

Supplementary file

Table S1. Donors, recipients, SAEs, and SARs of tissues (13 years) and organs (5 years) during the study period, *N (%)*.

	Donations	Distributed/Transplants	SAEs	Total SARs/ SARs CPP	Incidence SARs ‰-1 SAR/"x" Tx
Tissues	N=34 306**	Distributed=156 763	N=118	N=36/35	
Ocular tissue	24 656	26 372 (16.8)		(-)	
Cornea	23 737	19 501 (12.4)		20 /19	0.97- 1/ 1026
Sclera	527	2041 (1.3)		(-)	
Amniotic membrane	392	4830 (3.1)		(-)	
Musculoskeletal tissue	3521	117 171 (74.7)		10	0.08- 1 / 11717
Skin	2358	170 (0.1)		0	
Valves	2063	1950 (1.2)		2	1.02- 1 / 1/975
Arteries	1708	1657 (1.1)		2	1.2 – 1/ 825
Other (includes eye drops)	NA	9612 (6.1)		2*	NA
Organs	N=2287***	Transplants=5569	N=72	N=53/49	
Kidney	3072	3822 (68.6)		33(30)	7.8 – 1 / 127.4
Liver	966	894 (16.1)		11(10)	11.2 – 1/ 89.4
Lung	829	459 (8.2)		5	10.9- 1/ 91.8
Heart	256	292 (5.2)		3	10.3 – 1/ 97.3
Pancreas	127	102 (1.8)		1	9.8 – 1/ 102

*Serum eye drops; **Deceased donors; *** Living and deceased donors; (-), no data; NA, not available; CPP. Certain, probable, possible; "x", number; Tx, transplants

Table S2. Detailed characteristics of serious adverse events related to tissue donation involving a risk from the donor (A) or tissue (B) and actions implemented following their notification.

	n	Criteria ^a	Stage	Cause	I ^{bc}	Investigations and proposed actions by BV advisory committee	
A) Donor-derived risk							
Blood Tests	24						
Viral							
Hepatitis B virus (DNA)	6	1, 2	Tests	DD	6	Discard tissues. Follow-up of organ recipients (2K) and, if required, prophylactic Tt: lamivudine. Implement NAT Initial result positive. Alert Tx centers 2CT, L, and 2K. Confirmatory RNA negative (non-reliable initial kit) Initial positive HIV NAT testing. Even confirmed false positive, MSK and 2CT discarded	
Hepatitis C virus (RNA)	2	1	Tests	DD /Material	6		
Human immunodeficiency virus (NAT)	1	1	Tests	DD	6		
Antibodies to hepatitis C virus	1	1, 2	Tests	DD	6		Discard tissues. Follow-up of organ recipients (L, 2K).
Antibodies to hepatitis B virus (HBc positive, HBs negative)	1	1, 2	Tests	DD	6		Discard tissues (2CT).
Bacterial							
Syphilis (Treponema pallidum Ab)	9	1, 2	Tests	DD	6	Before donation routine RPR test negative. Discard tissues. Follow-up of 2CT, MSK and organ (6K, 2L) recipients.	
Parasite							
Antibodies to <i>Toxoplasma gondii</i> (IgM)	3	1, 2	Tests	DD	4	Discard 2CT. Follow Lu, L, Pc, and 4K recipients.	
Antibodies to <i>Trypanosoma cruzi</i>	1	1, 2	Tests	DD	4	Discard tissues. Follow-up of 2CT recipients. If required, prophylactic Tt of organ (2K) and MSK (F) recipients with benznidazole, trimethoprim/sulfamethoxazole.	
Blood cultures							
<i>Clostridium</i> sp.	5	1, 2	Tests	DD	6	Discard tissues. Follow-up of 10CT recipients. If Tt required: prophylaxis with clindamycin.	
<i>Enterococcus faecalis</i>	2	1	Tests	DD	6	Discard tissues. Prophylaxis of 2CT recipients with vancomycin.	
<i>Candida</i> spp.	2	1, 2	Tests	DD	6	Discard tissues. Follow-up and, if required, Tt of organ (2K) and tissue (2CT) recipients.	

