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DIALYSIS OUTCOMES AND
PRACTICE PATTERNS STUDY

Key hemodialysis practice changes and their impact

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Key lessons from 20 years:

Outline

1. Rising burden of dialysis
2. HD practices
 - Vascular access
 - Adequacy / volume
 - Anemia
 - MBD
3. Unmet needs & looking ahead

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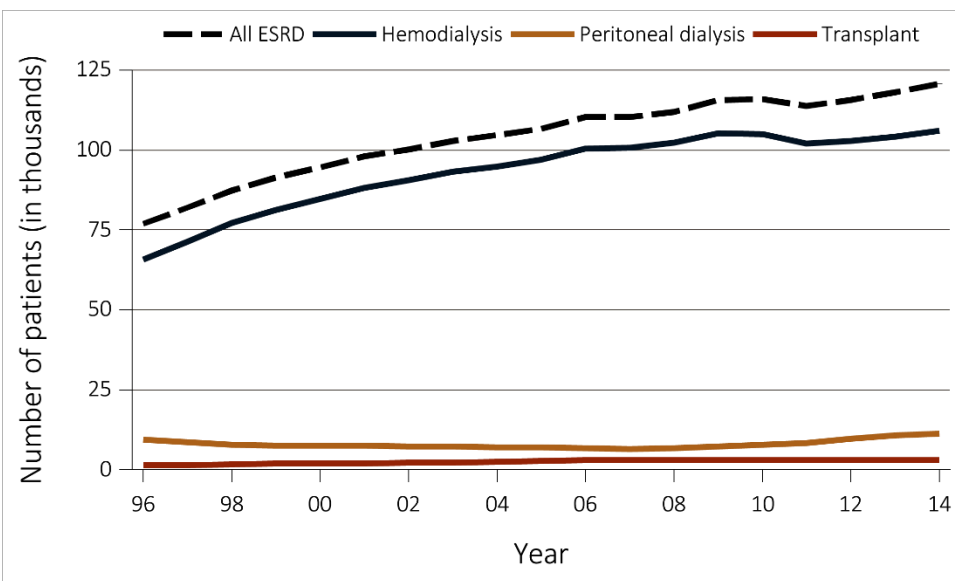
DIALYSIS OUTCOMES AND
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Rising Burden of Dialysis

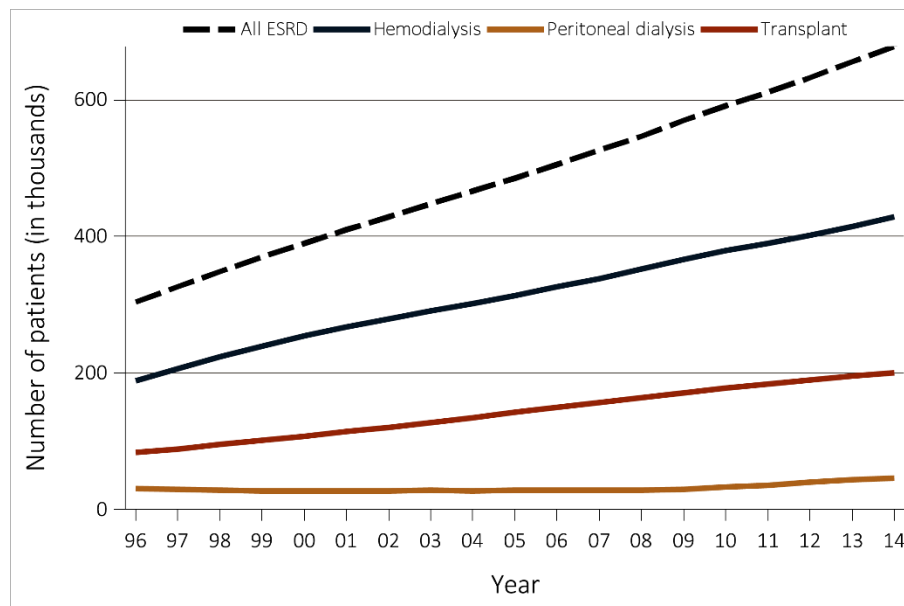
Incidence, Prevalence,
Mortality

USRDS: Trends in the annual number of ESRD incident and prevalent cases (in thousands) by modality, in the U.S. population, 1996-2014

Incidence



Prevalence

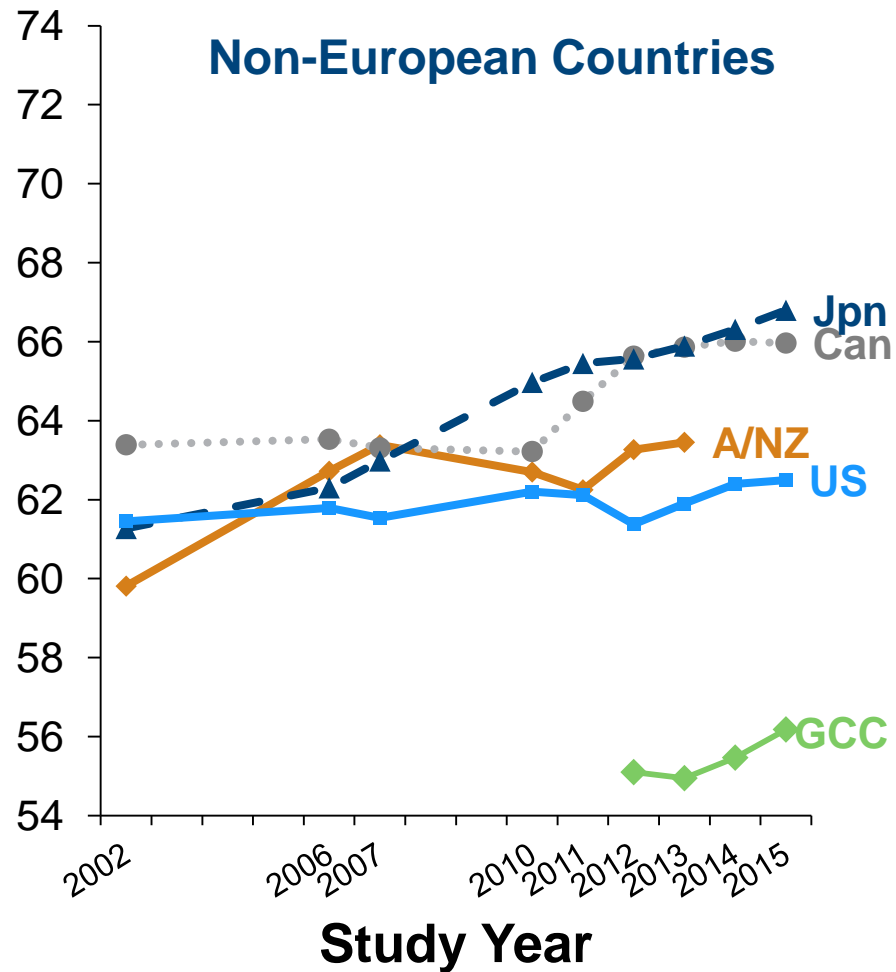


Age Trends by Country

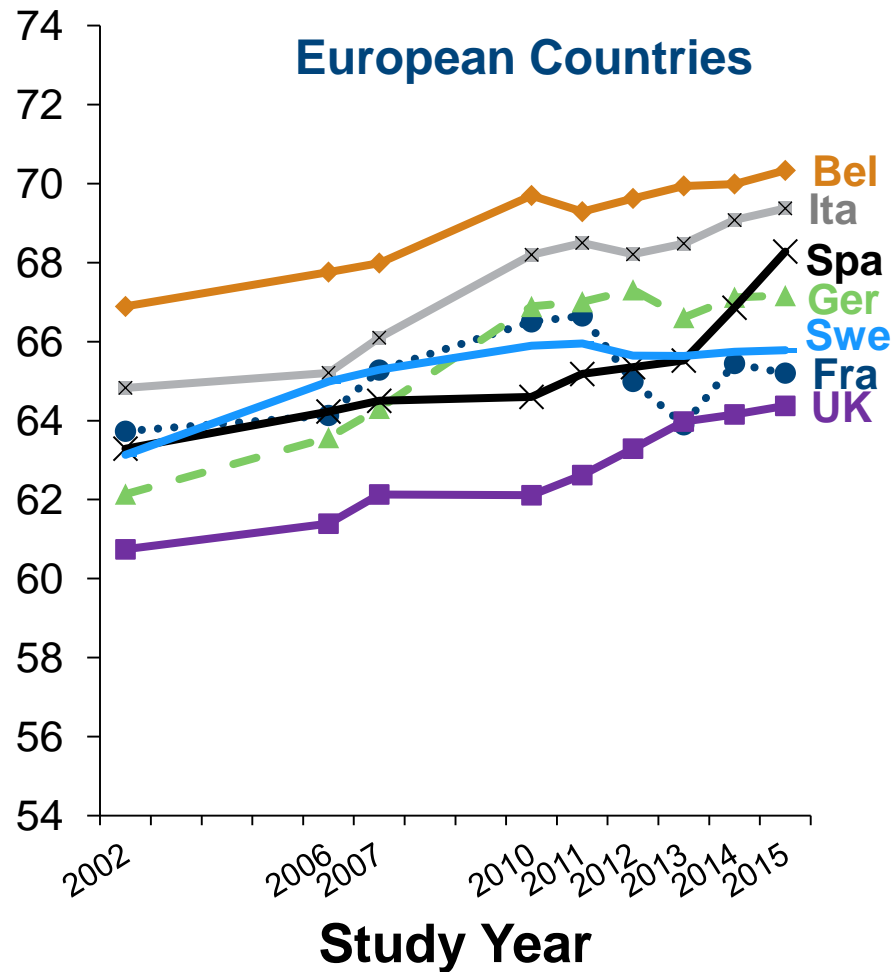
DOPPS 2-5 (2002-2013)

Mean age (years)

