Market assessment and recommendations to increase access to oxygen and pulse oximetry in Indonesia

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#### **MAILING ADDRESS**

PO Box 900922 Seattle, WA 98109 USA

#### ADDRESS

2201 Westlake Avenue Suite 200 Seattle, WA 98121 USA

TEL: 206.285.3500 FAX: 206.285.6619

www.path.org



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Contact information:

Lisa Smith, Market Dynamics Officer, PATH Email: lsmith@path.org

# **Contents**

Abbreviations	iv
Executive summary	v
Background information	7
Project background	7
Indonesia project work	7
Current status of safe oxygen delivery	9
Overview	9
Oxygen delivery	9
Pulse oximetry	11
Supply landscape	12
Procurement landscape	13
Regulatory landscape	14
Guidelines	14
Quantification of need	15
Estimating the total need: Quantification based on number of beds and facilities system	
Estimating gaps in availability: Quantification based on existing availability and	•
Maintenance	
Financing landscape	20
Key stakeholders and roles	20
Market analysis	23
Recommended activities and next steps	26
Appendix A. Contacts and interviews	28
Appendix B. Indonesia stakeholder framework	29
References	30

### **Abbreviations**

ASPAK Aplikasi Sarana Prasarana dan Alat Kesehatan (Application Infrastructure and Medical

Devices)

BKKBN Badan Kependudukan dan Keluarga Berencana Nasional (National Family Planning

Coordinating Board)

CHAI Clinton Health Access Initiative

GDP gross domestic product

HIV human immunodeficiency virus

IDAI Ikatan Dokter Anak Indonesia (Indonesia Pediatric Society)

IKATEMI Ikatan Elektromedis Indonesia (Association of Electromedic Equipment Technicians)

LKPP Lembaga Kebijakan Pengadaan Barang/Jasa Pemerintah (national procurement

agency)

LPM liters per minute

MOH Ministry of Health

PDPI Perkumpulan Dokter Paru Indoneisa (Indonesian Society of Respirology)

RMNCAH Reproductive, Maternal, Newborn, Child and Adolescent Health

ROP retinopathy of prematurity

TB tuberculosis

UNICEF United Nations Children's Fund

WHO World Health Organization

# **Executive summary**

PATH is working to identify market-based solutions to ensure high-quality oxygen is readily available and properly used with pulse oximetry where it is most needed. This project is global in scope, with a focus on four countries—Ethiopia, India, Indonesia, and Kenya. The objective is to gain insights that will enable low- and middle-income countries to improve access to oxygen and pulse oximetry in their public health systems. The information in this report focuses on oxygen access in Indonesia and was collected through a combination of desk research and in-country stakeholder interviews and observations. It is intended to guide key decision-makers in Indonesia as they work to improve access to safe oxygen delivery, which is defined as the presence of an operational oxygen generating, or reliably filled, oxygen source with trained health care workers and supporting devices such as pulse oximeters.

Oxygen availability in the Indonesian public health system is highly dependent on a facility's geographic location. In urban centers and higher population regions, oxygen is often available in gas cylinders or liquid oxygen tanks. These areas have higher volume sales and relatively stable infrastructure. The gas production industry, which provides oxygen for both medical and industrial use, have prioritized distribution here. In remote areas, supply chain/logistical challenges and limitations in available infrastructure (e.g., electricity access) have made it difficult to access oxygen. Poor infrastructure coupled with smaller sales volumes create fewer incentives for oxygen supply companies to sell their products in remote regions. Despite geographic complexities, Indonesia has national regulations and guidelines for oxygen delivery technologies. Clear instruction on the equipment required at each level of the health system as well as separate guidelines on the use and installation of medical gas systems in facilities have contributed to broader access.

Generally, oxygen concentrators are not commonly found in Indonesian health facilities; however, the Ministry of Health (MOH) Respiratory Disease Sub-directorate has worked to increase awareness about these devices and has purchased and distributed more than 500 devices to various provinces in the last five years. The MOH hopes that by distributing these devices, local governments will recognize the value and consider concentrators as an alternative facility-based oxygen source. There is also potential for increased access to oxygen generation technology (e.g., oxygen plants co-located at or distributing to nearby health facilities), particularly in remote parts of the country. The nationally maintained Aplikasi Sarana Prasarana dan Alat Kesehatan [ASPAK, Application Infrastructure and Medical Devices] has tracked information on device deployment, which may be particularly helpful in designing an improved oxygen deployment strategy in the future.

Although the value of pulse oximetry is acknowledged by many health care decision-makers, pulse oximeters are not included in guidelines that describe the standard equipment that should be included in a health center. As a result, devices are less available compared to oxygen delivery devices, especially at the health center level. A first step to increasing access to pulse oximeters at the health center level could include updating these guidelines.

A number of stakeholders play an active role in oxygen and pulse oximetry availability. The most active are the MOH, in particular the Health Service Facility Directorate and Respiratory Disease Subdirectorate, and the World Health Organization (WHO) Reproductive, Maternal, Newborn, Child and Adolescent Health (RMNCAH) unit. The United Nations Children's Fund (UNICEF), although not as active

in supplying medical products, plays a strong programmatic role, particularly in remote areas. Other key stakeholders include clinicians and professional organizations such as Ikatan Dokter Anak Indonesia (Indonesian Pediatric Society), the Indonesian Society of Respirology, and Ikatan Elektromedis Indonesia (Association of Electromedical Engineering Indonesia). These organizations play an important role in developing national medical standards and treatment guidelines, conducting training, collecting baseline data for monitoring and evaluation efforts, and lobbying for policy change. Industry members, both medical gas distribution and installation companies, are another key stakeholder group. These groups are often influential in developing oxygen guidelines and recommendations.

Based on an analysis of registration data, Indonesia has a strong supply of appropriate products available for sale in country. To further support availability, the MOH has developed an online procurement system (e-Katalog) to facilitate coordinated ordering of medical products despite the decentralized governance structure. While this system provides a helpful example for procurement in other decentralized countries, there are challenges in its execution. Continued work is underway to encourage hospitals and health centers to procure through the online platform. In addition, a global pricing analysis indicates there may be opportunities for further price reductions for products listed on the e-Katalog.

Where oxygen is available, there is a need for increased training to ensure it is delivered safely and effectively. The MOH Respiratory Disease Sub-directorate worked with the WHO Family Health unit to update WHO's 2011 guidelines, *The Clinical Use of Oxygen in Hospitals With Limited Resources: Guidelines for Health-Care Workers, Hospital Engineers and Managers*, which could provide much needed guidance to health care workers in the field. However, due to limited stakeholder coordination and access to funding, the updated guidelines have not been ratified or distributed. There would be great value in coordinating stakeholders (e.g., MOH, WHO, clinicians, and professional societies) to finalize this document for distribution, particularly in an operationalized flip book format to enhance ease of use.

In summary, Indonesia is well positioned to further strengthen access to safe oxygen delivery. The country benefits from a strong network of medical gas suppliers, existing medical gas regulations, and medical device guidelines; online procurement (e-Katalog) and asset management (ASPAK) systems; and an invested group of stakeholders. There are a number of activities that could be undertaken to capitalize on these existing strengths to improve safe delivery and increase availability in remote areas. These activities include finalizing and disseminating *The Clinical Use of Oxygen in Hospitals With Limited Resources: Guidelines for Health-Care Workers, Hospital Engineers and Managers*, negotiating prices with e-Katalog suppliers, and determining the optimal oxygen product mix for remote settings.

