UNOS Region 8 MELD29 Trial Analysis of the Results

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Background - 1

- The CMS “Final Rule” for allocation of deceased donor organs stipulates that organs should be distributed in as wide an area as is consistent with good outcomes. The rationale was twofold:
- Getting organs quickly to the sickest patients would be expected to improve overall outcomes of liver transplantation.
- More equitable in terms of geography.

Background - 2

- UNOS Region 8 addressed this issue about 3 years ago, and in a compromise agreed to share deceased donor livers regionally for non-Status 1 patients if their Laboratory MELD score was ≥ 29.
- UNOS accepted this variance as a test of the impact of wider sharing of livers.
- The agreement was to accept this variance in Region 8 for two years, then review the impact of this wider sharing.

Significance of this Experiment

- Previous estimates of the impact of wider regional sharing have been based on *modeling what would be expected to happen* with a change of policy and depend on a number of assumptions.
- The Region 8 MELD 29 experience is the result of an *actual "real world" test* of one specific policy in one of UNOS's 11 Regions.

General Approach

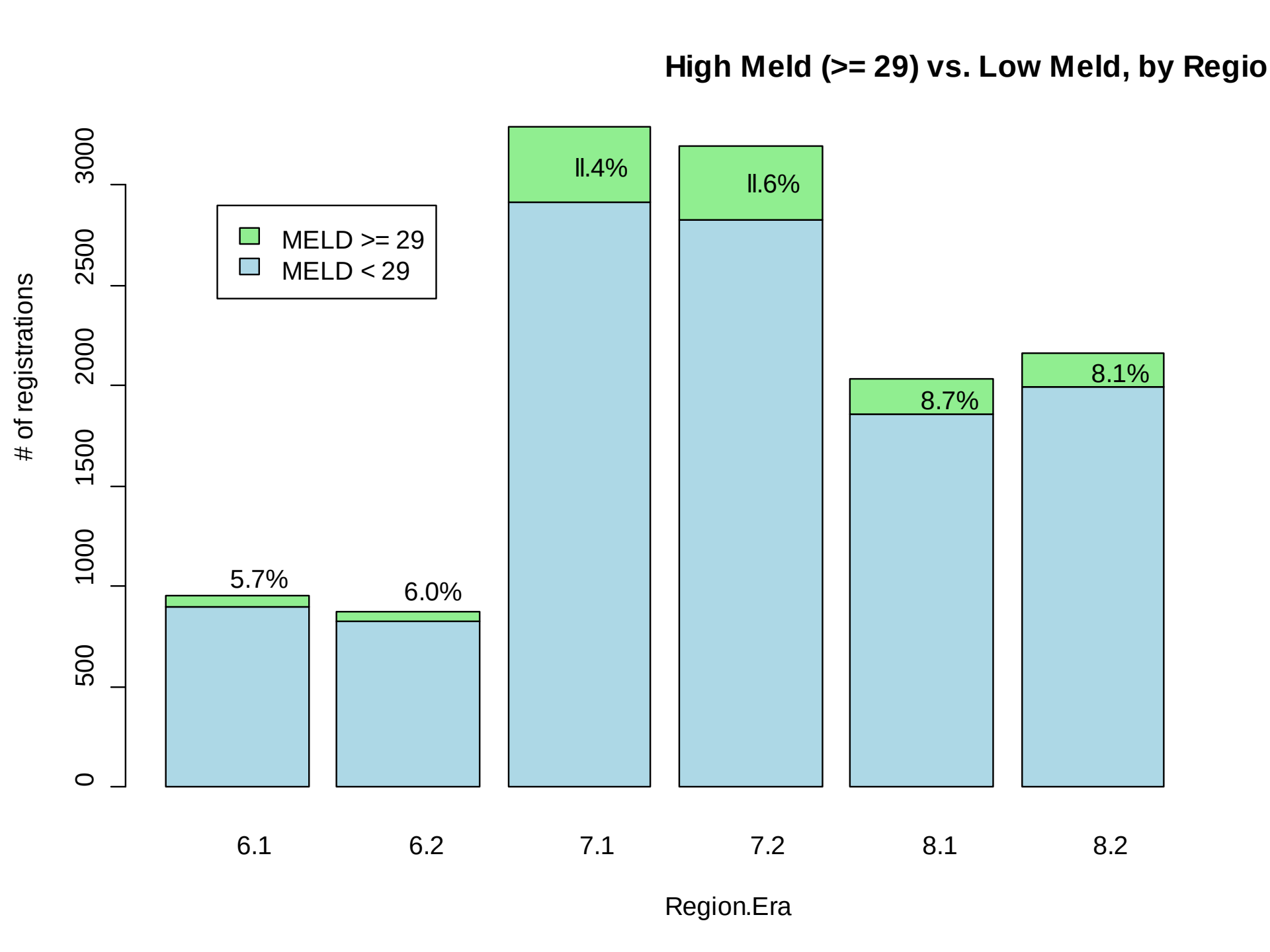
- The UNOS Region 8 MELD29 Policy was activated on 8 May 2007. Two eras:
  - Era 1: 7 May 2005 – 8 May 2007
  - Era 2: 9 May 2007 – 17 April 2009
- Compare outcomes of *all* patients listed during these two eras in Region 8, using outcomes in two similar UNOS Regions – Regions 6 and 7 – as time controls.

