Published in final edited form as:
*Transplantation*. 2013 July 27; 96(2): 211–216. doi:10.1097/TP.0b013e3182970619.

# Underreporting of Liver Transplant Waitlist Removals due to Death or Clinical Deterioration: Results at 4 Major Centers

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## Abstract

**Background—**Few studies have evaluated the accuracy of UNOS/SRTR data among patients listed for liver transplantation. Of particular importance for transplant policy and practice is whether patients' outcomes are coded properly.

**Methods—**Using data from four transplant centers, we identified all liver transplant candidates removed from the waitlist from February 27th, 2002 to July 24, 2010, with a specific focus the removal code of "other."

**Results—**Among non-transplanted patients at these centers, 2,206 patients were removed for death or clinical deterioration. Of these, 8.6% (189/2,206) were misclassified—they were assigned the UNOS removal code of "other." Among these 189 misclassified patients, 128 became medically unsuitable, 35 died, and 26 became too sick to transplant. Nearly one-half (46.8%) of

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[1]David Goldberg participated in research design, writing of the paper, performance of the research, and data analysis. National Institutes of Health (grant 1-F32-DK-089694-01 from the National Institute of Diabetes and Digestive and Kidney Diseases). Health Resources and Services Administration (contract 234-2005-370011C). The contents are the responsibility of the authors alone and do not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the US Government. The author has no potential conflict of interest.

[2]Benjamin French participated in research design, writing of the paper, performance of the research. The author has no potential conflict of interest.

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misclassified patients were removed due to advanced HCC. Among true waitlist removals for death, only 35/1593 (2.2%) were misclassified. Conversely, of true removals for clinical deterioration, 154/612 (25.2%) were misclassified, with significant (P<0.001) center variation: 4.4% (Baylor), 8.0% (Georgetown), 32.6% (University of Pennsylvania), and 45.0% (Mount Sinai). Extrapolating this data to the entire United States, if "other" patients who truly died or clinically deteriorated were recoded appropriately, there would be an additional 2,525 (95% CI: 2,046–3,102) patients removed from the waitlist due to death (331) or clinical deterioration (2,194) since 2002.

**Discussion—**A substantial proportion of patients truly removed from the waitlist for death or clinical deterioration were misclassified as "other." Thus analyses using the UNOS or SRTR database may underestimate the true proportion of patients removed from the waitlist for clinical deterioration.

### Keywords

Liver transplantation; waitlist removal; hepatocellular carcinoma; misclassification

## Background

Most large studies assessing waitlist outcomes of patients listed for liver transplantation use the United Network for Organ Sharing (UNOS) or The Scientific Registry of Transplant Recipients (SRTR) databases. Data in these databases are derived from reports submitted to UNOS by individual transplant centers.[1,2] Thus, the data upon which we generate clinical and policy decisions regarding liver transplantation rely upon the accuracy of reporting of the more than 100 U.S. liver transplant centers.

Few studies have evaluated the accuracy of UNOS/SRTR data among patients listed for liver transplantation.[3] Of particular importance for transplant policy and practice is whether patients' outcomes are coded properly. When a patient is removed from the waitlist, he/she is coded as being removed for one of fifteen reasons, including six codes for transplantation, three codes related to death or clinical deterioration, and six miscellaneous codes (Table 1).[2] However, there are no specific criteria or definitions set forth by UNOS to guide transplant centers on what code to use when removing a patient from the waitlist. Although transplant centers are responsible for having appropriate documentation to support their reason for removal, these decisions are not routinely evaluated, except if they are reviewed during a UNOS site survey.

