Final Report

OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) Descriptive Data Request

Update Data Collection to Align with U.S. Public Health Service (PHS) Guideline, 2020
1 Year Monitoring Report

DHHS Contract No. 250-2019-00001C
Date Completed: December 1, 2024

Prepared for:
Ad Hoc Disease Transmission Advisory Committee (DTAC)
Committee Meeting

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Background/Purpose

The updated 2020 Public Health Service (PHS) Guideline for assessing solid organ donors for HIV, HBV and HCV infection was implemented into Organ Procurement and Transplantation Network (OPTN) policy on March 1, 2021. Changes included a shorter risk criteria inclusionary timeframe, removal of the term "increased risk", and the removal of four risk criteria. Discrete fields to capture which specific PHS risk criteria donors met were added into UNet on September 14, 2023. Prior to this implementation, information about specific risk criteria could be written in several different text fields or included as attachments in the donor record, making it difficult and labor-intensive to analyze trends with donors that met risk criteria outlined in the 2020 PHS Guideline. Collecting more granular data will help with identifying potential impacts on recipient safety through trends in transplantation of organs from donors with specific PHS risk criteria, and could inform future iterations of the PHS Guideline for assessing solid organ donors for HIV, HBV and HCV infection, with which OPTN policy must and does align. For more information on these data collection changes, please refer to the policy notice found here: https://optn.transplant.hrsa.gov/media/0jpfyplo/data-change-notice_dtac_phs.pdf

Strategic Plan Goal or Committee Project Addressed

Promote living donor and transplant recipient safety

Committee Request

The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available to compare performance before and after the implementation of this policy:

- Count (%) of deceased donors with reported PHS risk factors for HIV, HBV and HCV, overall and by organ type
- Count (%) of deceased donors with reported PHS risk factors for HIV, HBV and HCV meeting each specific risk criteria, overall and by organ type (post-policy implementation only)
- Organ utilization rates for deceased donors with reported PHS risk factors for HIV, HBV and HCV by organ type

These metrics will be presented to the Ad Hoc Disease Transmission Advisory Committee (DTAC) 1-year and 2-years post-policy implementation.

Data and Methods

Data Sources:

Organ Procurement and Transplantation Network (OPTN) data as of December 13, 2024 were used for this analysis. The OPTN data system includes data on all donors, waitlisted candidates, and transplant recipients in the U.S., submitted by the members of the OPTN. Deceased donor data were collected from the Deceased Donor Registration (DDR) form.

Cohort:

The Update Data Collection to Align with U.S. Public Health Service (PHS) Guideline, 2020 policy was implemented on September 14, 2023. This report compares metrics for 1 year before and after this implementation date. The pre-implementation era is defined as September 13, 2022 to September 13, 2023, and the post-implementation era as September 14, 2023 to September 13, 2024. The dates for the pre- and post-policy eras are set to contain exactly 365 days. Data are subject to change based on future data submission or correction.

Deceased donors with at least one organ recovered for the purpose of transplantation from September 13, 2022 to September 13, 2024 are included in this analysis. Information regarding specific PHS risk criteria is available

post-policy implementation only, and is provided for deceased donors with at least one organ recovered for the purpose of transplantation who had PHS risk factors for blood-borne disease transmission reported on their DDR form between September 14, 2023 and September 13, 2024. Living donors are not required to report risk factors for HIV, HBV or HCV transmission and are excluded from all analyses.

Methods:

This report shows the proportion and number of deceased donors by policy implementation era, PHS risk factors for blood-borne disease transmission, and organ type. Due to small sample sizes for Pancreas and Intestine donors, stratifications by organ type are limited to Kidney, Liver, Heart and Lung to avoid potential identifiability. Utilization rates and organ non-use rates pre- and post-policy by PHS risk factors for blood-borne disease transmission are included. Utilization rate is defined as the number of organs transplanted divided by the total number of available organs from donors with at least one organ recovered for the purpose of transplant. For the purposes of utilization rate calculation, it is assumed that all donors have two kidneys and two lungs available for transplantation. Non-use rate is defined as the number of organs recovered for the purpose of transplant but not transplanted divided by the total number of organs recovered for the purpose of transplant.