Non-European Countries

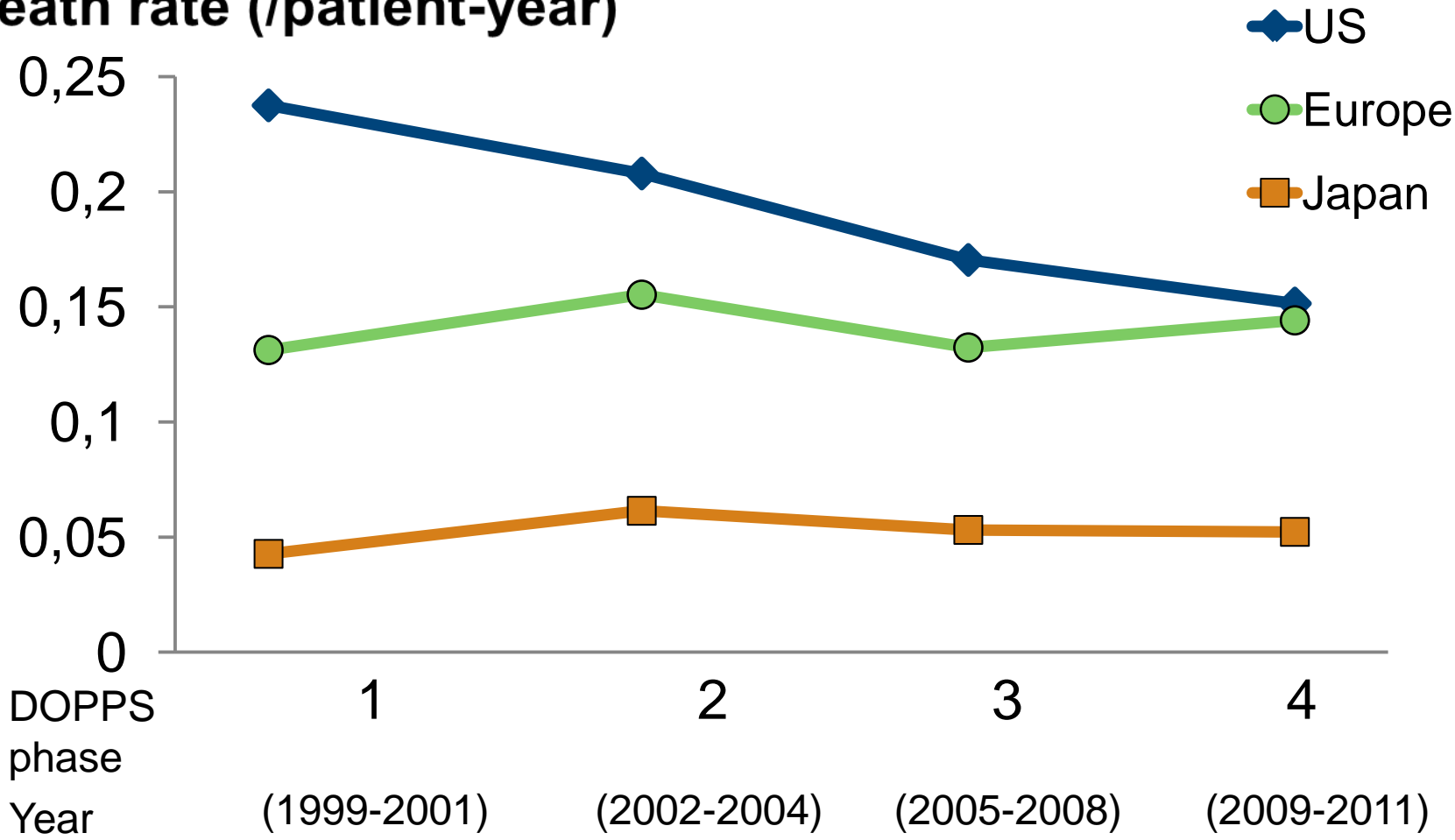


European Countries



Changes in Death Rates Over Time, by Region

Death rate (/patient-year)



***Improvements in fistula use, Kt/V, phosphorous control, and hemoglobin may explain some of the decline in mortality**

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Key Practice Changes & Impact

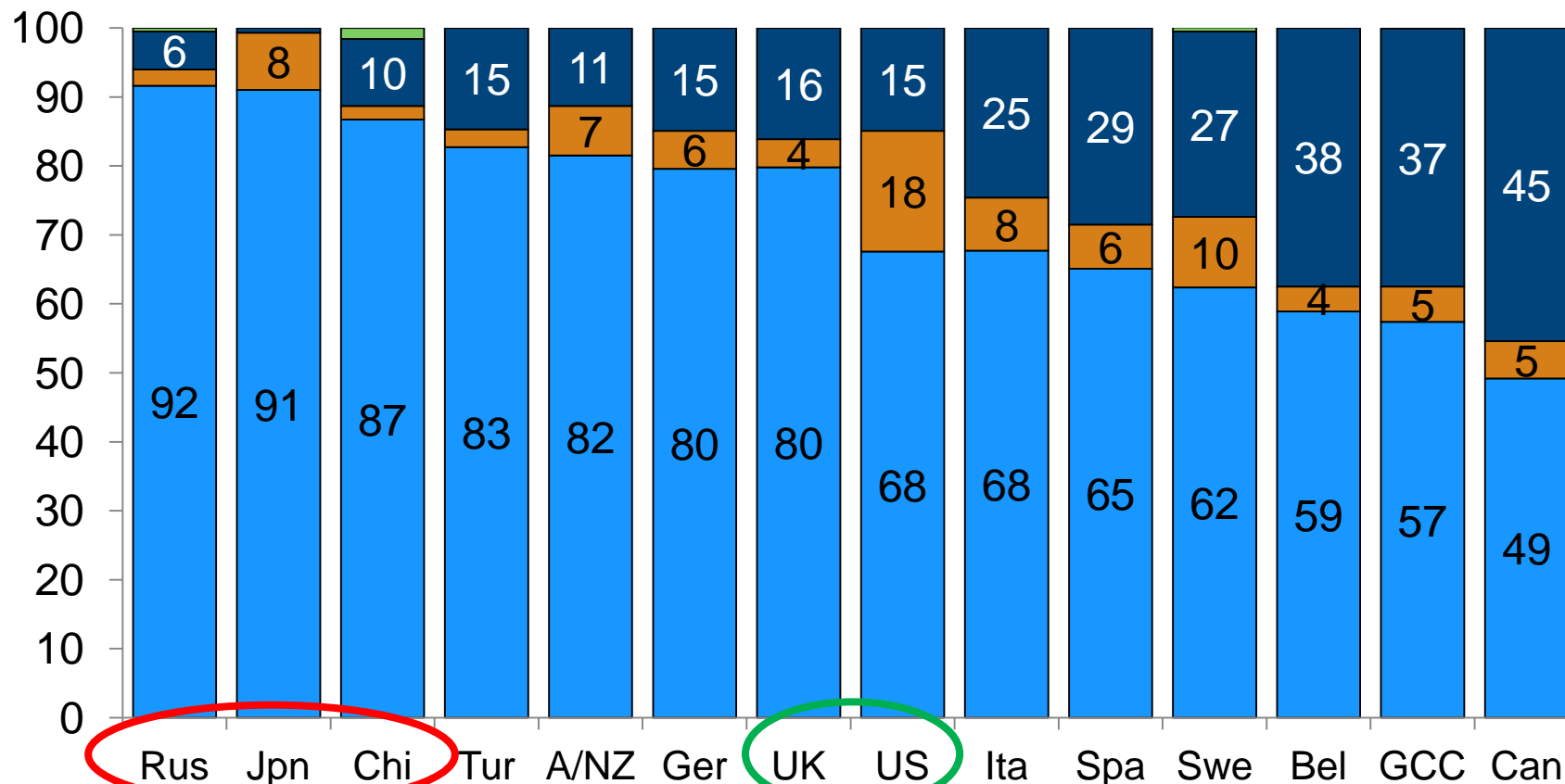
Vascular Access

Vascular access use^a – prevalent patients

DOPPS 5 (2012-2014)

% of Patients

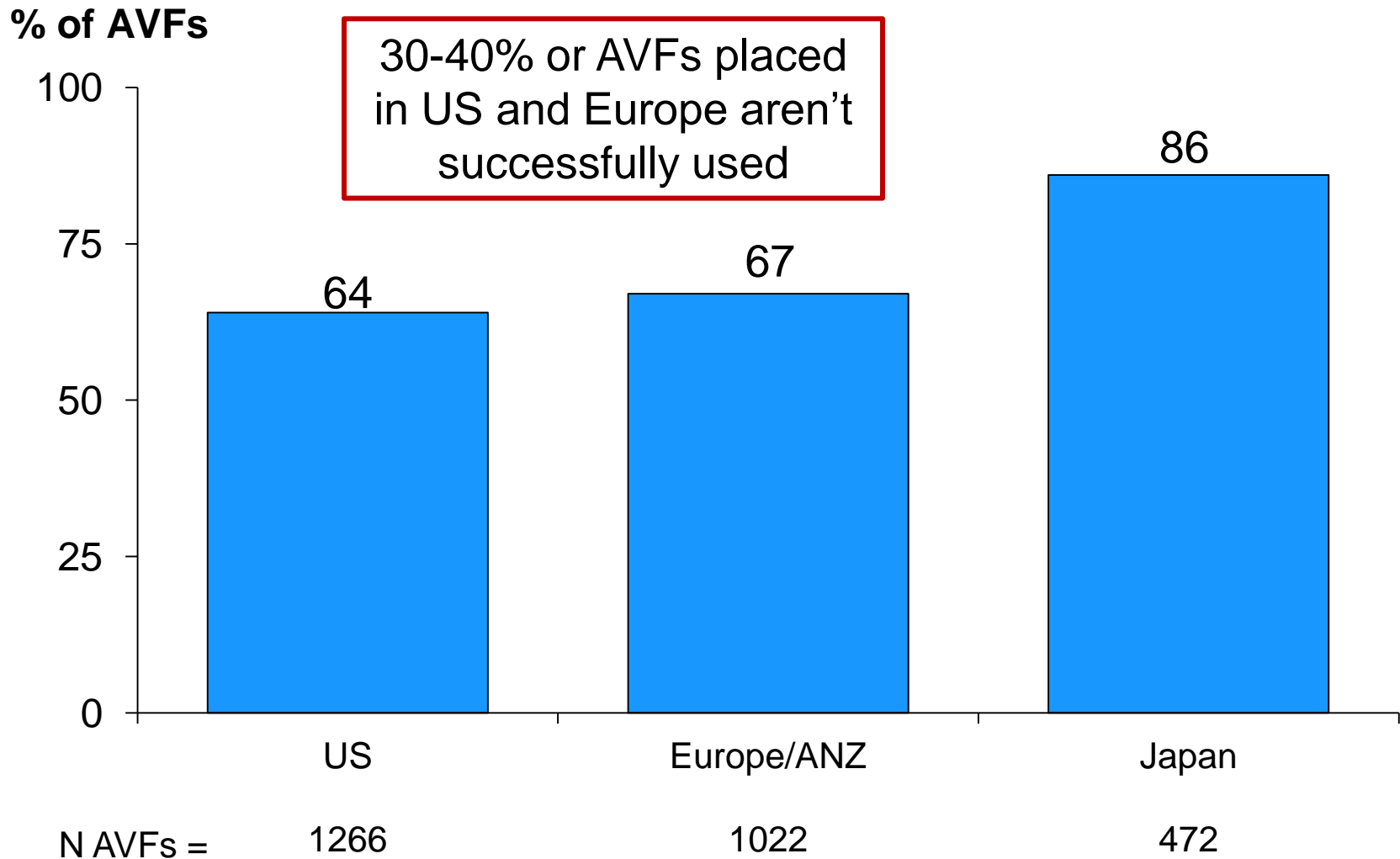
■ AV-fistula ■ AV-graft ■ Catheter ■ Other



