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

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Abbreviations

CDSCO	Central Drugs Standard Control Organization
CE	Conformité Européene (European Conformity)
CHAI	Clinton Health Access Initiative
CHC	community health center
FDA	Food and Drug Administration
HTA	Health Technology Assessment
IPHS	Indian Public Health Standards
ISO	International Organization for Standardization
LPM	liter per minute
MOHFW	Ministry of Health and Family Welfare
NHM	National Health Mission
NHSRC	National Health Systems Resource Centre
PHC	primary health center
PIP	Program Implementation Plan
PSA	pressure swing adsorption
RKS	Rogi Kalyan Samities
RMNCH+A	Reproductive, Maternal, Newborn, Child, and Adolescent Health
SNCU	Sick Newborn Care Unit
SpO_2	peripheral capillary oxygen saturation
UNICEF	United Nations Children's Fund
UP	Uttar Pradesh
UP TSU	Uttar Pradesh Technical Support Unit
US	United States
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. 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. In partnership with local stakeholders, four countries were selected for in-depth work: Ethiopia, India, Indonesia, and Kenya. The information in this country report focuses on India and is intended to guide key decision-makers in India 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. The information in this report was collected through a combination of desk research and in-country stakeholder interviews and observations.

Oxygen availability in India varies depending on the location and the type of facility. The services available and quality of care at different levels of the health system vary by state. This work focused primarily on the states of Bihar and Uttar Pradesh (UP) due to the high burden of pneumonia in those areas. In general, oxygen is more available at higher levels of care. 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, has prioritized distribution here. In remote areas, supply chain/logistical challenges make oxygen access more difficult. Additionally, many companies that supply oxygen cylinders and/or liquid oxygen limit their distribution radius to 50 kilometers. Beyond this, they will either not deliver or charge additional costs to deliver. Oxygen concentrators are in use in many facilities, but maintenance is often an issue due to dust, high temperature, and humidity.

Procurement for oxygen is typically done at the facility level; however, payments are often delayed. If payments for oxygen could be aggregated at the state level under a single or small number of procurement contracts, it would likely remove the administrative burden from the lower levels of the health system. It could also remove risk for the suppliers by increasing transparency in payment and, in turn, ensure more consistent supply.

Facility visits in UP and Bihar showed that while cylinders were available, they were often empty or unusable due to malfunctioning or leaking regulators. When asked, most facility staff would indicate that oxygen was available in the facilities when, in fact, it was not. Systems are needed to ensure that oxygen is not only present but also functional and properly used. It is important to emphasize this concept of functional availability when conducting assessments and developing training for health care workers.

Stakeholders in India acknowledge the value and importance of pulse oximeters; however, these devices are not frequently found outside larger health facilities. This could be improved if the Indian Public

Health Standards (IPHS), which list the medical equipment required at each level of the health system, were updated to include pulse oximetry in primary health centers (PHCs) and subcenters. Advocacy could also help by promoting the inclusion of pulse oximeters in existing clinical policies and guidelines (e.g., *Strengthening Facility Based Paediatric Care* and the *Facility Based Newborn Care Neonatal Resuscitation Module 2014*) to improve the amount of available funding and encourage regular procurement. Additionally, as with oxygen, the level at which pulse oximeter procurement is done depends on the dollar value of the procurement. If procurement were centralized at the state or district level, it could simplify maintenance and ordering for replacement probes and other parts.

In summary, the greatest challenge for India is not commercial availability of oxygen and pulse oximeters but, rather, ensuring the functional availability and rational use of both at the appropriate levels of the health system. There are many potential activities that could be undertaken to improve safe access to oxygen. These recommendations are described at the end of this report.

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 India 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[a] in India.

It should be noted that at the time in-country observations in this report were made (April 2016), this project was focused specifically on oxygen concentrators as the oxygen source. This early work was centered on understanding where and how oxygen concentrators could fill a gap in existing oxygen delivery approaches. As a result of the findings during this preliminary data analysis and subsequent work in Kenya and Indonesia, the scope of this project expanded to include a broader range of oxygen supply technologies, including oxygen plants, cylinders, and liquid oxygen. The rationale for this increase in scope was the realization that the gap in oxygen access was larger than oxygen concentrators alone could fill and that a practical solution to supply oxygen for the variety of needs in a public health system requires a holistic mix of available products.

[a] 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.

India 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 organizational partnerships and unique health systems in order to draw conclusions based on a range of scenarios and experiences.

PATH's oxygen work in India was led by representatives in PATH's India Country Program office in partnership with a project team based in Seattle, Washington. The country office in India 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 India and partnered with the country office to visit health facilities and meet with key stakeholders to discuss the current state of oxygen delivery, including any barriers and potential opportunities for improvement.

In-country work for this project began in February 2016 and is planned to continue through early 2018. At the time this report was written (November 2017), the team had collected more than 40 documents, visited 19 health facilities, and met with more than 50 stakeholders in the private and public sectors in Andhra Pradesh, Bihar, New Delhi, and Uttar Pradesh (UP). The full list of interviewed contacts is included in Appendix A. Findings from these meetings, combined with desk research and analysis of more than 40 documents, form the basis of this report. Due to resource limitations, this report does not include systematic input from a large sample of health facility staff.

Table 1. Focus country selection criteria.

Criteria	General description	Background details for India
Potential for impact	Assessment of the public health need based on key health metrics, including burden of acute respiratory infections, mortality ranking for children under five years old, etc.	India has the second-largest population in the world with more than 1.2 billion people.[*] This creates tremendous potential for impact. Deaths of children under five years old in the country are more due to pneumonia and severe diarrhea than all other infectious diseases. Pneumococcal pneumonia is responsible for an estimated annual 5.6 *lakh* (560,000) cases and 1.05 *lakh* (105,000) deaths in India. Respiratory infections, tuberculosis, malaria, and diarrheal diseases cause about one-quarter of all deaths in the country.[†] In addition, the population of India is increasingly experiencing a double burden of disease with an epidemiological transition toward chronic diseases.
Potential market size	Assessment of the local market opportunity based on population size, gross domestic product, qualitative assessment of local market maturity, etc.	India represents a large potential market based on its population size. Furthermore, the health care sector is growing at a compound annual growth rate of 16 percent and is expected to reach US$280 billion by 2020.[**] India is considered a key market by many companies due to its expanding population, the number of public and private hospitals

		under construction and equipped with medical devices, and the growing number of indications for which oxygen is prescribed.
Decision-making authority	Assessment of local decision-making authority, particularly for the procurement of medical devices (e.g., decentralized versus centralized).	India is a group of states and union territories. Each member of the union has its own set of rules, which are based on guidelines developed by the central government. Generally, health is a devolved responsibility for the states under each state's National Health Mission. The public health system is a three-tier structure of primary (subcenters and primary health centers), secondary (community health centers and district hospitals), and tertiary (medical colleges and advanced medical research institutes) facilities. The central government owns and manages the referral hospitals with specialized facilities (tertiary); the respective state governments control other referral hospitals, medical colleges, and the lower-level health care facilities.
Available financial resources	Assessment of financial resources available for health care services (based on health care spending as a percentage of gross domestic product, country income classification, etc.).	In the last several years, India has increased its public health expenditure; however, expenditure as a percent of gross domestic product remains low. Despite this, India is a lower-middle-income country and relies less heavily on donor financing. Procurement of medical devices is largely financed using domestic resources. Increased budget allocation and more efficient procurement of medical devices and after-sales services are needed to ensure consistent access.

* National Health Mission (NHM), Government of India. *National Health Profile 2017*. New Delhi, India: NHM; 2017.
† World Health Organization (WHO). *Management of Severe Malaria: A Practical Handbook*. 3rd ed. Geneva: WHO; 2012. Available at http://apps.who.int/iris/bitstream/10665/79317/1/9789241548526_eng.pdf.
** Indian healthcare sector to grow to $280 billion by 2020: Report. *The Economic Times*. Updated September 1, 2015. Available at http://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/indian-healthcare-sector-to-grow-to-280-billion-by-2020-report/articleshow/48742696.cms.

Status of safe oxygen delivery in India

The current state of safe oxygen delivery in India is described below. These findings are based on the PATH team's discussions with key stakeholders, including representatives from the India Ministry of Health and Family Welfare (MOHFW); the governments of Madhya Pradesh, Bihar, and UP; the World Health Organization (WHO); and the United Nations Children's Fund (UNICEF). A full list of stakeholders can be found in Appendix A.

