



Centro Nazionale Trapianti
Italian National Transplant Centre

ISTITUTO SUPERIORE DI SANITÀ



Rete
Nazionale
Trapianti

Report


2020

ANNUAL ACTIVITY


ITALIAN NATIONAL TRANSPLANT NETWORK





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by the Director-General


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01 ORGAN DONATION

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02 ORGAN PROCUREMENT

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03 ORGAN TRANSPLANTATION

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04 WAITING LISTS

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05 TISSUE DONATIONS AND TRANSPLANTS

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06 CONSENT FOR ORGAN AND TISSUE DONATION

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07 ADVERSE EVENTS AND REACTIONS

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INTRODUCTION

*by the Director General of the National Transplant Centre
Dr. Massimo Cardillo*

2020 was a year that, in addition to radically changing of our lives, subjected health systems to a level of pressure and strain that has been unknown in recent history. Italy was the first country in the Western world to be hit by the Covid-19 pandemic and it has paid (and is still paying) a high price in terms of the spread of the virus. The intensive care workers of our hospitals have had to face dramatic scenarios without having had time to prepare for the management of such an event.

*Yet, despite all this, donations and transplants did not stop: the impact of the pandemic was mainly concentrated in the two periods of the first and second waves and led to an **overall decrease in transplant activity of less than 10%, compared to the previous year.***

*This result is to be considered as acceptable, especially when compared to what has happened in other large European countries **(United Kingdom -27%, France -25%, Spain -19%);** %); only Germany had a lower decline (-7%).*

The Italian National Transplant Network has, therefore, demonstrated its solidity and ability to respond effectively to the critical issues that the spread of the virus has caused.

*Since the report of the first cases, the National Transplant Centre (Centro Nazionale Trapianti; CNT), supported by expert advice, governed the Network by defining the criteria for the safety of donors compared to the risk of infection transmission (mandatory testing for the presence of the SARS-CoV-2 virus in the Bronchoalveolar lavage of all deceased donors), the safety of recipients (definition of Covid-free pathways) and strongly emphasizing, within the institutions (such as the Ministry of Health and the regions) the need to support donations and transplants with respect to the risk of weakening the very structures responsible for these activities **organ transplantation is, in fact, an essential level of care, which must be guaranteed to** patients on the waiting list, and the possibility of using the organs of a deceased potential donor cannot be postponed to a later time.*



DESPITE THE FACT THAT ITALY HAS GREATLY SUFFERED FROM THE SPREAD OF THE VIRUS IN 2020 DONATIONS AND TRANSPLANTS HAVE NOT STOPPED: THERE WAS A DECREASE OF LESS THAN 10% COMPARED TO 2019, CONFIRMING THE SOLIDITY AND EFFECTIVENESS OF THE TRANSPLANT NETWORK. TRANSPLANT REPRESENTS AN ESSENTIAL SERVICE THAT MUST BE GUARANTEED.





THE IMPACT OF THE PANDEMIC HAS AFFECTED OUTPATIENT TRANSPLANT ACTIVITIES AND RECENTLY IMPLEMENTED DONATION PROGRAMS, SUCH AS DONATIONS AFTER CARDIAC DEATH, HOWEVER, 2020 WAS ALSO A YEAR OF EXCEPTIONAL SURGERIES: THE FIRST UTERUS TRANSPLANT IN ITALY, THE FIRST EUROPEAN LUNG TRANSPLANT IN A PATIENT WITH IRREVERSIBLE LUNG DAMAGE FROM SARS-COV-2 AND THE WORLD'S FIRST CASES OF USING AN ORGAN, NAMELY LIVER, FROM A COVID-19 INFECTED DONOR.



*In the report, particular attention is given to the measurement of the potential of donation in the regions, through the analysis of the numbers of cases of deaths with brain injuries in intensive care. This is an important indicator and it is the main working tool for hospitals and regional coordinators. The data continue to indicate **large regional variability on this indicator**, but above all they reveal a system capacity that is not yet mature enough to manage this part of the process. In regions where the donation pathway is managed and there is a timely registration of cases, the results in terms of reporting potential donors are evident.*

*The National Transplant Centre recently launched an **audit programme of Regional Transplant Centres** (Centri Regionali Trapianti; CRT), with the priority objective being to identify critical issues in donation pathways in hospitals, including through the recognition of the organizational assets of the structures that are responsible for these activities, as had been foreseen in the National Donation Plan.*

*The pandemic has also had an impact on more recently implemented donation programs, which are therefore more fragile, such as donations after cardiac death. From this point of view, we hope that the **policy document that is currently being defined on supervised donation after cardiac death**, (the result of a significant effort by the whole Network), can constitute a useful contribution to support hospitals that wish to undertake this activity.*

*Predictably, the impact of **the pandemic affected** transplant activities that could be rescheduled, such as **transplantation from living donors and tissue transplantation**, as well as all **outpatient activities** which are typical of the patient's care pathway, before and after surgery. This situation has generated many critical issues, and has required a particular commitment of health facilities to organize different care pathways, privileging, where possible, remote consultation, partly to limit the access of patients to hospital facilities for reasons of safety.*

*But 2020 was also a year of **exceptional surgical operations**, , such as the **first uterus transplant in Italy**, performed by the Catania centre in August: **the first European lung transplant in a patient with irreversible lung damage by SARS-CoV-2**, performed in Milan; the first cases in the world of **the use of organs, namely liver, from a positive donor for Covid-19 infection**.*

The results of this protocol, in particular, have aroused particular interest in the international community, since they document the possibility of the safe use, under particular conditions, of these donors' organs.

*The National Transplant Centre then devoted attention and commitment to the realization of a **COVID-19 infection risk monitoring platform** (including the consequences of infection) **in patients on the waiting list and in transplanted patients**. Thanks to a fruitful collaboration with the platform of the Italian National Institute of Health, by cross-referencing the data present in the Transplant IT System (Sistema Informativo Trapianti; SIT), CNT was able to measure the fragility of these categories of subjects, and to indicate to the Ministry that these individuals should be included among the priority categories for access to the vaccine. These indications have been accepted, although the speed of application of the measures has been different in the various regions.*

*But we know that transplant patients because of immunosuppression, similarly to patients on the waiting list (since they are on dialysis or in any case have symptoms of end-stage organ failure), may have a reduced response to the vaccine, so **the next challenge for the National Transplant Centre is to measure the protective effect of the vaccine in these categories**. This will soon be possible thanks to the collaboration with the Covid platform of the Italian National Institute of Health, and with the cross-referencing of data from the vaccine platform of the Ministry of Health.*

*Data on transplant activity reflect the participation of most transplant centres in national allocation programmes, which represent a valuable resource for the most vulnerable categories of patients on the waiting list; the analysis of tables that cross-reference the data regarding the residence of patients with those of the transplant sites is also very useful: **it once more confirms the important phenomenon of the migration of patients to regions that have higher levels of donation, and therefore of transplantation**. These tables also contain the finding, while still numerically limited, of international patients, mostly paediatric patients, who access transplantation in Italy: the National Transplant Centre is constantly engaged in the definition of agreements with the countries of these patients in order to regulate these flows and to stimulate the countries themselves to implement their own effective donation programs.*



DURING THE PANDEMIC THE NATIONAL TRANSPLANT CENTRE WAS FOCUSED ON THE CREATION OF A PLATFORM FOR MONITORING THE RISK OF COVID-19 INFECTION IN PATIENTS ON THE WAITING LIST AND IN PATIENTS FOLLOWING TRANSPLANTATION, THE NEXT CHALLENGE (IN COLLABORATION WITH THE ITALIAN NATIONAL INSTITUTE OF HEALTH AND THE MINISTRY OF HEALTH) IS TO MEASURE THE PROTECTIVE EFFECT OF THE VACCINE IN THESE CATEGORIES OF PATIENTS.





THE INCREASED
OPPOSITION
RATES IN
MUNICIPALITIES
IS A SIGNIFICANT
ALARM BELL FOR THE
ENTIRE TRANSPLANT
SYSTEM MORE
GENERALLY, THE
SUBJECT OF
COMMUNICATION
WITH CITIZENS IS
A PRIORITY OBJECTIVE,
WHICH REQUIRES
EVEN GREATER
COMMITMENT,
SINCE IT IS
ESSENTIAL TO
INCREASE TRUST
IN OUR SYSTEM,
WHICH IS AN EXCELLENT
COMPONENT OF THE
NATIONAL HEALTH
SERVICE.



Waiting list data still underline **the necessity to respond to a need that is not adequately met**.

Waiting times on the list are still too high and, for some types of transplant, there is a worrying mortality of patients on the waiting list.

The National Transplant Centre created a tool for patients waiting for transplantation, or following transplantation, that aims to listen to their needs and expectations. This tool has been used widely, and it has been confirmed that the main expectation of a patient on the list is to receive the transplant as soon as possible.

The final part of the report is, as always, dedicated to the topic of ascertaining **whether citizens wish to donate in their local municipality office**, when their identity card is issued or renewed. Unfortunately, we have seen an **increase**, albeit a slight one, **in refusal rates in municipalities**, which exceeds rates recorded in intensive care from family members. This is an **important warning sign**, as refusal to harvesting manifested in life cannot be overcome even by the most capable and well-trained of doctors who deal with families in intensive care.

This data confirms that **simplifying access to the expression of donation consent, if not accompanied by appropriate and effective communication campaigns on the subject**, risks causing a **negative effect**: indeed, we know that refusals are almost always the result of fear and poor information. The National Transplant Centre, with the Ministry of Health, sees **an increased commitment to communicating with citizens as a priority**, to make sure there is growing confidence in the transplant system, an excellent component of the National Health Service.

Finally, I would like to thank all the staff of the National Transplant Centre who, while experimenting with new organizational work formulas, has ensured over recent months not only the continuity of activities, with its usual professionalism and dedication, but has also accepted the new challenges that the pandemic has posed to us from multiple points of view. Teamwork is the essence of our Network and this publication is a testament to it.

Enjoy reading!



Organ DONATION



2020 SNAPSHOT

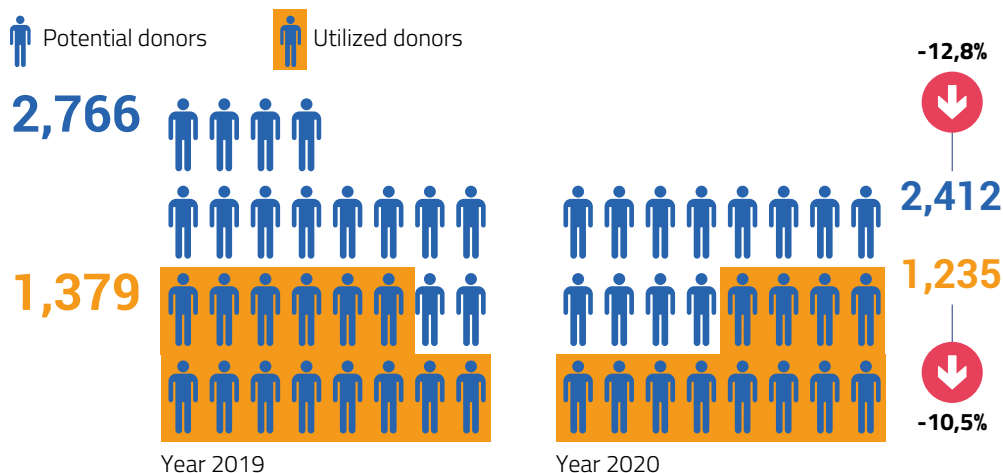
The impact of the SARS-CoV-2 pandemic on health activities has inevitably involved the Transplant Network, resulting in an abrupt but restrained decrease in activity. **Compared to the previous year, 2020 saw a slight reduction in all the main indicators of the donation process:** in particular, the donors utilized for transplant purposes were 1,235 compared to 1,379 in 2019.

At the root of this decline was the overload of intensive care involved on the front line in the treatment of Covid-19 patients and, at the same time, the overload of essential operational units for the reporting, procurement and donation of organs and tissues for transplant purposes.

The most obvious signal of the saturation of intensive care - and the consequent impact on donation activity - **concerned the decline in the reporting of potential donors (determination of death)** registered in 2020 (2,412 compared to 2,766 in 2019).

The crisis, however, has highlighted the strength of Italy in the field of donation and transplantation, highlighting the solidity of our organizational structure: the Network was able to respond adequately to the emergency situation, identifying concrete solutions to critical issues and supporting those who were in greater difficulty. In the health emergency that hit Italy, the first country in Europe to face Coronavirus in the winter of 2020, the Network has demonstrated with great strength the nature of its "team" approach, working with dedication, professionalism and humanity.

A TWO-YEAR COMPARISON



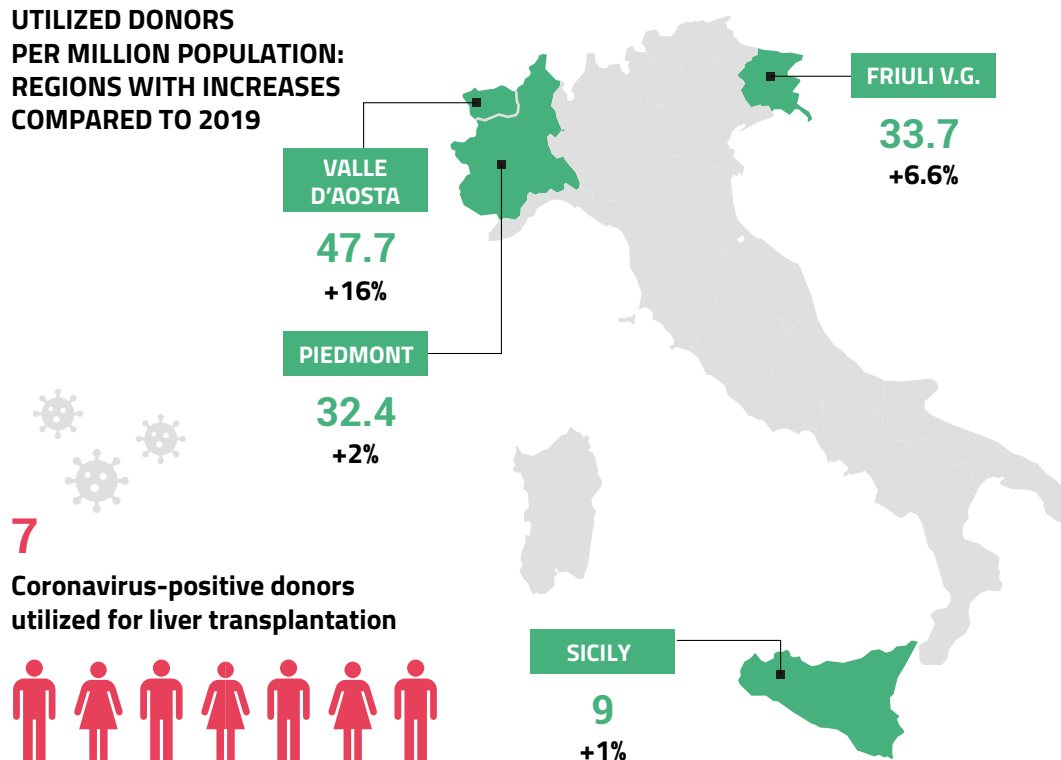
THE GRADUAL RECOVERY AFTER THE LOCKDOWN

The main indicators of the donation process have been monitored weekly since the beginning of the health emergency. **The greatest difficulties were encountered in the weeks immediately following 24 February 2020**, that is to say, after the detection of the first two outbreaks of Coronavirus in Italy in the areas of Lodi and Vo' Euganeo.

There was a sudden drop-in activity and minimum weekly values of 26 potential donors reported (determination of death) and 11 donors utilized throughout the national territory were reached, against an average of 56 and 30 respectively in the previous 8 weeks. The evolution of knowledge related to the transmission of SARS-CoV-2 infection, together with the timely measures of containment and the measures put in place by the Network to guarantee donation pathways, has contributed to a progressive, albeit fluctuating, recovery. **Unfortunately, the average activity values, recorded in the weeks before the outbreak began in Italy, were not reached in the following months.**

Encouraging signs came from some regions which, in 2020, increased compared to the previous year. Examples include Piedmont and Valle d'Aosta, whose main indicators of the donation process, **reported up to 2019**, increased.

UTILIZED DONORS PER MILLION POPULATION: REGIONS WITH INCREASES COMPARED TO 2019



7

Coronavirus-positive donors
utilized for liver transplantation



In terms of Southern regions, however, the only region that improved the rate of donors utilized PMP (per million population) was Sicily, despite a slightly lower number of determinations of death when compared to the previous year and a very low rate (9).

THE TIRELESS WORK OF THE NATIONAL TRANSPLANT CENTRE

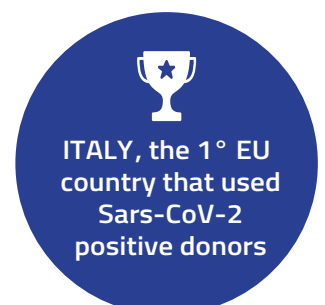
Ensuring continuity of care for transplant patients, in accordance with the highest standards of quality and safety, has always been a priority for the Network.

As with other diseases and infections that are potentially transmissible with transplantation - which are still present nationally or globally, such as the West Nile Virus or the Dengue virus - the National Transplant Centre immediately activated specific surveillance for Coronavirus. **The first provision of the Centre addressed to the entire Transplant Network dates back to 27 January 2020**, when Coronavirus seemed to be limited to the Chinese province of Hubei.

Since then, **a total of 22 circulars** have been issued concerning both epidemiological surveillance and operational indications for the maintenance of donation and transplant pathways. These provisions, together with the fundamental contribution of our **task force of experts**, known as *second opinion*, also allowed the use, in selected cases and in total safety, of SARS-CoV-2 positive donors.

Italy was the first European country to use, for transplant purposes, donors who died from other causes but who tested positive for Covid-19.

According to the National Transplant Centre guidelines, patients must be in a serious clinical condition and SARS-CoV-2 positive (or having recovered from a previous Covid-19 infection), so that, in the opinion of the medical team responsible for the transplantation, the risk of death or development of serious diseases, related to staying on the waiting list, makes the result of the possible transmission of donor-recipient disease acceptable.



THE BRAIN INJURY REGISTER

The role of the **Local coordinator (Coordinatore Locale; CL)** was introduced in Italy by law N°91 of 01/04/1999. The law (Article 12 law 91/99) defines the functions of the CL who, in the reorganization of the National Transplant Network, **plays a key role:**

- **in identifying the potential donor;**
- **in the promotion of information, education and cultural growth of the general public in the field of transplantation.**

The agreement of the Conferenza Stato Regioni of 21 March 2002 (Rep. Acts 14/14) identifies the **Brain Injury Register** as an **an operational tool of the CL**, necessary for monitoring the process of identifying potential donors who die in intensive care. Since 2006, all Italian regions have implemented a **Registro Cerebrolesi Regionale**. From the same year, as part of the **SIT**, the **Brain Injury Register**, was established, which the regional centres feed into on a monthly basis. It is important to remember that the register was created with the purpose of monitoring the process related to donors whose death has been determined by neurological criteria (*Donation after Brain Death, DBD*).

THE REGISTER: IN BRIEF



Operational tool of the Local Coordinator



It monitors the process of identifying potential donors who die in intensive care



Each Region has adopted its own Brain Injury Registry



Established at the national level, the Brain Injury Registry is fed with data from the regions

2006

Year the register was established

THE AIM OF THE REGISTER

Monitor the identification process of the potential donor through the use of "key indicators" that

- **highlight any critical situations at regional and/or local levels;**

- **verify the effectiveness of the corrective actions taken to improve the efficiency of the process.**

Timely monitoring of all deaths with severe brain injury indicates the maximum potential of the region and of individual hospitals and departments, and in an important management and governance tool for Regional Transplant Centres, the National Transplant Centre and the entire National Transplant Network.

INDICATORS

1st indicator



The per million population (PMP) rate of deaths with brain injury (Brain Injury Deaths PMP, also referred to as Proc 0). This is an indicator of the effectiveness of the system and highlights **how many deaths occurred in intensive care in subjects with severe brain injuries** (minimum requirement for organ donation after determination of death by neurological criteria) in proportion to the resident population of each region.

The **national value of 79.1** constitutes, at a regional level, a very wide range of variation, between a minimum of 17.8 in Basilicata and a maximum of 154.7 in the Friuli Venezia Giulia region.

The Regional Epidemiology of deaths does not justify this variability, which could be linked to various *policies* concerning centralization and appropriateness of intensive care admissions (with the exclusion of patients dying in wards other than intensive care wards), but also because of a shortcoming in the reporting of all deaths with brain injury in intensive care. The magnitude of this variability is a critical point of the system that requires further exploration and, possibly, an analysis through auditing, revision of hospital discharge cards (Schede di Dimissione Ospedaliera; SDO) and organizational and functional support of hospital coordination, in order to quantify and minimize the phenomenon of “*silent donor*”.

The most important objective, therefore, is **to improve the ability to monitor and correctly document deaths with acute brain injury in resuscitation in all regions**; given the high variability of this index, it is not possible to analyse the other indicators of the register without interpreting them in combination with Proc 0.

2nd indicator



The rate of effective donors per million population (PMP), it expresses the real donation capacities of the Italian regions.

Again, regional variations are very significant in terms of the **national average value of 20.2**. It is important to highlight how, in Italy, there are regional realities with extremely high activity values.

An example of this is the Tuscany region, which, with a value of 46.1 effective donors PMP, reaches levels of excellence that are even higher than the main international *benchmark* (such as, for example, the Spanish context). If all regions currently below the national average were to reach this threshold, Italy would be among the best nations in the world in terms of donation.

3rd indicator



Called Proc 1, **it highlights the percentage of deaths with brain injury that become effective donors.** As demonstrated earlier, this indicator is strongly influenced by the strong variations in indicators described above.

A high value of Proc 1 must be paired with high values of Proc 0 in order for a region to be considered efficient in terms of donations.

The average Italian value for the year 2020 was 25.5%, while the Tuscany region has confirmed that it has a high donation efficiency, with a value of 31.1% against a Proc 0 of 148.3 PMP.

