

Session 3
**OPTN Policy Development and
Feedback from RFI / Highlights
of concepts being explored**

April 12, 2010

Policy development Process

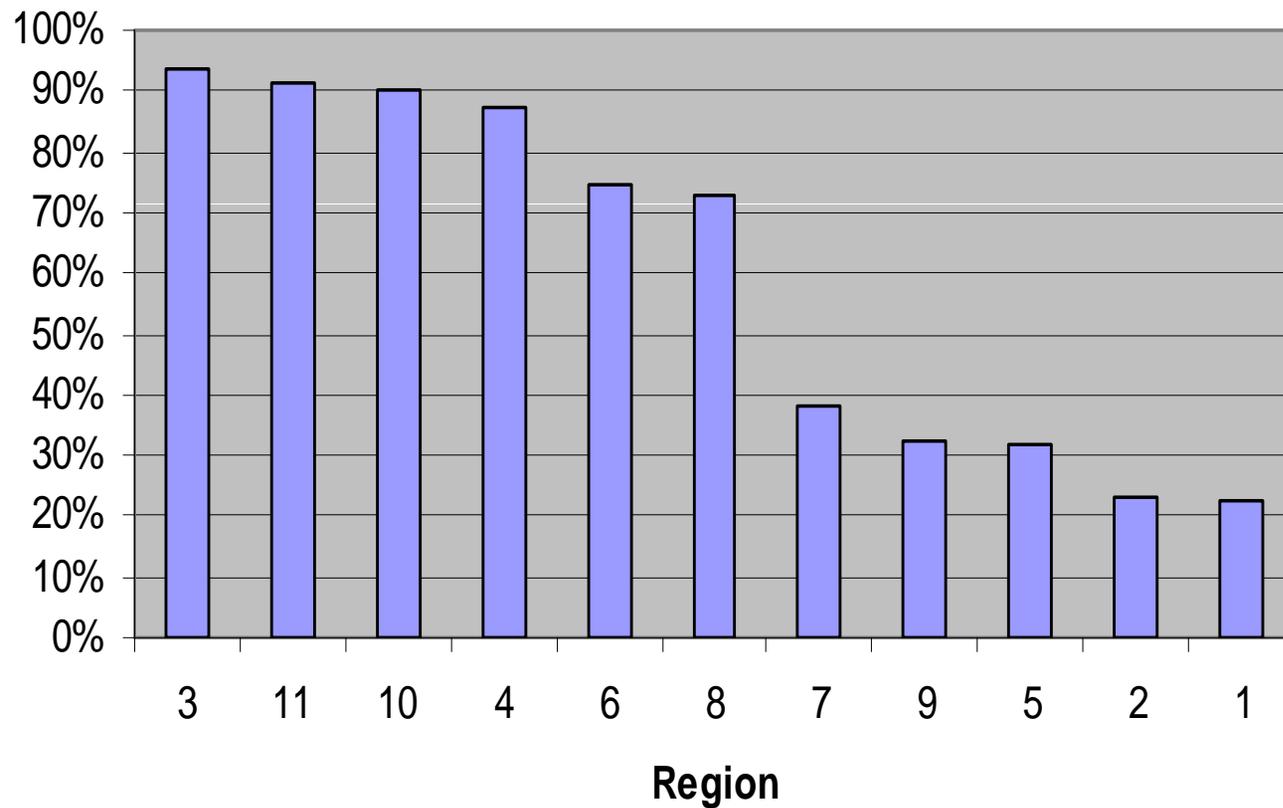
Brief Overview

- Committee discusses concept(s)
- Evidence gathered, proposal developed
 - Several Committee cycles
- Public Comment, usually 90 days
- Committee reconsiders proposal
 - Review of public comment
 - Votes to submit to Board (or not)
- Board consideration

Limitations of Current System

- Death and Transplant Rates vary by Region and DSA
- DSAs/Regions are not uniform in size or for risk of liver disease.
- DSAs not designed for equitable distribution
 - “Chance of dying should not depend on your ZIP code”

Patients with Liver Cancer Transplanted Within 3 Months of Listing



OPTN Final Rule

§ 121.8 Allocation of organs.

