On-site generation of medical oxygen – a safe, reliable, and cost-effective alternative to delivered oxygen

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Table of Content

- Overview of different medical oxygen supply methods
- Oxygen 93 vs. 99
  - USP 93 and Eur. Ph. 93
- Why Oxygen 93 is **safe**
  - Discuss research done over a long period of time
- Why on-site oxygen is **reliable**
  - Always on-site
  - Multiplicity
  - ISO standard 10083
- Where on-site oxygen is **cost-effective**
  - US market research
  - Price drivers
  - Cost comparison
- Conclusion

Overview of different medical oxygen supply methods

- Bulk

- Packaged
  - Dewars
  - Cylinders

- On-site oxygen concentrators (OCs)
  - Home concentrators
  - Disaster preparedness / mobile field hospitals
  - Civilian hospitals

Two different “types” of medical oxygen associated with these delivery methods: Oxygen 99 and Oxygen 93

- Bulk: Oxygen 99 ($O_2$99)
- Packaged: depends on source
- On-site oxygen concentrators: Oxygen 93 ($O_2$93)

How the US and European Pharmacopeias define Oxygen 99 and Oxygen 93

US Pharmacopeia

	O_2 99	$O_2$93
O2:	>= 99%	90-96%
CO2:	<= 0.03%*	<= 0.03%*
CO:	<= 0.001%*	<= 0.001%*
H2O:	N/A	N/A
NO:	N/A	N/A
NO2:	N/A	N/A
SO2:	N/A	N/A
Oil:	N/A	N/A
Odor:	no odor	no odor

*No in-line testing of these 2 gases required in the US.

European Pharmacopeia

	O_2 99,5	$O_2$93
O2:	>= 99.5%	90-96%
CO2:	<= 300 ppm	<= 300 ppm
CO:	<= 5 ppm	<= 5 ppm
H2O:	<= 67 ppm	<= 67ppm
NO:	N/A	<= 2 ppm
NO2:	N/A	<= 2 ppm
SO2:	N/A	<= 1 ppm
Oil:	N/A	<= 0.1 mg/m3
Odor:	N/A	N/A

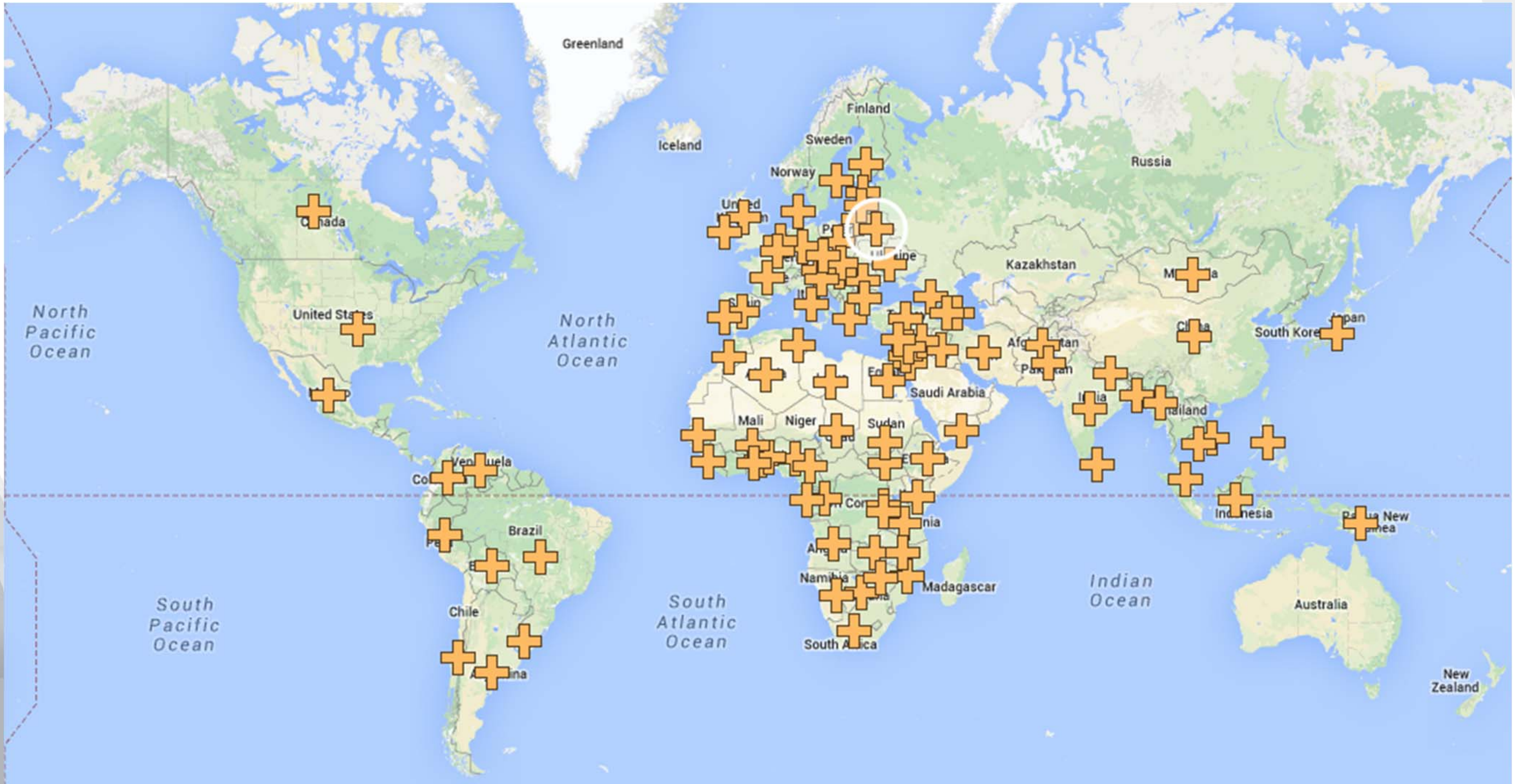
With N_2 and Ar content being the difference, what is the medical impact?

