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Ethics committees in the time of COVID-19

I comitati etici al tempo del COVID-19

Eleonora Monaco, Lorenza Pisano, Laura Nasato, Giulia Lorenzoni, Dario Gregori, Matteo Martinato

Unit of Biostatistics, Epidemiology and Public Health, Department of Cardiac-Thoracic-Vascular Sciences and Public Health, University of Padua, Padua (Italy)

Corresponding author: Matteo Martinato; matteo.martinato@unipd.it

ABSTRACT

BACKGROUND: ethics committees (ECs) protect the rights, safety, and well-being of research participants and ensure the scientific correctness of clinical research. COVID-19 pandemic and the lockdown from 9 March to 16 May 2020 have potentially influenced several activities, including ECs.

OBJECTIVES: to assess the impact of COVID-19 outbreak on Italian ECs and their performance during the lockdown.

DESIGN: cross-sectional survey.

SETTING AND PARTICIPANTS: the survey was conducted in mid-June 2020 in Italy contacting all the 90 local ECs.

MAIN OUTCOME MEASURES: amount and kind of activities performed during the lockdown, characteristics of submitted studies and adoption of standard protocols of evaluation of research applications during the pandemic. Chi-square test was used to estimate the differences between territories with higher incidence (HI) and lower incidence (LI) of COVID-19.

RESULTS: 258 questionnaires were collected from 46 ECs that participated in the study. Ten were excluded due to missing substantial data. Responses were divided into two groups according to location of EC: the HI (125 responses) and the LI (123 responses). Seventy-five percent of the HI describe an increase in the number of studies submitted, while 53% of the LI does not (p=0.001). Due to the pandemic and its effects on research, the 15% of participants belonging to HI territories reported that consideration and respect of research-related and general ethical principles could have decreased, as well the adoption of standard protocols of evaluation of research applications. EC secretariats located in HI Regions moved to smart working more than in LI ones (75% vs 59%; p=0.001). Where the EC workload increased significantly, it was reported that it was impossible to perform an accurate analysis of the submitted documentation, with the effect of providing a favorable opinion to studies of not excellent quality, though always ensuring the respect of ethical principles and patients' safety.

CONCLUSIONS: COVID-19 impact on ECs has been heavier in HI territories, but smart working has been effective in ensuring EC activities and the subsequent activation of clinical studies potentially useful to face the pandemic. Clear differences arise between ECs belonging to the Italian Regions that have recorded a HI of COVID-19 cases compared to those located in Regions with a LI of cases. In some EC members' perception, the high number of studies in the most affected Regions together with the emergency experienced during the lockdown may have exposed ECs to the risk of decreasing the adoption of ethical principles and standard protocols of evaluation of research applications.

Keywords: ethics committees, pandemic, COVID-19

WHAT IS ALREADY KNOWN

- **Ethics committees play a vital role in the review and evaluation of studies, especially during the outbreak of a novel disease, that shows the fundamental importance of research in discovering and studying new prevention strategies, diagnosis, and treatments.**

WHAT THIS PAPER ADDS

- **Italian ethics committees of most affected Regions have suffered the effects of the COVID-19 pandemic in terms of increased workload than less affected Regions.**
- **In some cases, in higher incidence territories, it has been reported a decrease in the adoption by ethics committees of ethical principles and standard protocols of evaluation of submitted research projects.**

RIASSUNTO

INTRODUZIONE: i comitati etici (CE) proteggono i diritti, la sicurezza e il benessere dei soggetti che partecipano alla ricerca e garantiscono la correttezza scientifica della ricerca clinica. La pandemia di COVID-19 e il conseguente periodo di *lockdown* in tutto il territorio italiano dal 9 marzo al 16 maggio 2020 hanno potenzialmente influenzato diverse attività, tra le quali quelle dei CE.

OBIETTIVI: valutare l'impatto dell'epidemia di COVID-19 sui CE italiani e sulle loro attività durante il periodo di *lockdown*.

DISEGNO: indagine trasversale.

SETTING E PARTECIPANTI: l'indagine è stata condotta a metà giugno 2020 contattando tutti i 90 CE locali presenti nella nazione.

PRINCIPALI MISURE DI OUTCOME: quantità e tipo di attività svolte durante il *lockdown*, caratteristiche degli studi presentati e adozione di protocolli standard di valutazione delle richieste di parere su progetti di ricerca durante la pandemia. Il test Chi quadrato è stato utilizzato per stimare le differenze tra i territori con maggiore incidenza (HI) e minore incidenza (LI) di COVID-19.