Oxygen delivery methods

Oxygen sources, summarized in Figure 1, include cylinders filled with either liquid or gaseous oxygen or on-site oxygen generation. Oxygen gas cylinders come in a wide variety of sizes. They can be used to provide oxygen directly to the patient or to power a centrally located manifold system. Gas cylinders are generally refilled by transporting them to an oxygen depot that is supplied with oxygen from a larger oxygen-generation plant. Liquid oxygen tanks are typically larger, weighing at least 55 kg (120 lb) and standing more than 0.75 m (30 in) in height. They provide the supply for a centrally located manifold system. Liquid oxygen tanks are generally stationary and are filled by a provider using a filling truck.

Liquid oxygen plants require a large initial capital expenditure and generally provide oxygen for both industrial and medical use in a region. One benefit of liquid gas is that it is 99 percent pure oxygen, whereas cylinders filled at a plant using pressure swing adsorption (PSA) technology generally average 93 percent pure oxygen. However, from a medical point of view, there are no serious issues to preclude the use of 93 percent oxygen.[1]

Figure 1. Oxygen equipment available in India.

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 O_2

- Generally, in large facilities.
- Can serve 20 to 2,000 beds.
- Size can be customized to meet specific need.

Oxygen-generation devices using PSA technology produce a continuous stream of oxygen (85.0 to 95.5 percent pure) by separating the nitrogen and oxygen in 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. Oxygen-generation devices include portable self-contained devices, generally referred to as oxygen concentrators, and larger oxygen plants that, once installed, are not easily mobile. There are two basic types of oxygen concentrators, stationary and portable. Portable units are typically battery operated and lightweight, with oxygen output between 1 to 3 liters per minute (LPM), which is sufficient for one adult. Portable units are generally not considered suitable for facility settings in low- and middle-income countries as they cannot support multiple patients, are generally not suitable for patients under five years old, and are relatively expensive. Stationary units are still mobile but are larger and heavier (30 to 100 lbs) than their portable counterparts and have greater oxygen output capacity (3 to 12 LPM). A subcategory of stationary concentrators is larger still and is capable of output of up to 90 LPM. These larger oxygen concentrators can support multiple patients, and some can provide oxygen at high enough pressure to support peripheral devices, such as anesthesia and continuous airway pressure devices. PSA

technology can also be scaled to service an entire facility. These units are typically referred to as PSA oxygen plants, and they typically require a large amount of space. PSA oxygen plants are capable of supplying oxygen directly to a facility, filling cylinders, or both.

Oxygen in the news

In September 2017, pediatric mortalities at a teaching hospital in Uttar Pradesh caught the attention of media outlets around and outside of India. Initial reports indicated that these deaths were due to a lack of oxygen resulting from outstanding payments to the supplier. An investigation conducted by the MOHFW concluded that a lack of oxygen was ultimately not to blame but that there were issues resulting from lack of payment and potentially from improperly trained staff.

Unfortunately, disruptions due to lack of payment are not uncommon; the PATH team has recorded disruptions in oxygen supply due to delayed payment in other countries as well. Even in middle-income countries and/or at higher levels of care in the health system, ensuring consistent access to oxygen is often not straightforward.

Oxygen consumption requires routine monitoring and advanced supply planning all while choices are made to prioritize use of limited resources for many public health interventions. At the same time, payment delays limit suppliers' working capital and impacts their business viability. Due to these unique dynamics of oxygen supply, PATH began investigating medical oxygen as not only a drug but also an essential utility. This framing may help identify more efficient procedures for the budgeting and payment of oxygen.

Oxygen availability in India

Based on interviews with key stakeholders and observations in Bihar, New Delhi, and UP, most oxygen is currently delivered using cylinders, and availability varies depending on the state, type of facility, and whether the facility is located in a rural or urban area. In general, oxygen is less available in lower-level facilities (e.g., primary health centers [PHCs]) and in more remote areas. This is because lower-level facilities are often more remote, do not have reliable electricity,[b] and have limited financial and human resources as compared to larger facilities.

There are many potential reasons for a lack of oxygen in any facility. These reasons include:

- Logistical/supply chain challenges associated with refilling cylinders and replacement parts for oxygen-generation devices.

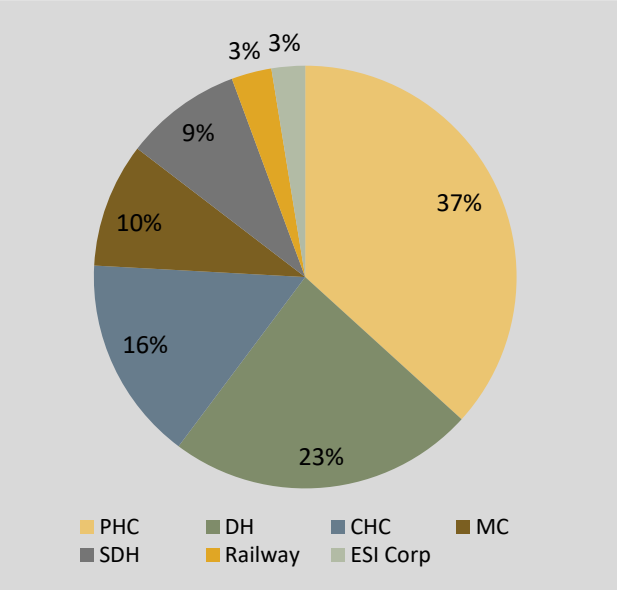
[b] Reliable electricity is defined as not only the presence of continuous electricity but also the absence of significant sags and spikes that can be detrimental to electromedical equipment.

- Expenses associated with refilling cylinders and/or maintenance/repair of oxygen-generation devices.
- Lack of health care worker training.
- Assumptions around the presence of a cylinder equating to oxygen availability.

Oxygen concentrators are in use in UP and Bihar. However, they are mainly found in higher-level facilities and are less common than cylinders. These are in place mostly because of programs that have required and/or provided oxygen concentrators. Most of the concentrators that the PATH team observed in Bihar were installed as part of the special newborn care unit and newborn corner programs piloted by UNICEF in 2008.[2]

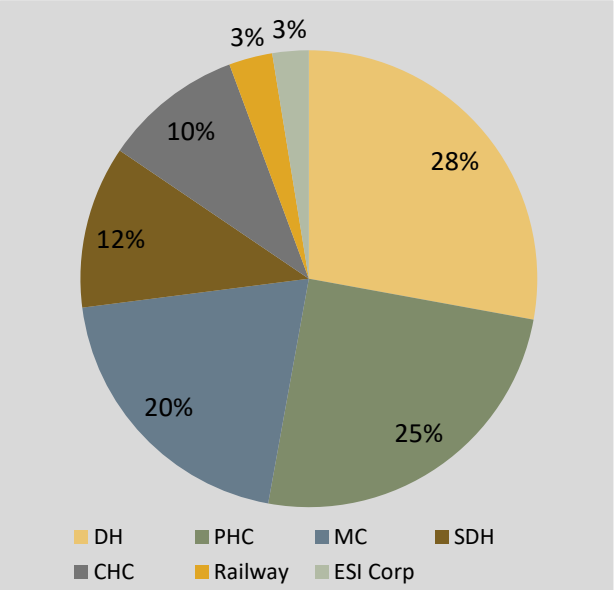
Using the publicly available information from the National Health Systems Resource Centre (NHSRC), PATH was able to determine which facilities and wards have oxygen concentrators and pulse oximeters most commonly. This information is summarized in Figure 2 and Figure 3**Error! Reference source not found.**. According to these data, most oxygen concentrators were found in PHCs. While 37 percent of concentrators in India are found in PHCs, the relative concentration to total number of PHCs (25,000) is still low. The highest concentration of oxygen concentrators was in district hospitals. The four most common wards where oxygen concentrators were found were the emergency ward, neonatal ward, surgical ward, and labor ward with 25 percent, 21 percent, 21 percent, and 16 percent of the total

Figure 2. Locations of oxygen concentrators in the public health system.



Abbreviations: CHC, community health center; DH, district hospital; ESI Corp, Employees' State Insurance Corporation; MC, medical college; PHC, primary health center; SDH, subdistrict hospital.

Figure 3. Locations of pulse oximeters in the public health system.



Abbreviations: CHC, community health center; DH, district hospital; ESI Corp, Employees' State Insurance Corporation; MC, medical college; PHC, primary health center; SDH, subdistrict hospital.

