

# Biomedical and clinical engineering contribution in WHO response for COVID-19 pandemic

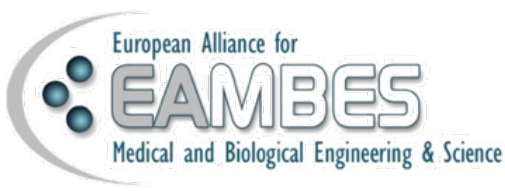
## Prof Leandro Pecchia

Professor of Biomedical Engineering, **University Campus Biomedico Roma**, Italy  
Professor of Biomedical Engineering, **University of Warwick**, UK  
Innovation Manager, R&D Blueprint and COVID-19, **World Health Organization** (WHO)

Director, *Applied Biomedical Signal Processing and Intelligent eHealth lab*  
Innovation Manager, R&D Blueprint and COVID-19, **World Health Organization**




President, **EAMBES** (2021-23)  
Secretary General, **IUPESM** (2022-2025)  
Secretary General, **IUPESM** (2018-2022)

Bressanone, 12/09/2022






**WARWICK**  
THE UNIVERSITY OF WARWICK

## Research interest

-  Applied *Biomedical signal processing*, *Internet of Things*, *Artificial Intelligence*
-  Early stage *Health Technology Assessment* (HTA) and User Need Elicitation methods
-  Medical Device design, regulation, assessment and management (Clinical Engineering)

## Main applications:

-  Active/healthy ageing, prevent disease or worsening and adverse events in later life
-  Disease Management Programs, patient pervasive monitoring and telemedicine
-  Medical devices and medical locations in low-resource settings and LMICs

## Main Projects

### *Current projects (£40mil total value, ~€3.5m our lab)*

1. 2021/2021, Edwards Lifescience, “HTA of AI-based Medical Devices”
2. 2021/2021, BT, “5G and well-being monitoring”
3. 2020/2024, H2020, **ODIN** Smart Hospital (AI/Robots for Hospitals, COVID-19)
4. [2020/2022, PandeVita, H2020 call on COVID, EAMBES proj]
5. 2020/2021, EPSRC, Hypoglycemia via AI and ECG in controlled environment
6. 2020/2022, Wellcome Trust, NoHypoglycemia
7. 2020/2023, H2020, **GATEKEEPER** (AI/IoT for Home Care, COVID-19)
8. 2018/2020, GCRF, Medical devices design for Sub-Saharan Africa

### *Former projects*

1. 2018/2019, EPSRC, Closed-loop control for optimising chemotherapy
2. 2016/2020, EPSRC IAA, HTA&Design of medical device in low-resource settings
3. 2015/2016, The Royal Society, Sleep quality & balance
4. 2014/15, European Commission, MAFEIP tool

# Applied Biomedical Signal Processing and Intelligent eHealth Lab

In response to the complexity of medical devices, we are a multidiscipline team

## Researchers



**Rossana Castaldo**  
BME  
Signal processing/AI



**Alessia Maccaro**  
Philosopher  
Medical Devices/  
Ethics/Africa



**Kallirroi Stavrianou**  
Med. Physics



**Matthew Phillips**  
MBA  
Proj. Admin.



**Muhammad Haleem**  
Computer Scientist  
Deep Learning  
Assistant Prof  
(RTDa)



**Silvio Pagliara**  
Electronic Eng  
Assistive Tech  
Assistant Prof  
(RTDa)



**Davide Piaggio**  
BME/EU  
Med Devices in LMICs  
Assistant Prof TT  
(RTD b)



## PhD Students

4<sup>th</sup> y



**Carlo Federico**  
Health Economist  
eHTA

3<sup>rd</sup> y



**Martina Andellini**  
BME  
HTA of Medical Devices

2<sup>nd</sup> y



**Katie Stokes**  
Biologist  
AI/LMICs

1<sup>st</sup> y



**Owain R. Cisuelo**  
Computer Scientist  
AI/Diabetes



**Abdulaziz Almuhaiani**  
BME  
AI/ Surgery



**Tim Siu Wang**  
Math  
Behavioural modelling



**Busola Oronti**  
BME  
Medical Devices



**Wanzi Su**  
Computer Scientist  
AI/App/Eye



# Intelligent Health Technology Lab

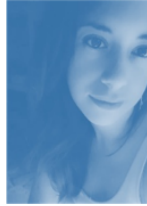
In response to the complexity of medical devices, we are a multidiscipline team

