Healing Technology

HOSA Canada 2021 ~ **May Day, 2021**

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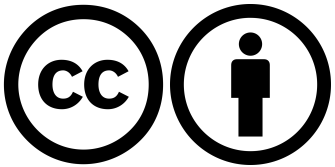

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Disclosure - Azad Mashari

Relationships with financial sponsors (APIL research group)

Research & Salary Support:

- UHN Foundation
- UHN-SHS Anesthesia Association
- UHN-SHS Academic Medical Organization
- Ontario Centers of Excellence (with TME Inc)
- NSERC

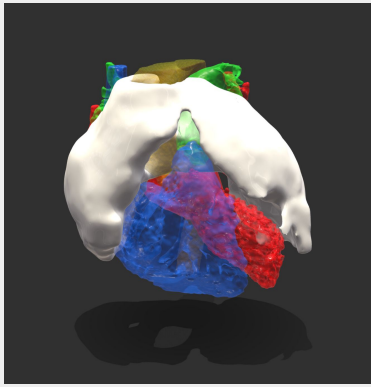
Speakers Bureau/Honoraria: Nil

Consulting Fees: Nil

Research Collaboration:

- Glia Inc. (COVID, other)
- Thornhill Medical Inc. (COVID, other)
- Promation Engineering (COVID)
- General Dynamics Land Systems - Canada (COVID)

Patents: Nil



Project repositories
https://github.com/tgh-apil

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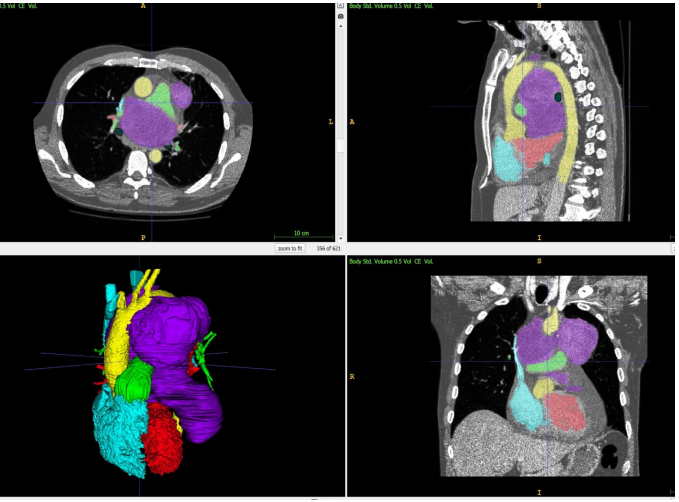
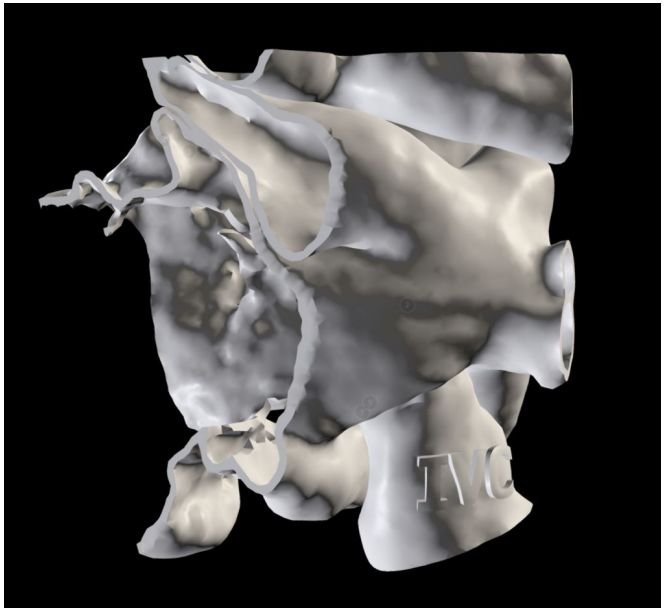
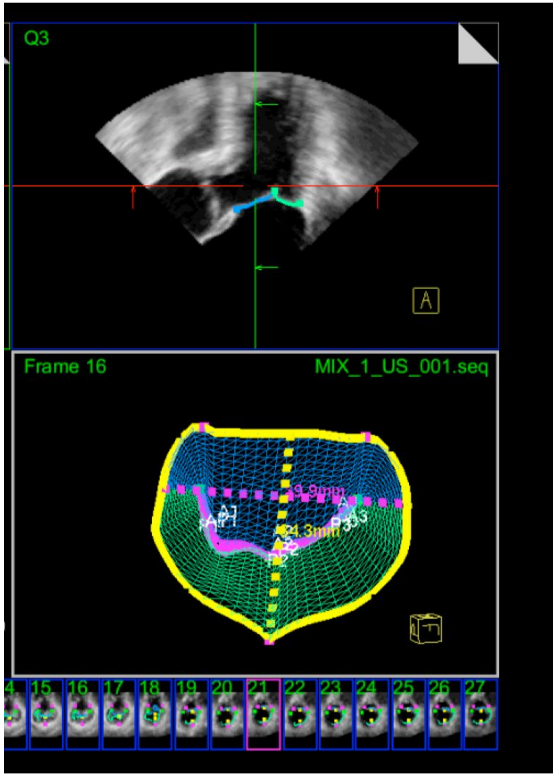
Claude Watson

Perioperative Imaging & Modeling (3D Echo, CT, MRI)







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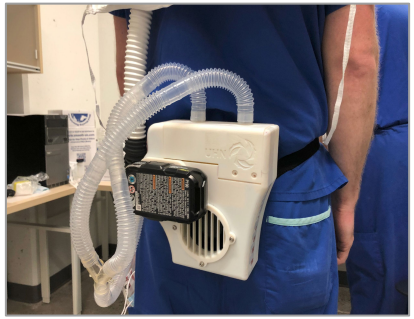
open source

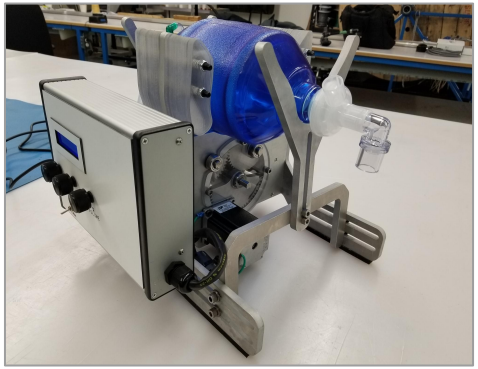
Procedural Phantoms (Based on CT, MRI and 3D Echo Images)