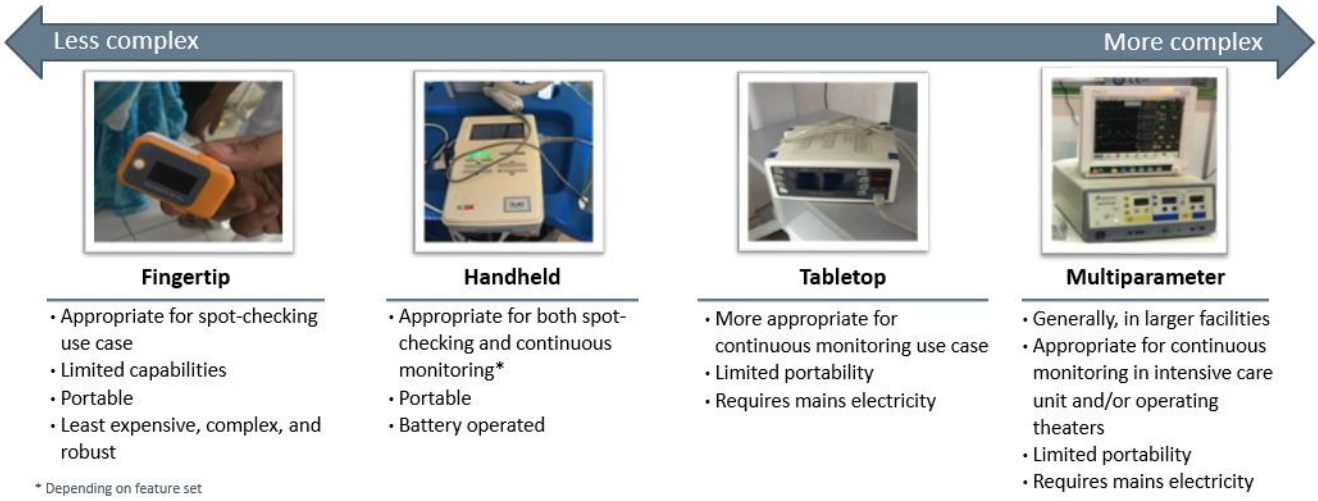
number, respectively.

Maintenance of oxygen concentrators remains a challenge, along with electricity availability and quality of electricity in more remote areas. However, the team observed oxygen concentrators in all states, including many that were still functioning after more than 10,000 hours of operation. The team did not have access to an oxygen analyzer, so it was not possible to assess the quality of the output of the machines beyond viewing the warning lights, which indicated proper operation.

Pulse oximetry

A number of different types of pulse oximetry devices were observed in the public health facilities visited. These devices ranged from simple fingertip pulse oximeters to multiparameter devices that provide information and continuous monitoring of several functions, such as blood pressure, heart rate, and SpO_2 (peripheral capillary oxygen saturation). The categories of SpO_2 monitoring devices are shown in Figure 4. As efforts to improve access to SpO_2 monitoring progress, it will be important to thoughtfully plan procurement based on the appropriate uses of the various options to ensure the use case is properly addressed.

Figure 4. Categories of SpO_2 monitoring devices.

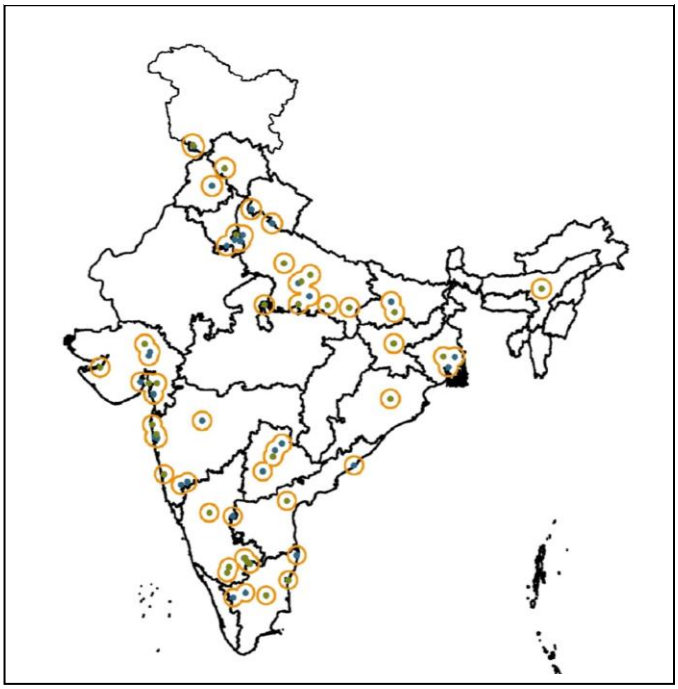


The importance and value of pulse oximetry is widely recognized by the stakeholders we spoke with in India. However, pulse oximetry is not widely available in the public health system; those oximeters that are available are found in higher-level facilities. According to the Indian Public Health Standards (IPHS) guidelines, pulse oximeters are only required as part of the equipment for noncommunicable diseases in community health centers (CHCs). Pulse oximeters are not mentioned in the IPHS guidelines as part of the required equipment for PHCs, newborn corners, or newborn stabilization units. Pulse oximetry is included in the IPHS guidelines for subdistrict/subdivisional hospitals and for district hospitals.

Looking at the NHSRC data for pulse oximeters in Figure 3, 28 percent of the total number of devices can be found in the 760 district hospitals. This is compared to 25 percent of the total spread throughout the more than 25,000 PHCs and 20 percent in the 5,000 CHCs. The relative concentration in both PHCs and CHCs is low, particularly when compared to district hospitals. Within the facilities, more than half (56 percent) of pulse oximeters can be found in the surgical ward. The next four most common locations are the neonatal (15 percent), labor (5 percent), emergency (5 percent), and intensive care (5 percent) wards.

Supply landscape

Figure 5. Locations of medical gas production and distribution in India.



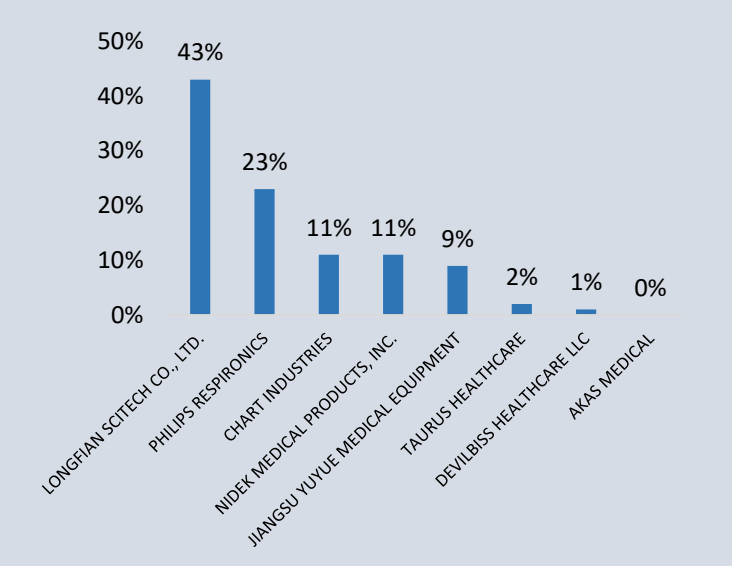
There are a number of medical device distributors and medical gas and liquid oxygen providers in India. As of August 2017, the project team conducted an initial assessment of gas cylinder and/or liquid oxygen suppliers in India and identified 30 providers. Figure 5 shows the location of the production and distribution hubs in blue and green, respectively. The orange circles indicate a 50-km distribution radius. Often, suppliers of cylinders and liquid oxygen do not deliver beyond 50 km from their oxygen plants or distribution centers. If they do, there is a surplus charged. Further landscaping is needed; however, this initial assessment illustrates potential gaps in service between the distribution radiuses that could cause limited oxygen availability.

There are many medical device distributors that carry a variety of oxygen delivery products in India. Some of these distributors are national, but a large number serve a single state or region. A preliminary analysis conducted by PATH using public NHSRC medical device inventory data (see the “Maintenance” section for more information) showed that there were more than 50 different brands of oxygen concentrators and more than 100 brands of pulse oximeters represented in just 16 of the total 36 states and union territories.

Further analysis of the public health sector market for oxygen concentrators suggested that two companies, Longfian Scitech Co., Ltd., and Philips Respironics, comprise 66 percent of this market segment (Figure 6). Of the leading 15 oxygen concentrator companies identified in the India device

inventory data, PATH confirmed that 11 had products with either United States (US) Food and Drug Administration (FDA) approval or bore the Conformité Européene (European Conformity or CE) mark; this indicated that the majority of devices being procured adhered to a stringent quality standard.

