Proposal to Change Pediatric Heart Allocation Policy

OPTN/UNOS Thoracic Organ Transplantation and Pediatric Transplantation Committees
Steve Webber, Thoracic Committee Chair
June 23-24, 2014

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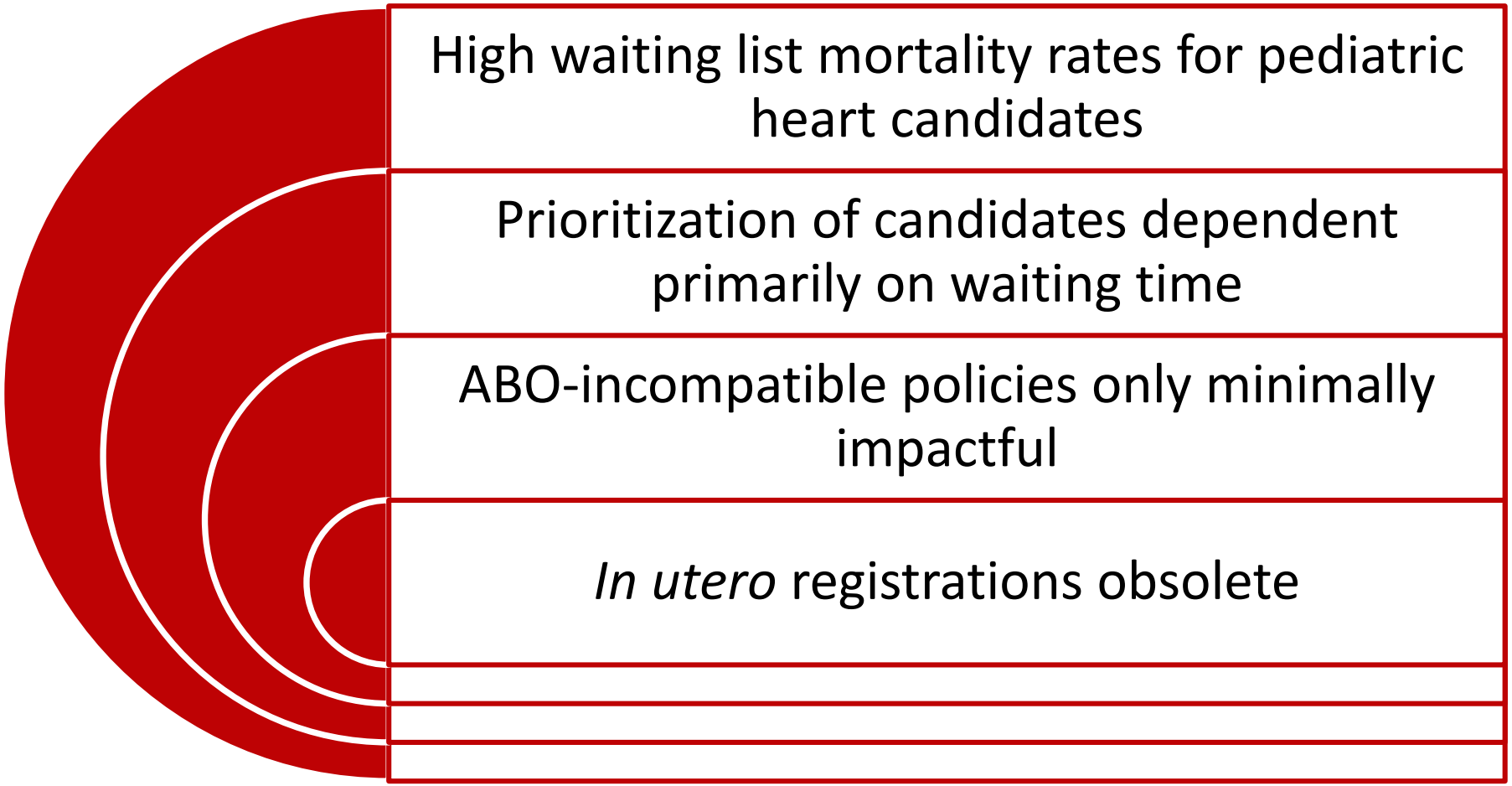
The Problems



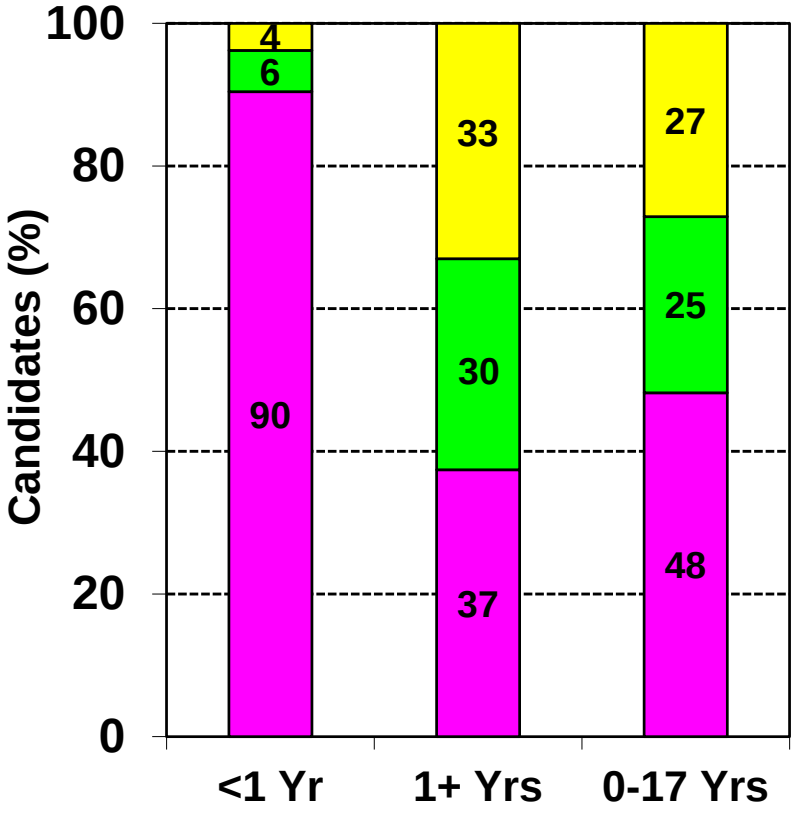
OPTN Strategic Plan

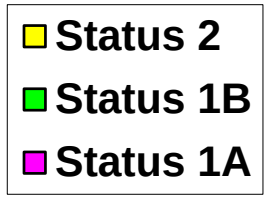
Goal: Improve survival for patients with end stage organ failure