RISULTATI: sono stati raccolti 258 questionari provenienti da 46 CE che hanno partecipato allo studio; 10 sono stati esclusi a causa della mancanza di risposta a domande fondamentali. Le risposte sono state suddivise in due gruppi in base alla sede del CE: in Regione a HI (125 risposte) oppure Regione a LI (123 risposte). Il 75% dei CE in territori HI descrive un aumento del numero di studi presentati, mentre il 53% di quelli in territori LI no (p=0,001). A causa della pandemia e dei suoi effetti sulla ricerca, il 15% dei partecipanti appartenenti ai territori HI ha riferito che la considerazione e il rispetto dei principi etici generali e legati alla ricerca potrebbero essere diminuiti, come anche l'adozione di protocolli standard di valutazione delle richieste di parere su progetti di ricerca. Le segreterie dei CE situati nelle Regioni HI hanno adottato lo *smart working* più di

quelle situate in Regioni LI (75% vs 59%; p=0,001). Quando il carico di lavoro dei CE è aumentato in modo significativo, è stato riferito che fosse impossibile eseguire un'analisi accurata della documentazione presentata, con l'effetto di fornire un parere favorevole a studi di qualità non eccellente, pur non inficiando il rispetto dei principi etici e continuando a garantire la tutela della sicurezza dei pazienti.

CONCLUSIONI: l'impatto di COVID-19 sui CE è stato più importante nei territori HI, ma lo *smart working* è risultato efficace nel garantire la prosecuzione delle attività dei CE e la successiva attivazione di studi clinici potenzialmente utili per affrontare la pandemia. Emergono evidenti differenze tra i CE appartenenti alle Regioni italiane HI rispetto a quelli situati in Regioni LI. È stato percepito da una piccola parte dei componenti dei CE in Regioni HI che l'elevato numero di studi proposti, unitamente all'emergenza sperimentata durante il *lockdown*, possa aver esposto il comitato al rischio di ridurre il rispetto dei principi etici e l'adozione di protocolli standard nella valutazione delle richieste di parere sui progetti di ricerca presentati.

Parole chiave: comitati etici, pandemia, COVID-19

INTRODUCTION

An outbreak of severe acute respiratory syndrome, named COVID-19, has been identified in Wuhan, China, in late December 2019, caused by a novel Coronavirus, SARS-CoV-2, and spread rapidly worldwide.[1] In Europe, Italy has been one of the most affected countries, with over 240,000 cases and 35,000 deaths.[2-5]

During the outbreak of a new disease, ethics committees (ECs) play an even more vital role in the review and assessment of studies, because of the urgent need to find the most suitable treatment and to quickly disseminate the results obtained to face the epidemic. To do so, ECs should minimize the time required from study submission to opinion, still ensuring respect for ethical principles and the subjects' protection, especially in case of interventional studies that may expose patients to additional risks.[6] As stated by the World Health Organization (WHO), "in time of a new epidemic outbreak there is a moral obligation to acquire new knowledge as soon as possible, in order to meet public health needs. However, despite the state of emergency, studies should not be conducted without a careful analysis of the risks and quality of the studies".[7] In this emergency, ECs should carry out an even more accurate assessment, because researchers may use investigational products, widen the inclusion criteria, not ensure adequate insurance coverage or not adequately inform vulnerable patients about risks related to study participation.[8] Therefore, it is clear that the COVID-19 pandemic have placed the Italian ECs in front of a deep challenge: the need to meet the request for a short term approval of the proposed studies with the need for an additional involvement in ensuring subjects' safety and wellbeing and the scientific validity of proposed research projects.[9] This challenge was made even more difficult by the national lockdown, from 9 March to 16 May 2020, that prescribed Italian public institutions, including ECs, to move to smart working.[10] Activities of the EC technical scientific secretariats, the EC administrative secretariats and, perhaps, also the work of members of ECs might have lost productivity, exposing the whole clinical research approval process to a significant slowdown.

This study aims to describe the possible effects of the COVID-19 pandemic and lockdown on the activities of the Italian ECs and how they faced the emergency, whether the staff of EC secretariats and committees' members experienced an increase in their workload and whether this has adversely affected the quality of the service provided and the adherence to ethical principles.

