

## **Towards Cooperation in the Pandemic Mid-Game**

Hosted By:

- Public Invention
- Helpful Engineering
- Make Magazine

With special thanks to Deepti, Avinash and Enrique!

## Motivation

#### The Pandemic has killed 328,000 people worldwide as of this morning.

Thousands of people right now are trying to save lives by preventing a shortfall of invasive and non-invasive ventilators.

This conference is to support and bring us together as a community to save lives.

The mechanism we are exploring is building open-source ventilators, which may lead to longer term

### **COVID-19** is a great creator of chaos and confusion!

Please be patient if we make some mistakes running this.

## Preliminaries

- We have Code of Conduct. Contact <u>deeptisharmagl@gmail.com</u> if anyone misbehaves.
- Please use our Slack channels at Helpful Engineering! The more side-conversations we have the better.
- Time will be kept very strictly!
- Hopefully we will produce videos after-the-fact (we have not practiced this.)

## Program

- I. 7:00 AM PDT, Introduction (15 minutes Rob Read):
- II. 7:15 AM PDT, Landscape and Modularization (Tim Artz, Rob Read, and Deepti Sharma) (20 minutes, 5 minute questions, 5 minute break)
- III. 7:45 AM PDT, Clinical Issues (Prof. Michelle Mellenthin, Dr. Erich Schulz) (20 minutes, 5 minute questions, 5 minute breaks)
- IV. 8:15 AM PDT Philanthropists, US Government (NIST) and Military (5-minute lightning talks)
- V. 8:45 AM PDT, From Workbench to Deployment: Sarah Benson-Konforty, MD , Narayan Sundararajan, (30 minutes)
- VI. 9:10 AM PDT, Michelle Lott on FDA Authorization
- VII. 9:15 Am PDT The Developing world Marcos Mendez from Brazil and Karene Melloul from Kenya, Rebecca Alcott of EWB USA (20 minutes, 5 minute questions, 5 minute break)
- VIII. 9:45 AM PDT Looking to the future (20 minutes, 5 minute questions, 5 minute break)
  - A. Karen Sandler to talk about open source medical devices in general
  - B. Dale Dougherty on "Plan C"
  - IX. 10:15 AM PDT Next steps Closing Ceremonies (15 minutes)

## Landscape and Modularization

Presenters:

Tim Artz and Rob Read (@robertleeread)

## 7:15 AM - 30 minutes





- Founded March 9, 2020 on the principle of Effective Altruism
- 3,400 users, 16,000+ in slack
- Started as a place where engineers who wanted to help could connect to build projects together
- Developed into incubator for COVID-19 related projects
- Vision Statement:

 Helpful Engineering is an international, open source community incubator focused on mobilizing people to help solve the Covid-19 pandemic and other critical issues. With thousands of volunteers worldwide, we support projects through innovations in engineering, community resources, software, and manufacturing.



- Anyone can join and start a project, utilizing HE's network and deep bench of talented engineers to create "swarm" project
- Once project has developed, can apply to be officially supported by HE unlocking additional resources such as manufacturing connections, legal assistance, publicity, and funding
- When project is ready to launch, HE assists in spinning off project into its own organization



- The Mask Project (<u>www.maskproject.tech</u>) is HE's first launched organization
  - Already delivered hundreds of thousands of Origami Face Shields, continues to produce and distribute to at-risk communities globally with open-source design
  - Developing safe, reusable, sterilizable respirators
- Helpful Engineering UK has delivered over 15,000 face shields to London hospitals, care homes, and clinics
- More PPE projects ongoing including respirators, N95 material, cloth masks



- Three officially supported Ventilator projects Offset Ventilator, ARMEE, RespiraWorks
- Three other active swarm ventilator projects
- Three ventilator "module" projects mostly flow/volume sensors
- PPE -> Ventilator Pipeline



#### HE and the Future of OSV

- Safety and Testing are #1 Priority Always
- Open Licensing and FDA Approval

- Benefits to consolidation, variety
- HE always open to a better way of doing things



# Building an Open Ventilator Ecosystem

Robert L. Read (@robertleeread) and Jenny Filipetti (@jennyfilipetti)





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Link to definition of evaluation criteria:	https://docs.google.com/docum	nent/d/e/2PA	CX-1vRI9yZ2	7KvslftcNvw	eHgH1A81p	O8gHL62T	NpY_VY-U	ELWdK9x-	4-3hNw3Dbl	kemClzExPsg8	8RfnxilP/pub			
Project Name	Project Link	Openness	Buildability (1 unit)	Community Support	Functional Testing	Reliability Testing	COVID-19 Suitability		Average	Manufactura bility (1000s)	Date Last Evaluated	Point of Contact	Team Needs	Drive
Ambovent	https://1nn0v8ter.rocks/AmboV	5	5	5	5 4	<b>ч</b> з	4	. 4	4.29	3	2020-05-15	dreliram@gmail.		AmbuE
Medtronic Puritan Bennett (PB) 5	http://newsroom.medtronic.com	4	2.5	4	5	5 5	4	5	4.21	4	2020-04-19			Pump
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Rice OEDK Design: ApolloBVM	http://oedk.rice.edu/apollobvm/	5	4	4	2.5	2.5	3	2.5	3.36	2.5	2020-04-19	amy.k@rice.edu		AmbuB
A.R.M.E.E. Ventilator	www.armeevent.com	5	5	4	4 2	2 3	2	2.5	3.36	5	2020-04-19	warrenkoch@gm		Pnuem
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OpenVentilator (PopSolutions)	https://www.popsolutions.co/er	5	3.5	4	3.5	5 3	2	2	3.29	3	2020-04-08	contact@openve		Bellow
Low-Cost Open Source	https://github.com/jcl5m1/venti	5	4	4	4 3	3 1	3	3	3.29	3	2020-04-19	https://github.con		Pump
DIY-Beatmungsgerät [Respirator]	https://devpost.com/software/d	5	4	3	2.5	5 2	3	3	3.21	0	2020-04-19	https://docs.goog		AmbuB
MakAir	https://github.com/makers-for-l	4.5	2.5	5	5 3	3 2	2	3	3.14			quentin.adam@c		
OperationAIR	https://www.operationair.org/	4	4	4	4 3	3 2	3	2	3.14		2020-05-05	info@operational		Mass F
PREVAIL NY	https://jmawireless.com/prevail	4.5	4	3	2.5	5 C	4	3.5	3.07	3.5	2020-04-19	customerservice		AmbuE
VentilAid	https://www.ventilaid.org/	5	4	4	4 3	8 C	2.5	2.5	3.00	2.5	2020-04-08	media@urbicum.		Bellow
CoroVent	https://www.corovent.cz/	3.5	2.5	4	4 4	L C	3.5	3.5	3.00		2020-04-10	simon.rakosnik@		Bellows
Flow-i Bridge Project	https://grabcad.com/library/flow	4	2.5	3	3 2	2 2	3.5	4	3.00		2020-04-25		clinical validation	n Servo (
Protofy Team OxyGEN	https://oxygen.protofy.xyz/	5	4	4	3	3 1	2	1	2.86	3	2020-04-19	https://www.oxyg		AmbuB

