

Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws

*Pediatric Transplantation Committee
June 2015*

The Problem

- NOTA requires the OPTN to “recognize the differences in health and in organ transplantation issues between children [under the age of 18] and adults...and adopt criteria, policies and procedures that address the unique health care needs of children.”
- Pediatric training and experience not currently required at programs that perform pediatric transplants.

Strategic Plan Alignment

Goal 3: Improve Patient Survival

Goal 5: Promote Patient Safety

- Establish pediatric membership requirements

Proposed Solution

- Establish a pediatric component that requires key personnel to demonstrate pediatric training and experience

Quality	Access
<ul style="list-style-type: none">• Programs performing any transplants in <18 year old	<ul style="list-style-type: none">• Lifetime experience
<ul style="list-style-type: none">• Organ-specific case volumes	<ul style="list-style-type: none">• No stratifications
<ul style="list-style-type: none">• Requires currency (last 2 yrs)	<ul style="list-style-type: none">• Conditional Pathway
<ul style="list-style-type: none">• No exceptions	<ul style="list-style-type: none">• Delayed implementation

Pediatric Kidney Component Qualifying Criteria

Pediatric Primary Kidney Surgeon

- Meet current Bylaws for Primary Kidney Surgeon (minimum case volume 30)
- 12 Kidney transplants in patients younger than 18

Pediatric Primary Kidney Physician

Meet Bylaws requirements outlined in one of the following sections of Appendix E (Membership and Personnel Requirements for Kidney Transplant Programs), Section E.3 (Primary Kidney Transplant Physician Requirements):

- 3.C (Three-year Pediatric Nephrology Fellowship Pathway)
- 3.D (Twelve-month Pediatric Transplant Nephrology Fellowship Pathway)
- 3.E (Combined Pediatric Nephrology Training and Experience Pathway)

Pediatric Liver Component Qualifying Criteria

Pediatric Primary Liver Surgeon

- Meet current Bylaws for Primary Liver Surgeon (minimum case volume 45)
- 18 liver transplants in patients younger than 18

Pediatric Primary Liver Physician

Meet Bylaws requirements outlined in one of the following sections of Appendix F (Membership and Personnel Requirements for Liver Transplant Programs), Section F.3 (Primary Liver Transplant Physician Requirements):

- 3.C (Three-year Pediatric Gastroenterology Fellowship Pathway)
- 3.D (Pediatric Transplant Hepatology Fellowship Pathway)
- 3.E (Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway)

Pediatric Heart Component Qualifying Criteria

Pediatric Primary Heart Surgeon

- Meet current Bylaws for Primary Heart Surgeon (minimum case volume 20)
- 8 heart transplants in patients younger than 18

Pediatric Primary Heart Physician

- Meet current Bylaws requirements for Primary Heart Physician
- Care for 8 heart transplant patients younger than 18 years of age
- Has certification in pediatric cardiology by American Board of Pediatrics

Pediatric Lung Component Qualifying Criteria

Pediatric Primary Lung Surgeon

- Meet current Bylaws for Primary Lung Surgeon (minimum case volume 10)
- 4 lung transplants in patients younger than 18

Pediatric Primary Lung Physician

- Meet current Bylaws requirements for Primary Lung Physician
- Either this individual or another member of lung transplant team is certified by American Board of Pediatrics in pediatric pulmonary medicine



Public Comment Themes and Supporting Evidence in Response

Should Not Define Pediatric as <18 Years Old

- NOTA defines child as less than 18 years old
- Consistent with CMS and American Academy of Pediatrics (AAP)
- Growth and development continue through adolescence
- Underlying diseases different for children vs. adults
- Alternative definition could compromise priority in allocation for older pediatric candidates

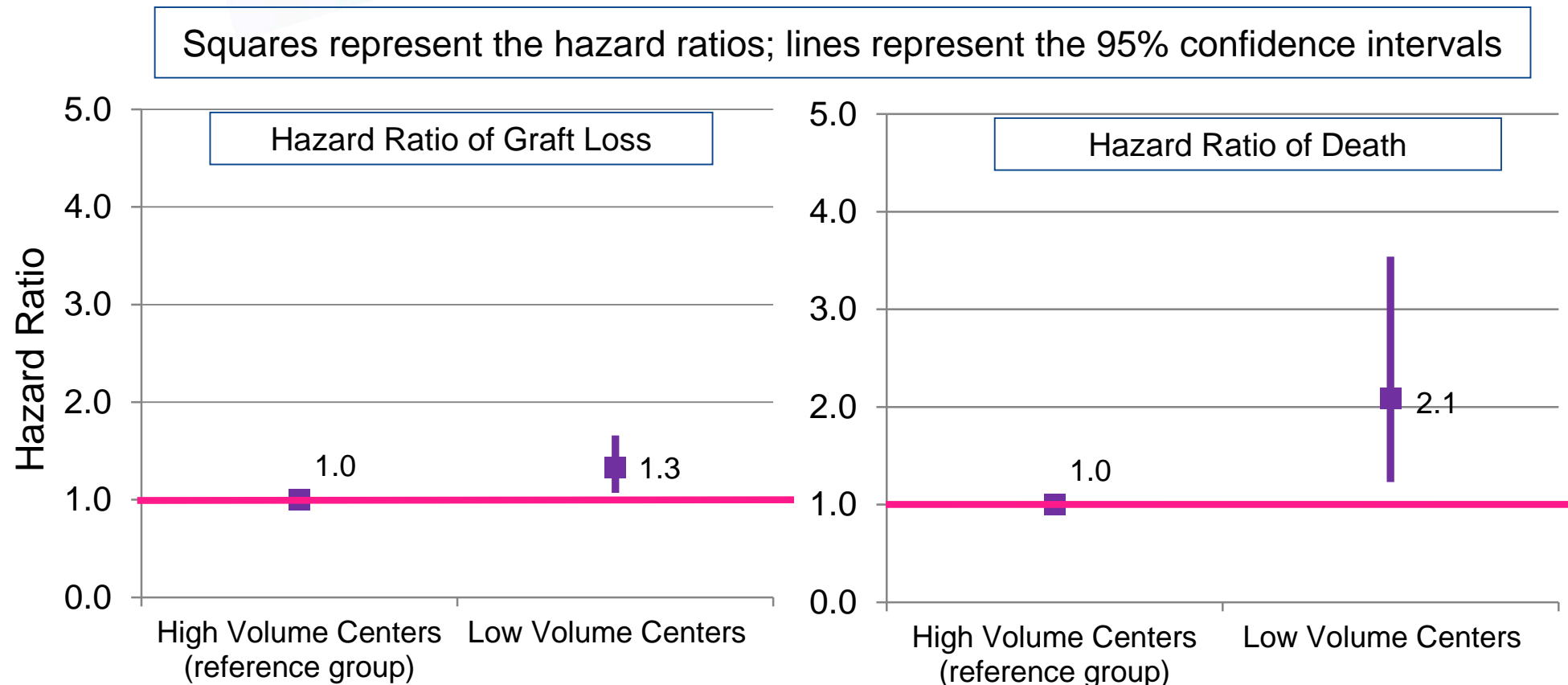
Lack Evidence of a Current Patient Safety Concern

