oxygen was never specifically captured or blamed in the end-of-life notes of the deceased neonates (huge in number) across these hospitals. However, this was well-known, strongly registered in the mind, and hence, inspired this research for a low-cost technology that could easily extend the reach of lifesaving oxygen to more neonates. The Politeoxygen splitter system (PSS) is a simple technology that can be installed in a SCBU using mostly locally available materials for construction and set up. Apart from its oxygen flowmeters which may be purchased from suppliers at big commercial cities in Nigeria, all the other components are obtainable from ordinary local markets in Nigeria. The installation of a standard PSS of eight service port capacity could be completed in 20 hours of work by two experienced engineers. The system is very simple to maintain and operationally quick to understand by the Nigerian clinical and nursing teams. The over 2,000 neonates who have been supported with the PSS within its last four years of usage at the Amina-centre Minna, Nigeria, suggests that this technology is potentially capable of ensuring that no other neonate in Nigeria dies of lack of oxygen therapy.

The PSS was a game-changer at the AFTH Abakaliki as the application of this technology suddenly eliminated the waiting time before any neonate could get oxygen – from only 6% of neonates receiving oxygen within 10 minutes to 96% post-PSS. Unlike the pre-PSS group at the AFTH SCBU, almost 100% of post-PSS neonates received oxygen as soon as this was prescribed, leading to prompt therapy initiation. Based on qualitative responses from AFTH

Abakaliki, the use of PSS eliminated oxygen cylinder hazards and may have possibly contributed to their observed reduction in the rate of infections owing to minimized cylinder traffic. It is the opinion of this author to recommend the PSS for scale up to cover the high simultaneous demands at public hospitals in Nigeria. This is highly affordable and particularly recommended for use at newborn centres of hospitals to enhance prompt far-reaching oxygen to neonates in poor settings.

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Conflicts of interest

I do not have any conflict of interest regarding the development of this device and the subsequent writing of this article.

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