

ASSURING HIGH QUALITY OUTCOMES WITH APPROPRIATE PATIENT ACCESS TO TAVR



TAVR MEDCAC
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Medtronic
Further, Together

DISCLOSURES

A. PIETER KAPPETEIN, M.D., PH.D.

- Employee and shareholder of Medtronic (major)
- Professor, Erasmus University Rotterdam

MEDTRONIC TAVR PROGRAM

COMMITMENT TO EXCELLENCE IN QUALITY AND OUTCOMES

Robust Structural Heart and TAVR Program

- First Medtronic commercial approval for TAVR in the US in 2014; CE Mark approval since 2007
- Continuous investment in TAVR technology to increase quality and improve outcomes
- Medtronic TAVR device design has demonstrated excellent procedural outcomes & durability

Committed Clinical Program

- 10,000+ patients enrolled globally in trials, including 3 pivotal RCTs; 50,000+ patients in national and industry registries
- Evaluating extreme, high, intermediate, and low risk patients, including expanded use: LGLO, Tav-in-Sav, ESRD, severe MR, severe TR, and patients with multiple co-morbidities
- Comprehensive data monitoring/auditing; independent adverse event adjudication; independent core labs for CT/echo evaluation; QoL & functional/health assessment

Rigorous Operator and Facility Training Program

- Didactic Training including Product, Procedure, and Patient Selection
- On-site comprehensive Heart Team training
- Expert physician and field case support for imaging, case planning, and procedure

EXISTING TAVR NCD ASSURES QUALITY AND ACCESS

PROPOSED GUIDELINES MAY LIMIT OPTIONS FOR PATIENTS

OUTCOMES ARE EXCELLENT UNDER CURRENT TAVR NCD

Comparable outcomes shown in
real-world registry vs. clinical trial
experience

Consistent positive outcomes
across range of site procedural
volumes in real-world registry

Continuing investment in
technology and training programs
will improve outcomes further