- Membership requirements most fundamental of OPTN criteria
- Primary surgeon and primary physician integral to transplant program leadership, share responsibility for long-term outcomes
- Higher volume centers have better long term graft and patient survival for pediatric kidney, liver and heart

Lack Evidence to Support Proposed Caseload Requirements

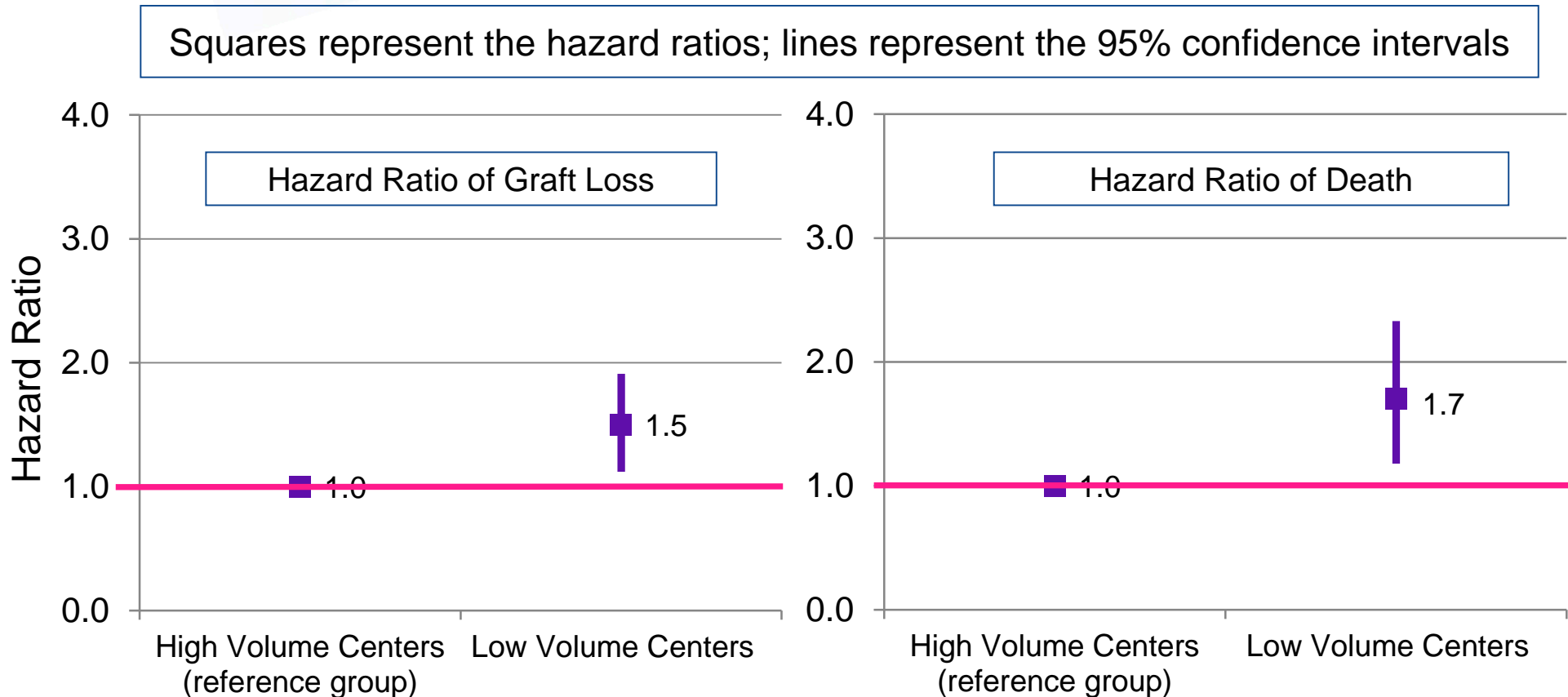
- Developed through clinical consensus of pediatric transplant experts
- Case volume requirements are a basic demonstration of experience, not outcomes
- Membership criteria for a pediatric component are intended to demonstrate a baseline of experience in pediatrics
- Significantly better graft and patient survival for pediatric KI, LI, and HR transplants performed at high versus low volume programs

Adjusted Hazard Ratio of Graft Loss and Death Within 5 Years for Pediatric Kidney Transplants, 2000-2010



Notes: Low volume centers: centers performing <12 pediatric kidney transplants in 2000-2010; High volume centers: centers performing 12+ pediatric kidney transplants in 2000-2010; Hazard ratio >1 indicates worse survival.

Adjusted Hazard Ratio of Graft Loss and Death Within 5 Years for Pediatric Liver Transplants, 2000-2010



Notes: Low volume centers: centers performing <18 pediatric liver transplants in 2000-2010; High volume centers: centers performing 18+ pediatric liver transplants in 2000-2010; Hazard ratio >1 indicates worse survival.

Need to Stratify Caseloads

- Initial proposal – too restrictive
 - Kidney surgeon – 12 cases, 6 in children <20kg
 - Liver surgeon – 18 cases, 9 in children <12 y/o, 5 technical variants
- Impossible to achieve consensus if caseloads stringent
- Would adversely impact access
- Committee response
 - Eliminate age/weight stratifications
 - Eliminate time constraints on experience
 - Maintain currency requirement

Proposal Limits Access

Number of Pediatric Transplants at Centers Meeting the Proposed Pediatric Volume Criteria, 1/1/05-7/31/14