Results

There were 16,149 deceased donors with at least one organ recovered for the purpose of transplant pre-policy, and 17,031 recovered post-policy.

Figure 1 and *Table 1* show deceased donors by policy implementation era and risk factors for blood-borne disease transmission as defined by the 2020 U.S. PHS Guideline. The distribution of PHS risk factors remained largely similar across both eras; there was a small decrease in donors with reported PHS risk factors post-policy.

Figure 1. Deceased Donors by Risk Factors for Blood-Borne Disease Transmission Status and Policy Era

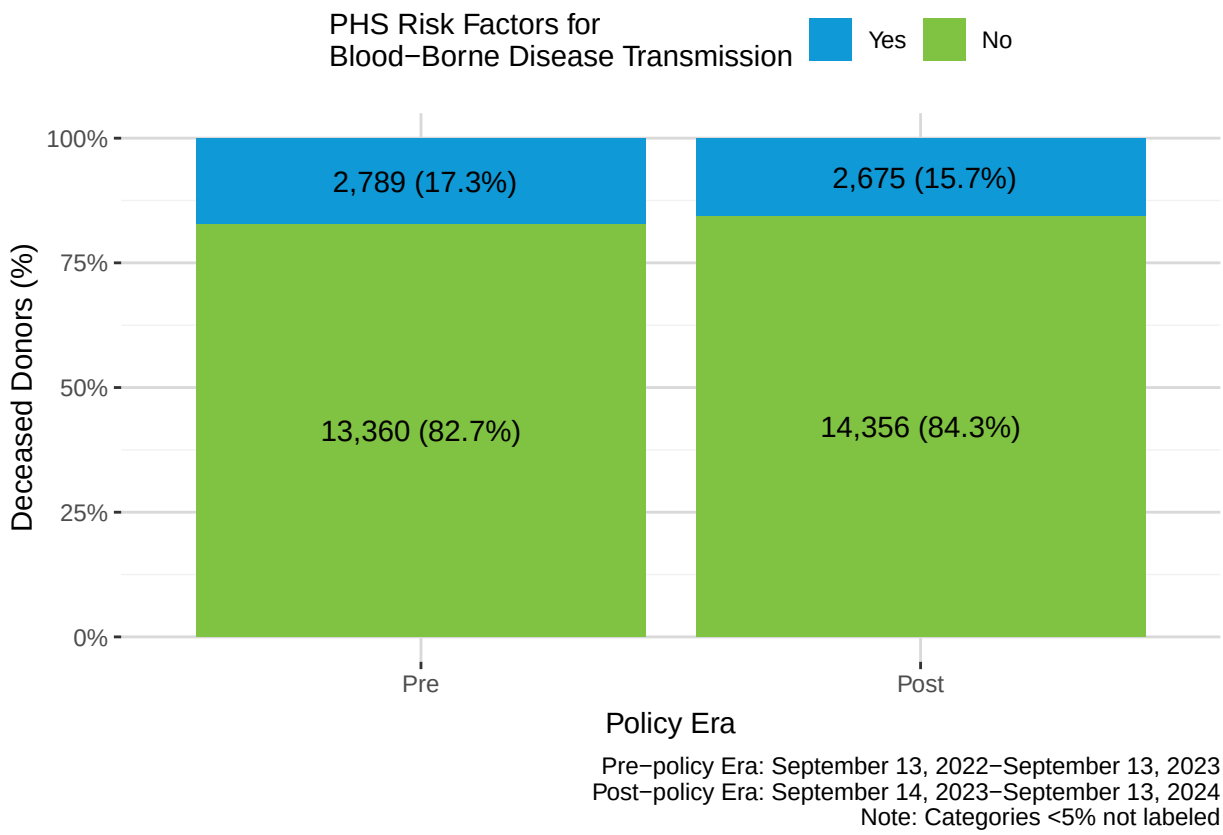


Table 1. Deceased Donors by Risk Factors for Blood-Borne Disease Transmission Status and Policy Era

	PHS Risk Factors for Blood-Borne Disease Transmission			
Policy Era	Yes	No	Not Reported	Total
Pre	2,789 (17.3%)	13,360 (82.7%)	0 (0.0%)	16,149 (100.0%)
Post	2,675 (15.7%)	14,356 (84.3%)	0 (0.0%)	17,031 (100.0%)

Figure 2 and *Table 2* show the proportion and count of deceased donors by policy implementation era, organ type, and donor PHS risk factors for blood-borne disease transmission. *Note* that data grouped by organ are not mutually exclusive; a donor that donated multiple organs will appear in the figure/table for each organ type donated. The distribution of donors by PHS risk factors remained consistent pre- to post-policy, with small decreases in the proportion of kidney and liver donors with reported risk factors post-policy implementation. A slightly higher proportion of heart donors were reported to have PHS risk factors for blood-borne disease transmission compared to other organ types.