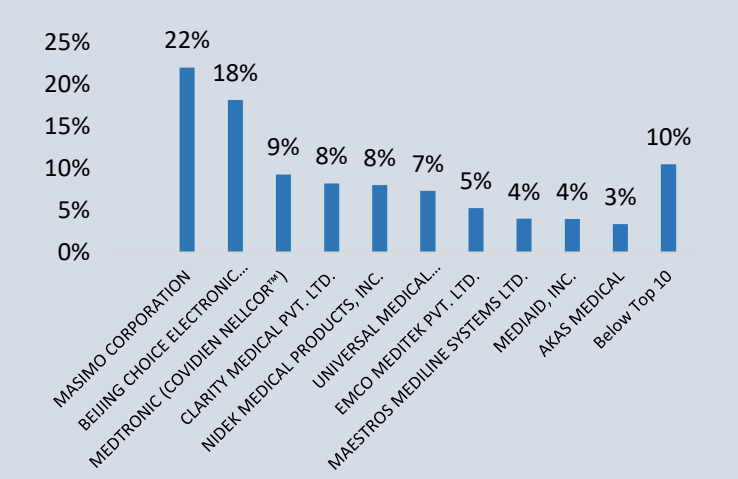
Figure 6. India oxygen concentrator public-sector market share by manufacturer, when known.



The public health sector market for pulse oximeters was slightly more fragmented in that five different manufacturers accounted for 65 percent of this market segment (Figure 7). Of the top 23 devices identified, 16 had either US FDA approval or the CE mark, also indicating that most devices met a stringent quality standard.

India currently imports 78 percent of its medical devices, but the country is working to reduce that number.[3] Medical devices are one of the 25 focus areas for the Make in India campaign. One of the goals of the Make in India program is to set up three manufacturing parks. The first of these parks has been set up in Andhra Pradesh. The Andhra Pradesh MedTech Zone offers a 33-year lease on manufacturing units and shared scientific and commercial facilities as well as on strategic support functions, such as human resources and technology transfer agencies.[4] In addition to subsidizing the cost to manufacture medical devices in India, the MedTech Zone and its associated Kalam Institute of Health Technology are focused on innovations to critical components of medical devices. These innovations may lower componentry costs, increase durability, and/or improve their appropriateness for low- and middle-income countries.

Figure 7. India pulse oximeter public-sector market share by manufacturer, when known.



Procurement landscape

India is a union of states and territories. As such, each member of the union has its own set of rules. The rules are based on the General Financial Rules that were developed by the Ministry of Finance, which guide the central government's procurement practices. Further guidelines for procurement are available in the *Manual on Policies and Procedures for Purchase of Goods*, but there is no central legislation governing procurement in India.

Furthermore, the public health system is a three-tier structure of primary (subcenters and PHCs), secondary (CHCs and district hospitals), and tertiary (medical colleges and advanced medical research institutes) facilities. The central government owns and manages the referral hospitals with specialized facilities (tertiary), whereas the respective state governments control the other facilities. Products procured through central and state health agencies typically require US FDA certifications. However, there are alternative options that may be appropriate for lower-risk classifications. One such option is ISO 13485 (International Organization for Standardization) certification, which indicates that the manufacturer has implemented a quality management system that adheres to international standards. It should also be noted that, in late 2016, the Indian MOHFW issued an advisory to all state governments and central health agencies to consider procurement of the medical devices approved by the Central Drugs Standard Control Organization (CDSCO; 14 devices in total[c]).[5]

Most public-sector hospitals procure independently and utilize tenders to establish annual supplier agreements and procure goods. The result is highly fragmented and poorly harmonized demand across a large number of small hospitals. By doing so, the purchase departments of hospitals play a crucial role in influencing the local market structure.[6] For medical devices, large volumes of concentrators and pulse oximeters would likely be procured at the state level. However, smaller quantities (or individual purchases) can be procured at the facility level, which further fragments demand. Decentralized ordering to this extent also makes it difficult to coordinate the use of technical specifications, leverage reference pricing, and efficiently provide training to end users and maintenance professionals. The result is that tenders are often granted in favor of the lowest-priced bidder. For example, a CHC could foreseeably buy a small volume of pulse oximeters without oversight from the state-procuring group, given their lower price point. This facility would then need training and maintenance for devices that, given the large number of suppliers, would likely be different than other facilities had procured. This could quickly become unmanageable given the number of facilities in a state or a district.

[c] Regulated devices include disposable hypodermic syringes; disposable hypodermic needles; disposable perfusion sets; in vitro diagnostic devices for HIV, hepatitis B, and hepatitis C; cardiac stents; drug-eluting stents; catheters; intraocular lenses; I.V. cannulas; bone cements; heart valves; scalp vein sets; orthopedic implants; and internal prosthetic replacements.

If product variants and supplier agreements were managed using a method like the online procurement catalog developed by the Government of Indonesia (e-Katalog), the market impact could be significant. An online 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.

Outside **coordinated ordering or harmonized procurement**, there remain areas where the procurement system could be strengthened. For example, **reference pricing** (e.g., a combination of past purchase prices, global retail prices,[d] and manufacturer-quoted price information) could provide a guide for procurement agents as they negotiate prices for oxygen concentrators, oxygen generation plants, and pulse oximeters. An **expanded centralized technical specification library** (i.e., an online repository managed centrally with updated technical specifications and key considerations for essential medical devices as the NHSRC has begun developing) could reduce the burden on local procurement agencies while also improving the appropriateness of procured devices. Both suggestions would require considerable sensitization of individuals that procure at all levels of the system, which would be a sizable undertaking. Many state procurers are unaware that a preliminary set of centralized technical specifications and reference resources exist, so further investment in these materials would require concurrent awareness building. In addition, while the aforementioned recommendations are specific to an assessment of oxygen delivery devices and pulse oximeters, they have broader applicability for state-level procurement of most medical devices.

[d] Sourcing global retail prices along with past purchase prices for different product use cases is key to ensure reference prices are not biased toward lowest-priced products rather than appropriate products for the intended use.

Guidelines

Guidelines are important for sustainable access to oxygen and pulse oximetry in the long term. Inclusion of safe oxygen delivery in key planning and guidance documents ensures that decision-makers consider oxygen and pulse oximetry when creating budgets and operational plans. Guidelines also provide insight into the government's priorities and plans and are a valuable resource for outside agencies as they try to support resource prioritization with supplemental funds. A review of two pediatric guidelines (*Strengthening Facility Based Paediatric Care* and the *Facility Based Newborn Care Neonatal Resuscitation Module 2014*) showed that oxygen and pulse oximetry are included in the recommended equipment and procedures. For example, *Strengthening Facility Based Paediatric Care* includes an oxygen source and pulse oximeters as part of the standard equipment for pediatric care in intensive-care, high-dependency, and standard pediatric wards for district hospitals.[7] Similar guidelines would be useful for the remaining facility types. The *Facility Based Newborn Care Neonatal Resuscitation Module* also calls for the use of pulse oximetry and oxygen blenders when providing oxygen to neonates.[8] However, these examples are only for neonates. There are additional opportunities in respiratory health and across the life course—particularly in maternal and geriatric health to specify safe oxygen delivery as a standard requirement.

Table 2. Summary of Indian Public Health Standards.

Facility type	Number of beds	Oxygen	SpO_2 monitoring
Subcenter	2–4	✓	✗
Primary health center	6	✓	✗
Community health center	30	✓	✓
Subdistrict hospital	31–50, 51–100	✓	✓
District hospital	100–500	✓	✓

Guidelines and strategies can also inform the type of equipment that should be included in each level of facility. India has several guidelines that provide guidance as to the types of services, equipment, and infrastructure that should be available at each level of the health system. These guidelines, such as the IPHS guidelines, are excellent resources and useful tools in helping to ensure the optimal quality level of health care. A review of the IPHS guidelines shows that oxygen is included in all levels of health facilities. However, pulse oximetry is not included for subcenters and PHCs in the guidelines. Minimum standards have also been created as part of the Clinical Establishments Act of 2010. These standards apply to private-sector facilities in the states where the act has been adopted. Similar to the IPHS, oxygen is listed as a requirement in all levels of health facilities. Pulse oximetry is only required in the higher-level

facilities.[e,9] As of November 2017, ten states and six union territories had adopted the Clinical Establishments Act.

While having guidelines that include oxygen and pulse oximetry is an important first step, the current IPHS and Minimum Standards for the Clinical Establishments Act list only where the oxygen should be available. The recommendation for the next iteration of these standards is to include more detail for where within a health facility oxygen is the highest priority as well as the types of oxygen sources best suited for those locations. It would be ideal to calculate the amount of oxygen needed by all the wards in a facility and recommend a solution to meet the total need. This is especially important as individual programs implement interventions that require oxygen. With its high-level view of the facilities and their requirements, the group responsible for the IPHS standards, the Directorate General of Health Services, could manage the oxygen requirements to ensure there is alignment across the programs. This would allow for more effective planning and more efficient oxygen delivery.

Regulatory landscape

The Medical Devices and Diagnostics Division of CDSCO (of the Directorate General of Health Services, MOHFW, Government of India) is responsible for the import, manufacture, sale, and distribution of medical devices as regulated in India under the provisions of the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945.[10] The Drugs Controller General of CDSCO is the regulatory authority that governs the medical device import regulations. The CDSCO has the online portal, SUGAM, for the import and registration of medical devices.

