

Lower Respiratory SARS-CoV-2 Testing for Lung Donors
Nine Month Post-Implementation Monitoring Report

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Executive Summary

The OPTN implemented an emergency policy on May 27, 2021 requiring lower respiratory testing by nucleic acid test (NAT) for SARS-CoV-2 (COVID-19) for all potential deceased lung donors, specifying that test results must be available prior to lung transplantation. On December 6, 2021, the OPTN Board of Directors approved this policy as permanent. This report presents data on COVID-19 lower respiratory testing for lung donors through February 2022.

Compliance with the lower respiratory testing requirement has been high with 99.9% (N=1781/1783) of transplanted lung donors receiving lower respiratory testing since policy implementation (**Figure 1** and **Table 1**). Test results were reported in DonorNet on or before the day of transplant for 99.4% of donors; results were entered in DonorNet after the day of transplant for six donors (0.3%) and test results were not found in DonorNet for five donors (0.3%) (**Figure 4**).

Post-implementation, 202 donors had a positive lower respiratory test (**Table 5**). 46.0% (N=93/202) of the donors with a positive lower respiratory test had at least one negative upper respiratory test result (**Table 7**).

Non-lung organs were recovered and transplanted from donors with positive lower respiratory tests (LRT+) (**Table 6**). Kidney discards were somewhat higher for LRT+ donors relative to all other donors recovered in the same time period (27.8% vs 25.8%), while the liver discard rate was lower for LRT+ donors (5.3% vs 9.4%). Heart utilization was lower for LRT+ donors (20.3% vs 27.5%).

Overall lung utilization varied by month, ranging from 14.3-17.2% since policy implementation (**Figure 7** and **Table 9**). Utilization of lungs from non-DCD donors ranged from 18.9-23.5%, while utilization of lungs from DCD donors ranged from 2.8-4.9%.

Background/Purpose

The OPTN implemented emergency policy on May 27, 2021 requiring lower respiratory testing by nucleic acid test (NAT) for SARS-CoV-2 (COVID-19) for all potential deceased lung donors. Test results must be available prior to lung transplantation. On December 6, 2021, the OPTN Board of Directors established this policy as permanent.

The OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) developed this policy in response to evidence that testing by upper respiratory specimen alone poses a patient safety risk to lung transplant recipients. There were four cases over a three-month period (December 2020 through February 2021) in which a deceased lung donor tested negative for COVID-19 by upper respiratory specimen, then retrospectively tested positive by lower respiratory specimen. Three of these cases resulted in donor-derived transmission to lung recipients, while the fourth case was a “near miss” resulting in lung discard. One lung recipient died as a result of the donor-derived transmission.

This report presents data on COVID-19 lower respiratory testing for lung donors through February 2022. Data are as of March 18, 2022 and are subject to change based on future submission or correction.

Strategic Plan Goal

Promote living donor and transplant recipient safety.

Committee Request

This policy will be evaluated monthly following implementation for 6 months and then again at 9 months, 1 year, 18 months, and 2 years post-implementation. The following metrics, and any others subsequently requested by the Committee, were evaluated and compared to an appropriate pre-implementation cohort:

- The number (and percent) of lung donors with no lower respiratory specimen testing reported each month post-implementation, overall and for DCD vs brain death donors
- Timing of lower respiratory test result reporting relative to lung transplant
- The number (and percent) of OPOs with recovered lung donors with no lower respiratory testing post-implementation
- Lung utilization rates by month, overall and for DCD vs brain death donors
- Heart utilization rates by month
- Kidney, liver, and pancreas discard rates by month
- Number and percent of donors with a positive SARS-CoV-2 lower respiratory test, overall and by month
- Number and type of organs recovered/transplanted from donors with a positive SARS-CoV-2 lower respiratory test
- Number of donors with discordant lower vs upper respiratory SARS-CoV-2 test results, overall and by month

Data and Methods

Data Sources

Analyses are based on OPTN data as of March 18, 2022. Donor data were submitted in DonorNet. COVID-19 testing information may be reported in the discrete COVID-19 infectious disease fields, free text fields, or attachments in DonorNet. COVID-19 testing information in this report is based on information reported in the discrete data fields and donor attachments. Natural language processing was used to identify donor attachments with terminology related to COVID (e.g., “COVID-19”, “COVID”, “SARS-CoV-2”) and lower respiratory testing (e.g., “BAL”, “tracheal aspirate”) in the attachment filename or description. Candidate information was submitted

through Waitlist and on the Transplant Candidate Registration (TCR). Data are subject to change based on future data submission or correction.

Cohort

Deceased donors with organs recovered for the purpose of transplant between January 1, 2021 and February 28, 2022 were included in this analysis.

The post-policy era includes donors recovered between May 27, 2021 - February 28, 2022.

Methods

In this report, organ utilization is assessed as utilization rate for thoracic organs (lung, heart), and discard rate for abdominal organs (kidney, liver, pancreas, intestine).

- Utilization rate was 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.
- Discard rate was 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

Lower Respiratory Testing

A total of 1783 deceased donors had lungs transplanted between the May 27, 2021 policy implementation and February 28, 2022. Of these, 99.9% (N=1781) had an indication in DonorNet that they received lower respiratory testing for COVID-19. **Figure 1** and **Table 1** show the number of lung donors by month and whether they received lower respiratory testing since January 2021.

Figure 1. Number of transplanted lung donors by month and whether the donor had lower respiratory testing for COVID-19

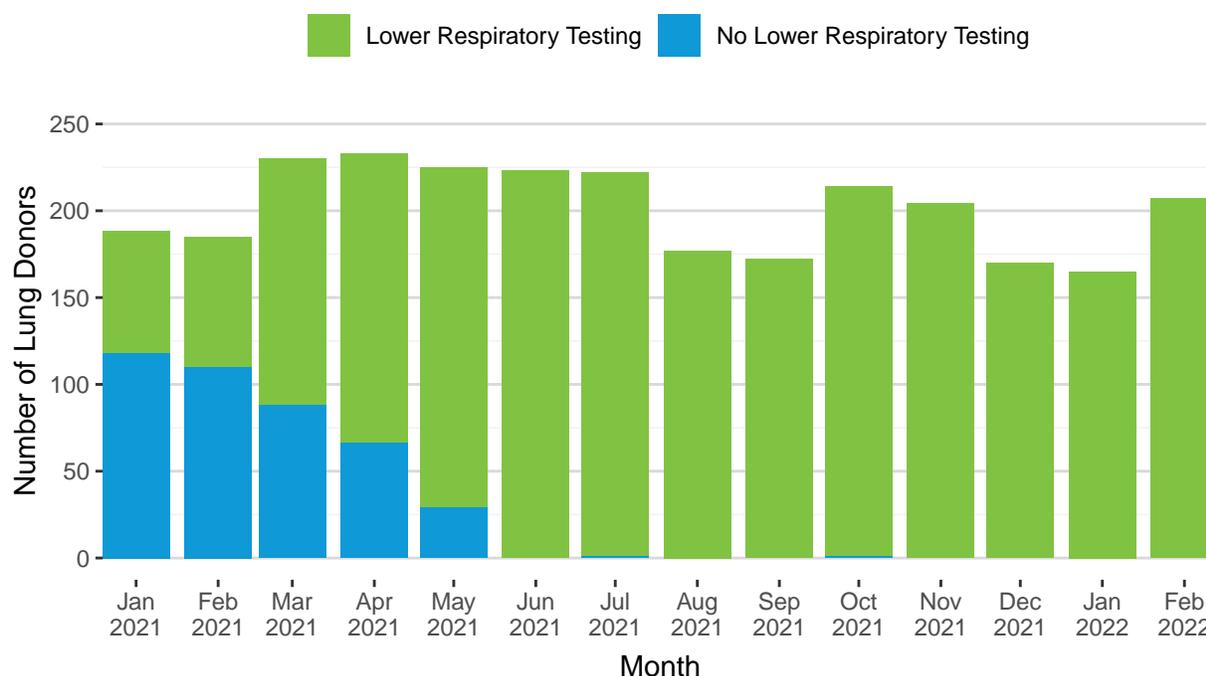


Table 1. Number of transplanted lung donors by month and whether the donor had lower respiratory testing for COVID-19

