Proposed plan of action of the task force on the use of ECMO in COVID-19 patients

Version 1 - 22 March 2020

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General recommendations

The task force has taken a **formal decision** in favour of **the strict regulation** of all indications of ECMO for COVID-19 patients **in the Île-de-France (IDF) region**, for a period of **three to four months**

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VA ECMO should be used to treat cardiogenic shock patients and other indications apart from COVID-19 (see below).

Number to call for VV ECMO: 01.84.82.75.44

Number to call for VA ECMO: 01.42.16.56.43

The shortage of circuits is a present reality which risks getting worse with unreasonable use and should be taken into account. This means an 'embargo' on the use of ECMO circuits in all hospitals possessing them. This embargo should only be lifted once advised to by a centre of expertise, appointed by the regional health board (ARS), in order to ensure the best possible use of this scarce resource.

Feedback from the preliminary cases appears to go against VV ECMO as an indication for COVID-19+ patients receiving rescue therapy (see contraindications).

There is **no place for ECCO2R** in the strategy for treating these patients or for any other indication until further notice.

ECCO2R circuits should be used as VA ECMO circuits, including all XENIOS circuits.

In the current climate, the VA ECMO programme for out-of-hospital cardiac arrest and ECMO for organ procurement must be swiftly re-evaluated (the task force recommends a temporary suspension, given the impact on the availability of equipment).

General recommendations for the treatment of ARDS with ECLS

Indications for veno-venous (VV) extracorporeal membrane oxygenation (ECMO)

VV ECMO should probably be considered in cases of severe ARDS with PaO_2/FiO_2 < 80 mmHg and/or where mechanical ventilation becomes dangerous due to the increase in plateau pressure, despite the optimisation of ventilator settings and prone positioning. The decision to introduce ECMO should be evaluated early, by contacting a centre of expertise, after optimising ARDS treatment, including increasing PEP, neuromuscular blockade and prone positioning.

GRADE 2+, STRONG AGREEMENT

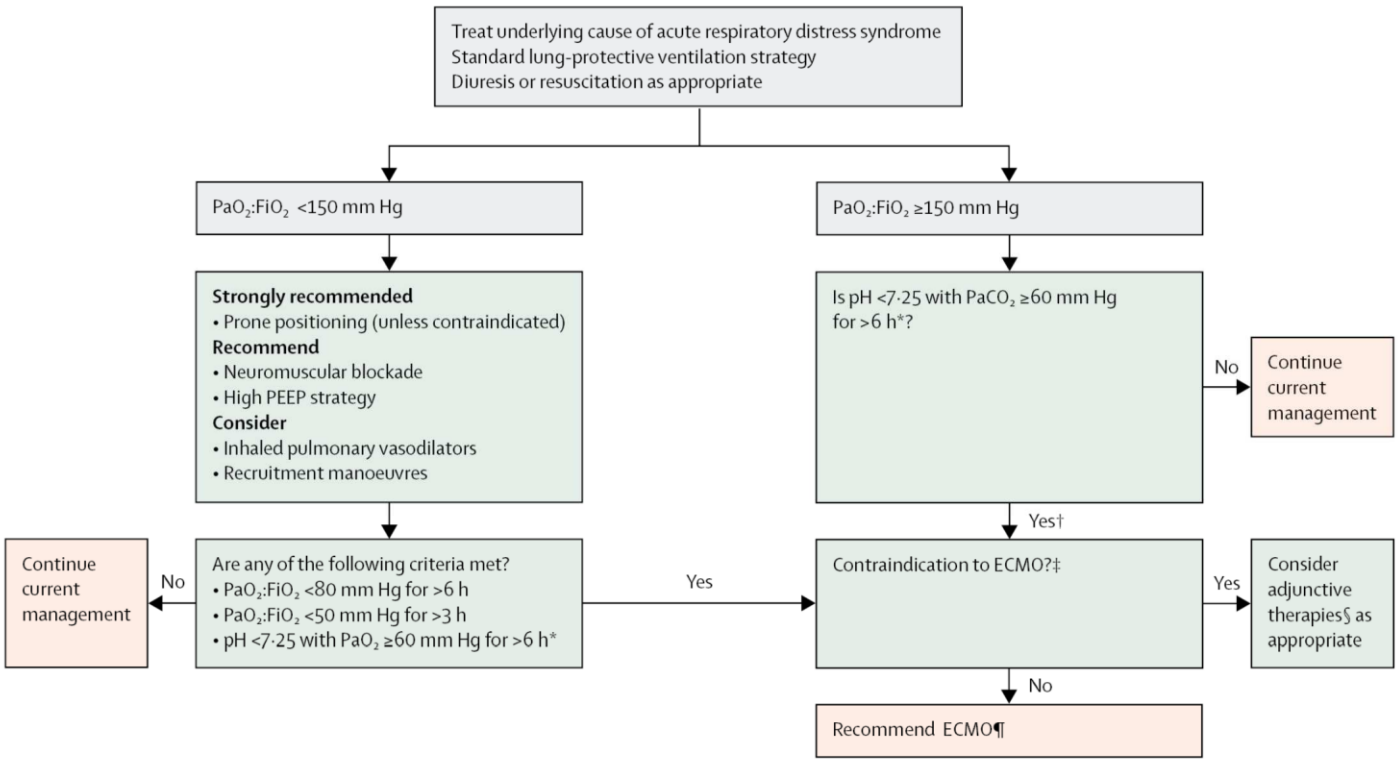
Indications of extracorporeal CO_2 removal (ECCO2R)