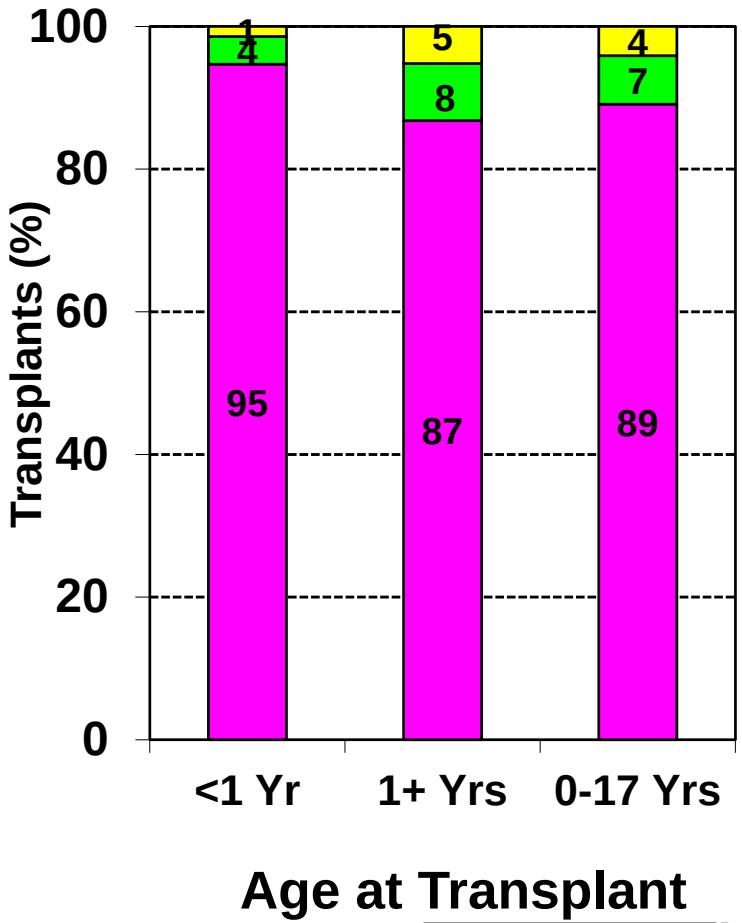
Goal: Increase access to transplants

Proposal 1: Redefine Pediatric Heart Status 1A and 1B Criteria

Distribution of medical urgency status for: (i) pediatric candidates on June 6, 2014, and (ii) pediatric recipients transplanted between January 2010 and December 2013







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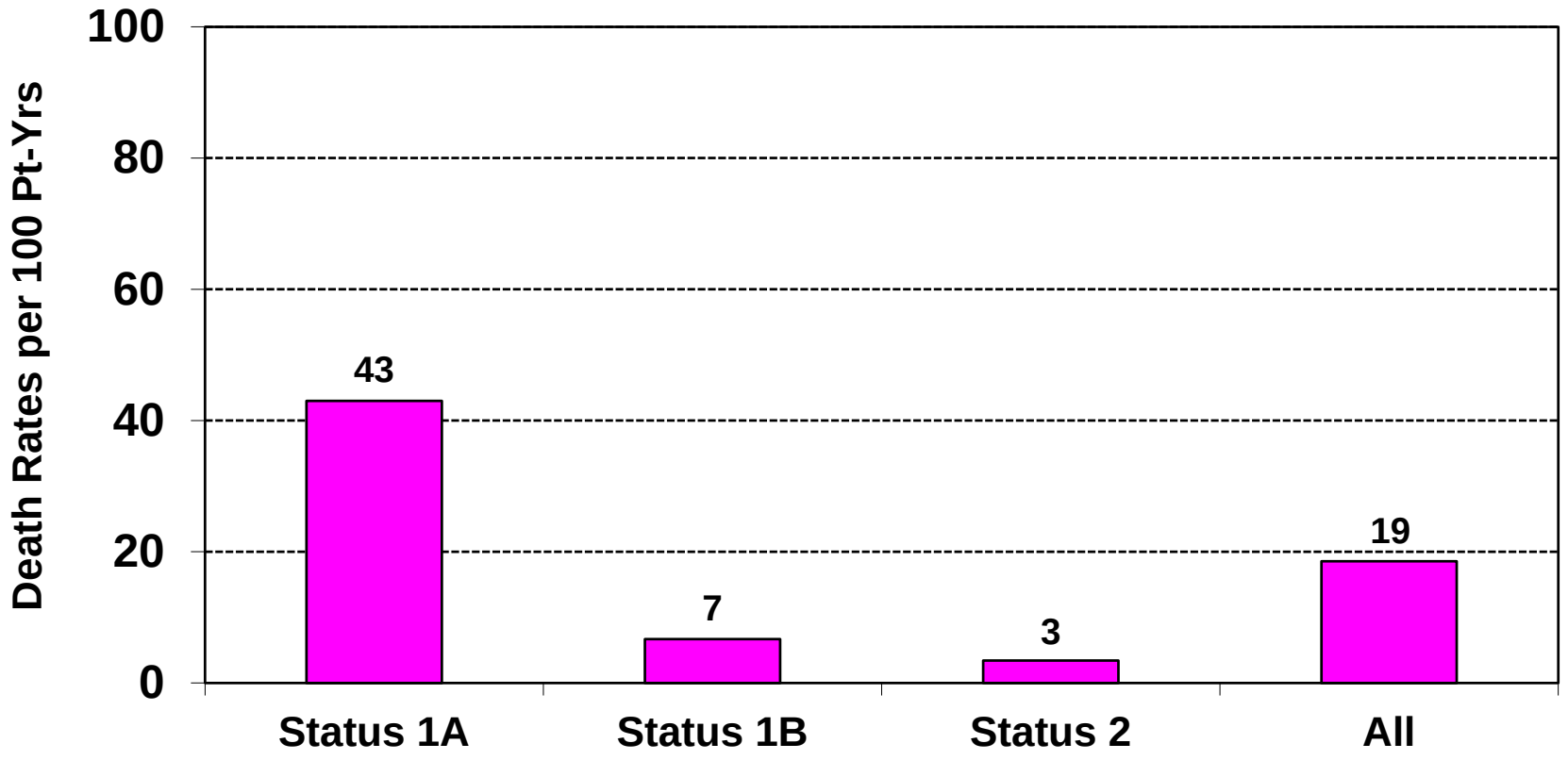
Death Rates in Different Status Categories for Pediatric Heart Candidates Aged 0-17 on the List during 5/6/09-12/31/13