Month	Lung Donors	N (%) with LRT
January 2021	188	70 (37.2%)
February 2021	185	75 (40.5%)
March 2021	230	142 (61.7%)
April 2021	233	167 (71.7%)
May 2021	225	196 (87.1%)
June 2021	223	223 (100%)
July 2021	222	221 (99.5%)
August 2021	177	177 (100%)
September 2021	172	172 (100%)
October 2021	214	213 (99.5%)
November 2021	204	204 (100%)
December 2021	170	170 (100%)
January 2022	165	165 (100%)
February 2022	207	207 (100%)

Prior to policy implementation, the proportion of transplanted lung donors not receiving lower respiratory testing decreased from 62.8% in January 2021 to 12.9% in May 2021. This proportion dropped to 0% in June 2021, the first full month post-implementation, and has remained below 1% in each month since the policy implementation (**Figure 2**).

Figure 2. Percent of transplanted lung donors not receiving lower respiratory testing for COVID-19 by month

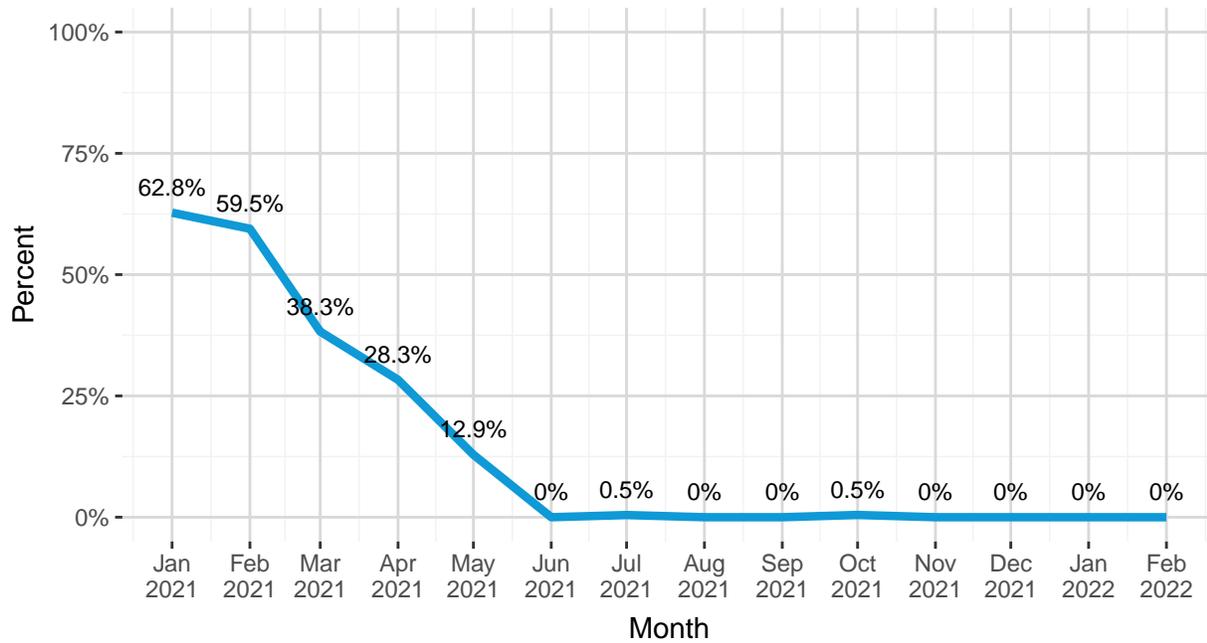


Figure 3 and **Table 2** show the number and proportion of lung donors receiving lower respiratory testing by month and DCD status.

Figure 3. Number of transplanted lung donors by month, DCD status and whether the donor had lower respiratory testing for COVID-19

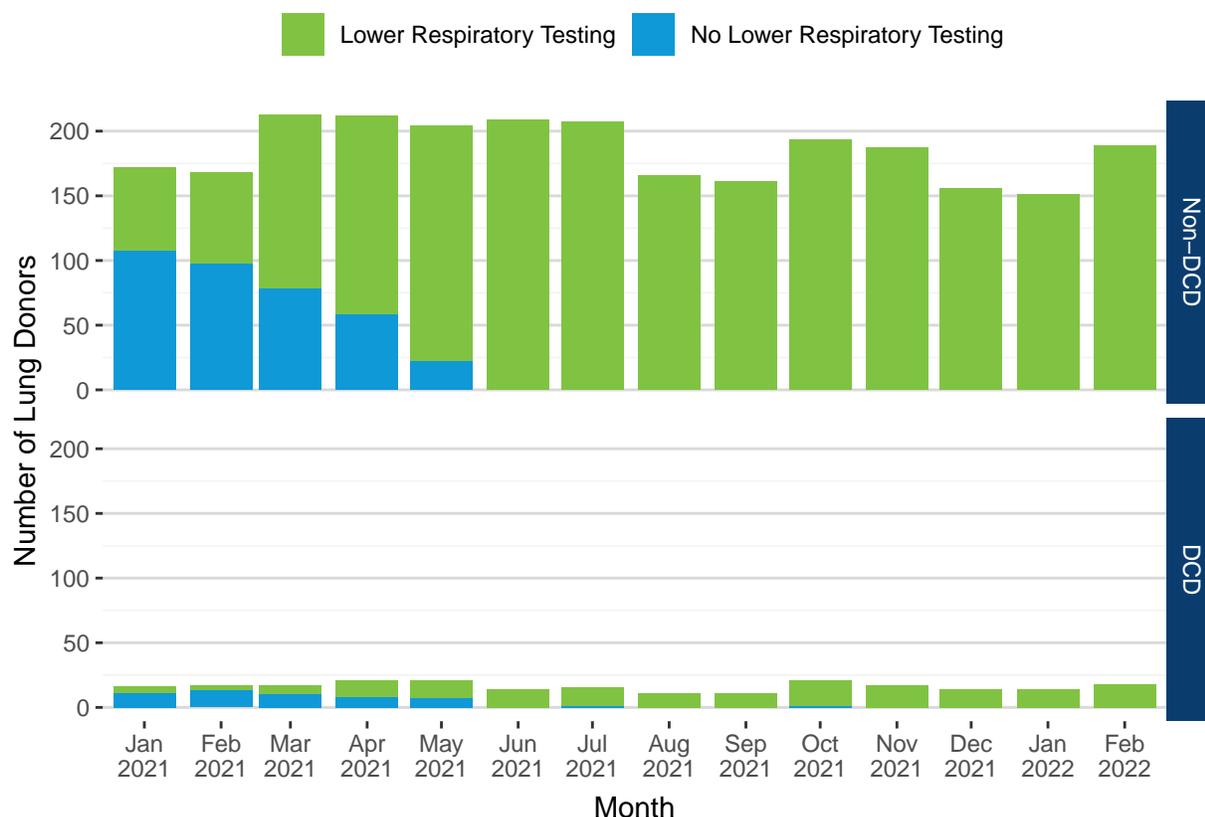


Table 2. Number and percent of transplanted lung donors by month, DCD status and whether the donor had lower respiratory testing (LRT) for COVID-19