# **Background information**

## Project background

"Addressing market inefficiencies to improve health outcomes" is a three-year (2016–2019) project being implemented by PATH. The project is funded by a grant from the Bill & Melinda Gates Foundation (Gates Foundation). The oxygen project is one of five projects funded under that grant and its purpose is to build on earlier technical work done around oxygen delivery devices and to identify market-based solutions to ensure high-quality oxygen is readily available and properly used where it is most needed.

Leveraging global insights along with detailed assessments conducted in four focus countries—Ethiopia, India, Indonesia, and Kenya—PATH intends to further assess and propose solutions to the unique market challenges for oxygen delivery devices and pulse oximeters in low- and middle-income countries. Project activities include in-depth assessments of the supply and demand of oxygen delivery devices and pulse oximeters to determine the levels of, and any potential barriers to, product availability, uptake, and use, followed by the development of a global strategy that will include recommendations to overcome identified barriers to access.

The following Indonesia market assessment was developed through a combination of desk research and in-country stakeholder interviews and observations. The project team collected information on the current need for and availability of medical oxygen, common oxygen delivery methods, relevant policies and regulations, procurement methods, and available financing. Based on this information and conversations with key stakeholders, the project team developed the recommendations in this report for key activities to increase access to safe oxygen delivery in Indonesia.

# Indonesia project work

Countries were selected for local market assessments based on a number of factors, which are described in more detail in Table 1. In general, the project team sought to identify four focus countries with key differences in order to draw conclusions based on a range of scenarios and experiences.

Table 1. Focus country selection criteria.

Criteria	General description	Background details for Indonesia
Potential for impact	Assessment of the public health need based on key health metrics, including burden of acute respiratory infections, under-five mortality ranking, etc.	Although much progress has been made to decrease child mortality since 1991, progress has slowed and neonatal mortality has increased as a percentage of under-five mortality, from 32% in 1991 to 59% in 2012. <sup>1</sup>

<sup>&</sup>lt;sup>i</sup> Safe oxygen delivery is defined as the presence of an operational oxygen generating, or reliably filled, oxygen source with trained health care workers and supporting devices such as pulse oximeters.

Criteria	General description	Background details for Indonesia
Potential market size	Assessment of the local market opportunity based on population size, gross domestic product (GDP), qualitative assessment of local market maturity, etc.	Indonesia has the fourth largest population in the world. This translates to a large potential market.
Decision-making authority	Assessment of local decision-making authority, particularly for the procurement of medical devices (e.g., decentralized versus centralized).	Each province, district, and city in Indonesia has its own local government and legislative body. Districts and cities are divided into sub-districts and further into villages. There are 514 districts/cities, 6,514 sub-districts, and 75,244 villages in the country. <sup>2</sup> Many governance decisions, including setting health care priorities, allocating budgets, and procurement, are made at the district level. This provides an opportunity to demonstrate scale and demand generation in a highly decentralized environment that can be leveraged in other countries with similar governance structures.
Available financial resources	Assessment of financial resources available for health care services based on health care spend as a percentage of GDP, country income classification, etc.	Indonesia is classified as a <b>lower middle-income country</b> by the World Bank and has the sixteenth largest economy, with a GDP of US\$862 billion in 2015. Health care spending in 2014 was equal to 2.8% of GDP. <sup>3</sup> This represents an opportunity to identify sources of financing to implement sustainable interventions to financial feasibility and health impact.
Other unique factor(s): For Indonesia, logistics and supply chain challenges	Determined according to the country under consideration.	Indonesia presents unique logistical challenges because it is the seventh largest country in the world in terms of sea and land area, comprising more than 17,000 islands. Supply chain and distribution solutions that are effective in Indonesia could be leveraged in other countries.

PATH's oxygen work in Indonesia was led by two in-country consultants and by a project team based in Seattle, Washington. Consultants began the first phase of this assessment by collecting relevant documentation and developing a landscape of relevant stakeholders. During the second phase, the Seattle-based project team visited Indonesia and partnered with the same two local consultants to meet with key stakeholders and discuss the current state of oxygen delivery, including any barriers and potential opportunities for improvement.

In-country work for this project began in October 2016 and continues in the form of ongoing technical assistance. At the time this report was written (December 2016–April 2017), the team had collected

more than 50 stakeholders in the private and public sectors. Findings from these meetings, combined with desk research and analysis of more than 30 documents, form the basis of this report.

# **Current status of safe oxygen delivery**

The current state of safe oxygen delivery in Indonesia is described below. These findings are based on the PATH team's discussions with key stakeholders: distribution companies and one local manufacturing company, the MOH, the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), professional organizations (e.g., Perkumpulan Dokter Paru Indonesia [PDPI, the Indonesian Society of Respirology], Ikatan Dokter Anak Indonesia [IDAI, the Indonesia Pediatric Society], Ikatan Elektromedis Indonesia [IKATEMI, the Association of Electromedic Equipment Technicians]), and others.

#### Overview

#### Oxygen delivery

Based on interviews with key stakeholders and observations in the field, oxygen is available in health facilities in the more populated and developed regions of Indonesia. In remote regions, which are usually less developed, access to oxygen is not as reliable due to challenges with supply chain logistics and electricity. This is especially true in areas in eastern Indonesia, such as Papua and West Papua.

Figure 1. Oxygen equipment available in Indonesia.



**Cylinders** 

- Available in multiple sizes.
- Found in all levels of the health system.



Manifold system

- Oxygen source can be liquid tank or gas cylinders.
- Generally, only in medium to large facilities.



Concentrator

- From 5 liters per minute up to 90 liters per minute.
- Can serve up to 15–17 adults at the same time.



Plant/liquid

- Generally, in large facilities.
- Can serve 20 to 2,000 beds.
- Customized to meet specific need.

<sup>&</sup>quot;The full list of contacts is included in Appendix A.

Oxygen sources include cylinders, filled with either liquid or gaseous oxygen, or on-site oxygen generation. Oxygen gas cylinders come in a wide variety of sizes and are able to provide oxygen directly to the patient or can be used to power a centrally located manifold system. Gas cylinders are generally refilled by transporting them to an oxygen depot that is supplied with oxygen routinely by an oxygen generation plant. Liquid oxygen tanks are typically larger, weighing at least 55 kg (120 pounds) and standing more than 0.75 m (30 inches) in height. They provide the supply for a centrally located oxygen piping system. Liquid oxygen tanks are generally stationary and are filled by a provider using a filling truck.

Oxygen generation devices usually use a technology called pressure swing adsorption to produce a continuous stream of oxygen (85 to 95.5 percent pure) from room air. These devices can be small enough to provide oxygen to a single patient or large enough to provide oxygen to a 2,000-bed hospital. This category includes portable self-contained devices, generally referred to as oxygen concentrators, and larger oxygen plants that are not portable. There are two basic types of oxygen concentrators, stationary and portable. Portable units are typically battery operated and lightweight with oxygen output between 1–3 liters per minute (LPM), which is sufficient for one adult. Portable units are generally not considered suitable for clinical settings in low- and middle-income countries, as they cannot support multiple patients and are relatively expensive. Stationary units are still portable but are larger and heavier (30–100 pounds) than their portable counterparts and have greater oxygen output capacity (3–12 LPM). A sub-category of stationary concentrators is larger still and capable of output up to 90 LPM. Oxygen concentrators are capable of supporting multiple patients and some can provide oxygen at high enough pressure to support peripheral devices such as anesthesia and continuous positive airway pressure devices.