Oxygen concentrators and pulse oximeters are not listed as notified medical devices[11] and currently do not need to be registered as medical devices. However, new medical device regulations will go into effect in 2018 that could change the existing classification of notified medical devices. The classification of both devices may remain unchanged; however, this has not been formally communicated.[12]

The Medical Devices Rules, 2017, issued by CDSCO, will replace India's Drugs and Cosmetics Act on January 1, 2018. The 2017 rules aim to standardize and regulate the medical devices manufacturing industry, to be on par with international standards. The new rules will separate medical device regulation from pharmaceuticals and see that they are in conformity with the Global Harmonization Task Force framework.[13] The revised registration forms also comply with forms agreed upon by the Association of Southeast Asian Nations, even though India is not a member. The new rules adopt a risk-based classification scheme for medical devices and in vitro diagnostics, as shown in Table 3. The State Drugs Controller will enforce the manufacture for sale or distribution of Class A and Class B medical

[e] Except cardiac units in clinics and polyclinics.

devices, whereas the Drugs Controller General will do so for all imported medical devices and the manufacture of Class C and Class D medical devices.

Table 3. Updated risk-based classification.

Classification	Risk
Class A	Low risk
Class B	Low-moderate risk
Class C	Moderate-high risk
Class D	High risk

If Australia, Canada, Japan, European Union countries, or the United States issue a free sale certificate for a medical device (which verifies the goods are approved for export), an Indian license will be granted without a clinical investigation. If imported from countries other than those listed above, regulatory requirements for pulse oximeters and oxygen concentrators will depend on how they are classified under the updated risk-based classification. A Class C or Class D medical device needs to establish safety and effectiveness through a clinical investigation in India, whereas a Class A or Class B medical device needs to establish safety and effectiveness through published data or clinical investigation as well as a free sale certificate, in the country of origin. For those devices requiring a clinical investigation, the new rules specify a two-phase clinical trial process, in which safety is assessed in a small number of patients before a larger pivotal efficacy study is initiated.[14] Device manufacturing sites in India must undergo audits by notified bodies, independent groups that evaluate companies against predetermined standards to obtain manufacturing licenses. Indian regulators will also require unique identification of medical devices and in vitro diagnostics starting on January 1, 2022.[15]

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. Each state and territory in India will have different oxygen requirements that can be met by unique combinations of products. The first step is to understand the total need or oxygen requirement. Ideally, states, districts, blocks, and individual facilities would have the ability to track their oxygen usage to determine their actual oxygen need. Oxygen need estimates are still possible without actual consumption data; however, they require informed assumptions.

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

1. The first model uses the types of wards and 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 wards, **to estimate the total oxygen need**.

2. The second model is based on the data collected through the NHSRC Biomedical Equipment Management and Maintenance Program and the India Public Health Standards **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 help determine the number of devices required per year to close existing gaps in equipment availability. The number of years the user would like to meet the goal for eliminating gaps in availability can be modified based on available funds or to inform future budget allocations.

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, block, district, or state or for an entire country. In India, PATH used facility data from the MOHFW to determine the types of wards and 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 4.

As an example, Table 4 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 subcenters. This model also incorporates 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 and the calculations in Table 4**Error! Not a valid bookmark self-reference.**, the total amount of oxygen required to meet the need of the public health system in India is estimated to be almost 700 billion liters of oxygen each year.

Table 4. Facilities and average oxygen need.

Facility type	Average number of beds	Bed type	# beds by type*	Total O_2 liters per minute (LPM)†	Annual oxygen need per facility (liters/year)	Estimated cylinder refills, per year, per facility‡	Estimated cost to provide cylinders§ (US$)
Primary health centers	6	General beds	5	5	7,621,200	1,270	$6,351
		Critical beds	1	10			
Community health centers	30	General beds	26	20	36,529,200	6,088	$30,441
		Critical beds	5	50			
Subdistrict hospitals	58	General beds	49	38	67,014,000	11,169	$55,845
		Critical beds	9	90			
District hospitals	267	General beds	227	170	304,979,400	50,829	$254,149

	Critical beds	40	410

*Assumes 85 percent general beds, 15 percent critical care.
† 0.75 LPM per general bed; 10 LPMs per critical bed.
‡ 6 m^3 cylinder.
§ Assumes refill cost of US$5.

Quantification for pulse oximeters is tied to the current IPHS standards. PATH determined the recommended number of pulse oximeters by looking at the average number of pulse oximeters required per the IPHS standards for each type of facility. These guidelines call for two pulse oximeters in each CHC, a minimum of three pulse oximeters in subdistrict hospitals, and an average of ten pulse oximeters in district hospitals. The guidelines do not call for pulse oximeters in PHCs; however, this model assumes one pulse oximeter per PHC. The total number of pulse oximeters was then calculated by multiplying the recommended number of pulse oximeters per facility by number of facilities at each level. Table 5 shows that 46,737 pulse oximeters would be required to meet the needs of all health facilities that are CHC and above.

Table 5. Pulse oximeters required to meet need in facilities Level 3 and above.

Facility type	Number of facilities	Average number of beds	Pulse oximeters per facility	Estimated total number of pulse oximeters required
Primary health centers	25,354	6	1	25,297
Community health centers	5,510	30	2	10,780
Subdistrict hospitals	1,020	58	3	3,060
District hospitals	760	267	10	7,600

These calculations assume no oxygen or pulse oximeters are currently available in the system. However, medical device inventories and facility assessments such as the one conducted by the NHSRC can be used to more accurately determine the gap in availability of oxygen delivery devices—such as pulse oximeters, oxygen cylinders, concentrators, plants, or liquid oxygen—and the functional status of those items.

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

The NHSRC data show the current availability of functioning oxygen delivery equipment and pulse oximeters in the public health system. By comparing this data to the India Public Health Standards, which describe the oxygen delivery equipment that should be available at each level of the health system, the model can determine the gap in equipment availability.

Analysis of the NHSRC data estimates that there are 13,000 pulse oximeters in the public health care sector, leaving an estimated gap of 33,000 devices. Subcenters are not included in the estimation, as they typically do not have staff physicians or inpatient beds, and auxiliary nurse midwives are not approved to provide oxygen independently. If subcenters were included and are assumed to require one pulse oximeter per facility, it would add more than 155,000 devices. A possible approach to scale-up in

subcenters would be to begin with delivery point subcenters, which are a subset of the 155,000 facilities.

Further, the gap in oxygen availability can inform a strategy to address the gap and improve access to safe oxygen delivery. Table 6 below shows the number of oxygen concentrators and the growth rate for scaling safe oxygen delivery in India using these methods, with a target goal of meeting the need in ten years.[f] The desired growth rate or target number of years can be adjusted in the model to assist in planning and budgeting activities.

Table 6. Estimated scale-up of oxygen concentrators required to meet the oxygen need in India.

Facility level	Assumed growth rate	Number of years until gap is closed	Average number of devices required per year
Primary health centers (PHC)	25%	10	4,240
Community health centers (CHC)	17%	10	949
Subdistrict hospitals	17%	10	544
District hospitals	22%	10	2,134

Maintenance

Medical device maintenance is a challenge in India due to limited funding and human resources, competing priorities, and the variation of equipment between regions. Despite the IPHS standards requiring preventive maintenance and prompt repair of equipment to ensure uninterrupted delivery of services and requiring annual maintenance contracts be in place for all equipment in subdistrict/subdivisional hospitals and district hospitals, there are still challenges. In fact, there is evidence that 30 to 60 percent of medical devices are not functional.[16] These challenges are due to many reasons, including a lack of biomedical engineers in the public health system, supply chain logistics required for management of spare parts and accessories, and a lack of budget allocation for maintenance.

Beyond using the standard methods stated in the IPHS standards, India is implementing some unique programs to overcome existing challenges in medical device maintenance. One is through UNICEF, which is training cold chain technicians on the maintenance of other essential medical technologies,

[f] The total number of devices needed to close the gap includes an assumption for device replacement every five years.

particularly those required for the special newborn care units. The impact of this program is unclear, as it was in the early implementation phase when the information for this report was collected.

The NHSRC has also implemented the Biomedical Equipment Management and Maintenance Program. This model uses a public-private partnership model to outsource medical device maintenance in the public health care system. Maintenance service providers were contracted on a state-by-state basis through a national tender process. The goal is to have one agency service 25 districts. As of April 2017, 23 states were in the process of rolling out the program: 14 had implemented the program, 6 were in the process of awarding the tender, and 3 were about to release the tender.

