

Medically Assisted Procreation in Malta: Consent, Autonomy and Regulation

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This article by **Amber Camilleri** was previously submitted as part of MCT2001 and is being published with the author's permission. This article delves into Maltese medical jurisprudence concerning patient consent, specifically focusing on procedures related to Medically Assisted Procreation. It examines the legal and ethical requirements for obtaining informed consent from prospective parents, highlighting its importance as a cornerstone of medical practice and patient autonomy in Malta. It additionally outlines the rights and responsibilities of all involved parties, including the prospective parents, medical practitioners, and the State through regulatory bodies like the Embryo Protection Authority. The article also details how Maltese legislation, such as the Embryo Protection Act, governs procedures, restricts practices like surrogacy, and mandates detailed written consent, ultimately balancing patient choice with ethical and legal boundaries.

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Introduction

Consent is known to be a universal cornerstone of medical practice. As a whole, it embodies the principle of respect for both an individual's physical and mental autonomy. In the realm of Medically Assisted Procreation (MAP), this concept of consent takes on an even greater significance, delving into deeply personal decisions made by the prospective parent or parents. In Malta, the legal framework surrounding MAP and patient consent is shaped by a unique mixture of cultural, religious, and ethical values, making it a particularly compelling topic to explore within the medical field.

This article delves into the broader scope of Maltese medical jurisprudence on consent, whilst also focusing on the specific context of MAP procedures. It aims to outline the rather intricate web of rights and responsibilities that bind the parties involved: the prospective parent(s), medical professionals, and ultimately the state. In doing so, this article will be examining key aspects of the Ethics of the Medical Profession Regulations, the Embryo Protection Act (EPA), and broader bioethical frameworks in order to highlight exactly how these principles safeguard the autonomy and dignity of prospective parent(s). By unpacking these elements, the discussion will shed light on how Maltese law seeks to balance the interests of all parties involved all whilst respecting ethical boundaries.

Foundations of Informed Consent in Medical Law

Consent is a critical aspect of a medical practitioner's duty, as highlighted in the Public Health Act, which defines consent as 'approval given by an individual without any force, fraud or threat'.¹ A patient's consent is generally a fundamental requirement for establishing a legal relationship between patients and medical practitioners.² Practitioners must ensure that consent is obtained legitimately since any form of coercion, fraud, or undue influence would render it invalid. Additionally, the improper disclosure of confidential information not in compliance with local legal requirements, would contravene the provisions outlined in the Ethics of the Medical Profession Regulations. Such violations could result in legal liability for unlawfulness or negligence.

Consent must also be given by a patient who has the capacity to do so, and it must be informed, meaning the patient should have access to sufficient information to make an educated decision. This principle aligns with the Charter of Patient Rights and Responsibilities, which explicitly states that

¹ Public Health Act, Chapter 465 of the Laws of Malta, Article 2.

² Daniel Bianchi, *Medical Law in Malta* (Wolters Kluwer 2023).

patients, including a prospective parent or prospective parents, must be given 'all information relative to a treatment or an operation to be undergone, including the associated risks and discomforts, side-effects and alternatives'.³ Furthermore, these principles are embedded in international bioethical standards, such as the Council of Europe's Convention on Human Rights and Biomedicine, whose Article 5 stipulates that 'an intervention in the health field may only be carried out after the person concerned has given free and informed consent'.⁴

Generally, adults are presumed capable of consenting unless specific circumstances prevent them from doing so.⁵ One such circumstance is a mental disability, which may hinder an individual's capacity to comprehend or process the necessary information to make an informed decision.⁶ Another is a physical condition that temporarily impairs consciousness, such as being in a coma caused by disease, trauma, or the influence of drugs.⁷ These factors align with the fundamental right of every individual to have control over what happens to their own body no matter what.

Historically, medical practitioners tended to take decisions on behalf of their patients, but modern practices emphasise respecting patient autonomy, making both the acceptance and refusal of consent essential. Additionally, while implied consent is sometimes applicable in specific medical situations, the Ethics of the Medical Profession Regulations underscore that consent should 'preferably be given in writing'. This reinforces how important written and tangible consent truly is in the context of ethical and legal standards.⁸

Link of Consent within MAP

This principle of consent extends to MAP procedures. In this context, consent involves a multidimensional understanding of medical, ethical, and legal aspects of the procedure. MAP in Malta is primarily regulated by the EPA, which governs various aspects of Assisted Reproductive Technologies (ARTs). The EPA requires informed consent as a prerequisite for any procedure: 'The consent of the prospective parent or parents who are to have access to MAP procedures is to be expressed in writing'.⁹ The Act even

³ Giuseppe Cotturi, Stefano A Inglese, Giovanni Moro, Charlotte Roffiaen and Consuelo Scattolon, 'European Charter of Patients' Rights Basis Document' (2022)

<https://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_co108_en.pdf> accessed 23 December 2024.