- **In short: $O_2$93 provides the same quality of care as $O_2$99.**
- In Canada, fifty-two hospitals were surveyed regarding their ten-year experience using oxygen concentrators as their primary oxygen supply.
  - There were no reported adverse consequences as a result of the source of oxygen and the authors concluded that oxygen concentrators which meet Canadian standards are “safe, reliable, and cost effective.”
  - Yet perhaps most revealing, many of the hospitals reported **Improved overall care and increased consumption** after switching to oxygen concentrators, as the reliable and cost-effective supply of oxygen provided by concentrators allowed them to prescribe oxygen more frequently. [1]
- After years of using $O_2$93 in the field, the US military has declared $O_2$93 acceptable in any clinical application. [2]
- “…The overall assessment of the medical factors discussed here does not lead to any serious medical reasons that would limit the use of $O_2$93 …” [3]

How about the impact on the devices administering the oxygen?

- In a study that examined the efficacy of the Mercury **tube-valve-mask**, patients were administered both $O_2$93 and $O_2$99 at 2 L/min, 3 L/min, and 4 L/min. The difference in the level of FiO_2 at 2 L/min and 4 L/min was one percent, while there was no difference in FiO_2 at 3 L/min. [4]
- "… In conclusion, we did not observe any adverse **ventilator** function utilizing either $O_2$93 or $O_2$99. Furthermore, there were no clinically significant differences between machine settings and actual measure oxygen concentration when using an OC as a primary source of supply. …" [5]
- "… Modern **anesthesia machines** which conform to CSA standards are not adversely affected when supplied by an oxygen concentrator…" [6]

Oxygen 93 has been accepted as a viable alternative in the majority of the world



Can oxygen concentrators meet the Pharmacopeias' standards?

European Pharmacopeia

	O_2 99,5	$O_2$93
O2:	>= 99.5%	90-96%
CO2:	<= 300 ppm	<= 300 ppm
CO:	<= 5 ppm	<= 5 ppm
H2O:	<= 67 ppm	<= 67ppm
NO:	N/A	<= 2 ppm
NO2:	N/A	<= 2 ppm
SO2:	N/A	<= 1 ppm
Oil:	N/A	<= 0.1 mg/m3
Odor:	N/A	N/A

Oxygen Concentrator Gas Sample

TYPICAL ANALYSIS RESULTS

Analyte	Source Air/Gas	Analyte Results	Specification Limits	Ambient Air/Gas	Reporting Limits*
Oxygen (Volume %)	95.7	Pass	90.0-96.0	N/A	0.5
Carbon Monoxide (ppmv)	<1	Pass	5	N/A	1
Total Gaseous Hydrocarbons including Methane (ppmv)	<5.0	N/A	N/A	N/A	1
Methane (ppmv)	<1	N/A	N/A	N/A	1
Carbon Dioxide (ppmv)	<25	Pass	300	N/A	25
Oil Mist & Particulate [COM:133] (mg/m³)	<0.01	N/A	N/A	N/A	0.01
Oil Mist (mg/m³)	<0.01	Pass	0.1	N/A	0.01
Particulate (mg/m³)	<0.01	N/A	N/A	N/A	0.01
Nitric Oxide (ppmv)	<0.1	Pass	2	N/A	0.1
Nitrogen Oxide (ppmv)	<0.1	Pass	2	N/A	0.1
Sulfur Dioxide (ppmv)	<0.1	Pass	1	N/A	0.1
Water (ppmv)	<2	Pass	67	N/A	2

How can we ensure the OCs meet the standard day in and day out?

- In-line measurement of
  - Oxygen
  - CO*
  - CO_2*
  - H_2O* (if desired)
- In case of non-compliance
  - Alarm
  - Product off-gasing so that it cannot reach patient
- Regular, e.g., yearly, compliance checks on other impurities, using detector tubes

*No in-line testing of these 3 gases required in the US.