<i>Enterobacter cloacae</i>	1	1, 2	Tests	DD	6	Discard tissues. Follow-up of organ (2K) recipients.
<i>Staphylococcus aureus</i>	1	1, 2	Tests	DD	6	Follow-up of organ (2K) and tissue (2CT) recipients.
<i>Granulicatella adiacens</i>	1	1, 2	Tests	DD	6	Prophylaxis 2CT recipients with linezolid.
<i>Staphylococci lugdunensis</i>	1	1	Tests	DD	6	Prophylaxis 2CT recipients with ciprofloxacin or levofloxacin.
<i>Bacillus cereus</i>	1	1	Tests	DD	6	Discard tissues and CT. Follow-up of MSK (2 Fz patella) recipients.
Bronchial aspirate cultures	2					
<i>Mucor</i> spp.	1	1, 2	Tests	DD	3	Discard tissues. Follow-up of organ (Lu, H, L, and 2K) recipients.
<i>Mycobacterium tuberculosis</i>	1	1	Tests	DD	6	Prophylactic Tt of 2CT recipients with isoniazid/rifampicin.
Malignancies	15					
Prostate adenocarcinoma	12	1, 2	Tests	DD	6	Tx 22CT recipients. Discard tissues. Follow-up of organ (Lu, 7L, 14K) recipients for ≥ 2 years.
Nodule not assessed (lung)	1	2	Tests	DD	6	Discard tissues (HV). Follow-up of organ (L, 2K) recipients.
Donor metastasis	1	1, 2	Tests	DD	4	Tx of 2CT recipients. Discard tissues (HV). Follow-up of organ (L, 2K) recipients.
Unexpected hepatocarcinoma	1	2	Tests	DD	4	Discard tissues (MSK, HV).
Donor medical contraindications	6					
Tuberculosis	2	1, 2	DE	DD	6	Discard tissues. Prophylactic Tt of organ (L, 2K) recipients with isoniazid, rifampin/rifabutin and ethambutol. Follow-up of 4CT recipients.
Monoclonal gammopathy	1	1	DE	DD	3	Discard tissues (skin and MSK tissue). Follow-up of 1CT recipient.
Lymphocyte meningoencephalitis (identified at autopsy)	1	2	DE	DD	4	Follow-up of organ (L, 2K, 2CT) recipients.
Alzheimer's disease (identified at autopsy, 4 months post-donation)	1	1, 2	DE	DD	4	Discard tissues (MSK, HV, skin). Follow-up of organ (2K) and 2CT recipients.
Infectious myocarditis (identified at autopsy)	1	1, 2	DE	DD	4	Follow-up of organ (L, 2K) and 2CT recipients.

SARs in organ recipients	4					
Liver cholangiocarcinoma identified in L recipient (explanted 4 years after Tx)	1	2	SAR	DD	4	No action taken.
Millar tuberculosis in K recipient (identified 4 months after Tx)	1	1, 2	SAR	DD	4	Discard tissues (MSK, Skin). Prophylactic Tt of organ (L, 2K) recipients. Follow-up of MSK, ART and 2CT recipients.
Creutzfeldt-Jakob disease in L recipient (identified 4 years after Tx)	1	1	SAR	DD	8	Follow-up of HV recipient.
Adenocarcinoma (identified in 2K recipients 2.5 years after Tx)	1	2	SAR	DD	4	Follow-up of 2CT, 28MSK (Fz), 13MSK (Ly), and 1H recipients. NT at 5y follow-up.

B) Tissue-derived risk

Tissue culture at recovery	7					
<i>Candida</i> spp. (2HV, 1ART)	3	1	Recovery	TQ	6	Discard tissues. Follow-up of 2CT and 3MSK tissue recipients.
<i>Clostridium</i> spp. (1 ART, 2MSK, CT)	3	2	Recovery	TQ	6	Discard tissues (2MSK, HV, ART). Prophylaxis of organ (Lu, H, LK, PcK, 4K) and 5CT recipients with clindamycin.
<i>Staphylococcus aureus</i> (2CT)	1	1	Recovery	TQ	6	Prophylaxis in 2CT recipients with erythromycin.
Processing culture	5					
<i>Clostridium</i> spp. (skin, pericardium, and MSK tissue)	3	1, 2	Processing	TQ	6	Discard tissues (2MSK, ART, HV, skin). Follow-up of organ (2K) recipients and 2CT. Prophylaxis in 4CT recipients with clindamycin.
<i>Aspergillus</i> spp. (MSK and ART tissue)	1	1, 2	Processing	TQ	6	Discard tissues (MSK, ART). Follow-up of 2CT, L, 2K and H recipients.
<i>Cupriavidus metallidurans</i> (MSK tissue processing solution). Contaminated	1	1, 2, 5	Processing	Material	8	Follow-up of 213MSK tissue recipients. Change in procedures (sterility test processing solution, 40 donors immobilize, alert other TEs if same solution used).
culture at the TE	7					
GPB (CT)	1	1, 2	Processing	TQ	6	Follow-up of 1K recipient. Prophylactic Tt of 1CT recipient with azithromycin.