Month	Non-DCD Donors		DCD Donors		Total	
	Donors	N (%) with LRT	Donors	N (%) with LRT	Donors	N (%) with LRT
January 2021	172	65 (37.8%)	16	5 (31.2%)	188	70 (37.2%)
February 2021	168	71 (42.3%)	17	4 (23.5%)	185	75 (40.5%)
March 2021	213	135 (63.4%)	17	7 (41.2%)	230	142 (61.7%)
April 2021	212	154 (72.6%)	21	13 (61.9%)	233	167 (71.7%)
May 2021	204	182 (89.2%)	21	14 (66.7%)	225	196 (87.1%)
June 2021	209	209 (100%)	14	14 (100%)	223	223 (100%)
July 2021	207	207 (100%)	15	14 (93.3%)	222	221 (99.5%)
August 2021	166	166 (100%)	11	11 (100%)	177	177 (100%)
September 2021	161	161 (100%)	11	11 (100%)	172	172 (100%)
October 2021	193	193 (100%)	21	20 (95.2%)	214	213 (99.5%)
November 2021	187	187 (100%)	17	17 (100%)	204	204 (100%)
December 2021	156	156 (100%)	14	14 (100%)	170	170 (100%)
January 2022	151	151 (100%)	14	14 (100%)	165	165 (100%)
February 2022	189	189 (100%)	18	18 (100%)	207	207 (100%)

The policy specifies that COVID-19 lower respiratory test results must be available prior to lung transplant. Since implementation, the majority of lung donors (94.3%, N=1681) had lower respiratory test results reported in DonorNet before the day of transplant. 5.1% (N=91) of donors had results entered in DonorNet on the same day as the transplant; 0.3% (N=6) had results reported after the transplant date; and 0.3% (N=5) did not have lower respiratory test results reported in the COVID-19 infectious disease fields or donor attachments (**Figure 4**).

Figure 4. Timing of lower respiratory test result reporting relative to lung transplant, May 27, 2021 - February 28, 2022

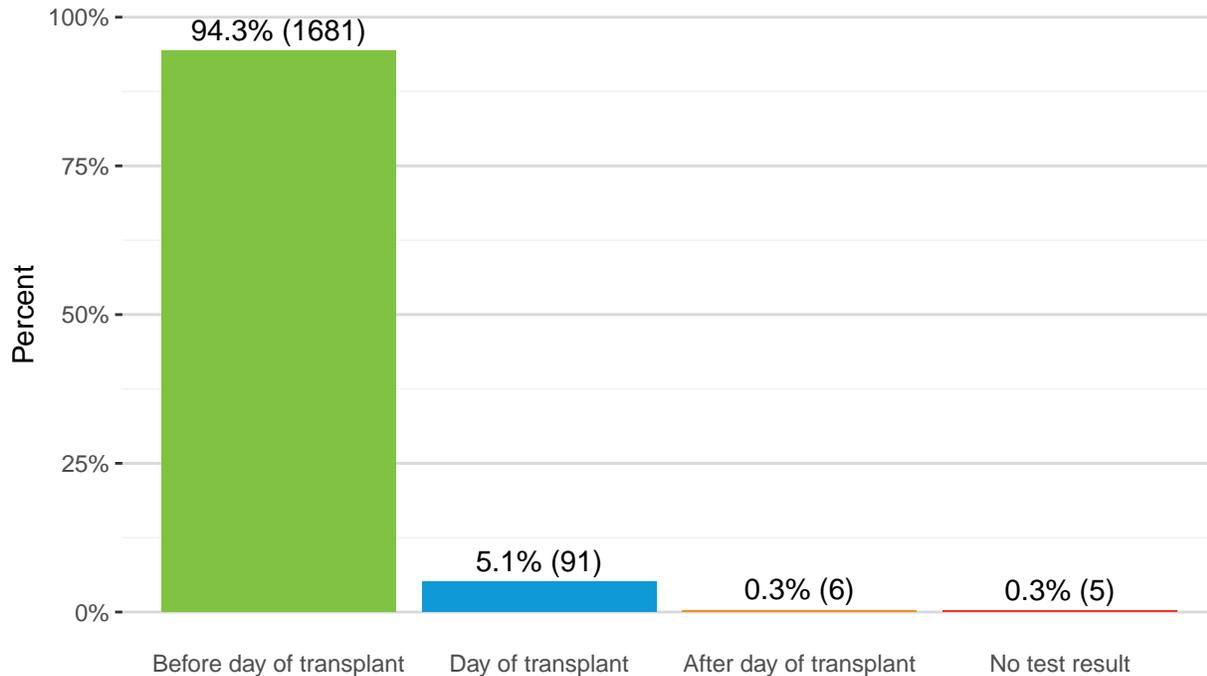


Table 3 shows the test method for lower respiratory tests reported in the COVID-19 infectious disease fields. 99.2% (N=2013) of the lower respiratory tests reported using the discrete data fields were nucleic acid tests. The 12 “Other, specify” free text responses are summarized in **Table 4**.

Table 3. Method of lower respiratory testing for transplanted lung donors with lower respiratory testing reported in DonorNet COVID-19 infectious disease fields, May 27, 2021 - February 28, 2022

Test Method	N	Percent
Nucleic acid detection	2013	99.2%
Antigen	4	0.2%
Other, specify	12	0.6%
Total	2029	100.0%

Note:

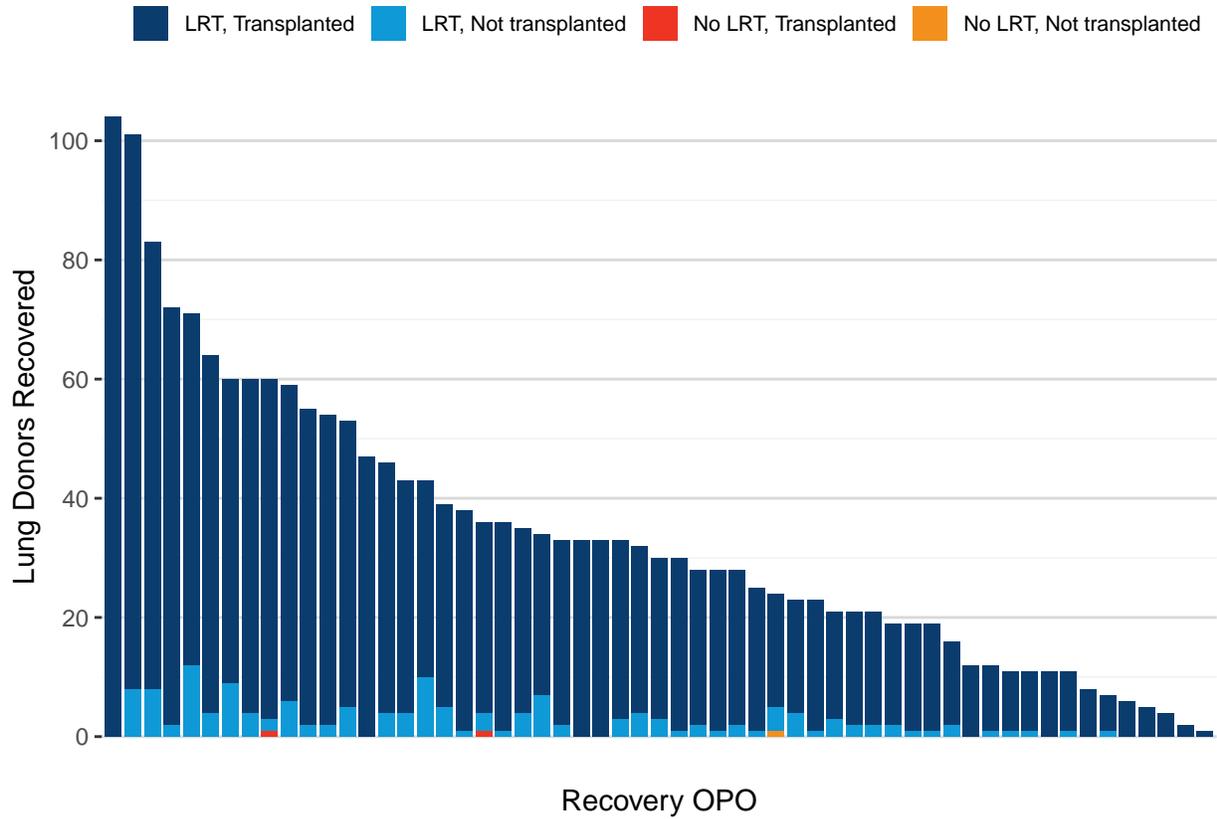
Multiple lower respiratory tests may be reported for the same donor. All test results are included.

Table 4. COVID-19 lower respiratory test method “Other, specify” free text responses

"Other, specify" responses	N
COVID BAL	3
OTHER	2
SARS CORONAVIRUS 2, PCR RAPID, V	2
ANTIGEN	1
BAL	1
BAL COVID TESTING	1
COVID PCR	1
REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	1
Total	12

A total of 57 OPOs have recovered lung donors post-implementation and all 57 have performed lower respiratory testing. **Figure 5** shows the number of lung donors recovered by each OPO and whether they received lower respiratory testing.

Figure 5. Number of lung donors recovered by OPO, May 27, 2021 - February 28, 2022



Since implementation, 202 donors had a positive lower respiratory test. **Table 5** shows the number and percent of donors with a positive LRT by month.

Table 5. Number and percent of recovered donors with a positive COVID-19 lower respiratory test by month, May 27, 2021 - February 28, 2022

Month	Donors Recovered	Donors with Positive LRT	Percent
May 27-31, 2021	202	1	0.5%
June 2021	1233	6	0.49%
July 2021	1255	6	0.48%
August 2021	1131	9	0.8%
September 2021	1105	12	1.09%
October 2021	1176	24	2.04%
November 2021	1161	18	1.55%
December 2021	1119	21	1.88%
January 2022	1088	57	5.24%
February 2022	1159	48	4.14%
Total	10629	202	1.9%

Table 6 describes organs recovered and transplanted from the 202 donors who had a positive lower respiratory test, compared with all other donors recovered in the same time period. One donor with a positive LRT had lungs transplanted; comments in DonorNet indicate that this was believed to be a false positive based on results of confirmatory tests.

Table 6. Organ utilization and discard rates for donors recovered May 27, 2021 - February 28, 2022 by COVID-19 lower respiratory test result

Organ	Donors with Positive COVID-19 LRT				All Other Donors			
	Organs Recovered	Organs TXed	Utilization Rate	Discard Rate	Organs Recovered	Organs TXed	Utilization Rate	Discard Rate
Kidney	385	278	68.8%	27.8%	19748	14644	70.2%	25.8%
Liver	132	125	61.9%	5.3%	7056	6391	61.3%	9.4%
Heart	41	41	20.3%	0%	2891	2865	27.5%	0.9%
Pancreas	12	11	5.4%	8.3%	989	701	6.7%	29.1%
Lung	2	2	0.5%	0%	3721	3393	16.3%	8.8%
Intestine	0	0	0%	-	75	74	0.7%	1.3%
Total Donors	202	176	-	-	10427	9255	-	-

Of the 202 donors with a positive lower respiratory test, 93 (46%) had at least one upper respiratory test that was negative (**Table 7**). 29 (14.4%) donors with a positive LRT also had a negative LRT result. There have also been 322 donors with discordant test results where a lower respiratory test was negative but an upper respiratory test was positive.

Table 7. Number of donors with discordant lower vs upper respiratory test results, May 27, 2021 - February 28, 2022

Month	Positive LRT, Negative URT	Negative LRT, Positive URT	Positive LRT, Negative LRT	Positive URT, Negative URT
May 27-31, 2021	1	5	0	5
June 2021	6	13	2	19
July 2021	5	21	2	29
August 2021	4	11	3	21
September 2021	4	22	2	31
October 2021	7	43	7	41
November 2021	9	28	3	38
December 2021	13	22	2	38
January 2022	22	74	5	97
February 2022	22	83	3	114
Total	93	322	29	433

Utilization and Discard Rates

Figure 6 and Table 8 show the number of donors recovered by month and DCD status.