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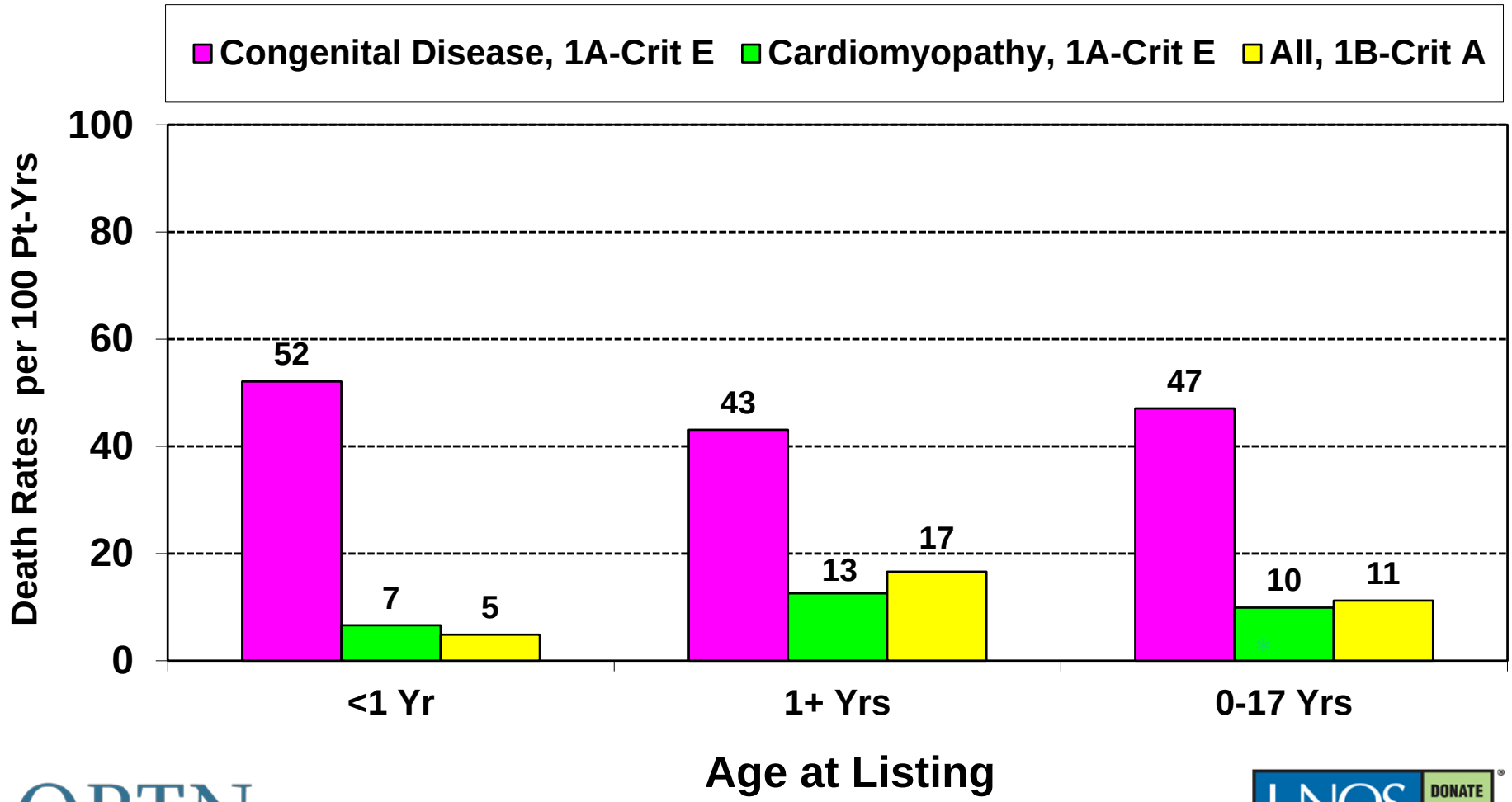
Death Rates in Status 1A-Crit E for Congenital Disease and Dilated Cardiomyopathy Diagnoses and Death Rates in Status 1B-Crit A, Pediatric Heart Candidates on the List during 5/6/09-12/31/13