<i>Granulicatella adiacens</i> (CCT)	1	1	Processing	TQ	4	Prophylactic Tt of 1CT recipient with linezolid.
<i>Klebsiella pneumoniae</i> (scleral tissue from FCT)	1	2	Processing	TQ	6	Prophylactic Tt (2CT) with intra-camera cefuroxime at the end of surgery and postoperative Tt with moxifloxacin. Follow-up of organ (2K) recipients.
<i>Serratia marcescens</i> (scleral tissue from FCT)	1	2	Processing	TQ	6	Follow-up of organ (2K) and tissue (2CT) recipients.
<i>Candida</i> spp. (CCT)	1	1	Processing	TQ	6	Follow-up of 1CT recipient.
<i>Rhodotorula</i> spp. (CCT)	1	1	Processing	TQ	6	No action taken.
<i>Burkholderia cepacia</i> (CCT)	1	1, 2	Processing	SF	4	Prophylactic Tt of 4CT recipients with cotrimoxazole.
Culture at the TC	22					
<i>Candida</i> spp. (CT and bronchoscopy culture)	5	1	Culture TC	TQ	6	Change procedures (avoid cross-contamination at recovery). Prophylactic Tt of tissue (9CT) recipients with fluconazole. Follow-up of organ (1K) recipient.
<i>Clostridium</i> spp. (HV, MSK tissue)	2	1	Culture TC	TQ	6	Prophylaxis of tissue (4CT, 1MSK) recipients with clindamycin.
Coagulase-negative <i>Staphylococcus</i> (AM, CT)	2	1	Culture TC	TQ	4	Follow-up of organ (2K, 1AM, 2CT) recipients. Change in procedures (sample testing).
<i>Escherichia coli</i> (MSK tissue, CT)	2	1	Culture TC	TQ	6	Follow-up of tissue (4CT) recipients and prophylactic Tt if required with cefixime. If symptoms, ertapenem.
<i>Exophiala</i> spp. (CT)	2	1, 2	Culture TC	TQ	6	Follow-up of tissue (4CT) recipients and, if required, prophylactic Tt with voriconazole/isavuconazole/posaconazole.
Multi-drug resistant <i>Staphylococcus epidermidis</i> (CT)	1	1, 2	Culture TC	TQ	6	Prophylactic Tt of tissue (2CT) recipients with linezolid.
<i>Streptococcus pyogenes</i> (MSK tissue)	1	1, 2	Culture TC	TQ	6	Prophylactic Tt of tissue (8MSK) recipients with amoxicillin/cephalosporin. Follow-up of tissue (2ART) recipients.
<i>Chryseobacterium</i> spp. (CCT)	1	1, 2	Culture TC	TQ	4	Prophylactic Tt of tissue (2CT) recipients with ciprofloxacin and topical moxifloxacin.
<i>Pseudomonas</i> and MRSA (MSK tissue)	1	1, 2	Culture TC	TQ	6	Follow-up of tissue (4MSK, 2CT) recipients.

<i>Proteus mirabilis</i> and <i>Escherichia coli</i> (CT medium)	1	1, 2	Culture TC	TQ	4	Follow-up of tissue (1CT) recipient.
<i>Bacillus cereus</i> (MSK tissue)	1	1, 2	Culture TC	TQ	6	Follow-up of tissue (2CT, MSK, ART) recipients.
<i>Acinetobacter lwoffii</i> (CT)	1	1, 2	Culture TC	TQ	6	Follow-up of tissue (2CT) recipients.
<i>Aureobasidium pullulans</i> (CT)	1	1, 2	Culture TC	TQ	6	Follow-up of tissue (2CT) recipients.
Microorganism NA (color change of the preservation solution)	1	1	Culture TC	HE	4	Change in procedure (review CT validation).
Other	12					
Tissue cross-over (left vs. right and proximal vs. distal)	2	3	Issue	SF	4	Change in procedures (staff training).
Sealing defect (cranial flap)	2	1, 4	Tissue validation	SF	4	Follow-up of 1 cranial flap recipient. Review procedures (sealing).
Corneal defect at TC. Tx cancelled	1	1	Tissue validation	HE	4	Review procedures (quality validation).
Loss of tissues (55DBM vials)	1	5	Transport	SF	4	Change in procedures (add checklist verification).
Tissue transplanted after the expiration date (MSK tissue)	1	3	Issue	SF	4	Follow-up of tissue (MSK) recipient.
Tendon rupture during Tx	1	4	Tissue validation	TQ	4	Review procedure (tendon validation).
HV not found during distribution	1	4	Issue	SF	6	Review procedure (add checklist once tissue matched).
DBM without osteoinductivity	1	1, 5	Tissue validation	SF	4	Review procedure (validation demineralization).
Fz CT arrives at TC	1	4	Transport	HE	4	Review procedure (staff training).
Damaged 28CCT due to an increase in the cell incubator temperature	1	5	Storage	EF	6	Discard equipment (design error in the control panel).