Figure 6. Deceased donors recovered by month and DCD status

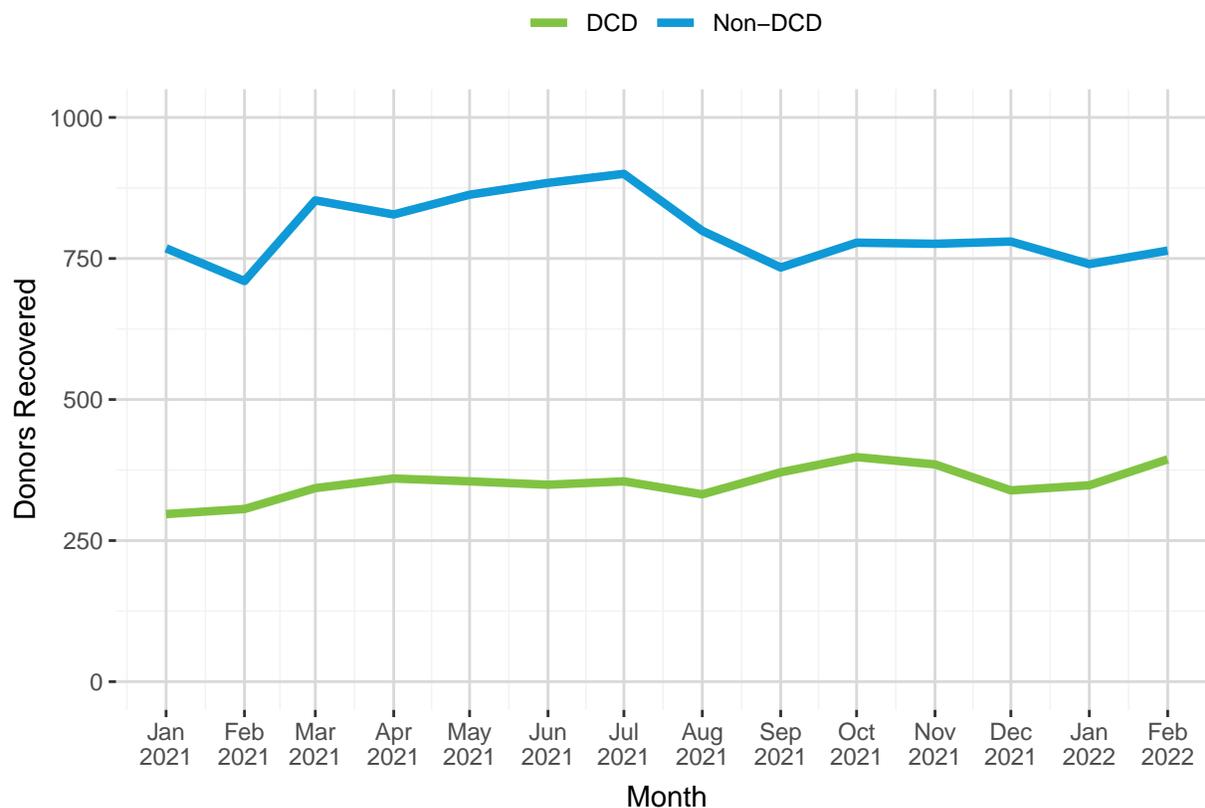


Table 8. Deceased donors recovered by month and DCD status

Month	Non-DCD	DCD	Total
January 2021	768 (72.1%)	297 (27.9%)	1065 (100.0%)
February 2021	710 (69.9%)	306 (30.1%)	1016 (100.0%)
March 2021	853 (71.3%)	343 (28.7%)	1196 (100.0%)
April 2021	828 (69.7%)	360 (30.3%)	1188 (100.0%)
May 2021	863 (70.9%)	355 (29.1%)	1218 (100.0%)
June 2021	884 (71.7%)	349 (28.3%)	1233 (100.0%)
July 2021	900 (71.7%)	355 (28.3%)	1255 (100.0%)
August 2021	799 (70.6%)	332 (29.4%)	1131 (100.0%)
September 2021	734 (66.4%)	371 (33.6%)	1105 (100.0%)
October 2021	778 (66.2%)	398 (33.8%)	1176 (100.0%)
November 2021	776 (66.8%)	385 (33.2%)	1161 (100.0%)
December 2021	780 (69.7%)	339 (30.3%)	1119 (100.0%)
January 2022	740 (68.0%)	348 (32.0%)	1088 (100.0%)
February 2022	765 (66.0%)	394 (34.0%)	1159 (100.0%)

Figure 7 and Table 9 show lung utilization rates by month and DCD status.

Figure 7. Lung utilization rates by month and DCD status

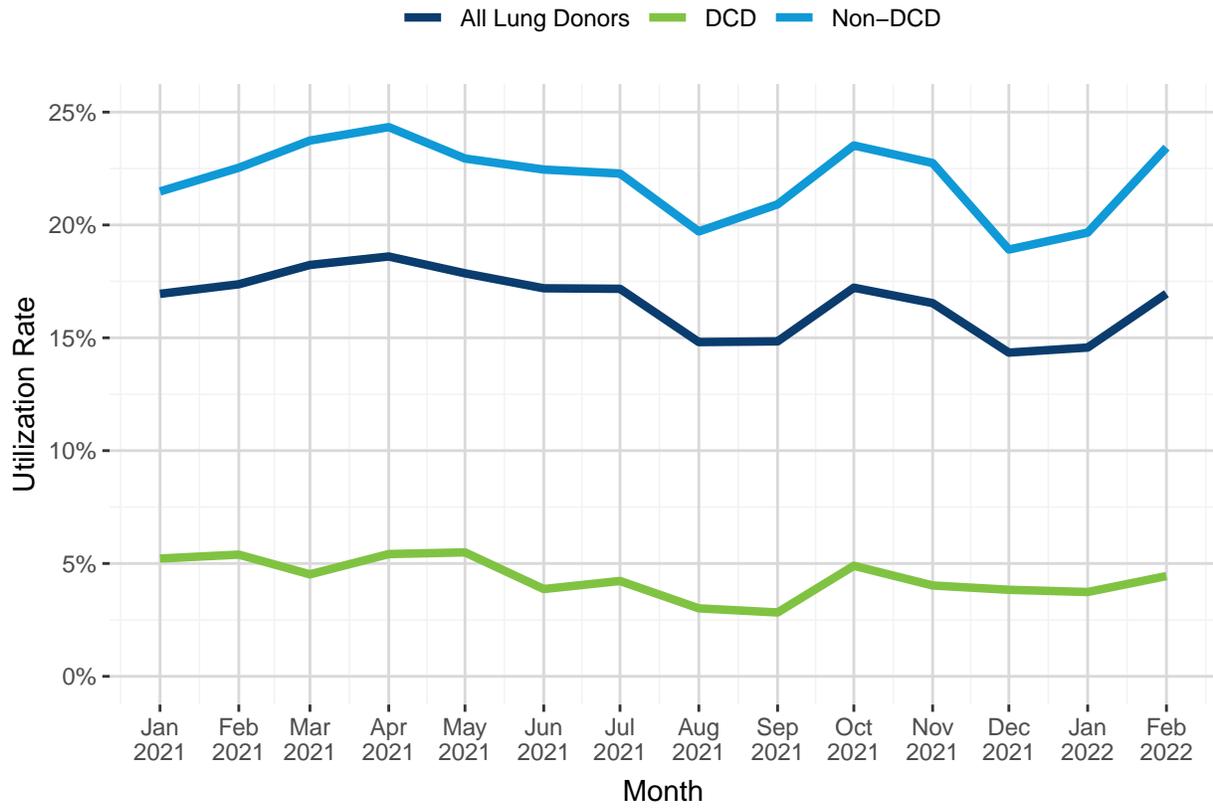


Table 9. Lung utilization rates by month and DCD status

Month	Donor Type	N Donors	Lungs Recovered	Lungs Transplanted	Utilization Rate
January 2021	Non-DCD	768	343	330	21.5%
	DCD	297	40	31	5.2%
	Total	1065	383	361	16.9%
February 2021	Non-DCD	710	344	320	22.5%
	DCD	306	47	33	5.4%
	Total	1016	391	353	17.4%
March 2021	Non-DCD	853	428	405	23.7%
	DCD	343	39	31	4.5%
	Total	1196	467	436	18.2%
April 2021	Non-DCD	828	421	403	24.3%
	DCD	360	46	39	5.4%
	Total	1188	467	442	18.6%
May 2021	Non-DCD	863	416	396	22.9%
	DCD	355	53	39	5.5%
	Total	1218	469	435	17.9%
June 2021	Non-DCD	884	407	397	22.5%
	DCD	349	45	27	3.9%
	Total	1233	452	424	17.2%
July 2021	Non-DCD	900	430	401	22.3%
	DCD	355	38	30	4.2%
	Total	1255	468	431	17.2%
August 2021	Non-DCD	799	341	315	19.7%
	DCD	332	28	20	3%
	Total	1131	369	335	14.8%
September 2021	Non-DCD	734	329	307	20.9%
	DCD	371	39	21	2.8%
	Total	1105	368	328	14.8%
October 2021	Non-DCD	778	389	366	23.5%
	DCD	398	49	39	4.9%
	Total	1176	438	405	17.2%
November 2021	Non-DCD	776	383	353	22.7%
	DCD	385	41	31	4%
	Total	1161	424	384	16.5%
December 2021	Non-DCD	780	323	295	18.9%
	DCD	339	45	26	3.8%
	Total	1119	368	321	14.3%
January 2022	Non-DCD	740	301	291	19.7%
	DCD	348	37	26	3.7%
	Total	1088	338	317	14.6%
February 2022	Non-DCD	764	381	358	23.4%
	DCD	394	55	35	4.4%
	Total	1159	436	393	17%

Figure 8 and **Table 10** show heart utilization rates by month.