The Lynn & Arnold Irwin APIL Advanced Perioperative Imaging Lab

open source

Open-Source, Locally-Manufacturable, Essential Medical Devices





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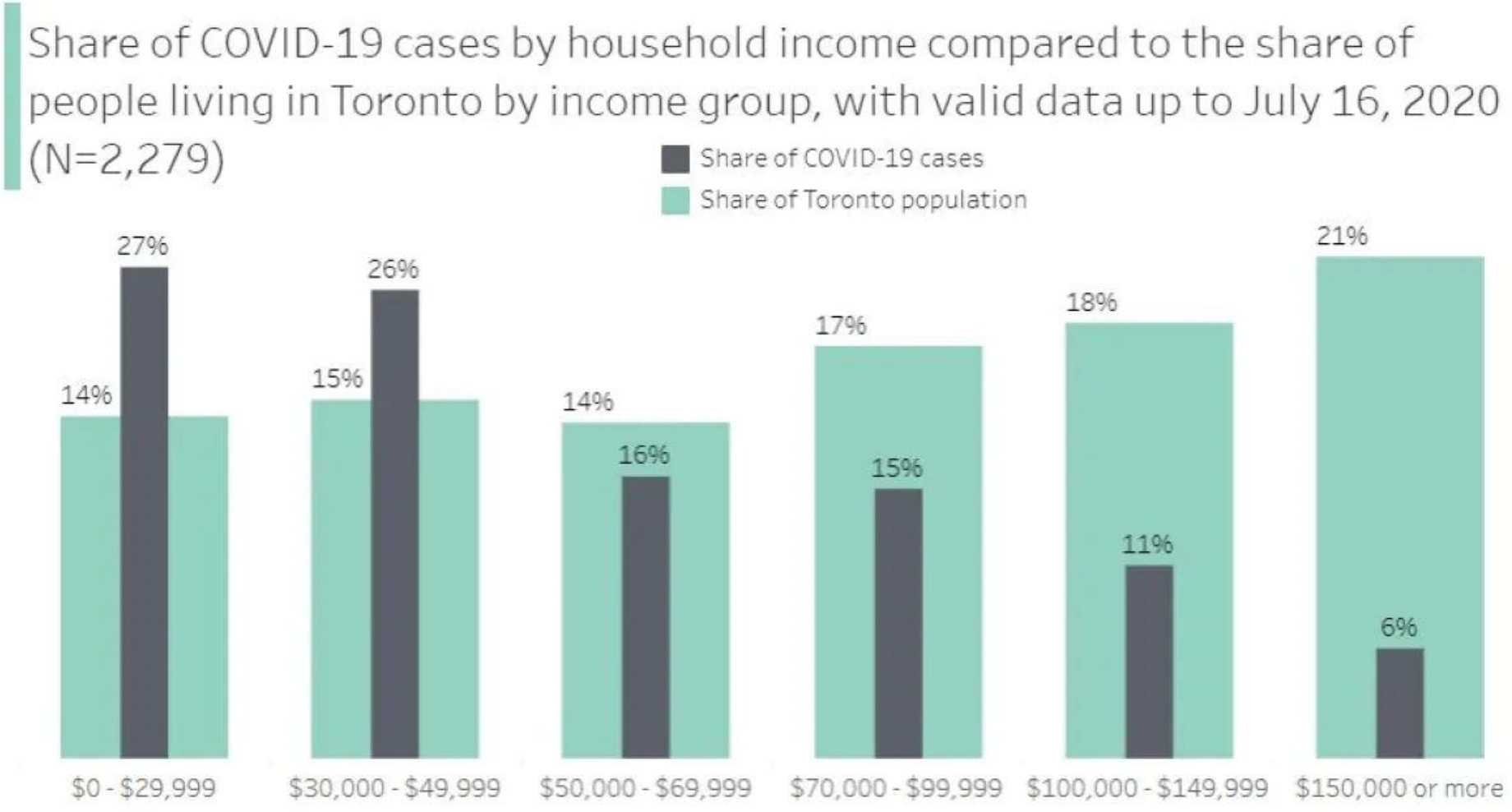
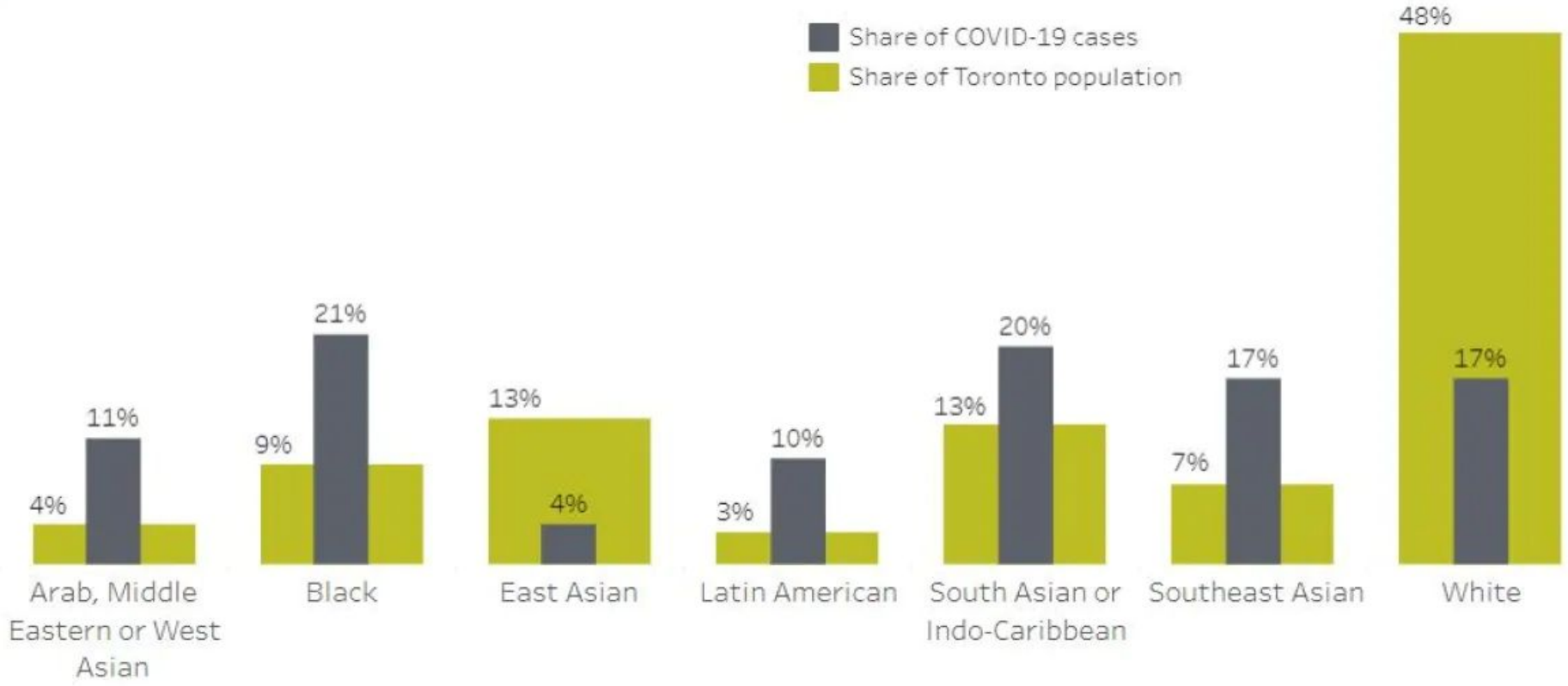
open source

glia equal care



https://www.cbc.ca/news/canada/toronto/toronto-covid-19-data-1.5669091

Share of COVID-19 cases among ethno-racial groups compared to the share of people living in Toronto, with valid data up to July 16, 2020 (N=3,861)



https://www.cbc.ca/news/canada/toronto/toronto-covid-19-data-1.5669091

Why?