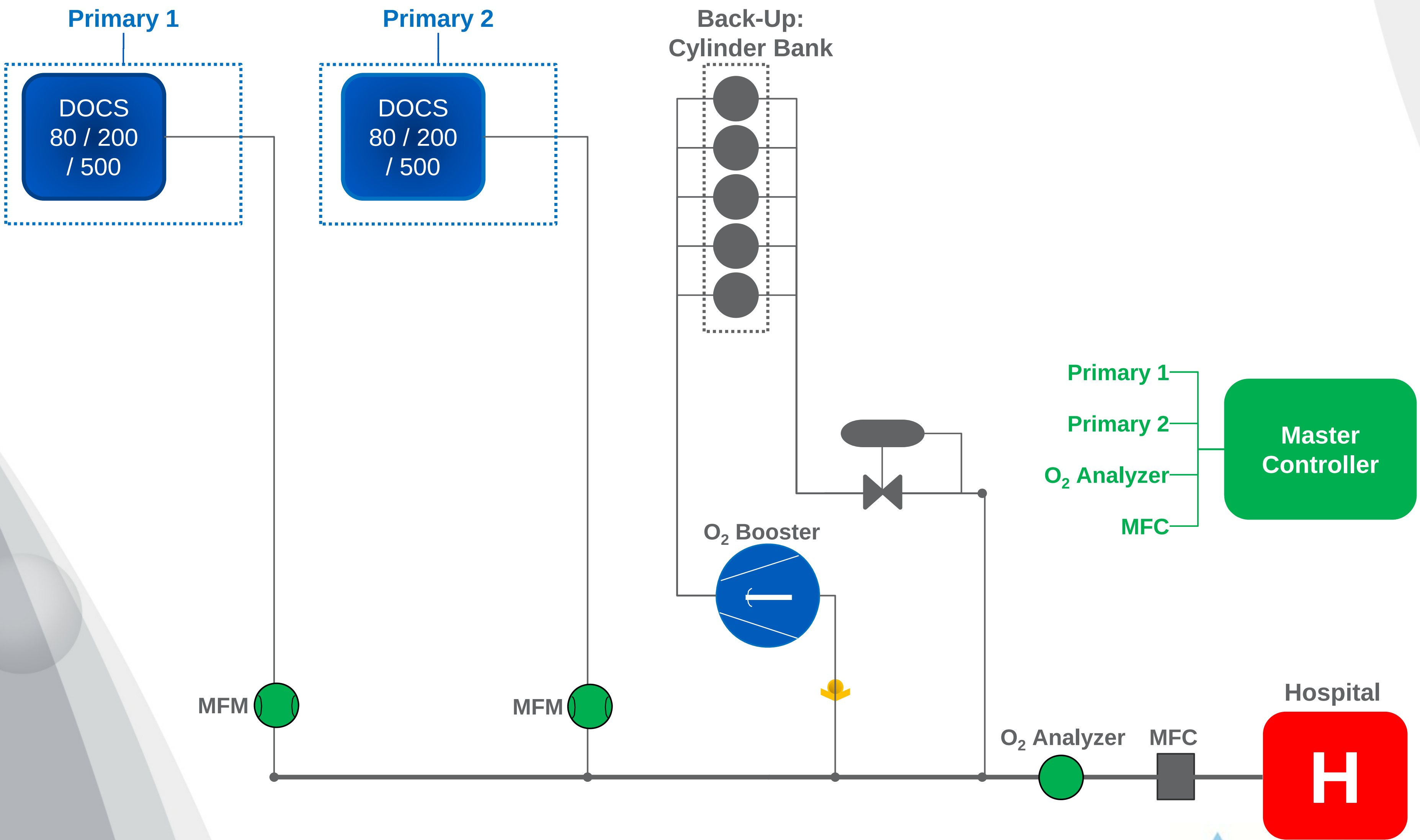
Given that we are dealing with oxygen, how can we ensure safety?

- Needs to be managed by professional personnel
- Equipment rooms to be equipped with ambient O_2 analyzers (>= 2)
- O_2 concentrator locations to be well ventilated and kept at safe distance from flammables
- Typical O_2 cleanliness standards apply for lines leading from OC to hospital central piping system
- On one hand, certain sections of NFPA 99 provide good guidance, e.g.,
  - 5.1.3.3.1.5 / 5.1.3.1.9: Selection of location / Location labeling
  - 5.1.3.3.3.3: Ventilation for motor driven equipment
  - 5.1.3.3.2: Design and construction of location
  - 5.1.3.5.4: Materials
  - 5.1.3.5.6: Relief valves
- On the other hand, it only mentions OCs twice, in a cylinder filling context
- That said, applying above points will lead to safe installation and operation
- **Remember:** bulk O_2 tanks, dewars, or cylinders constitute a much larger safety risk due to the immensely high stored energy

How can we guarantee reliable supply in case something breaks?

- Introduction of ISO 10083 Oxygen Concentrator Supply System (OCSS)
  - Primary 1 source alternatives
  - Primary 2 source alternatives
  - Back-up
- "… This purpose of this International Standard is to specify minimum safety and performance requirements for oxygen concentrator supply systems used to deliver oxygen-enriched air to a medical gas pipeline distribution system. The minimum oxygen concentration produced by oxygen concentrator supply systems is specified. …"
- Elimination of supply chain risks of delivered oxygen actually increases the reliability of having medical oxygen available when needed

Possible Hospital ISO 10083 Oxygen Concentrator Supply System Layout



What happens in the event of a power outage?