Figure 2. Deceased Donors by Risk Factors for Blood-Borne Disease Transmission Status, Policy Era, and Organ Type

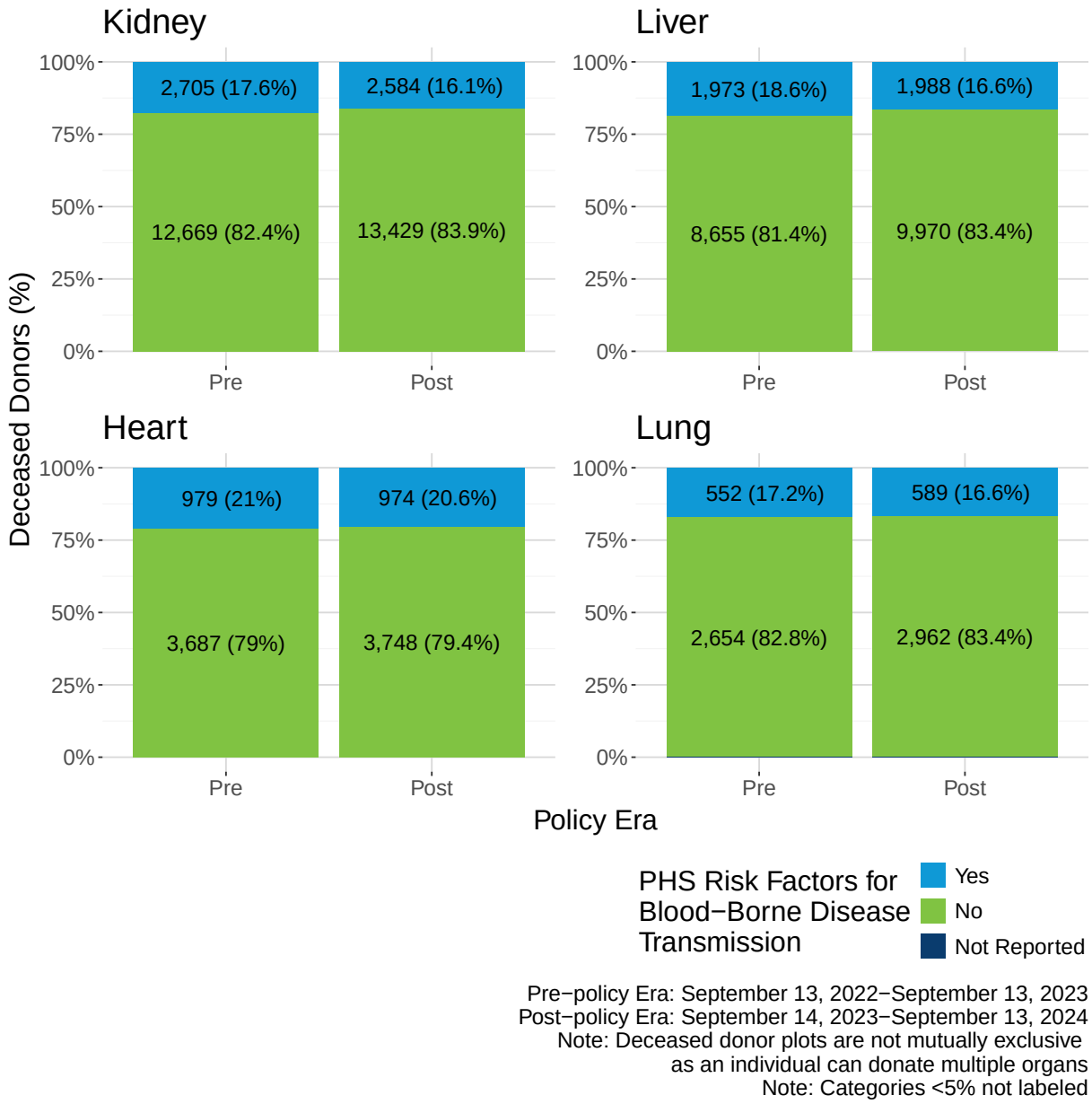
