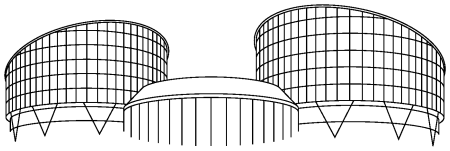

EUROPEAN COURT OF HUMAN RIGHTS
COUR EUROPÉENNE DES DROITS DE L'HOMME

THIRD SECTION

DECISION

Application no. 20192/07
E.M. and Others
against Romania

The European Court of Human Rights (Third Section), sitting on 3 June 2014 as a Chamber composed of:

Josep Casadevall, *President*,
Alvina Gyulumyan,
Ján Šikuta,
Dragoljub Popović,
Luis López Guerra,
Johannes Silvis,
Iulia Antoanella Motoc, *judges*,
and Santiago Quesada, *Section Registrar*,

Having regard to the above application lodged on 6 May 2007,

Having regard to the partial decision of 12 June 2012,

Having regard to the observations submitted by the respondent Government and the observations in reply submitted by the applicants,

Having deliberated, decides as follows:

THE FACTS

1. The applicants, E.M., C.M. and I.L.M., are Romanian nationals who were born in 1939, 1962 and 1964 respectively and live in Bucharest. The first applicant is the mother of the second and third applicants. They were represented by Mr I. Olteanu, a lawyer practising in Bucharest.

2. The Romanian Government ("the Government") were represented by their Agent, Ms C. Brumar, of the Ministry of Foreign Affairs.

A. The circumstances of the case

3. The facts of the case, as submitted by the parties, may be summarised as follows.

4. Mr I.M., a reserve colonel (*colonel în rezervă*), was the first applicant's husband and the second and third applicants' father. On 30 May 2005 he died in hospital, aged seventy-three, following an operation and a two-week convalescence period.

1. Mr I.M.'s treatment and death in hospital

5. On 22 April 2005 Mr I.M. developed symptoms of icterus (a yellow discoloration of the skin or whites of the eyes, indicating excess a bile pigment in the blood) and, together with the applicants, went to the military clinic for a consultation. He underwent some tests and was immediately admitted to the Carol Davila Central Emergency Military Hospital ("the hospital") for further investigations and treatment. His diagnosis was "cholestatic jaundice due to cholestatic calculus – left renal lithiasis clinically significant for approximately three days" (*icter colestatic prin calcul colestatic – de circa trei zile litiază renală stânga*). Neither the patient nor his family was informed of the diagnosis.

An ultrasound scan performed that evening in the hospital revealed a pancreatic tumour and the patient was prescribed treatment by the doctor on duty, Dr C.D. After two days of treatment, the jaundice disappeared. The treatment continued for two more days.

6. On 26 and 27 April 2005 Dr C.D. ordered further examinations of the patient's abdomen, pancreas and bile ducts. I.M. thus underwent a computerized tomography scan (a form of X-ray examination in which the X-ray source and detector rotate around the object to be scanned and the information obtained can be used to produce cross-sectional images by computer) on 3 May 2005 and an ultrasound endoscopy on 6 May 2005. An MRI test (magnetic resonance imaging, a non-invasive method of examination of body organs by recording the responses to radio waves, or other forms of energy, of different kinds of molecules in a magnetic field) was recommended but never carried out. Throughout this time, the applicants were at the hospital with the patient, but they were allegedly not given any information by the medical team.

Dr C.D. conferred with his colleague Dr R.P. and decided, on the basis of the test results, that the patient probably had a pancreatic tumour of a kind requiring surgery.

According to the applicants, neither the patient nor his family was properly informed of the diagnosis, the nature of the intervention, its risks, or its actual duration. The medical team told them that they were going to perform a "routine" operation lasting about an hour and a half, and which had a 100 % chance of success.

7. On 18 May 2005 Dr R.P., assisted by Drs C.D., V.S., and S.V., and by the specialist anaesthetist Dr D.C., performed the surgery and removed the tumour along with parts of the patient's pancreas, stomach and duodenum. The intervention lasted for some seven hours.

