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Clinical data transmission in intensive care unit: what have we learned from COVID-19?

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Abstract

The COVID-19 pandemic, besides stimulating new integrated assistance systems 1, has altered the clinical approach in I.C.U., the management of medical information, and the methods of communication between doctors and family members. The transmission of news between the hospital and the family was ensured via a multimedia network, replacing the understanding between doctor and family established with *de visu* meetings. The pandemic emergency has forced healthcare professionals to adopt this new method of communication, exposing the doctor to a series of critical issues related to the transmission of sensitive data. A review of the scientific literature underlines that not many articles deal with regulations and issues related to the processing of health data in the COVID period; however, there are many challenges such as security risks, privacy, ethical and process standardization issues. We believe that this topic should be the subject of an urgent debate, deepening the matter with a specific medico-legal background.

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Key word: COVID-19; communication; intensive care; telemedicine.

Contributions: VP, FC conceptualization; AV, GL writing original draft and editing; MCP writing review and validation. All authors critically revised the manuscript and approved the final version for submission.

Conflict of interest: the authors declare no potential conflict of interest, and all authors confirm accuracy.

Ethics approval and consent to participate: not applicable.

Patient consent for publication: not applicable.

Availability of data and materials: all data generated or analyzed during this study are included in this published article.

Funding: this commentary received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Received: 7 June 2023.
Accepted: 20 July 2023.

Acute Care Medicine Surgery and Anesthesia 2023; 1:26
doi:10.4081/amsa.2023.26

According to the historical background, it would be useful to support the scientific debate on an issue that has not been dealt with very much: the COVID-19 pandemic, besides stimulating new integrated assistance systems,[1] has altered the clinical approach in Intensive Care Units (ICU), the management of medical information and the methods of communication between doctors and family members.[2]

In ICU, more than in other care settings, the role of an intensivist is crucial in communicating with the family of critically ill patients because the information to be provided may have a greater emotional impact,[3] especially since the patient is often unable to communicate.[4] To worsen the emotional background, at the time of admission to ICUs, most patients experience anxiety, depression, isolation, and loneliness, which may continue even after discharge.[5] In this context, because ICU patients face psychological and physical stress, starting in the second half of the 1990s, less restrictive policies on visiting hours for relatives began to be considered.[6]

The spread of the "open intensive care unit" approach occurred in the last decade, with the introduction of guidelines dedicated to supporting family members in the ICU. The concept behind "open intensive care units" consists of the vision of a "ward in which one of the goals of the medical team is the rational reduction or abolition of time, physical, and relational restrictions."[7]

In addition, the growing advent of the concept of multidisciplinary care for the critically ill patient has drawn attention to the importance of the intervention of all healthcare personnel, in their relationship with the patient and his or her family members, also in accordance with what is expressed in art. 5 of the 1997 Oviedo Convention, which states that any information aimed at consent concerns all healthcare personnel, concerning their competencies, although the strictly nosological component is a physician prerogative. The continuous presence of ICU nurses, with the use of effective empathic communication skills, can positively impact the healthcare team's relationship with family members and patients.[8]

In this scenario, the open ICU suffered a major setback with the onset of the pandemic, which has denied direct contact

between the patient and his or her family, elevating the physician to the only contact, albeit indirect, between relatives.[9] The face-to-face medical disclosure, which was daily ensured to family members, often turned into a telephone communication with an unknown face-to-face person, who was often informed of sensitive data concerning the hospitalized patient. The transmission of news between the hospital and the family was ensured via a multimedia network, replacing the understanding between doctor and family established with *de visu* meetings and suggesting the telephone call as the only method of communication.