INCREASED VOLUME REQUIREMENTS MAY LIMIT ACCESS FOR PATIENTS

Reduced number of centers
eligible to perform TAVR
procedures

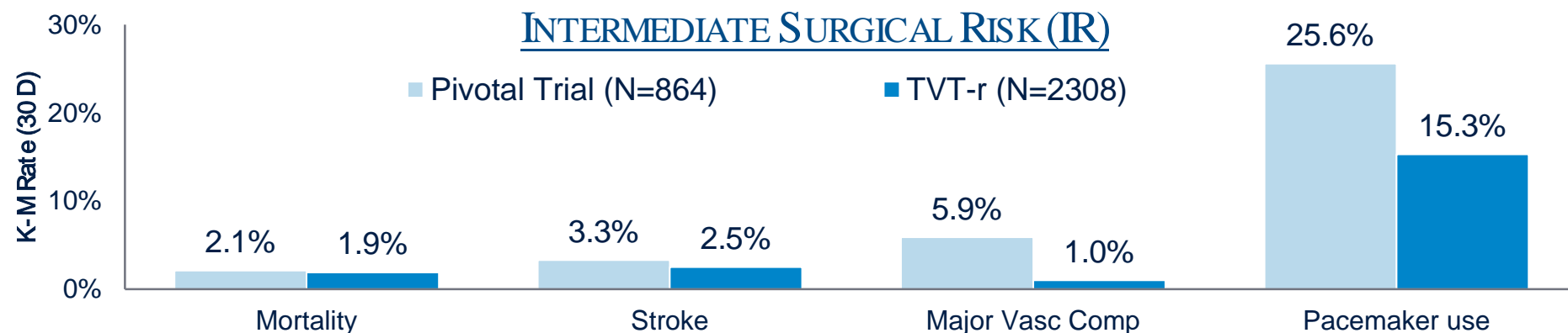
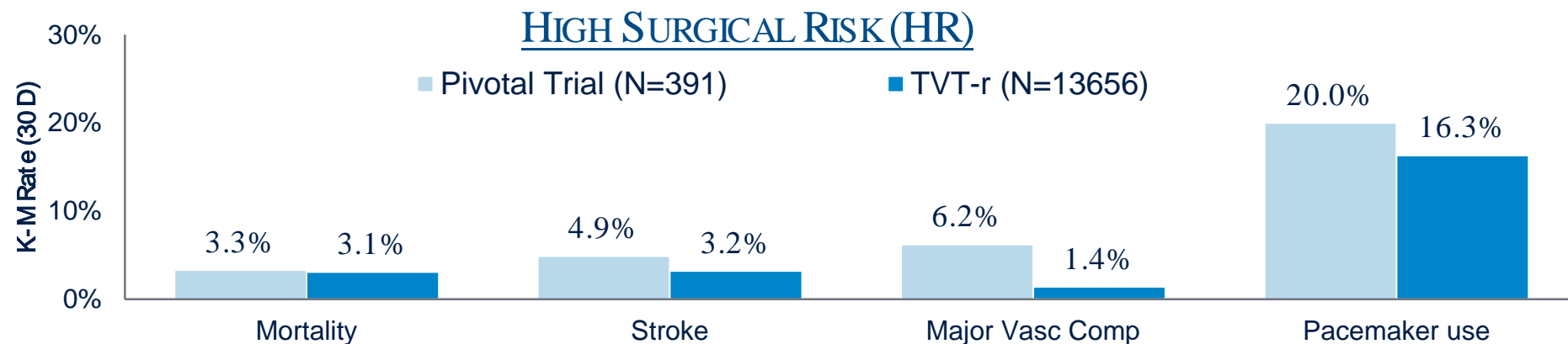
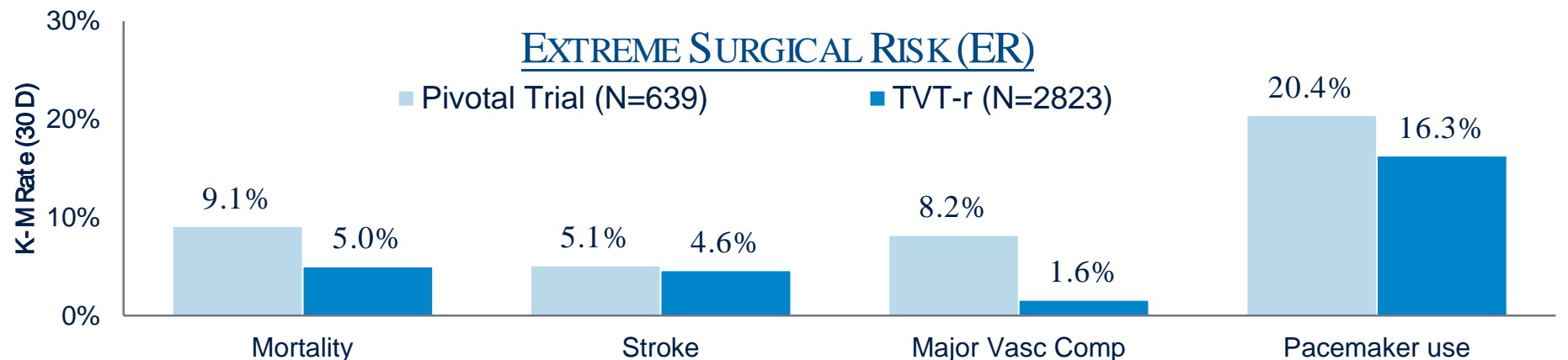
Burden of travel, time, and costs to
reach eligible centers

Patients have significant mortality
risk with delayed treatment

CMS policymaking should maintain quality while protecting patient access to TAVR therapy

MEDTRONIC PIVOTAL TRIAL & TVT-R (EVOLUT R/ EVOLUT PRO)

