



The 2012 and 2015 National Tissue Recovery through Utilization Survey Report

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Executive Summary

The purpose of the National Tissue Recovery through Utilization Survey (NTRUS) report is to provide a comprehensive view of tissue banking activities. The survey collected quantitative data related to referral assessment, recovery, and testing of deceased and living tissue donors, and the processing, storage and distribution of human tissue. All 125 U.S. tissue establishments (banks) that were identified as performing at least one of these functions in 2012 or 2015 were asked to participate in the survey. To reduce the possibility of double counting tissue grafts, the survey did not solicit participation from facilities that receive tissue for further processing from another tissue processor.

Data was collected on a wide range of tissue types recovered from living and deceased donors. For deceased donations, these included: 1) musculoskeletal tissue, such as bone and cartilage; 2) soft tissue, such as ligaments, tendons, and nerves; 3) skin; 4) cardiac and vascular tissue; and 5) cellular tissue. For living donations, these included: 1) birth tissue, such as the amniotic membrane, amniotic fluid, and umbilical cord tissue; 2) autologous parathyroid and bone; and 3) skin for allogeneic use. To facilitate comprehension of survey terms, an “NTRUS Definitions of Terms” document was made available to survey participants and is included with this report.

Survey results are organized under seven sections. Within each section, selected metrics are compared across the two data collection periods (2012 and 2015), including some metrics that cover the same activities from the 2007 American Association of Tissue Bank (AATB) survey. Survey sections are the following: Activities tissue types and inspections, Referrals, Authorizations and informed consent, Recovery and acquisition, Tissue processing, Tissue storage, Tissue distribution, and finally Communicable disease testing and adverse outcome reports.

For 2015, 53 banks indicated whether they included the following 3 requests or statements on their authorization form for deceased donors. The questions and responses were as follows: Does your authorization form include a request or statement regarding 1) for-profit or not-for-profit involvement or restrictions on the gift (46 yes and 7 no responses); 2) international distribution of the gift (50 yes and 3 no responses); and 3) cosmetic/aesthetic use of the gift (29 yes and 24 no responses).

For 2015, 13 banks indicated whether they included the following 3 requests or statements on their consent form for living donors. The questions and responses were as follows: Does your consent form include a request or statement regarding 1) for-profit or not-for-profit involvement or restrictions on the gift (11 yes and 2 no responses); 2) international distribution of the gift (10 yes and 3 no responses); and 3) cosmetic/aesthetic use of the gift (6 yes and 7 no responses).

The reported number of deceased donors from whom tissue was recovered for transplantation increased by more than 30 percent from 2007 (29,799 donors) to 2015 (39,121 donors). In comparison, living tissue donors experienced more than a 30-fold increase from 2007 (581 donors) to 2015 (19,218 donors).

Twenty-nine banks (91 percent of banks that reported processing tissue from deceased donors in 2012) processed 2,858,264 grafts and 31 banks (87 percent of banks that reported processing tissue from deceased donors in 2015) processed 3,447,732 grafts – an increase in the number of processed grafts by approximately 20 percent. Regarding living donation, 13 banks processed 265,185 grafts from living donors in 2012 and 16 banks (80 percent of banks that reported processing tissue from living donors in 2015) processed 442,484 grafts.

For 2015, 46 banks (100 percent of banks that reported processing tissue) provided information about sending human tissue to another bank for further manufacturing. Only 8 banks reported sending tissues

to another bank for further manufacturing.

For 2012, 35 banks (90 percent the banks that reported distributing musculoskeletal tissue from deceased donors) distributed 1,982,010 musculoskeletal grafts and for 2015, 39 banks (93 percent of the banks that reported distributing musculoskeletal tissue from deceased donors) distributed 2,343,015 musculoskeletal grafts – an increase in the number of distributed grafts by approximately 18 percent.

Methods

The NTRUS was distributed to all U.S. tissue establishments that provided or engaged in one or more services involving tissue from living or deceased persons for transplantation in 2012 or 2015. The services included assessing donor eligibility, obtaining authorization and/or informed consent, donor testing, and the recovery, processing, storage, and distribution of tissue. Key information collected from both years, and from a previous 2007 survey by AATB, was compared where possible.

Building on the AATB 2007 survey of tissue banks, some questions were revised and a number of new questions were added with input from relevant HHS agencies and AATB membership. The final survey tool comprised 7 survey sections for the year 2015 and 7 abbreviated sections for the year 2012. In order to maximize data quality, a pilot study was performed before conducting the full-scale survey. Seven tissue banks participated in the pilot study and reviewed the survey questions between February 2, 2017 and March 10, 2017. Edits were made to individual survey sections based on participant feedback.

Tissue banks were identified from the AATB membership list and the Food and Drug Administration (FDA) Human Cell and Tissue Establishment Registration (HCTER) database. U.S. tissue banks that handle certain types of tissues are required to register with FDA and identify the services they provide with the types of tissues handled for each service provided. The final list comprised 125 tissue banks; of these banks, 107 were AATB accredited tissue establishments and 18 were non-accredited tissue establishments selected for their referral and recovery services.

On July 31, 2017, contacts at each tissue bank received an email that described the survey, requested participation, and provided instructions for accessing the NTRUS survey portal and completing the on-line survey. The portal for each tissue bank was individualized to show only the survey sections for completion based on information from the HCTERS database and the AATB membership list. To maximize responses, an email address was provided for any questions; non-responders received email and telephone reminders; and the survey was extended several weeks. Data collection concluded on September 29, 2017.

The survey findings are subject to several limitations. Some tissue banks did not complete certain survey sections, although most of these non-responders were small banks. Survey sections were not audited with variation in response rate to individual questions occurred. Additionally, participants were instructed to answer zero or 999 if the answer to any given question was none or not obtainable, respectively. These instructions were not followed consistently by all the participating banks, and therefore it was not possible to account for the answers 0, in most cases, and 999 in the analysis of the results. Therefore, the value 999 was treated as null (or N/A), as well as the value 0 for almost all questions and related subparts. Nonresponse and the variability in response to individual questions may result in underestimations and increase uncertainty of results. High response rates indicate a greater likelihood that survey results reflect the characteristics of the target population.

Results

Activities, Tissue Types and Inspections

Activities Performed by Tissue Banks – Comparison of 2015 and 2012 Results

Information about activities performed was provided by 112 of 125 (90%) banks in 2015 and 100 of 114 (88%) banks in 2012. The ranking of the activities, based on the banks that responded to the survey, is presented in Figure 1. The 9 most often mentioned activities performed were donor eligibility assessment (67% in 2015, and 69% in 2012), tissue storage (61.6% in 2015, and 58% in 2012), tissue recovery (56.3% in 2015, and 58% in 2012), tissue distribution (51.8% in 2015, and 48% in 2012), donor authorization (50% in 2015, and 53% in 2012), donor testing (44.6% in 2015, and 42% in 2012), processing (41.1% in 2015, and 34% in 2012), informed consent (39.9% in 2015, and 33% in 2012) and acquisition (11.6% in 2015, and 10% in 2012).

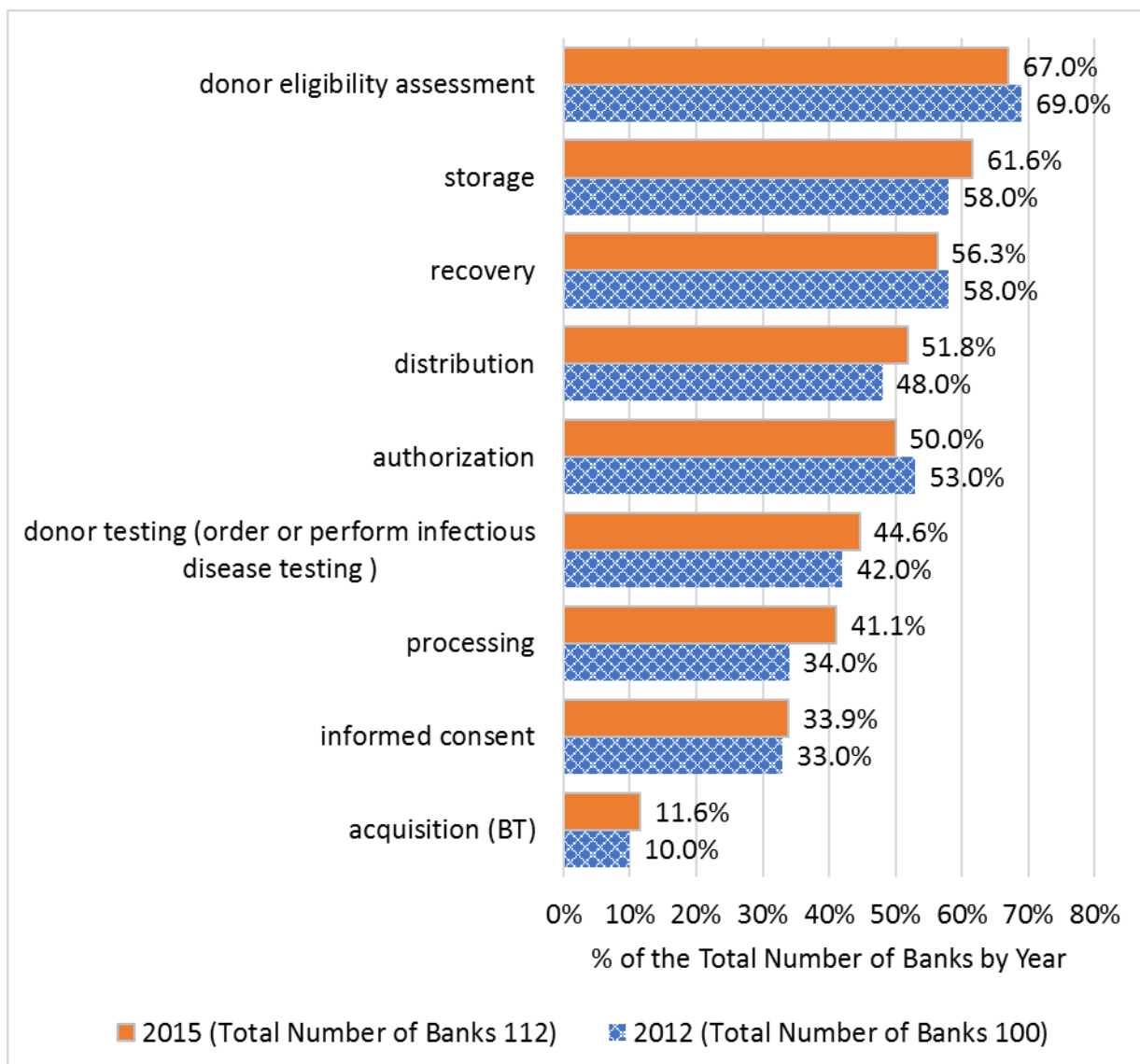


Figure 1 - Percentage of Banks by Activity - Comparison of 2015 (112 Banks) and 2012 (100 Banks)

Types of Tissues Handled by Tissue Banks – Comparison of 2015 and 2012 Results

Information about the types of human tissues handled (e.g., recovered, processed, stored) were provided by 112 of 125 (90%) banks in 2015 and 99 of 114 (87%) banks in 2012. The ranking of the types of human tissues handled, based on the banks that responded, is presented in Figure 2. The 10 most frequently reported tissue types were musculoskeletal tissue (85.7% in 2015, and 90.9% in 2012), skin (62.5% in 2015, and 70.7% in 2012), cardiac tissue (51.8% in 2015, and 56.6% in 2012), vascular tissue (50.9% in 2015, and 54.5% in 2012), osteoarticular grafts (34.8% in 2015, and 41.4% in 2012), birth tissue (25.9% in 2015, and 15.2% in 2012), cellular tissue (14.3% in 2015, and 12.1% in 2012), autologous tissue (8.9% in 2015, and 9.1% in 2012), dura mater (1.8% in 2015, and 2.0% in 2012) and surgical bone (0.9% in 2015, no data for 2012)

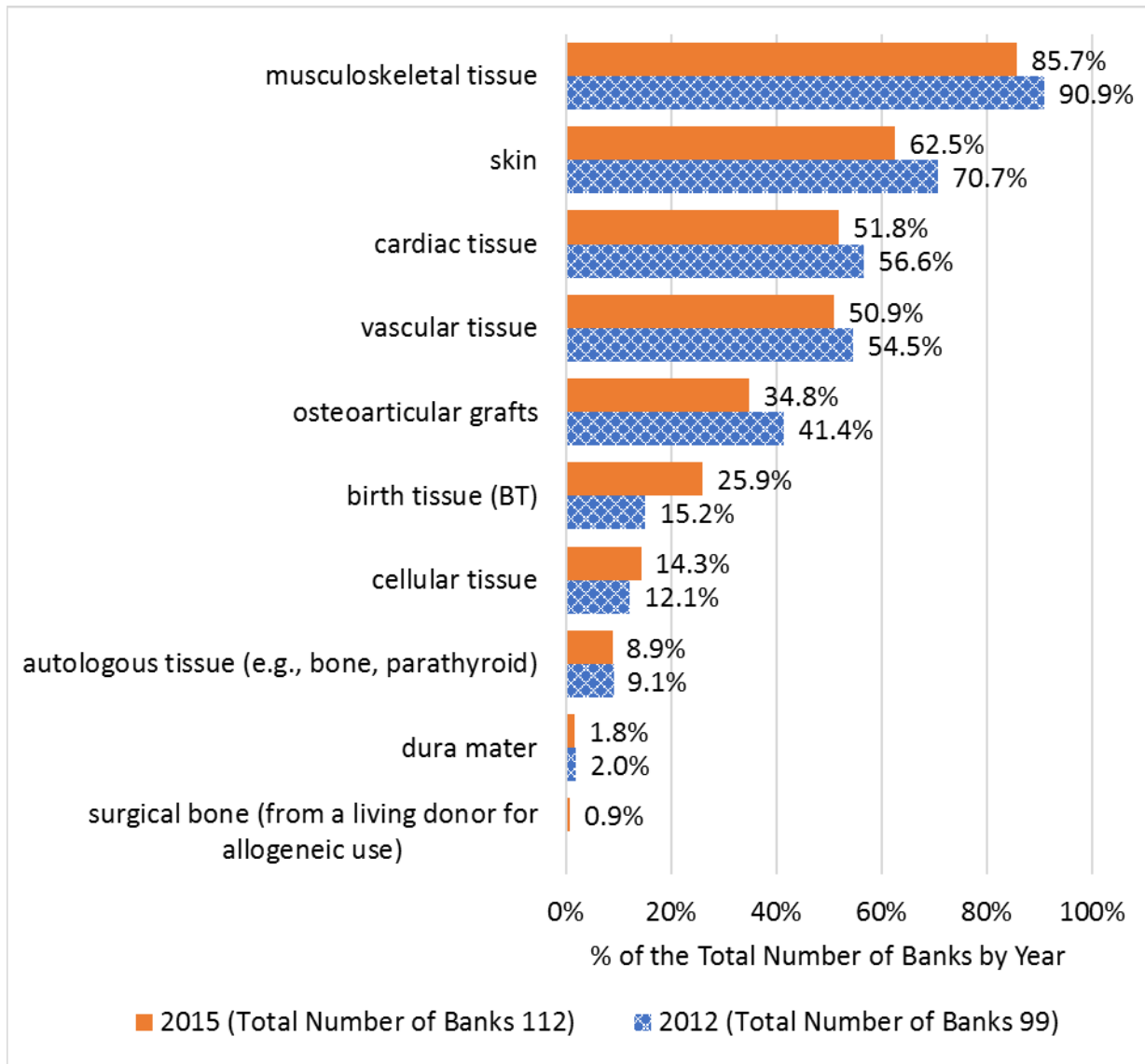


Figure 2 - Percentage of Banks by Type of Human Tissue Handled - Comparison of 2015 (112 Banks) and 2012 (99 Banks)

Number of Inspections at Tissue Bank Facilities in 2015

Of the 112 banks responding to the 2015 survey, 84 (75%) banks reported inspections at their facilities by one or more of the following inspection authorities: American Association of Tissue Banks (AATB), the U.S. Food and Drug Administration (FDA), the Australia Therapeutic Goods Administration TGA, and the South Korea FDA. In addition to their main facility, some tissue banks have one or more satellite facilities. A total of 214 facility inspections were reported in 2015; 121 of which were carried out by the U.S. FDA, 81 by the AATB, 6 by the South Korea FDA and 6 by the Australia TGA (Figure 3).

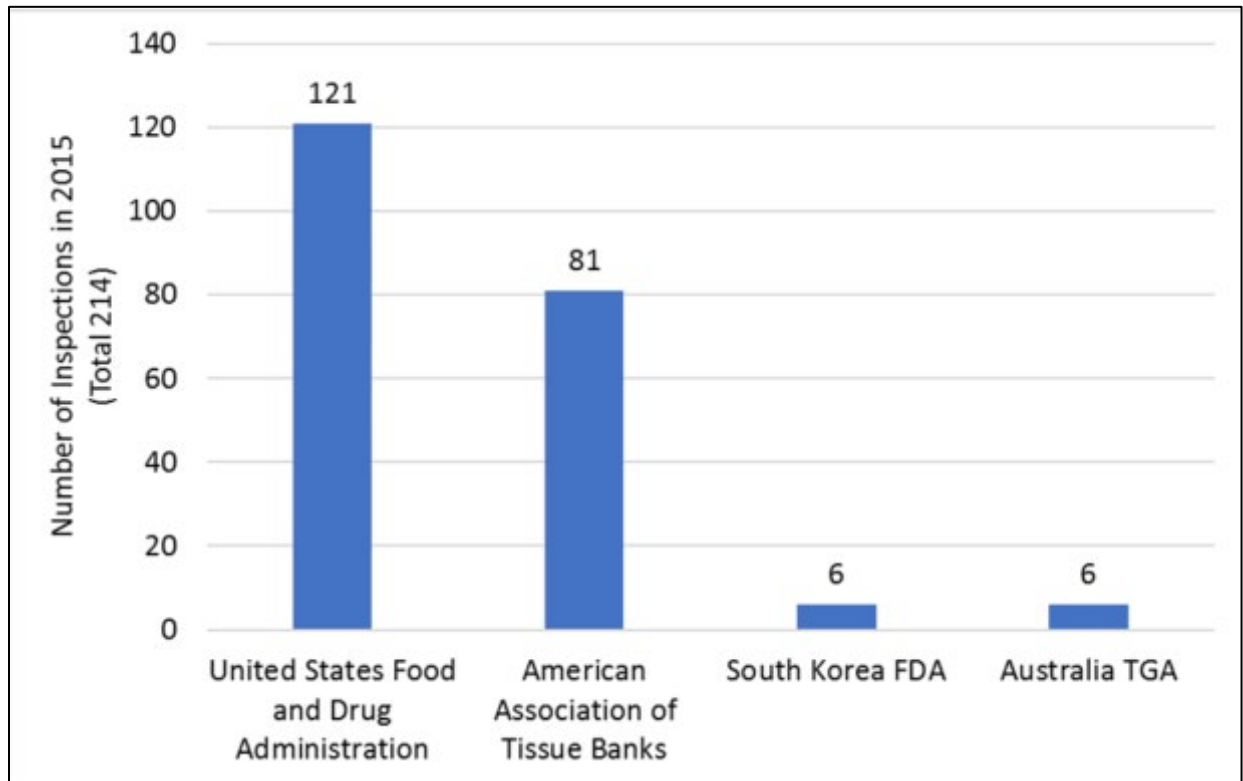


Figure 3 - Number of Inspections at Tissue Banks Facilities in 2015 (84 Banks)

Number of Citations of Noncompliance Issued by the Inspection Authorities in 2015

Of the 84 banks that reported inspections at their facilities, 57 (67.9%) banks were issued a total of 317 citations of noncompliance by one or more of the following inspection authorities: AATB, U.S. FDA, Australia TGA, and South Korea FDA (Figure 4). The AATB issued a total of 278 citations of noncompliance among 49 (86%) of the banks, the US FDA issued 32 citations, Australia TGA issued 6 citations and the South Korea FDA issued 1 citation.

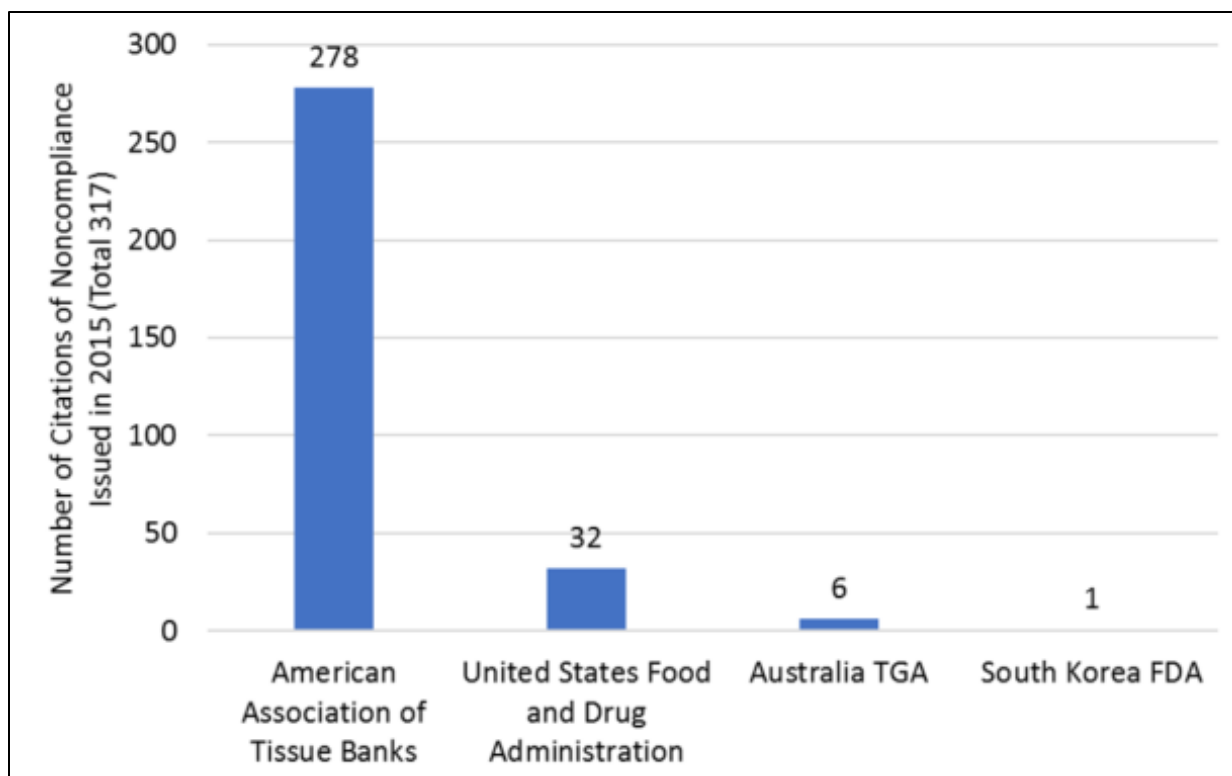


Figure 4 - Number of Citations of Noncompliance Issued by the Inspection Authorities in 2015 (57 Banks)

Inspections and Citations of Noncompliance Issued by Other Inspection Authorities in 2015

Of the 112 banks responding to this survey, 66 (59%) banks reported inspections at their main and/or satellite facilities by one or more of the following inspection authorities: tissue bank (or third party on behalf of another tissue bank), state agency, Clinical Laboratory Improvement Amendments (CLIA), International Organization for Standardization (ISO), College of American Pathologists (CAP) (Table 1). A total of 147 facility inspections were carried out, which resulted in 131 citations of noncompliance being issued among 31 of 66 banks. Thirty-six tissue banks (or a third party) carried out 93 facility inspections and issued 58 citations of noncompliance among 15 banks. Eight state agency authorities carried out 23 facility inspections and issued 31 citations of noncompliance among 6 banks. CLIA carried out 9 facility inspections and issued 1 citation of noncompliance among 9 banks. ISO carried out 18 facility inspections and 27 citations of noncompliance among 7 banks. CAP carried out 4 facility inspections and 14 citations of noncompliance among 2 banks.

Table 1 - Number of Facility Inspections and Citations of Noncompliance Issued by Other Inspection Authorities in 2015

Other Inspection Authorities	Number of Inspections at Tissue Bank Facilities	Number of Citations of Noncompliance
Tissue Bank (or third party on behalf of another tissue bank)	93	58
State Agency	23	31
CLIA	9	1
ISO	18	27
CAP	4	14
Total	147	131

Referrals, Authorization and Informed Consent

The number of tissue banks that responded to the survey on referrals, authorizations and informed consent for deceased and/or living donors was 71 of 82 (87%) banks for 2015 and 66 of 82 (80%) banks for 2012.

Deceased Tissue Donors

Number of Banks that Received Deceased Tissue Donor Referrals and Number of Received Referrals – Comparison of 2015 and 2012 Results

Fifty-six banks reported receiving deceased tissue donor referrals in 2015 and provided the number of referrals. Of the 55 banks that reported receiving deceased tissue donor referrals in 2012, 53 provided the number of referrals.

The information presented in Table 2 is incomplete; therefore, it does not allow for calculating the increase in the number of deceased tissue donor referrals from 2012 to 2015. In 2015, 56 banks received a total of 908,251 deceased donor referrals (median 12,547, average 16,219). In 2012, 53 banks received a total of 898,914 deceased donor referrals (median 12,832, average 16,961).

Although both the average and median values are provided in Table 2, the preferred measure of central tendency is the median due to a positive skew in the data.

Table 2 - Number of Deceased Tissue Donor Referrals in 2015 (56 Banks) and 2012 (53 Banks)

Year	Number of Banks that Provided Information	Total Number of Deceased Tissue Donor Referrals	Average Number of Deceased Tissue Donor Referrals	Median Number of Deceased Tissue Donor Referrals
2015	56	908,251	16,219	12,547
2012	53	898,914	16,961	12,832

Number of Deceased Tissue Donor Referrals by Source

Of the 56 banks that reported receiving deceased tissue donor referrals in 2015, 55 reported the source accounting for 856,352 referrals. The ranking of the referral sources in 2015 is presented in Figure 5. The 9 most reported referral sources were hospitals with 776,962 referrals (90.7% of the total), medical examiners/coroners with 64,955 referrals (7.6% of the total), and extended care facilities/nursing homes with 11,224 referrals (1.3% of the total), law enforcement with 1585 (.03% of the total), funeral homes with 562 referrals (% of the total is negligible), first responders with 547 referrals (% of the total is negligible), OPO with 400 referrals (% of the total is negligible), donor family with 101 referrals (% of the total is negligible) and other with 16 reported referrals (% of the total is negligible). The 3 most reported referrals sources accounted for 99.6% of the total referrals received by the 55 banks in 2015.

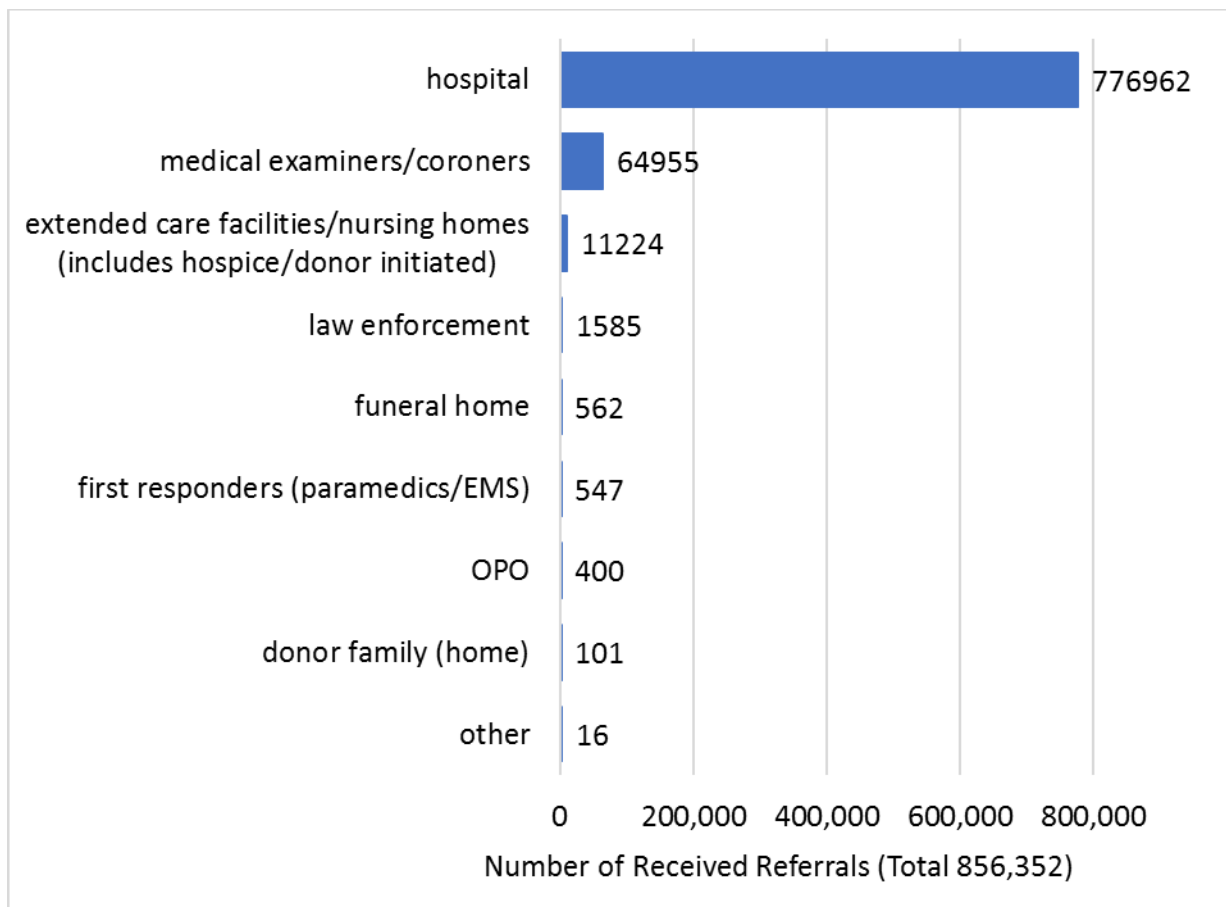


Figure 5 - Number of Deceased Tissue Donor Referrals by Source in 2015 (55 Banks)

Number of Banks that Received Living Tissue Donor Referrals and Number of Referrals – Comparison of 2015 and 2012 Results

Of the 8 banks that reported receiving living tissue donor referrals in 2015, 7 provided the number of referrals. Six banks reported receiving living tissue donor referrals in 2012 and provided the number of referrals.

The information presented in Table 3 is incomplete; therefore, it does not allow for calculating the increase in the number of living tissue donor referrals from 2012 to 2015. In 2015, 7 banks received 14,381 living tissue donor referrals (median 303, average 2,054). In 2012, 6 banks received 3,811 living donor referrals (median 93, average 635).

Although both the average and median values are provided in Table 3, the preferred measure of central tendency is the median due to a positive skew in the data.

Table 3 - Number of Received Living Tissue Donor Referrals in 2015 (7 Banks) and 2012 (6 Banks)

Year	Number of Banks that Provided Information	Total Number of Living Tissue Donor Referrals	Average Number of Living Tissue Donor Referrals	Median Number of Living Tissue Donor Referrals
2015	7	14,381	2,054	303
2012	6	3,811	635	93

Number of Living Tissue Donor Referrals by Source

The source of the referrals, along with the number of received referrals, was reported by 7 banks in 2015. The ranking of the referral sources is presented in Figure 6. The 2 main referral sources accounted for 95.6% of the total referrals and were physicians with 10,469 referrals and hospital delivery/birth centers with 3,278 referrals. The other two referral sources were hospital surgical department with 604 referrals and family/donor initiated with 30 referrals.

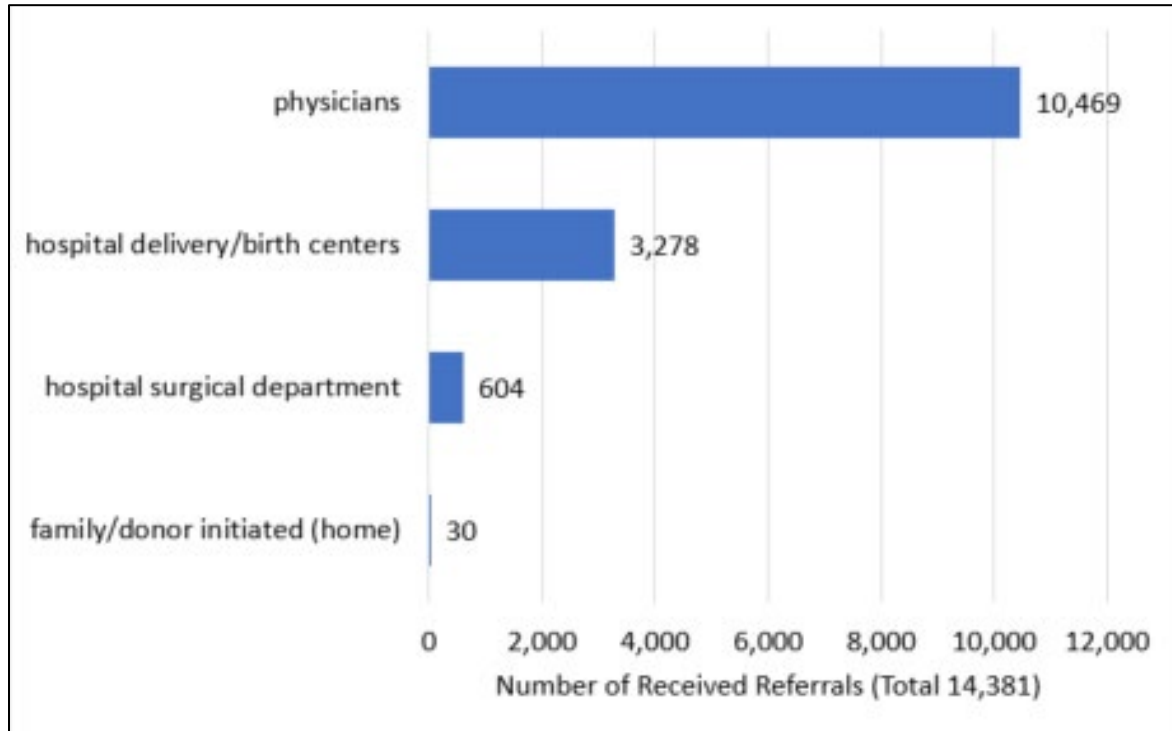


Figure 6 - Number of Living Tissue Donor Referrals by Source in 2015 (7 Banks)

Number of Requested Authorizations and Number of Obtained Authorizations for Deceased Tissue Donors

For 2015, 54 banks reported having requested authorizations to recover tissue from deceased tissue donors. Of the 54 banks, 50 provided the number of requested authorizations, and 52 provided the number of obtained authorizations.

As presented Table 4, 50 banks requested a total of 121,349 authorizations (median 1,642, average 2,427), and 52 banks obtained a total of 54,546 authorizations (median 691, average 1,049). To generalize the outcome of the authorization process, the authorization obtainment rate (obtained/requested) was calculated for the totality of the 50 banks as well as the bank level. While the overall obtainment rate (total obtained/total requested) was 44.8% in 2015, the obtainment rate at bank level indicates that 50% of the banks had an obtainment rate above 48% (median) 50% (average).

Although both the average and median values are provided in Table 4, the preferred measure of central tendency is the median due to non-normally distributed data.

Table 4 - Authorizations for Deceased Tissue Donors in 2015

Requested Authorizations, Obtained Authorizations and Authorization Obtainment Rate	Number of Banks that Provided Information	Total	Average	Median
Requested	50	121,349	2,427	1,642
Obtained	52	54,546	1,049	691
Obtainment Rate (%) at Bank Level	50	N/A	50%	48%
Overall Obtainment Rate (%)	50	44.5%	N/A	N/A

Additional Information on Deceased Tissue Donor Authorizations

The banks were asked to respond to 5 questions regarding deceased tissue donor authorizations. As presented in Table 5, 15,132 requests were not made because an authorizing person was not available; 66,584 requests for authorization were denied; 24,198 requests where authorization was obtained, tissues were not recovered; 35,423 of the obtained authorizations came from an authorizing person or persons; and 29,712 of the obtained authorizations came from first person/donor designation/donor registry. The combined total of the last two responses exceed the reported number of obtained authorizations (54,546) by 10, 559. One possible explanation is that some banks had tissue donor authorizations that came from an authorizing person or persons as well as from the second source (i.e., first person, donor designation, or donor registry).

Table 5 - Additional Information on Authorizations for Deceased Tissue Donors in 2015

Additional Information on Deceased Tissue Donor Authorizations	Number of Banks that Provided Information	Total
Authorizing person (e.g., spouse) was not available	50	15,132
Requests for authorization that were denied	50	66,584
Obtained authorizations for which tissues were not recovered	51	24,198
Obtained authorizations that came from an authorizing person or persons	50	35,423
Obtained authorizations that came from first person/donor designation/donor registry	48	29,712

Requests or Statements on the Authorization Form for Deceased Tissue Donors

For 2015, 53 banks indicated whether they included the following 3 requests or statements on their authorizations form. The questions and responses were as follows: Does your authorization form include a request or statement regarding 1) for-profit or not-for-profit involvement or restrictions on the gift (46 yes and 7 no responses); 2) international distribution of the gift (50 yes and 3 no responses); and 3) cosmetic/aesthetic use of the gift (29 yes and 24 no responses).

Number of Referrals Determined Ineligible for Deceased Tissue Donation (Prior to Going on Site for Recovery) – Comparison of 2015 and 2012 Results

For 2015, 59 banks reported conducting donor eligibility evaluations of deceased tissue referrals; of these banks, 58 provided the number of referrals determined ineligible for deceased tissue donation. For 2012, 55 banks reported conducting donor eligibility evaluations of deceased tissue referrals; of these banks, 47 provided the number of referrals determined ineligible for deceased tissue donation.

As presented in Table 6, in 2015, 58 banks determined 765,912 referrals (median 8,824, average 13,205) ineligible for deceased tissue donation; and in 2012, 47 banks determined 617,868 referrals (median 10,754, average 13,146) ineligible for deceased tissue donation.

Although both the average and median values are provided in Table 6, the preferred measure of central tendency is the median due to the positive skew in the data.

Table 6 - Number of Referrals Determined Ineligible for Deceased Tissue Donation (Prior to Going on Site for Recovery) in 2015 (58 Banks) and 2012 (47 Banks)

Year	Number of Banks that Provided Information	Total Number of Ineligible Referrals	Average Number of Ineligible Referrals	Median Number of Ineligible Referrals
2015	58	765,912	13,205	8,824
2012	47	617,868	13,146	10,754

[Reasons for Determining Referrals Ineligible for Deceased Tissue Donation \(Prior to Going on Site for Recovery\)](#)

For 2015, 48 of the 58 banks that conducted deceased donor eligibility evaluations provided the reasons for determining deceased referrals ineligible for tissue donation. The ranking of reasons for determining 507,204 deceased referrals ineligible for donation are presented in Figure 7. The 12 reported reasons and the corresponding number of ineligible referrals were medical history (223,002), age (207,442), infectious disease testing (17,695), behavioral risk history (16,931), time restrictions (10,527), trauma (6,096), medical examiner/coroner restrictions (5,930), Processor reached capacity/deferred (2,870), plasma dilution (2,597), travel/residence history (2,175), funeral home restrictions (1,670) and other reasons (weight, family declined, sepsis etc.) (10,269). Medical history and age represent 85% of the ineligible referrals. Note: The reasons for ineligibility do not account for 258,708 (33%) ineligible referrals reported by 10 banks.

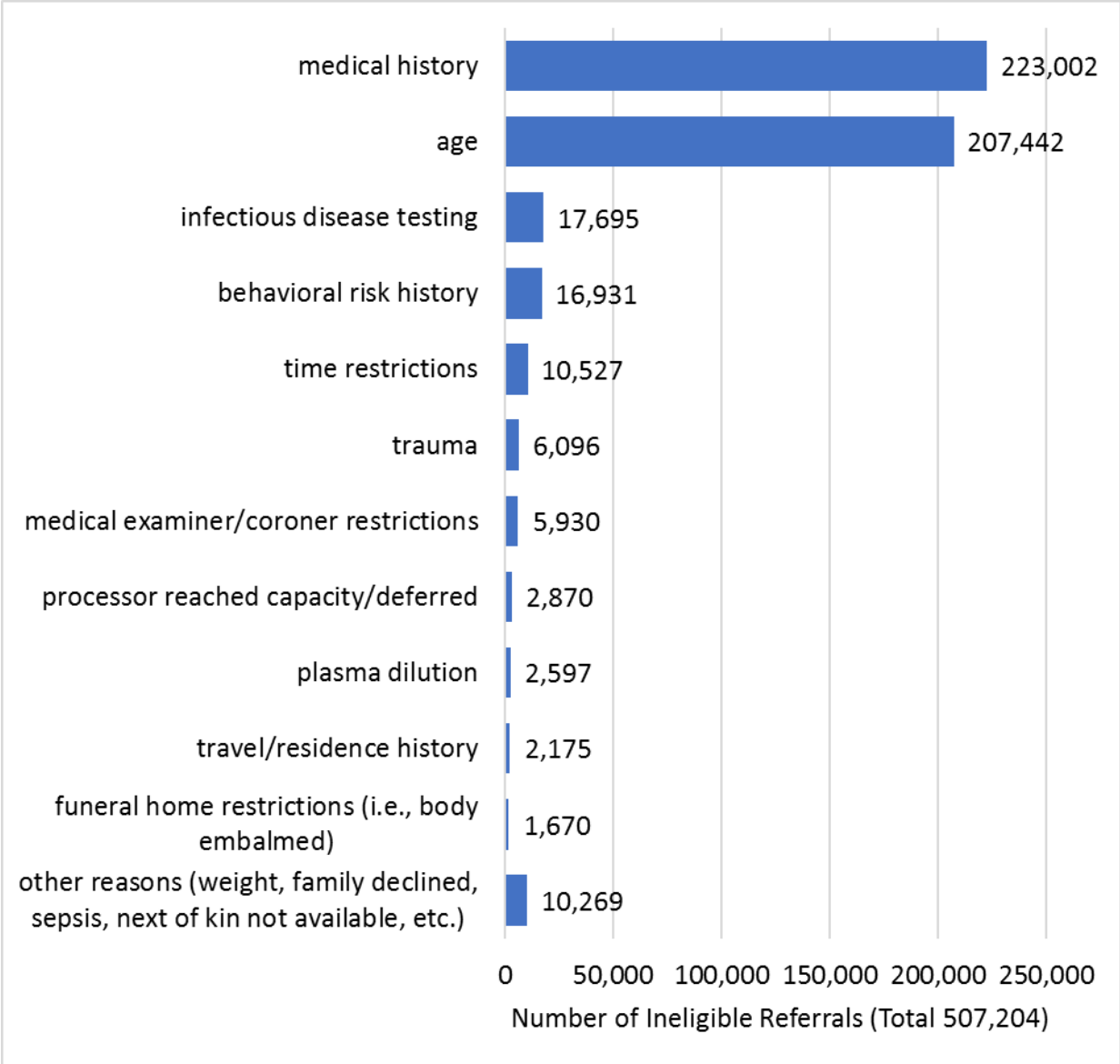


Figure 7 - Reasons for Determining Referrals Ineligible for Deceased Tissue Donation (Prior to Going on Site for Recovery) in 2015 (48 Banks)

Living Tissue Donors

Number of Requested Informed Consents, Obtained Informed Consents, Denied Informed Consents, and Obtained but not Acquired Informed Consents for Living Tissue Donors

For 2015, 13 banks reported obtaining informed consent from living tissue donors; of these banks, 9 (69.2%) reported requesting a total of 5,640 informed consents, and 11 (84.6%) reported obtaining a total of 16,991 informed consents. Of these 11 banks, 4 reported a total of 109 informed consents were denied and 5 reported a total of 658 informed consents were obtained but tissue was not acquired.

