



MINISTERIO  
DE TRANSPORTES, MOVILIDAD  
Y AGENDA URBANA

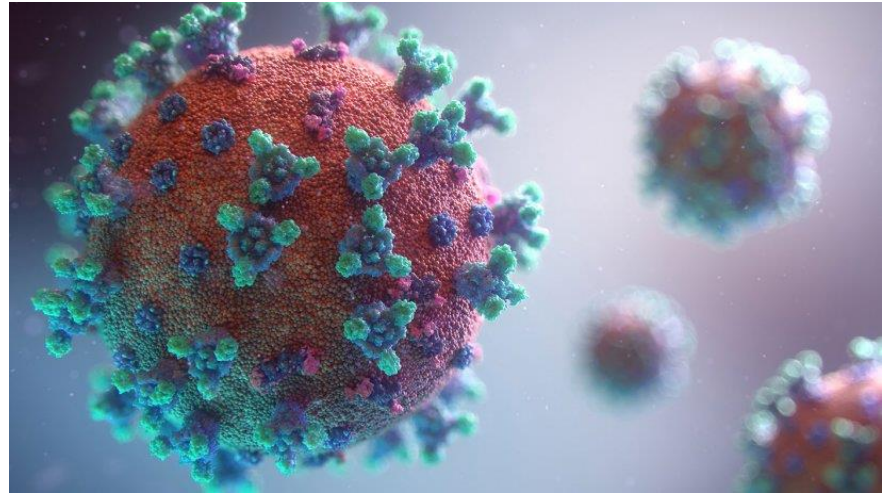


## **“AME’s COVID19: Procedures & Results”.**

Dr. Francisco Rios Tejada  
AESA Chief Medical Assessor

AMABEL Meeting 2nd October 2020

## Disclaimer Information

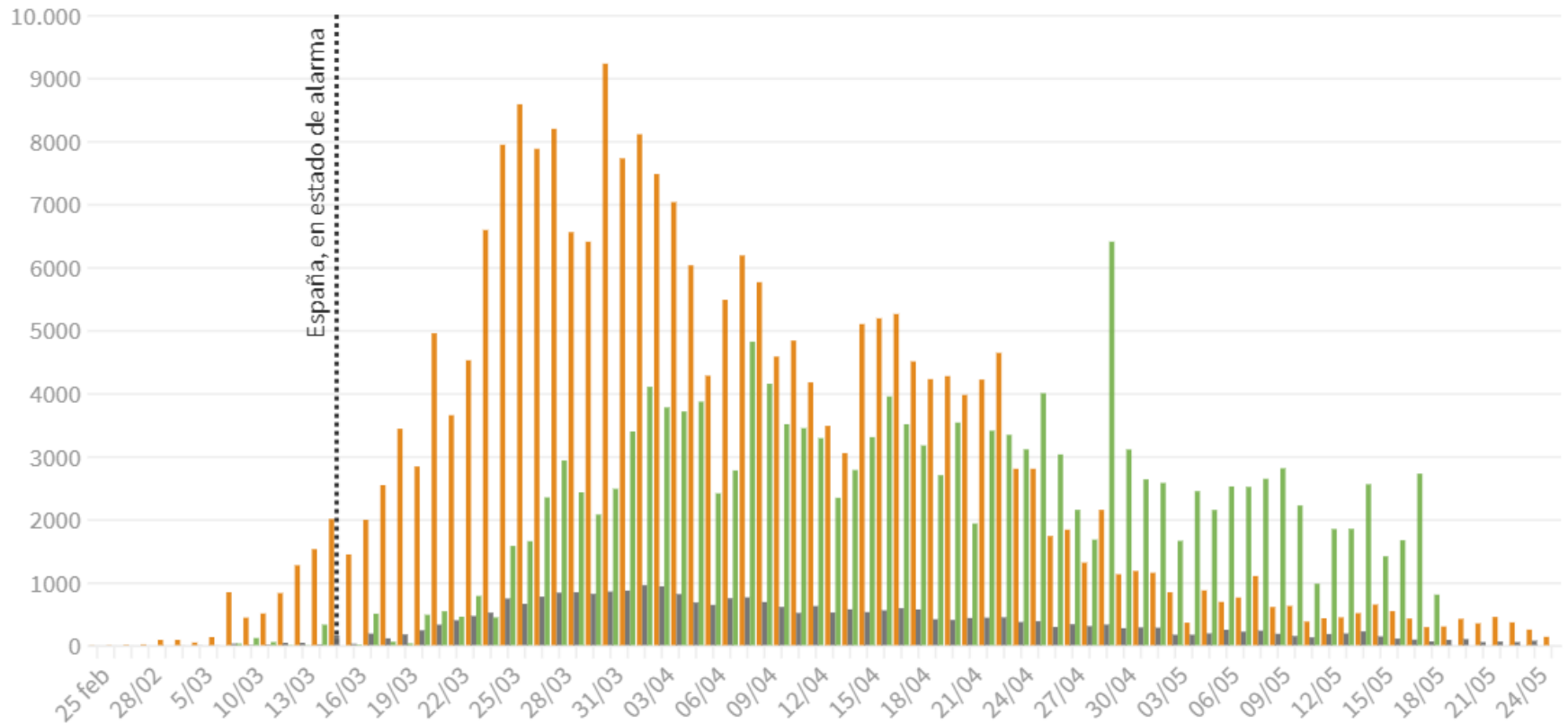


- AMABEL Meeting.
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- I will not discuss off-label use and/or investigational use in this presentation.
- This presentation are intended for information purposes only, and should not necessarily reflect the opinion of AESA nor EASA.

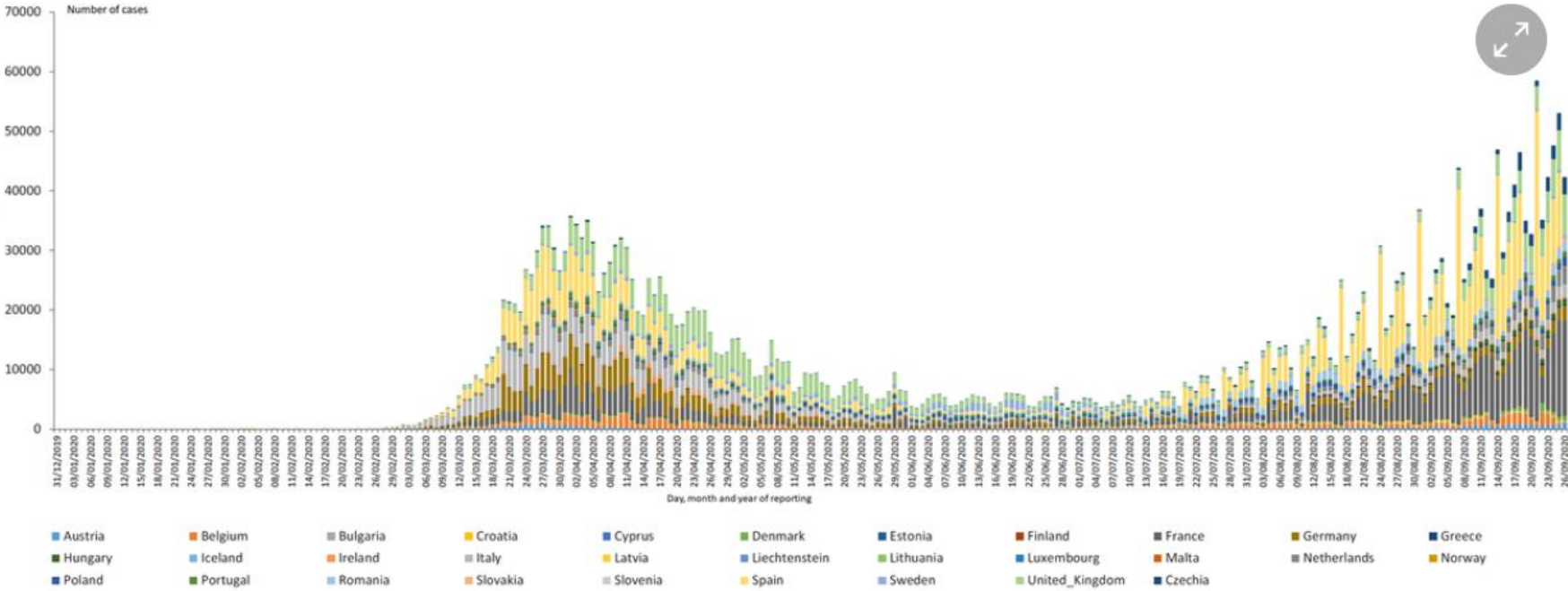


COVID 19: Daily progress of **new cases**, deaths and **recovered**.

