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Editorial article

Medico-legal issues regarding from the COVID-19 pandemic☆

Aspectos médico-legales derivados de la pandemia de la COVID-19

Josep Arimany-Manso[a,b,c], Carles Martin-Fumadó[a,b,d,*]

[a] Cátedra de Responsabilidad Profesional Médica y Medicina Legal, Universitat Autònoma de Barcelona, Barcelona, Spain
[b] Área de Praxis, Servicio de Responsabilidad Profesional, Colegio de Médicos de Barcelona, Consejo de Colegios de Médicos de Catalunya, Barcelona, Spain
[c] Departamento de Salud Pública, Universidad de Barcelona, Barcelona, Spain
[d] Facultad de Medicina, Universitat Internacional de Catalunya, Barcelona, Spain

The new coronavirus (SARS-CoV-2) and its infection (COVID-19) has rapidly become a global threat to health. To a certain extent, science fiction has become reality. Factors inherent to the globalised world in which we live and which we must assume as regards epidemiology,[1] such as the constant movement of the population, and winter, favoured the rapid spread of the virus throughout the planet, causing a major health crisis which forced WHO to declare, on 11th March 2020, the COVID-19 pandemic.[2]

We have witnessed the health system's reaction to a huge and simultaneous demand for medical care, with the reconversion of facilities, uses and professional roles and the commitment of health professionals (HPs), which has led to a paradigm shift in healthcare. Healthcare, as we knew it, has probably changed for good. As HPs around the world have faced up to their professional responsibilities in the fight against this pandemic, different medical-legal and ethical aspects have emerged, deserving special consideration.

During the COVID-19 pandemic, HPs have been confronted with disaster scenarios with insufficient resources (beds in intensive care units, ventilators, ECMO. . .) for the large number of critically ill patients. This has meant that, in addition to prioritising patients or establishing an order of medical care, the rationing of resources has been necessary, both in the hospital and in the nursing homes and socio-healthcare settings, which implies assigning a resource (either a treatment or a diagnostic test against SARS-CoV-2) to one patient and not assigning it to another, so that the patient's vital prognosis depends on this decision.[3]

In order to support HPs in making critical clinical decisions, consensus documents have been designed, based on strictly medical criteria, supported by clinical decision *scores*[4] and based on key ethical values.[5] In these cases, exemplary transparency is necessary on the criteria used for the allocation of healthcare resources and on the making of clinical decisions of special impact. There is a need to explain clearly to patients, families, HPs, the community, and the media the circumstances motivating rationing, and what does it entail, if applicable.[6]

On the other hand, the rationing of resources must be distinguished from the limitation of life support (LLS) or withdrawal of life support (WLS), typical of end-of-life care. LLS is a measure used in the critical patient environment that refers to the decision not to establish, or withdraw, any life support action in a certain patient when it is believed that it does not provide a significant benefit. In this sense, the COVID-19 pandemic has not involved any alteration in healthcare decision-making in relation to LLS cases.

The emergency scenario has led to an exponential use of telemedicine, which had already been an accepted practice in medical care, but which has now become established and widespread, with the intention of becoming a standard of care.[7]

Telemedicine makes it possible to maintain access and continuity of care for patients and to support frontline professionals, optimising face-to-face services and minimising infections through transmission of COVID-19, thus preventing new outbreaks of infection.[8]

Despite its proven value, its widespread use has been associated with medical-legal controversies. The main problem posed by telephone communications is obtaining informed consent by proxy in those cases in which it must legally be in writing. In this exceptional situation, when dealing with non-competent patients and for therapeutic purposes, it is considered acceptable to obtain verbal consent by telephone, always making a record of it in the medical history.[9]

In the presence of a non-competent patient, without an advance directive document and without contact relatives, the HPs, in a consensual manner with the team, can carry out the action that represents the greatest benefit for the patient. If the situation is not a matter of life-saving urgency (or high-risk emergency), but is highly desirable, judicial authorisation should be sought.[9]

In the case of virtual telemedicine consultations, which were already common in health care, there are not so many problems, beyond the convenience of its registration in the medical record. In any case, the virtual consultation should not interfere with the basic principles of the doctor-patient relationship: mutual respect,

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* Corresponding author.
E-mail address: carles.martin@comb.cat (C. Martin-Fumadó).

independence of clinical assessment, autonomy of the patient and confidentiality.

Outbreaks are exceptionally stressful events for HPs as they face extremely traumatic experiences.[10] In addition, during the current pandemic, some professionals have had to care for patients despite the difficulties in obtaining adequate personal protective equipment (PPE). Faced with this situation, questions arise about the balance between the doctor's duty to care for patients, his obligations to protect his family and loved ones, and his right to protect his own health.[6] This concern is compounded by the desire of professionals not to commit an offence under the criminal code ̈failure to provide assistance¨, which penalises anyone who fails to provide assistance to a person.