...

(b) Allocation performance goals. Allocation policies shall be designed to achieve equitable allocation of organs among patients consistent with paragraph (a) of this section through the following performance goals:

...

(3) Distributing organs over as broad a geographic area **as feasible** under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency;

What is “Feasible?”

- What limits feasibility?
 - Cold Ischemia Time
 - Driving versus Flying
 - Organ placement

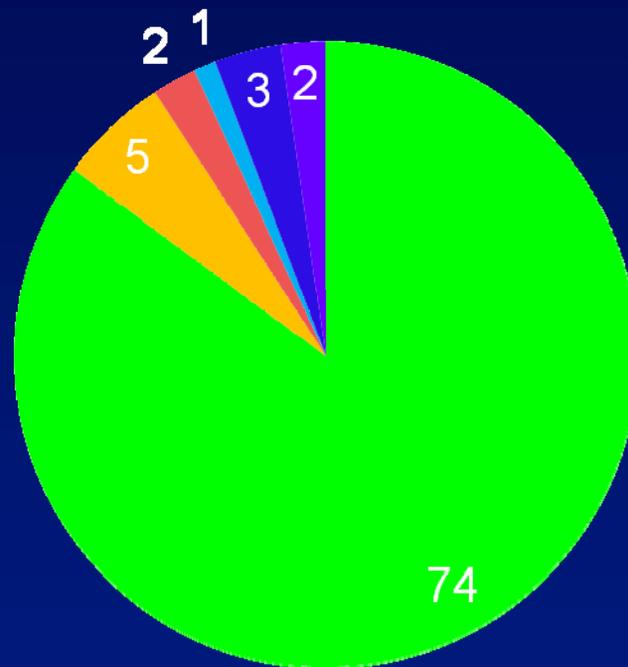
Concerns About Change

- Will increase in organ export:
 - Hurt local donation efforts?
 - Hurt small programs?
- Will increased organ travel
 - Decrease outcome?
 - Increase cost?
 - Increase risk associated with team travel?
- Will change in local use decrease access by eliminating local centers or increase access by allowing a greater at risk population access.

Liver Request for Information (RFI)