4th indicator



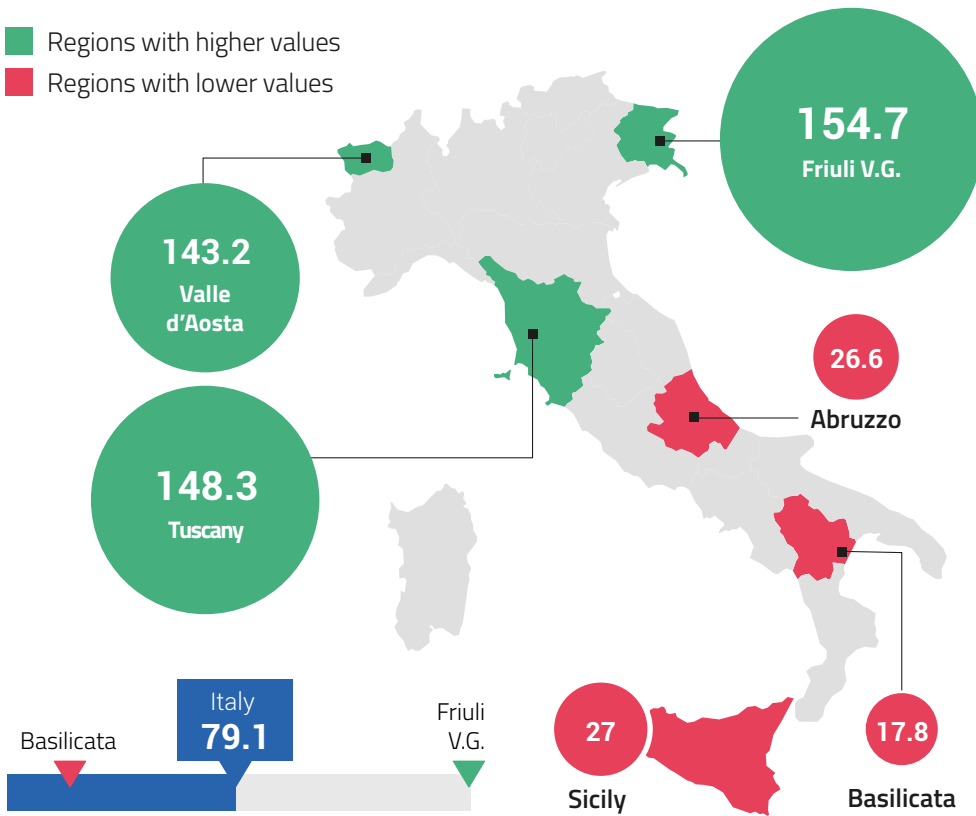
Another efficiency indicator, named **Proc 2**, is an indicator of efficiency that **highlights the percentage of deaths with brain injury that are determined by neurological criteria.**

Again, in the context of a **national average value of 47.8%**, to be able to identify regions with high efficiency it is necessary to add high values of Proc 0 to Proc 2. In addition to the region of Tuscany, which was confirmed as a leader in Italy in terms of donation after brain death (DBD), we can highlight the excellent organization of Piedmont and Veneto, in terms of good values of Proc 0 (91.1 and 118.8 PMP), optimal values of Proc 1 (31.5% and 26.8%), and Proc 2 (52.9%, and 48%).

1st INDICATOR: DEATHS with BRAIN INJURY PMP

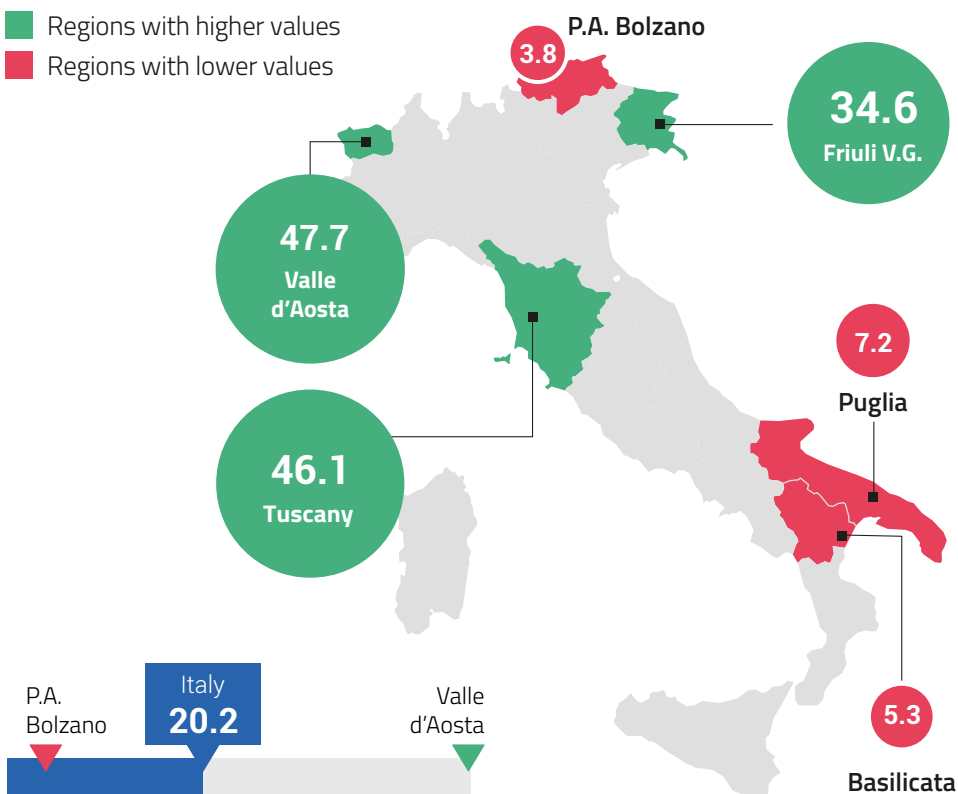
■ Regions with higher values

■ Regions with lower values

**2nd INDICATOR: EFFECTIVE PMP**

■ Regions with higher values

■ Regions with lower values



THE DONOR IDENTIKIT

AGE

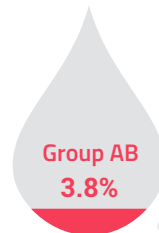
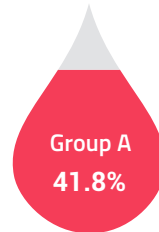
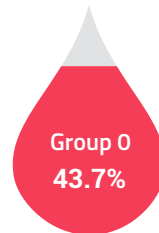
Although there are some slight fluctuations, the average age of donors in our country saw an increasing trend **until 2018**, the year in which – for all the main indicators of the process – it was **well over 60**. **In the last two years we have recorded a slight and progressive decline: the average age of donors, in 2020, was 60.4 years for potential donors reported (determination of death) and 59.7 years for donors utilized**, compared to an average of 61 and 59.8 years of the previous year, respectively.

The slight reduction may be attributable to the increase in the activity of donation after cardiac death (DCD), which usually has a lower average age than donors whose death is determined by neurological criteria.

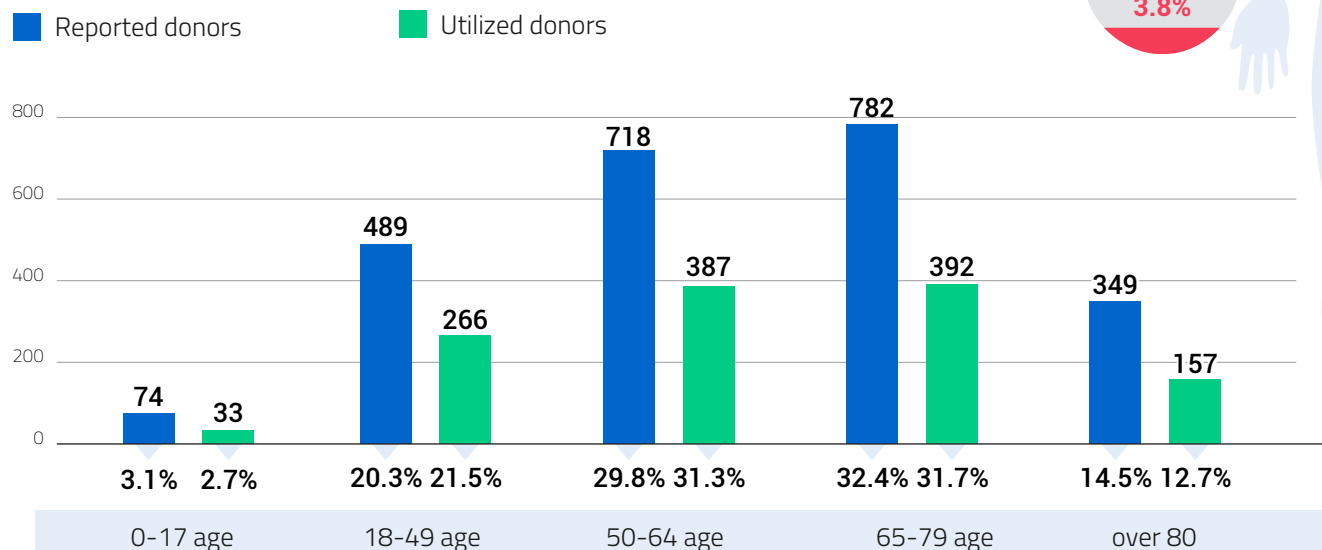
BLOOD TYPE

Group O and Group A are more represented in all types of donors: this distribution reflects the higher frequency of these groups in the Italian population.

UTILIZED DONORS BY BLOOD TYPE



AGE GROUPS BY TYPE OF DONOR

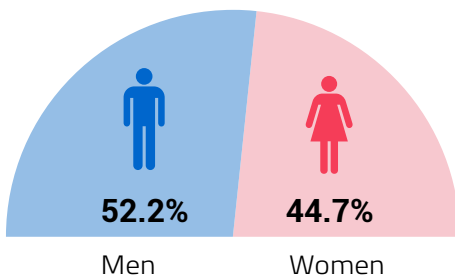


GENDER

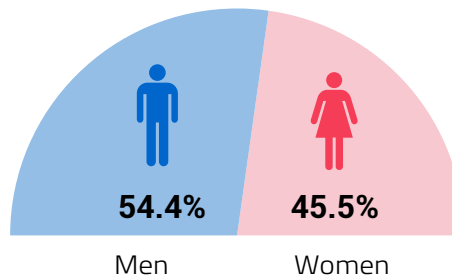
Male donors are slightly more common across all types. In particular, it should be noted that - both for potential donors reported (determination of death) and for donors utilized - there is, respectively, a prevalence of male donors of 52.2% and 54.4% compared to 44.7% and 45.5% of female donors.



REPORTED DONORS



UTILIZED DONORS



REFUSALS TO DONATE

The refusal rate to organ and tissue donation *post mortem* is persistent and constant in Italy: on average, 3 out of 10 potential donors fail to get to harvesting due to a refusal declared in life or due to the opposition of the family members with the right to do so (in cases of spousal non-consent). In 2020, the percentage of refusal to donate was 30.2%, resulting in the exclusion of 728 potential donors. Despite the fact that the restrictions made it necessary to change communication tools and methods, there was a decrease of almost one percentage point compared to the figure found in 2019 (31.1%). This decrease, although slight, could be attributable to greater public confidence in the National Health Service, which, during the pandemic, was confirmed as a highly efficient system. Unfortunately, there were still significant differences between the regions of the North - with refusals almost always below the national average - and those of the Centre-South, with worrying percentages of dissent that far exceed the Italian average.

30.2%

Opposition
rate in 2020

728

Non-utilized
donors due to
refusal

-9.3%

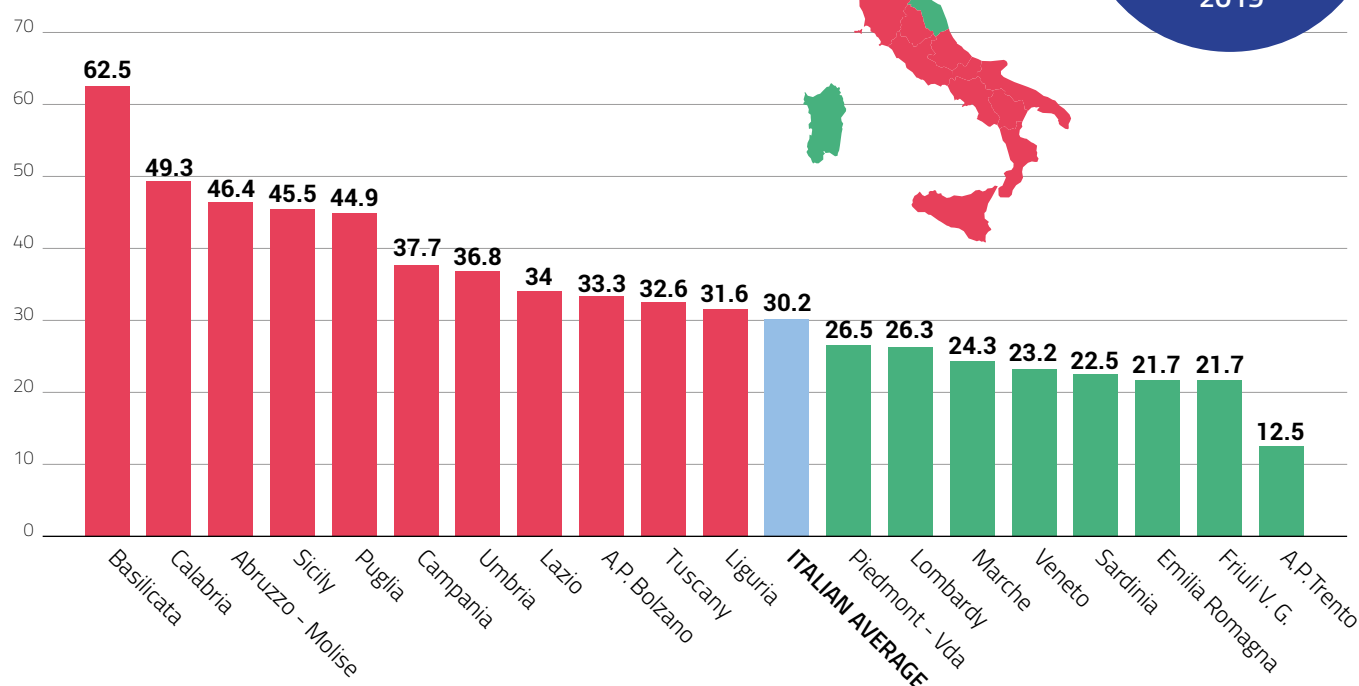
Oppositions
compared with
2019

COMPARISON BETWEEN THE ITALIAN REGIONS

Data %

■ Above average regions

■ Below average regions



DONATIONS AFTER CARDIAC DEATH

The COVID-19 pandemic also affected DCD donations with a peak decrease of 86% in March but, overall, of 17% compared to 2019.

However, controlled DCD donations (cDCD), which reflect the limitation of intensive care (IC) treatments, have expanded: the number of hospitals that have accepted Italian recommendations for **the care of dying patients is growing, albeit with a noticeable difference between regions.**

The regional organization of mobile support teams for donor perfusion allows cDCD donation in a greater number of hospitals. In 2020, the Italian Consensus project for cDCD donation was developed, which will promote a uniform and shared approach to organizational, ethical, legal and clinical issues. This will make it easier to define actionable procedures in a larger number of Italian hospitals, to offer the option of organ and tissue donation both for Donation After Cardiac Death (DCD) and Donation After Brain Death (DBD) in all intensive care end-of-life patients.

Uncontrolled DCD (uDCD) is for now realized, thanks to considerable clinical-organizational skills, in only a few Italian Reference Centres for treatment with extracorporeal life support of very serious cardiocirculatory insufficiency, in particular in Tuscany. Consideration should also be given to the complexities of managing the relationship with the family members of the potential donor, given the limited time in which this type of donation takes place. **However, it is important to consider that uDCD donation could become, due to the number and younger age of possible donors, an important area of increasing deceased organ donation.** However, the possibility of DBD or DCD donation in subjects treated with emergency extracorporeal life support (ECLS/ECMO) has been consolidated.

The use of organs was much greater in cDCD donation where the potential donor is "flagged" only in the absence of refusal (in life or by family members) and of clinical contraindications at the time of withdrawing treatments. **Refusal among potential uDCD donors was, on the other hand, 18%.**

-17%

DCD donations
compared to 2019

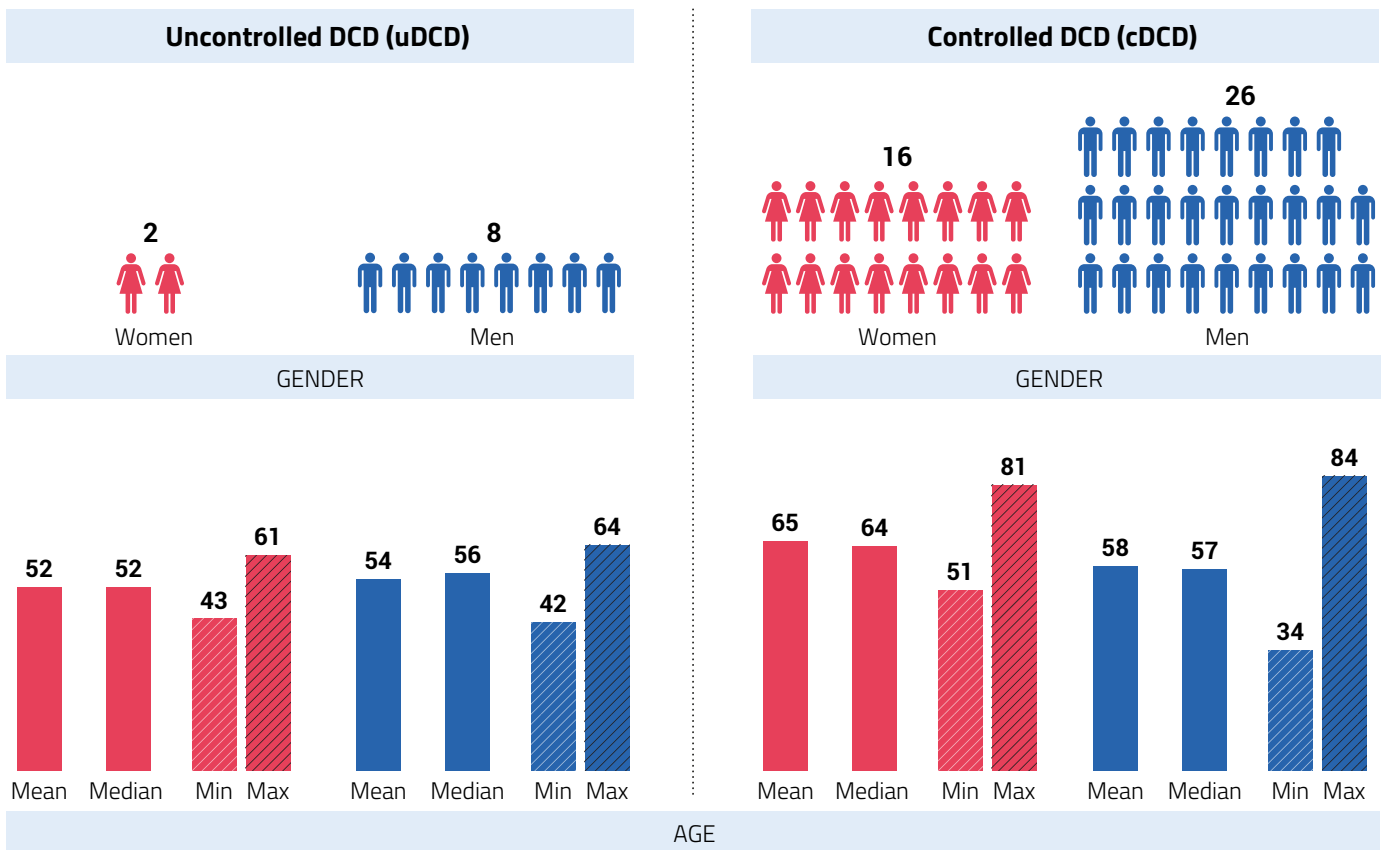
+64%

Centres reporting
DCD donors in
the last 3 years

cDCD is greatly affected by the advanced age of patients in IC, with a clear prevalence of haemorrhagic stroke and post-anoxic brain injury compared to traumatic injury. **However, in 2020, organs from cDCD donors over 80 years of age were successfully utilized, with a median of more than 60 years**, well beyond the limits previously included in international protocols.

The goal to be achieved in Italy is still far from the reality of some European countries where DCD exceeds 25% of total donors.