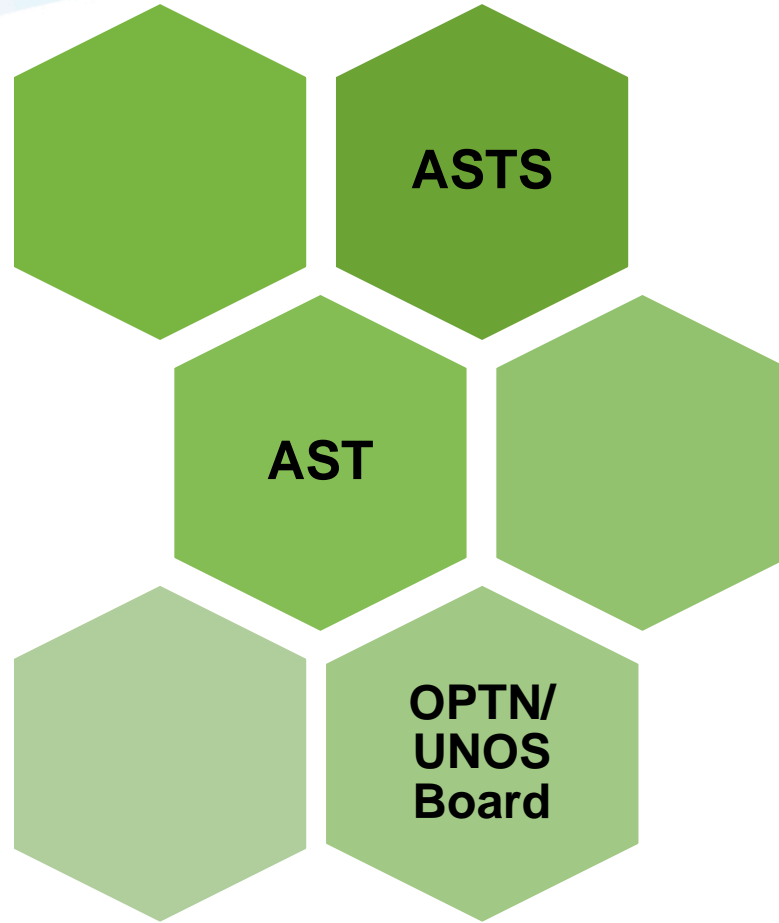
Organ	Transplants at Centers Meeting the Proposed Criteria (N)	% of Total Pediatric Transplants
Kidney	7,479	98.4
Liver	5,207	97.0
Heart	3,366	97.8
Lung	472	92.5

- Adults and pediatric patients, especially in sparsely populated areas, have to travel to designated transplant centers

Supportive Public Comment

- Children are different from adults, with a variety of unique needs that require subspecialty care (N=28)
- Promotes quality of care and safety (N=23)
- Proposal is balanced and has little impact on access to care (N=13)
- Requirements need to cover all patients <18 years old (N=10)
- Proposal is long overdue and contributes to the transparency of the OPTN (N=8)

Post-Public Comment Outreach



What Members will Need to Do

- If applying for a pediatric component:
 - Attend webinar
 - Obtain and complete application
 - Notify OPTN of any personnel changes
- If not applying for a pediatric component:
 - Notify OPTN
 - Follow transition plan to remove pediatric candidates from waiting list

Overall Project Impact

Product

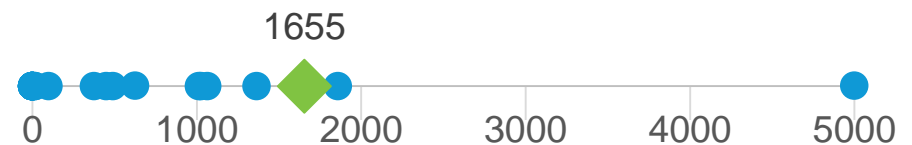
Bylaws

Target Population Impact:

Pediatric Transplant Candidates and Recipients

Total IT Implementation Hours

1,655/16,680



Total Overall Implementation Hours

2,230/23,685



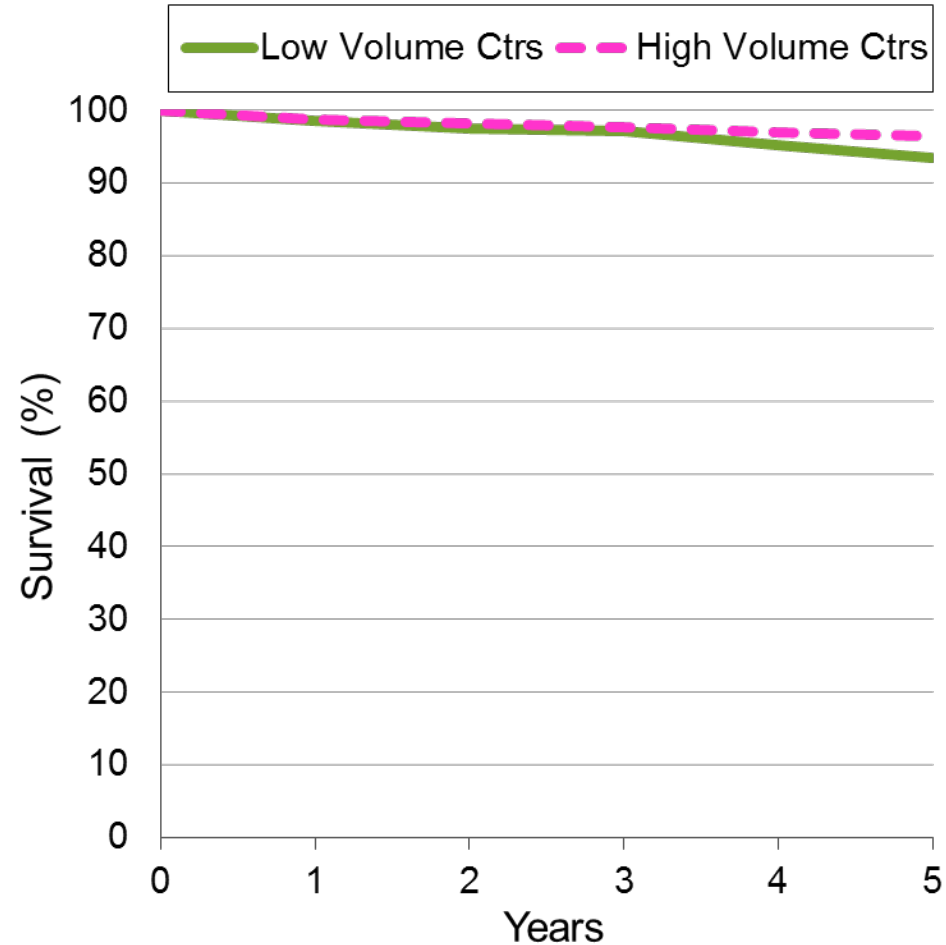
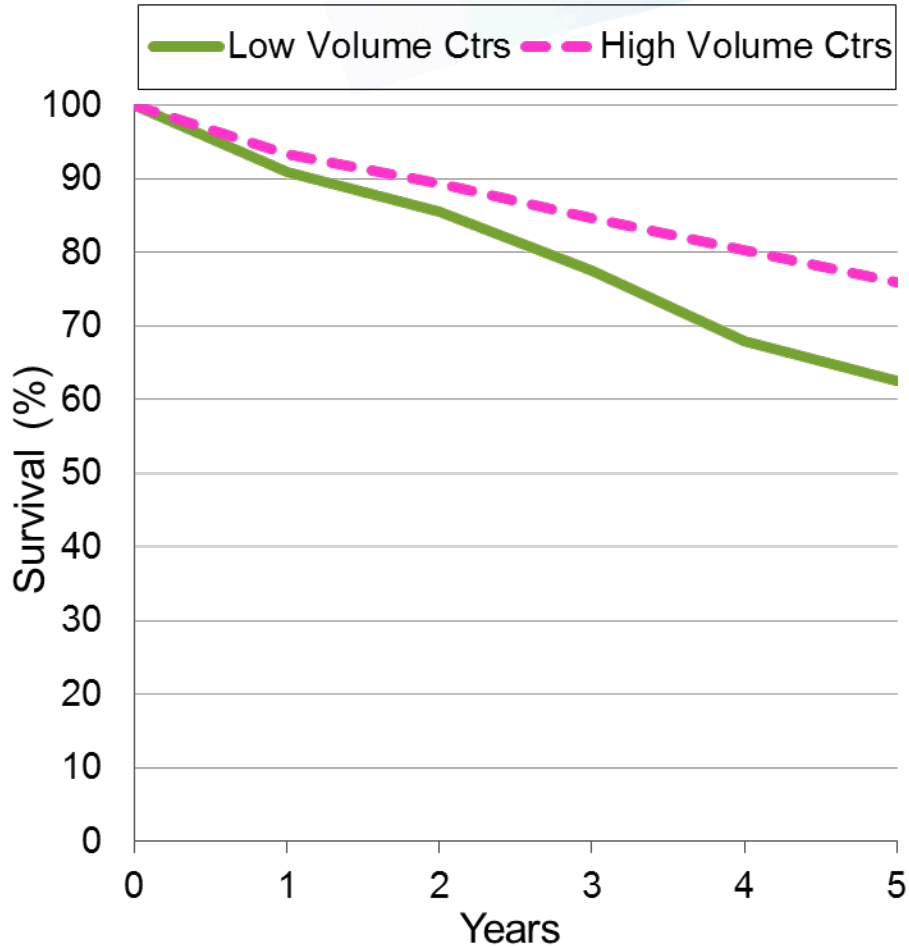
Board Policy Group Recommendation