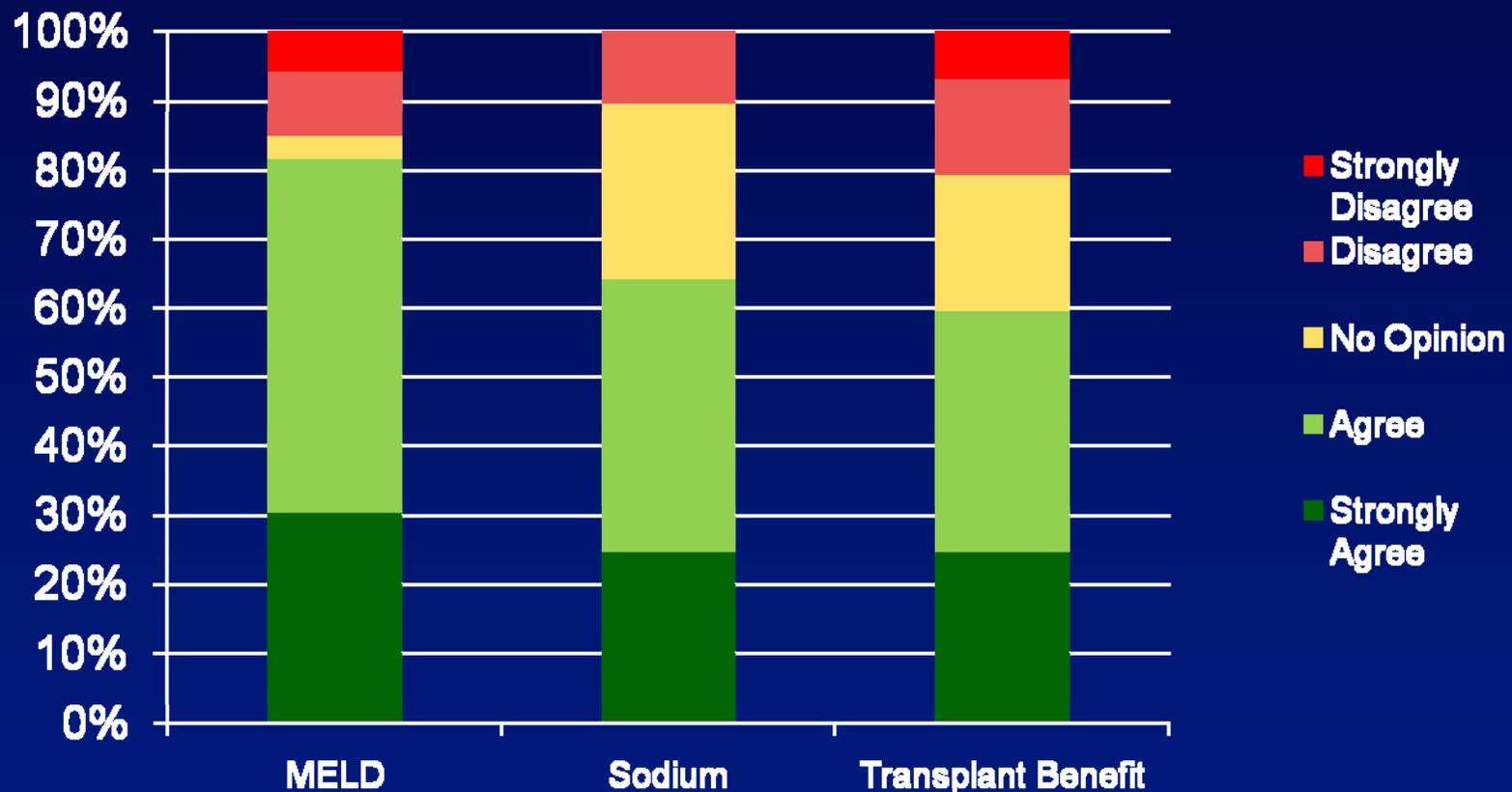
- Issued on 12/18/2009
- Background, Broad Concepts
- Survey Questions
 - Closed out 2/1/2010
- 87 Responses

