



Annual Report 2018

Tissue donation & processing within the non-profit network
of German Society for Tissue Transplantation (DGFG)

Please note: The following report is not a complete translation of the Annual Report in German. If you are missing any information, please do not hesitate to contact us.

DGFG

DEUTSCHE GESELLSCHAFT FÜR
GEWEBETRANSPLANTATION
GEMEINNÜTZIGE GESELLSCHAFT mbH



Ladies and Gentlemen, dear partners,

with the 12th annual report of the DGFG, I am pleased to share with you insights into the developments in our nationwide tissue network. 2018 was a very special year in many ways: Thanks to the commitment of all employees and partners involved in tissue donation, preparation and transplantation, we were able to realize more than 16 percent more tissue donations than in the previous year. The expansion of our donation network by many new coordinators located at new sites in Hamburg, Oldenburg, Heidelberg, Erfurt and Wuppertal certainly contributed to this. However, we are particularly grateful that almost 3,000 donors said "yes". This shows that the willingness to donate and the solidarity in society are great.

Our employees and colleagues in the tissue banks once again made the most of every donation in 2018 and contributed to a safe and timely supply of tissue. Together with research institutions and clinics, research was carried out into the improvement of transplants and innovative tissue preparations as the AmnioClip-plus, which was recently approved for use in ophthalmology.

We were also able to achieve a lot in 2018 in terms of educational work: We published a film on bone and cartilage donation as well as on heart valve donation. These great projects have been made possible by donations from many transplant recipients and network partners, the Trauma Foundation and the second charity run at the Hannover Marathon.

Nevertheless, there is a high shortage of heart valves in the care of patients in Germany, which we can only counter together. The expansion of our donation after cardiac death (DCD) programme for cardiovascular tissues and the increase in organ donation have led to a slight improvement, but in 2019 we will continue to focus on this issue.

Please feel free to send us your feedback, questions or suggestions. New partners are very welcome – please get in touch!

Martin Börgel, Managing Director/CEO



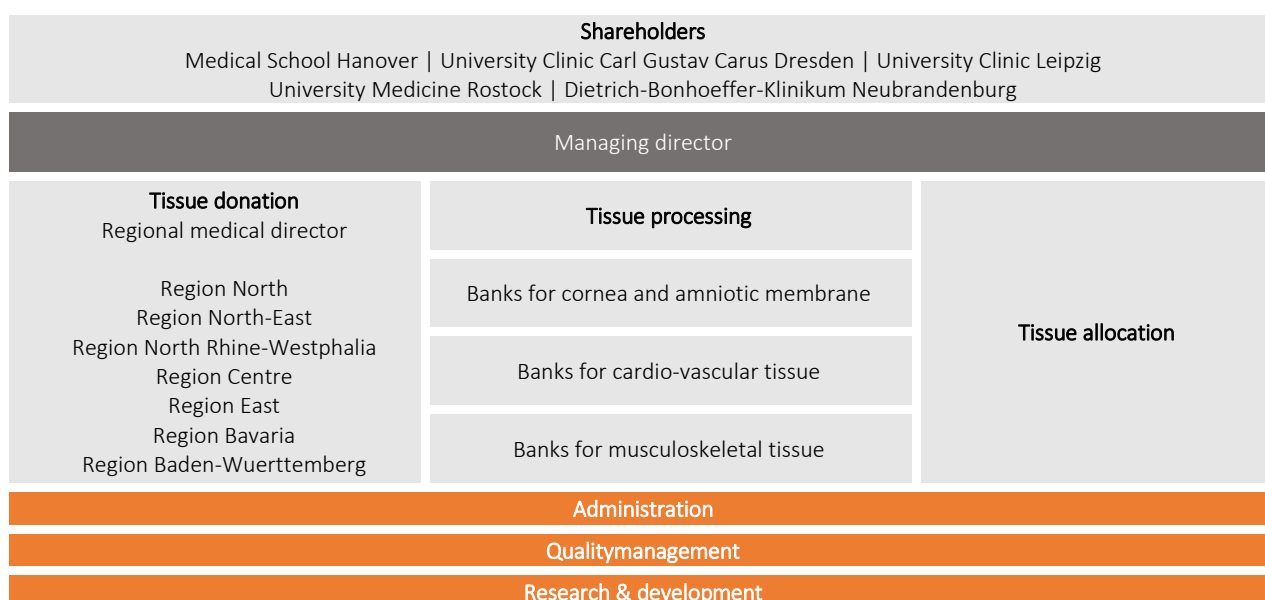
Who we are

The DGFG is based in Hanover. 46 tissue donation coordinators at 28 locations ensure tissue donation throughout Germany day and night. The DGFG operates three tissue banks in Hanover, Kiel and Rostock. In addition, the DGFG cooperates on a contractual basis with other tissue banks in processing and tissue allocation.