In light of the available data, it is not possible to put forward recommendations of the use of low-flow extracorporeal CO_2 removal techniques for ARDS in COVID-19 patients.

NO RECOMMENDATION

NB: These indications are based on the Official Expert Recommendations of the Francophone Society of Intensive Medicine - Treatment for Acute Respiratory Distress Syndrome (ARDS) for adults in the preliminary phase.

Flow chart for decision-making for identifying patients who could benefit from ECMO for ARDS (*Lancet Resp Med, 2019 PMID: 30642778)*



NB

If a patient presents with signs of severe ARDS (PaO_2/FiO_2 < 100 mmHg) for more than three hours, it is advisable to quickly make pre-emptive contact with those overseeing ECMO, in anticipation of a decision.

Organisation of systems (Île-de-France (IDF)/Greater Paris Public Hospital Authority (AP-HP))

Adaptation of ECMO indications according to available resources (consoles including ECMO circuits:)

The outlook as regards the supply of ECMO circuits over the next three to four months is bleak (information confirmed by manufacturers). The ongoing shortage of ECMO circuits has prompted the Greater Paris Public Hospital Authority (AP-HP) and Île-de-France (IDF) region to adopt a number of measures:

1. **The decision to introduce VV or VA ECMO (excluding post-cardiotomy ECMO), once verified by a team with considerable experience with ECMO (e.g. Bichat or Pitié hospitals), according to common criteria for VV ECMO in COVID-19+ patients. A mobile unit may not move on until the indication has been verified. (If there are several centres of expertise, there is no single route a priori.)**
2. **Once an indication is verified, the mobile emergency cardiorespiratory unit oversees the introduction of ECMO in conjunction with the local team.**
3. As regards the AP-HP: circuit orders/stock are managed centrally to ensure that all hospitals have real-time information on stock levels (and possible repairs between hospitals). Stock management should be spread over four to five months. Given that 20% of circuits and 30% of consoles are available in non-AP-HP hospitals, **the IDF regional health authority has imposed the following requirement**:
    a. All console/circuit use, irrespective of the indication, must be reported to the General Agency of Equipment and Health Products/the regional health authority, so as to centralise stock management and indication analyses
4. **To define "reasonable" indications for ECLS/ECMO** for non-COVID-19 patients (each hospital should define these) and to inform the central administrator of circuit stocks
5. **To limit the number of hospitals treating COVID-19+ patients on ECLS/ECMO for ARDS**
   The technique should be reserved for hospitals where it is used to a sufficient extent, in order to avoid unintentional misuse due to a lack of experience connecting and sustaining ECMO. Each circuit that is damaged represents a potential life lost.
   The hospitals with the most experience in this technique (> 20/year) are intended to provide these patients with first-line treatment, like cardio-thoracic surgery hospitals.
   Intensive care units occasionally treating patients on ECMO are encouraged to treat these patients in conjunction with centres of expertise.
   Centres that did not provide ECMO before COVID-19 are not intended to do so and, therefore, are not intended to receive the machines or consumable supplies.
6. Prospective follow-up of outcomes (ECMO tab of the eCRF of the COVID-ICU study) **EVERY FRIDAY AFTERNOON IN ORDER TO REFINE INDICATIONS**
7. Standardisation of the indications for ECMO circuit replacements (IDF

ECMO HOTLINE)

a. The replacement of ECMO membranes should be discussed with an expert from the ECMO HOTLINE.