N Patients: 445 1573 1123 346 287 595 296 2906 399 504 437 438 792 486

^a At study entry regardless of time on dialysis since at DOPPS enrollment

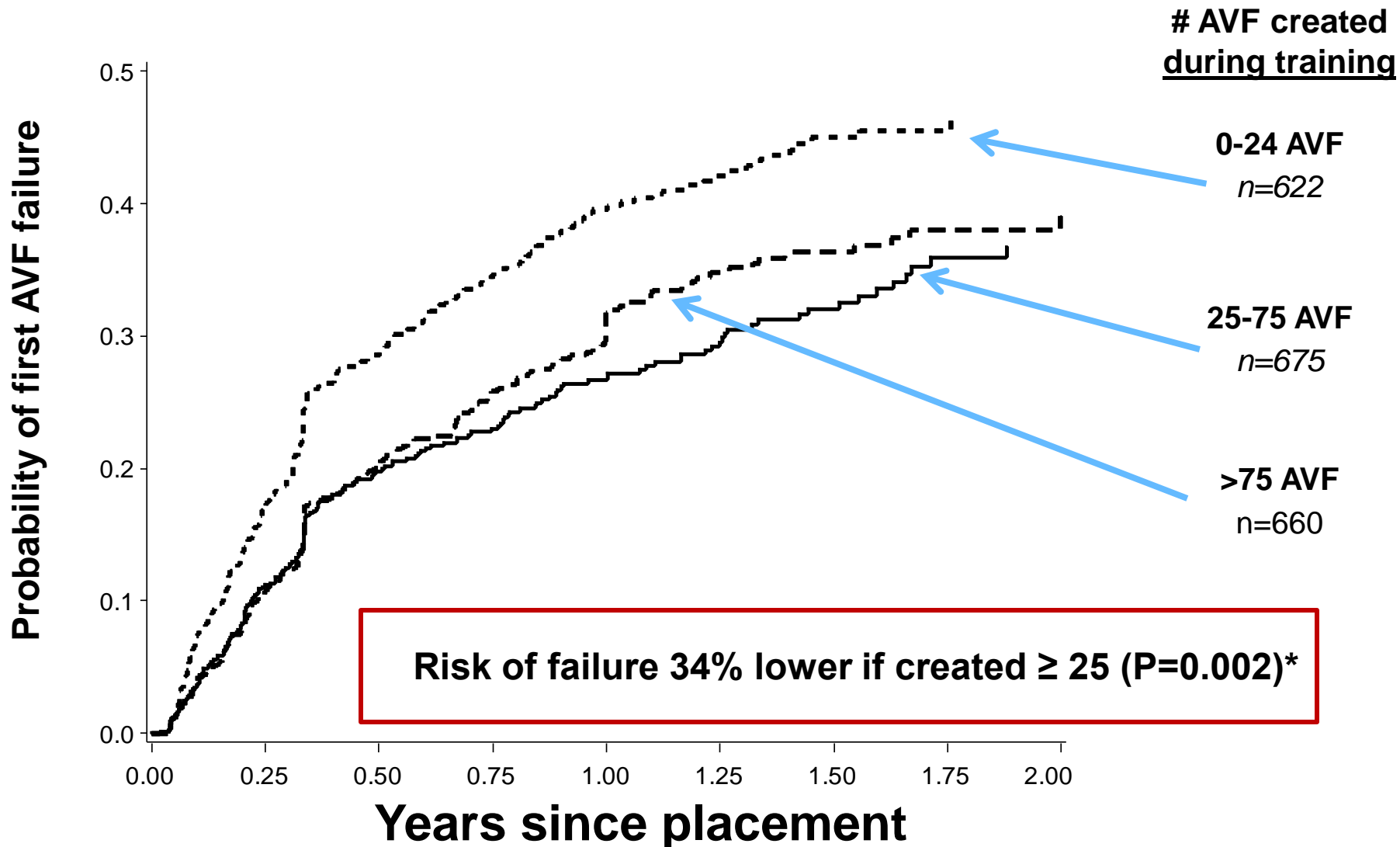
AVF maturation success*, by region



***AVF maturation success was defined as use \geq 30 days**

Restricted to AVFs created in DOPPS 4 and 5 (2009-2015) in US, Europe, Australia and New Zealand, and Japan

Time to Primary Fistula Failure by Number Created by Surgeon During Training

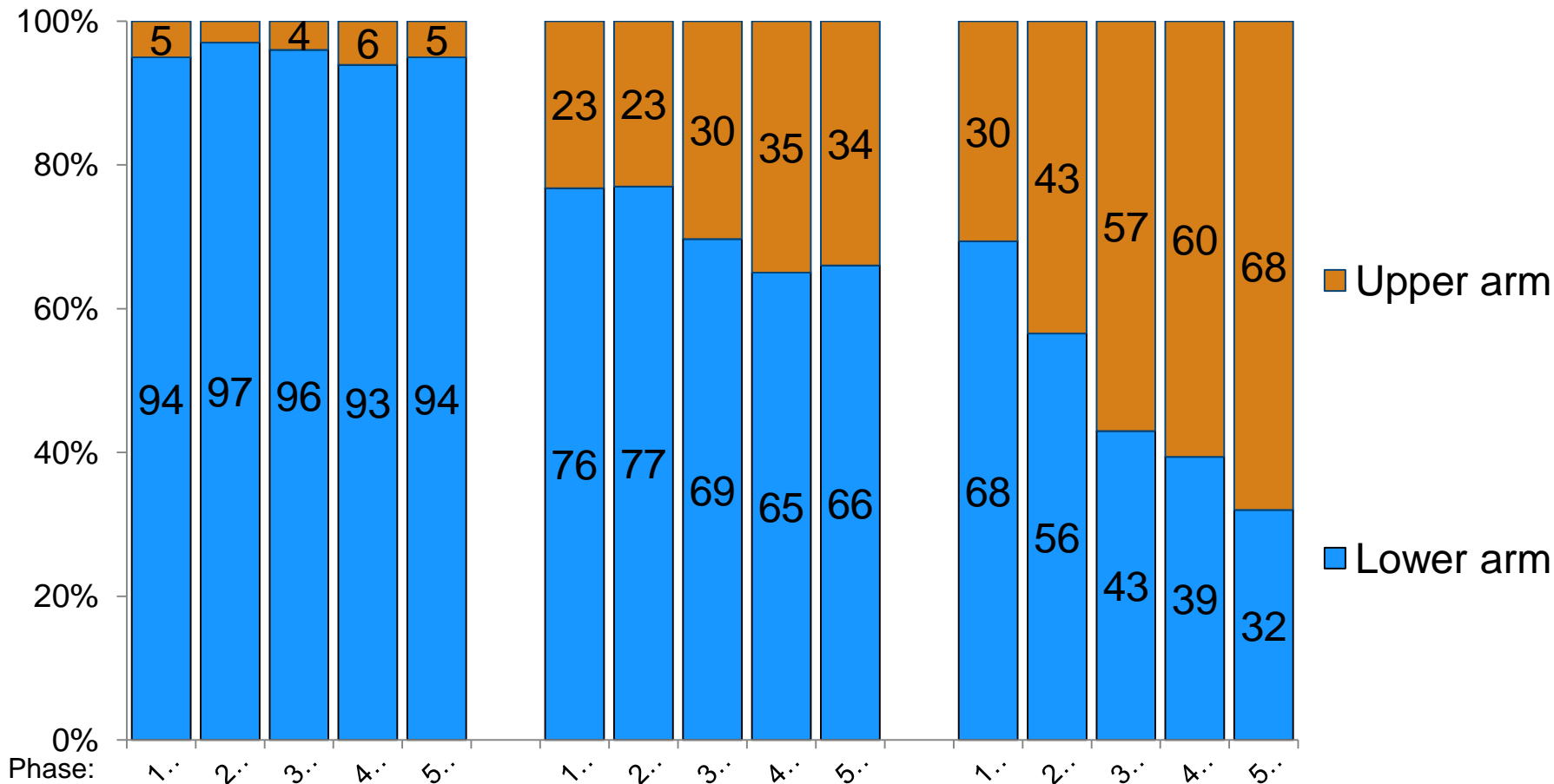


* Adjusted for age, sex, race, vintage, 14 comorbidities, prior catheter use, country

AV Fistula location, by region and phase

DOPPS 1-5 (1996-2015)

% of AVFs



NAVFs:

N Fac:

Japan

Europe/ANZ

US

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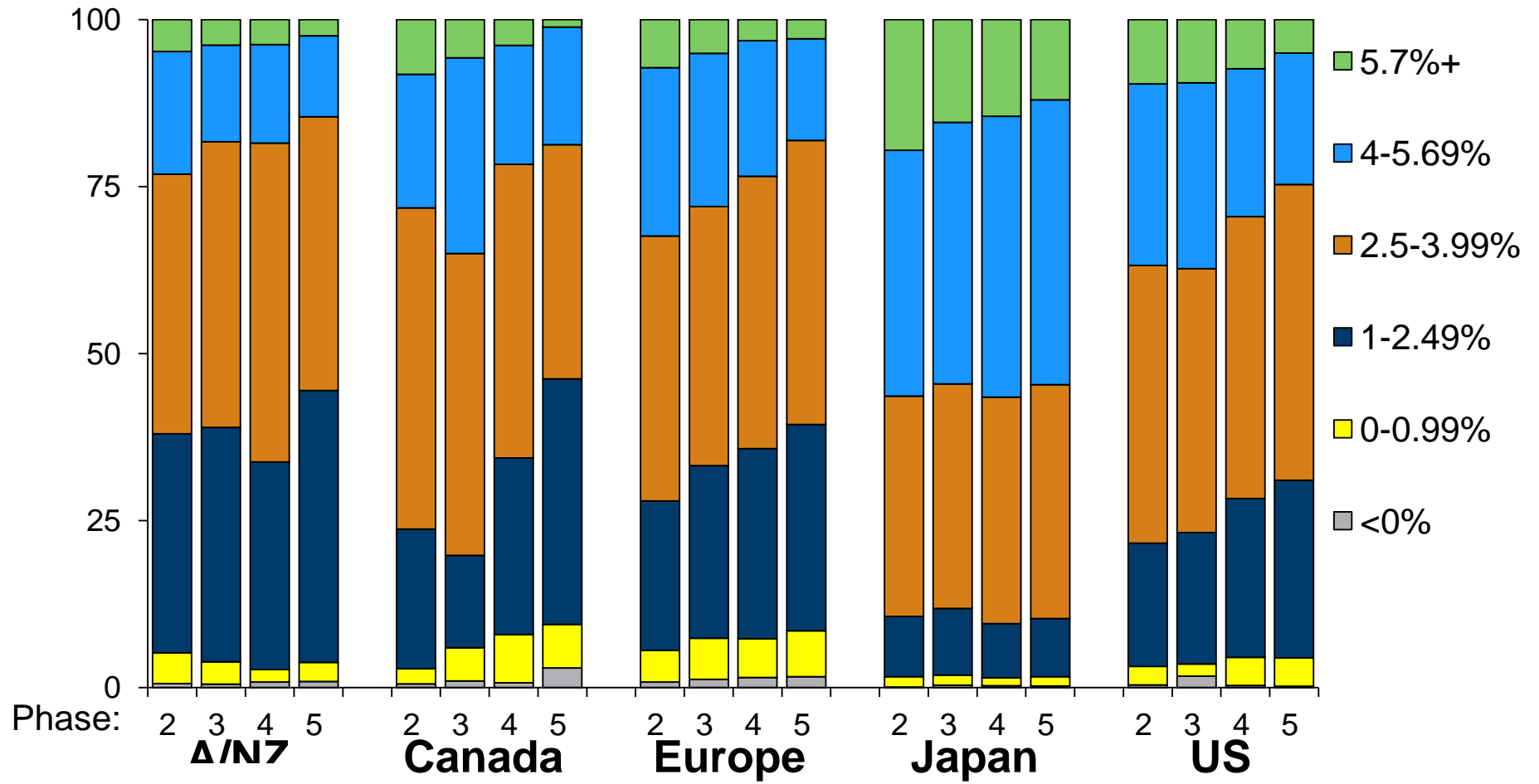
Key Practice Changes & Impact

Adequacy / Volume

Intradialytic weight gain, by DOPPS phase

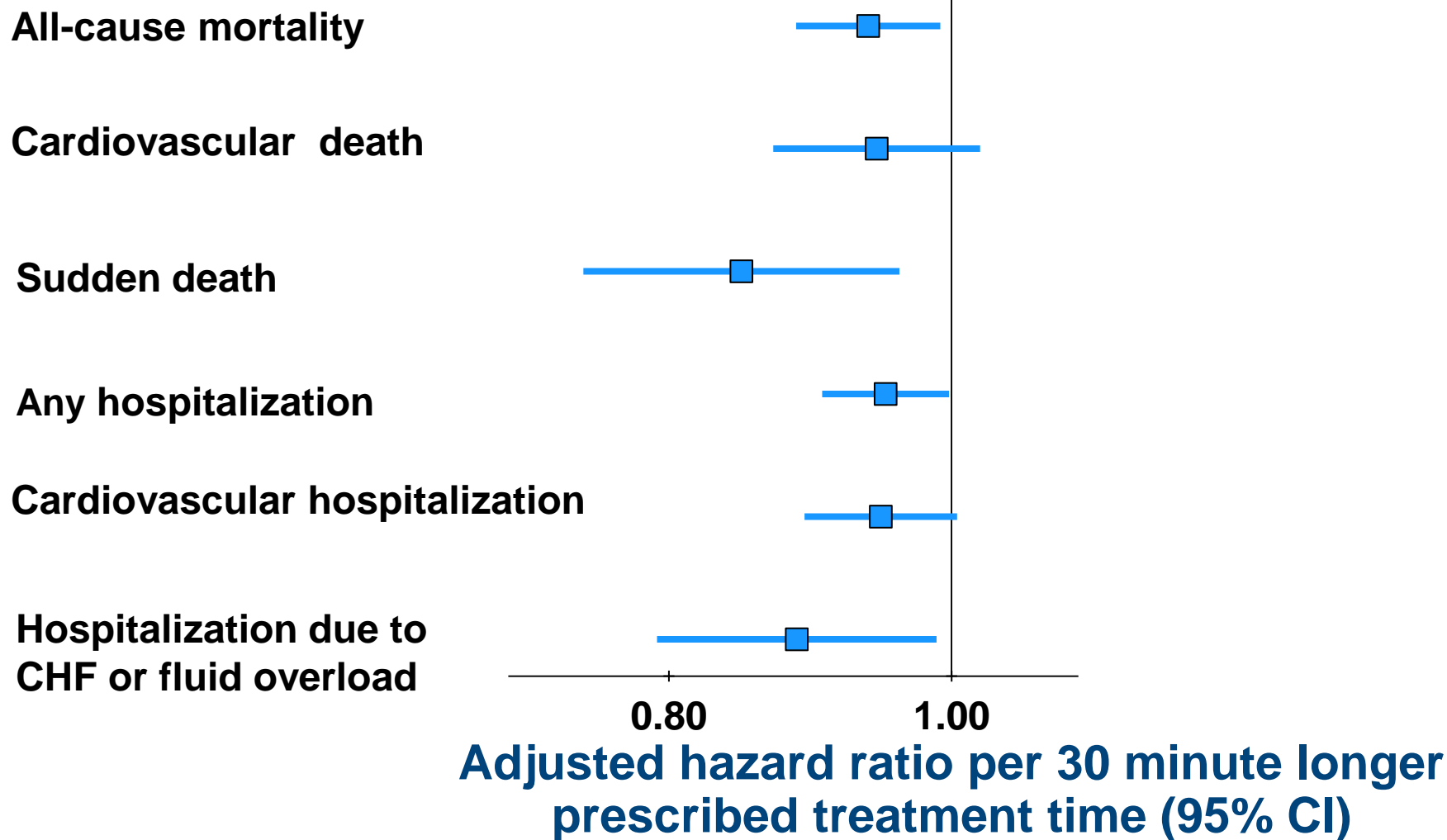
DOPPS 2-5 (2002-2015)

% of patients



IDWG expressed as % of post-HD weight

Lower Mortality & Hospitalization Risks in Facilities with Longer Treatment Time (Facility Practice-based Analysis)



DOPPS 1-4 . Adjusted for age, sex, race, time on dialysis, BMI, 13 summary comorbid conditions, residual kidney function, spKt/V, catheter use, stratified by country & study phase. CHF = congestive heart failure

Tentori et al. *NDT*, 2012

Treatment time, by country

DOPPS 5 (2012-2015)