The allocation office with four employees in Hanover is available to all transplant centres in Germany. The DGFG currently allocates corneas, amniotic membranes, heart valves, blood vessels and bone preparations and coordinates the donation of islet cells.

Since 2007, the DGFG has established a nationwide network of numerous clinics, tissue banks and transplanting institutions. Hannover Medical School, the University Hospital Leipzig and the University Hospital Carl Gustav Carus Dresden were the first to support the organisation. In 2015 the University Medicine Rostock and in 2017 the Dietrich-Bonhoeffer-Klinikum Neubrandenburg were added as further partners to the society.

Tissue donation is an altruistic act. Therefore, tissue donation belongs to a non-profit and publicly controlled area. Donors and their families want to selflessly help other people. Due to this fact the DGFG strictly rejects commercial and private donation concepts. As institutions under public law, the shareholders of the DGFG are subject to the control of their federal states. The DGFG itself is audited by the authorities of the federal states and municipalities as well as the Paul Ehrlich Institute.













Our goals

DGFG staff provide donors and their next-of-kin with comprehensive and neutral information on the possibility of tissue donation. This also includes information on the extent to which tissue is removed and the outcome of the donation. The goal of every conversation is a stable decision. Informed consent (or decline) is key: Even months and years later, we want relatives to stand behind their decision. The will of the donor must be fulfilled: If a person wants to donate tissue after their death, this must be made possible.

For more than 20 years, the DGFG has been supplying patients in Germany with high-quality and safe tissue transplants.

Ever since, the development of tissue donation in Germany as well as the support of tissue banks and transplantation centres have been the core objective of the DGFG network.

We are working towards a sustainable, self-sufficient supply of patients in Germany with tissue transplants.

	Preservation of the charitable character of the tissue donation	Establishment of new scientific methods	
	Expansion of the nationwide network for tissue medicine	Support and conduct of scientific studies	
	Providing patients in Germany with safe tissue transplants	Public education on tissue donation	
	Continuous adaptation and optimization of quality standards	Cooperation with international partners	

Opt-in – Tissue donation in Germany (for now)

The legal basis for consenting to tissue donation is the Transplantation Act. In Germany, a declaration-based solution has been established in 2012 for both organ and tissue donation. Tissue donation after death is only possible with the written or orally expressed consent of the donor. Every citizen is supposed to regularly receive information on organ and tissue donation from their health insurance. These invite their insurees to voluntarily make a decision for or against organ and tissue donation and to document this decision, e.g. in a donation card. The decision is neither stored by health insurances nor in a central register. If the will is not known, the relatives can make a decision in the spirit of the deceased.

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Local Court Hannover: HRB 62567 | CEO: Martin Börgel (Dipl.-Kfm.)

Deutsche Gesellschaft für Gewebetransplantation gemeinnützige Gesellschaft mbH | Headquarter: Hannover

www.gewebenetzwerk.de

Structural changes may occur in the course of 2019. A draft for a new law proposes the opposite solution: an opt-out system in which the consent to organ and tissue donation is principally presumed – unless there is a documented objection (e.g. in a register).



DGFG – Reliable partner in tissue donation

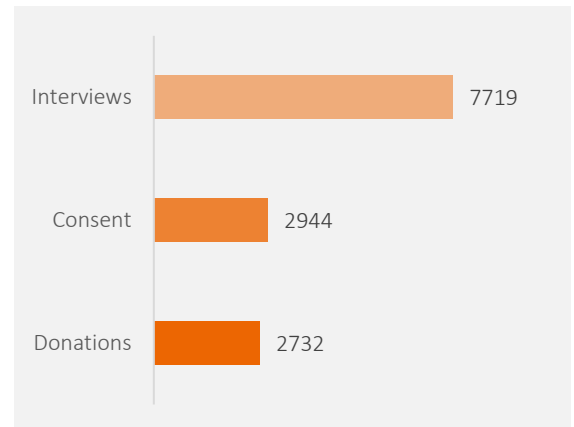
In 2018 about 955,000 people died in Germany. The majority of the deceased could donate tissue. Despite this high number of potential donors, doctors and hospitals continued to source tissue from abroad last year. The DGFG assumes that the need for tissue transplants could be completely covered by national donation programmes if well organised.

The pre-condition for any successful tissue donation is the notification of potential donors by medical institutions. These clinics work together with the DGFG on a contractual basis. Municipal and church hospitals as well as large hospital associations such as the Knappschaftskrankenhäuser, Sana-, Helios- und Asklepios-Kliniken report potential tissue donors to the DGFG. In addition, tissue donations take place within the framework of *mobile* tissue removals, e.g. organ donations, in numerous other facilities. The coordinators of the DGFG, in coordination with the regional medical management, check every report regarding the suitability of the deceased for a tissue donation. They conduct or support the conversation with the relatives and advise the clinics. A DGFG physician contacts the relatives before each tissue removal to confirm consent and answer questions. In the case of a tissue donation, the coordinators organise the collection of the tissue, arrange blood tests and coordinate the transport to the tissue bank.

