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NEWS

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Opiates at the end of life in an emergency department in Spain: euthanasia or good clinical practice?

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The Severo Ochoa Hospital opened in 1987 to serve the city of Leganés south of Madrid. With 425 beds for a catchment area of 400,000 inhabitants it is the hospital with the lowest ratio of beds per 1,000 inhabitants in the Madrid Region and one of the lowest in all of Spain. Despite this shortcoming it has pioneered a model of patient care that integrates specialist care in the community (Health Centres) and in the hospital, and in recent years the hospital has received several awards in recognition of its outstanding activity.

On July 2002 an anonymous accusation was sent to the Director General of the Madrid Healthcare Institute (IMS). The IMS then requested information from the hospital management regarding an alleged increase in mortality in the Emergency Unit. The Medical Director and Manager replied with a report that explained the increase in mortality compared with the same period of 2001 based on the following: (a) There had been a 20% increase in the number of patients attending at the Emergency Unit in the previous 4 years. (b) No Palliative Care Unit existed in the hospital. (c) There was a shortage of beds in the hospital catchment area: 1.2/1,000 inhabitants vs. Madrid Region overall, 2.6/1,000. (d) The Emergency Unit had been enlarged and improved during 2001: 400 m^2 additional space, 20 more boxes, and in particular the setting up of a two-bed unit for terminal patients. (e) The admission rate of inpatients through the Emergency Unit was 82%, vs. Madrid Region overall 62%. Furthermore, a comparative study of opiate and benzodiazepine use in the Emergency Unit had shown that their increase use was clearly related to the increased number of patient-days in the Unit. This first incident of anonymous accusation was then closed without any further significance.

During the first semester of 2003, following a medical records review of terminal sedation patients' deaths at the Emergency Unit undertaken by the hospital Mortality Commission, some doubts were raised regarding indications and doses. The Hospital General Manager requested from the General Direction of the Madrid Region IMS an external audit by the Medical Inspection. This investigation went on for 3 months, during which time medical inspectors analyzed medical records and interviewed Emergency Unit personnel, finding that both physicians and nurses considered sedation to be highly positive for terminal patients admitted to the Unit who could not be transferred to a palliative care unit or to another hospital ward. The conclusions and recommendations of their final report were: (a) "No unequivocally objective reasons were found that could lead one to believe that medical decisions had been taken that might be considered liable to disciplinary action for malpractice." (b) "The framework of the Emergency Unit is adequate, as it allows patient treatment with dignity, clinical support, and the presence of the family." (c) "No complaints or reluctance has been observed on the part of patients' families, which constitutes a clear endorsement for the administration of terminal sedation." (d) "In all cases the medical records verify the awareness of and informed consent by the family of terminal sedation."

Notwithstanding this report the physician responsible for the Emergency Unit (Chief of Service) asked for a new review by the Ethics Commission of another hospital. This external report, produced after 2 months of analysis, concluded that there had been no instance of malpractice, and that medical decisions taken regarding sedations in terminal patients were adjusted to *lex artis*. This process was carried out without causing any alarm in public opinion because of the absolute confidentiality maintained throughout review.

Nevertheless, in March 2005 a new anonymous accusation was brought to Madrid Region Ministry of Health that led to a situation similar to that in 2002. Following a week-long inspection the Regional Minister of Health publicly claimed that there was evidence of 400 cases of probable euthanasia, and without delay he dismissed the physician in charge of the Emergency Unit, along with the Medical Director and the Hospital General Manager. At this point there arose a genuine social alarm as it was the Minister of Health himself who announced this situation. Euthanasia is not permitted under Spanish law.