^a Criteria for reporting SAEs as described in the SoHO V&S guidelines²: 1, inappropriate tissues/cells have been distributed for clinical use; 2, the event could have possible implications for other patients or donors; 3, the event resulted in a mix-up of tissues/cells; 4, the event resulted in loss of any irreplaceable autologous tissues or cells or any highly matched (i.e. recipient specific) allogeneic tissues or cell; 5, the event resulted in the loss of a significant quantity of unmatched allogeneic tissues/cells. ^b Potential impact calculated by multiplying likelihood of recurrence and the highest score of individual, system and distribution consequences (Eustite V&S tools v2.1c). Impact classification: minor (0-3), moderate (4-6), moderate-high (8-9), or extreme (10-20) impact. ^c https://www.notifylibrary.org/sites/default/files/EUSTITE%20Vigilance%20Tools%20Wallchart_0.pdf

AM, amniotic membrane; AT, arterial tissue; GPB, Gram-positive bacillus; CT, corneal tissue; CCT, cultured corneal tissue; CV, cardiovascular; DBM, demineralized bone matrix; DE, donor evaluation; F, fresh; Fz, frozen; H, heart; HBc, hepatitis B core antigen; HBs, hepatitis B surface antigen; HV, heart valves; I, impact; K, kidney; L, liver;; Lu, lungs; Ly, lyophilized; MRSA, methicillin-resistant *Staphylococcus aureus*; MSK, musculoskeletal; NA, not available; NAT, nucleic acid testing; NT, no transmission; SAR, severe adverse reaction; DD, Donor disease without transmission,; TQ, tissue quality and/or safety; TC, transplant center; TE, tissue establishment; Tt, treatment; Tx, transplant.

Table S3. Description of serious adverse reactions related to tissue transplantation N=36.

Notify library taxonomy: Harm to a recipient (Level #1) - adverse occurrence taxonomy

Level #1	Level #2	Level #3	Level #4	Type of tissue	Detection time (days)	Imputability ^d	I ^a	Re-transplant
Harm to a recipient (36)	Infection (22)	Fungal (11)	<i>Candida</i> spp. (9) ND (2)	CT (6) CCT (4) FCT (1)	1-90	Probable (6) Possible (4) Unlikely (1)	4-6	Yes (5) No (1) NA (3)
		Fungal and bacterial (1)	<i>Fusarium</i> spp + <i>Pseudomonas</i> spp.	CT (1)	<30	Probable	9	No
		Bacterial (8)	<i>Bacillus cereus</i> <i>Bacteroides stercoris</i> Bacterial, ND <i>Clostridium</i> spp. <i>Enterobacter cloacae</i> (2) <i>Staphylococcus epidermidis</i> <i>Proteus mirabilis</i> + <i>Staphylococcus lugdunensis</i>	FCT ICW (Fz) ^c (2) Proximal femur (Fz) Long peroneal tendon (Fz) ICW (Fz) Autologous serum (eye drops) DBM (Ly) ^b	<30	Certain (1) Probable (4) Possible (3)	4-6	NA
		Infection, ND (2)	FCT Autologous serum (eye drops)	<30	Certain Probable	4-6	No NA	
	Miscellaneous (14)	Undue exposure to risk Transplant cancelled (3)	Cornea (poor quality)	FCT Osteochondral (F) Achilles tendon (Fz)	0	Certain-Process related (2) Probable	4	No NA (2)
			Osteochondral (Fz versus F graft)					
			Achilles tendon (without calcaneus)					