Over 100 somewhat open-source ventilator projects right now... a better way to use thousands of skilled engineers is to modularize the problem.



## Example of Sensor Module: The VentMon T0.1



Four shipped as May 18th, thanks to Lauria Clarke. Inquire to obtain one free of charge.

## But Standards are Key:

- PIRDS -- Public Invention Respiration Data Standard (<u>https://github.com/Publnv/PIRDS-respiration-data-standard</u>)
- Standardizes dimensional units and accuracies and time-marking
- Thanks to Lauria Clarke and Geoff Mulligan
- Byte-level standard for I2C...but JSON binding as well.

B0	B1	B2	B3	B4	B5	B6	B7	B8	B9	B10	B11		
.W.	measurement type identifier	device type identifier	device location	time B0	time B1	time B2	time B3	measurement B0	measurement B1	measurement B2	measurement B3		
char	char	char	char	unsigned integer				signed integer					

BO	B1	B2	B3	B4	B5	B6	B7	B8	B9	B10	B11
'M	Ŧ	'B'	2	0	0	3	5	0	2	5	0

## Standards (PIRDS) allow teamwork. Check out the live A.R.M.E.E. device: <u>http://ventmon.coslabs.com/</u> <u>http://ventmon.coslabs.com/breath\_plot?i=98.196.66.243</u> <u>http://98.196.66.243/webcam/?action=stream</u>



Many thanks to the MillionVents/ A.R.M.E.E. team for helping us to demonstrate the VentMon!

Check out there fascinating, no-moving-parts ventilator: http://45.79.18.170/?utm\_content=129328864&utm \_\_medium=social&utm\_source=twitter&hss\_channel =tw-1238615235478642689

## If we had a control standard (PIRCS)...

https://github.com/PubInv/pubinv-respiration-co ntrol-standard/blob/master/PIRCS.md

We could build an "Air Drive" that separates the problem of producing medical gases in a carefully controlled way.

<u>The Pressurizer</u> by Rob Giseburt is a first stab at this.

With a standard, the "bag squeezer" could be replaced with a pump, or a fan, or a pressure valve.



Standards can give us "plug compatibility' or even "hot swappability". "Bag Squeezers" can be replaced with pumps which can be replaced with pressure valves, all quickly.



## Principles that demand Openness and Modularity

90% testing, 10% design

- Engineering Modularity => Supply Chain Resilience
- Softening/Smartening => Versatility through replaceability
- Mutability of Design => Flexibility of Treatment
- Cooperating Teams => Faster Deployment through Critical Path
- Openness => Confidence through Peer Review and 3rd Party Testing

An Open Ecosystem Handles Uncertainty and Possible Future Needs.

Time spent on non-smart invasive ventilators has not been wasted! But must be extended.

#### ?? UNKNOWN ??



## To Build and Open Ecosystem...

Share your work immediately---right now---with a free-libre or permissive license.

Invite 3rd parties to test your work as soon as possible.

Value documenting your work so that others can reuse it.

A large community requires a large investment in communication.

## **Clinical Issues**

Presenters:

Prof. Michelle Mellenthin, PhD, Colorado Mesa University.

Dr Erich Schulz, MBBS, FANZCA, Brisbane, Australia. (@ErichSchulz)

7:45 AM - 30 minutes

# Pulmonary Biomechanics of ARDS and Ventilator Induced Lung Injury

Michelle Mellenthin, PhD

Vent-Con 2020

## A Special Thanks to Collaborators

- Bradford Smith, PhD
- The Smith Lab
- Jason Bates, PhD
- Richard Albert, MD
- Katharine Hamlington-Smith, PhD



## **Goal of This Presentation**

# **Define the problem.** How do you ventilate someone *safely* with ARDS?





make surfactant).

Image from: http://www.aboutcancer.com/lung\_xrays\_normal.htm

Middle sized air tubes

(Bronchii)

Air sacs

(Alveoli)

Smallest air tubes

(Bronchioles)

## Acute Respiratory Distress Syndrome





### **ARDS:** Fluid in the lungs.

Mechanical Ventilation: machine that replaces normal breathing.

## Pre COVID-19: ARDS by the Numbers

Influenced Persons in the US:

- 40% mortality rate (closer to 50% in COVID-19)
- 75,000 annual deaths

Many researchers that study ARDS feel that to improve care we need:

- Models that predict safe ventilation for each individual.
- Customized care in the clinic.