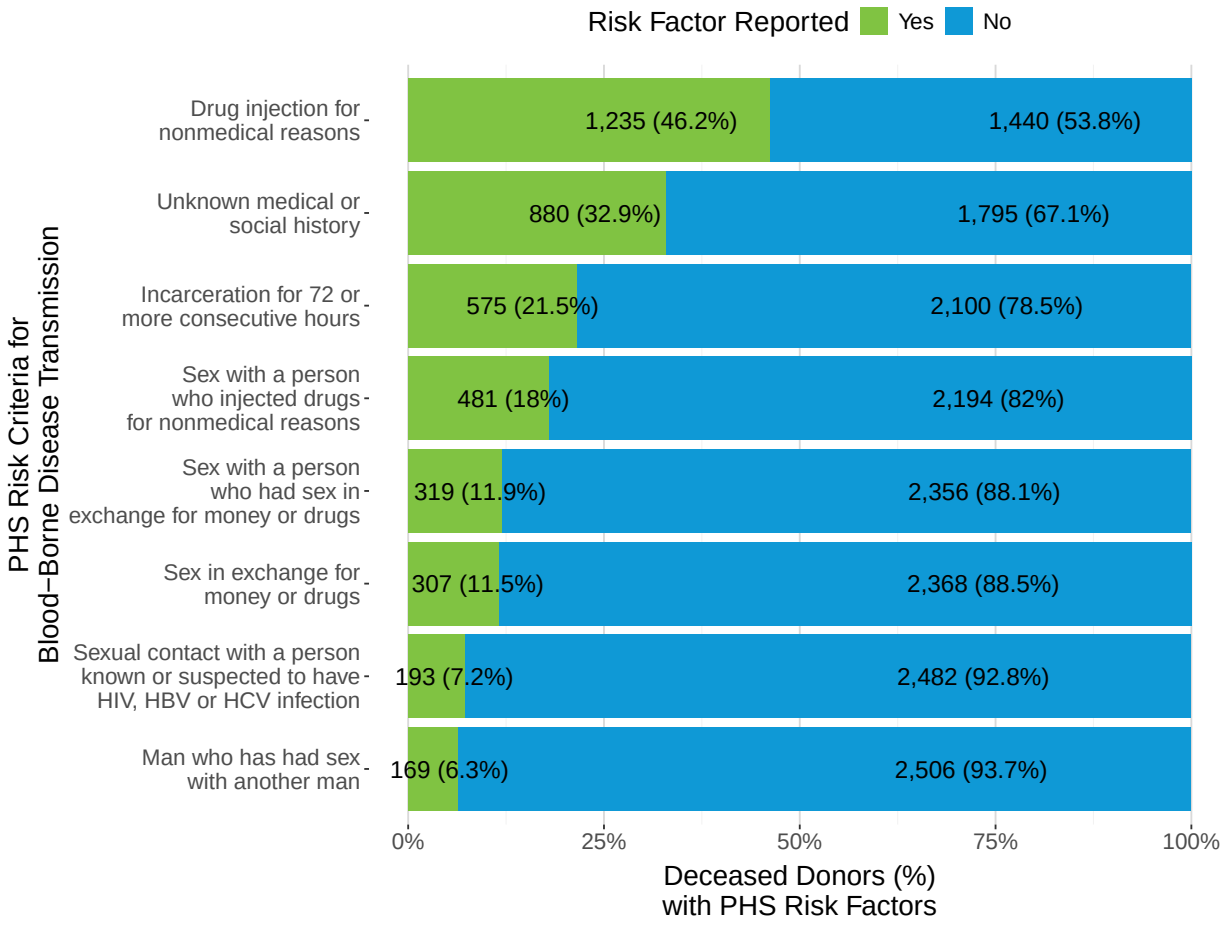


Table 2. Deceased Donors by Risk Factors for Blood-Borne Disease Transmission Status, Policy Era, and Organ Type