		Graft failure (7)	Descemet membrane detachment Edema Early tendon rupture Late tendon rupture	FCT(2) CCT (3) Patellar tendon (Fz) Long peroneal tendon (Fz)	0-300	Probable (5) Possible (2)	4-6	Yes (4) NA (3)
		Cardiovascular complications (4)	Thrombosis Rupture (3)	Femoral artery Iliac artery Pulmonary heart valve Aortic heart valve	0-40	Certain (2) Probable (1) Possible (1)	6-8	No
<p>^a Impact minor: 0-3; moderate: 4-6; moderate-high: 8-9; extreme: 10-20; calculated by multiplying likelihood of recurrence (score 1-5) and the highest score of individual, system and distribution consequences (score 0-4) from Eustite V&S tools (https://www.notifylibrary.org/sites/default/files/EUSTITE%20Vigilance%20Tools%20Wallchart_0.pdf) ^b Facial cellulitis after tooth extraction. ^c Surgical wound exudate. ^d Imputability: SOHO V&S Guidance for Competent Authorities: Communication and Investigation of Serious Adverse Events and Reactions associated with Human Tissues and Cells source (https://www.notifylibrary.org/sites/default/files/SOHO%20V%26S%20Communication%20and%20Investigation%20Guidance.pdf); CCT, cultured corneal tissue; CT, corneal tissue; F, fresh; FCT, fresh/hypothermic corneal tissue; Fz, frozen; I, impact; NA, not assessable; Tx, transplant.</p>								

Table S4. Serious adverse events related to organ donation according to the type of organ donor. *N* (%).

DBD (N=1031)	DCD (N=665)	Living (N=663)	<i>P</i>
41 (3.9)	30 (4.5)	1 (0.2)	<0.0001

DBD, donation after brain death; DCD, donation after circulatory death.

Table S5. Detailed characteristics of serious adverse events related to organ donation involving a risk from the donor (A) or organ (B) and actions implemented after their notification

	n	Criteria ^a	Stage	Cause	I ^b	Investigations and proposed actions by BV advisory committee
A) Donor-derived risk						
Blood tests	19					
Viral	8					
Hepatitis B virus, HBc positive, HBs negative	1	3	Blood testing	DD	6	Follow-up and monitoring of serology in organ (H, 2K) recipients.
Hepatitis B, HBsAg positive	1	3	Blood testing	HE	6	First result positive. Only 2 Lu accepted. Confirmatory test: negative. It was a transcription error (human error) and for this a SAE was opened to review procedures and train staff.
Hepatitis B virus, DNA positive HBcore positive	1	3	Blood testing	EF	6	Initial DNA positive. Confirmed negative. Review organ (BiLu, L, 1K, 1KPe) vaccination and serology monitoring. Discard tissues (C, MSK, HV, skin, ART). If required, prophylactic Tt with lamivudine.
Hepatitis B virus DNA positive	1	3	Blood testing	DD	6	Review organ (2K) vaccination and serology monitoring. Discard tissues (CT, MSK, HV, skin, ART). If required, prophylactic Tt with lamivudine; if seroconversion, Tt with entecavir.
Antibodies to hepatitis C virus	1	2	Blood testing	HE	3	Donation accepted as HCV Ab negative (transcription error). After Tx repeated and confirmed serology positive. Prophylactic Tt of Lu recipient: velpatasvir, sofosbuvir and glecaprevir, Pibrentasvir for 2K and serology monitoring.
Human immunodeficiency virus (NAT)	1	2	Blood testing	EF	4	Initial result positive. Confirmatory test negative (SAE investigation detected non-reliable test kit at the transplant centre)
Antibodies to cytomegalovirus	1	1	Blood testing	DD	3	Repeat and confirm serology (initial false negative), review organ (2K) serology, PCR monitoring and prophylactic Tt with valganciclovir (paediatric recipients).
Antibodies to Human T-lymphotropic virus types 1 and 2 (performed at TE)	1	1	Blood testing	DD	4	Discard of tissues (CT, MSK). NT to organ (K) recipient due to Tt with antiretroviral therapy.