# So, why is ARDS so hard to treat?

Image from: https://www.nejm.org/doi/story/10.1056/feature.2013.11.13.18?page=

## Pigs with ARDS and Ventilator Induced Lung Injury





#### **Healthy Lung**

#### **Injuriously Ventilated**

Images from: Nieman, et al. "A Physiologically Informed Strategy to Effectively Open, Stabilize, and Protect the Acutely Injured Lung" *Frontiers in Physiology*. 2020

## Pigs with ARDS and Ventilator Induced Lung Injury



High Dynamic Strain: lung was allowed to collapse

#### **Healthy Lung**

#### **Injuriously Ventilated**

The dynamic strain was adjusted using the airway pressure release ventilation (APRV) mode by changing the expiratory duration, which changed tidal volume size
# A thin slice of lung tissue...



# Uninjured vs Injured Lung Tissue



#### Healthy Lung



ARDS / Injuriously Ventilated

# Mechanisms of Ventilator Induced Lung



E. Uninjured alveolar surface with wrinkles and some particle coating, cell junctions  $\longrightarrow$ , type 2 cell \*

# **Atelectrauma** Volutrauma 5 um

C. Injured surface  $\Delta$ , transition from disrupted to intact surface  $\Rightarrow$ , intact surface  $\bullet$ , crack in surface  $\Rightarrow$ 

#### **Healthy Lung**

#### **Unhealthy Lung**

# An ARDS researcher's perspective....



Within the lung, everything is **mechanically interdependent**. And, the injury is unevenly distributed. So, if we can understand how injury spreads, we can improve care.

# From ARDS & VILI Research...

- Because the lung is mechanically interdependent, micro-scale forces can influence regional stability.
- Patient-Specific models are not quite ready for prime time.
- Heterogeneous strain is very injurious!!!
  - Hard to avoid since high strain and high pressure are needed up open up the most injured areas.





# **Summary:** What does this mean?



Patients with COVID-19 may develop viral pneumonia, which can progress to ARDS and cause them to be <u>on a ventilator for</u> <u>days to weeks</u>. Identifying safe ventilation becomes even more challenging due to the fact that the mechanical properties of an ARDS lung can change fairly rapidly. <u>Consequently, care is</u> <u>difficult even with the best technology</u>.

# Feel free to contact me with further questions.

Michelle Mellenthin, PhD

mmellenthin@coloradomesa.edu

#### OpenVentCon2020: Clinical Issues

Dr Erich Schulz, Senior Staff Anaesthetist, Mater Health Services Brisbane, Australia <u>@ErichSchulz</u>





### Too much to talk about

So I wrote a document on what engineers need to know about ventilators.

Then I wrote another <u>smaller set of scrappy notes on why and how ventilation</u> <u>and ventilatators in the Covid19 outbreak have beens so confusing</u> (this contains references for some of the figures I've stolen)

# How did I get involved?

- I'm an expert in putting people to sleep and waking people up again, this happens to require learning advanced respiratory physiology and included 1000's of hours using ventilators
- Thanks to excellent local public health I've had a <u>fair bit of time on my</u> <u>hands</u>
- When the call went out for ventilators I realised that:
  - many of the attempts to make ventilators, while galant, were missing an adequate briefing
  - the problem was solvable but it was going to require inter-team teamwork

#### Caveates

I'm an anaesthetist, not an epidemiologist, and I'm not an intensive care specialist.

No one really knows with with 100% certainty what optimal respiratory therapy is. Many of our therapies are based on "best guesses" by expert panels

There is considerable wriggle room and ambiguity in existing protocols, and the evidence base is thin.

# Human respiratory physiology is complicated

The good news is:

- you don't need to know much of it
- much of it is beyond your control
- physics is physics (pressure, flow, temperature, humidity, oxygen concentration)