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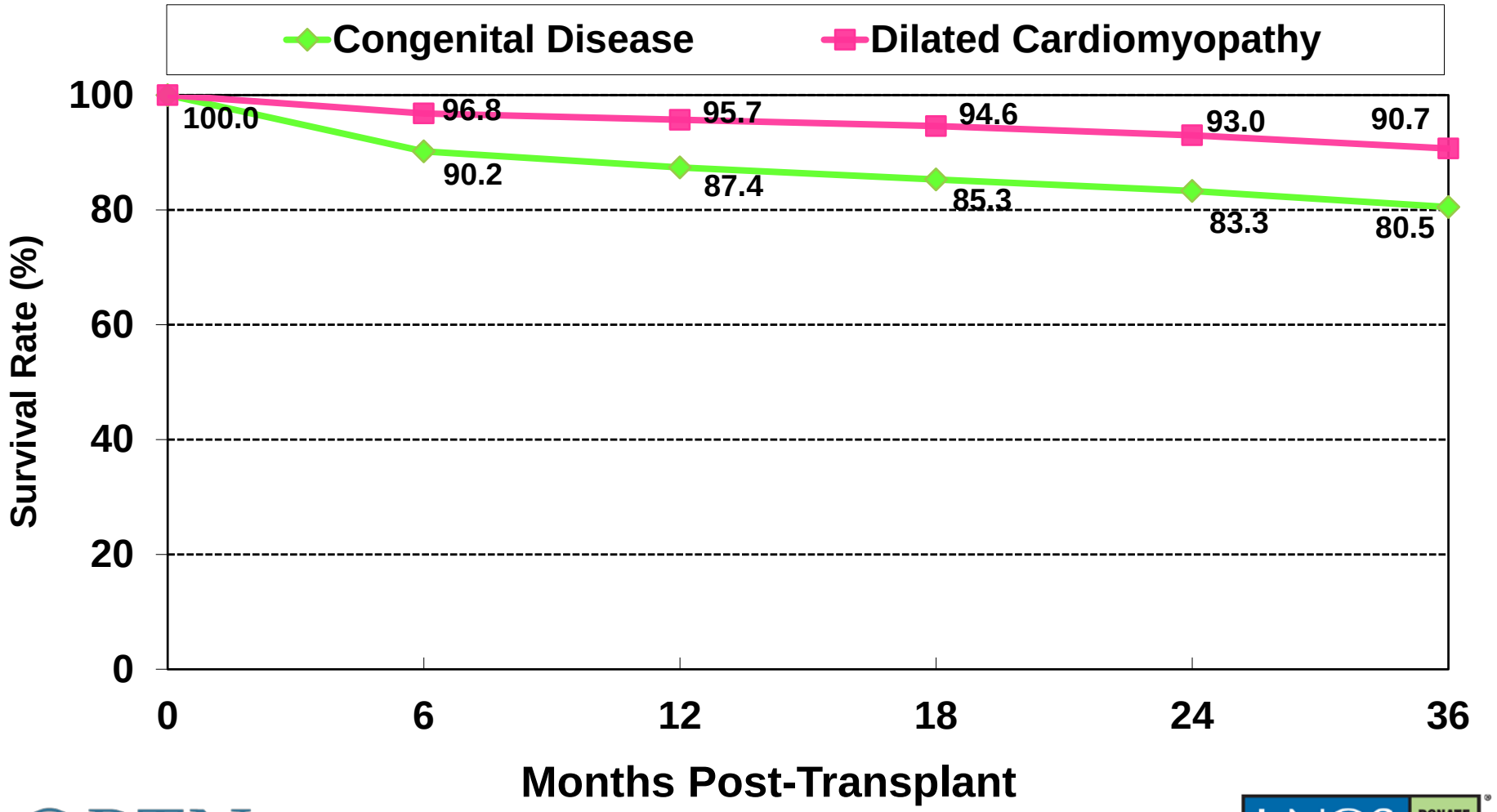
Kaplan-Meier Patient Survival for Pediatric Heart Transplant Recipients Aged 0-17 Yrs with Congenital Heart Disease and Cardiomyopathy Diagnoses, 5/6/09-6/30/13



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Note: Log-rank p-value < 0.0001

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Proposal 1: Redefine Status 1A and 1B

Proposed Status 1A

1. Continuous mechanical ventilation
2. Intra-aortic balloon pump
3. Ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent or prostaglandin infusion
4. Hemodynamically significant congenital heart disease and requires multiple intravenous inotropes/high dose single intravenous inotrope
5. Mechanical circulatory support device
6. Exception

Proposed Status 1B

1. Requires infusion of ≥1 inotropic agents (but not Status 1A)
2. <1 at registration and diagnosis of hypertrophic or restrictive cardiomyopathy
3. Exception

*Hospital admission required for status 1A(1) through (4)

Proposals 2 & 3: Expand ABOi Policies

Current ABOi Policy

Candidate is less than 1 and:

- Is Status 1A or 1B
- Reported current isohemagglutinin titer information for A or B blood type antigens within the last 30 days

Candidate is at least 1 and:

- Registered before turning 2
- Is Status 1A or 1B
- Reported current isohemagglutinin titers $\leq$ 1:4 for A or B blood type antigens within the last 30 days
- Has not received treatments in the last 30 days to reduce titer values to $\leq$ 1:4

Between 11/22/10 and 11/21/12:

388 pediatric registrations <2 years old at listing with a non-AB blood type and initial status of 1A or 1B

- 140 (36%) indicated a willingness to accept an ABOi heart

259 heart alone transplants for recipients <2 at listing with non-AB blood type and initial status of 1A or 1B

- 26 (10%) were ABOi
  - 25 of the ABOi transplants were performed in recipients <1 at both listing and transplant

Comparable outcomes between ABOc and ABOi in infants and young children

Proposal 2: Modify criteria to qualify for ABO-incompatible heart offers

Increase qualifying isohemagglutinin titer to 1:16 or less for candidates:

- At least 1 at the time of the match run
- Registered before turning 2
- Status 1A or 1B
- Reported isohemagglutinin titers ≤ 1:16 for A or B blood type antigens from a blood sample collected within the last 30 days
- Has not received treatments that may have reduced isohemagglutinin titers to ≤ 1:16 within 30 days of when this blood sample was collected

Proposal 3: Change allocation priority

Primary Classification

- All Status 1A and Status 1B candidates <1

Secondary Classification

- All candidates >1 and registered before turning 2 and eligible to receive ABOi heart offers

Proposal 4: Eliminate *In Utero* Registrations

Supporting Evidence

Only 24 candidates registered *in utero* since 2000

- 22 born at the time of waiting list removal
- 1 removed *in utero* for improved condition
- 1 allocated a heart *in utero*
- No more than 2 registrations/year (except for 2002 and 2004)
- Inadequate evaluation of *in utero* candidates

Proposal 4: Eliminate *in utero* registrations

Public Comment Feedback

Public Comment Response Tally					
Type of Response	**Response Total**	**In Favor**	**In Favor as Amended**	**Opposed**	**No Vote/ No Comment/ Did Not Consider**
Individual	66	27	n/a	34	5
Regional	11	10	1	n/a	n/a
Committee	20	2	n/a	n/a	18

Post-Public Comment Changes

- Require admission to transplant hospital for Status 1A candidates (besides MCSD)
- Exception criteria changed to match adult policy
- Specify qualifying CHD diagnoses for Status 1A(4)
- Reporting timeframes for isohemagglutinin titers for ABOi recipients

6.5.A Allocation of Hearts by Blood Type

Pediatric candidates that are less than one year old at the time of the match run and registered as status 1A or status 1B, including candidates qualified to receive a heart from a deceased donor of any blood type, will be classified as a primary blood type match candidate.

