Constrained medical oxygen supply chain in India during COVID-19: Red-tapism, the elephant in the room?

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Short Report

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Abstract

Background:

Recent disruption of medical oxygen during second wave of COVID-19 has caused nationwide panic. This study attempts to objectively analyze the medical oxygen supply chain in India along the principles of value stream mapping (VSM), identify bottlenecks and recommend systemic improvements.

Methodology:

Process mapping of the medical oxygen supply chain in India was done. Different licenses & approvals, their conditions, compliances, renewals among others were factored-in. All relevant circulars, official orders, amendments and gazette notifications pertaining to medical oxygen since April 2020 were studied and corroborated with information from PESO official website.

Findings:

All steps of medical oxygen supply chain right from oxygen manufacture to filling, storage and transport up to the end users; have regulatory bottlenecks. Consequently flow of materials is sluggish and very poor information flow has aggravated the inherent inefficiencies of the system. Government of India has been loosening regulatory norms at every stage, which is reactive rather than proactive policy making.

Discussion:

Regulatory bottlenecks have indirectly fuelled the informal sector over the years, which is not under Government's control. This has also caused difficulties in clamping down black-marketing and hoarding. Technology enabled, data-driven regulatory processes with minimum discretionary human interface is the way to go.

Summary

Summary Box:

What is already known about this subject?

- Shortage of medical oxygen during the second wave of COVID-19 has caused severe crisis in Indian healthcare.
- Government of India has taken drastic steps to address the crisis.

What does this study add?

- Value Stream Mapping approach has been used to study the medical oxygen supply chain in India.
- Insights on regulatory bottlenecks at different levels of medical oxygen supply chain
- Provides possible reasons behind the ongoing medical oxygen crisis.
- Proposes plausible long-term systemic solutions for the problem.
- No such study till date from India, therefore first of its kind.

Recommendations for Policy & Practice?

- The study proposes a technology based data-driven regulatory processes with minimum discretionary human interface.
- Better ease-of-doing business for the medical oxygen industry.
- Systemic changes that can further improve regulation and yet keep processes easy for all stakeholders.
- Can be used to improve government policy making, from reactive to being more proactive.

Background

Today entire humanity is grappling with the deadly impact of the COVID 19, which is rapidly mutating and changing its nature as it travels across world. Second wave of COVID 19 caught India by complete surprise and policy paralysis has further weakened the situation in the entire country. It has pushed Indian healthcare to the brink. The fast rising pandemic has uncovered many long-standing inherent weaknesses in the Indian healthcare system.

Recent disruption in supply of medical oxygen to healthcare establishments has struck at the very heart of the healthcare system and triggered an alarm at the national level. The crisis has put not just the executive & government but also the judiciary into an overdrive. Oxygen from industries has been diverted for medical purposes among many other radical moves and yet the crisis looms big.

So, what got us here? As with any disaster situation, there are many schools of thought and needless to say, because of its political ramifications, oversimplifying the problem by vilifying select few stakeholders appears to be an easy way out. Some narratives point to a deficient production capacity, which is not agreed by some experts. Failures to maintain supply chain, a surge in consumption, irrational usage, hoarding among others are vaguely tossed around to be the cause.

It is therefore important to have an objective assessment of the system right from the point of production, all the way to the point of consumption/ usage of medical oxygen. This can help us understand the bottlenecks and improvements can be planned at a systemic level to avert future disasters. Value Stream Mapping helps in identifying wasteful activities, improve efficiency of systems by studying the flow of materials and information. An assessment of the medical oxygen supply chain along this approach can shed more light on the possible causes, which has been done in the current study.

Aim

To study the medical oxygen supply chain along the principles of value stream mapping, identify bottlenecks and recommend improvements.

Methodology

1. Process mapping of medical oxygen supply chain was done with an approach of value stream mapping. It was done in lines with Gas Cylinder Rules 2016 (GCR 2016) and Static & Mobile Pressure Vessels (Unfired) Rules 2016 (SMPV 2016). Different approvals, licenses required, conditions of licenses, renewal of licenses, inspections among others were studied and factored in.
2. All relevant circular, official orders, memos, amendments, Government of India gazette notifications pertaining to medical oxygen from April 2020 were studied and findings incorporated.
3. Relevant information pertaining to each step in the process mapping was taken from PESO (Petroleum & Explosives Safety Organization) official website (www.peso.gov.in) and findings incorporated.