		PHS Risk Factors for Blood-Borne Disease Transmission			
Organ Type	Policy Era	Yes	No	Not Reported	Total
Kidney	Pre	2,705 (17.6%)	12,669 (82.4%)	0 (0.0%)	15,374 (100.0%)
	Post	2,584 (16.1%)	13,429 (83.9%)	0 (0.0%)	16,013 (100.0%)
Liver	Pre	1,973 (18.6%)	8,655 (81.4%)	0 (0.0%)	10,628 (100.0%)
	Post	1,988 (16.6%)	9,970 (83.4%)	0 (0.0%)	11,958 (100.0%)
Heart	Pre	979 (21.0%)	3,687 (79.0%)	0 (0.0%)	4,666 (100.0%)
	Post	974 (20.6%)	3,748 (79.4%)	0 (0.0%)	4,722 (100.0%)
Lung	Pre	552 (17.2%)	2,654 (82.8%)	0 (0.0%)	3,206 (100.0%)
	Post	589 (16.6%)	2,962 (83.4%)	0 (0.0%)	3,551 (100.0%)

Figure 3 and *Table 3* show the specific PHS risk criteria reported for deceased donors with reported PHS risk factors for blood-borne disease transmission post-policy implementation. *Note* that data grouped by specific risk criteria are not mutually exclusive as multiple risk criteria can be reported for a single donor; a donor with multiple reported criteria will appear in the figure/table for each risk criteria reported. The most frequently reported risk criteria post-policy implementation was "drug injection for non-medical reasons", reported for nearly half of all donors with reported PHS risk factors for blood-borne disease transmission, followed by "unknown medical or social history", and "incarceration for 72 or more consecutive hours". The least frequently reported risk criteria was "man who has had sex with another man". The pediatric-specific risk criteria of "child breastfed by a mother with HIV infection" and "child born to a mother with HIV, HBV, or HCV infection" were not reported for any donors post-policy implementation.

Figure 3. Deceased Donors with Reported PHS Risk Factors for Blood-Borne Disease Transmission by Specific PHS Risk Criteria, Post-Policy Implementation



Post−policy Era: September 14, 2023−September 13, 2024
Note: Plot is not mutually exclusive as multiple risk factors can be reported for a single donor

Table 3. Deceased Donors with Reported PHS Risk Factors for Blood-Borne Disease Transmission by Specific PHS Risk Criteria, Post-Policy Implementation

PHS Risk Criteria for Blood-Borne Disease Transmission	Risk Factor Reported	
	Yes	No
Drug injection for nonmedical reasons	1,235 (46.17%)	1,440 (53.83%)
Unknown medical or social history	880 (32.90%)	1,795 (67.10%)
Incarceration for 72 or more consecutive hours	575 (21.50%)	2,100 (78.50%)
Sex with a person who injected drugs for nonmedical reasons	481 (17.98%)	2,194 (82.02%)
Sex with a person who had sex in exchange for money or drugs	319 (11.93%)	2,356 (88.07%)
Sex in exchange for money or drugs	307 (11.48%)	2,368 (88.52%)
Sexual contact with a person known or suspected to have HIV, HBV or HCV infection	193 (7.21%)	2,482 (92.79%)
Man who has had sex with another man	169 (6.32%)	2,506 (93.68%)

Figure 4 and *Table 4* show the specific PHS risk criteria reported for deceased donors with reported PHS risk factors for blood-borne disease transmission post-policy implementation by organ type. "Drug injection for non-medical reasons" was the most frequently reported specific risk criteria post-policy implementation across all organ types.