Under the Biomedical Equipment Management and Maintenance Program, service providers are required to begin by conducting an inventory mapping to inform which devices require immediate repair. Once repaired or replaced, contractors are then required to maintain equipment with an average uptime of 95 percent and a maximum downtime of seven days for a single device. To ensure services are available for patients, if a device is expected to be down for more than one and a half days, the service provider is expected to immediately provide a substitute device. The additional services the companies are contracted to perform include equipment testing, calibration and auditing, user training, and monitoring. The monitoring tools created for this program are often web-based tools that provide real-time information on a facility-by-facility basis.

During a conversation in January 2016 with Jitendar Sharma, former head of the Health Technology Division of the NHSRC, he estimated that this program has the potential to save the country 60 billion Indian rupees. The program model will also save money because annual maintenance contracts will no longer be necessary, and those that are in place will not be renewed. Finally, the publicly available NHSRC inventory data have utility beyond that of maintenance alone and have informed many analyses included in this report.[g]

Financing landscape

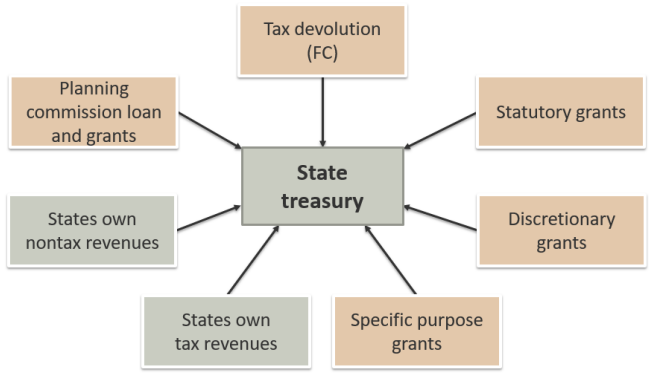
India largely funds health care through use of domestic resources. According to a recent document estimating health spending in 2013–2014, the total health care spending in India for that period was US$68 billion. Of this, US$63 billion was on health care services, and US$5 billion was on capital expenditures, including building construction and infrastructure. Much of health spending (68 percent) is attributed to households, with government expenditure accounting for 29 percent, or about US$19.5 billion. Of the government share, states and union territories provided US$12.7 billion (66 percent), and

[g] Data may be accessed from the NHSRC website on the Healthcare and Technology Innovation subpage under “Database of Medical Equipment” at http://nhsrcindia.org/category-detail/database-of-medical-equipment/MTY5.

the national government funded US$6.7 billion (34 percent). Funds from external sources, such as foreign governments or nongovernmental organizations, accounted for only 0.25 percent of the total health care expenditure in 2013–2014.[17]

Although they share certain responsibilities with the central government, the states and union territories are largely responsible for the health care of their populations. The division of responsibilities is given in Appendix B. Each state develops its own health care delivery plan, independent of the central government. However, the states are required to allocate some funds to national programs. The various sources of revenues for the state government are shown in Figure 8.

Figure 8. State government revenue generation.*



Abbreviation: FC, Financial commission.

*Adapted from: National Health Accounts Technical Secretariat, National Health Systems Resource Center, Ministry of Health and Family Welfare, Government of India. *National Health Accounts—Guidelines for India 2016*. New Delhi: Government of India; 2016.

At the national level, the MOHFW allocates funds to the states primarily based on population. States with weak socioeconomic and health indicators are then given an extra weighting to ensure resources are directed toward areas with more critical needs. To allocate funds from the central government, the government requires states to develop Program Implementation Plans (PIPs) on an annual basis. The PIPs build from the blocks (smaller governing units) to the districts and are aggregated at the state level. PIPs are developed based on annual guidelines provided by the National Health Mission. Guidelines for the 2016/2017 financial year had 12 priorities, including strengthening district hospitals and rolling out free drug services. State PIPs are then submitted to the National Program Coordination Committee for approval. Once the National Program Coordination Committee approves the state PIP, the Financial Management Group of the MOHFW at the central government requests the funds to be released by the Integrated Finance Division. Funds are then transferred to the respective states. Once transferred to the states, funds for state-level expenditure are subtracted, and the remaining funds are transferred to the district health societies based on the approved District Health Action Plans.

Health facilities also have access to funds beyond national funds requested through the PIP process. The funds include Rogi Kalyan Samities (RKS), annual maintenance grants, and untied funds. Interestingly, there are anecdotal stories that these funds often go unspent, which could be an opportunity to fund improvements to oxygen infrastructure such as piped systems in CHCs.

The specifics of each funding type are as follows:

- RKS: Allocated based on the facility type and its level of activity. “Rogi Kalyan Samities” translates to “patient welfare committee” and, as the name suggests, RKS funds are managed by a committee. As

stated in the guidelines for RKS in public health facilities, the purpose of funds is to improve the functioning and service provision in public health facilities, increase participation, and enhance accountability. Notable objectives for fund use include ensuring availability of essential drugs, ensuring the facilities comply with the IPHS, and enabling efficient use of land and buildings.[18] RKS funds are collected through fees for certain services performed, donations, loans, grants, and rental fees for public spaces.

- Annual maintenance grants: Allocated based on the type of facility for improving and maintaining physical structures and infrastructure. The RKS approves use of annual maintenance grants. Operational guidelines for financial management published by the national MOHFW outline use of funds for such things as installing, replacing, and repairing water and electric lines as well as making payments for these utilities. In the future, oxygen may also qualify for maintenance grants if it is positioned as an essential utility like water and electricity.

- Untied funds: Also allocated based on facility type and level of activity. The purpose of united funds is to fill remaining financial gaps not covered by other resources. These funds are also governed by the RKS. There are many uses of funds described in the operational guidelines for financial management. Equipment purchases are not an approved use of funds. However, water and electricity payments are allowed. If oxygen were reclassified as a utility, untied funds could be leveraged to ensure that payments for oxygen do not lapse.

Key stakeholders and roles

There are many stakeholders in India that affect access to safe oxygen delivery:

- **Industry:** There are a variety of stakeholders in the medical device industry in India. Medical gas distribution and installation companies play a prominent role in oxygen delivery. However, given the costly nature and logistical challenges of 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:** Local manufacturing of medical devices is not a large part of the market in India, but it is growing. Currently, most medical devices are imported from global manufacturers through local or regional distributors. Some larger companies (e.g., GE Healthcare, Philips, and Masimo) have established offices in India.
    - **Medical device distribution companies:** There are many medical device distributors in India. These companies play an integral role brokering sales between manufacturers and end users. Distributors are typically responsible for registering a product with regulatory bodies, interacting

with purchasers, and completing any after-sales services required. Depending upon the manufacturing company's strategy, they may elect to sell their products through more than one distributor.

- **Medical gas distribution and installation companies:** Medical gas production and distribution companies likely supply a large portion of the medical oxygen in India. These companies provide oxygen in both gas and liquid forms.

- **Central Drugs Standard Control Organization (CDSCO)**: CDSCO is the central drug authority under the Drugs and Cosmetics Act with responsibilities including regulatory control over the import of drugs, approval of new drugs, and clinical trials. CDSCO is currently the main authority regulating medical devices. However, this may change as the Medical Device Rules 2017 are implemented. CDSCO oversaw the development of the Medical Device Rules 2017 for regulating the manufacture, import, sale, clinical investigation, and other related matters concerning medical devices.

- **The Department of Health and Family Welfare:** The Department of Health and Family Welfare is a subdivision of MOHFW. It oversees the public health care system. Major programs include the National Health Mission (NHM), communicable and noncommunicable diseases, injury and trauma, and others.

  - **National Health Mission (NHM):** The NHM is a centrally sponsored scheme implemented in all states and union territories, with special focus on empowered action groups and northeastern states. The NHM was launched in 2005 with an objective of providing quality health care in the remotest rural areas by making it accessible, affordable, and accountable. The key features of the Mission include making the public health delivery system fully functional and accountable to the community. NHM also oversees decentralization of health and human resource management, rigorous monitoring and evaluation against standards, coordination of health with related programs, and innovation and flexible financing.

    - **Reproductive, Maternal, Newborn, Child, and Adolescent Health (RMNCH+A):** RMNCH+A is a division of the NHM, which is under the MOHFW of the Government of India. The RMNCH+A division is one of the more active public health programs and is a key partner in safe oxygen delivery. The child health program focuses on high-priority interventions that improve child survival and address mortality in infants and children under five years old. Facility-based newborn care, which includes newborn care corners, special newborn care units, and newborn stabilization units, are all outfitted with oxygen.

