

Telematic solutions in plastic surgery during COVID-19 pandemic: liability issues and risk management

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To the Editor,

The complete lockdown because of coronavirus disease 19 (COVID-19) pandemic was imposed by the Government in Italy on March, 9th 2020. Our Modena University Hospital is located in Emilia-Romagna which was the second most affected Italian Region (1,2). The intensive care unit was used to admit infected patients from other regions of northern Italy. In our unit we mostly dealt with breast reconstruction (3-5), head and neck reconstruction (6-10), post-bariatric surgery (11) and hand surgery (12,13). Surgical elective procedures were halted in order to allow an appropriate use of all the hospital resources. Moreover, limitations for plastic surgery consultations and for follow-up of previous surgical procedures were imposed in order to minimize the risk of contagion in waiting rooms and outpatient clinics. All the first appointments booked for non-urgent problems such as post-bariatric procedures, macromastia, benign tumors or delayed breast reconstruction were postponed. Surgical emergencies were allowed: traumas, tumors and soft tissue infections such as necrotizing fasciitis. We have identified telemedicine as an alternative way to follow patients during this time of the lockdown especially in the following situations: patients already having an appointment in the outpatient clinic at the time of lockdown to decide whether to cancel, postpone or maintain their appointment; visual information of the clinical condition in order to evaluate the severity of skin lesions and surgical complications for the decision

to keep or postpone the appointment; the appropriate time for suture or drains removal in order to avoid unnecessary in-patient visits.

Our most important priority was to determine the technology resources available in our hospital. Our hospital did not have the possibility to use a teleconferencing software for audiovisual encounter which matched our needs: certification of platform security in terms of privacy and data transmission matters, integration with the patient's medical record for documentation and billing purposes, high server capacity to support remote video visits without interruption. Devices with a microphone and a high-resolution camera were not available in our unit. Moreover, we have experienced other difficulties. Surgeons in our department are not prepared to use real-time remote video technology for patient management. Guidelines for an appropriate selection of patients which could be served via telemedicine had to be created.

Telemedicine concerns the remote use of medical skills where the need arises. It is used in order to facilitate patient management and optimize healthcare resources. For these reasons, it must be regulated by healthcare organizations for legal, ethical, medicolegal and risk management aspects (14,15). This is a different way for healthcare organization to change the doctor-patient relationship approach with new levels of responsibility. While device manufacturers are responsible for the technical aspects, healthcare facilities should guarantee security of telematic procedures

in terms of virtual patient access and telematic data management by supplying appropriate technological facilities. In particular, the clinicians should ensure the telematic treatment process supervision through constant dialogue with new professional figures such as the telemedicine system administrator (15).

The use of telemedicine may involve different technical problems (16-21). In terms of responsibility, service providers are not liable for damage deriving from technical default, except in the case of serious misconduct. Furthermore, if telemedicine becomes a standard practice, not using it could constitute legally punishable negligent behavior. Legal issues about medical liability for diagnostic and/or therapeutic errors can be related to data and privacy protection and informed consent for electronic health service with certified digital signature. Health data transmission through the use of telematic systems implies that patient information could remain available to an unknown number of subjects. Legal issues about conflicts of jurisdiction among nations for malpractice problems and a possible telematic service inaccessibility for technological malfunctions should be taken into consideration. The high risk of compensation for damages related to these problems requires the insurance coverage to be reviewed, extending the insurance guarantee to these events as well. Furthermore, detailed traceability of telematic operators' activities might be a risk management task such as verifying accurate training of clinicians to limit possible medical errors and adverse events and ensure safe patient care.

The United States Department of Health and Human Services has implemented the Health Insurance Portability and Accountability Act (HIPAA) compliance guidelines for the COVID-19 pandemic, allowing the use of consumer applications (eg, FaceTime or Whatsapp) based on "good faith" attempts to provide patient care during the pandemic (22-24). Nevertheless, in Italy the use of video communication tools has not been liberalized.

During an audiovisual encounter, electronic medical record is essential to document the medical communication, the duration of the encounter, the possible verbal consent and for billing purposes. For the

medical staff, the need for learning and training about the use of virtual platform is mandatory. Guidelines about patient selection and telemedicine workflow and patient education on telemedicine are important issues. Telemedicine has to be within patient care guidelines of the unit and within scope of practice as defined by the hospital/state. Even if we have experienced an important need to use telematic solutions, liability and risk management issues has greatly limited this possibility in our unit. The need of telemedicine in the time of COVID-19 pandemic has encouraged us to implement future virtual encounters in order to reduce unnecessary in-person visits by taking into consideration all legal, ethical and medico-legal aspects.

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