Tissue donations

In 2018, the tissue banks in the DGFG network recorded 5,786 tissue entries. This corresponds to a total increase of 18 percent compared to the previous year. All types of tissue have increased significantly. Musculoskeletal tissue has been donated since 2015 in a cooperation under the responsibility of the University Tissue Bank of Charité Berlin. It will therefore no longer be included in the statistics of the DGFG. In 2018 there were five bone donations in the framework of this collaboration. In another cooperation with the trauma surgery at Medical School Hannover, two people donated bones.

Next-of-kin interviews and tissue donations in 2018



In 2018, the coordinators of the DGFG processed more than 36,000 death notifications. The coordinators and responsible physicians take great care in selecting potential donors. Only if there are no medical reasons for exclusion and if it is expected to be bearable, an informative interview of the relatives takes place. A total of 7,719 interviews were held about tissue donation. 2,944 people or their next-of-kin agreed to donate tissue.

Since relatives often do not know the will of the deceased, they refuse to donate tissue. A clear oral declaration of will towards ones family or a completed organ and tissue donor card relieves relatives from the burden of decision-making.

	2014	2015	2016	2017	2018
Cornea	3.664	4.020	4.512	4.507	5.249
Musculoskeletal tissue	0	0	0	0	0
Heart valves	136	144	148	196	313
Blood vessels	128	138	142	177	195
Placenta	13	17	21	15	29
Total	4.201	4.341	4.823	4.895	5.786

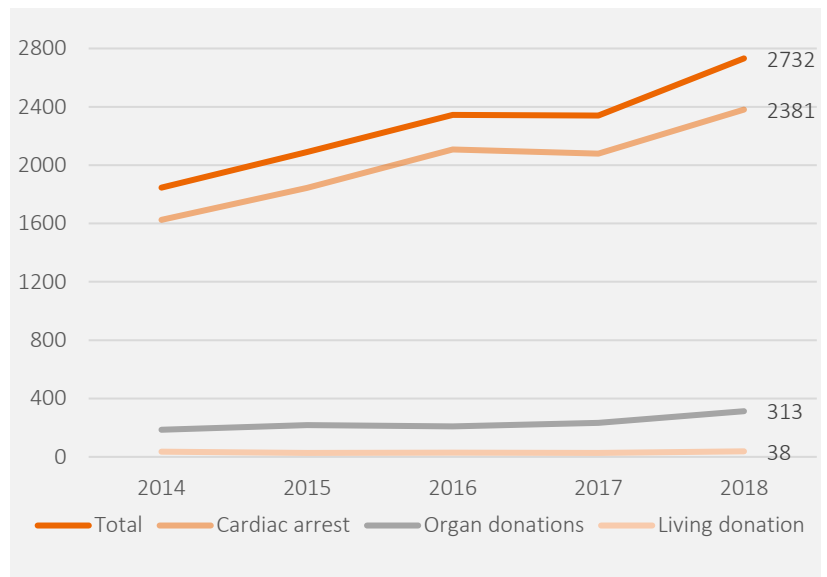
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Tissue donors

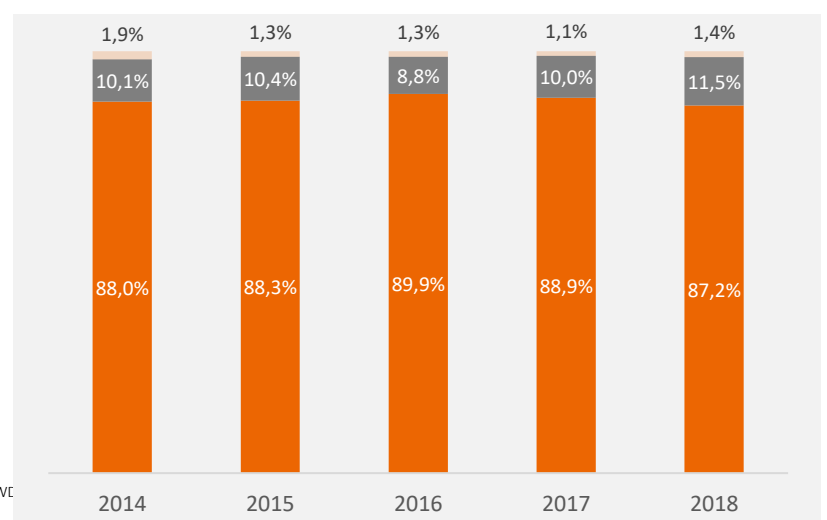
DGFG is the only tissue establishment in Germany with locations across the country. For hospitals, DGFG is thus the most important supraregional partner for tissue medicine. Tissue donations are possible in almost all medical institutions. These include acute hospitals and rehabilitation clinics, but also institutes for forensic medicine and pathology. In exceptional cases, corneal donation is also permitted in suitable rooms of funeral parlours. In 2018, there were 955 organ donations in Germany. In the DGFG network alone, there were 2,694 tissue donors (without living donors). In cooperation with the German Organ Donation Foundation (DSO), the DGFG coordinated 313 tissue donations from multi-organ donors – 34 percent more than the year before. But not all organ donations also involve tissue donation. The reasons for this are to find in the lack of consent, the presence of medical reasons for exclusion and also the non-report of organ donors to the DGFG.

