



DIALYSIS OUTCOMES AND
PRACTICE PATTERNS STUDY

**New Study Directions and Early
Findings: PDOPPS and CKDOPPS**

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Arbor Research Collaborative for Health

CKDopps: Special Thanks

- **Brazil** – Support provided in part by AbbVie
- **France** – Affiliated with CKD-REIN
 - CKD-REIN is funded by a public-private partnership including grants from Agence Nationale de la Recherche Programme "Investissements Avenir", Programme Hospitalier de Recherche Clinique PHRC 2010 and 7 industrial partners)
- **Germany** – Affiliated with the Scientific Institute for Nephrology (WiNe Institute)
- **Japan** – Affiliated with Reach-J (public funding)
- **U.S.** – Support provided in part by Keryx

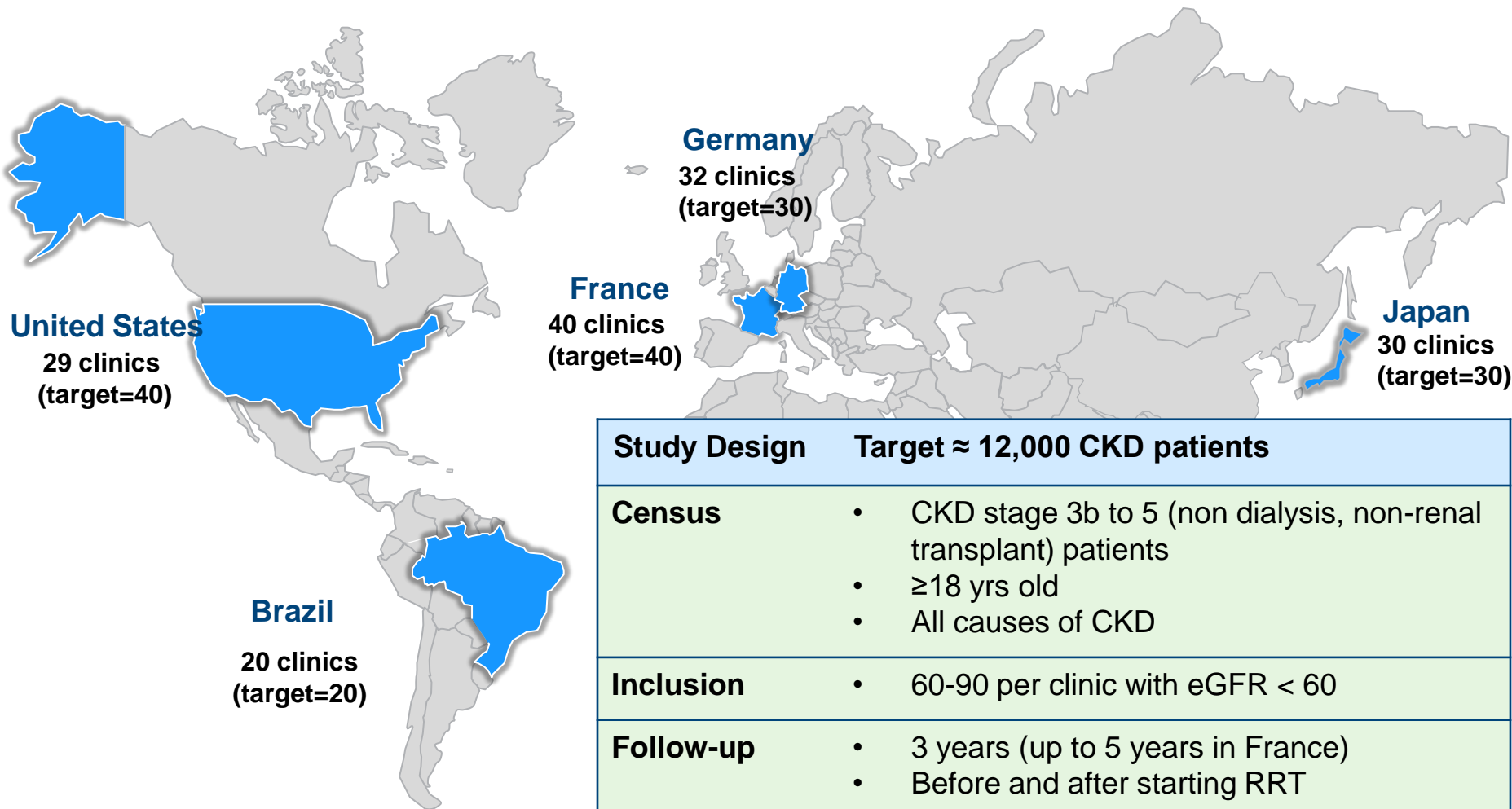
Outline

- **Background, Goals, Design, and Progress**
- **Early Descriptive Data from Brazil, France, Germany & US**
- **Transition to dialysis**

CKDopps – Key Questions (Advanced CKD)

1. What is the **optimal timing of dialysis** start with respect to mortality, hospitalizations, and patient-reported outcomes?
2. What are the best practices to **optimize dialysis access use at dialysis start**?
3. What **practices delay progression to kidney failure** among advanced CKD patients?
4. How do these best practices **differ by patient characteristics**, e.g., age, gender, diabetes, proteinuria level?
5. For what types of patients is **conservative kidney management** (without dialysis) a reasonable option?