COVID-19 (PCR)	1	1	Blood testing	SF	6	Review procedure. Add checklist before Lu transplantation.
Bacterial	4					
Syphilis (Treponema pallidum Ab)	4	3	Blood testing	DD	6	RPR negative routine pre-transplant donor screening. Prophylactic Tt of organ (7K, 2L) recipients with penicillin G benzathine. Discard tissues (4CT, 4MSK, 2HV, 3skin).
Parasite	7					
<i>Strongyloides stercoralis</i>	1	3	Blood testing	DD	6	Prophylactic Tt of organ (PcK) recipient with ivermectin. NT.
<i>Strongyloides stercoralis</i> , <i>Plasmodium falciparum</i>	1	3	Blood testing	DD	6	Initially positive both parasites. Lu, L, 2K recipients start prophylactic Tt with artemether/lumefantrine and ivermectin. Confirmatory test reveals plasmodium negative so Tt cancelled. SAE opened to validate Plasmodium Real Time PCR Detection Kit Discard tissues (C, MSK).
<i>Strongyloides</i> , <i>Schistosoma</i>	1	3	Blood testing	DD	6	Prophylactic Tt organ (Lu, L, 2xK) recipients with ivermectin. NT. Discard tissues (2C, MSK, HV, ART, skin).
Schistosomiasis/	1	3	Blood testing	DD	6	No Tt for schistosomiasis (BiLu, L, 2K). Discard tissues (2CT, MSK, HV, skin).
Antibodies <i>Toxoplasma gondii</i> (IgM)	1	3	Blood testing	DD	4	Prophylactic Tt of MSK recipients with trimethoprim/sulfamethoxazole. Organs already covered. Follow-up of organ (BiLu, L, 2K) recipients.
Antibodies <i>Leishmania</i> spp.	1	3	Blood testing	DD	2	No actions taken in organ (2K) recipients.
Blood cultures	1					
<i>Enterobacter cloacae</i>	1	3	Culture	DD	6	Prophylactic Tt with carbapenems in organ (BiLu, 2K) recipients. Discard tissues (C, HV, MSK, Skin ART).
Incomplete donor characterization	6					
Missing samples for cross-matching	4	2	Donor charact.	SF	4	Review procedures and staff training (5K). 1K was not transplanted because it was for a hyperimmunized recipient.
Missing samples for anti-EBV	2	2	Donor charact.	SF	4	Review procedures and staff training. Follow-up of organ (3K) recipients.
HLA	1					

Error in HLA donor result interpretation	1	2	Donor charact.	HE	3	Review procedures and staff training. Creation of a new decision algorithm when new techniques implemented. 1K recipient was hyperimmunized and could not be transplanted.
Bronchoscopy culture	4					
<i>Mycobacterium tuberculosis</i>	1	3	Culture	DD	6	Prophylactic Tt recommended for organ (2Lu, LK, K) recipients with isoniazid, rifampin, rifabutin and ethambutol.
<i>Citrobacter freundii</i>	1	3	Culture	DD	6	Prophylactic Tt of organ (BiLu, H, L, 2K) recipients with ertapenem/ciprofloxacin in
<i>Influenza A virus</i>	1	3	Culture	DD	6	Prophylactic Tt in organ (Lu) recipient with oseltamivir.
<i>Bacillus cereus</i>	1	3	Culture	DD	6	Prophylactic Tt with meropenem in organ (H, L, 2K) recipients. Discard tissues (2CT, MSK, Skin ART).
Pathology	23					
<i>Mycobacterium avium</i> (ganglion)	1	3	Pathology	DD	6	Prophylactic Tt of organ (Lu, LK, K, NT at 7y) recipients with azithromycin/ethambutol/rifampicin.
Breast adenocarcinoma ^c	1	4	Autopsy	DD	6	Discard (MSK, HV) tissues except for CT. Follow-up of organ (L, 2K, NT at 5y) recipients.
Gastrointestinal stromal tumor	1	4	Autopsy	HE	4	Review procedure (establish early alert). Follow-up of organ recipients 2K (NT at 5y).
Colon adenocarcinoma (living donor)	1	4	Living donor follow-up	DD	6	Follow-up of 1K recipient (NT at 5y+5m).
Enteral adenocarcinoma ^c	1	4	Autopsy	DD	8	Liver-kidney explant and retransplantation in 3 weeks (LK, 1K, NT at 7y).
Severe dysplasia (esophagus)	1	4	Autopsy	DD	4	Review procedure (establish early alert). Follow-up of organ (Lu, L, 2K, NT at 6y) recipients.
Neuroendocrine pancreatic tumor (initially benign) ^{c,d}	2	4	Pathology	DD	4	Follow-up of organ (Lu, 2K, L, NT at 5y) recipients. One case (Lu recipient) died due to other causes.
Hepatocellular adenocarcinoma ^{c,e}	1	4	Autopsy	DD	6	Follow-up of 2K recipients (NT at 5 years). Discard tissues (MSK, HV), except for CT.