Number of tissue donors 2014-2018



In 2018, a total of 2,732 people in the DGFG network donated tissue. This is an increase of almost 17 percent compared to the previous year: In 2017, 2,340 donors donated tissue. 87.1 percent were donors after cardiovascular arrest. The number of 38 living donors (placenta and heart valves) is relatively low. The number of brain-dead donors from organ donation increased significantly from 233 to 313 donors.

Proportion of tissue donors from organ donation, living donors and cardiovascular deaths



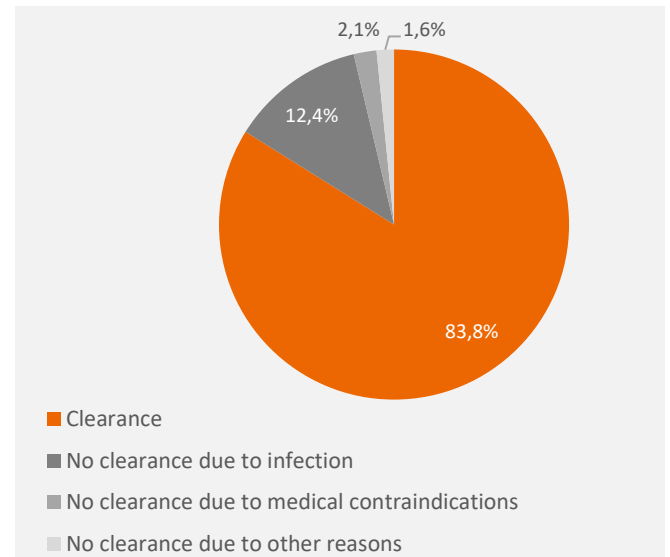
In the DGFG network, the proportion of tissue donors from organ donation has been around 10 percent for years. In 2018 it rose slightly to 11.5 percent. Heart valves and blood vessels currently originate almost exclusively from organ donation and thus after cerebral death. As organ donation has been stagnating at a low level for years in Germany, the donation of cardiovascular tissue is also limited. The DGFG is therefore increasingly setting up donation programmes for cardiac valves and blood vessels after cardiovascular death.



Donor clearance

The safety of the transplant recipient comes first and is much more strictly regulated than in organ donation. Therefore and despite careful pre-selection, the DGFG can not release every tissue removed for a tissue preparation according to § 8d/1 Medicinal Product Act (AMG). Reasons for this are, for example, contraindications which are subsequently established, unsuitable blood samples or the detection of infectious diseases in the blood test. In practice, this means that not every tissue donation is suitable for transplantation: In the tissue bank, unexpected cell losses can occur in corneas. Employees can find that a tissue is not suitable due to scarring or they can detect germs that makes transplantation unsafe. This results in the difference between donated and transplanted tissue preparations. In 2018, for example, the transplant rate for corneas was 73.8 percent (exclusion reasons such as positive virology or high cell loss deducted).

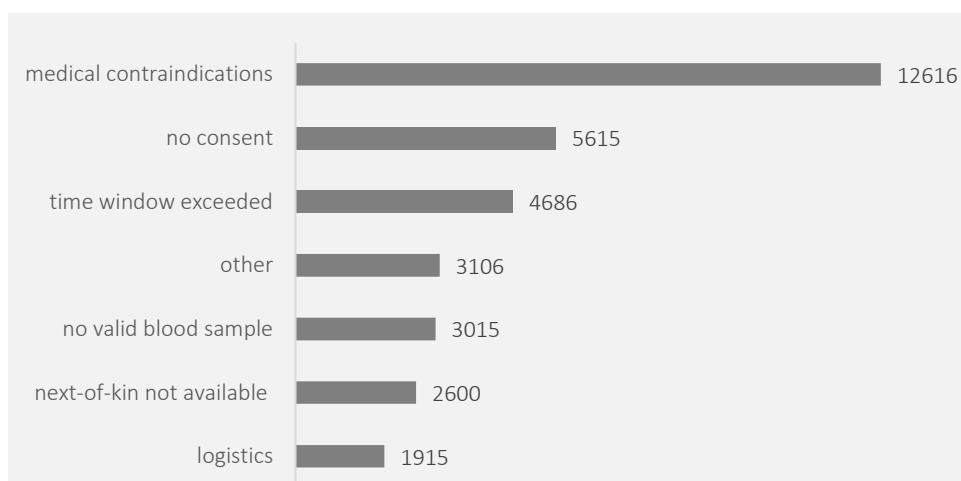
Clearance rate for tissue processing



Around 84 percent of all tissue donations were released in 2018. Approximately twelve percent were unable to release tissue due to blood tests. Nearly two percent could not be released due to other reasons or subsequently identified contraindications.