CKDopps Protocol & Countries (2016)



Study Design	Target \approx 12,000 CKD patients
Census	<ul style="list-style-type: none">• CKD stage 3b to 5 (non dialysis, non-renal transplant) patients• ≥ 18 yrs old• All causes of CKD
Inclusion	<ul style="list-style-type: none">• 60-90 per clinic with eGFR < 60
Follow-up	<ul style="list-style-type: none">• 3 years (up to 5 years in France)• Before and after starting RRT
Data collection (longitudinal)	<ul style="list-style-type: none">• Abstraction from medical records• Nephrologist survey• Patient questionnaire

CKDopps Recruitment Status

Country	Sites Recruited Target	Sites Recruited	Patient Enrollment Target	Patients Enrolled
Brazil	20	20	1,600	903
France	40	40	3,200	3,033
Germany	30	32	1,800	1,810
Japan	30	29	2,400	207
United States	40	30	3,200	1,289
Total	160	151	12,200	7,242

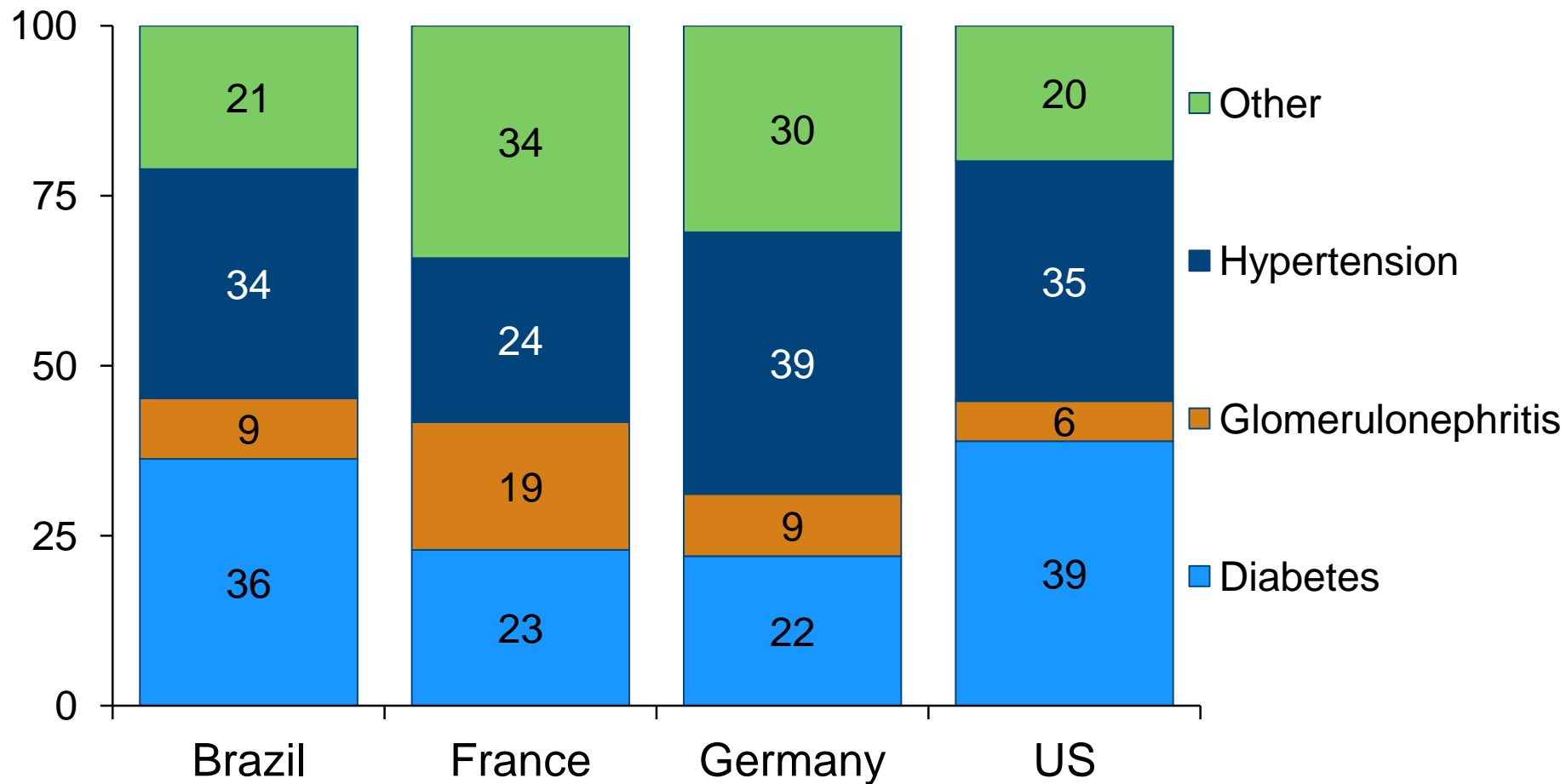
As of 7/5/2016

Outline

- **Background, Goals, Design, and Progress**
- **Early Descriptive Data from Brazil, France, Germany, and U.S.**
- **Transition to dialysis**