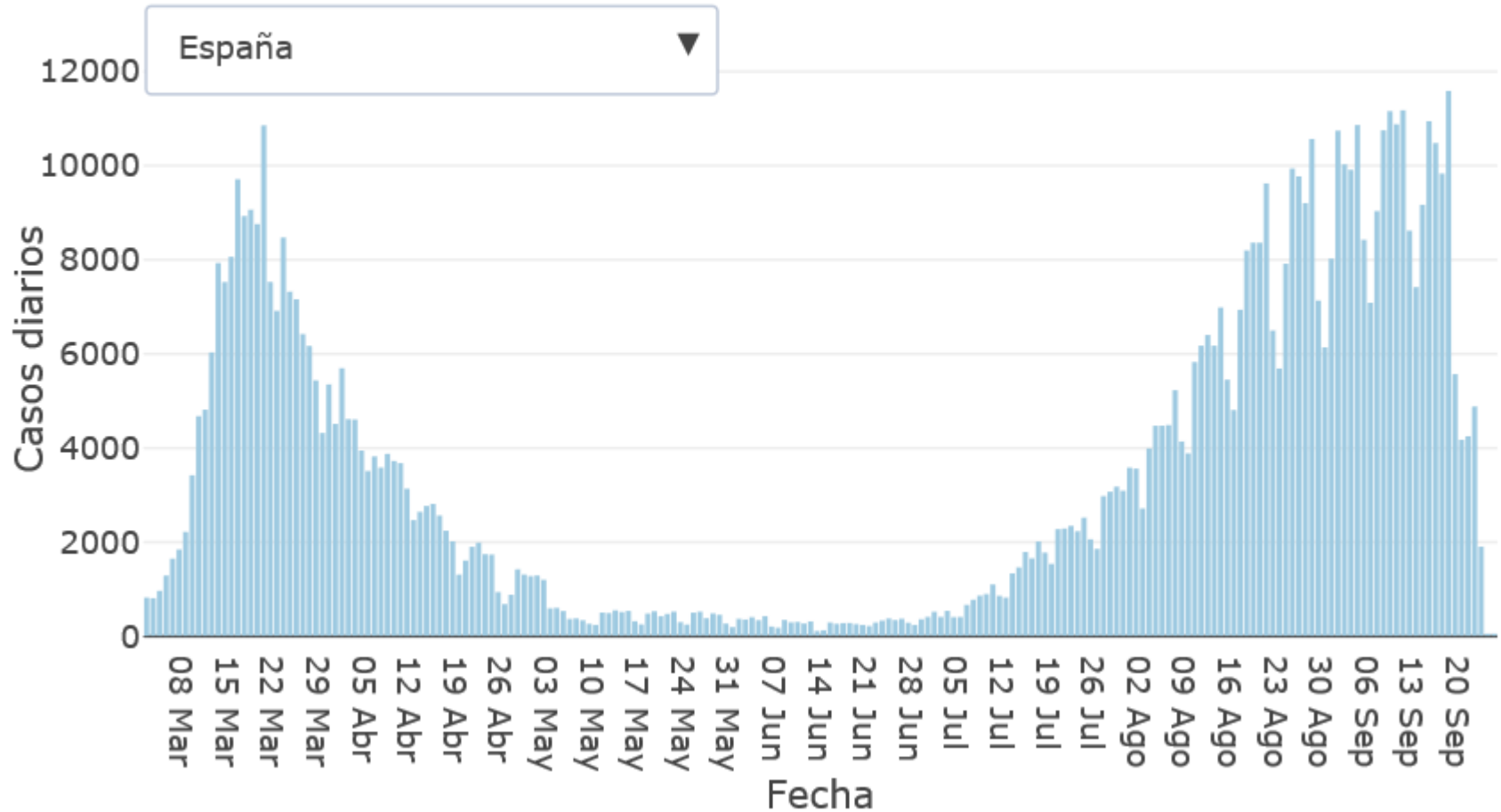
Evolución diaria de **casos**, **muer**tes y **recuperados** nuevos con coronavirus en España