A fractal of a problem … not just local

Massive inequalities in the social determinants of health

- Baseline health status
- Ability to isolate/distance (**housing, job and food security, paid sick leave** …)
- Access to information, PPE

Barriers to translating existing knowledge, technology and resources into practice
E.g. ventilators, essential drugs, oxygen, vaccines, PPE

- **IP bottlenecks** - All production flowing through single source
- Vulnerable and **outdated supply chain** infrastructure
- Limited **manufacturing & testing capacity**

Supply Chain Failure

Sparks:

- Rapid increase in global demand
- Closures, worker illness, hoarding, export controls

Tinder:

- **Just-in-time** systems - low stockpiles
- High reliance on **disposable** products and components
- **No advanced emergency planning** in most jurisdictions: e.g. N95s
- **Decentralized supply chain management**: stock information, purchasing; hospitals and LTC fending for themselves on open market
- **Centralized sourcing**: often single supplier with access to relevant **IP** (drugs, devices, vaccines)
- **Limited local manufacturing capacity**: 90% of health products in NA from China. 73% of Mouth/nose protection devices.
- Inability to **evaluate new/alternative products** rapidly

SCANH
Supply Chain Advancement Network in Health

Snowdon A. (2021) Key Characteristics of a Fragile Healthcare Supply Chain. CanCOVID Speaker Series https://www.youtube.com/watch?v=hrooLCxsCRY

Immediate solutions?

Collaboration & open knowledge sharing: e.g virus genome, vaccine *development and testing*

Wide access to information

Low-cost **local manufacturing** infrastructure (open source device repositories, 3D printing and other local manufacturing technologies)

But …

- Is it likely to be **effective** (enough)?
- Is it **safe** (enough)? (design AND production)

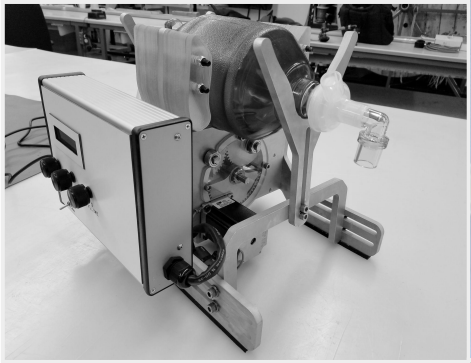
Innovation in technologies for translating existing technologies to the practice of healing

Emergency Use Medical Device Development

Face shields
Reusable Silicone Stop-Gap Respirator
Reusable Snorkel Mask-Based PAPR

Ventilator Sharing System
Aerosol Reducing NIV Mask
BVM-Based Emergency Use Ventilator

Evaluation of BVMs for Pre-oxygenation
Open Ventilator Evaluation Framework
Open Ventilator Controller Platform



Ventilator Shortages ...

Problem:

1. Sudden **global surge of critically ill** patients requiring ventilators
2. Rapidly **exhausted ventilators stocks** even in well-resourced countries
3. **Reduced non-invasive ventilation use** for non-COVID indications out of concern for spreading **infection** >> Increased pressure on limited ventilator supply
4. Limited options for **respiratory support of patients in remote communities** in Northern Canada in the event of outbreaks

Aerosol-Reducing Non-Invasive Ventilation Mask

Goal: Develop a locally manufacturable NIV mask that minimized aerosol generation. For use in transport, hospitals and remote health stations

Progress:

- Developed and tested rapidly in collaboration with Glia & General Dynamics Land Systems-Canada
- May 2020 Health Canada Interim Order Authorization
- Extensive consultation & collaboration with Indigenous community leadership, northern health care providers, Indgenous Services Canada and ORNGE to evaluate device usability
- Clinical trial and further testing to evaluate device safety and efficacy

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equal care

The Lynn & Arnold Irwin
APIL Advanced Perioperative Imaging Lab

References:

1. https://github.com/GliaX/Aerosol-Reducing-Mask
2. Final Report of Device Testing and Clinical Trial Data ARM v1.0

Aerosol-Reducing NIV Mask: Clinical Trial (N = 6+8)

Clinical Trial at London Health Sciences Center

Western University HSREB

Pts. prescribed NIV in ED randomized to ARM or control mask.

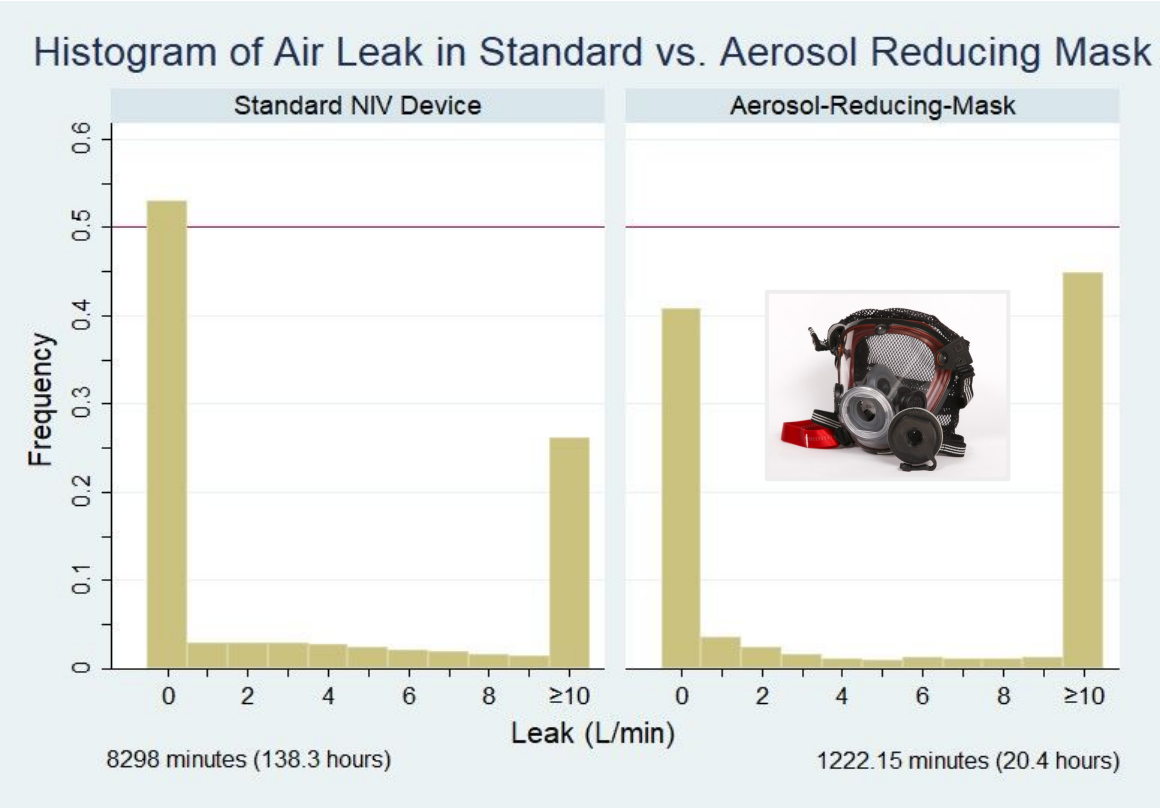
Upto 24 hours.