Cancellation reasons for tissue donations

Not every notification of a potential tissue donor by a hospital leads to a donation. The coordinators examine each individual case very carefully. In many cases, they have to cancel the notification. By far the most common cause is the existence of medical reasons for exclusion: Coordinators cancel every third donation because of a contraindication. However, it is also relatively common for no consent to be obtained during the interview, for the time window for a tissue sample to be too short or for no valid blood sample to exist. 2,600 times, relatives could not be reached within the time window permitted for tissue removal.

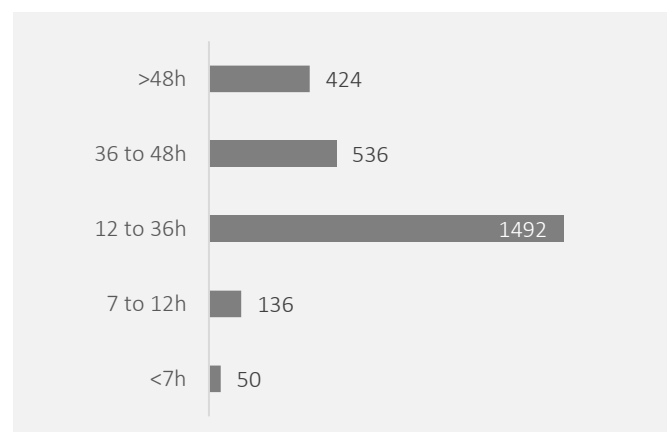




Time window from time of death to tissue removal

Corneal donations are possible up to three days after death. At the latest, 72 hours after death processing must have started. Statistics show that almost two thirds of donated corneas are removed up to 36 hours after death. This period gives the relatives the opportunity to make a stable decision supported by all family members. Cardiovascular tissues are predominantly removed in the course of organ donations directly in the operating theatre. In this case, the maximum time window until removal is 36 hours after cardiac death.

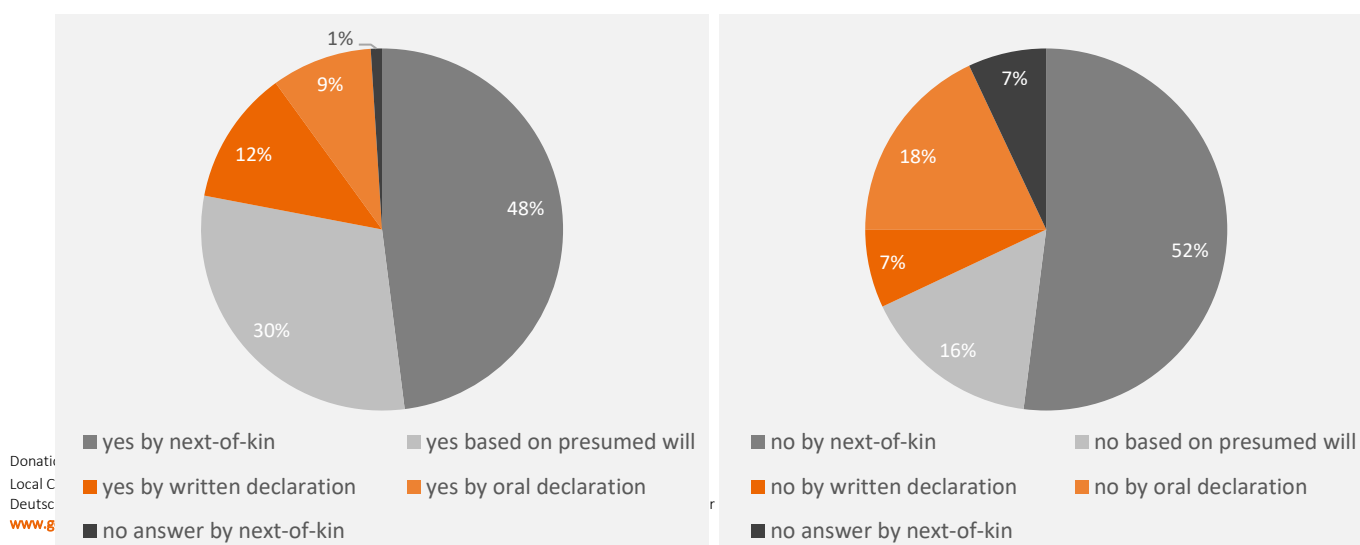
Period from death to removal of ophthalmologic tissue



Expression of will

The will of the deceased is often not known to relatives. Only 21 percent of donations are made on the basis of an oral or written declaration of will. In the case of decline, 25 percent of the deceased expressed their opposition to a tissue donation in writing or verbally. Half of all decisions for or against tissue donation are made by relatives on the basis of their own values. A further 30 percent of the decisions for a tissue donation are made on the basis of the presumed will of the donor. 16 percent of the declined tissue donations are based on the presumed will. These figures clearly show that there are great uncertainties in the families. A conversation during ones lifetime or a donation card can provide security and relief to loved ones.