UTILIZED DCD DONORS



Organ PROCUREMENT



AN OVERVIEW

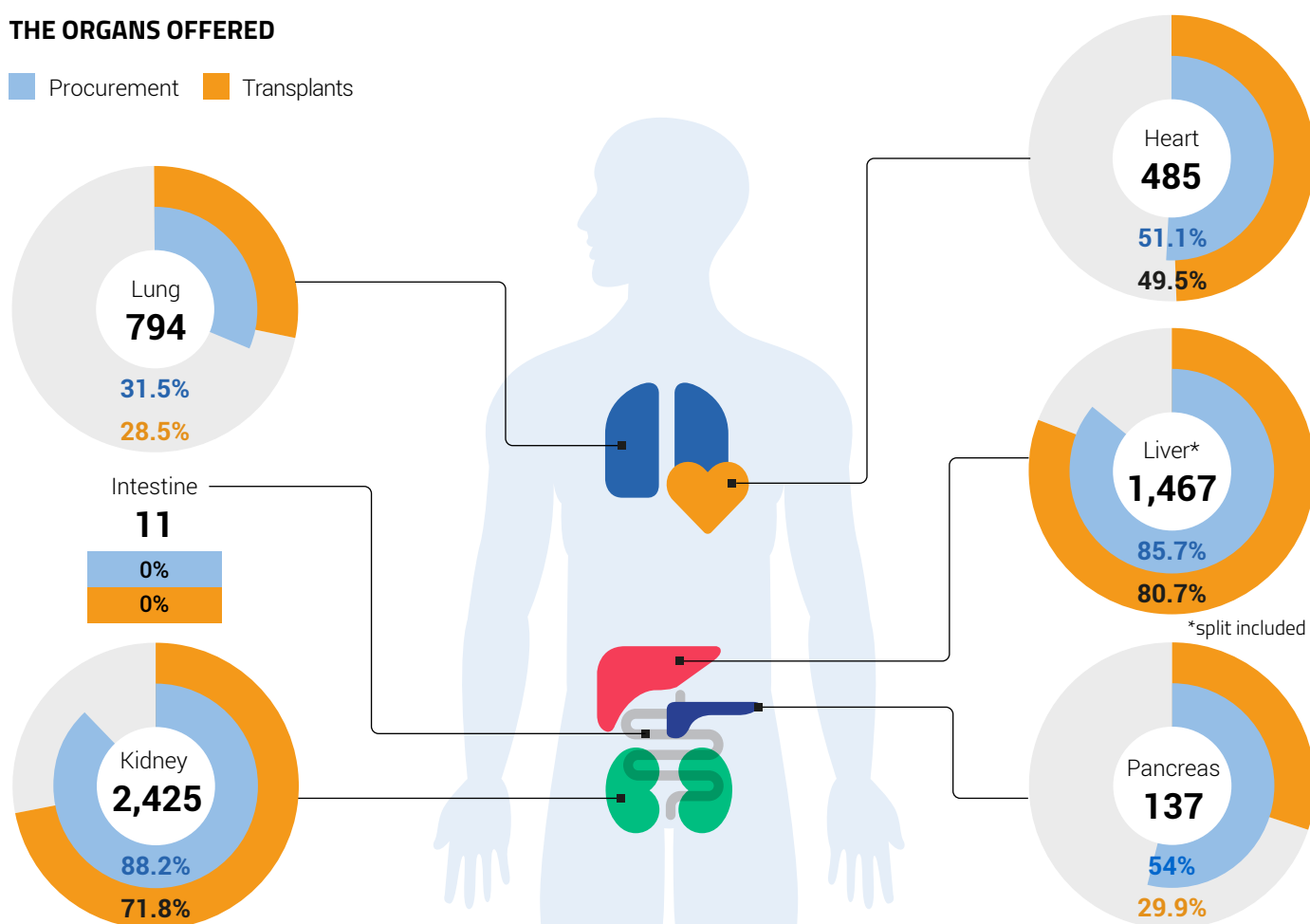
The relationship between the number of organs offered and the organs harvested is related to the ability of acceptance of the transplant centres on the basis of two main criteria: the quality of the organ and the composition of the waiting list.

As represented by the flows below, this ratio is reduced if you take into account the number of organs transplanted compared to those offered and harvested, because of the **eligibility checks** of the organ to be used for transplant purposes.

In addition, 2020 was marked by the additional difficulty, linked to the pandemic, of the reduced capacity of transplant centres to fully carry out their regular activities.

THE ORGANS OFFERED

■ Procurement ■ Transplants



ORGAN PATHWAYS

Transplant, from late Latin *transplantāre*, composed of the classic *trāns* - beyond - and *plantāre* - plant. Literally, transfer stably from one place to another. Starting from etymology is the most effective way to explain why, in the collective imagination, transplantation is associated with the journey, or the pathway that the donated organ takes to reach the best recipient. From the analysis of the data at a national level, it can be said that there is not always a direct route between organs procured within a regional reality and operations carried out in the same region.

In this sense, national transplant programmes, such as the **urgent programme** and the **paediatric program**, that have priority over regional ones and for which it is essential to break down any form of local or regional barriers. Factors, such as the intrinsic characteristics of the donated organ, the composition of waiting lists and the varying distribution of transplant centres in the local area, become determining factors.

In 2020 the etymological and conceptual link between **transplant and journey (pathways)** took on an even more relevant connotation because we often had to move beyond regional borders to achieve the goal of using all the organs available, respecting the donation and transplanting in those who needed it. Making these journeys (pathways), however, has been difficult due to pandemic-related restrictions. Among the various obstacles encountered, there was the absence of many means of transport on which the system regularly relies on: one example is the drastic reduction of the routes travelled by scheduled flights, a fundamental support for the transport of organs.

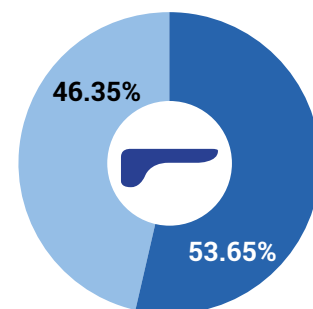
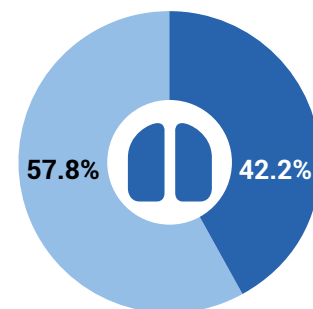
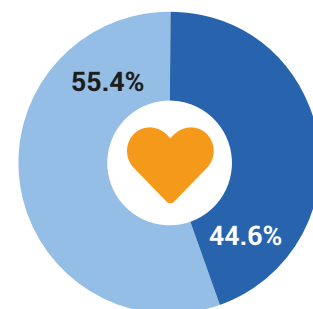
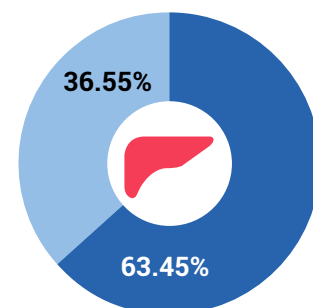
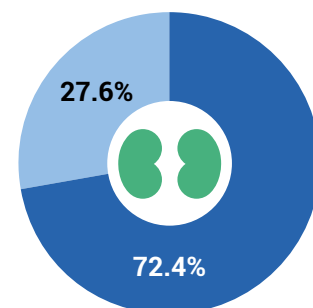
Once again, however, the organization and the Network ensured a quick and effective adaptation, allowing it to face the most difficult cases and making sure that all necessary journeys were completely correctly.

ORGANS DONATED AND TRANSPLANTED

■ Within the region ■ Outside the region

Kidney	Liver*	Heart	Lung	Pancreas
1,741	1,185	240	226	41
1,261	752	107	97	22
480	433	133	129	19

* split included



THE CALDES INDEXES

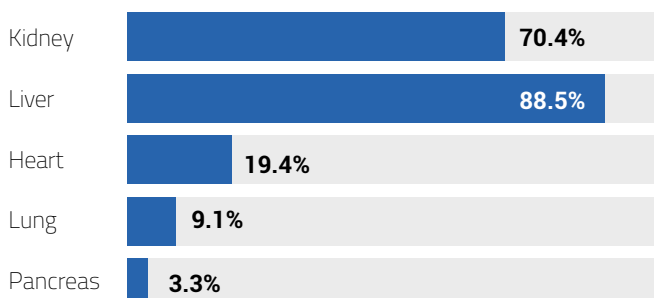
The “Caldes” indexes (from the name of a locality in Trentino) are indicators that evaluate the organ individually, both in terms of efficiency in the procurement process and in the transplantation process. They are placed next to the most well-known indicators that measure the performance of our system, such as the donation rate per million population.

At the national level, the index of **Caldes 1** outputs **levels of procurement compared to theoretically available organs**, extremely different for each organ. These differences can be attributed to the existence of more or less stringent criteria to proceed with harvesting; this is the case of the heart, which, compared to all other organs, has stricter population limits; considering that in our country the average age of donors is increasing, it predictably has an index of Caldes 1 that is lower than for other organs.

On a national basis, the index of **Caldes 2**, or **the ratio of total organs transplanted to that of organs harvested**, is slightly less than 100% for kidney (99.9%), liver (99.9%), heart (99.2%) and lung (97.3%), while it is 100% for the split of liver and pancreas. These values indicate a balance between the donation process and that of using the organ for transplant purposes. Compared to this indicator, the differences are attributable to the performance of the individual regions: realities with values that are much higher than 100% reflect a transplant capacity that is higher than the number of donors registered in their area. Once again, it is the regions of northern Italy that report the highest indices per single transplant program: indeed, in this area there is the largest number of existing hospital facilities in our country.

CALDES 1 INDEX VALUES PER ORGAN

Year 2020



CALDES 2 INDEX VALUES PER ORGAN

Year 2021



EXCHANGES WITH FOREIGN COUNTRIES

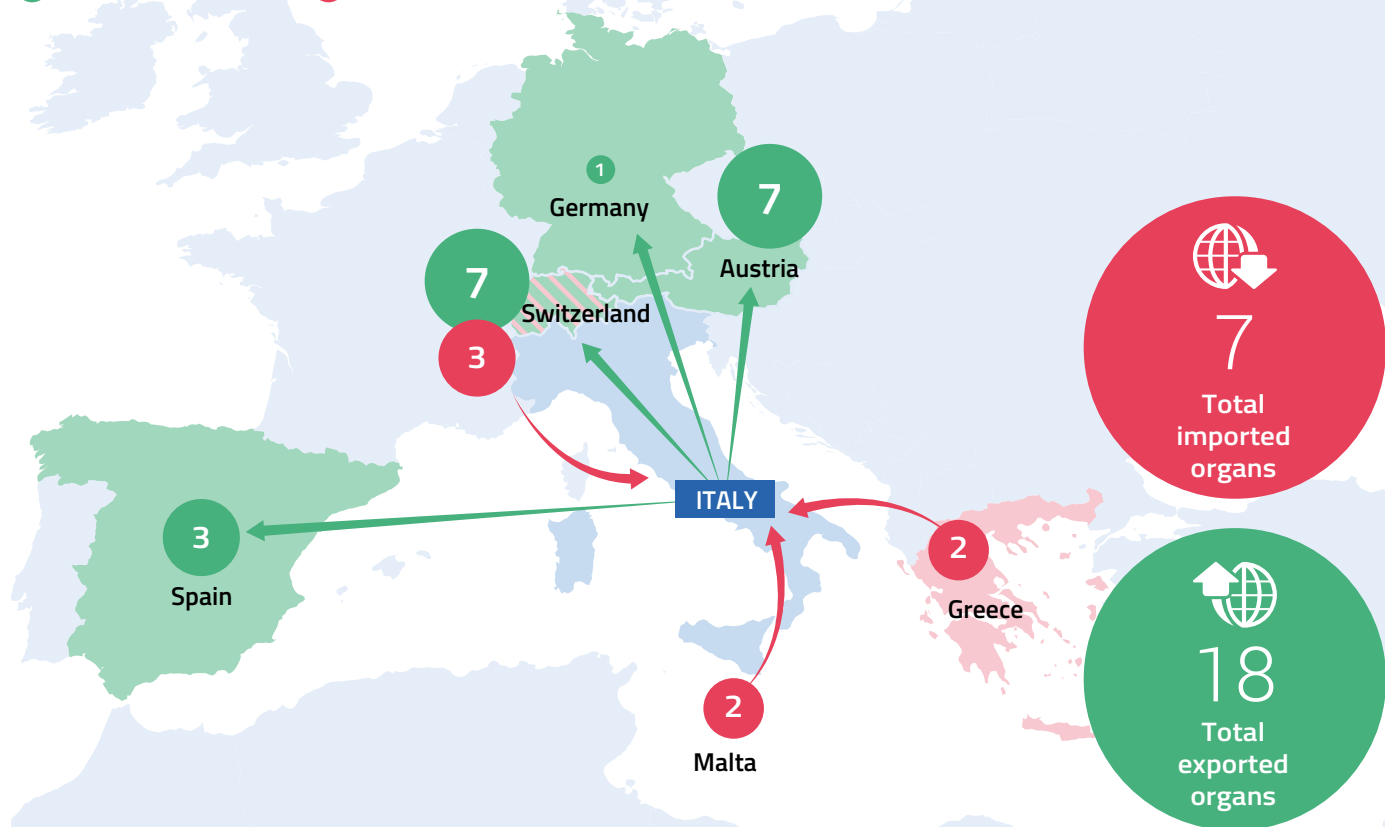
In 2020, Italy accepted 7 organs from foreign countries while there were 18 organs of Italian donors accepted by foreign organizations (data refer to deceased donors only).

The exchange of organs with foreign countries is based, on the one hand, on the assumption that there are no compatible recipients in the proposing country and, on the other, on the presence of specific international agreements in force.

One of these, for example, concerns the Autonomous Province of Bolzano, which shares the organs procured and the patients on the waiting list with an Austrian transplant centre.

2020 MOVEMENTS

● Exported organs ● Imported organs



TRANSPLANTATION

Organ

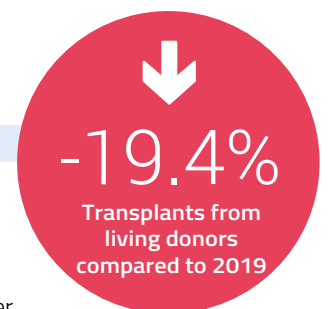
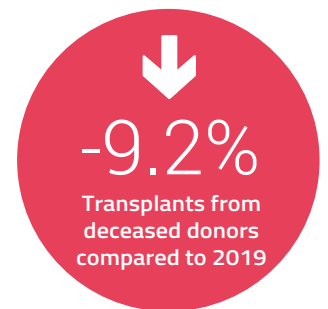
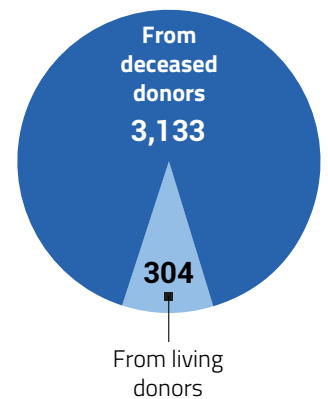


2020 SNAPSHOT

While 2019 had ended with the second-best performance ever in terms of transplants performed, in 2020 there is a reversal due to the SARS-CoV-2 pandemic. Indeed, transplants, **in 2020 there is a reversal due to the SARS-CoV-2 pandemic**. Indeed, transplants **from deceased donors numbered 3,133** compared to 3,451 in 2019; **from living donors there were 304**, compared to 363 operations of the previous year. The total number of transplants from deceased donors suffered a significant decrease and, in particular, it is evident that the periods of greatest decline correspond to the weeks in which the pressure on intensive care was most acute due to the worsening epidemiological picture in our country.

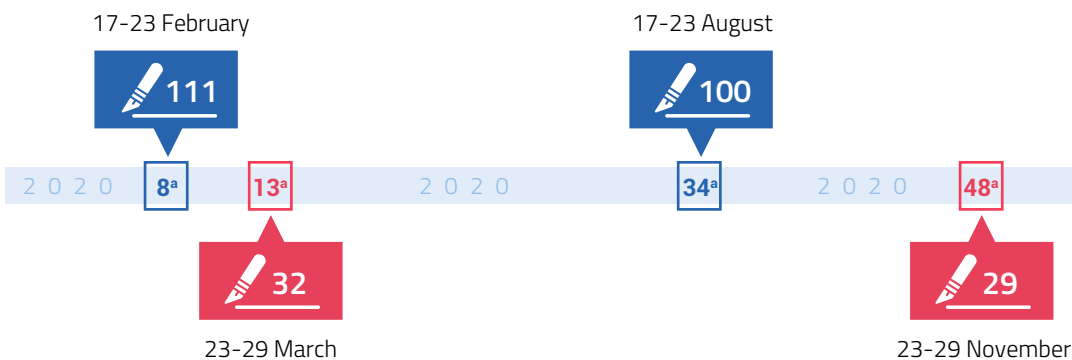
In detail: **the activity of transplantation from deceased donors, in the thirteenth (23-29 March) and forty-eighth (23-29 November) weeks, corresponding to the crucial days of the first and second waves of the pandemic, reached minimum values - respectively - of 32 and 29 transplants / week.** In the other periods of the year, we found substantial resilience in the activity, recording peaks of 111 transplants in the eighth week (pre-pandemic, 17-23 February) and 100 transplants in the thirty-fourth week (17-23 August), during a more favourable epidemiological phase. **The living donor program experienced a more significant decline related to the suspension of programmable and non-urgent surgical activities,** adopted by several hospital trusts as a strategy for the reorganization and expansion of intensive care places to deal with the health emergency.

TRANSPLANTS PERFORMED IN 2020



THE TREND OF TRANSPLANTS WEEK BY WEEK

■ Maximum values ■ Minimum values



RESEARCH ACTIVITY IN 2020

The cumulative incidence (CI) of SARS-CoV-2 infection in solid organ recipients is 1.02%, higher than in non-transplanted recipients (CI=0.4%), and the risk is greater, equal to 2.89%, in Lombardy, one of the regions most affected by the pandemic in 2020. These are the main results of an important epidemiological surveillance conducted by the National Transplant Centre by cross-referencing the data of the SIT and the registers of the Covid *Task Force* of the National Institute of Health.

From the study, published in the *American Journal of Transplantation*, **there is also a higher incidence in heart transplant recipients (1.57%) and a lower incidence in liver recipients (0.63%).** Mortality due to SARS-CoV-2 infection was also found to be higher in the transplanted population (30.6%) than in the general population (15.4%), with lower and overlapping incidence with the general population in liver recipients (15.7%). The epidemiological analysis, which involved the entire National Transplant Network, covered the first four months of the health emergency in Italy (from 21 February to 22 June 2020) with an observation of the population up until 30 September 2020.

It is a study of the Italian National Transplant Network that identifies a **possible correlation between the presence of certain HLA antigens** (the genetic system responsible for regulating the immune system in humans) **and increased predisposition both to SARS-CoV-2 infection and a negative clinical course.**

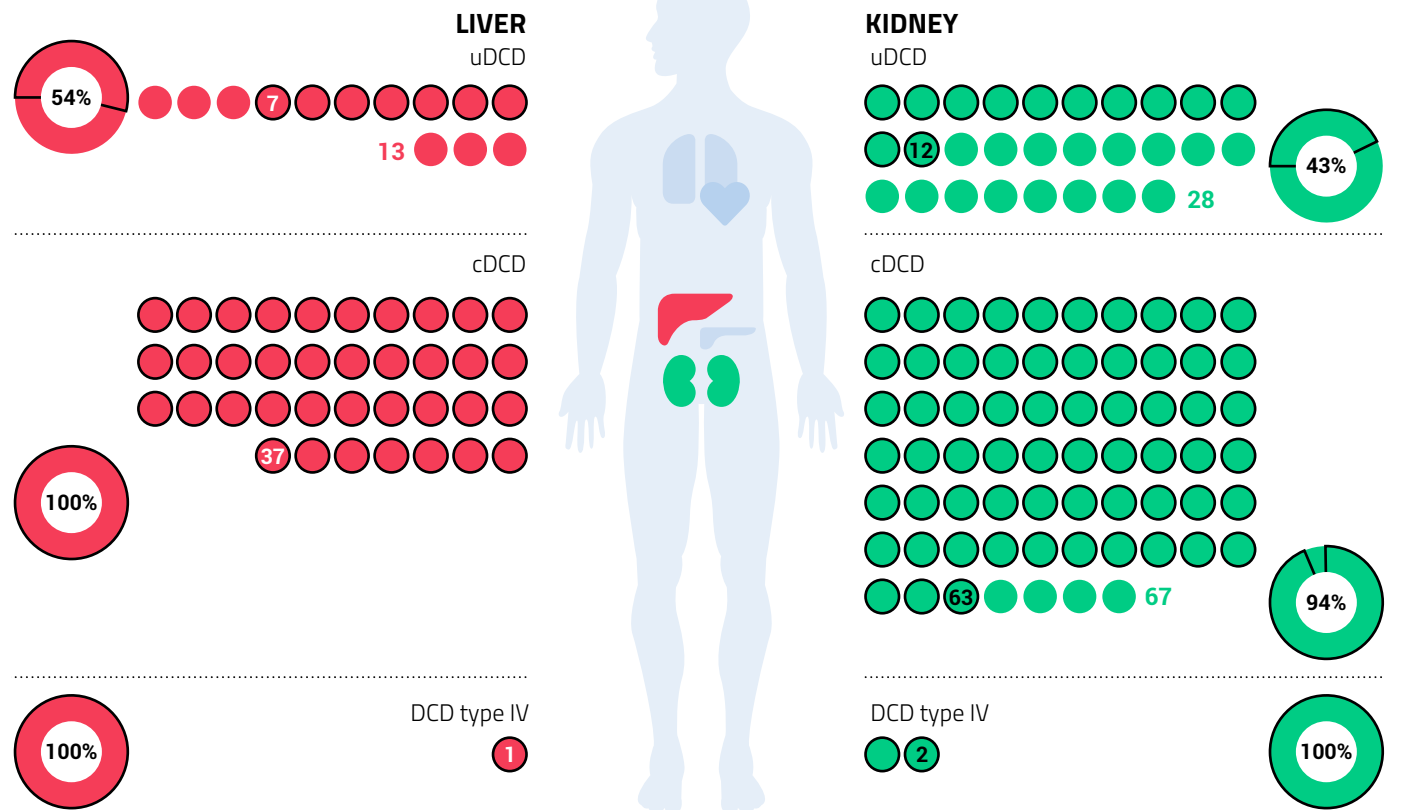
The research, published in the journal *Transplantation*, highlighted that the presence of the HLA-DRB1*08 variant in the subjects analysed (solid organ transplants and patients on the waiting list) was associated with more cases of positivity (with approximately a two-fold increase) and more deaths from Covid-19 (a three-fold increase). The study, which collected data on Coronavirus-positive patients present as of 22 March 2020 in the epidemiological surveillance register of the Italian National Institute of Health, also confirms a **slightly higher risk of infection for people with blood group A compared to group O.**

TRANSPLANTS FROM DONATION AFTER CARDIAC DEATH

In 2020, 114 Donation after Cardiac Death (DCD) organ transplants were carried out: the organs came, mainly, from controlled DCD (cDCD), with a percentage of use greater than 80% compared to 31% of uncontrolled donations (uDCD).

Seventy nine (79)% of the organs procured were transplanted: the percentage increases to 100% if livers are taken into account and 94% if kidneys harvested from a cDCD donor are considered. All livers that were perfused *ex situ* - and a third of those that were not perfused were utilized. Despite the innovative combined harvesting procedure during normothermic regional perfusion, there were only 3 (double) lung transplants, all perfused *ex situ*. The follow-up data available (on operations performed up to 2019) seem to demonstrate good transplant survival rates for both liver and kidney, with particular reference to organs from cDCD donors; these rates are similar to those recorded, in the same period, for transplants from donors whose death was established by neurological criteria.