METHODS

STUDY DESIGN, SETTING, AND PARTICIPANTS

A web-based electronic survey was sent in late June 2020 to all 90 Italian ECs listed in the Italian drug agency (AIFA) website[11] and was open to all professionals involved in each EC. All data have been collected anonymously with only one mandatory question (EC location, in terms of Italian administrative Region) in order to make it possible to assess differences, if any, among territories with high COVID-19 incidence (HI) – Piedmont, Lombardy, Veneto, and Emilia-Romagna Regions – and territories with low COVID-19 incidence (LI), according to Italian Ministry of Health data.[12] Considering the anonymous data collection, and that no personal data would be collected from participants, the involved ECs were not asked to provide a formal favourable opinion on the study protocol; in addition, the request to participate in the study was sent to the official contact point e-mail address of every single EC and not to every single EC member or EC secretariat staff, asking to disseminate the link to the survey to EC members and staff.

DATA COLLECTION TOOL

The questionnaire was created from scratch and it was made of 59 items; however, the survey was built to provide questions customised for each respondent, so each participant could be asked to answer to 7 up to 19 questions providing a maximum completion time of 10 minutes.

After the initial identification of a pool of items, the items were reviewed by qualified experts, such as former EC members and clinical research associates (CRAs) employed in an academic clinical trial center (CTC).

The final draft of the questionnaire was tested and validated (content validity) in its final e-form appearance in order to check the correct functionality of branching logic rules and to record compiling time. No reliability validation (internal consistency, test-retest reliability, and in-

ter-rater reliability) has been performed due to the kind of questionnaire developed for the study and its intended use. A preliminary pilot testing was performed on a small sample of respondents (No. 7) before being distributed including a deep interview to assess the questionnaire was performed with every subject involved in the pilot testing. The final version (table S1, on-line supplementary materials) was accessible through a link provided by an e-mail message sent to the official contact e-mail address of each EC. Study data were collected and managed using Research Electronic Data Capture (REDCap),[13,14] a secure, web-based application designed to support data capture for research studies, hosted at Department of Cardiac-Thoracic-Vascular Sciences and Public Health of University of Padua.

MAIN OUTCOME MEASURES

Survey items, after collecting information regarding the profile of responder, explore the following topics:

1. if EC activities were maintained or not during the pandemic and consequent lockdown;
2. if ECs were maintained fully operative or not;
3. if any kind of priority was provided to COVID-19 related research;
4. which working modality was implemented and which was in place after the end of lockdown (i.e., smart working, in-office, web conferencing, etcetera);
5. if and how the workload changed;
6. if there were any slowdown;
7. if, in the opinion of respondent, it was experienced any decrease in the consideration and respect of research-related ethical principles such as those stated in Helsinki Declaration, Oviedo Convention, and in International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines; this may be due to the urgency of approval of COVID-19 related studies and/or the hypothetical larger amount of studies to be assessed by the EC.

DATA MANAGEMENT AND ANALYSIS

Descriptive statistics were reported as I quartile/median/III quartile and percentages (absolute numbers). The distribution of the responses to the survey from the ECs located in HI compared to LI Regions was compared using the Chi-squared and the Wilcoxon tests as appropriate.
A logistic regression model with random effects on the ECs was estimated to assess if EC located in HI Regions experienced an increase in the number of studies submitted during the lockdown compared to EC located in LI Regions.
Statistical analyses were done using R software, within rms, lme4, and mapIT packages.

RESULTS

SAMPLE DESCRIPTION

The survey was sent to all 90 Italian ECs; 258 questionnaires were completed by people referring to 46 ECs pertaining to 18 out of 20 Italian Regions. Ten questionnaires were excluded due to lack of information pertaining to EC location.

REGION	COMPLETED SURVEYS	PARTICIPATING ECs	
	No.	No.	%
Basilicata	7	1/1	100
Emilia Romagna	30	3/3	100
Friuli Venezia Giulia	15	1/1	100
Molise	10	1/1	100
Trentino Alto Adige / Südtirol	2	2/2	100
Umbria	5	1/1	100
Lombardia	67	13/20	65
Abruzzo	1	1/2	50
Marche	2	1/2	50
Sardegna	13	1/2	50
Toscana	2	2/4	50
Veneto	18	3/6	50
Piemonte	10	3/6	50
Lazio	11	6/13	46
Campania	29	3/7	43
Sicilia	6	3/8	37.5
Puglia	19	2/6	33
Calabria	1	1/3	33
Liguria	0	0/1	0
Valle d'Aosta	0	0/1	0

Table 1. Completed surveys and participating ECs, by Region.
Tabella 1. Survey completate e CE partecipanti, per Regione.