Contraindications of VV ECMO in the present context:

- Age > 70 years
- Severe comorbidities (e.g. COPD with home O_2 therapy, progressive cirrhosis (Child-Pugh class B/C) or progressive heart failure)
- Severe immunodeficiency (e.g. cancer of the blood, non-managed HIV or treatment for solid tumours)
- Solid organ transplant patients will be discussed on a case-by-case basis and are not excluded a priori
- Cardiac arrest (except if a helper is present and CPR is initiated immediately at low flow for < 15 minutes)
- Mechanical ventilation > 10 days prior to ECMO
- Multiple organ failure

NB: **THESE CONTRAINDICATIONS COULD CHANGE OVER TIME, ACCORDING TO FEEDBACK.**

IN ANY CASE, THE DECISION TO INTRODUCE ECMO IS TO BE MADE BY THE ECMO REGULATION GROUP.

APPENDICES

ECMO consoles in the AP-HP and Île-de-France (according to the declaration of 18 March):

Hospital	GETINGE		Medtronic	LIVANOVA		XENIOS		ABBOTT	TOTAL	
	Cardiohelp	Rotaflow	Biomedicus	SCPC	Lifebox	DS	ECO2R	Levitronix		
AP-HP La Pitié	10	16	5	4	1	11	1	6	54	
AP-HP Necker	4	4		4		2			14	
AP-HP Ambroise Paré Hospital	1								1	
AP-HP HEGP	2	6					2		10	**126**
AP-HP Trousseau	1	3				4			8	
AP-HP Bichat		10				2			12	
AP-HP Henri Mondor		2		4	1		1		8	
AP-HP Lariboisière		2				1	1		4	
AP-HP Kremlin-Bicêtre		2		1			1		4	
AP-HP Tenon		2					1		3	
AP-HP Cochin		1					2		3	
AP-HP St Antoine							1		1	
Avicenne							1		1	
Raymond Poincaré (Garches)							1		1	
Beaujon		1							1	
Louis Mourrier						1			1	
CCML Le Plessis Robinson		3		2		5			10	
Foch Suresnes Hospital		4		2					6	
St Joseph				1					1	**39**
Parly 2 Le Chesnay		2							2	
Clinique Ambroise Paré				1					1	
IMM				3					3	

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Massy				2					2	**Non-AP-HP**
CCN St Denis		3							3	
HIA Percy	1								1	
Corbeil						2			2	
Jossigny (Est Francilien)		1				1			2	
CH Villeneuve St Georges							3		3	
Delafontaine						2			2	
Pontoise Hospital	1								1	
TOTAL	20	62	5	24	2	31	15	6	**165**	
	82		**5**	**26**		**46**		**6**		
	GETINGE		**Medtronic**	**LIVANOVA**		**XENIOS**		**ABBOTT**		

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Consumable supplies (ECMO sets, cannulas and other) in the AP-HP and Île-de-France (according to the declaration of 18 March):

	GETINGE		LIVANOVA	XENIOS		ABBOTT	EUROSET	TOTAL	
Hospital	**Cardiohelp**	**Rotaflow**	**SCPC**	**DS**	**ECO2R**	**Centrimag**	**Double**		
AP-HP La Pitié	45	56	39	23		5	*24*	168	**311**
APHP Necker	7	6	10					23	
AP-HP Ambroise Paré Hospital	2							2	
APHP HEGP	0	33						33	
APHP Trousseau	4	1						5	
AP-HP Bichat		30						30	
AP-HP Henri Mondor		24						24	
AP-HP Lariboisière				5				5	
AP-HP Kremlin-Bicêtre		4	7		1			12	
AP-HP Tenon		1						1	
AP-HP Cochin		2						2	
AP-HP St Antoine					2			2	
Avicenne				0				0	
Raymond Poincaré (Garches)					2			2	
Beaujon				0				0	
Louis Mourrier				2				2	
CCML Le Plessis Robinson		5	10	5				20	**82**
Foch Suresnes Hospital		7	2					9	
St Joseph			2					2	
Parly 2 Le Chesnay		2						2	
Clinique Ambroise Paré			3					3	
IMM			7					7	
Massy			4					4	

CCN St Denis		6						6	**Non-AP-HP**
HIA Percy	1							1	
Corbeil				2	2			4	
Jossigny (Est Francilien)		5		3				8	
CH Villeneuve St Georges				10				10	
Delafontaine				2	2			4	
Pontoise Hospital	2							2	
TOTAL	61	182	84	52	9	5	*24*	**393**	
	243		**84**	**61**		**5**			
	GETINGE		**LIVANOVA**	**XENIOS**		**ABBOTT**			

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Update of the General Agency of Equipment and Health Products (AGEPS) of 18/03/2020

I have just had an update with Ms Vrech Getinge and Mr Grolleau Fresenius Xenios.