RELATIONSHIP BETWEEN PROCUREMENT AND TRANSPLANTS



KIDNEY TRANSPLANTS

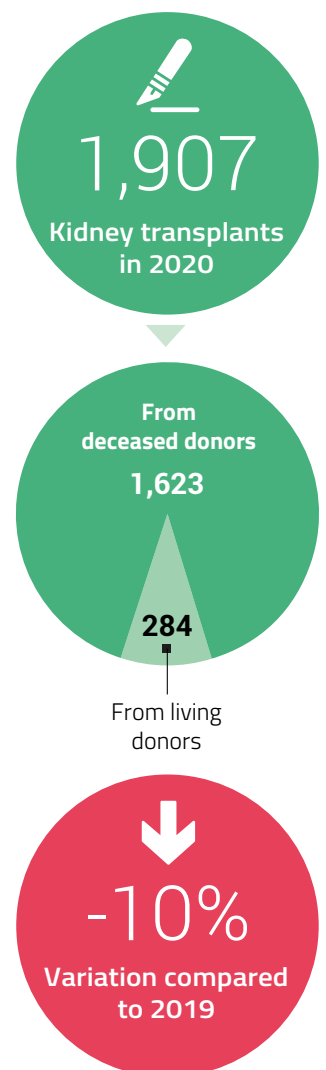
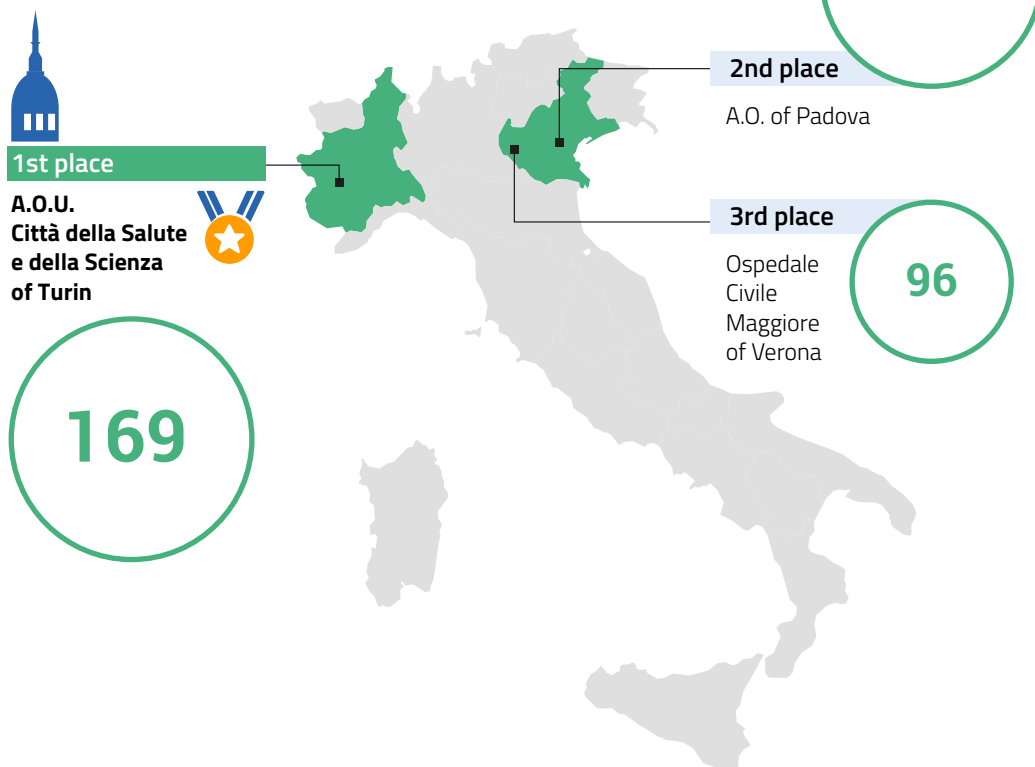
In 2020, 1,907 kidney transplants were performed. In detail: 1,623 from deceased donors (111 for double kidney and 61 combined with another organ) and 284 from living donors. For both types, there was a slight decrease compared to 2019 (-10%), in line with the contraction of all health activities in the country as a result of the coronavirus pandemic. Patients who received the transplant from deceased donors in 2020 waited for 2.07 years on average on the waiting list.

CENTRES

As had happened in 2019, **A.O.U. Città della Salute e della Scienza of Turin** was the centre that performed the most kidney transplants in 2020 with **169 overall** and was also a leader for transplants in hyperimmune patients; followed by A.O. di Padova (139) and Ospedale Civile Maggiore of Verona (96).

THE PODIUM

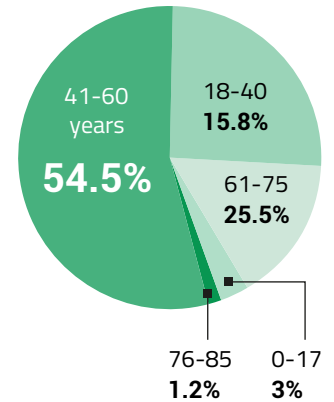
○ Number of transplants



AGE

More than half of transplant patients in 2020 (54%) were between 41 and 60 years old, followed by patients between 61 and 75 years (25%). Overall, there were 49 transplants from deceased donors of paediatric age (0-17 years). Ospedale Pediatrico Bambino Gesù (14 operations), Ospedale S. Martino of Genoa (13) and Ospedale Maggiore Policlinico of Milan (10) are the Centres with the greatest activity in paediatric patients.

TRANSPLANTS BY AGE GROUPS

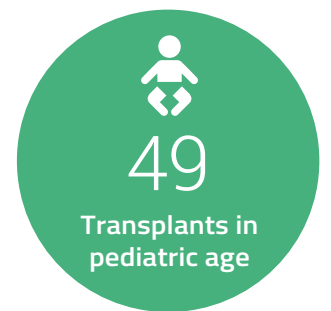


REGIONS AND PATIENTS

Of the regions with an active transplant program, **Calabria, Campania and Puglia are those with intense extra-regional mobility**, recording percentages of transplants in favour of their own citizens, conducted outside the region, about **40-50%**. **Veneto is by far the most “welcoming” region**, with almost half of the transplants (183/282) performed in patients from other regions. Emilia Romagna is the leading one for cross-mobility: 64 of the 148 transplants performed in the Centres of Emilia Romagna were in favour of citizens coming from other regions, but almost as many patients resident in Emilia Romagna received transplants in surrounding regions (Veneto and Lombardy).

MOBILITY

- Welcoming region
- Cross-mobility region
- Intense extra-regional mobility



TRANSPLANTS FROM LIVING DONORS

After the increase in previous years, 2020 saw a substantial reduction in the number of living donor transplants. Some centres have had to reduce and, in some cases, suspend their living kidney transplant programs in view of the severe resource constraints resulting from the commitment of hospitals to counter the Coronavirus pandemic.

Padua is the centre with the highest volume of activity. Of note, the excellent performance of the centre in Bari, over the last three years there has been a substantial increase in the number of operations compared to the previous period.

Also, the **cross-over program in 2002, nationally and internationally, suffered a slowdown**. Indeed, the pandemic has led to the suspension of the evaluation of cross-over *chains* initiated thanks to the availability of a Samaritan donor. In the second half of the year the DECK (DECEased Kidney Paired Exchange) program was reactivated: using the kidneys of two deceased donors it was possible to use 3 pairs from living donors. As regards international *crossover*, it was possible to carry out only one *match-run* between Italian, Spanish and Portuguese couples, leading to the use of only one Italian couple. The Centres involved were those of Padua and Gemelli in Rome.

BEST PERFORMANCE

- Centres with intense volumes of activity
- Centres involved in international crossover



TRANSPLANT IN PATIENTS WITH DISABILITIES

At Policlinico of Bari, a very rare kidney transplant was carried out on a young deaf-blind man. The operation involved 64 professionals and 5 teams.



THE PROTOCOL IN KPD MODE

The protocol for the implementation of kidney transplantation from a living donor in kidney paired donation (KPD) mode was revised on 20 January 2020 and included the transplantation chains with living donors in cross-over mode, the chains with a Samaritan kidney donor and the chains with kidneys from deceased donors (DECK programme).

LIVER TRANSPLANTS

In recent years, transplant activity has remained stable, with more than 1,200 annual operations: after the record of 2017 (1,295 total interventions) and the excellent result of 2019 (1,277), **2020 saw a slight decline compared to the previous year (1,182)**. This occurred despite the pandemic, two peaks in infections and critical health management have helped slow its evolution. To support this evidence, an average waiting time to transplant was stable when compared to 2019. However, it must be considered that the data provided is global and does not take into account the type of programme, which can affect it considerably.

CENTRES

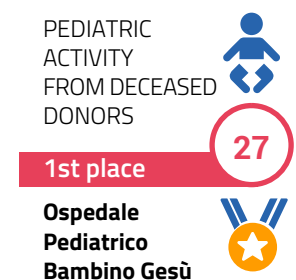
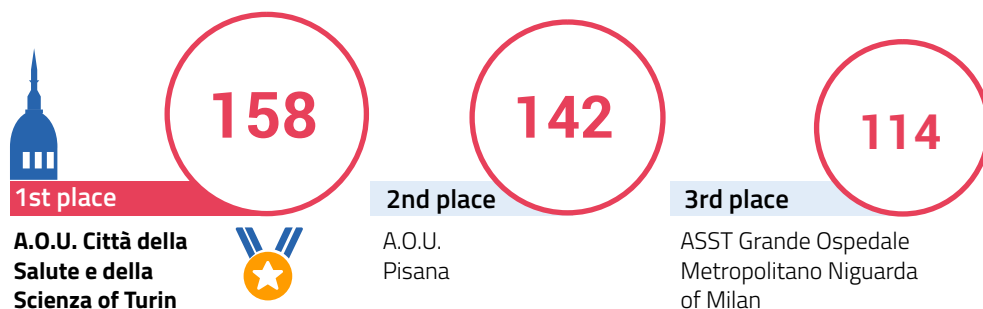
The Lombardy centres, strongly affected by the pandemic, ended 2020 with a **minimal reduction compared to the previous year (-14%)**.

The transplant activity of the **Northern macro area**, where 60% of the total number of centres is located, **saw a reduction of less than 5%** compared to the previous year. In particular, A.O.U. Città della Salute e della Scienza of Turin ended 2020 with an increase (+8.2%) - the result of great organization and efficiency - making it the centre with the highest number of transplants performed (158). Centres that were confirmed as high-volume centres include A.O.U. Pisana (142) and the ASST Grande Ospedale Metropolitano Niguarda of Milan (114), whose decrease, when compared to 2019, was minimal. As part of the National Paediatric Programme, Ospedale Pediatrico Bambino Gesù of Rome had the highest number of deceased donor transplants (27), followed by Bergamo (22), Palermo Is.Me.TT. (8), Padua (5), Turin (6), Bologna (1) and Genoa (1).



THE PODIUM

○ Number of transplants



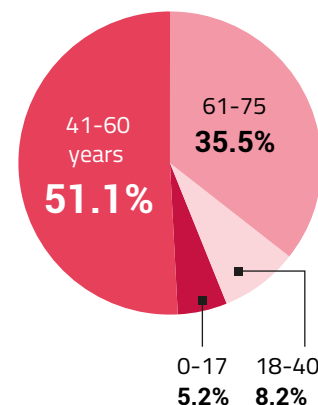
AGE

More than half of the transplanted patients (51.1%) are in the 41-60 age group demonstrating that the recipients tend to be young.

However, in 35.5% of cases those who benefited from a transplant were patients included in the 61-75 range: the figure is significant since it testifies that the age does not represent, with particular reference to the liver, an absolute contraindication to transplantation.

Finally, **61 transplants in patients aged 17 years and under**, were performed, a number that was stable when compared to 2019.

TRANSPLANTS BY AGE GROUPS

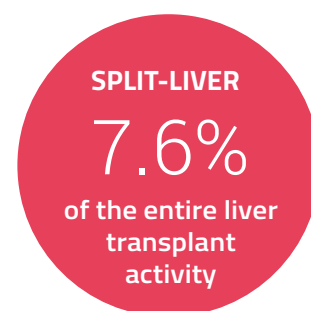
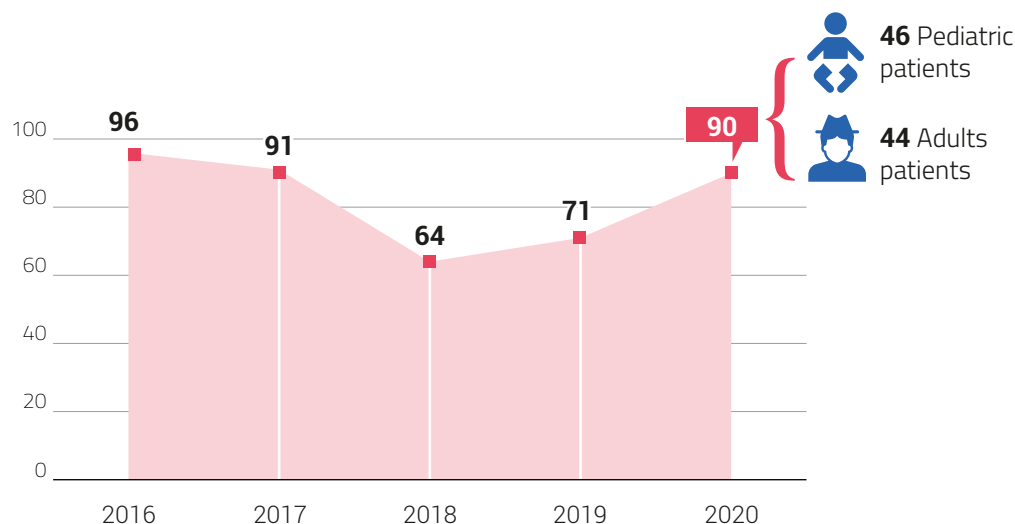
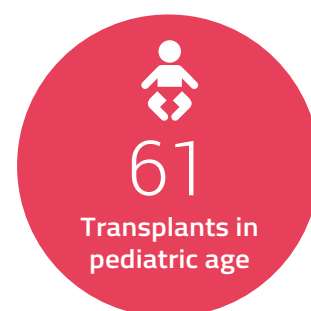


ONE DONOR, TWO TRANSPLANTS: INCREASE IN SPLIT-LIVER ACTIVITY

In 2020 there was a significant resumption of operations carried out with the **split-liver technique, which, by dividing the liver into two portions, allows the transplant capacity of the organ to be doubled.**

There has therefore been a return to the rate of **90 annual operations**, in line with data from 2016 and 2017, when a *policy* was introduced where by the application of this technique was mandatory for all donors who are aged 50 years and under and have a standard risk. The good result achieved in 2020 also reflects the modification of some allocation rules, introduced at the beginning of the year, with the aim of implementing the activity and reversing the trend recorded in the two-year period 2018-2019.

From the 90 split-Liver procedures, 44 transplants were performed on adult recipients and 46 on paediatric recipients.



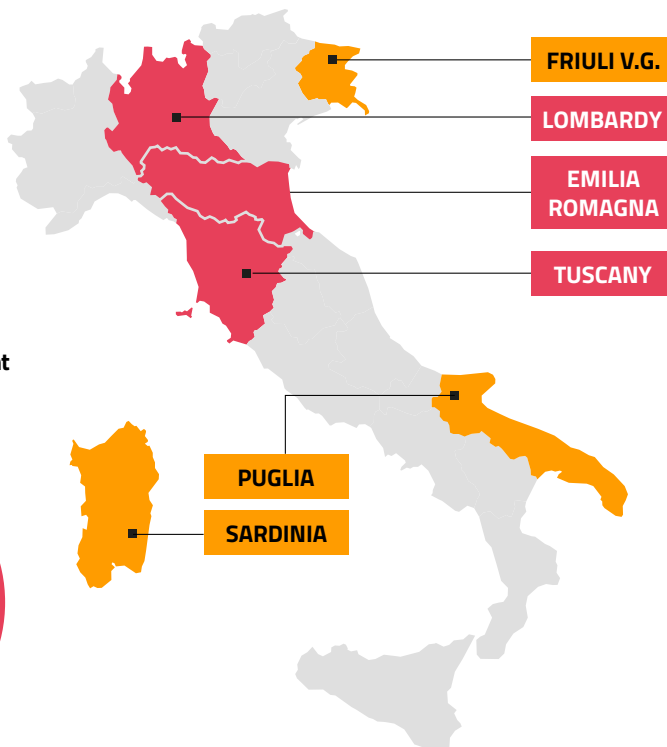
REGIONS AND PATIENTS

More than two-thirds (68.8%) of the transplants performed in 2020 involved patients who were resident in the region where the operation took place, the remaining 31.2% were, on the other hand, attributable to a trend in mobility from South to North.

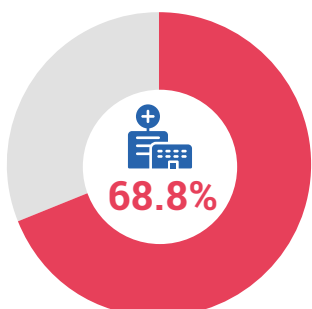
In percentage terms, Tuscany (46.5%), Emilia Romagna (34.7%) and Lombardy (31.2%) recorded the largest share of the transplants that involved patients from other regions, while Puglia, Sardinia and Friuli-Venezia Giulia only transplanted patients who were resident in the same region.

MOBILITY

- Welcoming region
- Regions which transplanted only its residents



Transplants on patients resident where the Transplant centre is located



UPDATES AND REVIEW

Deliberated in 2020 (and in force from May 2021) updates of the following national protocols: National super urgencies, Macro area emergencies, Split-Liver. The paediatric algorithm for liver was also changed and then added to the National Paediatric Protocol.



SARS-COV-2 DECEASED DONOR TRANSPLANTS

In 2020, 7 liver transplants were performed from deceased donors with SARS-CoV-2 positivity, in total safety and on selected cases as established by the first protocol of the National Transplant Centre on the matter dated August 21st.

LIVING DONOR TRANSPLANT ACTIVITY

Living donor transplant activity remained stable in 2020 compared to 2019 and continued to represent an important share of the total, especially in the paediatric field. **20 transplants were performed nationwide, 15 of them paediatric (75%) and 5 adults (25%).**

The centres with the largest volume of activity, from 2011 to 2020, are the Is.Me.TT. of Palermo (66 total operations) and Ospedale Pediatrico Bambino Gesù of Rome (65). Compared to 2020, the Is.Me.TT. of Palermo recorded the highest number of transplants (12) - 2 of them in adults - followed by Ospedale Pediatrico Bambino Gesù (3) and the hospitals of Padua (2), Modena (2) and Bologna (1).

In particular, the activity of the Centres of Emilia Romagna concerned adults exclusively.

THE PODIUM

○ Number of transplants



HEART TRANSPLANTS

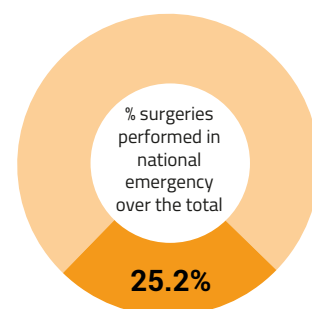
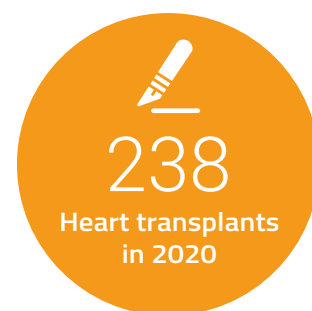
Despite the difficulties related to the SARS-CoV-2 health emergency, in 2020 the heart transplant activity saw **only a slight decrease (-3.2%)**, with a record **238 transplants** compared to 246 in 2019. Heart transplants combined with other organs continue to represent a small share (0.8%) compared to the total number of transplants, only 2 interventions of this type having been carried out in 2020. The percentage of transplants performed under national emergency was 25.2% (44.3% in 2019), while in 17.2% of cases the operation was performed on patients in macro area urgency, according to the new heart allocation methods foreseen by the current protocol, in force since 9 March 2020. The average waiting times for patients on the Standard List overlapped with those of 2019, while there was an increase in the average waiting times for patients on the paediatric list.

CENTRES

From 2011 to 2020, the centres that performed the **most operations** were **A.O. of Padova (286)**, the ASST Grande Ospedale Metropolitano Niguarda of Milan (271), Ospedale Santa Maria della Misericordia of Udine (227) and the Policlinico Sant’Orsola Malpighi of Bologna (223). From the analysis of the data of the last two years, the structures that suffered the most from the effects of the pandemic were Bergamo, with 10 fewer transplants compared to 2019, and Milan, which went from 34 to 23. In contrast, some centres continued to record a **positive trend**, in particolare **Padua and Naples**. The latter is confirmed to be the centre of the Central-South area with the largest volume of activity: 23 transplants carried out in 2020.