Reported cause of CKD

% of patients



N Pts: 615

2,393

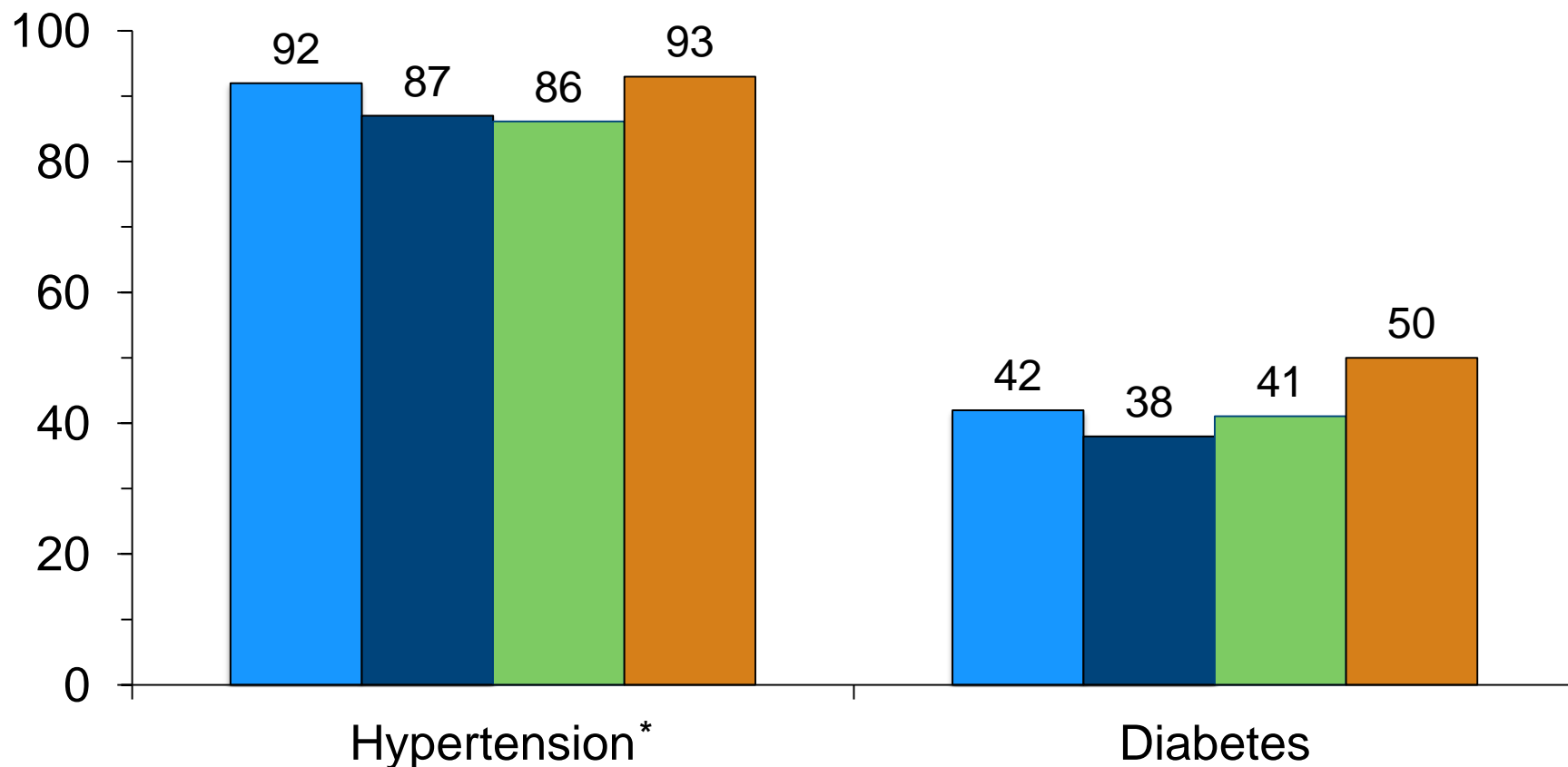
1,028

911

Prevalence of hypertension and diabetes

% of patients

■ Brazil ■ France ■ Germany ■ US

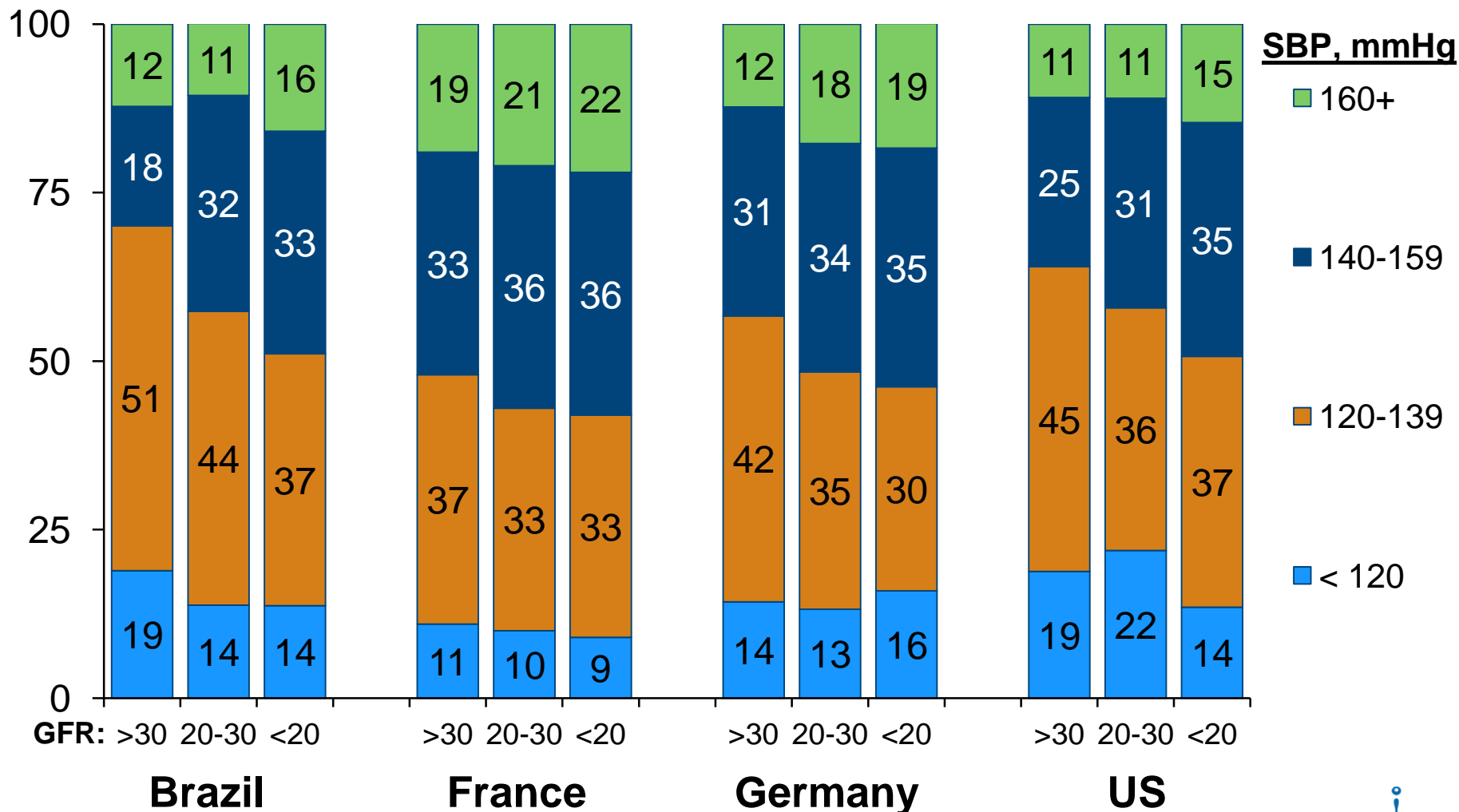


* Among sampled patients

PRELIMINARY: From CKDopps census (all clinic patients); N=14,769 (France), 925 (Germany), 2,034 (Brazil), 3,341 (US); eGFR < 60 mL/min/1.73m²