      The facility-based care initiative is also focused on an online reporting network to generate real-time data on common ailments for newborns in the health system. In the future, this may help inform quantification efforts for essential supplies, such as oxygen. The child health unit also launched the India Newborn Action Plan in 2014, is responsible for training

medical officers and staff nurses on high-quality newborn care and is overseeing a child death review so it can make corrective action for implementation of child health interventions. It has a specific focus on the reduction of morbidity and mortality due to acute respiratory infections, for which it has made clear guidelines for the use of oxygen and injectable antibiotics for inpatient treatment of severe cases and for procuring required equipment—including nebulizers, pulse oximeters, and relevant antibiotics—at each level of care.

- **National Health Systems Resource Centre (NHSRC)**: The NHSRC is a WHO-collaborating center set up under the MOHFW. It was established as a technical-assistance organization whose primary mandate is to assist in policy and strategy development for the MOHFW and across all states and union territories. The organization's goal is to improve health outcomes through governance reform, health system innovations, and improved information sharing among all stakeholders.

  Its Healthcare Technology & Innovation practice area specifically focuses on improving health care with the following activities:

  1. Ensure universal access to essential medicines and devices.
  2. Write specifications to get the best value for money when procuring medical devices.
  3. Assess technologies that public health systems should adopt for increased effectiveness and those that should be avoided due to reasons of safety or poor cost-effectiveness.
  4. Identify areas and develop an ecosystem for innovation to prioritize more appropriate technologies.

  The NHSRC has developed a public-private partnership model for medical device maintenance at all levels of the health system, supported by a 24/7 customer-care call center and advanced maintenance contracts and/or warranties. The commercial partnership between the public entity (state health department) and private agencies are for a fixed dollar value to provide maintenance of medical devices in public health facilities; this does not include the costs of repairs for devices already under annual maintenance contract, warranty, or spare parts agreements.

  Additionally, the NHSRC has developed product-specific videos on medical technology management. These videos include oxygen concentrators and pulse oximeters.

- **United Nations Children's Fund (UNICEF)**: UNICEF is a lead technical partner in India for newborn and child health. Safe oxygen delivery is linked to many of its programs—such as the development of the India Newborn Action Plan—including a bottleneck analysis, identification of strategic intervention packages and monitoring indicators, implementation of the Integrated Management of Newborn and Childhood Illness program, strengthening of facility-based newborn care in the country by increasing institutional delivery, and scale-up of Sick Newborn Care Units (SNCUs), which

were first piloted by UNICEF with the Government of West Bengal in the Purulia district. Oxygen concentrators and pulse oximeters are included as SNCU equipment.

UNICEF is also a part of the National Cold Chain and Vaccine Management Resource Center. This center has started a program—run by the State Health Transport Organization (Government of India, Pune), in collaboration with UNICEF—to train cold chain technicians in the maintenance and repair of equipment included in the special neonatal care units. This training provides hands-on experience through immediate repair of the devices and helps users and technicians with ongoing device use, including unique feature sets as well as preventive maintenance thereafter.

- **Clinton Health Access Initiative (CHAI)**: At the time of this report, the CHAI India Country Office was aiding safe oxygen delivery scale-up efforts in the state of Madhya Pradesh in direct partnership with the Madhya Pradesh government. Work began in 2017 with an assessment of existing availability in the public health sector. The approach to this work is informed by CHAI's efforts to scale up safe oxygen delivery in Ethiopia, Nigeria, and Uganda.
- **World Health Organization (WHO) India country office**: From 2012 to 2013, the WHO India country office brought together engineers, researchers, health care professionals, industry experts, and government in a fellowship program to conduct health technology assessments (HTAs) for various health care interventions. The purpose of this fellowship was to highlight the contribution that HTAs can make in promoting informed technology-related policymaking in health care and, perhaps, promote the inclusion of HTAs in health systems, particularly in developing and emerging countries. The output of this fellowship program was a compendium report that included steps for filling technology gaps in the public health care sector with 12 HTAs, including one for oxygen therapy in chronic obstructive pulmonary disease patients and the use of oxygen concentrators.
- **Uttar Pradesh Technical Support Unit (UP TSU)**: UP TSU is a consortium of health and development partners that support the Government of UP in achieving its reproductive, maternal, newborn, child, adolescent, and nutrition health goals. The UP TSU is a key technical partner of the Government of UP. They are involved in mapping existing equipment, particularly RMNCH+A and pneumonia equipment, which includes oxygen and electricity availability. This unit has staff embedded within each level of the health system to support the government with planning, management, and assessment of health interventions. The UP TSU has a diarrhea and pneumonia subcomponent where they introduce pneumonia and diarrhea specialists in each district. They have supported the procurement of pulse oximeters after baseline research indicated that identifying pneumonia was a core challenge. In addition, in the last year, the UP TSU also began providing technical assistance in the development of the state corporation for procurement in UP, helping to think through state-level harmonization of device procurement. This work may yield important evidence in convincing other states to do the same.

Market dynamics analysis

Market dynamics refers to 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. In a market analysis, 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 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 short-listed 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 India. Each of the market attributes assessed is described in Table 7 below.

Table 7. Summary of strengths and weaknesses of the Indian market for safe oxygen delivery devices.

Market attribute	Strengths	Challenges
AWARENESS Extent to which end users, health care providers, and key influencers can make informed choices about product use.	The child health and maternal health programs in the national Ministry of Health and Family Welfare are receptive to developing and adopting updated oxygen-related guidelines and disseminating these to each state. They also have identified several opportunities for emphasizing safe oxygen delivery in existing initiatives, such as the SNCUs and high-dependency units for mothers. Recent (perceived) oxygen supply disruptions have brought oxygen to the forefront of people's minds, and they are receptive to discussing how best to increase functional availability.	Decentralized decision-making for health care procurement and guideline adoption create variable uptake of national recommendations at the state, district, and community levels. Procurement decision-making may be further decentralized (beyond the state level), depending on the quantity and cost of a procurement request, thus further fragmenting demand and making it difficult to ensure that appropriate products are procured. There is limited awareness of functional availability. For example, health care workers will often assume oxygen is available if a cylinder is present, but those cylinders are often empty or are unusable due to faulty regulators. Health care workers are often unaware of proper safe oxygen delivery methods—when and how to deliver oxygen.
AFFORDABILITY Extent to which the price point maximizes market efficiency between payers and suppliers to support health outcomes.	Stakeholders commented that financing was less of a barrier and, instead, technical assistance is required to strengthen procurement and implementation capacity. There are many devices available at a wide range of prices. Most available	Key procurement decision-making criteria include technical specifications, company eligibility requirements, and price. However, price appears to be the ultimate decision criterion for procurement in each state, which can impact the quality of devices that are ultimately purchased.

Market attribute	Strengths	Challenges
	devices have approval from a stringent regulatory authority. The NHSRC has developed a master list of pricing based on previous procurement to increase awareness of fair prices. This document lists the low, medium, and high prices for a device and links to the technical specifications that were used for procurement. New regulations and tax structures reduce the customs and import taxes for key components of medical devices.	Without medical device regulation, there is no method to ensure high-quality products are procured over lesser-quality, less-expensive products. There is also no systematic method of verifying companies' quality claims. India actively discourages imports of finished goods by imposing high tariffs and import duties, which may add to the cost of devices to the end consumer. The NHSRC pricing information is based off previous purchases that likely prioritized the lowest price in device selection. These prices are now used to inform PIP budget allocations, which could have the unintended impact of reinforcing the lowest-price product bias. Total cost of ownership is not a routine budgeting practice in India. NHSRC pricing information reflects the initial capital expenditure of equipment but does not compare the price range of products over the lifespan. Facilities are often late making payments to oxygen suppliers, causing shortages in supply. Oxygen supply is not optimized to ensure the most cost-effective and efficient delivery methods, which leads to increased costs and delays in supply.
AVAILABILITY Capacity and stability of global supply to meet demand, and consistency of local access at service delivery points.	NHSRC, a WHO-collaborating center that is closely linked to the national Ministry of Health and Family Welfare, provides guidance to states on device procurement and selection in the absence of national medical device regulation. NHSRC also conducts health technology assessments to inform which medical devices should be prioritized for procurement in India.	Medical equipment data collected by NHSRC are inconstant across states and require considerable time to clean and combine to effectively map current availability and gaps in availability. This limits their usefulness for reporting or planning, particularly for conducting analyses across states.[h] There are no comprehensive data on oxygen availability—particularly oxygen generation plants and their distribution networks, storage vessels, and accurate numbers of cylinders—in the health care system, so the extent to which there are gaps is not fully known.

[h] As of September 2017, NHSRC communicated that quarterly updates to equipment data are made by state contractors and that this information is now managed through state websites.