According to Organ Procurement and Transplantation Network (OPTN) data as of March 25, 2011, among the 39,171 waitlist removals (excluding those patients removed for transplantation) since 2002, 9,039 (23.1%) were removed for "other" reasons (Table 1). Because UNOS does not specify the precise reason for removal of "other" patients, prior studies utilizing the UNOS or SRTR databases have treated these patients one of two ways, they are: a) excluded in logistic regression analyses with the binary outcome of transplantation vs. death/removal due to clinical deterioration [4]; b) censored in time-to-waitlist dropout survival analyses, such as Cox regression, at the time of removal.[4,5]

Unfortunately, these approaches create several problems if substantial proportions of "other" patients are in fact removed due to death or clinical deterioration, including biasing comparisons or reducing statistical power by having fewer outcomes. Most importantly though, by excluding or censoring some patients who actually deteriorated clinically or died, such outcome misclassification may produce overly optimistic depictions of waitlist outcomes (e.g., underreporting the true rate of waitlist removal for death or clinical deterioration).[6]

Additionally, although data in the SRTR and UNOS databases is supplemented by data from the Social Security Death Master File (SSDMF), many of the publicly available SRTR data reports are based only on reported deaths (not including those who died after removal) and "too sick" removals that are accurately submitted to UNOS.[7–9] Additionally, as of November 1, 2011, the Social Security Administration (SSA) will no longer be able to disclose death information obtained through state records, decreasing the ascertainment of death outcomes by approximately 35%.[10] Given this, it is imperative that we have a full understanding of the true outcomes of waitlisted candidates.

We designed the present study to answer two questions: 1) what is the true percentage of patients removed due to death or clinical deterioration and what was the percentage of these removals that were misclassified as "other;" and 2) what is the impact of these misclassifications on the reporting of waitlist outcomes.

## Results

From February 27, 2002 through July 24, 2010, there were 2,191 patients added to the liver transplant waitlist at Baylor University, 1,997 at the University of Pennsylvania, 1,372 at Mount Sinai, and 946 at Georgetown University. The four centers represented three UNOS regions (2, 4, and 9), and performed approximately 7% of all U.S. liver transplants during the study period. During this time period, there were a total of 1,994 waitlist removals (which includes patients listed prior to February 27, 2002 but still on the waitlist at that time) at the University of Pennsylvania, 1,026 at Georgetown University, 1,834 at Baylor, and 2,137 at Mount Sinai. Among all waitlist removals across the four centers, there was significant variation in the proportion coded as removed for transplantation, death, clinical deterioration, "other", or miscellaneous reasons (Table 2a). Table 2a lists the number of patients transplanted and removed from the waitlist for death, clinical deterioration, "other" reasons, or miscellaneous reasons, among the four centers.

The overall rate of misclassification (removals for death or clinical deterioration coded as "other"/true removals for death or clinical deterioration) among the four centers was 8.6% (189/2,206), however given the differences in the "number at risk" of being misclassified due to the different denominators in the "died" and "clinical deterioration" categories, we present the data stratified by cause of waitlist removal. Of true removals for clinical deterioration among the four centers (Table 2b), 154/612 (25.2%) were misclassified, with significant ($P<0.001$) center variation: 4.4% (Baylor), 8.0% (Georgetown), 32.6% (University of Pennsylvania), and 45.0% (Mount Sinai). Conversely, only 2.2% (35/1,593) removals for death were misclassified, with 0.0% at Georgetown, 0.3% at Baylor, 1.6% at the University of Pennsylvania, and 4.6% at Mount Sinai ($P<0.001$ comparing the proportion of misclassified deaths per center). The Kappa for inter-rater reliability was very good, with the Kappa at each center being >0.80.

### Factors associated with misclassification

Among the "other" patients who were removed for death or clinical deterioration, 45.5% were listed with a diagnosis of Hepatitis C (HCV), 15.8% had alcoholic liver disease, and 9.5% had hepatitis B. Among true removals for death or clinical deterioration, there were significant differences in the rates of misclassification based on diagnosis ($P=0.002$). While only 2.7% (6/226) of removals for death or clinical deterioration in patients with non-alcoholic steatohepatitis (NASH) were incorrectly coded as "other," 9.1% (86/947) of removals for hepatitis C, 11.3% (7/55) of removals for autoimmune hepatitis, and 18.6% (18/97) of removals for hepatitis B were incorrectly coded as "other".

Table 3 lists the true reasons for removal for "other" patients who in fact were removed due to death or clinical deterioration. Nearly one-half (46.8%) of patients were removed due to advanced hepatocellular (HCC; Table 3), including patients with HCC outside of Milan or University of California-San Francisco (UCSF) criteria, multifocal HCC, HCC with portal vein invasion, or metastatic HCC. Five of the six patients misclassified due to cholangiocarcinoma had primary sclerosing cholangitis.