Systolic blood pressure, by CKD stage

% of patients



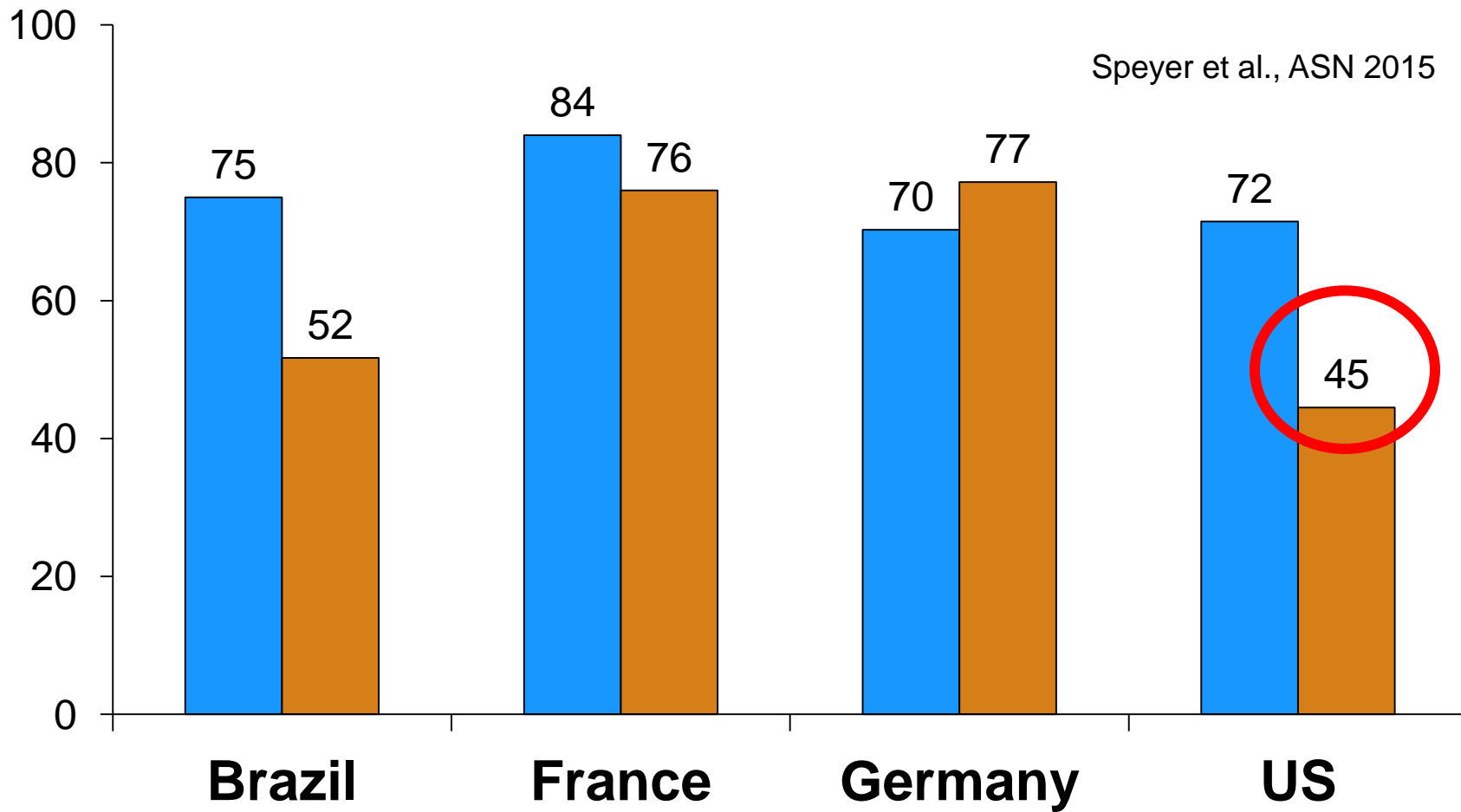
KDIGO 2012: Individualize BP targets; avoid postural hypotension