Outcome: Leak L/min.

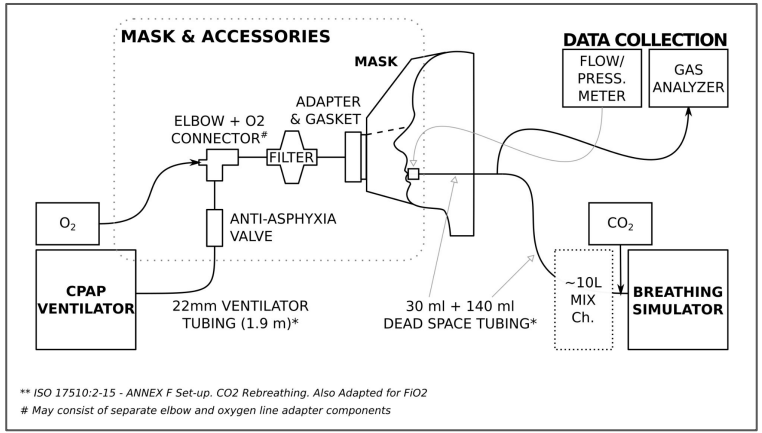
Stopped early after 14 participants
(6 ARM; 8 control) due to loss of equipoise

Device did not reduce leaks

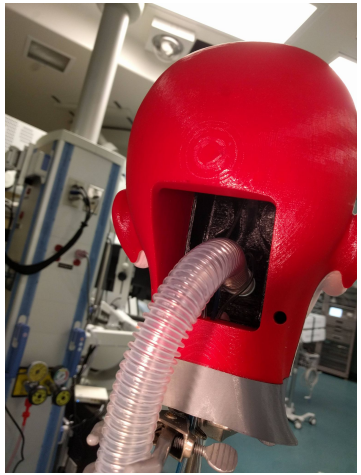
No adverse events



Aerosol Reducing Mask - CO_2 Re-breathing Test *(ISO 17150:2)*



Test Condition	End-Tidal CO2 %	End-Tidal CO2 (mmHg)	Increase from baseline (%)	Acceptable Increase (%)
Baseline: No mask/CPAP	5.04	40	-	-
CPAP 5 cm H2O	5.70	46	**13.1**	20
CPAP 10 cm H2O	4.31	35	**-14.4**	20
CPAP 20 cm H2O	2.30	18	**-54.3**	20
Fault: Patient connection port occluded	8.35	67	**65.7**	60
Fault: CPAP connected with no flow	8.36	67	**65.8**	60



- **Risk** of significant **CO_2 rebreathing** in event of ventilator failure or disconnection.
- Only appropriate for **supervised use**.
- Not practical with current staffing shortages.

Aerosol-Reducing NIV Mask - Quality Control

Health Canada Interim Order Authorization for Clinical Use **May 2020**.

- IO required minimal testing data for Class II device

We undertook additional evaluation after IO authorization

- Testing showed **failure to meet ISO requirements for CO2 rebreathing**
- Clinical Trial: **no reduction in mask leak** overall.
- User feedback (RT, RN): several **significant usability limitations**

Device sales suspended **Nov 2020**. No units sold. Back to the drawing board.

- At the time device was under consideration for deployment by ORNGE & Indigenous Services Canada

Aerosol-Reducing NIV Mask - Spin Offs

Multi-Subspecialty Education for low-Resource Settings (MSERS)
https://apil.ca/multi-subspecialty-education-for-low-resource-settings-msers/

- Evolved out of meetings to introduce device to northern providers for feedback and deployment planning

Incidental finding of significant safety issues with other devices

Some BVM Manual Resuscitators are NOT Safe for Preoxygenation

- New model at UHN & CAMH due to shortage of regular model
- Assumed equivalence since HC approved
- Large leak through expiratory port during spontaneous inspiration in new model.
- **Effective delivered FiO_2 35-60% during negative pressure inspiration.**
- Relevant international standard CSA/ISO 10651-4:2002 only requires 35%. Does not require competence of patient valve.
- Models used before voluntarily exceeded the standard.

References:

1. https://github.com/tgh-apil/BVM-Evaluation
2. MS in preparation.

https://github.com/tgh-apil/BVM-Evaluation

Stop-gap Silicone Respirator Mask (William Ng)

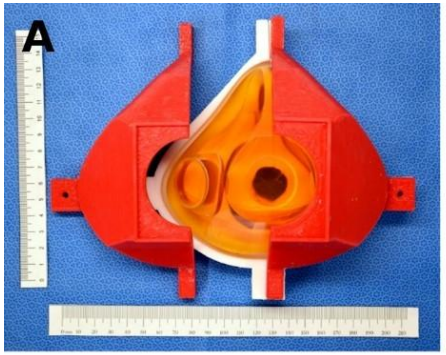
Goal: Develop a locally manufacturable, reusable respirator meeting or exceeding N95 protection

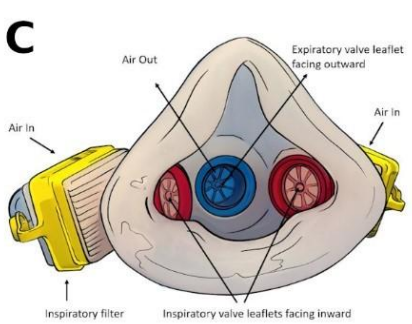
Progress:

- Second generation design. Exceeds N95 filtration performance. Validated in 40 HCW.
- Undergoing testing and refinement to meet technical standards for resistance and CO_2 retention.
- Planned application for HC.

References:

1. https://github.com/tgh-apil/Reusable-N95-Respirator
2. Ng et al. PLoS ONE. 2020; 15(11):e0242304.
3. Anwari et al. PLoS ONE. 2021;16(3):e0247575.





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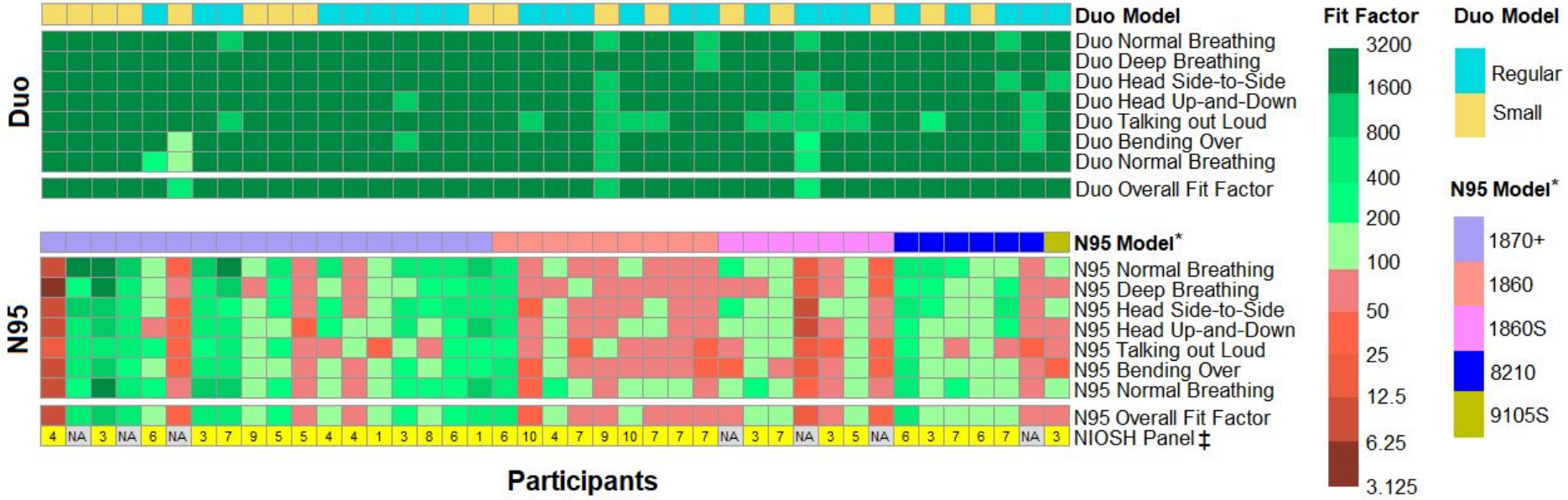
Stop-Gap Respirator (Duo) vs N95:
Quantitative Fit Testing in 40 HCW