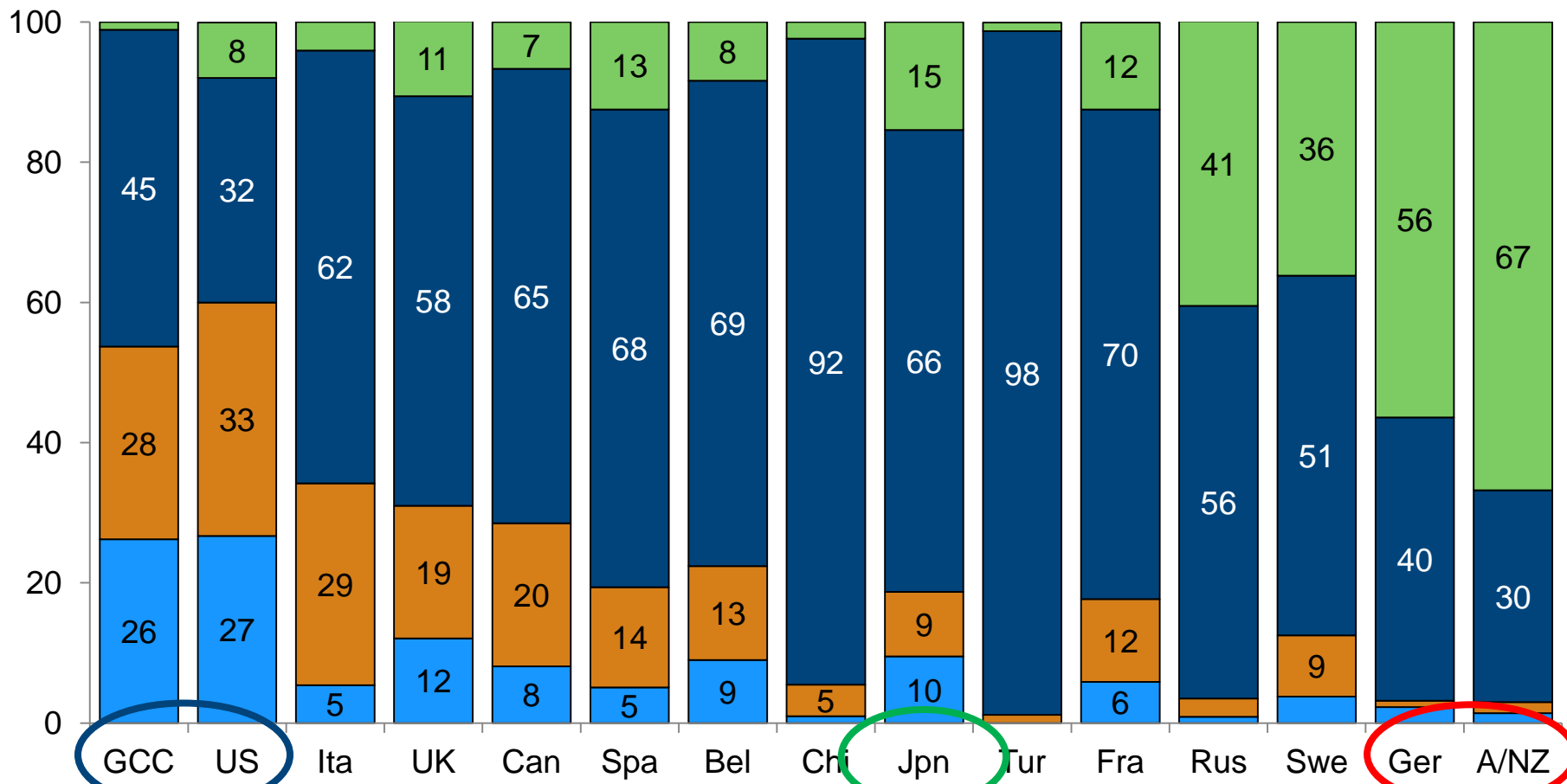
% of patients

180 min

210 min

240 min

270 min

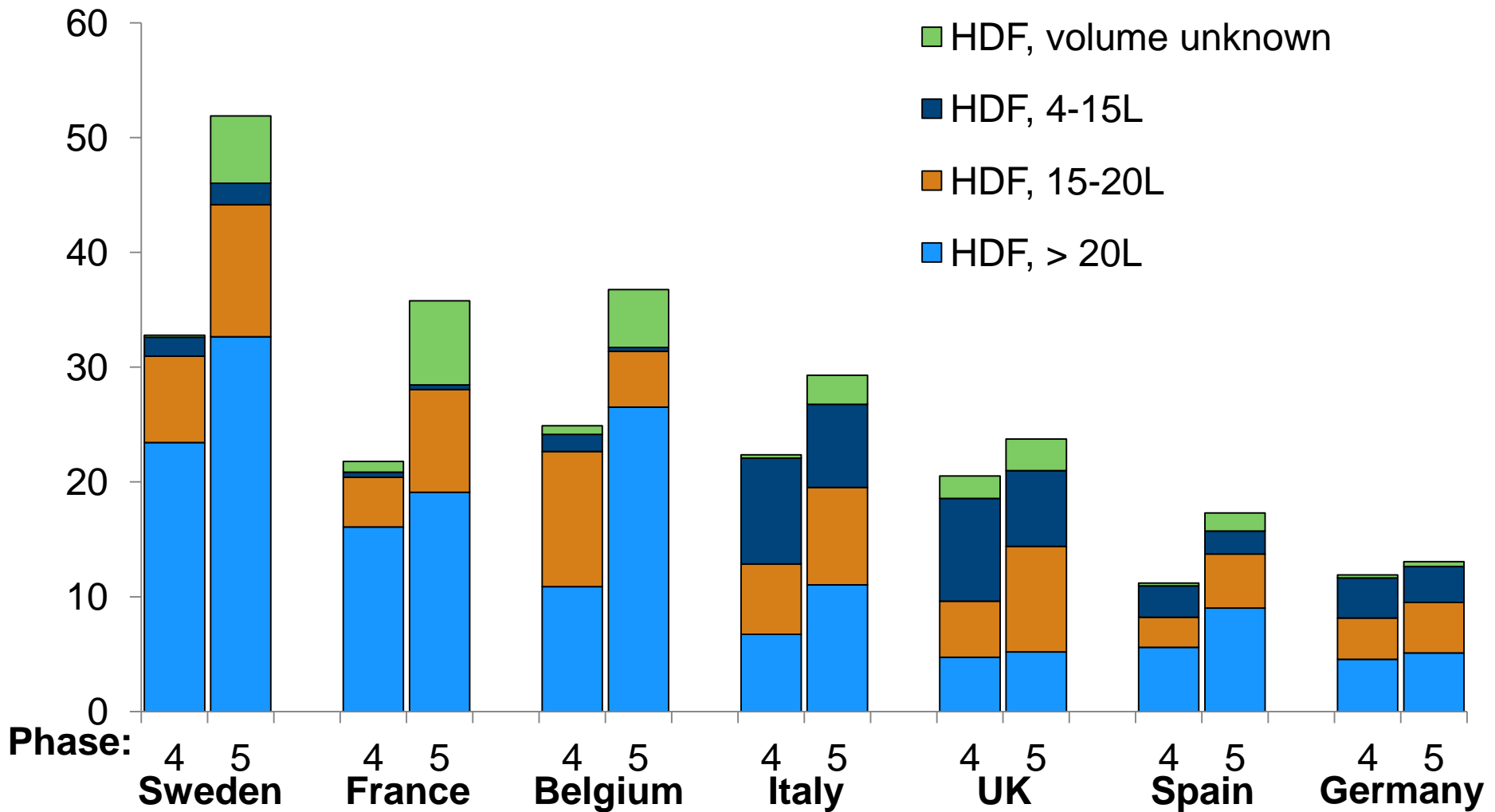


N pts:	721	2933	444	365	406	455	888	1553	323	169	466	312	555	368
Mean:	215	219	230	232	234	237	239	239	240	242	251	253	269	271

HDF use, by replacement fluid volume

DOPPS 4,5 (2009-2015)

% of patients on HDF



DOPPS phase 4: 2009-2011, DOPPS phase 5: 2012-2015

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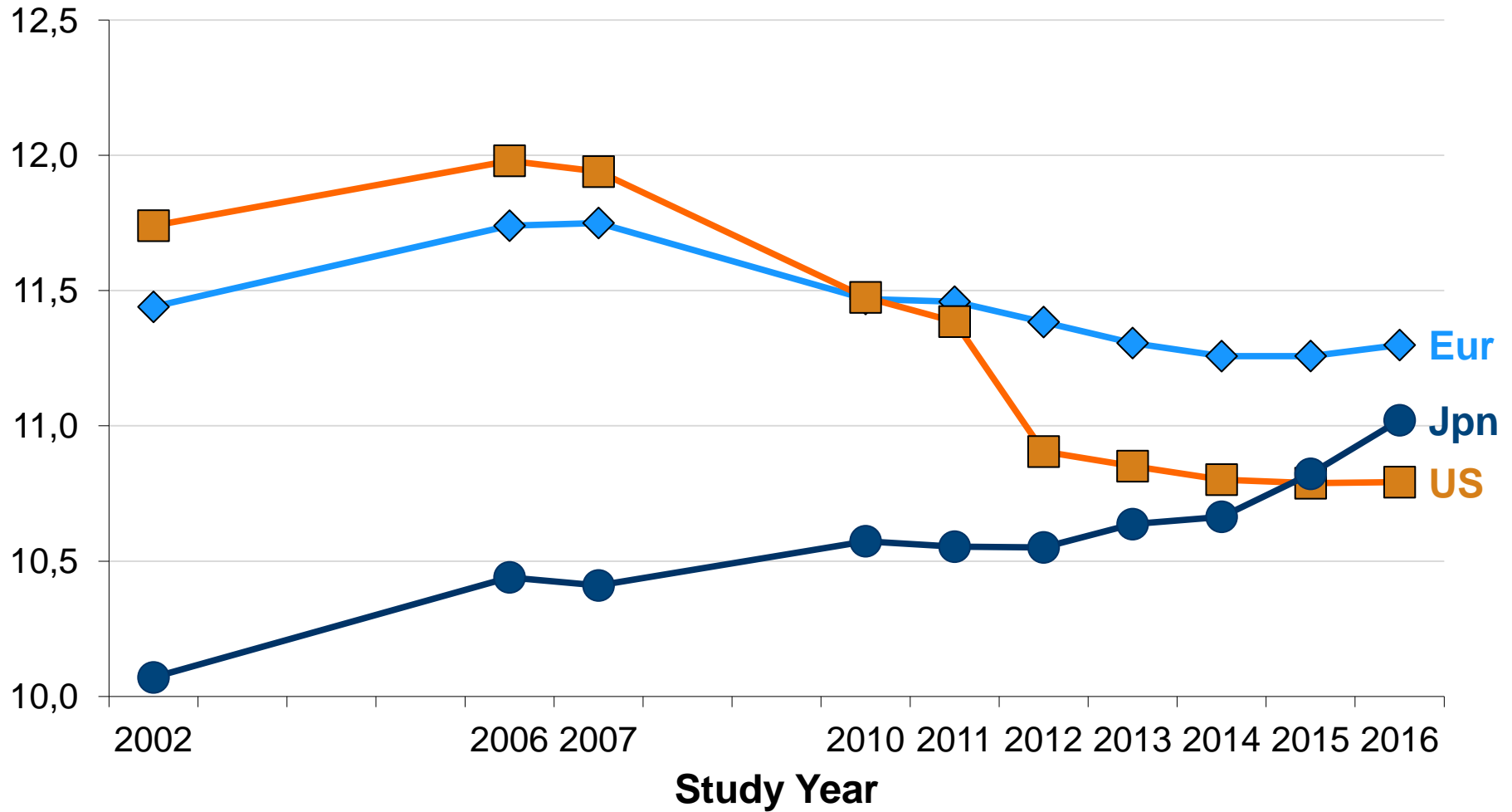
Key Practice Changes & Impact

Anemia

Mean Hemoglobin Trends

DOPPS 2-6 (2002-2016)