A joint document by SIAARTI (Italian Society of Anaesthesia, Analgesia, Intensive Care and Pain Therapy), ANIARTI (Italian Society of Critical Care Nurse), SICP (Italian Society of Palliative Care), and SIMEU (Italian Society of Emergency Medicine) called 'COMUNICoVID' of April 18th, 2020 sets out how to communicate with family members in complete isolation, also providing a checklist for telephone and video calls to family members and suggesting email or, more generally, written communication, as a complementary strategy;[10] the content of this document is taken up in May 2020 in the ISS (Istituto Superiore di Sanità) Report 19 n. 40/2020: in particular, this report focuses on the multiple repercussions that the isolation of patients and relatives entails and on the consequent need to promote sustainable communication procedures in emergency conditions but, at the same time, complete and effective for those to whom they are addressed. In this sense, the adoption of a series of communicative measures is suggested, including the establishment of contact as direct as possible with the interlocutor, the use of understandable language, transparency regarding the actual health conditions of the patient, the attention not creating incorrect expectations, the correct handover between staff members in charge of communication and the establishment of a pre-determined daily window of communication, also suggesting to specify to the relatives that any change in the state of health of the assisted person would be promptly communicated.

As far as the legal aspect is concerned, it is premised that the acquisition of formal consent by the assisted person to share data would be preferable when possible, but that such sharing could, in any case, be considered legitimate, even possibly with the help of telematic supports, by the art. 17-bis c.2 of Law no. 27 of 24 April 2020, which allows the transmission of personal data to private subjects "where this is indispensable to carry out the activities connected to the management of the current health emergency" unless this does not affect the dignity of the patient. However, the validity of this provision is specifically established until the end of the state of emergency.[11]

The pandemic emergency has forced healthcare professionals to adopt this new method of communication, exposing the ICU personnel to a series of critical issues related to the transmission of sensitive data. The identification of the interlocutor only by voice is not safe; in addition, the shortage of human resources linked, among other things, to the high personnel turnover that occurred during the pandemic both due to age factors and due to problems related to burnout and fear of contagion,[12] cannot ensure the presence of a medical disclosure dedicated staff. A review of the scientific literature underlines that not many articles deal with regulations and issues related to the processing of health data in the COVID period; however, there are many challenges such as security risks, privacy, ethical and process standardization issues.[13] Recent studies testify how contact with both the doctor and the patient is essential for the family; digital supports such as video calls reduced the feeling of distance between family and hospitalized relatives.[14] There's still the matter of the correct interlocutor identification and the communication of sensitive data on certified channels.

The implementation of telemedicine, besides broadening the horizon of home medical care,[15] could also improve this aspect; however, healthcare professionals need updated guidelines.[16] Since May 25th, 2018, the General Data Protection Regulation (GDPR) 2016/679, which governs the processing of personal data, has become fully applicable in all E.U. countries. With Provision no. 55 (March 7th, 2019), the ItalianGuarantor for the Protection of Personal Data has provided useful clarifications on the application of this regulation in the healthcare area, given the adaptation decree no. 101/2018.

In a nutshell, the current legislation on clinical and personal data processing tells us that: i) the processing of health data is always prohibited, except for reasons of public interest and/or for treatment purposes (for example, preventive medicine, diagnosis, assistance, and management of health and/or social services); ii) the consent of the interested party is not required for the processing of data aimed at or explicitly connected to personal care and when the data processing is implemented by health professionals or other professional figures subject to the obligation of professional secrecy; iii) consent from the interested party is required for any other purpose, including the use of medical apps, the delivery of online reports, and the consultation of electronic health records; iv) the Privacy Policy is conceived, according to article 13 of the GDPR, as a communication to the interested party of the purposes and methods of processing of their data by the data controller himself, who is called to respect the so-called principle of *accountability* with the duty to ensure transparency and fairness right from the design stage; v) each structure belonging to the SSN or which deals with the processing of a high flow of personal and health data is obliged to appoint a Data Protection Officer (DPO).[17]

It appears evident that this legislation does not provide for precise regulation of the sharing of sensitive data through telematic channels. We believe that this topic should be the subject of an urgent debate, deepening the matter with a specific medico-legal background complemented by experts in ethics and health management, especially since WHO Director-General Tedros Ghebreyesus declared COVID-19 "over as a global health emergency" on May 5th, 2023.

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