

## EDITORIAL

# At the heart of life: the Italian National Transplant Centre's enduring commitment

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Organ and tissue transplantation is a medical miracle, a testament to human solidarity and scientific advancement. At the core of Italy's successful transplant program lies the Centro Nazionale Trapianti (CNT), or National Transplant Centre, established by Law 91/1999 and housed within the Istituto Superiore di Sanità (ISS). The CNT coordinates and supervises all activities related to the donation, allocation and transplantation of organs, tissues, and cells across the national territory, as central authority ensuring the safety, quality, transparency, and traceability of the entire process, upholding an impartial vision that prioritizes the needs of patients suffering from end-stage organ failure.

CNT's general activities are broad, encompassing the technical, scientific, and organizational oversight of the Italian Transplant Network, made up of regional and autonomous province coordinating centres, transplant centres and hospital intensive care units. Among its several tasks, there are coordination and regulation, data management through the Transplant Information System (TIS), communication and training and international relations. The centre is extensively engaged in international activity, focusing on relations, EU-funded projects, cooperation agreements, and participating in international organ exchanges.

A pivotal element in the efficiency of the Italian Transplant Network is the CNToperativo (CNTo), an internal operational structure established at the CNT around 2013: it functions as the 24/7 engine room, providing continuous, systematic oversight and coordination for the most time-critical aspects of the transplant process. Its primary activities include interfacing with all regional and local levels of the Network, maintaining a continuous flow of information to ensure timely decision-making as well as being responsible for the rapid, impartial evaluation of donor and organ suitability for

transplantation purposes. It manages the allocation of organs for special national transplant programs, ensuring that even the most complex or rare cases are handled with efficiency and equity across the country. The establishment and subsequent evolution of the CNTo marked a significant turning point, contributing to the systemic growth of donation and transplant numbers in Italy by enhancing the network's organizational effectiveness and speed of response.

Scientifically, the CNT leverages the rich data from the TIS to drive evidence-based medicine. By collecting and analyzing data on donation, organ quality, and transplant outcomes, it supports several scientific studies and monitors program quality. This robust data-driven approach allows for the development and refinement of clinical protocols, such as those related to Donation after Circulatory Determination of Death (DCD), which are crucial for expanding the donor pool. The CNT's ability to evolve its protocols – like the controlled DCD programs – demonstrates its commitment to integrating cutting-edge medical practices safely and systematically into the national framework.

Organizationally, the CNT embodies a model of centralized governance that ensures a uniform application of safety and ethical standards while respecting regional specificities. This three-level coordination structure (national, regional, local) has proven to be effective in fostering a collaborative environment, with all operators working in synergy. The steady growth in both donation and transplant figures over the last two decades (e.g., up to a 54% increase in donations and 33% in transplants between 2004 and 2024) highlights the validity of this organizational model in enhancing transparency, efficacy, and efficiency for the ultimate benefit of the patient.

As a department within the ISS, the leading public technical and scientific body of the Italian National

Health System, CNT's mandate is intrinsically linked to public health and clinical excellence.

A significant area of collaboration concerns the safe use of organs from donors positive for Hepatitis C Virus (HCV). With the advent of highly effective Direct-Acting Antivirals (DAAs) to cure HCV, the CNT, leveraging the scientific guidance of the ISS, has obtained by the Italian Drug Agency (Agenzia Italiana del Farmaco, AIFA) the authorization to the full reimbursement of these drugs, even for the prompt treatment of HCV infection after an organ or bone marrow transplantation. This allows to utilize HCV-positive organs for both HCV-positive and, in carefully selected cases, HCV-negative recipients. This effective strategy, which involves treating the recipient post-transplant with DAAs, has been instrumental in safely expanding the organ donor pool, demonstrating a dynamic, patient-centric approach to tackling historical contraindications for transplantation.

Another relevant synergy is the application of the Regulation on Substances of Human Origin (SoHO). As the national authority for the donation and transplantation of organs, tissues, and cells, the CNT works closely with the Italian National Blood Centre, the ISS and the Italian Ministry of Health to implement and enforce EU and national safety and quality standards for all human origin substances used in therapy. This ensures compliance with rigorous health and safety requirements for tissues and cells, including their procurement, processing, storage, and distribution through authorized tissue institutes and banks. This collaboration guarantees that the system adheres to the highest European standards, safeguarding recipient health.

Looking ahead, the CNT's focus is on building upon its successful performance and tackling emerging challenges to improve further, namely by:

- *expanding the donor pool*: a major strategic objective is the further development and standardization of DCD programs across all regions, particularly the controlled DCD pathway, by investing in training and the necessary infrastructure, such as mobile Nor-

mothermic Regional Perfusion (NRP) teams. Efforts will also continue to improve the identification of potential donors in Intensive Care Units (ICUs) and to support donor families through compassionate, effective communication;

- *promoting innovation and technology*: the CNT will continue to promote and monitor the use of advanced technologies, such as organ preservation and reconditioning devices (e.g., ex vivo perfusion systems), to improve the quality and extend the usability of organs that might otherwise be discarded. The continuous evolution of the TIS will also be paramount to manage increasingly complex data and ensure the system remains robust and adaptive;
- *fostering public engagement and ethics*: reinforcing the culture of donation through targeted public campaigns and educational initiatives remains a core commitment. Furthermore, the CNT must continue to navigate complex ethical and legal considerations – such as the emerging fields of xenotransplantation and the use of bioengineered tissues – ensuring that all advancements are introduced with the utmost respect for human dignity and public trust.

In conclusion, the Centro Nazionale Trapianti is far more than a regulatory body; it is the guiding force of a highly complex and ultimately successful National Transplant Network. Through its centralized operational efficiency (CNToperativo), its scientific rigor, and its crucial partnerships with the ISS, the CNT has secured Italy's position as a leader in Europe for organ donation and transplantation. Its ongoing work is an essential contribution to national public health, offering the invaluable gift of life and health to thousands of patients each year.

#### **Conflict of interest statement**

The Authors declare no conflicts of interest regarding this manuscript.

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