## Researchers



### **Post-doc**

AI, Robot, IoT for the  
Hospital of the Future  
ODIN  
(Assegnista)



### **Anna Aversa**

Research Assistant  
AI & Clinical Engineering  
ODIN  
(Assegnista)

## PhD Scholarships



### **Scholarship**

On BME for  
SDGs



### **Scholarship**

On BME for  
SDGs



### **Scholarship**

AI, IoT rehab  
ODIN



### **Scholarship**

AI for POC  
ODIN

# How can we use this expertise to improve Medical Devices in LMICs?



For improving medical device effectiveness and safety in LMICs we have to overcome the Cartesian Fragmentation of Knowledge (i.e., no silos).

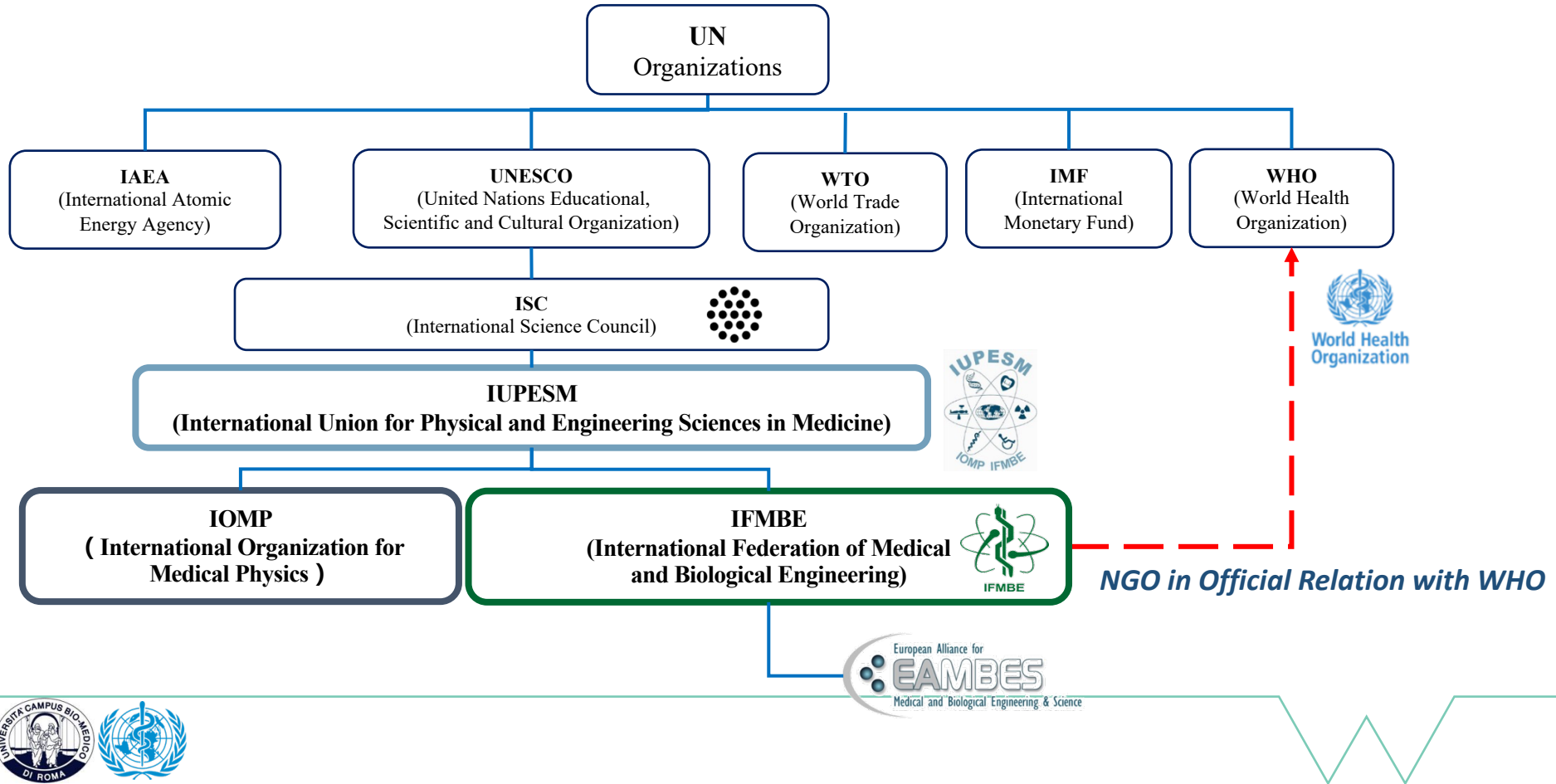
Therefore we focus on:

- Design
- Regulation
- Management
- Assessment

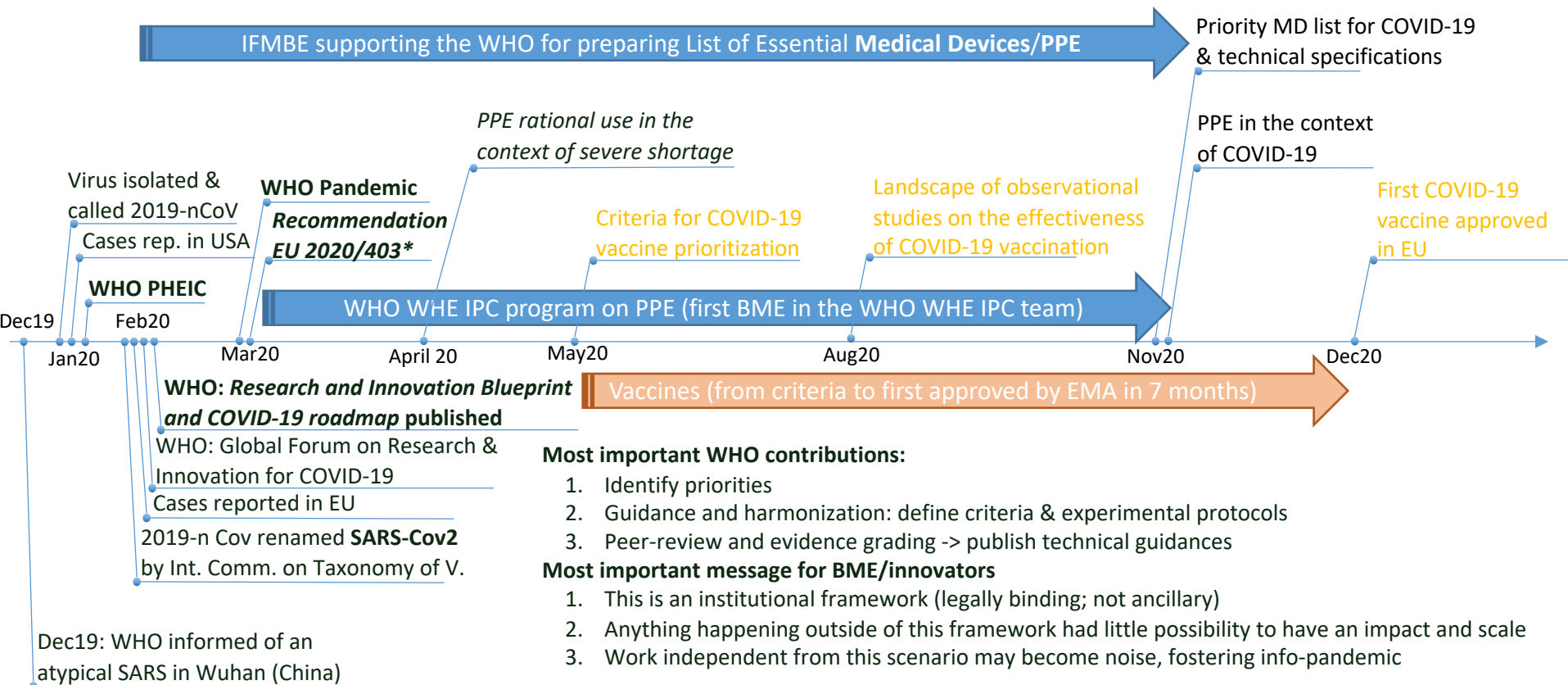


8 field studies in 24 months: Benin, Ethiopia, South Africa, Nigeria, Uganda

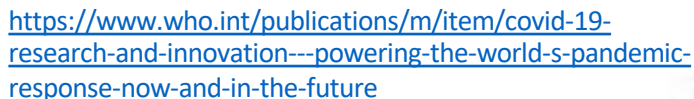
# BME Ecosystem







\* For the first time, EU Commission granted a waiver for MD/PPE manufacturing, suggesting to manufacturers/innovators to use other than traditional standards and unified norms, referring explicitly to WHO documents and technical guidance. 7/24