- Discussion agenda, approve

Resolution 11 (page 47)

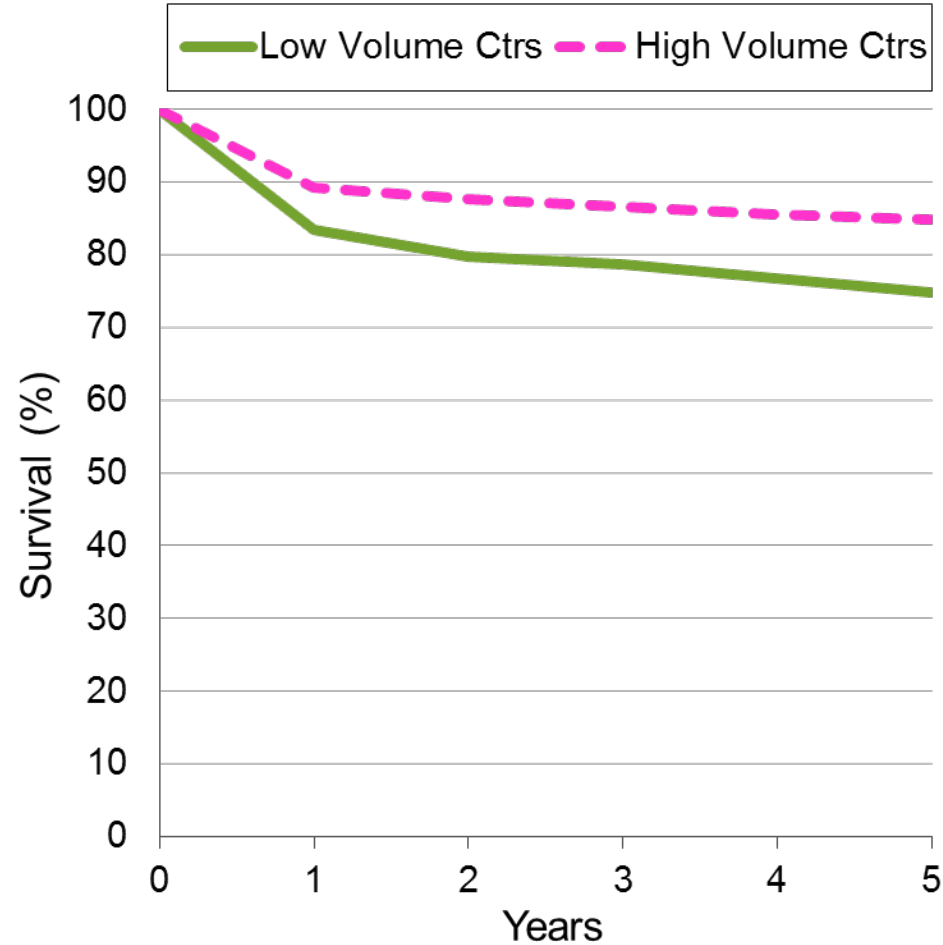
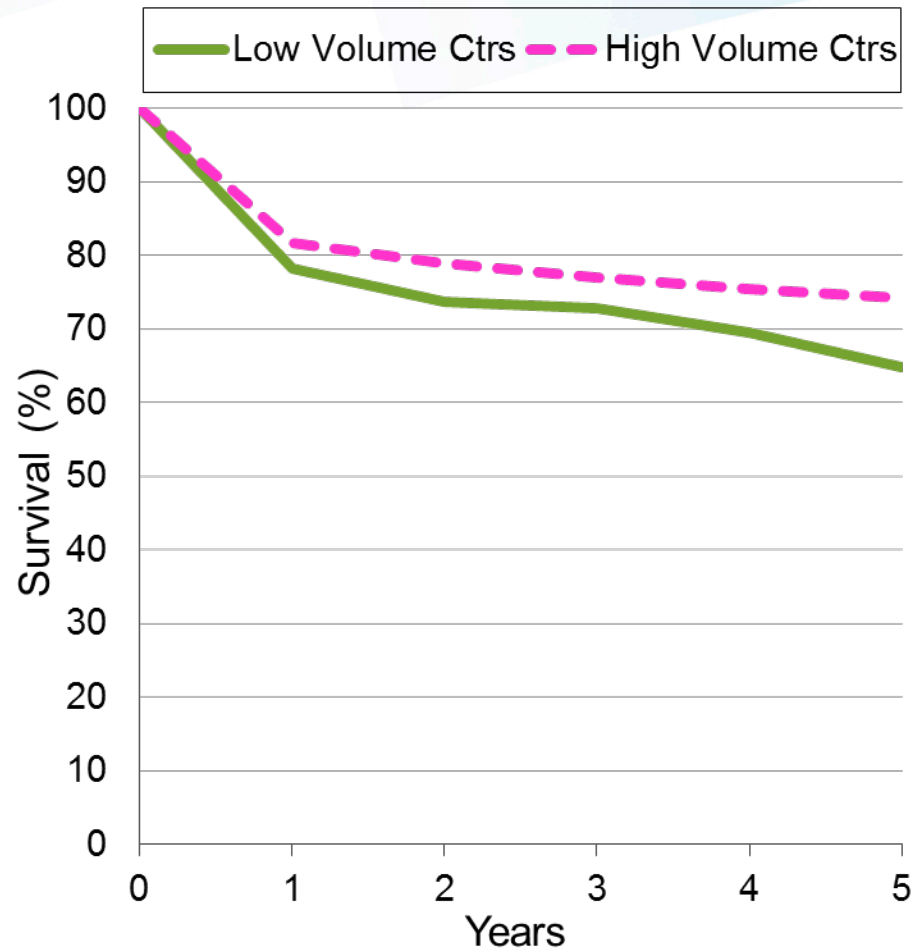
- RESOLVED, that changes and additions to Appendix E.2 (Primary Kidney Transplant Surgeon Requirements), Appendix E.3 (Primary Kidney Transplant Physician Requirements), Appendix E.5 (Kidney Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), Appendix F.2 (Primary Liver Transplant Surgeon Requirements), Appendix F.3 (Primary Liver Transplant Physician Requirements), Appendix F.6 (Liver Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), Appendix G.2 (Primary Pancreas Transplant Surgeon Requirements), Appendix G.3 (Primary Pancreas Transplant Physician Requirements), Appendix G.8 (Pancreas Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), Appendix H.2 (Primary Heart Transplant Surgeon Requirements), Appendix H.3 (Primary Heart Transplant Physician Requirements), Appendix H.4 (Heart Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), Appendix I.2 (Primary Lung Transplant Surgeon Requirements), Appendix I.3 (Primary Lung Transplant Physician Requirements), and Appendix I.4 (Lung Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), are modified as set forth in Exhibit A of the Pediatric Transplantation Committee's report to the Board, effective pending implementation and notice to members.