#### Non linearities (there's a bit going on here)



#### Shunt and deadspace (AKA VQ mismatch)



## There are protocols





#### But solid evidence behind them is patchy

VE	NTILATION			NAT-1
23	In adults with COVID-19, we suggest starting supplemental oxygen if the peripheral oxygen saturation (SpO <sub>2</sub> ) is < 92%, and recommend starting supplemental oxygen if SpO <sub>2</sub> is < 90%	Weak		Weak
	apu2 is < sum	Strong		
24	In adults with COVID-19 and acute hypoxemic respiratory failure on oxygen, we recommend that SpO7 be maintained no higher than 96%	Strong		Strong
25	For adults with COVID-19 and acute hypoxemic respiratory failure despite conventional oxygen therapy, we suggest using HFNC over conventional oxygen therapy	Weak		5.7.1.5 <b>P</b>
26	In adults with COVID-19 and acute hypoxemic respiratory failure, we suggest using HFNC over NIPPV	Weak		
27	In adults with COVID-19 and acute hypoxemic respiratory failure, if HFNC is not available and there is no urgent indication for endotracheal intubation, we suggest a trial of NIPPV with close monitoring and short-interval assessment for worsening of respiratory failure	Weak		Strong
28	We were not able to make a recommendation regarding the use of helmet NIPPV compared with mask NIPPV. It is an option, but we are not certain about its safety or efficacy in COVID-19	No recommendation		Weak
29	In adults with COVID-19 receiving NIPPV or HFNC, we recommend close monitoring for worsening of respiratory status, and early intubation in a controlled setting if worsening occurs	Best practice statement		vican.
30	In mechanically ventilated adults with COVID-19 and ARDS, we recommend using low tidal volume (Vt) ventilation (Vt 4–8 mL/kg of predicted body weight), over higher tidal volumes (Vt > 8 mL/kg)	Strong		Weak
31	For mechanically ventilated adults with COVID-19 and ARDS, we recommend targeting plateau pressures (Pplat) of < 30 cm H <sub>2</sub> O	Strong	1	
32	For mechanically ventilated adults with COVID-19 and moderate to severe ARDS, we suggest using a higher PEEP strategy, over a lower PEEP strategy.	Strong	$\backslash$	Weak
	Remarks: If using a higher PEEP strategy (i.e. PEEP > 10 cm H2O), clinicians should monitor patients for barotrauma		$\backslash$	
33	For mechanically ventilated adults with COVID-19 and ARDS, we suggest using a conservative fluid strategy over a liberal fluid strategy	Weak	$\backslash$	
34	For mechanically ventilated adults with COVID-19 and moderate to severe ARDS, we suggest prone ventilation for 12-16 h, over no prone ventilation	Weak	$\backslash$	
35.1	For mechanically ventilated adults with COVID-19 and moderate to severe ARDS: we suggest using, as needed, intermittent boluses of neuromuscular blocking agents (NMBA), over continuous NMBA infusion, to facilitate protective lung ventilation	Weak		No
35.2	In the event of persistent ventilator dyssynchrony, the need for ongoing deep sedation, prone ventilation, or persistently high plateau pressures, we suggest using a continuous NMBA infusion for up to 48 h	Weak		recommendation
36	In mechanically ventilated adults with COVID-19 ARDS, we recommend against the routine use of inhaled nitric oxide	Weak	$\setminus$	
37	In mechanically ventilated adults with COVID-19, severe ARDS and hypoxemia despite optimizing ventilation and other rescue strategies, we suggest a trial of inhaled pulmonary vasodilator as a rescue therapy; if no rapid improvement in oxygenation is observed, the treatment should be tapered off	Weak	$\setminus$	Best practice
38	For mechanically ventilated adults with COVID-19 and hypoxemia despite optimizing ventilation, we suggest using recruitment maneuvers, over not using recruitment maneuvers	Weak	$\setminus$	statement
39	If recruitment maneuvers are used, we recommend against using staircase (incremental PEEP) recruitment maneuvers	Strong	\	
40	In mechanically ventilated adults with COVID-19 and refractory hypoxemia despite optimizing ventilation, use of rescue therapies, and proning, we suggest using venovenous (VV) ECMO if available, or referring the patient to an ECMO center	Weak		Strong
	Remark: Due to the resource-intensive nature of ECMO, and the need for experienced centers and healthcare workers, and infrastructure, ECMO should only be considered in carefully selected patients with COVID-19 and severe ARDS			١

#### We have data but it is hard to interpret (ICNARC report 15 May 2020)

Patient	Patients receivir respiratory s (N=485	support *	Patients receiving only basic respiratory support * (N=1727)				
characteristic	Discharged alive Died in from critical care critical care		Discharged alive from critical care	Died in critical care			
	n (%)	n (%)	n (%)	n (%)			
Age at admission (years)							
16-39	242 (72.5)	92 (27.5)	176 (97.2)	5 (2.8)			
40-49	403 (66.7)	201 (33.3)	235 (92.9)	18 (7.1)			
50-59	678 (49.9)	681 (50.1)	405 (91.2)	39 (8.8)			
60-69	542 (35.7)	978 (64.3)	339 (80.5)	82 (19.5)			
70-79	216 (22.9)	726 (77.1)	200 (61.7)	124 (38.3)			
80+	16 (17.0)	78 (83.0)	53 (51.5)	50 (48.5)			
Sex							
Female	641 (48.3)	686 (51.7)	471 (82.5)	100 (17.5)			
Male	1457 (41.3)	2069 (58.7)	938 (81.1)	218 (18.9)			
Ethnicity							
White	1272 (44.1)	1614 (55.9)	979 (80.6)	236 (19.4)			
Mixed	23 (34.3)	44 (65.7)	21 (87.5)	3 (12.5)			
Asian	260 (38.1)	422 (61.9)	148 (77.5)	43 (22.5)			
Black	196 (41.4)	278 (58.6)	84 (84.0)	16 (16.0)			
Other	142 (49.1)	147 (50.9)	70 (90.9)	7 (9.1)			

owing to the emerging nature of the epidemic, the sample of patients with COVID-19 represented in this table is biased towards patients with shorter lengths of stay in critical care prior to discharge or death, i.e. those who died or recovered quickly.

## **Commonest problems**

- underpowered
- poor user-interface
- inadequately instrumented
- dangerous failure modes (partial failure, sensor drift)

#### Powerful ventilator can be gentle. Who do you want to carry you down the stairs?





#### If we're making ventilators....



# If we're making ventilators...

- make them smart
- make them powerful (at least 100L/min, ideally 150L/min peak flow)
- ensures they fail safe
  - redundant sensors will save lives
- don't add to the burden imposed on an over-run health care system
- we don't really need "bridge ventilators"

# If we're making NIV hoods

• reduce fresh gas flows from 75 litres per minute

# Philanthropists and US Government

## Presenters (5 minutes each):

- Marta Belcher of Protocol Labs,
- Jochai Ben-Avie of MOSS,
- Dr. Edward R. Griffor, Associate Director, Smart Grid and Cyber Physical Systems Program Office, National Institute of Standards and Technology
- Kristin Jones Maia, U.S. Army Medical Materiel Development Activity (USAMMDA)

### 8:15 AM - 30 minutes

Smart Grid and Cyber-Physical Systems Program

# **AGILE PRODUCTION PLATFORM**

**E. Griffor, NIST** ASSOCIATE DIRECTOR FOR CYBER-PHYSICAL SYSTEMS



# **Agile Production**

Adaptive Redesign, Guided Integration, Intelligent Supply, Demand Anticipation, Trust Networks





#### Challenge

The COVID-19 pandemic is driving a surge in demand exceeding conventional production capacity in certain sectors, including medical equipment, personal protective equipment, and pharmaceuticals, while idling many others.

#### Approach

 Create a community-driven innovation environment for real-time re-purposing of existing capacity to meet surge and recovery requirements.