⁴ Council of Europe, '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 (Oviedo, 4 April 1997) ETS No 164.

⁵ Maurice N Cauchi, Kevin Aquilina and Bridget Ellul, *Health, Bioethics and the Law* (Malta University Press 2006).

⁶ *ibid.*

⁷ *ibid.*

⁸ Ethics of the Medical Profession Regulations, S.L. 464.17, Regulation 22.

⁹ Embryo Protection Act, Chapter 524 of the Laws of Malta, Article 18.

lists, in detail, the information that must necessarily be provided by the medical practitioner regarding the procedure, thereby ensuring that prospective parent(s) fully understand and voluntarily agree to all aspects of the treatment.¹⁰ The Act explicitly prohibits practices such as surrogacy, embryo donation, and the use of embryos for research or commercial purposes.¹¹ Furthermore, the EPA, in Article 6(b), restricts the fertilisation of more than two ova during any given cycle to address ethical concerns related to the creation and storage of surplus embryos.

Key Rights and Responsibilities of Prospective Parent(s)

Prospective parents, individuals or couples seeking access to MAP in Malta bear significant rights and responsibilities in the consent process. These rights and responsibilities include understanding the procedure, autonomy in their decision-making, joint consent as well as ethical considerations by said parent(s).

Prospective parent(s) must ensure they have a thorough understanding of the serious procedures involved in MAP, including in-vitro fertilisation (IVF) and other ARTs. They must understand the risks associated with the procedures, including the possibility of multiple births, the potential health risks to both the woman and child, and the chance of treatment failure.¹² They must take into account the legal implications of embryo creation, cryopreservation, and donation, including the implications for filiation and the potential for legal disputes.¹³

They must understand and consent to the implications of cryopreservation, including the options available if a gamete provider dies or becomes mentally incapacitated. This includes the possibility of embryo adoption and the legal framework surrounding it. Additionally, the prospective parent(s) must make informed decisions regarding the fate of supernumerary embryos, choosing between cryopreservation, donation for adoption, or allowing them to perish.¹⁴ The EPA emphasises minimising the creation of supernumerary embryos by limiting the number of fertilised eggs based on the prospective parents' consent to cryopreservation.¹⁵ If consent for cryopreservation is given, it can be withdrawn in writing before fertilisation. However, once fertilisation has occurred, the resulting embryos are protected by law, and prospective parent(s) cannot withdraw their consent for cryopreservation.

¹⁰ *ibid.*

¹¹ *ibid.*

¹² *ibid.*

¹³ *ibid* Article 9.

¹⁴ Daniel Bianchi (n 2).

¹⁵ Embryo Protection Act (n 9).

Furthermore, they must understand the legal and ethical implications of third-party gamete donation, including the confidentiality agreements involved and the absence of a filiation link between the donor and the resulting child. It is imperative for prospective parent(s) to not hold back and participate actively by asking questions and seeking clarification to fully understand the scientific and procedural aspects of MAP.

As for autonomy in their decisions, this is a known fundamental right of prospective parent(s). In Maltese legislation, the Constitution itself protects the right of personal freedom and the right of decision-making, which includes decisions about medical procedures like MAP.¹⁶ It is essential that prospective parent(s) can make these choices freely, without any external pressure from others. This idea also connects to international human rights laws, such as the European Convention on Human Rights, which heavily focuses on respecting individual autonomy.

In cases involving couples, joint consent is not only an ethical requirement but also a legal obligation under the EPA, explicitly stating that 'where the prospective parents are married or in a stable relationship, their consent shall be expressed jointly in writing in the prescribed form'.¹⁷ This makes sure that both partners are in agreement on moving forward with MAP, showing the shared responsibility in their future parenthood.

Key Duties and Obligations of Medical Practitioners

As previously mentioned, the EPA mandates that, prior to performing any procedure related to MAP, the responsible medical practitioner must provide the prospective parent(s) with detailed written information, which information must be observed as clear, comprehensive, and truthful. This obligation bestowed on the medical practitioner is not merely ethical but also legal, rooted in professional regulations such as the Ethics of the Medical Profession Regulations and the Health Care Professions Act.