Resolution 19

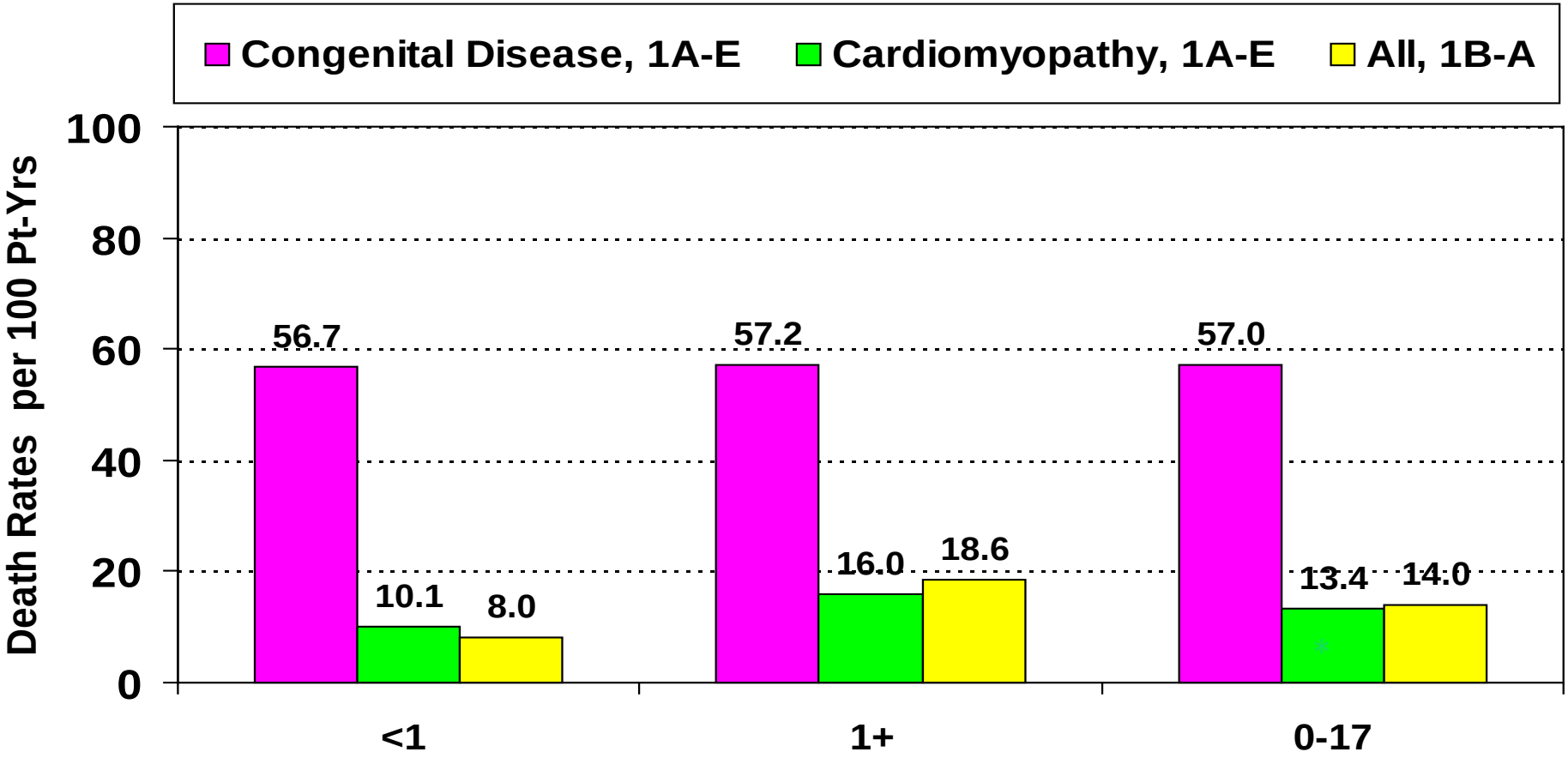
RESOLVED, that Policies 3.4.H (In Utero Candidate Registrations); 5.3.C (Pediatric Heart Acceptance Criteria); 6.1 (Status Assignments); 6.1.D (Pediatric Heart Status 1A Requirements); 6.1.E (Pediatric Heart Status 1B Requirements); 6.1.F (Pediatric Heart Status 2 Requirements); 6.3 (Status Exceptions); 6.3.A (RRB and Committee Review of Status Exceptions); 6.4 (Waiting Time); 6.5.A (Allocation of Hearts by Blood Type); 6.5.B (Sorting Within Each Classification); 6.5.C (Allocation of Hearts from Donors at Least 18 Years Old); and 6.5.D (Allocation of Hearts from Donors Less Than 18 Years Old) are modified as set forth in Resolution 19, effective pending programming and notice to the OPTN membership.

FURTHER RESOLVED, that the congenital heart disease diagnoses are approved, as set forth in Exhibit C to the Thoracic Committee's report to the Board, effective pending programming and notice to the OPTN membership.

*Page 86 of Board book

Additional Data Slides

Waiting List Death Rates in Status 1A-E for Congenital Disease and Dilated Cardiomyopathy Diagnoses and Death Rates in Status 1B-A, Pediatric Heart Candidates on the Waiting List during 5/6/09-7/31/11