THE PODIUM

○ Number of transplants



AGE

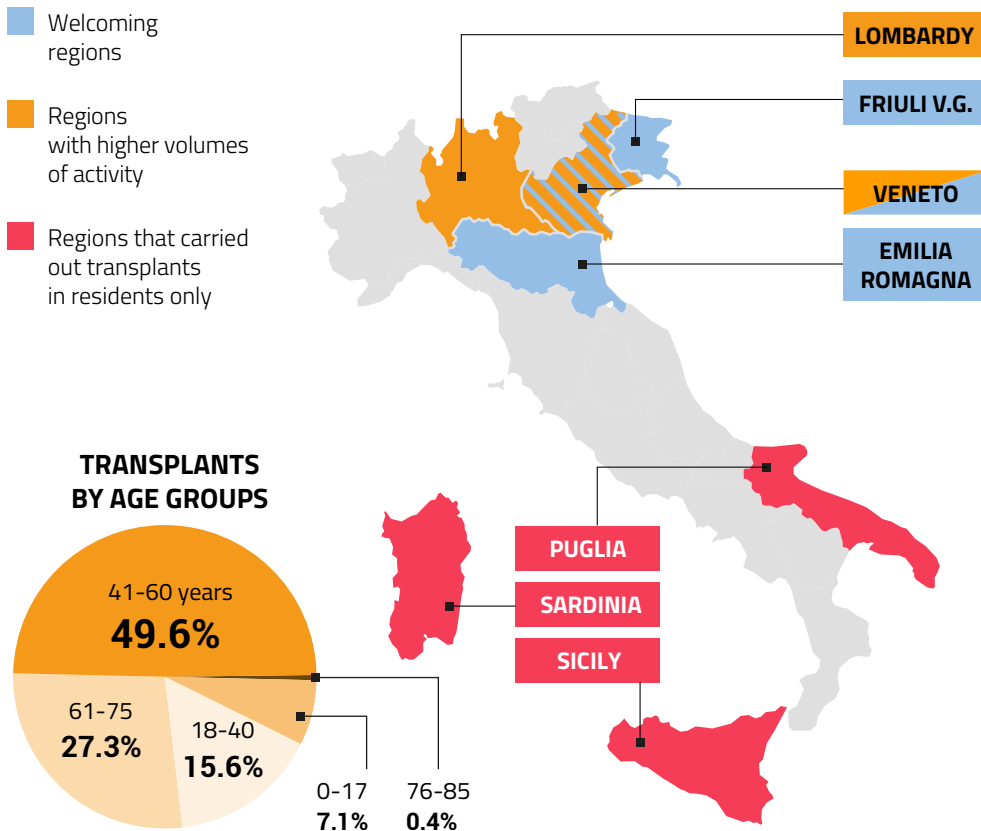
Almost half of transplant patients in 2020 were between the ages of 41 and 60 (49.6%), an increase compared to 2019 (44.7%).

In 27.7% of cases patients were over 60 and, of these, in only one case was the transplant performed on a 76-year-old recipient on the ordinary waiting list: it was an extraordinary event, indicative of the effort to increase the age of heart transplant candidates.

Transplant patients in the range 0-17 (paediatric recipients) are consistently around 7%.

REGIONS AND PATIENTS

The **Friuli Venezia Giulia region** (61.9%) was confirmed in 2020 as having the largest percentage of transplanted patients living outside the region, followed by Emilia Romagna (33.3%) and Veneto (24.5%); the latter is the first region by volume of activity with 49 total transplants, Lombardy (41) is in second place. In contrast, in Puglia, Sardinia and Sicily only patients living in the region were transplanted.



A NEW HEART FOR A 76-YEAR-OLD

In 2020 a heart transplant was carried out on a recipient who was 76 years old, on the standard waiting list, while in about 50% of cases transplant patients are aged between 41 and 60 years.



THE NEW URGENCY REGULATION

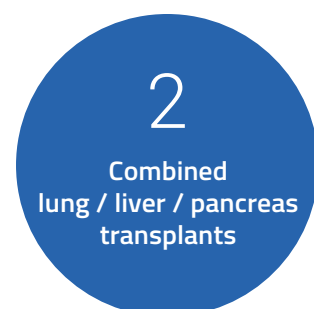
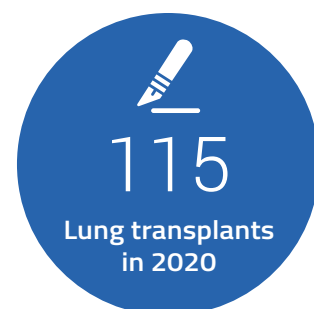
From 9 March 2020 the new "Regulation of heart emergencies at a national and a macro area level" came into force, and two commissions of experts were established in order to evaluate special urgent requests, one for paediatric recipients and the other for adult.

LUNG TRANSPLANTS

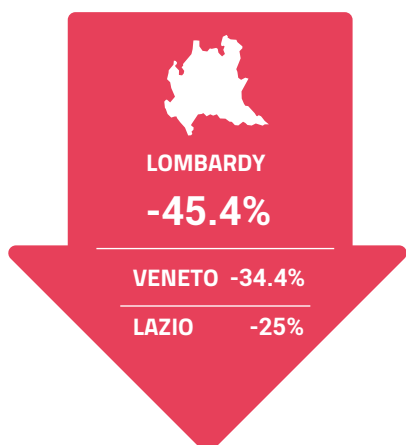
The pandemic has disrupted the growth trend of lung transplant activity of recent years, returning the number to the values of 5 years ago. In 2020, compared to 2019, the **percentage reduction** of the total number of transplants was **24.8%**, covering all types; in particular, the number of single transplants almost halved compared to the previous year (-42.8%). The average waiting time for transplantation is just over a year, with almost all centres having waiting times of less than a year and only three centres (Pavia, Palermo and Roma Sapienza) with times that exceed 2 years. The positive note concerns the execution of two combined lung/liver/pancreas transplants, complex operations from the point of view of peri-operative and allocation management; a demonstration of the clinical and organizational excellence of our Network despite the critical issues due to the pandemic.

CENTRES

The reduction in activity has affected, to varying degrees, almost all transplant centres. The region most affected was Lombardy (-45.4%), followed by Veneto (-34.4%) and Lazio (-25%) in line with the pandemic trend and the consequent impact on regional health systems. Increases, albeit minimal, occurred in some centres (Bologna, Siena, Ospedale Pediatrico Bambino Gesù) that historically carried out smaller volumes of activities, less than 10 transplants/year.



REGIONS WITH THE GREATEST REDUCTION IN ACTIVITY



CENTRES THAT EXPERIENCED AN INCREASE IN TRANSPLANTS



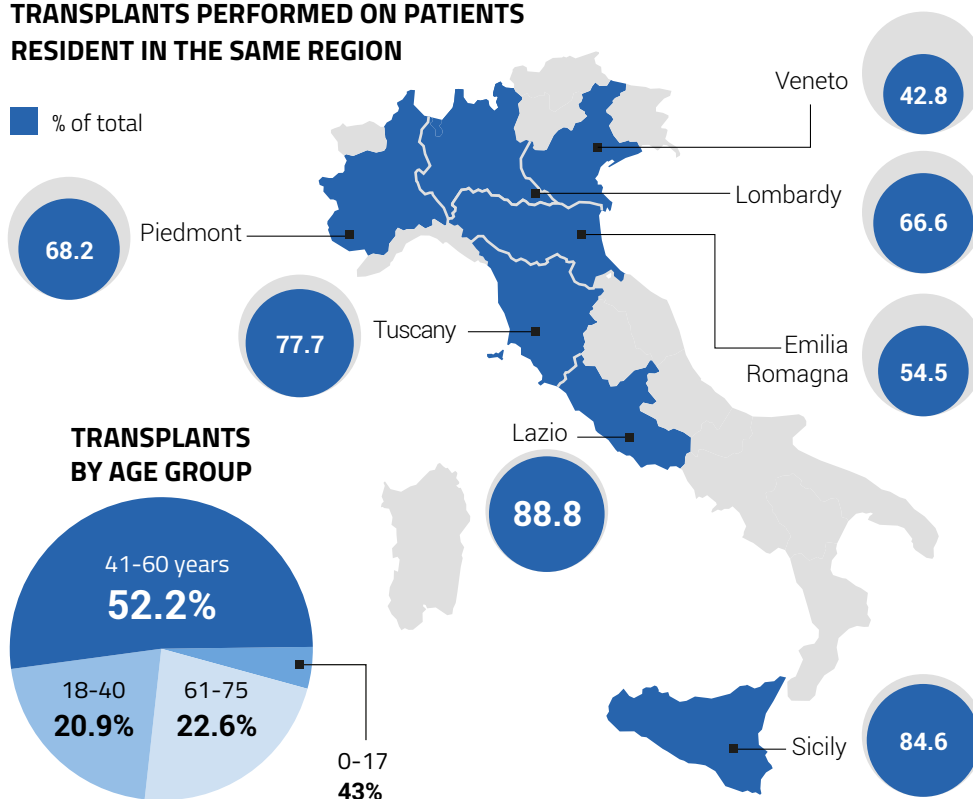
AGE

Fifty-two point two (52.2)% of transplants were performed in patients between 41 and 60 years of age, 20.9% in patients aged 18 to 40 years and 22.6% in patients aged over 60. The data confirms that **age is not a limiting factor** in terms of access to transplantation and that Italian transplant centres have high management capabilities, both for young and older transplanted patients. 16.5% of transplants were carried out on clinical emergency recipients and 6% on paediatric recipients.

REGIONS AND PATIENTS

Seven Italian regions act as “collectors of care needs” in terms of transplantation and, being aware of this role, share the available resources between resident and non-resident patients in the same regional reality. Mobility affects all regions transversely (both those in which the transplant centre is present and those without it) in full respect of the principle of freedom of choice of the citizen, which maintains the right of fair access to healthcare regardless of the region of residence. In 2020, despite the difficulties in mobility caused by the health emergency, **35% of transplants were carried out on non-residents**, while 65% came from a region where there is a transplant centre.

TRANSPLANTS PERFORMED ON PATIENTS RESIDENT IN THE SAME REGION



ITALIAN PRIMACY

The first lung transplant in Europe in a patient affected by Covid-19 was completed in May 2020 at the Policlinico of Milan. The efficiency of the Transplant Network has led to an important success of the National Health Service.



TRANSPLANTS AND COVID-19

The “pilot protocol for lung transplantation in recipients with Covid-19 infection outcomes” (21 October 2020), sets the goal of evaluating the safety and efficacy of lung transplantation in patients with ARDS (acute respiratory distress syndrome) and interstitial pulmonary fibrosis post - Covid-19.

PANCREAS TRANSPLANTS

In the decade from 2011 to 2020, pancreatic transplant activity has remained constant, with a total of 507 operations, most of which were achieved in the years 2012 and 2016 (67 transplants per year), while the lowest values are from 2017 (39). **2020 values (41) are in line with the previous two years** (41 also in 2018, 42 in 2019). Transplant activity combined with kidney transplantation is about five times greater compared to that of pancreas transplantation activity alone. Combinations with other organs are sporadic.

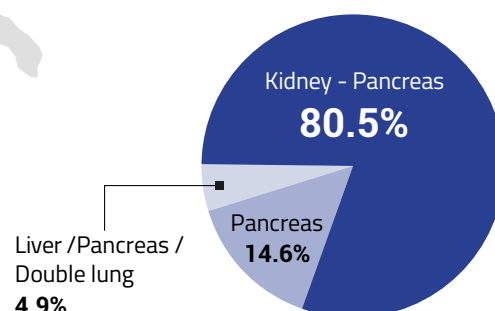
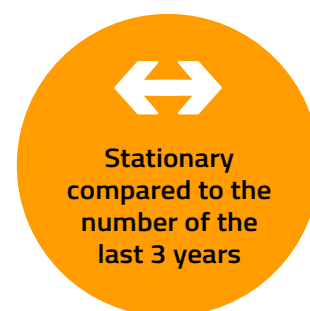
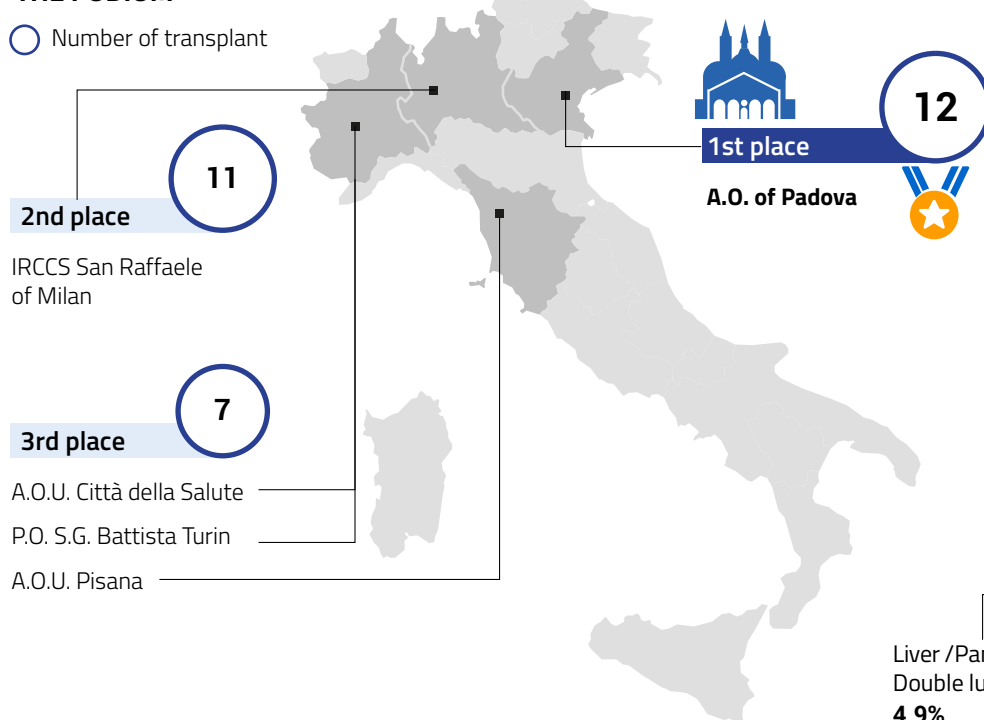
The average transplant waiting time was about 11 months in 2020.

CENTRES

From 2011 to 2020, **the centres that performed the most operations were located in the North**: IRCCS San Raffaele of Milan (116), A.O.U. Pisana (103) and the A.O. di Padova (99). In 2020 those with highest activity level were: the A.O. di Padova (12), IRCCS San Raffaele of Milan (11), A.O.U. Pisana (7), A.O.U. Città della Salute (7) and P.O.S.G. Battista Torino (7).

THE PODIUM

○ Number of transplant



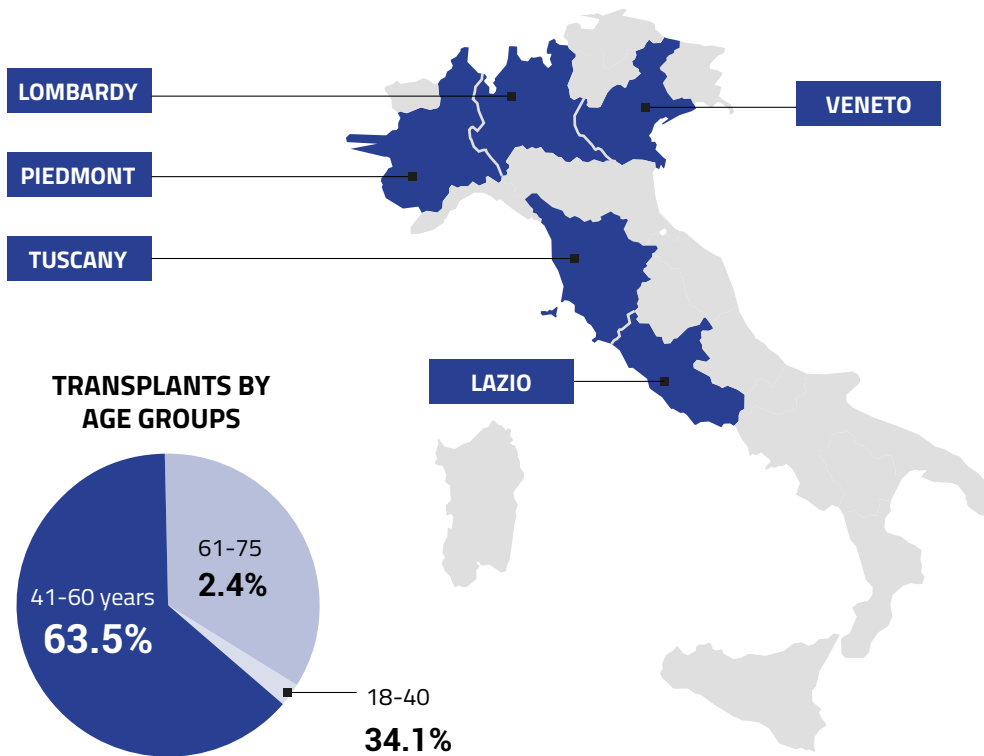
AGE

In 2020, pancreas transplantation was performed **only in adult patients**, mainly in the age group **between 41 and 60 years (63.5% of cases)**, followed by 18-40 (34.1%) and 61-75 (2.4%).

REGIONS AND PATIENTS

In 2020, pancreatic transplant activity took place in 5 regions: to access such a program, patients often turned to centres located in a region other than the region of residence, with the exception of those living in Lombardy and Veneto.

ALL ACTIVITY IN 5 REGIONS



WAITING LISTS



AN OVERVIEW



Fluctuations in the number of patients on the transplant waiting list reflect multiple factors.

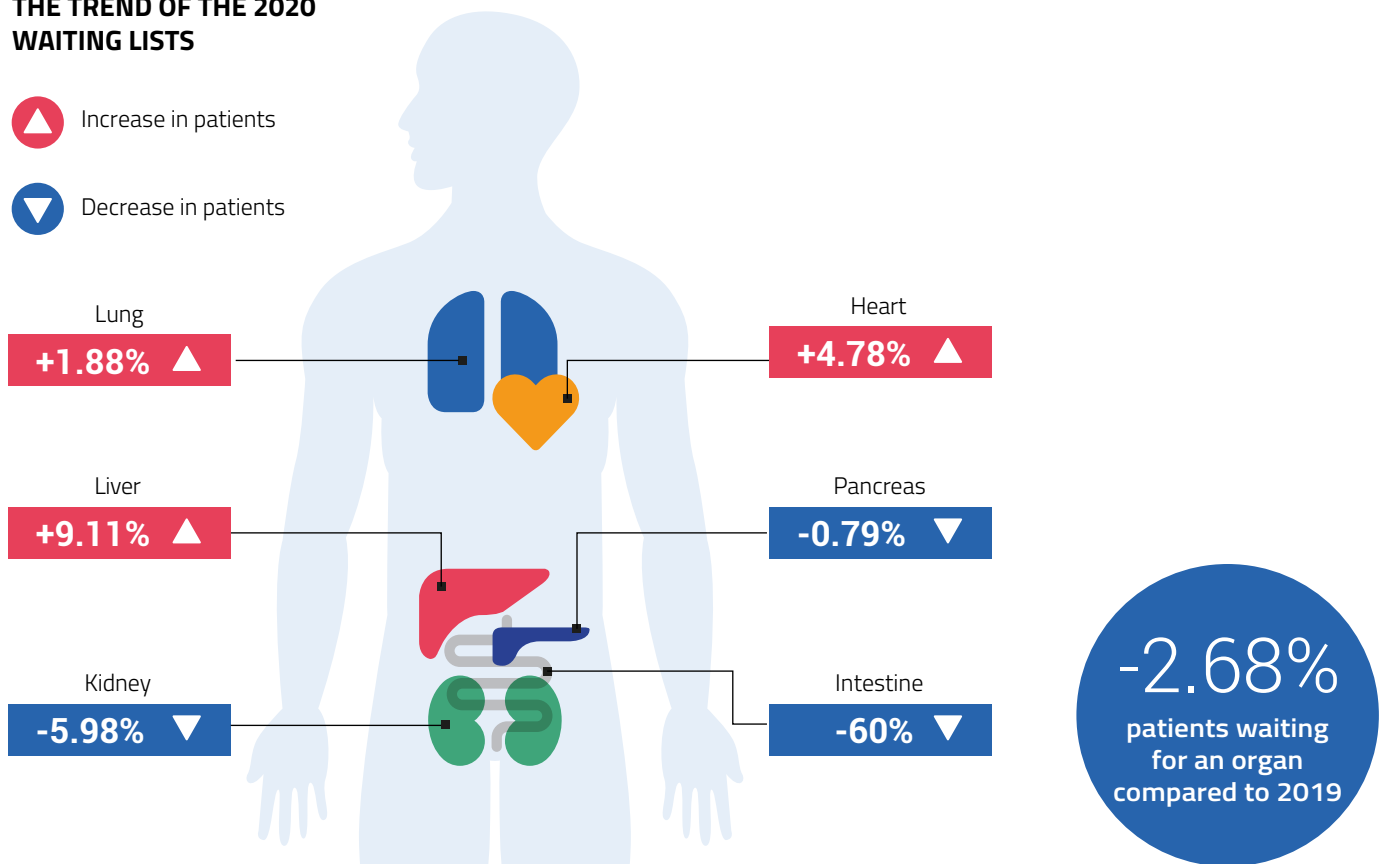
In 2020, due to the pandemic, additional causes were added, such as the suspension of outpatient activities and organizational difficulties and access to services in health facilities.

Compared to 2019, there was a decrease in patients waiting for an organ (-2.68%); a result attributable to the reduction of those waiting for a kidney, intestines and pancreas compared to an increase noted for patients waiting for heart, liver and lungs.

Compared to patients waiting for kidneys, the significant decrease was due to fewer new entries on the list (-24%) and the significant increase in mortality in the list (+0.8%). These data are likely to be correlated with a higher mortality rate from SARS-CoV-2 infection for this category of frail patients, on dialysis, waiting for a non-life-saving organ with long waiting times on the list.

THE TREND OF THE 2020 WAITING LISTS

-  Increase in patients
-  Decrease in patients



WAITING LISTS: KIDNEY

From 1 January to 31 December 2020, the ITT value (*Intention To Treat*, based on the total of patients enrolled as of 31 December 2019 and the number of new admissions in 2020) had **10,267 registrations**, the mortality rate was 2.3% while the satisfaction index in the list was **15.8%**.

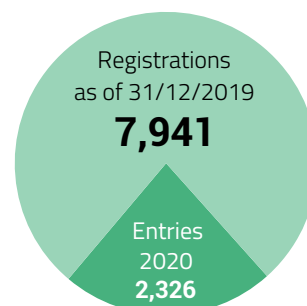
During 2020, **2,843** of the 7,941 patients on the waiting list on 31 December 2019 **dropped out of the list**: 1,623 because of transplantation, 239 because of death and 980 because of being suspended for ineligibility - temporary or permanent.

In the same period **2,326 patients were listed** for whom, as of 31 December 2020, 7,424 patients were on the active list for kidney transplantation.

AVERAGE WAITING TIMES



Average time on waiting list does not take into account suspension periods. In addition, in the case of centres with a limited waiting list at the end of the year, the average waiting value can often be strongly influenced by particularly complex clinical cases.