8. The tests run after the surgery showed that the tumour had been benign.

9. The applicant was placed in the intensive care unit under the supervision of Dr D.C. He remained there until his death.

The family was not officially allowed access to the intensive care unit until two days before the patient's death. For the first few days after the operation, the patient's general state was stable. However, his general health started to deteriorate and he developed a high fever. He was prescribed broad spectrum antibiotics, which were provided by his family, pending the results of further blood tests.

10. On 26 May 2005 blood tests were ordered and the results revealed the presence of two types of bacteria: klebsiella and meticillin-resistant staphylococcus.

11. Meanwhile, his health continued to deteriorate and he finally slipped into a coma. He was in this state when, on 27 May 2005, Dr R.P. operated on him again to remove an abscess and some blood clots which had formed after the first operation.

12. On 28 May 2005 the applicants spoke with the anaesthetist on duty, who – in Dr D.C.'s absence – acquainted them with the patient's real diagnosis and informed them of the type of surgery he had undergone on 18 May and of the suspicion of a bacterial infection.

On the evening of 28 May 2005 the patient died of septic shock and multiple organ dysfunctions; he was taken to the hospital mortuary.

13. The third applicant signed a discharge form provided by the hospital, which read:

> "... [we] request that no autopsy be performed as the cause of death is known and we have no complaints concerning the treatment and care provided by the medical and paramedical personnel."

14. The applicants collected the deceased's personal belongings and found that the medicine they had brought to the hospital had not been administered to the patient.

2. Complaints lodged with the College of Doctors

15. On 30 May 2005, while her father's body was still in the hospital mortuary, the second applicant brought the case to the attention of the College of Doctors. She sent her complaint to both the Bucharest branch and the National Chamber of the College, by e-mail and by normal post. She informed both associations that her father had contracted a bacterial infection while in the intensive care unit of the hospital and asked that an

autopsy be performed before the burial, which was scheduled for the following day.

16. The disciplinary committee of the Bucharest College of Doctors gave no reply to the request for an autopsy but opened an investigation into the patient's death, hearing evidence from the applicants and the doctors. It gave its decision on 12 October 2005, ruling that no medical errors had been made, but reprimanding Dr R.P. for his failure to seek the patient's consent before the surgery, as required by Law no. 46/2003.

17. The applicants objected to the committee's conclusions and their appeal was heard by the superior disciplinary committee of the National College of Doctors.

18. Drs S.V. and V.S. from the medical team that had performed the surgery on 18 May 2005 submitted written statements to the effect that together they had sought the patient's written consent before the intervention and that the consent form had been attached to the file. The statements were typewritten and identical. The head of the surgery department at the hospital submitted a written statement clarifying that no patients had been operated on in that period without a consent form being attached to their file. Dr I.P., a specialist doctor from a different hospital, was asked to comment on the treatment choices made by Dr R.P. He gave his opinion on 11 January 2006, stating that, in general, icterus was a condition that required surgical intervention under any circumstances, and that – according to the guidelines – the surgery performed in Mr I.M.'s case had presented a certain risk, but one that had not been increased by the patient's age; he also considered that the post-operative complication and ensuing death had fallen within the generally accepted risks for such an operation.

19. On the basis of the evidence presented, on 7 July 2006 the National College of Doctors terminated the disciplinary proceedings against Dr R.P. Relying on the two written statements given by the two doctors, the authority considered it established that the patient's consent had been obtained but that the consent form had been lost.

20. The second applicant lodged an action for the decision adopted on 7 July 2006 to be quashed, pointing out that Drs R.P. and D.C. (the anaesthetist) had disregarded the patient's rights and well-being in that they had failed to perform all the requisite tests before the operation, in particular an MRI scan, and had failed to inform either the patient or his family of the real diagnosis and the risks of the surgery and to obtain the patient's consent before the intervention; she also contended that the post-intervention care had been deficient. She reiterated that the patient had contracted a bacterial infection in hospital, which in her opinion had contributed to his death.