Aplikasi Sarana Prasarana dan Alat Kesehatan [ASPAK, Application Infrastructure and Medical Devices] is a nationally managed database with information on the location and functionality of medical equipment throughout the Indonesian health system. This data suggests that most health facilities across Indonesia, regardless of the level of care (e.g., hospitals or puskesmas [community health centers]), rely on manifold systems with gas oxygen cylinders or liquid oxygen (see Figure 2, below). Companies that produce oxygen in both gas and liquid form have a strong presence in Indonesia as do the companies that install oxygen piping systems that use liquid tanks and/or gas cylinders as the oxygen source. While current medical gas policy clearly summarizes oxygen cylinder distribution and piping systems, the detail on, and utility of, facility-based oxygen generation plants is lacking. This could be an area of potential future recommended policy revision.

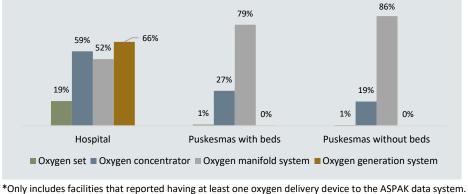


Figure 2. Oxygen delivery method among facilities that have access to oxygen.\*

Oxygen concentrators are less common than cylinders and maintenance remains a challenge, particularly in remote areas of the country, where they are most needed due to poor availability of cylinders. Unless an argument can be made for a system of concentrators and cylinder back-up, demand for oxygen concentrators may be limited to home care use and use in outlying facilities with reliable electricity. To promote the use of oxygen concentrators in public health facilities, the MOH Respiratory Disease Sub-directorate purchased more than 500 devices in the last five years. These devices were purchased in the hope that they would provide a positive example to the districts, which would consider concentrators as an alternative and/or back-up oxygen source. Although these concentrators are deployed, their exact locations are unknown, as each respective province and subsequently district was ultimately responsible for placement of devices in individual health facilities. Decentralized management of the health system, including medical devices, has made it difficult to track information on device deployment as well as to follow up on preventative and corrective device maintenance.

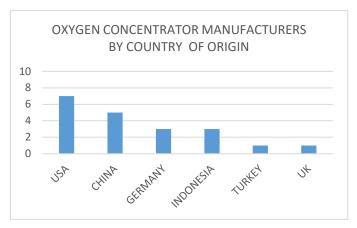
#### **Pulse oximetry**

The importance and value of pulse oximetry is widely recognized by most stakeholders in Indonesia.

However, according to country stakeholders and ASPAK data, pulse oximetry is not widely available in the public health system (see Quantification section). There is support for these devices at the national level, as evidenced by the procurement of 750 pulse oximeters over the last three years by the MOH Respiratory Disease Sub-directorate. However, further advocacy at the provincial and district levels of decisionmaking is required to expand access to the more than 9,500 health centers in Indonesia (approximately 3,400 of which have inpatient capabilities).

Figure 3. MOH-registered oxygen concentrator manufacturers by country of origin.

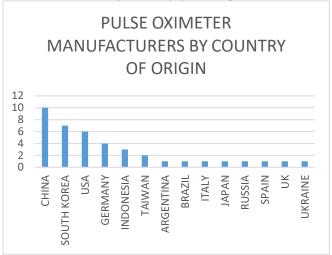
Source: MOH, Pharmacy Health Equipment Registration unit.



The medical device registration database at the MOH shows that 40 pulse oximeter manufacturers are registered to sell 70 different models in Indonesia. All manufacturers registered to sell their devices in the country have been approved by the domestic MOH regulating body; 33 also have approval from a stringent regulatory authority outside of Indonesia (United States Food and Drug Administration or European Conformity), which is an additional indicator of quality. Note that this does not include devices registered as patient or cardiac monitors, which often include pulse oximetry.

Figure 4. MOH-registered pulse oximeter manufacturers by country of origin.





### Supply landscape

There are a number of medical devices on the market in Indonesia. Medical device registration data show 42 portable oxygen generation devices (20 manufacturers) and 70 pulse oximeters (40 manufacturers) registered with marketing authorization. Of these, five companies are based in Indonesia: three oxygen concentrator manufacturers—Pt. Sani Tiara Prima, Pt. Sinko Prima Alloy, and Zulimand—and two pulse oximeter manufacturers—Elitech and Fyrom International. The remaining manufacturers are from a variety of countries, with China, South Korea, and the United States most represented, as shown in Figures 2 and 3. Similar to pulse oximeters, the majority of oxygen concentrator manufacturers (17) have approval from a stringent regulatory authority in addition to Indonesia's regulatory body.

Of the domestic manufacturers, one company in particular, Fyrom International, has taken an interest in safe oxygen delivery and has worked with a prominent local neonatologist, Dr. Rinawati Rohsiswatmo, to develop a new, portable air/oxygen blender and continuous positive airway pressure device, the MIX-SAFE, designed to help prevent retinopathy of prematurity (ROP) in newborns who need oxygen. This device is unique in that it can be used in a hospital or health center setting but also has portable, cylinder-based air and oxygen supplies so it can be used to transport infants during referral. The result of a unique collaboration between industry and clinicians, the MIX-SAFE is currently listed on the e-Katalog (described in the following section) and marketed in Indonesia through distributors. As of November 2016, the national MOH had purchased 470 MIX-SAFE devices for distribution to health facilities. Fyrom produces an oxygen concentrator that is available on the e-Katalog. The company has also created a model of the MIX-SAFE that includes pulse oximetry and a battery-operated oxygen concentrator.

### Procurement landscape

Device availability is supported by the government-sponsored, web-based procurement system managed by the national procurement agency, Lembaga Kebijakan Pengadaan Barang/Jasa Pemerintah (LKPP), in partnership with the MOH Pharmacy Directorate. This e-procurement platform was launched in 2012 with two primary functions: (1) to provide a direct procurement platform for local procurement units (e-Katalog) and (2) to provide an electronic tender platform to suppliers (Sistem Pengadaan Secara Elektronik). Since 2012, central government agencies and regional governments are required to make 75 percent and 40 percent, respectively, of their purchases using the e-Katalog system.

The government e-Katalog offers more than 73,000 items across 54 product categories. The medical devices category lists more than 13,000 items, including 13 oxygen concentrator models from 10 manufacturers and 21 different pulse oximeter models from 12 manufacturers. E-Katalog utilization by local procurement units was not available at the time this report was written. However, qualitative interviews with stakeholders suggest there are opportunities for expanded use of the platform. Interviews indicated that this slow uptake could be attributed to two potential factors: the limited number of devices available and the method in which devices were initially added to the e-Katalog. The limited number of devices is due to the fact that pharmaceutical products were the initial focus of e-Katalog and medical device inclusion is just now catching up. The process for adding devices has also changed more recently. Previously, suppliers proposed product inclusions. Now, government institutions must request product additions. This change is expected to increase confidence in the quality of devices on the catalogue.

Indonesia is the only country in this global market assessment with an online procurement catalogue and ordering system. This system is a major step forward in transparency, increases the ability to negotiate price through pooled volumes, and ensures quality and accountability in a highly decentralized health system. The market impact of such an approach is considered significant, as this platform could potentially:

- Harmonize product variants to increase purchase volumes as well as simplify ongoing maintenance and spare parts purchases.
- Consolidate market intelligence to more effectively select appropriate products as well as negotiate on prices.
- Support continued decentralized decision-making with guide rails to optimize procurement.