# Distribution of laboratory confirmed cases of COVID-19 in the EU/EEA and the UK, as of 26 September



## Curva epidémica

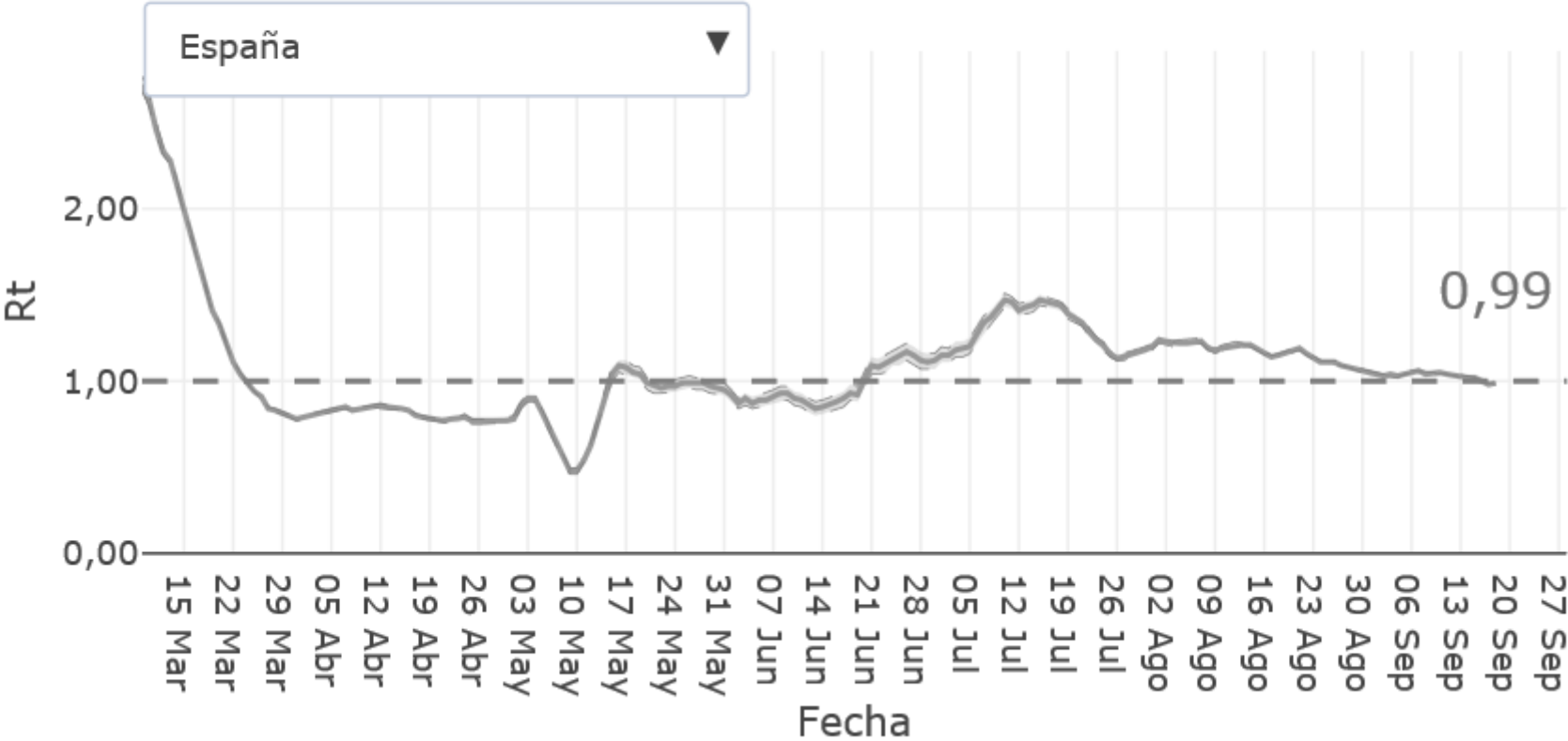


20th Sept 2020



## Instant Basic Reproductive Number (Rt)

### Número reproductivo básico instantáneo (Rt)



27th Sept 2020

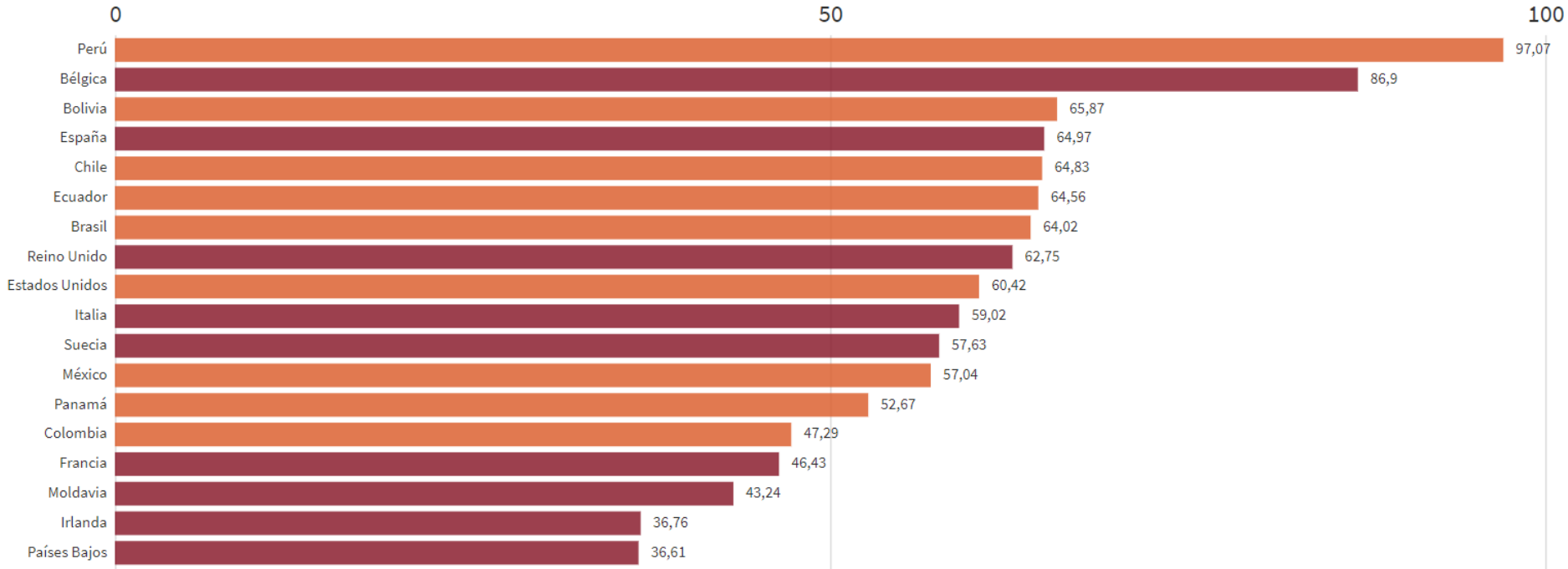


## Death Rate/100.000 population

Países con más muertes con coronavirus por 100.000 habitantes

Se incluyen solo países con más de un millón de habitantes

Selecciona para filtrar por continente → ● Asia ● Europa ● África ● América ● Oceanía



15/09/2020



## AME

- Still valid procedures and protocols designed in the 1st Wave.
- Protection measures in place during the exam.
- Attention to applicants that will show up by the time of the corresponding renewal or revalidation and got COVID19 during the 1st wave.

## AUTHORITY

- Follow up available data of COVID19: Incidence & consequences (Risk Assessment).
- Up to date procedures
- Re-arrange oversight: On site very complicate.
- Education: turn into e-learning/webinar/distant learning.
- EASA guidelines, recomendations and standarization among MS



- To assist the AME by furnishing guidelines and management instructions able to identify aircrew and ATCO applicants, that in any way have been associated with the COVID19.



**Help AME**

- To indicate suitable directions and framework to follow, in order to identify the compatibility of the exposed candidate and what it is established in the EASA Regulation, concerning Infectious diseases and hence COVID19, to assure flight safety.



**Suitable for flying duties**





Agencia Estatal  
de Seguridad Aérea

## PRACTICAL GUIDELINES FOR THE EVALUATION OF COVID19 CASES FOR AMEs & AMCs

## GUIA PRÁCTICA PARA EVALUACIÓN DE CASOS COVID19 POR AMES Y AEMCS

A-DMA-CV19-01 L10  
AGENCIA ESTATAL DE SEGURIDAD AÉREA

Cualquier copia impresa o en soporte informático, total o parcial de este documento se considera como copia no controlada y siempre debe ser contrastada con su versión vigente en la web.

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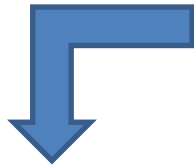


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**Air transport has been demonstrated a powerful vector of transmission, therefore we must assure the actual fitness, which means free COVID disease in aircrew members and ATCOs, if we want to secure the aviation activity.**



**The aeromedical evaluation either by AME or AeMCs, seems to be critical in those individuals who might be exposed to the disease in any of the aspects or domains showed by COVID19.**



## **1178/2011**

### **MED.B.040 Infectious diseases**

*a) Applicants will be considered unfit if any clinical diagnosis or medical history of any infectious disease that might interfere with the safe exercise of the privileges of the licence.*

### **AMC1 MED.B.040 Infectious disease**

*(a) Infectious disease General*

*In cases of infectious disease, consideration should be given to a history of, or clinical signs indicating, underlying impairment of the immune system.*



## ATCO.MED.B.040 Infectious Diseases

b) applicants with symptoms or diagnosis of infectious disease such (\*):

- 1) Syphilis;
- 2) active tuberculosis;
- 3) infectious hepatitis;
- 4) tropical diseases,

Should be deferred to the authority in order to be evaluated. A fit assessment can be evaluated after a complete recovery and report of specialist will demonstrate that treatment does not interfere with the privileges of the licence.

(\*) can be extrapolated to COVID-19

## AMC1 ATCO.MED.B.040 Infectious disease

*(a) Infectious disease — General*

*In cases of infectious disease, consideration should be given to a history of, or clinical signs indicating, underlying impairment of the immune system.*



**Guidance on aircraft cleaning and disinfection**  
in relation to the COVID-19 pandemic

**Safety Information Bulletin Aerodromes – Operations**

**SIB No.: 2020-02R5**

**Issued: 30 June 2020**

**Subject: Coronavirus COVID-19 Pandemic — Operational recommendations**

**Guidance on the management of crew members**  
in relation to the COVID-19 pandemic

**COVID-19 Aviation Health Safety Protocol. *Operational guidelines for the management of air passengers and aviation personnel in relation to the COVID-19 pandemic***





**The applicant must be specifically asked by the AME about items:**

- **105 (other respiratory diseases),**
- **128 (other diseases),**
- **129 (hospitalization),**
- **130 (medical visit) displayed in the application form and associated to COVID19.**

**The AME:**

- **Will collect whatever medical reports provided by the applicant and,**
- **Will ask about his/her Labour and Social Security Medical Status.**





**It will be necessary to identify:**

- **Diagnosis, course of treatment and hospital admission.**
- **In case of mild disease, what kind of preventive measures has been followed, including quarantine and possible confirmed contacts.**

**A comprehensive review:**

- **Medical reports: clinical data, complementary testing, Lab testing, image diagnosis, and treatment provided, including oxygen therapy or assisted ventilation.**







Attention will be paid to presence of comorbidity and complications.

Once the data has been collected:

1. Find out if information provided is good enough for an appropriate aeromedical assessment or if any additional testing we think it might be necessary for a final adequate assessment.
2. In situ or referrals: temperature, TC/TCAR, thoracic ecography, pulmonary function test, SpO2 follow-up, disnea scale (MRC) & quality of life, 6 min walk test, ECG (QT/QTc), echocardiography, comorbidity, target organs involvement and specialist report.





## **Attention!!**

**Keep in mind that infection by COVID 19, is a dynamic process, that respond to a variable clinical course, but with a quite uniform syndromic expression.**

**Disease course may vary from a mild evolution, treated at home and phone follow-up to medical ambulatory /visit medical follow-up, to hospital admission or ICU care.**





**The ever-changing nature of this illness means that we need to change our focus on the effect of the infection.**



**AME should consider the changes and scientific evidence and the situation of the disease at the time of the applicant examination.**