# BME contributions to the WHO during COVID

## BME contributions to WHO

1. *Priority list of Medical devices for...*
2. *Human Resources for Medical Devices (advocacy, recognition, training)*
3. *Nomenclature*
4. *Procurement and technical specifications*
5. *Country support*
6. *Policy, resolutions and regulatory frameworks*
7. *Continuous monitoring and survey*

### *WHO Medical Device technical series*

1. *Policy*
2. *HR for Medical Devices. The role of BMEs*
3. *Regulation*
4. *Health Technology Assessment*
5. *Management and use*
6. *Priority Medical Devices*
7. *Atlas*

### *Compendium of innovative Medical Devices for LMICs*

1. ...then years this year!



# BME contributions for IPC and PPE

## Criteria for sustainable innovation

1. Multi-criteria
2. Have clear understanding of local-needs/scenario
3. Clearly addressed regulatory, clinical, HTA, IP, HTM, local manufacturing



Regulatory assessment	Proceed	Proceed with caution	Not acceptable	Not Applicable
Technology evidence assessment - risk/benefit ratio	High	Medium	Low	Not Applicable
Technology evidence assessment - Impact	High	Medium	Low	Not Applicable
Summary:				
Innovation		Innovation aspect in the domain		
Technology readiness level (TRL)	1-3	3-7	8-9	
Technology evidence assessment	Recommended	Recommend with caution	Not recommended	Not Applicable
Health technology and engineering management	High appropriateness for low-resource settings	Moderate appropriateness for low-resource settings	Low appropriateness for low-resource setting	Not Applicable
Technology transferability	Fully transferable	Partly transferable	Not transferable	Not Applicable
Openly access intellectual property	Fully open access	Limited open access	No open access	Not Applicable
Local production	High appropriateness for low-resource settings	Moderate appropriateness for low-resource settings	Low appropriateness for low-resource setting	Not Applicable

# Preparedness

*“The doctors were unable to cope, since they were treating the disease for the first time and in ignorance: indeed, the more they came into contact with sufferers, the more liable they were to lose their own lives. No other device of men was any help. [...] In the end, people were overwhelmed by the disaster and abandoned efforts against it. [...]*

*I shall give a statement of what it was like, which people can study in case it should ever attack again, to equip themselves with foreknowledge so that they shall not fail to recognize it. I can give this account because I both suffered the disease myself and saw other victims of it”*

Thucydides, 430 BC (...2500 years ago...)

# Preparedness

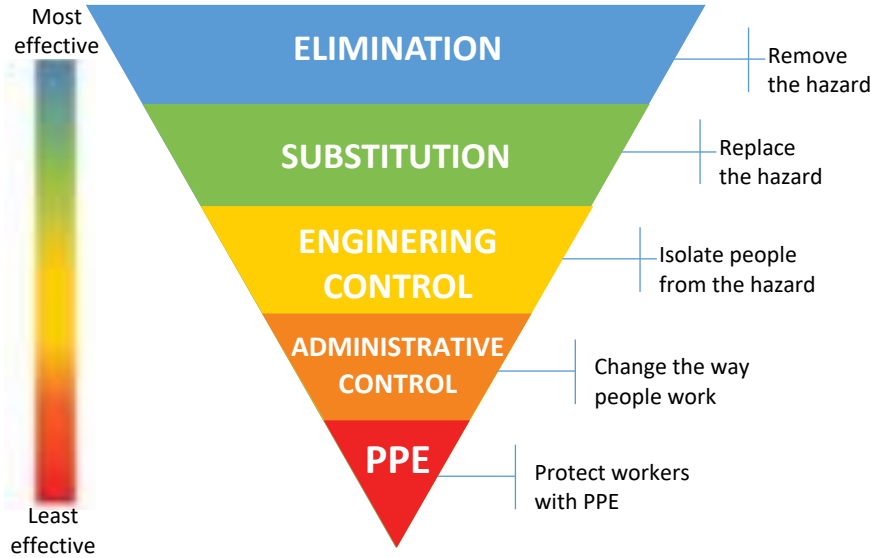
## United Nations:

