

# THE LANCET

## Respiratory Medicine

### Supplementary appendix 2

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**Clinical Characteristics and Outcomes of Patients with COVID-19 on Mechanical  
Ventilation in Argentina: a Prospective, Multicenter Cohort Study**

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**Supplemental Appendix**

## SATI-COVID-19 Study Group

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**Collaborative Group Sociedad Argentina de Terapia Intensiva-COVID-19 (SATICOVID-19): centers, local investigators, and number of patients included in the protocol**

Hospital	City	Site researchers	Number of patients included
1. Hospital Provincial Dr. Castro Rendón	Neuquén, Provincia de Neuquén	Macarena Andrian Julián Ivacachi	169
2. Sanatorio Güemes	Ciudad Autónoma de Buenos Aires	Ignacio Romero Carla Garay	131
3. Hospital Dr. A. Posadas	El Palomar, Provincia de Buenos Aires	Damián Piezny Judith Sagardía	116
4. Hospital Santojanni	Ciudad Autónoma de Buenos Aires	Marco Bezzi Silvia Borello UTI-COVID-19: Verónica Mandich Daniel Chiacchiara	88
5. Hospital Dr. J. A. Fernandez	Ciudad Autónoma de Buenos Aires	Carla Groer Constanza García Almirón Ana Kovac	85
6. Sanatorio Anchorena San Martín	San Martín, Provincia de Buenos Aires	Sebastián Torres Cristian Cesio	63
7. Hospital Francisco López Lima	General Roca, Provincia de Río Negro	Cristina Orlandi Rosana Hernández	62
8. Sanatorio Otamendi	Ciudad Autónoma de Buenos Aires	Paolo Nahuel Rubatto Birri Matías Mugno	61
9. Sanatorio de Los Arcos	Ciudad Autónoma de Buenos Aires	Florencia Valenti Raúl Alejandro Gómez	60
10. Hospital Dr. F. J. Muñiz	Ciudad Autónoma de Buenos Aires	Eleonora Cunto Viviana Chediack	54
11. Hospital Interzonal de Agudos San Martín	La Plata, Provincia de Buenos Aires	María Gabriela Sáenz Cecilia Marcheha	52
12. Complejo Médico de la Policía Federal Argentina Churrucá Visca	Ciudad Autónoma de Buenos Aires	Norberto Tiribelli María Guaymas	51
13. Sanatorio Anchorena	Ciudad Autónoma de Buenos Aires	Vanina Aphalo Daniela Vazquez	50
14. Hospital del Cruce N.º Kirchner	Florencio Varela, Provincia de Buenos Aires	Yasmin Saad Diego Sanchez	44
15. Hospital Italiano	La Plata, Provincia de Buenos Aires	Federico Iglesias Pablo Casteluccio	43
16. Clínica Santa Isabel	Ciudad Autónoma de Buenos Aires	Bernardo Lattanzio Sebastián Eiguren	40
17. Sanatorio Mitre	Ciudad Autónoma de Buenos Aires	Diego Noval Sebastián Fredes	38
18. Hospital Simplemente Evita	González Catán, Provincia de Buenos Aires	Gabriela Izzo Horacio Cabrera	36
19. Hospital Británico	Ciudad Autónoma de Buenos Aires	Mario Pozo Santiago Sac	31
20. Hospital M. y L. de La Vega	Moreno, Provincia de Buenos Aires	Nicolás Tornatore Julia Sakugawa	31
21. Hospital Dr. R. Carrillo	Ciudadela, Provincia de Buenos Aires	Celeste Villafañe Antonio Di Sibio	29
22. Sanatorio CEMIC	Ciudad Autónoma de Buenos Aires	Patricio Maskin Pablo Rodríguez	29
23. Sanatorio de La Trinidad Palermo	Ciudad Autónoma de Buenos Aires	Nicolás Nihany Mariela Mogadouro	28
24. Clínica Bazterrica	Ciudad Autónoma de Buenos Aires	Fernando Pálizas (h) Emiliano Cornú	27
25. Hospital Privado de la Comunidad	Mar del Plata, Provincia de Buenos Aires	Mariano Esperatti Juan Manuel Pintos	27
26. Sanatorio Mater Dei	Ciudad Autónoma de Buenos Aires	Gustavo Badariotti Gonzalo Echevarría	26
27. Hospital San Felipe	San Nicolás, Provincia de Buenos Aires	Ana María Mazzola Cecilia Giuggia	25
28. Hospital San Juan de Dios	La Plata, Provincia de Buenos Aires	Nahuel Dargains Alejandra Turano	24
29. Hospital Dr. D. Velez Sarsfield	Ciudad Autónoma de Buenos Aires	Florencia Pugliese Marcos Zec Baskarad	24
30. Sanatorio Itoiz	Avellaneda, Provincia de Buenos Aires	Mariana Chamadoira Juan Carlos Medina	23
31. Clínica Olivos	Olivos, Provincia de Buenos Aires	Marina Búsico Fernando Villarejo	22
32. Hospital Eva Perón	Merlo, Provincia de Buenos Aires	Hugo Collazos Tania Huanca	20

33. Hospital Centenario	Rosario, Provincia de Santa Fe	Juan Carlos Pendino Lionel Talamonti	19
34. Hospital Héroes de Malvinas	Merlo, Provincia de Buenos Aires	Fernando Skrzypiec Claudia Tascón	19
35. Sanatorio Dupuytren	Ciudad Autónoma de Buenos Aires	Gabriela Genovese Hugo Alul	19
36. Hospital Universitario Austral	Pilar, Provincia de Buenos Aires	Agustina Zavattieri Ana Julieta Herrera	17
37. Hospital Diego Paroissien	Isidro Casanova, Provincia de Buenos Aires	Norma Rosales María Gabriela Quintana	16
38. Sanatorio Las Lomas	San Isidro, Provincia de Buenos Aires	Alejandro Riso Vazquez Martín Lugaro	16
39. Hospital Dr. J·M· Cullen	Santa Fe, Provincia de Santa Fe	Eduardo Díaz Rousseaux Marcelo Falcone	14
40. Hospital El Carmen	Godoy Cruz, Provincia de Mendoza	Fernando Kurban Matías Cini	14
41. Hospital Central	Mendoza, Provincia de Mendoza	Graciela Zakalik Carlos Pellegrini	13
42. Clínica Pueyrredon	Mar del Plata, Provincia de Buenos Aires	Gabriela Fernández	12
43. Hospital Zonal Dr. R Carrillo	Bariloche, Provincia de Río Negro	Juan Pablo Sottile Sol Barrios	11
44. Hospital Baldomero Sommer	General Rodríguez, Provincia de Buenos Aires	Orlando Hamada Verónica Mendiluce	10
45. Hospital Municipal	Chivilcoy, Provincia de Buenos Aires	Dario Villalba Florencia Sacco	10
46. A R Martínez Guerrero			
47. Hospital R-Santamarina	Tandil, Provincia de Buenos Aires	Vito Mezzina Carlos Servin	10
48. Sanatorio San Lucas	San Isidro, Provincia de Buenos Aires	Mónica Quinteros Hernan Nuñez	10
49. Clínica La Pequeña Familia	Junín, Provincia de Buenos Aires	María Luz Campassi David Banegas	9
50. Hospital Dr. I Pirovano	Ciudad Autónoma de Buenos Aires	Carina Balasini	9
51. Hospital San José	Pergamino, Provincia de Buenos Aires	Victoria Leiva Franco Maicol	9
52. Sanatorio de La Trinidad	San Isidro, Provincia de Buenos Aires	Gustavo Domeniconi Verónica Vilaseca	9
53. Hospital Naval Dr. P·Mallo	Ciudad Autónoma de Buenos Aires	Alejandra Barrientos Florencia Larocca	8
54. Hospital de Trauma Dr. F·Abete	Malvinas Argentinas, Provincia de Buenos Aires	Liliana Kumar Rosa Luna	7
55. Hospital Centro Gallego	Ciudad Autónoma de Buenos Aires	Martín Deheza Lonardi Agustina Oholeguy	6
56. Clínica Santa Bárbara	Ciudad Autónoma de Buenos Aires	Joaquín Carnero Echeagaray	6
57. Hospital Bonorino Udaondo	Ciudad Autónoma de Buenos Aires	Carla Marazzi Plácido Helca Regis	5
58. Hospital María A·Ferrer	Ciudad Autónoma de Buenos Aires	Federico Rópolo	5
59. Hospital Zonal Dr. A·Margara	Trelew, Provincia de Chubut	Adrián Bobadilla Vivian Thomas	5
60. Hospital A·Balestrini	Ciudad Evita, Provincia de Buenos Aires	Nydia Funes Nelson Cintia Villavicencio	4
61. Hospital Mi Pueblo	Florencio Varela, Provincia de Buenos Aires	Pedro Machare Norma Aramayo	4
62. Sanatorio Parque	Rosario, Provincia de Santa Fe	Cecilia González	2
63. Hospital Municipal Dr. P Solanet	Ayacucho, Provincia de Buenos Aires	Mariano Ferriccioni	1
64. Hospital SAMIC	El Calafate, Provincia de Santa Cruz	Judith Bergesio	1

**Ethical permissions**

Of 63 participant ICUs, 27 had their own Institutional Ethics Committees, which gave approval to the study. Three ICUs stipulated their approval on the decision of the Central Committee of Research of the Province of Buenos Aires; and 1 ICU on the decision of the Ethics Committee of the Hospital Interzonal de Agudos San Martin de La Plata.

The 32 remaining ICUs stipulated their approval on the decision of the Committee of Ethics in Research of the Argentine Society of Intensive Care Medicine. Only 2 institutional Ethics committees defined the requirement of informed consent.



**Table A1: Frequency of signs and symptoms.**

	<b>Number (%)</b>
Dyspnea	1443/1,909 (76)
Fever (>38°3)	1424/1,909 (75)
Cough	1188/1,909 (62)
Asthenia	441/1,909 (23)
Myalgia	428/1,909 (22)
Sore throat	343/1,909 (18)
Headache	315/1,909 (17)
Diarrhoea	177/1,909 (9)
Anosmia	141/1,909 (7)
Neurological manifestations	133/1,909 (7)
Chills	126/1,909 (7)
Ageusia	108/1,909 (6)
Nausea	83/1,909 (4)
Vomiting	70/1,909 (4)
Acute chest pain	20/1,909 (1)
Abdominal pain	19/1,909 (1)
Malaise	16/1,909 (1)
Skin rash	12/1,909 (1)
Lymphatic node enlargement	8/1,909 (0)
Arthralgia	5/1,909 (0)
Other symptoms	16/1,909 (1)

Data are expressed as n/N (%)

**Table A2.:Respiratory variables and mechanical ventilation management over time in the entire group of patients, and comparisons between the subgroups of survivors and nonsurvivors.**