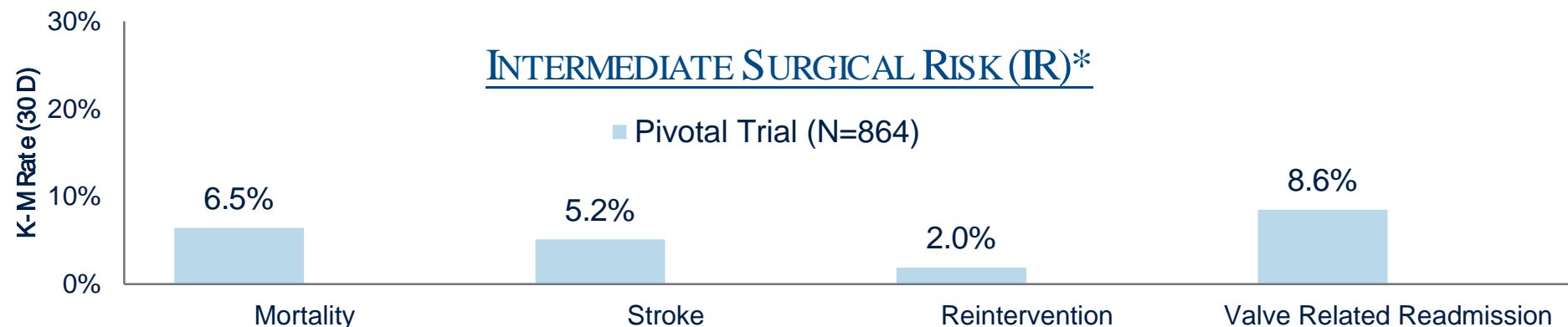
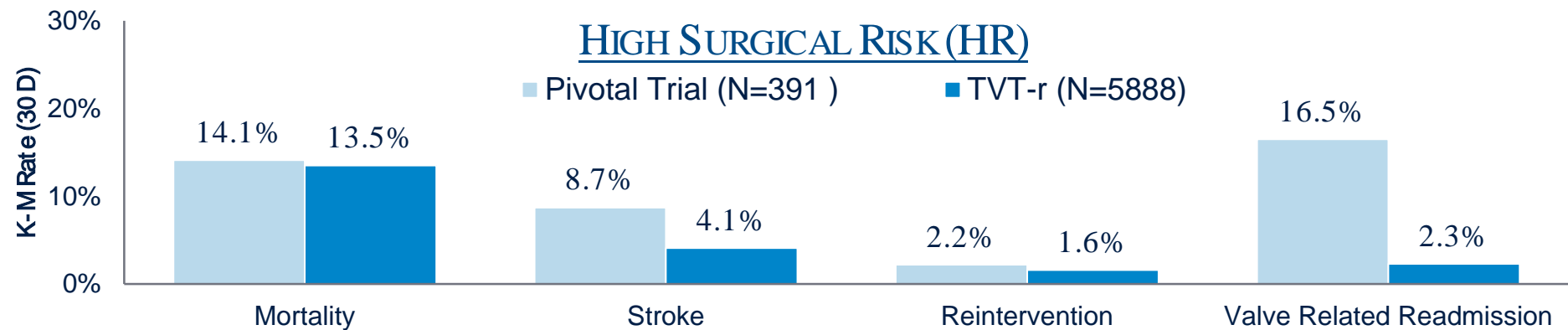
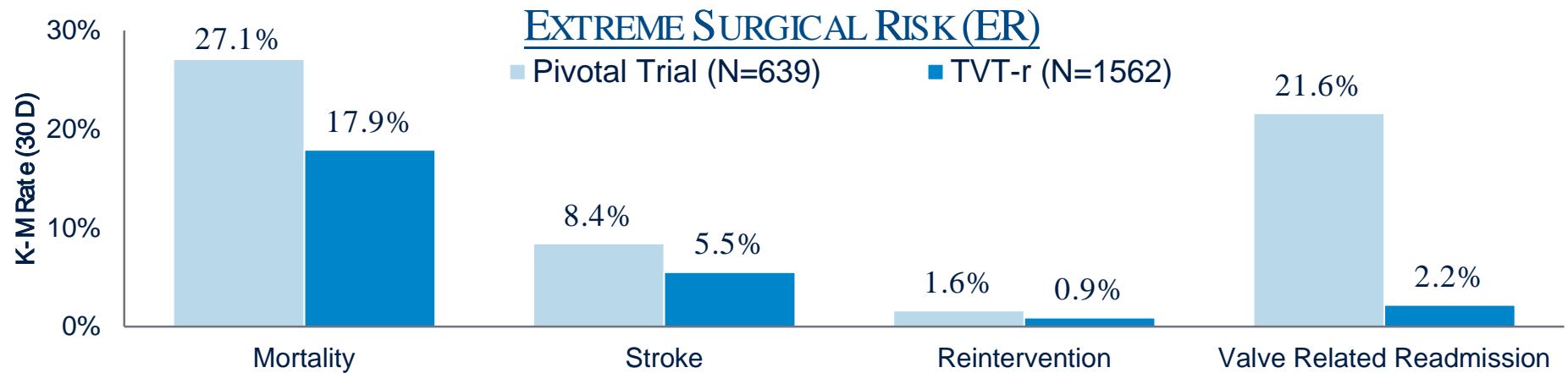
30 DAY COMPLICATION RATES CONSISTENT IN REAL-WORLD DATA VS TRIAL POPULATION



TVT-r: Evolut R and Evolut PRO procedures implanted in a native valve through 2017Q3

MEDTRONIC PIVOTAL TRIAL & TVT-R (EVOLUT R/ EVOLUT PRO)