Among those with available MELD score data at the time of removal, misclassified patients had significantly lower laboratory MELD scores than those classified correctly (16.4 ± 7.8 vs. 22.9 ± 11.1 P<0.001). As 38.1% (72/189) of misclassified patients were missing final MELD data, this variable was excluded from the regression model. Misclassified patients had significantly longer waitlist time (993 ± 1075 days vs. 741 ± 908 days, P<0.001) prior to removal, compared with those waitlisting candidates who died or were too sick, and were coded correctly.

In univariable models, male gender, Asian race, Medicare or Medicaid insurance, older age at listing, and hepatitis B were associated with increased odds of misclassification (Table 4; Supplementary Table 1). Conversely, NASH as the primary diagnosis was associated with decreased odds of misclassification. In multivariable models treating transplant center as a fixed effect, only male gender, Medicaid insurance, and older listing age remained significantly associated with increased misclassification, while NASH was still associated with a lower odds. The results of the final multivariable model were unchanged when only the University of Pennsylvania and Mount Sinai were considered (data not shown).

After adjusting for the variables in the multivariable model, significant center variation remained, with Baylor (OR: 0.12, 95% CI: 0.05–0.26) and Georgetown (OR: 0.14, 95% CI: 0.06–0.34) having significantly less misclassification. To further evaluate potential center-level causes of misclassification, we examined other center characteristics that may lead to these differences, and found that the median MELD at transplant was similar at the University of Pennsylvania, Georgetown, and Mount Sinai, the median listing MELD was the same at all 3 centers, and the median time from listing to transplantation was longest at Georgetown, followed by University of Pennsylvania, Baylor, and Mount Sinai. Lastly, the proportion of transplants in patients with HCC was similar across all three centers. Given these data, these factors are unlikely to explain the center-level differences in misclassification.

### National impact of misclassification on reporting of waitlist outcomes

Generalizing the results from these 4 centers to the complete UNOS data file, and recoding "other" removals who truly were removed for death or clinical deterioration correctly, yielded an additional 331 waitlist deaths and 2,194 removals due to being too sick and/or medically unsuitable (Table 5). Overall, there would approximately be an additional 280 removals for death or clinical deterioration per year (overall 2,525 additional removals for death or clinical deterioration since 2002 [95% CI 2,041–3,096] or 11.9% additional removals for death or clinical deterioration [95% CI: 8.6–14.5]).

## Discussion

This multi-center study found that a substantial number of patients truly removed from liver transplant waitlists for death or clinical deterioration were misclassified as being removed for "other" reasons, with approximately 25% of patients truly removed for clinical deterioration being miscoded. If this observed proportion of misclassifications is uniform across the U.S., this would suggest that adverse outcomes on the liver transplantation waitlist are nearly 12% more common than reported, reflecting a greater degree of liver

scarcity than commonly recognized. Given the recent changes in the reporting of deaths in the SSDMF (as of 11/1/11, the SSA will no longer disclose death information obtained through state records) the accuracy of waitlist outcomes is of even greater concern.[10]

There has been a concerted effort to reduce the amount of data provided to UNOS, and available in the UNOS database. This includes less detailed reporting to UNOS on cause of death information for transplant recipients and specific explant pathology on patients transplanted for HCC (pathologic data is not available in UNOS datasets). However, accuracy of removal reasons from the waitlist is important from a research perspective, to ensure that outcomes research utilizing the UNOS database is not subject to bias, and from a clinical perspective, so policy decisions made using UNOS data are based on the most accurate data available. Without specific criteria defining each removal code though, this misclassification may persist.