	Day1 (n=1990)				Day3 (n=1842)				Day7 (n=1699)				p value interaction of the 3 groups with time, and with time and mortality*
	All	Survivors	Non survivors	p	All	Survivors	Non survivors	p	All	Survivors	Non survivors	p	
Respiratory rate (breaths/minute)	24 [20-26]	24 [20-26]	24 [20-27]	0.019	24 [22-28]	24 [20-26]	25 [22-28]	<0.0001	24 [21-26]	24 [20-26]	25 [22-28]	<0.0001	-Time 0.666 -Time and mortality <0.0001
SaO <sub>2</sub> (Pulse oximetry) (%)	95 [93-97]	96 [94-97]	95 [92-97]	0.0003	96 [94-97]	96 [94-98]	95 [93-97]	<0.0001	96 [94-97]	96 [94-98]	95 [93-97]	<0.0001	-Time <0.0001 -Time and mortality <0.0001
FiO <sub>2</sub>	0.60 [0.45-0.80]	0.50 [0.40-0.70]	0.60 [0.50-0.80]	<0.0001	0.45 [0.40-0.55]	0.40 [0.45-0.50]	0.50 [0.40-0.60]	<0.0001	0.45 [0.40-0.55]	0.40 [0.35-0.50]	0.50 [0.40-0.60]	<0.0001	-Time <0.0001 -Time and mortality <0.0001
paO <sub>2</sub> (mmHg)	88 [75-109]	89 [78-110]	87 [74-106]	0.018	85 [73-104]	88 [75-106]	83 [72-101]	<0.0001	84 [73-99]	85 [75-102]	83 [72-98]	0.025	-Time <0.0001 -Time and mortality <0.0001
pCO <sub>2</sub> (mmHg)	46 [40-55]	45 [39-53]	47 [40-56]	0.0027	45 [40-52]	44 [39-50]	46 [40-54]	0.0003	46 [40-54]	45 [40-51]	47 [41-56]	0.015	-Time 0.284 -Time and mortality <0.0001
pH	7.31 [7.24-7.37]	7.33 [7.27-7.38]	7.29 [7.22-7.35]	<0.0001	7.36 [7.30-7.40]	7.38 [7.33-7.41]	7.34 [7.28-7.39]	<0.0001	7.38 [7.32-7.42]	7.40 [7.35-7.43]	7.36 [7.30-7.41]	<0.0001	-Time <0.0001 -Time and mortality <0.0001
Bicarbonate (mEq/L)	23 [20-25]	23 [21-26]	22 [19-25]	<0.0001	25 [22-28]	25 [23-28]	24 [21-28]	<0.0001	25 [22-28]	25 [23-28]	24 [21-28]	<0.0001	-Time <0.0001 -Time and mortality <0.0001
Base excess(mEq/L)	-3 [-6,-1]	-3 [-5,0]	-4 [-7,-1]	<0.0001	-1 [-4,2]	0 [-2,3]	-1 [-5,2]	<0.0001	2 [-2,4]	2 [0,5]	1 [-4,4]	<0.0001	-Time <0.0001 -Time and mortality <0.0001
Lactate (mmol/L)	1.8 [1.4-2.2]	1.7 [1.3-2.1]	1.8 [1.4-2.4]	<0.0001	1.9 [1.4-2.4]	1.7 [1.3-2.3]	1.9 [1.5-2.1]	<0.0003	1.8 [1.4-2.4]	1.8 [1.3-2.4]	1.9 [1.4-2.5]	0.012	-Time 0.04 -Time and mortality <0.0001
PaO <sub>2</sub> /FIO <sub>2</sub>	160 [111-218]	174 [127-228]	147 [104-211]	<0.0001	193 [149-250]	210 [172-273]	177 [135-228]	<0.0001	190 [144-246]	209 [168-266]	173 [129-220]	<0.0001	-Time 0.04 -Time and mortality <0.0001
Tidal volume (ml/kg predicted body weight)	6.1 [6.0-7.0]	6.2 [6.0-7.0]	6.1 [6.0-6.9]	0.741	6.4 [6.0-7.0]	6.3 [6.0-7.0]	6.4 [6.0-7.0]	0.98	6.5 [6.0-7.1]	6.8 [6.0-7.2]	6.4 [6.0-7.0]	0.0006	-Time <0.0001 -Time and mortality 0.018
PEEP (cmH <sub>2</sub> O)	10 [8-12]	10 [9-12]	10 [8-12]	0.903	10 [8-12]	10 [9-12]	10 [8-12]	0.990	10 [8-12]	10 [9-12]	10 [8-12]	0.990	-Time <0.0001 -Time and mortality 0.781

Plateau pressure (cmH <sub>2</sub> O)	23 [20-26]	22 [19-25]	23 [20-26]	<0-0001	22 [20-25]	22 [19-24]	23 [20-26]	<0-0001	22 [20-25]	21 [19-24]	23 [20-26]	<0-0001	-Time 0-013 -Time and mortality <0-0001
Respiratory system Compliance (ml/cmH <sub>2</sub> O)	36 [29-44]	38 [41-46]	34 [26-43]	<0-0001	37 [30-45]	39 [32-48]	35 [28-45]	<0-0001	36 [29-45]	40 [32-49]	34 [27-43]	<0-0001	-Time <0-0001 -Time and mortality <0-0001
Driving pressure(cmH <sub>2</sub> O)	12 [10-14]	11 [9-13]	12 [10-14]	<0-0001	11 [9-14]	11 [9-12]	12 [10-14]	<0-0001	12 [10-14]	11 [9-13]	12 10-15]	<0-0001	-Time 0-017 -Time and mortality <0-0001
Richmond Agitation-Sedation Scale of -5 or -4 points	1,779/1,827 (97%)	753/773 (97%)	1,026/1,054 (97%)	0-927	1,596/1725 (93%)	649/739 (88%)	947/986 (96%)	<0-0001	1,146/1411 (81%)	441/616 (72%)	705/795 (89%)	<0-0001	p <0-001 for comparison between the three groups

\*According to generalized estimating equation method for correlated data.

Data are shown as median [IQR].

P values corresponding to comparisons between survivors and nonsurvivors at each time point were adjusted by Bonferroni correction.

Missing values are shown in Table A6.

**Table A3. Comparison of epidemiological and severity-of-illness variables over the months of the study.**

	April 2020	May 2020	June 2020	July 2020	August 2020	September 2020	October 2020	p value
Age	62 [49-73]	60 [47-70]	61 [51-70]	62 [52-70]	62 [53-70]	60 [52-68]	62 [52-75]	<0.0001
APACHE II score	17 [10-24]	11 [8-18]	16 [11-21]	15 [10-20]	15 [11-19]	14 [10-20]	15 [11-18]	<0.0001
SOFA score	7 [4-9]	5 [4-8]	5 [3-7]	5 [3-5]	5 [3-7]	6 [4-8]	5 [4-7]	<0.0001
Mortality	32/68 (47)	46/88 (52)	122/248 (49)	235/440 (53)	340/549 (62)	243/374 (65)	80/132 (61)	<0.0001

APACHE II, Acute Physiology and Chronic Health Evaluation; SOFA, Sequential Organ Failure Assessment.  
Data are expressed as medians and [25<sup>th</sup>-75<sup>th</sup>] percentiles, or n (%).

**Epidemiological information about COVID-19 in Argentina (Updated March 23, 2021)**

Peak of daily cases: 15,106 September 28<sup>th</sup>, 2020<sup>1</sup>

Population of Argentina 45,496,119 inhabitants<sup>2</sup>

COVID-19 cases: 2,261,577<sup>2</sup>

Total cases/100,000 inhabitants: 4970<sup>2</sup>

Deaths/100,000: 120 5<sup>3</sup>

Total deaths: 54,823<sup>3</sup>

Case-fatality rate: 2.4%<sup>3</sup>

**References:**

1. Ministerio de Salud Argentina. Nuevo coronavirus COVID-19. Información epidemiológica. Accessed March 24, at: <https://www.argentina.gob.ar/salud/coronavirus-COVID-19/sala-situacion>
2. Worldometers coronavirus. Accessed March 24 at: [www.worldometers.info/coronavirus](http://www.worldometers.info/coronavirus)
3. Johns Hopkins Coronavirus Resource Center Accessed March 24, at: <https://coronavirus.jhu.edu>

**Table A4. Primary and concomitant causes of death.**

	<b>Primary cause of death (n= 1,079)</b>	<b>2<sup>nd</sup> Concomitant cause of death (n=486)</b>	<b>3<sup>rd</sup> Concomitant cause of death (n=117)</b>
Refractory hypoxemia*	462/1,079 (43)		
Septic shock	337/1,079 (31)	175/486 (36)	
Multiorgan dysfunction syndrome	190/1,079 (18)	229/486 (47)	80/117 (68)
Acute myocardial infarction	16/1,079 (1)	4/486 (1)	1/117 (1)
Acute heart failure	12/1,079 (1)	8/486 (2)	3/117 (3)
Stroke	8/1,079 (1)	6/486 (1)	
Do-not-resuscitate order	6/1,079 (1)	37/486 (8)	20/117 (17)
Pulmonary thromboembolism	1/1,079 (0)		
Other	48/1,079 (4)	26/486/486 (5)	10/117 (9)

Data are expressed as n/N (%).

\*Of the 462 patients in whom refractory hypoxemia was recognized as the main cause of death, septic shock and multiorgan dysfunction syndrome were also identified as secondary and tertiary causes, respectively, in 174 (38%) and 139 (30%) patients.

Refractory hypoxemia was defined as  $\text{PaO}_2/\text{FiO}_2 \leq 100$  despite high ventilation support, or  $\text{PaO}_2/\text{FiO}_2 < 100$  at least for 1 hour, or an inability in maintaining plateau pressure of less than  $< 30 \text{ cm H}_2\text{O}$  with a  $\text{Vt}$  of  $4 \text{ mL/kg}$  ideal body weight, or presence of persistent barotrauma.

**Table A5. Multivariable Cox regression model for independent predictors of hospital mortality.**

	<b>Hazard Ratio</b>	<b>Std· Err·</b>	<b>p&gt; z </b>	<b>[95% CI]</b>
Age	1·02	0·00	<0·0001	1·01-1·03
Requirement of vasopressors on day1	1·29	0·12	0·008	1·07-1·55
Acute kidney injury	1·66	0·17	<0·0001	1·36-2·03
Endotracheal intubation outside the ICU	1·37	0·15	0·005	1·10-1·71
Charlson score	1·16	0·03	<0·0001	1·11-1·23
Month of admission	1·10	0·04	0·005	1·03-1·18
Driving pressure on day1	1·05	0·01	<0·0001	1·03-1·08
PaO <sub>2</sub> /FIO <sub>2</sub> on day 1	0·998	<0·0001	0·001	0·997-0·999
D-dimer	1·02	0·06	<0·0001	1·01-1·03
pH on day 1	1·01	0·01	<0·0001	1·00-1·01

Harrell's C concordance statistic p=0·68.

The model does not include interaction terms.

Age, Charlson score, month of admission, driving pressure on day 1, PaO<sub>2</sub>/FIO<sub>2</sub> on day 1, d-dimer and pH on day 1 are continuous variables. Requirement of vasopressors on day1, acute kidney injury and endotracheal intubation outside the ICU are considered binary variables.

**Table A6. Missing data for epidemiological variables, comorbidities, blood chemistry data, complications and management**

	Missing Data (n, %)		
	All patients	Survivors	Nonsurvivors
<b>Epidemiological variables</b>			
Age	0 (0)	0 (0)	0 (0)
Male sex	0 (0)	0 (0)	0 (0)
Weight (kg)	82 (4.3)	32 (39)	45 (59)
Body mass index (kg/m <sup>2</sup> )	98 (5.1)	41 (42)	57 (58)
<b>Comorbidities</b>			
Arterial hypertension	0 (0)	0 (0)	0 (0)
Obesity (BMI ≥30)	0 (0)	0 (0)	0 (0)
Diabetes	0 (0)	0 (0)	0 (0)
Respiratory disease	0 (0)	0 (0)	0 (0)
Ischemic heart disease	0 (0)	0 (0)	0 (0)
Chronic kidney disease	0 (0)	0 (0)	0 (0)
Chronic heart failure	0 (0)	0 (0)	0 (0)
Immunosuppression*	0 (0)	0 (0)	0 (0)
Oncohematological diseases	0 (0)	0 (0)	0 (0)
Chemotherapy (previous 6 months)	0 (0)	0 (0)	0 (0)
Chronic liver disease	0 (0)	0 (0)	0 (0)
Solid organ transplantation	0 (0)	0 (0)	0 (0)
Bone marrow transplantation	0 (0)	0 (0)	0 (0)
Pregnancy or post-partum	0 (0)	0 (0)	0 (0)
Presence of cardiovascular disease*	0 (0)	0 (0)	0 (0)
Charlson comorbidity score	280 (14.7)	126 (45)	154 (55)
No comorbidities	0 (0)	0 (0)	0 (0)
<b>Habits and drug utilization</b>			
Utilization of ACE inhibitors or AII receptor blockers	0 (0)	0 (0)	0 (0)
Smoking habit	0 (0)	0 (0)	0 (0)
Utilization of statins	0 (0)	0 (0)	0 (0)
Utilization of beta-blockers	0 (0)	0 (0)	0 (0)
Alcohol-related problem	0 (0)	0 (0)	0 (0)
Duration of symptoms prior to admission	98 (5.1)	44 (45)	54 (55)
Days between hospital and ICU admission	1 (0)	1 (0)	0 (0)
<b>Respiratory Management before ICU admission</b>			
Prior utilization of non-invasive mechanical ventilation	0 (0)	0 (0)	0 (0)
Duration of non-invasive mechanical ventilation, days	5 (7.3)		
Prior utilization of high flow nasal cannula	0 (0)	0 (0)	0 (0)
Duration of high flow nasal cannula use, days	1 (0)	0 (0)	1 (0)
Prior requirement of invasive mechanical ventilation before ICU admission	0 (0)	0 (0)	0 (0)
Length of mechanical ventilation before ICU admission (days)	0 (0)	0 (0)	0 (0)
Endotracheal intubation in the ICU	37 (1.9)	19 (50)	18 (50)
<b>Variables of severity of disease, first 24 hours in the ICU</b>			