Category that best describes your affiliation with transplant



■ Transplant Center ■ OPO ■ Candidate ■ Recipient ■ Other ■ no response

RFI Survey: Allocation Questions

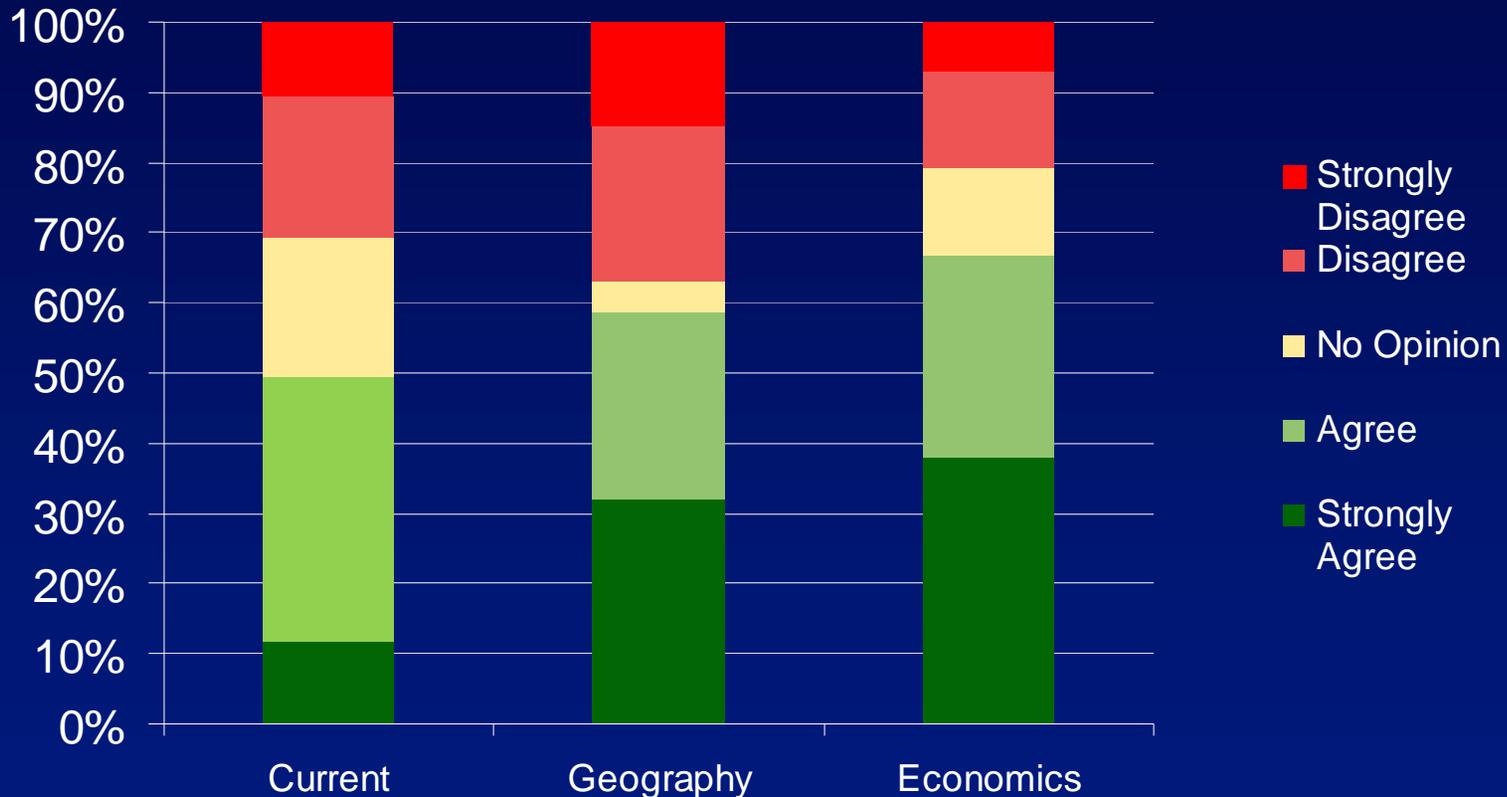


The current allocation system (MELD/PELD) is appropriate to rank candidates for liver transplantation.

Incorporating serum sodium in the MELD/PELD score would improve the allocation system.

Use of transplant benefit would improve the allocation system.