Practitioners are reasonably expected to adhere to the highest standards of professionalism, ensuring that their patients are neither coerced nor misled. Informed consent is therefore, not a one-time event but rather a dynamic process of both communication and clarification. In adhering with these standards, medical practitioners must inform prospective parent(s) about the options available if a person providing gametes or embryos either dies or becomes mentally incapacitated. Furthermore, medical practitioners have a responsibility to respect the special status of the embryo, which includes a prohibition on wilfully causing the death of said embryo.¹⁸

Medical practitioners must ensure that MAP procedures are only

¹⁶ Constitution of Malta, Article 32.

¹⁷ Embryo Protection Act (n 9).

¹⁸ Embryo Protection Act (n 9) Article 16.

performed when there is a reasonable chance of success and do not pose undue risks to the health of the woman or child. This includes the consideration of the age of the prospective parent. The protocol established by the Embryo Protection Authority sets the maximum permissible age for embryo transfer at 48 years old.¹⁹ The issue of consent is an important consideration in the debate surrounding the imposition of this maximum age limit for access to MAP. While medical evidence may justify these restrictions, it is important to consider whether such measures adequately balance the state's objectives with the rights of individuals to make informed and autonomous decisions relating to their private and family life, as stipulated by Article 8 of the European Convention on Human Rights.

The legal obligations of medical practitioners evidently intersect with the concepts of confidentiality and professional secrecy. The Embryo Protection Authority (Protocol) Regulations also outline guidelines on the handling of sensitive information regarding patients. For instance, medical practitioners must discuss with patients the extent to which their information may be shared with other members of the multidisciplinary team who are involved in the procedure. While the usual position is to maintain confidentiality, there are certain instances where disclosure may be necessary. More specifically, the regulations emphasise that 'absolute confidentiality is inappropriate' in cases of suspected abuse.²⁰ In addition, they state that informed consent should generally be sought before disclosing confidential information. However, if obtaining consent is not possible, it may still be necessary to share such information 'in the best interest of the individual'.²¹ The disclosure should be limited to what is essential and shared only with the Embryo Protection Authority or law enforcement, strictly on a need-to-know basis.²²

The ethical considerations in MAP, within the legal relationship between a patient and a medical practitioner, are two-fold. This, in turn, means that the ethical considerations apply not only to the patient but also to the medical practitioner, as exemplified by situations in which a health care professional may be exempted from participating in procedures related to MAP on grounds of conscience.²³ However, it is important to note that this exemption does not apply to providing assistance before or after these procedures. While this exemption protects the practitioner's autonomy and moral beliefs, it does not absolve them of their professional responsibility to assist the patient in accessing care before or after the procedure.

¹⁹ Embryo Protection Authority, 'Protocol' (3rd edn, 2022) <<https://embryoprotectionauthority.gov.mt/wp-content/uploads/2023/12/Protocol.pdf>> accessed 26 December 2024.

²⁰ *ibid.*

²¹ Embryo Protection Act (n 9).

²² Daniel Bianchi (n 2).

²³ Embryo Protection Act (n 9) Article 20.

Role of the State and Regulatory Bodies

As one can see, regulatory oversight plays a crucial role in upholding the ethical and legal standards of the consent process. The Embryo Protection Authority, established under the EPA, oversees compliance with these standards. It ensures that medical practitioners and facilities adhere to the stipulated requirements, such as the provision of detailed information and the significant documentation of informed consent. The Authority also addresses ethical dilemmas that may arise, such as the use of donated gametes or embryos, ensuring that these practices align with the moral and legal principles which are found in Malta.

Furthermore, the Authority has the power to intervene in cases where malpractice or ethical breaches are suspected, thereby reinforcing the accountability of medical practitioners and safeguarding the rights of prospective parent(s) and their potential child. External sources, such as the European Society of Human Reproduction and Embryology, corroborate the importance of regulatory frameworks in MAP, noting that such oversight fosters adherence to the best and most efficient international practices.²⁴