12 MONTH OUTCOMES CONSISTENT IN REAL-WORLD DATA VS TRIAL POPULATION

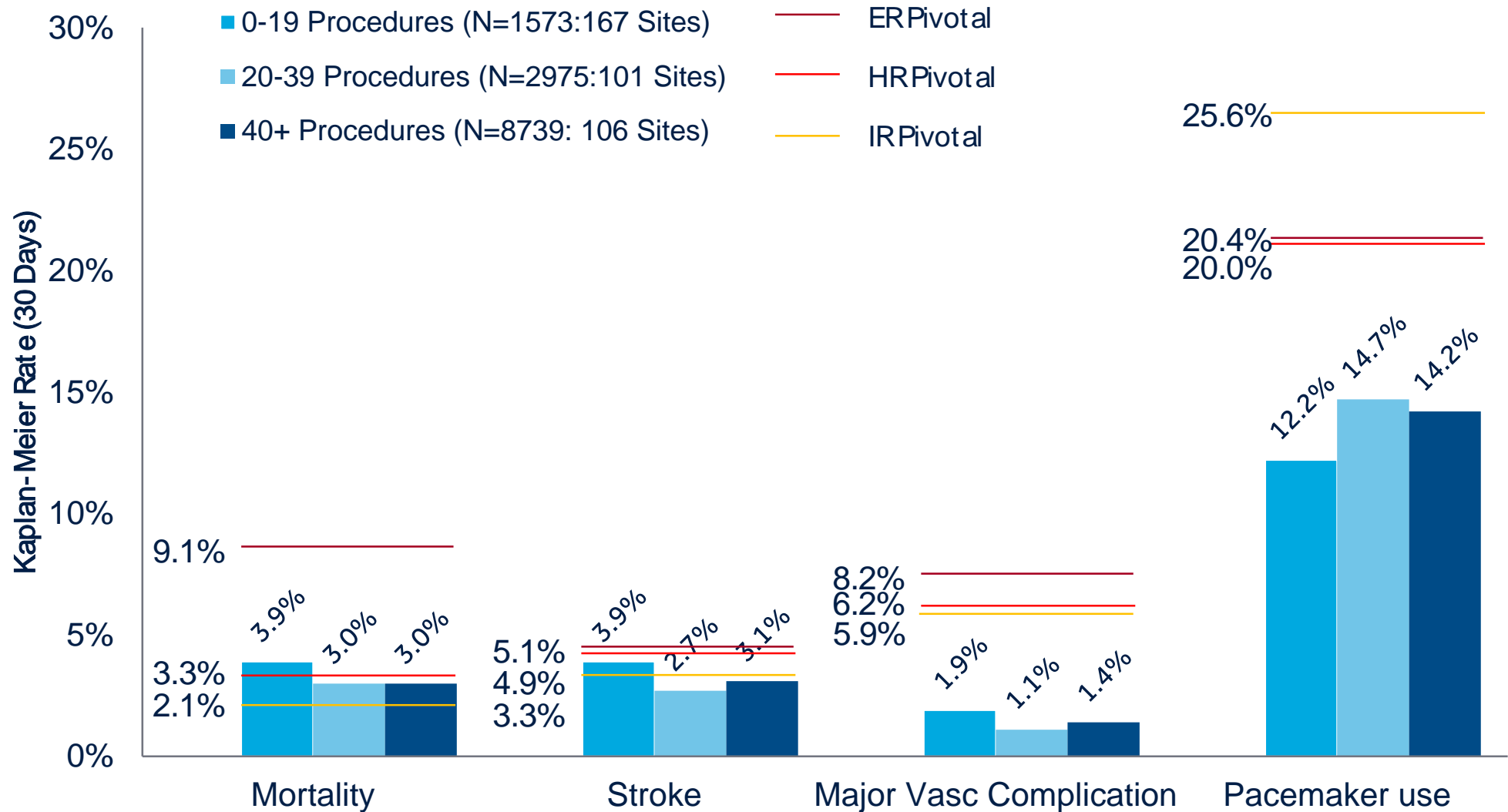


*Intermediate Risk commercial use 12 month data not shown since <12 months have elapsed since indication granted
TVT-r: Evolut R and Evolut PRO procedures implanted in a native valve through 2016Q3