- All medical gas alarms and systems require redundant wiring and to be connected to back-up generators to prevent any power outage to affect critical care (NFPA 99 ref.)
- Hospitals typically have diesel powered backup generators. The on-site oxygen generator would have redundant wiring just like the alarm panels at the tank farm so they could use the same backup generator redundancy and support

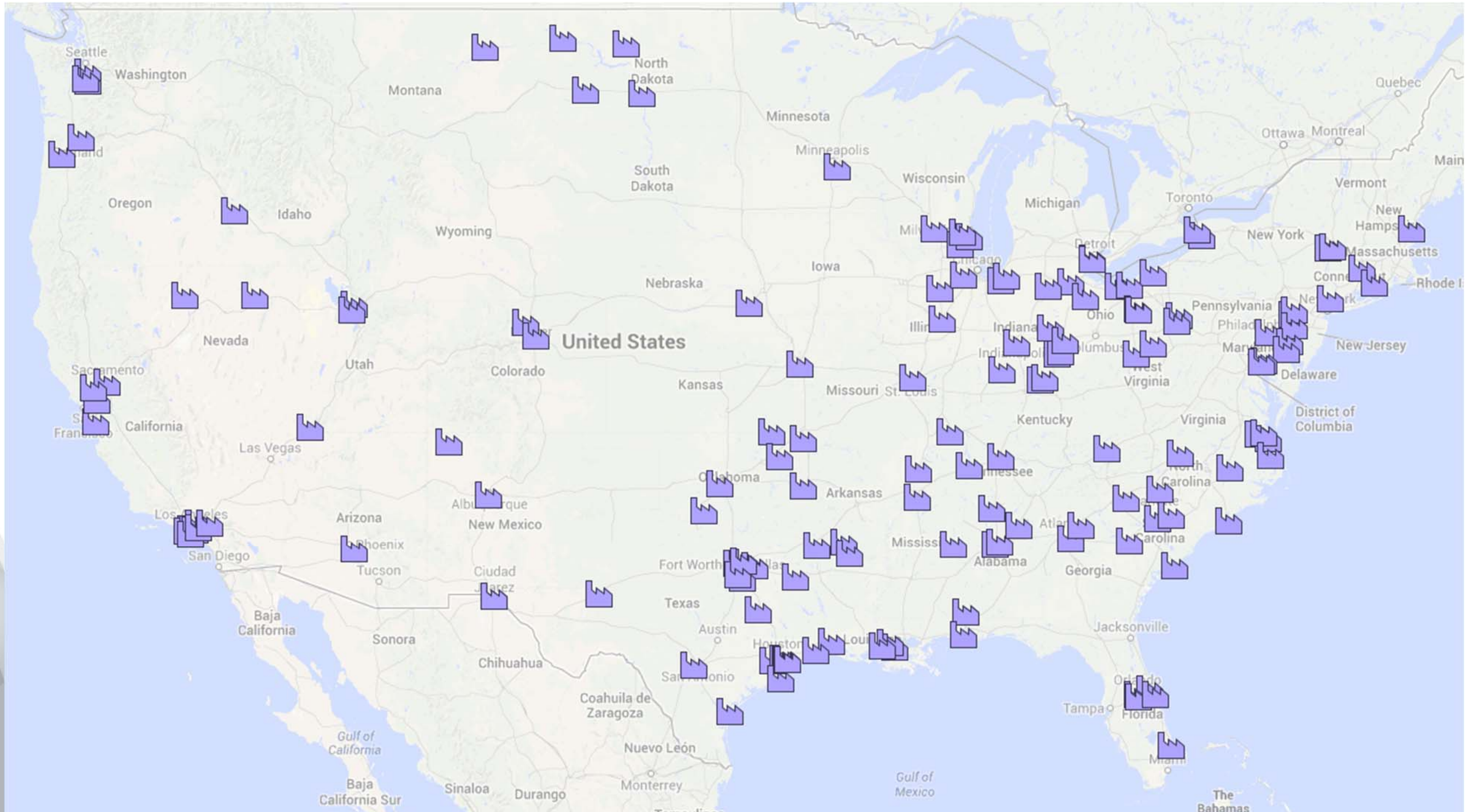
And what is the FDA's position?

- In short: it varies…
- While the FDA is concerned about the mixing of Oxygen 93 and Oxygen 99…
- …It approved many indications for use for on-site oxygen concentrators using Oxygen 93 or oxygen–enriched air
  - Home concentrators have been approved by FDA, with a 85% O2 purity
  - Cylinder filling allowed
  - Use in remote locations
  - Ambulatory patient use
  - Back-up for hospitals
- Many precedents already exist where on-site oxygen concentrators are used in hospitals, e.g., several Hawaii locations
- In the end, as for any other drug, it is the responsibility and right of the local MD whether to administer Oxygen 93 or not