ACEi or ARB prescription, by CKD stage Among diabetics

% of patients

■ eGFR 30-59 ■ eGFR 15-29

Speyer et al., ASN 2015

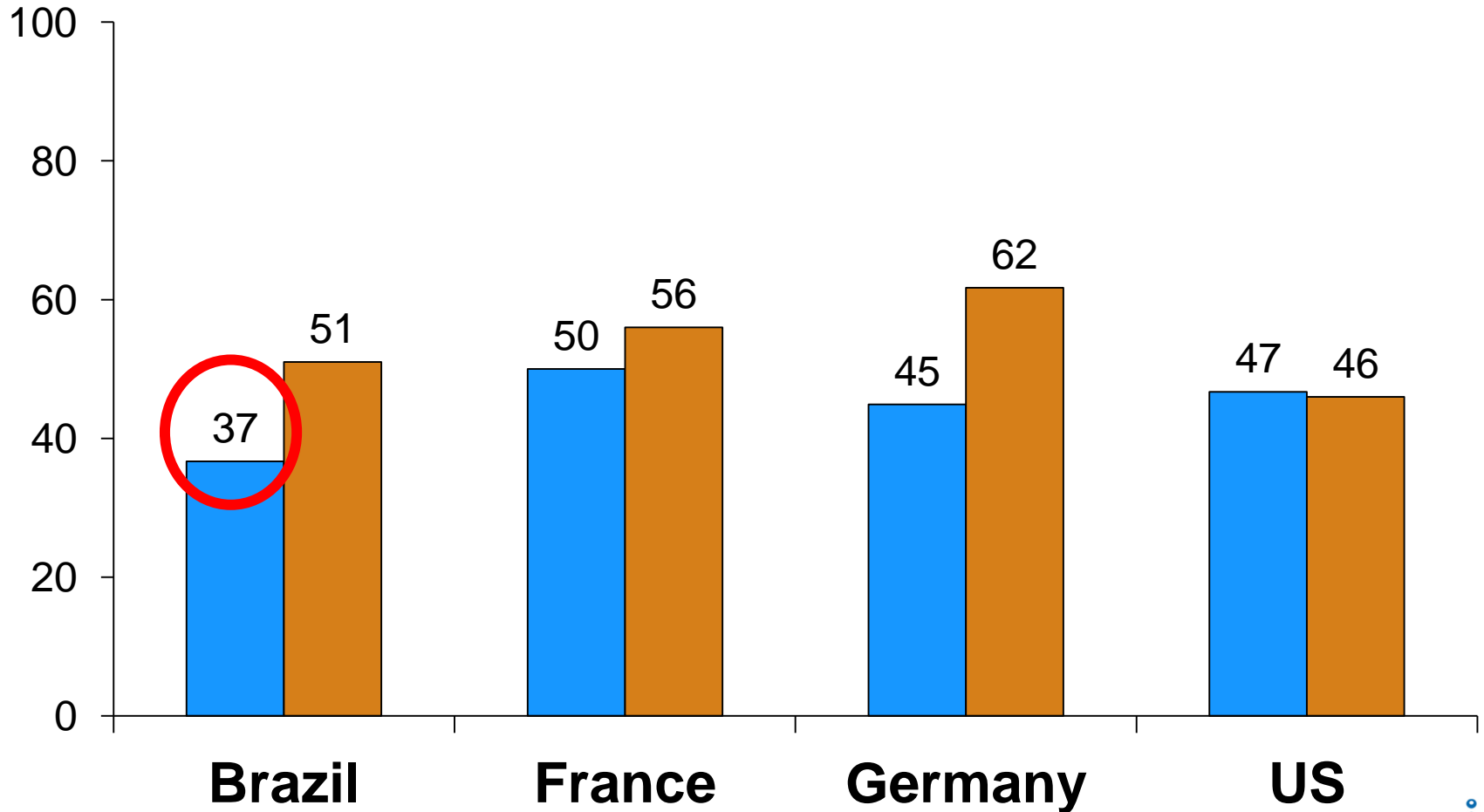


KDIGO 2012: Use RASi in diabetic adults with CKD and/or proteinuria

Insulin prescription Among diabetics

% of patients

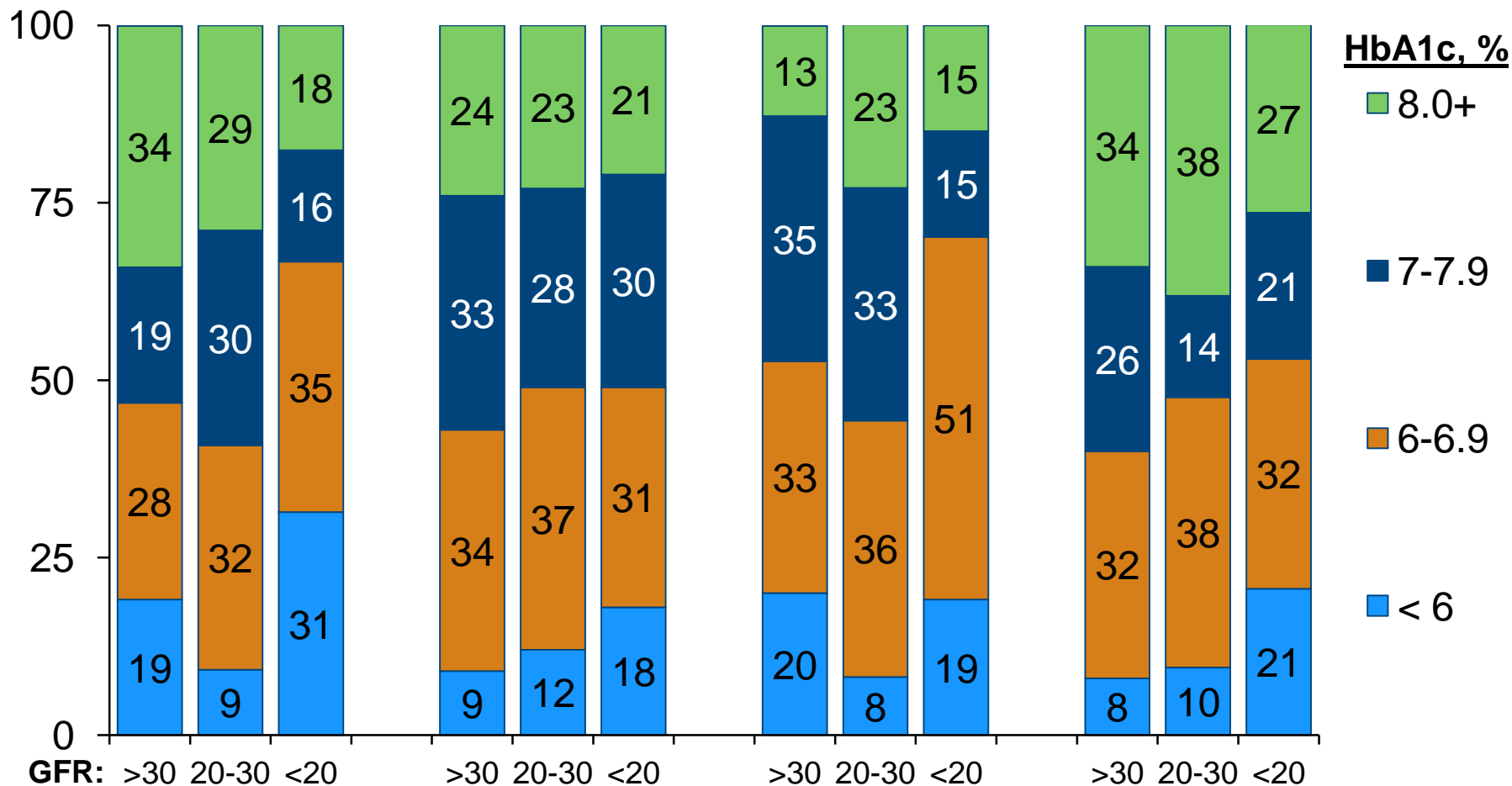
■ eGFR 30-59 ■ eGFR 15-29



HbA1c, by CKD stage

