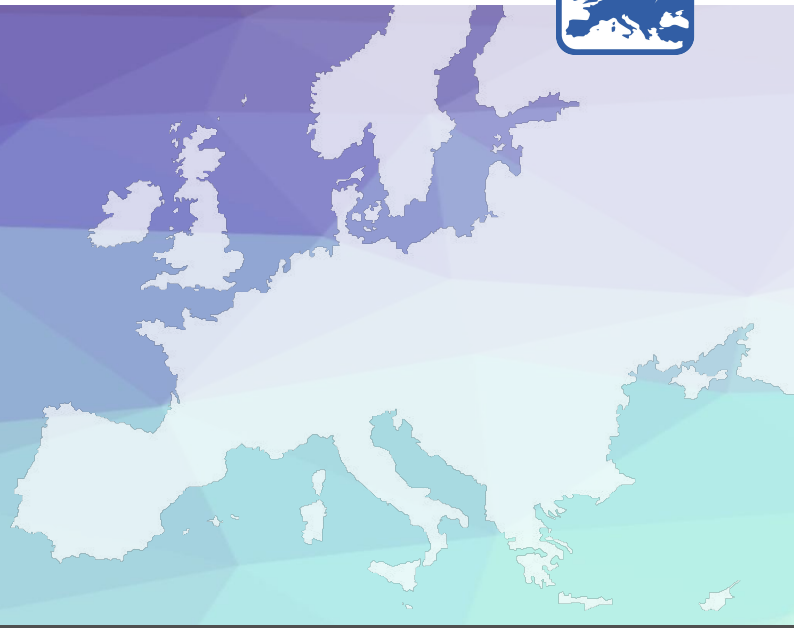
Vall d'Hebron Hospital

Challenges of a tertiary hospital's ethics committee in evaluating research during the COVID-19 pandemic. The CEICOV study.



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None of the authors have any conflicts of interests

Introduction

The COVID-19 pandemic has led to an increase in research activity worldwide. The Vall d'Hebron University Hospital (VH) Research Ethics Committee (VH-REC) modified its procedures to adapt to give out the opinion in a short period of time.

Objectives

We aimed to describe the characteristics of the evaluated studies during the first wave of the pandemic.

Methods

Clinical trials (CT), post-authorization studies (PAS) and research projects (RP) related to COVID-19 evaluated by the VH-REC, from 16th of March to 21st of June of 2020 were included. The analysis was performed with RStudio through usual descriptive method.

Results

157 studies were evaluated: 10 CT, 16 PAS and 131 RP, in **25 bi-weekly** telematic meetings.

The main services involved were Infectious Disease, Intensive Medicine and Pneumology.

The median time for the evaluation of the protocols was **3 days**.

58.6% (92) required further clarifications, of which **8 [IQR (3-14)]** did not respond. The most frequent causes were aspects of the *patient's informed consent sheet, data protection and biological samples*.

The final opinion was favorable in **93% (146)** and unfavorable in 2% (3).

TABLE 1. BASELINE CHARACTERISTICS OF COVID-19 PROTOCOLS EVALUATED BY THE VH-REC DURING THE OUTBREAK OF THE FIRST PANDEMIC WAVE.

		CT	PAS	RP	TOTAL
		N=10 n(%)	(N=16)	(N=131)	(N=157)
COMMERCIAL PROMOTER	Yes	6 (60)	-	2 (1)	8 (5)
	No	4 (40)	16 (100)	129 (98)	**149 (95)**
PARTICIPATING CENTERS	Unicentric	5 (50)	12(75)	68 (52)	**85 (54)**
	Multicentric National	4 (40)	4 (25)	45 (34)	53 (34)
	Multicentric International	1(10)	-	18 (14)	19 (12)
PRIMARY ENDPOINT OF THE PROTOCOL	Clinical symptoms	**7 (70)**	**12 (75)**	72 (55)	91 (58)
	Laboratory results	3 (30)	3 (19)	31 (24)	37 (24)
	Health status questionnaire	-	-	20 (15)	20 (13)
	Imaging tests	-	1 (6)	8 (6)	9 (6)
SEVERITY OF COVID-19 DISEASE IN THE POPULATION*	Ambulatory	-	2 (13)	21 (16)	23 (15)
	Hospitalized Mild Disease	3 (30)	1 (6)	9 (7)	13 (8)
	Hospitalized Severe Disease	**7 (70)**	2 (13)	24 (18)	33 (21)
	Every severity grade	-	**8 (50)**	**60 (46)**	68 (43)
	Not specified in the protocol	-	3 (19)	17 (13)	20 (13)
SPECIAL INTEREST GROUPS**	Health care professionals	-	2 (13)	14 (11)	**16 (10)**
	Pregnancy and neonates	-	1 (6)	8 (6)	9 (6)
	Immunosuppressed (includes oncology patients)	-	4 (25)	12 (9)	16 (10)

CT: Clinical trial; PAS: Post-authorization study; RP: Research project *Severity of the COVID disease of the population included in each study evaluated was assessed consistently with the 7 point WHO scale. **Please, note that percentages in this category have been calculated over the total of studies (n=157), but there is no overlap among Special Interest Groups studies.

Conclusions

- The expansion of clinical research related to COVID-19 resulted in an increase of REC activity, which had to **adapt rapidly** in order to give out the opinion in a short period of time.
- The included protocols show a special concern on certain interest groups and are less likely to be commercially promoted.
- The information here shown could be useful to compare with research trends in no pandemic period, or to research tendency in COVID-19 disease during different pandemic periods.
- This project's registry ***is being extended to other tertiary hospitals*** from our setting and a ***follow-up of the protocols*** already included is underway.