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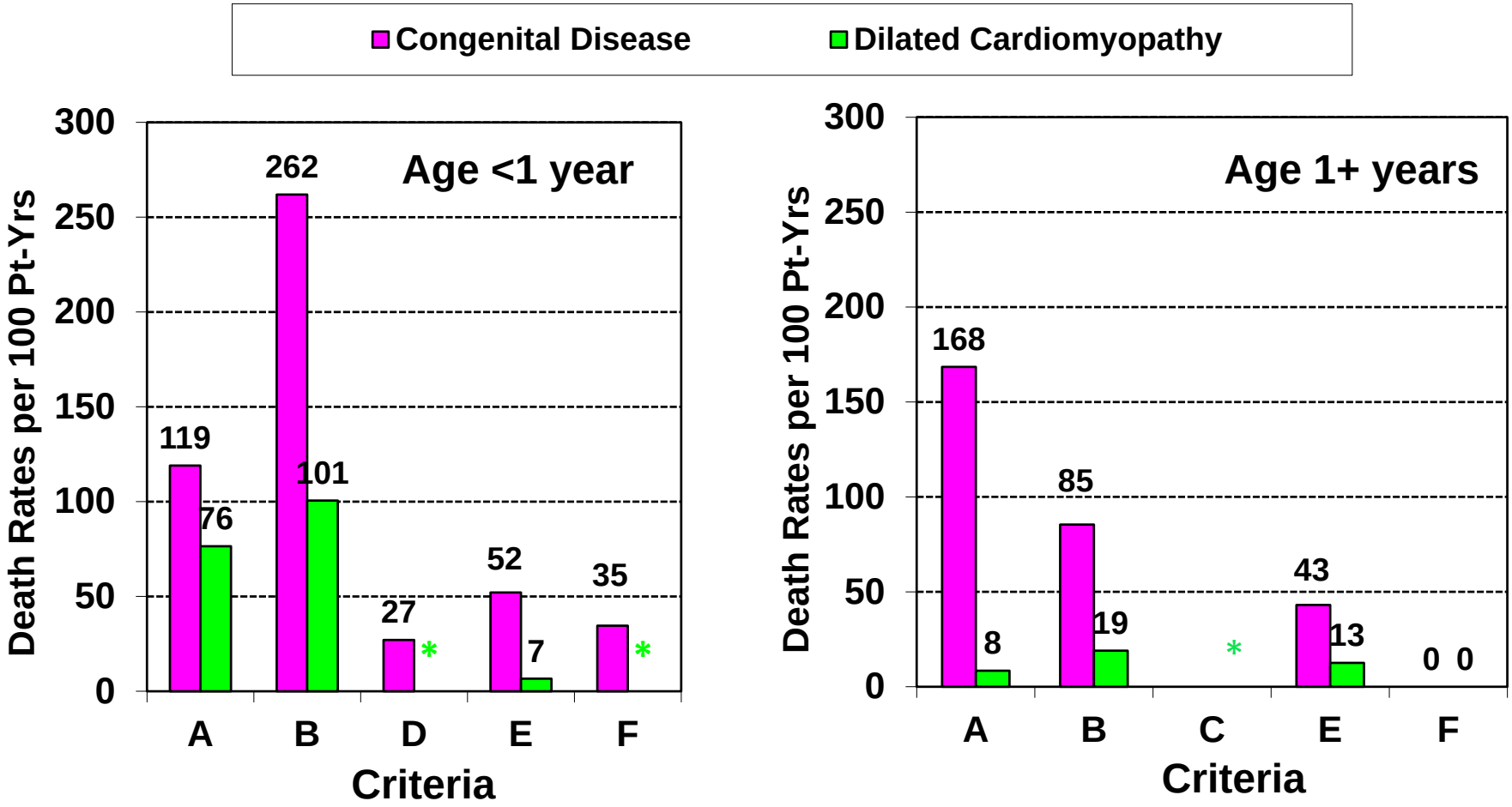
Death Rates per 100 Pt Yrs in Status 1A Criteria for Pediatric Heart Candidates by Age Group at Listing with Congenital Disease and Dilated Cardiomyopathy Diagnoses during 5/6/09-12/31/13



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Note: "*" denotes death rate not computed due to no. of patients<10.
There were no patients 1+ years old in Criteria C with congenital disease.

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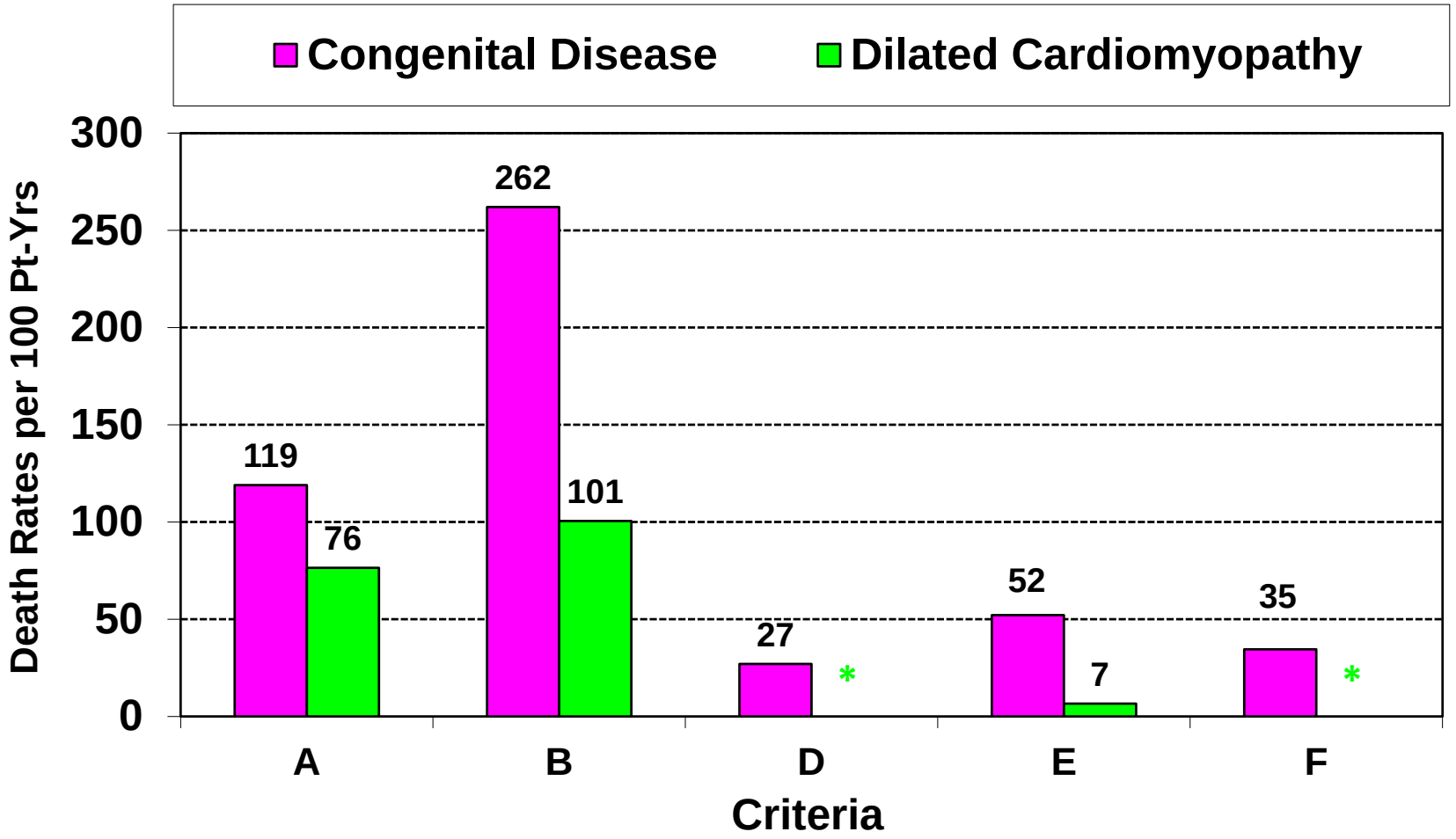
Death Rates per 100 Pt Yrs in Status 1A Criteria for Pediatric Heart Candidates Aged <1 Yr at Listing with Congenital Disease and Dilated Cardiomyopathy Diagnoses during 5/6/09-12/31/13



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Note: "*" denotes death rate not computed due to no. of patients<10.