#### Adaptive Redesign

An automotive systems designer is tasked with using a cabin fan from a light truck as the basis for a new ventilator design and uses the online environment to find options for hoses, fittings, valves, housings, etc. (available in the needed quantity and timeline) and assemble vetted suppliers shippers, distributors, and the enabling contracts to create a complete, viable business model in fractional time.



#### Guided Integration

A designer of a new ventilator uses online resources to compare options for alternative parts and components, including design conflicts and tradeoffs, fit to requirements, materials specifications, product dimensions, suitability for certification, availability, etc. to select those that enable production and distribution to meet demands for timeliness, cost, reliability, quality, and quantity.



Image credit: thomasnet.com



#### Intelligent Supply



A fleet of refrigerated trucks used to deliver bulk perishables to restaurant supply distributors is idled by pandemic conditions. The fleet owner uses the online environment to repurpose these vehicles to deliver perishable medical supplies, including vaccine and test reagents, to test labs, drive-through test sites, clinics, and hospitals, by using the online environment to compose the connection between a suite of manufacturers and a host of customers. The Agile Production environment enables any participant in the chain – customers, materials producers, manufacturers and assemblers, freight companies, distributors, designers, or entrepreneurs - to compose an complete, functional supply chain.

> Image credit: smartwitness.com



#### Demand Anticipation

A community emergency response manager uses AI-enabled demand prediction capability based on AP platform data from previous events and from other locations that are ahead in the timeline to set procurement processes in motion to ensure essential medical supplies and equipment are in place when needed.



Actual Confirmed Cases On:			Projected Cases For:							
5/1	5/2	5/3	5/4	5/5	5/6	5/7	5/8	5/9	5/10	5/11

Image credit: iem.com



#### Trust Networks

A new supply chain partner – whether a customer, manufacturer, distributor, or other – uses a combination of third party certificate authority and platform reputation services, enabled by cryptographic distributed ledger technology, to obtain validated information on the identity, reliability, and performance of other supply chain partners and on required parts, systems, and process certificates and authorizations.





#### **Action Plan**

#### **Action Plan:**

Amplify current individual efforts with an online environment that creates

network effects, enabling companies in every region, in every sector, and of every size to add their capabilities to the coronavirus response and recovery effort.

#### **Central Elements:**

- Build on existing resources and capabilities => Timeliness
- Mobilize private sector solutions => Sustainable Economics
- Enable distributed capabilities => Resilience



#### **Parts List**

- Platform that connects users to existing supplier inventories across diverse sectors
- Interfaces that enable vendors, shippers, suppliers, etc. to link their existing data resources (catalog, service list, schedule, route, tooling specs, etc.) to the platform
- Intelligent, Al-enabled search capability that bridges sector-specific spec/requirement vocabularies (semantics) and structure
- User interfaces tailored to user type and application
- "Best of breed" tools for:
  - Enabling supplier discovery;
  - enabling comparison of adaptation requirements among component alternatives;
  - supporting dynamic supply-chain assembly;
  - supporting offer/response capabilities connecting supply to demand;
  - supplier evaluation
  - o etc.



#### Design


### Agile Production Technical Working Group (AP WG)

#### DRAFT

CHARE Group is free and open to participation by anyone and consensus documents produced by the group will be openly available to everyone via website posting.

The first phase of the AP WG effort will focus on developing a consensus technical plan for adapting existing platform(s) capabilities to connect selected data sources for prioritized products (PPE) and enable an offer/response market for posting needs/requirements (offers) and receiving proposals (response).

The second phase includes initial deployment(s) and testing of instances prioritized by the WG. Subsequent work may include expanding the range of data sources, adding capabilities from the logistics and market services sectors, and adding tailored interfaces, query capability, and additional tools and services supporting supply chain composition.

# FOUNDING MEMBERS

- 3-5 Platform Providers/Developers
- 3-5 Data Aggregators



## Working with:



#### II THOMAS" COVID-19 Response Suppliers COVID-19 Response Suppliers Displaying 1 to 25 out of 566 suppliers



**IBM Rapid Supplier Connect:** Emergency supplier onboarding and inventory availability

#### Find Deloitte. **Supply**PRISM<sup>™</sup>

with

A holistic analytics platform of cognitive-enabled products, managed services, and integrated solutions designed to drive powerful visibility into your digital supply network with timely predictive and prescriptive insights



BR



HEADLINES

FEMA SUPPORT THE FIGHT AGAINST COVID-19 OPPORTUNITIES

JOINT ADVANCED MANUFACTURING WORKING GROUP

D-19 RI

PROGRAMS & TECHNOLOGIES NEWS EVENTS MEMBERSHIP & SERVICES C



# **Agile Production**

Adaptive Redesign, Guided Integration, Intelligent Supply, Demand Anticipation, Trust Networks





# Investors and Entrepreneuring

Presenters:

Sarah Benson-Konforty, MD, CEO

Narayan Sundararajan CTO, Grameen Intel Social Business; Co-Founder, LifeMech <u>www.grameen-intel.com</u>

8:45 AM - 30 minutes



The Funding Roadmap

From Design to Deployment and Production



#### The Basics

You've got an Idea, now what?

•Define the problem you're solving

- •Research and know your market
- •Talk to other people to validate your idea

Common entrepreneurial biases: "No one else is doing it" "We own the market entirely"



3 T's – Team, Trust, Timing 🛛

### IT TAKES A VILLAGE TO BUILD A COMPANY

Find your complimentary co-founders, Investors invest in people not products and ideas.

MFAC.

EMFI

- Build a well-balanced team Diversity is key.
- Business Plan Have a clear vision & know your numbers
- Story-telling
- Know what you do not know or what you're missing.
- Know your market and competition
- Build a good foundation and don't skip steps, make sure all legal agreements and protections are in place.
  CAP Table, Articles of Incorporation, Founders Agreement, IP Agreements, NDAs, this will increase the likelihood of getting funded.