- disaster preparedness involves “*forecasting and taking precautionary measures before an imminent threat when warnings are possible*”
- This involves 3 phases: **prepare, respond, restore**

## WHO Emergency program (WHE):

- **Coordination:**
  - planning, costing, and financing, and
  - integrate (COVID-19) into broader health systems/strategies
- **Community protection:**
  - WHO focused most of its effort for improved vaccination campaigns as well as public and social measures for reducing and controlling the spread of the virus (**this is based on based on the CDC hierarchy of risk control**)
- **Clinical Care**, based on the strengthening of triage and early recognition, infection prevention and control (IPC) measures, and restoring essential healthcare services.
- Access to **countermeasures**, based on increased monitoring of variants, and the strengthening of supply chains to ensure equitable access to required drugs, medical devices and PPE.
- **Collaborative surveillance**, based on integrated surveillance for several strains of viruses and cases, deaths, and hospitalizations, and on the expansion of genomic sequencing capacities.

# Preparedness



## Elimination:

- removing the hazard.
- In the case of COVID-19, produce sterilizing vaccines (*i.e.*, vaccines that could prevent the infection).
- While the results achieved with the vaccination campaigns are unprecedented for safety and effectiveness, none of the vaccines resulted sterilizing.
- COVID-free wards...

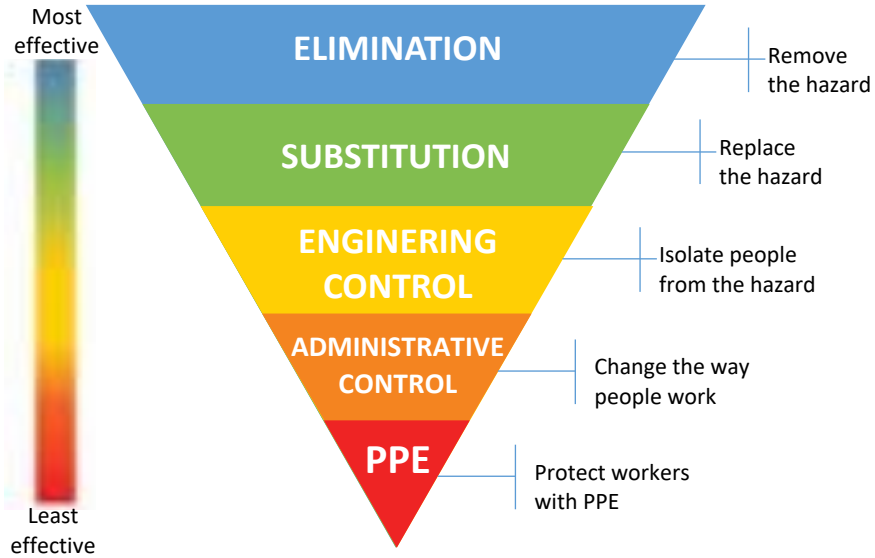
## Substitution:

- replacing clinical procedures and interventions with less risky ones
- COVID-19:
  - social measures such as remote work, distance learning and prioritization of outdoor/non-crowd activities, as well as
  - health measures such as choosing non-aerosol-generating surgical procedures as explained later in this section

## Engineering Control:

- minimizing unnecessary exposition (people and fomites) to the hazard with engineering measures.
- This involves hospital engineering measures such as pressure control (e.g., inverted pressure), ventilation, filtration, water management, filtering rooms,
- COVID-19: Social measures: increased use of barriers/partitions and an increased attention to those measures also beyond the hospital setting (e.g., public transport)

# Preparedness



## Administrative Controls:

- changing the way people work, when a residual exposition is still present, acceptable or unavoidable.
- reorganization of (healthcare) working processes in order to ensure the minimization of exposition, the enforcement of clean/dirty paths.
- COVID-19: administrative control was also extended beyond the hospital with social measures such as restricting indoor shopping/dining, reduced indoor density.

