Republic of San Marino

San Marino Bioethics Committee

RESPONSE TO THE REQUEST FOR AN OPINION ON THE ETHICAL ADMISSIBILITY OF THE ADMINISTRATION OF LIFE-SAVING DRUGS IN SAN MARINO IN EMERGENCY SITUATIONS BY SSI 118 NURSING STAFF

Approved on 10 September 2024

The San Marino Bioethics Committee (CSB) has been asked by the Director of the Emergency Care and Short Stay Complex Operational Unit, Dr. Alessandro Valentino, for an opinion on the ethical admissibility of administering life-saving drugs in San Marino in emergency situations by the 118 nursing staff of the Social Security Institute.

The CSB convened Dr. Chiara Manuzzi, delegate of Dr. Valentino, who anticipated the formal request, explaining the situations in which nurses, as the rule stands, cannot administer life-saving drugs in San Marino in emergency situations, in the absence of a doctor.

The CSB then analysed the request received and, at its meeting on 10 September 2024, unanimously issued the following opinion:

Although the primary objective of medicine is to protect life and this is an absolute priority, the issue regarding the autonomous administration of life-saving drugs in San Marino by nurses in emergency situations is complex and requires a careful and thorough analysis of the many factors involved. It is certainly appreciated that the bioethical dimension of the issue in question has been noted, in the awareness of how necessary and urgent it is to promote this specific sensitivity in all areas of clinical medicine and not only with regard to emergency/urgency situations.

Bioethical considerations, which include, inter alia, issues related to the competence and responsibility of medical and non-medical health professionals and to patient protection, outline a complex framework that makes immediate approval and implementation problematic and risky. On this issue, it would be advisable to have a constructive debate; the search for solutions to improve healthcare in emergency situations, while respecting bioethical principles, remains a priority objective, all the more so in the current healthcare context, which is increasingly struggling due to the growing shortage of economic and professional resources.

Although the issue concerns first of all the professional figure of the nurse, the first aspect that must be considered relates to *medical autonomy*, i.e. the need to call into question the authority of the professional figure of the doctor, and conversely the authority of the other non-medical (and non-nursing) professional figures who carry out diagnostic, laboratory, but also care/therapeutic and preventive health activities. This may appear paradoxical, because it imposes a comparison between the authority of two or more professional figures with the reciprocal exclusion of competences, activities and responsibilities, and the (only apparent) affirmation of a hierarchy among them; but at the same time it allows to outline professional profiles (regulatory and historical), the fields of application and the contents of specific activities also with a view to determining reciprocal responsibilities, starting from what *can only belong* to one or the other of the two or more figures on the basis of deontological, cultural and anthropological elements.

Indeed, medical autonomy, a fundamental principle of bioethics and modern medicine, is enshrined in the patient's right to make informed and conscious decisions about his or her own health and the health treatment to be received. For example, it should be borne in mind that *Informed Consent* (or Valid Information and Consent) envisages an exclusive role for the doctor, who has the duty to

provide the patient with complete and comprehensible information on his or her condition, on the therapeutic options available, and on the risks and benefits of each treatment, with the aim of obtaining a valid and informed consent to treatment. The purpose is to foster and promote the patient's necessary *decision-making competence* and the therapeutic alliance as the primary element at the basis of the principle of personal sharing and sustainability of the social system. The relevance of elements such as respect for the person and for one's own values, beliefs and preferences is implicit and must be respected in the doctor's decision-making process, as well as in the self-determination will of the patient, who has the right to decide autonomously and freely on matters relating to his or her own health, without coercion or external pressure.

Indeed, this makes the figure of the doctor *unique*, because it is *anthropologically significant*.

It must be made clear that the issue in question only marginally involves the different technical and scientific knowledge of the professions of doctor and nurse. It is also true that nurses, like doctors, may have to deal with complex ethical dilemmas, for which training and the capacity for critical judgement are of fundamental importance, and, in that case, they should rely on adequate and sufficient preparation, to be gained from their own training.

However, especially in view of the predominantly critical circumstances in which the administration of life-saving drugs is required, the diversification of the boundaries of responsibility between doctor and nurse is required above all to defend the patients' right to their own protection under appropriate care, both on a formal level and in terms of practical application. As already mentioned, this principle is rooted in the fundamental anthropological profile of the *care-giver* with respect to the *care-receiver*, i.e. of the *doctor*, according to its cultural understanding, at the bedside of the *sick person*.

In other words, the principle of *medical autonomy*, essentially original and established by tradition, states that the doctor - and only the doctor - has the ability, competence and responsibility to make decisions independently based on his or her professional judgement and knowledge of the patient. Such principle could, therefore, be violated if the nurse is also indifferently delegated the choice to administer life-saving drugs, creating confusion about the roles and potential conflicts between the two professional figures.

For the avoidance of doubt, the affirmation of the primary and *original* role of the doctor does not consist in the sterile and arrogant defence of a position from a corporate point of view. Quite the opposite. On the contrary, there is a strong fear that supporting a *spread of responsibilities* between different professionals might tend to blur their respective roles, to the detriment of the patient, who would be deprived of his or her right to refer to the doctor's professionalism, which is also clearly recognisable in the assumption of responsibilities.

To explain the concept on the basis of bioethical principles, it seems appropriate to recall, among them, that of *non-maleficence*. Indeed, maintaining a clear identification of roles is aimed at protecting the patient from possible confusing elements that could cause him or her harm, all the

more so in the aforementioned critical clinical conditions in which the need for urgent intervention is more pressing.

It can, however, be said that the *operativeness* imposed by the emergency/urgency situations typical of Resuscitation and Intensive and Semi-intensive Care Units (without excluding all possible remaining clinical conditions), especially in the need to save lives, may indeed require that immediate interventions be carried out indifferently by whichever health professional is directly involved, whether a doctor or a nurse. That is, the nurse may also be called upon to intervene urgently but *at a distance* with respect to an effective mediation by the doctor. In such circumstances, the practical application of appropriate therapeutic means and measures aimed at ensuring survival should always fall, at least formally, under the responsibility of doctors, albeit it is within their power to delegate, to their best knowledge and belief, their choices to another health professional.

Ospedale di Stato. Rep. San Marino
Unità Organizzativa Complessa
Pronto Soccorso - Degenza Breve
Direttore Dott. Alessandro Valentino

Spett.le Comitato Bioetico,

sulla base di quanto discusso in riunione in data 6 giugno us, richiedo il parere del Comitato sulla somministrazione di farmaci sul territorio da parte del personale infermieristico 118 dell'ISS.

A tale proposito sottolineo come la mancanza del medico in servizio 118 in orario 20-07.30 renda assolutamente necessario che, in situazione di estrema gravità, gli infermieri intervenuti sul territorio possano liberamente somministrare terapie ai pazienti senza il preventivo assenso di un medico.

Sono stati pertanto stabiliti protocolli che possano essere seguiti dagli infermieri, a tutto vantaggio della qualità del servizio offerto dal soccorso territoriale e, in ultima analisi, dei pazienti soccorsi.

Tali protocolli riguardano situazioni cliniche nelle quali gli infermieri 118 possano somministrare terapie salvavita, sulla base di quanto in atto negli Stati nei quali non sia prevista la presenza di personale medico sul territorio.

Ringraziando porgo distinti saluti

San Marino, 12/06/2024

Dott. Alessandro Valentino

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