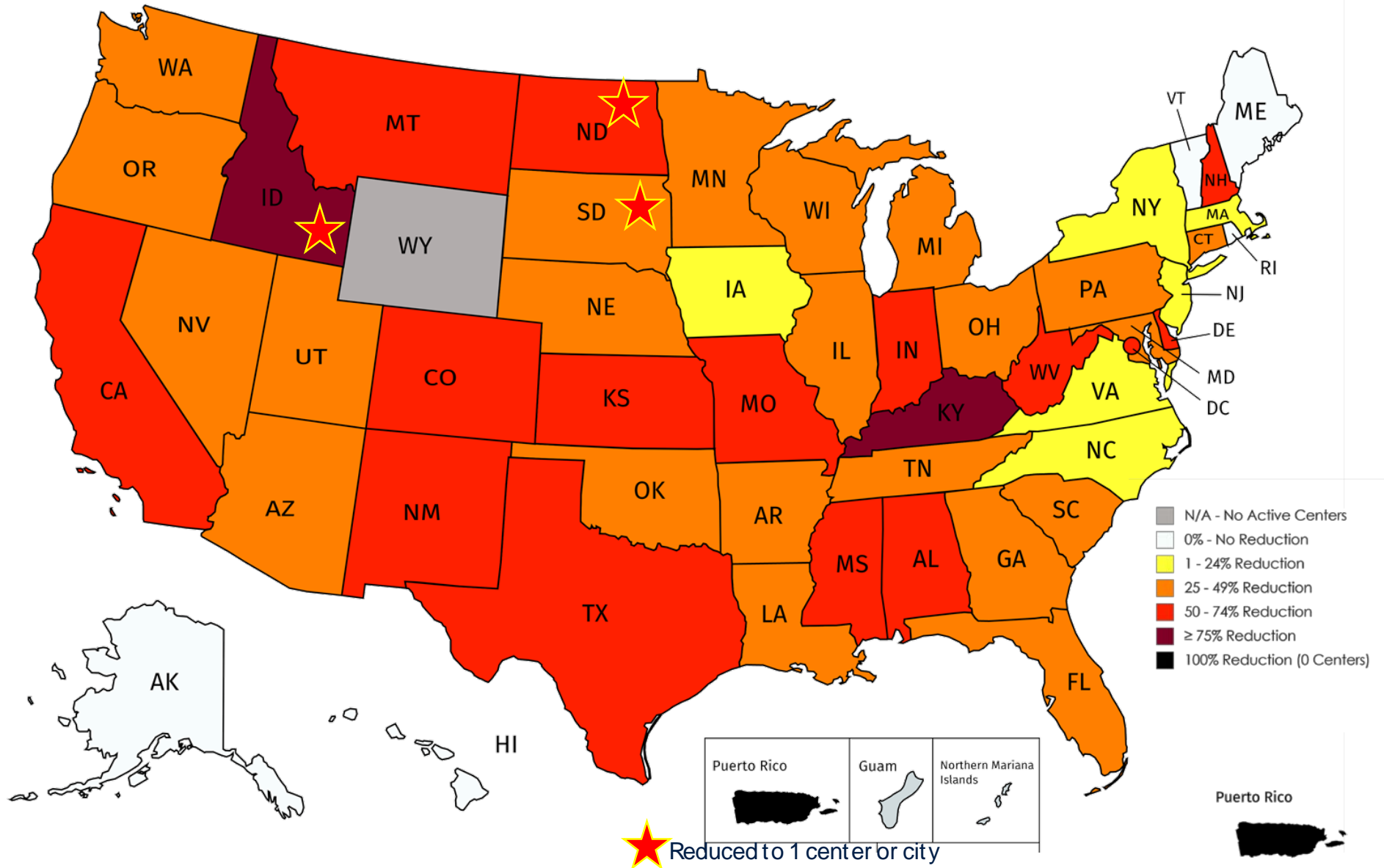
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TVT-R COMMERCIAL USE DATA BY ANNUAL SITE VOLUME