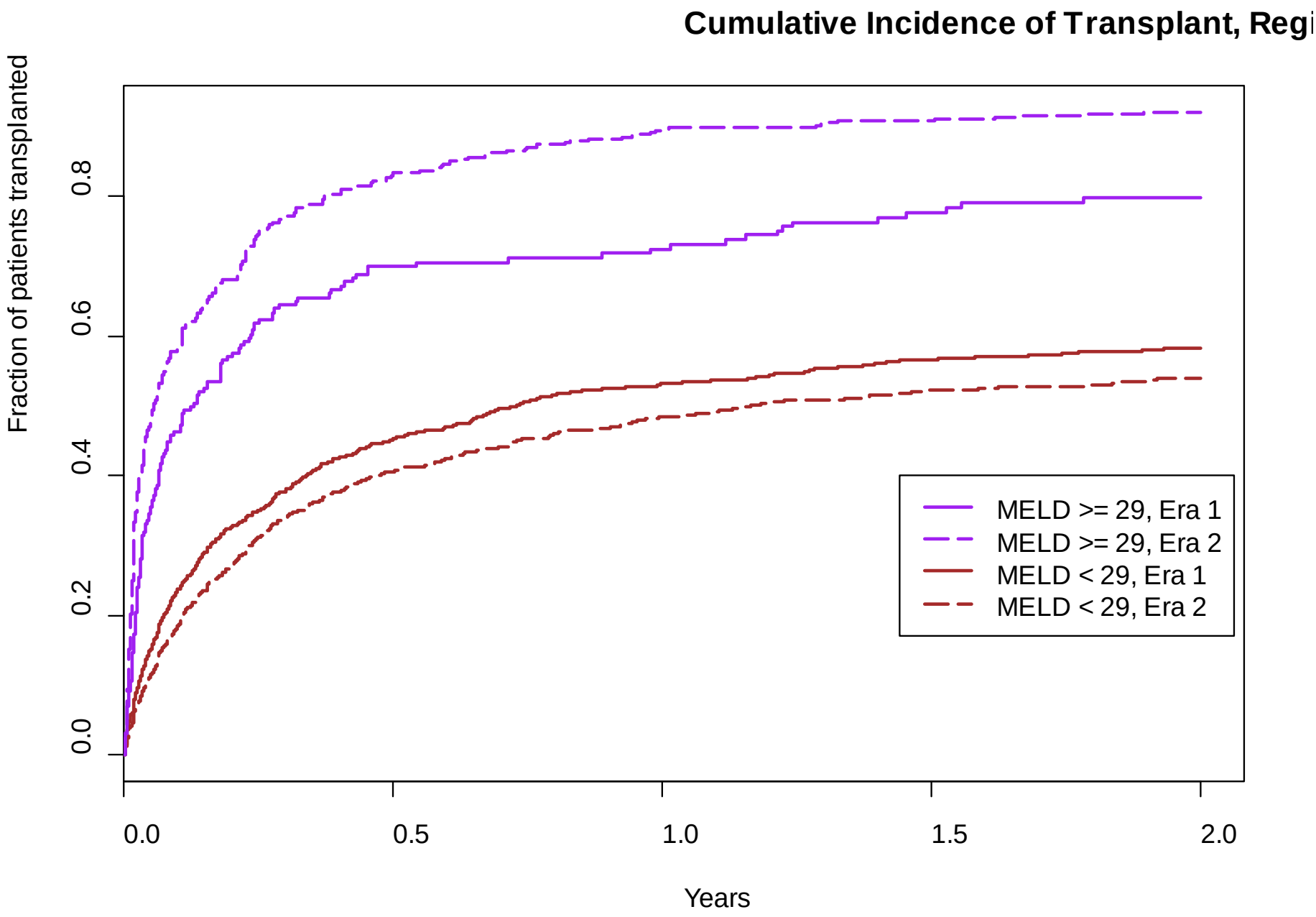
Competing Risks Analysis

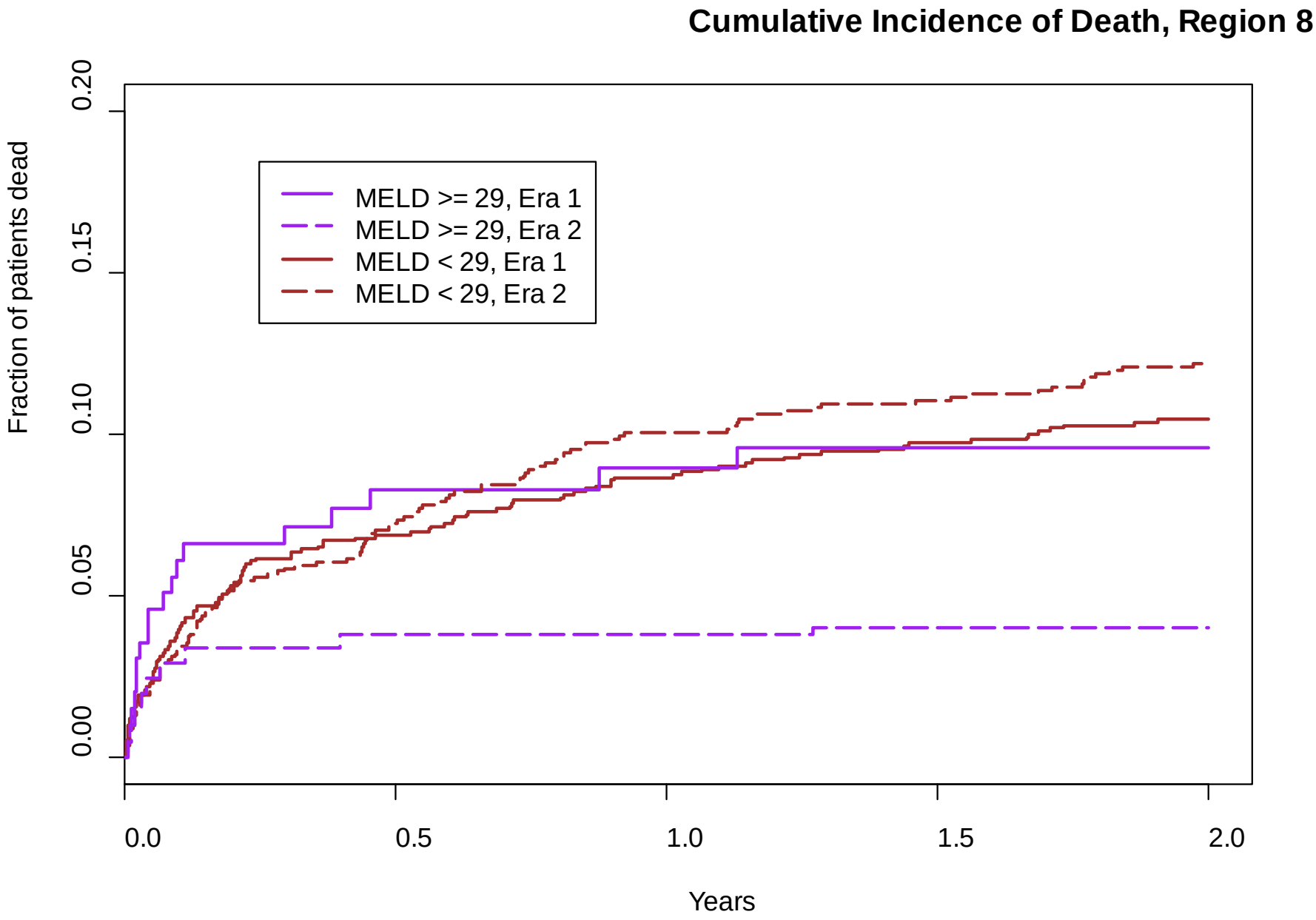
- There are four possible outcomes following listing for a deceased donor liver transplant:
  - Receiving a deceased donor liver transplant
  - Dying on the waiting list
  - Being removed for any of several other reasons
  - Remaining on the waiting list
- We present cumulative incidence graphs showing the fraction that have actually experienced one of the first three specific competing events.