Unadjusted Kaplan-Meier Survival by Center Volume* for Pediatric Kidney Transplants, 1/1/95-12/31/10



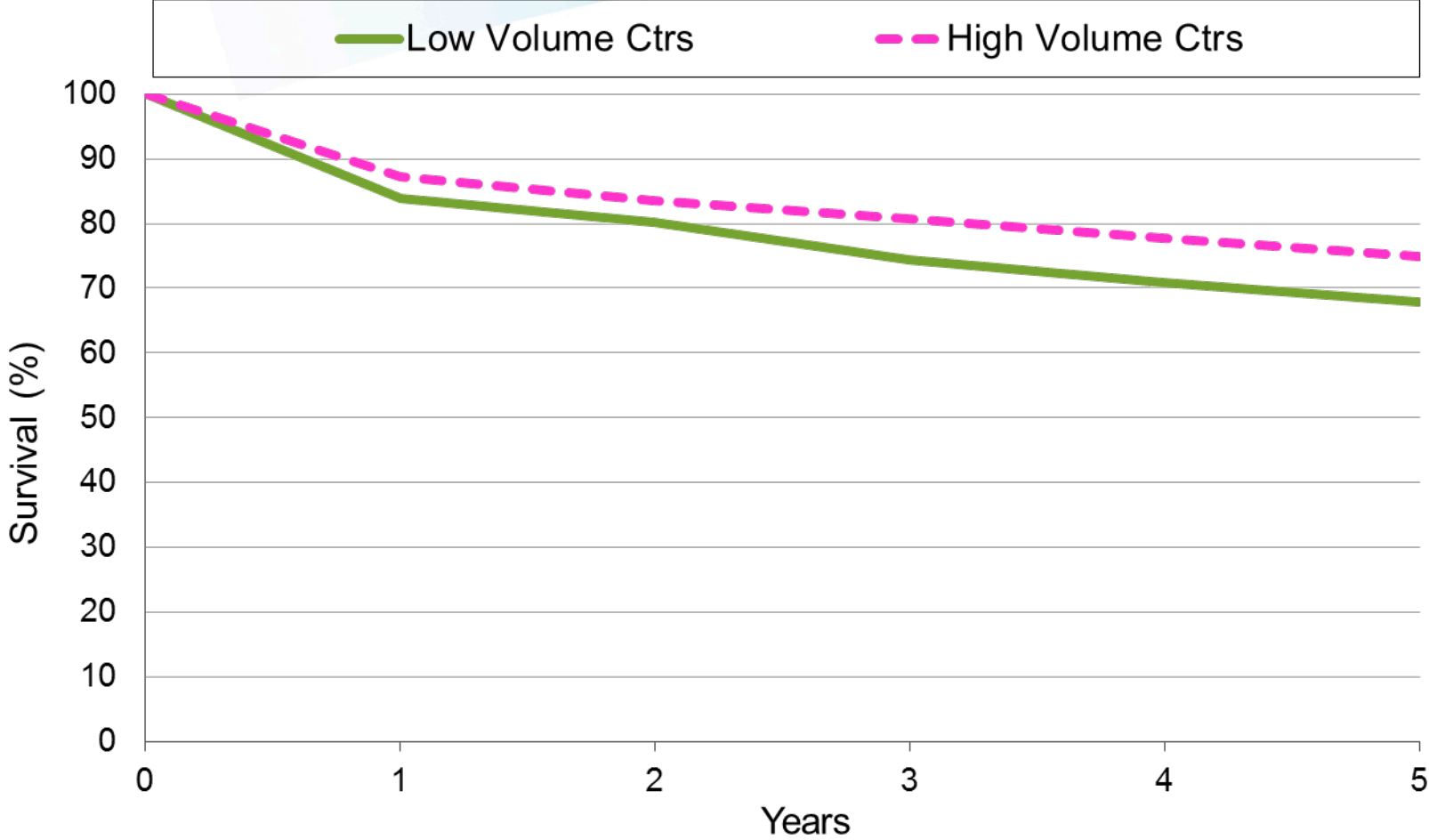
*Low volume: Ctrs with <12 transplants in 1995-2010;
High volume: Ctrs with 12+ transplants in 1995-2010

Unadjusted Kaplan-Meier Survival by Center Volume* for Pediatric Liver Transplants, 1/1/95-12/31/10