UNOS relies on individual centers to submit data that are accurate and reliable, but these results suggest this is not always the case. While the Adult-to-Adult Living Donor Transplant Registry (A2ALL) study group performed a detailed database comparison of the SRTR and A2ALL databases, finding substantial missing data in the SRTR database compared to the A2ALL database, the study investigators did not quantify the potential impact of this missing data.[3]

The differences noted in the proportions of misclassifications among centers merits further exploration, as the available data do not provide specific reasons why such variability in misclassification exists. Mount Sinai, the University of Pennsylvania, and Georgetown University operate in donor service areas with similarly high MELD scores at transplantation, resulting in a potential greater risk for waitlist dropout due to death or clinical deterioration as patients achieve higher MELD scores. However, MELD score at transplantation would not explain our findings, as despite similarly high MELD scores at transplantation at these three centers, there were significant differences in misclassification rates by center. Similarly there was not a correlation between median wait time from listing to transplantation and rates of misclassification. One potential explanation for why misclassifications occur, and why there is such variability, rests on the process by which data is submitted to UNOS. At Baylor University and Georgetown University, the patient selection committee decides on a specific reason for removal, in accordance with the UNOS removal codes, while at Penn and Mount Sinai, specific reasons for removal are not explicitly made according to the UNOS coding scheme. Future work will focus on a detailed examination of center-specific practices that lead to misclassification, in order to develop interventions to decrease this in the future.

The proportion of patients misclassified was markedly higher among those truly removed for clinical deterioration. This likely is due to the fact that when a patient died prior to de-listing, the cause of removal is evident. However, when a patient is removed for other reasons, such as advanced HCC, the reason for removal may be less clear, especially when one is using the UNOS removal guides to categorize the reason for removal. As outlined in Table 5, if the rates of misclassification observed in these four centers were seen across the United States, then there were a significantly greater number of patients who were removed from the waitlist for death or clinical deterioration than currently reported. Of the waitlist removals for death or clinical deterioration that may not be captured, our data suggest that the vast majority (2,194/2525; 86.9%) are patients who in fact were removed for clinical deterioration. This is due to the fact that 81.5% of the misclassified patients in fact were removed not for death, but for a clinical deterioration (Table 3). Also, as the total number of waitlist removals for death are greater than twice the removals for being “too sick to transplant,” while the number of misclassified patients who were “too sick” was greater than

four times that of patients who died, the percentage change is markedly greater for the "too sick" category.

Our study has limitations. First, while a strength of our study is that the number of "other" removals captured in this study represents nearly 10% of the total number of "other" removals in the country, the data were obtained from only four centers. The large variability in rates of misclassification across centers raises the question of the generalizability of our data. Further research therefore is needed to determine what the overall rate of misclassification is across the country. Given the available data, we are only able to hypothesize why misclassifications occur. In determining the proportion of patients who truly died or were removed from the waitlist for clinical deterioration, yet were coded as other, we had to assume that all patients coded as died, too sick, or medically unsuitable were accurately coded. Given prior work demonstrating that over 80% of these patients die within 2 weeks of waitlist removal, we are confident in this assumption.[11] Finally, we do not have data on presence of HCC at the time of listing on all patients. The primary diagnosis at listing at each center was based on the etiology of chronic liver disease (i.e. hepatitis C), even in the presence of HCC. Additionally, HCCs that developed in patients while on the waitlist, yet did not lead to waitlist removal, were not captured. Such data cannot be obtained without full medical record review of all waitlist patients at each center.

In summary, our research demonstrates that nearly 9% of patients removed from the waitlist for death or clinical deterioration are misclassified as being removed for "other" reasons. If this rate of misclassification is seen nationally, then there would be significant under-reporting of the true number of waitlist removals for death or clinical deterioration. Approximately half of these misclassifications are related to HCC. These misclassifications may result from a lack of specific guidance as to what defines each removal code, different practices at transplant centers determining the reason for removal, or the lack of specific codes for conditions such as HCC. We would propose that the UNOS removal codes be revised to better reflect the reasons why patients are removed from the waitlist (Table 1), which might help researchers and policymakers who utilize the UNOS database to evaluate outcomes of waitlisted transplant candidates. Also, we would recommend that UNOS specifically define what the "other" category encompasses, specifically removal due to loss to follow-up, psychosocial reasons, and non-compliance (i.e. waitlist candidates who do not comply with outpatient alcohol rehabilitation or follow-up with medical appointments), and not due to clinical deterioration. As data reported to UNOS plays a major role in outcomes research in the field of liver transplantation, it is imperative that we have the most accurate, reliable data available. An important direction for future research is to explore center-level process characteristics (including testing the hypotheses mentioned in this section) that are associated with misclassification.