30 DAY COMPLICATION RATES COMPARABLE ACROSS SITE VOLUMES



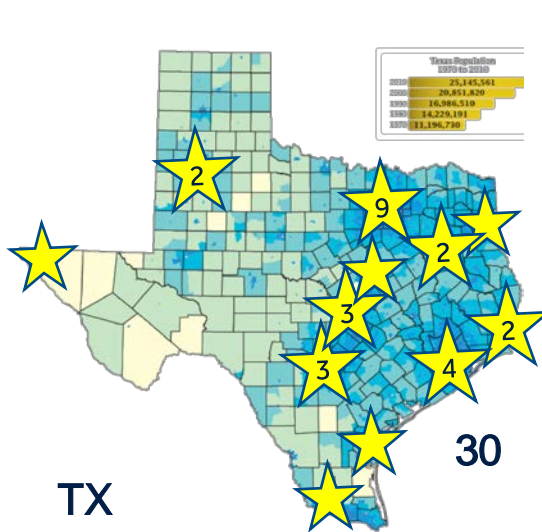
540 EXISTING TAVR CENTERS COULD BE REDUCED TO 330



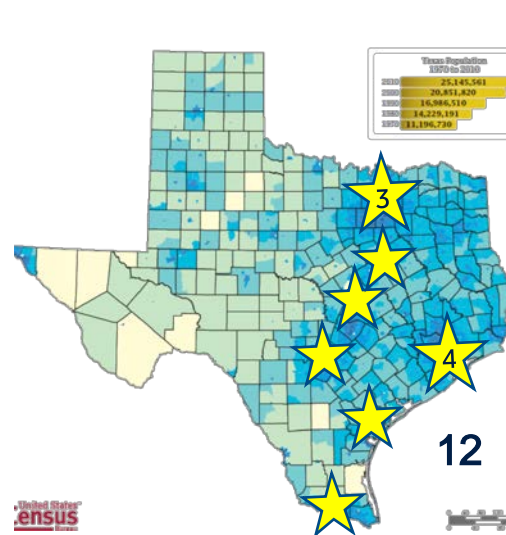
Source: Kappetein AP et al. The Impact Of Proposed Case Volume Thresholds on Transcatheter Aortic Valve Replacement Center Certification and Medicare Beneficiary Access . Poster presented at: TVT 2018, 2018 Jun 18-20; Chicago, IL