21. On 14 March 2007 the Bucharest County Court gave judgment in the case. It noted that a criminal investigation had taken place, that the medical experts consulted by the prosecutor had expressed the opinion that the

patient's death had not been caused by medical error, and that on the basis of that opinion the case had been closed (see paragraph 26 below). It therefore dismissed the applicants' action and upheld the decision of the National College of Doctors.

22. The second applicant appealed against the decision delivered by the County Court, but in a final decision of 23 November 2007 the Bucharest Court of Appeal dismissed the appeal and upheld the findings of the lower court.

3. Criminal complaint against the doctors

23. On 14 June 2005 the second applicant lodged a criminal complaint against the doctors who had treated her father, naming in particular the two surgeons Drs R.P. and C.D. and the anaesthetist, Dr D.C. They addressed their complaint to the prosecutor's office attached to the High Court of Cassation and Justice and the Bucharest military prosecutor's office. As the doctors were career officers, the military prosecutor took over the case and opened an investigation into involuntary manslaughter.

24. Dr R.P. gave a statement before the military prosecutor. He maintained that the patient's death had not been directly caused by the surgery and that it had been impossible to establish the cause of death beyond doubt as the family had refused an autopsy. Dr D.C. declared that the patient had received adequate treatment and his death had not been caused by medical negligence.

25. The prosecutor sought the advice of the Mina Minovici National Institute for Forensic Medicine ("the National Forensic Institute"), asking it to explain the nature and cause of death, whether the treatment had been appropriate to the diagnosis, whether there had been errors of medical practice and conduct (*erori de tehnică şi conduită medicală*) and, if so, how such errors had contributed to the patient's death.

26. On 6 September 2005 the National Forensic Institute issued an expert medical report regarding the case. It took into account the patient's medical log during his stay in the hospital and the opinion expressed in general terms about Mr I.M.'s condition by Dr B.M., a specialist surgeon at a different hospital from the one where the patient had been treated. It concluded that the cause of death had been multiple organ failure and sepsis occurring during the evolution of a post-surgical abscess. It considered that the treatment had been appropriately determined and administered and that there had been no medical errors at any stage (diagnosis, medical treatment, surgery and post-surgical care).

27. On the basis of the conclusions of the expert medical report, on 13 October 2005 the prosecutor decided not to prosecute Drs R.P. and C.D.

28. The first and second applicant objected to the outcome of the prosecutor's investigation. They pointed out, in particular, that the expert medical report had failed to examine the question of the bacterial infection

contracted in the hospital and that the prosecutor had not taken account of the absence of consent for the surgery.

29. On 8 December 2005 the Chief Prosecutor of the Bucharest Military Prosecutor's Office dismissed the above-mentioned complaints, finding, in particular, that the expert medical report had not confirmed the applicants' allegations.

30. The applicants lodged a complaint against that decision with the Bucharest Military Court; as they became more familiar with the expert medical report, they raised several objections to it and asked that the case be remitted to the prosecutor for further investigation. On 7 April 2006 the court dismissed their complaint as ill-founded, on the basis of the medical report of 6 September 2005.

31. The second applicant appealed against that decision. She contested the accuracy of the expert medical report, stating that Dr B.M. was not an accredited medical expert, and that the conclusions of the report were flawed. She requested that a new expert examination be carried out. She also complained that at the hospital the applicants had been informed of a diagnosis that was different from that appearing on the official documents presented by the hospital as evidence, and that it had only been on the basis of the erroneous diagnosis that her brother had signed the discharge form concerning the autopsy. In any case, she considered that her father's death had been suspicious, as it had followed what appeared to be a good recovery; moreover, since the presence of hospital bacteria had been identified, an autopsy should anyway have been performed with or without the family's endorsement. She also pointed out in this connection that as soon as they had become aware of the misrepresentation by the hospital, the applicants had appealed to the College of Doctors to demand an autopsy in the case.