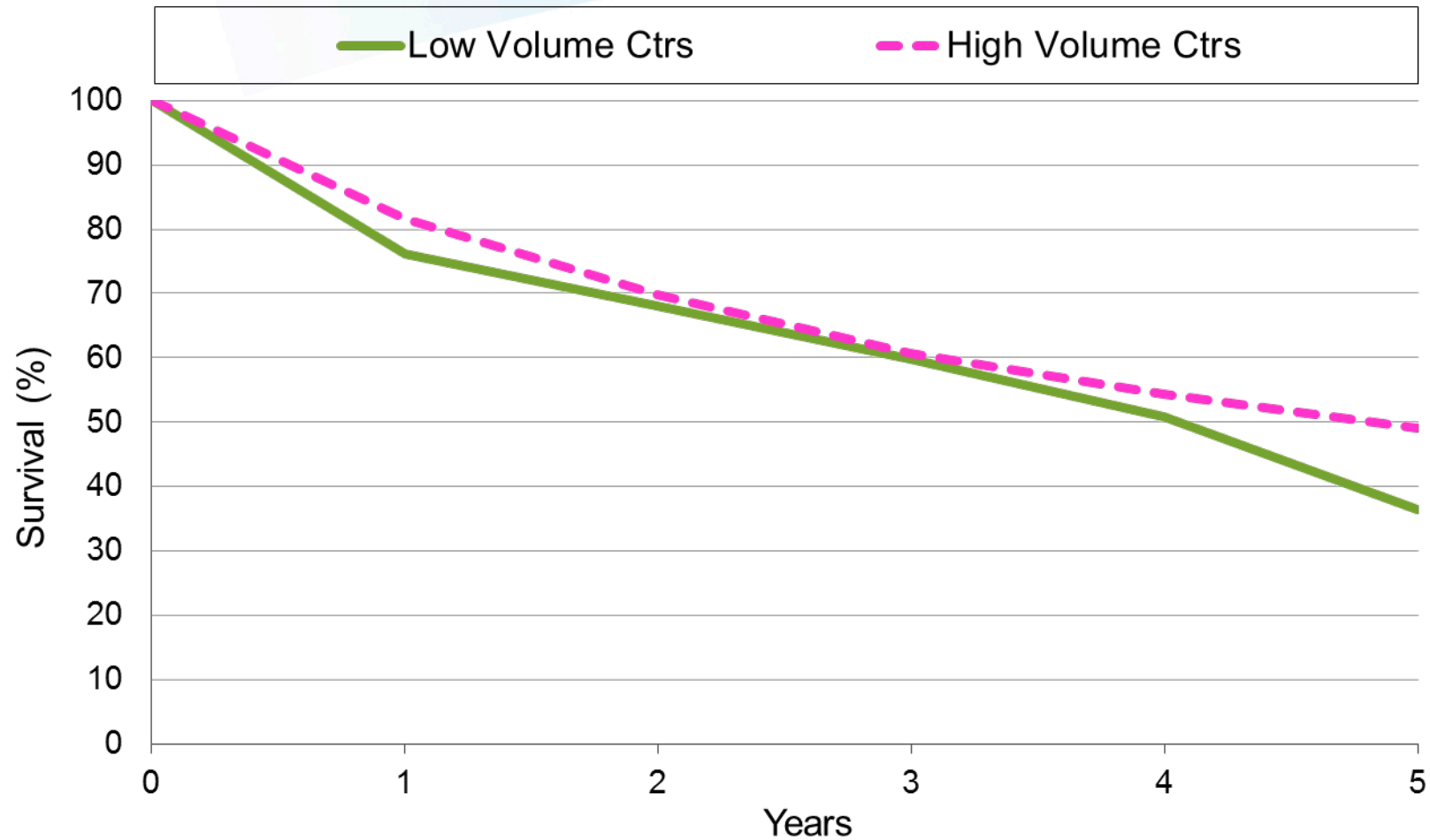
*Low volume: Ctrs with <18 transplants in 1995-2010;
High volume: Ctrs with 18+ transplants in 1995-2010

Unadjusted Kaplan-Meier Survival by Center Volume* for Pediatric Heart Transplants, 1/1/95-12/31/10



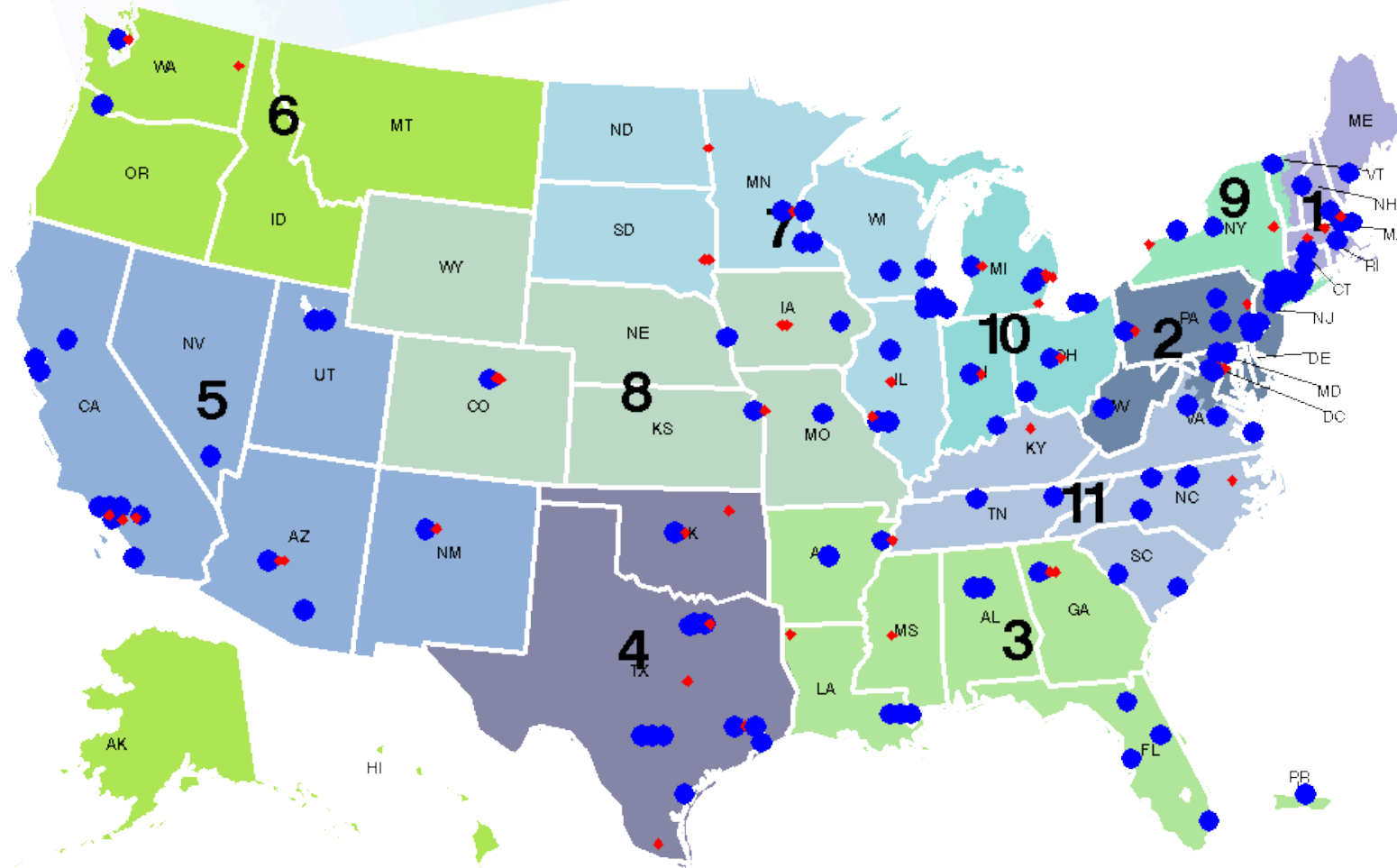
*Low volume: Ctrs with <8 transplants in 1995-2010;
High volume: Ctrs with 8+ transplants in 1995-2010