Results/ Findings

Process mapping of medical oxygen supply chain was done. It starts with the manufacture of oxygen, followed by largely two streams viz, oxygen cylinders and liquid oxygen. Figure 1 provides an overview of the entire supply chain along with licenses required/ statutory requirements for each step, right from the point of production all the way to the point of consumption/ end users. The entire system can be studied in 5 parts viz,

- i. Manufacture of Oxygen,
- ii. Manufacture, filling & storage of cylinders,
- iii. Manufacture, filling & storage of pressure vessels,
- iv. Transportation and
- v. Hospitals/ end users

i. Manufacture of oxygen:

Demand for medical oxygen during the pandemic has gone up almost four times, from 750MT/day to approx. 2800MT/day. Currently, during the COVID-19 pandemic, around 50% of the total Liquid Oxygen production is being used for medical purpose in comparison to around 15% usage during the pre-COVID period. But the overall production capacity remains more or less the same.

The government has taken measures like diversion of oxygen from other industries(1) and floated a global tender for procurement of Liquid Oxygen(2) in an attempt to tide over the immediate crisis.

Financial viability of cylinder fillers was under question due to which the ex-factory price of oxygen was recently capped (3).

In a desperate attempt to boost overall production capacity, Central Drugs Standard Control Organization (CDSCO) issued circular promising license to manufacturers of industrial oxygen to manufacture medical oxygen within 24 hours of applying, under the Drugs & Cosmetics Act 1940 & Rules(4). *Manufacture of oxygen has therefore been tightly controlled & regulated, which is now being loosened during the crisis.*

ii. Manufacture, filling & storage of cylinders:

Oxygen delivery through cylinders is one of the key modalities of oxygen supply, especially for small hospitals, nursing homes, day care facilities and remote areas. Around 80% of the hospitals in India are less than 50-bedded(5) and most of them would be dependent on oxygen cylinders for their medical oxygen needs.

The shortage of oxygen cylinders has become more evident during the pandemic. With only 17 approved high-pressure gas cylinder manufactures(6) and 11 approved multi-function valves manufacturers (7), India is undoubtedly grappling with shortage of oxygen cylinders. Government of India has allowed conversion of use of industrial cylinders for filling medical oxygen and floated tender for immediate procurement of oxygen cylinders in a damage control mode.

Figure 2 illustrates the complete process of oxygen supply through cylinders and helps to identify the bottlenecks.

The government has also relaxed the restrictions for filling and storage of oxygen cylinders. Filling of oxygen cylinders round-the-clock has been allowed, which was otherwise not allowed without approval. Even the license renewal process has been relaxed to ease the constraints. Obtaining licenses requires clearances from inspecting authorities, which has been a bottleneck for long. Enabling Third Party Inspection Agencies (TPIAs) for this purpose is a welcome step, but so far there are 15 approved TPIAs across the country(8). Not-to-mention the other approvals from district administration, fire authorities, labor norms etc.

Seamless flow of information amongst all stakeholders is the lifeline for any industrial systems. The recent circular instructing all the registered facilities to provide a daily update on the inventory status (9) (10) sheds light on the lack of real-time data with the regulators and possibly tells us the reason for the inertia in the system.

iii. Manufacture, filling & storage of pressure vessels:

The other important source for larger hospitals and establishments is the liquid oxygen (LOX), which is also very tightly regulated at every step. Right from the stage of manufacture of pressure vessels to maintaining them with regular filing of compliance requires clearances from recognized inspectors/

competent persons. The PESO official website (As on 30th April 2021) enlists *only 316 recognized inspectors/ competent persons with valid licenses across India, with wide regional disparities* (Table 1).

State/ UT	Number of recognized Competent Person/Inspector with valid license under SMPV (U) Rules 2016
ANDAMAN NICOBAR	0
ANDHRA PRADESH	2
ARUNACHAN PRADESH	0
ASSAM	2
BIHAR	0
CHHATTISGARH	0
CHANDIGARH	0
DAMAN DIU	0
DELHI	15
DADAR & NAGAR HAWELI	0
GOA	0
GUJARAT	42
HARYANA	1
HIMACHAL PRADESH	0
JHARKHAND	0
JAMMU KASHMIR	0
KARNATAKA	12
KERALA	10
LAKASHADWEEP	0
MEGHALAYA	0
MAHARASTRA	133
MANIPUR	0
MADHYA PRADESH	2
MIZORAM	0
NAGALAND	0
ODISHA	0

PUNJAB	3
PONDICHERRY	0
RAJASTHAN	0
SIKKIM	0
TELANGANA	6
TAMILNADU	20
TRIPURA	0
UTTARAKAND	0
UTTAR PRADESH	19
WEST BANGAL	49
GRAND TOTAL	316

Table 1: State-wise distribution of recognized competent person/ inspector under SMPV (U) Rules 2016 (Source: PESO official website as on 30th April 2021)

The shortage of LOX containers and trucks has surfaced in the light of increase in demand. The Government is grappling with these problems by relaxing certain norms and diverting resources from other industries. Use of ISO tank containers for domestic LOX transport has been allowed(11). Tankers that were being used for liquid nitrogen/ argon and LNG (Liquefied Natural Gas) are being converted for liquid oxygen(12)(13). The renewal process has also been relaxed to fasten the processes(14).