Thyroid carcinoma ^e	1	2	Donor charact.	HE	8	Follow-up of organ recipients (Lu, H, 2K, NT at 2y 8m).
Hodgkin's lymphoma ^{e,f}	1	4	Pathology	SF	6	Follow-up of organ recipients (Lu, L, Pc-K, K, NT at 2y+7m). Monitoring of organ recipient liquid biopsies.
Prostatic adenocarcinoma	10	4	Pathology	DD	6	Follow-up of organ recipients (19K, 3L, 4Lu, NT from 6y to 2y+4m) and discard tissues (10MSK, 4HV, 5SK, ART), except for (10CT).
Prostatic intraepithelial neoplasia	2	4	Pathology	DD	6	Discard tissues (2MSK, HV, 2SK, ART). Follow-up of organ recipients (3K, 1L, 1Lu, NT at 3y) except for 2CT.
B) Organ-derived risk						
Malignancy	8					
Renal cell carcinoma	4	4	Procurement	OQ	6	Discard tissues (MSK) except for CT. Follow-up of organ recipients (2K, 1L, NT from 2-6y).
Papillary renal carcinoma	2	4	Procurement	OQ	6	Discard tissues (2MSK, HV) except for CT. Follow-up of organ recipients (3Lu, 2L, 1H, 2K, NT at 4y).
Cystic renal tumor	1	4	Pathology	OQ	4	Discard tissues (HV) except for CT. Follow-up of organ recipients (L, 1K, NT at 2y).
Hepatocarcinoma	1	4	Pathology	OQ	4	Discard tissues (MSK) except for CT. Follow-up of organ recipients (2K, NT at 5y)
Lesion or alteration of vascular function						
Sectioned artery	2	1	Procurement	HE	6	Artery repair, with good functionality (2K).
Kidney injury due to an inappropriate biopsy	1	1	Procurement	HE	4	Cancellation of Tx (1K).
Necrotizing glomerulonephritis	1	1	Perfusion	HE	6	Cancellation of Tx (1K).
Perfusion						
ESBL-producing <i>Klebsiella pneumoniae</i>	1	1	Preservation solution	DD	6	Treatment of organ (K) recipient with ceftazidime/avibactam for 21 days.
Preservation or packaging						
Fz kidney	2	2	Preservation	SF	4	Review procedure for organ preservation and packaging. Staff training.(2K).
Kidney at room temperature	1	2	Preservation	SF	4	Review procedure for organ preservation and packaging. Staff training (1K).
Fz lung and packaging deficiency	1	2	Preservation	SF	4	Review procedure for organ preservation and packaging. Staff training (Lu).

Lung packaging deficiencies (Fz and not sterile) 1 2 Preservation SF 4 Review procedure for organ preservation and packaging. Staff training (Lu).

^a Criteria for reporting organ SAEs as described in the EFRETOS project: 1, deviations from operating procedures or other adverse event during the chain from donation to transplantation that might lead to a SAR; 2, deviations in operating procedures or steps during the chain from donation to transplantation, with a potential high impact on the health of the patient and easy to be prevented; 3, infection or positive serological status discovered in an organ donor when ≥ 1 organ has been transplanted; 4, malignant tumor discovered in an organ donor when ≥ 1 organ has been transplanted; 5, discovery of any other potentially transmissible disease in an organ donor when ≥ 1 organ has been transplanted; 6, other. ^b Potential impact calculated by multiplying likelihood of recurrence and the highest score of individual, system and distribution consequences (Eustite V&S tools v2.1c). Impact classification: minor (0-3), moderate (4-6), moderate-high (8-9), or extreme (10-20) impact. https://www.notifylibrary.org/sites/default/files/EUSTITE%20Vigilance%20Tools%20Wallchart_0.pdf

^c Unacceptable risk according to the guide to the quality and safety of organs for transplantation of the Council of Europe. ^d Pancreas for research. ^e Analysed due to a history of cirrhosis. ^f Previously identified as thymoma.