Requests or Statements on the Consent Form for Living Tissue Donors

For 2015, 13 banks indicated whether they included the following 3 requests or statements on their consent form. The questions and responses were as follows: Does your consent form include a request or statement regarding 1) for-profit or not-for-profit involvement or restrictions on the gift (11 yes and 2

no responses); 2) international distribution of the gift (10 yes and 3 no responses); and 3) cosmetic/aesthetic use of the gift (6 yes and 7 no responses).

Number of Referrals Determined Ineligible for Living Tissue Donation (Prior to Going on Site for Recovery) – Comparison of 2015 and 2012 Results

For 2015, 8 banks reported conducting donor eligibility evaluations of living tissue referrals prior to going on site; of these banks, 7 provided the number of referrals determined ineligible for living tissue donation. For 2012, 5 banks reported conducting donor eligibility evaluations of living tissue referrals prior to going on site; of these banks, 3 provided the number of referrals determined ineligible for living tissue donation.

As presented in Table 7, the total number of referrals determined ineligible for living tissue donation were 207 (median 8, average 29.6) in 2015, and 65 (median 10, average 21.7) in 2012.

Table 7 - Number of Referrals Determined Ineligible for Living Tissue Donation (Prior to Going on Site for Recovery) in 2015 (7 Banks) and 2012 (3 Banks)

Year	Number of Banks that Provided Information	Total Number of Ineligible Referrals	Average Number of Ineligible Referrals	Median Number of Ineligible Referrals
2015	7	207	29.6	8
2012	3	65	21.7	10

Reasons for Determining Referrals Ineligible for Living Tissue Donation (Prior to Going on Site for Recovery)

For 2015, 5 of the 7 banks that conducted living donor eligibility evaluations provided the reasons for determining 38 living referrals ineligible for tissue donation. As presented in Figure 8, the main reasons were: medical history 14, infectious disease testing 8, travel/residence history 8, behavioral risk history 7 and vaginal delivery 1. Note: The reasons for ineligibility do not account for 169 (81.6%) ineligible referrals reported by 2 banks.

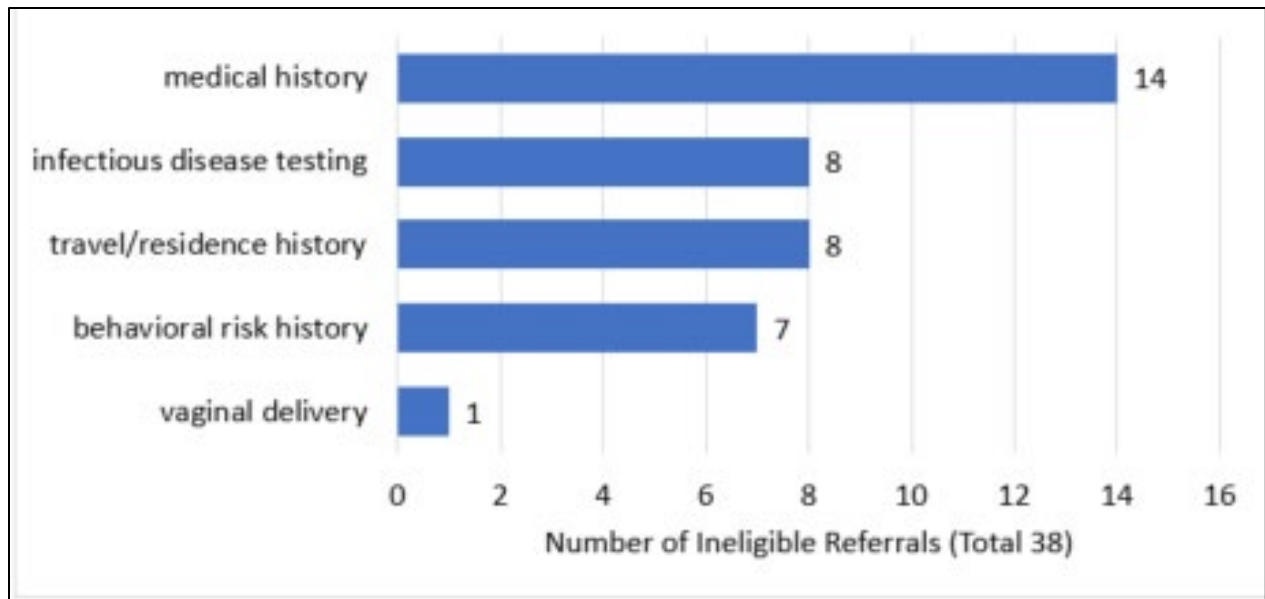


Figure 8 - Reasons for Determining Referrals Ineligible for Living Tissue Donation (Prior to Going on Site for Recovery) in 2015 (5 Banks)

Recovery and Acquisition

The number of tissue banks that responded to the survey on recovery and acquisition for deceased and/or living donors was 70 of 79 (88.6%) banks for 2015 and 65 of 79 (82.3%) banks for 2012.

Deceased Tissue Donors

Number of Deceased Donors from Whom Tissue Was Recovered for Transplantation

The number of deceased donors from whom tissue was recovered for transplantation was provided by 60 of 62 (96.8%) banks that reported recovering deceased donor tissue in 2015; 56 of 57 (98.2%) banks that reported recovering deceased donor tissue in 2012, and by 77 (100%) banks in 2007.

As presented in Table 8, tissues were recovered from 39,121 deceased donors in 2015 (median 485, average 652), 35,112 deceased donors in 2012 (median 457, average 627), and 29,799 donors in 2007 (average 387). The information provided for 2012 and 2015 is incomplete; therefore, it does not allow for calculating the increase in the number of deceased donors. Although both the average and median values are provided in Table 8 for the years 2015 and 2012, the preferred measure of central tendency is the median due to a positive skew in the data.

Table 8 – Number of Deceased Donors from Whom Tissue Were Recovered for Transplantation - Comparison of 2015 (60 Banks), 2012 (56 Banks) and 2007 (77 Banks)

Year	Number of Banks that Provided Information	Total Number of Deceased Tissue Donors Recovered	Average Number of Deceased Tissue Donors Recovered	Median Number of Deceased Tissue Donors Recovered
2015	60	39,121	652	485
2012	56	35,112	627	457
2007	77	29,799	387	N/A

Recovered Deceased Tissue Donors Whom Were Also Ocular Donors, Organ Donors or Had an Autopsy Performed – Comparison of 2015, 2012 and 2007 Results

Not all the banks that reported recovering tissue from deceased donors were able to give information about the number of recovered donors whom were also ocular donors, organ donors, or had an autopsy performed. The response rate for ocular donors was 74.2% for 2015 and 67.9% for 2012. The response rate for organ donors was 92% for 2015 and 73.2% for 2012. The response rate for donors whom had an autopsy performed was 75.8% for 2015 and 85.7% for 2012.

As presented in Figure 9, 2015 had the highest percentage of recovered deceased tissue donors whom were also ocular donors (43.6% vs. 36.9% in 2012 and 39% in 2007). However, the survey response rate for ocular donors was very low in 2012 (67.9%). There is a clear decreasing trend in recovered deceased donors whom had an autopsy performed, with 2015 having the lowest percentage (20.4% vs. 23.3% in 2012, and 27% in 2007). The percentage of recovered deceased donors whom were also organ donors remains stable (9% in 2015, 8.1% in 2012 and 9% in 2007).

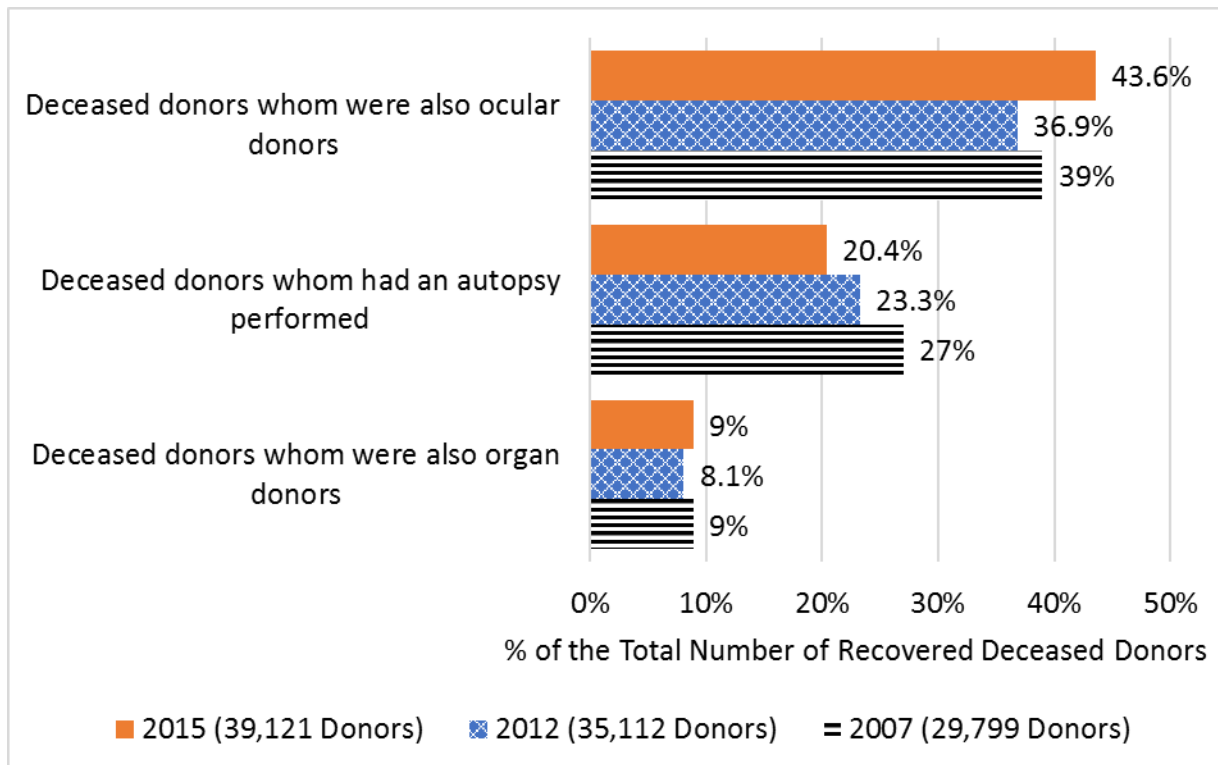


Figure 9 - Percentage of Deceased Tissue Donors Whom Were Also Ocular Donors, Organ Donors, Or Had an Autopsy Performed - Comparison of 2015, 2012 and 2007

Tissue Types Recovered for Transplantation from Deceased Donors in 2015

In 2015, of the 62 banks that reported recovering tissues for transplantation from deceased donors, 59 (95.2%) banks provided information about the type of tissue they recovered, as well as the total number of recovered deceased donors by tissue type.

As presented in Figure 10, most banks recovered musculoskeletal tissue (98.3%), skin (89.8%), cardiac tissue (89.9%) , vascular tissue (84.7%) and dura matter (1.7%).

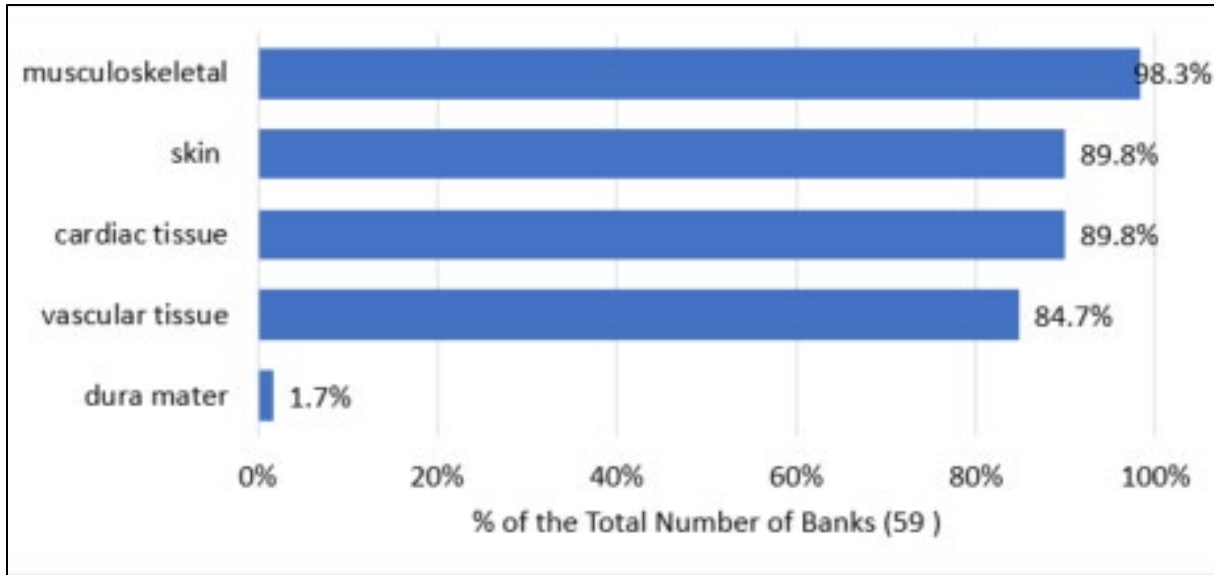


Figure 10 - Percentage of Banks by Type of Tissue Recovered from Deceased Donors for Transplantation in 2015 (59 Banks)

As presented in Figure 11, musculoskeletal tissue was recovered from 31,726 donors; skin was recovered from 24,758 donors; cardiac tissue was recovered from 6,174 donors; vascular tissue was recovered from 5,099 donors; nerve tissue was recovered from 222 donors; adipose tissue was recovered from 212 donors; and dura mater was recovered from 72 donors. Note: A donor could be counted more than once, depending on the types of tissues that were recovered.

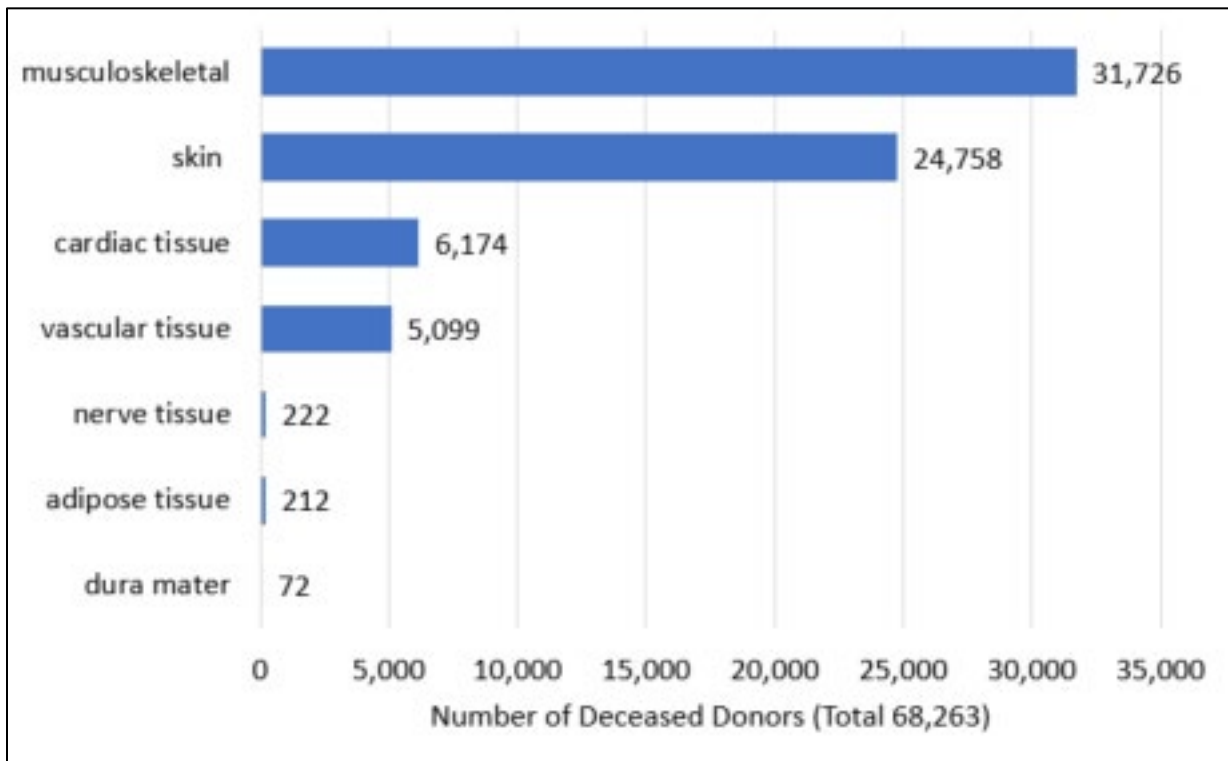


Figure 11 - Number of Deceased Donors by Type of Tissue Recovered for Transplantation in 2015 (59 Banks)

Sites Where Tissues Were Recovered for Transplantation from Deceased Donors

In 2015, of the 62 banks that reported recovering tissues for transplantation from deceased donors, 59 (95.2%) banks provided information about the tissue recovery sites.

As presented in Figure 12, most tissue recoveries (86.5%) from deceased donors occurred at three types of sites: 18,331 (47.7%) recoveries occurred at dedicated tissue recovery sites; 11,047 (28.6%) recoveries occurred in health care facility operating rooms; and 4,063 (10.5%) occurred in medical examiner offices (dedicated rooms). Other tissue recoveries by recover site were funeral home 1,857 (% of the total is negligible), hospital morgue 1,759 (% of the total is negligible) and medical examiner office (open autopsy area) 1,593 (% of the total is negligible).

Graph showing number of deceased donor tissue recoveries by recovery site.

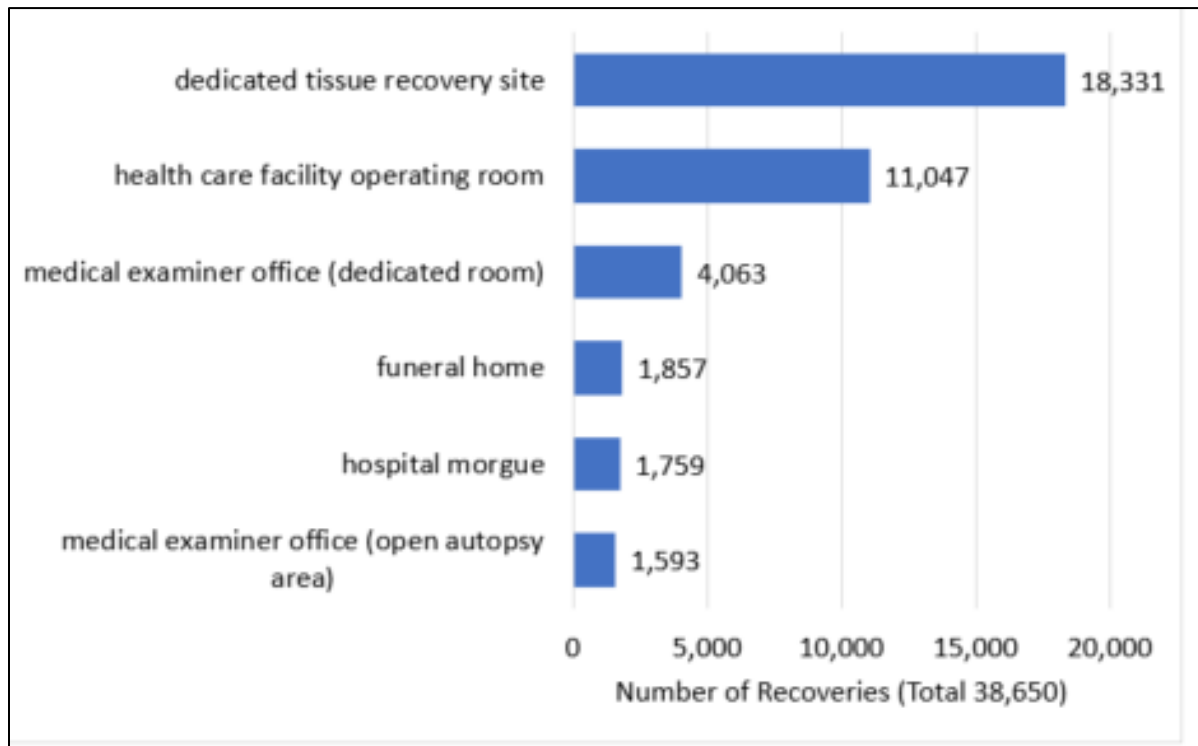


Figure 12 - Number of Deceased Donor Tissue Recoveries by Recovery Site in 2015 (59 Banks)

Gender and Age Category of Deceased Donors from Whom Tissues Were Recovered for Transplantation

In 2015, of the 62 banks that reported recovering tissues for transplantation from deceased donors, 55 (88.7%) banks provided information about the gender and the age category for a total number of 36,180 donors. As presented in Figure 13, more than two thirds of the deceased donors were male (24,702 donors, or 68.3% of the total). 11,478 donors or 31.7% were female.

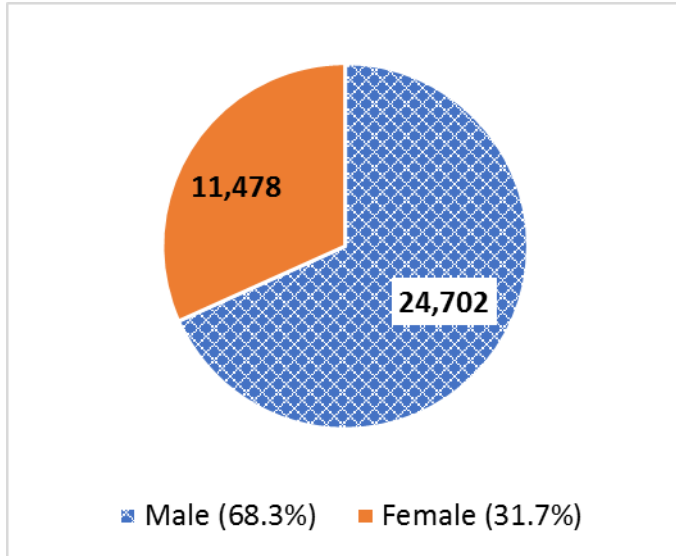


Figure 13 - Number of Deceased Donors by Gender in 2015 (55 Banks)

As presented in Figure 14, the male donors dominated across all age categories. Nearly half (49.6%) of the total deceased donors were between 51 and 70 years old. The age categories with the least donors were below 20 years old (4.9%) and above 80 years (4.8%). In detail, from 0-12 years 1.1% were male, 0.6% were female, 13-20 years, 2.3% were male, 0.9% were female, 21-30 years 4.0% were male, 1.6 % female, 31-40 years, 4.4 % were male, 2.4% female, 41-50 years 8.0% were male, 4.3% were female, 51-60 years, 15.3% were male, 7.3 % female, 61-70 years 18.6% were male, 8.4% female, 71-80 years, 11.7% were male, 4.2 % were female, over 80 years 2.85 were male, 2.0% were female.

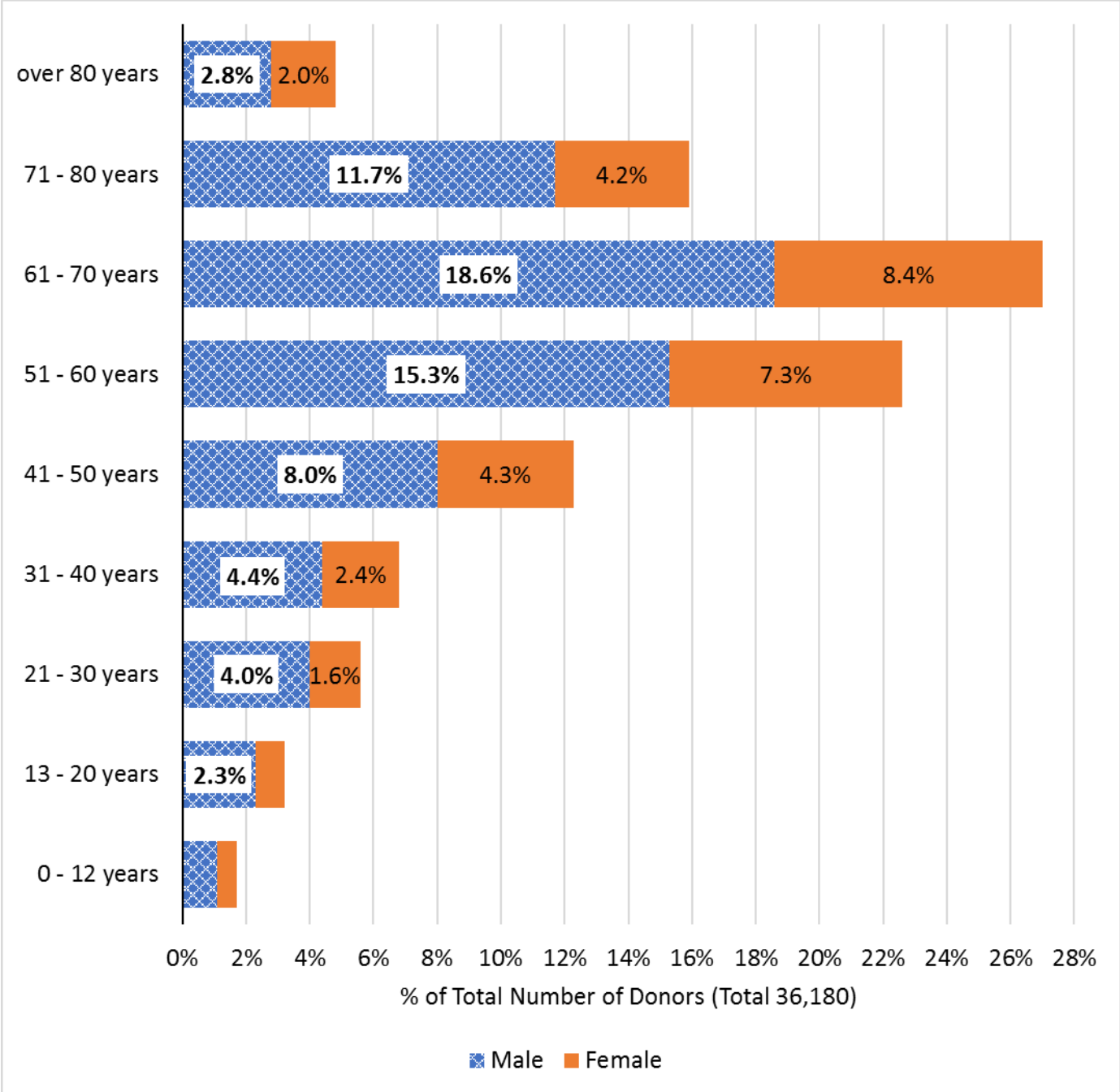


Figure 14 - Distribution of Male and Female Deceased Donors across Age Categories in 2015 (55 Banks)

Number of Deceased Donors from Whom Tissues Were Recovered for Research
 For 2015, 20 banks indicated that they recovered tissues for research from a total of 1,157 deceased donors. The median value was 19 and the average value was 58.

Living Tissue Donors

Number of Living Donors from Whom Tissue Was Recovered for Transplantation
 The number of living donors from whom tissue was recovered for transplantation was provided by 8 of 13 banks in 2015; 7 banks in 2012; and by 7 banks in 2007.

The information provided in Table 9 is incomplete; therefore, it does not allow for calculating the increase in the number of living donors from 2012 to 2015 and from 2007 to 2015. In 2015, 8 banks reported recovering tissues for transplantation from 19,218 living donors (median 1,257, average 2,402). For 2012, 7 banks reported recovering tissues for transplantation from 4,376 living donors (median 224, average 625). For 2007, 7 banks reported recovering tissues for transplantation from 581 living donors (median could not be calculated, average was 83).

Although both the average and median values are provided in Table 9 for the years 2015 and 2012, the preferred measure of central tendency is the median due to a positive skew in the data.

Caveat: The number of autologous tissue donors is not included in the count of living donors for 2015 and 2012.

Table 9 - Number of Living Donors from Whom Tissue Were Recovered for Transplantation - Comparison of 2015 (8 Banks), 2012 (7 Banks) and 2007 (7 Banks)

Year	Number of Banks that Provided Information	Total Number of Living Tissue Donors Recovered	Average Number of Living Tissue Donors Recovered	Median Number of Living Tissue Donors Recovered
2015	8	19,218	2,402	1,257
2012	7	4,376	625	224
2007	7	581	83	N/A

Tissue Types Recovered for Transplantation from Living Donors in 2015

For 2015, 4 banks reported recovering autologous tissues for transplantation from living donors; of these banks, 4 reported recovering autologous bone from 344 donors and 3 reported recovering autologous parathyroid from 45 donors.

For 2015, of the 13 banks that reported recovering tissues for transplantation from living donors, 8 banks provided information about the type of birth tissue they recovered, as well as the total number of recovered living donors by birth tissue type.

As presented in Figure 15, all 8 banks acquired placenta, 62.5% of the banks acquired umbilical cord and 37.5% of the banks acquired amniotic fluid 2015.

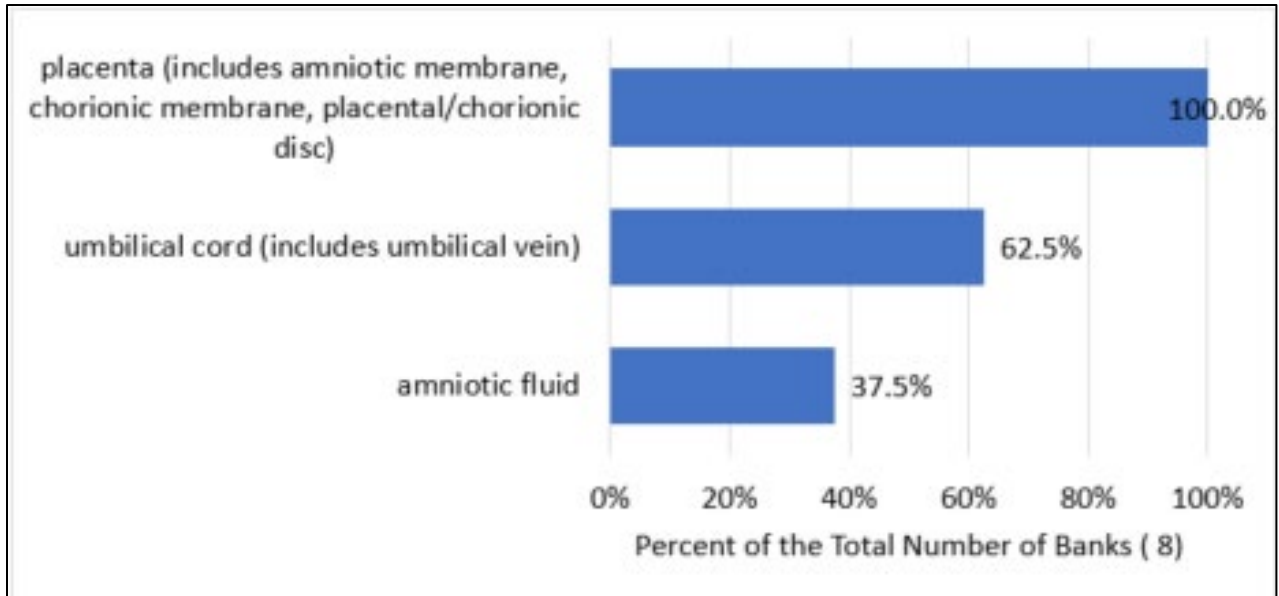


Figure 15 - Percentage of Banks by Type of Birth Tissue Acquired from Living Donors for Transplantation in 2015

As presented in Figure 16, placenta tissue was acquired from 15,538 living donors, umbilical cord tissue was acquired from 6,293 living donors and amniotic fluid was acquired from 41 living donors. Note: A donor could be counted more than once, depending on the types of tissues that were acquired.

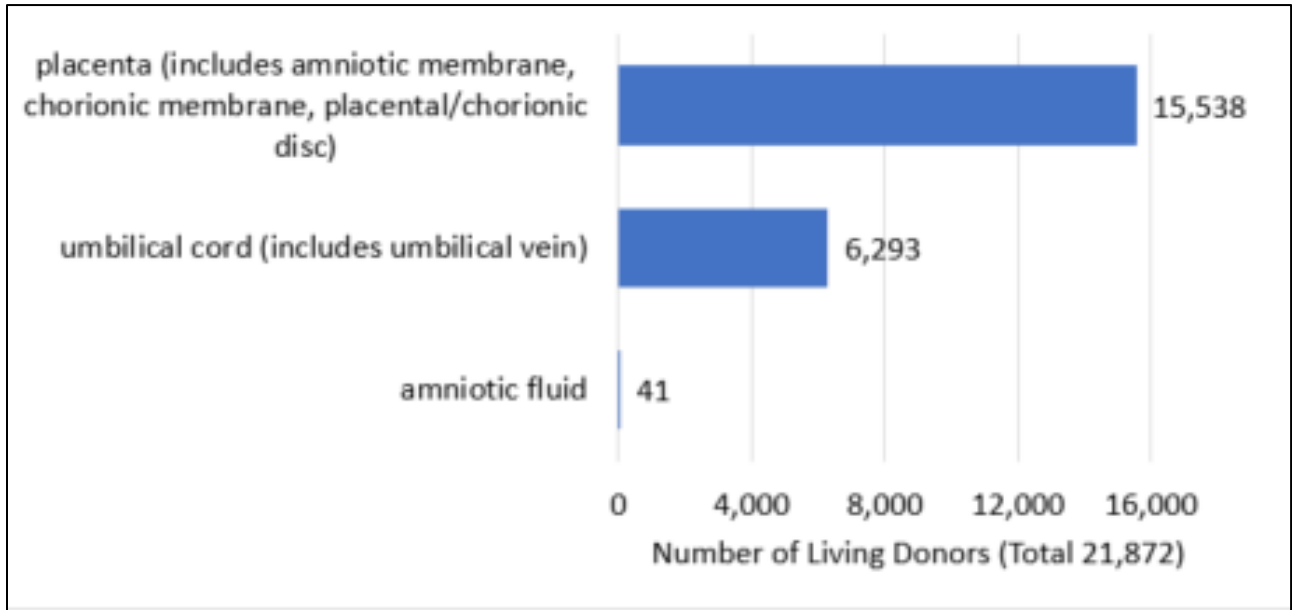


Figure 16 - Number of Living Donors by Type of Birth Tissue Acquired for Transplantation in 2015

Number of Birth Tissue Donors Who Delivered by Cesarean Section

For 2015, 8 banks indicated that a total of 20,115 donors of birth tissue delivered by cesarean section. The median value was 899 and the average value was 2,514.

Number of Living Donors from Whom Tissues Were Recovered for Research

In 2015, 4 banks indicated that they recovered tissues for research from a total of 973 living donors. The median value was 86 and the average value was 243.

Gender and Age Category of Living Donors from Whom Tissues Were Recovered for Transplantation

In 2015, of the 13 banks that reported recovering tissues for transplantation from living donors, 7 banks provided information about the age category for a total number of 5,316 donors.

Only one bank reported receiving tissue for transplantation from 9 living male donors. The male donors represented only 0.2% of the living donors, and they were within the age category 21 - 30 years old.

As presented in Figure 17, most female living donors (88.7%) had ages between 21 and 40 years old. In detail, female living donors 13-20 years were 10.6 %, 21-30 years were 63.8%, 31-40 years were 24.9% and 41-50 years were 0.7%.

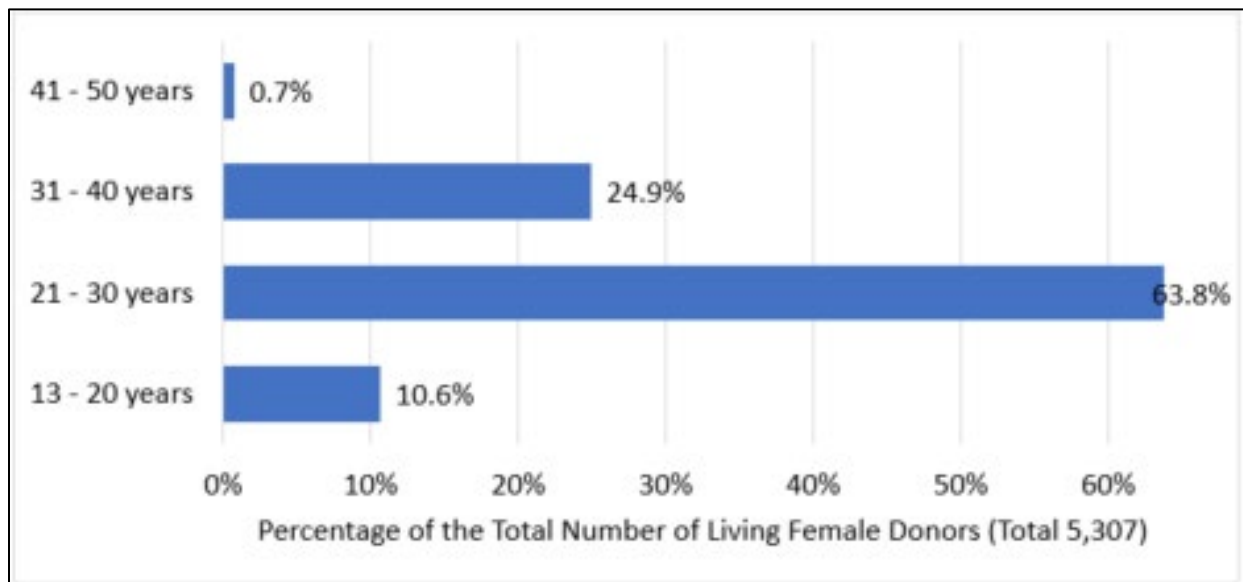


Figure 17 - Distribution of Female Living Donors across Age Categories in 2015 (7 Banks)

Deceased Tissue Donors

Number of Deceased Donors Determined Ineligible for Tissue Donation at the Recovery Site – Comparison of 2015 and 2012 Results

For 2015, 62 banks reported recovering tissues from deceased donors for transplantation; of these banks, 48 provided information on deceased donor ineligibility for tissue donation at the recovery site. For 2012, 57 banks reported recovering tissues from deceased donors for transplantation; of these banks, 38 provided information on deceased donor ineligibility for tissue donation at the recovery site.

As presented in Table 10, for 2015, 48 banks determined 5,241 deceased donors (median 38, average 109) ineligible for tissue donation at the recovery site; and, in 2012, 37 banks determined 5,697 deceased donors (median 42, average 146) ineligible for tissue donation at the recovery site.

Although both the average and median values are provided in Table 10, the preferred measure of central tendency is the median due to the positive skew in the data.

Table 10 - Number of Deceased Donors Determined Ineligible for Tissue Donation at the Recovery Site in 2015 (48 Banks) and 2012 (37Banks)

Year	Number of Banks that Provided Information	Total Number of Ineligible Deceased Donors	Average Number of Ineligible Deceased Donors	Median Number of Ineligible Deceased Donors
2015	48	5,241	109	38
2012	37	5,697	146	42

Reasons for Determining Deceased Donors Ineligible for Tissue Donation at the Recovery Site – Comparison of 2015 and 2007 Results

For 2015, 51 of the 62 banks that reported recovering tissues from deceased donors for transplantation provided the reasons for determining a total of 5,302 deceased donors to be ineligible at the recovery site. This information is not available for 2012.

As presented in Figure 18, the reasons for determining most of the deceased donors to be ineligible at the recovery site (85.7% in 2015 and 81.5% in 2007) were: chart findings (39.5% in 2015 and 25.4% in 2007), physical assessment findings (34.9% in 2015 and 36.6% in 2007), logistics (11.3% in 2015 and 19.8% in 2007), related to blood sample (5.9% in 2015 and 9.5% in 2007) and other (8.3% in 2015 and 8.8% in 2007).

Caveat: the 2007 results were available in percentages expressed from the total number of donors (deceased 98% and living 2%).