## Materials and Methods

### Patients

We included all patients listed for liver transplantation, and subsequently removed from the waitlist between 2/27/02–7/24/10, from the University of Pennsylvania, Mount Sinai Medical Center, Baylor University Medical Center, and Georgetown University University Medical Center. (2/27/02 was chosen as the start date as that was the first date the MELD score was used.) A single data abstractor at each center identified all patients removed from the waitlist with the UNOS removal code of "other," based on data in each center's computerized database.

We also included all patients removed from the transplant waitlists at these four centers during the study period with the waitlist removal code of "died," "too sick to transplant," or

"medically unsuitable." These data were obtained from a UNOS Standard Transplant Analysis and Research (STAR) file. These patients were subsequently coded as either died on the waitlist (UNOS removal code of "died") or removed for clinical deterioration ("too sick to transplant" or "medically unsuitable"). Although the true outcomes of each of these patients was not individually verified, we felt confident about the accuracy of these codes, as prior research using Social Security Death Master File verification has demonstrated that waitlist candidates removed with one of these codes either die on the waitlist, or within a short period of time after removal, confirming the accuracy of such removal codes.[11]

## Misclassifications

Two blinded abstractors at each center reviewed these patients' medical records to determine if removals for "other" reasons constituted clinical deterioration, defined as death, being too sick to transplant, or medically unsuitable for transplant (e.g. a medical or surgical contraindication to transplant, such as advanced HCC). A detailed reason for removal was collected for each patient. We then used the 15 UNOS removal codes (Table 1), to code each patient's true reason for waitlist removal, to be consistent with UNOS data (i.e. an "other" patient who died would receive a code of 8, the UNOS removal code for "died"). Finally, to maintain consistency with outcomes studies using UNOS data, and to guide future research, we divided patients into two groups, clinical deterioration as cause of removal (yes or no), defined as being reclassified as "medically unsuitable," "too sick to transplant," or "died."

We quantified misclassification as a function of all removals for death or clinical deterioration—the percentage of all removals due to death or clinical deterioration that were misclassified as "other." We first calculated the total number of "true removals" for death or clinical deterioration as: a) those receiving the UNOS removal code of "died," "too sick to transplant," or "medically unsuitable" from the four centers plus b) "other" removals from the four centers who in fact were removed for death or clinical deterioration. We then calculated the percentage of all removals due to death or clinical deterioration that were misclassified as "other" by dividing the number of "other" removals who died or were too sick to transplant by the total number of "true removals" for death or clinical deterioration.

We used Fisher's exact and chi-square tests to evaluate differences in misclassification based on center. We also used chi-square tests to determine if among patients truly removed for death or clinical deterioration, there were different proportions misclassified as "other" based on primary diagnosis at listing. We calculated a kappa coefficient and 95% confidence interval was calculated for each center to determine the inter-rater reliability of the two blinded abstractors for determining whether an "other" removal in fact was removed for death or clinical deterioration.

Lastly, we constructed a multivariable logistic regression model to identify the risk factors associated with misclassification, among those who truly were removed for death or clinical deterioration. The outcome of the model was misclassified: yes/no. We included fixed effects for transplant center to account for difference in the risk of being misclassified across centers. We selected other independent variables for inclusion in the final model if they were independently associated with the outcome ($P<0.05$). Variables tested included gender, race, primary insurance at listing, age at listing, and primary diagnosis at the time of listing (HCV, hepatitis B, autoimmune hepatitis, NASH, primary sclerosing cholangitis, primary biliary cirrhosis, HCC, alcohol-induced, and other). We also fit a multivariable logistic regression model to determine if significant center variation remained, by including center as a covariate, to determine if there was significant variability across centers, adjusting for patient factors.

### National Extrapolation

To calculate the additional number of removals due to death or clinical deterioration if all "other" patients had been correctly classified, we first calculated the proportion of true removals for death or clinical deterioration that were correctly classified (removals for death or clinical deterioration coded correctly/total number of removals for death or clinical deterioration) among the four centers. Additionally, we calculated a 95% confidence interval for the proportion of correctly classified removals. We then calculated, using UNOS data, the number of patients coded as being removed for death or clinical deterioration since 2002.