There remain areas where the procurement system could be strengthened. For example, a global pricing analysis indicated there are opportunities for further price reductions for oxygen concentrators and pulse oximeters listed on the e-Katalog. This is despite LKPP's limits on the margins distribution companies may charge. With Indonesia's large population and a decentralized procurement system in place, it may be possible to more effectively leverage coordinated ordering to further reduce device prices. However, a number of hospitals in Indonesia continue to procure devices independently of the e-procurement system, which limits the ability to pool device volumes.

### Regulatory landscape

The registration process for companies interested in selling products in Indonesia is managed by the MOH Directorate General of Pharmaceutical Services and Medical Devices. Indonesia follows the European Union model of risk-based classification. Classification under this system includes three classes ranging from low risk (1) to high risk (3). Oxygen concentrators and pulse oximeters are both classified as 2b/C. As Table 2 shows, the timeline to a class determination for any device is 7 days and the evaluation timeline is 100 days for a class 2b/C device. The cost to register a class 2 device is 3,000,000 rupiah (Rp; approximately US\$22).

Table 2. Regulatory approval timeline and cost.

Class	Class determination process	<b>Evaluation process</b>	Cost
1/A	7 days	45 days	Rp 1,500,000
2a/B	7 days	90 days	Rp 3,000,000
2b/C	7 days	100 days	Rp 3,000,000
3/D	7 days	120 days	Rp 5,000,000

Source: Directorate General of Pharmaceutical Services and Medical Devices, Medical Device Distribution Licensing Service Guideline; 1 USD to approximately 13,333 Rupiah. Oanda.com. Retrieved May 1, 2017.

Indonesia has implemented a single web-based registration system that integrates all requirements. Through this portal, it is possible to apply for a registration number, production license, and distributor's license. Registration requirements include compliance with International Organization for Standardization standard 13485 and good distribution practices. Indonesian regulations also require a local distributor licensed through the MOH. Marketing authorization is based on an assessment of safety, quality, and efficacy of a product, and the license is valid for five years. Spare parts and accessories are not required to be registered and will be associated with the product's registration number.

#### Guidelines

Oxygen is listed on the National List of Essential Medicines under general anesthetics, and oxygen and pulse oximeters are included in facility guidelines that describe the services and equipment that should be available at each level of the health system. For puskesmas, guidelines currently call for oxygen cylinders in emergency, obstetric, postpartum, and general inpatient wards. Oxygen concentrators are specified as part of infant resuscitation equipment. It should be noted that while acute respiratory infection timers are required in the postpartum care set, pulse oximeters are not part of the standard equipment for puskesmas, according to MOH regulation 75 (2014) on public health centers (puskesmas).

The MOH has created a regulation, MOH regulation 56 (2014), that describes the equipment that should be included in hospitals. These regulations call for oxygen cylinders, oxygen concentrators, and pulse oximeters in various wards. In total, the guidelines call for nine oxygen sources and 12 pulse oximeters across 24 different wards, including emergency, obstetrics, pediatrics, and internal medicine. However, based on our analysis of regulation 56, it is not explicitly listed that pulse oximetry should be present when oxygen is being administered.

Recommendations to improve guidelines include expanding the use of oxygen on the list of essential medicines to include the treatment of hypoxemia. This will encourage facilities to place a higher priority on oxygen availability outside of the operating theater. Further, including pulse oximeters in puskesmas guidelines and clarifying locations of oxygen and pulse oximeters in hospitals to ensure they are colocated at all times would help to increase safe oxygen delivery.

#### Quantification of need

Due to the variety of oxygen delivery technologies available in the market and the range of settings in which they are used, thoughtful analysis of product mix and deployment is essential when designing health system solutions. Indonesia's diverse geography and the extremes between modern cities and difficult-to-access rural communities create a wide range of oxygen requirements. Depending on variables such as available infrastructure, each area will require a unique combination of products to meet the need in the most efficient manner.

PATH developed two models to quantify the need and potential demand for oxygen in Indonesia:

- The first model uses the average number of beds in each type of facility, as well as the number of facilities in the health system and the average oxygen consumption for various types of beds, to estimate the total oxygen need.
- 2. The second model is based on the data collected through the ASPAK database to estimate the gap in existing oxygen availability and potential demand based on prescribed national guidelines.

Both models are useful tools to assist in planning scale-up of safe oxygen delivery. Estimates such as these help determine the gaps in equipment availability and allow decision-makers to determine the number of devices required to meet the need. These calculations can then help the user determine the amount of time or budget allocation required to eliminate gaps based on priorities and available resources.

# Estimating the total need: Quantification based on number of beds and facilities in the public health system

PATH developed a quantification model to estimate the amount of oxygen and number of pulse oximeters required to meet the estimated oxygen need in the public health care systems of several high-priority focus countries—Indonesia, India, Ethiopia, and Kenya. This model uses the same estimation approach industry uses to determine oxygen needs. It can be used for an individual facility, district, province, or for an entire country. In Indonesia, PATH used facility data from the *Indonesia Health Profile 2014* to determine the average number of beds in the different types of health facilities and the total number of facilities. Using this information, the model calculates the estimated amount of oxygen in liters required by each level of facility annually, as shown in Table 3.

As an example, Table 3 also shows the number of cylinder refills and the associated cost to meet the annual need for each level of facility. It should be noted that this example assumes oxygen is only

available in facilities with inpatient capabilities and therefore excludes puskesmas that do not have beds. This model can be modified to include adjustable inputs that are helpful as a decision tool. For example, the percent of facilities that have access to oxygen can be varied to estimate the current coverage of oxygen as well as the requirements to increase coverage to a desired goal. Depending on available infrastructure and resources, there are many different product mix solutions that can be deployed to meet this need.

Using the total number of facilities reported by the *Indonesia Health Profile 2014* and the calculations in Table 3, the total amount of oxygen required to meet the need of the public health system in Indonesia is estimated to be almost 328 billion liters of oxygen each year.

Table 3. Facilities and average oxygen need.

Facility type	Average number of beds	Bed type	# beds by type*	Total O <sub>2</sub> liters per minute (LPM) <sup>†</sup>	Annual oxygen need per facility (liters/year)	Estimated cylinder refills, per year, per facility <sup>‡</sup>	Estimated cost to provide cylinders <sup>§</sup> (US\$)
Puskesmas with	7	General beds	6	5	7,621,200	1,270	\$6,355
beds	,	Critical beds	1	10		1,270	<del>30,333</del>
District hospitals 128	120	General beds	109	82	142,831,800 23,80	22 006	\$119,030
		Critical beds	19	190		23,800	
Specialty hospitals	60 ·	General beds	51	38	67,408,200	44 225	¢50 175
		Critical beds	9	90		11,235	\$56,175

<sup>\*</sup>Assumes 85 percent general beds, 15 percent critical care.

Quantification for pulse oximeters is tied to the type of facility and number of wards or beds. Current regulations do not list pulse oximetry as necessary equipment for puskesmas. Based on MOH regulation 56, each district hospital and specialty hospital should have at least 12 pulse oximeters.