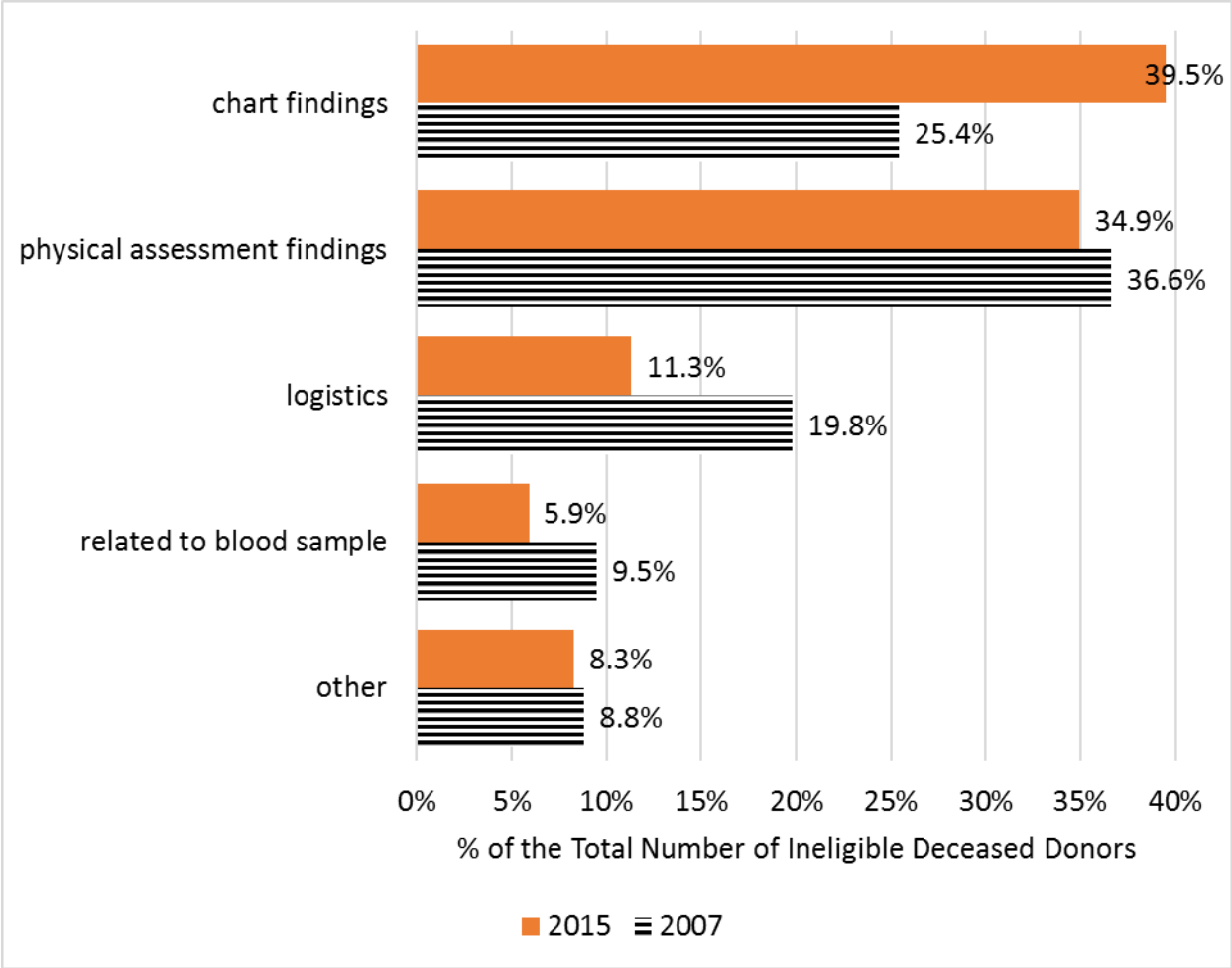


Figure 18 - Reasons for Determining the Deceased Donors Ineligible at the Recovery Site - Comparison of 2015 and 2007

Number of Deceased Donors Determined Ineligible for Tissue Donation After Recovery – Comparison of 2015 and 2012 Results

For 2015, 62 banks reported recovering tissues from deceased donors for transplantation; of these banks, 43 provided information on deceased donor ineligibility for tissue donation after recovery. For 2012, 57 banks recovered tissues from deceased donors for transplantation; of these banks 31 provided information on deceased donor eligibility for tissue donation after recovery.

As presented in Table 11, for 2015, 43 banks determined 3,309 deceased donors (median 56, average 77) ineligible for tissue donation after recovery; and, in 2012, 31 banks determined 2,235 deceased donors (median 53, average 72) ineligible for tissue donation after recovery.

Although both the average and median values are provided in Table 11, the preferred measure of central tendency is the median due to the positive skew in the data.

Table 11 - Number of Deceased Donors Determined Ineligible for Tissue Donation After Recovery in 2015 (43 Banks) and 2012 (31 Banks)

Year	Number of Banks that Provided Information	Total Number of Ineligible Deceased Donors	Average Number of Ineligible Deceased Donors	Median Number of Ineligible Deceased Donors
2015	43	3,309	77	56
2012	31	2,235	72	53

Reasons for Determining Deceased Donors Ineligible for Tissue Donation After Recovery – Comparison of 2015 and 2007 Results

For 2015, 37 banks provided the reasons for determining a total of 2,684 deceased donors to be ineligible after recovery. The number of banks that provided this information is not available for 2007.

As presented in Figure 19, the reasons for determining these deceased donors to be ineligible after recovery for 2015 and 2007 were: infectious disease testing (53.9% for 2015 and 39.1% in 2007), pre-processing cultures (16% for 2015 and 23.8% in 2007), medical history (15.2% for 2015 and 18.7% in 2007), autopsy results (6.8% for 2015 and 7.1% in 2007), behavioral risk history (3.1% for 2015 and 3.7% in 2007), tissue quality (2.5% for 2015 and 1.7% for 2007) and other (2.5 % for 2015 and 5.9% for 2007) .

Caveat: the 2007 results were available in percentages expressed from the total number of donors, (deceased 98% and living 2%).

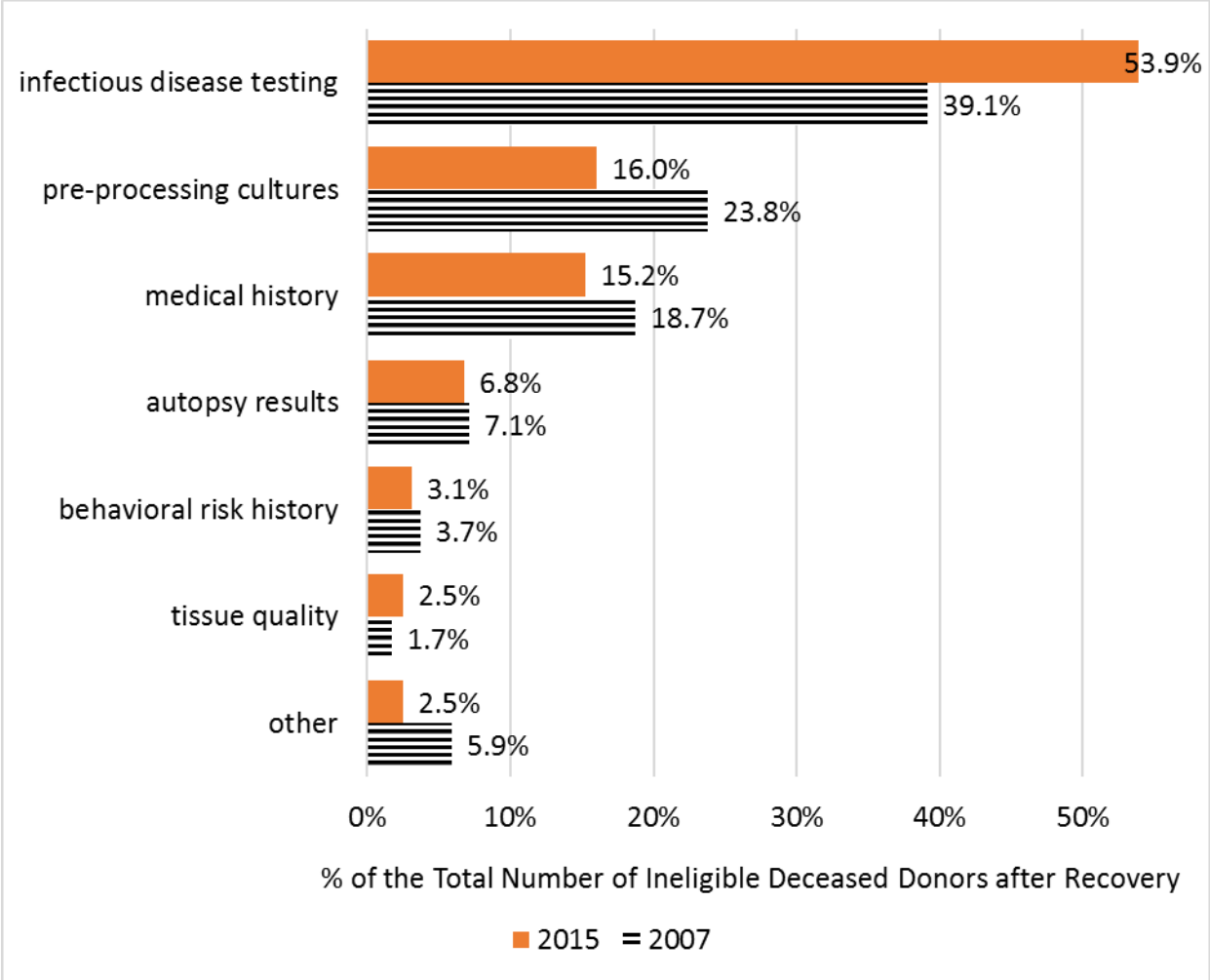


Figure 19 - Reasons for Determining the Deceased Donors Ineligible After Recovery - Comparison of 2015 and 2007

Living Tissue Donors

Number of Living Donors Determined Ineligible for Tissue Donation at Acquisition – Comparison of 2015 and 2012 Results

For 2015, 13 banks reported acquiring tissues from living donors for transplantation; of these banks, 3 provided information on the number of ineligible living donors at acquisition. For 2012, 9 banks reported acquiring tissues from living donors for transplantation; of these banks, 2 provided information on the number of ineligible donors at acquisition.

As presented in Table 12, for 2015, 3 banks determined 847 living donors (median 62, average 282) to be ineligible for tissue donation at acquisition; and, for 2012, 2 banks determined 16 living donors (average 8) to be ineligible for tissue donation at acquisition.

Table 12 - Number of Living Donors Determined Ineligible for Tissue Donation at Acquisition in 2015 (3 Banks) and 2012 (2 Banks)

Year	Number of Banks that Provided Information	Total Number of Ineligible Living Donors	Average Number of Ineligible Living Donors	Median Number of Ineligible Living Donors
2015	3	847	282	62
2012	2	16	8	N/A

Reasons for Determining Living Donors Ineligible for Tissue Donation at Acquisition in 2015

In 2015, 3 banks provided the reasons for determining 847 living donors to be ineligible at acquisition. As presented in Figure 20, most of these living donors (86.2%) were determined to be ineligible due to chart findings (510 donors, 60.2% of the total) and microbiology of tissue (220 donors, 26.0%). Other reasons for ineligibility were related to blood sample (63 donors 0.07%), delivered prior to scheduled data without the bank’s knowledge (35 donors 0.04%), logistics (16 donors 0.02%), informed consent rescinded (2 donors % is negligible) and vaginal delivery (1 donor % is negligible).

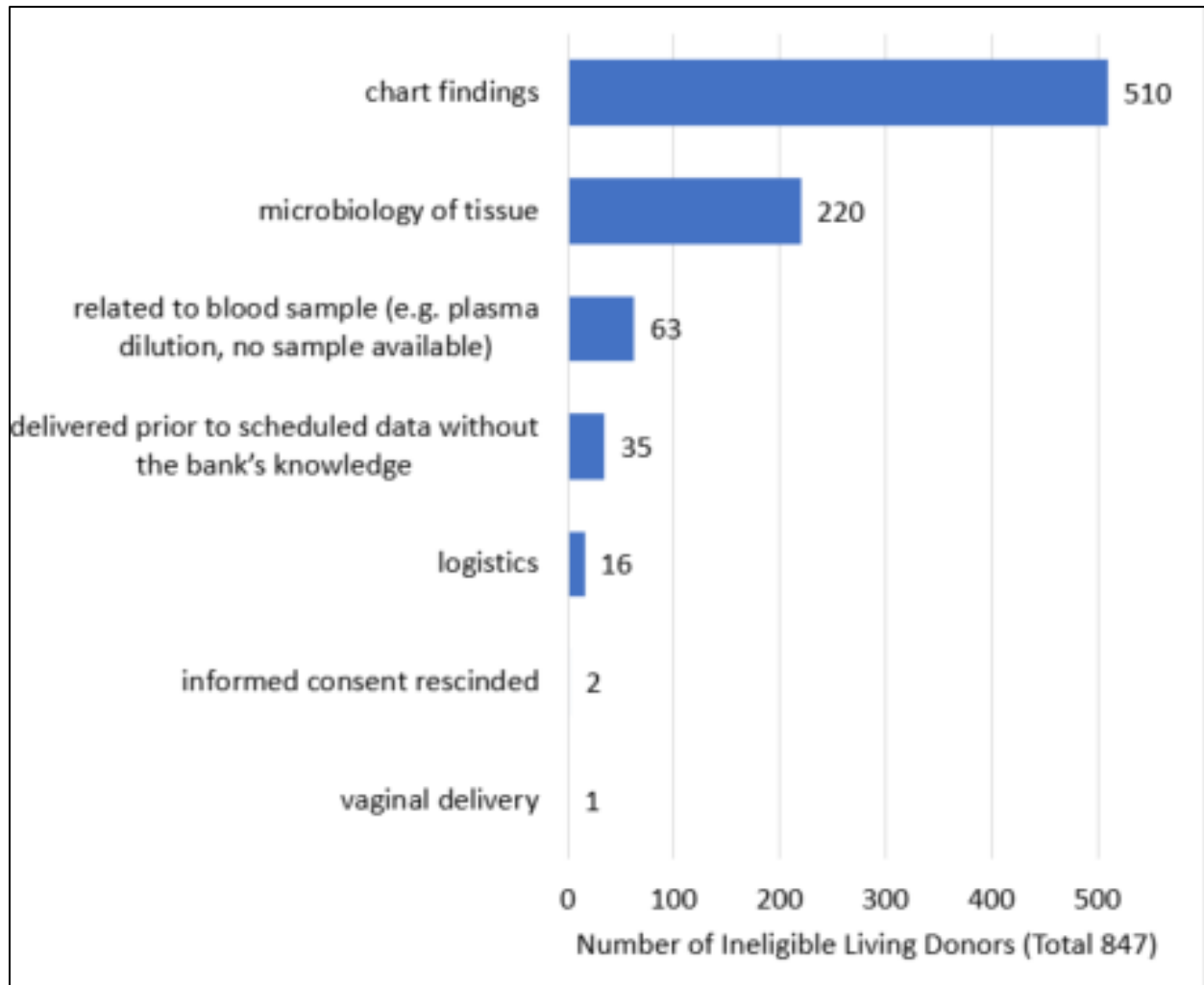


Figure 20 - Reasons for Determining Living Donors Ineligible at Acquisition in 2015 (3 Banks)

Number of Living Donors Determined Ineligible for Tissue Donation After Acquisition - Comparison of 2015 and 2012 Results

In 2015, 13 banks acquired tissues from living donors for transplantation; of these banks, 6 provided information on ineligibility of living donors for tissue donation after acquisition. In 2012, 9 banks acquired tissues from living donors for transplantation; of these banks, 5 provided information on the ineligibility of living donors for tissue donation after acquisition.

As presented in Table 13, for 2015, 6 banks determined 2,017 living donors (median 153, average 336) to be ineligible for tissue donation at acquisition; and, for 2012, 5 banks determined 450 (median 26, average 90) living donors to be ineligible for tissue donation at acquisition.

Table 13 - Number of Living Donors Determined Ineligible for Tissue Donation After Acquisition in 2015 (6 Banks) and 2012 (5 Banks)

Year	Number of Banks that Provided Information	Total Number of Ineligible Living Donors	Average Number of Ineligible Living Donors	Median Number of Ineligible Living Donors
2015	6	2,017	336	153
2012	5	450	90	26

Reasons for Determining Living Donors Ineligible for Tissue Donation After Acquisition in 2015

For 2015, the same 6 banks provided the reasons for determining 1,716 of these living donors to be ineligible after acquisition. As presented in Figure 21, most living donors (94.4%) were determined ineligible after acquisition due to: medical history (565 donors, 32.9% of total), behavioral risk history (385 donors, 22.4% of total), infectious disease testing (371 donors, 21.6% of total), pre-processing culture (300 donors, 17.5% of total), tissue quality (67 donors 0.04% of total), issues with DRAI (12 donors 0.01% of total), incomplete records (5 donors % is negligible), expired processing time (4 donors % is negligible), positive HSV (4 donors % is negligible), no preprocessing culture collected (2 donors % is negligible) and blood specimen timed out (1 donor % is negligible).

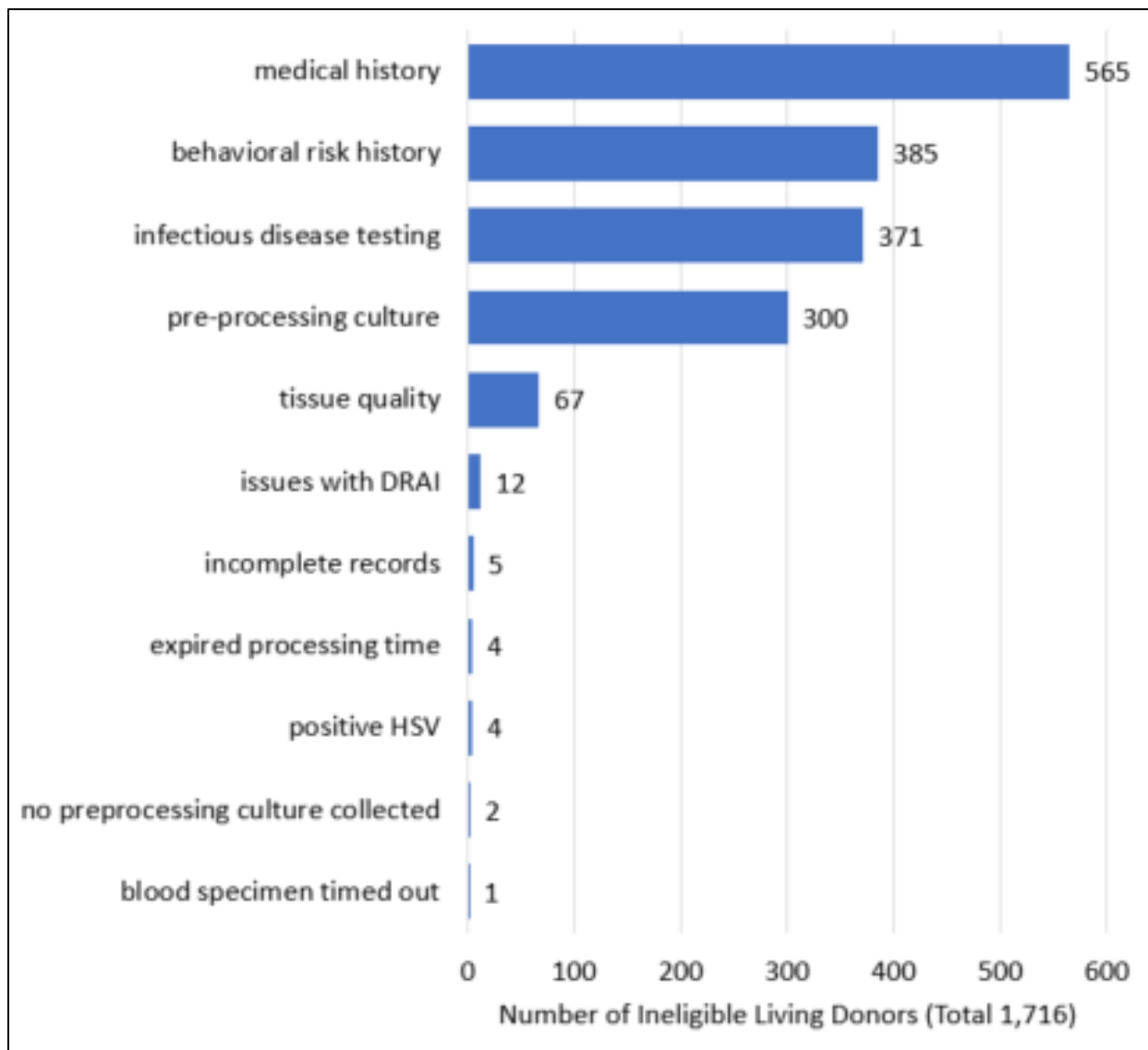


Figure 21 - Reasons for Determining Living Donors Ineligible After Acquisition in 2015 (6 Banks)

Deceased and Living Donors

Tissue Types Forwarded for Processing

Of the 70 banks that responded, 12 reported forwarding tissue for processing into cell therapy products, biologics, or drugs. Eight banks reported forwarding bone and 5 reported forwarding adipose tissue.

Tissue Processing

Information about tissue processing was provided by 44 of 45 (97.8%) banks for 2015 and 40 of 44 (90.9%) banks for 2012.

Deceased Donors

Types of Tissues Processed from Deceased Donors – Comparison of 2015 and 2012 Results

The number of banks that reported processing tissues from deceased donors was 35 for 2015 and 32 for 2012. The ranking of tissue types from deceased donors, based on the number of banks that processed

them is presented in Figure 22. The tissue types that most banks process are musculoskeletal, processed by 82.4% of banks in 2015 and 84.4% of banks in 2012; soft tissue, processed by 58.8% of banks in 2015 and 62.5% of banks in 2012; skin, processed by 52.9% of banks in 2015 and by 43.8% of banks in 2012; cellular tissue, processed by 17.6% of banks in 2015 and 6.3% in 2012; vascular tissue, processed by 11.8% of banks in 2015 and by 6.3% of banks in 2012; cardiac tissue, processed by 8.8% of banks in 2015 and by 9.4% of banks in 2012 and dura matter, processed by 2.9% of banks in 2015 and by 3.1% of banks in 2012.

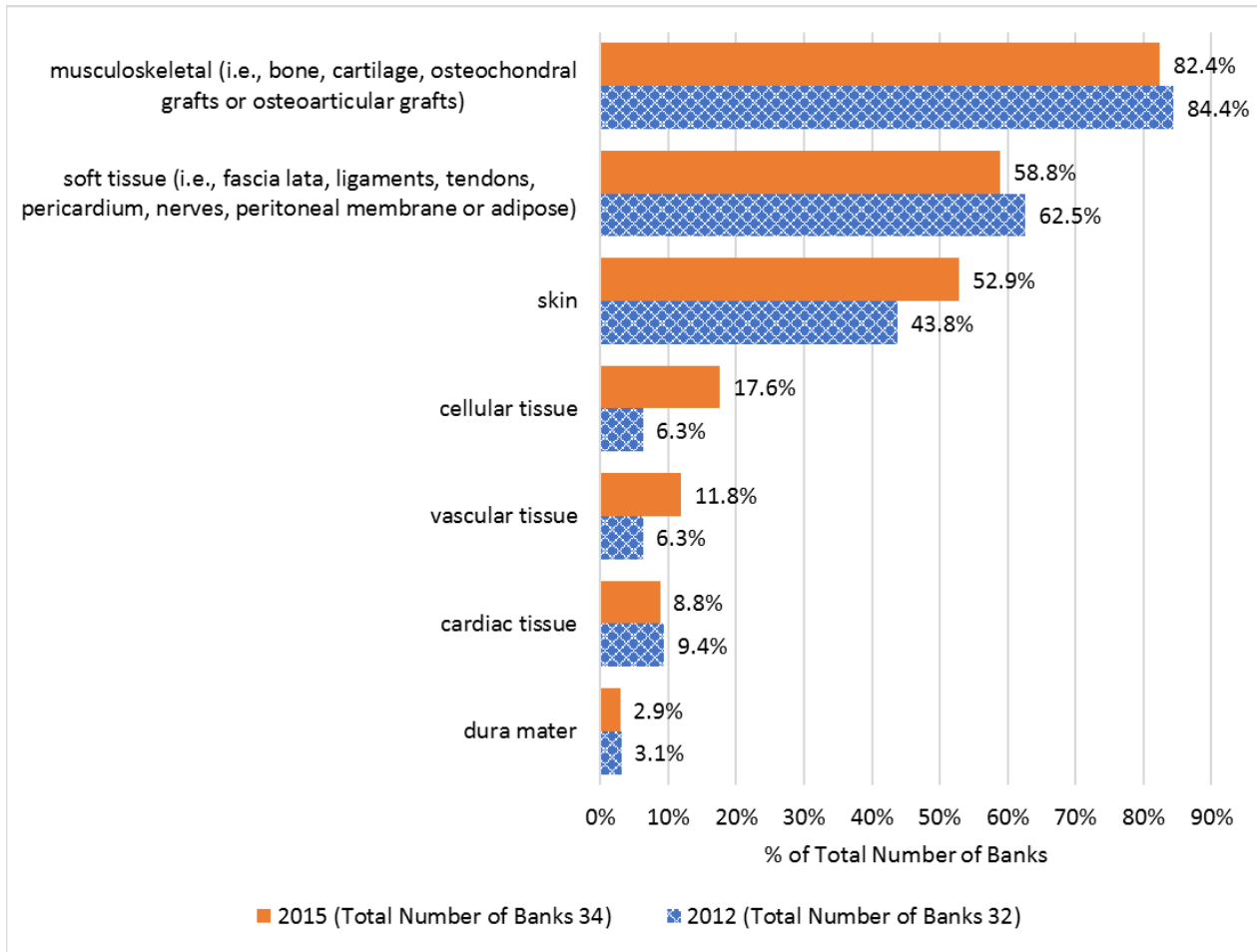


Figure 22 - Percentage of Banks by Types of Tissues Processed from Deceased Donors - Comparison of 2015 (35 Banks) and 2012 (32 Banks)

Number of Grafts Processed from Deceased Donors – Comparison of 2015 and 2012 Results

The number of grafts processed was provided by 31 of 35 (88.6%) banks that reported processing tissue from deceased donors in 2015 and by 29 of 32 (90.6%) banks in 2012.

As presented in Table 14, 31 banks processed 3,447,732 grafts from deceased donors in 2015 (median 42,122, average 111,217), and 29 banks processed 2,858,264 grafts from deceased donors in 2012 (median 40,297, average 98,561).

Although both the average and median values are provided in Table 14, the preferred measure of central tendency is the median due to the positive skew in the data.

Table 14 - Number of Grafts Processed from Deceased Donors - Comparison of 2015 (31 Banks) and 2012 (29 Banks)

Year	Number of Banks that Provided Information	Total Number of Grafts	Average Number of Grafts	Median Number of Grafts
2015	31	3,447,732	111,217	42,122
2012	29	2,858,264	98,561	40,297

Musculoskeletal Tissue Processed from Deceased Donors in 2015

Twenty-two of 28 (78.6%) banks that indicated they processed musculoskeletal tissues also reported the number of deceased donors by type of musculoskeletal tissue processed. The results were as follows: bone tissue, processed by 22 banks from 195,744 donors; cartilage tissue, processed by 8 banks from 1,775 donors; fresh/refrigerated osteochondral grafts, processed by 5 banks from 2,684 donors; frozen/cryopreserved osteoarticular grafts, processed by 5 banks from 801 donors; and frozen/cryopreserved osteochondral grafts, processed by 5 banks from 352 donors. No banks reported processing fresh/refrigerated osteoarticular grafts. Note: a donor may be counted more than once, depending on tissue types processed.

Soft Tissue Processed from Deceased Donors in 2015

Sixteen of 20 (80%) banks that indicated they processed soft tissue also reported the number of deceased donors by type of soft tissue they processed. The results were as follows: tendons, processed by 16 banks from 32,343 donors; ligaments, processed by 14 banks from 15,576 donors; fascia lata, processed by 12 banks from 8,918 donors; pericardium, processed by 8 banks from 2,958 donors; and adipose tissue, processed by 1 bank from 487 donors. No banks reported processing rotator cuffs, nerves, or peritoneal membranes. Note: a donor may be counted more than once, depending on tissue types processed.

Skin Tissue Processed from Deceased Donors in 2015

Nineteen of 20 (95%) banks that indicated they processed skin from deceased donors also reported the number of deceased donors by type of skin tissue processed. The results were as follows: dermal tissue (including acellular/decellularized), processed by 11 banks from 12,073 donors; split thickness skin, processed by 10 banks from 24,559 donors; lyophilized skin, processed by 5 banks from 767 donors; and dehydrated skin, processed by 1 bank from 3,247 donors. No banks reported processing desiccated skin. Note: a donor may be counted more than once, depending on tissue types processed.

Vascular Tissue Processed from Deceased Donors in 2015

The 4 (100%) banks that indicated they processed vascular tissue from deceased donors also reported the number of deceased donors by type of vascular tissue processed. The results were as follows: vein grafts, processed by 4 banks from 5,487 donors and arteries, processed by 3 banks from 1,715 donors. Note: a donor may be counted more than once, depending on tissue types processed.

Cardiac Tissue Processed from Deceased Donors in 2015

The 3 (100%) banks that indicated they processed cardiac tissues from deceased donors also indicated the number of deceased donors by type of cardiac tissue processed. The results were as follows: valved conduits, processed by 3 banks from 4,689 donors; non-valved conduits, processed by 3 banks from 740 donors; patch grafts, processed by 3 banks from 2,796 donors; and aortoiliac grafts, processed by 1 bank

from 700 donors. Note: a donor may be counted more than once, depending on tissue types processed.

Other Types of Tissues Processed from Deceased Donors in 2015

For 2015, 14 banks provided information about the special types of tissue they processed. As presented in Figure 23, the most frequent types of tissues processed in 2015 were: tissue as a device (19,019 deceased donors), cellular tissue (1,520 deceased donors) tissue as a biological product (254 deceased donors) and dura mater (56 deceased donors). No banks reported processing tissues as a drug. Note: A donor could be counted more than once depending on the types of tissue processed.

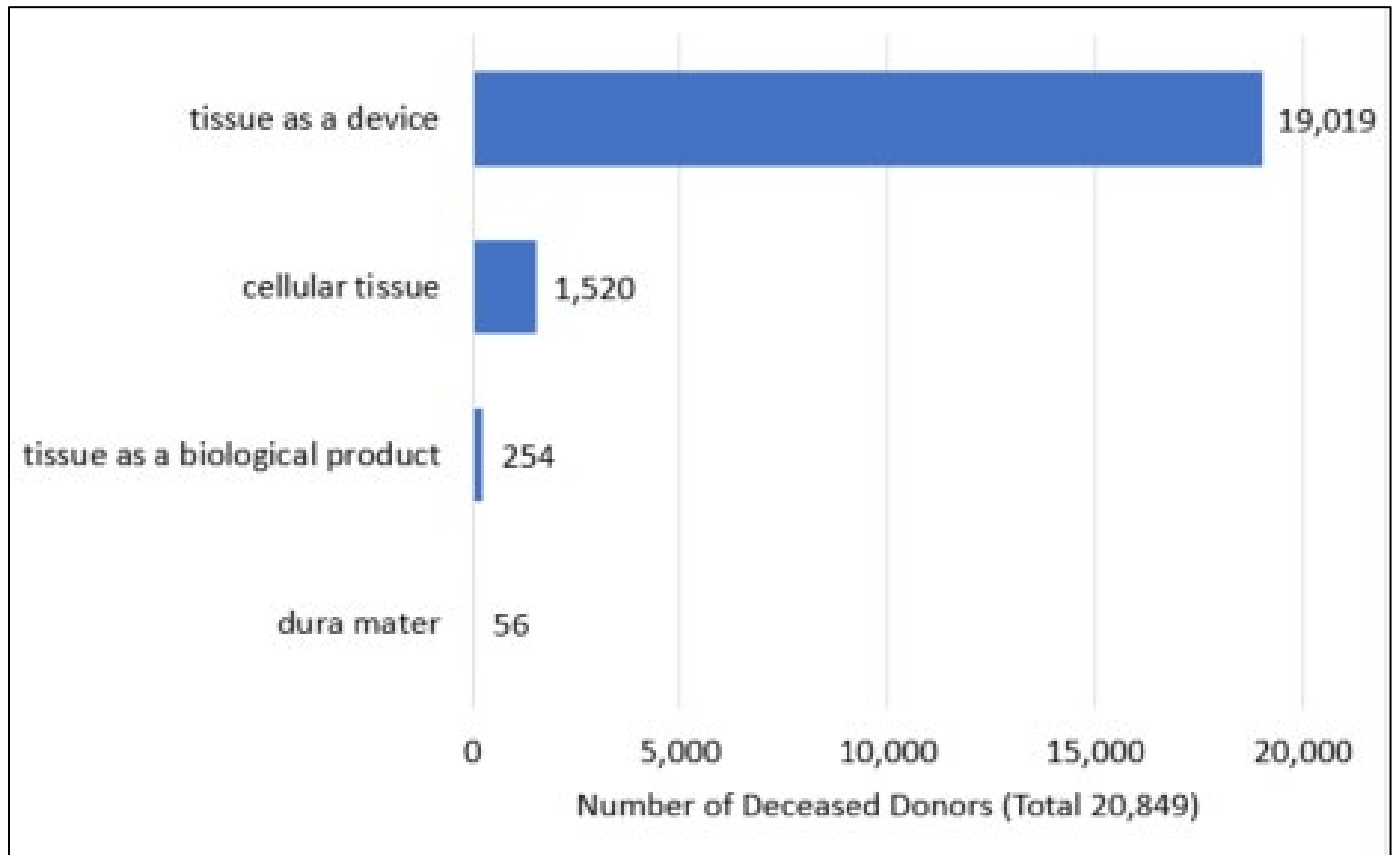


Figure 23 - Types of Tissues Processed from Deceased Donors in 2015 (14 Banks)

Living Donors

Number of Grafts Processed from Living Donors – Comparison of 2015 and 2012 Results

The number of grafts processed from living donors was provided by 16 of 20 (80%) banks in 2015 that reported processing tissue from living donors and by 13 banks in 2012.

As presented in Table 15, 16 banks processed 442,484 grafts from living donors in 2015 (median 8,285, average 27,655); and 13 banks processed 265,185 grafts from living donors in 2012 (median 1,121, average 20,399).

Although both the average and the median values are provided in Table 15, the preferred measure of central tendency is the median due to the positive skew in the data.

Table 15 - Number of Grafts Processed from Living Donors - Comparison of 2015 (16 Banks) and 2012 (13 Banks)

Year	Number of Banks that Provided Information	Total Number of Grafts	Average Number of Grafts	Median Number of Grafts
2015	16	442,484	27,655	8,285
2012	13	265,185	20,399	1,121

Types of Birth Tissues Processed from Living Donors in 2015

For 2015, 15 banks reported processing birth tissue from living donors and provided information about the types of birth tissue they processed.

As presented in Figure 24, the most frequent types of birth tissues processed were: amniotic membrane (18,354 living donors), amniotic + chorionic membrane (11,417 living donors), amniotic fluid (3,656 living donors), umbilical cord tissue (3,097 living donors), chorionic membrane (1,390 living donors) and amniotic membrane with umbilical cord tissue (133 living donors). Note: A donor could be counted more than once depending on the types of tissue processed.

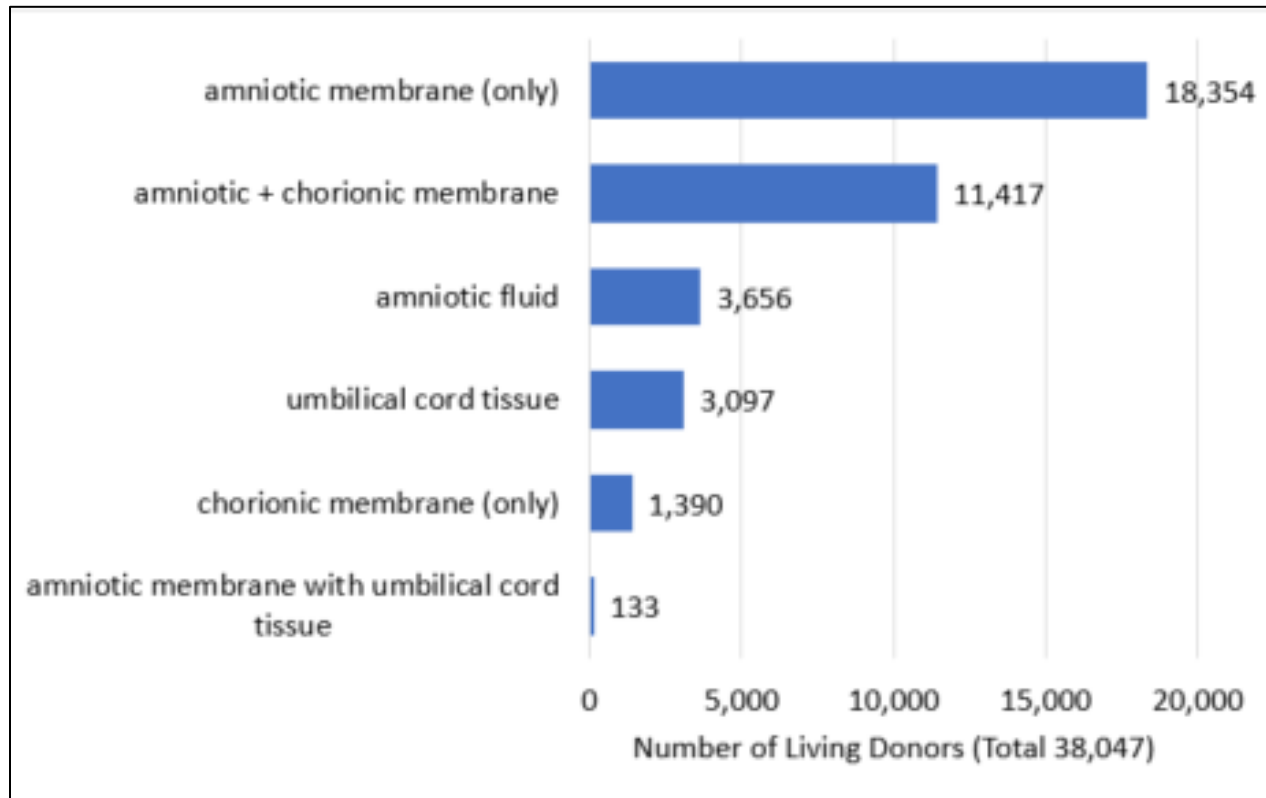


Figure 24 - Types of Birth Tissues Processed from Living Donors in 2015 (15 Banks)

Other Tissues Processed from Living Donors in 2015

Six banks indicated that they processed other types of tissues from living donors, and reported the number of donors by type of tissue processed. The results were as follows: autologous parathyroid, processed by 3 banks from 108 donors; tissue as a device, processed by 2 banks from 131,781 donors; autologous bone, processed by 2 banks from 94 donors; surgical bone, processed by 1 bank from 900 donors; and skin for allogeneic use, processed by 1 bank from 50 donors. No banks reported processing

tissues as a biological product or tissues as a drug. Note: A donor could be counted more than once depending on the types of tissue processed.

Deceased and Living Donors

Radiation Treatments Prior to Processing (Non-Terminal Irradiation)

For 2015, 41 banks (91.1% of the banks that reported processing human tissues) provided information about pre-processing radiation treatments. Of the 41, banks, 38 indicated they did not treat tissues with radiation prior to processing; 1 bank used gamma radiation only below 1.5 Mrads (<15kGy); 1 bank used gamma radiation only between 1.5 and 2.5 Mrads (15-25 kGy); and 1 bank used gamma radiation only above 2.5 Mrads (>25 kGy). No banks reported using electronic beam radiation only.

Final Radiation Treatments for Tissues (Terminal Irradiation)

For 2015, 44 banks (97.8% of the banks that reported processing human tissues) provided information about final radiation treatments. Of the 44 banks, 10 indicated they did not treat tissues with radiation as a final treatment and 34 indicated the final radiation treatment used (Figure 25). Sixteen banks used gamma radiation only between 1.5 and 2.5 Mrads (15-25 kGy), 13 banks used gamma radiation only above 2.5 Mrads (>25 kGy); 13 banks used electron beam radiation only; and 6 banks used gamma radiation only below 1.5 Mrads (15 kGy).

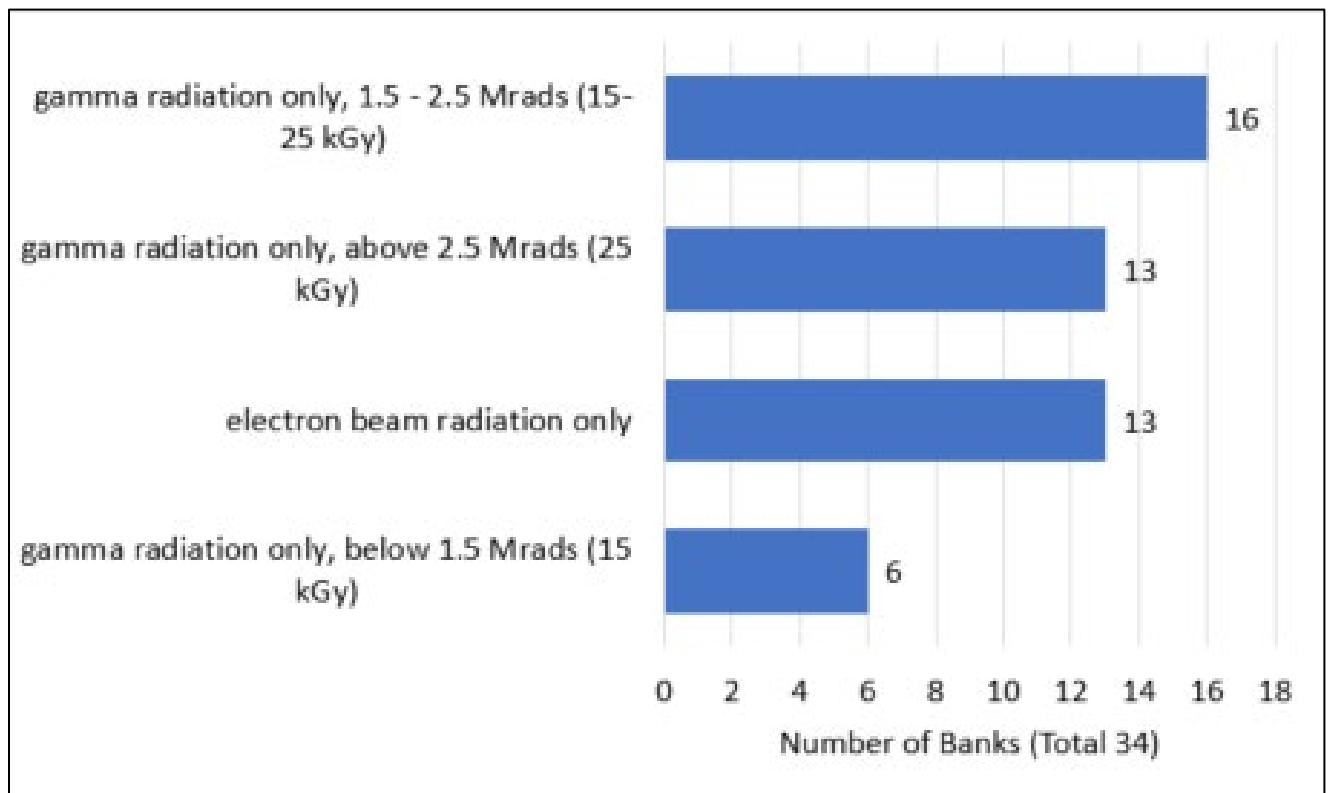


Figure 25 - Final Radiation Treatments Applied to Human Tissues in 2015 (34 Banks)

Deceased Donors

Methods of Processing Musculoskeletal Grafts from Deceased Donors (Terminal Sterilization)

For 2015, 25 of 28 (89.3%) banks that reported processing musculoskeletal grafts from deceased donors provided information about the methods they used to process a total of 3,981,112 musculoskeletal

grafts from deceased donors. Ten of these banks indicated that they did not use terminal sterilization methods for a total of 680,028 musculoskeletal grafts. As presented in Figure 26, in 2015, 20 banks applied terminal sterilization methods to a total of 1,319,457 musculoskeletal grafts processed from deceased donors. The most grafts processed by treatment methods were: gamma radiation only (642,362 grafts), Allowash® only (384,846 grafts), electron beam radiation only (169,397 grafts), ATP® only (122,657 grafts) and ethylene oxide only (195 grafts).