APACHE II	37 (1.9)	19 (50)	18 (50)
SOFA <sub>24-h</sub>	42 (2.2)	29 (69)	13 (31)
Pre-intubation respiratory rate	235 (12.3)	103 (44)	132 (56)
Oxygen saturation by pulse oxymetry at admission	251 (13.1)	114 (45)	137 (55)
Extension of lung infiltrates over 3-4 quadrants on CXR or CT scan	258 (13.5)	106 (41)	152 (59)
Requirement of vasopressors	0 (0)	0 (0)	0 (0)
Fluid balance in the first day, mL	86 (4.5)	45 (52)	41 (48)
<b>Blood chemistry variables</b>			
Haemoglobin, g/L	33 (1.7)	21 (63)	12 (34)
White blood cell count, × 10 <sup>9</sup> per L	21 (1.1)	14 (66)	7 (34)
Lymphocyte count, × 10 <sup>9</sup> per L	318 (16.6)	120 (38)	198 (62)
Platelet count, × 10 <sup>9</sup> per L	19 (0.9)	13 (68)	6 (32)
Aspartate aminotransferase, U/L	40 (2.0)	18 (45)	22 (55)
Alanine aminotransferase, U/L	42 (2.2)	19 (45)	23 (55)
Total bilirubin, µmol/L	67 (3.5)	28 (42)	39 (58)
Lactate dehydrogenase, U/L	336 (17.6)	129 (38)	207 (62)
Blood urea nitrogen, mmol/L	20 (1.0)	11 (55)	9 (45)
Creatinine, µmol/L	28 (1.5)	12 (43)	16 (57)
D-dimer, mg/L	597 (31.2)	212 (36)	385 (64)
Ferritin, ng/mL	693 (36.3)	237 (34)	456 (66)
<b>Complications, and evolution variables</b>			
ARDS development	0 (0)	0 (0)	0 (0)
Prone position utilization in ARDS	0 (0)	0 (0)	0 (0)
Number of sessions	74 (6.3)	28 (38)	46 (62)
Duration of sessions (hours)	74 (6.3)	28 (38)	46 (62)
Shock during the evolution	0 (0)	0 (0)	0 (0)
Acute kidney injury	0 (0)	0 (0)	0 (0)
Renal replacement therapy	0 (0)	0 (0)	0 (0)
Ventilator-associated pneumonia	0 (0)	0 (0)	0 (0)
Bacteremia (all microorganisms)	0 (0)	0 (0)	0 (0)
Bacteremia (Gram-negative bacilli)	0 (0)	0 (0)	0 (0)
Maximum fever	527 (27.6)	209 (40)	318 (60)
Maximum fever ≥ 39°	527 (27.6)	209 (40)	318 (60)
Thromboembolic complications	0 (0)	0 (0)	0 (0)
Dexametasone utilization	0 (0)	0 (0)	0 (0)
Convalescent plasma utilization	0 (0)	0 (0)	0 (0)
Tracheostomy	0 (0)	0 (0)	0 (0)
Length of mechanical ventilation (days)	6 (0.3)	4 (67)	2 (33)
Length of ICU stay (days)	6 (0.3)	4 (67)	2 (33)
Length of hospital stay (days)	23 (1.2)	21 (90)	2 (10)

Data are presented as n (%).

**Table A7. Report of missing physiological and ventilation management data on days 1, 3 and 7 from ICU admission.**

	Day 1 n=1,909			Day 3 n=1,842			Day 7 n=1,699		
	All	Survivors	Non-survivors	All	Survivors	Non-survivors	All	Survivors	Non-survivors
Respiratory rate	77 (4)	32 (42)	45 (58)	102 (6)	41 (40)	62 (60)	114 (7)	48 (42)	66 (58)
SaO <sub>2</sub>	102 (5)	43 (42)	59 (58)	125 (7)	54 (43)	74 (57)	142 (9)	60 (42)	82 (58)
FiO <sub>2</sub>	69 (4)	22 (32)	47 (68)	95 (5)	27 (28)	68 (72)	110 (7)	33 (30)	77 (70)
PCO <sub>2</sub>	40 (2)	20 (50)	20 (50)	59 (3)	28 (47)	31 (53)	98 (6)	46 (47)	52 (53)
pH	39 (2)	19 (49)	20 (51)	62 (3)	30 (48)	32 (52)	96 (6)	45 (47)	51 (53)
Base Excess	75 (4)	38 (51)	37 (49)	89 (5)	46 (52)	43 (48)	132 (8)	59 (45)	73 (55)
Lactate	199 (10)	80 (40)	119 (60)	247 (13)	104 (42)	143 (58)	253 (14)	104 (41)	149 (59)
PaO <sub>2</sub> /FiO <sub>2</sub>	72 (4)	24 (33)	48 (67)	106 (6)	55 (52)	51 (48)	140 (9)	71 (51)	69 (49)
Tidal volume	84 (4)	28 (22)	56 (78)	95 (5)	30 (32)	65 (68)	147 (9)	43 (29)	104 (71)
PEEP	55 (3)	18 (33)	37 (67)	70 (4)	24 (34)	46 (66)	118 (8)	39 (33)	79 (67)
Plateau Pressure	105 (6)	39 (37)	66 (63)	142 (8)	51 (36)	91 (64)	272 (17)	95 (35)	177 (65)
Respiratory System compliance	91 (5)	39 (43)	52 (57)	128 (6)	69 (53)	59 (47)	281 (18)	146 (52)	135 (48)
Driving Pressure	91 (5)	39 (43)	52 (57)	131 (7)	69 (53)	62 (47)	275 (17)	140 (51)	135 (49)

Data are presented as n (%).

**Figure A1. Variables of oxygenation, acid-base status and arterial lactate levels in survivors and nonsurvivors, at days 1, 3 and 7.**

A time-group interaction is present in all variables ( $p < 0.001$ ). The differences between survivors and nonsurvivors are at each time point, when present, are shown as \* ( $p < 0.01$ ), corrected for multiple comparisons.

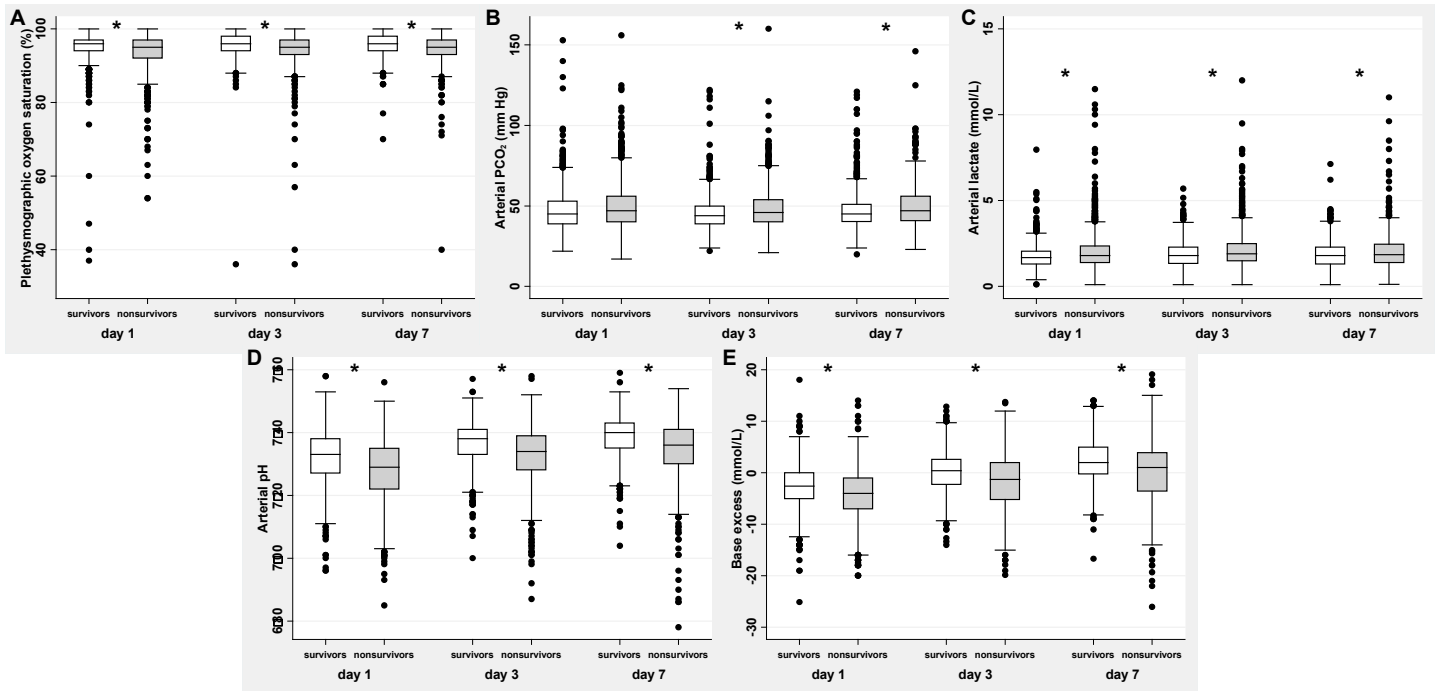
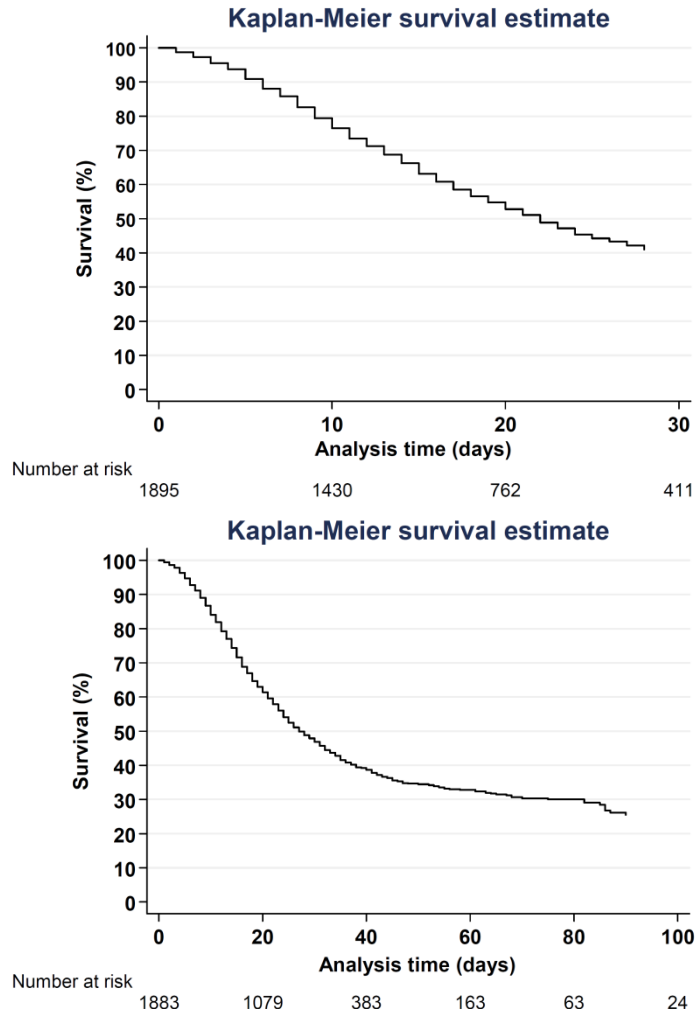


Figure A2. Survival curves for the entire population at 28-day (upper panel) and at 90-day (lower panel).