Overall **Pass Rate**:

- **N95: 58.5%** (most failures in dynamic maneuvers; difference across models)
- **Reusable SGR: 100%**

What was made (first 6 months)

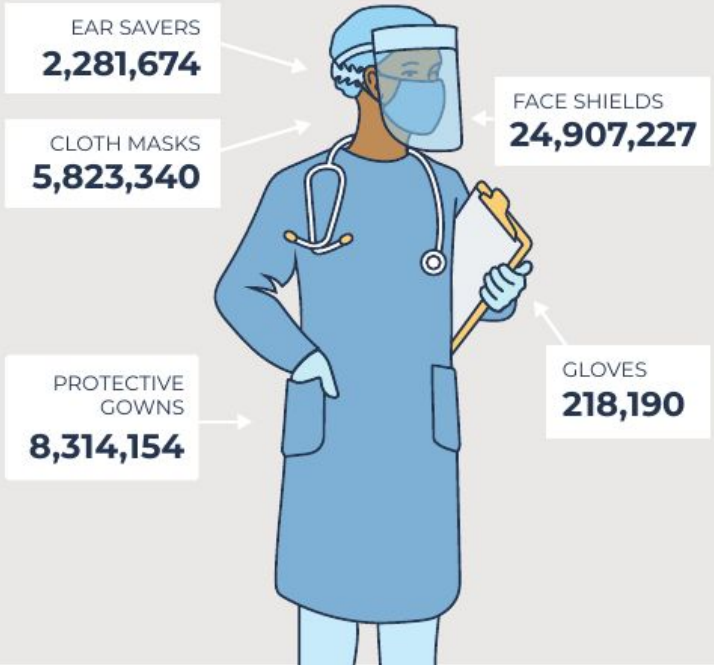
Created hundreds of new open source designs for medical supplies

200+ DESIGNS

available in the OSMS Library for **35 categories of PPE & supplies**

6,000% increase in unique visitors to the NIH 3D Print Exchange within 24 hours of engaging the maker community

Numerous medical inventions



Manufactured & delivered

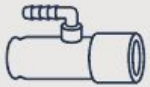
OVER 48 MILLION pieces of PPE and medical supplies

worth $271 million

including critical items such as:

NASAL SWABS
45,000

PAPR HOODS
59,289



VENTILATOR PORTS
4,021

https://OSMS.li/impact

The Work Ahead

Open Source Device Development Process	
Quality Management Administrative System	+
Risk Management Framework	+
Problem Identification	++
Specifications	+/-
Iterative Design, Prototyping, Formative Testing	+++
Formal testing & Validation	+
Supply Chain & Manufacturing Process Design	+/-
Formal Evaluation (bench, clinical, standards conformance)	+/-
Regulatory Approval	+/-
Manufacturing	+
Distribution	+
Post-marketing surveillance	+/-

Conclusions

"Technology has built the house in which we all live"

- *Ursula Franklin*

Technology: **Ways of doing things** - *not just the gadget, but the process by which the gadget comes about, is made, translated to* ***practice***

Some of the most needed forms of innovation are not very flashy - *the unrealized potential of what we have already invented or learned*

Active & critical engagement in healing technologies is increasingly necessary for the effectiveness of our health care systems

Further Reading

Creative Commons (2020) Now Is the Time for Open Access Policies—Here's Why. Creative Commons
https://creativecommons.org/2020/03/19/now-is-the-time-for-open-access-policies-heres-why

Ursula Franklin (1989) The Real World of Technology. CBC Massey Lectures
https://www.cbc.ca/radio/ideas/the-1989-cbc-massey-lectures-the-real-world-of-technology-1.2946845

International Organization for Standardization (2019). Medical devices — Application of risk management to medical devices (ISO 14971:2019(E)).
https://www.iso.org/standard/72704.html

Acknowledgements

S. Ajami, E. Al-Azazi, K. Behdinan, J. Butt, M. Al-Mandhari, S. Ansari, N. Ayach, V. Anwari, J. Carroll, R. Caragata, D. Clinkard, M. Dinsmore, S. Doshi, J. Duffin, D. Duncan, L. Fedorko, J. Fisher, D. Gucciardo, E. Grinspun, J. Han, J. Qua Hiansen, K. Kazlovich, B. Li, T. Loubani, J. May, A. Mbadjeu Hondjeu, C. McFarlane, W. Ng, S. Plimmer, S. Russell, D. Singh, C. Wakem, I. Waller, M. Xiao, T. Yan ...

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The Lynn & Arnold Irwin

APIL Advanced Perioperative Imaging Lab

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Ventilator Splitting System

Society of Critical Care Medicine
The Intensive Care Professionals

ABOUT SCCM + | COMMUNICATIONS + | EDUCATION CENTER + | FUNDAMENTALS + | MEMBER CENTER + | PROFESSIONAL DEVELOPMENT +

SCCM > Emergency Resources: COVID-19 > Advocacy

Consensus Statement on Multiple Patients Per Ventilator

Issued: March 26, 2020, 12:00 p.m.