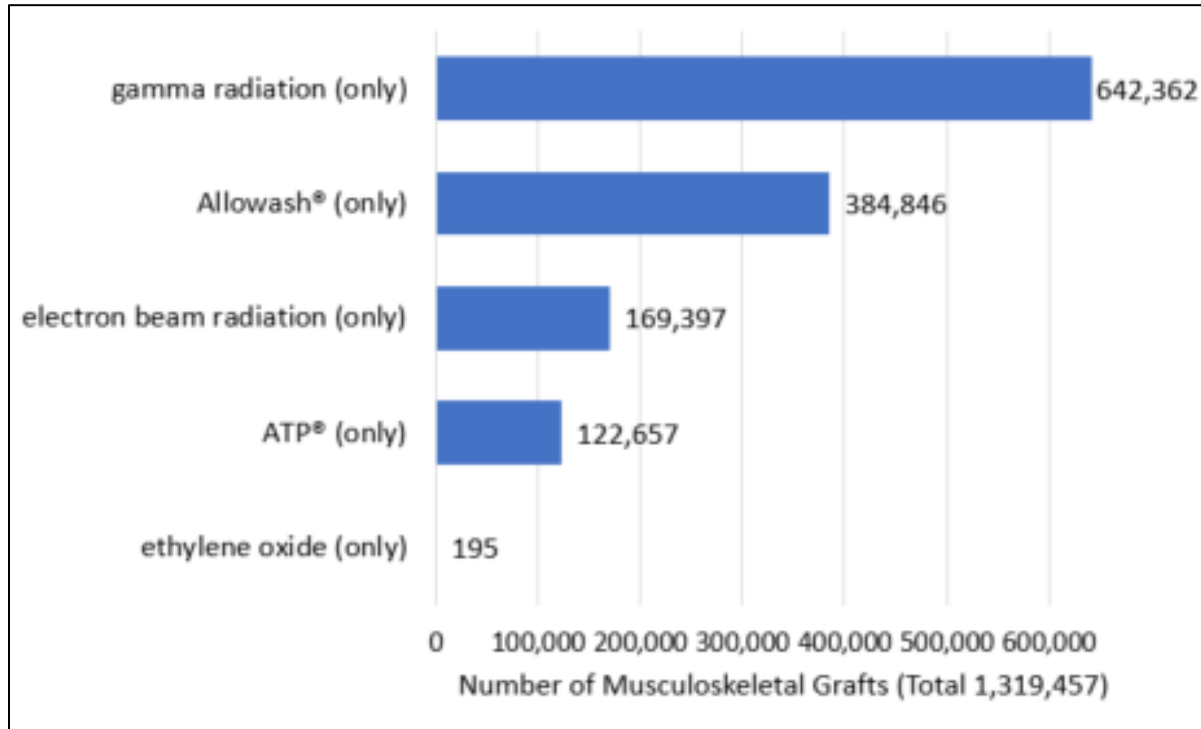


Figure 26 - Terminal Methods of Processing Musculoskeletal Grafts from Deceased Donors in 2015 (20 Banks)

Additionally, banks were given the possibility to indicate other methods that were used for processing musculoskeletal grafts from deceased donors along with the number of grafts that were processed. Four banks used 4 different proprietary methods to process 340,816 musculoskeletal grafts. Four banks used 5 different methods that combined antibiotics and radiation (listed in mrad - milliradian) to process 162,237 musculoskeletal grafts. Eight banks used 9 different methods that combined proprietary/patented methods followed by radiation to process 1,478,574 musculoskeletal grafts.

Methods of Processing Soft Tissue Grafts from Deceased Donors (Terminal Sterilization)

For 2015, 16 of 20 (80%) banks that reported processing soft tissue grafts from deceased donors provided information about the methods they used to process a total of 460,081 soft tissue grafts from deceased donors. Four of these banks indicated that they did not use terminal sterilization methods for a total of 15,759 soft tissue grafts. As presented in Figure 27, in 2015, 12 banks applied terminal sterilization methods to a total of 131,295 soft tissue grafts from deceased donors. The most grafts processed by treatment methods were: gamma radiation only (60,206 grafts), Allowash® only (43,147 grafts), BioCleanse® Process only (26,227 grafts) and electron beam radiation only (1,715).

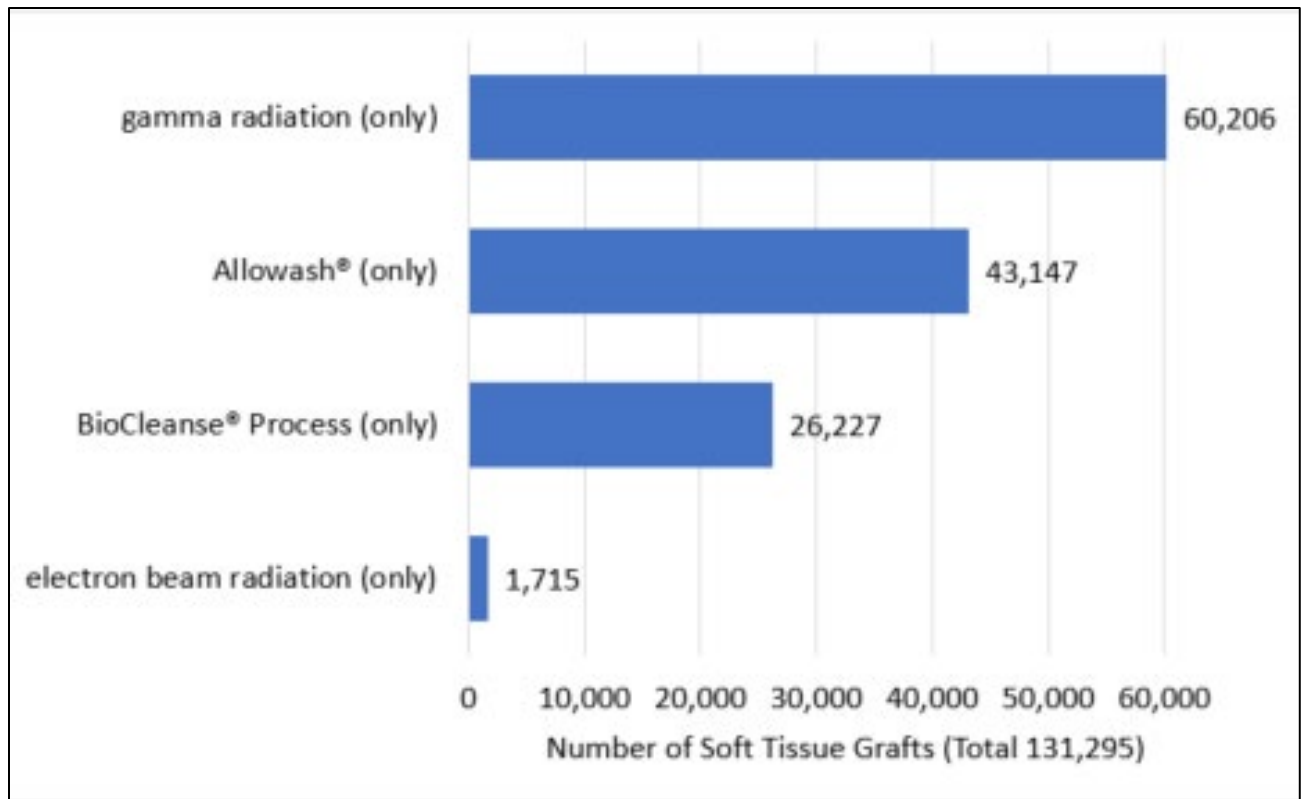


Figure 27 - Methods of Processing Soft Tissue Grafts from Deceased Donors in 2015 (12 Banks)

Additionally, banks were given the possibility to indicate other methods that were used for processing soft tissue grafts from deceased donors along with the number of grafts that were processed. Three banks used 3 different proprietary methods to process 37,851 soft tissue grafts. Two banks used 2 different methods that combined antibiotics and radiation (listed in mrad - milliradian) to process 1,898 soft tissue grafts. Seven banks used 4 different methods that combined proprietary/patented methods followed by radiation to process 103,256 soft tissue grafts.

Methods of Preservation for Cardiac Tissue Grafts from Deceased Donors

For 2015, 3 banks (100% of the banks that reported processing cardiac tissue grafts from deceased donors) provided information about the methods of preservation.

As presented in Table 16, in 2015, the 3 banks preserved a total of 8,798 cardiac grafts. The most used method was controlled-rate electronic programmable freezing, which was used to preserve 97.9% of the cardiac grafts.

Table 16 - Methods of Preservation of Cardiac Tissue Grafts from Deceased Donors in 2015 (Banks 3)

Methods of Preservation	Number of Banks	Number of Cardiac Tissue Grafts from Deceased Donors
Controlled-rate electronic programmable freezing	3	8,798
Proprietary method	1	188
Grand Total	3	8,986

Finished Cardiac Tissue Grafts – Comparison of 2015 and 2012 Results

Three banks reported processing cardiac grafts into finished tissue in 2015, and 4 banks in 2012.

As presented in Table 17, 7,223 finished cardiac tissue grafts were processed in 2015; 2,235 (30.9%) cardiac grafts were of the acellular/decellularized type and 4,988 (69.1%) cardiac grafts were not acellular/decellularized.

Note that the number of finished acellular/decellularized cardiac grafts in 2012 is heavily skewed by one bank that produced 30,000 of this type of cardiac grafts. This bank did not process cardiac tissue grafts in 2015.

Table 17 - Types of Finished Cardiac Tissue Grafts from Deceased Donors – Comparison of 2015 (3 Banks) and 2012 (4 Banks)

Year	Number of Banks that Provided Information	Number of Finished Acellular / Decellularized Cardiac Grafts	Number of Finished NOT Acellular / Decellularized Cardiac Grafts	Total Finished Cardiac Tissue Grafts
2015	3	2,235	4,988	7,223
2012	4	31,713	4,836	36,549

Methods of Preservation for Vascular Tissue Grafts from Deceased Donors

For 2015, 4 banks (100% of the banks that reported processing vascular tissue grafts from deceased donors) provided information about the methods of preservation. Controlled-rate electronic programmable freezing was used to preserve a total of 8,450 vascular tissue grafts.

Finished Vascular Tissue Grafts – Comparison of 2015 and 2012 Results

Information about the types of finished vascular tissue grafts was provided by 3 banks in 2015 (75% of the banks that processed vascular tissue grafts from deceased donors), and by 3 banks in 2012.

As presented in Table 18, the banks reported only finished vascular tissue grafts that were not acellular/decellularized (5,630 in 2015, and 4,899 in 2012).

Table 18 - Finished Vascular Tissue Grafts from Deceased Donors - Comparison of 2015 (3 Banks) and 2012 (3 Banks)

Year	Number of Banks that Provided Information	Number of Finished NOT Acellular / Decellularized Cardiac Grafts
2015	3	5,630
2012	3	4,899

Methods of Processing Skin Grafts from Deceased Donors (Terminal Sterilization)

For 2015, 17 of 20 (85%) banks that reported processing skin grafts from deceased donors provided information about the methods they used for processing 523,942 skin grafts from deceased donors. Eight of these banks indicated that they did not use terminal sterilization methods to process 195,592 skin grafts.

As presented in Figure 28, in 2015, 6 banks used terminal sterilization methods to process 63,071 skin grafts. The two processing methods reported were electron beam radiation only (56,440 skin grafts) and gamma radiation only (6,631 skin grafts).

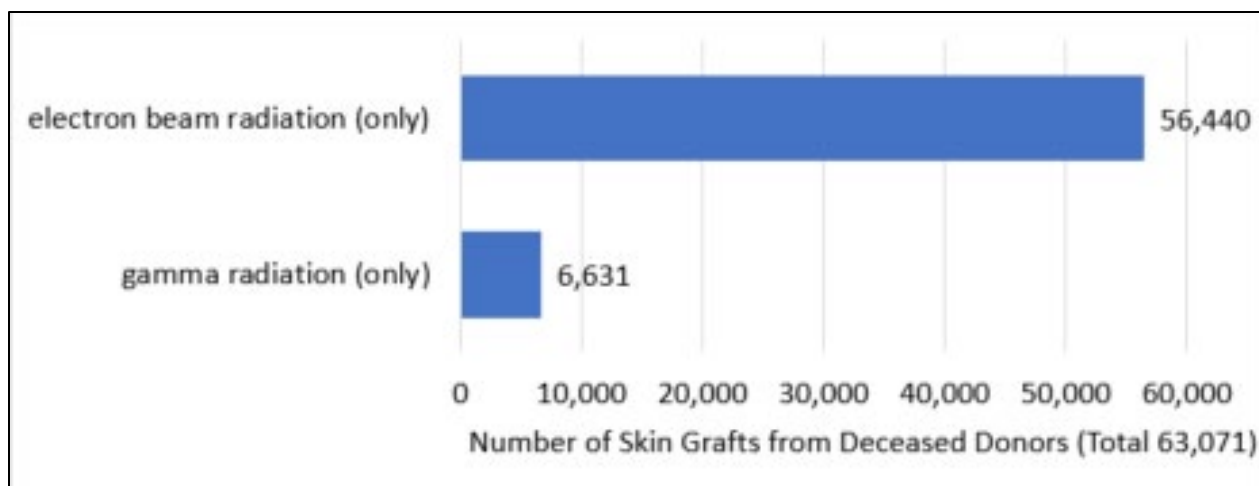


Figure 28 - Methods for Processing Skin Grafts from Deceased Donors in 2015 (6 Banks)

Additionally, banks were given the possibility to indicate other methods that were used for processing skin grafts from deceased donors along with the number of grafts that were processed. Five banks used 5 different proprietary methods to process 177,370 skin grafts. Two banks used 2 different methods that combined antibiotics and radiation (listed in mrad - milliradian) to process 4,197 skin grafts. Five banks used 5 different methods that combined proprietary/patented methods followed by radiation to process 83,712 skin grafts.

Living Donors

Methods of Processing Birth Tissue from Living Donors (Terminal Sterilization)

In 2015, 15 of 20 (75%) banks that reported processing tissue from living donors provided information about the methods they used to process 1,004,366 birth tissue grafts. Five banks indicated they did not use terminal sterilization methods to process 76,306 birth tissue grafts. As presented in Figure 29, in 2015, 10 banks used terminal sterilization methods to process 584,647 birth tissue grafts. The most grafts processed by treatment method were: Purion® Process only (241,722 grafts), electron beam radiation only (198,927 grafts), gamma radiation only (84,564 grafts), Cryotek™ Process only (55,048 grafts) and filtration only (4,386 grafts).

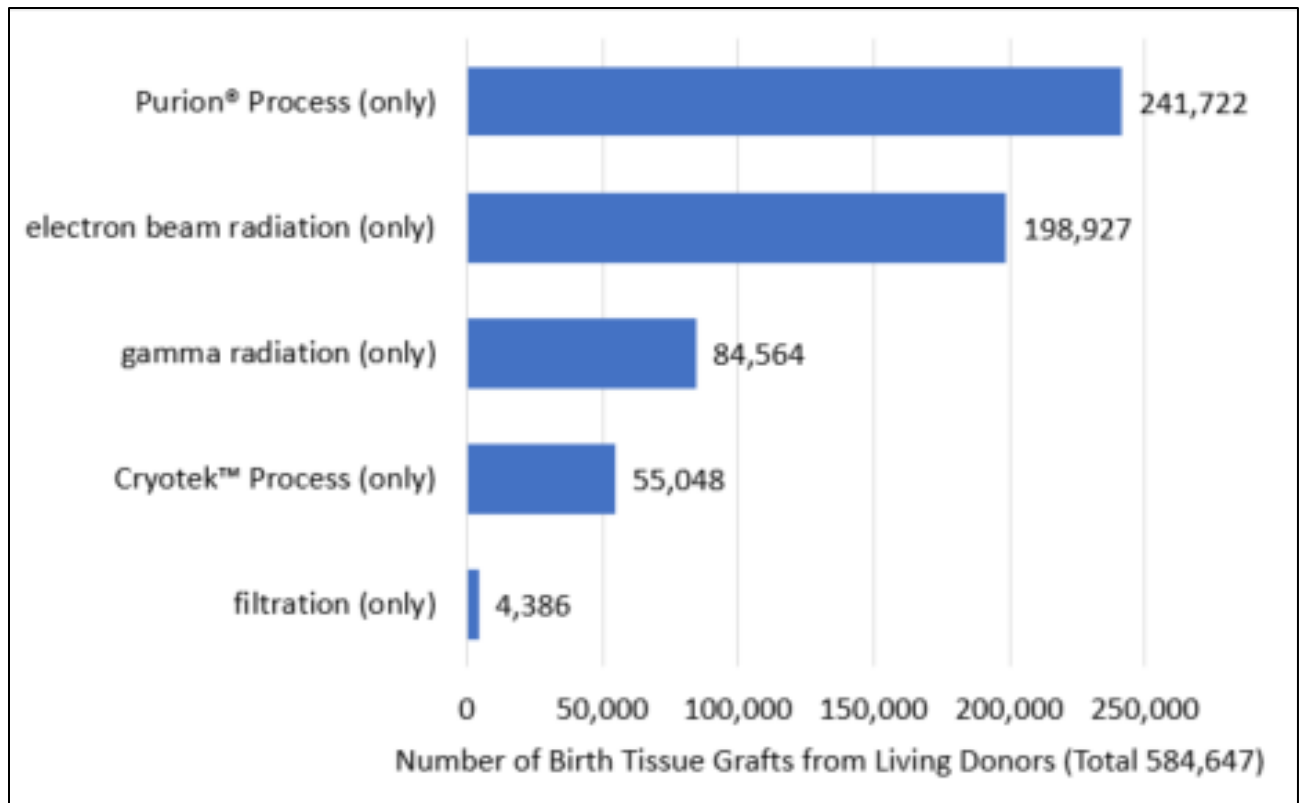


Figure 29 - Methods for Processing Birth Tissue Grafts from Living Donors in 2015 (10 Banks)

Additionally, banks were given the possibility to indicate other methods that were used for processing birth tissue from living donors along with the number of grafts that were processed. Five banks used 4 different proprietary methods to process 79,987 birth tissue grafts. Three banks used 3 different methods that combined antibiotics and radiation (listed in mrad - milliradian) to process 244,065 birth tissue grafts. Two banks used 2 different methods that combined proprietary/patented methods followed by radiation to process 19,361 birth tissue grafts.

Applications for Demineralized Bone from Living Donors

In 2015, 18 banks (90% of the banks that processed tissues from living donors) provided information about the type applications for which they processed demineralized bone. Ten banks (50% of the banks that processed tissue from living donors) indicated that they did not process demineralized bone.

As presented in Figure 30, 8 banks (40% of banks that processed tissues from living donors) processed demineralized bone. The most often mentioned applications were: orthopedic surgery, dental/periodontal procedures (7 banks each), neurosurgery (1 bank) and application unknown (1 bank).

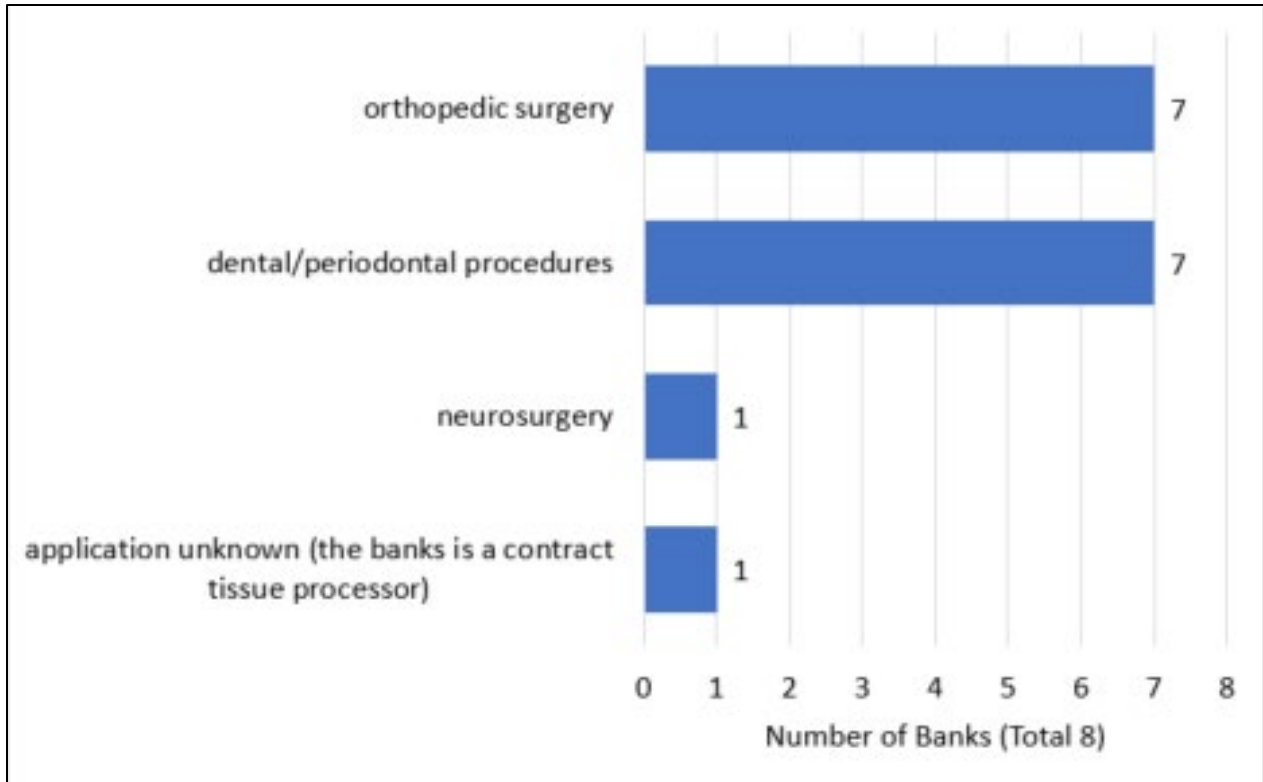


Figure 30 - Applications for Demineralized Bone from Living Donors in 2015 (8 Banks)

Skin for Use as Fresh Grafts from Living Donors

In 2015, 19 banks (95% of the banks that processed tissues from living donors) provided information about the skin they processed for use as fresh grafts. While 9 banks (45%) indicated they processed skin from living donors, only 1 bank (5%) processed skin for use as fresh grafts.

Methods of Preservation for Skin Grafts from Living Donors

In 2015, 8 banks (88.9% of the banks that processed skin from living donors) provided information about the methods of preservation for a total of 31,682 sq. ft. of skin grafts.

As presents in Figure 31, the most important methods of preservation for skin grafts from living donors were: heat sink freezing (16,602 sq. ft. skin), controlled-rate electronic programmable freezing (12,468 sq. ft. skin), ethanol soak (2,448 sq. ft. skin), refrigeration only (94 sq. ft. skin) lyophilization (35 sq. ft. skin) proprietary (33 sq. ft. skin) and ambient (2 sq. ft. skin).

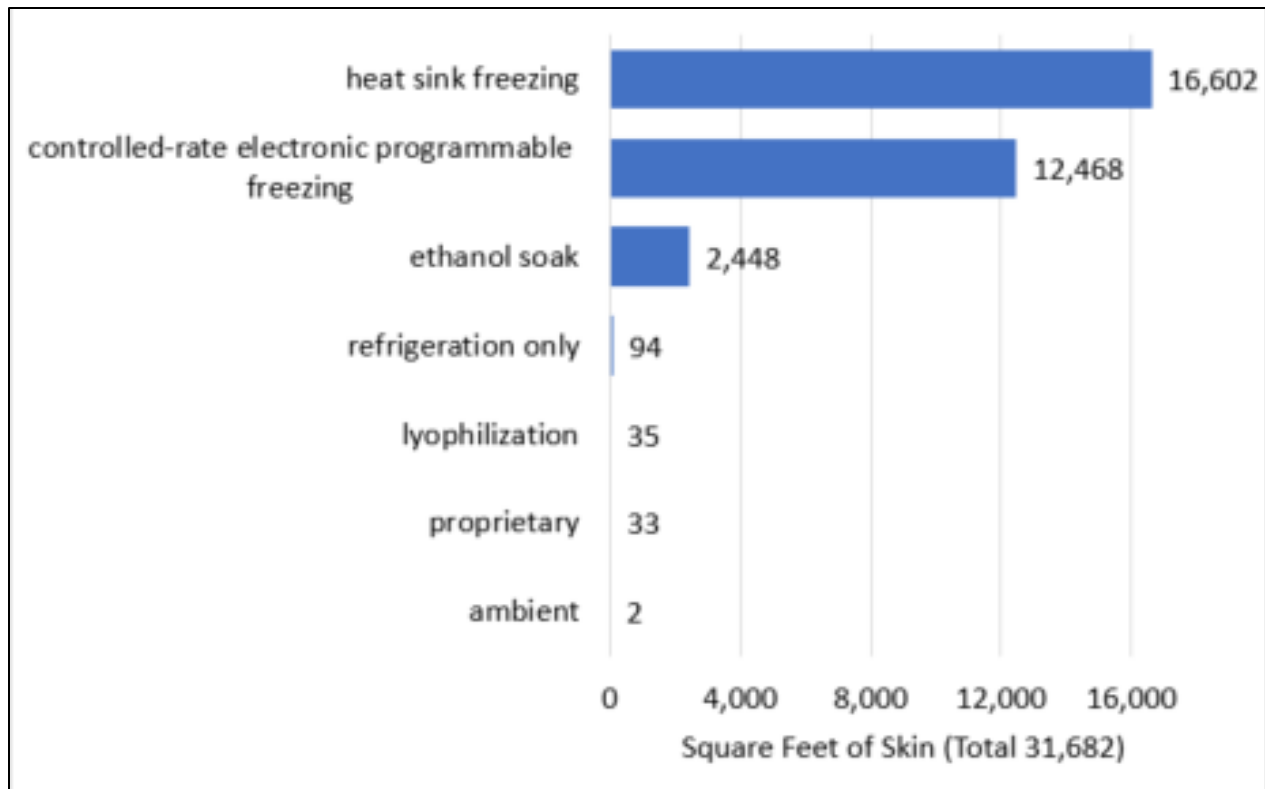


Figure 31 - Methods of Preservation for Skin Grafts from Living Donors in 2015 (8 Banks)

Finished Skin Tissue Grafts – Comparison of 2015 and 2012 Results

Information about the types of finished skin tissue grafts was provided by 6 banks in 2015 (66.7% of the banks that processed skin tissue grafts from living donors), and by 10 banks in 2012.

As presented in Table 19, 21,313 finished skin tissue grafts were processed in 2015; 4,426 (20.8%) skin grafts were of the acellular/decellularized type, and 16,887 (79.2%) skin grafts were not acellular/decellularized. In 2012 25,905 finished skin tissue grafts were processed, 12,126 (46.8%) skin grafts were of the acellular/decellularized, and 13,779 (53.2%) skin grafts were not acellular/decellularized.

Table 19 - Types of Finished Skin Tissue Grafts from Living Donors – Comparison of 2015 (6 Banks) and 2012 (10 Banks)

Year	Number of Banks that Provided Information	Number of Finished Acellular / Decellularized Skin Grafts	Number of Finished NOT Acellular / Decellularized Skin Grafts	Total Finished Skin Tissue Grafts
2015	6	4,426	16,887	21,313
2012	10	12,126	13,779	25,905

Methods of Preservation for Finished Birth Tissue Grafts from Living Donors

In 2015, 14 banks (93.3% of the banks that processed birth tissue from living donors) provided information about the methods used to preserve a total of 437,664 units of finished birth tissue.

As presented in Figure 32, most of the units of finished birth tissue (92%) were preserved with the following methods: dehydration (247,261 units of birth tissue), simple freezing (67,698 units of birth

tissue), controlled-rate electronic programmable freezing (60,851 units of birth tissue), desiccation (13,475 units of birth tissue), lyophilization (8,196 units of birth tissue), stabilization (5,886 units of birth tissue), refrigeration only (i.e. provided for use as fresh) (5,279 units of birth tissue), ambient (1,950 units of birth tissue) and wet-NaCl ambient temperature (68 units of birth tissue).

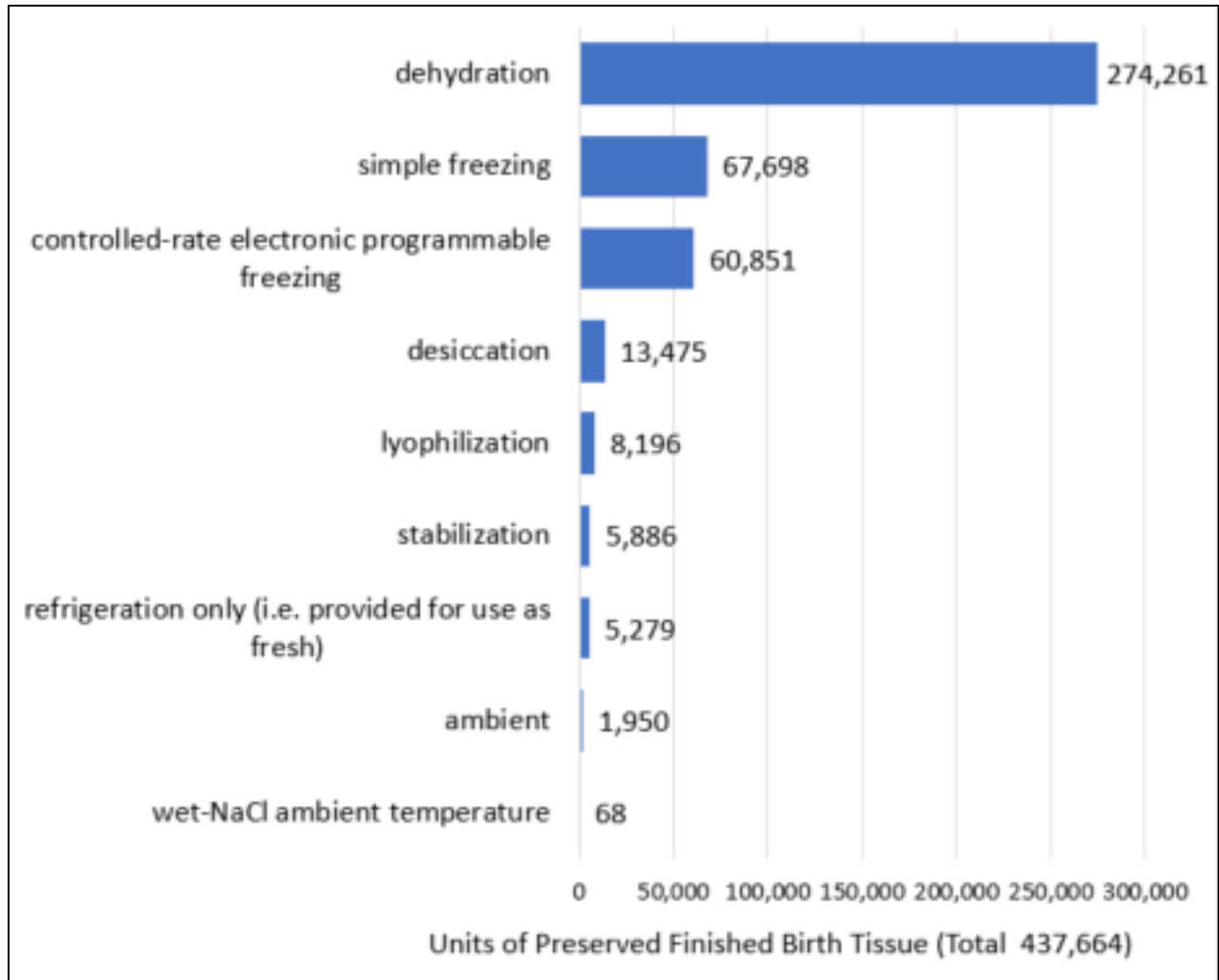


Figure 32 - Methods of Preservation for Finished Birth Tissue from Living Donors in 2015 (14 Banks)

Finished Birth Tissue Units – Comparison of 2015 and 2012 Results

Information about the types of finished birth tissue units was provided by 11 banks in 2015 (73.3% of the banks that processed birth tissue grafts from living donors), and by 6 banks in 2012.

As presented in Table 20, 425,369 finished birth tissue units were processed in 2015; 30,545 (7.2%) birth tissue units were of the acellular/decellularized type, and 394,824 (92.8%) birth tissue units were not acellular/decellularized. In 2012, 1,869 (1.4%) birth tissue units were of the acellular/decellularized type, and 132,139 (98.6%) birth tissue units were not acellular/decellularized.

Table 20 - Types of Finished Birth Tissue Grafts from Living Donors – Comparison of 2015 (11 Banks) and 2012 (6 Banks)

Year	Number of Banks that Provided Information	Number of Finished Acellular / Decellularized Birth Tissue Units	Number of Finished NOT Acellular / Decellularized Birth Tissue Units	Total Finished Birth Tissue Units
2015	11	30,545	394,824	425,369
2012	6	1,869	132,139	134,008

Applications for Birth Tissue Grafts

In 2015, 14 banks (93.3% of the banks that processed birth tissue from living donors) provided information about the types of applications for which they processed birth tissue.

As presented in Figure 33, the most often mentioned applications for birth tissue are as follows: leg/foot ulcers (12 banks), orthopedic (9 banks), burns and neurosurgical and spine (7 banks each), general surgical (6 banks), ophthalmic (4 banks), dental/periodontal (2 banks), tendonitis, joint pain, scalp injections, plantar fasciitis (1 bank), wound cover (1 bank) and application unknown (1 bank).

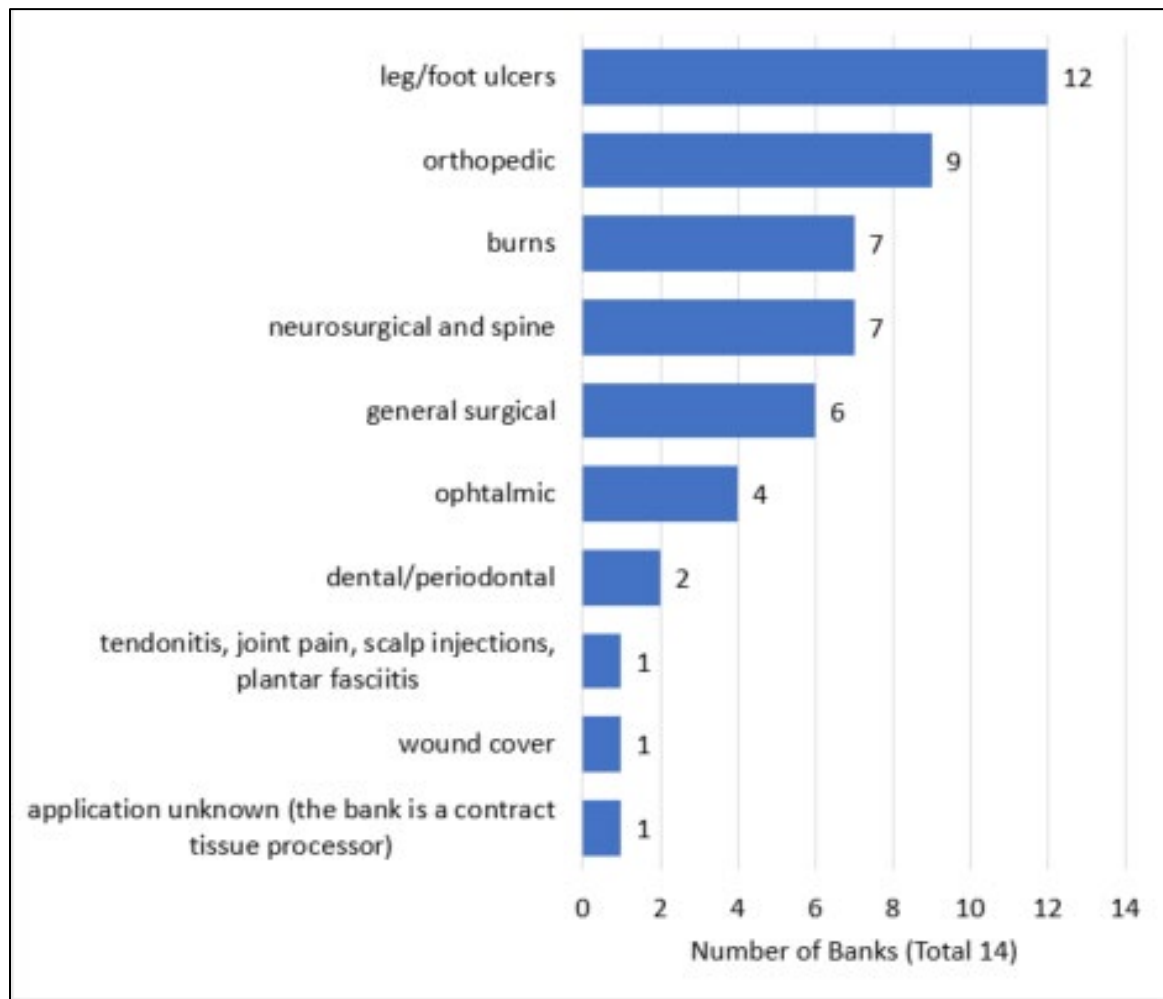


Figure 33 - Applications for Birth Tissue Grafts in 2015 (14 Banks)

Human Tissue Sent for Further Manufacturing

In 2015, 46 banks (100%) provided information about sending human tissue to another bank for further manufacturing. Only 8 banks (17.4%) sent tissues to another bank for further manufacturing.

Tissue Storage

The number of banks that responded to the survey on tissue storage was 77 in 2015 and 67 in 2012.

Types of Stored Unprocessed Tissues from Deceased Donors

For 2015, 40 banks (51.9% of the banks that stored human tissues) stored unprocessed tissues from deceased donors.

As presented in Figure 34, the most often mentioned tissue types from deceased donors that were stored unprocessed are as follows: musculoskeletal tissue and skin (29 or 72.5% of banks, each), soft tissue (24 or 60% of banks), vascular tissue (5 or 1.3% of banks), cardiac tissue (4 or 0.1% of banks), cellular tissue (4 or 0.1% of banks), dura mater (1 or 0.03% of banks) and sample for research (1 or 0.03% of banks).

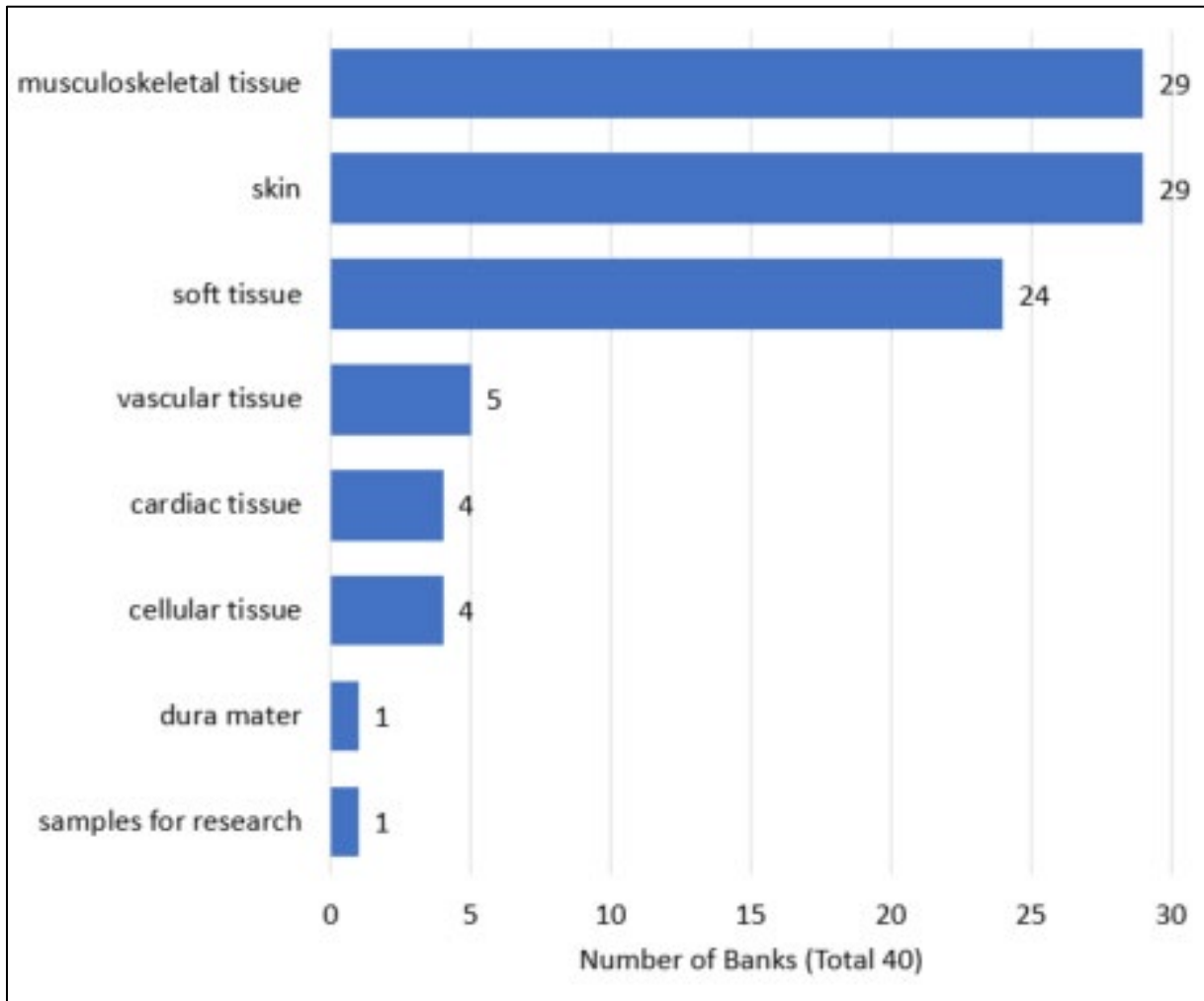


Figure 34 - Types of Stored Unprocessed Tissue from Deceased Donors in 2015 (40 Banks)

Types of Stored Unprocessed Tissues from Living Donors

In 2015, 24 banks (31.2% of the banks that stored human tissues) reported storing unprocessed tissues from living donors.