The second applicant emphasised the absence of informed consent from either the patient or his family before the operation and pointed out that that failure on the part of the hospital had prevented them from making informed decisions, for instance seeking a second opinion from a specialist doctor.

32. In a final decision of 6 November 2006 the Bucharest Territorial Military Court dismissed the appeal. The court referred to the conclusions reached by the College of Doctors, which, in its opinion, had given an exhaustive account of the facts and was better placed than the courts to give a specialist opinion.

4. Complaint to the Ministry of Defence

33. On 30 May 2005 the second applicant forwarded to the Ministry of Defence a copy of the complaint she had sent to the College of Doctors on the same day. The Ministry of Defence was responsible for the administration of the hospital. Later on she expanded the complaint,

claiming that the hospital had also failed to provide the patient with clerical assistance when he was dying.

34. On 14 and 30 June 2005 the Medical Department of the Ministry of Defence replied to the second applicant's complaint. It informed her that the medical treatment given to her father had been adequate and that the surgery performed had fallen within the generally accepted range as regards the risk of complications and fatality, given the patient's age (seventy-three) and medical history. It also stated that the procedures for sterilisation of instruments in the hospital were in accordance with the existing guidelines and beyond reproach.

B. Relevant domestic law and practice

35. The Patients' Rights Act (Law no. 46/2003) expressly states that there is an obligation to inform a patient about any surgical intervention proposed, the risks involved in the surgery, alternative treatment, and the diagnosis and prognosis (Article 6). The Law also regulates the patient's right to seek a second medical opinion (Article 11).

According to Article 37 of the Act, a breach of a patient's rights may result in disciplinary or criminal action, depending on the applicable law.

36. The judgment delivered in *Eugenia Lazăr v. Romania* (no. 32146/05, §§ 41-54, 16 February 2010) describes in detail the relevant domestic law and practice concerning the delivery of expert forensic reports and the authorities competent to issue them, as well as the relevant domestic law and practice concerning the civil liability of medical staff.

37. Under Article 4 of the Hospital Act (Law no. 270/2003), the hospital has to ensure adequate standards of accommodation, hygiene and food as well as the prevention of hospital-acquired infections, in accordance with the regulations issued by the Minister of Health and Family. The hospital is liable for any damage sustained by patients as a result of the quality of the medical treatment or because of the standards of accommodation, hygiene, food and the prevention of hospital-acquired infections if such damage is established by the competent authorities. Under the same provision, where the damage is caused through medical fault, the liability lies with the person who committed the tort (*răspunderea este individuală*).

COMPLAINT

38. The applicants complained that Mr I.M. had met his death in a public hospital as a result of inaccurate diagnosis and inadequate medical care and that the investigation into his death had been ineffective, leaving them

without any means of obtaining redress for the loss incurred. They relied on Articles 2, 3, 6, 8 and 14 of the Convention.

THE LAW

39. Raising a series of arguments, the applicants complained about the circumstances surrounding Mr I.M.'s death in hospital and the investigations into his death. They relied on Articles 2, 3, 6, 8 and 14 of the Convention.

40. The Court, since it is master of the characterisation to be given in law to the facts, considers that the applicants' allegations should be examined solely under Article 2 of the Convention, which, in so far as relevant, reads:

> "1. Everyone's right to life shall be protected by law. ..."

A. The parties' arguments

1. The Government

41. The Government argued that the applicants had failed to observe the six-month time-limit in respect of proceedings before the College of Doctors. They further pointed out that it was only Ms C.M., the second applicant, who had pursued the actions at domestic level and therefore she alone had the standing to bring the present application before the Court. They also argued that the applicants had failed to bring a complaint against the hospital under the Hospital Act, whereby a hospital could be held liable – under the general tort law conditions (Articles 998-999 of the former Civil Code) – for damage sustained by patients.