The above-named organizations advise clinicians that sharing mechanical ventilators should not be attempted because it cannot be done safely with current equipment. The physiology of patients with COVID-19-onset acute

High risk of

- **Barotrauma**: Inability to control distribution of shared tidal volume
- **Hypoventilation** in patient with higher lung compliance
- **Disconnection or blockage** of one circuit affecting both co-ventilated patients
- **Cross Infection**

Ventilator Splitting: Cerberus

J. Han, D. Singh, J. Fisher

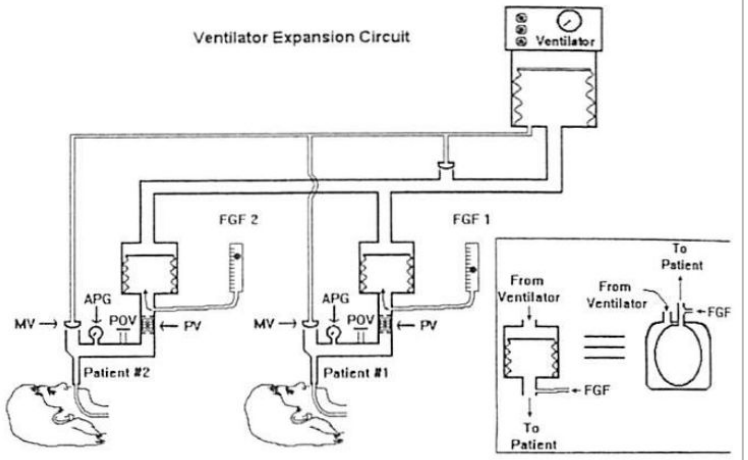
Joe Fisher

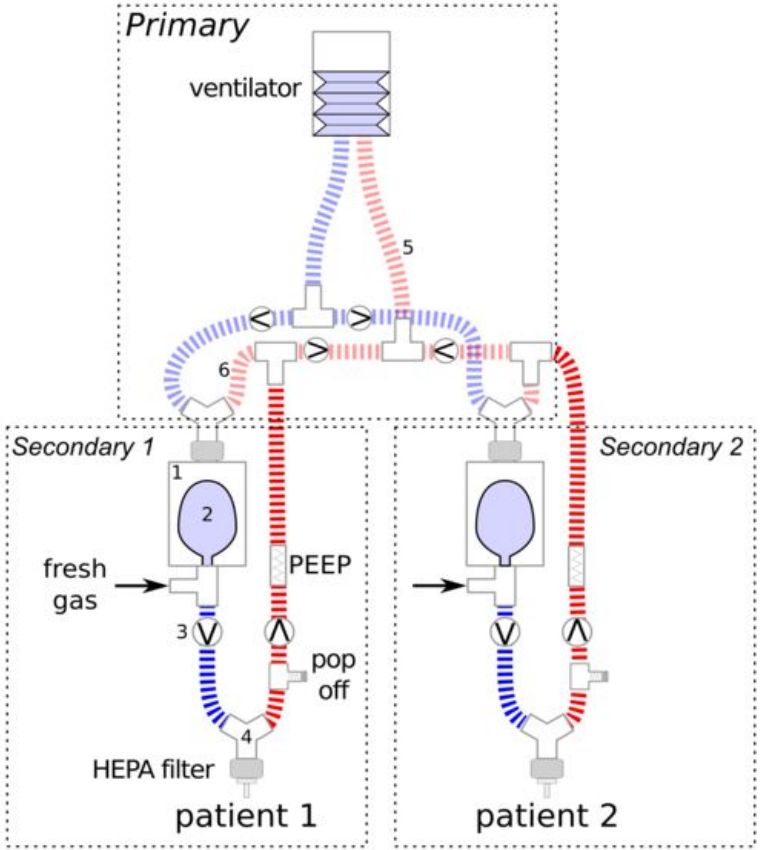
CRITICAL CARE MEDICINE

Apparatus and Techniques

Improvised automatic lung ventilation for unanticipated emergencies

DORON D. SOMMER; JOSEPH A. FISHER, MD, FRCP; VIVEKANAND RAMCHARAN, BSc; SUSAN MARS
DMITAR M. VIDIC, BSc, RRT





Ventilator Splitting: Cerberus

J. Han, D. Singh, J. Fisher

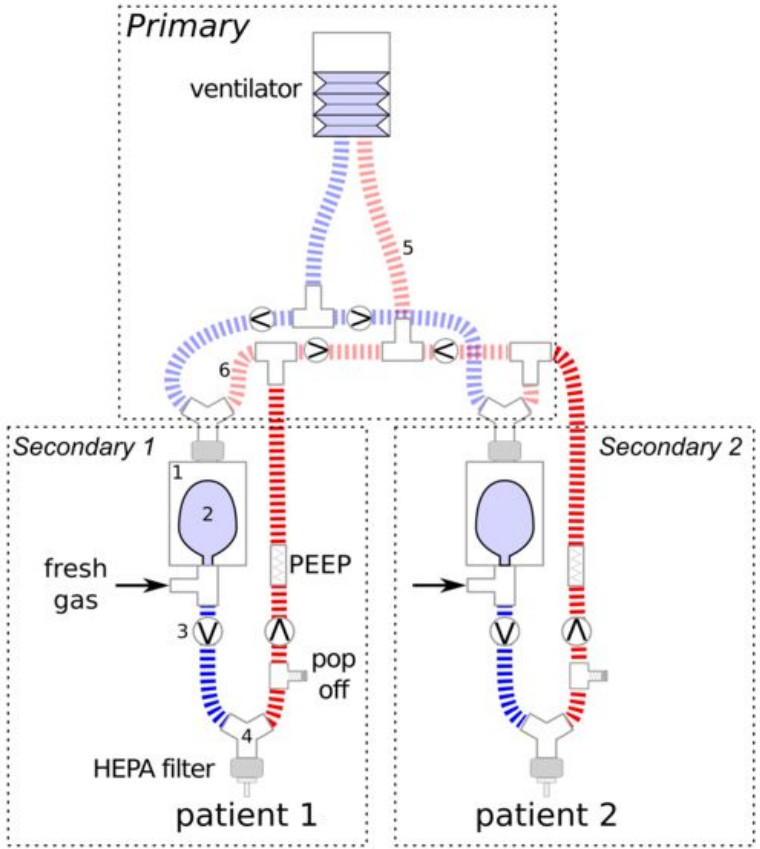
Goal: To build and test an emergency use splitter system that addresses these limitations.

Progress:

- Massive collaborative effort involving over 100 people across U of T and academic hospitals
- System refined and bench validated
- Validated in two pigs (34 and 80 Kg)
- 40 units (80 patient circuits) ordered for UHN in June 2020
- **Still unable to obtain some "off-the-shelf" parts**

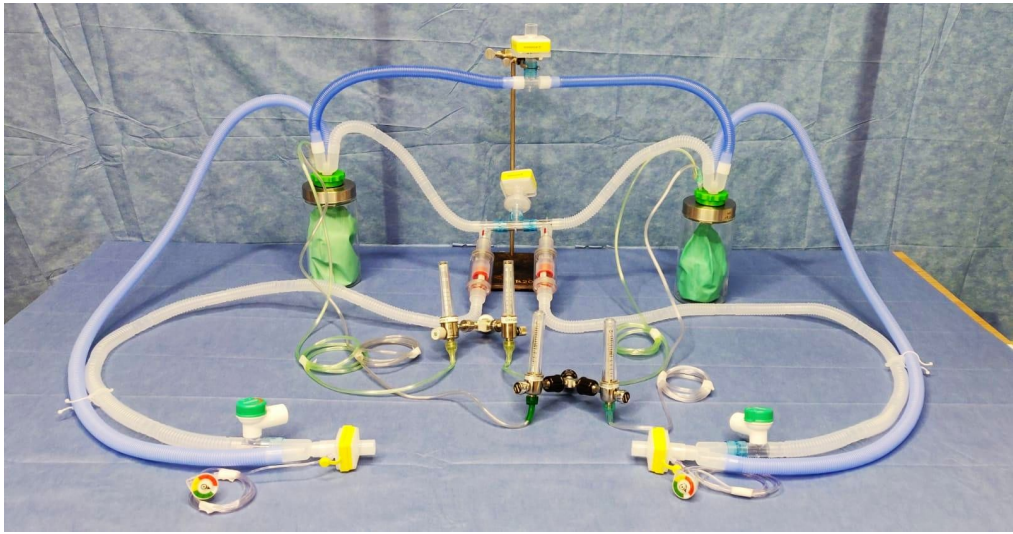
References:

1. https://github.com/tgh-apil/Cerberus-Multivent
2. Han et al. Critical Care Explorations. 2020 May;2(5):e0118.
3. Porcine validation paper in preparation.