One hundred twenty-five (125) surveys were completed from ECs located in HI Regions, while the remaining 123 from ECs located in LI territories. The higher number of answers (67) come from ECs located in the most affected territory (Lombardy), but it should be taken into account that 20 out of 90 ECs are located in this territory. Figure S1 represents the number of respondents per Region (S1a) and the percentage of ECs per Region providing at least one respondent (S1b); data are also presented in table 1.
Most respondents are members of ECs (62%): 23% of the respondents are employed in EC secretariat (15% in the scientific area, 8% in the administrative area), while 10% were the President or the Vice-president of the EC. The remaining 4% of the respondents described themselves as EC secretary, technical consultants, hospital medical manager's delegates or biostatistician. Details are described in table S2.

CHANGES IN EC ACTIVITIES DURING THE PANDEMIC

During the lockdown, only 2% of ECs completely stopped every activity and 6% had a partial reduction; 47% continued working regularly without providing priority to pandemic related research while the remaining 45% continued performing their activities on a regular basis but providing full priority to studies related to COVID-19.

Most EC secretariats located in HI territories (75%) moved to smart working, while only a small part of them continued their operations in the usual workplace (19%) or adopted a mixed approach to both home-based and in-office work (6%) scheduling up to 2 or 3 days per week in office, in order to perform activities needed to guarantee EC functioning. Even though the radical change in *modus operandi*, 91% of respondents believes that working from home and performing telematic meetings did not slow down activities performed by the EC. It was asked to the remaining 9%, who experienced a slower functioning, why in their opinion this happened: some of the EC members describe several difficulties in participating to conference calls, due to unstable Internet connection and to the lack of immediate interaction with other members; some described that homebased working without useful documents or tools, otherwise available in their office, could have caused delays in providing an opinion on submitted studies and a decrease in their productivity.

When asking how the work had changed, 43% of the respondents (working as part of an EC secretariat) declared to perceive that the amount of work was higher than before and 12% that it was much higher than before. This perception is in line with the perception of a larger amount of research projects submitted considering that 61% of ECs claimed that, due to the pandemic, the number of studies submitted to the EC increased.

DIFFERENCES AMONG EC BASED IN HI OR LI TERRITORIES

The majority (75%) of EC secretariats based in HI territories moved all activities to smart-working, while the ones based in LI territories performed their activities mixing both smart-working and in office more than that in HI territories (23% vs 6%; p<0.001); details are described in figure S2.

Furthermore, a statistically significant difference was detected in the perception of the amount of studies submitted to ECs located in HI territories, where the 75% of participants described the perception of an increase, compared to the ones located in LI ones, where the 53% does not describe a perception of an increase (p<0.001); details are described in figure S3. The results of the regression model show that in the HI Regions there has been a statistically significant difference in the perception of the amount of submitted studies (OR 5.58; CI 1.75-22.25; p=0.005).

The perceived workload of 63% of the ECs in HI territories increased, while the perceived workload of 55% of those in LI ones decreased or remained unchange; details are described in figure S4.

For what concerns the perceived compliance to ethical principles in evaluating protocols during the lockdown, i.e., those stated in Helsinki Declaration and Oviedo Convention and the ones stated in ICH-GCP guidelines, in the 15% of the committees located in HI territories consideration and respect of such ethical principles might decreased (in LI territories only in the 4%; p=0.04; 148/248 missing data); details are described in figure S5. When asked to explain, participants reported a lower quality of study protocols submitted, an inadequate judgement mainly due to limited available time frame for documents assessment, a decrease of strictness in methodology evaluation, even though, in their opinion, patient protection was always ensured. Cases have been reported where, due to the increased workload, it has not been possible to perform an accurate analysis of the submitted documentation, proceeding to providing favorable opinion to studies of not excellent quality, but always respecting ethical principles and patient safety. In some other cases it was reported that the assessment of some aspects related to the processing of personal data and obtaining informed consent had to be postponed in order to allow the study conduction. Survey data are presented in table 2.

DISCUSSION

Data collected shows that most of the HI Regions reported an increase in workload resulting, in some cases, in a decrease in the application of standard protocols and checklists of assessment of proposed research projects.