Market attribute	Strengths	Challenges
	The Andhra Pradesh MedTech Zone is a subsidized manufacturing park created to support the development of domestic medical equipment manufacturing. The MedTech Zone has shared space for testing and other universally needed functions to reduce local manufacturing costs. Manufacturers within the space also benefit from exemptions from certain taxes and preference in tender considerations. NHSRC contracted third-party collection of information regarding existing medical equipment in every state; this information includes device, manufacturer, device status (functioning versus nonfunctioning), date of installation, and placement within the health facility (type of health facility and ward). This information is being leveraged to effectively understand current use, which will then be expanded to model gaps in use and/or appropriate substitutions for more appropriate use.	It is difficult to quantify financial commitments and disentangle state-level procurement decision-making to accurately estimate the true demand potential and attract high-quality industry to the Indian market. IPHS standards do not clearly define how much oxygen is required at each level of health facility, nor do they describe the optimal methods for providing oxygen. IPHS standards do not require pulse oximetry in primary health centers or subcenters.
ASSURED QUALITY Level of evidence that a product is consistently efficacious and safe.	NHSRC has launched a state-level biomedical engineering maintenance program in 21 states for medical equipment, with the intent to scale nationally. UNICEF is piloting a cold chain technician training program to leverage existing technician trainings for other essential medical equipment (e.g., equipment most commonly found in special newborn care units). This could conceivably be extended to include oxygen supply devices.	New medical device regulations will go into effect in January 2018, but they are still limited in their scope and the number and type of devices that they cover. There is poor awareness of maintenance contracts or programs, such as the NHSRC maintenance program, among health facility workers; as a result, equipment repairs are pursued locally or not at all. There are many distributors—both national and subnational—that influence product procurement. Accountability to maintain the devices distributors sell and/or to respond in a timely manner remains poor.

Market attribute	Strengths	Challenges
APPROPRIATE DESIGN Degree to which possibilities of technology maximize cultural acceptability.	Use of NHSRC medical equipment data, further assessment of medical device appropriateness, and current deployment approaches may be completed.	Many states are unaware of, or choose not to leverage, the NHSRC procurement resources, including technical specifications. Instead, states often create their own through technical working groups to establish technical and procurement specifications; this results in varied approaches to device assessment and deployment in each state.

Abbreviations: IPHS, Indian Public Health Standards; NHSRC, National Health Systems Resource Centre; PIP, Program Implementation Plan; SNCU, Sick Newborn Care Unit; UNICEF, United Nations Children's Fund; WHO, World Health Organization.

Recommended activities and next steps

In general, pulse oximetry devices are relatively available in the higher-level heath facilities in India. There are also a variety of oxygen sources available. However, safe oxygen delivery in the public health system highly depends on a facility's available resources, management, and geographic location. In urban centers and higher-population regions, oxygen is generally more available. In remote areas, supply chain/logistical challenges and infrastructure limitations (e.g., electricity access) limit access to oxygen.

There are a number of potential interventions that stakeholders in India can undertake to improve access to safe oxygen. National interventions include updating policies and guidelines such as the IPHS to include more clear guidance for oxygen and pulse oximetry at all practical levels of the health system. Interventions at the state level include conducting availability assessments and developing safe oxygen scale-up strategies for key states. Strengthening procurement and budgeting practices at the state and facility levels would also improve oxygen supply reliability. As evidenced at the Accelerating Access to Oxygen convening held in Dubai in November of 2017, there is strong political will at the national and state levels (UP and Madhya Pradesh) to increase access to oxygen.

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 India to discuss next steps among their peers and within the MOHFW. India was well represented at this meeting with four representatives from the MOHFW: two from the national level, one from Madhya Pradesh, and one from UP. Additionally, there were representatives from the Andhra Pradesh MedTech Zone and the NHSRC.

Appendix A. Contacts and interviews

REGION	STAKEHOLDER TYPE				
	GOVERNMENT	DISTRICT	FACILITY	PARTNERS	SUPPLIERS
New Delhi	• **CDSCO**, Advisor • **Central Medical Services Society**, General Manager, Procurement • **MOHFW,** Additional Secretary & Mission Director, NHM • **MOHFW**, Joint Secretary • **MOHFW**, Deputy Commissioner, Child Health • **MOHFW**, Deputy Commissioner, Maternal Health • **MOHFW**, Deputy Director General, Health Services • **MOHFW**, Deputy Assistant Director General, Noncommunicable Diseases • **NHSRC**, Consultant, Health Technology and Innovations • **NHSRC**, Director WHO Collaborating Centre for Priority Medical Devices and Health Technology Policy	NA	NA	• **Gates Foundation**, Country Lead, Maternal and Child Health • **Gates Foundation**, Head, Information and Computer Systems (ICT) and Supply Chain, India • **UNICEF**, Health Specialist (Neonatology) • **WHO**, Focal Point for Health Products • **UNICEF**, Supply and Procurement Manager • **Safdarjung Hospital and Vardhman Mahavir Medical College/Indian Academy of Pediatrics,** Professor and Consulting Pediatrician • **Lady Hardinge Medical College,** Professor and Consulting Neonatologist • **Andhra Pradesh MedTech Zone,** CEO & Managing Director*	• **INOX Air Products**, Manager—Sales (Medical) • **Masimo**, Country Manager—India and the Subcontinent • **Mahajan Imaging**, Founder and Chief Radiologist • **MediRent**, VP Sales and Marketing • **Sanrai International**, CEO and Founder, Business Development
Uttar Pradesh	• **NRHM**, Joint Director for Reproductive Child Health for Director General-Family Welfare • **National Health Mission**, General Manager of Child Health • **National Health Mission**, General Manager of Immunization	• **CMO** of Gorakhpur • **CMO** of Lucknow • **Central Medical Supply Division**, Director • **DH Balrampur**, Chief Medical SP	• **CHC Shanti Nagar,** CMO Health Education Officer • **CHC Lucknow**, MO, Pharmacist • **PHC Lucknow**, Nurse • **CHC Korabi**, SP • **CHC Sanjanpur**, CMO; Surgeon • **PHC Pepralli**, SP • **CHC Campiergei**, SP, MO, Staff Nurse • **PHC Kauriram**, MO	• **TSU**, Team Leader—Pneumonia and Diarrhea Program • **TSU**, Deputy Director/Technical Team Leader—UP Pneumonia and Diarrhea Project • **KGMU**, Professor • **Gorakhpur MC**, HOD Medicine and Pediatrics • **UNICEF**, Child Survival Consultant • **UNICEF**, Child Health Specialist	NA

Bihar	• **SHS**, Chief of Immunization • **BMSICL**, Medical Equipment Procurement	• **DH Gaya,** CMO/DIO • **DH Vaishali,** CS, aCMO • **DH Gardanibagh,** aCMO	• **PHC Jehanebad,** General Pediatrician • **PHC Manipur,** MO • **PHC Bodh Gaya**, Nurse • **Sub-DH Vaishali**, SP	• **UNICEF**, Health Officer	NA

* The Andhra Pradesh MedTech Zone is not located in New Delhi, but the topic of conversation was in regard to the whole of India and the meeting is, therefore, classified under the New Delhi meetings.

Abbreviations: aCMO, acting chief medical officer; CEO, chief executive officer; CHC, community health center, CMO, chief medical officer; CS, civil servant; DH, district hospital; DIO, district immunization officer; HOD, head of department; KGMU, King George Medical University; MC, medical college; MO, medical officer; SHS, State Health Society; SP, superintendent; TSU, Technical Support Unit; UNICEF, United Nations Children's Fund; VP, vice president; WHO, World Health Organization.

Appendix B. Division of health responsibilities

Schedule Seven of the Constitution of India[19] divides various responsibilities between the union (center) and the states. It divides the responsibilities into three lists—the Union List, State List, and Concurrent List. The Union and State Lists describe responsibilities that solely belong to the center or the states. The Concurrent List describes the subjects that are under the joint jurisdiction of the center and states. The union is not solely responsible for any aspects health care.

Concurrent List

1. Prevention and control of communicable diseases.
2. Prevention of adulteration of foodstuffs.
3. Control of drugs and poisons.
4. Vital statistics.
5. Economic and social planning.
6. Population control and family planning.
7. Preparation of health education materials for creating health awareness through Central Health Education Bureau.
8. Collection, compilation, analysis, evaluation, and dissemination of information through the Central Bureau of Health Intelligence.
9. National Medical Library.

State list

1. Study of the health problems and needs in the state and planning of schemes to solve the problems.
2. Provision of curative and preventive services.
3. Provision for control of milk and food sanitation.
4. Prevention of any outbreak of communicable diseases.
5. Promotion of health education.
6. Promotion of health programs, such as school health, family planning, occupational health, etc.
7. Supervision of public health facilities.
8. Establishment of training courses for health personnel.
9. Coordination of all health services with other state departments, such as the department of education, among others.
10. Establishment and maintenance of medical institutions with necessary infrastructure.

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