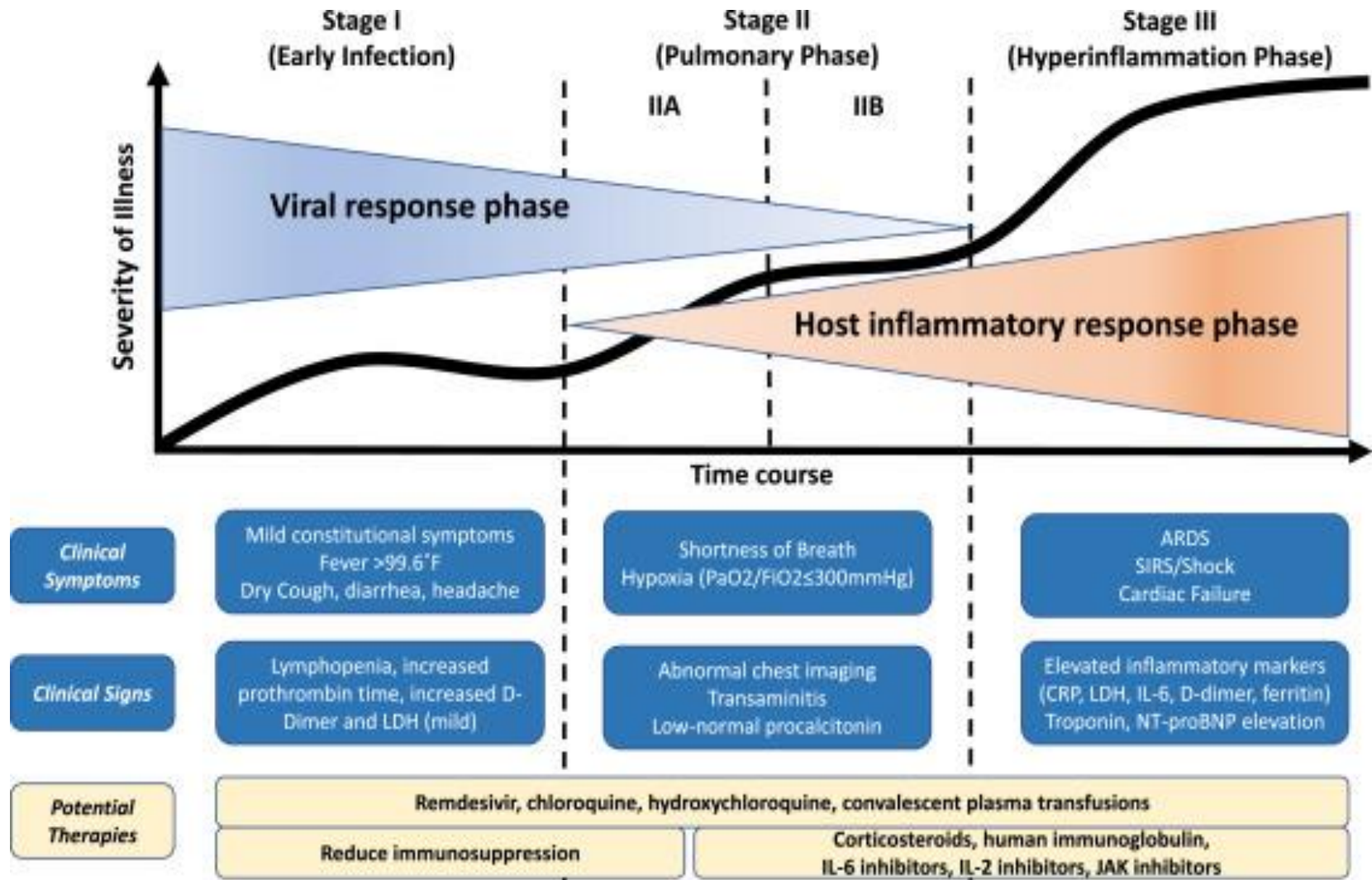




**Evidence showed that classification scheme of Siddiqi, might be modified by adding a fourth or a fifth phase, where systemic non pulmonary complications (cutaneous, eye, neurologic, renal, cardiac, coagulation disorders), age involvement (kids) or respiratory complications such pulmonary fibrosis and some others not yet clearly defined.**

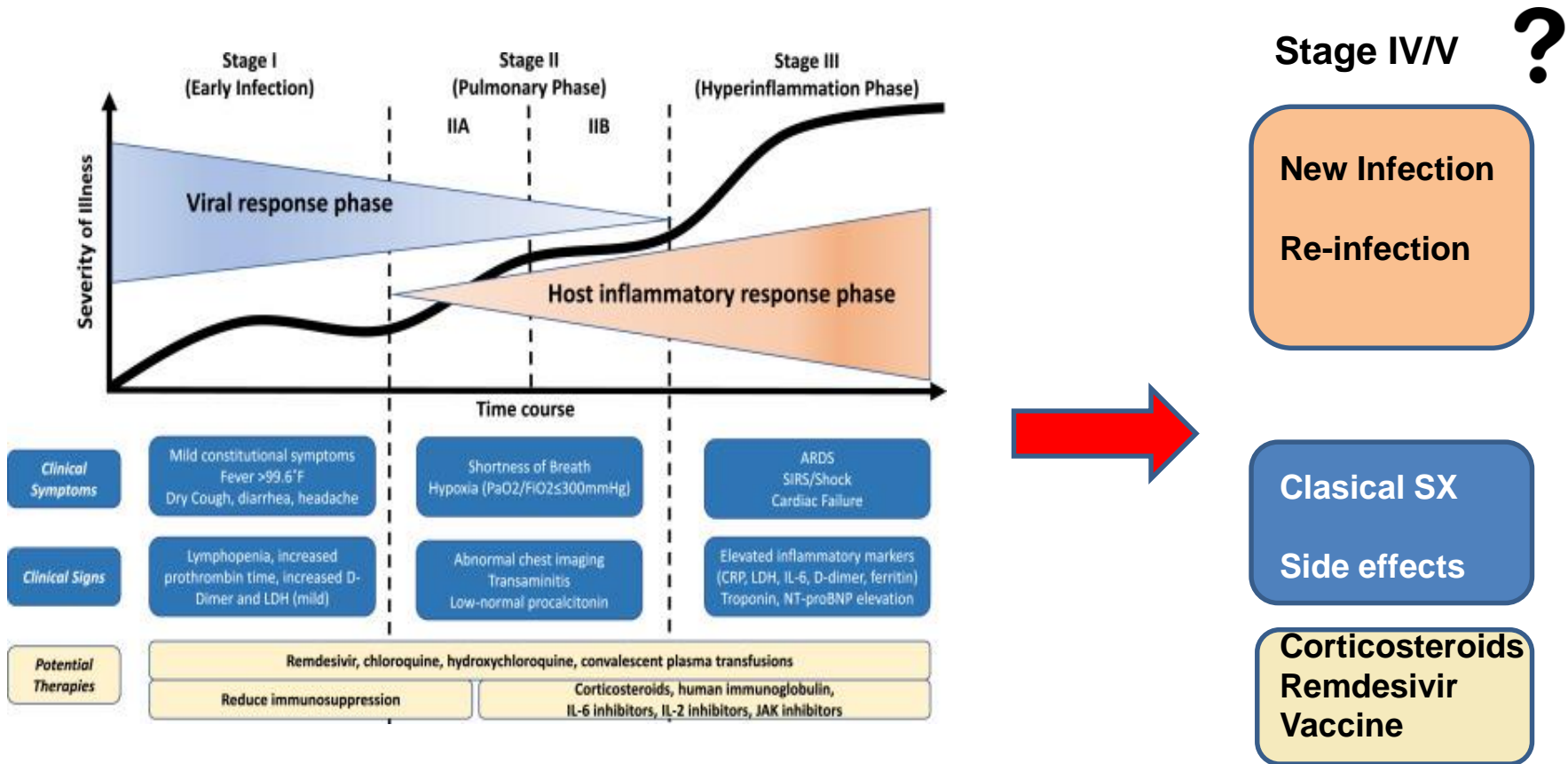


# COVID19: Phases



*COVID19: Clinical-Therapeutic Staging Proposal. Hasan K. Siddiqi*



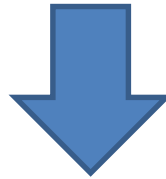


**COVID19: Clinical-Therapeutic Staging Proposal. Hasan K. Siddiqi (Modified)**





Evidence showed that classification scheme of Siddiqi, might be modified by adding a fourth or a fifth phase, where systemic non pulmonary complications (cutaneous, eye, neurologic, cardiac, coagulation disorders), age involvement (kids) or respiratory complications such pulmonary fibrosis and some others not yet clearly defined.



It is necessary to rule out complications and take into account the possibility to check additional testing if we want to rule out target organs involvement such heart and lungs (Echocardiography, Respiratory Function test, Image diagnosis).