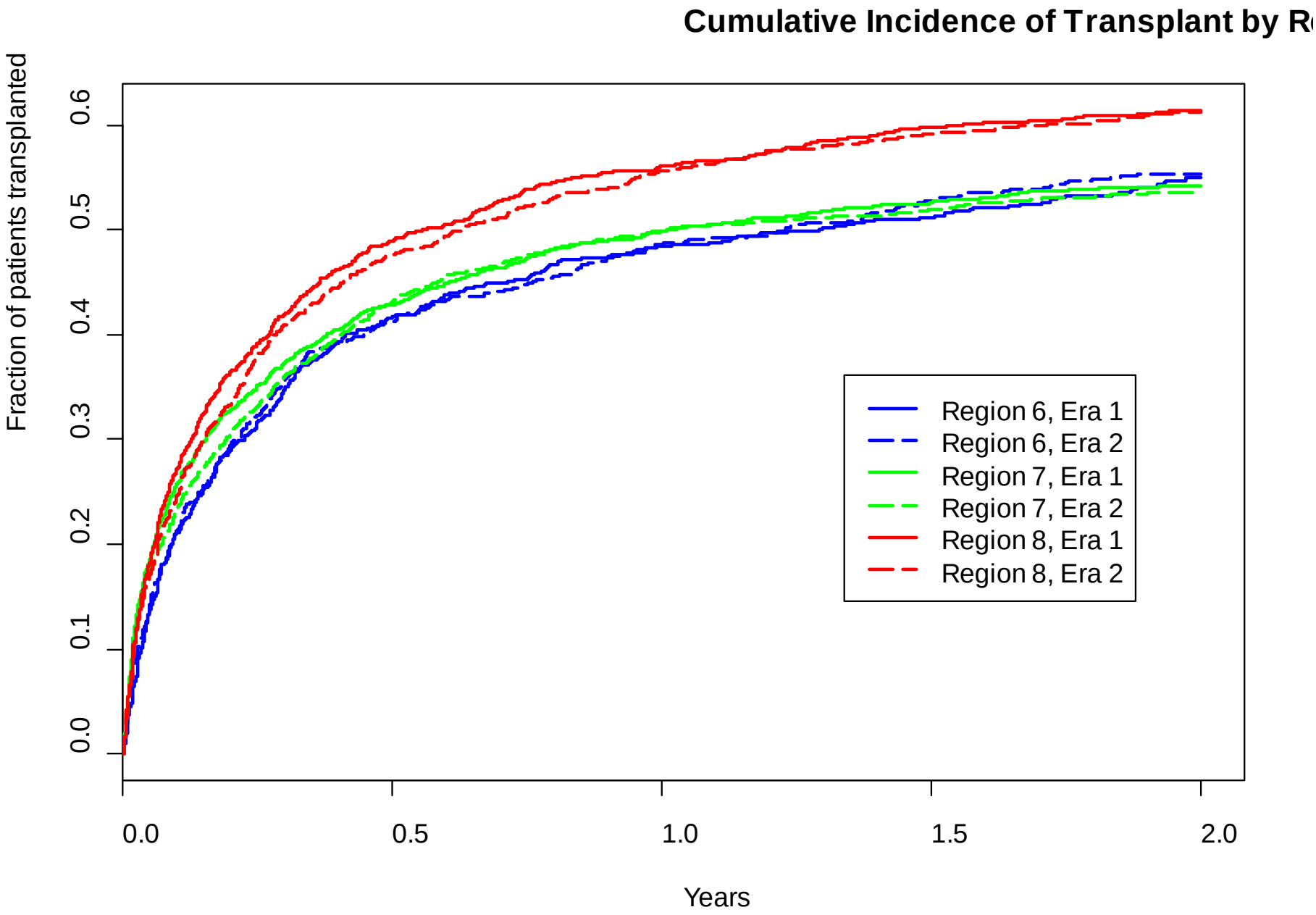
Study Population

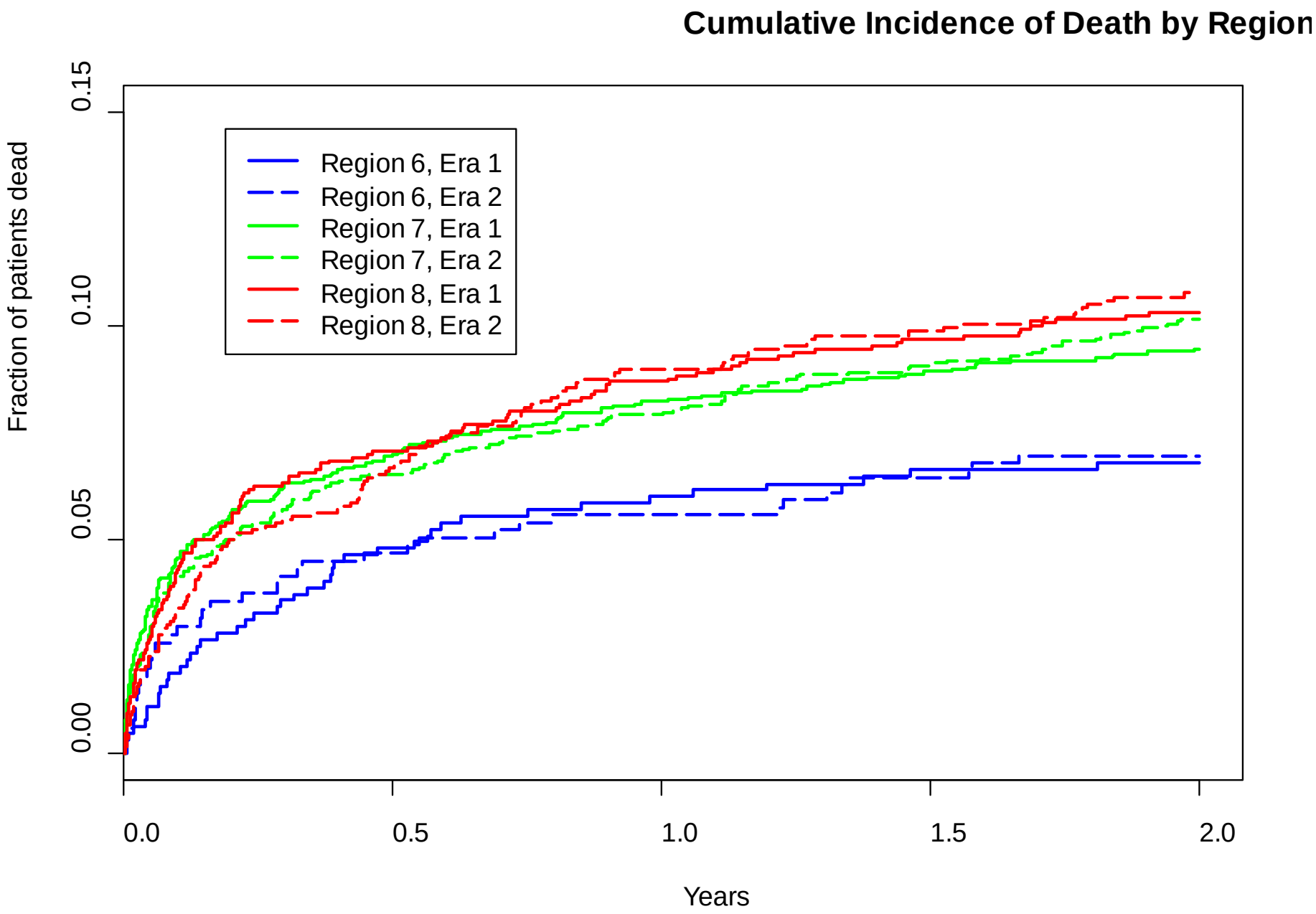
- 10,333 patient registrations listed in UNOS Regions 6, 7, or 8 at some time between 7 May 2005 and 19 April 2009. (Multiple listings are treated as separate records since we are interested in outcomes of *listings.)*
- Recovered death information from SSDMF death index.
- Recovered information about transplants at other centers from other patient registrations.
- Removed 457 registrations for patients *Inactive* on that center's wait list for the entire period above.