## PPE:

- protecting the workers with dedicated equipment (masks, gloves, face-shields) when exposition with residual risk factors is unavoidable.
- COVID-19,
  - this opened completely novel scenarios including
    - universal masking (i.e., using PPE as a social measure),
    - prolonged masking (i.e., using PPE in healthcare settings during the whole working shift)
  - and the introduction of novel equipment
    - PPE (e.g., FFP/N95),
    - medical devices (e.g., surgical masks),
    - community-masks (completely novel!!)



“Wild” innovation...



# EXCLUSIVE-Ferrari, Fiat look at helping Italy make ventilators in coronavirus crisis

HEALTH NEWS - APRIL 23, 2020 / 10:34 PM / UPDATED 2 YEARS AGO

UK cancels order for simple ventilators, needs more complex ones: source

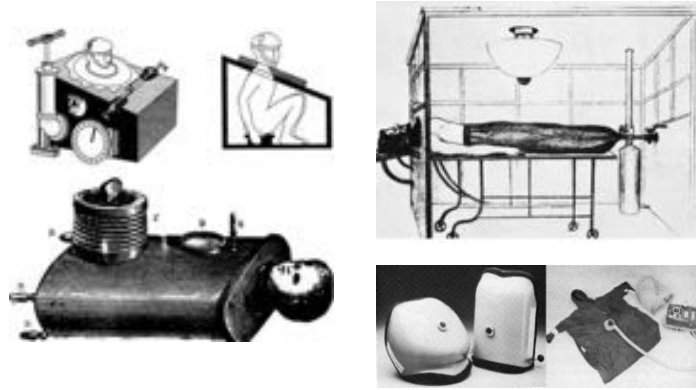
Coronavirus : 6 000 respirateurs produits... pour rien ?

Par Jacques Morin, Cellule investigation de Radio France

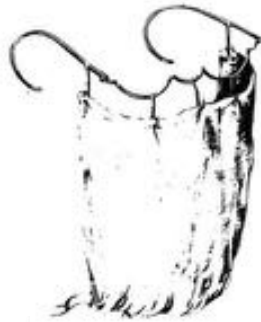
Mis à jour le jeudi 23 avril 2020 à 12h35 Publié le jeudi 23 avril 2020 à 06h31



# Medical ventilator VS face mask



Time span <100 years



Time span 700 years



# COVID-19 and PPE shortage

Every month, frontline health responders around the world need these supplies (and more) to protect themselves and others from #COVID19

- 89 million masks
- 30 million gowns
- 1.59 million goggles
- 76 million gloves
- 2.9 million liters hand sanitizer



#COVID19  
#coronavirus



## Grave Shortages of Protective Gear Flare Again as Covid Cases Surge

Five months into the pandemic, the U.S. still hasn't solved the problem. The dearth of supplies is affecting a broad array of health facilities, renewing pleas for White House intervention.



World Business Markets Breakingnews Video More

HEALTHCARE & PHARMA | APR 22, 2020 | 6:10 PM | UPDATED 6:10 PM

### In Britain's COVID-19 wards, doctors say they do not have enough gowns

By Alister Smead

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Shortage of personal protective equipment endangering health workers worldwide



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Health | Coronavirus

## Coronavirus: The NHS workers wearing bin bags as protection

By Chloe Power  
BBC News

11 April 2020



Coronavirus pandemic

# COVID-19 and PPE

When COVID-19 pandemic started, the world discovered that PPE were not safe and effective as expected, especially not for global coverage: i.e., lay people are not skilled in PPE (appropriate use), unlike healthcare workers; using PPE during a pandemic can present risks (e.g., self-contamination, fit may reduce compliance...)