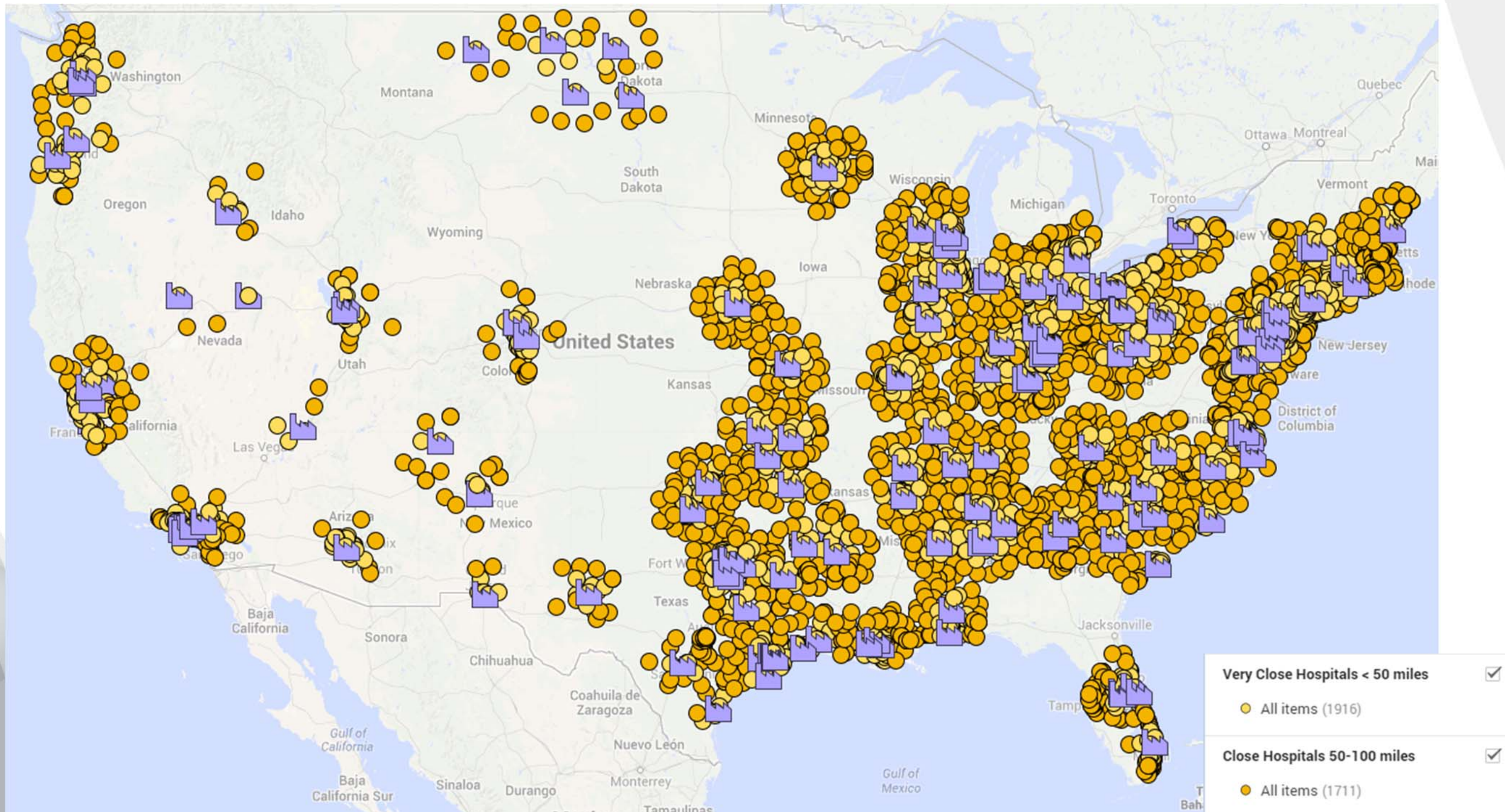
Does it make economic sense?

- The cost drivers of commercially made oxygen delivered to the site
  - Location of Air Separation Units (ASUs)
  - Hospital Size – oxygen consumption (# of beds good indicator)
    - Lower demand -> higher price for hospital
    - Lower demand -> oxygen "packaged" in dewars/cylinder -> price for hospital even higher
  - Regional demand/supply and competition factors