RFI Survey: Distribution Questions - I

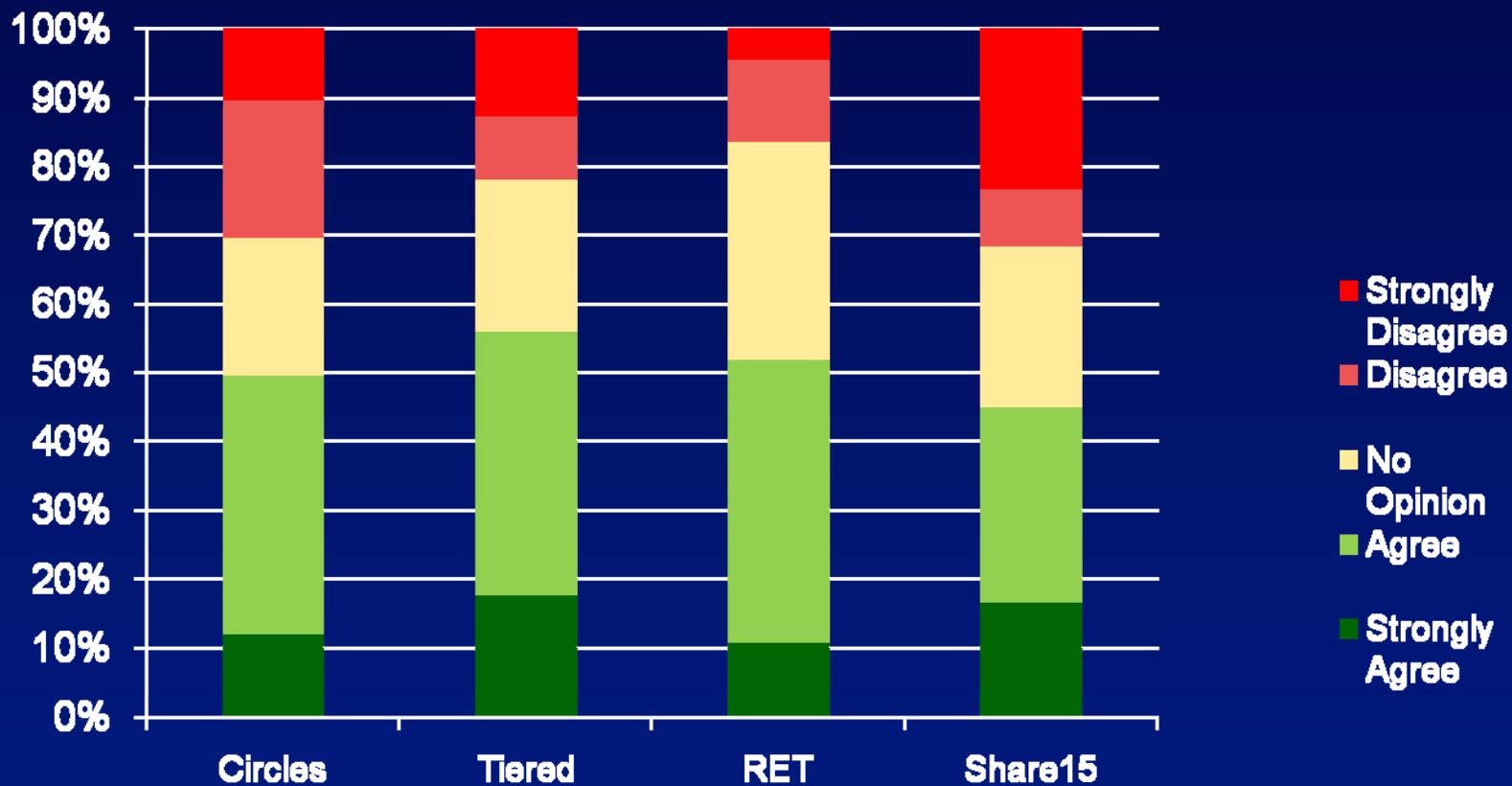


The current system (DSA as local, regional, national) is appropriate for distributing livers to candidates.

Reducing the geographic disparity in access to liver transplantation should be a high priority for the OPTN.

When the Liver Committee evaluates proposals, it should consider the economic impact any distribution policy changes might have on transplant centers

RFI Survey: Distribution Questions - II



Concentric circles should be considered as a basis for national policy.

Tiered sharing, such as the Region 8 "Share 29" should be considered for national policy

A "risk-equivalent threshold" should be considered for national policy

Share 15 National should be considered for national policy.

Concepts Explored

With LSAM Modeling (Using MELD/PELD and Tx Survival Benefit)