Under the assumption that the national proportion of patients truly removed for death or clinical deterioration were misclassified with similar frequency to our aggregated four-center data, we then divided the nationally reported UNOS data of waitlist removals for death or clinical deterioration by the proportion of patients correctly classified in our data. This was repeated for each category, and for the 95% confidence intervals. For example, if among the four centers, 100 patients truly died on the waitlist, but only 90 were coded as "died" (with 10 coded as "other"), then the correctly classified proportion would be 90%. Extrapolating this to national data, if 9,000 patients were coded as dying, then we would estimate that there may potentially be 10,000 patients who truly died on the waitlist (9,000/0.9).

All statistical analyses were performed using Stata 11.[12]

The studies were approved by each of the institutional review boards of the participating centers.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Abbreviations

| | |
|---|---|
| **UNOS** | United Network for Organ Sharing |
| **SRTR** | Scientific Registry of Transplant Recipients |
| **OPTN** | Organ Procurement and Transplantation Network |
| **SSDMF** | Social Security Death Master File |
| **SSA** | Social Security Administration |
| **HCV** | Hepatitis C |
| **HCC** | Hepatocellular carcinoma |
| **NASH** | Non-alcoholic steatohepatitis |
| **UCSF** | University of California-San Francisco |
| **PBC** | Primary biliary cirrhosis |
| **A2ALL** | Adult-to-Adult Living Donor Transplant Registry |
| **STAR** | Standard Transplant Analysis and Research |

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## Table 1

UNOS-specified codes for classifying waitlist removals

| Categorization of UNOS removal codes |
|---|
| Transplantation |
| Deceased donor transplant |
| Transplanted at another center |
| Deceased donor emergency transplant |
| Deceased donor multi-organ transplant |
| Patient died during transplant procedure |
| Living donor transplant |
| Death or clinical deterioration |
| Died |
| Medically Unsuitable |
| Candidate condition deteriorated, too sick to transplant |
| Miscellaneous |
| Other * |
| Transferred to another center |
| Refused transplant |
| Candidate condition improved |
| Candidate listed in error |
| Candidate removed in error |

* Includes removals for reasons including non-compliance, loss to follow-up, and removal for psychosocial reasons (i.e. drug or alcohol use)

## Table 2

Data on waitlist removals and other removals per center from 2/27/02–7/24/2010

**a) Removals per center, based on UNOS coding***

| Center | Transplanted, N (%)†‡ | Coded as death, N (%)†‡ | Coded as clinical deterioration, N (%)†‡ | Coded as "other," N (%)†‡ | Coded as miscellaneous, N (%)†‡** |
|---|---|---|---|---|---|
| Penn, N=1,994 | 1,099 (55.1) | 432 (21.7) | 130 (6.5) | 183 (9.2) | 150 (7.5) |
| Georgetown, N=1,026 | 523 (51.0) | 217 (21.2) | 104 (10.1) | 95 (9.3) | 87 (8.5) |
| Baylor, N=1,834 | 1,161 (63.3) | 345 (18.8) | 131 (7.1) | 109 (5.9) | 88 (4.8) |
| Mount Sinai, N=2,137 | 955 (44.7) | 564 (26.4) | 93 (4.4) | 425 (19.9) | 100 (4.7) |

**b) Other removals per center based on center-level and UNOS data**

| Center | True removals for death * | Misclassified deaths per center, N (%)† | True removals for clinical deterioration* | Misclassified clinical deteriorations per center, N (%)†‡ |
|---|---|---|---|---|
| Penn | 439 | 7 (1.6) | 193 | 63 (32.6) |
| Georgetown | 217 | 0 (0.0) | 113 | 9 (8.0) |
| Baylor | 346 | 1 (0.3) | 137 | 6 (4.4) |
| Mount Sinai | 591 | 27 (4.6) | 169 | 76 (45.0) |
| Totals | 1593 | 35 (2.2) | 612 | 154 (25.2) |

*Waitlist removals include patients listed prior to 2/27/02 but removed after this date. This data does not account for patients still on the waitlist as of 7/24/10. Data provided from each center and from UNOS data.