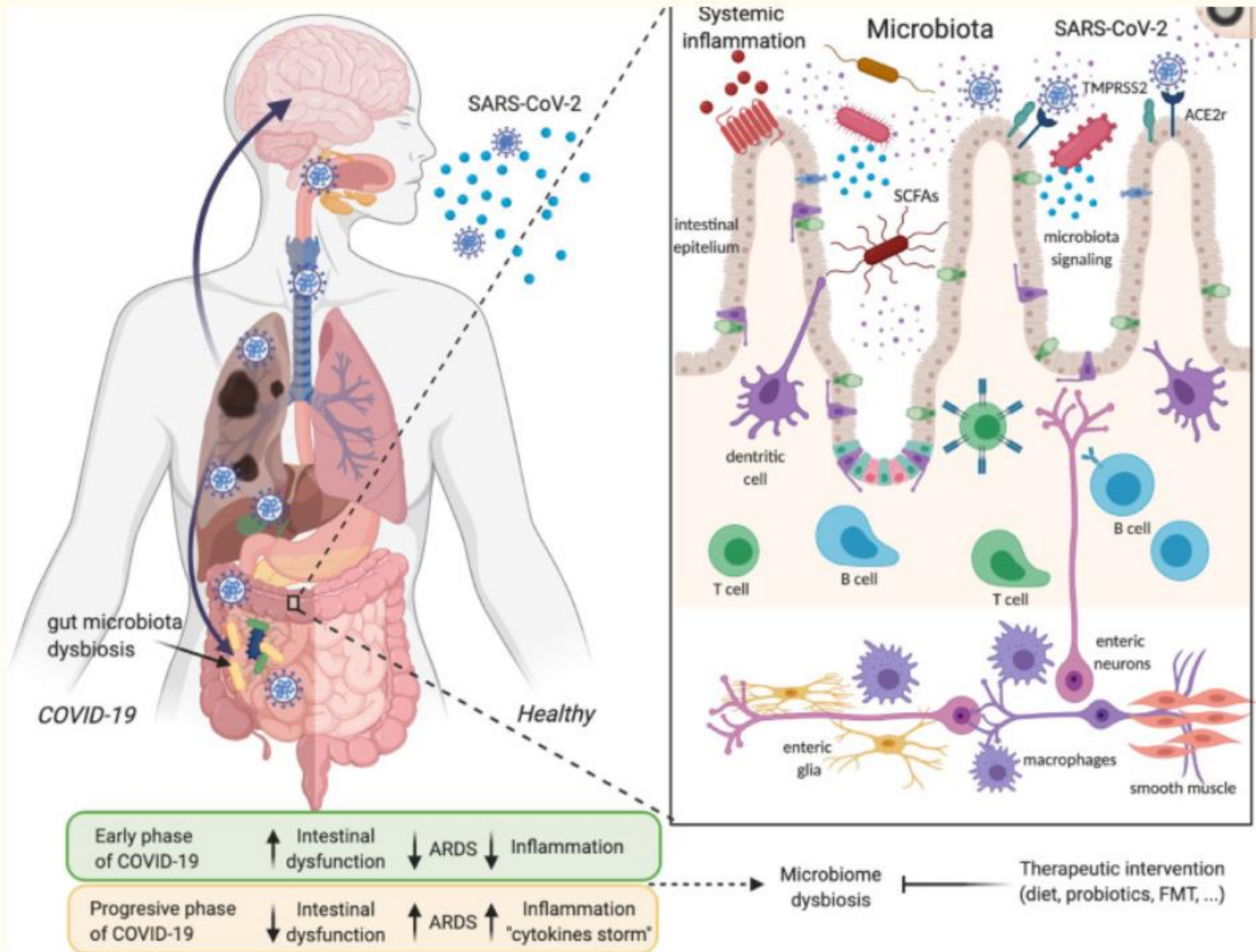


System	Side Effects
Upper Airways	Anosmia, ageusia, cough, mucous
Lower Airways	Dispnoea, cough, chest pain
Muscle & Joints	Weakness, erratic pain
Neurocognitive	Loss of attention, memory loss & sleepness
Neurological	Neurodegenerative disease, stroke, brain hemorrhage, encephalitis, peripheral nerve damage.
Psychological	Anxiety, depression, psychosis
Digestive/Renal	Gut microbiota dysbiosis, Electrolytic disturbance, Acute Kidney Injury, Renal replacement therapy
Others	Loss weight & hair





# Gastro-intestinal side Effects



- **6MWD** increased from 16% to 43%: **57% to gain.**
- **Fatigue, exercise intolerance**, and poor concentration can be particularly problematic. Unfortunately, optimal management remains unclear.
- While the effects of COVID-19 for the pulmonary circulation are being defined, several lines of evidence suggest that the molecular features of SARS-CoV-2 infection are strikingly similar to what is seen in **pulmonary vascular disease development, promoting endothelial dysfunction, lung coagulopathy and microthrombi, and hemodynamic impairments (Table).**
- A pragmatic approach to primary care management might include first line investigations such chest radiography and oxygen saturation measurements, with referral to secondary care where **lung pathology needs investigation.**

*BMJ 2020; 370 doi: <https://doi.org/10.1136/bmj.m3001> (Published 03 August 2020) Cite this as: BMJ 2020;370:m3001*

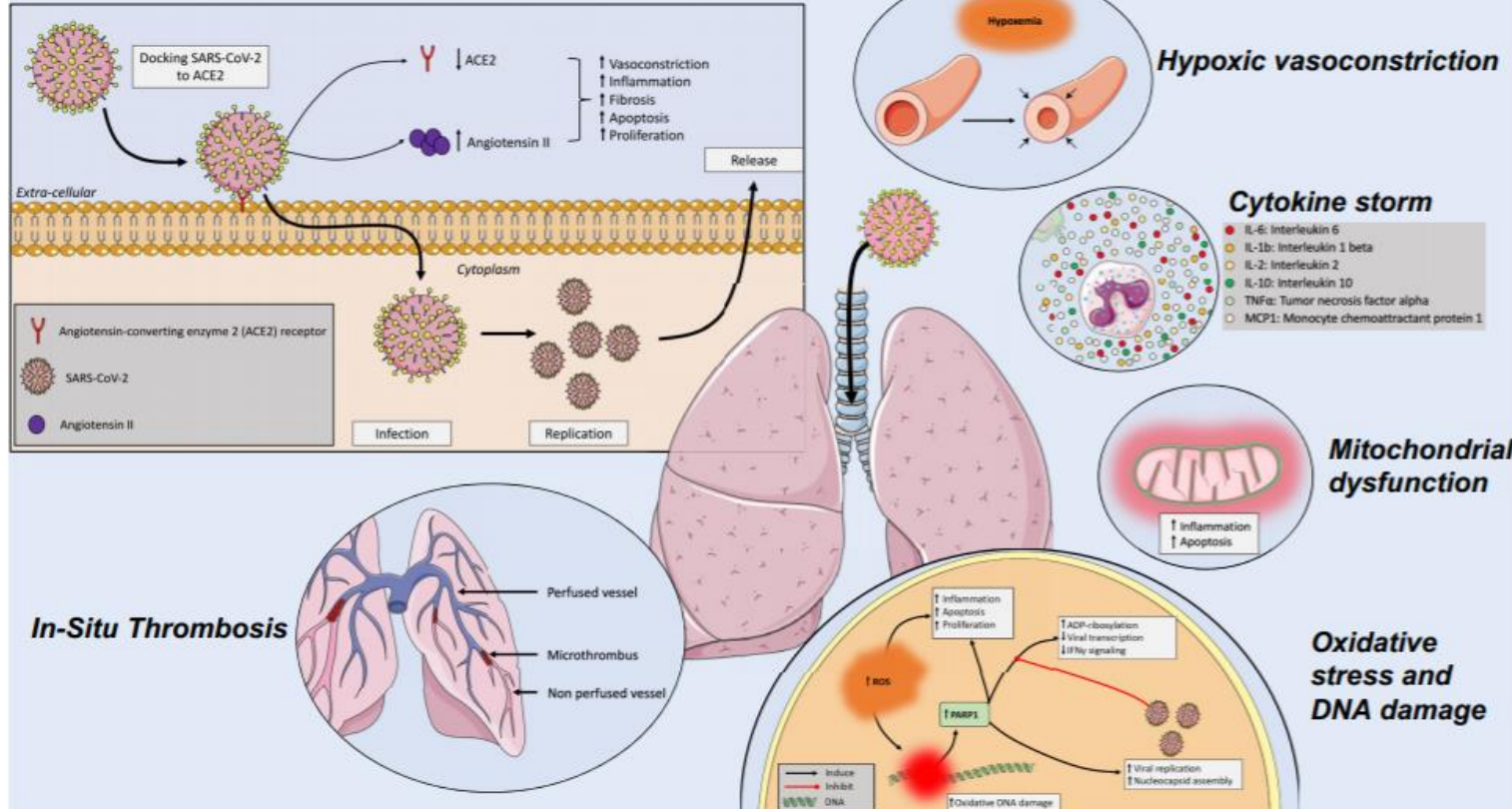
*Am J Physiol Lung Cell Mol Physiol 319: L277–L288, 2020. First published June 17, 2020; doi:10.1152/ajplung.00195.2020*



D

## COVID-19 AND PULMONARY VASCULAR DISEASES

### Angiotensin-converting enzyme 2



# Pulmonary Side Effects

	COVID-19	PH
Symptom		
Dyspnea	+++	+++
Fatigue	+++	+
Inflammation		
Endotheliitis	+++	+*
Vasculitis	+++	+*
Myocarditis	+	-
Proinflammatory cytokines	↑↑↑	↑↑†
Thrombosis, microthrombi		
D-dimers	↑↑↑	↑
Prothrombin	↑	↑
DNA damage		
PARP	↑	↑↑
RAA activation	+	+++
ACE 2	↓↓	↓
Angiotensin 2	↑↑↑	↑↑
Cardiac injury		
Ejection fraction	↓*	↓‡
Troponin	↑↑	↑
Natriuretic peptide	↑	↑↑↑
RV dilatation	↑	↑↑↑
Pulmonary vascular thickness	↑	↑↑↑
Mitochondrial dysfunction	↑	↑↑
ROS	↑	↑↑
Endothelial dysfunction	↑	↑↑
HPV	↑	↑↑↑§

HPV, hypoxic pulmonary vasoconstriction; PARP, poly-ADP ribose polymerase; PH, pulmonary hypertension; RAA, renin-angiotensin-aldosterone system; ROS, reactive oxygen species; RV, right ventricle. \*Occasionally; †group 1 pulmonary hypertension; ‡group 2 pulmonary hypertension; §group 3 pulmonary hypertension. ↑ increased, ↑↑ generally increased, ↑↑↑ frequently increased, ↓ decreased, + observed, ++ generally observed, +++ frequently observed.







## SECUELAS LA COVID19 EN EL PARÉNQUIMA PULMONAR ¿FIBROSIS?

- Pocos datos hasta el momento
- Extrapolados de:
  - SARS-CoV: 62% de pacientes con patrón intersticial al alta. Los cambios fibróticos mejoraron sobre todo el primer año y después gradualmente hasta los 15 años de seguimiento (4,6% del parénquima afectado).
  - MERS-CoV: cambios fibróticos en 1/3 de los pacientes al alta
- COVID19: Recuperación radiológica semanas tras el alta (del 8,1% de estudios normales al alta al 53% a las 3 semanas)
- Recuperación lenta clínica, pacientes sintomáticos meses después de la infección (disociación clínico-radiológica) (muscular? Cardíaca?)
- Generalmente la fibrosis se da en pacientes más graves y en UCI (SDRA) pero no todos los paciente con fibrosis han tenido distrés (neumonía organizada?)