Similar issues have also been detected in other countries seriously affected by the pandemic, such as China. The study by Zhang et al. aims to identify the most efficient method to allow Chinese ECs to evaluate studies rigorously and quickly.[8] The study was carried out at the EC of Henan Provincial People's Hospital and shows how the use of emergency video conferences and methods of electronic transmission of documentation has increased the number of evaluation sessions from 1 to 4 every 35 days. However, it is necessary to consider that the research has been limited to the small number of studies examined by a single EC. Other authors believe that, in an emergency, ECs should apply ethical principles in a more flexible way, streamline work, and simplify procedures as much as possible, i.e., changing the process of obtaining informed consent. Xitao Ma et al. propose that ECs rationalize the procedure by temporarily removing informed consent or just the signature of informed consent forms,[15] i.e., oral informed consent may be used in the first place, and a written consent may be obtained after data collection. However, this proposal seems to be in contrast to ICH-GCP guidelines and to the International ethical guidelines for health-related research involving humans prepared by the Council for International Organisations of Medical Sciences (CIOMS) in collaboration with the WHO which states that "the individual informed consent of participants is obtained even in a situation of duress, unless the conditions for a waiver of informed consent are met"; moreover, the informed consent should be written in a manner and language comprehensible to people who are under duress. In addition, the guidelines de-

	LI REGIONS (123)		HI REGIONS (125)		ALL (248)		P-VALUE
	No.	%	No.	%	No.	%	
EC ACTIVITIES PERFORMED DURING THE LOCKDOWN							
All activities performed regularly	52	43	64	51	116	47	0.054
Priority to COVID-19 research	56	46	54	43	110	45	
Only specific types of studies have been processed	4	3	6	5	10	4	
Only urgent activities have been performed	5	4	1	1	6	2	
All activities have been stopped	5	4	0	0	5	2	
MEETING MODALITY							
Telematic session	103	93	118	95	221	94	0.651
In presence	2	2	1	1	3	1	
Both	5	5	5	4	10	4	
EC SECRETARIAT WORK MODALITY							
Smartworking	64	59	88	75	152	67	<0.001
In presence	19	18	23	19	42	19	
Other	25	23	7	6	32	14	
PERCEIVED SLOWDOWN DUE TO SMARTWORKING							
Yes	9	8	12	10	21	9	0.579
No	102	92	111	90	213	91	
ADVERSE EFFECTS OF SMARTWORKING							
Yes	3	3	9	7	12	5	0.248
No	107	96	113	91	220	94	
Not pertinent	1	1	2	2	3	1	
PERCEIVED SLOWDOWN DUE TO SOCIAL DISTANCING IN OFFICE							
Yes	6	6	5	4	11	5	0.053
No	57	54	46	39	103	46	
Not pertinent	43	41	67	57	110	49	
INCREASE IN THE NUMBER OF SUBMITTED STUDIES							
Yes	55	47	93	75	148	61	<0.001
No	62	53	31	25	93	39	
POSSIBLE SHITFT TO SMARTWORKING IN THE FUTURE							
All activities could be carried out remotely	25	23	38	32	63	28	0.317
Some activities must be performed in presence	82	76	79	67	161	71	
CHANGE IN WORKLOAD							
Lower	5	5	2	2	7	3	0.043
Equal	54	50	41	35	95	42	
Superior	39	36	58	49	97	43	
Considerably superior	10	9	17	14	27	12	
EC WORK MODALITY AFTER LOCKDOWN							
Remote activities	45	42	69	59	114	51	0.031
In presence and remote activities	58	54	43	37	101	45	
In presence activities	5	5	5	4	10	4	
ON-LINE EC MEETINGS							
Yes	101	94	109	92	210	93	0.737
No	7	6	9	8	16	7	
PERCEPTION OF DECREASED COMPLIANCE WITH ETHICAL PRINCIPLES							
Yes	2	4	8	15	10	9	0.040
No	54	96	46	85	100	91	
CHANGES IN SUBMISSION PROCEDURES							
Yes	43	37	37	30	80	33	0.235
No	73	63	87	70	160	67	

Table 2. Survey results.
Tabella 2. Risultati dell'indagine.

clare that ECs should develop procedures to ensure appropriate and flexible mechanisms for ethical review and monitoring. ECs could pre-select study protocols in order to facilitate and accelerate ethical review in a crisis.