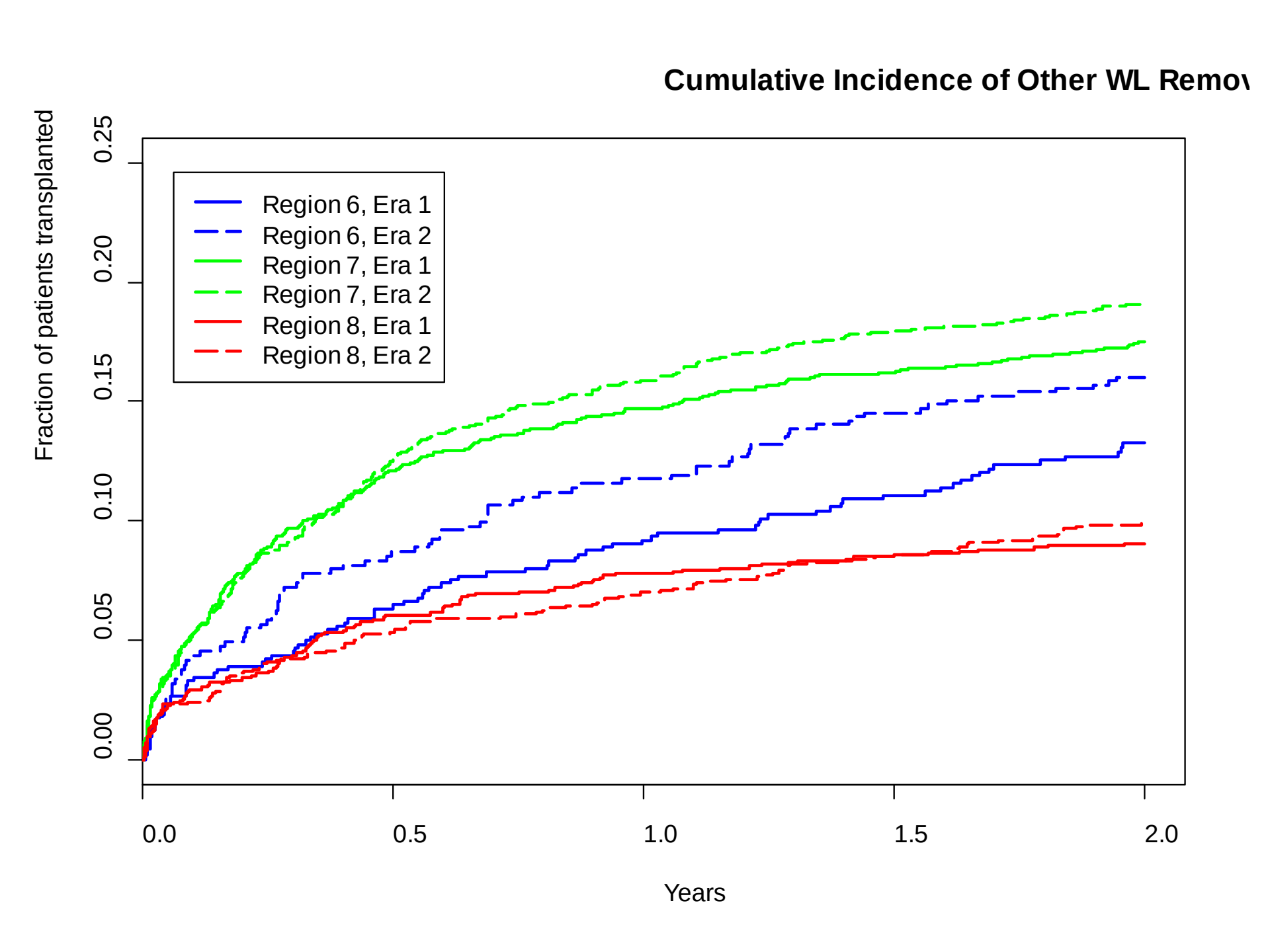

High Meld (>= 29) vs. Low Meld, by Regio
# of registrations
0
500
1000
1500
2000
2500
3000
MELD >= 29
MELD < 29
5.7%
6.0%
ll.4%
ll.6%
8.7%
8.1%
6.1
6.2
7.1
7.2
8.1
8.2
Region.Era


Cumulative Incidence of Transplant, Regi
Fraction of patients transplanted
0.0
0.2
0.4
0.6
0.8
0.0
0.5
1.0
1.5
2.0
Years
MELD >= 29, Era 1
MELD >= 29, Era 2
MELD < 29, Era 1
MELD < 29, Era 2


Cumulative Incidence of Death, Region 8,
Fraction of patients dead
0.00
0.05
0.10
0.15
0.20
0.0
0.5
1.0
1.5
2.0
Years
MELD >= 29, Era 1
MELD >= 29, Era 2
MELD < 29, Era 1
MELD < 29, Era 2