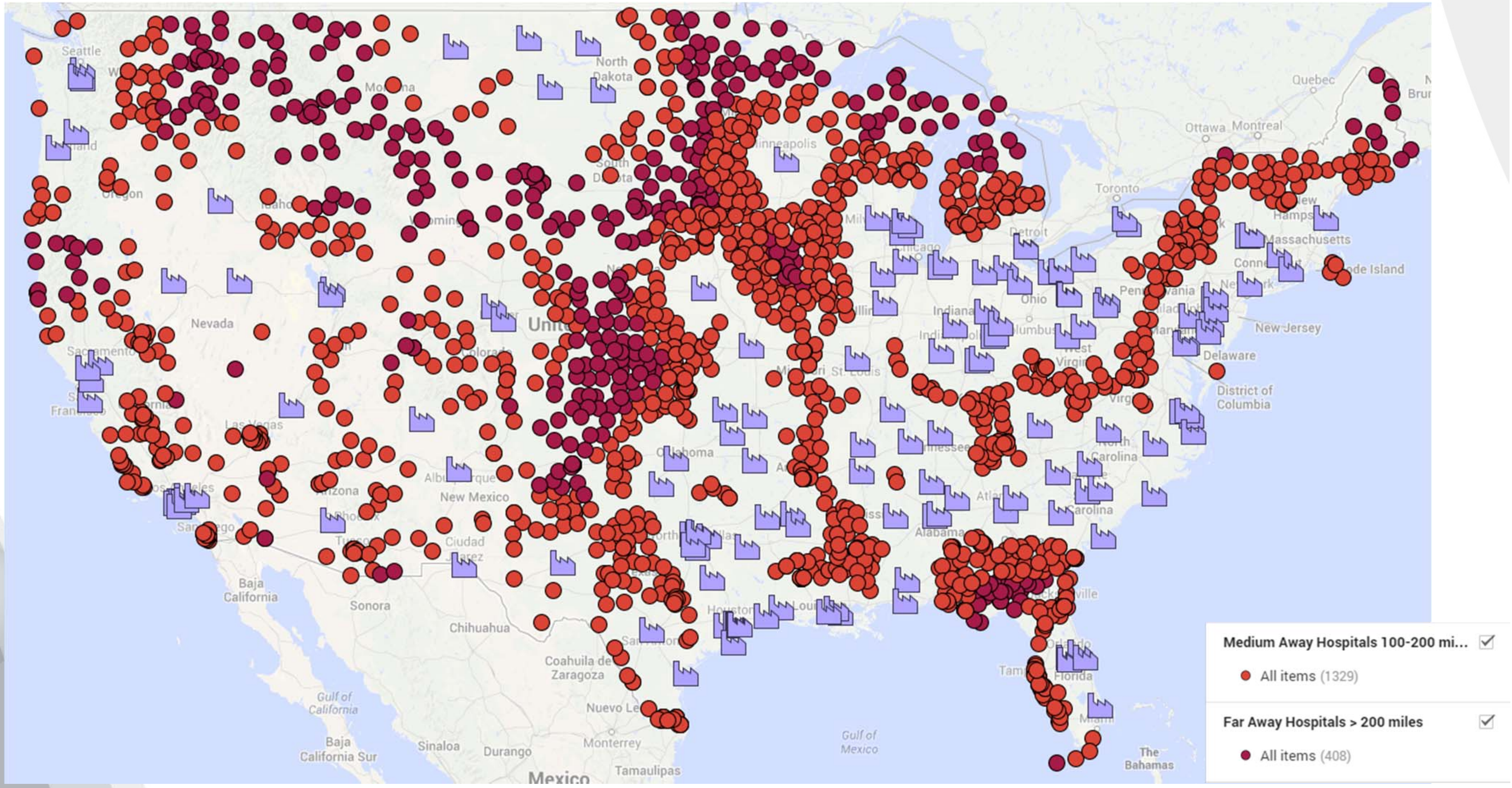
ASUs in the US



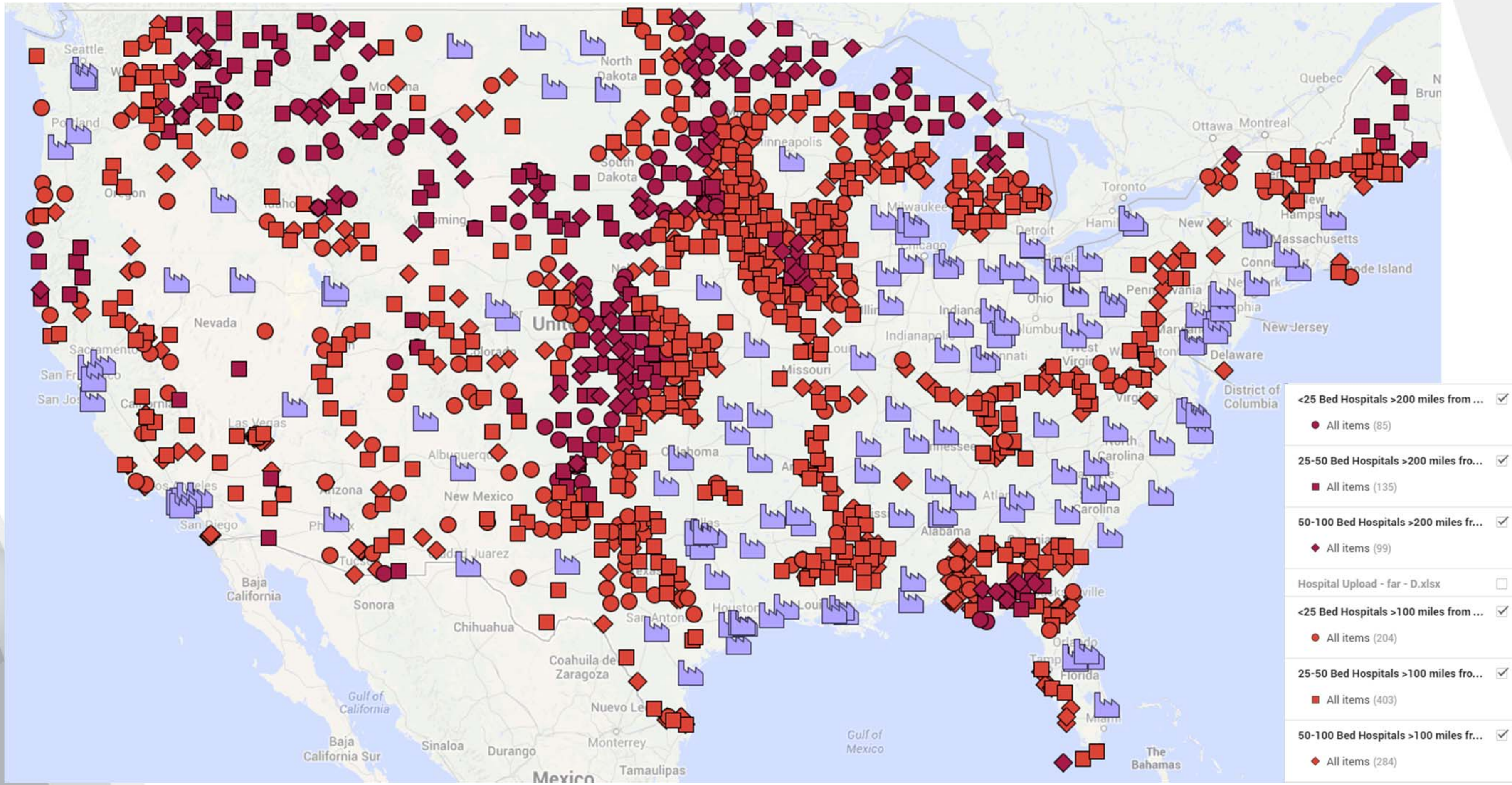
4,600 hospitals with < 100 miles Distance to ASUs – low/reasonable logistics cost → lower price for hospital



