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Brian M. Shepard
Executive Director & CEO

CONFIDENTIAL MEDICAL PEER REVIEW

February 27, 2019

Via Electronic Mail

James D. Eason, M.D., FACS
Surgical Director, Liver Transplant Program
Methodist University Hospital
Suite 340
1211 Union Avenue
Memphis, TN 38104

Dear Dr. Eason:

The Performance Analysis and Improvement Subcommittee (PAIS) of the OPTN/UNOS Membership and Professional Standards Committee (MPSC) met on February 26, 2019, and continued its review of the adult liver transplant program at Methodist University Hospital.

Using a statistically driven method, the Scientific Registry of Transplant Recipients (SRTR) uses blinded data derived from UNetSM to identify programs in which actual one-year patient and/or graft survival falls below the expected rates given individual center donor and recipient characteristics. In brief, the SRTR, using a Bayesian approach to statistical modeling, provides the MPSC with a report detailing program expected survival rates, observed survival rates, the estimated hazard ratio and the probability that the hazard ratio is greater than an established threshold.

The MPSC will review a transplant program if it has a higher hazard ratio of mortality or graft failure than would be expected for that transplant program. A transplant program is identified for review by the MPSC if the program meets one of the following criteria for graft and/or patient survival:

- 1) The probability is greater than 75% that the hazard ratio is greater than 1.2, or
- 2) The probability is greater than 10% that the hazard ratio is greater than 2.5.

The MPSC previously identified this program as one with low one-year graft and patient survival rates relative to expected rates for transplants performed between July 1, 2014 and June 30, 2017. The data are summarized below and in the attached SRTR report:

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2.5 Year Cohort	Survival Outcome Below Expected	Graft survival within 1 year of transplant			Patient survival within 1 year of transplant		
		# of grafts	Observed	Expected	# of transplants	Observed	Expected
Fall 18 CSR (Jul 2015-Dec 2017)	Graft & Patient	276	85.4%	90.4%	262	88.2%	92.8%
Spring 18 CSR (Jan 2015-Jun 2017)	Graft & Patient	283	83.8%	90.0%	271	86.9%	92.4%
Fall 17 CSR (Jul 2014-Dec 2016)	Graft & Patient	281	84.6%	89.9%	270	87.0%	92.3%

Based on data entered into UNetsm as of 10/31/2018

During the February 26, 2019 meeting, the PAIS reviewed the report submitted by Methodist University Hospital on December 13, 2018. As a result of its review, the Subcommittee acknowledges that the program is dedicated to improving its outcomes, but notes that recent outcomes do not seem to be improving. Review of the external consultant's report indicated understaffing at nearly every position except for the transplant surgeon. The review detected cultural issues related to true involvement of the multidisciplinary team. There are also concerns around the lack of exclusion criteria as noted in the external review. The PAIS requests that the program provide the following:

- An updated plan for quality improvement based on the external review.
- Specific updates to the staff recruitment. Include the positions that are posted, positions filled, and onboarding updates.
- Revised protocols since October 2018:
 Pre-transplant recipient selection and evaluation; Donor organ selection and acceptance; Peri-transplant management including surgical procedures and protocols; Post-transplant management protocols; and Hospital specific staffing and quality control.
- Periodic activity reports and transplant logs: An activity report form and a transplant log reflecting current UNetsm data are enclosed. Please validate the information on this report, complete any fields that are blank, and return it to UNOS. If any element of the pre-printed data is incorrect, please make the appropriate changes in UNetsm by April 16, 2019, as well as record them on this form.
- Include a synopsis for any graft loss or death that occurred within one year of transplant since your last submission of synopses.

All of these reports are due on **April 16, 2019**, and will be reviewed by the PAIS during its July 2019 meeting.

Please be aware that this correspondence and all related documents and information are protected by applicable peer review statutes. Members are required to maintain the confidentiality of information provided in the confidential medical peer review processes and settings. Therefore, all inquiries, deliberations, recommendations, and actions of the MPSC and its subcommittees must be kept confidential by members during the review process and after the matter is closed. The Board of Directors may make public certain final adverse actions as delineated in the Bylaws as public actions.