Yet again the information gaps are evident from the recent circulars(9), wherein the regulators do not have real-time information about the inventory status. Figure 3 outlines the processes involved in oxygen supply through containers/ pressure vessels and highlights the bottlenecks.

iv. Transportation:

Transportation of oxygen from source to end-users is a key aspect and is tightly regulated as well. The conditions of license have strict regulations on all aspects ranging from where these vehicles can be parked, their routes, manpower aspects among others. Provisions in the Motor Vehicle Act 1988 regulate the inter-district, intra-state and inter-state movement of these vehicles with restricted timings for plying on roads.

In view of the crises the government has intervened at this level as well by relaxing the norms and allowed free movement of oxygen carrying vehicles across all states and issued orders to this effect as well (15). Despite these steps, problems persisted and there was a need for closer monitoring. Recently, Vehicle Location Tracking (VLT) on all oxygen tankers has been ordered for better tracking and real-time

information on inventory(16). The pandemic has therefore compelled relaxation of norms and adoption of technology, which otherwise would have been unlikely.

v. Hospital/ end users:

The end user base is diverse ranging from large tertiary care hospitals to small nursing homes & clinics and spread wide across the country. The hospital/ healthcare establishments also need to have necessary licenses depending on whether their oxygen requirements are met through cylinders or LOX. There is no real-time data on consumption patterns or requirement of oxygen in hospitals, which is yet another blind spot for both industry and policy-makers.

Data-driven decision-making is at the heart of efficient industry and effective policies. In the absence of credible data, both seem to have suffered over the years and in-turn stifled response to the surge created by the pandemic. Whether to prevent hoarding, black-marketing or to rationalize distribution of oxygen to different hospitals, availability of quality data would have made a huge difference.

Discussion

It is *unequivocally clear* from the value stream mapping approach that the entire supply chain right from the point of oxygen manufacture, storage, and transport to the point of consumption is fraught with *regulatory bottlenecks*. These have double detrimental effects. Firstly, the mainstream/ formal system is rendered inefficient with many wasteful steps that render the existing industry less amenable for changes and deters new entrants. This translates to inability to quickly adapt during crises situation like the current pandemic.

Secondly, such a rigid, restrictive system strongly incentivizes mushrooming of informal sector, which starts fulfilling the needs of smaller users who cannot afford the cost and time overruns of red tape. Wherever there is demand, supply will always find its way. The grey or black-market flourish under such circumstances to meet the needs of small setups like nursing homes, clinics etc. who cater to the masses.

The government or regulators do not have any data on these grey/ black markets and consequently are unable to regulate them. This means a significant segment of healthcare could possibly be using medical oxygen from sources where neither quality nor safety can be ascertained. This also reflects in the inability of the government to control black marketing during current crisis.

There is almost *no real-time data* even from the formal channel. The recent circulars mandating daily reporting of inventory status reiterates the same. A robust system requires seamless information flow between all stakeholders, which is clearly lacking in this case. Imagine the government had real-time data on oxygen manufactured, number of cylinders/LOX containers/ LOX trucks, their distribution, quality checks and filling status, the current situation could have definitely been better managed with data driven policies rather than reactive ones. Industry players could have innovated and geared up for changing

needs and the hospitals/ end users could have improved their systems, as information networks closely knit the ecosystem (Figure 4).

The existing system has certainly faltered during the pandemic, with hospitals turning away patients requiring oxygen support or ventilators(17). The domestic industry is not able to meet the rising demand, which has forced to government to look for import of oxygen(17). Unless we substantially change the system- the biomedical, maintenance, distribution and the economic purchasing system for medical oxygen, we would certainly be back in the same situation in 5 years(18).

Davidescu et al studied the main characteristics and perspectives of Romanian Medical oxygen market. The study found that the Romanian medical oxygen market is an oligopoly with a small number of producers and had significant segmentations(19). Even in the current study it was found that the medical oxygen ecosystem in India is tightly regulated, with not many players and significant regulatory bottlenecks.