42. On the merits, the Government contended that since 2007 the Ministry of Health had run national programmes for the prevention of hospital infections. Moreover, under the Hospital Act and the ensuing regulations, hospitals were obliged to take specific measures to address the danger of nosocomial infections. Such a risk could only be reduced, however, and never completely eliminated. They pointed out that the applicants had not raised any specific issue of deficiency in this area and that – in so far as the treatment administered to Mr I.M. was concerned – the nosocomial infection had been properly addressed.

43. They further argued that by refusing to have an autopsy performed, the applicants had created a crucial obstacle to ascertaining the circumstances of Mr I.M.'s death. Furthermore, despite their initial refusal, the autopsy could still have been performed should they subsequently have indicated that wish to the hospital. In any event, the medical opinions

concurred as to the necessity for surgery, the adequacy of the treatment administered and the cause of death.

2. The applicants

44. The applicants contested the Government's objection of failure to comply with the six-month rule. They also argued that the Government's assertions concerning *locus standi* implied excessive formalism in the application of the Convention rules. They had all suffered as a result of Mr I.M.'s death and were all equally interested in finding its cause and apportioning responsibility for his death. They had started the domestic proceedings together and although they had not all signed the subsequent procedural documents, they continued to act together in taking their decisions as a family. They further disputed the Government's allegations concerning the non-exhaustion of domestic remedies.

45. On the merits the applicants contended that neither the proceedings before the College of Doctors nor those before the prosecutor had been effective. They reiterated that the patient had been operated on without his prior informed consent and that the bacterial infection had not been properly dealt with by the hospital. Furthermore, they pointed out that in their complaints to the authorities they had raised the matter of the nosocomial infection and had disproved the Government's argument that the risk of infection could not be completely eliminated.

B. The Court's assessment

46. The Court notes that the Government raised several objections. However, it considers that there is no need to examine them separately, in so far as the application is in any case inadmissible for the reasons explained below.

47. The Court reiterates that the positive obligations enshrined in Article 2 of the Convention require States to make regulations compelling hospitals, whether public or private, to adopt appropriate measures for the protection of their patients' lives. They also require an effective independent judicial system to be set up so that the cause of death of patients in the care of the medical profession, whether in the public or private sector, can be determined and those responsible be held accountable (see, among other authorities, *Calvelli and Ciglio v. Italy* [GC], no. 32967/96, § 49, ECHR 2002-I; *Vo v. France* [GC], no. 53924/00, § 90, ECHR 2004-VIII; *Eugenia Lazăr*, cited above, § 66-71; and *G.N. and Others v. Italy*, no. 43134/05, §§ 69, 80 and 81, 1 December 2009). However, if the violation of the right to life or personal integrity is not perpetrated intentionally, the positive obligation imposed by Article 2 to set up an effective judicial system does not necessarily require the provision of a criminal-law remedy in every case. In the specific sphere of medical

negligence the obligation may, for instance, also be satisfied if the legal system affords victims a remedy in the civil courts, either alone or in conjunction with a remedy in the criminal courts, enabling any liability on the part of the doctors concerned to be established and any appropriate civil redress, such as an order for damages and the publication of the decision, to be obtained. The imposition of disciplinary measures may also be envisaged (see *Calvelli and Ciglio*, cited above, § 51).

48. Turning to the facts of the case under consideration, the Court notes that, following a medical procedure performed by Drs R.P., C.D., V.S., S.V. and D.C. and the ensuing intensive care, Mr I.M. lost his life in the hospital.

49. When they were apprised of the patient's hospital record, the applicants contested the adequacy of the medical care received and requested that the real cause of death be properly established. They took three actions to that effect: a disciplinary complaint lodged with the College of Doctors, a criminal complaint lodged with the prosecutor and a request submitted to the Ministry of Defence. At no point, either before the domestic courts or before the Court, did they claim that the death had been inflicted intentionally on the patient.

