Regional Variability In Liver Waiting List Removals Causes False Ascertainment Of Waiting List Deaths

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I have no financial relationships to disclose within the past 12 months relevant to my presentation

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Introduction

- Waitlist removals for "too sick to transplant," "medically unsuitable," or "refused transplant" are generally thought to be associated with high mortality after removal
- In studies of mortality these categories are either censored (treated as survivors) or treated as deaths
- The categories are not well defined and guidelines do not exist, which could lead to Regional differences in how these categories are used



Objectives

- Assess how accurate the traditional models of death ascertainment are, including categories "death" + "too sick" + "medically unsuitable"
- Determine if Regional variability in waitlist deaths is in part due to differences in the way the poorly defined removal categories are used.
- Establish (an) optimal model(s) to reduce inaccuracy and false ascertainment of death.



Methods

- Data source: OPTN STAR file
 - 103,364 patients active on the OPTN liver transplant
 waiting list at any time in the period 5/8/2003 4/17/2011.
- We constructed a mixed Cox model of all individual demographic and clinical covariates, <u>excluding Region</u>, to estimate baseline relative risks for transplantation and for death for each individual patient listing.
- individual baseline relative risks were included as "offsets" in subsequent mixed model analyses to assess the variability of the impact of Region on the risk (likelihood) of transplantation and of death.



Results1: Removals for All Causes Other than Transplant or Death

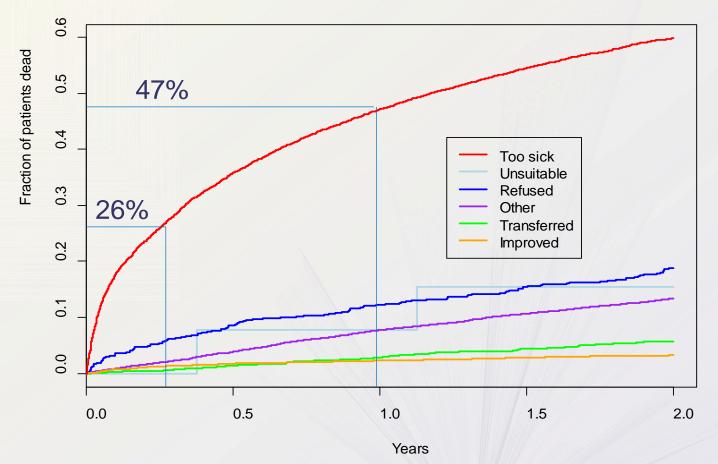
Initial Listings=103,364

Delisting: neither transplantation nor death: 21,176

Removal Reason	Number	Percent of
		total
Other	8,033	37.9
Too sick	6,434	30.4
Improved	4,597	21.7
Transferred	1,486	7.0
Refused	602	2.8
Unsuitable	13	0.1
Removed in error	11	0.1
	6	SCIENTIFIC

Mortality was 26% at 90 days and 47% at one year following delisting for "too sick"

Death After Removal from the Waitlist no



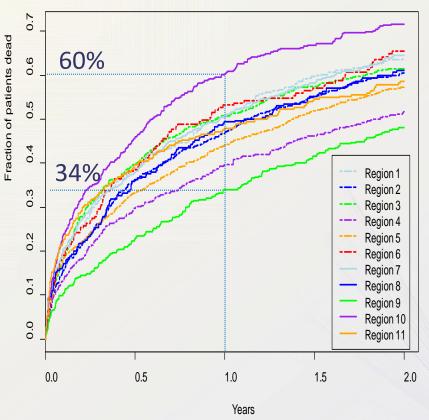


There was substantial variability by OPTN region in the risk of death following removal from the list as "too sick,"

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Deaths after Removal for "too sick"

Ratio of removals for "too sick" to "death" by OPTN Region



Region	WL	Removals for	Ratio
	Deaths	"too sick"	
1	759	391	0.51
2	1,931	929	0.48
3	895	675	0.75
4	1,435	565	0.39
5	2,826	1,522	0.54
6	203	190	0.94
7	1,070	619	0.58
8	807	281	0.35
9	1,754	403	0.23
10	713	516	0.72
11	1,034	343	0.33

New Models for Ascertainment of Death

Traditional models (do not include SSADMF deaths):

- 1. List only: Removals for Deceased donor transplant at the listing center and death on the list
- 2. List + "too sick": Removals for Deceased donor transplant at the listing center and death on the list + removal as "too sick."

New Models (Include SSADMF deaths and UNOS reported deaths)

- 3. 90 days: Any death on the list or <u>within 90 days of removal from</u> the list, censoring for any transplant (living or deceased donor, at the listing hospital or elsewhere)
- 4. One year: Any death on the list or within 365 days of removal from the list, censoring for any transplant (living or deceased donor, at the listing hospital or elsewhere)
- 5. Ever: Any death on the list or ever after removal from the list, censoring for any transplant (living or deceased donor, at the listing hospital or elsewhere).



Model variance for impact of Region on "risk" of death

Model	Variance for death	Model/90 day model
1. List only	0.0327	1.92
2. List + "Too	0.0262	1.54
sick"		
3. 90 Day	0.0170	(reference)
4. 1 Year	0.0137	0.81
5. Ever	0.00911	0.54

Regional variance of the risk of death for Model 3 is only
52% as large as the estimated variance of
Model 1, and only 65% as
large as the variance for
Model 2.

Discussion: Variance In Ascertainment Of Death Can Be Reduced By Using SSADMF Reported Deaths

- Traditional models for ascertaining death lack sensitivity and specificity.
- The 90-day model, which includes all SSADMF ascertained deaths within 90 days of delisting (Model 3) accounted for the majority of the deaths (including many missed by UNOS reporting), and did not include "false deaths" ascertained by including "too sick" as death.
- The 90 day model accounted for most of the reduction in Regional variance in deaths (by 48% compared with Model 1 and by 35% compared with Model 2).
- Models 4 &5 are similar to model 3, but with longer follow up; Model 5 is used for SRTR Center Specific reporting.



Summary

- The way removal categories are used varies substantially among regions, and this is associated with marked differences in reported mortality by region.
- Traditional models to ascertain death which rely on deaths reported to UNOS and other removal codes (eg :too sick") result in spurious regional variance in death:
- While true differences in risk of death exist among regions, these differences are clouded by inaccurate ascertainment of death when traditional models are used.
- The variance can be substantially reduced by including deaths reported to SSADMF.
- Including deaths reported to SSADMF by 90 days has the advantage of biological plausibility, relative completeness, and efficiency.