Antonio GE, et al. *Radiology*. 2003;228(3):810-815. doi:10.1148/radiol.2283030726  
Sing, P, et al. *Bone Res*. 2020; 8, 8 <https://doi.org/10.1038/s41413-020-0084-5>  
M. Das, et al. *Indian J Radiol Imaging*. 2017; vol. 27, no. 3, pp. 342-349

**Dra. Irene Martín**



Pulmonary Fibrosis?



Just a few data so far

## Extrapolate from:

- SARS-CoV: 62% of Pt with Interstitial Pattern at discharge time. After 15 years a 4,6 % still affected.
- MERS-CoV: Fibrotic changes in 1/3 of Pt at discharge time.

## COVID19

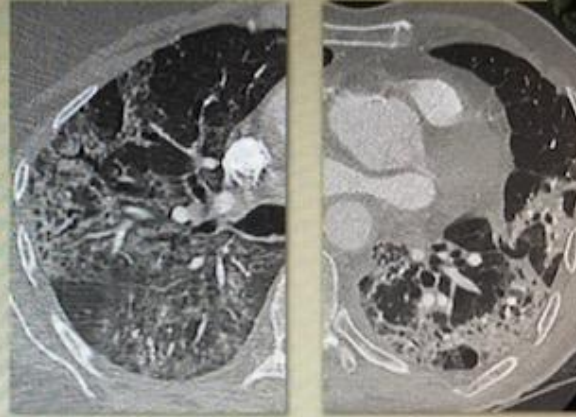
- At discharge time 8,1% normal radiology and 53% normal after 3 weeks.
- Very slow and torpid recovery: several months after, Pts still symptomatic, with normal radiolog: **Clinical- Radiological dissociation.**
- Presence of fibrotic radiological pattern more associated to severe COVID19 findings.
- Discussion: many Pulmonary specialist agree on dissociation in between clinical findings and Spo2, Espirometry and radiological status.
- Need to study other causes: Muscular, Cardiac, Trombotic....

## •Fibrosis en COVID-19:

- Bandas parenquimatosas
- Reticulación
- Bronquectasias de tracción
- Interfases irregulares.

## •Factores de riesgo para fibrosis

- Edad↑
- Hipertensión
- Disnea y RPM↑
- Linfopenia
- ↑PCR e IL6
- ↑días de estancia hospitalaria
- Ingreso en UCI
- Más días de tratamiento con corticoides y antirretrovirales



## Findings

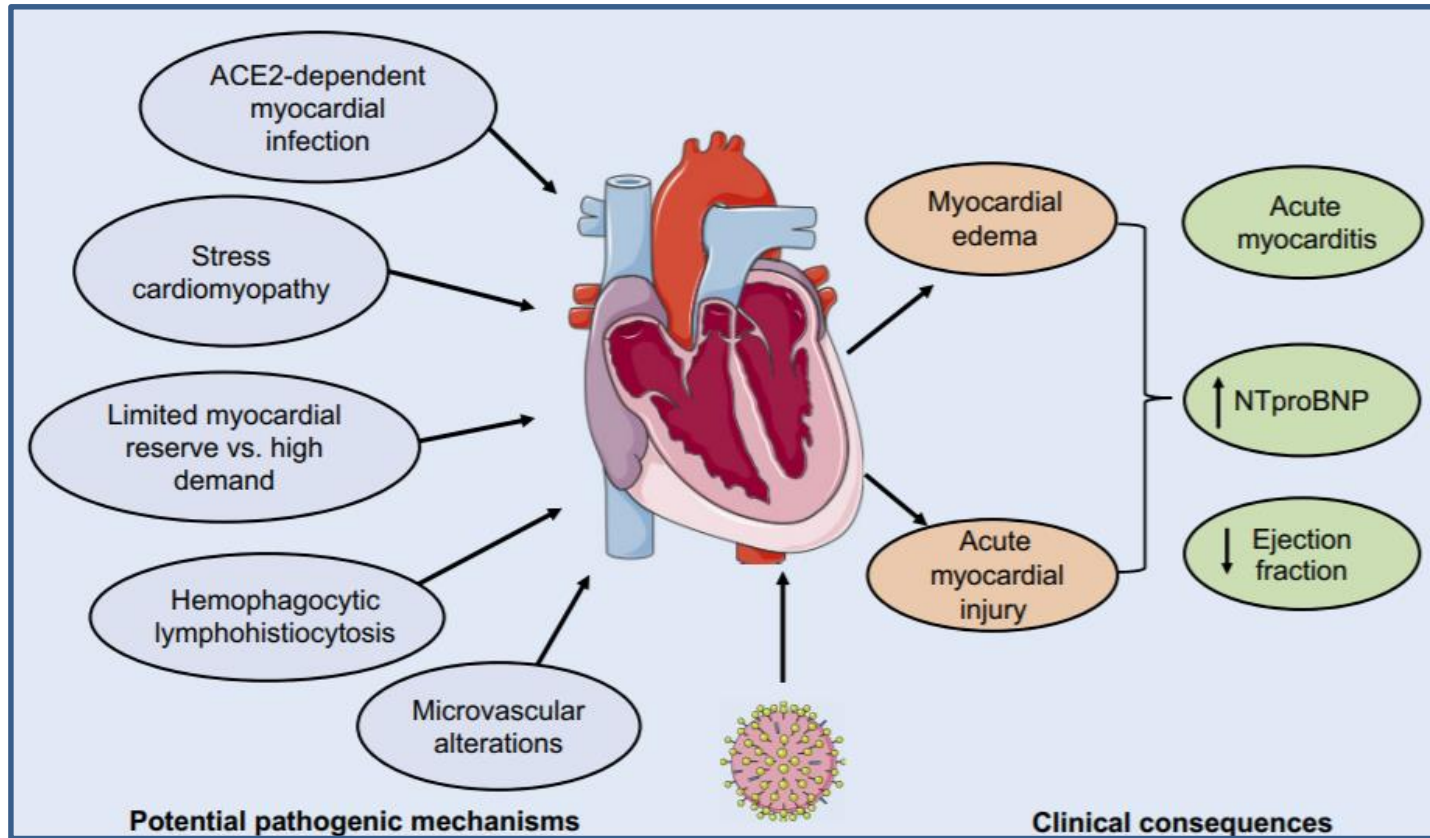
- Parenchymal bands
- Reticulation
- Traction Bronchiectasis
- Irregular interphases

## Risk Factors for Fibrosis

- Age
- Hypertension
- Dispnoea
- Lymphopenia
- PCR and IL6 elevated
- Number of Hospitalization days
- ICU
- TX Steroids and antiretrovirals



## COVID-19 AND PULMONARY VASCULAR DISEASES

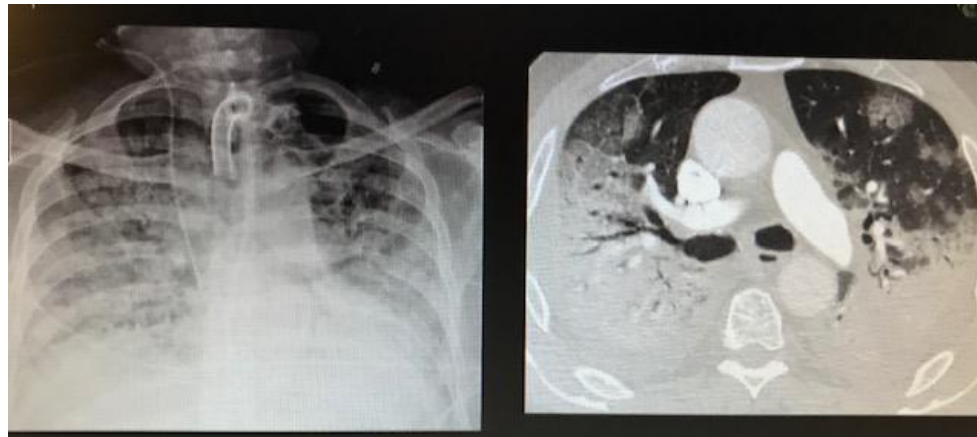


**Myocarditis**  
**Pericarditis**  
**Arrhythmias**





- Long term effects still unknown
- Follow up studies needed
- Multi-organ involvement
- Still questions to answer:
  - Pathophysiology of the infection
  - Fatal complications: PTE and Difuse Endotelial Disorders
  - Role of comorbidities
  - Characteristics of host and viral load





The AME should take into account psychological and mental involvement as a consequence of family or acquaintance mourning, long stay in ICU, and financial consequences due to loss of employment, layout etc. Labour consequences in the aeronautical environment is critical. Such scenario should be explored in the mental health interview.