Again, using the total number of facilities reported in the *Indonesia Health Profile 2014* and the number of pulse oximeters required by regulation, almost 28,000 pulse oximeters would be required to meet the need. If each puskesmas were also required to have one pulse oximeter, this number would rise to 38,000. These calculations assume no oxygen or pulse oximeters are currently available in the system. However, by combining these estimates with ASPAK data (facilities with pulse oximeters, oxygen cylinders, concentrators, or plants and the functional status of those items), the gap in availability can be determined. The gap in oxygen availability can then inform a strategy to address the gap and improve access to safe oxygen delivery.

#### Estimating gaps in availability: Quantification based on existing availability and facility standards

PATH worked with the MOH to examine Indonesia's ASPAK database and understand the gap in availability for oxygen delivery devices as well as other medical devices. At the time of analysis, July 2017, the ASPAK database contained thousands of facility infrastructure and health equipment types. As

<sup>† 0.75</sup> LPM per general bed; 10 LPMs per critical bed.

<sup>‡ 6</sup> m³ cylinder.

<sup>§</sup> Assumes refill cost of US\$5.

an example, a search of oxygen concentrators in the system results in a list of health facility levels by province that have and do not have this device. Data can be downloaded to provide additional details: equipment count, number functioning, capacity, district, facility name, and facility ID. With permission from the MOH, PATH used this database to help analyze current access to safe oxygen delivery across Indonesia. For the purposes of this analysis, access to oxygen is defined as having at least one of the following: oxygen set, oxygen concentrator, oxygen generation system, oxygen manifold system.

As expected, higher levels of the health system (hospitals) have greater access to oxygen. Puskesmas also have a relatively high percentage of facilities with access to oxygen, although nine provinces have a particularly low percentage of puskesmas with beds with low access to oxygen (Figures 5 and 6).

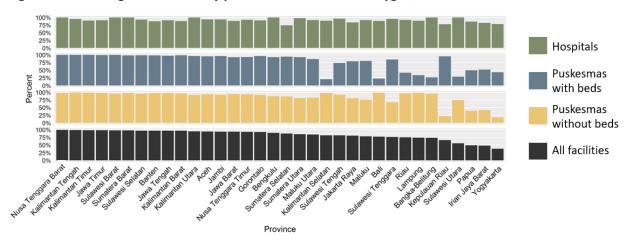
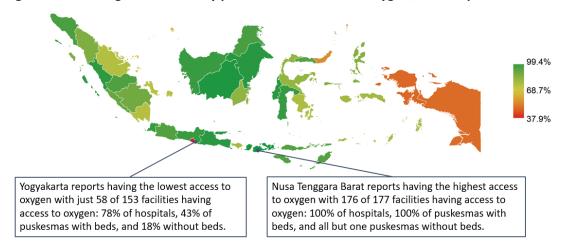


Figure 5. Percentage of facilities by province with access to oxygen, bar chart.





Among the 84 percent of puskesmas with beds that report having some access to oxygen, ASPAK data suggest the average facility <u>does not</u> have enough oxygen to meet its needs of 7 to 9 LPM. PATH compiled an analysis to compare the annual oxygen output available from existing equipment with the estimated annual oxygen need (based on the average number of beds and oxygen output in liters per

minute) at a puskesmas with inpatient services and found that most puskesmas are estimated as having a shortfall in oxygen access (Table 4). This shortfall could be met by scaling up an appropriate number of oxygen cylinders or oxygen concentrators.

Table 4. Estimated annual oxygen access shortfall in puskesmas with beds.

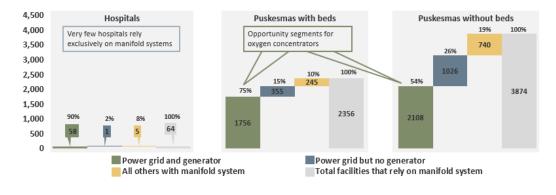
	Puskesmas with beds (number of facilities)			
Oxygen source	Cylinder-based manifold system only (2,189)	Cylinder-based manifold system and oxygen concentrator (855)		Oxygen concentrator only (205)
Average number of cylinders	5	6	NA	NA
Average number of concentrators	NA	NA	1	1
Annual oxygen output (liters)	1,560,000	1,872,000	2,526,923	2,526,923
Total annual oxygen output (liters)	1,560,000	4,398	3,923	2,526,923
Annual oxygen need (liters)	7,621,200	7,621,200 7,62		7,621,200
Annual shortfall (liters)	6,6061,200	3,222	2,277	5,094,277

#### **Assumptions:**

- Estimates are based on 100 percent occupancy and usage rates to ensure oxygen delivery device procured can supply maximum health facility patient load.
- Cylinder output is estimated using a 6,000 liter cylinder refilled once per week.
- Oxygen concentrator output is estimated using a 5-LPM device operating 50 weeks a year.

In particular, puskesmas that rely on oxygen manifold systems, are attached to the national power grid, and have a power generator represent a segment of the market where a shortfall in access could be made up using cost-effective oxygen concentrators. Given adequate power supply, rational procurement and power costs, and cylinder refill and delivery costs that are not abnormally low, oxygen concentrators are, in general, more cost-effective than cylinder-based manifold systems. Figure 7 illustrates the segment of the market where oxygen concentrators may provide a viable and cost-effective solution to safe oxygen delivery in puskesmas.

Figure 7. Health facilities that rely exclusively on manifold systems for oxygen.



Although most puskesmas have access to some oxygen via oxygen manifold systems (cylinders), the vast majority do not record having the equipment necessary to deliver oxygen safely—pulse oximeters or

bedside monitors. According to ASPAK, across Indonesia, 10 percent of facilities have pulse oximeters—72 percent of hospitals, 3 percent of puskesmas with beds, and 6 percent of puskesmas without beds. Of the 1,114 pulse oximeters recorded in the ASPAK dataset, 662 are in hospitals, 111 are in puskesmas with beds, and 341 are in puskesmas without beds. Figure 8 illustrates the gap in access to pulse oximeters or bedside monitors. Blue and yellow bars indicate the market segment where these devices might add considerable value.

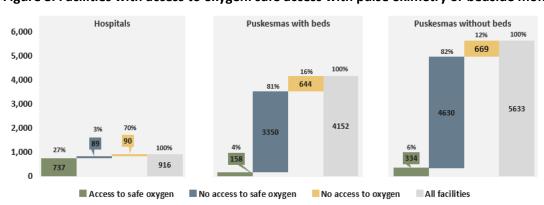


Figure 8. Facilities with access to oxygen: safe access with pulse oximetry or bedside monitors.

The data recorded in ASPAK provides considerable insight into current equipment access. Using ASPAK data, national equipment guidelines, and electricity access data, one can determine where there might be opportunities for improving access to different types of equipment (e.g., electromedical or non-electromedical) at each health facility. One key limitation of this analysis is that ASPAK data does not record information about device manufacturer, brand, or installation date. So, while data may indicate widespread availability, the appropriateness and consistency of that availability for each level of the health system is unknown. That is, there is no data on the refill frequency for oxygen cylinders in a facility or different brands of equipment to determine how well they meet technical specifications. ASPAK records only the number of cylinders or oxygen concentrators available. Similarly, analyses that compare existing access with estimated need, as in Table 4, are not a standard for ASPAK and require pairing inventory data with quantification models. Modifications to ASPAK could further its existing utility for health care decision-makers in Indonesia.