The potential solution to these problems lies in digitization and automation. A study from Xie et al from China emphasizes how predictive modeling and data analytics can be used for optimal allocation of resources in disaster situations like COVID-19, where there is not enough time to ramp up production capacity(20). A location-based ubiquitous crowdsourcing approach for emergency supply of oxygen cylinders for patients in need by Barachi et al demonstrates how technology platforms can be leveraged (21).

Informational continuity is the foundation for building a credible digital solution(22) for monitoring. Majority of parameters involved in all the processes of medical oxygen are objective and machine-readable. This means KPIs (Key Performance Indicators) can be measured, captured, shared and monitored in near real-time across a common network working on IoT (Internet of Things) or Block chain. This can help to create a robust system with continuous quality improvement as illustrated in Figure 4.

Conclusion

“Regulation” in the Indian context has unfortunately been more of *“Restriction”*, which is a colonial hangover. The existing systems are definitely more restrictive rather than regulatory. There is more deterrence and burden on players in the formal/ mainstream who fall under the *“Regulatory”* ambit, which has its obvious fallouts.

Quality and Safety are of paramount importance especially in the medical oxygen industry. Regulation in true sense would actually improve the overall quality and safety by bringing in better monitoring without causing unnecessary obstructions in the process-flow. By leveraging technology the government can not only improve monitoring but also make it easy for the industry to grow. Industry players can be incentivized to shift from the informal side to the mainstream by simplifying the process, which can be a game-changer.

Bringing in technology based data-driven regulatory processes with minimum discretionary human interface is the way forward. Digital India Mission and its components like e-Governance have been creating remarkable ease for citizens & businesses in other sectors. The current crisis opens an opportunity to introspect & revamp the medical oxygen industry with digitization and align it with Make in India initiative. We can start by acknowledging fallouts of *red-tapism, the elephant in the room*.

Declarations

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References

1. Ministry of Health & Family Welfare G of I. "Supply of oxygen for industrial purposes by manufacturers and suppliers to be prohibited from 22/4/21" Dt: 18/04/21 [Internet]. Government of India; 2021 p. D.O.No.17/S(HFW)/MO/2021. Available from: <https://aiigma.org/wp-content/uploads/2021/04/D.O.-Letter-to-HS-Medical-Oxygen-Supply-18-April-2021.pdf>
2. HLL Lifecare Ltd. "SHORT TERM GLOBAL TENDER ENQUIRY DOCUMENT FOR PROCUREMENT OF IMPORTED LIQUID MEDICAL OXYGEN" 16/04/21 [Internet]. Government of India; 2021 p. Tender No. HLL/SOURCING/COVID-19/018-RT/2021. Available from: https://aiigma.org/wp-content/uploads/2021/04/TED_OXYGEN-Import-Tender-HLL-final-16.04.pdf
3. The Gazette of India E. "Price control order for medical oxygen" Dt 25/09/21 [Internet]. India: Extraordinary, PART II- Section 3- Sub-section (ii); 2021 p. CG-DL-E-26092020-222006. Available from: <https://aiigma.org/wp-content/uploads/2020/09/222006.pdf>
4. Central Drugs Standard Control Organization (CDSCO). "Granting permission to manufacture of industrial oxygen to manufacture oxygen for medical use in the light of COVID-19 Reg" Dt. 07/04/20 [Internet]. India: Government of India; 2020 p. No. DCGI/Misc/2020(96). Available from:

<https://peso.gov.in/web/updates/granting-permission-manufacturers-industrial-oxygen-manufacture-medical-oxygen>