1,800 hospitals with > 100 miles Distance to ASUs – higher logistics cost → higher price for hospital



1,200+ hospitals are small and not close…
→ the price gets pretty high!



Hospitals with > 100 miles distance to ASU and < 100 beds

Some Delivered Oxygen Price Examples (delivered in bulk or cylinders)

		Proximity to ASU	
	Delivered Oxygen Price Example ($ per 100 scf)	very close - under 50 miles	not close - over 100 miles
Hospital Size / Delivery Method	large - 250 + beds, bulk delivery	$ 0.35	$ 0.70
	smaller - 50-100 beds, cylinder delivery	$ 1.50	$ 3.00

How Do Oxygen Concentrators Compare? (Operating Cost Level)

		Proximity to ASU	
	Delivered Oxygen Price Example ($ per 100 scf)	very close - under 50 miles	not close - over 100 miles
Hospital Size / Delivery Method	large - 250 + beds, bulk delivery	$ 0.35	$ 0.70
	smaller - 50-100 beds, cylinder delivery	$ 1.50	$ 3.00

		Proximity to ASU	
	On-Site OC Operating Cost ($ per 100 scf)	very close - under 50 miles	not close - over 100 miles
Hospital Size / Delivery Method	large - 250 + beds, bulk delivery	$ 0.25	$ 0.25
	smaller - 50-100 beds, cylinder delivery	$ 0.34	$ 0.34

		Proximity to ASU	
	On-Site OC Savings ($ per 100 scf)	very close - under 50 miles	not close - over 100 miles
Hospital Size / Delivery Method	large - 250 + beds, bulk delivery	**28%**	**64%**
	smaller - 50-100 beds, cylinder delivery	**78%**	**89%**

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How Do Oxygen Concentrators Compare? (Full Cost Level Incl. 5-Year Equipment Lease)

		Proximity to ASU	
	Delivered Oxygen Price Example ($ per 100 scf)	very close - under 50 miles	not close - over 100 miles
Hospital Size / Delivery Method	large - 250 + beds, bulk delivery	$ 0.35	$ 0.70
	smaller - 50-100 beds, cylinder delivery	$ 1.50	$ 3.00

		Proximity to ASU	
	On-Site OC Operating + Lease Cost ($ per 100 scf)	very close - under 50 miles	not close - over 100 miles
Hospital Size / Delivery Method	large - 250 + beds, bulk delivery	$ 0.57	$ 0.57
	smaller - 50-100 beds, cylinder delivery	$ 0.79	$ 0.79

		Proximity to ASU	
	On-Site OC Savings ($ per 100 scf)	very close - under 50 miles	not close - over 100 miles
Hospital Size / Delivery Method	large - 250 + beds, bulk delivery	-61%	19%
	smaller - 50-100 beds, cylinder delivery	47%	74%

Conclusion

- Oxygen 93 is a viable alternative to currently delivered oxygen in not all, but many cases
- It is proven
- It is safe
- It is reliable
- It can yield significant cost savings