Ventilator Splitting: Cerberus

J. Han, D. Singh, J. Fisher



Strengths

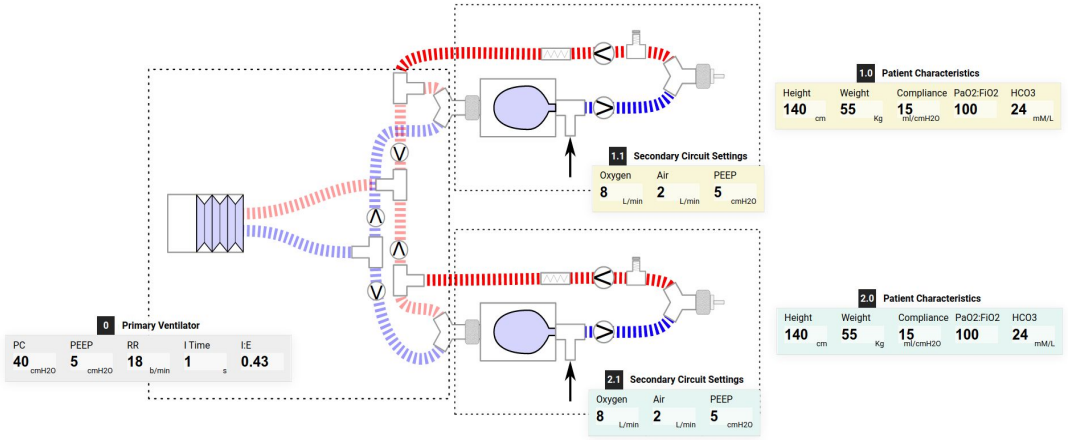
- Independent control of TV, FiO_2, PEEP
- Catastrophe on one side (disconnection, obstruction) does not affect other side
- Isolated gas paths to each patient

Challenges

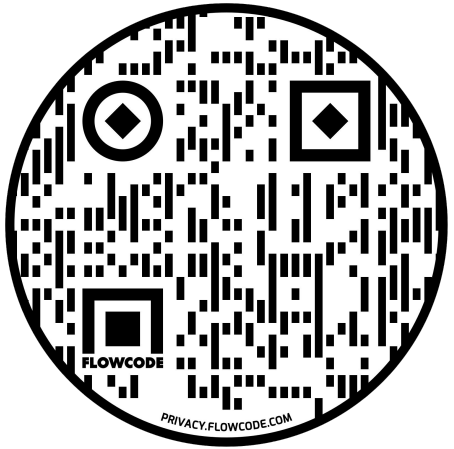
- Volume control only
- Deep sedation
- No weaning
- < 48 hours of emergency use
- Close monitoring (1 provider to max 2 patients)
- **Adjustment is not intuitive ...**

Ventilator Splitting: Cerberus Model & Simulator

Eitan Grinspun, Isaac Waller, Bai Li, James Duffin



https://ventilator-simulator.now.sh



Change the inputs above, then click the "Simulate" button to see results below.

Suggest Settings | + Simulate | Reset

Primary Vent					Patient 1									Secondary 1			Patient 2									Secondary 2		
PC	PEEP0	RR	IT	IER	H	W	Cr	PF	VT	FIO2	PaO2	PaCO2	HCO3	pH	FGFtot	PEEP	APEEP	H	W	Cr	PF	VT	FIO2	PaO2	PaCO2	HCO3	pH	FGFtot	PEEP	APEEP
40	5	18	1	0.43	140	55	15	100	555.56	0.84	84.2	25.93	24	7.59	10	5	14.8	140	55	15	100	555.56	0.84	84.2	25.93	24	7.59	10	5	14.8

Click on a row to reset input values to those values. Current values are **bold**

Expert mode (show all variables)

Point-of-Care Manufacturing & Testing: What has been achieved?

Class I devices - Tens of millions of face shields, stethoscopes, cloth masks made & reached frontlines, many following standard regularly pathways (relatively simple for Class I)

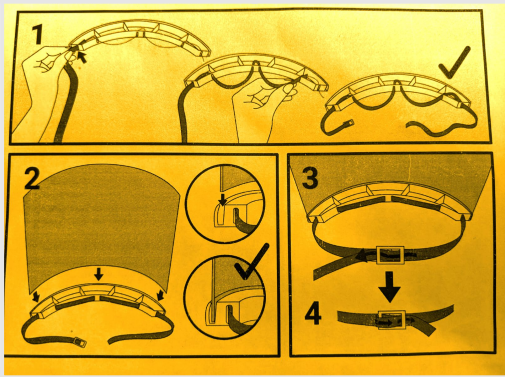
Class II & III - Vast number of collaborations developing open source Class II and III devices
N95 Respirators, Swabs, Ventilation Masks, Ventilator components, Ventilators...

- Massive investment of volunteer resources; significant public funding (swabs, ventilators)
- A few devices received emergency use approval (e.g. HC IO, FDA EUA)

Dramatic growth in networks and communities of open source developers, small-medium scale manufacturers, academics, health care providers

Increasing awareness of the potential of local point of care manufacturing

Increasing awareness of the limits of current regulatory processes



Enabling Network Infrastructure

OPEN SOURCE INFORMATION

We were able to prepare and organize **weeks before the virus reached our country** due to the experiences, resources, procedures, source files, etc. shared by the maker community as a whole.

Andres Hermes
TecLab, Guatemala

COMMUNITY NETWORKS

71% of respondents depended on networks, community platforms and personal introductions

It's been fantastic **not only to share but compare and review** what people have been doing.

Sam Haynor
Something Labs,
San Francisco, CA

VETTED DESIGNS

50% of respondents made use of open source design repositories

Without the **pre-vetted designs** AND **production instructions** we would have spent too much time reinventing the wheel and not enough time producing.

Nathaniel Fairbanks
MakeIt Labs, Nashua, NH

https://OSMS.li/impact

Now Is the Time for Open Access Policies—Here's Why


Victoria Heath and Brigitte Vézina
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Creative Commons. Now Is the Time for Open Access Policies—Here's Why. Creative Commons https://creativecommons.org/2020/03/19/now-is-the-time-for-open-access-policies-heres-why/ (2020).

Safety & Quality Control Failure

Damage control & Fallout:

- Accelerated regulatory approval pathways >>> **Quality control failure**
- Rapid retooling, accelerated manufacturing >>> **Quality control failures**
- Market competition >>> skyrocketing prices (1000% increase N95s, Swabs …) >>> Incentive for **unscrupulous production**

Digital Stockpile?