†Percentage equals the proportion of all removals for that specific reason.

‡P<0.001 for chi-square test comparing the proportion removed for each reason, among all waitlist removals, across all 4 centers.

**Excludes other removals and includes patients removed with the UNOS codes of transferred to another center, refused transplant, candidate condition improved, candidate listed in error, candidate removed in error

*True removals for death or clinical deterioration equals patients coded as removed for death or clinical deterioration in UNOS database plus "other" patients who truly were removed for death or clinical deterioration

†Misclassified patients are patients truly removed for death or clinical deterioration, but coded as "other" respectively The percentage is defined as: (number of removals for death or clinical deterioration coded as "other")/(true number of removals for death or clinical deterioration). P<0.001 comparing the proportion of misclassified deaths per center

‡P<0.001 comparing the proportion of misclassified removals per center

## Table 3

True reasons for waitlist removal [*]

| Reason for Misclassification | N (%) |
|---|---|
| Advanced HCC | 88 (46.8) |
| Too sick or medically unsuitable [†] | 40 (21.2) |
| Died prior to waitlist removal | 35 (18.5) |
| Non-HCC malignancy [‡] | 26 (13.8) |

[*] Reasons for misclassification among the 189 “other” patients that were misclassified

[†] Defined as medical record stating patient too sick or medically unsuitable, including co-morbid disease, cardiac disease, sepsis/active infection, or portal venous anatomy precluding transplantation.

[‡] Includes cholangiocarcinoma

## Table 4

Factors associated with misclassification among all patients removed for death or clinical deterioration

| Variable | Univariable Odds Ratio (95% CI) | Multivariable Odds Ratio (95% CI) | P-value* |
|---|---|---|---|
| Male gender | 1.54 (1.11–2.15) | 1.51 (1.01–2.23) | 0.04 |
| Race* | | | |
| White | 1.0 | 1.0 | |
| Black | 0.91 (0.59–1.42) | 0.97 (0.61–1.56) | 0.90 |
| Asian | 2.26 (1.37–3.76) | 1.66 (0.89–3.11) | 0.11 |
| Other | 4.73 (1.89–11.82) | 2.55 (0.90–7.22) | 0.08 |
| Primary Insurance at listing | | | |
| Private | 1.0 | 1.0 | |
| Medicare | 1.88 (1.33–2.65) | 1.36 (0.92–2.03) | 0.12 |
| Medicaid | 1.57 (1.01–2.43) | 2.25 (1.35–3.76) | 0.002 |
| Age at listing† | 1.88 (1.57–2.23) | 1.94 (1.58–2.38) | <0.001 |
| Primary diagnosis at the time of listing** | | | |
| Hepatitis C | 1.0 | 1.0 | |
| Hepatitis B | 2.28 (1.31–3.98) | 1.12 (0.57–2.23) | 0.73 |
| NASH | 0.27 (0.12–0.63) | 0.21 (0.09–0.50) | <0.001 |

*Hispanic only coded in UNOS data

†Odds ratio for every 10 year increase in age

## Table 5

Impact of Misclassifications on UNOS Data [*]

| UNOS Removal Category | Original UNOS data [*] | Correction factor used [†] | Revised data including misclassified others, N (95% CI) [‡] |
|---|---|---|---|
| Died [†] | 14,766 | 0.978 | 15,097 (14,996–15,229) |
| Too sick to transplant [‡] | 6,526 | 0.748 | 8,720 (8,342–9,165) |
| Composite died/too sick [††] | 21,292 | N/A | 23,817 (23,338–24,394) |

[*] According to OPTN data as of 3/25/11

[†] The correction factor was based on the proportion correctly classified within each category, or 1-the proportion misclassified. For the died group, the correction factor (correct classification) was 1−(35/1,593), and for the clinical deterioration group, it was 1−(154/612)

[‡] Revised numbers equal the UNOS data plus the additional patients in that removal category if “other” patients had been correctly classified

[**] % Change=(Original numbers-Revised Numbers)/Original Numbers

[††] The composite values reflect the sum of the individual values for died and too sick to transplant. There was no correction factor for the composite endpoint, as the data was calculated by summing the two values given the different weights of each of the two components of the composite endpoint.