Appendix

References

- [1] Friesen, R.M., Raber, M.B., Reimer, D.H., "Oxygen concentrators: a primary oxygen supply source," Can J Anesth 1999;46:1189.
- [2] Janny, S., "The Clinical Utilization of Oxygen 93% in Civilian Markets", 2005; P. 7
- [3] T. Prien, I. Meineke, K. Zuechner, J. Rathgeber, "Sauerstoff 93 – eine neue Option auch fuer deutsche Krankenhaeuser", Anaesth Intensivmed, 2013; 54:466-472. Translated Title: "Oxygen 93 – a new option for German hospitals". Quote translated from German.
- [4] Mitchell, Brent E., Baker, Raymond, Gardner, Stephanie M., Holloway,l Aaron F., Todd, Larry A., "A Descriptive Study of the Percentage of Oxygen Delivered Using the Mercury Tube-Valve-Mask Breathing Circuit at 2 L/min Flow Rates," Texas University Health Science Center, Defense Technical Information Center, 2002.
- [5] Walker, Les, Bee, M., Friesen, R.M., "Effects of oxygen concentrators on ventilator oxygen delivery", Can J Anesth 2010; 57:708-709
- [6] Friesen, R.M., "Oxygen concentrators and the practice of anaesthesia" Can Anaesth 1992; 39:R80-9

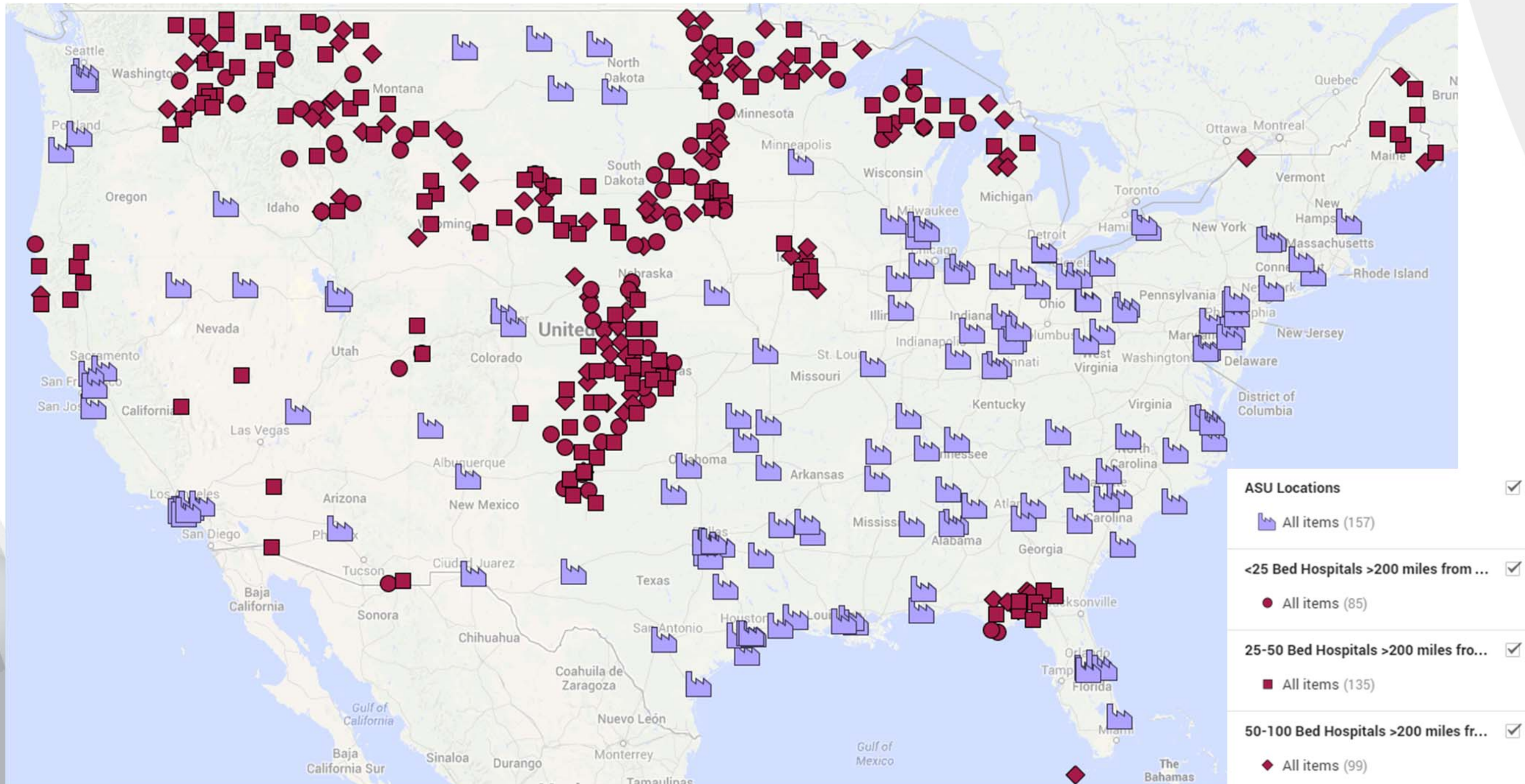
Data Sources

- American Hospital Assocation (AHA) Database
- PCI Gases Market Research
- http://www.eia.gov/electricity/monthly
- Quote from equipment leasing company

Cost Comparison Assumptions

- Cost of power = $0.10 / kWh
- Average oxygen consumption of 1.9 lpm per hospital bed
- 5-year lease interest rate = 3%
- Larger hospital case uses PCI Gases' DOCS 500 as OC
- Small hospital case uses PCI Gases' DOCS 200 as OC

350 hospitals are small and very far…
→ extremely high price!



Hospitals with > 200 miles distance to ASU and < 100 beds

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