As presented in Figure 35, the most often mentioned tissue types from living donors that were stored unprocessed are as follows: placenta (16 or 66.7% of banks), amniotic fluid (8 or 33.3% of banks), autologous bone (6 or 25% of banks), umbilical cord tissue and autologous parathyroid (5 or 20.8% of banks, each), skin for allogeneic use (2 or 0.08% of banks), amnion for allogeneic use (2 or 0.08% of banks), Wharton’s jelly (1 or 0.04% of banks), chorion for allogeneic use (1 or 0.04% of banks) and autologous cranial flaps (1 or 0.04% of banks).

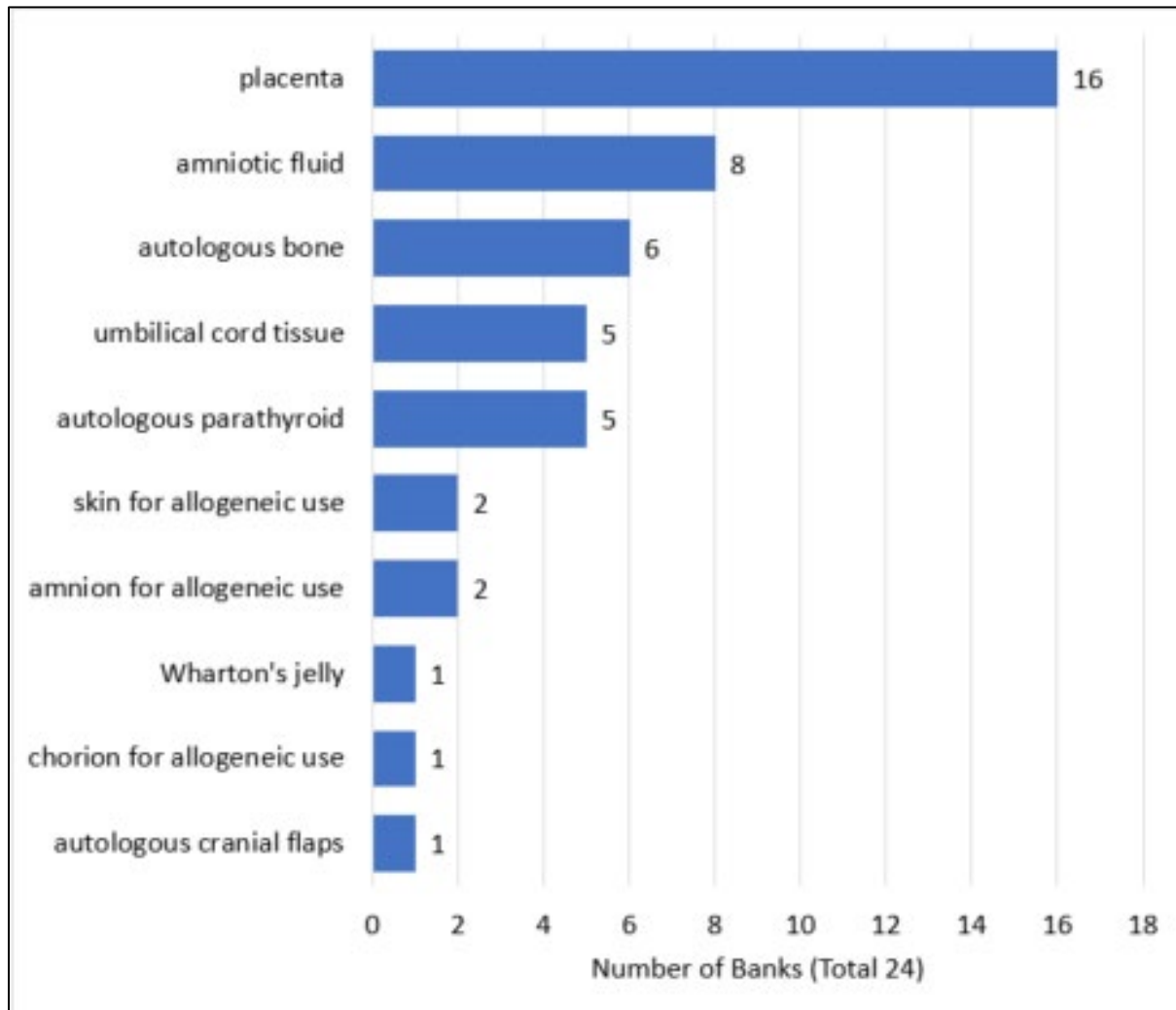


Figure 35 - Types of Stored Unprocessed Tissues from Living Donors in 2015 (24 Banks)

Stored Processed Tissue from Deceased Donors - HCT/Ps Regulated Solely under Section 361 of the PHSA

The number of banks that provided information about storage of processed tissues from deceased donors was 76 in 2015 (98.7% of the banks that stored human tissues) and 67 in 2012 (100% of the banks that stored human tissues).

The number of banks that reported storing processed tissues from deceased donors was 52 for 2015

(67.5 of the banks that stored human tissues), and 47 for 2012 (70.1% of the banks that stored human tissues).

Types of Stored Processed Musculoskeletal Tissue from Deceased Donors – Comparison of 2015 and 2012 Results

The number of banks that reported storing processed musculoskeletal tissue from deceased donors was 46 for 2015 (88.5% of the banks that stored processed tissues from deceased donors) and 41 for 2012 (87.2% of the banks that stored processed tissues from deceased donors).

A comparison of the ranking of processed musculoskeletal tissue types according to the percentage of banks that stored them in 2015 and 2012 is presented in Figure 36. The results are as follows: bone (100% banks in both years), cartilage (45.7% of banks in 2015, and 43.9% of banks in 2012), osteochondral grafts (30.4% of banks in 2015, and 31.7% of banks in 2012), meniscus (28.3% of banks in 2015, and 31.7% of banks in 2012), and osteoarticular grafts (17.4% of banks in 2015, and 17.1% of banks in 2012).

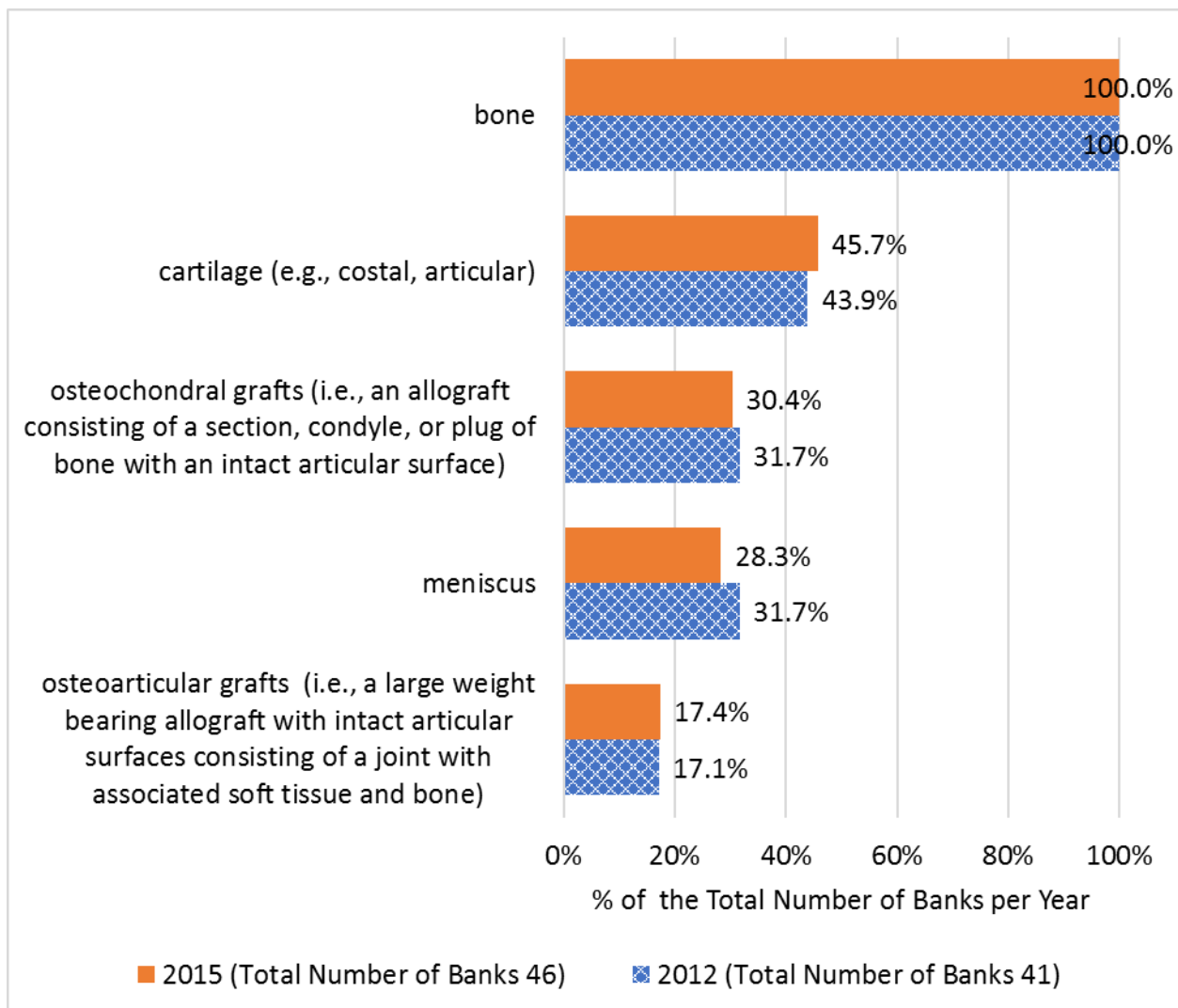


Figure 36 - Types of Stored Processed Musculoskeletal Tissues from Deceased Donors in 2015 (46 Banks) and 2012 (41 Banks)

Types of Stored Processed Soft Tissue from Deceased Donors – Comparison of 2015 and 2012 Results

The number of banks that reported storing processed soft tissue from deceased donors was 33 for 2015 (63.5% of the banks that stored processed tissues from deceased donors) and 32 for 2012 (68.1% of the banks that stored processed tissues from deceased donors).

A comparison of the ranking of processed soft tissue types according to the percentage of banks that stored them in 2015 and 2012 is presented in Figure 37. The results are as follows: tendons (93.9% of banks in 2015, and 93.8% of banks in 2012), ligaments (75.8% of banks in 2015, and 71.9% of banks in 2012), fascia lata (72.7% of banks in 2015, and 68.8% of banks in 2012), pericardium (57.6% of banks in 2015, and 56.3% of banks in 2012), nerves (12.1% of banks in 2015, and 12.5% of banks in 2012), rotator cuff (6.1% of banks in 2015, and 6.3% of banks in 2012), and peritoneal membrane (6.1% of banks in 2015, and 3.1% of banks in 2012).

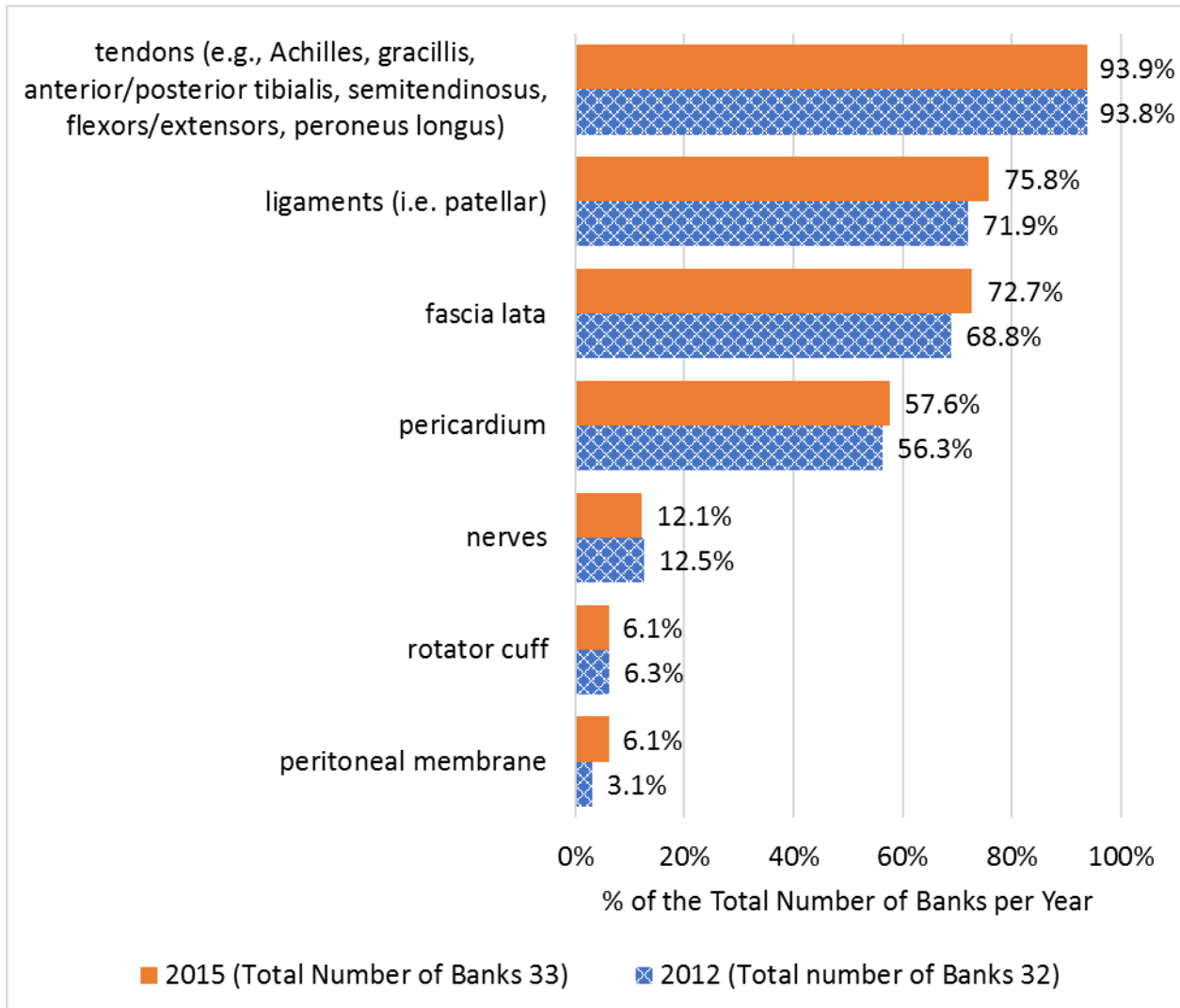


Figure 37 - Types of Stored Processed Soft Tissues from Deceased Donors in 2015 (33 Banks) and 2012 (32 Banks)

Types of Stored Processed Cardiac Tissue from Deceased Donors – Comparison of 2015 and 2012 Results

The number of banks that reported storing processed cardiac tissue from deceased donors was 7 for

2015 (13.5% of the banks that stored processed tissues from deceased donors) and 6 for 2012 (12.8% of the banks that stored processed tissues from deceased donors).

A comparison of the ranking of processed cardiac tissue types according to the number of banks that stored them in 2015 and 2012 is presented in **Error! Reference source not found.** The results are as follows: valved conduits (7 banks in 2015, and 5 banks in 2012), non-valved conduits (6 banks in 2015, and 5 banks in 2012), patch grafts (6 banks in 2015, and 4 banks in 2012), and aortoiliac grafts (1 bank in both years).

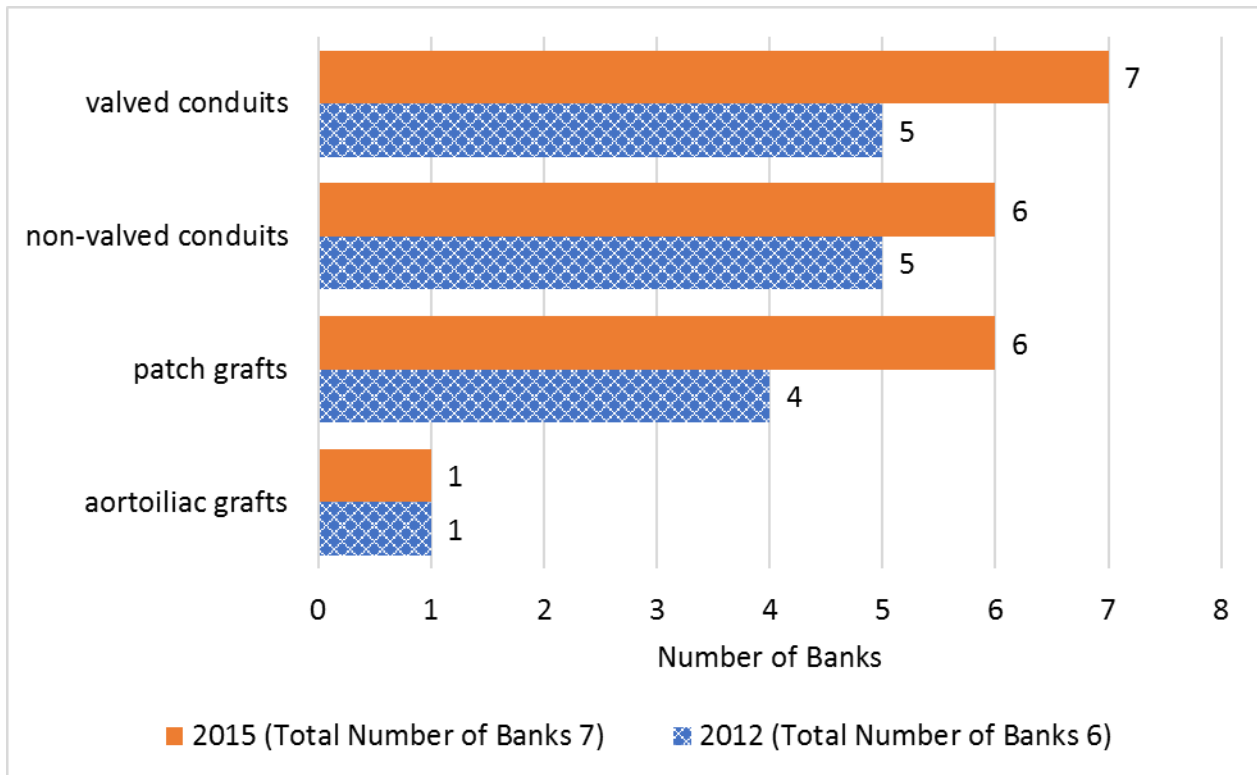


Figure 38 - Types of Stored Processed Cardiac Tissues from Deceased Donors in 2015 (7 Banks) and 2012 (6 Banks)

Types of Stored Processed Vascular Tissue from Deceased Donors – Comparison of 2015 and 2012 Results

The number of banks that reported storing processed vascular tissue from deceased donors was 9 for 2015 (17.3% of the banks that stored processed tissues from deceased donors) and 7 for 2012 (14.9% of the banks that stored processed tissues from deceased donors).

As presented in Figure 39, processed vein grafts were stored by all banks that stored vascular tissue in both years, and processed arteries were stored by 7 banks in 2015 and by 4 banks in 2012.

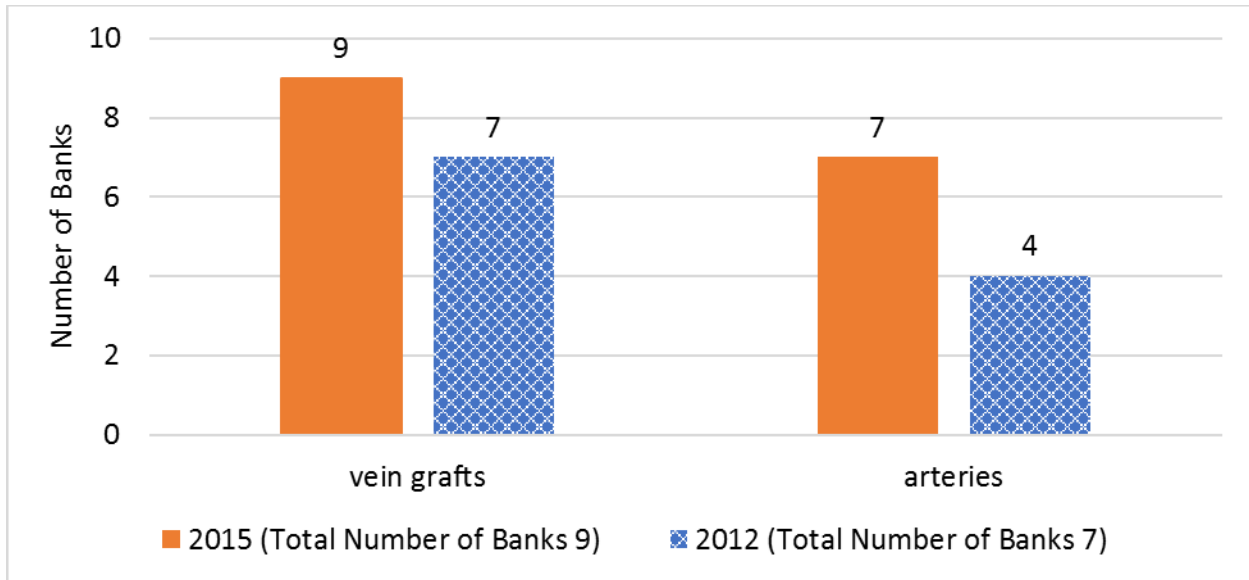


Figure 39 - Types of Stored Processed Vascular Tissues from Deceased Donors in 2015 (9 Banks) and 2012 (7 Banks)

Types of Stored Processed Skin Tissue from Deceased Donors – Comparison of 2015 and 2012 Results

The number of banks that reported storing processed skin tissue from deceased donors was 27 for 2015 (51.9% of the banks that stored processed tissues from deceased donors) and 25 for 2012 (53.2% of the banks that stored processed tissues from deceased donors).

A comparison of the ranking of processed skin tissue types according to the percentage of banks that stored them in 2015 and 2012 is presented in Figure 40. The results are as follows: dermal tissue (77.8% of banks in 2015, and 80% of banks in 2012), split thickness (55.6% of banks in 2015, and 48% of banks in 2012), lyophilized (29.6% of banks in 2015, and 32% of banks in 2012), and dehydrated (14.8% of banks in 2015, and 12% of banks in 2012).

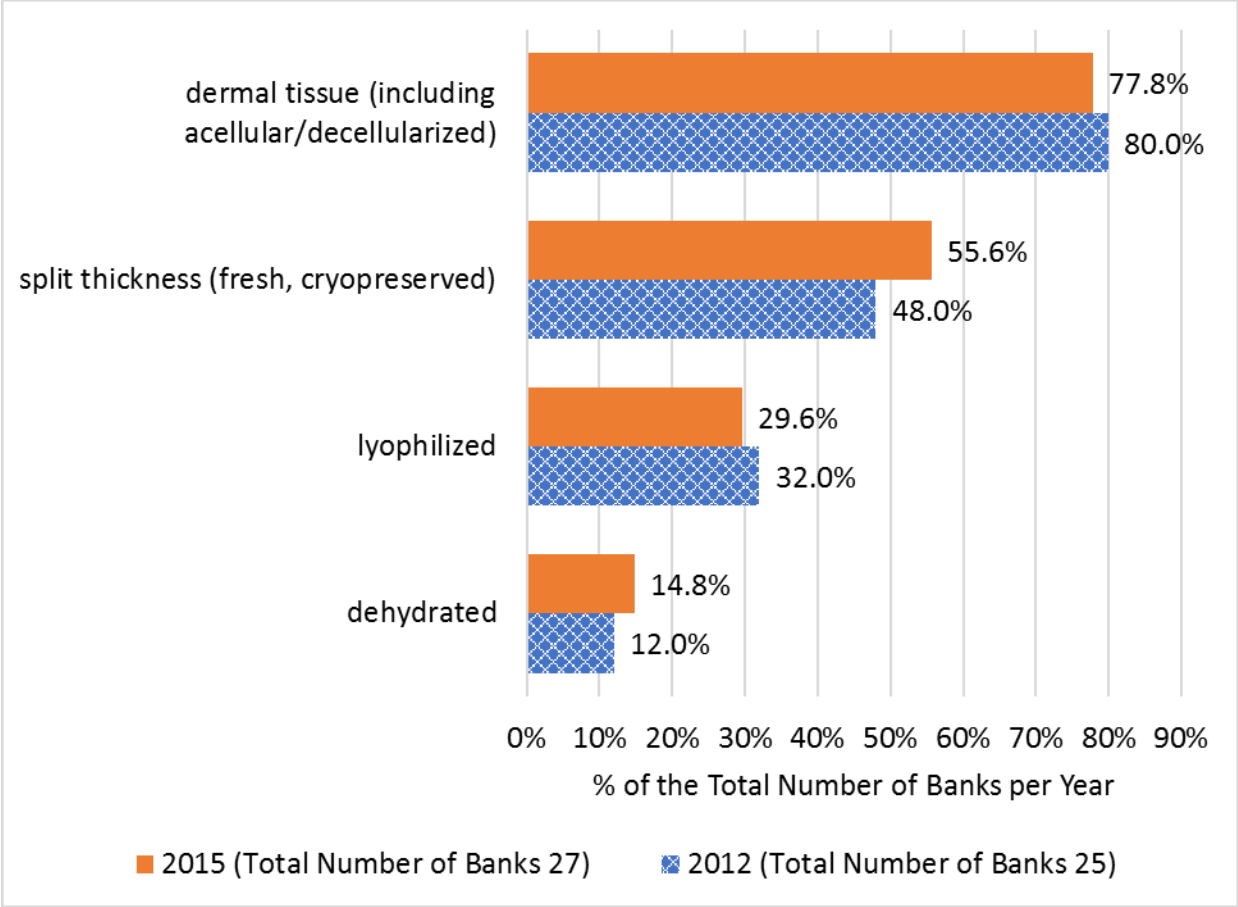


Figure 40 - Types of Stored Processed Skin Tissues from Deceased Donors in 2015 (27 Banks) and 2012 (25 Banks)

Other Types of Stored Processed Tissue from Deceased Donors

The number of banks that reported storing other types of processed tissue from deceased donors was 13 for 2015 (25% of the banks that stored processed tissues from deceased donors).

As presented in Figure 41, processed cellular tissue was stored by 12 banks, and processed dura mater, Allograft, DBm and Memoderm were stored by 1 bank each.

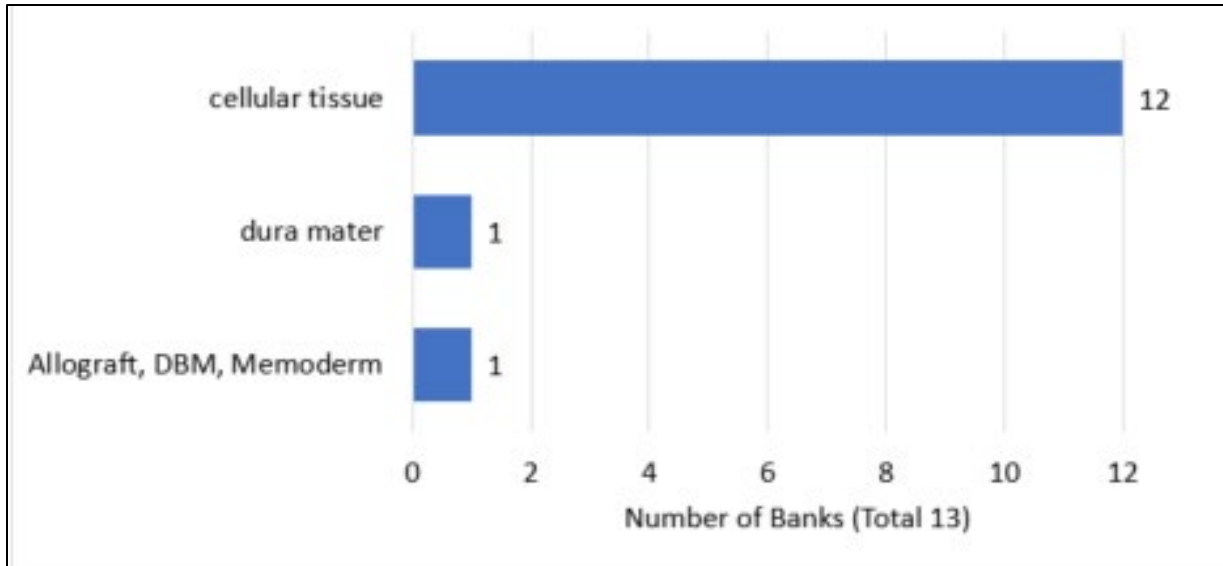


Figure 41 - Other Types of Stored Processed Tissue from Deceased Donors in 2015 (13 Banks)

Stored Processed Tissue from Living Donors - HCT/Ps Regulated Solely under Section 361 of the PHSA

The number of banks that provided information about storage of processed tissues from living donors was 77 in 2015 (100% of the banks that stored human tissues) and 67 in 2012 (100% of the banks that stored human tissues).

The number of banks that reported storing processed tissues from living donors was 32 for 2015 (41.6% of the banks that stored human tissues), and 18 for 2012 (26.9% of the banks that stored human tissues).

Types of Stored Processed Birth Tissue from Living Donors – Comparison of 2015 and 2012 Results

The number of banks that reported storing processed birth tissue from living donors was 27 for 2015 (84.4% of the banks that stored processed tissues from living donors) and 12 for 2012 (66.7% of the banks that stored processed tissues from living donors).

A comparison of the ranking of processed birth tissue types according to the percentage of banks that stored them in 2015 and 2012 is presented in Figure 42. The results are as follows: amniotic membrane (92.6% of banks in 2015, and 91.7% of banks in 2012), amniotic + chorionic membrane (44.4% of banks in 2015, and 50% of banks in 2012), amniotic fluid (40.7% of banks in 2015, and 8.3% of banks in 2012), umbilical cord tissue (25.9% of banks in 2015 and 16.7% of banks in 2012), and chorionic membrane (14.8% of banks in 2015, and 16.7% of banks in 2012). The ranking of birth tissue types is similar in both years, except for amniotic fluid which would be in the 5th position in 2012.

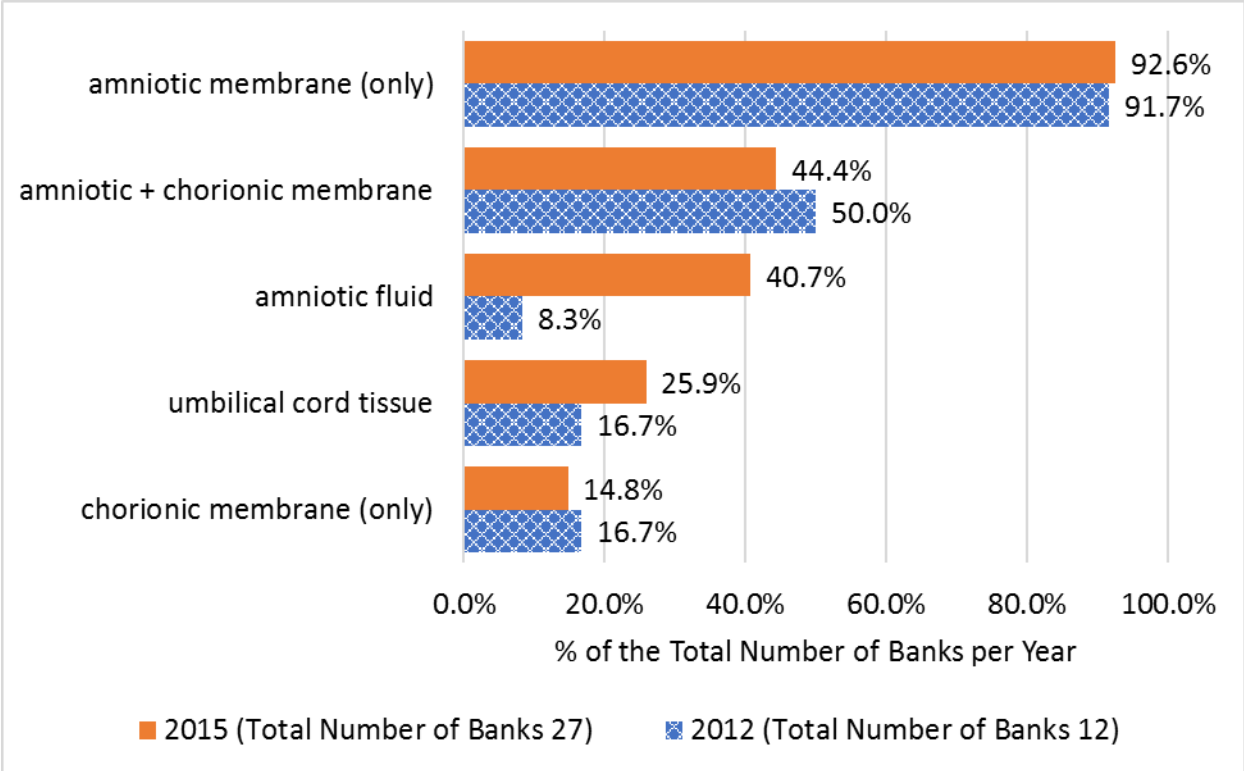


Figure 42 - Types of Stored Processed Birth Tissues from Living Donors in 2015 (27 Banks) and 2012 (12 Banks)

Other Types of Stored Processed Tissue from Living Donors – Comparison of 2015 and 2012 Results

The number of banks that reported storing other types of processed tissue from living donors was 9 for 2015 (28.1% of the banks that stored processed tissues from living donors), and 9 for 2012 (60% of the banks that stored processed tissues from living donors).

As presented in Figure 43, the other types of processed tissue from living donors that were the most mentioned by the banks were: autologous bone (4 banks in 2015, and 6 banks in 2012), autologous parathyroid (4 banks in 2015, and 5 banks in 2012), skin for allogeneic use (2 banks in 2015, and 3 banks in 2012), surgical bone (2 banks in 2015, and 1 bank in 2012), fibroblasts and keratinocytes from skin (1 bank in 2015, and 1 bank in 2012), autologous cranial flaps (1 bank in 2015, and 1 bank in 2012) and placenta (amnion) (1 bank in 2012).

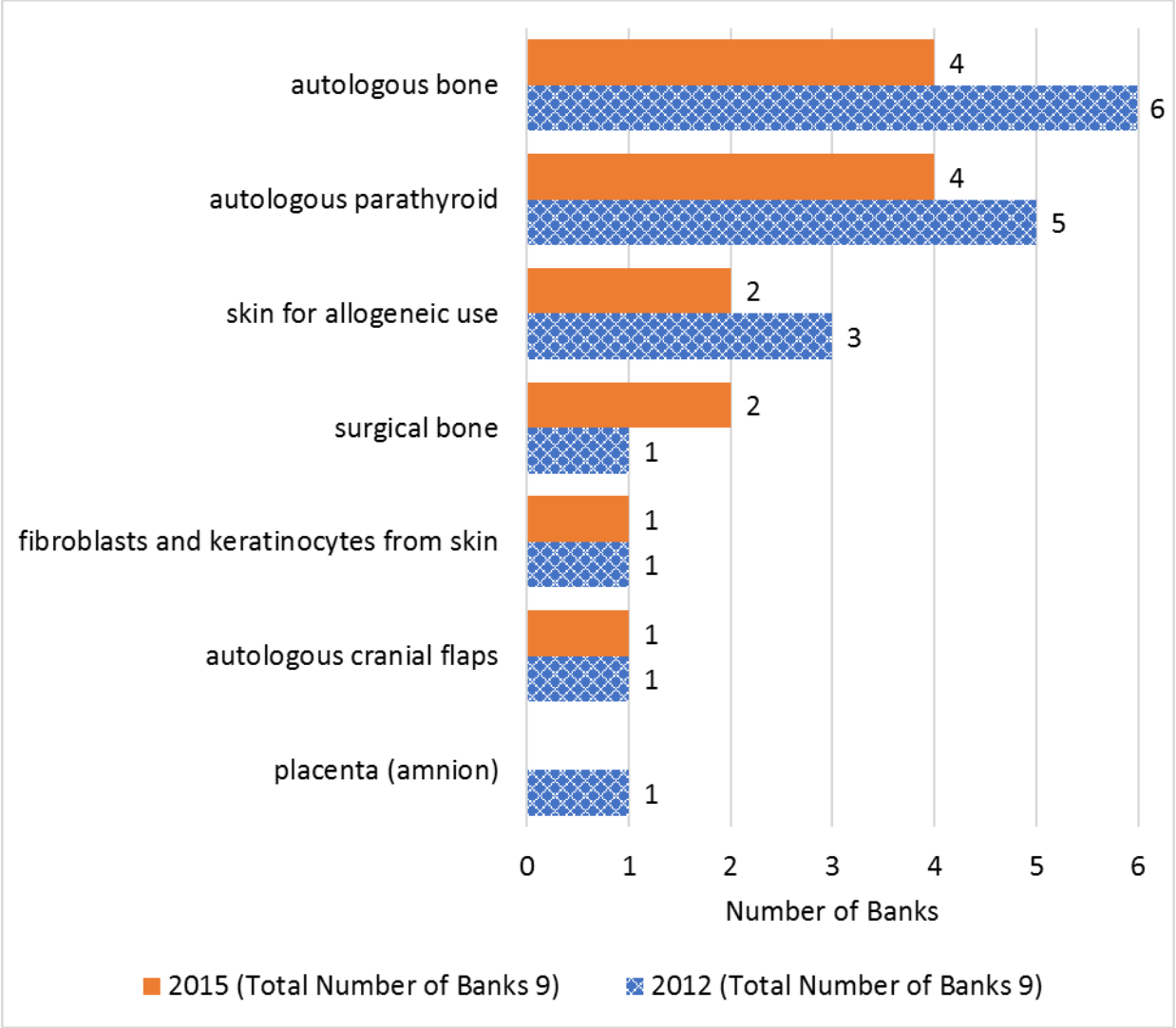


Figure 43 - Other Types of Stored Processed Tissue from Living Donors in 2015 (9 Banks) and 2012 (9 Banks)

Storage Methods for Recently Recovered and Processed Tissue from Deceased and Living Donors

In 2015, 73 banks (94.8% of the banks that stored human tissues) provided information about the storage methods.

The ranking of the storage methods, according to the percentage of banks that used them, is presented in Figure 44. The top 5 methods are as follows: long term freezing at temperature below -40°C were used by 68.5% of the banks; ambient method was used by 49.3% of the banks; refrigeration between 0°C and 10°C was used by 45.2% of the banks; controlled room storage at temperatures between 15°C and 30°C was used by 35.6% of the banks; cryopreservation at temperature below -100°C was used by 28.8% of the banks; frozen-short term (-20°C to -40°C) was used by 17.8% and other methods (finished product (AP) 20°C to 23°C; freezing at: -75°C, -80°C or ≤-120°C was used by 5.5% of banks.

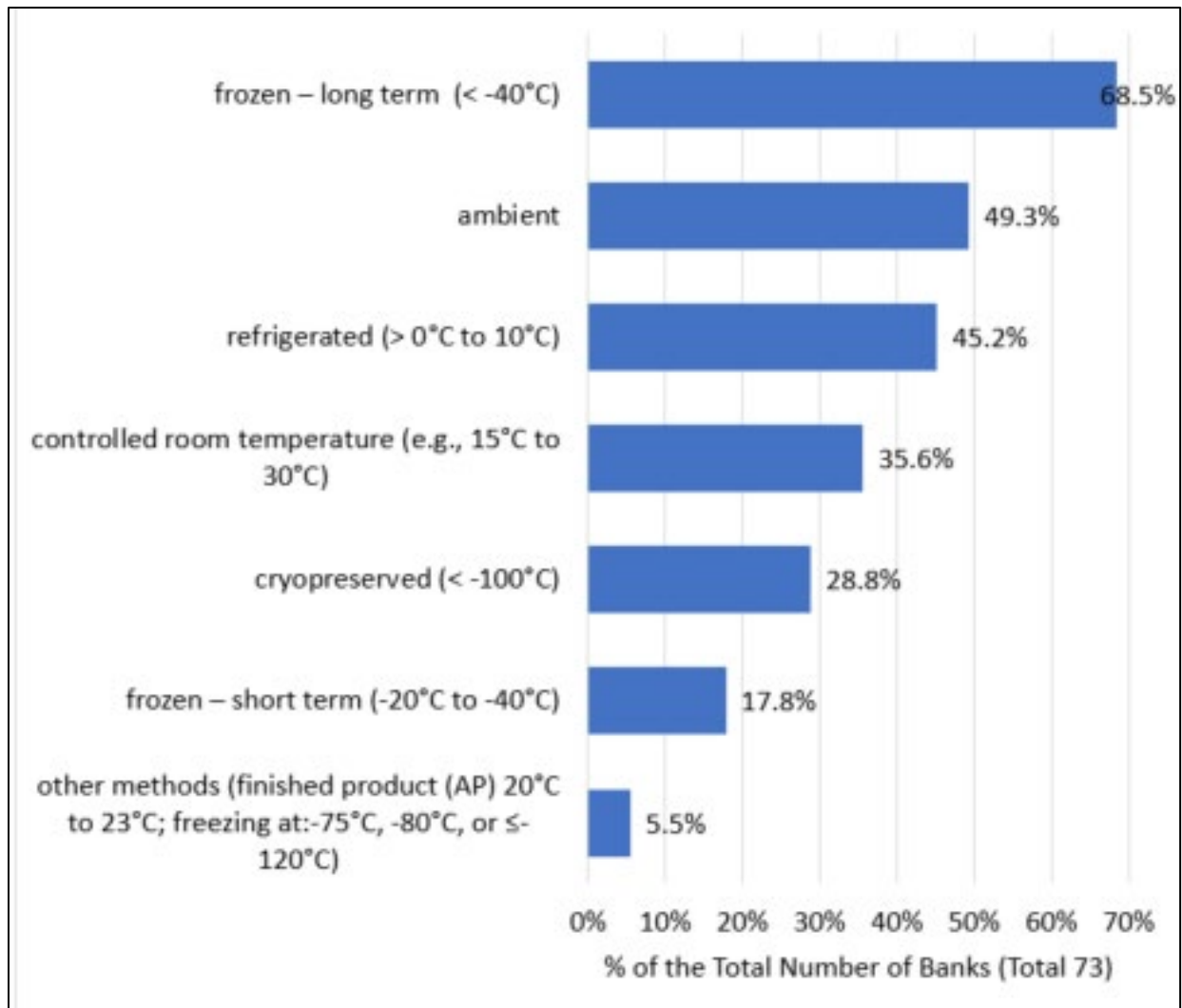


Figure 44 - Methods of Storage for Recently Recovered and Processed Tissues from Deceased and Living Donors in 2015 (73 Banks)

Tissue Distribution

The number of banks that responded to the survey on tissue distribution was 59 in 2015 and 51 in 2012. The number of banks that distributed tissues from deceased donors was 49 in 2015 (83.1% of the banks that distributed human tissues) and 42 in 2012 (82.4% of the banks that distributed human tissues). The number of banks that distributed tissues from living donors was 29 in 2015 (49.2% of the banks that distributed human tissues) and 17 in 2012 (40.5% of the banks that distributed human tissues).