The Regional Public Prosecutor requested from the Regional Ministry a series of documents, whose release was delayed by the health authorities beyond the period that could considered reasonable. The subsequent report from the Regional Public Prosecutor nevertheless established no evidence of criminal responsibility in relation to the alleged malpractice. In spite of this the Regional Ministry declared that "administrative irregularities" had been come to light, based on information discovered in the (confidential) minutes of the hospital Clinical Commissions. These minutes were used irregularly, in a prejudiced manner, and, quite shockingly, leaked to the media. Since that time the Regional Ministry of Health has allowed the additional leaking of var-

ious confidential medical documents, including the minutes and resolutions of the hospital Mortality Commission. It also carried out the illegal removal ("theft") from the hospital of 400 medical records, without following the established procedures for their custody.

Shortly thereafter the Regional Health Ministry appointed its own "Commission of Experts," consisting of selected senior physicians, probably in order to neutralize the conclusions of the enquiry carried out by the Public Prosecutor, who was unlikely to draw any conclusions against the medical staff of the hospital Emergency Unit. The membership of this Commission was: one psychiatrist, one pediatrician, one Social Security medical inspector, one anesthesiologist, and two oncologists, none of them having any experience in palliative care and some of them allegedly with strong religious biases in medical ethics. This Commission was therefore considered seriously prejudiced by hospital physicians and many in the medical and legal communities. It produced a report purporting to be a scientific paper, but several prestigious clinicians and epidemiologists found it was seriously fraught with methodological, conceptual, and factual errors. The most contentious statement of the Commission report referred to the possible "reversibility" of terminal patients' conditions. The medical community not only at Severo Ochoa Hospital but throughout Spain considered this report one-sided and scientifically lacking. As an alternative, they called for: (a) a fair professional review by the Madrid Medical College regarding any alleged instances of medical malpractice, and (b) intervention by the judiciary should there be any evidence of wrongdoing, thus denying any such role to the Regional Health Ministry itself.

It is important to note that between 2003 and 2005 no formal complaint had been brought against the Emergency Unit of the hospital despite the very sensitive nature of these matters, the media publicity given to them, and the active involvement of the Regional Minister in the matter.

The campaign against Severo Ochoa Hospital and its medical staff has caused incalculable damage. As the President of the Spanish Scientific Palliative Care Association noted, "malpractice would be to allow the sick to die in pain." This is in fact a phenomenon that is now beginning to take place due to fear on the part of patients and their relatives, as well as physicians anticipating possible lawsuits [1, 2]. This situation has caused serious damage to trust by patients and population trust towards the public health service, in fact beyond the Madrid Region.

Opiates are required at the end of life, and sedation/analgesia has long been recognized as good clinical practice. The intensive care setting is no exception. The recent Consensus Conference [3] on "Challenges in end-of-life care in the ICU" stated that, "The patient must be given sufficient analgesia to alleviate pain and distress; if such analgesia hastens death, this 'double effect' should not detract from the primary aim to ensure comfort." Sykes et al. [4] have recently shown in a palliative care unit that sedatives used at the end of life actually do not decrease survival of dying patients.

Even the Catholic Church, which is very sensitive to these issues, long ago dealt with it in its official position towards sedation and analgesia in terminal conditions. In 1957 Pope Pius XII, for example, addressing the National Congress of the Italian Society of Anesthesiology pointed out that, "If the use of narcotics would cause by itself two different effects: on one side, the relief of pain and, on the other side the shortness of life, then it would be legitimate" [5]. More recently Pope John Paul II wrote in his 1995 encyclical "Evangelium Vitae" that, "In effect, in this case death is neither wanted nor sought, though there may incur in this risk for reasonable motives. Simply an effective way of relieving pain is intended, using analgesics made available by the medicine." [6]

In recent years much has been said about medical responsibilities, including intensive care, in end-of-life care, showing that the awareness of dilemmas in terminal cases has reached the level of public opinion. Authorizing the prescription of opiates at the end of life has been recognized by courts in the United Kingdom for decades; a law in France on "Patients' rights and the end-of-life" was passed in March 2005 which explicitly declares that the administration of analgesia and sedation is not a criminal offense [7]: "In no way should the circumstance be used other than in the context of a professional activity which is full of prudence and sensitivity, and in consonance with patients and family."

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