# Responsibilities of science and technology - *Responsible thinking, responsible actions, responsible silence*



- COVID-19 created a **global lack of essential medical devices and PPE**
- As a consequence, **myriads of DIY solutions** were proposed and fomented on media worldwide (using the Hoover filters as a mask, 3D printing respirators using cotton filters etc.)
- **This approach is unsustainable and very dangerous:** critical sectors as MDs or PPEs require postgraduate education, years of experience and deep knowledge of relevant international standards to ensure safety, efficacy and resilience.
- The virtuous example came from Italy (SIARE, FIAT and FCA, Ferrari and the Italian Government) should be expanded to other critical sectors.
- Much of this chaos could have been avoided if decision-makers had consulted with domain experts, aka biomedical and clinical engineers
- **BMEs must focus on what it is needed (beyond being cool or no!)**



# Inadequacy of regulatory frameworks in time of crisis and LRSs: PPE and COVID-19

- Regulations require that PPE comply with tests and parameters set by international standers in order to be marketed/distributed
- Those standards are:
  - too generic;
  - mainly written be sellers with the aim at covering the wider possible market (e.g., getting the mask into any working place: hospital, foundry, sawmill...)
- For instance:
  - Visors have to pass the bullet test. While this is reasonable for sawmill, this is not for hospital
  - Masks have to pass heating test ad very high temperature (e.g., 75 degrees). Reasonable for a founder, not for hospitals
- We systematically analysed the needs and requirements for PPE in hospitals proposing a frugal set of essential tests that masks and visors should have been tested against, in order to be safe and effective.
- E.g., for Mask, only 3 tests are required (compared to the 20+ required by relevant standards):
  - Filtering
  - Breathability
  - Fitting

Pecchia L, Piaggio D, Maccaro A, Formisano C, Iadanza E. The inadequacy of regulatory frameworks in time of crisis and in low-resource settings: personal protective equipment and COVID-19. Health and technology. 2020 Nov;10(6):1375-83.





A. Maccaro, D. Piaggio, S. Pagliara, L. Pecchia, *“The role of ethics in science: a systematic literature review from the first wave of COVID-19”*, Health and Technology 2021

**AIMS:** To understand the impact and the perception of the pandemic during the first wave (January-June 2020) and the consequences one year later.

**METHODS:** PubMed was systematically searched up May 2020 to identify studies that took into consideration various ethical issues that have been arising from the Covid-19 outbreak.

**RESULTS:** 38 studies out of 233 met our inclusion criteria and were fully analysed. Accordingly, this review touches on themes such as fairness, equity, transparency of information, the duty of care, racial disparities, the marginalisation of the poor, and privacy and ethical concerns.

**CONCLUSIONS:** Reflecting one year after the outbreak of the pandemic, it is clear that the ethical issues linked to Covid-19 are many, particularly sensitive, and still need to be investigated further. Moreover, the need for the integration of ethics not only as a “humanitarian” enrichment to scientific studies, but as a moral compass in times of crises, is even clearer.



A. Maccaro, D. Piaggio, C. Dodaro, L. Pecchia, *Biomedical engineering and ethics: reflections on medical devices and PPE during the first wave of COVID-19*, BMC Medical Ethics, 2021

**AIMS:** To investigate and analyse the relation among ethical issues emerged during Covid-19 pandemic and Biomedical Engineering

**METHODS:** bioethical analysis

**RESULTS&CONCLUSIONS:** Among the most recurrent ethical issues surfaced during the first months of COVID-19, there are: **allocation of resources, the responsibilities of science, and the inadequacy and non-universality of the norms and regulations on biomedical devices and personal protective equipment.**

These ethical issues, analyzed one year after the first wave of the pandemic, come together in the appeal for

- responsible thought
- responsible action
- responsible silence

This highlights the importance of interdisciplinarity and the definitive collapse of the Cartesian fragmentation of knowledge, calling for the creation of more fora, where this kind of discussions can be promoted.



A. Maccaro, D. Piaggio, M. Vignigbe, A. Stingl, L. Pecchia

“Covid-19 pandemic - Social and Healthcare dynamic impact in Benin”, Health Promotion International, 37(4), daac105

**RESULTS&CONCLUSIONS:** Despite the preparedness to COVID-19 due to the promoted governmental measures, a peculiar management of the pandemic emerged. The latter, in fact, although noteworthy, did not overcome the typical technical challenges of medical locations in low-resource settings. This, together with the controversial transmission and reception of scientific information, and local beliefs caused significant economic and social consequences, exceeding the benefits related to the containment of the virus.



# Conclusions

- There is a huge need for more and well trained BMEs
- International stakeholders are eager to get support
- We have to better understand the needs/view of international stakeholders
- Ethics is not an embellishment, but the only way to cope with emergency when regulations fail
- We need:
  - Responsible thinking
  - Responsible actions
  - ...responsible silence, when needed!