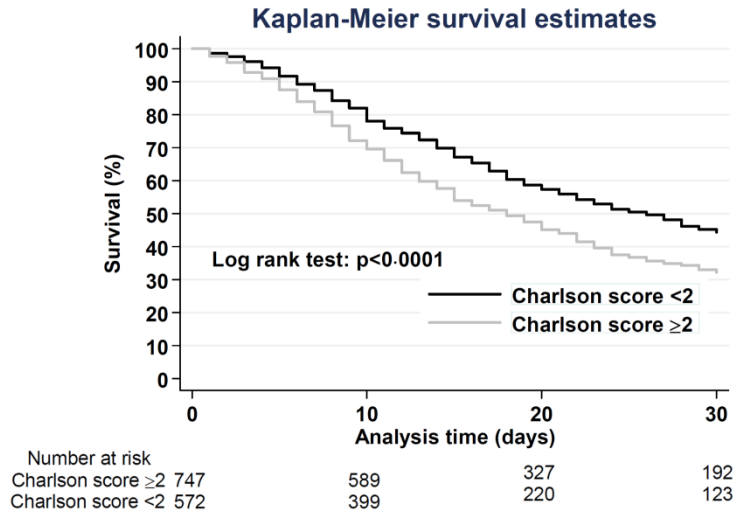
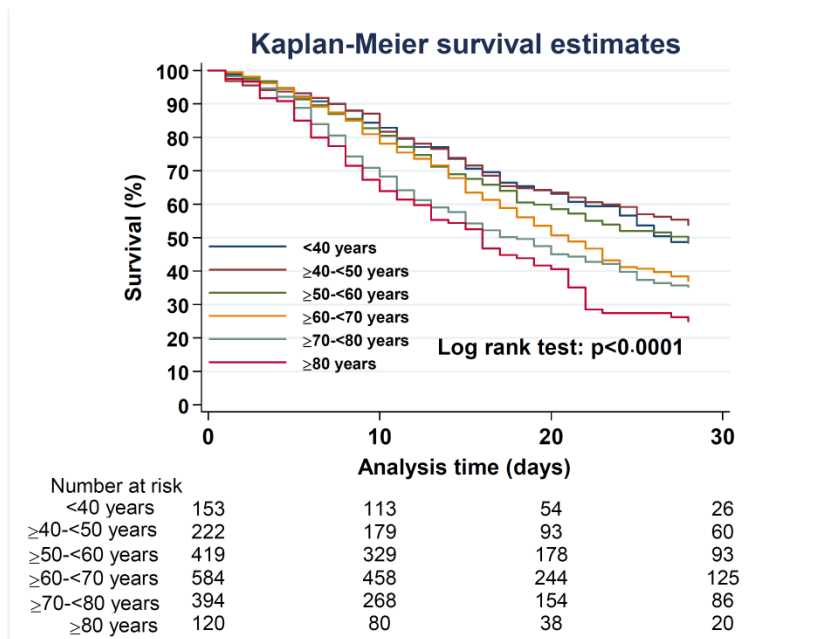
**Figure A3. Survival curve for patients with comorbidities according to Charlson score.**

Figure A4. Survival curve for patients according to categories of age.



## **Appendix: Definitions**

### **Comorbid conditions:**

**Respiratory Disease:** Documentation of any pulmonary disease in the patient's chart as past medical history including, but not limited to asthma, chronic obstructive pulmonary disease (COPD GOLD Definitions), or interstitial lung disease (ILD).

**Chronic heart failure:** Documentation of a previous diagnosis of cardiac failure in the clinical records.

**Chronic Kidney Disease** Defined as abnormalities of kidney function, present for >3 months, documented by a reduction of glomerular filtration rate <60 mL/min/1.73 m<sup>2</sup>.

**Obesity:** body mass index (BMI) ≥30 kg/m<sup>2</sup>.

**Morbid obesity:** BMI>40 kg/m<sup>2</sup>.

**Diabetes:** Patients with a history of diabetes type 1, type 2, or gestational.

**Rheumatological Disease:** Documentation of any autoimmune disease in the patient's chart as past medical history including, but not limited to rheumatoid arthritis or systemic lupus erythematosus (SLE), scleroderma, and sarcoidosis.

**Malignant Neoplasm:** When present within in the last 5<sup>th</sup> year since diagnosis.

**Corticosteroid utilization:** Defined as patient taking any of the following: "betamethasone", "budesonide", "cortisone", "dexamethasone", "methylprednisolone", "prednisone", "triamcinolone", in dose equivalent to 10 mg or more of methylprednisolone.

**Immunocompromised Patient:** A patient taking any of the following: "azathioprine", "cyclosporine", "verolimus", "tacrolimus", "sirolimus", or a drug comprised under the category "corticosteroids".

**Arterial hypertension:** Blood pressure ≥130/80 mmHg (2017 American College of Cardiology and American Heart Association definition).

**Angiotensin-converting-enzyme inhibitors (ACE-I):** A patient taking any of the following: "benazepril", "captopril", "enalapril", "lisinopril", "perindopril", "ramipril".

**Angiotensin II receptor blockers (ARB):** A patient taking any of the following: "candesartan", "irbesartan", "losartan", "olmesartan", "telmisartan", "valsartan".

**Statin:** A patient taking any of the following: atorvastatin,"rosuvastatin","simvastatin", pravastatin.

**Severity-of-disease scores:**

**Acute Physiological and Chronic Health Evaluation disease Classification System II (APACHE II):** Score commonly used in critical care medicine to predict mortality upon admission to the ICU. It quantifies the severity of the acute illness and also allows assessing the severity of preexistent chronic medical status. The worst values achieved by the patient in the first 24 hours of admission to the intensive care unit should be used, from 0 to 71 points.

**Sequential Organ Failure Assessment (SOFA):** Score that numerically quantifies the number and the severity of organ dysfunction in six organ systems (respiratory, coagulation, liver, cardiovascular, renal, and neurologic), from 0 to 4 points. 0-2 points are considered organ dysfunction; 3 and 4 points are considered as organ failure.

**Multiorgan Dysfunction Syndrome (MODS):** Progressive dysfunction or failure of two or more organ systems.

**Richmond Agitation-Sedation Scale (RASS):** Instrument designed to assess the level of alertness and agitated behavior in critically-ill patients.



Score	Description
+4	Combative, violent, danger to staff
+3	Pulls or removes tube(s) or catheters; aggressive
+2	Frequent nonpurposeful movement, fights ventilator
+1	Anxious, apprehensive, but not aggressive
0	Alert and calm
-1	Awakens to voice (eye opening/contact) >10 seconds
-2	Light sedation; briefly awakens to voice (eye opening/contact) <10 seconds
-3	Moderate sedation; movement or eye opening. No eye contact
-4	Deep sedation; no response to voice, but movement or eye opening to physical stimulation
-5	Unarousable; no response to voice or physical stimulation

### **Respiratory and mechanical ventilation variables**

**Tachypnea(on spontaneous ventilation):** Is defined as respiratory rate  $\geq 22$  breaths/minute.

**End-inspiratory pressure (plateau pressure):** Pressure measured at the **end** of the **inspiratory** phase of a ventilator-cycled tidal volume. The ventilator is programmed not to allow expiratory airflow at the **end** of the inspiration for a set time, typically half a second.

**Respiratory system compliance:** Is defined as the change in lung volume per unit change in pressure gradient, in the absence of flow ( $\Delta V/\Delta P$ ). It is calculated as tidal volume/(plateau pressure–PEEP), and expressed in mL/cmH<sub>2</sub>O.

**Driving pressure:** Indicates the decreased functional size of the lung observed in patients with ARDS. It is calculated as plateau pressure minus PEEP, and expressed in cmH<sub>2</sub>O.

**Refractory hypoxemia:** PaO<sub>2</sub>/FiO<sub>2</sub>  $\leq 100$  despite high ventilation support, or PaO<sub>2</sub>/FiO<sub>2</sub> <100 at least for 1 hour, or an inability in maintaining plateau pressure of less than <30 cm H<sub>2</sub>O with a Vt of 4 mL/kg ideal body weight, or presence of persistent barotrauma.

### **Complications:**

**Acute Respiratory Distress Syndrome (ARDS):** Acute respiratory failure, with onset over 1 week or less; characterized by the presence of bilateral opacities consistent with pulmonary edema on CT scan or chest radiograph; hypoxemia defined as  $\text{PaO}_2/\text{FiO}_2$  ratio  $<300$  mmHg with a minimum of 5 cmH<sub>2</sub>O of PEEP (or CPAP), and not fully explained by cardiac failure or fluid overload (Berlin Definition, 2013).

**Shock:** Mean arterial blood pressure  $\leq 65$  mmHg plus evidence of tissue hypoperfusion.

**Septic shock:** Requirement of vasopressors to maintain a mean arterial pressure to maintain a mean arterial blood pressure  $\leq 65$  mmHg, plus lactate levels  $>2$  mmol/L after an adequate fluid resuscitation, in a patients with suspected or confirmed infection.

**Acute Kidney Injury (AKI):** Increase in serum creatinine by  $\geq 0.3$  mg/dL ( $26.5$   $\mu\text{mol/L}$ ) within 48 hours; or increase in serum creatinine to  $\geq 1.5$  times baseline, which is known or presumed to have occurred within the prior 7 days; or urine volume  $\leq 0.5$  mL/kg/h for 6 hours.

**Ventilator-Associated pneumonia:** In a patient undergoing mechanical ventilation for  $\geq 48$  hours, clinical suspicion and presence of new pulmonary infiltrates, or persistent, unresolving infiltrates in chest-ray or in CT; plus two of the following: fever, leukocytosis, purulent tracheal secretions; plus one of the following positive culture of secretions obtained via endotracheal suctioning: ( $\geq 10^6$  cfu/ml), or bronchoalveolar lavage fluid ( $10^4$  cfu/mL), or of pleural fluid or lung tissue.

# **Clinical Characteristics and Outcomes of Patients with COVID-19 on Mechanical Ventilation in Argentina: A Prospective, Multicenter Cohort Study The SATICOVID Study**

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## **ORGANIZED BY**

Sociedad Argentina de Terapia Intensiva (SATI)

## **GENERAL DESCRIPTION**

The main objective of the present study is to determine ICU and in-hospital mortality associated with COVID-19 infection and its independent predictors, in patients admitted to adult ICUs in Argentina with a requirement for mechanical ventilation.

Secondary objectives include: determining epidemiological and clinical data in patients with COVID-19 disease; the associated morbidity, the support and therapeutic measures implemented, and the evolution of these patients upon discharge from the ICU.

Likewise, characteristics of each ICU will be recorded, and a survey will be carried out on the management of the COVID-19 pandemic, which will require information on the additional availability of critical resources for the care of patients admitted to the ICU. Likewise, characteristics of the ICU and hospitals will be registered.

## **INTRODUCTION**

In December 2019, China reported cases of acute respiratory disease caused by a new betacoronavirus (SARS-CoV-2), called COVID-19 by WHO. In January 2020 this entity issues an alert about the emergence of this new disease around the world, and in March declares it a pandemic. In March 2020 WHO reports 266,073 confirmed cases, with Europe being the most expanding focus (>128,500 confirmed cases) (1). The reported overall mortality rate is 4.2%. These mortality data could be different, due to the lack of a reliable denominator (2). Severe cases account for about 14-15% of those reported, and admission to the ICU is highly variable according to different publications, from 5% to more than 25% in (3-5). The mortality reported in these publications ranges from 21 to 28%, with the development of acute respiratory distress syndrome (ARDS) being one of the most severe complications associated with high mortality (3-5). However, the time of onset of symptoms of severe acute respiratory failure has shown significant variability between these studies, with a median onset of 2, 5 and 14 days from the onset of symptoms of the disease (1-4).