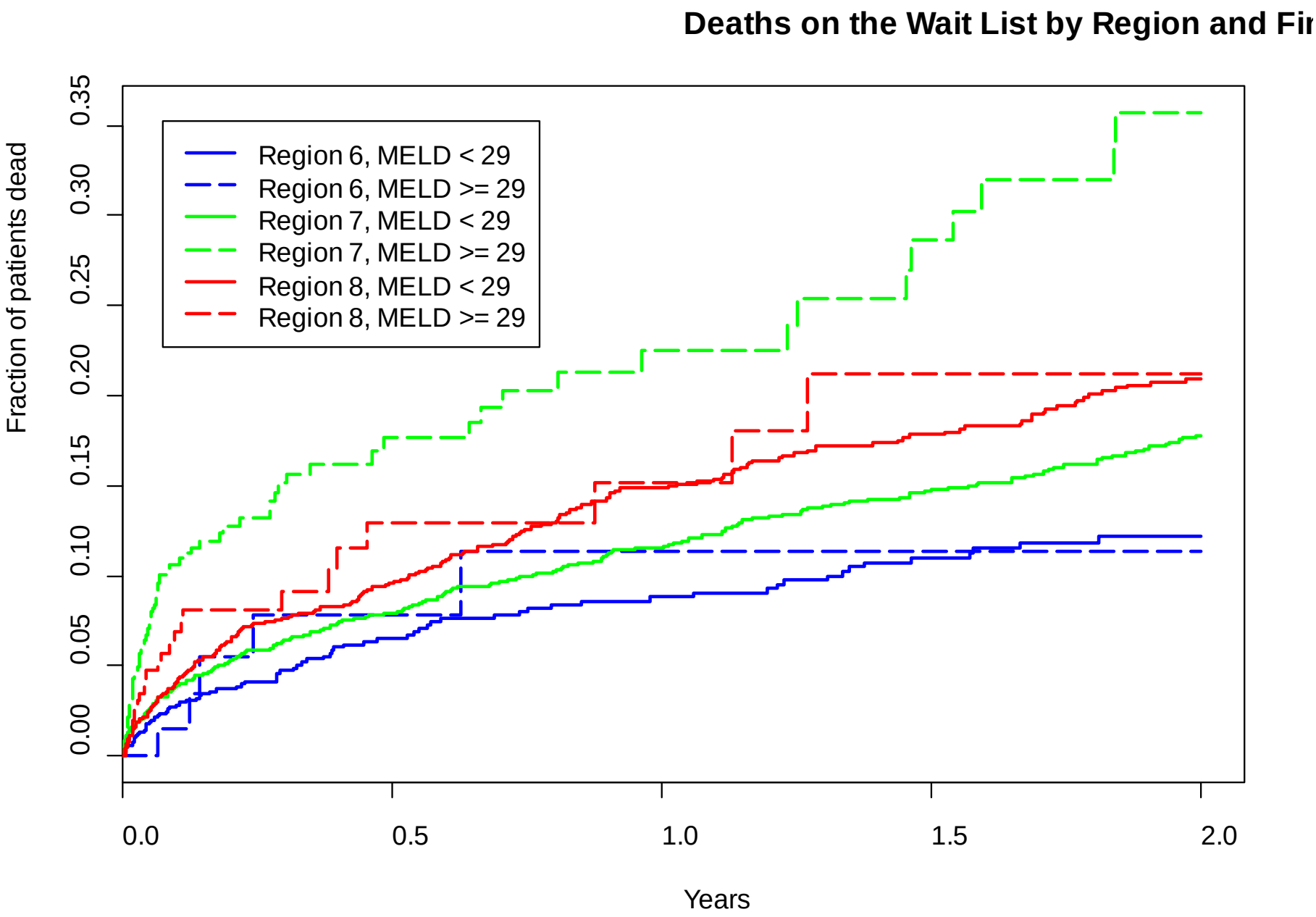

Cumulative Incidence of Transplant by R
Fraction of patients transplanted
0.0
0.1
0.2
0.3
0.4
0.5
0.6
0.0
0.5
1.0
1.5
2.0
Years
Region 6, Era 1
Region 6, Era 2
Region 7, Era 1
Region 7, Era 2
Region 8, Era 1
Region 8, Era 2


Cumulative Incidence of Death by Region
Fraction of patients dead
0.00
0.05
0.10
0.15
Region 6, Era 1
Region 6, Era 2
Region 7, Era 1
Region 7, Era 2
Region 8, Era 1
Region 8, Era 2
0.0
0.5
1.0
1.5
2.0
Years


Cumulative Incidence of Other WL Remov
Fraction of patients transplanted
0.00
0.05
0.10
0.15
0.20
0.25
Region 6, Era 1
Region 6, Era 2
Region 7, Era 1
Region 7, Era 2
Region 8, Era 1
Region 8, Era 2
0.0
0.5
1.0
1.5
2.0
Years

A Possible Explanation

- Given that the laboratory MELD score is such a strong predictor of death on the wait list, it is surprising that transplanting these patients faster (leaving lower risk patients on the waiting list longer) is not associated with an overall reduction of mortality.
- A possible explanation: Laboratory MELD score at removal from the waiting list in Region 8 (like Region 6 but unlike Region 7) is *not* associated with a different risk of death.


Deaths on the Wait List by Region and Fir
Region 6, MELD < 29
Region 6, MELD >= 29
Region 7, MELD < 29
Region 7, MELD >= 29
Region 8, MELD < 29
Region 8, MELD >= 29
Fraction of patients dead
0.00
0.05
0.10
0.15
0.20
0.25
0.30
0.35
0.0
0.5
1.0
1.5
2.0
Years

Other Impacts of MELD29

- There were no differences between Regions in post-transplant patient survival.
- There were no significant between eras in the recovery of deceased donor livers, or use of living donors, splits, DCD livers, fraction of Status 1, PELD, or “exception” cases.
- There were relatively minor increased costs related to increased shipping of organs, CIT, and increased length of stay.

Summary

- The Region 8 MELD29 policy had its intended effect of shortening substantially the time to transplant for and reducing the waiting list death of patients with Laboratory MELD scores ≥ 29.
- Despite this, there was no net effect on the entire listed population in Region 8, compared with Regions 6 and 7, on:
  - Time to transplantation
  - Death on the waiting list or prior to transplant
  - Graft loss or patient death following transplant
  - Overall death following listing

Conclusions

- There is no support from the UNOS Region 8 MELD 29 experience for the hypothesis that wider sharing of livers for patients with higher MELD scores will reduce overall waiting list or ultimate mortality. There was also no adverse impact.
- There were modest “costs” of this policy in terms of increased Regional sharing (higher transportation costs), increased cold ischemia time, and length of initial hospital stay.
- These “utility” findings do not necessarily address “equity” issues.