Figure 4. Deceased Donors with Reported PHS Risk Factors for Blood-Borne Disease Transmission by Specific PHS Risk Criteria and Organ Type, Post-Policy Implementation

Post−policy Era: September 14, 2023−September 13, 2024
Note: Plot is not mutually exclusive as multiple risk factors can be reported for a single donor

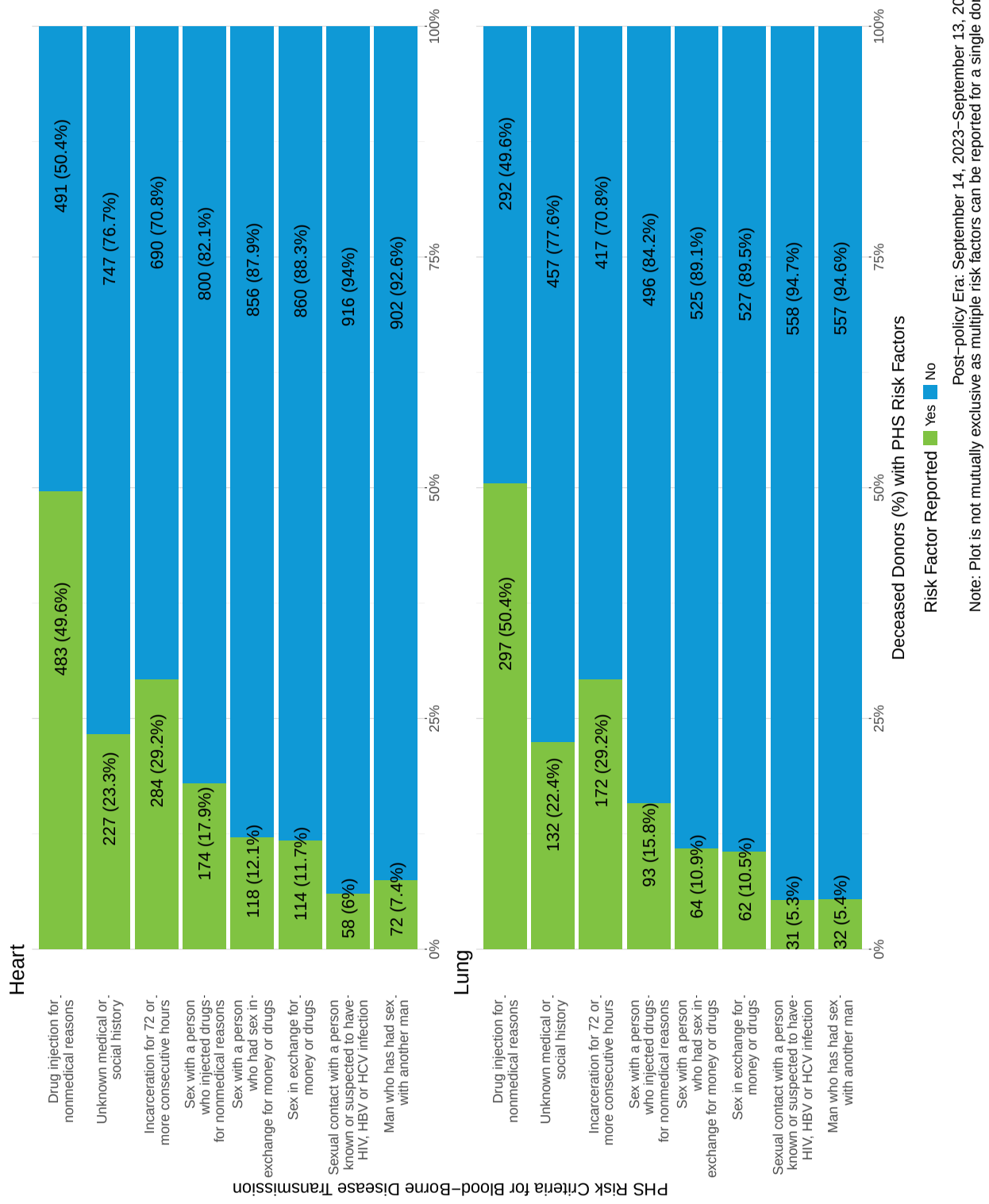

Heart
Drug injection for nonmedical reasons
483 (49.6%)
491 (50.4%)
Unknown medical or social history
227 (23.3%)
747 (76.7%)
Incarceration for 72 or more consecutive hours
284 (29.2%)
690 (70.8%)
Sex with a person who injected drugs for nonmedical reasons
174 (17.9%)
800 (82.1%)
Sex with a person who had sex in exchange for money or drugs
118 (12.1%)
856 (87.9%)
Sex in exchange for money or drugs
114 (11.7%)
860 (88.3%)
Sexual contact with a person known or suspected to have HIV, HBV or HCV infection
58 (6%)
916 (94%)
Man who has had sex with another man
72 (7.4%)
902 (92.6%)
Lung
Drug injection for nonmedical reasons
297 (50.4%)
292 (49.6%)
Unknown medical or social history
132 (22.4%)
457 (77.6%)
Incarceration for 72 or more consecutive hours
172 (29.2%)
417 (70.8%)
Sex with a person who injected drugs for nonmedical reasons
93 (15.8%)
496 (84.2%)
Sex with a person who had sex in exchange for money or drugs
64 (10.9%)
525 (89.1%)
Sex in exchange for money or drugs
62 (10.5%)
527 (89.5%)
Sexual contact with a person known or suspected to have HIV, HBV or HCV infection
31 (5.3%)
558 (94.7%)
Man who has had sex with another man
32 (5.4%)
557 (94.6%)
0%
25%
50%
75%
100%
PHS Risk Criteria for Blood−Borne Disease Transmission
Deceased Donors (%) with PHS Risk Factors
Risk Factor Reported Yes No
Post−policy Era: September 14, 2023−September 13, 2024
Note: Plot is not mutually exclusive as multiple risk factors can be reported for a single donor

Table 4. Deceased Donors with Reported PHS Risk Factors for Blood-Borne Disease Transmission by Specific PHS Risk Criteria and Organ Type, Post-Policy Implementation

Organ Type	PHS Risk Criteria for Blood-Borne Disease Transmission	Risk Factor Reported	
		Yes	No
Kidney	Drug injection for nonmedical reasons	1,204 (46.59%)	1,380 (53.41%)
	Incarceration for 72 or more consecutive hours	564 (21.83%)	2,020 (78.17%)
	Man who has had sex with another man	165 (6.39%)	2,419 (93.61%)