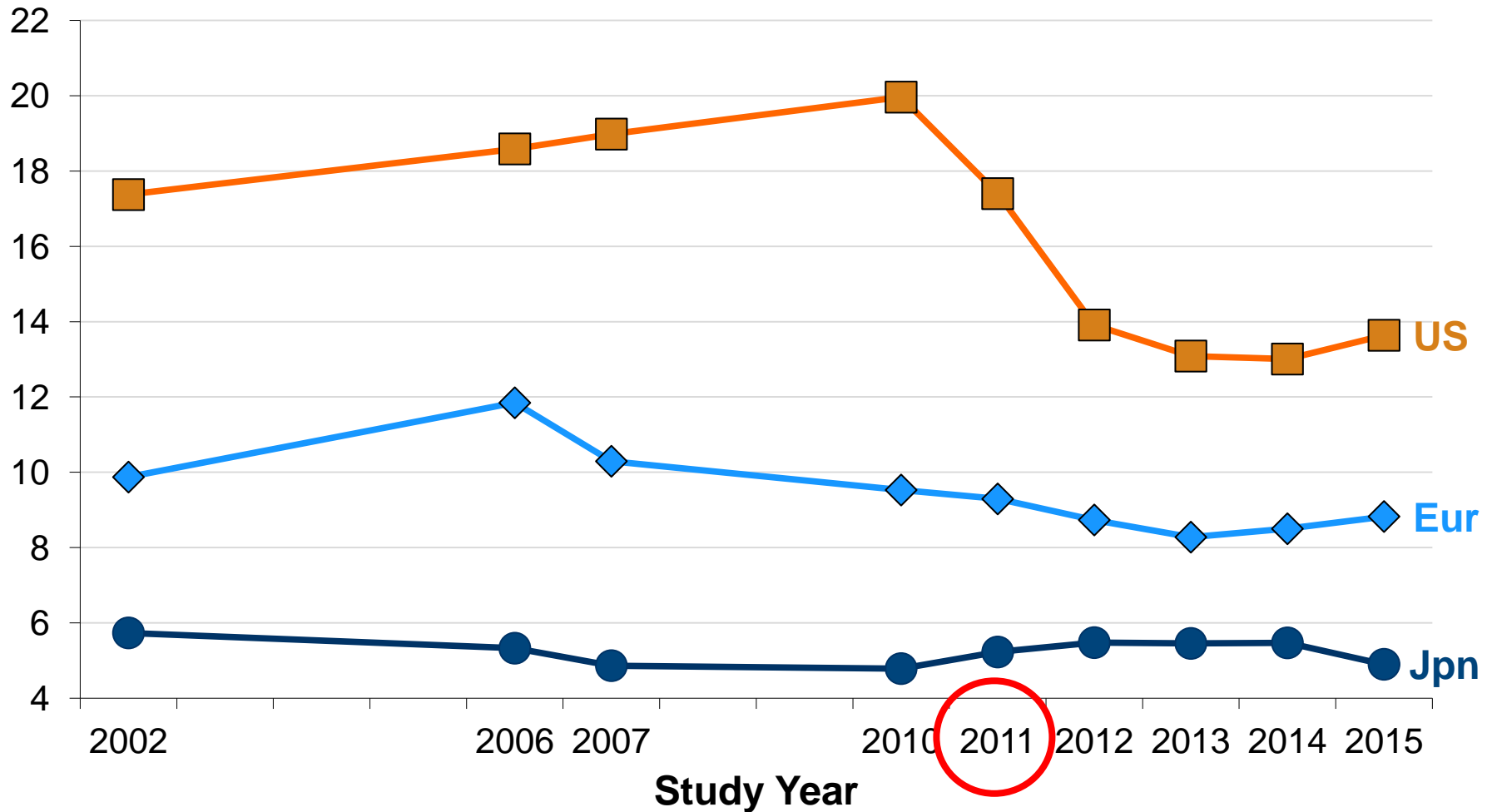
Mean Hemoglobin (g/dL)



Prescribed Mean ESA Dose Trends

DOPPS 2-5 (2002-2015)

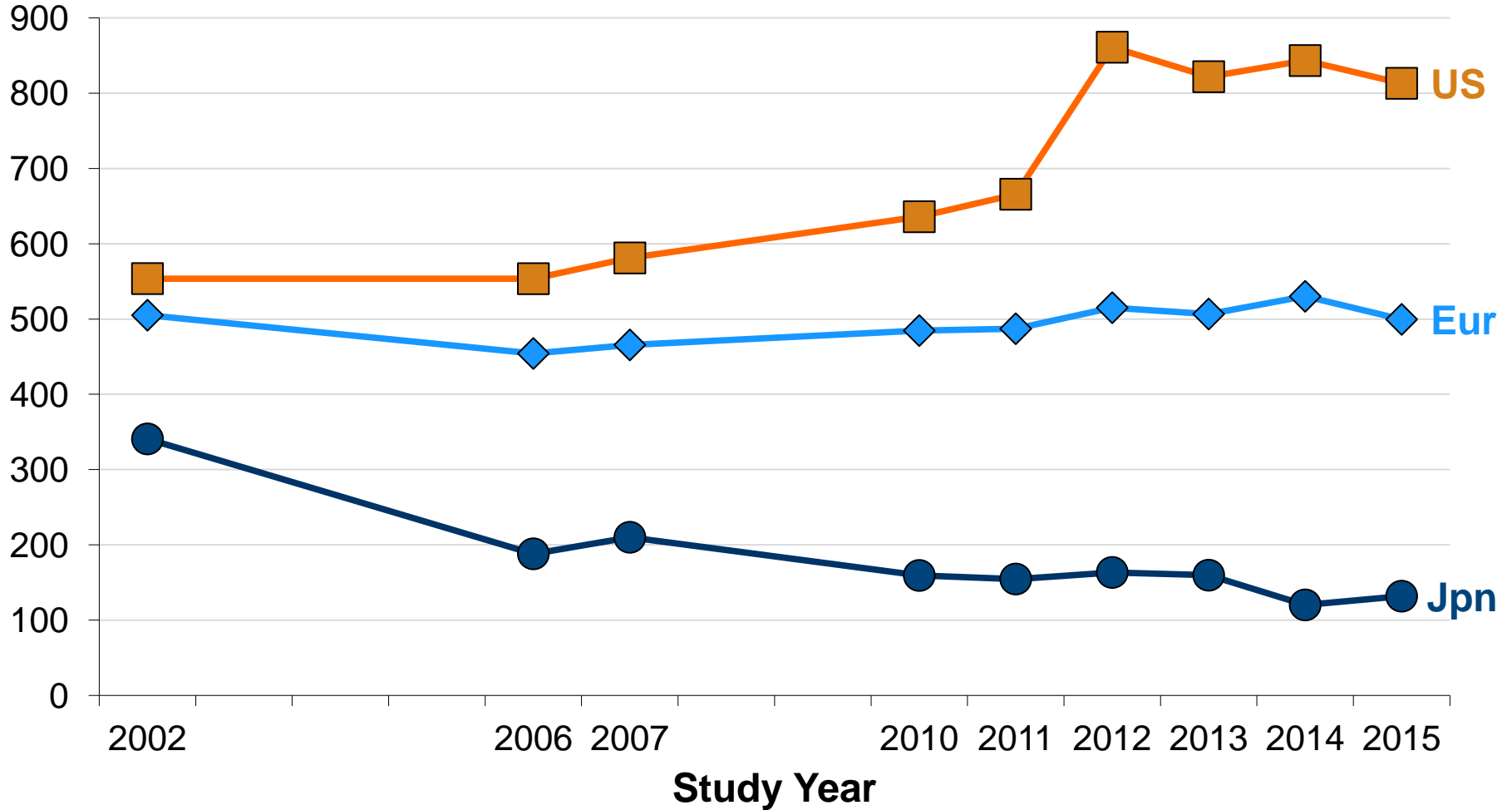
Mean ESA dose* (x1000 units/week)



Mean Ferritin Trends

DOPPS 2-5 (2002-2015)

Mean Ferritin (ng/mL)



IV Iron Dose and All-Cause Mortality

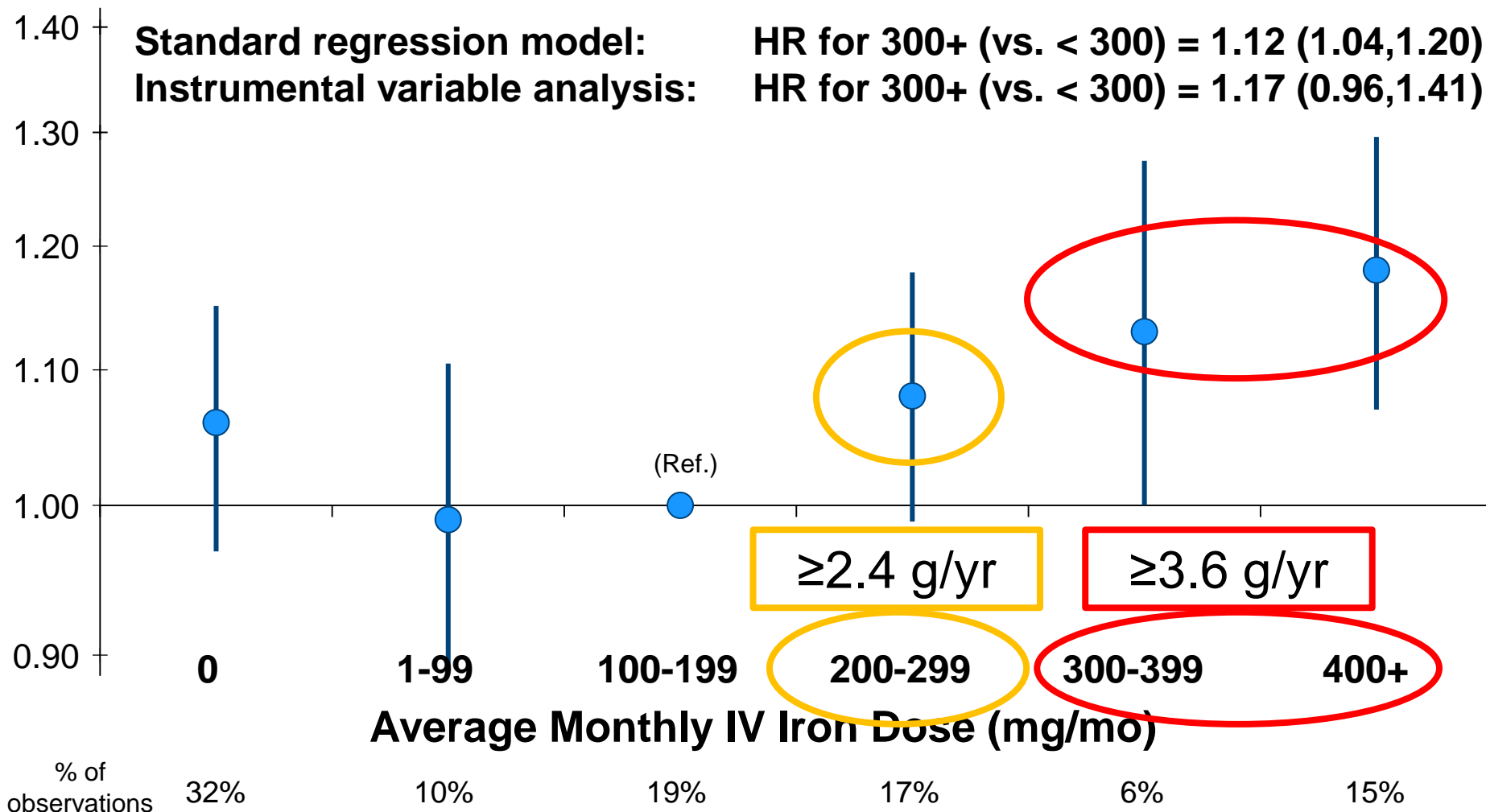
Hazard Ratio (95% CI)

Standard regression model:

HR for 300+ (vs. < 300) = 1.12 (1.04,1.20)

Instrumental variable analysis:

HR for 300+ (vs. < 300) = 1.17 (0.96,1.41)