TAVR CENTER REDUCTIONS PARTICULARLY AFFECT RURAL AREAS

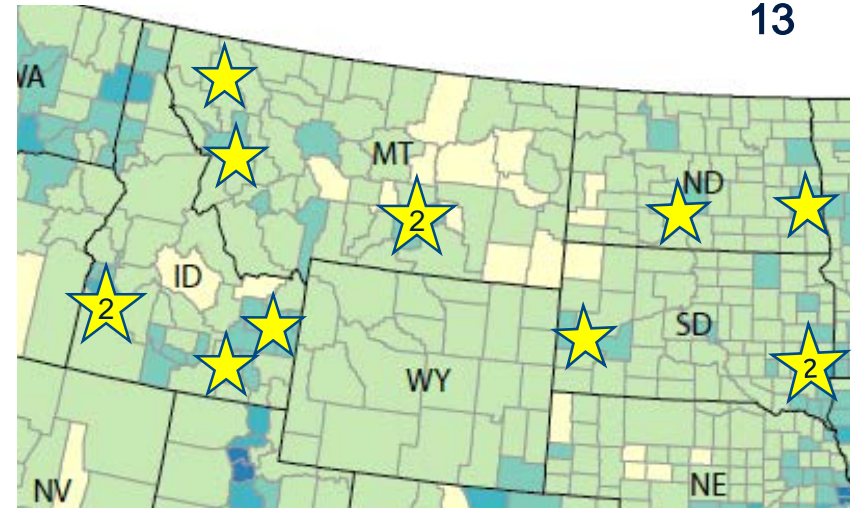
2017 TAVR CENTERS



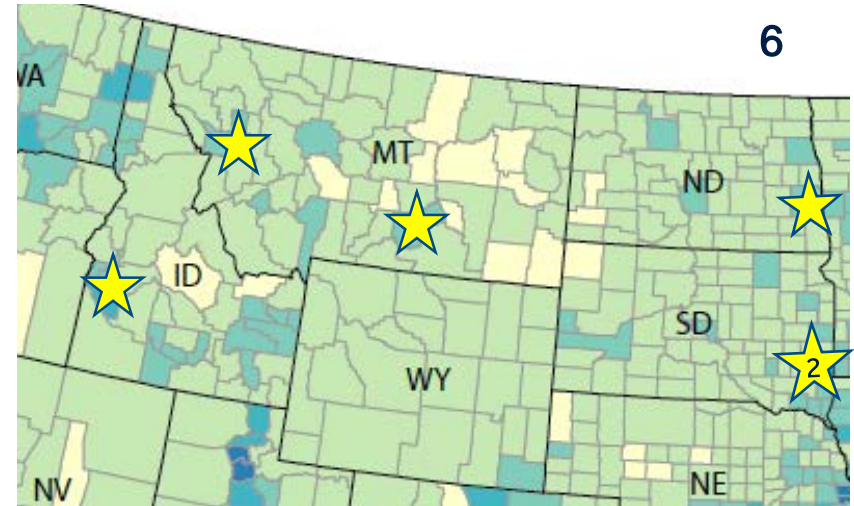
ELIGIBLE CENTERS TO CONTINUE*



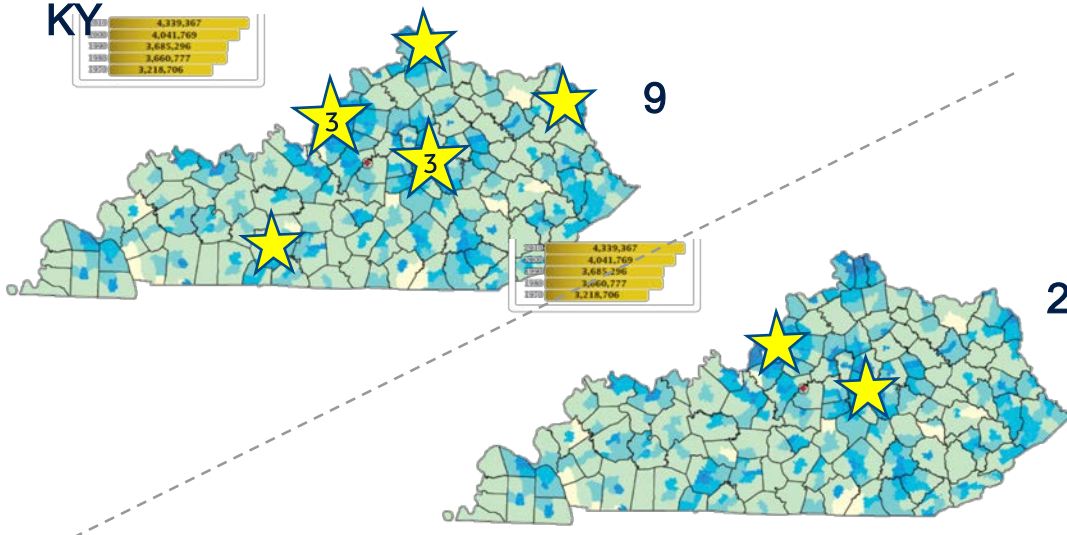
2017 TAVR CENTERS



ELIGIBLE CENTERS TO CONTINUE*



KY



2

* ELIGIBILITY BASED ON FACILITY VOLUME REQUIREMENTS STATED IN 2017 DRAFT GUIDANCE

Sources: Kappetein AP et al. The Impact Of Proposed Case Volume Thresholds on Transcatheter Aortic Valve Replacement Center Certification and Medicare Beneficiary Access .
 Poster presented at: TVT 2018, 2018 Jun 18-20; Chicago, IL and U.S. Department of Commerce Economics and Statistics Administration U.S. Census Bureau
<https://www.census.gov/geo/maps-data/maps/thematic.html>

TAVR CENTER REDUCTIONS HAVE MULTIPLE NEGATIVE IMPLICATIONS

Limitation of Treatment Options for Patients

- Reductions in the number of TAVR sites will reduce opportunities for patients to learn about TAVR and participate in shared decision-making about treatment options for AS
- Patients in rural areas may be disproportionately affected by decreases in the availability of TAVR centers

Delay of Timely Access to Treatment

- Travel burden and costs may be increased for patients and caregivers
- Potential capacity issues and increased waiting time for intervention may arise in remaining centers that continue to perform TAVR procedures