#### Maintenance

Medical device maintenance is a challenge in Indonesia due to great variation between regions and types of equipment. Despite this, efforts are underway to address the challenge of maintenance. Draft guidelines are under review to establish units for maintaining medical devices in a specific geographic catchment area. Maintenance units are small teams based at the provincial and district levels to manage maintenance of medical devices in public health facilities. Provincial units consist of roughly ten individuals—one administrator, three to four calibrators, and four to five technicians—and will have capability to manage more complex technologies. District units will be smaller and will handle more routine maintenance and repairs. The maintenance guidelines are planned to begin a pilot phase in 2017/2018.

Challenges to the success of this model include ensuring sufficient budget is allocated for labor and transportation as well as maintaining stocks of replacement parts. Another challenge is that hospitals function independently of the district health offices, which complicates coordination across the multiple tiers of the health system. Moving forward, it will be important for the MOH to incorporate the ASPAK system with routine and corrective maintenance services to effectively manage medical device assets throughout the health system.

### Financing landscape

Financing for medical devices comes from multiple sources: the national government, provincial governments, district governments, and individual health facilities. Funds from the national government are typically tied to MOH vertical disease programs such as malaria, tuberculosis, and HIV, which are also responsible for forecasting required quantities. At the provincial and district levels, funds are allocated by the provincial and district health offices, which are responsible for all disease areas as well as forecasting. The exception is family planning, which is not primarily under the MOH. Instead, it is provided by BKKBN (Badan Kependudukan dan Keluarga Berencana Nasional [National Family Planning Coordinating Board]) through centrally linked provincial-level offices. Health facilities also have the ability to procure pharmaceuticals and medical devices to ensure they are made available. Due to the fragmented funding sources and decentralized decision-making, it is necessary to work with stakeholders at all levels of the health system to make progress on a particular intervention.

# Key stakeholders and roles

There are many stakeholders in the Indonesian health care system that impact access to safe oxygen delivery. See Appendix B for a diagram that describes how different stakeholder groups relate to one another.

- Industry: There are a variety of stakeholders in the medical device industry in Indonesia. Medical gas distribution and installation companies play a prominent role in oxygen delivery. However, given the costly nature and logistical challenges servicing remote regions of the country, access in these areas remains less consistent. The same limitations are true for medical device distributors that sell oxygen concentrators and pulse oximeters. Further work needs to be done to align business incentives with public health objectives to improve access in all parts of the country.
  - Manufacturers: Indonesia's medical device industry is growing but is not as well established as the pharmaceutical manufacturing sector. However, industry growth is a national priority and growth in the device industry is expected to continue. There are currently three oxygen concentrator manufacturers (Pt. Sinko Prima Alloy, Fyrom International, and Zulimand) and three pulse oximeter manufacturers (Elitech, Fyrom International, and Sani Tiara Prima) in the country. To note, Fyrom International utilizes Masimo pulse oximetry technology in its devices and manufactures the aforementioned MIX-SAFE device for air/oxygen blending.
  - Medical device distribution companies: There are a number of medical device distributors in Indonesia. These companies play an integral role between manufacturers and end users, as Indonesian law does not allow manufacturers to distribute their own products. Distributors are typically responsible for registering a product with regulatory bodies, interacting with purchasers, and completing any after-sales services required. Due to the challenges associated

- with Indonesia's unique landscape, it is common for a manufacturer to contract with many distributors to extend sales across different regions of the country.
- Medical gas distribution and installation companies: Medical gas production and distribution companies supply the majority of oxygen in Indonesia. The largest providers of medical oxygen are Aneka Gas, Linde, Air Liquide, and Air Products. These companies provide oxygen in both gas and liquid forms. Contacts estimated that 80 percent of oxygen produced is used for industrial purposes, and 20 percent is for medical use. In addition to the medical gas production companies, there are a number of companies that install medical gas piping systems. The medical gas installation companies have a professional organization that plays a prominent role in shaping policy around oxygen access, which could be why there is a bias toward oxygen cylinder–based systems.
- **LKPP:** Indonesia's procurement agency, LKPP, was formed in 2007 as a non-ministerial government agency. LKPP reports directly to the president of Indonesia and is coordinated by the National Development and Planning Agency. LKPP is responsible for management of the e-procurement system, which harmonizes government purchases including procurement of medicines and medical equipment. Although requests can be made to procure outside of the e-procurement system, LKPP plays an important role as intermediary between suppliers and health facilities. LKPP manages product inclusion on e-Katalog, negotiates prices for products on e-Katalog, and coordinates orders across health facilities before placing requests with suppliers.
- Medical professionals and teaching hospitals: Medical professionals are well respected in the Indonesian health system and play a key role in disseminating guidelines. This is best evidenced for safe oxygen use by Dr. Rinawati Rohsiswatmo, a leading neonatologist in Indonesia. Dr. Rinawati realized that the nature of available oxygen systems was linked to an increased prevalence of ROP among newborns, a condition that can lead to retinal detachment and blindness. Over-oxygenation of premature infants increases the risk of ROP, and the increase in its incidence was likely an unforeseen consequence of increased oxygen use in health facilities without adaptation and proper monitoring for safe delivery to infants. Dr. Rinawati has collected important evidence for this trend and increased national awareness on this issue. As a result of Dr. Rinawati's work, Indonesia now has a stronger focus on ensuring safe oxygen delivery among newborns, and a unique air/oxygen blender product, the MIX-SAFE, was developed locally. Her work also made a strong case for improved access to pulse oximetry and safe oxygen delivery training programs.
- Ministry of Health: The national MOH has many directorates and sub-directorates. While oxygen
  could fall under the remit of many of these, as of 2016 there were no coordinated efforts for
  improving access to safe oxygen delivery. Since 2017, the Health Facilities Directorate has taken on a
  leadership role in coordinating national plans to ensure consistent access to safe oxygen delivery
  with other ministry directorates. The key units whose responsibilities include oxygen and their
  respective roles are described below.
  - Health Service Facility Directorate: The Health Service Facility Directorate is a valuable partner in improving access to oxygen as it is leading much of the national coordination to establish a national strategy for ensuring access to safe oxygen delivery. The Directorate is made up of three groups that are responsible for preparing oxygen gas regulations and the regulation stating that all health centers must have oxygen therapy available. The latest set of oxygen gas regulations was published in February 2016 and includes oxygen concentrators. However, the language around available oxygen sources could be clarified to better define oxygen generation technologies.

The Health Service Facility Directorate also collects information on the locations and working status of medical devices in the public health system. The ASPAK database is a valuable resource to understand the gap in availability for oxygen delivery devices as well as other medical devices. It is also informative in determining an optimal oxygen deployment strategy based on electricity availability.

o **Family (child and maternal) Health Directorate:** The Family Health Directorate is primarily focused on asphyxia (which accounts for about 30 percent of neonatal conditions) and views oxygen as a treatment for pneumonia (which is the responsibility of the Respiratory Disease Sub-directorate) and not necessarily within its infant illness focus. However, IDAI reported that the Family Health unit had recently purchased 470 MIX-SAFE devices. Information on the deployment of these devices was not available.

One potential link this directorate has to safe oxygen delivery is a large United States Agency for International Development—funded maternal and child health project—Expanding Maternal and Newborn Survival. This project focuses on neonatal health and could be leveraged to increase treatment for neonates and conditions associated with prematurity.

MOH Respiratory Disease Sub-directorate: The Respiratory Disease unit, which is responsible for management of pneumonia, has procured and distributed 538 oxygen concentrators over the last five years. It has also procured 750 pulse oximeters over the last three years. While this is an impressive start, there is still much work to be done to meet the needs of the approximately 8,000 remaining health centers that require oxygen concentrators and pulse oximeters.