50. The Court notes that the two sets of adversarial proceedings (disciplinary and criminal) took place in parallel. Each set of proceedings took into account the findings of the other and their conclusions were consistent. Moreover, the conclusions of the medical opinions and of the forensic report adduced before the respective courts consistently confirmed the adequacy of the medical care as regards both the surgery and the post-surgical treatment, and ruled out any medical negligence. Both the prosecutor's decision and the College of Doctor's decision were based on these medical opinions as well as on other evidence (notably oral and written statements from those concerned). The position expressed independently by the Ministry of Defence also concurred regarding the adequacy of the medical care and absence of negligence. The unfavourable outcome for the applicant does not suffice to find the respondent State liable under its positive obligations arising from Article 2 of the Convention (see *Sevim Güngör v. Turkey* (dec.), no. 75173/01, 14 April 2009).

51. It is true that the objections raised by the applicants concerning the presence of hospital bacteria were never sent to the National Forensic Institute. However, those arguments were formulated in the initial complaints and, in preparing their medical opinion, the experts took into account the entire medical file, which contained information on the presence of the nosocomial infection and the treatment administered by the doctors, thus also including what was done to address the infection. There are no grounds to presume that the presence of hospital bacteria was ignored by the experts in their opinions.

52. The Court accepts that the presence of bacteria could be examined from the standpoint of the adequacy of the procedures put in place by the

hospital to deal with nosocomial infections. In their letter to the applicants, the Ministry of Defence specifically addressed the matter (see paragraph 34 above). The applicants did not contest that answer, nor did they lodge a separate action in tort against the hospital. The Court reiterates that the purpose of an action in tort is primarily to establish liability and not only to offer pecuniary redress (see *Rădulescu v. Romania* (dec.), no. 29158/05, § 49, 7 May 2013). Where it is questionable whether the applicants could have obtained a new expert opinion concerning Mr I.M.'s death (see *Eugenia Lazăr*, cited above, § 90), the Court observes that the presence of a nosocomial infection was not refuted by any of the medical opinions issued in the case. Therefore there was enough evidence for a civil court to examine the merits of a separate action in tort against the hospital.

53. Moreover, given the promptness which with the criminal investigation was conducted (one year and five months in all), the action in tort had not been time-barred at the time when the proceedings instigated against the doctors ended.

54. Lastly, the applicants complained about the alleged failure to obtain consent from the patient. The Court has emphasised that it is important for individuals facing risks to their health to have access to information enabling them to assess those risks. It has considered it reasonable to infer from this that the Contracting States are bound, by virtue of this obligation, to adopt the necessary regulatory measures to ensure that doctors consider the foreseeable impact of a planned medical procedure on their patients' physical integrity and to inform patients of these consequences beforehand in such a way that the latter are able to give informed consent. In particular, as a corollary to this, if a foreseeable risk of this nature materialises without the patient having been duly informed in advance by doctors, the State Party concerned may be held directly liable under Article 8 for this failure to provide information (see *Trocellier v. France* (dec.), no 75725/01, § 4, ECHR 2006-XIV; *Vo*, cited above, § 89; *Codarcea v. Romania*, no. 31675/04, § 105, 2 June 2009; and *Pretty v. the United Kingdom*, no. 2346/02, § 63, ECHR 2002-III). The Court has also found it unacceptable that an operation could be performed without observing the rules and the safeguards created by the domestic system itself in this respect (see *Csoma v. Romania*, no. 8759/05, § 57, 15 January 2013).

55. In the present case, the domestic courts investigated the matter of the existence of prior consent and considered that, although the consent form was missing from the patient's file, that absence was compensated by the two written statements made by doctors from the medical team that had operated on the patient. The Court defers to the findings of the domestic authorities, which are ultimately better placed to assess the matter.

56. In the light of the above, the Court finds no indication in the circumstances of the present case that there has been a failure by the respondent State to provide a mechanism to establish whether there was any

criminal, disciplinary or civil liability on the part of the hospital or of the medical staff involved in the patient's treatment.

It follows that the application must be rejected as being manifestly ill-founded within the meaning of Article 35 §§ 3 and 4 of the Convention.

For these reasons, the Court unanimously

Declares the remainder of the application inadmissible.

Santiago Quesada
Registrar

Josep Casadevall
President