Increased Mortality Risk

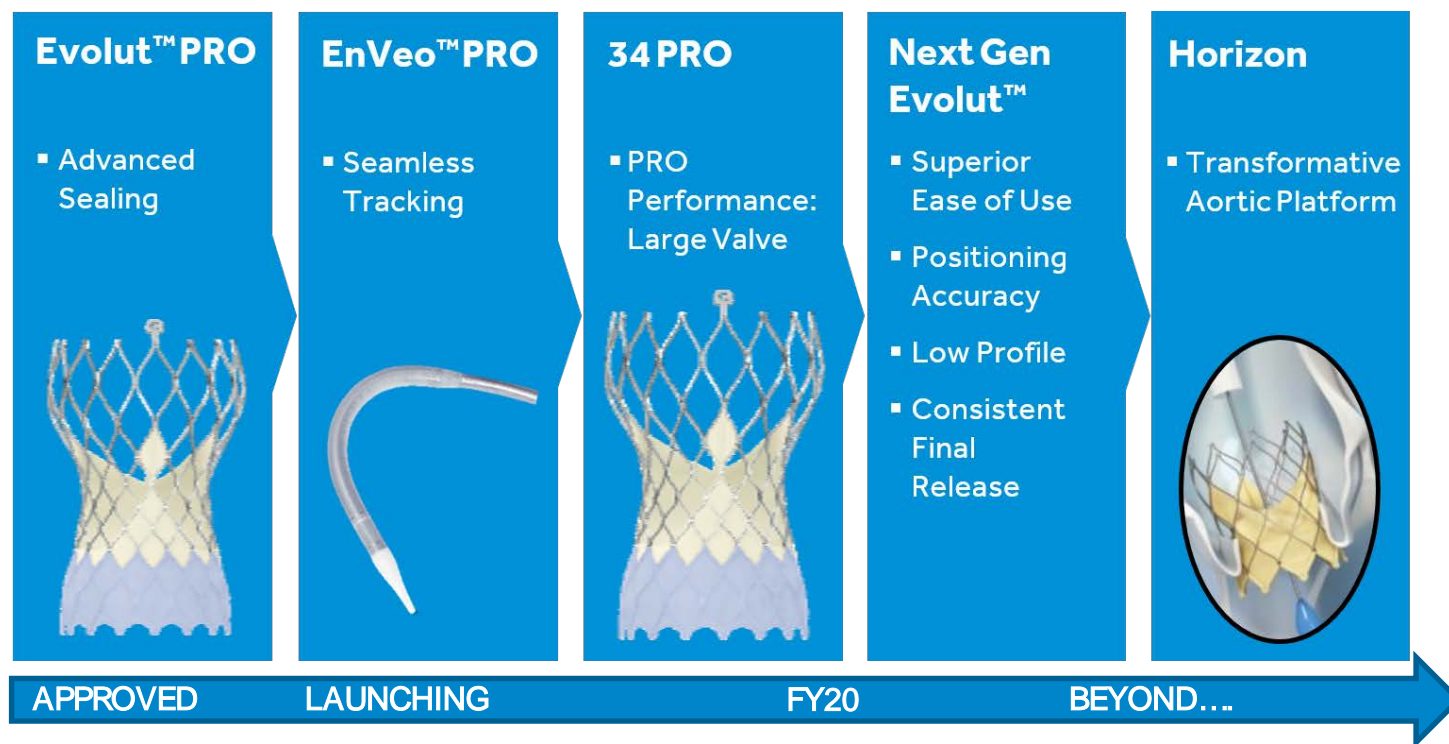
- Mortality risk is known to be high when severe aortic stenosis patients are symptomatic – up to 50% at 1 year when left untreated¹
- Patients at extreme or high risk for surgery who lose access to TAVR could be subject to higher mortality risk than patients who retain access to TAVR

¹Leon M.B., et al., Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery. N Engl J Med, 2010. 363(17):1597-607

MEDTRONIC THERAPY DEVELOPMENT

CONTINUOUS INVESTMENT IN TAVR INNOVATION

MEDTRONIC TAVR PRODUCT PIPELINE



- Evolut platform iterations improving ease of use to complement market leading safety and efficacy
- Transformative Horizon platform meeting the needs of low risk patients while maintaining key benefits of Medtronic's self-expanding, supra-annular platforms

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APPENDIX

STATE BY STATE REDUCTIONS IN TAVR CENTERS UNDER PROPOSED GUIDELINES

State	Hospitals with TAVR - FY2017 claims	Hospitals That Would Meet TAVR and SAVR Volume Thresholds
US Total	540	330

State	Hospitals with TAVR- FY2017 claims	Hospitals That Would Meet TAVR and SAVR Volume Thresholds
AK	1	1
AR	4	3
CA	49	24
CT	7	5
DE	2	1
GA	14	8
IA	5	4
IL	16	10
KS	4	2
LA	7	4
MD	7	5
MI	21	13
MO	18	8
MT	4	2
ND	2	1
NH	4	2
NM	2	1
NY	24	22
OK	8	6
PA	29	21
RI	1	1
SD	3	2
TX	30	12
VA	13	10
WA	12	8
WV	4	2

State	Hospitals with TAVR- FY2017 claims	Hospitals That Would Meet TAVR and SAVR Volume Thresholds
AL	8	3
AZ	14	10
CO	9	4
DC	2	1
FL	48	27
HI	1	1
ID	4	1
IN	12	5
KY	9	2
MA	13	11
ME	3	3
MN	12	7
MS	5	2
NC	13	11
NE	4	3
NJ	13	12
NV	5	3
OH	18	13
OR	7	5
PR	3	0
SC	11	7
TN	16	9
UT	5	3
VT	1	1
WI	13	8
WY	0	0

Source: Kappetein AP et al. The Impact Of Proposed Case Volume Thresholds on Transcatheter Aortic Valve Replacement Center Certification and Medicare Beneficiary Access . Poster presented at: TVT 2018, 2018 Jun 18-20; Chicago, IL