Cox regressions were adjusted for age, vintage, gender, black race, baseline catheter use and 13 comorbidities, ESA weekly dose, Hgb, spKt/V, s.albumin, and creatinine, BMI, white blood cells, s. ferritin and TSAT; stratified by phase and country, accounting for facility clustering effects. N=32,435, DOPPS 2,3,4. In JP sample: 3% were in 200-299 category, and 2% were in 300+ category

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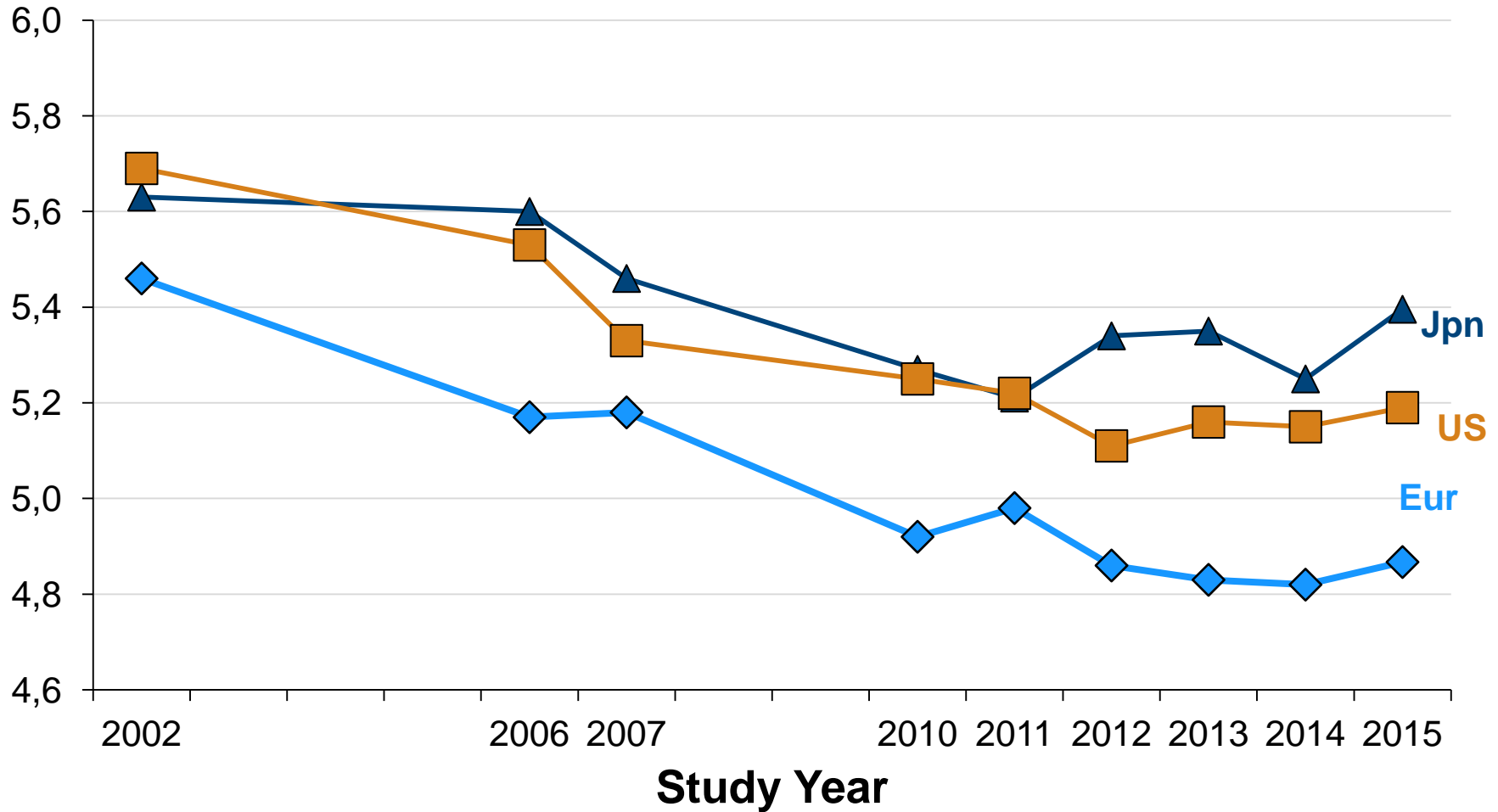
Key Practice Changes & Impact

Mineral Bone Disorder

S. Phosphorus Trends

DOPPS 2-5 (2002-2015)

Mean S. PO₄ (mg/dL)

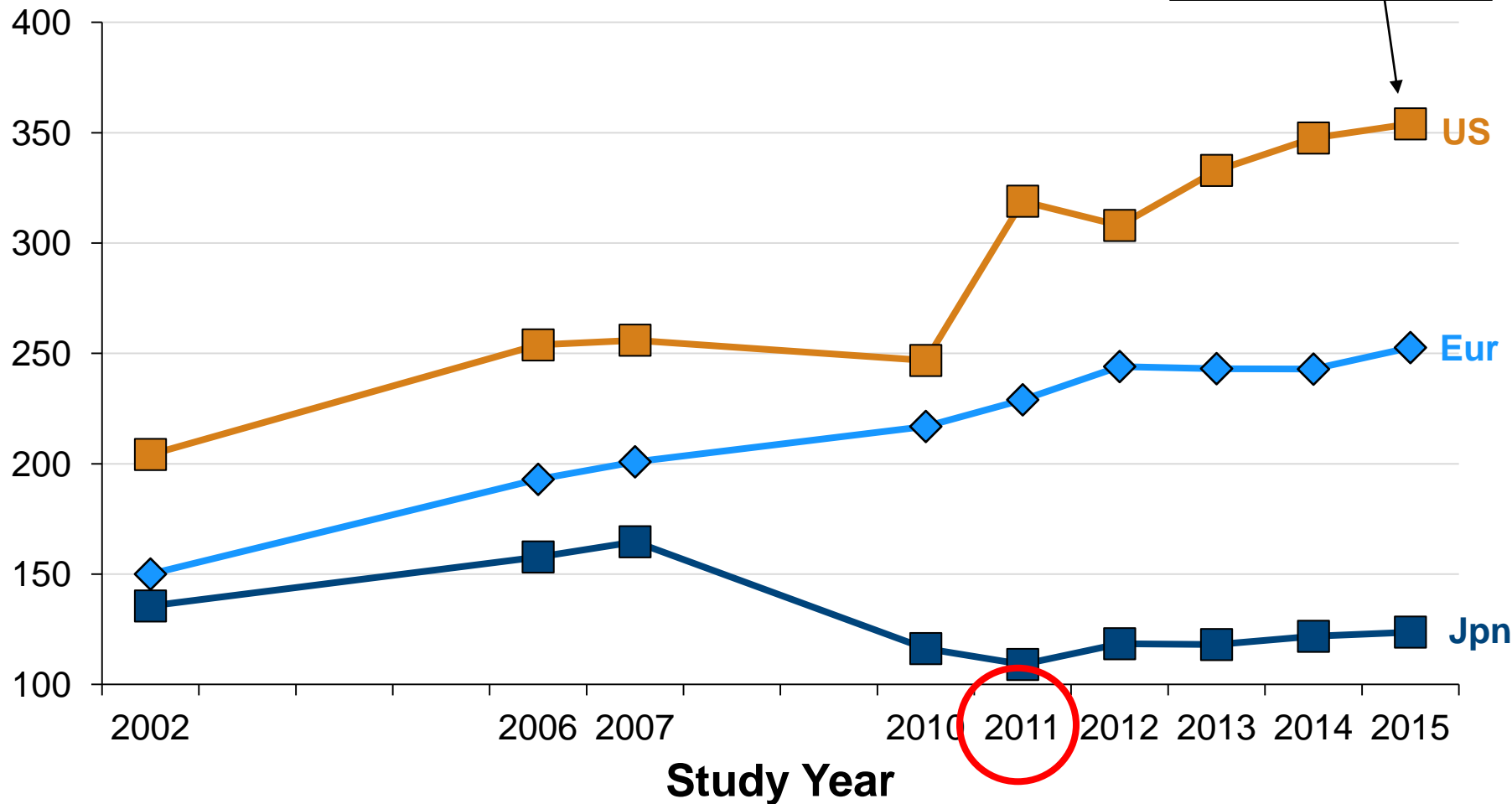


Median PTH Trends

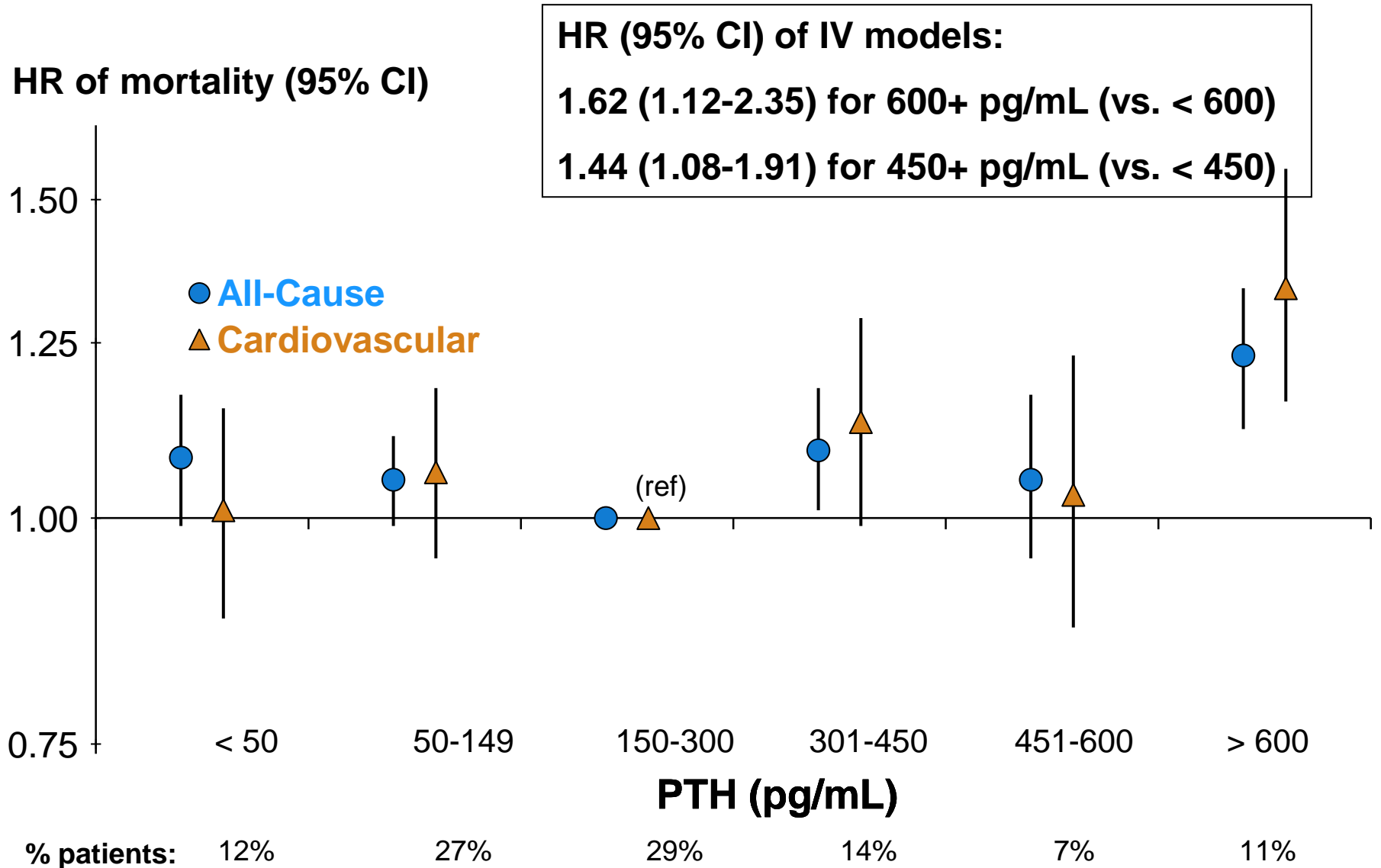
DOPPS 2-5 (2002-2015)