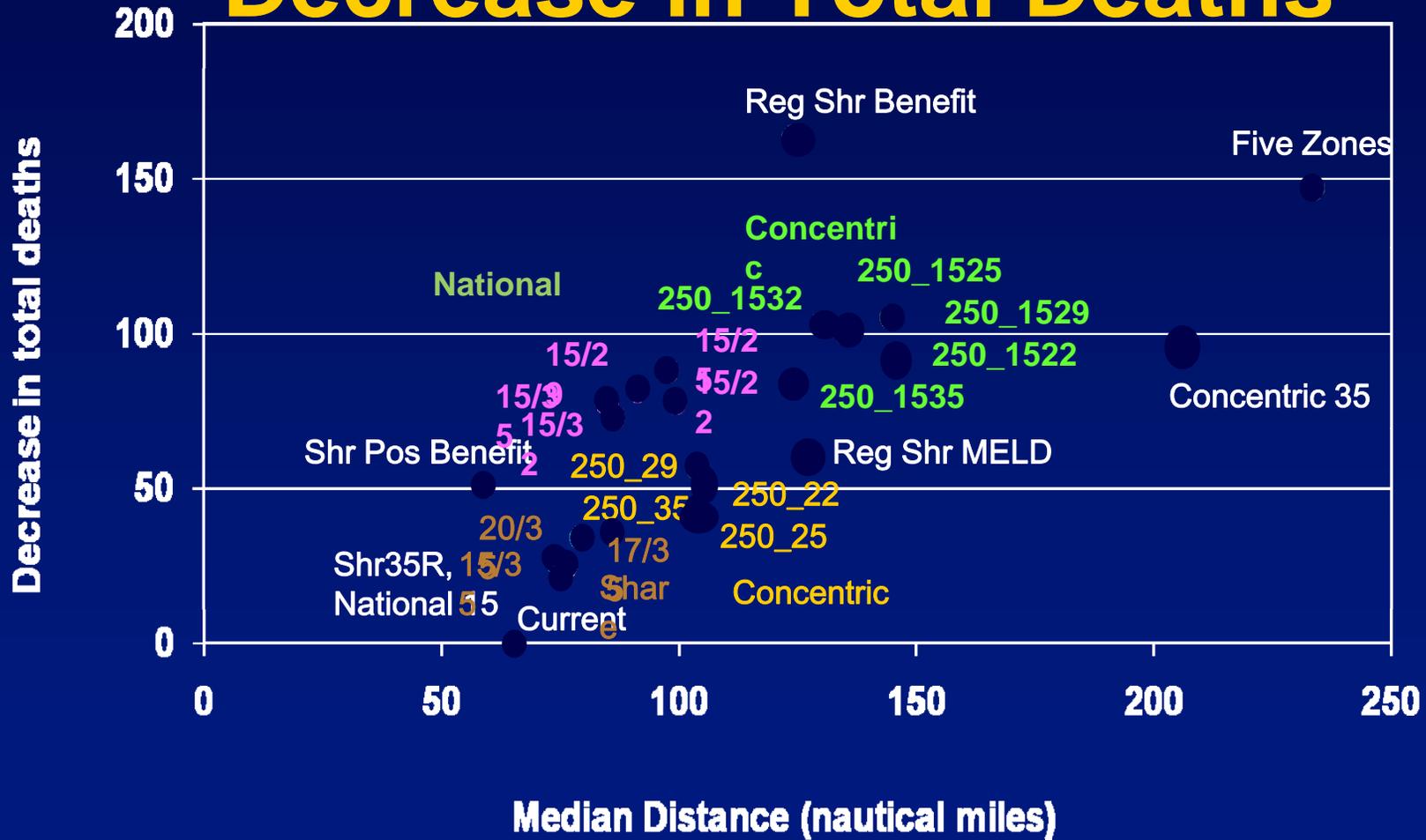
- Tiered Regional Sharing w/ various thresholds
- Share 15 National
- Concentric Circles

Not yet modeled: % of waiting list, “risk equivalent threshold”