Figure 8. Heart utilization rates by month

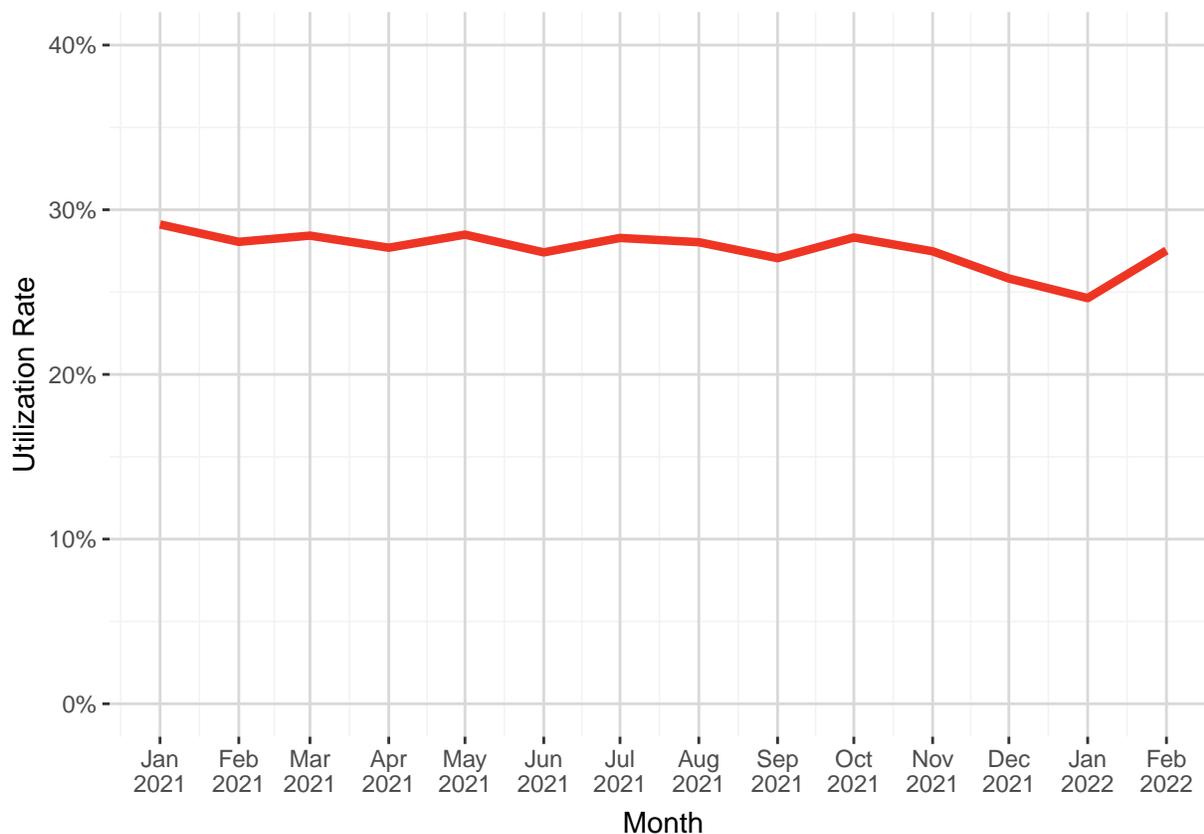


Table 10. Heart utilization rates by month

Month	N Donors	Hearts Recovered	Hearts Transplanted	Utilization Rate
January 2021	1065	311	310	29.1%
February 2021	1016	290	285	28.1%
March 2021	1196	347	340	28.4%
April 2021	1188	332	329	27.7%
May 2021	1218	349	347	28.5%
June 2021	1233	342	338	27.4%
July 2021	1255	356	355	28.3%
August 2021	1131	323	317	28%
September 2021	1105	300	299	27.1%
October 2021	1176	337	333	28.3%
November 2021	1161	323	319	27.5%
December 2021	1119	291	289	25.8%
January 2022	1088	268	268	24.6%
February 2022	1159	323	319	27.5%

Figure 9 and Table 11 show kidney, liver, and pancreas discard rates by month.