- Good research can save you a lot of valuable time
- Set clear goals and roadmap
- Avoid distractions



#### 5 PHASES OF THE DESIGN THINKING PROCESS

#### Non Dilutive

•Grants

Philanthropic Funds

- Licensing
- Royalty Financing
- •University Funding / Grants
- •Debt financing





•Friends and Family

Angles

Family Offices

•VCs

•Incubators / Accelerators

- 1. Corporate giving programs for nonprofit startups
- 2. Grant-giving private foundations
- 3. Federal nonprofit grant programs and endowments
- 4. State- and municipal-funded grant resources
- 5. Bonus nonprofit startup grant tips
  - 6. Donation by people who share same ideals









	SBIR	STTR
Phase I - Feasibility/Proof-of-Concept	Up to \$150K for 6 months	Up to 225K for 12 months
Phase II - Development	Up to \$1M for 24 months	Up to \$1M for 24 months
Partner - Academic, Non-Profit or Federally Funded R & D Center	Optional	Required
Budget Allocation Phase I		Min. of 40% to small businesses Min. of 30% to research partner
Primary Employment of Principal Investigator (PI)	small business	either small business or research partner

Investment in Federal "needs"
Lead to procurement contract

#### 2. Seed Money for private Industry

Investment in high impact technologies benefiting the economy and having a social global influence

•Hard to obtain and time consuming

•Prolonged submission process with low success rates

Strict deadlines



# Tips

•Know the system

•Build your case and know how to tell your story

•Use a multi-submission strategy

- Find a common ground, people who serve the same cause and promote a similar agenda
- Be in touch with Hospitals, Doctors, Clinics across the world they might be one of your check writers
- Investor Groups
- Humanitarian Aid organizations serving distressed areas
- Governments
- Strategic Partnership that can lead to an investment

Aligned vision

•It's not only about the money

•Make sure they can provide guidance and help along the way

•It's always about the people and relationships.





Looking forward to connecting

Dr. Sarah Benson-Konforty, - Palo Alto, CA Entrepreneur, Medical Doctor and Investor

https://www.linkedin.com/in/sarahbkmd/ sarah.bensonkonforty@gmail.com





# Thank you.

# (Brief) FDA Authorization

Presenters:

# Michelle Lott, HelpfulEngineering, Principal and Founder, IeanRAQA

# 9:10 AM - 5 minutes



# FDA Authorization: Ventilators

### **Michelle Lott, RAC**

Principal & Founder, leanRAQA

### **Mission Critical: Design Control**





# **FDA templates**

- Pre-EUA/EUA INTERACTIVE REVIEW TEMPLATE for Ventilator, Ventilator Tubing Connectors, and Ventilator Accessories
  - A. Basic Information (Purpose, Applicant, Device Proprietary or Brand name, Model number, Indications for use, Regulatory Information (approval/clearance status in US), Marketing status in any other country, Unmet need)
  - B. EUA Section II Information (Product labelling, Applicable standards, Quality System, Other QM standards, power supply, Authorized labeling)
  - C. EUA Section IV Conditions of Authorization
  - D. Criteria for Safety, Performance, and Labeling (DoC, Device Specifications and Instructions for Ventilators and Accessories, Reprocessing and Shelf Life Information, Facility requirements (as applicable), Labelling requirements for Conditions of Use, Continuous Ventilator Splitters (Adapters for Multiplexing)

#### E. Benefit/Risk Assessment

- F. FDA Summary of Documentation and Review [For FDA Internal Use Only]
- G. Interaction Review Log
- H. Next Steps

michelle@leanraqa.com



# **Technical Standards for Ventilator EUA**

#### > 20 standards





# **Case Study: Electrical Safety Design Requirements**

#### IEC 60601-1

Medical electrical equipment – Part 1: General requirements for **basic safety** and essential performance

#### IEC 60601-1-2

Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: **Electromagnetic compatibility** – Requirements and tests I

#### IEC 60601-6

Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: **Usability** 

#### IEC 60601-1-8

Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for **alarm systems** in medical electrical equipment and medical electrical systems



# **Case Study: Electrical Safety Design Requirements**

#### ► Electrical Medical Device Requirements – Just a Start

Cord must protect against reversing polarity	Terminal mains must not be accessible to user and patient.	Circuit diagram with component part list, calibration, specific repairable items.	Use of specific tools for servicing device to be defined.	
Detachable power cord	Non-detachable power cord.	Only trained service personnel can perform installation, assembly, maintenance, and repairs.		
MOOP: Air clearances and Voltage creep are required to keep the user safe from the system power.				
Oxygen rich environment of greater than 23.5% must be mitigated				

through the device power supply design.

## Medical Device Power Supply



### Hold the Phone! New Requirements from Marketing





michelle@leanraqa.com

# **Case Study: Electrical Safety Design Requirements**

#### EN 60601-1-11

Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the **home healthcare environment** 

#### EN 60601-2-49

Medical electrical equipment – Part 2-49: Particular requirements for the safety of **multifunction patient monitoring** equipment

#### FDA Home Use Devices Initiative

- "Guidance for Industry and Food and Drug Administration Staff: Design Considerations for Devices Intended for Home Use"
- Labeling repository for medical devices that have been approved or cleared for home use.