As of 21 March 2020, cases in Latin America were increasing, with countries such as Brazil, Chile, Ecuador, Peru and Argentina among the countries with the highest number of confirmed cases, being classified as countries with community circulation of the virus (1). Not having yet data on the behavior of this new disease in our country, the Argentine Society of Intensive Care (Sociedad Argentina de Terapia Intensiva, SATI) launched the SATICOVID-19 study to describe and analyze the characteristics, risk factors and evolution of patients with COVID-19 who are admitted to the UCIs of our country and require mechanical ventilation (MV).

The main objective of the present study is to determine the in-hospital mortality associated with COVID-19 infection and its independent predictors, in patients admitted to adult ICUs in Argentina on MV. Secondary objectives include to identify epidemiological and clinical data and mechanical ventilation management in patients with COVID-19, and to determine support and therapeutic measures implemented by their assistant physicians, and the evolution and complications developed by these patients during their ICU stay.

Likewise, characteristics of each ICU will be recorded, and a survey will be carried out on the management of the COVID-19 pandemic, which will require information on the additional availability of critical resources for the care of patients admitted to the ICU. The opinion about the management of the pandemic by the different governmental strata will be required, in order to detect possible points of improvement in the external management of the pandemic.

## **METHODS**

### **Study Type and Design:**

Multicenter prospective cohort study to be carried out in adult UCIs with COVID-19 and severe acute respiratory failure that leads them to mechanical ventilation. This study will be conducted during the COVID-19 pandemic; but a partial and subsequent analysis of the data collected within 45 days of initiating may be carried out. This could occur by July 1, but this date is subject to change given the dynamic nature of viral transfer behavior.

Interventions: No intervention will be administered.

### **Study Population:**

Patients >18 years who are RT-PCR positive for SARSCov-2, admitted to participating ICUs, and requiring mechanical ventilation.

### **Exclusion Criteria:**

- Patients with severe respiratory infections / pneumonia due to another proven etiology.
- Patients RT-PCR negative for SARS CoV-2.

### **Sampling Method:**

- Non-Probability Sample
- Consecutive ICU admissions
- Minimum Age: 18 Years

- Maximum Age: no age limit established
- Enrollment: 800 (Anticipated)
- Target Follow-Up Duration: 9 Months

### **Outcome Measures**

Primary Outcome Measure:

1. Hospital mortality: Refers to patients dying in the hospital, whatever the cause, after ICU discharge (Time Frame: From date of inclusion to date of death from any cause, assessed up to 90 days)

Secondary Outcome Measures:

1. ICU Mortality: Refers to patients dying during their stay at the ICU, whatever the cause (Time Frame: From inclusion up to 90 days.)
2. Independent predictors of mortality: Variables independently associated with mortality, according to Cox regression. (Time Frame: Through study completion, up to 90 days)
3. Length of invasive mechanical ventilation (in days)
4. Patterns of change in physiological respiratory and mechanical ventilation variables on days 1, 3 and 7 for the entire group, and in survivor and nonsurvivor subgroups

### **Procedures**

Each participating unit will designate a Principal Investigator (PI), and at least one Secondary Investigator. They will then need to complete the following forms:

\*Form A- Hospital /ICU Form: collects data relevant to the Hospital and intensive care unit (or sites intended to treat patients who meet inclusion criteria). This form must be filled out at the end of the study, but will require data that the investigator must collect from the day the first patient enters the study. It must be filled in by the head of service/ward/coordinator of the ICU, or by the principal investigator. Data on the availability of resources during the pandemic period and the opinion on pandemic management by different government bodies will also be recorded.

\*Form B- Case Report Form (CRF): affiliation, epidemiological, clinical, laboratory, evolution and complication data for each of the patients included in the study.

\*Form C- Mechanical Ventilation Form: data belonging to detailed aspects of MV belonging to each of the patients included in the study.

Each participating ICU needs to record the number of ALL patients admitted to the ICU (whatever the pathology) during the study in order to be able to quantify later, from the total number of admissions, how many were caused by SARS-CoV-2 infection. Similarly, the number of ALL patients on MV

(whichever the cause) will be recorded, so as to quantify the number of patients ventilated for COVID-19 in relation to the total number of patients on MV.

This information will be registered on Form A.

### **Variables**

The following patient variables will be recorded in forms B and C.

#### **FORM B.**

DATES (in days, month, year: dd/ mm/yy):

- Date of Hospital ADMISSION
- Date of ICU ADMISSION
- Date of INITIATION of mechanical ventilation
- Date of END of mechanical
- Date of DEATH (if applies)
- Date of ICU DISCHARGE . In case of patient death, this date is similar to date of death.
- Date of HOSPITAL DISCHARGE In case of patient death, this date is similar to date of death.
- Symptom duration before hospital admission (in days

ON ICU ADMISSION, the following variables will be registered:

#### Epidemiological data:

- Age (in years)
- Sex (as female/male)
- Weight (in kg)
- Height (in cm)
- Body mass index (BMI) as  $\text{Weight (in kg)} / (\text{height in meters})^2$
- Ideal body weight for estimation of tidal volume: Calculated after usual equations taking into account sex and height

#### Risk factors for COVID-19 (Comorbidities)

- Respiratory Disease: Documentation of any pulmonary disease in the patient's chart as past medical history including, but not limited to asthma, chronic obstructive pulmonary disease (COPD GOLD Definitions), or interstitial lung disease (ILD).
- Chronic heart failure: Documentation of a previous diagnosis of cardiac failure in the clinical records.

- Chronic Kidney Disease Defined as abnormalities of kidney function, present for >3 months, documented by a reduction of glomerular filtration rate <60 mL/min/1.73 m<sup>2</sup>.
- Obesity: body mass index (BMI) ≥30 kg/m<sup>2</sup>.
- Morbid obesity: BMI>40 kg/m<sup>2</sup>
- Diabetes: Patients with a history of diabetes type 1, type 2, or gestational.
- Rheumatological Disease: Documentation of any autoimmune disease in the patient's chart as past medical history including, but not limited to rheumatoid arthritis or systemic lupus erythematosus (SLE), scleroderma, and sarcoidosis.
- Malignant Neoplasm: When present within in the last 5<sup>th</sup> year since diagnosis.
- Corticosteroid utilization: Defined as patient taking any of the following: "betamethasone", "budesonide", "cortisone", "dexamethasone", "methylprednisolone", "prednisone", "triamcinolone", in dose equivalent to 10 mg or more of methylprednisolone.
- Immunocompromised Patient: A patient taking any of the following: "azathioprine", "cyclosporine", "verolimus", "tacrolimus", "sirolimus", or a drug comprised under the category "corticosteroids".
- Arterial hypertension: Blood pressure ≥130/80 mmHg (2017 American College of Cardiology and American Heart Association definition).
- Angiotensin-converting-enzyme inhibitors (ACE-I): A patient taking any of the following: "benazepril", "captopril", "enalapril", "lisinopril", "perindopril", "ramipril".
- Angiotensin II receptor blockers (ARB): A patient taking any of the following: "candesartan", "irbesartan", "losartan", "olmesartan", "telmisartan", "valsartan".
- Statin: A patient taking any of the following: atorvastatin, "rosuvastatin", "simvastatin", pravastatin. of the following: "benazepril", "captopril", "enalapril", "lisinopril", "perindopril", "ramipril".



-Charlson score of comorbidities: total score, as calculated as the sum of values for each condition from the following table:

	Score
Acute myocardial infarction	1
Congestive heart failure	1
Peripheral vascular disease	1
Cerebrovascular disease	1
Dementia	1
Chronic lung disease	1
Conective tissue diseases	1
Gastrointestinal ulcer	1
Mild liver disease	1
Moderate or severe liver disease	3
Diabetes	1
Diabetes with end-organ injury	2
Hemiplegia	2
Mosertae-to-sever-kidney disease	2
Neoplasia	2
Leukemia	2
Lymphomas	2
Solid metastasis	6
AIDS	6

#### Clinical variables

-The signs and symptoms present on admission and during previous days will be recorded in the present table. More than 1 symptom can be selected.

	YES	NO
Fever > 37° 5 on admission or during previous days		
Dyspnea		
Headache		
Cough		
Sore throat		
Nasal congestion		

Chills		
Myalgias		
Nausea		
Asthenia		
Vomiting		
Diarrhoea		
Skin rash		
Lymphatic node enlargement		
Ageusia		
Anosmia		
Alteration of consciousness (Glasgow <15)		
Acute chest pain		
Abdominal pain		
Other		

-Register the maximum fever value experienced by the patient since the beginning of signs and symptoms.

Severity of the acute illness on admission

The following scores will be registered:

-Acute Physiological and Chronic Health Evaluation disease Classification System II (APACHE II): Score commonly used in critical care medicine to predict mortality upon admission to the ICU. It quantifies the severity of the acute illness and also allows assessing the severity of preexistent chronic medical status. The worst values achieved by the patient in the first 24 hours of admission to the intensive care unit should be used, from 0 to 71 points.

-Sequential Organ Failure Assessment (SOFA): Score that numerically quantifies the number and the severity of organ dysfunction in six organ systems (respiratory, coagulation, liver, cardiovascular, renal, and neurologic), from 0 to 4 points. 0-2 points are considered organ dysfunction; 3 and 4 points are considered as organ failure.

Cardiovascular	Respiratory	Hepatic	Renal	CNS	Hematologic	TOTAL POINTS

-Presence of shock on admission, defined as the requirement of vasopressors to maintain MAP $\geq$ 65 mmHg after adequate fluid resuscitation)

- Measurement of lactate level (in mmol/L) if available.

Laboratory variables on admission

	Value
Haemoglobin, g/L	
White blood cell count, $\times 10^9$ per L	
Lymphocyte count, $\times 10^9$ per L	
Platelet count, $\times 10^9$ per L	
Aspartate aminotransferase, U/L	
Alanine aminotransferase, U/L	
Total bilirubin, $\mu\text{mol/L}$	
Lactate dehydrogenase, U/L	
Blood urea nitrogen, mmol/L	
Creatinine, $\mu\text{mol/L}$	
D-dimer, mg/L	
Ferritin, ng/mL	

## Respiratory and mechanical ventilation monitoring variables

- Tachypnea (on spontaneous ventilation): Is defined as respiratory rate  $\geq 22$  breaths/minute.
- Utilization of non-invasive ventilation (NIV). (NO/YES) and its duration in days
- Type of interface utilized for NIV: (Face mask/Helmet)
- Site of beginning of NIV: (ICU/Emergency Department/Other)
- Date of endotracheal intubation (dd/mm/yy)
- Site where endotracheal intubation was performed: (ICU/Emergency department/Another ward)
- Fluid balance (as total fluid input - total fluid output) between days 2 and 1 from admission, in ml

The following image description, physiological respiratory, acid base and mechanical ventilation variables will be recorded, before the intubation procedure, and on days 1, 3 and 7 of mechanical ventilation. The worst values are to be recorded.

	Pre-intubation values	Day 1 (Worst values)	Day 3 (Worst values)	Day 7 (Worst values)
Extension of lung infiltrates in chest x-ray or in CT-scan, as number of quadrants (from 1 to 4)				
Respiratory rate (Breaths per minute)				
Fraction of inspired O <sub>2</sub> Oxygen (FiO <sub>2</sub> )				
SaO <sub>2</sub> (measured by pulse oxymeter)				
pH				
PaO <sub>2</sub> (mmHg)				
PCO <sub>2</sub> (mmHg)				
CO <sub>3</sub> H (mEq/L)				
Base Excess (mEq/L)				
SaO <sub>2</sub> (measured by Co-oxymeter, if available)				
Pa O <sub>2</sub> / FiO <sub>2</sub>				
Lactate (mmol/L)				
Tidal volume (in ml Kg of ideal body weight)	X			
PEEP (cmH <sub>2</sub> O)				
Plateau pressure (cmH <sub>2</sub> O)				
Richmond Agitation sedation scale (RASS) (from -5 to +4 points)				

Richmond Agitation-Sedation Scale (RASS): Instrument designed to assess the level of alertness and agitated behavior in critically-ill patients.