The Respiratory Disease Sub-directorate also recently worked with the WHO Family Health unit to update WHO's 2011 guidelines, *The Clinical Use of Oxygen in Hospitals With Limited Resources: Guidelines for Health-Care Workers, Hospital Engineers and Managers.* These guidelines are translated to Bahasa Indonesia and are ready to print and distribute. The Respiratory Disease unit is in need of support to operationalize these guidelines, to conduct training on safe oxygen delivery, and to better monitor devices in the field.

This unit has also conducted a number of surveys of the respiratory disease field situation, including the provision of oxygen. Such data would be a valuable asset in helping to identify gaps in access and in developing a national oxygen strategy.

- Pharmacy Health Equipment Registration unit: This Pharmacy Health Equipment Registration unit is responsible for the registration of all medical equipment and the licensing of all medical equipment suppliers. This medical equipment registration process is well documented and understood. As stated above, a number of oxygen concentrators and pulse oximeters are listed on the e-Katalog system, which is run by the LKPP in partnership with the MOH.
- Professional organizations: Professional organizations in Indonesia play an important role
  establishing national medical standards and treatment guidance, conducting training, collecting
  baseline data for monitoring and evaluation efforts, and lobbying for policy change. Three
  associations that have a particular interest in safe oxygen delivery are IDAI, PDPI, and IKATEMI. IDAI
  and the PDPI have expressed interest in supporting national efforts to increase access to safe
  oxygen, including oxygen for chronic obstructive pulmonary disease and asthma, in the public and
  private health sectors.
- **UNICEF:** UNICEF's Supply Division is generally less active in Indonesia. This may be due in part to the country's middle-income status and, in general, less reliance on external financing and technical

assistance. As such, much of UNICEF's work has focused on building capacity in lower-income portions of the country, including Eastern Indonesia. UNICEF worked with IDAI to revise the standard of newborn care to include oxygen. UNICEF also partnered with the pediatric, nurses, and biomedical engineer associations to build capacity within health centers for nurses to maintain medical devices. Another relevant UNICEF program was the pilot of a mobile maintenance program for medical equipment. UNICEF has considerable experience working in Indonesia, with several offices in key locations, and could be instrumental in identifying solutions for the more remote regions of the country.

• World Health Organization: The WHO Child Health RMNCAH unit is a strong advocate for improved access to oxygen in Indonesia. The WHO Indonesia office has worked in the safe oxygen delivery space for a number of years and has spearheaded development of seminal guidelines such as *The Clinical Use of Oxygen in Hospitals With Limited Resources: Guidelines for Health-Care Workers, Hospital Engineers and Managers*. This 2011 document was updated and translated into Bahasa Indonesia in 2016 in partnership with the MOH Respiratory Disease Sub-directorate and will be a valuable resource to increase access to oxygen in Indonesia. However, the Respiratory Disease Sub-directorate requires additional support to organize stakeholders and print and disseminate the document. Additionally, the WHO RMNCAH unit is supporting a trial in a top referral hospital to provide evidence that pulse oximeters improve the quality of care for newborns.

Other potential WHO partners include the Health Systems unit and the Emergency unit. The Health Systems unit is interested in supporting access to health technologies and would be a valuable partner, as oxygen is a cross-systems issue. The Emergency unit is primarily focused on influenza surveillance and not on respiratory illness, so oxygen would not fall within its remit despite the interest and activity of its counterpart within the MOH, the Respiratory Disease Sub-directorate.

# **Market analysis**

Market dynamics is a set of skills and approaches that are used to evaluate access to products and services as a function of regular interactions among key stakeholders (e.g., producers, purchasers, and consumers) on the supply and demand sides of the market. Interactions are assessed by the effectiveness and efficiency of key attributes of market health: affordability, availability, assured quality, appropriate design, and awareness. In global health, market analyses help inform market shaping interventions where time-bound investments are made to proactively influence market conditions in order to improve health outcomes. These investments are typically made after the current market is thoroughly assessed, key market inefficiencies are identified, and potential interventions to address inefficiencies are shortlisted by their feasibility and potential for positive impact.

Market shaping efforts in global health seek to support sustainable access to medicines and technologies by catalyzing new market development and/or improving existing ones. The PATH team is using a market dynamics perspective to identify potential methods for improving access to oxygen in Indonesia. Each of the market attributes assessed are described in Table 5 below.

Table 5. Summary of strengths and weaknesses in the market.

Market area	Strengths	Weaknesses
	The strategy the national MOH has used includes procuring oxygen concentrators for community health centers in selected provinces/districts to sensitize decision-makers to the technology.	The WHO clinical use of oxygen document was never disseminated to the intended audiences.  The language in the national medical
	WHO Indonesia has been active in the oxygen space for some time. In 2011, WHO published <i>The Clinical</i>	gas regulations was left intentionally vague to benefit members of the oxygen cylinder industry.
AWARENESS  Extent to which end users, health care	Use of Oxygen in Hospitals With Limited Resources: Guidelines for Health-Care Workers, Hospital Engineers and Managers, which was	Pulse oximeters are not included as standard equipment for health centers.
providers, and key influencers can make informed choices about product use.	updated in 2016 and translated into Bahasa Indonesia by WHO Indonesia for local use.	Most users have experience with oxygen cylinders and believe that oxygen delivery is synonymous with
	The MOH issued new medical gas regulations in February 2016.	cylinder-based delivery. However, there is poor awareness of other alternative oxygen sources and/or for planning multiple oxygen
	There are additional regulations that outline required medical equipment for hospitals and community health facilities; these include oxygen concentrators, oxygen cylinders, and pulse oximeters as standard equipment for hospitals.	sources (redundancy), which may be more appropriate for specific use cases; additional training needs for safe oxygen delivery are poorly understood.
	The e-Katalog transparently lists the retail price, government-negotiated price, and shipping prices for regions across the country.	Due to the logistical challenges in an island nation, shipping costs are substantial and often a key driver of the landed cost of medical devices.
AFFORDABILITY	LKPP, the national procurement	Spare parts are not stocked locally
Extent to which the price point maximizes market efficiency between payers and	agency, regulates the margins distribution companies may charge, which limits the mark-ups that result from multiple tiers in the supply	for medical equipment and require importing, often from Singapore, which can take weeks.
suppliers to support health outcomes.	chain.  Market prices for the public health sector are public information and so companies may be better able to assess the business opportunity given	In general, the prices of oxygen concentrators and pulse oximeters are much higher in Indonesia than in the global marketplace. For example, Nidek Nuvo Lite e-Katalog price = \$2,375; online at Vitality
		•

Market area	Strengths	Weaknesses
	Procurement units throughout the country can transparently compare devices, including features, price, and associated shipping costs, to effectively assess the value of products against alternative options.	Medical devices require a national marketing authorization as well as national approval for distributors to market said devices; both processes have separate fee structures.  Oxygen concentrators as compared
		to oxygen cylinders remain a substantial upfront capital expenditure; few procurement units compare the total cost of ownership of these two devices.
		It is unclear how successful the online procurement approach is at pooling procurement across health facilities, particularly for emergency orders.
	Registration processes for medical devices are clearly outlined for both facility and home-care products.  The online procurement catalogue (e-Katalog) negotiates and manages	Large-volume purchases made by the MOH are often for products that are not on the e-Katalog, which raises the question of how effective the e-Katalog is in practice.
AVAILABILITY  Capacity and stability of global supply to meet demand and consistency of local access at service	public-sector device prices and product selection.  The MOH, through the Respiratory Disease Sub-directorate, has procured oxygen concentrators (538) and pulse oximeters (750) for community health centers over the last five years.	The oxygen gas installation association has strong lobbying power with the MOH and influences policy decisions for oxygen deployment strategies; however, the association is not incentivized to serve the most remote, rural communities requiring medical gas.
delivery points.	The MOH Directorate of Family Health has procured 470 oxygen air blenders (MIX-SAFE) for neonatal resuscitation.  The MOH now requires all health facilities to report existing medical equipment to the ASPAK database.	Some feel oxygen concentrators could be appropriate for outlying islands, where the distribution system for cylinders is significantly delayed; however, those regions are a smaller segment of the market and lack the infrastructure to support equipment requiring electricity. There is little engagement with industry (manufacturers and distributors) to specifically
		incentivize remote distribution of safe oxygen delivery.