Among diabetics

% of patients



Brazil

France

Germany

US

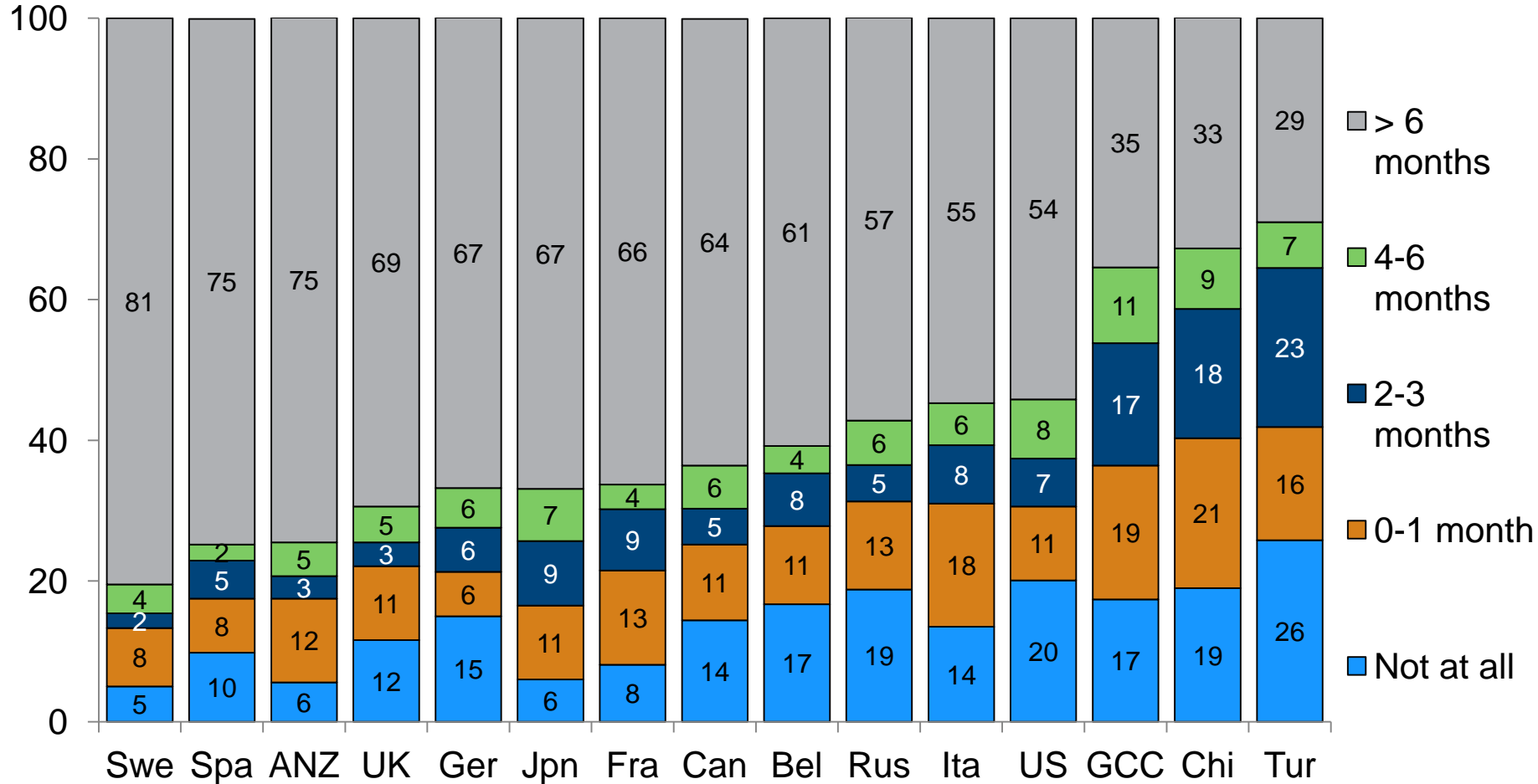
KDIGO 2012: Target hemoglobin A1c ~7.0%

Outline

- **Background, Goals, Design, and Progress**
- **Early Descriptive Data from Brazil, France, Germany & US**
- **Transition to dialysis**

Timing* of first nephrology visit before starting dialysis (DOPPS)