Consent versus decline





Tissue banks within the DGFG network (figures as of 01.05.2019)

Heart Valve Bank Kiel/DGFG

University Clinic Schleswig-Holstein – Campus Kiel

Heart valves

In 191

Out 60

Blood vessels

In 141

Out 52

Tissue Bank Brunswick

Municipal Hospital Brunswick

Heart valves

In 44

Out 22

Blood vessels

In 53

Out 23

Cornea

In 160

Out 72

Tissue Bank Hanover/DGFG

Cornea

In 1,218

Out 857

Cornea Bank Kiel

University Clinic Schleswig-Holstein – Campus Kiel

Cornea

In 101

Out 59

Lions Cornea Bank Würzburg

University Clinic Würzburg – University Eye Clinic

Cornea

In 228

Out 179

Miners' Tissue Bank Sulzbach

Miners' hospital Saar

Cornea

In 445

Out 351

Lions Cornea Bank Heidelberg

Eye Clinic of University Clinic Heidelberg

Cornea

In 103

Out 58

Cornea Bank Stuttgart

Clinic Stuttgart

Cornea (in development)

Cornea and Tissue Bank Schwerin

Cornea

In 937

Out 699

Amniotic membrane

In 2,629

Out 1,646

Cornea Bank Rostock

University Medicine Rostock – Eye Clinic

Cornea

In 781

Out 502

Cornea Bank Greifswald

University Medicine Greifswald – Eye Clinic

Cornea

In 613

Out 398

Middle German Cornea Bank Halle

University Clinic Halle (Saale) – Eye Clinic

Cornea

In 663

Out 492

University Tissue Bank of Charité

University Medicine Berlin – Institute for Transfusion Medicine

Cornea & bone n/a

Inselzelltransplantationszentrum Dresden – University Clinic Carl Gustav Carus Dresden

The Inseltransplantationszentrum Dresden is currently the only institution in Germany that can perform islet cell transplants. The prerequisite is the donation of pancreas. The DGFG is responsible for the coordination.

Decellularized heart valves – Corlife

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Local Court Hannover, HRB 62567 | CEO: Martin Borge (Dipl.-Kfm.)

Decellularized heart valves (ESPOR and ARISE) initiated by the Hanover Medical School.

After completion of the studies, the DGFG allocates the decellularized heart valves upon request of cooperating clinics.

The processing is carried out by corlife. In 2018, the DGFG allocated 42 heart valves within the framework of this new cooperation.



The DGFG Network

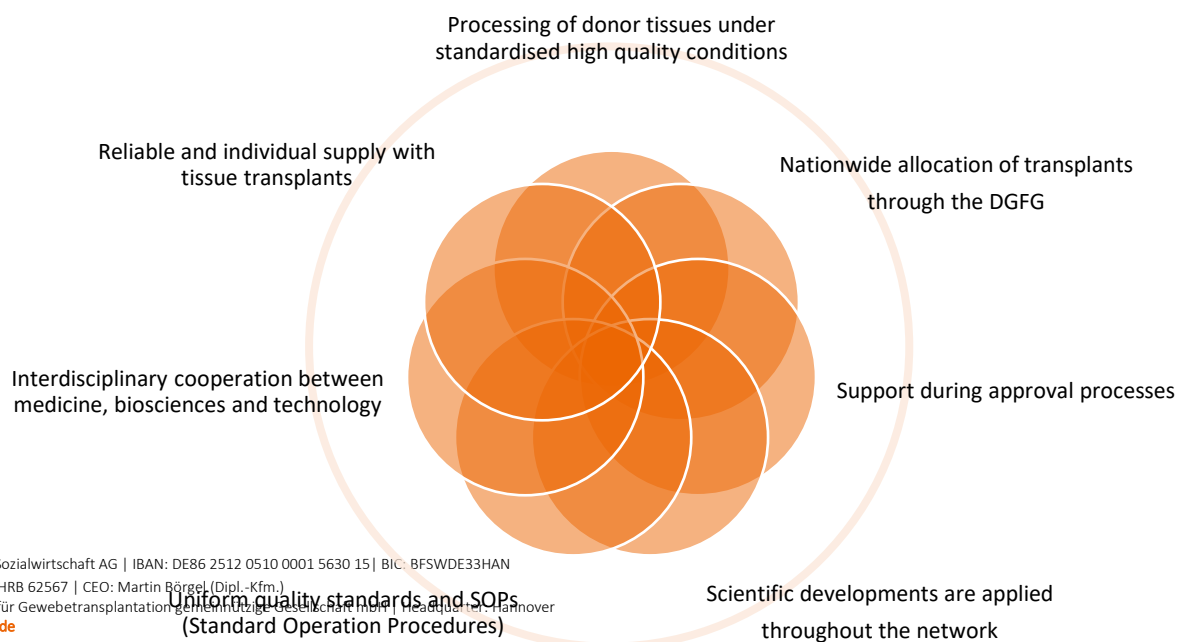
In more than 20 years of existence, the DGFG has built a network of its own and cooperating tissue banks. It operates the heart valve bank Kiel, the corneal bank Rostock and the tissue bank Hannover. The tissue banks of the University Clinic Carl Gustav Carus Dresden, the University Clinic Leipzig and the Hanover Medical School were merged into the latter.