Although the situation concerning the supply of circuits was virtually normal at the end of last week, it has become significantly worse.
Suppliers are reporting updates of the situation to the French National Agency for Medicines and Health Products Safety (ANSM), Ms Français. For GETINGE, the situation is very strained, with resources being under-allocated. For example, of the orders already processed, 166 HLS circuits and 113 PLS circuits are still pending delivery.
The delivery time for consoles is 19 weeks for Rotaflow and 20 weeks for CardioHelp.
However, the AP-HP has two BCT and one CCH consoles that are not being used. Ms Vrech is to send me a precise update.
There are no more FRESENIUS XENIOS circuits available: 0 NOVALUNG X-LUNG, end of the MEDOS circuits...no visibility of supply capacities
…
However, there are 60 ECCO2R circuits, 25 of which have a short shelf life.
Maximum blood flow: 4.5 l. Circuits a little shorter.
As regards consoles, it is possible to use ECCO2R consoles, including those that do not rotate: BCT and RPC.
Suppliers have reported orders from French hospitals that have never provided ECMO or ECCO2R ⓪ **the need for national regulation.**

I have asked for your to be copied into emails from the suppliers.

Yours faithfully,

Manuelle Panczer
Head of the Biomedical Equipment Evaluation and Sales sector Sales Department
AGEPS

Tables included in the article "Planning and Provision of ECMO Services During COVID-19 and Other Emerging Infectious Disease Outbreaks"

Lancet Resp Med, 2020, doi.org/10.1016/S2213-2600(20)30121-1

Building systems that support equipment, facilities and personnel is critical to ensuring optimal patient care, as well as family and staff safety during an EID. Processes that enhance safe and coordinated movement of critically ill patients, staff, and life-sustaining equipment is equally important. Clear communication, coordination of resource allocation, and staff education are key components of preparedness. Facilities to house trained multidisciplinary staff and equipment are also vital.

Organisation of ECMO activity during a pandemic

Provision of ECMO during a epidemic of infectious disease outbreak

- ❑ ECMO resource planning and allocation
- ❑ Personnel assignments and contingency plans
- ❑ Staff training and ECMO refresher courses
- ❑ Infection control measures prior to and during ECMO initiation
- ❑ Patient transfer on ECMO support
- ❑ ECMO weaning, decannulation and post ECMO care
- ❑ Post-mortem care
- ❑ Staff support
- ❑ Ethical considerations
- ❑ Quality assurance and collaborative research

ECMO resource planning and allocation

Essential

- ❑ Maintain a dedicated manifest of personnel trained in the care of patients on ECMO
- ❑ Maintain a contemporaneous log of equipment serviced and ready to deploy
- ❑ Regional tracking of equipment and disposables can help distribution of these supplies based on need.
- ❑ Areas of care facilities should outline areas for donning and doffing of PPE and PAPR
- ❑ Effective communication and co-ordination to facilitate inter-hospital transfers and distribution of workload
- ❑ Predict and prepare for a surge of patients to expert ECMO centers

Desirable

- ❑ Clustering of patients in expert ECMO facilities
- ❑ Develop regional ECMO response systems
- ❑ Conservation of limited supplies
- ❑ Nominate local and regional ECMO coordinators

Personnel training and ECMO refresher courses during a pandemic

Personnel training and ECMO refresher courses

- ❑ Training should be site specific and should target multi-disciplinary team members.
- ❑ Training should be led by faculty preferably with experience in simulation education
- ❑ Staff members should be trained in the correct handling of infected body secretions and laboratory specimens
- ❑ Following adequate PPE training, use of all ECMO related equipment must be practiced
- ❑ Simulated ECMO cannulation/decannulation practice while donning PPEs and PAPR
- ❑ Simulated ECMO transfer drills while donning PPRs and PAPR
- ❑ Regular simulated ECMO trouble shooting drills to while donning PPE / PAPR