Distribution of Tissue from Deceased Donors - HCT/Ps regulated NOT solely under Section 361 of the PHSA For 2015, 29 banks (59.2% of the banks that reported distributing tissues from deceased donors) provided information about the distribution of special types of tissue.

As presented in Figure 45, 23 banks (79.3%) reported distributing tissue as a device, and 8 banks (27.6%) distributed tissue as biological product.

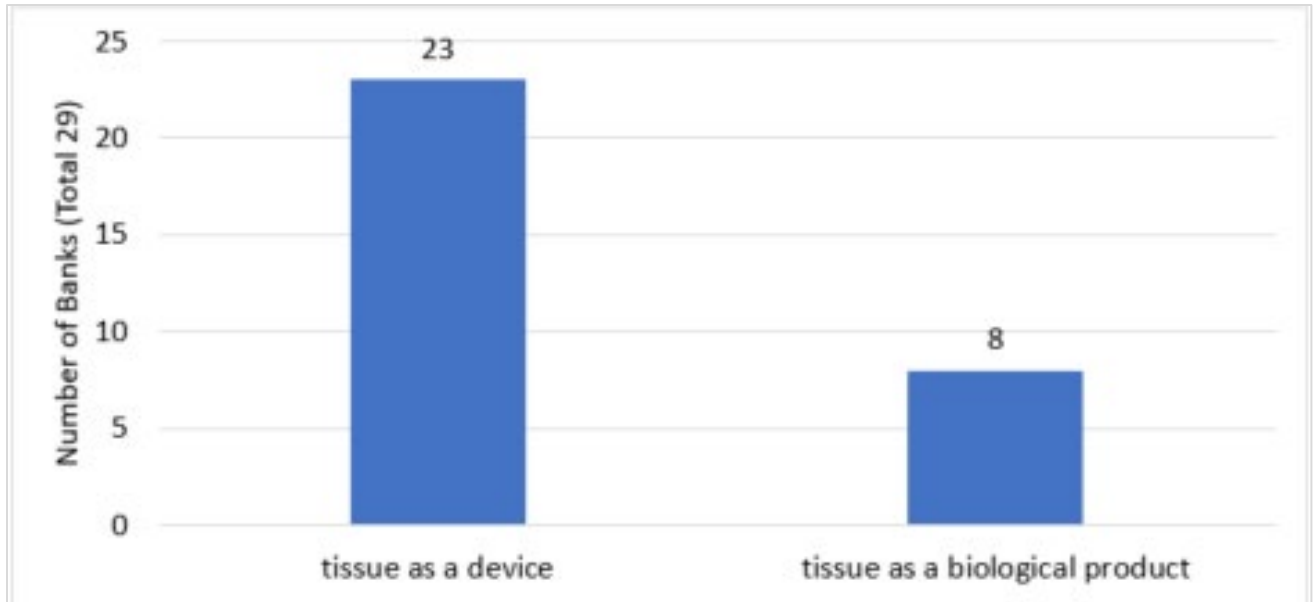


Figure 45 - Distribution of Special Types of Tissues from Deceased Donors in 2015 (29 Banks)

Distribution of Finished Tissue Grafts from Deceased and Living Donors by Receiving Institution

For 2015, 44 banks (74.6% of the banks that reported distributing human tissues) provided information about the distributed finished grafts from deceased and living donors by receiving institution.

As presented in Figure 46 most tissue banks reported distributing finished tissue grafts to the following institutions: hospitals/medical facilities (86.4% of banks), U.S. tissue distribution intermediaries (52.3% of banks), international tissue distribution intermediaries (34.1% of banks), physicians/dentists (29.5% of banks) and another tissue bank (22.7% of banks).

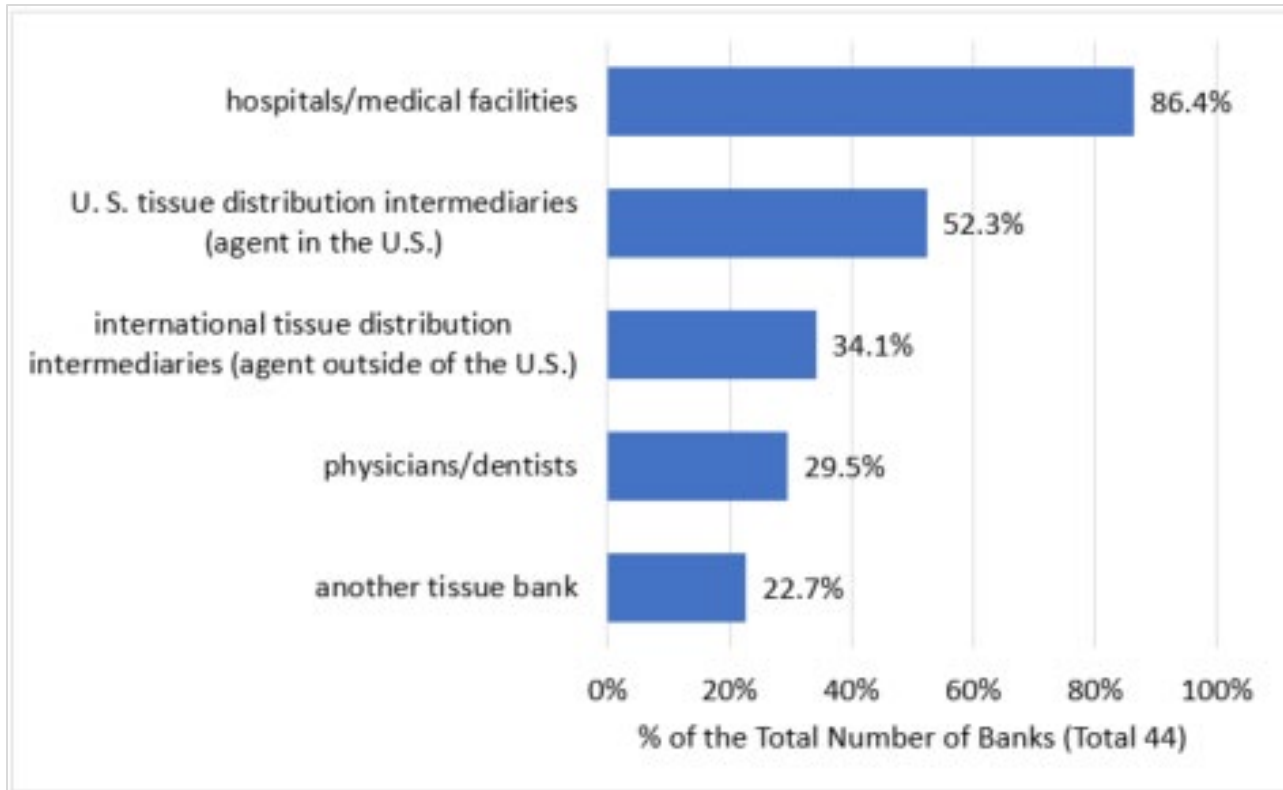


Figure 46 - Distribution of Finished Tissue Grafts from Deceased and Living Donors by Receiving Institution in 2015 (44 Banks)

The 44 banks (74.6% of the banks that distributed human tissues) distributed a total of 2,715,286 finished tissue grafts to 5 types of institutions (Figure 47). Most (87.7%) of the finished tissue grafts were distributed to the following places: hospitals/medical facilities (1,111,554 finished tissue grafts, or 40.9% of the total), U.S. tissue distribution intermediaries (943,982 finished tissue grafts, or 34.8% of the total), another tissue bank (324,760 finished tissue grafts, or 12% of the total) physicians/dentists (195,532 finished tissue grafts, or 7.2% of the total) and international tissue distribution intermediaries (agent outside of the U.S.) (139,458 finished tissue grafts, or 5.1% of the total).

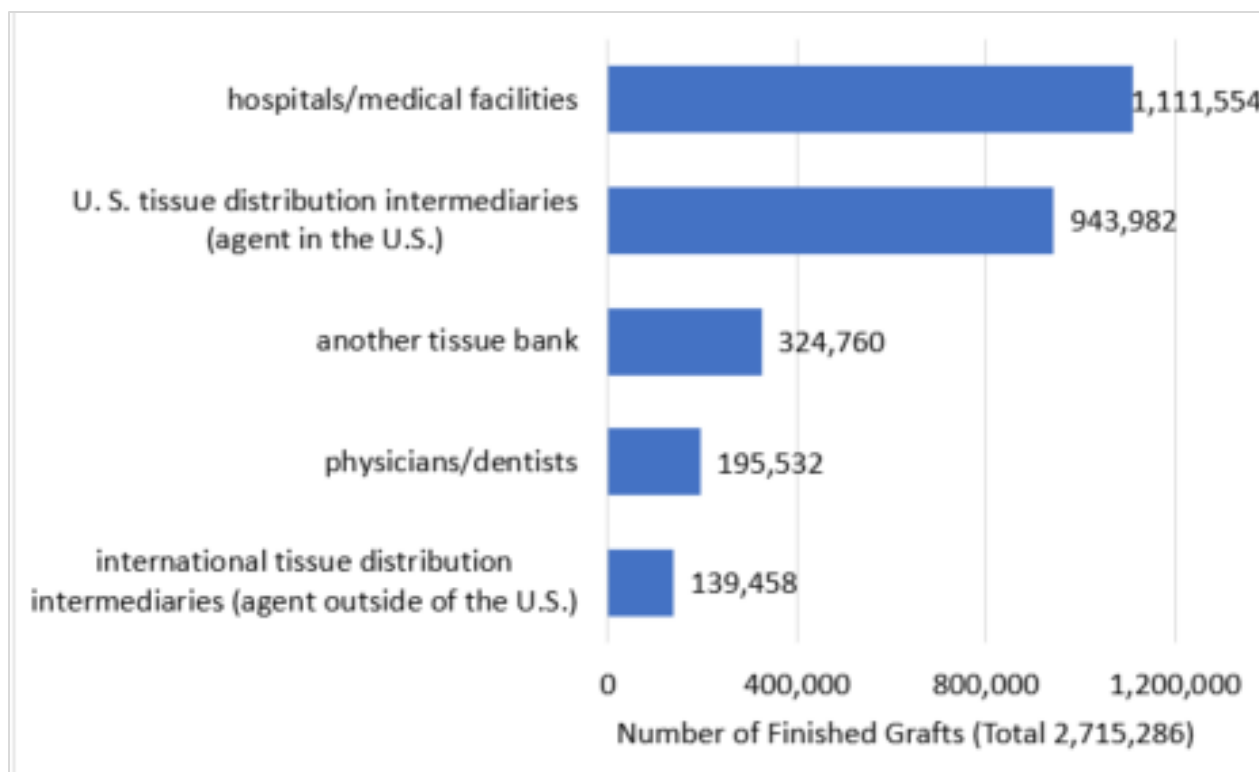


Figure 47 - Number of Finished Tissue Grafts from Deceased and Living Donors by Receiving Institution in 2015 (44 Banks)

Deceased Donors

The number of banks that distributed tissues from deceased donors was 49 in 2015 (83.1% of the banks that distributed human tissues), and 42 in 2012 (82.4% of the banks that distributed human tissues).

Types of Distributed Musculoskeletal Tissue from Deceased Donors – Comparison of 2015 and 2012 Results

For 2015, 40 banks (95.2% banks that reported distributing musculoskeletal tissue from deceased donors) provided information about the types of musculoskeletal tissue they distributed. For 2012, 35 banks (89.7% banks that reported distributing musculoskeletal tissue from deceased donors) provided information about the types of musculoskeletal tissue they distributed.

The ranking of the musculoskeletal tissue types from deceased donors, according to the percentage of banks that distributed them, is presented in Figure 48. The 7 most distributed musculoskeletal tissue types are as follows: demineralized cortical bone (75% of banks in 2015, and 54.3% of banks in 2012), cancellous bone (72.5% of banks in 2015, and 68.6% of banks in 2012), corticocancellous bone (65% of banks in 2015, and 54.3% of banks in 2012), demineralized cancellous bone (57.5% of banks in 2015, and 57.1% in 2012), proprietary spinal grafts (52.5% of banks in 2015, and 54.3% of banks in 2012), large segment (47.5% of banks in 2015, and 45.7% of banks in 2012), non-proprietary spinal grafts (42.5% of banks in 2015, and 51.4% of banks in 2012), cartilage (e.g., costal, articular) (30% of banks in 2015, and 34.3% of banks in 2012), meniscus (22.5% of banks in 2015, and 25.7% of banks in 2012), osteochondral grafts-fresh/refrigerated (17.5% of banks in 2015, and 22.9% of banks in 2012), osteoarticular grafts - frozen/cryopreserved (12.5% of banks in 2015, and 17.1% of banks in 2012) and osteoarticular grafts - fresh/refrigerated (2.9% of banks in 2012).

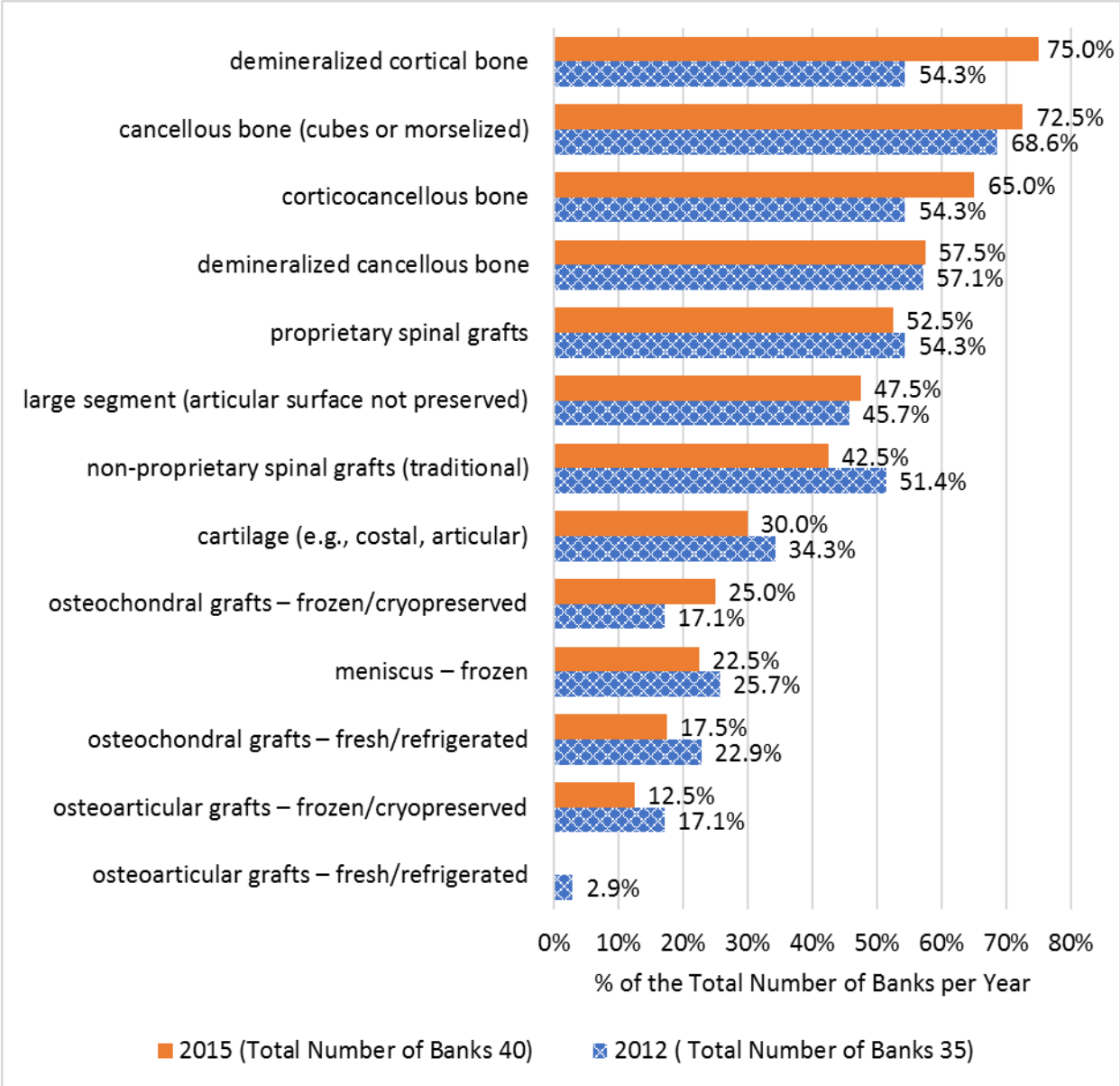


Figure 48 - Types of Distributed Musculoskeletal Grafts from Deceased Donors in 2015 (40 Banks) and 2012 (35 Banks)

As presented in Figure 49, most musculoskeletal tissue grafts distributed (96.7% in 2015, and 96.2% in 2012) were of the following types: cancellous bone (702,271 grafts in 2015, and 597,742 grafts in 2012), demineralized cortical bone (550,431 grafts in 2015, and 345,017 grafts in 2012), corticocancellous bone (529,405 grafts in 2015, and 295,040 in 2012), proprietary spinal grafts (468,265 grafts in 2015, and 375,693 grafts in 2012), demineralized cancellous bone (135,479 grafts in 2015, and 103,659 grafts in 2012) and other (80,326 grafts in 2015 and 66,926 in 2012). The musculoskeletal tissue types that represented less than 3% of the number of distributed grafts per year were grouped under the name “other” (non-proprietary spinal grafts, large segment, cartilage, meniscus, osteochondral grafts and osteoarticular grafts).

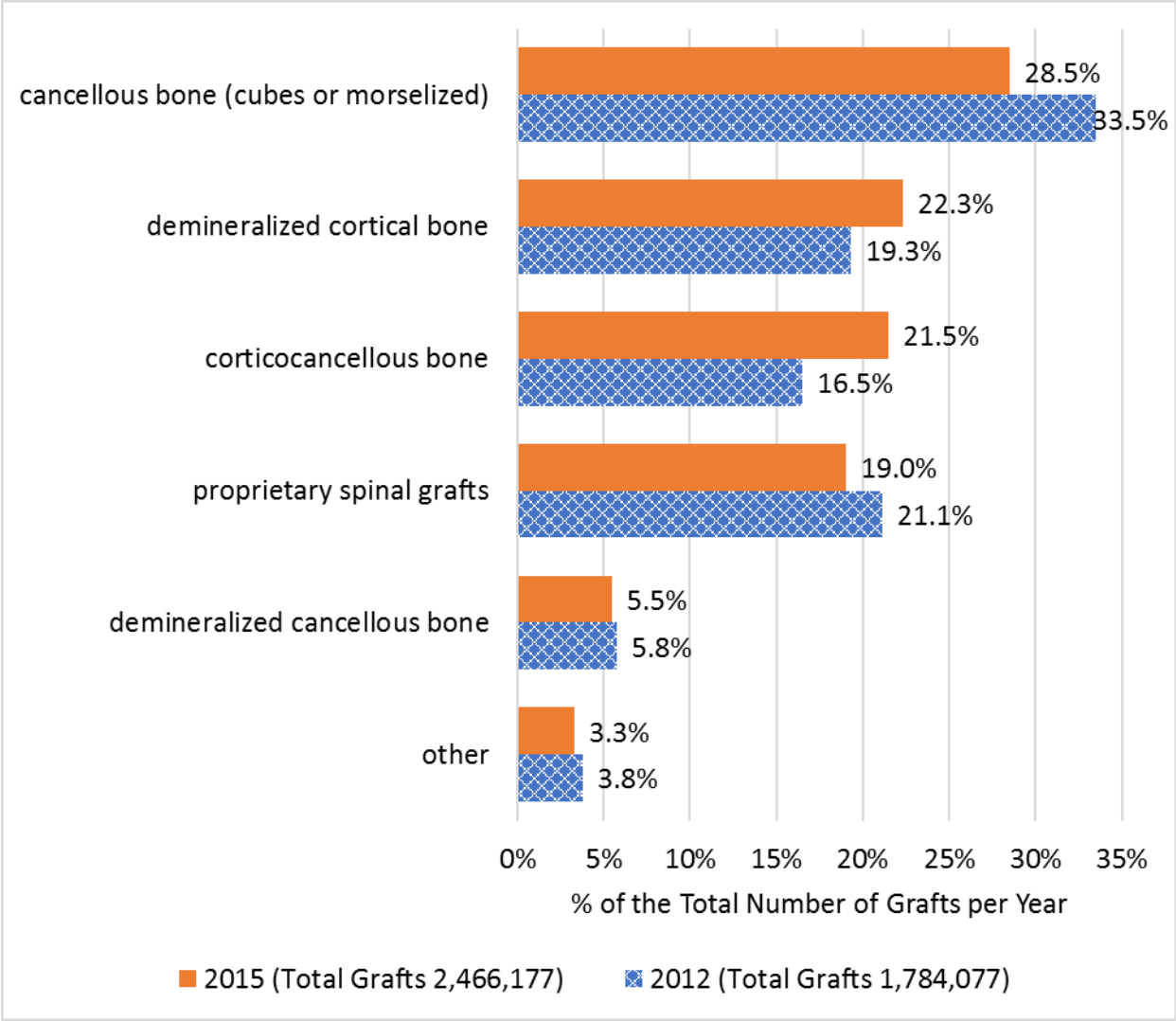


Figure 49 - Number of Grafts by Types of Musculoskeletal Tissue from Deceased Donors Distributed in 2015 (40 Banks) and 2012 (35 Banks)

TOTAL Number of Distributed Musculoskeletal Grafts from Deceased Donors – Comparison of 2015 and 2012 Results

Note – The total number of distributed musculoskeletal grafts includes more types of musculoskeletal tissue than those presented above in Figure 49. Therefore, the total number of grafts reported by the banks can be smaller if the response rate to this specific question in the survey was smaller.

The total number of distributed musculoskeletal grafts from deceased donors was provided by 39 banks for 2015 (92.9% of the banks that distributed musculoskeletal tissue from deceased donors) and by 35 banks for 2012 (89.7% of the banks that distributed musculoskeletal tissue from deceased donors).

As presented in Table 21, 39 banks distributed 2,343,015 musculoskeletal grafts from deceased donors in 2015 (median 11,217, average 60,077); and, 35 banks distributed 1,982,010 musculoskeletal grafts from deceased donors in 2012 (median 18,000, average 56,629).

Although both the average and the median values are provided in Table 21, the preferred measure of

central tendency is the median due to the positive skew in the data.

Table 21 – TOTAL Number of Distributed Musculoskeletal Grafts from Deceased Donors - Comparison of 2015 (39 Banks) and 2012 (35 Banks)

Year	Number of Banks that Provided Information	Total Number of Grafts	Average Number of Grafts	Median Number of Grafts
2015	39	2,343,015	60,077	11,217
2012	35	1,982,010	56,629	18,000

Types of Distributed Soft Tissue from Deceased Donors – Comparison of 2015 and 2012 Results

For 2015, 26 banks (83.9% banks that distributed soft tissue from deceased donors) provided information about the types of soft tissue they distributed. For 2012, 26 banks (86.7% banks that distributed soft tissue from deceased donors) provided information about the types of soft tissue they distributed.

The ranking of the soft tissue types from deceased donors, according to the percentage of banks that distributed them, is presented in Figure 50. The 4 most distributed soft tissue types are as follows: tendons (96.2% of banks in both years), ligaments (76.9% of banks in 2015, and 80.8% of banks in 2012), fascia lata (73.1% of the banks in both years), pericardium (57.7% of the banks in 2015, and 50% in 2012), nerves (15.4% of banks in 2015, and 11.5% of banks in 2012), rotator cuff (7.7% of banks in both years), dura mater (3.9% of banks in both years) and peritoneal membrane (3.9% of banks in 2012).

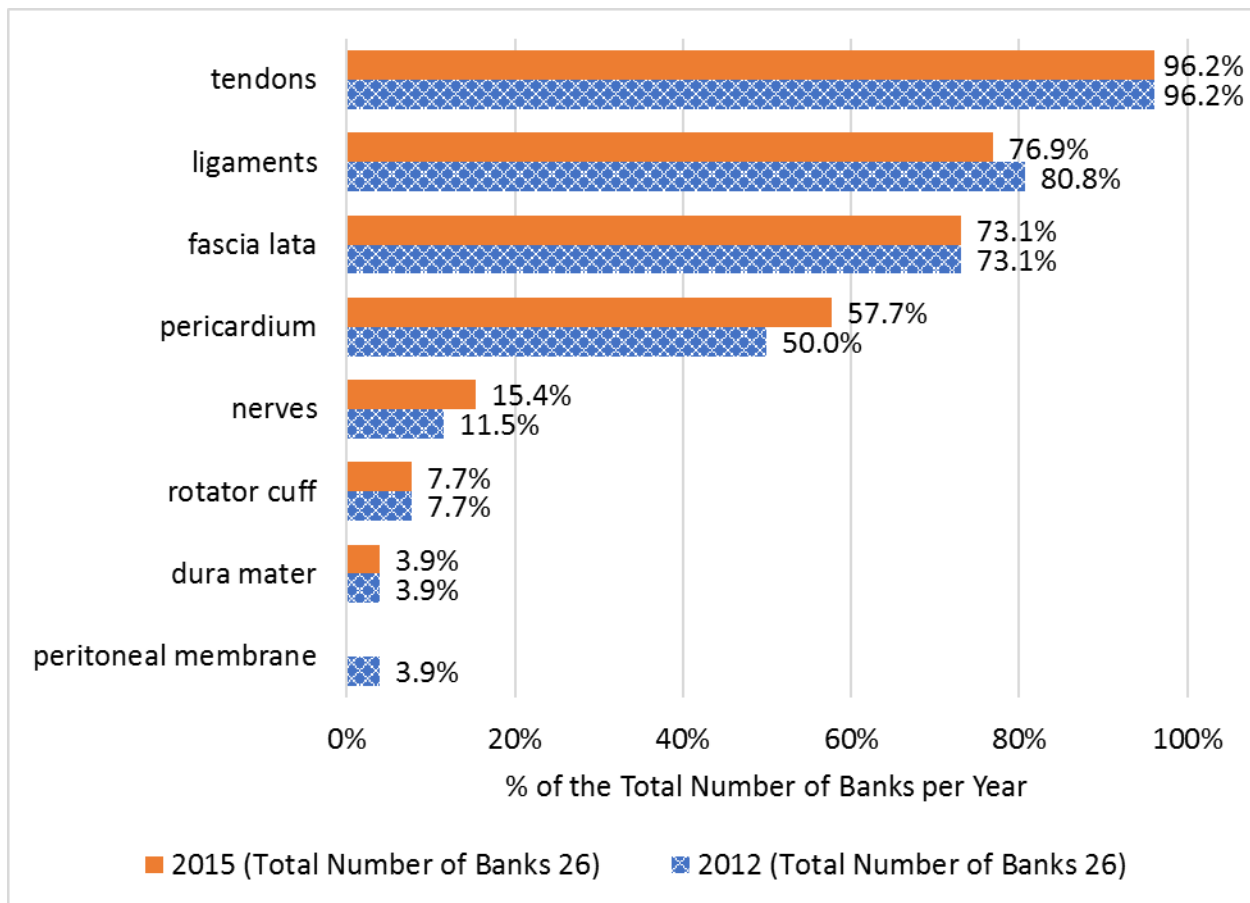


Figure 50 - Types of Distributed Soft Tissue Grafts from Deceased Donors in 2015 (26 Banks) and 2012 (26 Banks)

As presented in Figure 51, most soft tissue grafts distributed (99.7% in 2015, and 99.6% in 2012) were of the following types: tendons (123,795 grafts in 2015, and 114,799 grafts in 2012), ligaments (24,175 grafts in 2015, and 23,088 grafts in 2012), pericardium (19,348 in 2015, and 38,127 in 2012), fascia lata (8,128 grafts in 2015, and 6,393 grafts in 2012) and other (450 in 2015, and 687 in 2012). The soft tissue types that represented less than 0.4% of the number of distributed grafts per year were grouped under the name “other” (nerves, dura mater, rotator cuff, and peritoneal membrane).

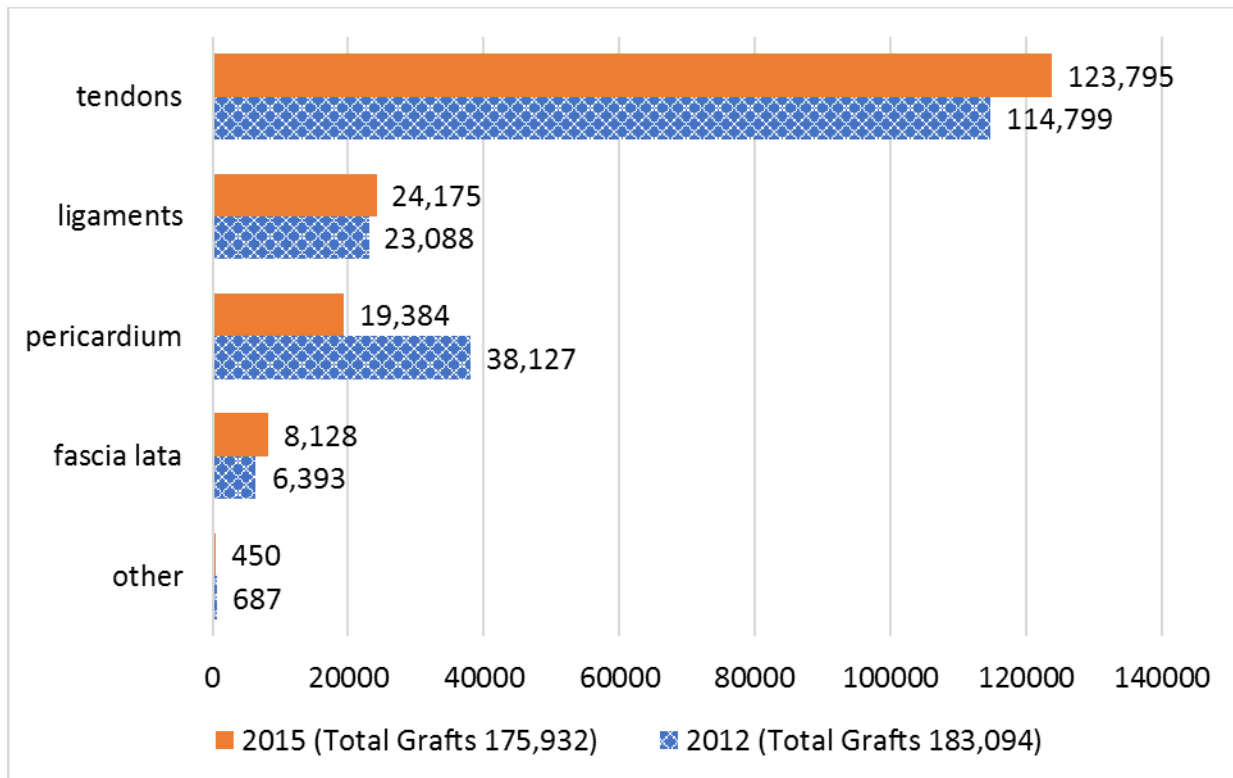


Figure 51 - Number of Grafts by Types of Soft Tissue from Deceased Donors Distributed in 2015 (26 Banks) and 2012 (26 Banks)

TOTAL Number of Distributed Soft Tissue Grafts from Deceased Donors – Comparison of 2015 and 2012 Results

Note – The total number of distributed soft tissue grafts includes more types of soft tissue than those presented above in Figure 51.

The total number of distributed soft tissue grafts from deceased donors was provided by 25 banks for 2015 (80.6% of the banks that distributed soft tissue from deceased donors) and by 26 banks for 2012 (86.7% of the banks that distributed soft tissue from deceased donors).

As presented in Table 22, 25 banks distributed 184,224 soft tissue grafts from deceased donors in 2015 (median 822, average 7,369); and, 26 banks distributed 191,092 soft tissue grafts from deceased donors in 2012 (median 681, average 7,350).

Although both the average and the median values are provided in Table 22, the preferred measure of central tendency is the median due to the positive skew in the data.

Table 22 - TOTAL Number of Distributed Soft Tissue Grafts from Deceased Donors - Comparison of 2015 (26 Banks) and 2012 (25 Banks)

Year	Number of Banks that Provided Information	Total Number of Grafts	Average Number of Grafts	Median Number of Grafts
2015	25	184,224	7,369	822
2012	26	191,092	7,350	681

Types of Distributed Cardiac Tissue from Deceased Donors – Comparison of 2015 and 2012 Results

All banks that distributed cardiac tissue from deceased donors in 2015 and 2012 provided information about the type of cardiac tissues they distributed.

The ranking of the cardiac tissue types from deceased donors, according to the number of banks that distributed them, is presented in Figure 52. The most often mentioned types of cardiac tissues were as follows: valved conduit (aortic valves) – cryopreserved (6 banks in both years), valved conduit (pulmonic valve) – cryopreserved (6 banks in 2015, and 4 banks in 2012), patch graft – cryopreserved (5 banks in 2015, and 4 banks in 2012), non-valved conduit (pulmonic) – cryopreserved (3 banks in both years), non-valved conduit (aortic) – cryopreserved (3 banks in both years), patch graft - acellular/decellularized (3 banks in both years), valved conduit (pulmonic valve) – acellular/decellularized (2 banks in both years), aortoiliac graft – cryopreserved (1 bank in 2015, and 2 banks in 2012), valved conduit (aortic valves) – acellular/decellularized (2 banks in 2012), aortoiliac graft – acellular/decellularized (1 bank in 2012), non-valved conduit (aortic) – acellular/decellularized (1 bank in 2012) and non-valved conduit (pulmonic) – acellular/decellularized (1 bank in 2012).

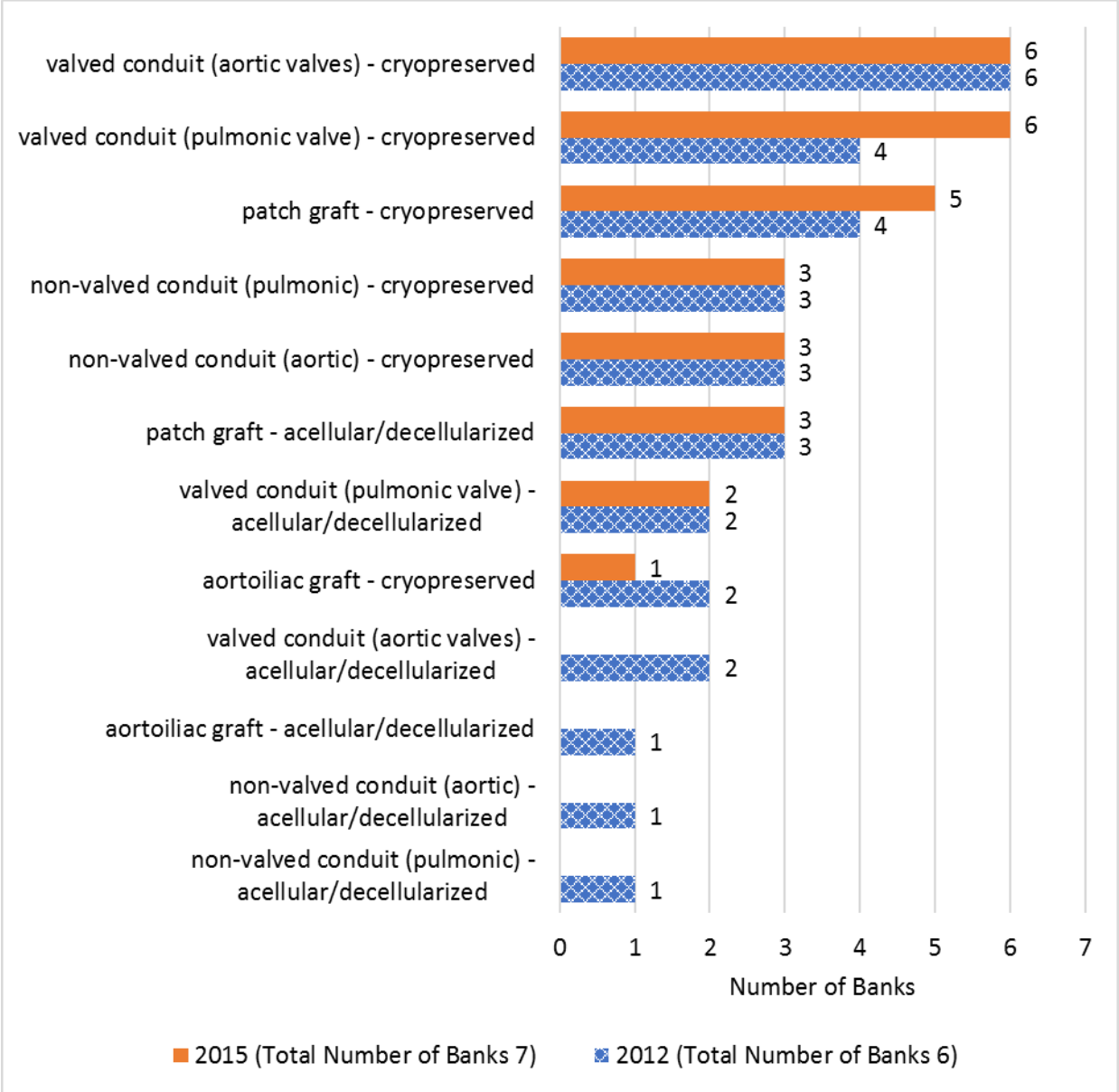


Figure 52 - Types of Distributed Cardiac Tissue Grafts from Deceased Donors in 2015 (7 Banks) and 2012 (6 Banks)

As presented in Figure 53, most cardiac tissue grafts distributed (93.6% in 2015, and 91.7% in 2012) were of the following types: valved conduit (aortic valves) – cryopreserved (1,745 grafts in 2015, and 1,016 grafts in 2012), patch graft – cryopreserved (1,280 grafts in 2015, and 1,543 grafts in 2012), patch graft – acellular/decellularized (1,256 in 2015, and 748 in 2012), valved conduits (pulmonic valve) – acellular/decellularized (735 grafts in 2015, and 511 grafts in 2012), valved conduit (pulmonic valve) – cryopreserved (664 grafts in 2015, and 895 grafts in 2012), valved conduit (aortic valves) – acellular/decellularized (837 grafts in 2012 only) and other (387 grafts in 2015 and 502 grafts in 2012).

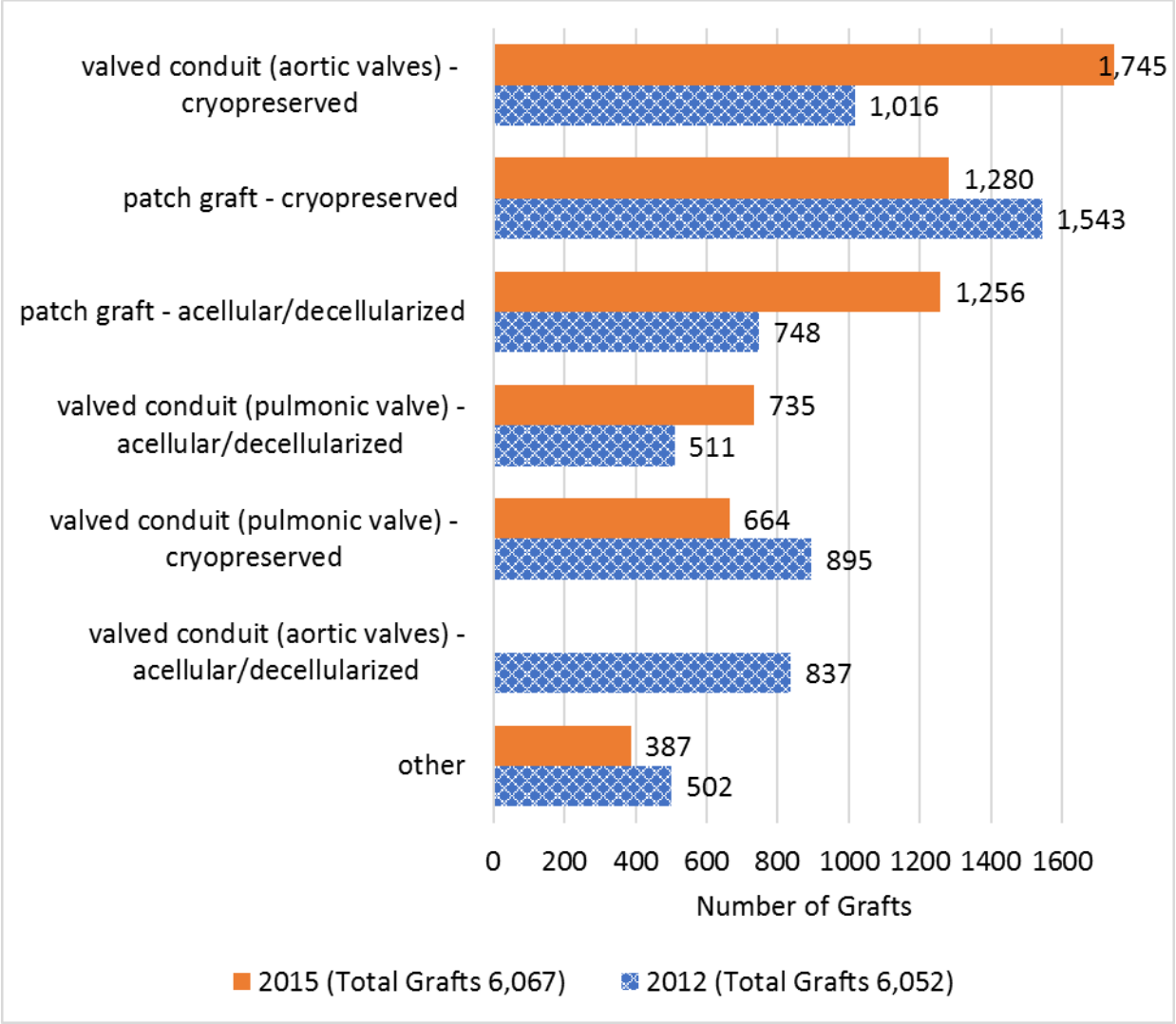


Figure 53 - Number of Grfts by Types of Cardiac Tissue from Deceased Donors Distributed in 2015 (7 Banks) and 2012 (6 Banks)

TOTAL Number of Distributed Cardiac Tissue Grfts from Deceased Donors

Note – The total number of distributed cardiac tissue grfts includes more types of cardiac tissue than those presented above in Figure 53. Therefore, the total number of grfts reported by the banks can be smaller if the response rate to this specific question in the survey was smaller.