Market area	Strengths	Weaknesses
ASSURED QUALITY  Level of evidence that a product is consistently efficacious and safe.	Medical equipment maintenance regulation is set to be finalized and piloted in 2017/2018.  The MOH Directorate General of Pharmaceutical Services and Medical Devices has a clear process for device registration and quality assurance.	ASPAK does not include automated queries that enable key decision-makers to identify and track gaps in essential medical equipment at the different levels of the health system.  Estimates for enacting the national medical equipment maintenance regulation are ambitious and will take considerable time to staff and implement.  Budgeting for maintenance is scarcely considered.  Directorates within the MOH procuring equipment centrally do not coordinate maintenance across all devices.
APPROPRIATE DESIGN  Degree to which possibilities of technology maximize cultural acceptability.	Device appropriateness can be assessed for the public health sector using e-Katalog; an initial assessment would suggest that devices on e-Katalog are functionally appropriate, although expensive.	It is unclear which technical specifications facilities leverage for oxygen delivery devices and pulse oximeters; there may be an opportunity to harmonize standards.  The use case for pulse oximeters at puskesmas is not well defined; as such, it is unclear if devices on e-Katalog are suitable should pulse oximeters be added to the required device list for these facilities.

# **Recommended activities and next steps**

In general, oxygen and pulse oximetry are available in Indonesia. Due to strong demand for industrial gases, there is also a ready supply of medical oxygen in liquid and gas form. In addition, e-Katalog has a number of good-quality products available. However, oxygen availability in the public health system is highly dependent on a facility's geographic location, and pulse oximetry is limited to higher-level facilities. In remote areas like Papua and West Papua, supply chain/logistical challenges and limitations in available infrastructure (e.g., electricity access) make access to oxygen difficult.

There are a number of activities to strengthen the local market and increase access to safe oxygen delivery in Indonesia. These recommendations include the following activities:

- Working with local partners to finalize and disseminate The Clinical Use of Oxygen in Hospitals With Limited Resources: Guidelines for Health-Care Workers, Hospital Engineers and Managers.
- Determining the optimal oxygen product mix for remote settings.
- Expanding the use of oxygen on the list of essential medicines to include the treatment of hypoxemia.
- Including pulse oximeters in puskesmas guidelines.

Stakeholders in the MOH, WHO, professional organizations, and PATH are well positioned to undertake this work and have developed a plan to move forward. An initial scale-up plan was created in preparation for the Accelerating Access to Oxygen convening held in Dubai in November 2017 and shared during the final day of country planning.

#### A2O2—Accelerating Access to Oxygen Convening

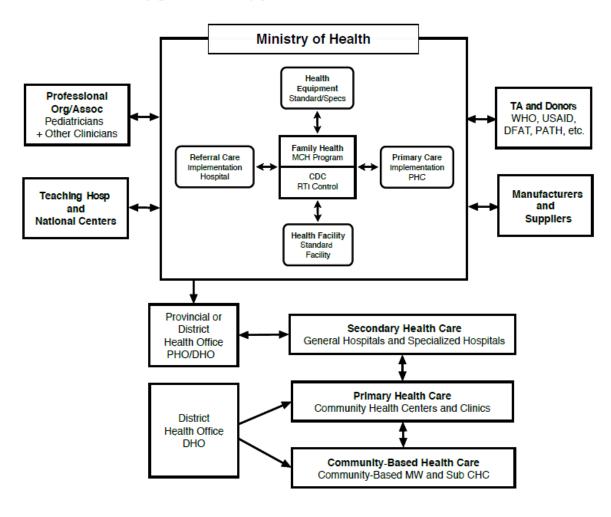
In November 2017, PATH held a stakeholder convening, with support from the Gates Foundation. This convening brought together industry representatives (manufacturers and distributors), country stakeholders from a variety of low- and middle-income countries (regulators, procurers, policymakers), and global partners (PATH, the Gates Foundation, UNICEF, WHO, CHAI) to share information and discuss opportunities for improving access to oxygen delivery technologies and pulse oximeters. This convening was an opportunity for stakeholders in Indonesia to share ideas with their peers and discuss next steps within the delegation. Indonesia was well represented at this meeting. The MOH sent four representatives including the heads of the Pneumonia and Clinical Engineering Directorates and the director of the Health Service Facility Directorate. Two individuals from LKPP, the chairman and the head of e-Katalog, attended. Additionally, the neonatologist that inspired the MIX-SAFE and three representatives from the local manufacturing company that produces it, PT Fyrom International, joined.

# **Appendix A. Contacts and interviews**

ORGANIZATION
Budi Kemuliaan Hospital
Global Systech Medika (GSM)
Ikatan Dokter Anak Indonesia (Indonesian Pediatric Society)
Ikatan Elektromedis Indonesia
(Association of Electromedical Engineering Indonesia)
Indonesian Society of Respirology
Jakarta Hospital for Maternal & Child Health
Lembaga Kebijakan Pengadaan Barang/Jasa Pemerintah (LKPP)
MOH Directorate Medical Devices Control and Household Supplies
MOH Directorate General for Drug and Medical Device Support
MOH Head of Standardization Section (Clinical Engineering)
MOH Health Service Facility Directorate
MOH Maternal, Newborn, Child Health Sub-directorate
MOH Respiratory Disease Sub-directorate
Pt. Binabakti Niagaperkasa
Pt. Fyrom International
Pt. Mandiri Jaya Medika
Pt. Mekar Abadi Pratama (Medical gas installation company)
Pt. Pendar Andhika Paramartha
Save the Children Indonesia/Jhpiego
UNICEF Indonesia
WHO Indonesia

# Appendix B. Indonesia stakeholder framework

# Oxygen Therapy Stakeholder Framework



## References

- 1. Child Health page. World Health Organization Country Office for Indonesia website. Available at <a href="http://www.searo.who.int/indonesia/topics/child-health/en/">http://www.searo.who.int/indonesia/topics/child-health/en/</a>. Accessed April 12, 2017.
- 2. Kode dan Data Wilayah Administrasi Pemerintahan (Permendagri No. 56-2015) page. Kementerian Dalam Negeri Republik Indonesia website. Available at <a href="http://www.kemendagri.go.id/pages/data-wilayah">http://www.kemendagri.go.id/pages/data-wilayah</a>. Accessed February 17, 2012.
- 3. Indonesia page. The World Bank website. Available at <a href="http://data.worldbank.org/country/indonesia">http://data.worldbank.org/country/indonesia</a>. Accessed April 12, 2017.