CA, competent authority; COVID-19, coronavirus disease 2019; Charact., characterization; CT, corneal tissue; DC, donation center; EF, equipment failure; ESBL, extended spectrum beta-lactamase; Fz, frozen; HE, human error; PCR, polymerase chain reaction; I, impact; LR, likelihood of recurrence; NAT, nucleic acid testing; OQ, organ quality; DD, Donor disease without transmission; SF, system failure; SOP, standard operating procedures; TC, transplant center; TE, tissue establishment; Tt, treatment; Tx, transplant; y, years

Table S6. Description of organ serious adverse reactions

Notify library taxonomy: Harm to a recipient (Level #1) - adverse occurrence taxonomy				Organ	Detection Time	Imputability ^b	Impact ^c
Level #1	Level #2	Level #3	Level #4				
Harm to a recipient	Infection transmission (17)	Bacterial (5)	<i>Escherichia coli</i> (2) ESBL-producing <i>Klebsiella pneumoniae</i> <i>Pseudomonas aeruginosa</i> <i>Enterococcus faecium</i>	Kidney (2) Liver (3)	1-14	Certain (3) Probable (2)	4-6
		Viral (4)	Hepatitis C virus Herpes simplex virus Hepatitis B virus (2)	Kidney Liver x3	30-850	Excluded (1) Probable (3)	4-8
		Parasitic (4)	<i>Strongyloides stercoralis</i> <i>Plasmodium falciparum</i>	Kidney x3 Heart	15-120	Certain (4)	6-12
		Fungal (4)	<i>Mucor</i> spp. <i>Aspergillus</i> spp. <i>Histoplasma</i> sp. <i>Candida tropicalis</i> ^a	Liver Lung Heart Pancreas-kidney	4-1700	Excluded (1) Certain (1) Possible (2)	4-6
	Malignancy (13)	Blood and lymphoid (2) Carcinoma of unknown primary site (1) Gastrointestinal (3) Kidney and urinary tract (3) Liver, gallbladder and bile ducts (1) Lung and lower respiratory tract (1) Soft tissue/sarcoma (2)	Diffuse B-cell lymphoma Adenocarcinoma unknown origin Small bowel adenocarcinoma Cholangiocarcinoma Renal cell carcinoma Space-occupying lesions Small cell carcinoma Kaposi's sarcoma	Kidney (8) Lung (2) Liver (3)	17-1460	Excluded (2) Certain (5) Probable (3) Possible (3)	4-8

	Miscellaneous complication (21)	Undue exposure to risk Transplant cancelled (8)	Poor perfusion and macroscopic appearance (unsuitable). Poor perfusion due to air entering into the circuit. Right kidney with 3 unpatched arteries. Left kidney with multiple cysts. Capsule and vein defects Wrong ABO recipient in waiting list Incorrectly diagnosed cholangiocarcinoma; identified next day as adenoma (lost opportunity to transplant) Inappropriate clinical application	Kidney (6) Liver (1) Lung (1)	-	Certain-Process (8)	4-8
		Delayed graft function (4)	Vein injury. Inappropriate perfusion and packaging Bleeding due to decapsulation and overly large biopsy (3)	Kidney (4)	-	Certain-Process x4	6
		Other: explant (5)	Incompatible ABO. Explanted in 3h Thrombosis Unappropriated preservation (thrombosis) Lung and lower respiratory tract malignancy ^d	Kidney (5)	1-26	Certain-Process (3) Certain (2)	4-6

		Surgical site complications (4)	Artery dissection, unable to be repaired Cysts occupying half of the surface Complex venous access and inappropriate perfusion Renal vein artery bleeding in the sinus, unable to be repaired	Kidney (4)	-	Certain-Process (4)	4
	Immunological complications (2)	Detrimental immunization	ABO immunization	Lung Kidney	1-2	Certain-process (2)	6
			HLA immunisation				

^aPresenting with acute pancreatitis and requiring an explant. ^bImputability. Table 1: DTAC classification of donor-derived disease transmissions Disease Ison MG, Nalesnik MA. An update on donor-derived disease transmission in organ transplantation. Am J Transplant. 2011;11(6):1123–30. ^c Impact. minor: 0-3; moderate:4-6; moderate-high:8-9; extreme: 10-20; calculated by multiplying likelihood of recurrence (score 1-5) and the highest score of individual, system and distribution consequences (score 0-4) from Eustite V&S tools (https://www.notifylibrary.org/sites/default/files/EUSTITE%20Vigilance%20Tools%20Wallchart_0.pdf). ^dTwo kidneys explanted one month after transplantation due to a donor autopsy revealing a lung malignancy. Both recipients were re-transplanted three and four years after explant and none had malignancy transmission after 7 years of close monitoring.ESBL, extended-spectrum-β-lactamase; Fz, frozen; I, impact; HLA, human leucocyte antigen; SAR,serious adverse reaction; Tx, transplant