For 2015, 6 banks (85.7% of the banks that distributed cardiac tissue from deceased donors) distributed a total of 6,060 grfts (median 305).

Types of Distributed Vascular Tissue from Deceased Donors – Comparison of 2015 and 2012 Results

All banks that distributed vascular tissue from deceased donors in 2015 and 2012 provided information about the type of vascular tissues they distributed.

The ranking of the vascular tissue types from deceased donors, according to the number of banks that distributed them, is presented in Figure 54. The most often mentioned types of vascular tissues were as follows: vein grafts (saphenous) – cryopreserved (7 banks in 2015, and 5 banks in 2012), arteries – cryopreserved (3 banks in both years) vein grafts (saphenous) – acellular/decellularized (1 bank in 2015) and vein grafts (iliac – cryopreserved (1 bank in 2015).

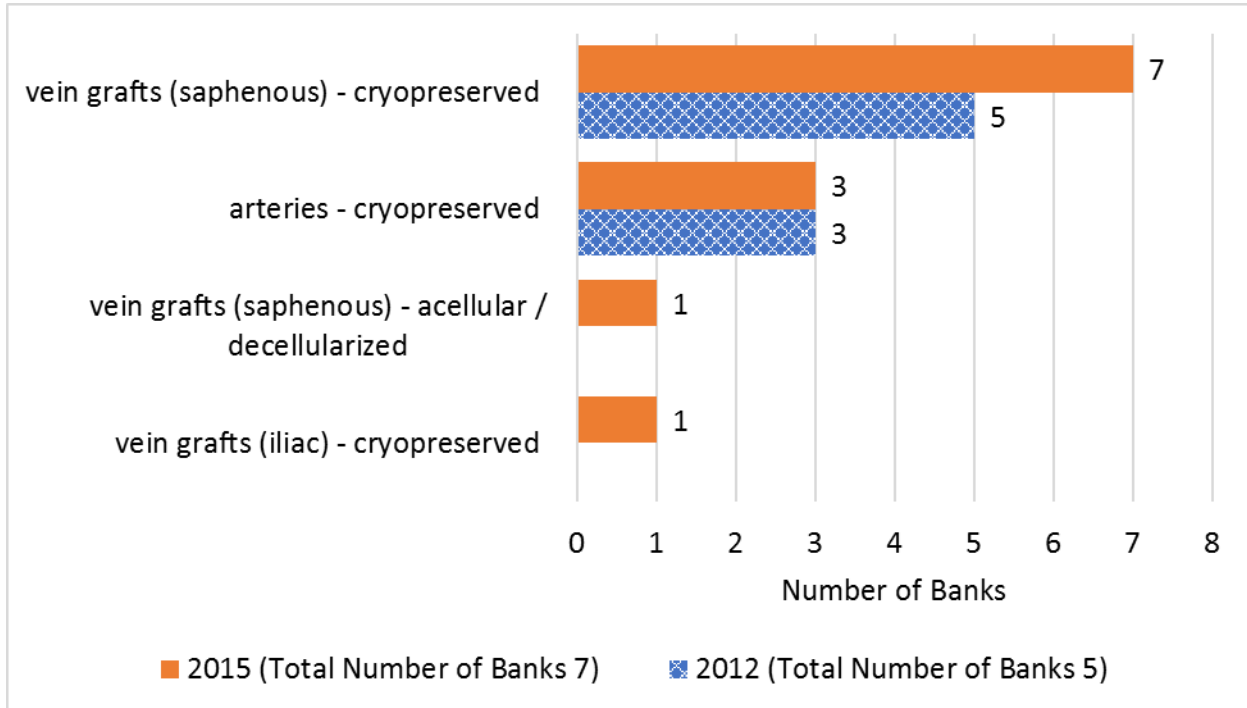


Figure 54 - Types of Distributed Vascular Tissue Grafts from Deceased Donors in 2015 (7 Banks) and 2012 (5 Banks)

As presented in Figure 55, most vascular tissue grafts distributed (97.7% in 2015, and 100% in 2012) were of the following types: vein grafts (saphenous) – cryopreserved (4,540 grafts in 2015, and 4,709 grafts in 2012), arteries – cryopreserved (473 grafts in 2015, and 461 grafts in 2012), vein grafts (saphenous) – acellular/decellularized (100 banks in 2015) and vein grafts (iliac) – cryopreserved (20 banks in 2015).

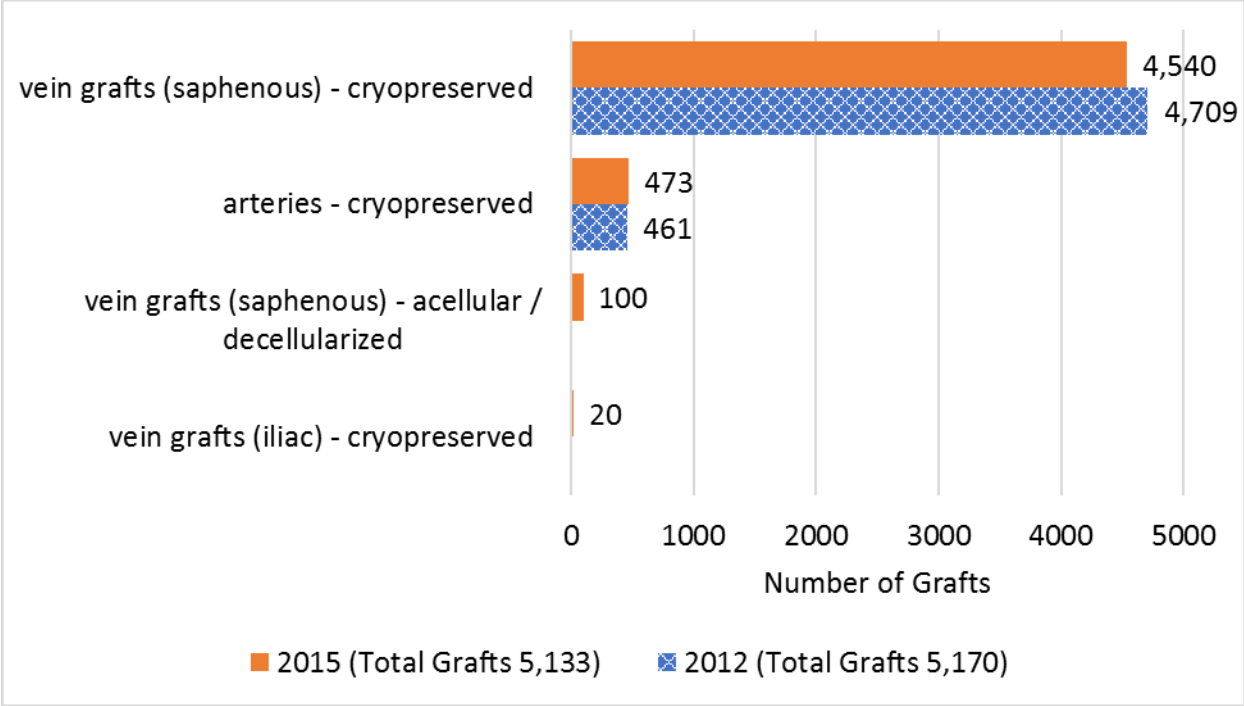


Figure 55 - Number of Grafts by Types of Vascular Tissue from Deceased Donors Distributed in 2015 (7 Banks) and 2012 (5 Banks)

TOTAL Number of Distributed Vascular Tissue Grafts from Deceased Donors – Comparison of 2015 and 2012 Results

Note – The total number of distributed vascular tissue grafts includes more types of vascular tissue than those presented above in Figure 55.

All the banks that distributed vascular tissue grafts from deceased donors for 2015 and 2012 provided the total number of grafts they distributed.

As presented in Table 23, 7 banks distributed 5,719 vascular grafts from deceased donors in 2015 (median 282, average 817); and, 5 banks distributed 5,174 vascular grafts from deceased donors in 2012 (median 80, average 1,035).

Table 23 - TOTAL Number of Distributed Vascular Grafts from Deceased Donors - Comparison of 2015 (7 Banks) and 2012 (5 Banks)

Year	Number of Banks that Provided Information	Total Number of Grafts	Average Number of Grafts	Median Number of Grafts
2015	7	5,719	817	282
2012	5	5,174	1,035	80

All 7 banks that reported distributing valved conduits (pulmonary valves) during 2015 responded to whether they were unable to fill, or were delayed in filling, requests received, based on the size of the pulmonary valve requested. The banks estimated this occurred 137 times during 2015.

Number of Units or Packages of Distributed Skin Tissue from Deceased Donors – Comparison of 2015 and 2012 Results

The number of banks that provided information about the number of units or packages of distributed skin from deceased donors was 20 banks for 2015 (95.2% of the banks that distributed skin from deceased donors) and was 19 banks for 2012 (100% of the banks that distributed skin from deceased donors).

As presented in Table 24, 20 banks distributed 324,386 units or packages of skin tissue from deceased donors in 2015 (median 1,692, average 16,219); and, 19 banks distributed 310,756 units or packages of skin tissue from deceased donors in 2012 (median 1,113, average 16,356).

Although both the average and the median values are provided in Table 24, the preferred measure of central tendency is the median due to the positive skew in the data.

Table 24 - Number of Units/Packages of Distributed Skin Tissue from Deceased Donors - Comparison of 2015 (20 Banks) and 2012 (19 Banks)

Year	Number of Banks that Provided Information	Total Number of Units/Packages	Average Number of Units/Packages	Median Number of Units/Packages
2015	20	324,386	16,219	1,692
2012	19	310,756	16,356	1,113

Note: Fifteen of the 20 banks that reported the amount of skin tissue distributed in units or packages also provided the amount distributed in square feet. For 2015, the 15 banks reported distribution of 39,573 square feet of skin tissue.

Types of Distributed Skin Tissue from Deceased Donors – Comparison of 2015 and 2012 Results

The number of banks that provided information about the types of distributed skin from deceased donors was 20 banks for 2015 (95.2% of the banks that distributed skin from deceased donors) and was 19 banks for 2012 (100% of the banks that distributed skin from deceased donors).

Note – The total numbers of U/P of skin tissue presented in Table 24 for 2015 and 2012 are smaller than those presented in Table 24 for 2015, and in Table 26 for 2012. This was caused by double counting of the same amount of U/P in two different skin tissue types. For example, a few banks counted the same amount of U/P, once as an acellular/decellularized skin type, and the second time as another type such as dehydrated or lyophilized.

Most U/P of skin (87% in 2015 and 95.4% in 2012) were of the first two types. As presented in Table 25, in 2015 most U/P of distributed skin were: dermal tissue (including acellular/decellularized; 232,311 U/P, 17 banks) and split thickness (fresh, cryopreserved; 71,144 U/P, 10 banks). As presented in Table 26, in 2012 most U/P of distributed skin were: acellular/decellularized (242,377 U/P, 12 banks), and frozen/cryopreserved (56,534 U/P, 9 banks).

Table 25 - Types of Distributed Skin Tissue from Deceased Donors in 2015 (20 Banks)

Types of Skin Tissue from Deceased Donors	Number of Banks That Provided Information	Total Number of Units/Packages of Skin Tissue
Dermal tissue (including acellular/decellularized)	17	232,311
Split thickness (fresh, cryopreserved)	10	71,144
Dehydrated	2	32,330
Lyophilized	3	13,018
Grand Total	20	348,803

Table 26 - Types of Distributed Skin Tissue from Deceased Donors in 2012 (19 Banks)

Types of Skin Tissue from Deceased Donors	Number of Banks That Provided Information	Total Number of Units/Packages of Skin Tissue
Acellular/decellularized	12	242,377
Frozen/cryopreserved	9	56,534
Lyophilized	6	14,428
Fresh	2	143
Grand Total	19	313,482

Number of Units of Distributed Tissue Devices from Deceased Donors

For 2015, 22 banks (44.9% of the banks that distributed tissues from deceased donors) distributed 616,548 units of 55 types of tissue devices from deceased donors.

Number of Units of Distributed Tissue Biological Products from Deceased Donors

For 2015, 8 banks (16.3% of the banks that distributed tissues from deceased donors) distributed 113,043 units of 24 types of biological products from deceased donors.

Living Donors

The number of banks that distributed tissues from living donors was 30 in 2015 (50.8% of the banks that distributed human tissues).

Types of Distributed Tissue from Living Donors

For 2015, 25 banks (83.3% banks that distributed tissue from living donors) provided information about the types of tissue they distributed.

The ranking of the tissue types from living donors, according to the percentage of banks that distributed them, is presented in Figure 56. The 5 most distributed tissue types were: amniotic membrane (88% of banks), amniotic fluid (36% of banks), autologous bone (20% of the banks), chorionic membrane (12% of the banks), umbilical cord tissue (8% of the banks), autologous parathyroid (4% of the banks) and skin for allogeneic use (4% of the banks).

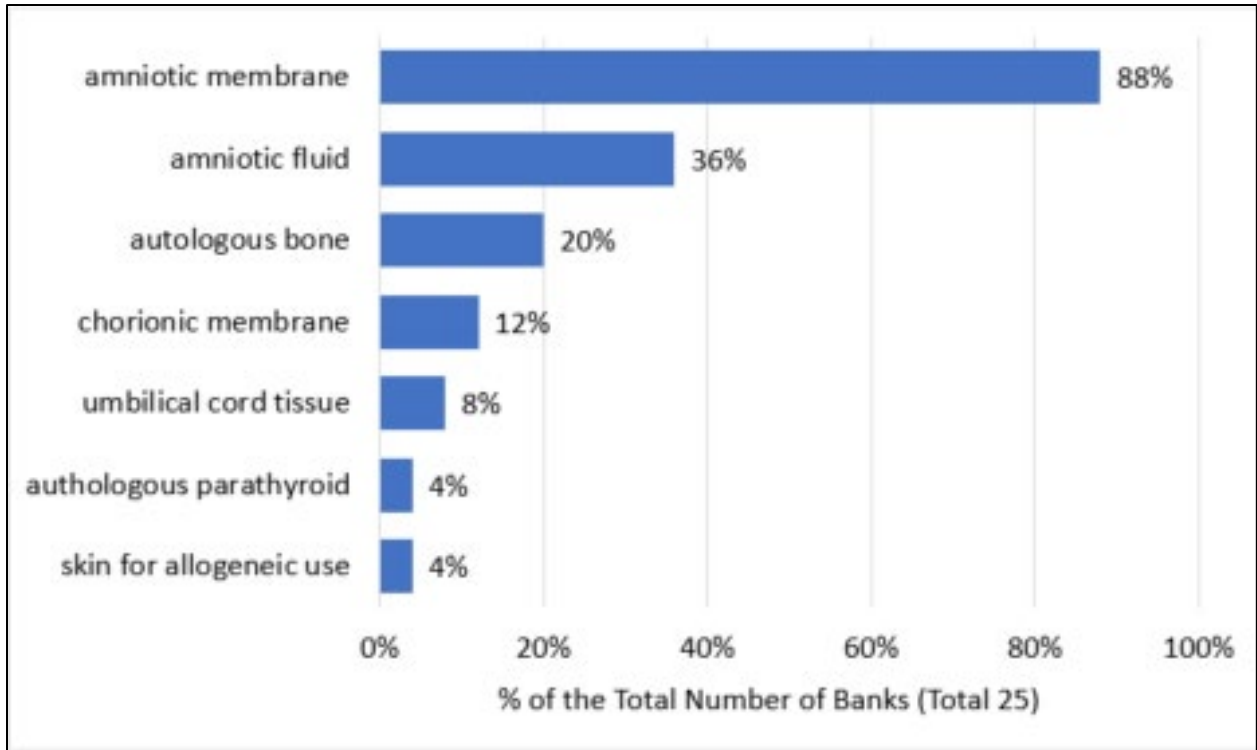


Figure 56 - Types of Distributed Tissues from Living Donors in 2015 (25 Banks)

As presented in Figure 57, most (97.8%) of the distributed tissue grafts from living donors in 2015 were of the following types: amniotic membrane (336,219 grafts), chorionic membrane (31,605 grafts), amniotic fluid (20,435 grafts), umbilical cord tissue (8,121 grafts), other (566 grafts). The tissue types that represented less than 0.1% of the number of distributed grafts per year were grouped under the name “other” (autologous bone, skin for allogeneic use, and autologous parathyroid).

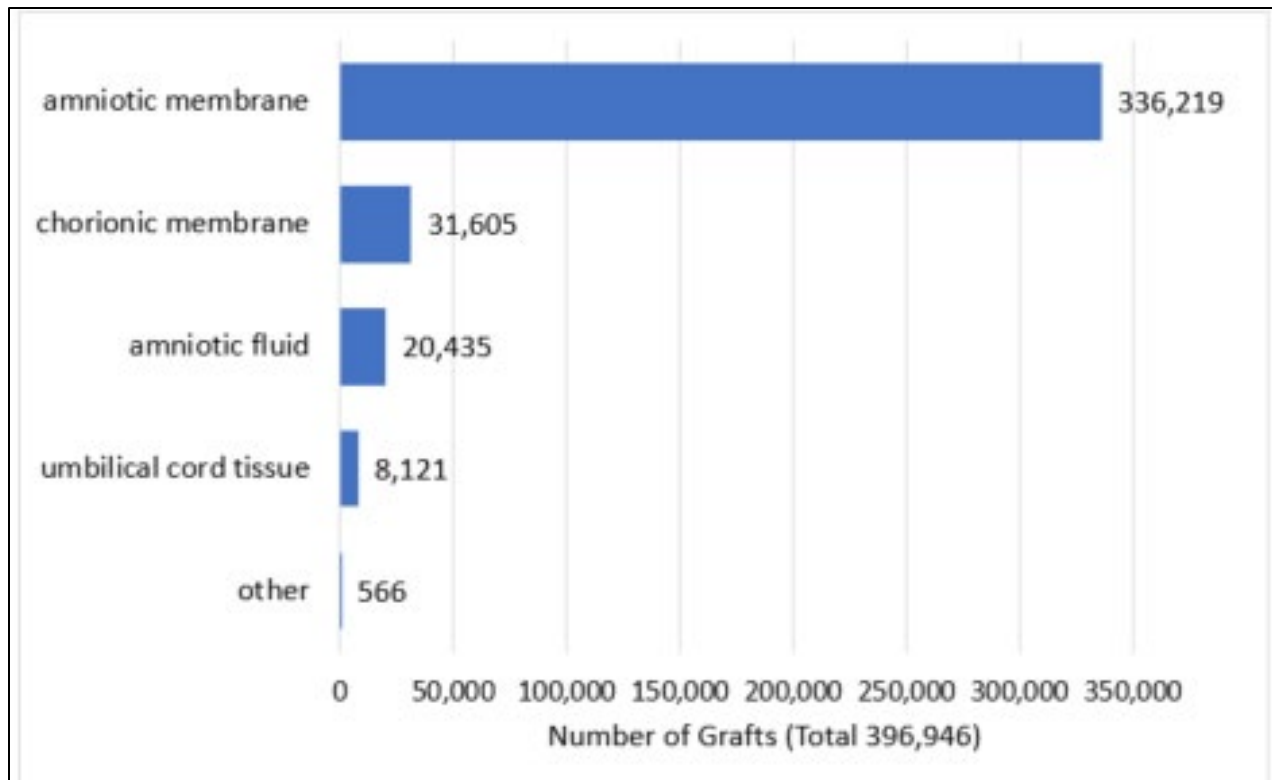


Figure 57 - Number of Distributed Tissue Grafts from Living Donors in 2015 (25 Banks)

TOTAL Number of Distributed Tissue Grafts from Living Donors

Note – The total number of distributed tissue grafts includes more types of tissue than those presented above in Figure 57.

For 2015, 26 banks (86.7% of the banks that distributed tissues from living donors) distributed a total of 430,662 tissue grafts from living donors (median 1,653).

Implant Reports

Number of Banks that Received Implant Reports for the Distributed Allografts

For 2015, 53 banks provided information on the percentage ranges of distributed allografts for which they received implant reports from hospitals/surgeons/dentists regarding the allografts' use.

As presented in Figure 58, 18.9% of the banks received implant reports for 0-25% of the distributed allografts; 34.0% of the banks received implant reports for 26-50% of the distributed allografts; 28.3% of the banks received implant reports for 51-75% of the distributed allografts; and, 18.9% of the banks received implant reports for 76-100% of the distributed allografts.

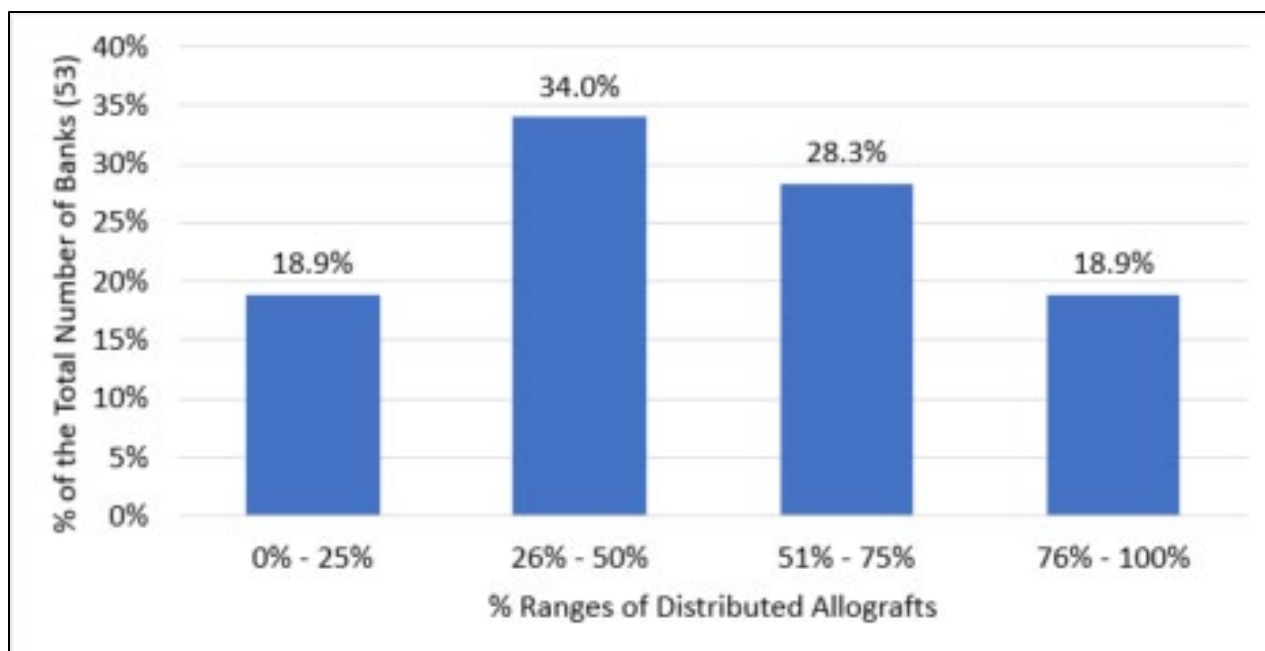


Figure 58 - Percentage of Banks that Received Implant Reports for the Distributed Allografts in 2015 (53 Banks)

Number of Banks that Tracked Electronically the Number of Implant Cards Submitted

For 2015, 27 banks reported tracking electronically the number of implant cards submitted by the hospitals/surgeons/dentists regarding the allografts' use.

International Distribution of Tissues from Deceased Donors

For 2015, 30 banks (50.8% of the banks that distributed human tissues) indicated that they distributed internationally tissues from U.S. donations.

Twenty-six banks (86.7% of the banks that reported distributing tissues internationally) exported tissues from U.S. deceased donors to 31 countries.

As presented in Table 27, the highest importer countries, according to the number of banks that provided them with tissues from deceased donors in the U.S. are as follows: United Kingdom (16 banks), Canada (15 banks), Korea/S. Korea (13 banks), Turkey (9 banks), New Zealand (8 banks), Chile, Colombia, Singapore, Switzerland (7 banks/country), Greece, Mexico (6 banks/country), Germany, Israel, Netherlands Peru (5 banks/country), Dominican Republic, Puerto Rico (4 banks/country), Austria, Italy, Taiwan, Thailand (3 banks/country), Guatemala, Panama (2 banks/country), Cyprus, Ecuador, El Salvador, Hong Kong, India, Japan, Spain, Sweden 1 bank/country.

Table 27 - List of Countries to which Tissues from U.S. Deceased Donations Were Distributed in 2015 (26 Banks)

Row Number	Country	Number of Banks	% of Total Number of Banks
1	United Kingdom	16	61.5%
2	Canada	15	57.7%
3	Korea/S. Korea	13	50.0%
4	Turkey	9	34.6%
5	New Zealand	8	30.8%

Row Number	Country	Number of Banks	% of Total Number of Banks
6	Chile, Colombia, Singapore, Switzerland	7 / country	26.9% / country
7	Greece, Mexico	6 / country	23.1% / country
8	Germany, Israel, Netherlands, Peru	5 / country	19.2% / country
9	Dominican Republic, Puerto Rico	4 / country	15.4% / country
10	Austria, Italy, Taiwan, Thailand	3 / country	11.5% / country
11	Guatemala, Panama	2 / country	7.7% / country
12	Cyprus, Ecuador, El Salvador, Hong Kong, India, Japan, Spain, Sweden	1 / country	3.8% / country
13	Total	26	100.0%

International Distribution of Tissues from Living Donors

For 2015, 7 banks (23.3% of the banks that reported distributing tissues internationally) exported tissues from U.S. living donors to 15 countries.

As presented in Table 28, the top importer countries, according to the number of banks that provided them with tissues from living donors in the U.S. are as follows: Argentina, Canada, Korea/S. Korea, United Kingdom (2 banks each) and Austria, Cyprus, Dominican Republic, Greece, Netherlands, New Zealand, Puerto Rico, Sweden, Switzerland, Taiwan, Turkey (1 bank each).

Table 28 - List of Countries to which Tissues from U.S. Living Donations Were Distributed in 2015 (7 Banks)

Country	Number of Banks
Argentina, Canada, Korea/S. Korea, United Kingdom	2 / country
Austria, Cyprus, Dominican Republic, Greece, Netherlands, New Zealand, Puerto Rico, Sweden, Switzerland, Taiwan, Turkey	1 / country
Number of Banks	7

Communicable Disease Testing and Adverse Outcome Reports

The number of banks that responded to the survey on communicable disease testing was 40 in 2015 and 39 in 2012.

Types of Tests Used to Confirm a Repeat-Reactive Syphilis Screening Test

For 2015, 40 banks provided information about the types of tests they relied upon to confirm a repeat-reactive syphilis screening test. Six of the 40 banks (15%) indicated that they did not perform confirmatory testing.

As presented in Figure 59, the most often mentioned tests were as follows: FTA-ABS (58.8% of the banks), CAPTIA TM Syphilis (T. Pallidum) – G (50% of the banks), VDRL, Olympus PK TP System, and ASI TPHA Test (14.7% of banks each), TPHA Screen (8.8% of banks), MHA-TP (2.9% of banks). Grouped under the name “other” are a variety of other tests that were mentioned each by 1 bank (2.9%) (BD Macro-Vue RPR, RPR (non-treponemal syphilis), RPR Titer, Serodia TP-PA, TP-PA, Fuji-Rubio RPR Confirmatory Treponemal antibody test, SCIMEDX IFA anti-Treponemal Pallidum, and Trinity BioTech-MarDx Diagnostics FTA-ABS Confirmatory test).

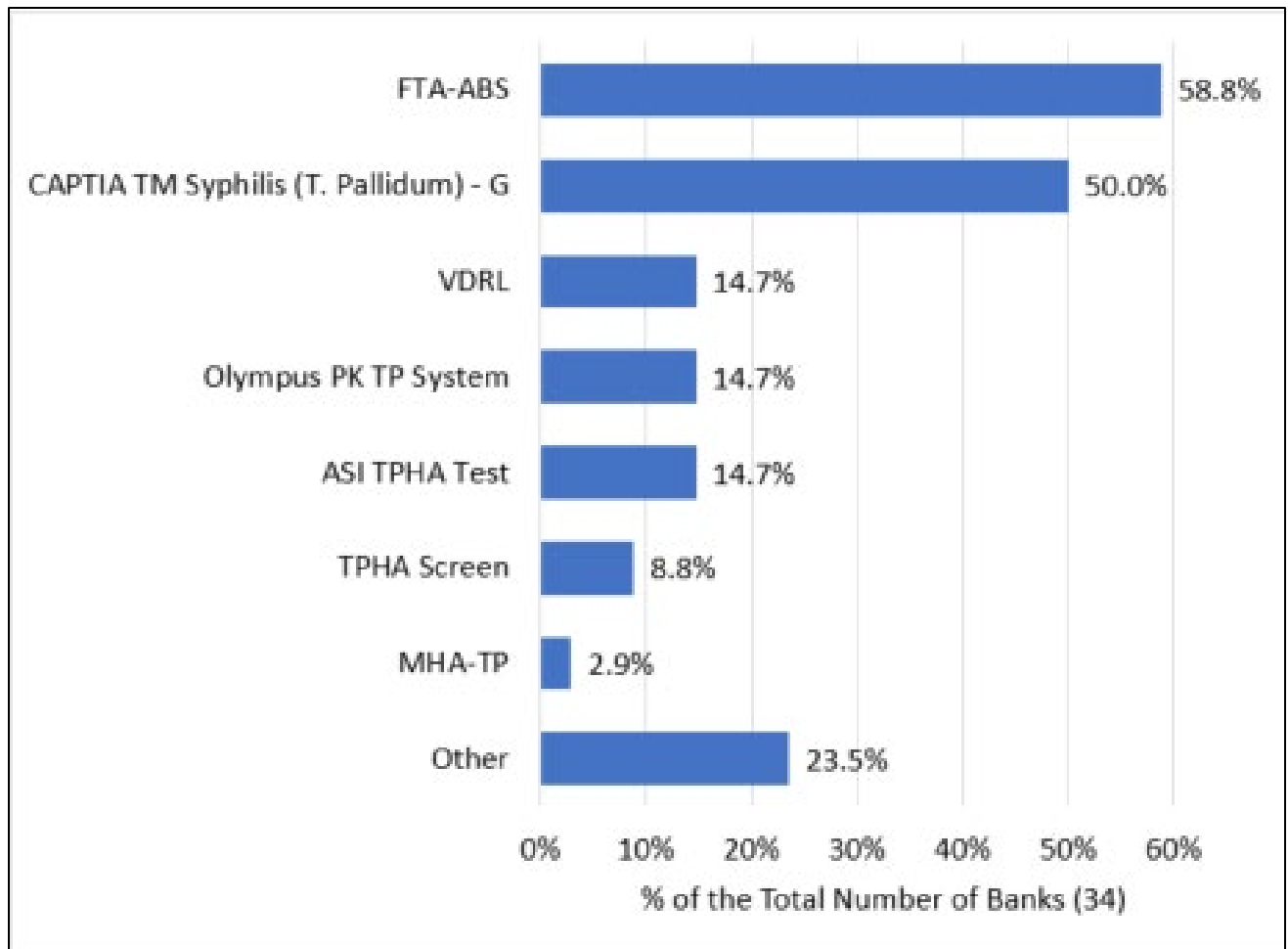


Figure 59 - Types of Tests Used to Confirm a Repeat-Reactive Syphilis Screening Test in 2015 (34 Banks)

Deceased Donors

Types of Assays Used to Screen Deceased Donors for Infectious Diseases

For 2015, 29 banks provided information about the assays they used to screen deceased donors for infectious diseases.

As presented in Figure 60, the most often mentioned types of assays were: HBsAg, Anti-HBcAb (total) (100% of banks each); Anti-HIV-1/2, Anti-HCV (96.6% of banks each); Anti-HTLV I/II, Non-treponemal (58.6% of banks each); NAT (HIV-1), NAT (HIV- 1/HBV/HCV), NAT (HCV), Treponemal (51.7% of banks each); NAT (HBV) (44.8% of banks); NAT (HIV- 1/HIV -2/HBV/HCV) (41.4% of banks); NAT (HIV-2) (34.5% of banks), NAT (HIV – 1/ HCV), Anti-HIV-2 (31.0%), NAT (WNV), Anti-HBcAB (IgM) (24.1% of banks) and Anit-T.cruzi, Anti-CMV (10.3% of banks).

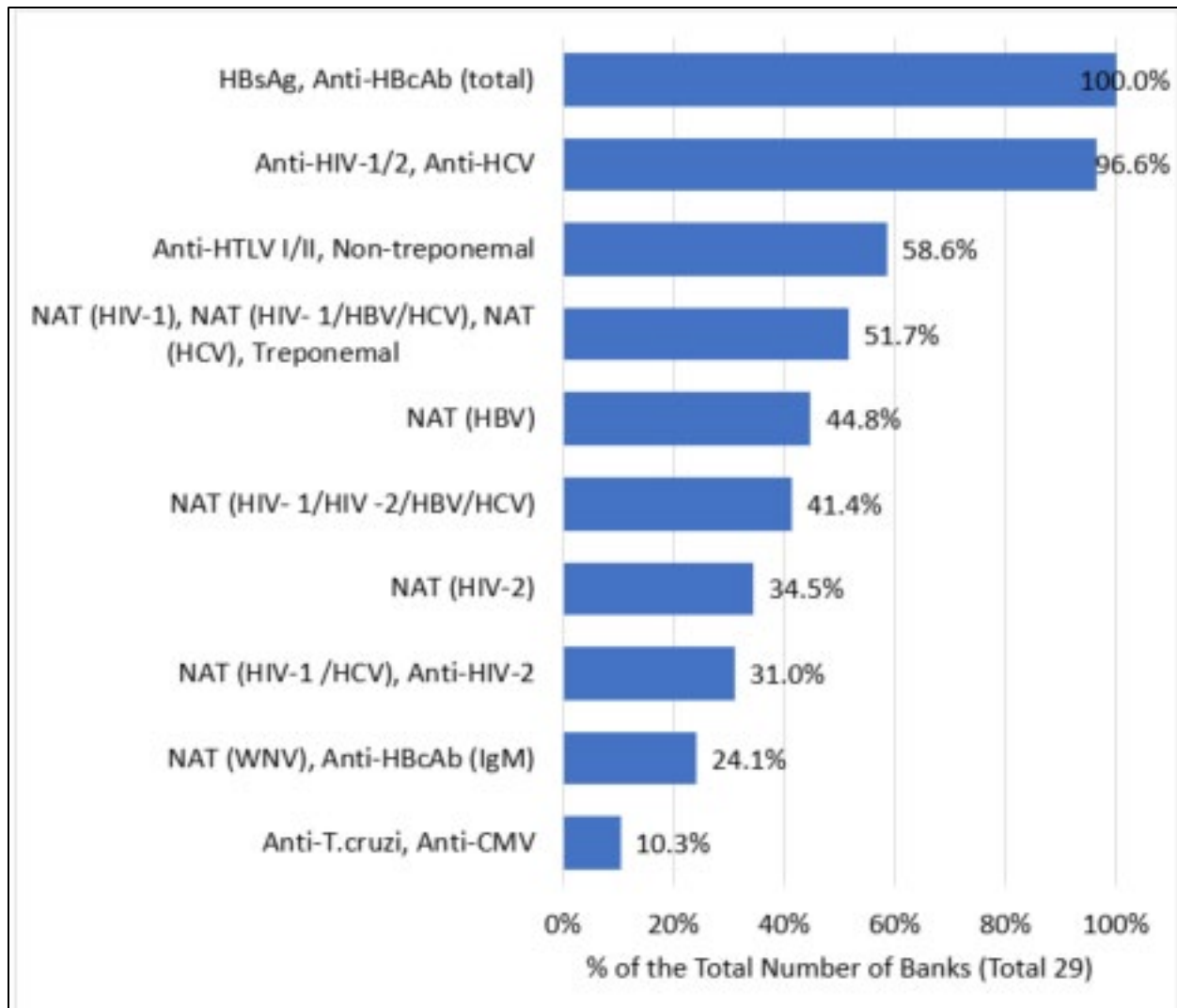


Figure 60 - Types of Assays used to Screen Deceased Donors for Infectious Diseases in 2015 (29 Banks)

Types of Assays Used for Confirmatory/Supplemental Testing of Deceased Donors

For 2015, 15 banks provided information about the assays they used for confirmatory/supplemental testing of deceased donors.

As presented in Figure 61, the most often mentioned types of confirmatory/supplemental testing assays were: Anti-HTLV I/II (80% of the banks); Anti-HIV-1/2, Anti-HCV, HBsAg (66.7% of banks each); Anti-HBcAb (total) (60% of banks); NAT (HBV), NAT (HIV-1), NAT (HCV) (53.3% of banks each); NAT (HIV-1/HBV/HCV) (46.7% of banks each); NAT (WNV), NAT (HIV-1/HCV), Anti-HIV-2, NAT (HIV-1/HIV-2/HBV/HCV), NAT (HIV-2) (40% of the banks each) and Anti-T.cruzi, Anti-HBcAb (IgM) (33.3% of the banks) and Anti-CMV (26.7% of the banks).

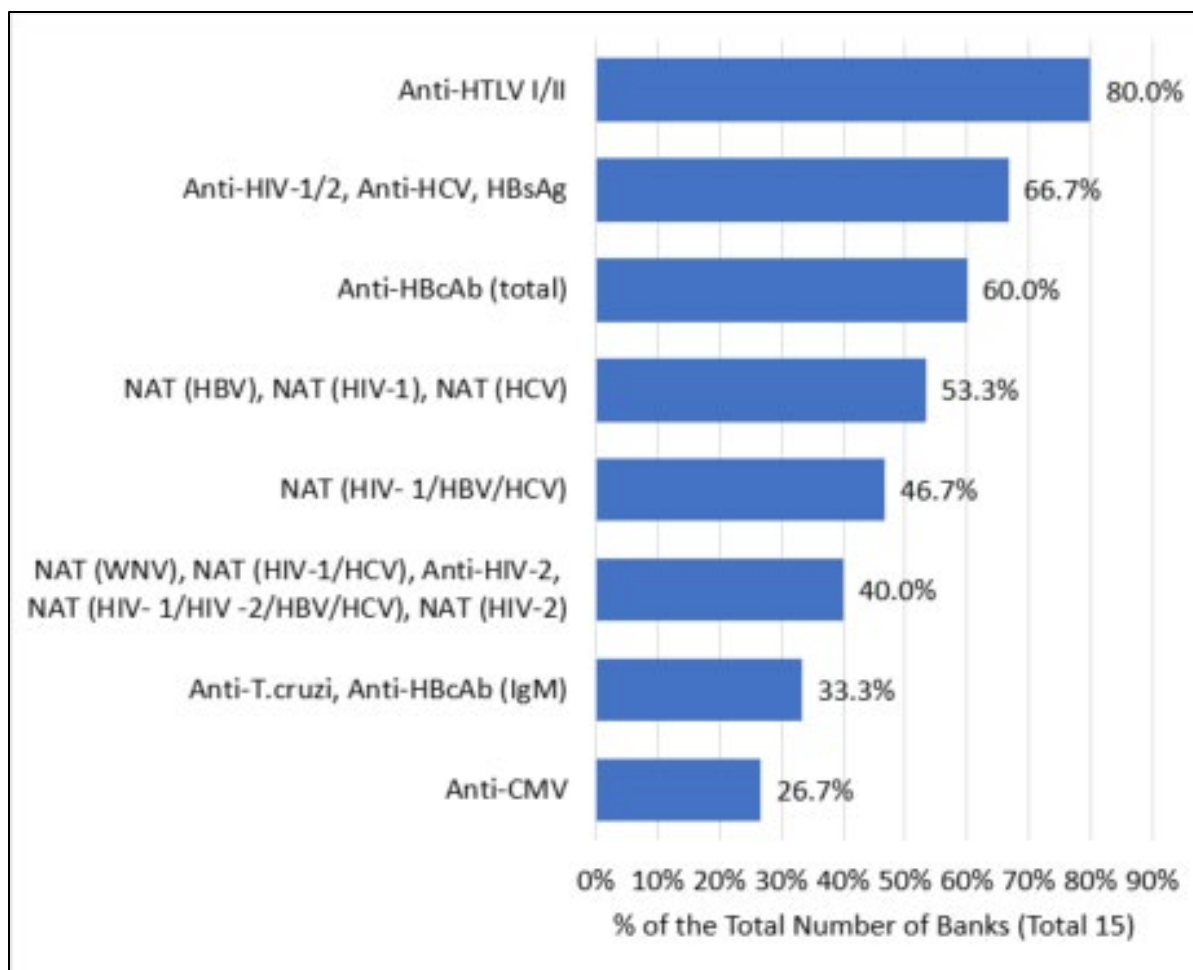


Figure 61 - Types of Assays Used for Confirmatory/Supplemental Testing of Deceased Donors in 2015 (15 Banks)

Living Donors

Types of Assays Used to Screen Living Donors for Infectious Diseases

For 2015, 18 banks provided information about the assays they used to screen living donors for infectious diseases.

As presented in Figure 62, the most often mentioned screening assays were as follows: HBsAg (100% of the banks); Anti-HBcAb (total), Anti-HIV-1/2 (94.4% of banks each); Anti-HCV (88.9% of banks); Anti-HTLV I/II (83.3% of banks); Non-treponemal (66.7% of banks); Treponemal (55.6% of banks); NAT (WNV), NAT (HIV-1/HIV-2/HBV/HCV), NAT (HIV-1/HBV/HCV) (50% of banks each); NAT (HCV) (44.4% of banks), Anti-CMV, NAT (HIV-2), NAT (HIV-1) (38.9% of banks), NAT (HIV-1/HCV), Anti-HIV-2 (33.3% of banks) and Anti-HBcAb (IgM), NAT (HBV) (27.8% of banks).