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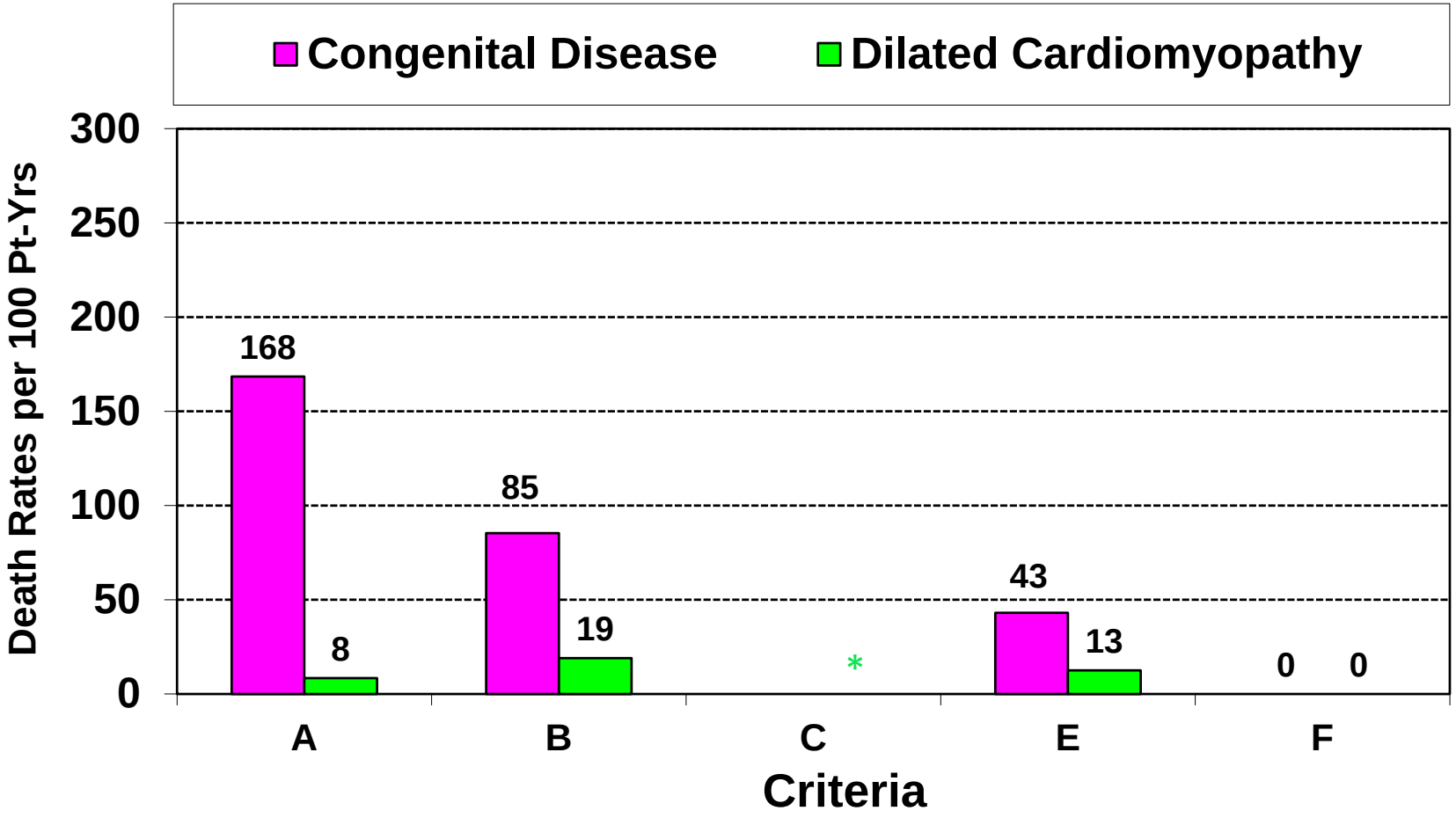
Death Rates per 100 Pt Yrs in Status 1A Criteria for Pediatric Heart Candidates Aged 1+ Yrs at Listing with Congenital Disease and Dilated Cardiomyopathy Diagnoses during 5/6/09-12/31/13



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Notes: "*" denotes death rate not computed due to no. of patients<10; there were no patients in Criteria C with congenital disease.