**ECA** Piloting Safety  
European Cockpit Association



**Dr. Simmons**

## European Aviation Mental Well-being Initiative (EAM-WELL)

JOINT STATEMENT BY LEADING EUROPEAN AVIATION ORGANISATIONS  
ON MENTAL WELL-BEING, IMPACTED BY COVID-19



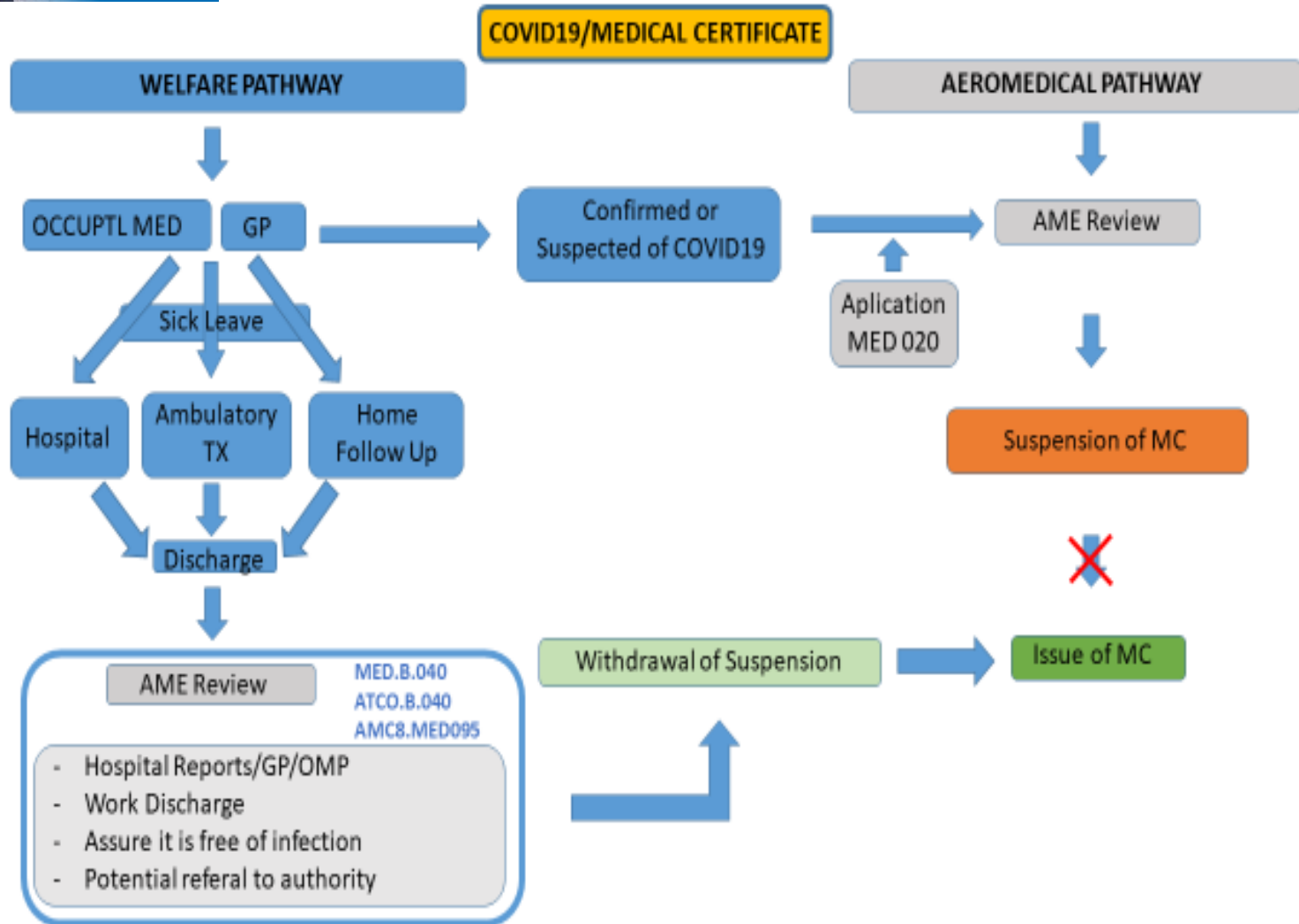


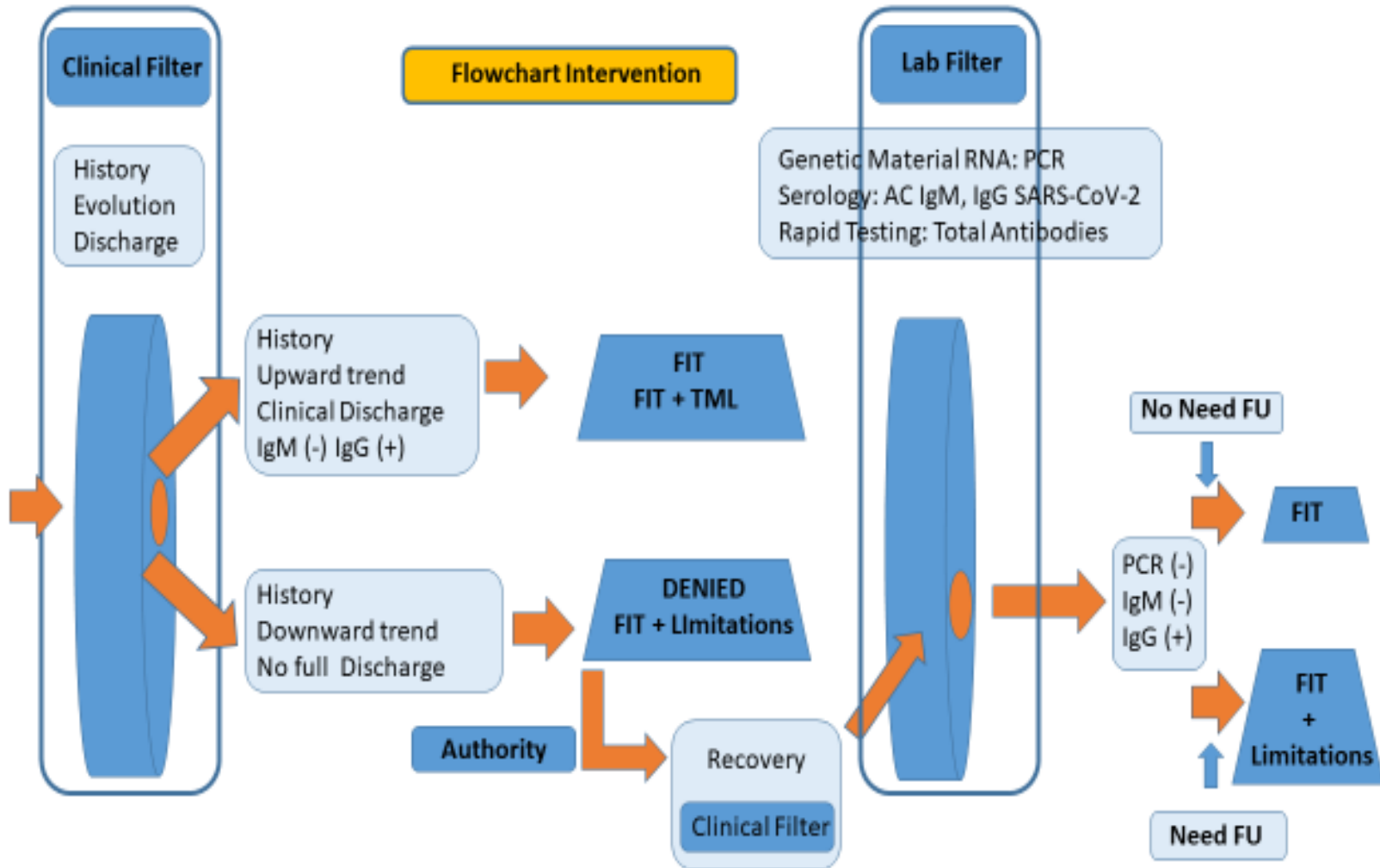
## DIAGNÓSTICO DE INFECCIÓN POR SARS-CoV-2 (LAB DIAGNOSIS of SARS-CoV-2)

PCR	IgM	IgG	Diagnóstico (Diagnosis)
-	-	-	Negativo (Negative)
+	-	-	Fase inicial de infección (Infection initial phase)
+	+	-	Fase temprana de infección (Infection second phase)
+	+	+	Fase activa de infección (Infection active phase)
+	-	+	Fase avanzada de infección (Infection advance phase)
-	+	-	Estadio temprano. Falso negativo PCR? (Early stage. False negative PCR?)
-	+	+	Enfermedad en evolución (Disease in progress)
-	-	+	Fase de resolución de infección (Infection resolved)



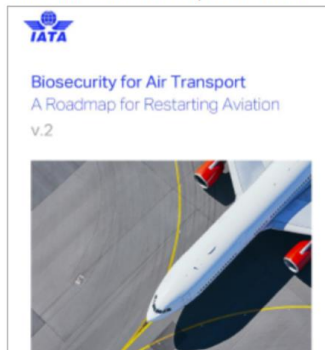
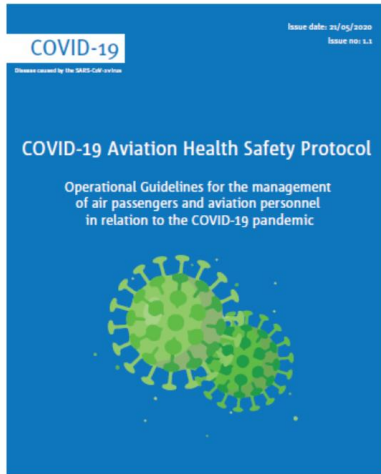
# COVID19: General Approach