Separate development from manufacturing

- **Open-source stockpile of essential devices**
  - device design & manufacturing plans
  - Testing procedures and data
  - QC plans
- **Emergency manufacturing networks** - local manufacturers, academic centers, community groups etc.
  - **Hospital based manufacturing & testing facilities**

Merlo S. (2020) Building Medical Supply Chain Resilience through a U.S. Manufacturing Reserve and Digital Stockpile. Day One Project; https://www.dayoneproject.org/post/u-s-prototyping-manufacturing-reserve-u-s-digital-stockpile

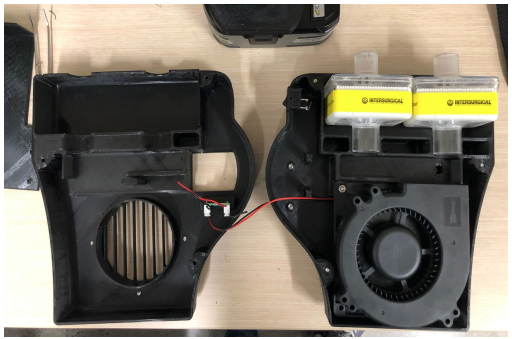
Positive-Pressure Air Purifying Respirator (PAPR) - Mod. Snorkel Mask

(L. Fedorko)

Goal: Develop a locally manufacturable, reusable PAPR

Progress:

- Designed, tested, and validated in 40 HCW.
- 50 units manufactured for UHN. Not deployed.
- Difficulty communicating (like other PAPRs)
- Planned application for HC.



References:

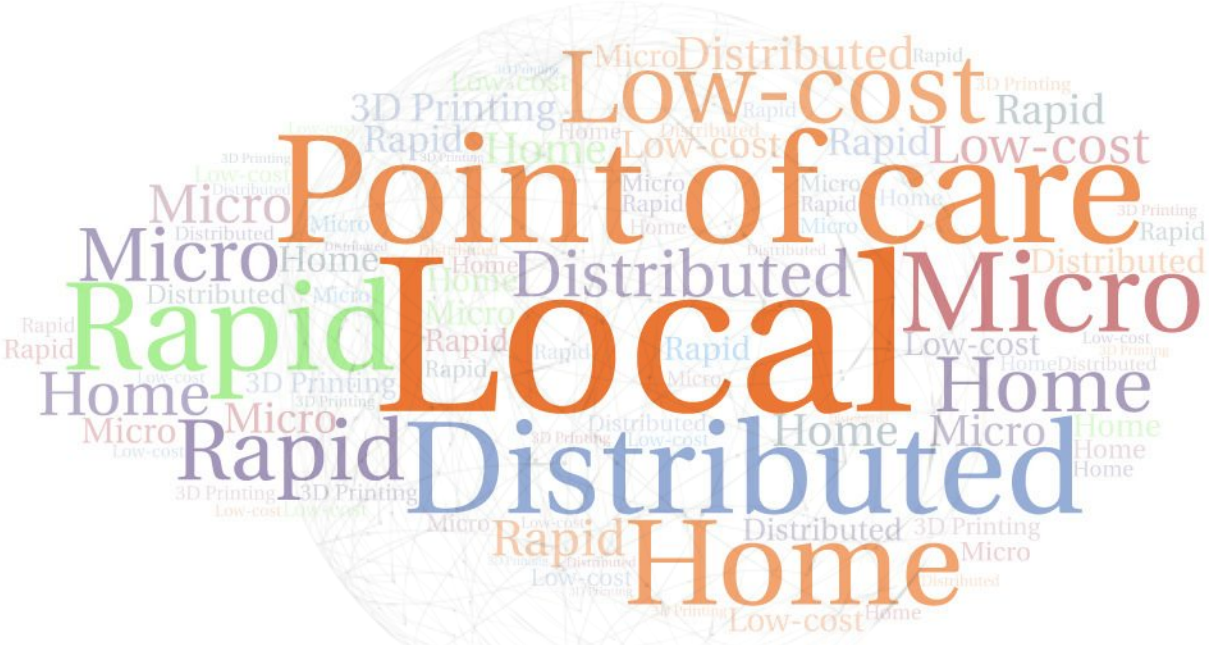
1. https://github.com/tgh-apil/PAPR
2. Clinkard et al. Anaesthesia. 2021;76(5):617–22.

N95 vs. Filtered Snorkel Mask vs. PAPR: Quantitative Fit Testing in 40 HCW

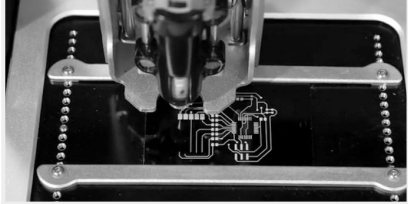
Respirator Feature Summary

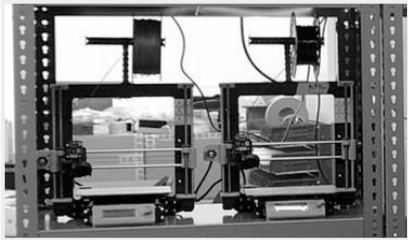
	Face Seal	Filtration Performance	Filtered Exhalation	Comfort	Voice
Disposable N95	+/-	+/-	+	+	+/-
3M Elastomeric	++	++	-	+/-	-
Duo Stop-Gap Silicone	++	++	+	+/-	-
Snorkel PAPR	+	++	-	+	-

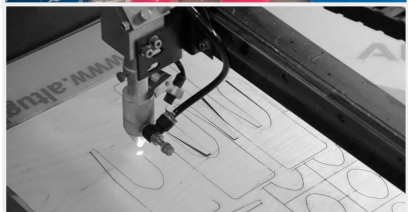
A family of Accessible Production Techniques *(e.g. molding)*
& Programmable Machines *(e.g. 3D printers)* for Making Health Care Products



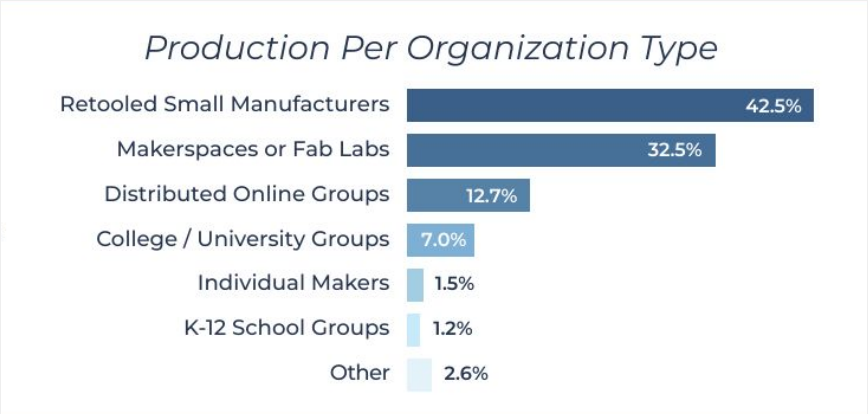
open source







Bird's Eye View



International survey by *Open Source Medical Supplies & Nation of Makers*

- **6 months March - Sept 1 CE (2020)**
- **1800 respondents from 86 countries**
- **42,000 people involved, 93% volunteers**