	Sex in exchange for money or drugs	297 (11.49%)	2,287 (88.51%)
	Sex with a person who had sex in exchange for money or drugs	309 (11.96%)	2,275 (88.04%)
	Sex with a person who injected drugs for nonmedical reasons	471 (18.23%)	2,113 (81.77%)
	Sexual contact with a person known or suspected to have HIV, HBV or HCV infection	185 (7.16%)	2,399 (92.84%)
	Unknown medical or social history	832 (32.20%)	1,752 (67.80%)
Liver	Drug injection for nonmedical reasons	926 (46.58%)	1,062 (53.42%)
	Incarceration for 72 or more consecutive hours	466 (23.44%)	1,522 (76.56%)
	Man who has had sex with another man	121 (6.09%)	1,867 (93.91%)
	Sex in exchange for money or drugs	237 (11.92%)	1,751 (88.08%)
	Sex with a person who had sex in exchange for money or drugs	250 (12.58%)	1,738 (87.42%)
	Sex with a person who injected drugs for nonmedical reasons	343 (17.25%)	1,645 (82.75%)
	Sexual contact with a person known or suspected to have HIV, HBV or HCV infection	138 (6.94%)	1,850 (93.06%)
	Unknown medical or social history	611 (30.73%)	1,377 (69.27%)
Heart	Drug injection for nonmedical reasons	483 (49.59%)	491 (50.41%)
	Incarceration for 72 or more consecutive hours	284 (29.16%)	690 (70.84%)
	Man who has had sex with another man	72 (7.39%)	902 (92.61%)
	Sex in exchange for money or drugs	114 (11.70%)	860 (88.30%)
	Sex with a person who had sex in exchange for money or drugs	118 (12.11%)	856 (87.89%)
	Sex with a person who injected drugs for nonmedical reasons	174 (17.86%)	800 (82.14%)
	Sexual contact with a person known or suspected to have HIV, HBV or HCV infection	58 (5.95%)	916 (94.05%)
	Unknown medical or social history	227 (23.31%)	747 (76.69%)

Lung	Drug injection for nonmedical reasons	297 (50.42%)	292 (49.58%)
	Incarceration for 72 or more consecutive hours	172 (29.20%)	417 (70.80%)
	Man who has had sex with another man	32 (5.43%)	557 (94.57%)
	Sex in exchange for money or drugs	62 (10.53%)	527 (89.47%)
	Sex with a person who had sex in exchange for money or drugs	64 (10.87%)	525 (89.13%)
	Sex with a person who injected drugs for nonmedical reasons	93 (15.79%)	496 (84.21%)
	Sexual contact with a person known or suspected to have HIV, HBV or HCV infection	31 (5.26%)	558 (94.74%)
	Unknown medical or social history	132 (22.41%)	457 (77.59%)