Score	Description
+4	Combative, violent, danger to staff
+3	Pulls or removes tube(s) or catheters; aggressive
+2	Frequent nonpurposeful movement, fights ventilator
+1	Anxious, apprehensive, but not aggressive
0	Alert and calm
-1	Awakens to voice (eye opening/contact) > 10 seconds
-2	Light sedation; briefly awakens to voice (eye opening/contact) < 10 seconds
-3	Moderate sedation; movement or eye opening. No eye contact
-4	Deep sedation; no response to voice, but movement or eye opening to physical stimulation
-5	Unarousable; no response to voice or physical stimulation

### Treatments

- Lopinavir/Ritonavir (YES/NO)
- Chloroquine or Hydroxychloroquine (YES/NO)
- Azithromycin (YES/NO)
- Oseltamivir (YES/NO)
- Steroids: (YES/NO)
  - o If YES, Register type of drug, daily dose and length of the treatment. Utilization of hydrocortisone at 200-300 mg de for treatment of septic shock is should not be considered in this item.
- Others (specify)
- Convalescent plasma infusion (YES/NO)
- RBD-specific polyclonal fragments of equine antibodies (YES/NO)
- Remdesivir (YES/NO)

### Evolution and complications

- Development of ARDS at any moment of the evolution (YES/NO)

It must be taken into account that since blood gases are not recorded every day in this protocol, ARDS may not have been registered in previous table

Definition: Acute Respiratory Distress Syndrome (ARDS): Acute respiratory failure, with onset over 1 week or less; characterized by the presence of bilateral opacities consistent with pulmonary edema on CT scan or chest radiograph; hypoxemia defined as PaO<sub>2</sub>/FiO<sub>2</sub> ratio <300 mmHg with a minimum of 5 cmH<sub>2</sub>O of PEEP (or CPAP), and not fully explained by cardiac failure or fluid overload (Berlin Definition, 2013).

If the patient experienced ARDS, register the date of diagnosis (dd/mm/yy), the worst PaO<sub>2</sub>/FIO<sub>2</sub> recorded and the PEEP (cmH<sub>2</sub>O) and FIO<sub>2</sub> set in in that moment.

If the patient had ARDS, register the following additional treatments utilized:

-PRONE POSITIONING (YES/NO) : Number of prone sessions and mean duration in hours.

-ECMO (YES/NO)

-NEGATIVE FLUID BALANCE (YES/NO)

- Development of SHOCK at any moment of the evolution (YES/NO)  
Definitions: *Shock*: Mean arterial blood pressure  $\leq 65$  mmHg plus evidence of tissue hypoperfusion  
*Septic shock* Requirement of vasopressors to maintain a mean arterial pressure to maintain a Mean arterial blood pressure  $\leq 65$  mmHg, plus lactate levels  $> 2$  mmol/L after an adequate fluid resuscitation, in a patients with suspected or confirmed infection
- Development of ACUTE KIDNEY INJURY at any moment of the evolution (YES/NO)  
Definition: Acute Kidney Injury (AKI): Increase in serum creatinine by  $\geq 0.3$  mg/dl ( $26.5 \mu\text{mol/L}$ ) within 48 hours; or increase in serum creatinine to  $\geq 1.5$  times baseline, which is known or presumed to have occurred within the prior 7 days; or urine volume  $\leq 0.5$  ml/kg/h for 6 hours.
- Utilization of any type of RENAL REPLACEMENT THERAPY during ICU stay (YES/NO)
- Development of ACQUIRED-HOSPITAL INFECTIONS during ICU stay (YES/NO)
  - Respiratory infections (YES/NO).  
Definition: Positive culture in respiratory samples (semiquantitative tracheal aspirate, bronchoalveolar lavage, protective-brush specimen)  
On admission:
    - S. pneumoniae (YES/NO)
    - H. influenzae (YES/NO)
    - S. aureus (YES/NO)
    - Influenza Virus A o B (YES/NO)
    - Parainfluenza Virus (YES/NO)

### Others (Specify)

During ICU stay: Indicate the microorganism isolated during the first episode of ventilator-associated pneumonia:

Pseudomona aeruginosa (YES/NO)

Acinetobacterbaumanii (YES/NO)

Klebsiella Pneumoniae (YES/NO)

Carbapenemase –producing Klebsiella (KPC) (YES/NO)

S. aureus (YES/NO)

Other Gram negative bacilli (YES/NO)

- Indicate the maximum value of fever during the evolution
- Indicate any other hospital-acquired infection, specifying the localization and isolated microorganism.

### Outcomes

- Extubation: NO/ YES Date (dd,mm,yy)
- Utilization of tracheostomy: NO/ YES Date (dd,mm,yy)
- Death of the patient: NO/ YES Date (dd,mm,yy)
- IF the patient died, indicate the most probable cause of death. More than one might be selected, if applies.
  - Refractory hypoxemia (YES/NO)  
Definition:  $\text{PaO}_2\text{FiO}_2 \leq 100$  despite high ventilation support, **or**  $\text{PaO}_2\text{FiO}_2 < 100$  at least for 1 hour, or an inability in maintaining plateau pressure of less than  $< 30 \text{ cm H}_2\text{O}$  with a  $\text{Vt}$  of 4 mL/kg ideal body weight, or presence of persistent barotrauma.
  - Refractory septic shock (YES/NO)
  - Multiple organ dysfunction syndrome (MODS) (YES/NO)  
Definition: Progressive dysfunction or failure of two or more organ systems.
  - Acute myocardial infarction (YES/NO)
  - Acute heart failure (YES/NO)
  - Stroke (YES/NO)
  - Other (YES/NO)
  - Limitation of life support (Added to one of the previous causes) (YES/NO)

### . Other complications

- Presence of thromboembolic episodes
  - Deep venous thrombosis. (YES/NO) If yes, register the site.
  - Pulmonary thromboembolism (YES/NO)
  - Ischemic stroke (YES/NO)

- Arterial emboli (YES/NO)
- Distal extremity ischemia (YES/NO)
- Other (YES/NO) (Register the site)

If the patient had a diagnosis of oncologic disease and was receiving treatment at the moment of admission, or had been receiving it for the 2 previous months, please select the type of treatment; more than one can be selected.

- Radiotherapy (YES/NO)
- Chemotherapy (YES/NO)
- Hormonotherapy (YES/NO)
- Directed therapy (monoclonal antibodies) (YES/NO)
- Immunotherapy (YES/NO)

#### FORM C.

##### Mechanical ventilation specific data

- Indicate what type Oxigenotherapy was utilized PREVIOUSLY TO ENDOTRACHEAL INTUBATION; More than one option can be selected.
  - Low-flow nasal cannula (< 6 L/m) (YES/NO)
  - Venturi mask  $\leq$  FIO<sub>2</sub> 50 % (YES/NO)
  - Mask with reservoir bag (YES/NO)
  - High-flow nasal cannula (HFNC) (YES/NO)
    - If HFNC was utilized, please register the Initial flow set (in L/min) and the initial FiO<sub>2</sub> utilized. Also register the number of hours elapsed between start of HFNC and endotracheal intubation.
    - Was the cause of HFNC failure identified? NO/YES
    - If it was identified, please specify which was.
- Prone position in non-intubated patients (YES/NO)
  - If it was utilized, please register the duration of the utilization, in days; and the mean hours per day of use
- Invasive mechanical ventilation: Select the predominant ventilation mode utilized (> 75% of the total duration of MV ), between volume-cpntrrolled ventilation (VCV), pressure-controlled ventilation (PCV), Airway– pressure release ventilation (APRV), Pressure support ventilation (PSV), Proportional-assist ventilation (PAV), Other (specify)



- Monitoring mechanical ventilation: indicate the values of the following variables during days 1, 3 and 7 of mechanical ventilation. Register the worst values.

	Day 1	Day 3	Day 7
Plateau pressure (cm H <sub>2</sub> O)			
Thoracopulmonary compliance (ml/ cm H <sub>2</sub> O)			
Driving Pressure (cm H <sub>2</sub> O)			

#### Definitions of the Mechanical ventilation variables

- Plateau pressure (End-inspiratory pressure): pressure measured at the end of the inspiratory phase of a ventilator-cycled tidal volume. The ventilator is programmed not to allow expiratory airflow at the end of the inspiration for a set time, typically half a second.
  - Thoracopulmonary compliance (Respiratory system compliance): is defined as the change in lung volume per unit change in pressure gradient, in the absence of flow ( $\Delta V/\Delta P$ ). It is calculated as tidal volume/Plateau pressure –PEEP, and expressed in ml/cmH<sub>2</sub>O
  - Driving pressure: indicates the decreased functional size of the lung observed in patients with ARDS. It is calculated as plateau pressure minus PEEP, and expressed in cmH<sub>2</sub>O
- Select the predominant strategy utilized for the titration of PEEP.
    - PEEP increments according to the response of oxygenation
    - PEEP/FiO<sub>2</sub> Table (ARDSNet study, NEJM 2000)
    - PEEP/compliance Table (Alveolar Recruitment for ARDS Trial (ART), JAMA 201
    - Other: Specify

The following HOSPITAL variables will be recorded in form A.

**FORM A.**

- Name of the hospital, city and province
- Type of hospital (select ONLY ONE CATEGORY):
  - Public (YES/NO);
  - Private (YES/NO)
  - Social Security Hospitals (YES/NO)
- Number of Hospital beds
- Maximum number of ICU beds during the study.
- Register how many critical care beds for assisting patients with COVID-19 were added during the study period, in relation to the pre-pandemic period.
- If critical care beds were added, register where this occurred
  - In the ICU (YES/NO)
  - In the Intermediate Care Unit (YES/NO)
  - In the Coronary Care Unit (YES/NO)
  - In Internal Medicine or other specialties wards (YES/NO)
  - In non-habitual sites (YES/NO)
  - In the Pediatric ICU, but to assist adults (YES/NO)
- During the study period, that is to say, from the day you started including patients, to the day of the end of the study, register the following data:
  - TOTAL number of ICU admissions (COVID-19 + Non COVID-19 patients)
  - TOTAL number of patients requiring mechanical ventilation (MV) for more than 24 hours ICU admissions (COVID-19 MV + Non COVID-19 MV patients)
  - TOTAL number of patients with COVID-19 admitted to the ICU and requiring MV.
  - TOTAL number of patients with COVID-19 admitted to the ICU but NOT requiring MV.
- Select the type of ICU
  - Medical
  - Surgical
  - Mixed (Medical-surgical)

- Register if there was extra personnel in the ICU during the study period, designed to assist patients or to do other tasks . (NO/YES).  
If yes, specify which type of personnel; more than one can be selected
  - Physicians (NO/YES).
  - Nurses (NO/YES).
  - Respiratory therapists (NO/YES).
  - Radiology or CT scan Technicians (NO/YES).
  - Maintenance and cleaning (NO/YES).
- Register If there were additional physicians available to assist patients in the ICU during the pandemic; register the percentage of NON critical care specialists.
- Register if there were enough ventilators to assist patients in the ICU (YES/NO)
- Register if enough devices to perform safe mechanical ventilation (tubes, HEPA filters, closed aspiration systems) were available during the study period as:  
1.NEVER /2.Most of the time NO/ 3.MOST of the time YES/4. ALWAYS
- Register if enough devices for protection barrier and protective personal equipment were available during the study period as:  
1.NEVER /2.Most of the time NO/ 3.MOST of the time YES/4. ALWAYS
- Qualify the management of the pandemic by the different health authorities
  - National Ministry of Health
    - 1. Very good
    - 2. Good
    - 3.Neutral
    - 4. Bad
    - 5. Very bad
    - 6. Does not know
  - Provincial Ministry of Health
    - 1. Very good
    - 2. Good
    - 3.Neutral
    - 4. Bad
    - 5. Very bad
    - 6. Does not know
  - Local Health authorities (Municipal)

- 1. Very good
- 2. Good
- 3. Neutra
- 4. Bad
- 5. Very bad
- 6. Does not know

## **MANAGEMENT AND ANONYMIZATION OF PATIENT DATA**

The anonymity of the patients included will be ensured, in accordance with Law 25326/00 on the Protection of Personal Data (arts. 2, 8, 10); and the Convention 108 (in Argentina since 6/1/19): on the protection of persons with respect to the automated processing of personal data, and Law 26529/09 on Patient Rights (Arts. 4, 6 and 19 inc.b) establish protections for health information, largely linked to informed consent (IC). Article 9ob provides for the emergency as an exception to the IC. At no time will the patient name appear on the case report form; only his/her initials will be requested, and then all data will be anonymized.