# **Case Study: Electrical Safety Design Requirements**

► Electrical Medical Device Requirements – Home Care

Minimum air clearances providing MOOP <sup>1</sup> / <sub>2</sub> those of MOPP	In general, specs for MOPP 2x those of MOOP		
MOOP Voltage Controls Start at 210V dc	MOPP Voltage Controls Start at 17Vdc		
MOOP vs MOPP			
Working Voltages for Device			
Air clearances and Voltage creep are required to keep the patient and user safe from the system power.			
Medical Home Care Device			

michelle@leanraqa.com



### **Dyson to the Rescue?**



- After UK call for ventilators, Dyson developed this ventilator in 10 days for \$25 Million
- Upon submission to MHRA for EUA, MHRA declared they did not need anymore ventilators
- MHRA felt that once a patient went on invasive ventilation, they were just as likely if not more to die than for non-invasive respiratory assist technologies



# **Successful Products will be**

- Non-invasive
- Respiratory assist
- ► Low infrastructure
  - Power source
  - Gas supply
  - Medical know-how
  - Doctors per capita
  - Low supply chain requirements
- Compliant with basic design controls and risk management
- Compliant with applicable standards



## Did you say free?



BSI is making available over 20 ISO standards worth thousands of dollars available for **FREE**: <u>https://www.bsigroup.com/en-GB/topics/novel-co</u> <u>ronavirus-covid-19/ventilators/</u>





#### Your regulatory strategy

Your regulatory submissions

Your quality systems and compliance

#### Your EMERGENCY USE

Your due diligence







#### Your grief counseling



lean RAQA Your Michelle Lott, RAC michelle@leanRAQA.com 520.275.9838

companies large mid-sized small startup

industries medical device emergency use biologics pharma cosmetics dietary supplements The Developing World Presenters:

- 1. Marcos Mendez from Brazil (10 min)
- 2. Karene Melloul from Kenya (10 min)
- 3. Rebecca Alcock EWB/Guatemala (5 min)

# 9:15 AM - 30 minutes

# With supply crisis, Mandetta asks citizen to make cloth mask

Minister of Health outlines scenario of extreme difficulty for the acquisition of basic supplies of protection against coronavirus

André Borges, Idiana Tomazelli, Julia Lindner, O Estado de S. Paulo April 1, 2020 | 19h48



BRASILIA - The Minister of Health, Luiz Henrique Mandetta, outlined a scenario of extreme difficulty for the acquisition of basic protection supplies against the **new coronavirus** and recommended that the population stop buying disposable masks and make their own protection piece, with cloth and elastic. Mandetta also stressed that social isolation, a measure criticized by President Jair Bolsonaro, is what has prevented Brazil from sinking into a "spiral of cases" of contamination.

### HEALTH HIGHLIGHTS

KNOW MORE



SP City Council approves creation of holiday this week



Coronavirus vaccine tested in humans generates safe response, says pharmacist



Mandetta backs off after stating that Pará would be the new epicenter of the covid-19 in Brazil

The scarcity of so-called Personal Protective Equipment (PPE), which includes masks, gloves and
### Teams collecting tests for national coronavirus research are arrested and beaten

In several municipalities, the test material was destroyed, and study teams had to leave the city and give up on the research, coordinators say



Published 2 days agoin 05/16/2020 Per Brasilia Newspaper 5









#### EXPRESS

#### Suspected overpricing of public purchases in the pandemic

Guilherme Henrique May 15, 2020 (updated 05/15/2020 at 8:44 pm)

PHOTO: PEPPODUCTION

Investigations focus on purchases of products such as respirators and masks by state and municipal governments



 TWO RESPIRATORS OF THE SH 300 MODEL, WHICH WERE ACQUIRED BY THE GOVERNMENT OF SÃO PAULO

The advancement of coronavirus in Brazil has put increasing pressure on the public and private health systems. There is a lack of ICU beds, respirators and personal protective equipment, essential in the treatment of the disease.

The complex scenario motivated the federal government to decree, in February 2020, the state of public calamity in the country, until the end of December. Among other things, the decree dispenses with the need to bid for purchases in the context of the pandemic.

The absence of bidding, a long process, can speed up the acquisition of items in the fight against coronavirus. On the other hand, signs of

#### MOST RECENT

INTERACTIVE What do you know about Pope John Paul II? Do the test Natan Novelli Tu

PODCAST Paulo Marinho: the businessman who aggravates Bolsonaro's crisis Antonio Mammi and Conrado Corsalette

COLUMNISTS History is not a medicine leaflet nor does it come with a prescription Lilia Schwarcz

GRAPHIC Deaths from covid-19 in the districts of the city of São Paulo Gabriel Zanlorenssi and Lucas Gomes

DEBATE What is expected of the State in managing the pandemic crisis? Alketa Peci and Sérgio Lazzarini

#### GRAPHICS



GRAPHIC

#### Respirators per 100 thousand inhabitants and proportion of SUS

IN FEBRUARY 2020







Observations: the data used to weight the population refer to the IBGE's 2019 estimates for states and municipalities. According to Datasus, a respirator or ventilator is a device used to maintain breathing in debilitated patients, in a coma, or under the effect of anesthetics. The equipment is used in emergencies, intensive care units and operating rooms.

Source: CNES (National Register of Health Establishments), within the Ministry of Health's Datasus system.





Kenya Emergency Network for Innovation

Efforts to produce the best fit for purpose ventilators and PPEs in Kenya

CombatCovid19KE

- Like much of the world, Kenya is currently facing daily increases in the number of people diagnosed with COVID-19
- It is putting tremendous pressure on already stretched health infrastructure
- It is now clear that Kenya will face acute shortages of personal protective equipment (PPE) and respiratory assistance devices.
- The central government and businesses are working to fast-track imports of the necessary equipment, but it simply won't be possible to acquire and distribute the necessary items quickly enough.
- It is inevitable that Kenya will face shortages that will cost lives.
- A group of people spontaneously came together.