Unadjusted Kaplan-Meier Survival by Center Volume* for Pediatric Lung Transplants, 1/1/95-12/31/10



*Low volume: Ctrs with <4 transplants in 1995-2010;
High volume: Ctrs with 4+ transplants in 1995-2010

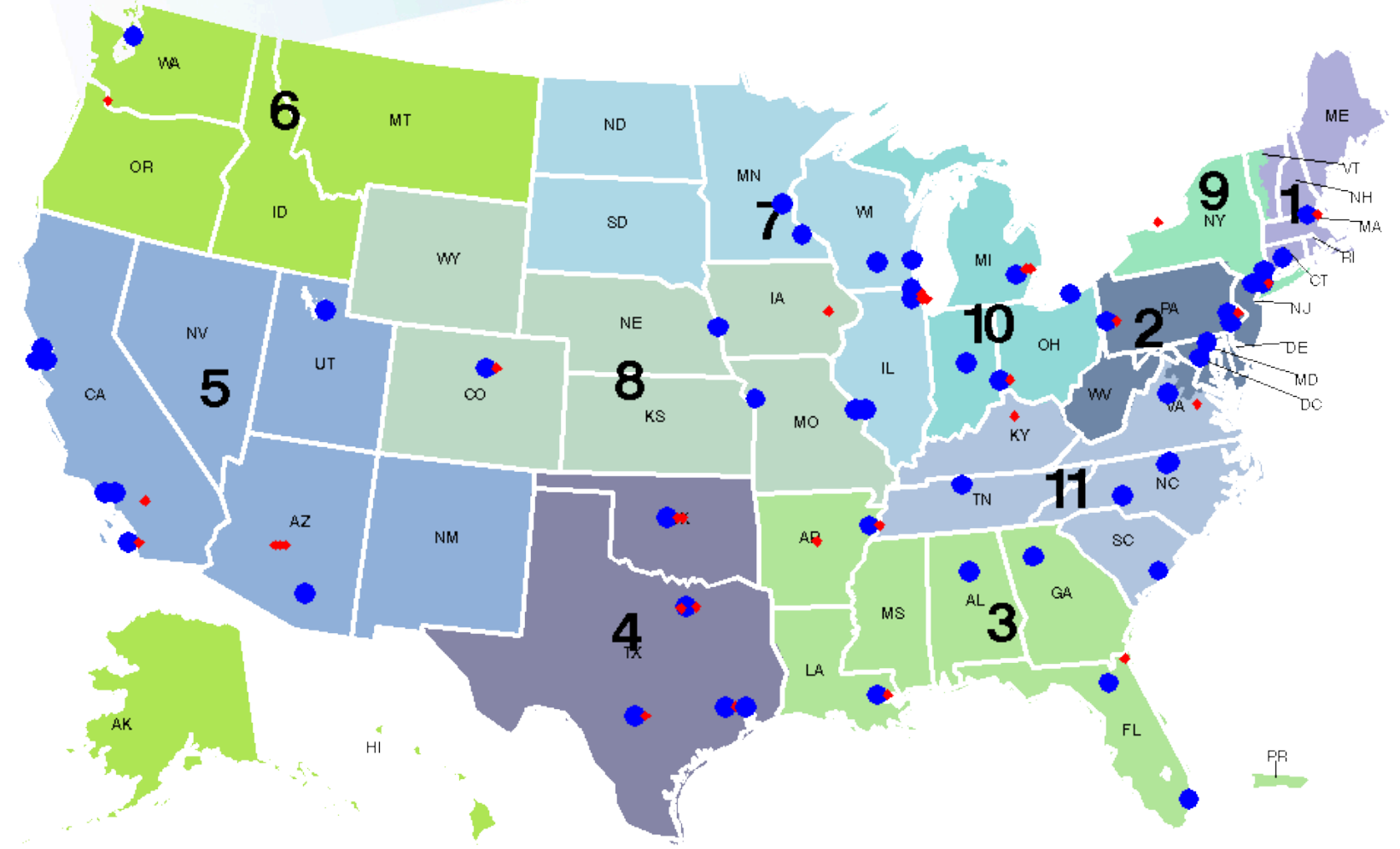
Geographic Location of Centers Performing Pediatric Kidney Transplants, 1/1/05-7/31/14



- Centers with ≥ 12 pediatric transplants
- Centers with < 12 pediatric transplants

98% of pediatric transplants were done at centers meeting the proposed volume criteria