COMPOSITION OF THE WAITING LIST

At a national level, the percentage of **patients resident in the region in which they are listed is 69.1%** and that of “extra regional” patients is 30.1%. The proportion of patients who come from regions with agreements with others for this type of operation (0.5%) remains marginal, as is the case for foreign patients (0.3%)

In the case of Ospedale Pediatrico Bambino Gesù, the centre for transplantation in the paediatric age group that welcomes patients from all over the Southern-Central area, the data are strongly influenced by the bidirectional flow between the neighbouring regions, while the situation of Padua and Verona is particularly significant, where more than half of the patients on the list come from other regions.

% REGION OF REGISTRATION / RESIDENCE

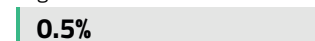
Same region of residence



Other region of residence



List of regions affiliated with region of residence



Foreign residence



WAITING LISTS: LIVER

From 1 January to 31 December 2020, the ITT value (*Intention To Treat*, based on the total of patients enrolled as of 31 December 2019 and the number of new admissions in 2020) **was 2,536 registrations**, the satisfaction index of the total list decreased only slightly (46.6%) compared to 2019 (49.5%), while the mortality rate on the list remained almost identical (4% compared to 4.2% in 2019), despite the difficult year.

In 2020 changes were released in the SIT that will allow more detailed analysis, for the current year, of the exits from the list for reasons other than death and the total *drop-out* list (such as deaths and the worsening of the clinical situation of patients on the list).

AVERAGE WAITING TIMES

The average waiting time on the list, despite the pandemic, remained stable compared to 2019 (1.55 years). It should be considered that the cases of inclusion on the PNP list and on the urgency list (super urgency/macro area) significantly influence the overall data, given that they are subject to very different allocation dynamics and it is not yet possible to calculate the timing after suspensions have been accounted for.



COMPOSITION OF THE WAITING LIST

At a national level, **in 2020, 67.4% of patients on the list were enrolled in transplant centres in their region of residence**, reflecting the same previously observed composition of transplant patients. 29.3% of patients were resident in another region, 1.1% were from abroad and 2.2% were patients enrolled in the list of regions affiliated with their region of residence for this type of operation.

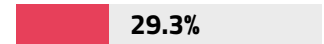
Only 8% of the recipients still enrolled in the list as of 31/12/2020 signed the consent to receive the organ from donors after cardiac death which, given the progressive increase of this type of donation, would be a valuable additional resource to increase transplantation capacity.

% REGION OF REGISTRATION/RESIDENCE

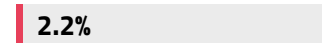
Same region of residence



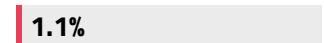
Other region of residence



List of regions affiliated with region of residence



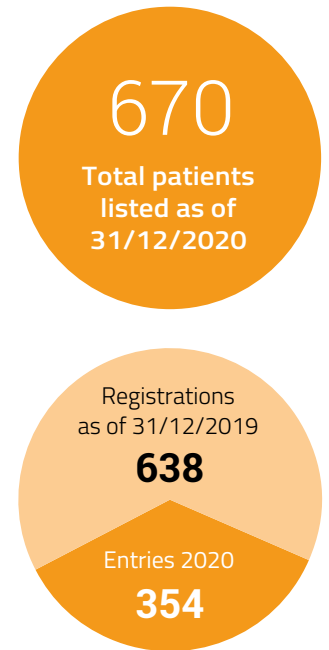
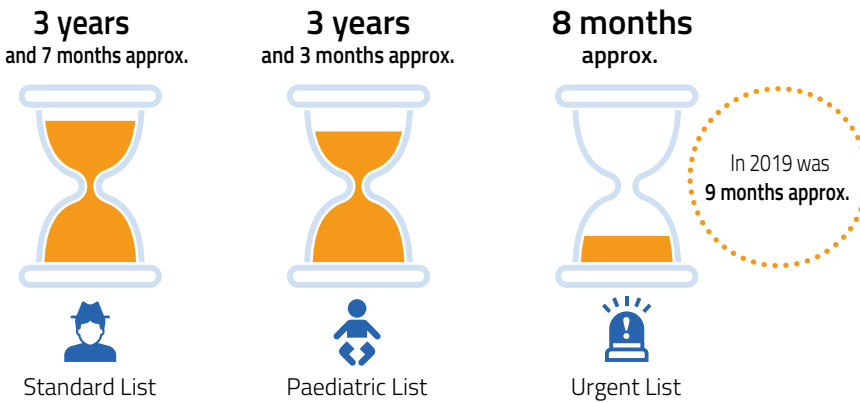
Foreign residence



WAITING LISTS: HEART

From 1 January to 31 December 2020, the ITT value (*Intention To Treat*, based on the total number of patients enrolled as of 31 December 2019 and the number of new entries in 2020) was **992 registrations**; the mortality rate on the list was 3.9% while the total satisfaction index for the list was 24%.

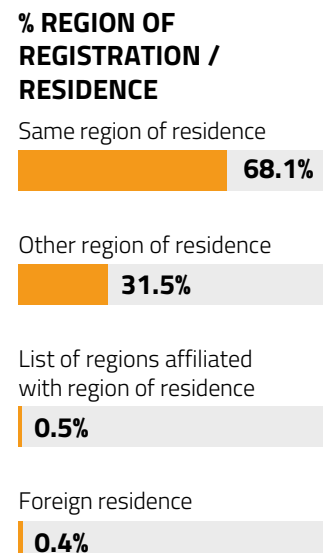
AVERAGE WAITING TIMES



Average waiting times on the list do not take into account suspension periods. In addition, in the case of centres with a limited waiting list at the end of the year, the average waiting value can often be strongly influenced by particularly complex clinical cases.

COMPOSITION OF THE WAITING LIST

At a national level, **68.1% of patients enrolled in 2020 were resident in the same region of the list in which they were enrolled**, 31.5% were resident outside the registration region and 0.4% were resident abroad. This composition reflects the picture of patients from the same or other region who received a transplant in our centres in 2020.

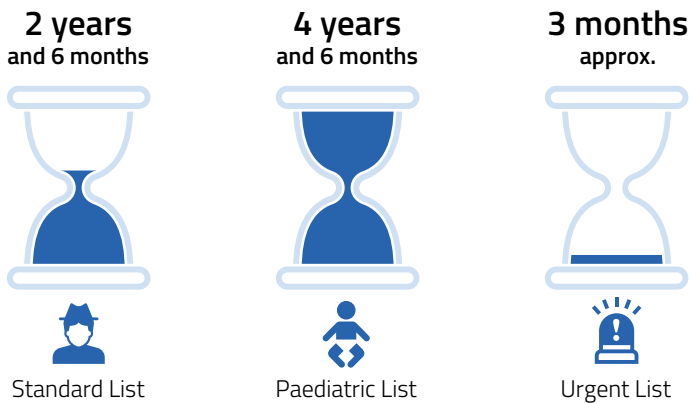


WAITING LISTS: LUNG

From 1 January to 31 December 2020, the ITT value (*Intention To Treat*, based on the total of patients enrolled as of 31 December 2019 and the number of new entries in 2020) was **492 registrations**; the mortality rate on the list was 7.5% while the total list satisfaction index was 23.4%

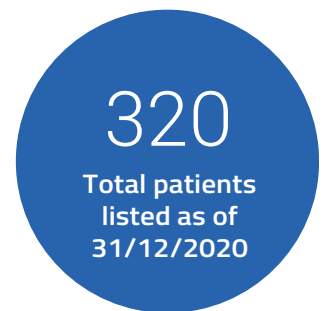
Despite the reduction of transplants, **the volume of the waiting list has not increased**, maintaining a stable balance between entries (178) and dropouts (172). The reduced number of new entrants compared to 2019 (230) was affected by the limitation of access to all health services and the mobility of the population.

AVERAGE WAITING TIMES



Average waiting times on the list do not take into account suspension periods. In addition, in the case of centres with a limited waiting list at the end of the year, the average waiting value can often be strongly influenced by particularly complex clinical cases.

The average waiting time is 2.59 years with most centres being below it, a centre with a peak of 12 years and two centres that have a time of 4 years. 6.2% of patients agreed to receive an organ from DCD.



COMPOSITION OF THE WAITING LIST

At a national level, waiting lists **are distributed in a similar way** between patients who are resident in the region where they are listed (47.2%) and those from another region (51.6%). A remaining share of 1.3% relates to patients from abroad.

% REGION OF REGISTRATION / RESIDENCE

Same region of residence



Other region of residence



Foreign residence



WAITING LISTS: PANCREAS

From 1 January to 31 December 2020 the ITT value (*Intention to Treat*, which indicates the number of patients on the waiting list for pancreatic transplantation in 2020) is **322**.

The pancreas transplant program can be for the pancreas alone or combined with other organs: kidney, liver and multi-organ. **The donor selection criteria are very selective and this helps to explain the long waiting times for patients on the list.**

AVERAGE WAITING TIMES

4 years
and 6 months approx.

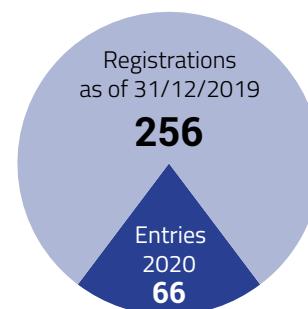


Standard List

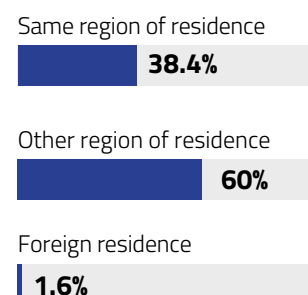
The average waiting time is 4.58 years (between 1.05 years of Ospedale Pediatrico Bambino Gesù of Rome and 14.22 years of Ospedale Umberto I of Ancona).

COMPOSITION OF THE WAITING LIST

At a national level, the proportion of patients who were resident in the same region in which they are listed is 38.4%, patients who are "extra region" make up 60%, while the share of foreign patients corresponds to 1.6%.



% REGION OF REGISTRATION / RESIDENCE



TISSUE DONATIONS and TRANSPLANTS



DONATIONS

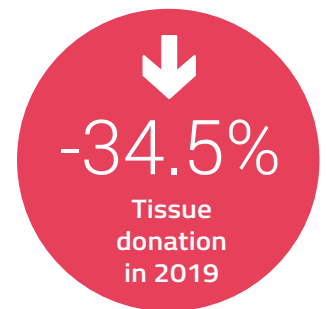
THE DONATION ACTIVITY

The tissue donation sector recorded, in 2020, **net decrease in activity, with a decrease of 34.5%** compared to 2019 due, mainly, to the difficulties related to the reorganization of the procurement centres during the SARS-CoV-2 pandemic.

In absolute terms, we went from 14,238 donations in 2019 to 9,325 in 2020. **The most obvious decreases were in musculoskeletal tissue donations (-47.5%), eye tissue (-31.2%) and vessels (-45.4%).**

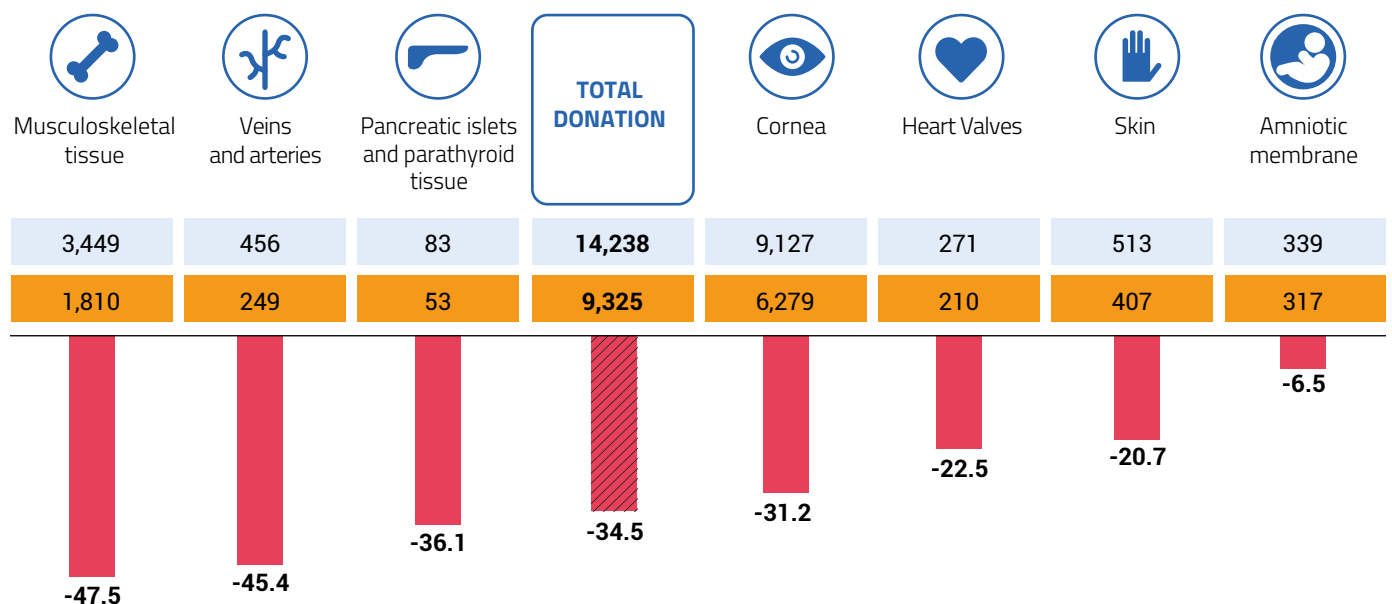
In donations of other types of tissues, the decline was less marked.

With reference to the type of donor, in 2020 there was a **significant reduction in living donation, especially in relation to bone and vascular tissues**, due to a likely decrease of elective operations in the year of the pandemic. On the contrary, thanks to the strong commitment of the harvesting network and the banks, it was possible to maintain **the number of deceased donors of musculoskeletal tissue.**



IN DETAIL

2019 2020 % Change compared to 2019



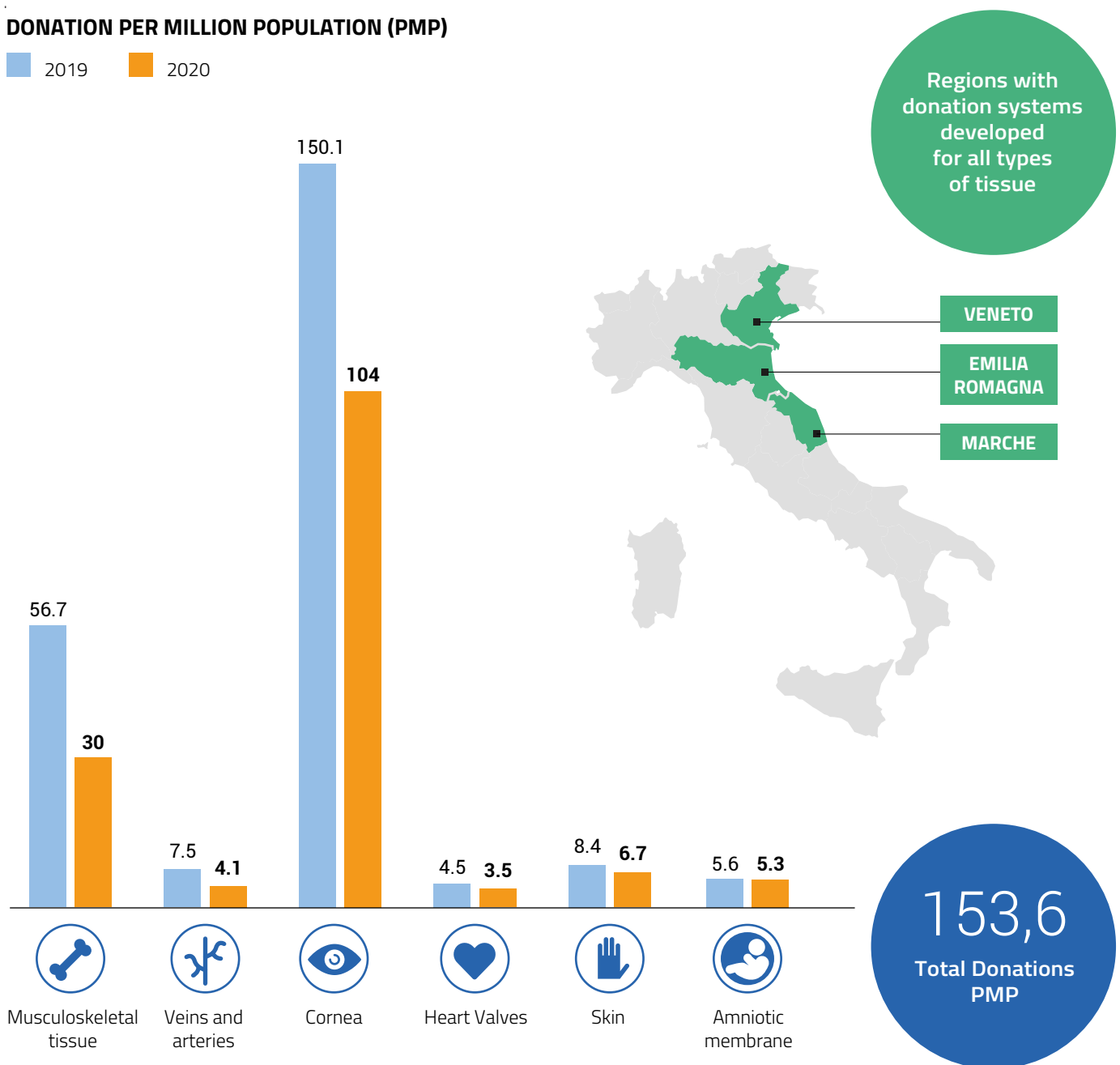
AMONG THESE TISSUES THE DONATION OF CORNEAS STANDS OUT

In 2020, the national value related to donation per million population (PMP) divided by tissue type showed the **highest data for corneal donation** (104.0 PMP), followed by musculoskeletal tissue (30.0 PMP), skin (6.7 PMP), amniotic membrane (5.3 PMP), blood vessels (4.1 PMP) and heart valves (3.5 PMP).

Emilia Romagna, Marche and Veneto are the regions where a donation system is developed for each type of tissue.

DONATION PER MILLION POPULATION (PMP)

■ 2019 ■ 2020



TRANSPLANT ACTIVITY

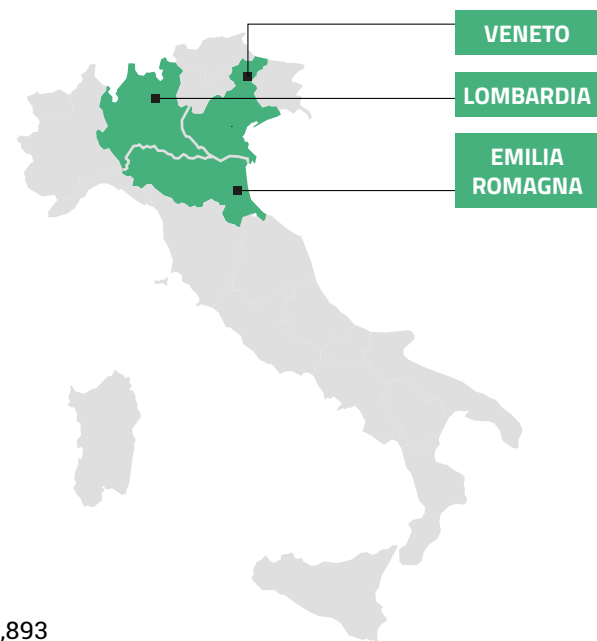
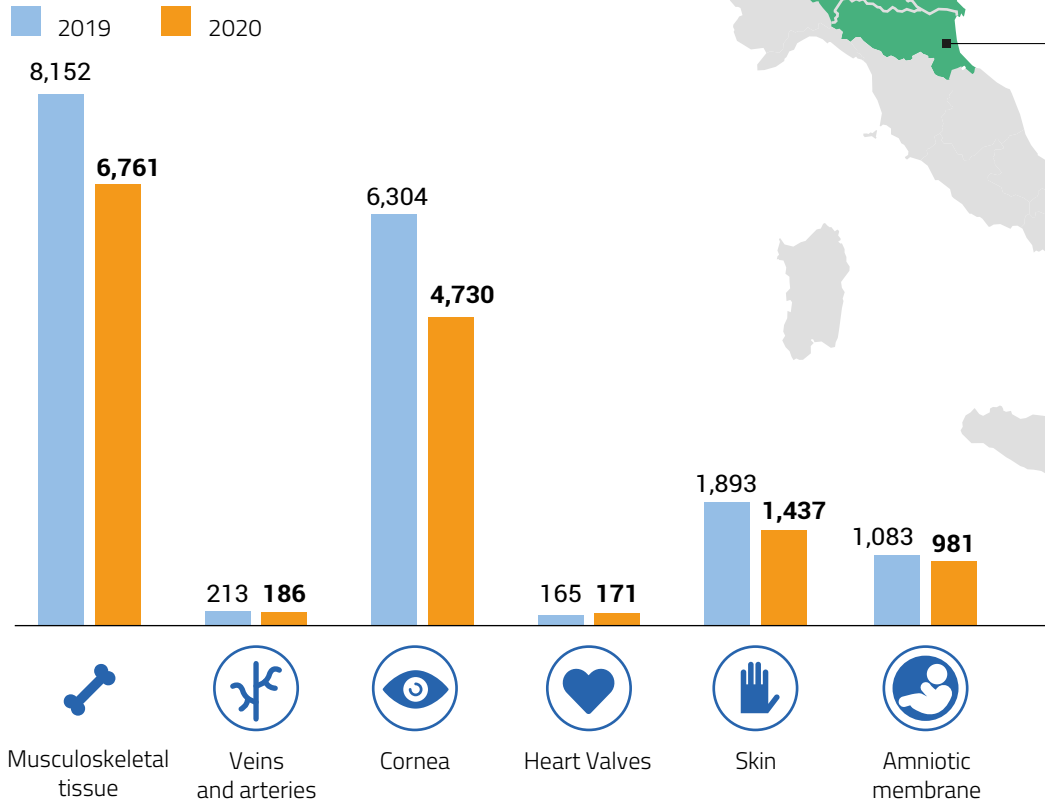
As was the case for most elective surgeries, tissue transplants also suffered a contraction since, due to the pandemic, some hospital facilities guaranteed activity only in cases of clinical emergency.