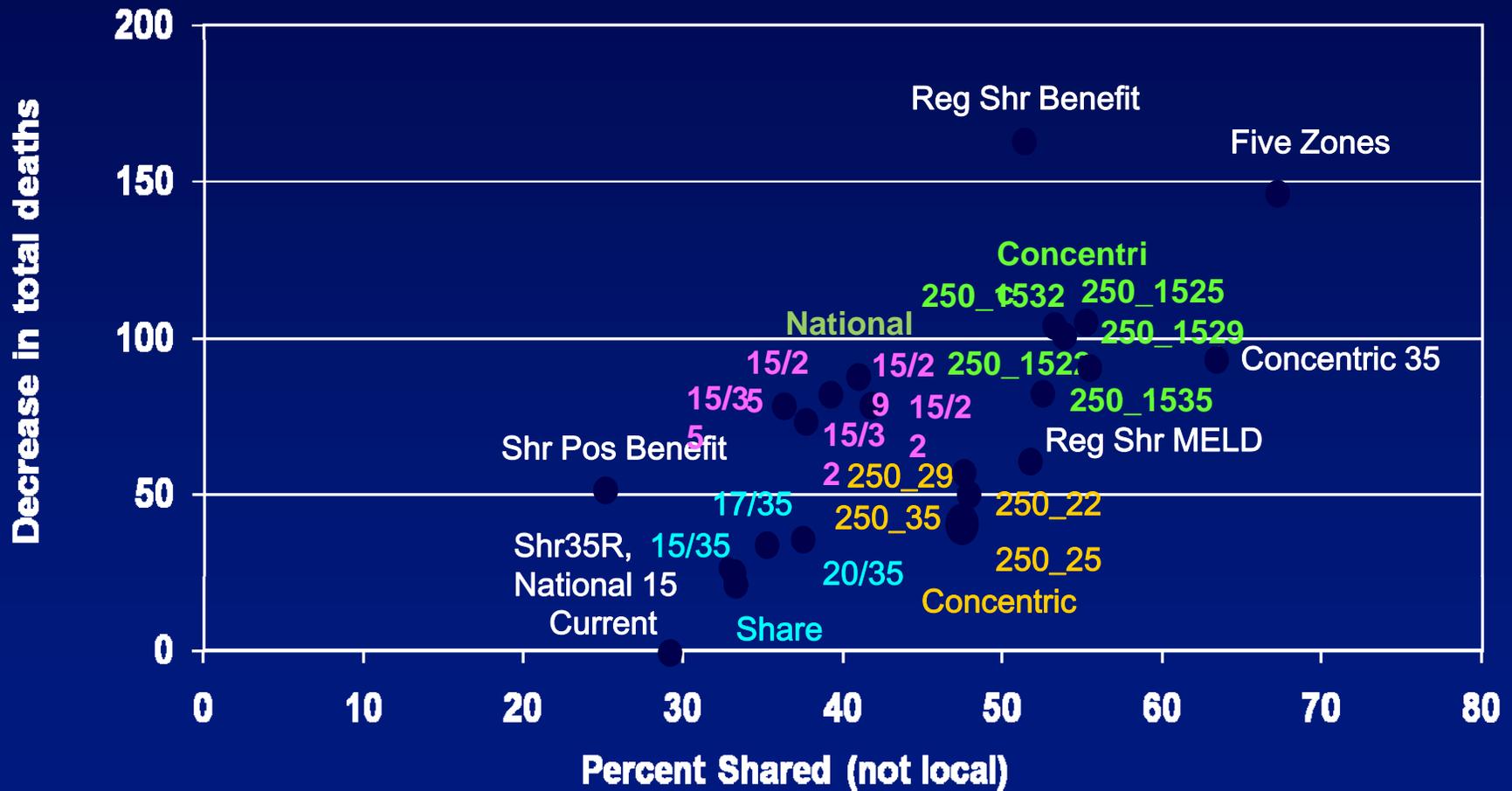
General Findings

- The further the organ travels, the greater the decrease in death.
- Modeled systems that result in more sharing outside of the local area decrease the risk of death

