Operation and transfusion performed without patient consent

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Case Reports

A significant judgment of the European Court of **Human Rights**

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 Klinik für Anästhesiologie, Intensivmedizin und Schmerztherapie Goethe-Universität Frankfurt Universitätsmedizin Frankfurt Theodor-Stern-Kai 7 60590 Frankfurt (Direktor: Prof. Dr. K. Zacharowski) On September 17, 2024, the European Court of Human Rights (ECHR) in Strasbourg delivered a decisive and groundbreaking judgment that significantly strengthens a patient's right to self-determination and personal autonomy.

Summary

Pindo Mulla v. Spain [GC], no. 15541/20, 17 September 2024

Time line

- May 2017: Mrs. Pindo Mulla diagnosed with uterine fibroid. Hysterectomy recommended.
- August 2017: In anticipation of surgery, she completed a Durable Power of Attorney refusing blood transfusions (DPA) and a similarly worded Advance Medical Directive (AMD).
- June 6, 2018, admitted to hospital in Soria, Spain, with bleeding from uterine fibroid. Doctors recommended blood transfusion; her refusal was recorded in her hospital
- June 8, 2018: transferred to Madrid hospital. During transfer, Madrid doctors applied to the judge for permission to impose blood transfusions. This was done although she was an adult, was fully conscious (GCS 15) and had repeatedly refused blood transfusions both orally and in writing by way of her DPA and AMD.
- The judge granted the Madrid doctor's request, without attempting

to speak with Mrs. Pindo Mulla or consulting her DPA or AMD (which were available in the national registry of advance directives) or her hospital records.

Ruling of the Grand Chamber

The 17 judges unanimously concluded that Mrs. Pindo Mulla's rights to autonomy, self-determination, and freedom of religion had been violated. Court concluded that:

- "the competent, adult patient has the right to refuse, freely and consciously, medical treatment notwithstanding the very serious, even fatal, consequences that such a decision might have. It is a cardinal principle in the sphere of health care that the right of the patient to give or withhold consent to treatment has to be respected" (para. 146)
- "the public interest in preserving the life or health of a patient must yield to the patient's interest in directing the course of his or her own life" (para. 148)
- "wishes of the patient must be treated as being of paramount importance" (para. 149)
- "it is important that [advance directive legislation] functions effectively to achieve its purpose." (para. 156)

Effect of Grand Chamber Judgment

Is binding on all 46 countries of the Council of Europe, which includes:

All countries of the European Union

Competing interests

The author declares no competing interests.

Kevwords Power of Attorney - ECHR

- All countries in mainland Europe (up to and including the Republic of Türkiye; does not apply to Russia)
- Malta
- The United Kingdom

Background

In 2017, Mrs. M. was diagnosed with a uterine myoma. The doctors recommended a hysterectomy and bilateral salpingectomy. The patient, a Jehovah's Witness, informed the doctors of her refusing blood transfusions. In the event she became incapable, she had also completed an advance medical directive stating that she objected to blood transfusion; that advance medical directive was registered in Spain's national registry of advance directives and was available to the doctors. In June 2018, Mrs. M.'s condition worsened to the point where she went to the local hospital in Soria. Within two days, her Hb level dropped to 4.7 g/dl. However, the hospital report noted that treatment with tranexamic acid was effective. The doctors decided to transfer the patient to La Paz University Hospital in Madrid to assess treatment with uterine artery embolization. The report indicates that there were no signs of bleeding at the time of transfer. Mrs. M. agreed to the transfer to La Paz University Hospital, believing that the bleeding could be arrested there without blood transfusion by means of uterine fibroid embolization, a well-established, effective, and minimally invasive treatment. During the transport, the patient was conscious, oriented, and responsive. Shortly after the transport began, there was a phone contact between a doctor at La Paz University Hospital and the accompanying doctor in the ambulance. The latter warned of the severity of the patient's condition. Mrs. M. informed the doctor at La Paz of her stance on blood

Three doctors from La Paz University Hospital then contacted the duty judge (juez de guardia) of the court (Juzgado de Instrucción) in Madrid. They informed him that a patient, who was a Jehovah's Witness, was being transferred

transfusions.

to La Paz University Hospital and incorrectly claimed that she would refuse all types of treatment. However, they did not inform the duty judge of the patient's identity or the fact that she was fully conscious and alert, had refused blood transfusions only, and had a legally valid advance medical directive which she had also registered in Spain's registry of advance directives. The duty judge informed the doctors after an hour that the necessary medical-surgical measures should be taken to protect the patient's life.

Upon arrival at the La Paz University Hospital, the patient was still responsive and conscious. She was not informed of the court order. Since the situation was classified as a medical emergency, the usual procedure for obtaining consent before surgical interventions was not followed. Mrs. M. still believed she would undergo uterine artery embolization without being informed of the nature of the upcoming procedure planned by the doctors. A hysterectomy and bilateral salpingectomy were performed without her knowledge or consent. During the operation, there was significant bleeding, and three units of packed red blood cells were administered.

The patient was only informed of the court order, hysterectomy, and blood transfusions the next day.

Medical Aspects

Since the patient was stable and responsive upon arrival at La Paz University Hospital and was not in hemorrhagic shock, there was no need to start the operation immediately. Mrs. M. should have been asked for her consent to hysterectomy and salpingectomy, especially since a hysterectomy carries the risk of significant blood loss. Moreover, she had been led to believe that La Paz University Hospital could perform uterine fibroid embolization. The patient would most likely not have consented to hysterectomy and its associated risks. The blood transfusions administered after the blood loss of 1,200 ml could have been avoided if a cell salvage device had been used to mitigate surgical blood loss. However, a more reasonable and safer option under these circumstances would have been to perform uterine artery embolization, if tranexamic acid or other agents (for example, high-dose contraceptives, progesterone, gonadotropin-releasing hormone) had not been effective enough.