% of patients

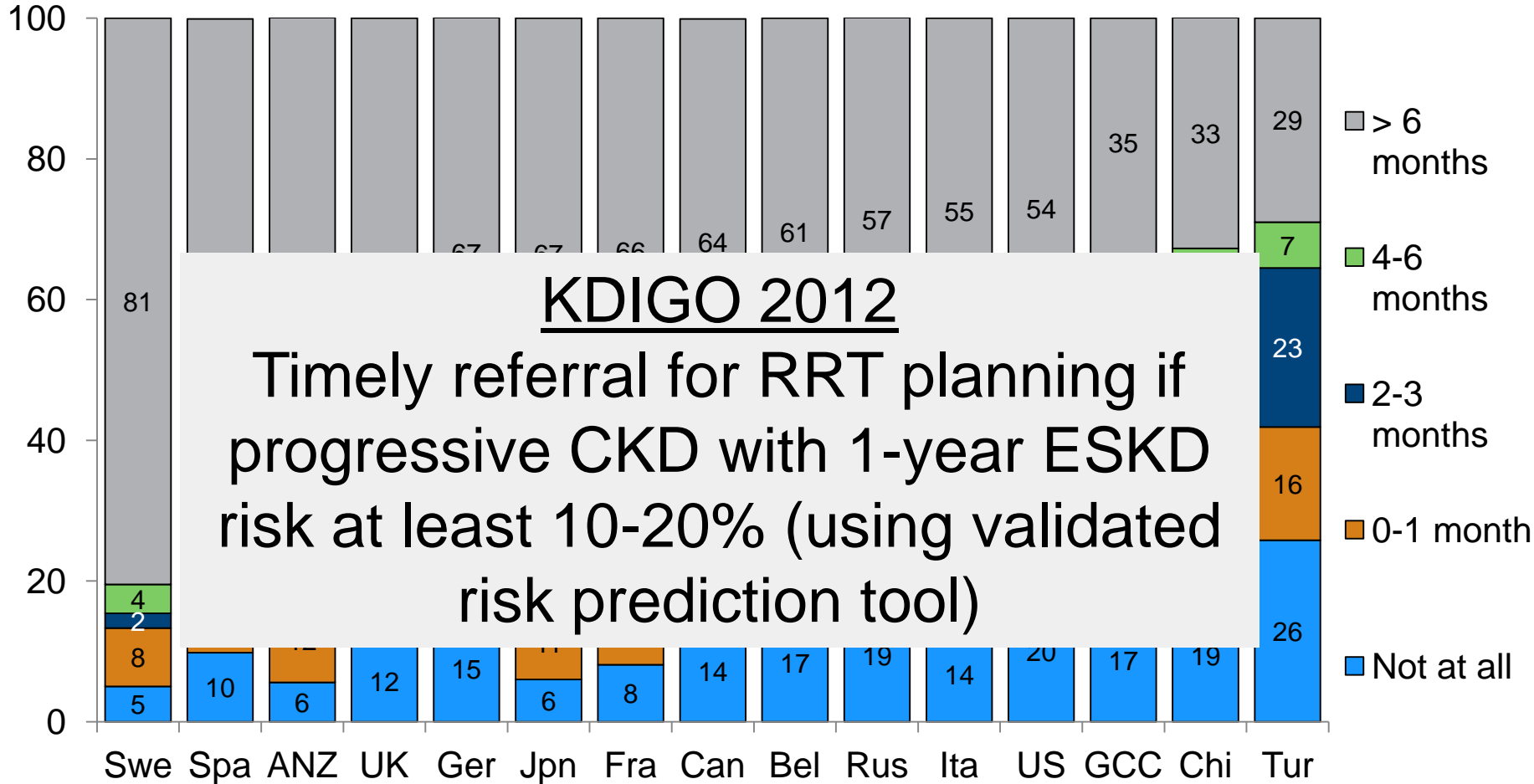


N Pts: 339 479 126 294 480 716 172 277 306 96 349 706 195 174 31

* From medical record, supplemented by patient reported time when not available in medical record; 2009-2014, patients on dialysis < 120 days at enrollment

Timing* of first nephrology visit before starting dialysis (DOPPS)

% of patients

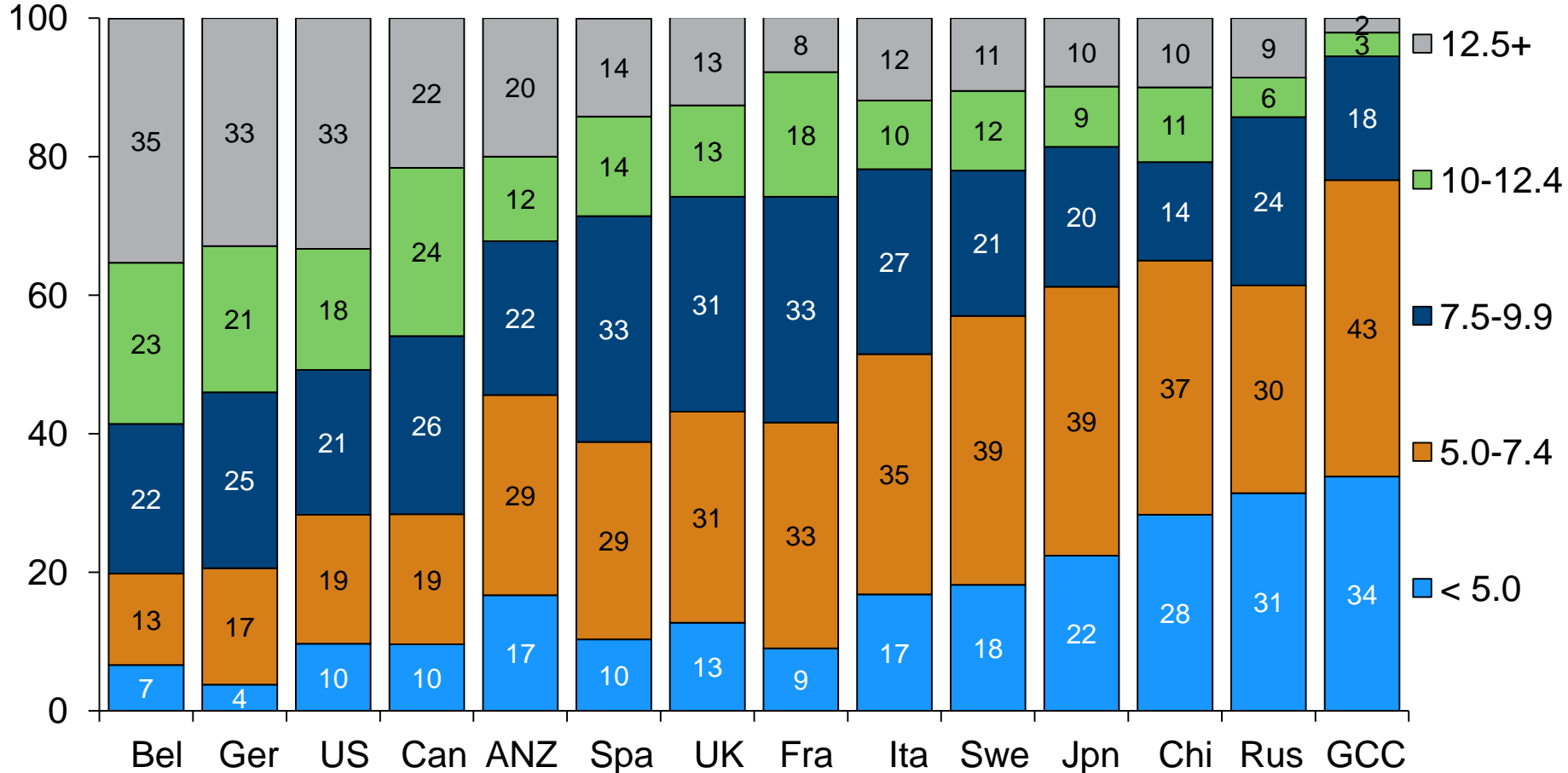


N Pts: 339 479 126 294 480 716 172 277 306 96 349 706 195 174 31

* From medical record, supplemented by patient reported time when not available in medical record; 2009-2014, patients on dialysis < 120 days at enrollment