Median Distance vs. Decrease in Total Deaths

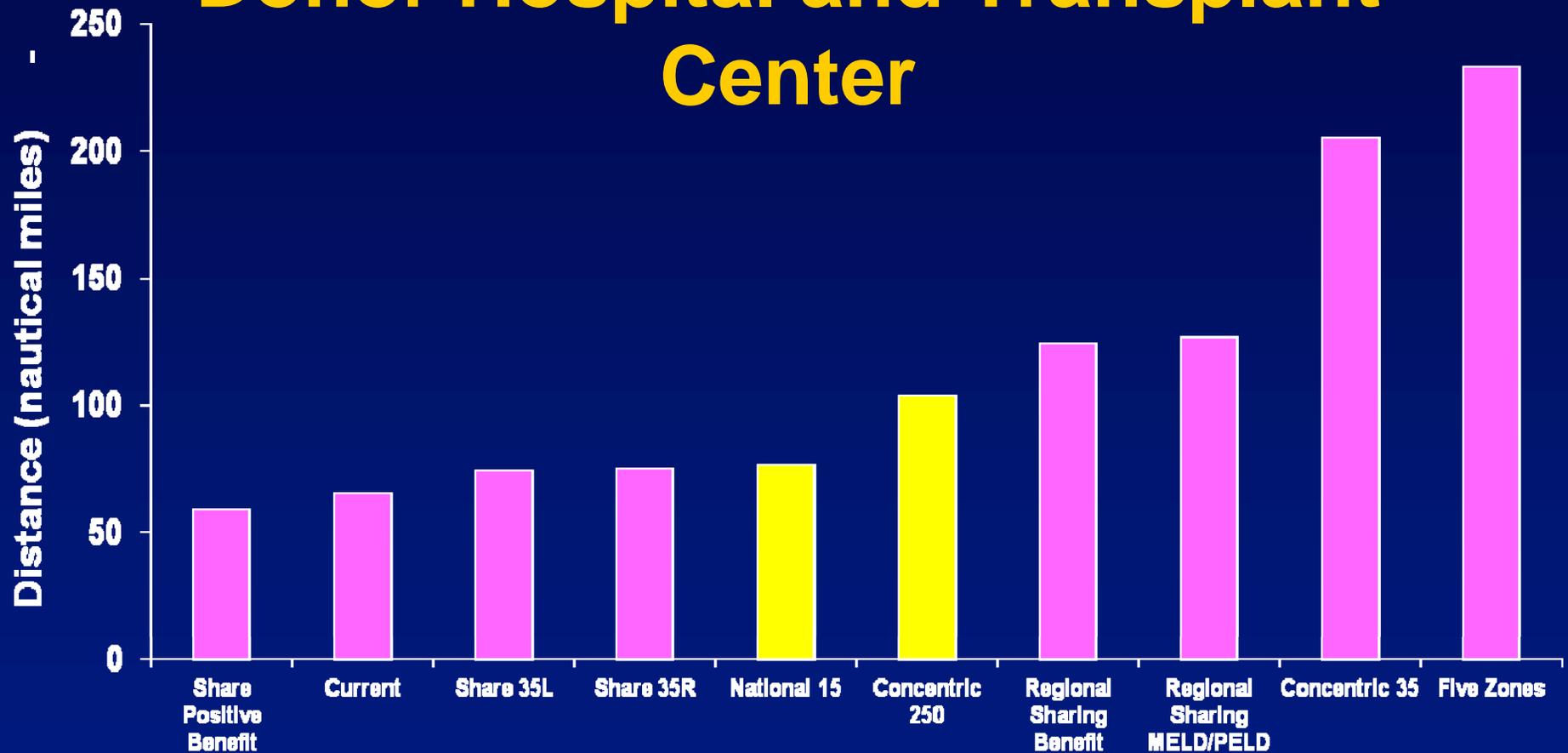


Percent Shared vs. Decrease in Total Deaths



The Change In Distances The Organ Travels Is Relatively Small

Median Distance Between Donor Hospital and Transplant Center



Data Request #3

Study Questions (Answers)

- *Adjusting for other recipient/donor factors, what is the relationship between length of stay of the recipient and the distance the organ travels as well as cold ischemia time?*
 - Length of stay increases by:
 - 0.07 days per 100 nautical miles
 - 0.32 days per 1 hour cold ischemia time

Cold Time and Distance

- Interaction between cold time and distance is complex.
- Most likely explanation is that there is a cold time that is acceptable and transplants are delayed for logistic reasons if within acceptable range and are done immediately if not.

Currently, Higher Risk Organs Are More Likely to Travel

For every increase of 1 in DRI, the probability of the transplant occurring outside the local area (i.e. regionally or nationally) increased 6.64 times [*odds ratio*=6.64, $p < 0.0001$].

Distance traveled increased by 162.8 nautical miles for every increase of 1 in DRI [*parameter estimate* = 162.8, $p < 0.0001$].

Summary

- Current regions and DSAs may not be ideal as units for distribution.
 - 50% of survey respondents want to maintain local.
 - 60% want to decrease disparity
- No preference of type of system to be examined

Models

- Increased sharing decreases deaths
- Increased cold ischemia time does effect LOS 3 hours~1day
- Lower quality organs are more likely to be shipped. Most likely being used in areas where the MELD scores are higher.

Predicted Distance between the Donor Hospital and the Transplant Center