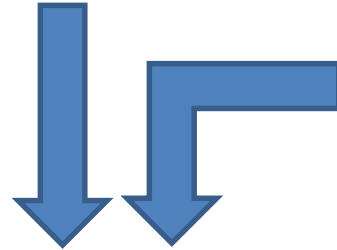


# AME: Sources of information

F-DEA-PDO-09 1.0 CLASIFICACION DE SEGURIDAD



## Clinical Bibliography



## AME



## National Law



ICAO

Doc 10144

ICAO Handbook for CAAs on the Management of Aviation Safety Risks related to COVID-19



World Health Organization

Coronavirus disease (COVID-19)

Situation Report - 151

Data as received by WHO from national authorities by 10:00 CEST, 19 June 2020

## OTHER SOURCES



GOBIERNO DE ESPAÑA

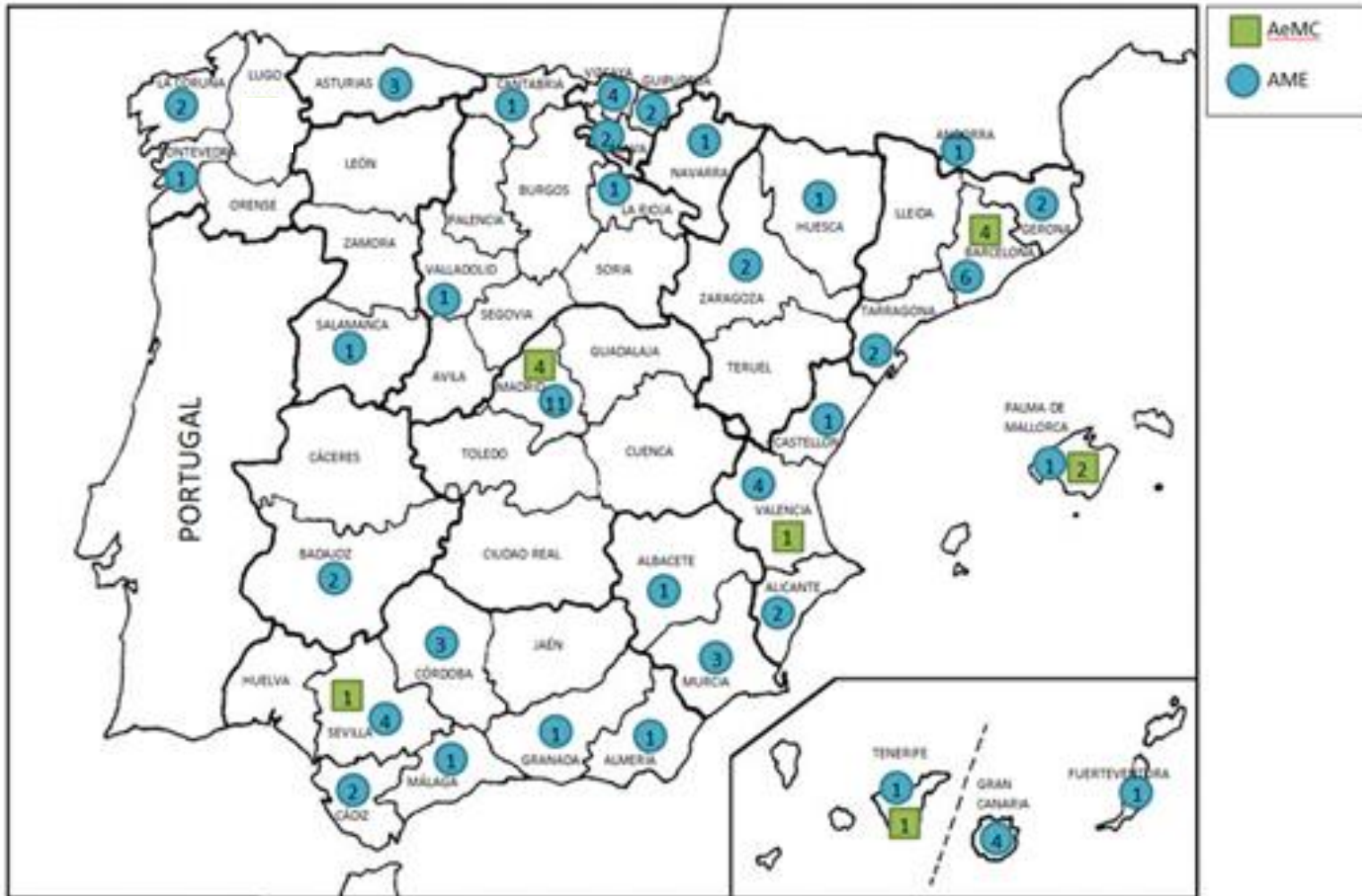
MINISTERIO DE TRANSPORTES, MOVILIDAD Y AGENDA URBANA







## Physicals between 1 March- 15 July 2020





## Review: 1 March- 15 July 2020

- 104 AMEs
- 13 AeMCs

102 VML.128 OML. SIC. Colectomía por adenocarcinoma de colon en 2014 y Diabetes mellitus tipo II. Actualmer  
128-ARTROSCOPIA DE RODILLA IZDA (APORTO INFORMES) EL 19-02-20. BUENA RECUPERACIÓN; 130- TEST SER  
Covid-19

101 Hipertensión ocular107 HTA130 Revisiones médicas y Baja por COVIDPadres con HTA e Hipercolesterolemia  
Gafas de cercaCovid positivo marzo 2020

Entre el 24 de marzo y el 27 de abril estuve de baja por COVID-19.

NO HA PRESENTADO CLINICA DE COVID19 Y LA PRUEBA DE ANTIGENO NEGATIVAHERMANA ASMA

Operación cataratas ojo izqd.Diabetes tipo 2 en control médicogafas de lecturaDiagnostico COVID marzo. Asintó

Visita médico: Urólogo chequeo rutinario, test COVID PCR y serología negativos en mayo

105 NEUMONIA BILATERAL (COVID-19)107 HPA CON TRATAMIENTO BALZAK 40-10, 1/DIA111 PERDIDA AUDITIVA

102. TIENE VNL POR PRESBICIA104. ALERGIA AL POLEN; NECESITA OCASIONALMENTE BILASTINA. BIEN TOLERA

102. GAFAS POR MIOPÍA, LLEVA VDLNOTA: ANAMNESIS NEGATIVA PARA COVID19

EN LA ANAMNESIS NO PRESENTA DATOS DE HABER PADECIDO COVID, NI RESEÑA CONTACTOS.

EN MARZO DE 2020 EPISODIO DE PROBABLE CORONAVIRUS DE SU HIJA DE 7 AÑOS Y LUEGO ESTUVO SU MUJER





## INCIDENCE OF COVID19

1 May-15 July 2020	Num Physicals	Num COVID19	%
Class 1	2280	34	<b>1,21</b>
Class 2	912	8	<b>0,87</b>
LAPL	870	5	<b>0,57</b>
CC	707	3	<b>0,42</b>
Class 3	472	9	<b>1,90</b>
<b>TOTAL</b>	<b>5848</b>	<b>59</b>	<b>1,00</b>
1 May-15 July 2019	Num Physicals	% Decrease 2019 vs 2020	
<b>TOTAL</b>	9196	<b>36,5</b>	



54 males out of 59  
5 females out of 59:

- 4 Class 3
- 1 Class CC

Mean Age	Class 1	Class 2	LAPL	Class CC	Class 3
	47	57	44,5	51	46

Mean Age	Severe	Moderate	Mild
	60,3	51,5	42



	Severe (ARDS)	Moderate/Pneumonia	Mild
Class 1	3	2	29
Class 2	1	0	7
LAPL	0	2	3
CC	1	1	1
Class 3	0	3	6
Total	5	8	46
%	<b>8,47</b>	<b>13,55</b>	<b>79,96</b>

### Class 1 Severe Cases:

- Rotary wing. ARDS. Issue TML 3 m
- Commercial. Bilateral Neumonia. Good recovery. Issue
- Commercial. Bilateral Neumonia. Severe sequelae. Attention & focus disorder. Denied





**Total of 59** {

- 40:** Clinical + Lab
- 19:** Clinical (mild cases)

**Mental Health issues: 3 cases**

- Class 1, family problem related to COVID
- Class 1, Medevac pilot, close involvement COVID
- Class 1, Comercial, ARDS, Attention disorder, loss memory



- AME guidelines has been demonstrated as a useful tool.
- AME approach under scientific up to date + EASA, ICAO, IATA .....
- 2nd Wave in place: AMEs alertness.
- AME preventive measures: Safety distance, protection, hygiene, etiquette.
- AME: Search for COVID19 HX, followup and potential side effects.
- Low incidence of COVID19 in aircrews.
- COVID19 severity  age related.
- Higher rates in Class 1 and 3.
- Most cases  mild and moderate outcomes.





**Thanks for your Attention**

**[senasa.frt@externomf.es](mailto:senasa.frt@externomf.es)**

**[www.seguridadaerea.gob.es](http://www.seguridadaerea.gob.es)**