STUDY LIMITS

Regarding the perceived decrease in the application of standard protocols and checklists of assessment of proposed research projects, the high number of missing data (148/258 vs median 32/258 across the whole questionnaire) should be taken into account. It should also be considered that in Italian Regions the number of ECs is not homogeneous. Some Regions, e.g., Lombardy, count more ECs than others: only in the city of Milan there are 9 ECs. So, it seems obvious that a larger amount of answers came from these territories, instead of those which have a smaller number of committees. However, also Lazio Region (LI territory) has a higher number of ECs (13) compared to other Regions, but only a few surveys have been completed in that area.

Since the largest amount of completed surveys came from Regions with HI, it could be interesting to assess if EC members felt in some way the need to provide a feedback to the work they made during the pandemic. This could be pointed out in further research.

CONCLUSIONS

Despite all the struggle and difficulties experienced in time of crisis, even the ECs of the most affected Regions perceive and declare that they have always managed to safeguard subject's safety and wellbeing and to continue to carry out activities as regularly as possible through smart working and telematic meetings; in fact no HI Region has completely stopped EC activities.

In view of the strong impact that the pandemic has had on some Italian Regions and in view of the CIOMS/WHO guidelines that, in case of health emergency, suggest streamlining the procedures of evaluation and ethical review, further research would be desirable in order to investigate possible solutions to accelerate the submission processes of studies while respecting ethical principles; in order to be able to promptly deal with any future health emergency avoiding possible situations of conflict between compliance with ethical principles and the urgency of approval of clinical research. These are ethical dilemmas that are also faced in normal conditions, but which are exacerbated in the event of an epidemic.

Conflict of interests: none declared.

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REFERENCES

1. Wang C, Horby P, Hayden F, Gao G. A novel coronavirus outbreak of global health concern. The Lancet 2020;395(10223):470-73.
2. Lorenzoni G, Lanera C, Azzolina D, Berchialla P, Gregori D. Is a more aggressive COVID-19 case detection approach mitigating the burden on ICUs? Some reflections from Italy. Crit Care 2020;24(1):1-2.
3. Aggiornamento casi COVID-19. Dipartimento della Protezione Civile. Available from: http://opendatadpc.maps.arcgis.com/apps/opsdashboard/index.html#/b0c68bce2cce478eaac82fe38d4138b1 (last accessed: 26.06.2020)
4. World Health Organization. Coronavirus Disease (COVID-19) Dashboard. Available from: https://covid19.who.int/?gclid=Cj0KCQjwudb3BRC9ARIsAEa-vUunCeaTAdxE-wjV0pvupaplzUqWF4WvzE-ifAzpu0Xfq3vEsjCIbzoaAssnEALw_wcB (last accessed: 26.06.2020)
5. Magnani C, Azzolina D, Gallo E, Ferrante D, Gregori D. How Large Was the Mortality Increase Directly and Indirectly Caused by the COVID-19 Epidemic? An Analysis on All-Causes Mortality Data in Italy. Int J Environ Res Public Health 2020;17(10):3452.
6. Luo Q, Qin T. Managing clinical trials for covid-19: the importance of ethics committees. BMJ 2020;369:m1369.
7. World Health Organization. Guidance for Managing Ethical Issues in Infectious Disease Outbreaks. 2016. Available from: https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1
8. Zhang H, Shao F, Gu J, Li L, Wang Y. Ethics Committee Reviews of Applications for Research Studies at 1 Hospital in China During the 2019 Novel Coronavirus Epidemic. JAMA 2020;323(18):1844-46.
9. Fritz Z, Huxtable R, Ives J, Paton A, Slowther AM, Wilkinson D. Ethical road map through the covid-19 pandemic. BMJ 2020;369:m2033.
10. Gregori D, Azzolina D, Lanera C, et al. A first estimation of the impact of public health actions against COVID-19 in Veneto (Italy). J Epidemiol Community Health 2020;74:858-60.
11. Registro nazionale centri clinici e Comitati Etici. Agenzia Italiana del Farmaco. Available from: http://www.agenziafarmaco.gov.it/content/registro-nazionale-centri-clinici-e-comitati-etici (last accessed: 26.06.2020)
12. Istituto Superiore di Sanità. Characteristics of SARS-CoV-2 patients dying in Italy. Report based on available data on June 18th, 2020. Available from: https://www.epicentro.iss.it/en/coronavirus/sars-cov-2-analysis-of-deaths (last accessed: 26.06.2020)
13. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42(2):377-81.
14. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an international community of software platform partners. J Biomed Inform 2019;95:103208.
15. Ma X, Wang Y, Gao T, et al. Challenges and strategies to research ethics in conducting COVID-19 research. J Evid-Based Med. 2020;13(2):173-77.