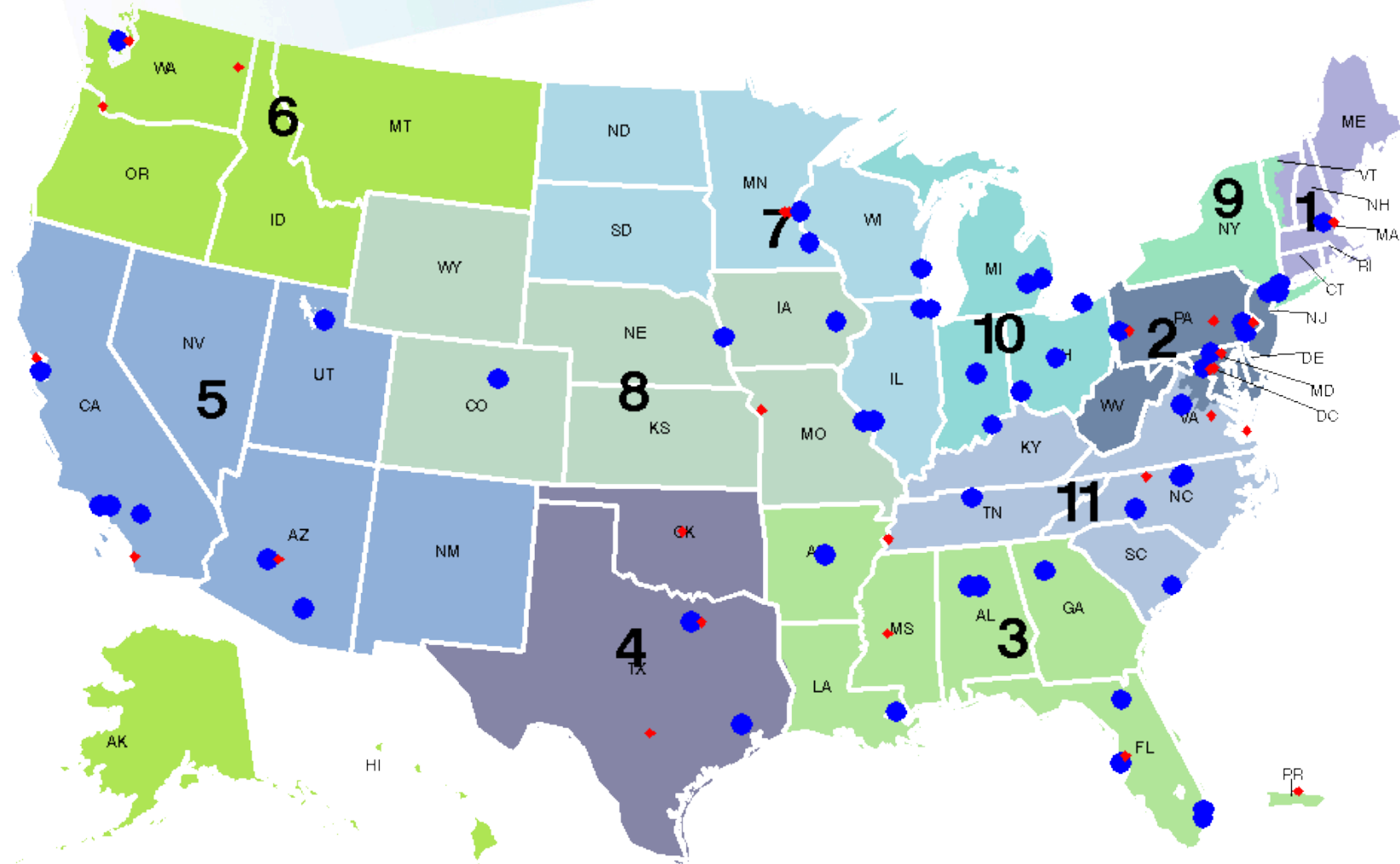
Geographic Location of Centers Performing Pediatric Liver Transplants, 1/1/05-7/31/14



- Centers with ≥ 18 pediatric transplants
- Centers with < 18 pediatric transplants

97% of pediatric transplants were done at centers meeting the proposed volume criteria

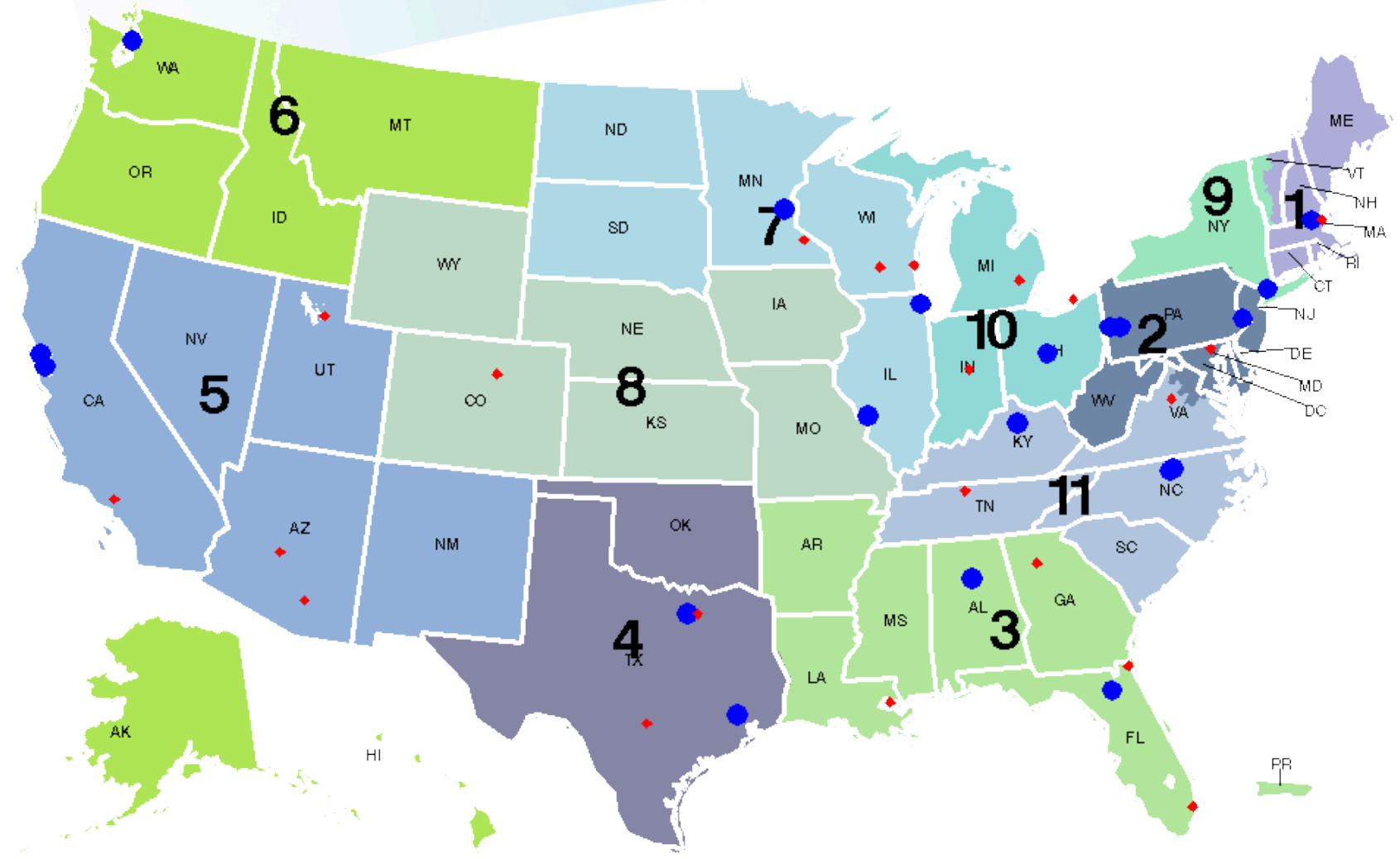
Geographic Location of Centers Performing Pediatric Heart Transplants, 1/1/05-7/31/14



- Centers with ≥ 8 pediatric transplants
- Centers with < 8 pediatric transplants

98% of pediatric transplants were done at centers meeting the proposed volume criteria

Geographic Location of Centers Performing Pediatric Lung Transplants, 1/1/05-7/31/14



- Centers with ≥ 4 pediatric transplants
- Centers with < 4 pediatric transplants

93% of pediatric transplants were done at centers meeting the proposed volume criteria