Maltese law also addresses scenarios involving individuals who may lack the capacity to provide informed consent. For instance, in cases where prospective parent(s) have impaired decision-making abilities, substitute decision-makers may be appointed to act on their behalf. This process follows the stipulations of the Mental Health Act and the Civil Code, which each establish the criteria and mechanisms for determining any incapacity. Under the Civil Code, individuals over the age of 18 who are unable to manage their affairs due to mental or physical conditions may be interdicted or incapacitated through a court decree.²⁵ The Mental Health Act further specifies that only a psychiatrist can certify an individual as lacking capacity, and such certification must be documented and approved by the Commissioner for Mental Health if it exceeds 14 days.²⁶ These substitute decision-makers, often appointed by the court, are obligated to act in the incapacitated individual's best interests while considering their previously expressed wishes and preferences.²⁷

Disputes and Incidents

Addressing disputes or withdrawal of consent is another critical area within the Maltese framework for MAP. Disputes may arise when one partner in a couple wishes to proceed with or withdraw from a treatment plan, particularly in cases involving the use of cryopreserved embryos or

²⁴ ESHRE, 'Embryo Transfer' (*eshre*) <<https://www.eshre.eu/Guidelines-and-Legal/Guidelines/Embryo-transfer>> accessed 26 December 2024.

²⁵ Civil Code, Chapter 16 of the Laws of Malta, Article 188A.

²⁶ Mental Health Act, Chapter 525 of the Laws of Malta, Article 24.

²⁷ *ibid* Article 26.

gametes. Maltese legislation under the EPA provides that the written consent of both parties is required before proceeding with MAP procedures. If one party chooses to withdraw consent, the process must halt immediately, regardless of the stage of treatment. thus, ensuring that both individuals' autonomy is respected and upheld.

In cases of disputes between parties, the courts may intervene to mediate and resolve conflicts, particularly when the interests of a potential child are at stake. Maltese jurisprudence emphasises balancing the rights of all parties involved, including the prospective parent(s) and the potential child. For example, if one partner seeks to use cryopreserved embryos against the wishes of the other, the court examines the original terms of consent and the ethical considerations to determine the outcome.

While direct case law on this exact scenario in Malta is limited, international precedents highlight the complexities of consent in IVF. For instance, in the case of *Evans v The United Kingdom*, the European Court of Human Rights upheld the principle that either party can withdraw consent at any stage of the IVF process, leading to cessation of the treatment.²⁸

MAP is further complicated by incidents that highlight systemic shortcomings in adherence to regulatory protocols. The EPA explicitly requires that written consent be obtained from all parties involved before any MAP procedure is initiated. Yet, incidents reported by the Embryo Protection Authority show rather significant breaches of this very principle.

For example, in 2020, there was a case at the MDH ART Clinic where a cryopreserved embryo was thawed and arrested without the proper approval from the Embryo Protection Authority.²⁹ More serious than this, the couple's consent forms had not even been signed before the procedure took place as the clinic claimed they had planned to get them signed after the fact. This clearly went against the law and the basic idea of informed consent.

Based off of further investigation, this was not the only issue at the clinic. Two more incidents occurred during patients' third IVF cycles. The Embryo Protection Authority determined these were not merely accidental oversights but deliberate actions, reflecting a disregard for regulatory governance. As a consequence, the clinic was fined €10,000, and its responsible personnel were reminded of their duty to ensure clear accountability with the law.

Similar problems were reported at a private facility, such as the St. James Conception Unit. In one case, a consultant scheduled an IVF procedure without sending the required paperwork, test results, or patient consent to

²⁸ *Evans v United Kingdom* App no 6339/05 (ECtHR, 10 April 2007).

²⁹ Embryo Protection Authority, 'Annual Work report: Trends and Figures of Fertility Treatments in Malta for 2020' (2021) <https://embryoprotectionauthority.gov.mt/wp-content/uploads/2023/12/Annual_Report_2020.pdf> accessed 27 December 2024.

the Embryo Protection Authority. Without these essential details, the Embryo Protection Authority could not approve the procedure. This in turn left a lot of questions unanswered, like how many oocytes (eggs) the patient had agreed to fertilise. It is not possible for the Embryo Protection Authority to approve procedures without clarity on what the patient has agreed to before the fact.

Concluding Remarks

Ultimately, informed consent is not just a legal obligation. It is a reflection of respect for human dignity and autonomy. The Maltese legal framework for MAP aims to ensure fairness and transparency for all parties involved. By emphasising shared decision-making and holding practitioners accountable, the system protects prospective parents whilst simultaneously upholding ethical standards. However, the aforementioned incidents do show that there is room for improvement in enforcing these safeguards which is absolutely imperative for such sensitive procedures.



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