In this context, **in 2020 there was a significant decrease in the number of transplants carried out (-20.1% compared to 2019), with significant decreases for donations of corneal tissue (-25%), skin (-24.1%) and musculoskeletal (-17.1%).** Less evident, however, was the reduction in the number of transplants related to vascular tissues and amniotic membrane. The only exception concerned heart valves transplants, which turn out to be slightly increased: 171 compared to 165 in 2019 (+6 units).

In three regions in 2020 - Emilia Romagna, Lombardy and Veneto - transplants were carried out with all types of tissues.

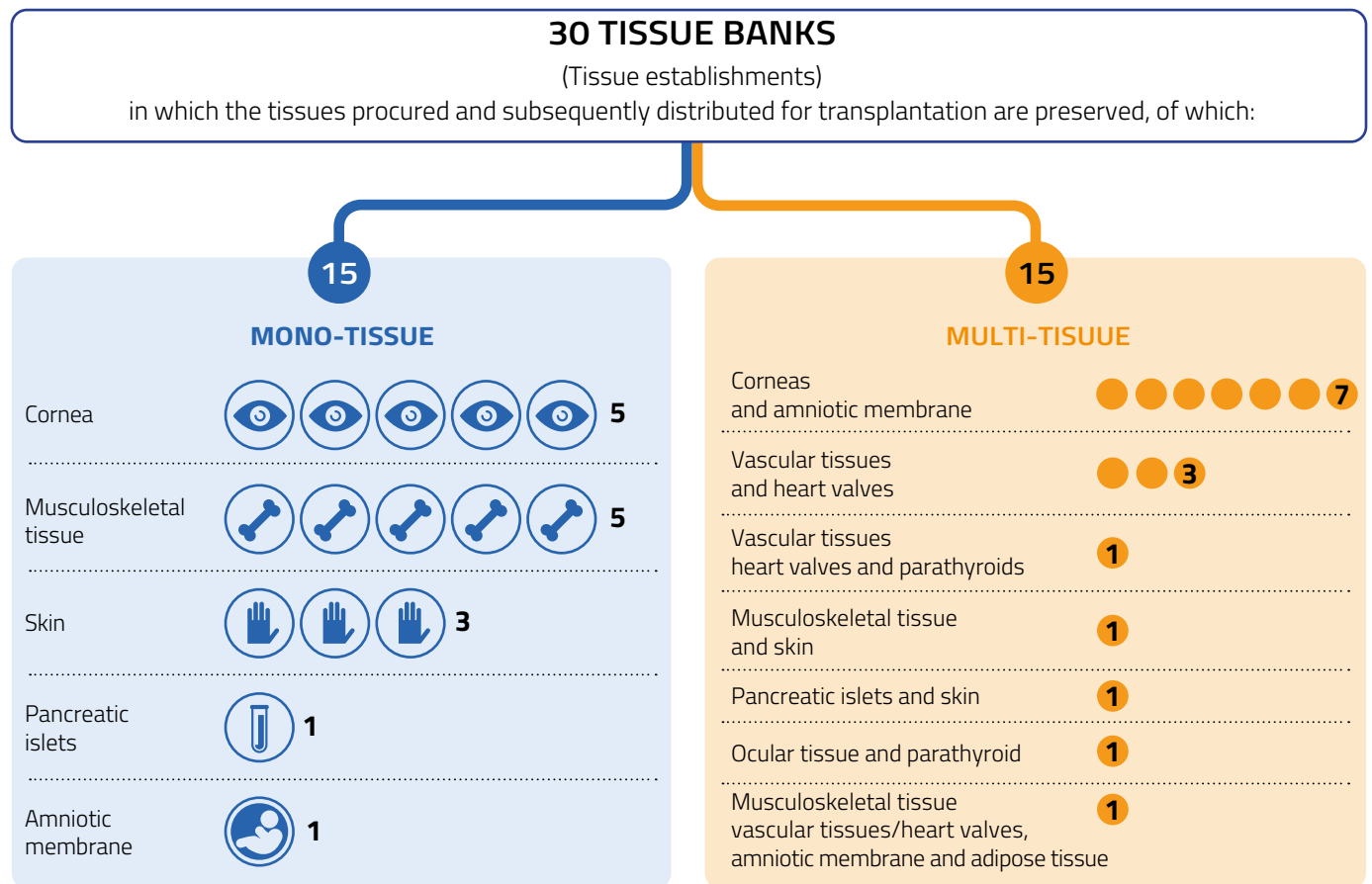
Regions with transplants for all types of tissues

TWO-YEAR COMPARISON



14,266
Transplants on 2019

BANK ACTIVITY



The activity data of the banks, divided by type of tissue and individual bank, confirm for 2020 the **negative trend in donations and transplantations**, with some noteworthy aspects:

Corneas



Unlike other tissues, corneal tissue cannot be preserved for a long time, and the reduction in the need for corneas has generated an excess of the availability of preserved ocular tissues. Despite the joint effort of the eye banks and the National Transplant Centre - to make the Network more efficient by setting up a National Exchange Network for any surplus corneas - **the general decline in activity** (from 9,127 in 2019 to 6,279 in 2020) **has affected almost all banks, except those of Lucca, Rome and, in part, Pavia**. Distribution also showed a significant decrease even if, after the decline in the second quarter, activity resumed without the usual reduction in the summer period.

Skin tissue



As regards the activities of **Skin Banks**, in 2020 there was a **26% decrease in donors**: after a significant reduction in the second quarter, the values then remained stable until the end of the year, with the only exception being the bank in Verona, which closed with a number of donors overlapping with 2019. The distribution of **skin tissue**, in line with the 2019 numbers, revealed a different trend in the four quarters of the year: the decline in the 2nd and the 4th reflected the most marked phase of the pandemic.

Cardiovascular tissues



In relation to the activities of **Cardiovascular Tissue Bank**, the number of donors in 2020 is comparable to that of the previous year, despite fluctuations related to the development of the pandemic, with a noticeable decrease in the 2nd and 4th quarters. The **Bank in Treviso** recorded the largest volumes of activity in this sector with a total increase of close to 30%, while the most significant reduction was that of the **Bank in Milan**, which nevertheless reported a clear recovery in the fourth quarter. The distribution of tissue in Italy has had a reduction of about 15%, in line with 2019.

Also for vascular tissue, the trend of the donation data was influenced by that of the pandemic: the activity of the **Bank in Treviso** (181 cadaver donors in 2020 compared to 133 in 2019).

In terms of distribution, however, the values of Bologna and Milan are in line with 2019, while Treviso – despite the decrease compared to the previous year – was characterized by a more constant trend, increasing through the quarters of the year.

Musculoskeletal tissue



Number of donors compared to 2019: this was especially caused by the decline in living donors (-58.7%), on the other hand deceased donors marked a slight reduction, although they were differently distributed.

In some regions, the procurement activity was almost non-existent, in others, such as Veneto, the number of donors grew (188 in 2020 compared to 158 the previous year). There was also a decrease, when compared to 2019, in the distribution of all types of musculoskeletal tissue, except for demineralised bone, for which the trend was equivalent to the previous year.

AN INCREASE IN CORNEAL TISSUE EXPORTATION

The import and export activity in foreign countries (EU and non-EU) involved three types of tissues:

- **cutaneous**, tissue, with the import of glycerol preserved DED (1.1 cm²), cryopreserved dermis (45 cm²) and the export of 2 packs of cryopreserved dermis;
- **corneal**, tissue, with the export of 791 pre-cut corneas for endokeratoplasty, a higher number than the 750 exported in 2019;
- **musculoskeletal**, tissue, with the export of 25 tissues, especially menisci.

In any case, the export activity did not have repercussions in Italy on the availability of tissues for transplants, given that such export is possible only in the absence of necessity within the national territory. In this sense, it includes the increase in exports of corneal tissue with limited storage capacity (about one month) - the use of which on a national scale was sharply reduced for some months of 2020, following the block of *routine* operations.

CONSENT for organ and tissue donation



THE GLOBAL PICTURE

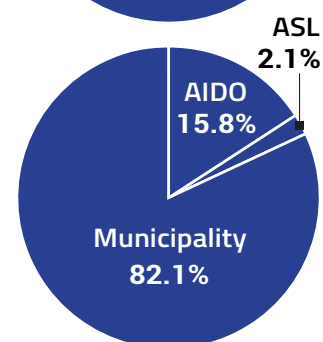
As of 31 December 2020, expression of consent in the matter of organ and tissue donation after death registered in the SIT were **8,829,233**; the adult population that made such declarations increased to 17.2% (+3.7% compared to 2019).

Also in 2020, there was confirmation of the tendency to use the issue or renewal of identity cards at registry offices of municipalities as an opportunity to express consent on organ and tissue donation. Indeed, the declarations registered with the Municipality represented **82.1% of the total** of SIT records; **AIDO 15.8%** (Associazione Italiana per la Donazione di Organi, Tessuti e Cellule; Italian Association for the Donation of Organs, Tissues and Cells) and **ASLs 2.1%** (Aziende Sanitarie Locali; Local Health Trusts) followed.

The SARS-CoV-2 pandemic, which led to the closure of public offices during the lockdown period of March and April 2020 and, subsequently, a reorganization of the activity of the public administration, also had an impact on the trend of declarations of consent registered in 2020. Indeed, **the decline in the number of declarations** collected in the year of the pandemic, compared to 2019, **was 18%** and the absolute figure indicates that in 2020 the declarations issued numbered only **1,966,676** (compared to 2,430,344 of the previous year).

This contraction is attributable to the reduction in the number of identity documents issued: indeed, in the March-May 2020 period electronic identity cards (CIE) numbered 357,000 per month against an average of 500,000 units per month. In addition, due to Coronavirus, for the entire period of the health emergency, the terms of validity of identity cards that were expiring were extended.

Overall, the opposition towards organ donation increased compared to the previous year: in 2020 the rate stood at **25.7% against 23.3% in 2019**. This figure, which takes into account the declarations made to the municipality, the ASL and AIDO, is lower than the oppositions detected in resuscitation and intensive care wards in our country.

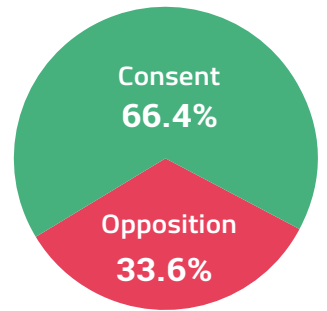
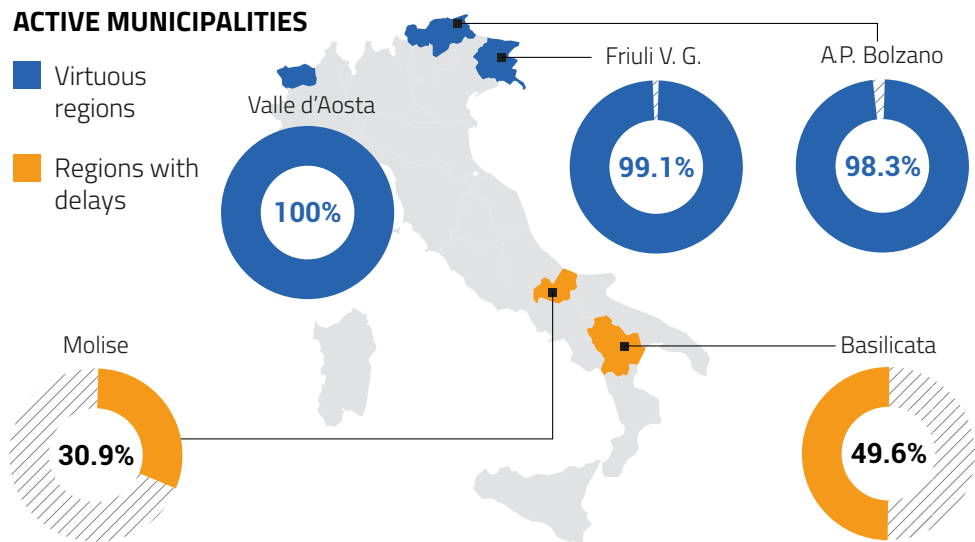


DATA FROM THE MUNICIPALITIES

2020 confirms the municipal registry office as the channel that was most used by citizens to express their consent on donation. The declarations issued to the municipality in 2020 numbered 1,958,298 (1,299,644 consents and 658,654 refusals).

In this context, the electronic identity card (CIE) system has almost entirely replaced the information systems of individual municipalities used for paper identity cards, as evidenced by the numbers: the incidence of **declarations transmitted by the CIE system is 99.79% compared to the total**. To promote this trend, on the one hand, is the uniformity of the procedural flow throughout the national territory (the bilingual version for the municipalities of the Autonomous Province of Bolzano began to operate in 2020) and, on the other hand, the immediacy of the procedure, since it overcomes the technical difficulties encountered in the past by municipalities.

With particular reference to the first half of 2020, the enabling process of the municipalities saw a clear slowdown, as the pandemic affected the ability to complete the activities necessary to start the service, such as the training program for the employees of the registry office and information for the population. However, in the second part of the year, the frequent use of online training made it possible to reach isolated locations, even in the presence of travel restrictions.



As of 31 December, the municipalities active in the transmission of declarations of consent numbered 6,633 (83.1% of Italian municipalities) with an increase of 4.28% on 2019. The best examples included Valle d’Aosta, the first region with 100% of active municipalities; Friuli Venezia Giulia (99.1%); The Autonomous Province of Bolzano (98.3%); Tuscany (96.7%); Liguria (95.2%). The greatest delays were recorded in Molise (30.9%) and Basilicata (49.6%).

ADDRESSED POPULATION

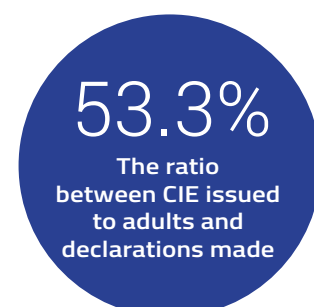
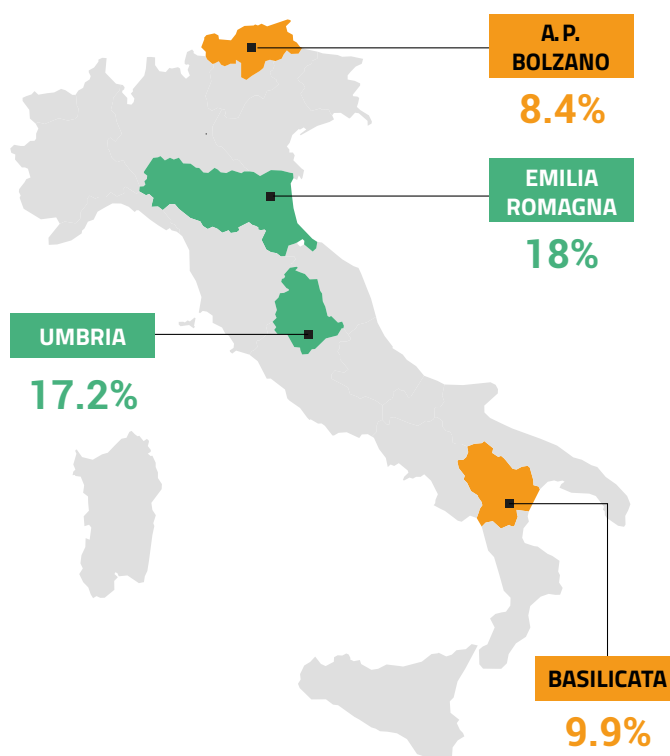
As of 31 December 2020, the population reached by the registration and transmission of declarations of consent was **57,154,466, or 94.24% of the total**, although there are still 1300 municipalities to activate. Similar proportions were recorded in terms of the **adult population involved, numbering 48,550,860** (94,72% of the total).

On average, the adult population who registered their consent to the municipality **increased to 14.9%**; the regions with the highest rate are Emilia Romagna and Umbria with 17.2%, those with the lowest values are the Autonomous Province of Bolzano and Basilicata.

In relation to electronic identity cards (CIE) issued in active municipalities alone, the ratio between declarations made and the number of electronic identity cards issued to citizens of legal age was 53.3%.

RATE OF DECLARATIONS OF CONSENT (ADULT POPULATION)

- Regions with highest rates
- Regions with lowest rates

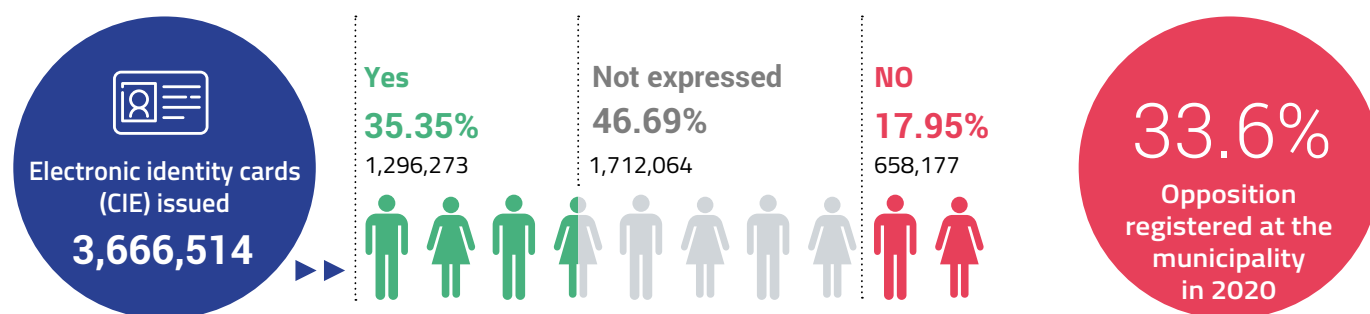


OPPOSITIONS IN THE MUNICIPALITIES: THE CIE SYSTEM IS GROWING

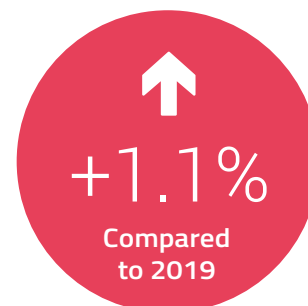
The data collected from 31 December 2020 indicates an overall refusal rate of 31.1%, with a slight increase compared to the same date of the previous year (+1.1%). In 2020, of those who made declarations to the municipality, 33.6% expressed a “no” to donation (once more, the increase compared to the previous year is 1.1%).

The increase in the opposition rate is more subdued if reference is only made to the declarations issued through the electronic identity cards (CIE), equal to +0.5% compared to 2019 (33.7% in 2020 against 33.2% in the previous year). Despite lower growth, the opposition rate related to the expression of consent made through the CIE system is, however, higher than the overall figure (33.7% against 31.1%) and, considering its spread, this value represents an alarm bell wake-up call for our system.

The causes of such a result are of a varied nature and are difficult to delineate, but fundamentally there is still an **insufficient dissemination of donor culture**; however, the introduction of the CIE system has revealed a phenomenon in the opposite direction, represented by the large number of citizens who decide to express themselves on the subject of organ and tissue donation compared to the identity documents issued. For this purpose, if we also take into account those who prefer not to make a declaration at the time of renewal of the identity card, the distribution becomes as follows:



The percentage of those who decided to express themselves on donation (53.3%), compared to people who opted for abstention on this question, constitutes an element for reflection regarding our system and confirms the **fundamental role of the registry office** in carrying out this service and in the ways in which it presents this opportunity to citizens.

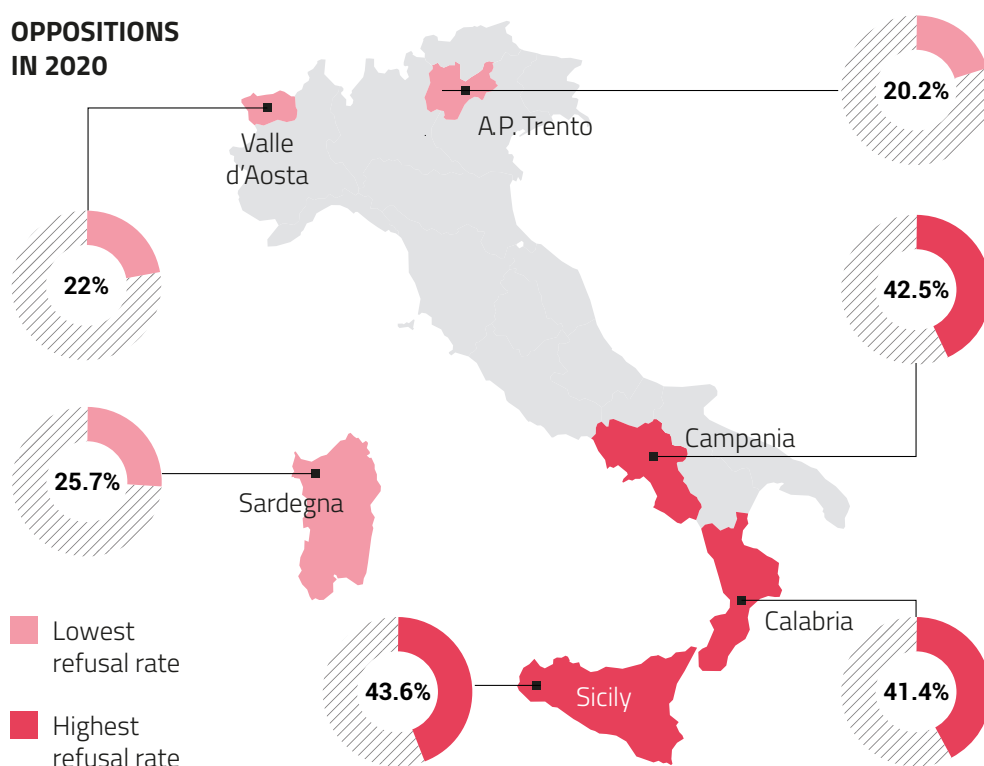


In this context, among the aspects to be taken into account are the increasingly **frequent requests to cancel** declarations made at the municipality every year, an option foreseen by the current legislation related to the processing of personal data.