Since there were apparently no signs of bleeding, it would have been more appropriate to optimize her tolerance of anemia while continuing to carefully monitor her in the following hours and days. Appropriate pharmacological agents such as intravenous iron and erythropoietin and, if necessary, vitamin B12 and folic acid should have been administered to accelerate hematopoiesis. Concomitantly, the volume and frequency of diagnostic blood tests should have been strictly limited. Although her hemoglobin level was low, the clinical picture confirmed that the patient compensated for this adequately, she was well oxygenated, her vital signs where within normal limits, and there was no evidence of organ dysfunction.

Legal Dispute

Before the relevant courts in Spain, Mrs. M. contested the reasoning behind the decision of the duty judge, stating that it was based on a unilateral request from the hospital in Madrid without consulting her and that the duty judge was not even informed of her identity. She argued that the facts had been distorted, as it had been assumed that she refused any form of treatment for her condition. There had been only one specific treatment she had refused – blood transfusion. She claimed that her patient autonomy and right to self-determination had been violated.

After her appeal was declared inadmissible by the Spanish Constitutional Court, the plaintiff complained before the ECHR, relying on Articles 8 and 9 of the European Convention on Human Rights, that her refusal of blood transfusion had been overruled by the national authorities.

She also submitted two expert medical opinions to the ECHR. Both opinions concluded that the complainant's life had not been in immediate danger based on the information in her medical record.

According to the evidence, the experts determined that her situation had been stable at the time of her arrival at La Paz University Hospital and that they saw no basis in the medical record to assume

that her mental clarity or capacity to make decisions had been impaired at that time. They stated that it would have been possible to treat her effectively according to her wishes without resorting

Convention for the Protection of Human Rights and Fundamental Freedoms

Article 8

Everyone has the right to respect for his private and family life ...

Article 9

Everyone has the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief and freedom, either alone or in community with others and in public or private, to manifest his religion or belief, in worship, teaching, practice and observance.

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine – The Oviedo Convention

Article 5

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

Article 9

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

Charter of Fundamental Rights of the European Union

Article 3

Everyone has the right to respect for his or her physical and mental integrity. In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law.

Universal Declaration on Bioethics and Human Rights was adopted by UNESCO's General Conference

Article 5

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected.

Article 6

Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information.

From the judgment of the ECHR, Application no. 15541/20, September 17, 2024

140. [...] the freedom to accept or refuse specific medical treatment [is] vital to self-determination and personal autonomy. A competent adult patient [is] free to decide on surgery or medical treatment, including blood transfusion.

146. [...] the competent, adult patient has the right to refuse, freely and consciously, medical treatment notwithstanding the very serious, even fatal, consequences that such a decision might have. It is a cardinal principle in the sphere of health care that the right of the patient to give or withhold consent to treatment has to be respected.

149. [...] the wishes of the patient must be treated as being of paramount importance.

151. The Court refers to Article 9 of the Oviedo Convention, according to which the previously expressed wishes of a patient who is not, at the time of the intervention, in a position to express his or her wishes "shall be taken into account".

156 [...] where a system has been put in place [recognizing the binding effect of advance medical directives] ... and it is relied on by patients who made use of it correctly, it is important that it functions effectively to achieve its purpose.

Why Don't Jehovah's Witnesses Accept Blood Transfusions?

The refusal of blood in connection with medical treatment results from a religious conviction based on Bible passages such as Genesis 9:4 and Acts 15:29. Resulting from that imperative of faith, Jehovah's Witnesses refuse the intravenous administration of whole blood and its components (erythrocytes, thrombocytes, leucocytes, and plasma). Whether or not a Jehovah's Witness accepts derivatives of the stated blood components (e.g., coagulation factors, prothrombin complex, immunoglobulins and albumin) depends on his individual conscience.

Further information on this issue can be found in the article:

- https://www.jw.org/en/jehovahs-witnesses/faq/jehovahs-witnesses-why-no-blood-transfusions/
- and in the article: Steuer/Dreuw, "Hemotherapy and Faith," in Religion Staat Gesellschaft, 2016, Issue 1–2, pages 203–233.
- An ethical and legal presentation can be found in the Ethics Guideline for the Treatment of Jehovah's Witnesses and Their Children, 2015. https://ethikkomitee.de/downloads/ethikleitlinie-zj-deutsch.pdf
- On the following website of Jehovah's Witnesses
 https://www.jw.org/en/medical-library/
 citations of peer-reviewed articles from leading medical journals that present clinical strategies to preempt allogeneic blood transfusions can be found.

to a blood transfusion. A public hearing before the ECHR took place on January 10, 2024, in Strasbourg.¹

Based on the fundamental rights mentioned in the box, the ECHR concluded: "In the Court's view, the shortcomings identified above ... indicate that the interference complained of was the result of a decision-making process which, as it operated in this case, did not afford

sufficient respect for the applicant's autonomy as protected by Article 8, which autonomy she wished to exercise in order to observe an important teaching of her religion. It follows that in the applicant's case her right to respect for private life under Article 8 of the Convention, read in the light of Article 9, has been violated."²

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¹ See video https://www.echr.coe.int/w/pindo-mulla-v-spain-no-15541/20-

² Judgment of the ECHR, Application no. 15541/20, September 17, 2024, 183, 184. The judgment, a legal summary of the ECHR, and the video of the hearing can be found at https://hudoc.echr.coe.int/eng#{%22itemid%22:[%22002-14378%22]}