With its clean room facility, it is one of the most modern facilities of its kind in Germany. The cornea and tissue bank Schwerin is a jointly operated non-profit institution with the Helios Kliniken Schwerin. Cooperation with other tissue banks takes place on an individual contractual basis. The network sets standards throughout Germany and is involved in national and international tissue medicine.

Tissue banks in the network benefit from joint personnel resources and standard operating procedures (SOPs). Depending on regional requirements, DGFG takes care of all necessary official permits and approvals.

There are individual cooperation models in the field of tissue processing.

Processing on behalf of the DGFG (subcontracting) for optimal utilization of existing capacities	Cooperation as DGFG's bank location to secure the local donation and transplantation programme	Establishment of a joint regional tissue bank with two or more shareholders
...for existing or new tissue banks that have their own permission for processing according to § 20c AMG.	...for facilities with an existing or a new tissue bank. The DGFG obtains official permits and approvals.	...for institutions wishing to establish a non-profit tissue bank. The cornea and tissue bank Schwerin corresponds to this model. The DGFG and the Helios Kliniken Schwerin are partners here.





Tissue allocation

The allocation of tissue transplants, along with tissue donation and processing, is one of the DGFG's core tasks. Every medical institution in Germany – from outpatient facilities to hospitals – can obtain corneas, heart valves, blood vessels, amniotic and bone preparations from the DGFG. Due to its nationwide network of tissue banks, the DGFG is able to process even highly urgent enquiries promptly.

Amniotic transplants are available the next working day. The placement of heart valves and blood vessels may take place as an emergency or within the framework of planned surgeries.

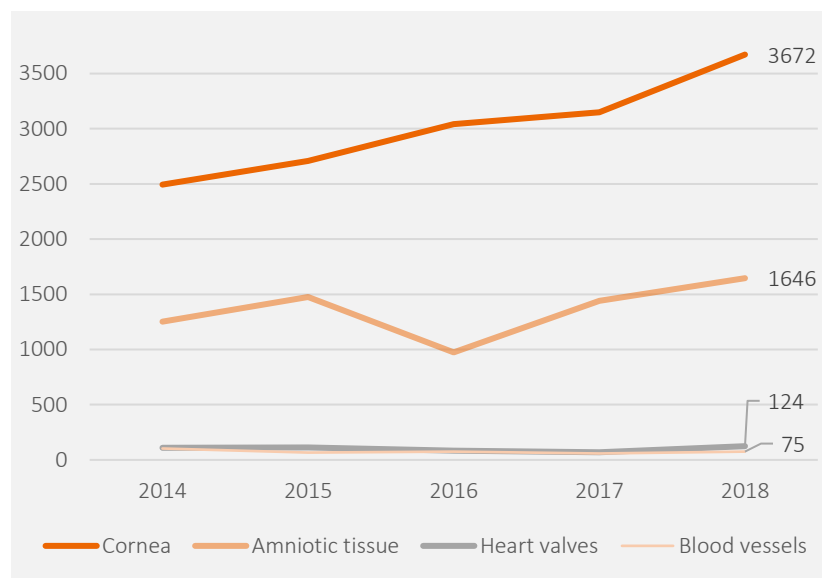
Delivered transplants

As in previous years, the total number of tissue transplants delivered by the DGFG increased significantly in 2018. In particular, the increased procurement of amniotic membrane and corneas contributed to this positive development.

More than half of the corneas supplied by German eye banks thus come from the DGFG network. In 2018, the DGFG has allocated 5,517 tissue transplants to patients, almost four times as many as in 2008.

346 LaMEK – corneal lamellae prepared for DMEK in the tissue bank – out of 3,672 corneal transplants were allocated in 2018.