Switch to oral active vitamin D at some US sites

Median PTH (pg/mL)



PTH and Mortality



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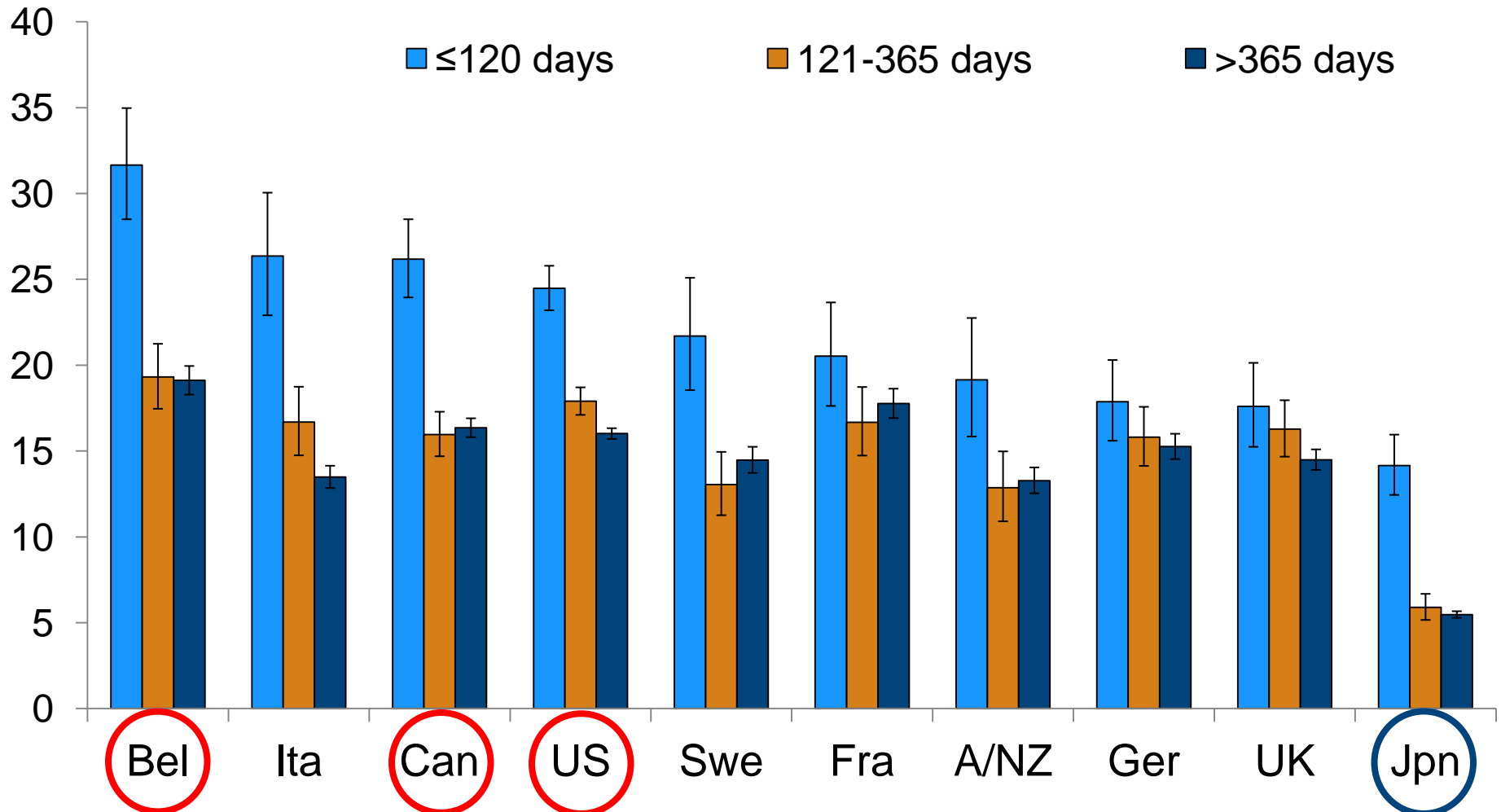
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Unmet Need

Improving Outcomes
During the Dialysis Transition Period

High Mortality Rates After Dialysis Start: DOPPS 2-5 (2002-2015)

Mortality rate (deaths per 100 patient years)

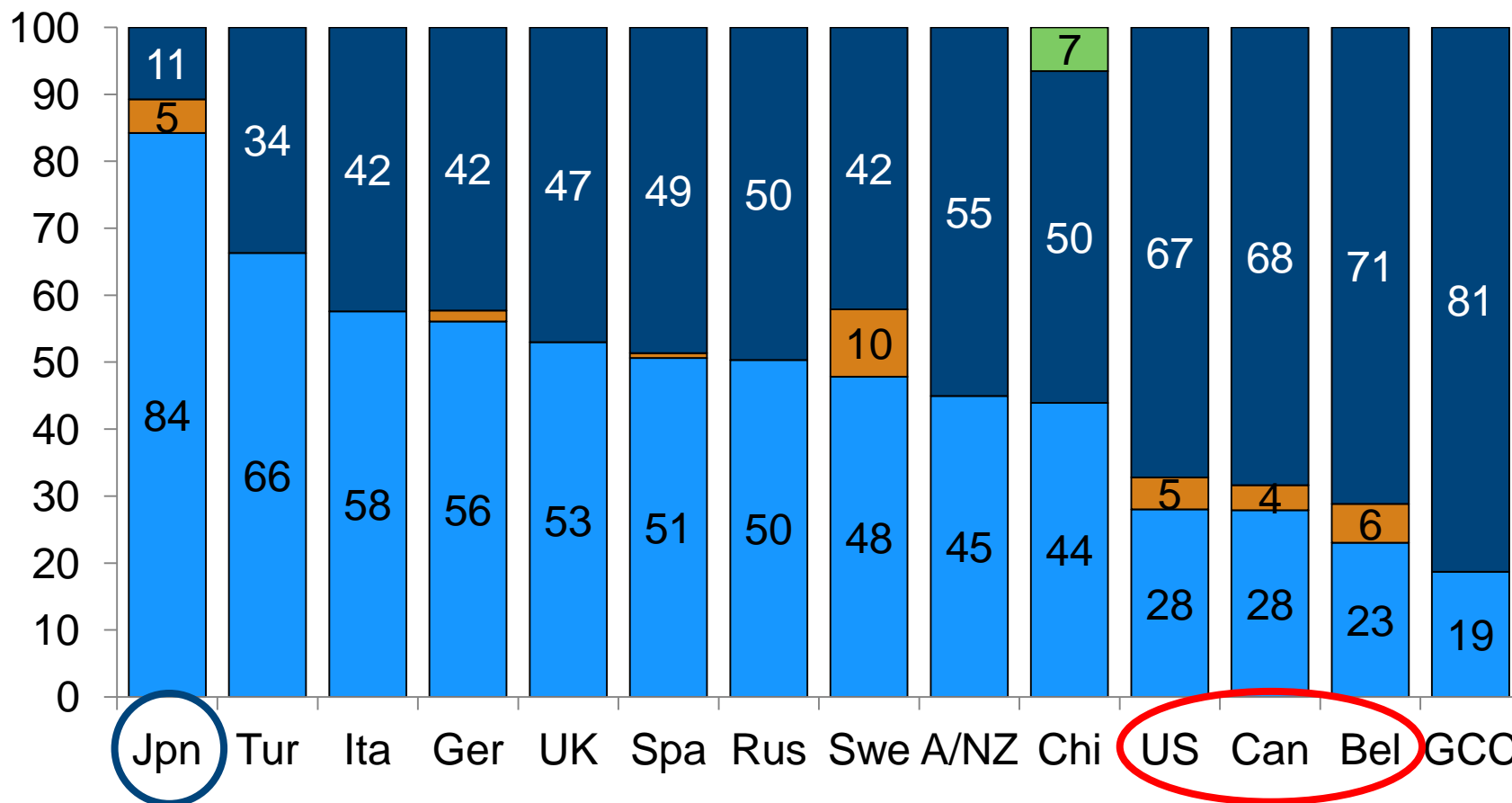


Vascular access use^a – incident patients

DOPPS 5 (2012-2014)

% of Patients

Other Catheter AV-Graft AV-Fistula



Jpn

US

N Patients: 149 13 59 120 40 123 36 81 11 50 334 68 53 73

^a At study entry for patients on dialysis ≤60 days at DOPPS enrollment

How can we improve outcomes among dialysis patients now?

- **Get ready!** Rising prevalence and age (higher societal burden of dialysis) for foreseeable future
- **For prevalent patients:** Prioritize longer treatment time, volume management, and improving nutrition over 'traditional' metrics (Kt/V, anemia, etc.)
- **For incident patients:** Better outcomes at onset of kidney failure *must be achieved*, but this requires both practice improvement and policy changes
- Prioritize the patient experience!

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Thank you