## **STATISTICAL ANALYSIS**

Prior to data analysis, two independent investigators will screen the database for errors against standardized ranges. Local investigators will be contacted in case of queries and for inconsistencies. Validated or corrected data were then entered into the database.

Variables will be reported as absolute numbers and percentages, and medians and [25<sup>th</sup>-75<sup>th</sup>] percentiles. Differences between survivors and nonsurvivors in recorded variables will be analyzed with chi-square or Fisher tests, t or Wilcoxon rank-sum tests, as appropriate. All tests will be two-sided, and a p value <0.05 will be considered statistically significant.

Generalized estimating equations will be used to account for correlations between respiratory variables in the entire group over time, and between subgroups of survivors and nonsurvivors. An unstructured correlation matrix was selected. P values for time-effect for the entire group and for time-subgroup interaction were calculated and adjusted for multiple comparisons with Bonferroni test.

Hospital mortality will be analyzed with time-to-event curves were plotted using the Kaplan–Meier method.

Cox regression analysis will be used to determine independent predictors of hospital mortality. Variables differing between survivors and nonsurvivors with a p value <0.20, according to chi-square or Fisher tests or to t or Wilcoxon rank-sum tests will be entered into the multivariable regression model. the predictive capacity of the model will be evaluated with Harrell's C test.

Data will be analyzed with Stata 14.0 (StataCorp LP, College Station, TX).

Sample size calculation:

Given that this was an observational study and there was no risk to patients, we sought to include as many patients as possible, with no pre-defined sample size. Missing data were not imputed.

## **DIFUSION OF THE STUDY**

As with the SATISEPSIS study in 2016, a wide call for participation in the SATICOVID study will be made through the SATIwebsite ([www.sati.org.ar](http://www.sati.org.ar)); in the Newsletter, and in the social networks of the SATI (Facebook, Instagram and Twitter).

## **REGISTRATION OF PARTICIPATION**

The centers intending to participate must send their intention to do so to the email [saticoronavirus@gmail.com](mailto:saticoronavirus@gmail.com)

They must submit:

- 1) Hospital Name.
- 2) City and Province.
- 3) Name of Principal Investigator, email and cell phone.
- 4) Name of Secondary Investigator, email and cell phone.

At that time, we will send you the aforementioned forms together with a request for fast track approval for the Ethics Committees of each institution, and also with a request for a waiver, given the emergency that the pandemic constitutes, in accordance with the aforementioned Convention 108, art. 9ob. If your Institutional Ethics Committee does not grant the exemption that the last request is not approved.

Centers that do not have an Independent Ethics Committee may surrogate to the Committee of Ethics in Research of the SATI.

The forms will be completed on paper and forwarded by scan/photo as an attachment to the mail box [saticoronavirus@gmail.com](mailto:saticoronavirus@gmail.com)

The SATI will staff a data-entry function to ensure the consistent download of data to the database. from informed consent, an informed consent model will be sent to you for use in the event

## **CONTACTS/LOCATIONS**

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<b>SATI-COVID-19</b>  <b>CASE REPORTING FORM</b>	<b>FORM - B</b>
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## CONFIRMED CASES OF COVID-19 IN PATIENTES ADMITTED TO THE INTENSIVE CARE UNIT ON MECHANICAL VENTILATION

### I. PATIENT INFORMATION

1. Name of the Hospital: \_\_\_\_\_
2. City: \_\_\_\_\_
3. Patient initials: \_\_\_\_\_
4. Age (years): \_\_\_\_\_
5. Sex (F/M): \_\_\_\_\_
6. Weight (kg): \_\_\_\_\_ Ideal body weight (kg): \_\_\_\_\_
7. Height (cm): \_\_\_\_\_
8. Symptom duration before hospital admission (days): \_\_\_\_\_

*Please register very carefully the following dates:*

9. Hospital **ADMISSION** date (dd/mm/yy) : \_\_\_\_\_
10. **ICU ADMISSION** date (dd/mm/yy) : \_\_\_\_\_
11. Date of **INITIATION** of mechanical ventilation (dd/mm/yy) : \_\_\_\_\_
12. Date of **END** of mechanical ventilation (dd/mm/yy) : \_\_\_\_\_
13. Date of **DEATH** (si corresponde) (dd/mm/yy) : \_\_\_\_\_
14. Date of **ICU DISCHARGE** (dd/mm/yy) (if applies) : \_\_\_\_\_
15. Date of **HOSPITAL DISCHARGE** (dd/mm/yy) (if applies) : \_\_\_\_\_

### II. DIAGNOSIS OF COVID-19

**II.1. CONFIRMATION OF SARS-CoV-2:**

YES  NO

- II.1.a Method of confirmation: PCR-RT YES  NO
- II.1.b PCR for coronaviruses: YES  NO

### III. SOURCE OF TRANSMISSION

III.1. Travel to a country with high viral transmission (China-Italy-Spain-France-USA-Brazil-Uruguay-Chile-Other)  YES  NO  
(If this was the case, specify which country): \_\_\_\_\_

III.2. Contact with a traveler to a country with high transmission:  
 YES  NO

III.3. In his/her job (if the patient is a health worker):  YES  NO  
Specify his/her role (Physician, nurse, other) \_\_\_\_\_

III.4. As patient admitted to a health venue (hospital, clinic, 3<sup>rd</sup> level institution) for a non-COVID condition.

YES  NO

III.5. In his/her job (if NOT a health worker)

YES  NO

III.6. From a relative/friend

YES  NO

III.7. Unknown

YES  NO

### IV. COMORBID CONDITIONS

IV.1. Register the following underlying diseases and medical conditions. You can select more than one.

Number	Disease/condition	Register
1	Respiratory: Asthma/COPD	
2	Diabetes	
3	Obesity	
4	Alcohol-related problem	
5	Current smoker	
6	Ischemic heart disease	
7	Chronic heart failure	
8	Arterial hypertension	
9	Chronic liver disease	

Number	Disease/condition	Register
10	Chronic kidney disease	
11	Treatment with immunosuppressive drugs	
12	Bone marrow transplantation	
13	Solid organ transplantation	
14	Oncohematological disease	
15	Habitual use of statins	
16	Habitual use of $\beta$ blockers	
17	Habitual use of ACE Inhibitor-A-2receptor antagonists	
18	Chemotherapy in the last 6 months	


19	Pregnancy	
20	Postpartum	

#### IV.2. Charlson score (global evaluation of comorbid conditions) .

**Total score (sum of the points corresponding to the individual conditions): \_\_\_\_\_points**

	Score
Acute myocardial infarction	1
Congestive heart failure	1
Peripheral vascular disease	1
Cerebrovascular disease	1
Dementia	1
Chronic lung disease	1
Conective tissue diseases	1
Gastrointestinal ulcer	1
Mild liver disease	1
Moderate or severe liver disease	3
Diabetes	1
Diabetes with end-organ injury	2
Hemiplegia	2
Mosertae-to-sever-kidney disease	2
Neoplasia	2
Leukemia	2
Lymphomas	2
Solid metastasis	6
AIDS	6

## V. ADMISSION TO THE ICU: CLINICAL DATA

V.1.a. Signs and symptoms on admission and during previous days (Select more than 1 if applies)

	YES	NO
Fever > 37° 5 on admission or during previous days		
Dyspnea		
Headache		
Cough		
Sore throat		
Nasal congestion		
Chills		
Myalgias		
Nausea		
Asthenia		
Vomiting		
Diarrhoea		
Skin rash		
Lymphatic node enlargement		
Ageusia		
Anosmia		
Alteration of consciousness (Glasgow <15)		
Acute chest pain		
Abdominal pain		
Other		

1.b. Register the Maximum value of fever \_\_\_\_\_

V.2. APACHE II Score: \_\_\_\_\_ Points: \_\_\_\_\_

V.3. SOFA at admission: Please register the scores (0-4); and not the individual variables of each variable

Cardiovascular	Respiratory	Hepatic	Renal	CNS	Hematologic	TOTAL POINTS

**V.4. Presence of shock on admission (requering vasopressors to mantain MAP $\geq$ 65 mmHg after adequate fluid resuscitation)**

NO       YES      Lactate level (if measured): \_\_\_\_\_ mmol/L

**V.5. Laboratory data**

	Value
Haemoglobin, g/L	
White blood cell count, $\times 10^9$ per L	
Lymphocyte count, $\times 10^9$ per L	
Platelet count, $\times 10^9$ per L	
Aspartate aminotransferase, U/L	
Alanine aminotransferase, U/L	
Total bilirrubin, $\mu$ mol/L	
Lactate dehydrogenase, U/L	
Blood urea nitrogen, mmol/L	
Creatinine, $\mu$ mol/L	
D-dimer, mg/L	
Ferritin, ng/mL	

**VI. RESPIRATORY MANAGEMENT**

VI.1.a. Was non-invasive ventilation utilized?  NO  YES

Duration on NIV: \_\_\_\_\_ days

VI.1.b. What was the interface utilized?

Face mask       Helmet

VI.1.c. Where was NIV started?  ICU  Emergency Department  
Other

VI.1.d. Was endotracheal intubation required?