5. Choudhury M, Datta P. Private Hospitals in Health Insurance Network in India: A Reflection for Implementation of Ayushman Bharat. Work Pap. 2019;(254):1–22.
6. PESO. Approved High Pressure Gas Cylinder Manufacturers-PESO [Internet]. 2021. p. As on 30th April 2021. Available from: <http://www.peso.gov.in/web/approved-high-pressure-gas-cylinder-manufacturers>
7. PESO. Multi Function Valves Manufacturers-PESO [Internet]. 2021. p. As on 30th April 2021. Available from: <http://www.peso.gov.in/web/multi-function-valves-manufacturers>
8. PESO. “Reduction in compliance burden-introduction of third party for prototype and batch-wise inspection of cylinders, valve & regulators-Reg” Dt. 05/04/21 [Internet]. India: Government of India; 2021 p. No.CVIII(3)125/CIR/GCR. Available from: <http://www.peso.gov.in/web/updates/reduction-compliance-burden-tpia-under-gas-cylinders-rules-2016>
9. PESO. “Additional conditions for form-E, form-F GCR 2016 and form LS-1A under SMPV(U) Rules 2016-Daily update of inventory”- Dt 24/07/20 [Internet]. India: Government of India; 2020 p. No.R.1(1)158/II/2020. Available from: <https://peso.gov.in/web/updates/additional-conditions-form-e-f-and-ls-1-under-smpvu-rules>
10. PESO. “Monitoring the inventory of liquid oxygen/medical oxygen in the country to ensure uninterrupted supply of oxygen to hospitals and other healthcare facilities due to nationwide lockdown for containment of COVID-19 pandemic” Dt. 18/04/2020 [Internet]. India: Government of India; 2020 p. D-21013/PBL/18-Exp. Available from: <https://peso.gov.in/web/updates/circular-monitoring-inventory-liquid-oxygen-medical-oxygen>
11. PESO. “Approval of ISO Tank Containers for Oxygen” [Internet]. India: Government of India; Available from: <https://aiigma.org/wp-content/uploads/2020/09/Approval-of-ISO-Tank-Container-for-Liquid-Oxygen.pdf>
12. PESO. “Permission for conversion of liquid Argon & Nitrogen road tankers into service of liquid oxygen” 14/04/21 [Internet]. Government of India; 2021 p. No.R.1(1)158/XI/20. Available from: <https://aiigma.org/wp-content/uploads/2021/04/1-1.pdf>
13. PESO. “Change in service of the cryogenic gas to be transported” 17/08/20. Government of India; 2020 p. No.R1(1)158/11/2020.
14. PESO. “Relaxation in rules to ease the availability of medical oxygen” 26/04/21 [Internet]. Government of India; 2021 p. D-18019/Comp/Implementation. Available from: <https://peso.gov.in/web/updates/relaxation-rules-ease-availability-medical-oxygen-second-wave-covid-19>
15. The Gazette of India E. “MINISTRY OF ROAD TRANSPORT AND HIGHWAYS ORDER EXEMPTING OXYGEN CARRYING VEHICLES” Dt. 21/09/21 [Internet]. India: Extraordinary, PART II- Section 3- Sub-section (ii); 2020 p. CG-DL-E-21092020-221846. Available from: <https://aiigma.org/wp->

content/uploads/2020/09/SO-3204-E-dated-21st-Septemebr-2020-carriage-of-oxygen-by-transport-vehicle-COVID-19-.pdf

16. Ministry of Road Transport & Highways. "Fixing of VLT devices on vehicles carrying oxygen (Oxygen containers)" 24/04/21 [Internet]. 2021 p. No.RT-23018/37/2021-T. Available from: <https://aiigma.org/wp-content/uploads/2021/04/fixing-of-VLT-deviceson-Oxygen-carrying-vehicles-24April2021.pdf>
17. Bhuyan A. Covid-19: India looks to import oxygen as cases surge, overwhelming hospitals. BMJ [Internet]. 2021;373:n1061. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/33888471>
18. Usher AD. Medical oxygen crisis: a belated COVID-19 response. Lancet (London, England) [Internet]. 2021;397(10277):868–9. Available from: [http://dx.doi.org/10.1016/S0140-6736\(21\)00561-4](http://dx.doi.org/10.1016/S0140-6736(21)00561-4)
19. Davidescu AA, Apostu SA, Stanciu-Mandruleanu C. Shedding Light on the Main Characteristics and Perspectives of Romanian Medicinal Oxygen Market. Healthcare. 2021;9(2):155.
20. Xie J, Tong Z, Guan X, Du B, Qiu H, Slutsky AS. Critical care crisis and some recommendations during the COVID-19 epidemic in China. Intensive Care Med [Internet]. 2020;46(5):837–40. Available from: <https://doi.org/10.1007/s00134-020-05979-7>
21. El Barachi M, Kamoun F, Hachani A, Belqasmi F, Ben Said A, Amri I. A location-based ubiquitous crowdsourcing approach for the emergency supply of oxygen cylinders. Pers Ubiquitous Comput. 2021;25(1):109–20.
22. Gowda NR, Kumar A, Arya SK, Ha V. The information imperative: To study the impact of informational discontinuity on clinical decision making among doctors. BMC Med Inform Decis Mak. 2020;20(1):1–10.

Figures

Figure 1

Overview of the medical oxygen supply chain in India

* Source: www.peso.gov.in (As on 30th April 2021)

Figure 2

Oxygen supply through cylinders

Figure 3

Oxygen supply through pressure vessels

Figure 4

Ideal information flow between stakeholders and Continuous Quality Improvement for a robust system