Table 5 shows deceased donor organ utilization rates by policy implementation era, PHS risk factors for blood-borne disease transmission and organ type. *Note* that donors pre- and post-policy for whom PHS risk factors were unknown are excluded from this section. Post-policy implementation, there was a small increase in the utilization rate for liver and lung regardless of donor risk factors. Kidney utilization rate decreased slightly pre- to post-policy regardless of donor risk factors. For heart, utilization increased slightly for donors with reported PHS risk factors, and decreased slightly for donors with no reported risk factors.

Table 5. Deceased Donor Organ Utilization Rates Pre- and Post-Policy by PHS Risk Factors for Blood-Borne Disease Transmission and Organ Type

		Deceased Donor Utilization Rate			
PHS Risk Factors for Blood-Borne Disease Transmission	Policy Era	Kidney	Liver	Heart	Lung
PHS Risk Factors Reported	Pre	75.7%	65%	34.7%	17.9%
	Post	75.3%	68.6%	35.7%	19.2%
No PHS Risk Factors Reported	Pre	67%	59%	27.2%	17.3%
	Post	64.5%	62.1%	25.7%	17.7%

Table 6 shows deceased donor organ non-use rates by policy implementation era, PHS risk factors for blood-borne disease transmission and organ type. *Note* that donors pre- and post-policy for whom PHS risk factors were unknown are excluded from this section. Among donors with reported PHS risk factors, non-use rates decreased slightly for kidney and liver and increased slightly for heart and lung post-policy implementation. Among donors with no reported PHS risk factors, non-use rates increased across all organ types post-policy.

Table 6. Deceased Donor Organ Non-Use Rates Pre- and Post-Policy by PHS Risk Factors for Blood-Borne Disease Transmission and Organ Type

Organ Type	PHS Risk Factors for Blood-Borne Disease Transmission	Policy Era	Donors	Organs Recovered	Organs Not Transplanted	Non-Use Rate
Kidney	PHS Risk Factors Reported	Pre	2,705	5,394	1,174	21.8%
		Post	2,584	5,145	1,116	21.7%
	No PHS Risk Factors Reported	Pre	12,669	25,205	7,312	29%
		Post	13,429	26,710	8,184	30.6%
Liver	PHS Risk Factors Reported	Pre	1,973	1,973	165	8.4%
		Post	1,988	1,988	158	7.9%
	No PHS Risk Factors Reported	Pre	8,655	8,655	856	9.9%
		Post	9,970	9,970	1,142	11.5%
Heart	PHS Risk Factors Reported	Pre	979	979	10	1%
		Post	974	974	19	2%
	No PHS Risk Factors Reported	Pre	3,687	3,687	48	1.3%
		Post	3,748	3,748	62	1.7%
Lung	PHS Risk Factors Reported	Pre	552	1,075	77	7.2%
		Post	589	1,129	104	9.2%
	No PHS Risk Factors Reported	Pre	2,654	5,090	467	9.2%
		Post	2,962	5,710	619	10.8%

Summary

The one-year monitoring report for the Update Data Collection to Align with U.S. PHS Guideline, 2020 policy showed that the majority of deceased donors did not have PHS risk factors for blood-borne disease transmission reported on the DDR form. The distribution of deceased donors by PHS risk factors remained largely similar pre- to post-policy, with deceased donors with reported PHS risk factors making up approximately 16-20% of kidney, liver, heart and lung donors. Specific PHS risk criteria data were collected post-policy implementation for donors with reported PHS risk factors. Among donors with reported risk factors, the most frequently reported risk criteria was "drug use for non-medical reasons" across all organ types. Post-policy, utilization increased for liver and lung regardless of donor risk factors. Among donors with reported risk factors, utilization increased for heart and decreased slightly for kidney. Non-use among donors with reported risk factors decreased slightly for kidney and liver, and increased slightly for heart and lung post-policy implementation. However, this implementation overlapped with other policies and further investigation may be needed to understand changes in utilization and non-use.