NO  YES date (dd/mm/yy) \_\_\_\_\_

**VI.1.e. Where was endotracheal intubation performed?**

ICU  Emergency department  Ward

**VI.1.f Please record fluid balance (total fluid input-total fluid output) between days 2 and 1 from admission: \_\_\_\_\_ml**

**VI.1.g Register the following values:**

	Pre-intubation values	Day 1 (Worst values)	Day 3 (Worst values)	Day 7 (Worst values)
Extension of lung infiltrates in chest x-ray or in TC-scan, as number of quadrants (from 1 to 4)				
Respiratory rate (Breaths per minute)				
Inspired O <sub>2</sub> Oxygen fraction (FiO <sub>2</sub> )				
SaO <sub>2</sub> (measured by pulse oxymeter)				
pH				
PaO <sub>2</sub> (mmHg)				
PCO <sub>2</sub> (mmHg)				
CO <sub>3</sub> H (mEq/L)				
Base Excess (mEq/L)				
SaO <sub>2</sub> (measured by Co-oxymeter, if available)				

Pa O <sub>2</sub> / FiO <sub>2</sub>				
Lactate (mmol/L)				
Tidal volume (in ml Kg of ideal body weight)				
PEEP (cmH <sub>2</sub> O)				
Plateau pressure (cmH <sub>2</sub> O)				
Richmond Agitation sedation scale (RASS) (from -5 to +4 points)				

## VII.TREATMENTS

Register the treatment(s) utilized for treatment of COVID-19 (More than 1 can be selected):

- 1. Lopinavir/Ritonavir
- 2. Chloroquine or Hydroxychloroquine
- 3. Azithromycin
- 4. Oseltamivir
- 5. Steroids: Register type of drug: \_\_\_\_\_  
Daily dose: \_\_\_\_\_  
Duration of treatment \_\_\_\_\_  
(Utilization of hydrocortisone at 200-300 mg de for treatment of septic shock is should not be considered in this item)
- 6. Others (specify) \_\_\_\_\_
- 7. Convalescent plasma infusion \_\_\_\_\_
- 8. RBD-specific polyclonal fragments of equine antibodies
- 9. Remdesivir

## VIII.EVOLUTION AND COMPLICATIONS

**VIII.1 Did the experience ARDS at any time during his/her ICU stay?**  
*(Take into account that since blood gases are not recorded every day in this protocol, ARDS may not have been registered in table VI.1.)*

NO

YES

**If the patient experienced ARDS, register:**

Date of diagnosis (dd/mm/yy)\_\_\_\_\_

Worst PaO<sub>2</sub>/FIO<sub>2</sub>\_\_\_\_\_ PEEP in that moment (cmH<sub>2</sub>O)\_\_\_\_\_

FIO<sub>2</sub> (in that moment)\_\_\_\_\_

**If the patient had ARDS, were any of these coadjuvants utilized?**

PRONE Number of prone sessions\_\_\_\_ Mean Duration  
 (hours)\_\_\_\_\_

ECMO

NEGATIVE FLUID BALANCE

**VIII.3. Did the patient experience SHOCK during the evolution, at any moment?**

NO

YES

**VIII.4. Did the patient develop acute renal failure at any moment of the evolution?**

NO

YES

**VIII.5. Did he or she require the utilization of renal replacement therapy?**

NO

YES

**VIII.6. Did the patient develop hospital infections? Positive culture in respiratory samples (semiquantitative tracheal aspirate, bronchoalveolar lavage, protective-brush specimen)**

VIII.6.a. On admission:  S. pneumoniae

H.influenzae



- S. aureus
- Influenza Virus A o B
- Parainfluenza Virus
- Others (Specify) \_\_\_\_\_

**VIII.6.b. During ICU stay: Indicate the microorganism isolated during the first episode of ventilator-associated pneumonia:**

- Pseudomona aeruginosa
- Acinetobacterbaumanii
- Klebsiella Pneumoniae
- Carbapenemase –producing Klebsiella
- S. aureus
- Other Gram negative bacilli (specify) \_\_\_\_\_

**VIII.6.c . Indicate the maximum value of fever during the evolution?**

\_\_\_\_\_

**VIII.6.d. Indicate any other hospital-acquired infection, specifying the localization and isolated microorganism.**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## **IX. OUTCOMES**

**IX.1. Was the patient extubated?**  NO  YES

Date: \_\_\_\_\_

**IX.2. Did the patient undergo tracheostomy?**  NO  YES

Date: \_\_\_\_\_

**IX.3. Did the patient die?**  NO  YES

Date: \_\_\_\_\_

**IX.4 If the patient died, indicate the cause of death. You can select more than one, if applies.**

- |   |  |
|---|--|
| <input type="checkbox"/> 1. Refractory hypoxemia        | <input type="checkbox"/> 6. Stroke   |
| <input type="checkbox"/> 2. Refractory septic shock     | <input type="checkbox"/> 6. Stroke   |
| <input type="checkbox"/> 3. Multiple organ dysfunction  | <input type="checkbox"/> 7. Other  |
| <input type="checkbox"/> 4. Acute myocardial infarction | <input type="checkbox"/> 8. Limitation of life support (Added to one of the previous causes) |
| <input type="checkbox"/> 5. Acute heart failure         |  |

## **X. OTHER INFORMATION**

**X.1. Did the patient experience one or more of the following thromboembolic episodes?**

- 1. Deep venous thrombosis. Site \_\_\_\_\_
- 2. Pulmonary thromboembolism
- 3. Ischemic stroke
- 4. Arterial emboli
- 5. Distal extremity ischemia
- 6. Other Site: \_\_\_\_\_

**X.2. If the patient had a diagnosis of oncologic disease, please select the treatment that he or she was receiving; more than one can be selected.**

- 1. Radiotherapy
- 2. Chemotherapy
- 3. Hormonotherapy
- 4. Directed therapy (monoclonal antibodies)
- 5. Immunotherapy

<p><b>SATI-COVID-19</b></p> <p><b>CASE REPORTING FORM</b></p> <p><b>MECHANICAL VENTILATION:</b></p> <p><b>SPECIFIC DATA</b></p>	<p><b>FORM - C</b></p>
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I. **Oxygenotherapy utilized PREVIOUSLY TO ENDOTRACHEAL INTUBACION**

More than one option can be selected.

1. Low-flow nasal cannula (< 6 L/m)
2. Venturi mask  $\leq$  FIO<sub>2</sub> 50 %
3. Mask with reservoir bag
4. High-flow nasal cannula (HFNC)

If HFNC was utilized, please register:

Initial flow \_\_\_ L/min      Initial FiO<sub>2</sub> \_\_\_\_

Number of hours between start of HFNC and endotracheal intubation \_\_\_\_

Was the cause of HFNC failure identified?  YES  NO

If it was identified, please specify \_\_\_\_\_

5. Prone position in non-intubated patients

If it was utilized, please register: \_\_\_\_\_

Number of days of utilization \_\_\_\_\_

Hours per day of utilization (mean value) \_\_\_\_\_

## II. INVASIVE MECHANICAL VENTILATION

II.1. Select the predominant ventilation mode utilized .

1. VCV      2. PCV      3. APRV      4. PSV      5. PAV+  
6. OTHER \_\_\_ Which? \_\_\_\_\_

## III. MONITORING MECHANICAL VENTILATION: INDICATE THE VALUES OF THE FOLLOWING VARIABLES

	Day 1	Day 3	Day 7
Plateau pressure (cm H <sub>2</sub> O)			
Thoracopulmonary compliance (ml/ cm H <sub>2</sub> O)			
Driving Pressure (cm H <sub>2</sub> O)			

## IV. WHICH WAS THE PREDOMINANT STRATEGY FOR TITULATION OF PEEP?

1. PEEP increments according to the response of oxygenation
2. PEEP/FiO<sub>2</sub> Table (ARDSnet 2000)
3. PEEP/compliance Table (ART study)
4. Other. Specify: \_\_\_\_\_

## V. WEANING OF MECHANICAL VENTILATION

IV.1. Could a phase of partial ventilation support be initiated?

- YES     NO

IV.1.a. Indicate the number of days between endotracheal intubation and initiation of partial ventilatory support:

\_\_\_\_\_ days

**IV.1.b. Predominant mode utilized for partial ventilatory support .**

- 1. PCV
- 2. VCV
- 3. PSV
- 4. PAV+
- 5. NAVA
- 6. OTHER. Which? \_\_\_\_\_

**IV.2. Could a spontaneous breathing test be initiated? (SBT)**

YES  NO

**IV.2.a. Date of the first SBT** (the first time the patient was disconnected from the ventilator with the purpose of starting the weaning process): \_\_\_\_\_

**IV.2.b. Was kind of SBT was used?**

- 1. T -tube
- 2. CPAP (5 cmH<sub>2</sub>O)
- 3. CPAP (0 cmH<sub>2</sub>O)
- 4. PSV (7cmH<sub>2</sub>O – 0 PEEP):
- 5. OTRA: \_\_ ¿Cuál? \_\_\_\_\_

**IV.2.c. Date of successful SBT:** \_\_\_\_\_

**a. Was non-invasive ventilation utilized after extubation?**

YES  NO

**b. Was high-flow nasal cannula utilized after extubation?**

YES  NO

**COVID -19 IMPACT ON THE ICU****FORM - A****Characteristics of the institution**

Fill one form per ICU at the end of the study.

This information will be handled under strict confidentiality

Name of the HOSPITAL: \_\_\_\_\_

Type of the Hospital: (1. Public, 2. Private, 3. Social Security): \_\_\_\_\_

City: \_\_\_\_\_

Province: \_\_\_\_\_

Your name: \_\_\_\_\_

Your email: \_\_\_\_\_

Your cell-phone: \_\_\_\_\_

**General information of the ICU.**

1. MAXIMUM GENERAL BED NUMBER IN THE HOSPITAL, DURING THE STUDY PERIOD

2. MAXIMUM ICU BEDS , DURING THE STUDY PERIOD

3. WERE ICU BEDS ADDED DURING THE STUDY PERIOD?

NO

YES

TOTAL Number of added beds:

Hospital sites where beds were added. More than one answer can be selected, if applies:

1. In the ICU
2. In the Intermediate Care Unit
3. In the Coronary Care Unit
4. In wards that admit patients of other medical specialties: internal medicine, surgery, others.
5. In non-habitual places
6. In Pediatric ICUs, but to treat adult patients

**4. DURING THE STUDY PERIOD, THAT IS TO SAY, FROM THE DAY YOU STARTED INCLUDING PATIENTS TO THE DAY OF THE END OF THE STUDY, REGISTER THE FOLLOWING DATA:**

**4.1 TOTAL NUMBER of PATIENTS ADMITTED TO THE ICU (COVID-19 + NON-COVID-19)**

**4.2. TOTAL NUMBER of PATIENTS ON MECHANICAL VENTILATION (COVID-19 + NON-COVID-19)**

**4.3. TOTAL NUMBER of PATIENTS ON MECHANICAL VENTILATION WITH COVID-19**

**4.4 TOTAL NUMBER of PATIENTS WITH COVID-19 THAT DID NOT REQUIRE MECHANICAL VENTILATION**

**5. Type of ICU according to the specialty**

1. MEDICAL\_\_\_
2. SURGICAL\_\_\_
3. MIXED (MEDICAL- SURGICAL) \_\_\_

**6. SINCE YOU BEGAN WITH THIS PROTOCOL, HOW MANY PATIENTS WITH POSITIVE TESTS WERE REGISTERED AT YOUR HOSPITAL?**

**7. WAS THERE ADDITIONAL HEALTHCARE PERSONNEL IN THE ICU DURING THE STUDY PERIOD?**

NO

YES. SELECT WHAT CORRESPONDS, MORE THAN ONE OPTION IS POSSIBLE

- 1. PHYSICIANS
- 2. NURSES
- 3. RESPIRATORY THERAPISTS
- 4. TECHNICIANS IN RADIOLOGY AND CT
- 5. MAINTENANCE AND CLEANING PERSONNEL

9. IF THERE WERE ADDITIONAL PHYSICIANS IN YOUR ICU, WHICH WAS THE PERCENTAGE OF NON-INTENSIVISTS, OVER THE TOTAL PHYSICIANS ADDED?

10. WERE THERE ENOUGH AVAILABLE VENTILATORS TO ASSIST PATIENTS?

NO

YES

11. WERE THERE ENOUGH DISPOSABLE DEVICES TO PERFORM SAFE MECHANICAL VENTILATION? (TUBES, HEPA FILTERS, CLOSE ASPIRATION SYSTEMS?)

1. NO

2. MOST OF THE TIMES, NO

3. MOST OF THE TIMES, YES

4. YES

12. WAS THERE ENOUGH PERSONAL PROTECTIVE EQUIPMENT AVAILABLE FOR RESPIRATORY AND CONTACT BARRIER PROTECTION (Gowns, gloves, surgical and N95 masks, goggles?)

1. NO

2. MOST OF THE TIMES, NO

3. MOST OF THE TIMES, yes

4. YES

14. PLEASE QUALIFY THE MANAGEMENT OF THE PANDEMIC BY THE HEALTH AUTHORITIES (OPTIONAL)

15.a: National Ministry of Health

1. VERY GOOD



- 2. GOOD
- 3. NEUTRAL
- 4. BAD
- 5. VERY BAD
- 6. DOESN'T KNOW

**15.b: Provincial Ministry of Health**

- 1. VERY GOOD
- 2. GOOD
- 3. NEUTRAL
- 4. BAD
- 5. VERY BAD
- 6. DOESN'T KNOW

**15.: Local, city authorities**

- 1. VERY GOOD
- 1. GOOD
- 3. NEUTRAL
- 4. BAD
- 5. VERY BAD
- 6. DOESN'T KNOW