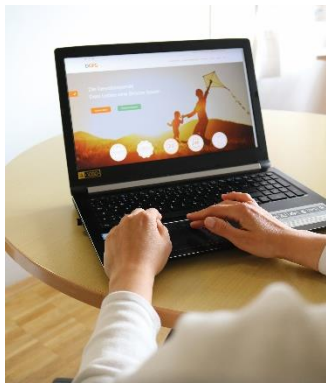
Tissue transplants provided by DGFG 2014-2018



With 3,672 successfully allocated transplants in 2018, we could help 16.6 percent more patients than in 2017. That is three times as much as ten years ago. The allocation figures for amniotic membrane are also up by 14 percent compared to the previous year. The DGFG has never before provided as many heart valves as in 2018: The total number more than doubled from 58 in the previous year to 124. The amount of allocated blood vessels remained stable at 75. Thus, in 2018, a large part of the transplanted blood vessels in Germany came from the cardiovascular tissue from the DGFG.



Promoting tissue donation and the DGFG network



Relaunch of www.gewebenetzwerk.de

The DGFG has redesigned its homepage www.gewebenetzwerk.de. The website offers a lot of content on the world of tissue medicine in Germany. News about new cooperations, donation successes, patient stories and employee portraits are now to be found under "News erLeben" (soon available in English). Cooperation partners from clinics, tissue banks or research institutions as well as doctors and generally interested parties will find all relevant information on tissue donation and the DGFG's non-profit network activities now online. In the press and media area, journalists have free access to background information, current press releases and images available for download.

Brochures and information sheets can be downloaded or ordered as print products on the website (most in German only). Special thanks go to the funding by the Federal Centre for Health Education (BZgA). An English version of the website's content is expected to be launched in August 2019.

Public education

In addition to the Federal Centre for Health Education (BZgA), health insurances and other public bodies, the DGFG is the information source for all private individuals, public institutions and medical institutions regarding questions related to tissue donation. Interested parties can order annual reports, information leaflets as well as organ and tissue donation cards from the DGFG as digital download or as printed materials. Together with local partners and self-help groups, DGFG employees participate in information events. In addition, the DGFG's press and public relations work is available to all journalists for special enquiries concerning tissue donation. The DGFG supports the organisation and execution of background talks or television shoots. Film teams from RTL Nord and ZDF were on site at the DGFG in 2018/19. Various press releases were picked up by regional as well as national online and printed media.

In October 2018, the DGFG presented an educational film on heart valve donation: Two transplant recipients tell their very own story in the film. In June 2017, the first film "The tissue donation – a gift for life" with a focus on corneal donation went online. One year later, another educational film on bone and cartilage donation was released, which was also financed thanks to the Trauma Foundation of Prof. Dr. med. Christian Krettek. These films were realised through fundraising activities of the DGFG, such as the annual fundraising run. For the second time, DGFG employees took part in the Hannover Marathon to draw attention to tissue donation in Germany. The raised donations in the amount of plus 2,000 Euro are used to promote public awareness about tissue donation.

On-site: DGFG at events

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In addition to providing general information on tissue donation at information events such as the "Organ Donation Day" or "Open House Day" events at cooperation partners, the DGFG also presents current research results from the tissue network at national and international conferences.



Training

Every day, DGFG coordinators and doctors are in contact with people who have just lost a loved one. In 2018, the tissue donation coordinators processed over 36,000 donor notifications. In nearly 8,000 conversations, they informed the relatives about the possibility of tissue donation – people who find themselves in exceptional situations. They bear a high responsibility with regard to this highly sensitive job in an emotionally very stressful environment. Within the first year, new employees must attend a basic training course of several days on how to conduct conversations and how to donate tissue. In addition, there are annual advanced training courses in communication with relatives, on medical and microbiological topics and on quality management.

The confrontation with grieving relatives and deceased people at work can be a burden. Every DGFG employee has the opportunity to take part in a group supervision.

Training offers for DGFG employees and network partners		
Basic training (once)	all new DGFG employees	Next-of-kin interview, tissue allocation, administration, quality management, legal basics, data protection
General DGFG training (yearly)	all DGFG employees	Deeper medical expertise, update & news in workflow, data protection, quality management, communication, administration
Additional training (yearly)	all DGFG coordinators	Next-of-kin interview & communication
Meet-up of medical team (several times per year)	all DGFG doctors	Case discussions, medical contraindication testing
Workshop tissue processing (yearly)	all employees from the DGFG & network tissue banks	Exchange of experience in processing, training of preparation methods, quality management

Our coordinators and doctors also pass on their expertise to the clinic staff in training courses, e.g. within a training on cardiovascular tissue donation.

European exchange programme

Last year, twelve DGFG staff members visited the tissue bank Fondazione Banca dei Tessuti (FBTV) in Treviso, Italy. The issue of the training was the removal of cardiovascular tissue. The groups, consisting of coordinators, doctors and quality management staff, accompanied the Italian colleagues in tissue donations. The FBTV is an important partner in the professional exchange both in tissue donation and tissue preparation.