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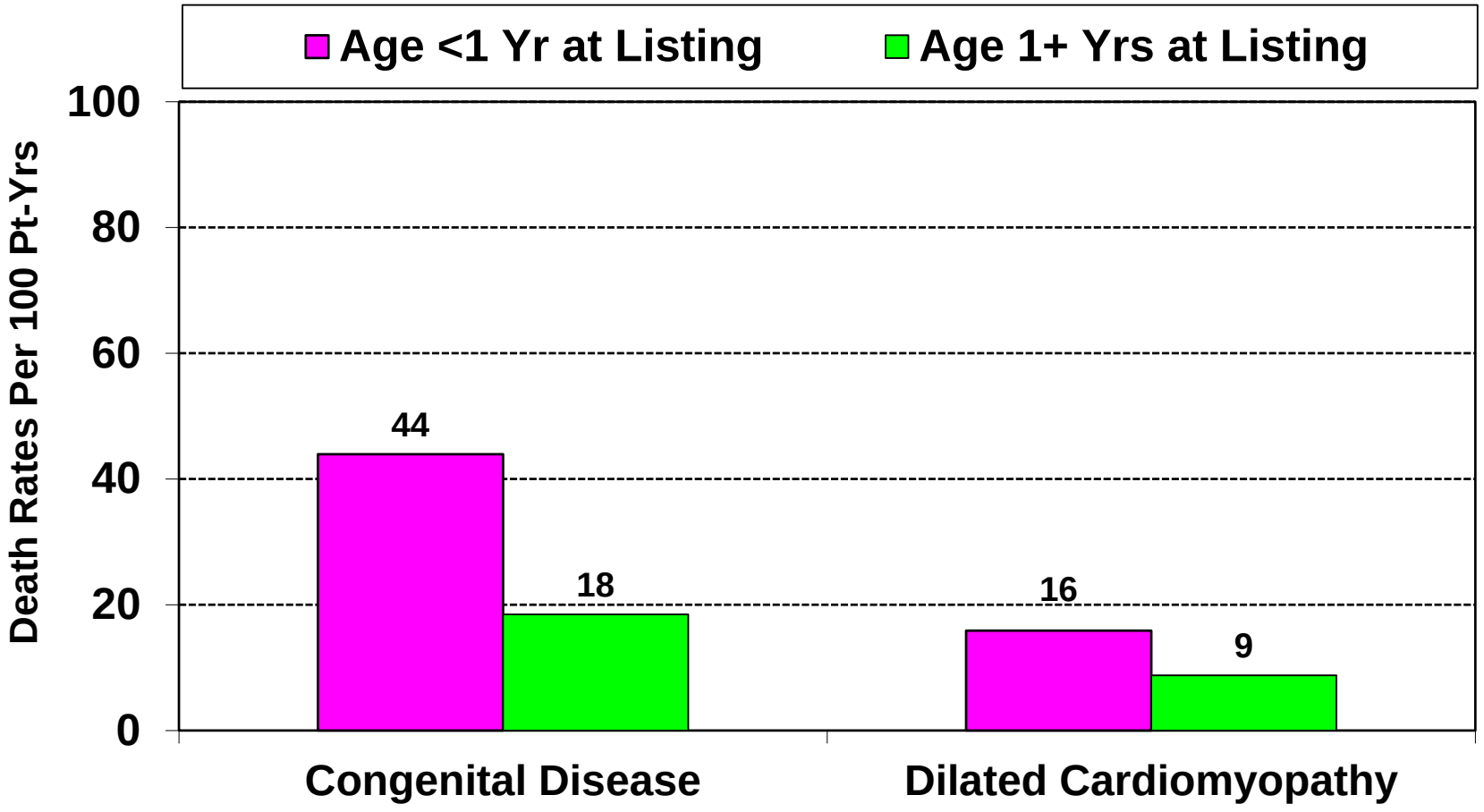
Death Rates per 100 Pt Yrs for Pediatric Heart Candidates on the List during 5/6/09-12/31/13 with Congenital Disease and Dilated Cardiomyopathy



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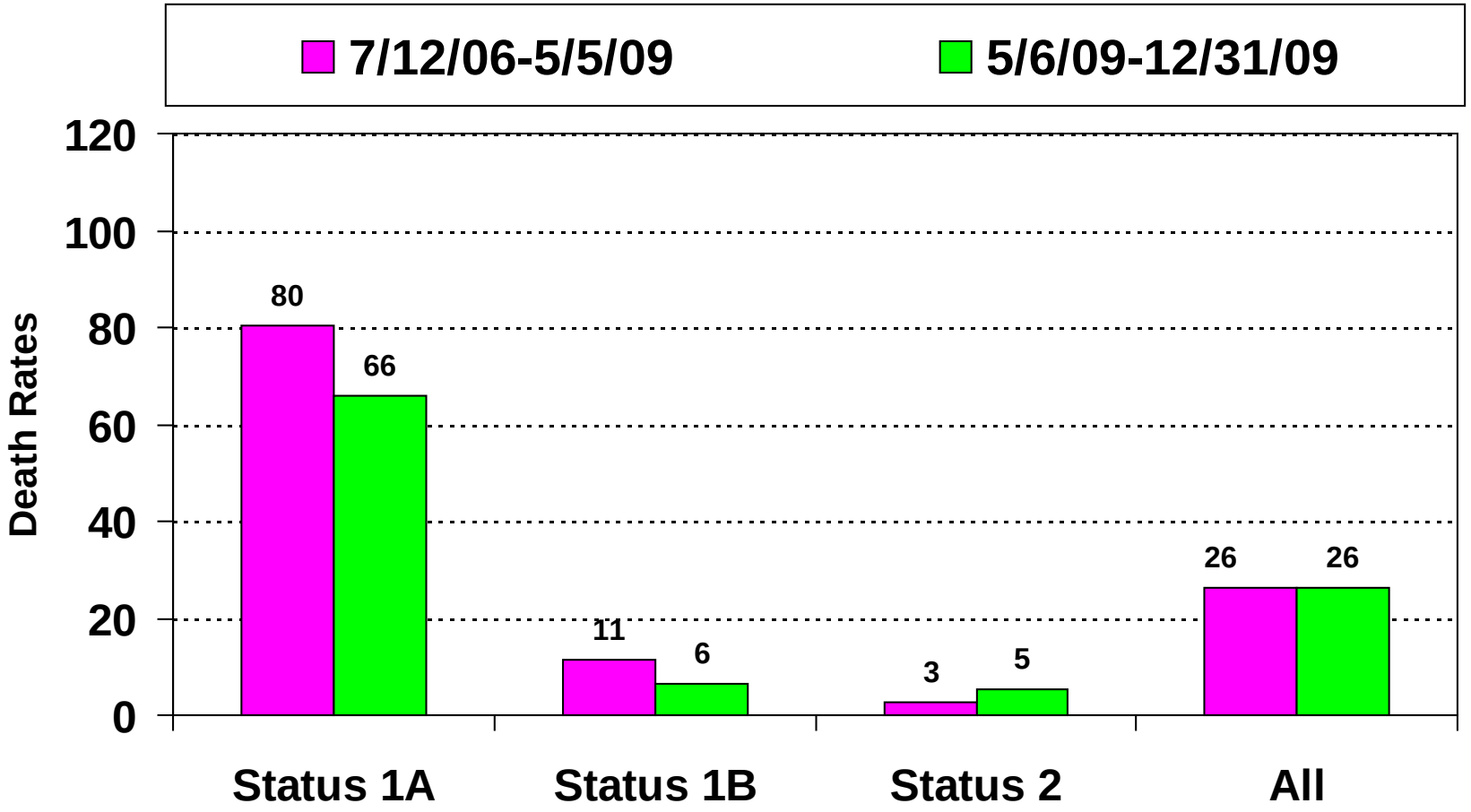
Death Rates per 100 Pt Yrs in Different Status Categories for Pediatric Heart Candidates <u>Aged 0-17</u> at Listing during 7/12/06-12/31/09



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