- Ventilators: 1 team passed regulation, 3 under review
- Face shields: 3D printed 300/day, Injection molded 4000/day
- Masks: 2 projects under development, 1 partnership with European firm
- CPAP: 3 projects under development, 1 partnership with US firm
- Decontamination boxes: 2 projects under development
- Oxygen: cylinder tracking project under development
- Oxygen Concentrator: 1 project under development

NJA Pumuaishi



Ventilate Africa

Kenyatta University

Counties





### Wins

- Access to knowledge
- Pooling resources
- Efficient sourcing
- □ Clearer process with government institutions
- Involvement of youth
- Sense of belonging
- □ Faster results
- □ Larger network and resources
- □ Leapfrog effect
- Global resources: Location does not matter

### Obstacles

### 🗅 Egos

- Blinding competition
- Perspective blurred by potential gain
- □ Corruption
- Not sustainable without some level of income
- Difficult partnership between non-profit and business
- Coordination does require time and curating information to make it work
- No suitable platform for multidisciplinary, multigenerational teams

- Network status: Non-profit vs sustainable impact business
- Legal aspects of the products: Liability framework
- Go beyond the dilemma: Simpler machine vs no machine
- Short-term emergency vs long-term investment into a local production
- Find a suitable working platform
- Legal framework of the network: What is the nature of a platform that includes all forms of organizations without creating further inequalities?

- □ Focus on renewable energy and robust batteries Unreliable power
- Comprehensive views Unreliable oxygen supply
- □ Single and simple user interface Insufficient health staff
- Source local material Expensive supplies and lack of visibility of the supply chain, hindered by C19
- Promote transparency Corruption
- Link information to fast decision-making Insufficient, unreliable data
- Involve public institutions and donors early Lengthy, inefficient procurement
- Built-in security and control systems Theft

- PPE and Respiratory Assistance devise are equal priorities
- We do not know enough to make definitive decisions, need to be able to expand fast while still supporting early movers
- Started with 12 ventilators teams: Supported the top 50% while helping the bottom 50% to pivot to CPAP or join the other ones
- Multi-partners collaboration to cover most of the chain
- Need a core team willing to commit for the medium-term with the following skills: engineering, data/computer science, fundraising, financial management, legal advice, distribution, sourcing, community management and project management

# ENGINEERS WITHOUT BORDERS













EWB-USA builds a better world through engineering projects that **empower communities** to meet their basic needs and **equip leaders** to **solve the world's most pressing challenges**.

### The EWB COVID-19 Response

- Personal Protective Equipment
- Medical Devices
- Infrastructure

- 100k+ units of PPE distributed to 12+ hospitals
- Survey of existing ventilators and diagnosis of any broken devices
- Isolation areas &
  - sanitation and water
  - systems at 4+ hospitals

### Field Notes





Contact Us!

Rebecca Alcock ralcock@wisc.edu

Engineers Without Borders USA University of Wisconsin Let us fight for every woman and every man to have the opportunity to live healthy, secure lives, full of opportunity and love. We are all time travelers, journeying together into the future. But let us work together to make that future a place we want to visit.

Be brave, be curious, be determined, overcome the odds. It can be done.

An excerpt from Brief Answers to the Big Questions by Stephen Hawking

# Looking to the Future

Presenters:

- 1. Karen Sandler and
- 2. Dale Dougherty

## 9:45 AM - 30 minutes

Karen M. Sandler she/hers @o0karen0o

Hello, VentCon! May 21, 2020





http://www.acme.com/heartmaker/ayc







Robert Stok (CC BY-SA 2 0) https://www.flickr.com/photos/robert\_stok/2411719254



## • 100 million lines

### • 1 million defects?



# I stopped using proprietary software wherever possible.





# Free/open source software is inevitable...



# ...but will it help us build a better future?



## Details matter.







#### 

### [Updating] Italian hospital saves **Covid-19 patients lives by 3D printing** valves for reanimation devices

The supply chain was broken, people and 3D printing rose to the occasion



Davide Sher • March 14, 2020



# Who will decide what is a health emergency and when it ends?



# Licensing matters.





# We need to invest in long-term health care stability.





Frederike Kaltheuner @F\_Kaltheuner

Now this is an exciting new possibility: a German town is running their own @jitsinews server so that schools and local choir groups don't have to rely on @Skype and @zoom\_us

 $\sim$ 

Video conferencing as public infrastructure

Cc @thenewpossible #newpossible





## Thank you!

• Conservancy is a 501(c)(3) charity, become a supporter!



- https://sfconservancy.org/supporte



## **Thanks and Final Thoughts**

Presenters:

Robert L. Read and Deepti Sharma

## 10:15 AM - 30 minutes

## Principles

- Flexibility of Treatment
- Engineering Modularity = Resilience
- Cooperating Teams = Faster Deployment to the First Life Saved
- Softening (smart components) = Versatility
- Openness = Confidence

## What if all 10,000 of us were One Team?

We would break the problem up like this:

### https://trello.com/b/u9VbhzXw/global-pandemic-ventilators

Global Pandemic Ventilators 🖙	Pandemic Ventilators Meta Team Free	Public   AB D DS Invi	te		🚖 Butler 🛛 … Show Menu
Standards ····	Software	Hardware Solutions	Quality Assurance	Finance	Manufacture and Deploy
Data Exchange Standard	Control GUI	Air Drive (Electric)	3rd Party Process	Donor Commitments	Assembly
Control Standard	Alarm GUI	Air Drive (Pressure)	Reliability Process	Production Cost Planning	Transport
Alarm Standard	Breath Analysis	Controller Hardware	Training	+ Add another card	Reuse and Recycle
+ Add another card 🛱	Mode Control Module	Tester	Documentation		Triage
	Respiration Calculations	Monitor	+ Add another card 🔹		+ Add another card
	+ Add another card	◎ 𝖓 1			
		+ Add another card 🛛 🛱			
		+ Add another card 🛱			

### Resources

- Slack channel
- Maker Faire
- Third Party Testing
- Funding Sources
- Modularity Trello Board
- Additional Resources: <u>Ask a Question/Share your work</u>
- Other Open Ventilator Efforts
- <u>Recordings</u>
- Social Entrepreneurship in the Developing World