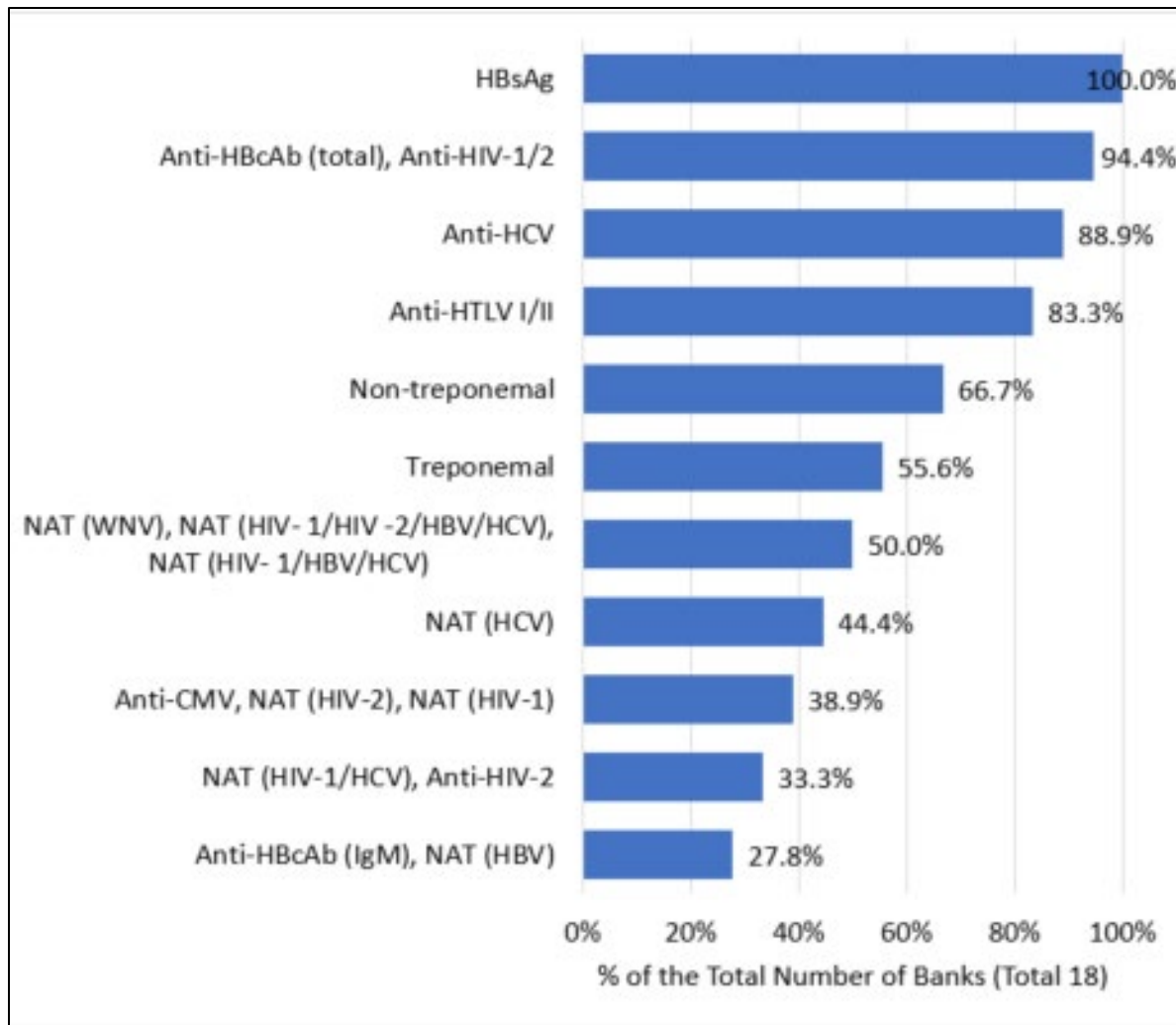


Figure 62 - Types of Assays Used to Screen Living Donors for Infectious Diseases in 2015 (18 Banks)

Types of Assays Used for Confirmatory/Supplemental Testing of Living Donors

For 2015, 7 banks provided information about the assays they used for confirmatory/supplemental testing of living donors.

As presented in Figure 63, the most often mentioned types of assays they used for confirmatory / supplemental testing of living donors were: Anti-HBcAb (IgM), Anti-HTLV I/II (57.1% of the banks each), Anti-HCV, Anti-HIV-1/2, Anti-T.cruzi, HBsAg, NAT (WNV) (42.9% of the banks each) and Anti-CMV, Anti-HBcAb (total), Anti-HIV-2, NAT (HBV), NAT (HCV), NAT (HIV - 1/HBV/HCV), NAT (HIV - 1/HIV - 2/HBV/HCV), NAT (HIV - 1), NAT (HIV -1/HCV), NAT (HIV - 2), NAT (HIV -2) (28.6% of banks).

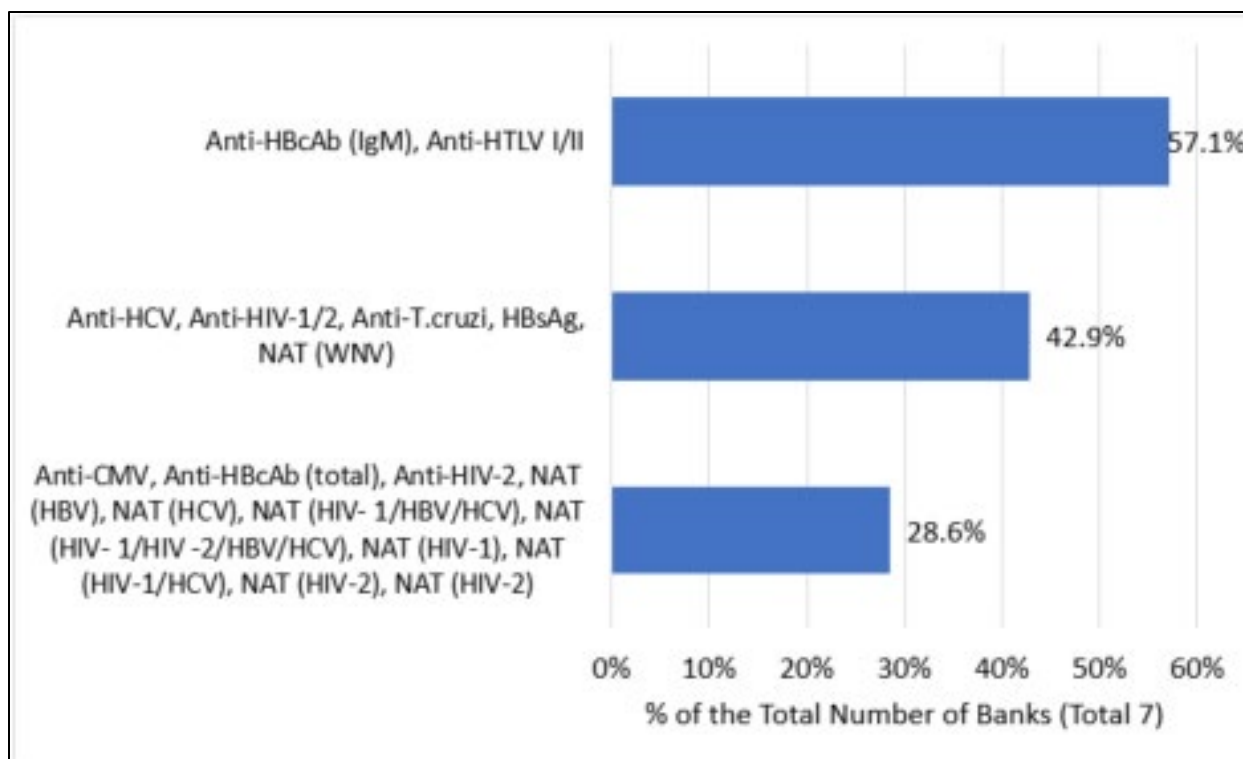


Figure 63 - Types of Assays Used for Confirmatory/Supplemental Testing of Living Donors in 2015 (7 Banks)

Adverse Outcome Reports for Tissue Products Regulated Solely Under Section 361 of the PHSA

For 2015, 33 of 34 (94.1%) banks that process tissue provided information on adverse event reporting. Of these 33 banks, 17 indicated receiving reports of suspected transmission of disease or graft failure following transplantation.

Received Reports of Suspected Transmission of Disease or Graft Failure Following Transplantation

For 2015, 16 banks received a total of 356 reports of suspected transmission of disease or of graft failure following transplantation (Table 29). Eleven banks received a total of 117 reports of graft failure (only) following transplantation. The causes of suspected transmission of disease are as follows: 147 bacterial infections (11 banks), 78 other infections (6 banks), 6 viral infections (6 banks), 5 malignancies (3 banks), 3 fungal infections (3 banks) and graft failure only 117 malignancies (11 banks).

Table 29 - Received Reports of Suspected Transmission of Disease or Graft Failure Following Transplantation in 2015 (16 Banks)

Causes of Diseases or of Graft Failure	Number of Banks that Provided Information	Total Number of Reports
Bacterial	11	147
Other infection	6	78
Viral	6	6
Malignancy	3	5
Fungal	3	3
Graft failure (only)	11	117
Grand Total	16	356

Number of Banks that Further Reported to the FDA the Received Reports of Suspected Transmission of Disease or Graft Failure Following Transplantation – Comparison of 2015 and 2012 Results

The number of banks that provided information about the reports of suspected transmission of disease or of graft failure following transplantation which were further reported to the FDA was 7 in 2015 and 8 in 2012.

As presented in Figure 64, most of the reports further transmitted to FDA were due to bacterial infections (62 reports in 2015, and 86 reports in 2012), other infections (14 reports in 2015, and 56 reports in 2012), viral (2 reports in 2015, and 1 report in 2012), graft failure (only) (1 report in 2015, and 4 reports in 2012), malignancy (1 report in 2015, and 1 report in 2012) and fungal (1 report in 2015, and 7 reports in 2012).

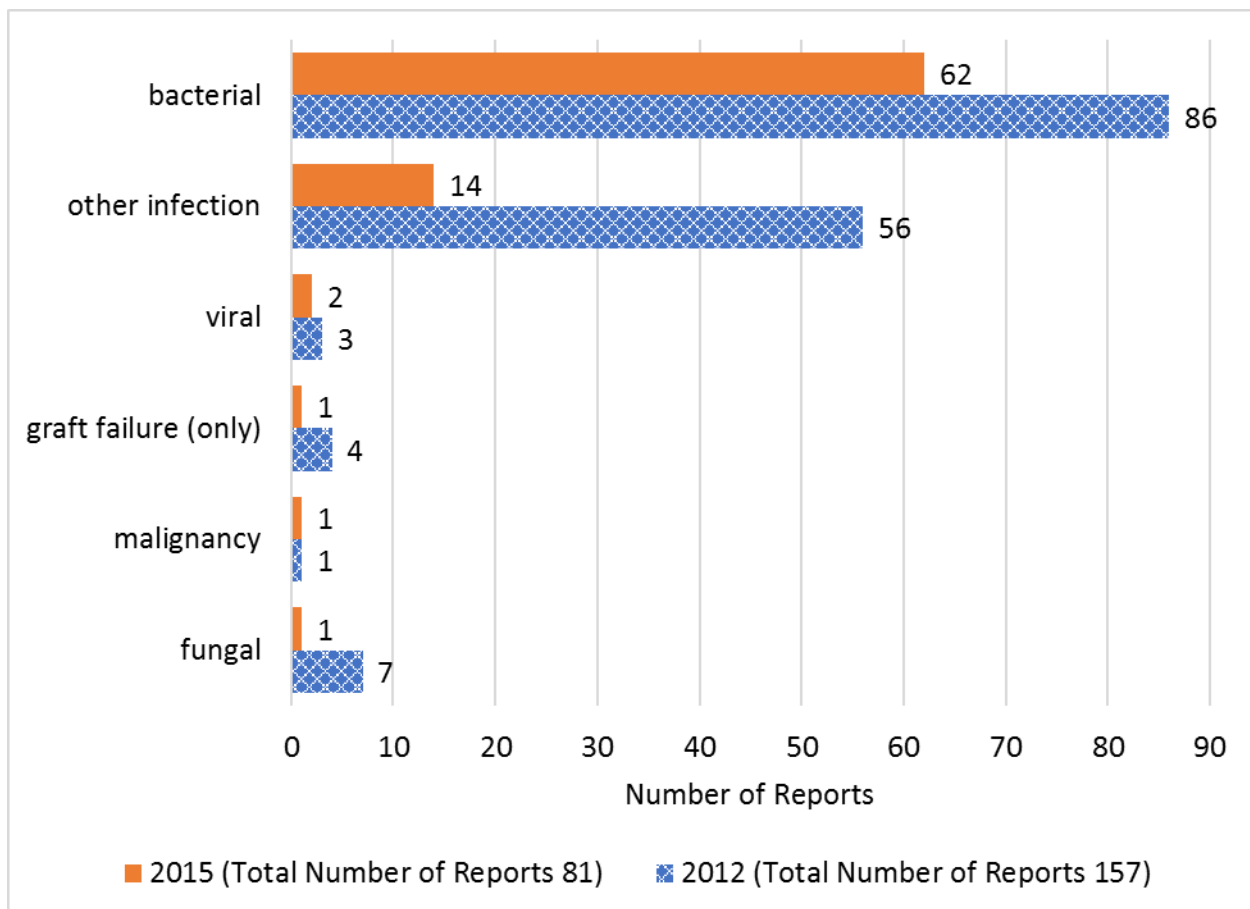


Figure 64 - Received Reports of Suspected Transmission of Disease or Graft Failure Following Transplantation Reported to the FDA in 2015 (7 Banks) and 2012 (8 Banks)

Number of Banks that Further Reported to International Health Authorities the Received Reports of Suspected Transmission of Disease Following Transplantation – Comparison of 2015 and 2012 Results

The number of banks that provided information about the reports of suspected transmission of disease or of graft failure following transplantation which were further reported to international health authorities was 1 in 2015 and 2 in 2012.

As presented in Figure 65, the reports further transmitted to international health authorities were due

to bacterial infection (3 reports in 2015, and 4 reports in 2012) and to other infections (2 reports in 2012).

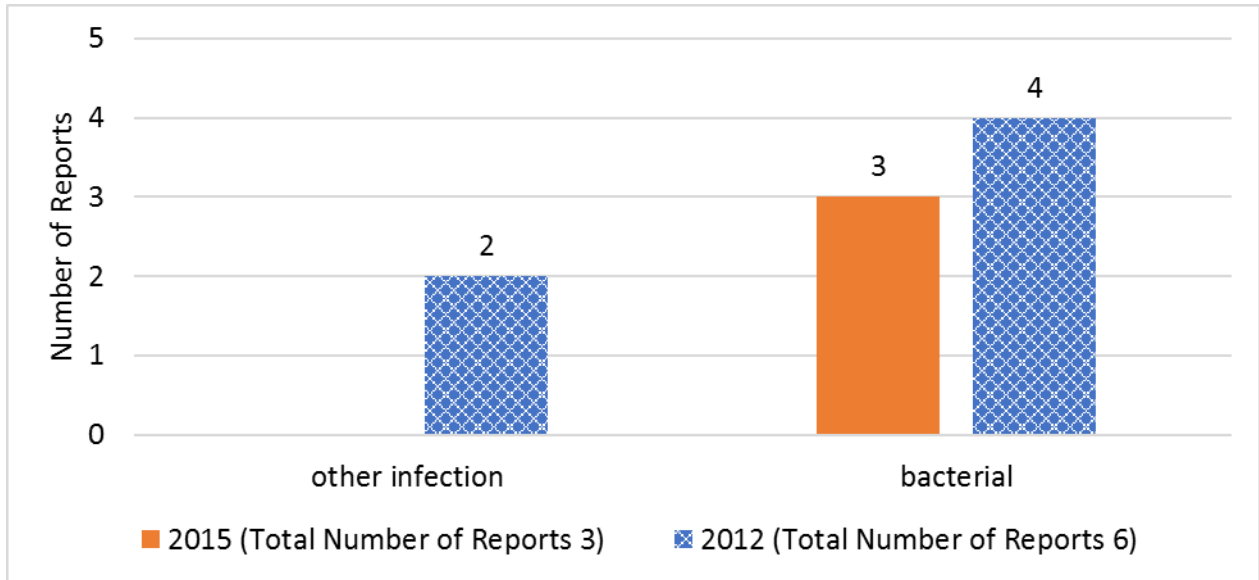


Figure 65 - Received Reports of Suspected Transmission of Disease or Graft Failure Following Transplantation Reported to International Health Authorities in 2015 (1 Bank) and 2012 (2 Banks)

Number of Banks that Further Reported to Local/State Health Authorities the Received Reports of Suspected Transmission of Disease or Graft Failure Following Transplantation – Comparison of 2015 and 2012 Results

The number of banks that provided information about the reports of suspected transmission of disease or of graft failure following transplantation which were further reported to local/state health authorities was 7 in 2015 and 6 in 2012.

As presented in Figure 66, most of the reports further transmitted to local/state health authorities were due to bacterial infections (49 reports in 2015, and 51 reports in 2012), other infections (14 reports in 2015, and 44 reports in 2012), graft failure only (3 reports in 2015, and 9 reports in 2012) viral (3 reports in 2015, and 3 reports in 2012), fungal (2 reports in 2015, and 3 reports in 2012) and malignancy (1 report in 2015).

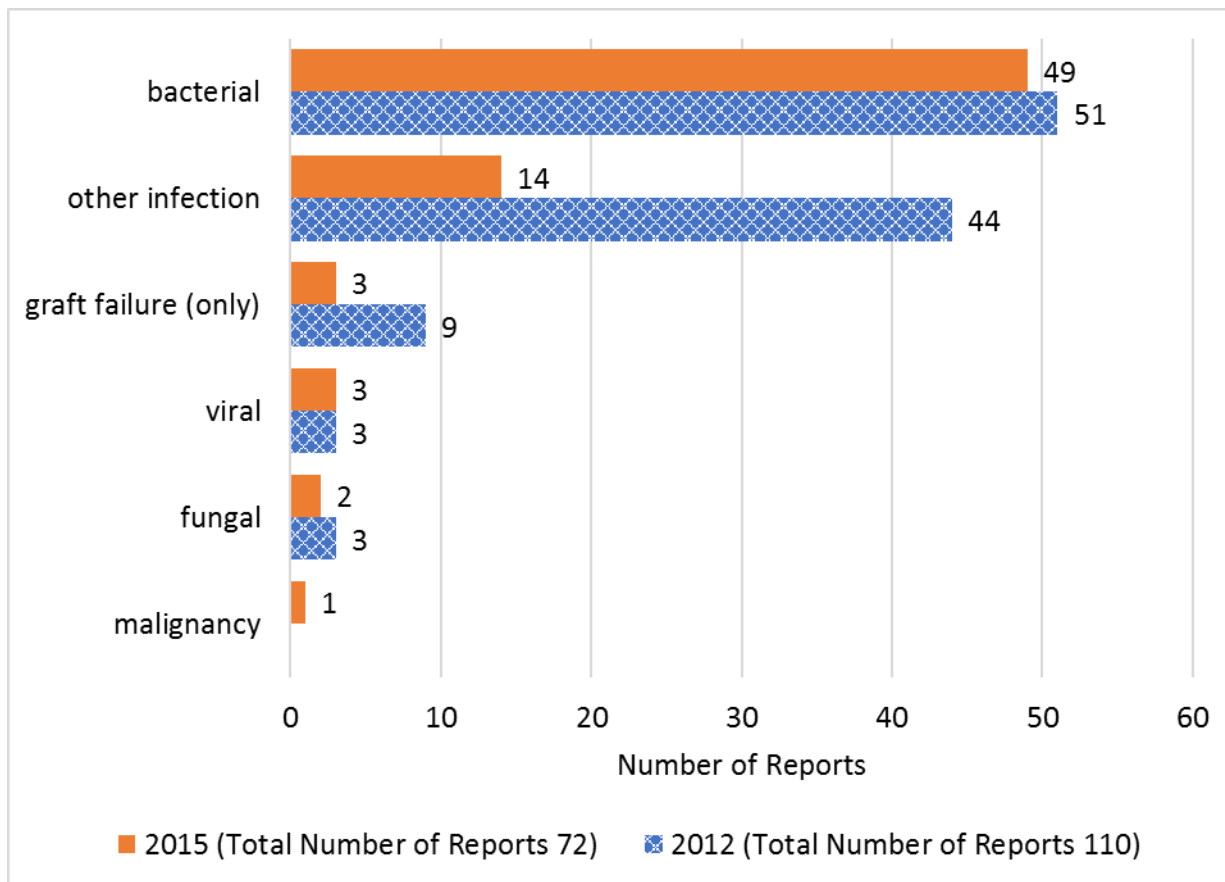


Figure 66 - Received Reports of Suspected Transmission of Disease or Graft Failure Following Transplantation Reported to Local/State Health Authorities in 2015 (7 Banks) and 2012 (6 Banks)

Received Reports of Suspected Transmission of Disease or Graft Failure Following Transplantation with the Assessment/Outcome: “Not Otherwise Specified”

For 2015, 14 banks received a total of 319 reports of suspected transmission of disease or of graft failure following transplantation with the assessment “not otherwise specified” (Table 30). Nine banks received a total of 108 reports of graft failure (only) following transplantation. The causes of suspected transmission of disease are as follows: 122 bacterial infections (10 banks), 76 other infections (5 banks), 5 viral infections (5 banks), 5 malignancies (5 banks), and 3 fungal infections (3 banks).

Table 30 - Received Reports of Suspected Transmission of Disease or Graft Failure Following Transplantation with Report Assessment “Not Otherwise Specified” in 2015 (14 Banks)

Causes of Diseases or of Graft Failure	Number of Banks that Provided Information	Total Number of Reports
Bacterial	10	122
Other infection	5	76
Viral	5	5
Malignancy	5	5
Fungal	3	3
Graft failure (only)	9	108
Grand Total	14	319

Number of Banks that Received Reports of Suspected Transmission of Disease or Graft Failure Following Transplantation with the Assessment/Outcome: “Resulted in Recipient Death” – Comparison of 2015 and 2012 Results

The number of banks that provided information about the received reports of suspected transmission of disease or of graft failure following transplantation with the outcome “resulted in recipient death” was 2 in 2015 and 2 in 2012.

As presented in Figure 67 most of the assessments/outcomes “resulted in recipient death” were due to other infections (15 reports in 2015, and 14 reports in 2012), bacterial infection (14 reports in 2015, and 13 reports in 2012), graft failure (only) (6 reports in 2015, and 3 reports in 2012), fungal (1 report in 2015, and 1 report in 2012) and viral (1 report in 2012).

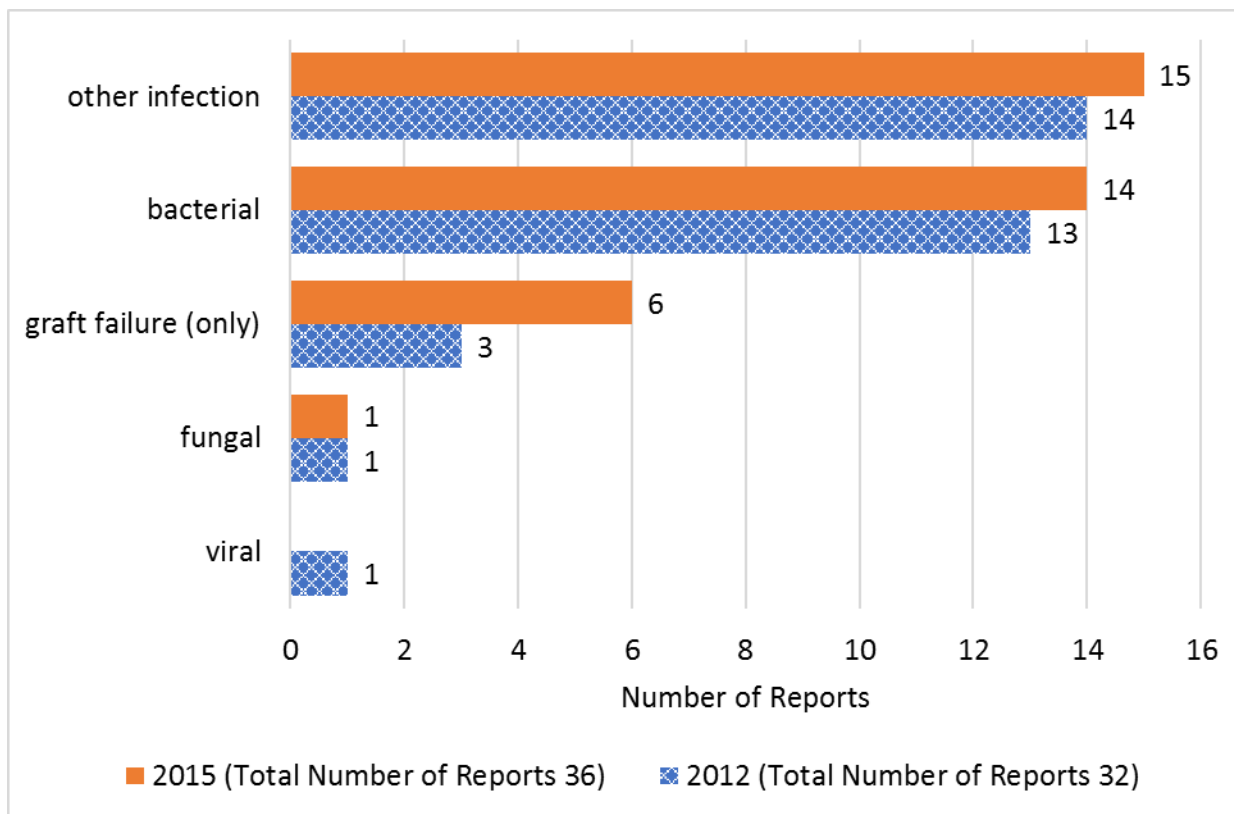


Figure 67 - Reports of Suspected Transmission of Disease or Graft Failure Following Transplantation with Report Outcome “Resulted in Recipient Death” in 2015 (2 Banks) and 2012 (2 Banks)

Adverse Outcome Reports for Tissue Products Regulated as: Tissue as a Device, Tissue as a Drug, or Tissue as a Biological Product

Number of Banks that Further Reported to the FDA the Received Reports of Suspected Transmission of Disease or Graft Malfunction Following Transplantation – Comparison of 2015 and 2012 Results

The number of banks that provided information about the reports of suspected transmission of disease or of graft failure following transplantation which were further reported to the FDA was 6 in 2015 and 8 in 2012.

As presented in Figure 68, most of the reports further transmitted to the FDA were due to bacterial infections (9 reports in 2015, and 24 reports in 2012), graft malfunction (only) (6 reports in 2015, and 1

report in 2012), other infection (3 reports in 2015, and 2 reports in 2012), viral (1 report in 2012), malignancy (1 report in 2012) and fungal (8 reports in 2012).

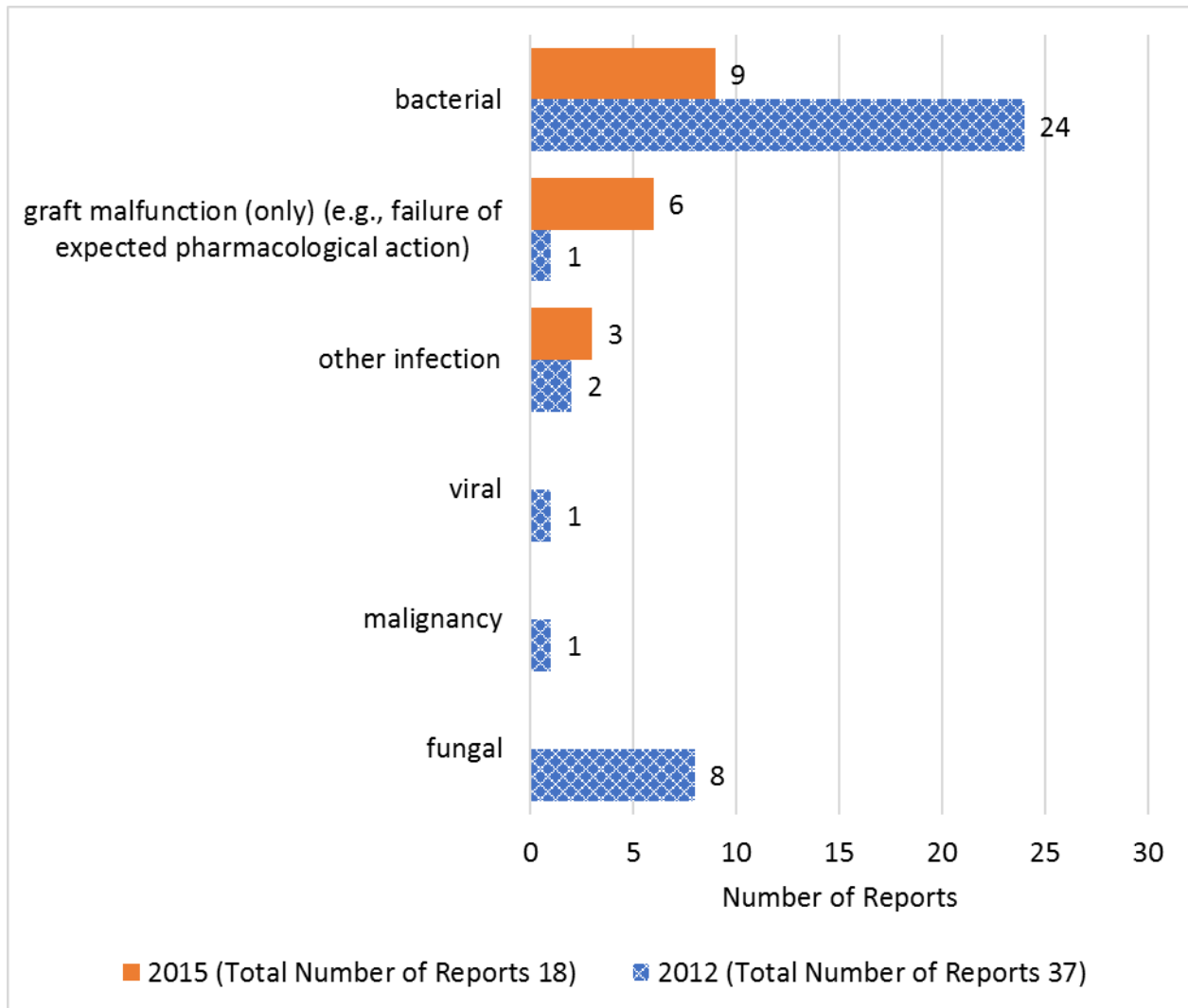


Figure 68 - Received Reports of Suspected Transmission of Disease or Graft Malfunction Following Transplantation Reported to the FDA in 2015 (6 Banks) and 2012 (8 Banks)

Number of Banks that Further Reported to Local/State Health Authorities the Received Reports of Suspected Transmission of Disease or Graft Malfunction Following Transplantation – Comparison of 2015 and 2012 Results

The number of banks that provided information about the reports of suspected transmission of disease or of graft failure following transplantation which were further reported to the local/state health authorities was 4 in 2015 and 5 in 2012.

As presented in Figure 69, most reports further transmitted to local/state health authorities were due to graft malfunction (only) (4 reports in 2015, and 2 reports in 2012), and to bacterial infections (3 reports in 2015, and 5 reports in 2012), other infection (1 report in 2015 and 2 reports in 2012) and viral (1 report in 2015 and 1 report in 2012).

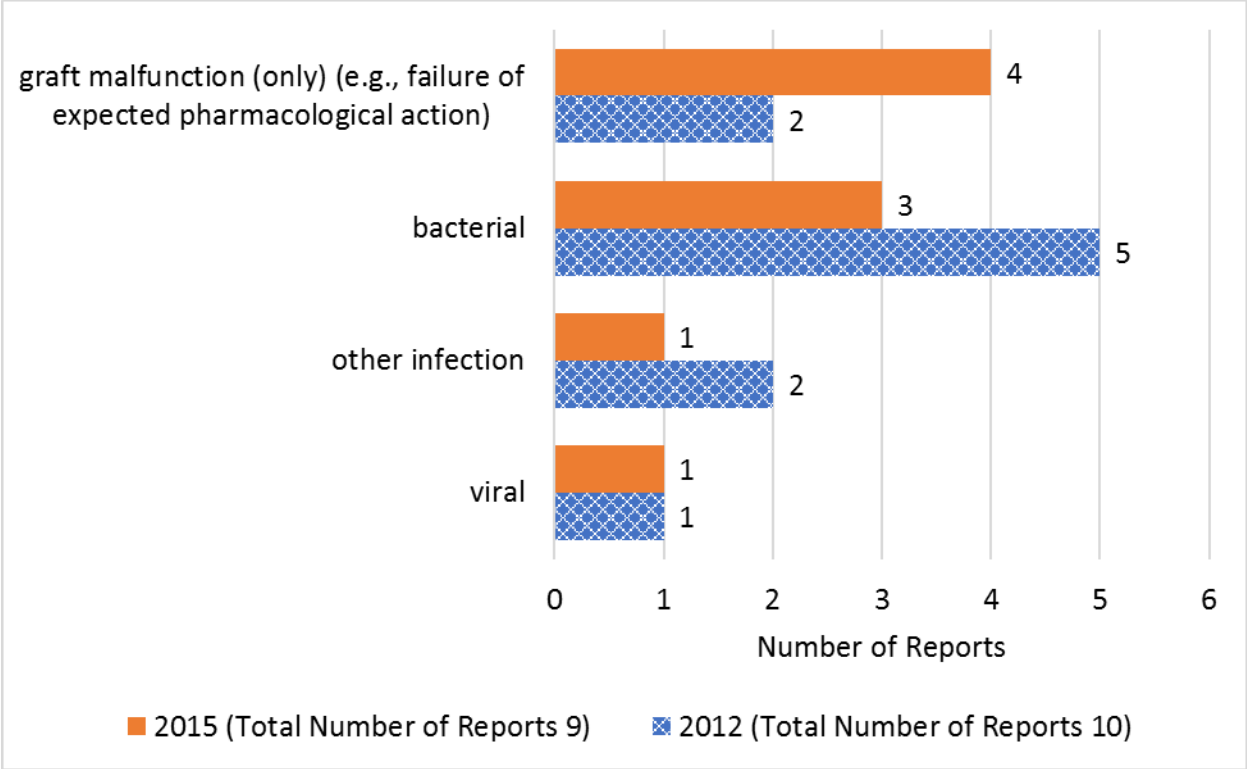


Figure 69 - Reports of Suspected Transmission of Disease or Graft Malfunction Following Transplantation Reported to Local/State Health Authorities in 2015 (4 Banks) and 2012 (5 Banks)

NTRUS – DEFINITIONS OF TERMS

From the AATB Standards for Tissue Banking

Words that are defined here appear throughout the survey.

ACQUISITION (BT) – The point after delivery at which tissue is under the control of the tissue bank.

ADVERSE OUTCOME – An undesirable effect or untoward complication in a recipient consequent to or reasonably related to tissue transplantation.

ALLOGENEIC – Used as an adjective to modify donation, tissue, donor or recipient when transplantation is intended for a genetically different person.

ALLOGRAFT – Tissue intended for transplantation into a genetically different person.

AORTOILIAC GRAFT – The distal segment of the abdominal aorta, including the bifurcation and proximal segments of both the left and right common iliac arteries.

ARTERIAL GRAFT – A segment of peripheral artery that is recovered, processed and preserved.

AUTHORIZATION – Permission given after adequate information concerning the donation, recovery and use of tissues is conveyed.

AUTHORIZING PERSON – Upon the death of the donor, the person, other than the donor, authorized by law to make an anatomical gift.

AUTOGRAFT – Tissue intended for implantation, transplantation or infusion into the living donor from whom it was recovered.

AUTOLOGOUS – Used as an adjective to modify donation, tissue, donor or recipient when donation is intended only from him/herself and transplantation is intended only to him/herself.

BIRTH TISSUE (BT) – gestational tissue donated at the time of delivery of a living newborn. This includes placenta, Wharton's jelly, amniotic fluid, chorionic membrane, amniotic membrane, placental/chorionic disc, umbilical veins, and umbilical cord tissue.

CARDIAC TISSUE – Tissue type that includes, but is not limited to, valved conduits, non-valved conduits, aortoiliac grafts, and patch grafts.

CELLULAR TISSUE – viable cells that are autologous or allogeneic, committed or uncommitted, and non-expanded.

CRYOPRESERVED – Frozen with the addition of, or in a solution containing, a cryoprotectant agent such as glycerol or dimethylsulfoxide.

DESICCATION – The removal of water from tissue. For example, desiccation methods may include chemical (alcohol), critical/supercritical drying, simple air drying, or drying in a desiccator.

DISTRIBUTION – A process that includes receipt of a request for tissue, selection of appropriate finished tissue, preparation for transport, any required inspections, and subsequent shipment and delivery of tissue to another tissue bank, tissue distribution intermediary, tissue dispensing service, or end-user.

DONOR ELIGIBILITY ASSESSMENT – The evaluation of available information about a potential donor to determine whether the donor meets qualifications specified in the AATB Standards

DONOR REGISTRY – A database established in accordance with law, consisting of legally valid documents of gift.

DURA MATER – A type of soft tissue that includes the pachymeninx (thick, membranous) tissue covering the brain.

END-USER – A health care practitioner who performs transplantation procedures.

FINISHED TISSUE – Tissue that has been fully processed, enclosed in its final container, labeled, and released to distribution inventory.

INFORMED CONSENT – Permission given by a living donor (LD) or client depositor who is presented with a description of the scope, use and any risks or benefits to her or him of the proposed donation, and who has been given the opportunity to ask questions and receive accurate answers. An LD who gives her or his informed consent to donation shall sign a record of the informed consent.

LIVING DONOR – A person who consents to the recovery or collection of his or her tissue, where recovery or collection is to take place while she or he is alive. For all living donors, (LD) standards apply, then tissue-specific standards apply. A living donor is a type of donor and, unless otherwise specified, standards that apply to donors in general apply to living donors.

LYOPHILIZED – Tissue dehydrated for storage by conversion of the water content of frozen tissue to a gaseous state under vacuum that extracts moisture.

NONCONFORMITY - A finding that identifies non-fulfillment of an accreditation requirement, standard, policy, process, procedure, or specification.

NON-TERMINAL IRRADIATION – Ionizing radiation used to reduce microbes prior to processing.

NON-VALVED CONDUIT – A length of cardiac outflow tract (aortic or pulmonic) from which the valve structure has been removed or intentionally rendered completely non-functional.

OSTEOARTICULAR GRAFT – A weight bearing allograft with intact articular surfaces, consisting of a joint with associated soft tissue and bone.

PATCH GRAFT – A segment of cardiac allograft conduit to be used in cardiovascular repair, replacement, construction, or reconstruction.

PHYSICAL ASSESSMENT – A recent ante-mortem or postmortem documented evaluation of a deceased donor's body that can identify evidence of: high-risk behavior and signs of HIV infection or hepatitis infection; other viral or bacterial infections; or, trauma to the potential recovery sites.

PHYSICAL EXAMINATION – A recent documented evaluation of a living donor's body to determine whether there is evidence of high risk behavior and that determines overall general health of the donor. After a donor risk assessment interview is completed and if any history is suspect, the physical examination should also encompass a directed examination (of a body part or region).

PLASMA DILUTION – A decrease in the concentration of the donor's plasma proteins and circulating

antigens or antibodies resulting from the transfusion of blood or blood components and/or infusion of fluids, e.g., colloid(s) and/or crystalloid(s).

PROCESSING – Any activity performed on tissue other than donor screening, donor testing, tissue recovery, collection, or acquisition functions, storage, distribution or dispensing. It includes but is not limited to disinfecting, sterilizing, packaging, labeling, and testing tissue.

RECOVERY – Obtaining tissue other than reproductive tissue from a donor that is intended for use in human transplantation, therapy, research or education.

RECOVERY SITE – The immediate area or room where a tissue recovery takes place (e.g., dedicated tissue recovery site, healthcare facility operating room, autopsy suite).

SATELLITE FACILITY – A facility operated or owned by the tissue bank and located in a physically separate location from its primary address, and where any tissue banking activities occur or where any tissue banking services are provided.

SKIN - A membranous soft tissue type that includes, but is not limited to epidermis and dermis.

STORAGE – The maintenance of tissue for future use.

SURGICAL BONE – Any bone from a living donor for allogeneic use such as a femoral head removed during surgery.

TISSUE – A functional group of cells. The term is used collectively in Standards to indicate both cells and tissue.

TISSUE BANK – An entity that provides or engages in one or more services involving tissue from living or deceased persons for transplantation purposes. These services include obtaining authorization and/or informed consent, assessing donor eligibility, recovery, collection, acquisition, processing, storage, labeling, distribution, and dispensing of tissue.

TISSUE DISPENSING SERVICE – Any entity that receives, stores, and provides tissue directly to an end-user for transplantation. Tissue dispensing services may or may not be tissue banks, depending on what other functions they perform.

TISSUE DISTRIBUTION INTERMEDIARY – An intermediary agent who acquires and stores tissue for further distribution and performs no other tissue banking functions.

TRANSPLANTATION – The transfer of an allograft or autograft to a recipient.

VALVED CONDUIT – An allograft heart valve with an attached length of cardiac outflow tract (aortic or pulmonary).

VASCULAR TISSUE – Tissue type that includes, but is not limited to arterial grafts and vein grafts.

VEIN GRAFT – A segment of vein that is recovered, processed and preserved.

This term/definition appears in an AATB Guidance Document (No. 9):

DEDICATED TISSUE RECOVERY SITE – A tissue recovery room under control of, and with access restricted by, the tissue recovery agency(ies). Other than tissue recovery or other aseptic activities (e.g.,

organ perfusion or packaging), no other activities occur here, and controls include cleaning, decontamination, maintenance, and monitoring.

Definitions specifically developed for use in the NTRUS:

Tissue as a Device – (i.e., products and combination products requiring PMA or 510k clearance; regulated under the FD&C Act as well as under 21 CFR Part 1271 from Section 361 of the PHSA)
Tissue as a Biological Product (i.e., products requiring BLA or IND; regulated under Section 351 of the PHSA and/or the FD&C Act, as well as under 21 CFR Part 1271 from Section 361 of the PHSA)

Tissue as a Drug – (i.e., products requiring IND/NDA; regulated under Section 201 of the FD&C Act, as well as under 21 CFR 1271 from Section 361 of the PHSA)

Ligaments – (i.e. patellar)

Tendons – (e.g., Achilles, gracilis, anterior/posterior tibialis, semitendinosus, flexors/extensors, peroneus longus)

Osteochondral Grafts – (i.e., an allograft consisting of a section, condyle, or plug of bone with an intact articular surface)