In the face of these moral and legal obligations of HPs, there are reciprocal obligations for governments and institutions to minimize risks to professionals to the greatest extent possible, for example by ensuring adequate infection control measures, preventive measures (PPE), and prioritising access to health care in the event of illness.[5,6] We understand as a priority the request of the HPs asking for effective, timely and necessary protection measures, in order to carry out their care activities in adequate conditions, both technically and ethically.

By 11 May 2020, 40,961 cases of COVID-19 had been notified to the RENAVE network affecting HPs (76.5% women), representing 16.37% of the total number of cases declared to RENAVE, with 52 deaths reported. As an epidemiological history of risk, 65.6% of the HPs had contact with people with respiratory infection, and 70.8% close contact with probable or confirmed COVID-19 cases.[11] These data support, without any doubt, the professional origin of the infections. In this context, the General Council of Official Medical Associations (CGCOM) expressly requested the Government to develop the necessary legal measures so that COVID-19 and its consequences in HPs were recognized as OD (occupational disease).[12] The legislation published during the crisis classifies these situations as work-related accidents, but only for the purposes of temporary disability compensation. However, since it is not included in the OD table, it is necessary to directly and exclusively prove the occupational origin of COVID-19 the remainder of assumptions (free pharmaceutical benefit, permanent disability pension, widow's pension, additional financial benefits and accident insurance). Recognition as an occupational disease (OD) would make it possible to avoid administrative and/or legal claims which are expected to be numerous.[13] In order to ensure the occupational consideration of 19-COVID infection in HPs, it is recommended to include in the medical record information about the professional activity that led to the infection, the epidemiological survey that supports the diagnosis of infection in the occupational setting, the diagnostic tests for SARS-COV-2, as well as the ancillary tests and PPE used during occupational exposure. In addition, the temporary disability reports must always consider the occupational risk, and in the case of death, the medical certificate of death (MCOD) must state, if applicable, the COVID-19 infection as the root cause.

Medical professional liability (MPL) is the obligation that doctors have to repair and satisfy the consequences of their voluntary and involuntary acts, omissions, and errors, within certain limits, incurred in the exercise of their profession. In practice, the analysis of this practice must be carried out in the context of the specific circumstances of each specific situation (what is legally called *lex artis ad hoc*, or the generally accepted standards of medical practice).

During the COVID-19 pandemic, health care faces a different practice scenario than usual and professionals act within the framework of a health system conditioned by the crisis, with great pressure on care, in the face of a new pathology and new regulations enacted. On the other hand, the pandemic has meant the cancellation of many scheduled medical events, with the consequent possible harm to patients. All this implies that, in the event of a hypothetical claim by MPL, each specific case must be evaluated, determining the different possible levels of responsibility; that of the professional himself, that of the institution and that of the administration.

Regarding the MCOD, it must be remembered that it is a medical-legal document that embodies a medical act of great legal significance. It allows the registration in the Civil Registry (CR) and the burial of the corpse, with prior authorization of the judge in charge of the CR. In addition to its legal importance, it has a great epidemiological impact, since mortality is one of the parameters used in the design and assessment of health policies.[14] The quality of the information contained in the MCOD is crucial in this regard, even more so in a health crisis like the current one. Mortality from COVID-19 and its monitoring has been a central issue in this crisis and, therefore, death certification has acquired great importance. To do this, following the WHO recommendations, the CGCOM[15] issued a statement on the certification procedure, as well as on the issuance of MCODs in both suspected and confirmed COVID-19 cases. The analysis of mortality is one of the cornerstones of epidemiology and the one corresponding to the year 2020 will allow us to know what happened during this pandemic. Unfortunately, the electronic MCOD has not yet been implemented. Otherwise, the information on the causes of death would have reached the authorities by telematic means and in almost real time.

One medico-legal aspect that the pandemic has brought to the fore is the involuntary institutionalization for reasons of public health in patients with COVID-19. Previously, these situations had arisen in conjunction with, for example, therapeutic hospitalisation in the control of tuberculosis.[16] Organic Law 3/1986, on special measures in the field of public health (LOMESP), recognises the competence of the health authorities to adopt measures (of recognition, treatment, hospitalisation or control), when required for urgent or necessary health reasons, provided that rational indications are found that suggest the existence of a danger to public health due to the specific health situation of a person or group of persons, or in order to control communicable diseases. The law on patient autonomy also provides for the possibility of carrying out clinical interventions without the patient's consent when there is a risk to public health, requiring that these interventions, carried out under the LOMESP, be brought to the attention of the legal authority if they involve mandatory institutionalization.[17] Faced with a person diagnosed with COVID-19, competent and previously informed, with hospital admission criteria and who refuses to comply with treatment, the hospital must inform the health authority to request a mandatory hospitalisation due to a risk to public health from the administrative court, competent in these cases, for their authorization or ratification.

Finally, we hope that when we definitively defeat the pandemic, the changes derived from learning from it and analysing the problems that the health system and HPs have had to face will start to be implemented. It will be time to propose improvement strategies that include appropriate solutions to the medical-legal problems that arise and that will allow us to be better prepared for the next crisis.

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