Figure 9. Kidney, liver and pancreas discard rates by month

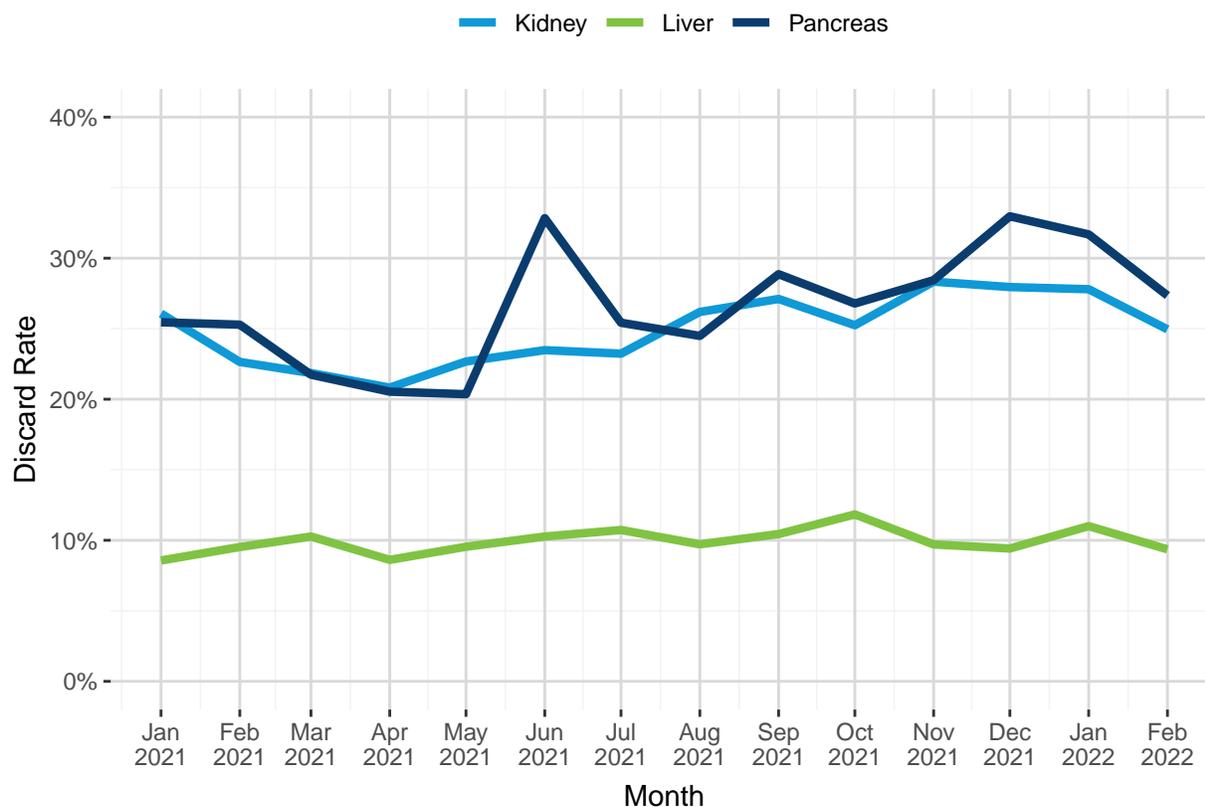


Table 11. Kidney, liver and pancreas discard rates by month

Month	Kidney			Liver			Pancreas		
	Recovered	Discarded	Discard Rate	Recovered	Discarded	Discard Rate	Recovered	Discarded	Discard Rate
January 2021	2021	527	26.1%	747	64	8.6%	110	28	25.5%
February 2021	1930	437	22.6%	714	68	9.5%	87	22	25.3%
March 2021	2265	495	21.9%	867	89	10.3%	138	30	21.7%
April 2021	2257	470	20.8%	836	72	8.6%	112	23	20.5%
May 2021	2342	531	22.7%	828	79	9.5%	113	23	20.4%
June 2021	2334	548	23.5%	867	89	10.3%	134	44	32.8%
July 2021	2376	552	23.2%	876	94	10.7%	118	30	25.4%
August 2021	2127	557	26.2%	772	75	9.7%	98	24	24.5%
September 2021	2110	572	27.1%	728	76	10.4%	97	28	28.9%
October 2021	2222	561	25.2%	769	91	11.8%	112	30	26.8%
November 2021	2202	624	28.3%	783	76	9.7%	109	31	28.4%
December 2021	2125	594	28%	754	71	9.4%	91	30	33%
January 2022	2054	571	27.8%	718	79	11%	101	32	31.7%
February 2022	2192	547	25%	780	73	9.4%	117	32	27.4%

Lung Waiting List

Figure 10 and Table 12 show the number of lung registrations waiting on the last day of each month. There was little change in lung waiting list volume after policy implementation.

Figure 10. Lung registrations waiting on the last day of each month, January 2021 - February 2022

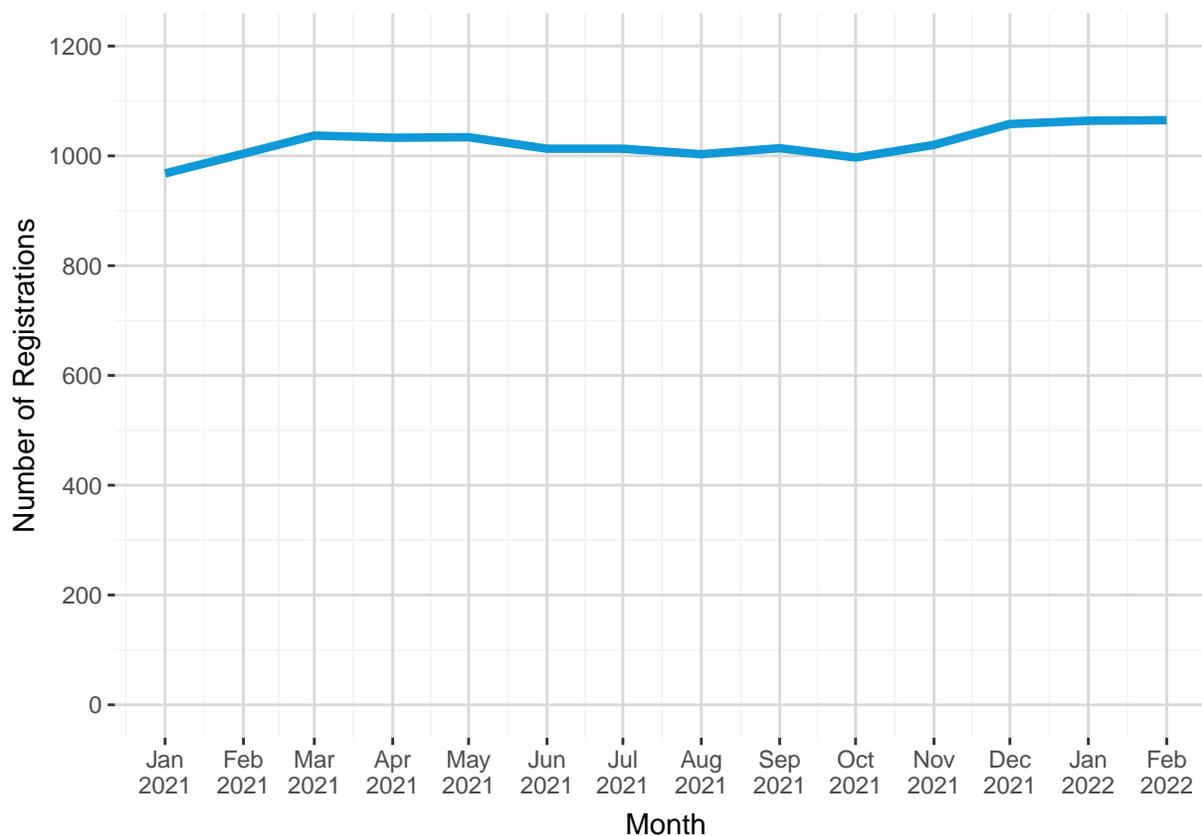


Table 12. Lung registrations waiting on the last day of each month, January 2021 - February 2022

Month	Registrations
January 2021	968
February 2021	1004
March 2021	1037
April 2021	1033
May 2021	1034
June 2021	1013
July 2021	1013
August 2021	1003
September 2021	1014
October 2021	997
November 2021	1020
December 2021	1058
January 2022	1064
February 2022	1065

Figure 11 and **Table 13** show the number of lung registrations waiting on the last day of each month by status. There was little change in the number of registrations in active status after policy implementation.

Figure 11. Lung registrations waiting on the last day of each month by status, January 2021 - February 2022