In this regard, even in 2020 there was adequate support for the network of municipalities and constant monitoring of the transmitted data, to promptly identify the critical issues present in the territory and put in place the necessary actions for improvement. In particular, some initiatives carried out by the National Transplant Network - that have involved numerous municipal administrations in order to face the phenomenon of the turnover of registry office personnel, a growing trend especially after the introduction of the CIE. The many training courses provided using web platforms have also often been utilized by municipalities that were already active in the registration of declarations of consent, both at the request of the municipality and in the face of critical situations identified by Regional Transplant Centers (CRT).

At the territorial level, however, the data showing a **higher opposition rate in Southern-Central regions** compared to others is confirmed and the trend in 2020 is generally negative compared to 2019. The regions with the highest refusal rates are Sicily, Campania and Calabria, while the realities with lower refusal than the national average are the Autonomous Province of Trento, followed by Valle d'Aosta, Sardinia, Veneto and Tuscany.

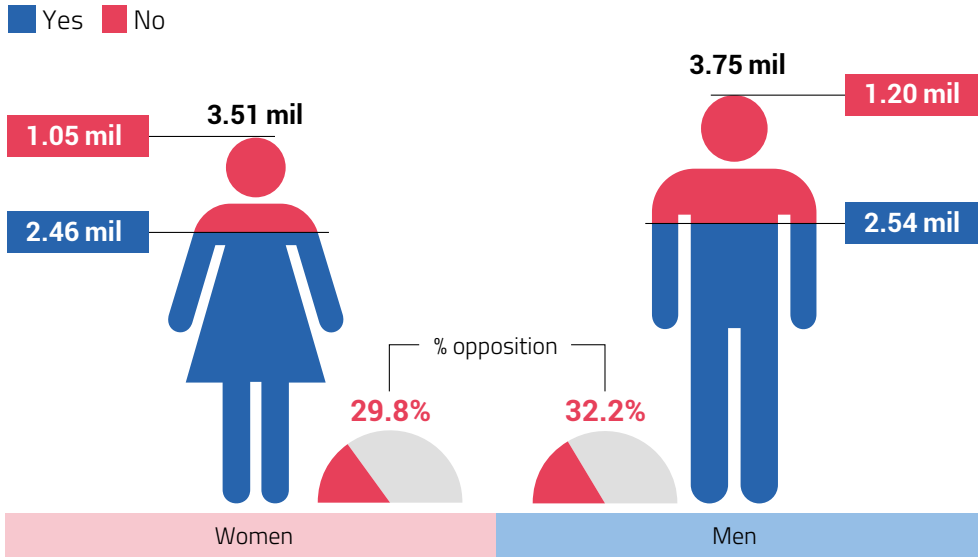
OPPOSITIONS IN 2020



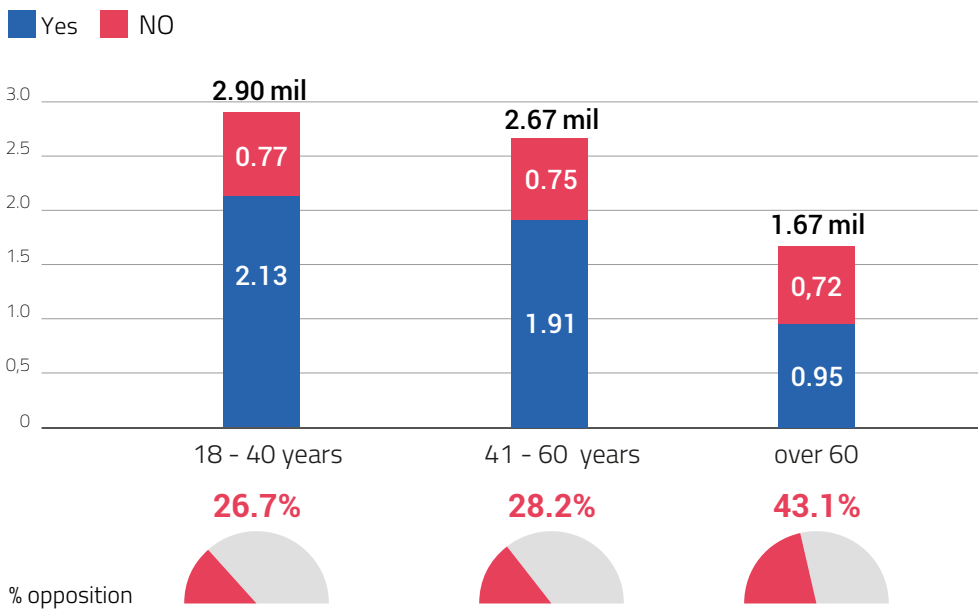

Highest opposition rate in Southern-Central Italy

Starting from this year, the data collection shows a breakdown of recorded declarations by gender and age groups.

DECLARATIONS BY GENDER



AND BY DEMOGRAPHIC GROUPS



DATA FROM ASLS AND AIDOS

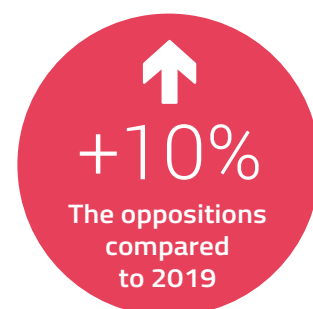
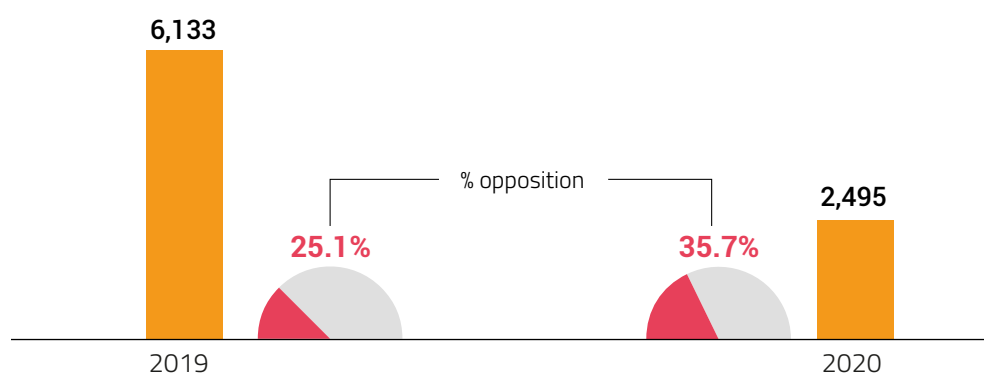
The declarations collected at the ASL public-facing offices and the holographic documents of AIDO members have always represented the choices in terms of donation **made in a voluntary form** by citizens: since 2000 in the first case; in the second, through the extensive work carried out by volunteers since 1973. The further decrease in expression of consent, recorded in 2020, is related both to the affirmation of the possibility of declare oneself at the municipality at the time of the renewal of the identity card, and to the objective difficulties resulting from the pandemic.

THE ASLS

The registration of declarations of consent to ASLs confirms, in 2020, the trend found in recent years, both in terms of absolute values and in terms of donation refusal. On the one hand, **the volume of declarations made in the year turns out to be less than half the value of the previous year** (from 6,133 declarations in 2019 to 2,495 in 2020); on the other hand, there has been an **increase in refusal by more than 10 percentage points** (from 25.1% in 2019 to 35.7% in 2020).

It should be noted that, since these numbers are low, this increase has a marginal impact on the percentage of overall refusal, which went from 10.8% in 2019 to 11.2% in 2020. The phenomenon is undoubtedly attributable to the frequent second thoughts of those who expressed their consent to donation on the occasion of the renewal of the identity document and decided to register their refusal with their ASL.

THE COMPARISON BETWEEN THE DECLARATIONS MADE IN THE TWO-YEAR PERIOD



At the regional level, the volume of declarations made in 2020 saw an average decrease of 60%: the exception was Friuli Venezia Giulia, where declarations increased compared to 2019. It is noted that only regions with a population of more than 4 million recorded more than 100 declarations in 2020.

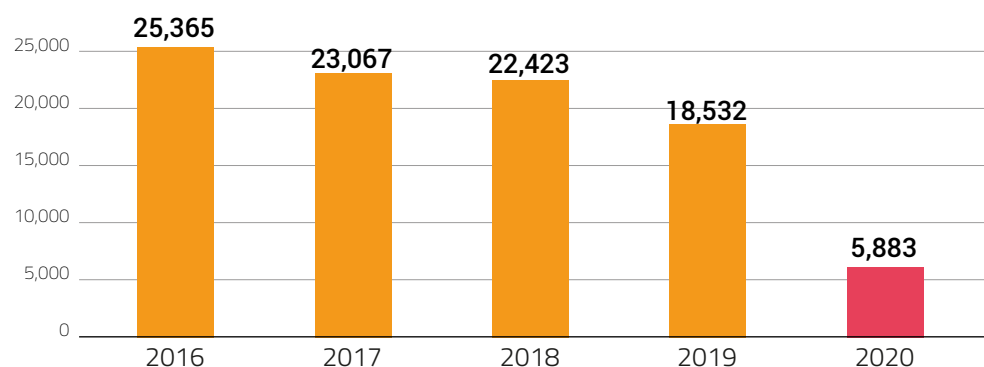
The decrease in declarations followed an increase in refusals, with some exceptions: Sardinia, Puglia, Friuli Venezia Giulia, Marche, Autonomous Province of Bolzano and Calabria, in decreasing order. The cases of Campania, Puglia and Calabria, where the percentage of "noes" was well below the national average and overall in the opposite direction of the trend as compared to the values recorded in the municipalities.

AIDOS

The collection of holographic declarations by the numerous volunteers who collaborate with the AIDO sections, distributed throughout the national territory **experienced a very difficult period due to the restrictions of the pandemic** which severely hampered the organisation of in-person awareness-raising initiatives.

In this context we can frame the negative performance of 2020, in which **new registrations were 5,883**, or just under a third compared to those of 2019. The aggregate total of holographic declarations present in the SIT increased to 1,395,442. The decrease affected all regions, with a decrease ranging from 39% to 77% in 2020.

THE DECLINE IN THE LAST 5 YEARS



ADVERSE events and REACTIONS



SYSTEM CONTROL

The National Transplant Network is one of the most complex and detailed in healthcare, seeing the involvement, **for every single donation event, of more than one hundred people.** Time and multi-professionalism are of great importance in this area.

THE TIME FACTOR

From the harvesting of the organ to the transplant an average of 10 hours passes: the time needed to perform tests, analysis and instrumental investigations on the donor is therefore necessary. There is a need to:



identify the most eligible transplant recipient and a possible *back-up*, in the event that the eligibility conditions of the selected patient temporarily fail;



move whole surgical teams in a timely manner, with air connections and often night flights, to reach donation sites - in Italy and Europe - for the procurement of organs that are functional to transplantation. In such a scenario, any unforeseen event that may lead to adverse events must be addressed and resolved in a timely manner.

MULTI-PROFESSIONALISM

The interaction of complementary professional figures - and the synergy of specific but different skills - contribute to the realization of transplants: this multi-disciplinarity makes this sector unique in the healthcare landscape. In such an articulated framework, the organizational-management aspect is crucial to secure each phase of the process.

Clinical risk management is one of the main tasks of the National Transplant Centre and the National Transplant Network: the credibility of the whole system inevitably rests on safe and quality procedures.



100
and beyond,
the people involved
in each donation
event

The main
commitment
of CNT and
the Network
is clinical risk
management

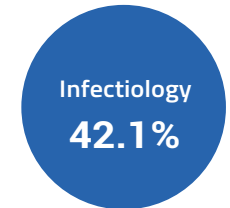
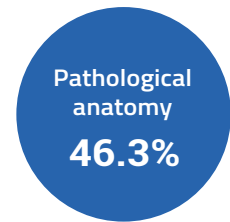
Among the tools that contribute to the safety of transplants, there is the **task force of experts** (noted as **second opinion**), called upon for **clinical cases of doubtful evaluation**. The national task force is made up of an anatomopathologist, a coroner, an infectious disease specialist, a haematologist, an immunologist and an intensive care specialist.

The “second opinion” provides the National Transplant Network with highly competent support and is an advisory group that health professionals can turn to during the evaluation process of the donor or individual organs.

From 2006 to 2020, the national task force has been consulted in over **6,000 cases**, providing concrete support to all healthcare professionals in the Network. In 2020, these second opinions examined and responded to **611 questions**, almost 50% of the total utilized donors. The main requests concerned questions of an anatomical-pathological and infectious nature: the latter linked, in particular, to the increasingly frequent finding of deceased donors with SARS-CoV-2 positivity or with a history of previous Covid-19 infection.

In addition, among the “antibodies” that our Network availed itself of in order to deal with the risk, there is the **reporting of adverse events and reactions**; since 2014, their reporting and management has been stored digitally within the SIT. This monitoring, through which the traceability linked to the donation event also occurs, is based on a constant harmonization of processes, the identification of the phases of the entire supply chain and the classifications and definitions of risk.

SECOND OPINION CLASSIFICATIONS 2020



Haematology



Immunology



Legal



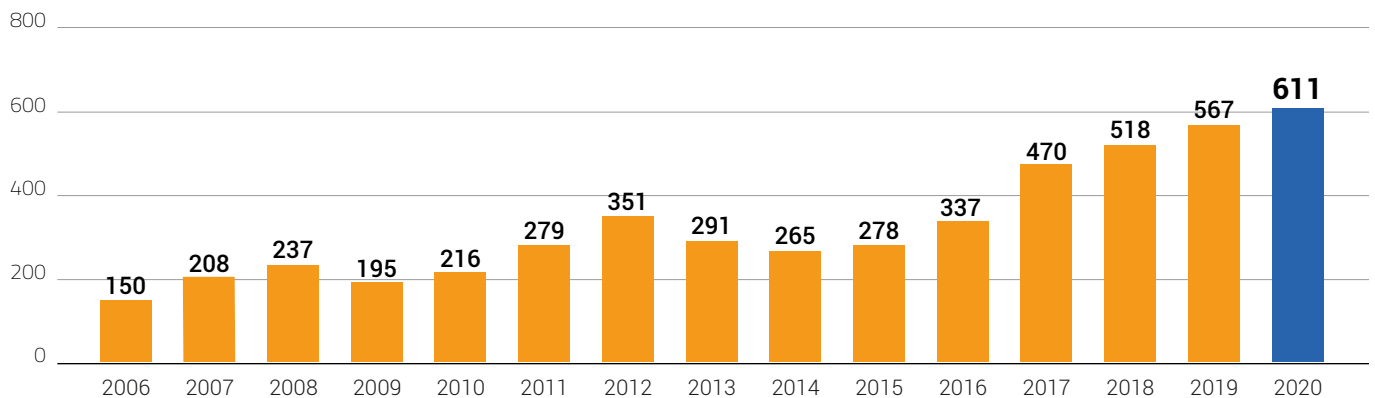
CNT



Resuscitation



ANNUAL TREND IN THE NUMBER OF CASES EXAMINED BY SECOND OPINION



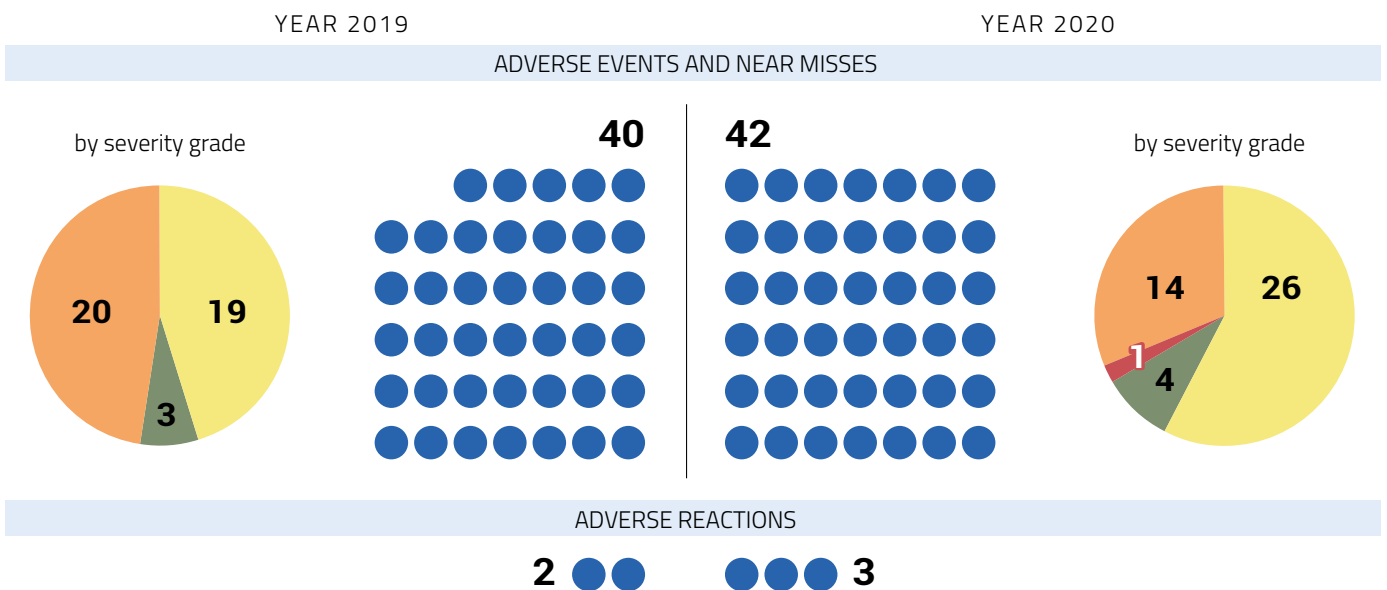
MONITORING

SEVERITY GRADE

There are 45 reports of adverse reactions and events recorded in 2020: this is the largest number of reports in the SIT since the digitized service was activated.

This increase, in step with the 2019 data, highlights that the National Transplant Network has gained appropriate awareness and competence in managing this aspect of the process. In addition, the increased number of reports is based on a greater confidence of the Network in how this type of communication is interpreted; indeed, in the past, reports were often omitted for fear of medical-legal implications while they actually represent an important monitoring tool of the system.

Compared to 2019, **there was a decrease in the absolute number of adverse events** (including, for example, the transplant failure due to organizational and logistical difficulties that affect the use of the organ) **while there was an increase in the absolute number of *near miss* errors** that do not trigger an adverse reaction because they are intercepted in a timely manner.



There were 3 **serious adverse reactions** (compared to 2 in 2019). Since 2014, the number of reports with a severe score has always been low: in 2020 there was only one red class report (with a high score for both severity and probability of repetition), orange class reports (with a high score for severity or probability of repetition) have decreased while yellow class reports have increased. Finally, the average score of the reports decreased, a result attributable to the effectiveness of the corrective measures taken over time.

FREQUENCY

In 2020 there was the highest percentage of adverse reactions and events compared to reported donations recorded since 2014, with **1.87%** (compared to 1.52% in 2019).

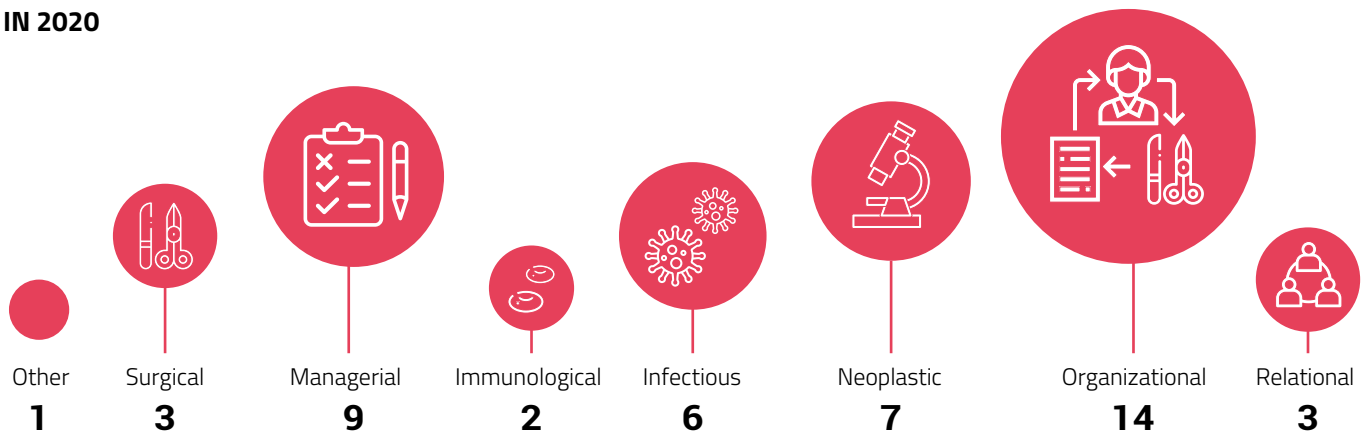
This increase may be attributable to an improvement in the compilation phase in the SIT of the identified adverse event, but also due to the decrease in the number of donors reported.

RISK CLASS

Monitoring the risk class allows the National Transplant Network to implement targeted interventions to reduce adverse events.

The organizational-management field is the most common among the risk classes in 2020, followed by all other events of a clinical nature. The pandemic has had a significant impact, not only on the whole of the National Health Service, but also on other systems that have always contributed to the efficiency of the System (for example, transport) thus resulting in the highest ever percentage (31%) of organizational events.

IN 2020



ROLE OF CNT IN BRIEF

The National Transplant Center (CNT) is the technical-scientific body of the Ministry of Health in charge of coordinating the National Transplant Network. The CNT was established by the Law n. 91, 1 April 1999 and it was located at the National Institute of Health. It works according the address lines and planning provided by the Ministry of Health, in agreement with the Regions and the Autonomous Provinces of Trento and Bolzano.

The CNT carries out functions of direction, coordination, regulation, training and vigilance of the transplant network, as well as operational functions for organ allocation of national transplant programs and, in particular, the urgency program, the paediatric program, the hyperimmune-patients program, the split-liver program, the kidney cross-over program, exchanges of organs with foreign countries, paybacks and surpluses.

The CNT exercises its functions in the following macro sectors: organs, tissues, hematopoietic stem cells and reproductive cells. Together with the Ministry of Health, the Regions and to the Autonomous Provinces, the CNT is the Competent Authority for aspects related to Organ donation, procurement, transplantation as well as for activities involving donation, banking and transplantation of tissues and cells.



Centro Nazionale Trapianti
Italian National Transplant Centre



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