If you have any questions, please contact Robyn Zernhelt, Sheila Foster, or Trung Le at (804) 782-4800.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa M. Stocks". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Lisa M. Stocks, RN, M.S.N., FNP
Chair, Membership and Professional Standards Committee

LMS: rmz

cc: Satheesh P. Nair, M.D., Primary Physician
Esther-Marie Carmichael, Interim Director of Transplant Quality
Leigh Ann Burgess, RN, B.S.N., CCTC, Primary Transplant Administrator
Program File

Scientific Registry of Transplant Recipients

**Center-Specific 1 Year Graft and Patient Survival Rates for 2.5-Year (CSRs),
Time Spans and Completeness of 1-Year Follow-up by Transplant Cohort**

Center ID	Age	Patient or Graft Survival	Cohort	% with Exp FU Forms	Review Flag	%1 Yr FU	#TX	#Failed	#Exp Failed	Actual Survival	Expected Survival	Obs-Exp Events	Obs/Exp Events	One-sided p-value	Mean Hazard Ratio	Pr HR > 1.2	Pr HR > 2.5
TNMH-TX1	Adult	Graft	CSR 2018 Fall	100%	X	100%	276	39	24.161	85.4%	90.4%	14.839	1.614	0.003	1.567	0.943	0.000
			CSR 2018 Spring	100%	X	100%	283	44	25.253	83.8%	90.0%	18.747	1.742	0.000	1.688	0.984	0.002
			CSR 2017 Fall	100%	X	100%	281	42	25.893	84.6%	89.9%	16.107	1.622	0.002	1.577	0.954	0.000
			CSR 2017 Spring	100%		100%	283	35	29.544	87.2%	88.7%	5.456	1.185	0.179	1.173	0.423	0.000
			CSR 2016 Fall	100%		100%	275	33	29.869	87.6%	88.2%	3.131	1.105	0.307	1.098	0.278	0.000
			CSR 2016 Spring	100%		100%	272	34	30.303	87.3%	88.4%	3.697	1.122	0.274	1.114	0.307	0.000
			CSR 2015 Fall	100%		100%	270	33	28.110	87.7%	88.5%	4.890	1.174	0.201	1.162	0.403	0.000
			CSR 2015 Spring	100%		100%	267	30	28.436	88.7%	88.7%	1.564	1.055	0.409	1.051	0.205	0.000
			CSR 2014 Fall	100%	X	100%	282	45	30.144	83.6%	88.0%	14.856	1.493	0.007	1.462	0.897	0.000
			CSR 2014 Spring	99.7%		100%	289	44	31.909	84.7%	88.1%	12.091	1.379	0.024	.	.	.
			CSR 2014 Jan	99.7%	X	100%	289	43	27.928	84.4%	89.0%	15.072	1.540	0.005	.	.	.
			CSR 2013 Jul	100%		100%	291	43	32.150	85.2%	88.4%	10.850	1.337	0.039	.	.	.
			CSR 2013 Jan	100%		100%	287	44	33.614	84.7%	87.7%	10.386	1.309	0.049	.	.	.
		Patient	CSR 2018 Fall	100%	X	100%	262	30	17.379	88.2%	92.8%	12.621	1.726	0.004	1.651	0.951	0.005
			CSR 2018 Spring	100%	X	100%	271	34	18.806	86.9%	92.4%	15.194	1.808	0.001	1.730	0.978	0.008
			CSR 2017 Fall	100%	X	100%	270	34	19.201	87.0%	92.3%	14.799	1.771	0.001	1.698	0.972	0.006
			CSR 2017 Spring	100%		100%	270	27	23.492	89.5%	90.7%	3.508	1.149	0.260	1.138	0.363	0.000
			CSR 2016 Fall	100%		100%	258	24	22.678	90.3%	90.4%	1.322	1.058	0.418	1.054	0.229	0.000
			CSR 2016 Spring	100%		100%	256	25	22.214	90.1%	91.0%	2.786	1.125	0.304	1.115	0.326	0.000
			CSR 2015 Fall	100%		100%	255	24	20.969	90.5%	91.0%	3.031	1.145	0.282	1.132	0.357	0.000
			CSR 2015 Spring	100%		100%	249	22	21.278	91.1%	91.0%	0.722	1.034	0.466	1.031	0.203	0.000
			CSR 2014 Fall	100%	X	100%	260	29	20.564	88.4%	91.4%	8.436	1.410	0.046	1.374	0.751	0.000
			CSR 2014 Spring	99.6%		100%	272	31	22.947	88.5%	91.2%	8.053	1.351	0.063	.	.	.
			CSR 2014 Jan	99.6%	X	100%	269	28	17.878	88.9%	92.6%	10.122	1.566	0.016	.	.	.
			CSR 2013 Jul	100%		100%	269	27	20.344	90.0%	92.3%	6.656	1.327	0.090	.	.	.
			CSR 2013 Jan	100%		100%	267	28	21.728	89.5%	91.8%	6.272	1.289	0.111	.	.	.

Multi-organ transplants are NOT INCLUDED in this report or in the statistical analysis used to determine expected deaths/failures.