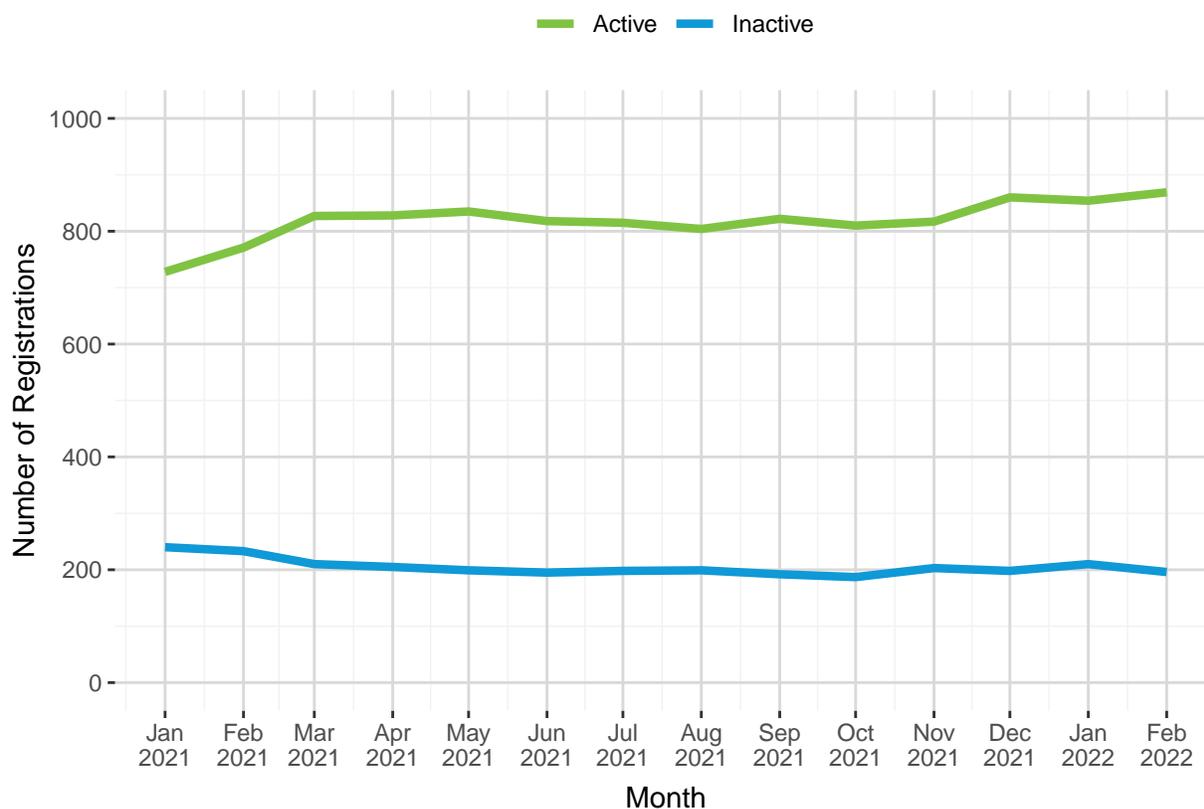


Table 13. Lung registrations waiting on the last day of each month by status, January 2021 - February 2022

Month	Active	Inactive	Total
January 2021	728 (75.2%)	240 (24.8%)	968 (100.0%)
February 2021	771 (76.8%)	233 (23.2%)	1004 (100.0%)
March 2021	827 (79.7%)	210 (20.3%)	1037 (100.0%)
April 2021	828 (80.2%)	205 (19.8%)	1033 (100.0%)
May 2021	835 (80.8%)	199 (19.2%)	1034 (100.0%)
June 2021	818 (80.8%)	195 (19.2%)	1013 (100.0%)
July 2021	815 (80.5%)	198 (19.5%)	1013 (100.0%)
August 2021	804 (80.2%)	199 (19.8%)	1003 (100.0%)
September 2021	822 (81.1%)	192 (18.9%)	1014 (100.0%)
October 2021	810 (81.2%)	187 (18.8%)	997 (100.0%)
November 2021	817 (80.1%)	203 (19.9%)	1020 (100.0%)
December 2021	860 (81.3%)	198 (18.7%)	1058 (100.0%)
January 2022	854 (80.3%)	210 (19.7%)	1064 (100.0%)
February 2022	869 (81.6%)	196 (18.4%)	1065 (100.0%)

Figure 12 and Table 14 show the number of lung registrations added to the waiting list by month.

Figure 12. Lung registrations added January 2021 - February 2022 by month

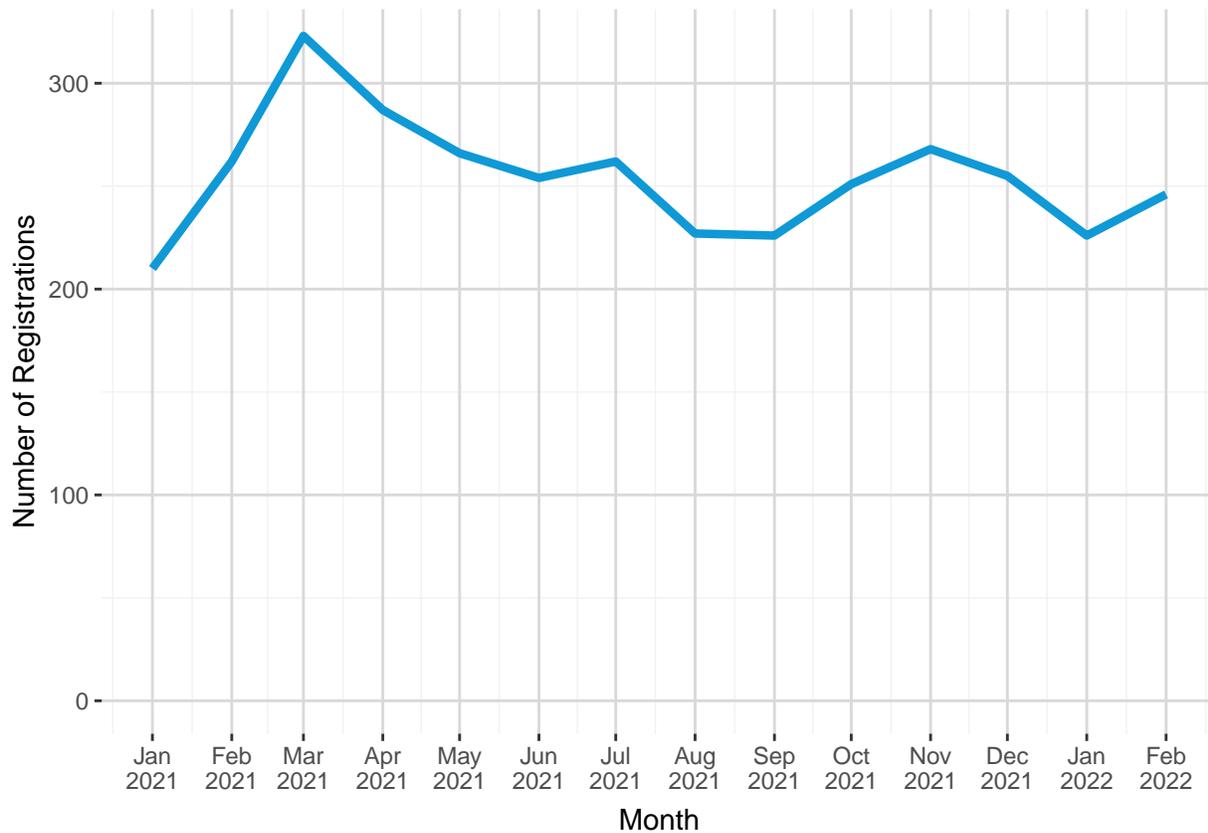


Table 14. Lung registrations added January 2021 - February 2022 by month

Month	Registrations
January 2021	210
February 2021	262
March 2021	323
April 2021	287
May 2021	266
June 2021	254
July 2021	262
August 2021	227
September 2021	226
October 2021	251
November 2021	268
December 2021	255
January 2022	226
February 2022	246

Conclusion

Compliance with the lower respiratory testing requirement has been high with 99.9% (N=1781/1783) of transplanted lung donors receiving lower respiratory tests since policy implementation. 99.4% of transplanted lung donors had test results reported in DonorNet on or before the day of transplant; six donors (0.3%) had test results reported after the day of transplant and test results were not found in DonorNet for five donors (0.3%). Since implementation, 202 donors (1.9%) had a positive lower respiratory test. 46.0% (N=93/202) of the donors with a positive LRT had at least one upper respiratory test that was negative. One donor with a positive LRT had lungs transplanted; comments in DonorNet indicate that this was believed to be a false positive based on results of confirmatory tests. Non-lung organs are being transplanted from donors with positive lower respiratory tests. The OPTN Ad Hoc DTAC will continue to monitor this policy at the frequency noted in the data monitoring plan.