eGFR at dialysis initiation (DOPPS)*

% of patients

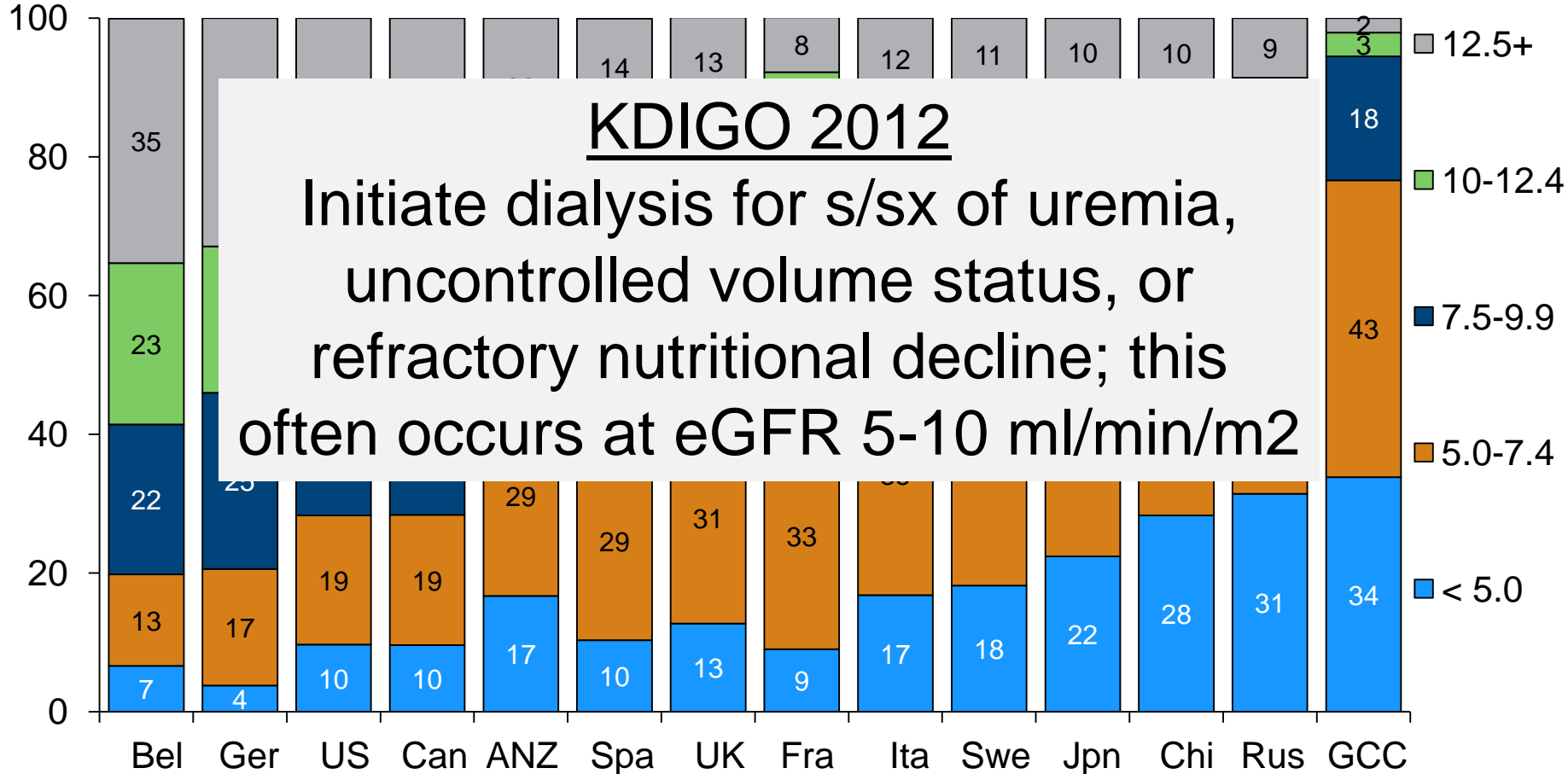


N Pts: 227...346...526...218...90... 319...197...89... 202...286...446...120...70... 145...
 Mean:

Adapted from Bieber et al. ASN abstract (2013)

eGFR at dialysis initiation (DOPPS)*

% of patients



N Pts: 227...346...526...218...90... 319...197...89... 202...286...446...120...70... 145...
Mean:

Adapted from Bieber et al. ASN abstract (2013)

Summary: CKDopps findings to date

- **CKDopps is designed to evaluate, and ultimately help improve, care for advanced CKD patients in ‘real-world’ nephrology clinics**
- **Important variations already identified across countries (case-mix, hypertension, DM)**
- **Early data shows that many practices deviate from KDIGO guidelines**
 - **Supporting evidence for some guidelines is weak, but not for all (e.g., low RASi use in US)**
- **Future work will evaluate practice/outcomes associations**

PD PPS

PERITONEAL DIALYSIS OUTCOMES
AND PRACTICE PATTERNS STUDY

PDOPPS: the Largest International Study of PD Practices



Acknowledgments

Warm thanks for PDOPPS support to:

Baxter Healthcare

Japanese Society for Peritoneal Dialysis

Canadian Institute for Health Research

National Health and Medical Research

Council of Australia

**Research for Patient Benefit programme, National
Institute for Health Research, UK**

**We're grateful to these organizations for their
commitment to making PDOPPS a reality**

PDOPPS - International Society for Peritoneal Dialysis (ISPD) Work Groups

Infection: prevention and management: David Johnson*, Fiona Brown, Beth Piraino, Judy Bernardini, Sharon Nessim, Neil Boudville, CC Szeto, John Collins

Clinical application of PD therapy: Raj Mehrotra*, Mathew Oliver, Helen Hurst, Rachael Morton, Alfonso Cueto Manzano, Dusit Lumlertgui

PD catheter access and function: Martin Wilkie*, Richard Fluck, Bak Leong Goh, Elaine Bowes, John Crabtree, Mark Marshall, Isaac Teitelbaum
Infection: prevention and management: David Johnson*, Fiona Brown, Beth Piraino, Judy Bernadini, Sharon Nessim, Neil Boudville, CC Szeto, John Collins

Dialysis prescription and fluid management: Angela Wang*, Simon J Davies*
Graham Woodrow, Andreas Vychytil, Wim Van Biesen, Hideki Kawanishi, Thyago de Moraes, Gillian Brunier

Patient training and education: Ana Figueiredo*, Valerie Price

Patient support: Fred Finkelstein*, Edwina Brown, Vanita Jassal, Fang Wei, Susanne Ljungman.

DOPPS Program: Framework for Hypotheses

PDOPPS

Patient Demographics

+

Patient Comorbidities

+

Practice Patterns

Patient Outcomes

Technique failure

PD-related infections

Mortality

Hospitalizations

PD access

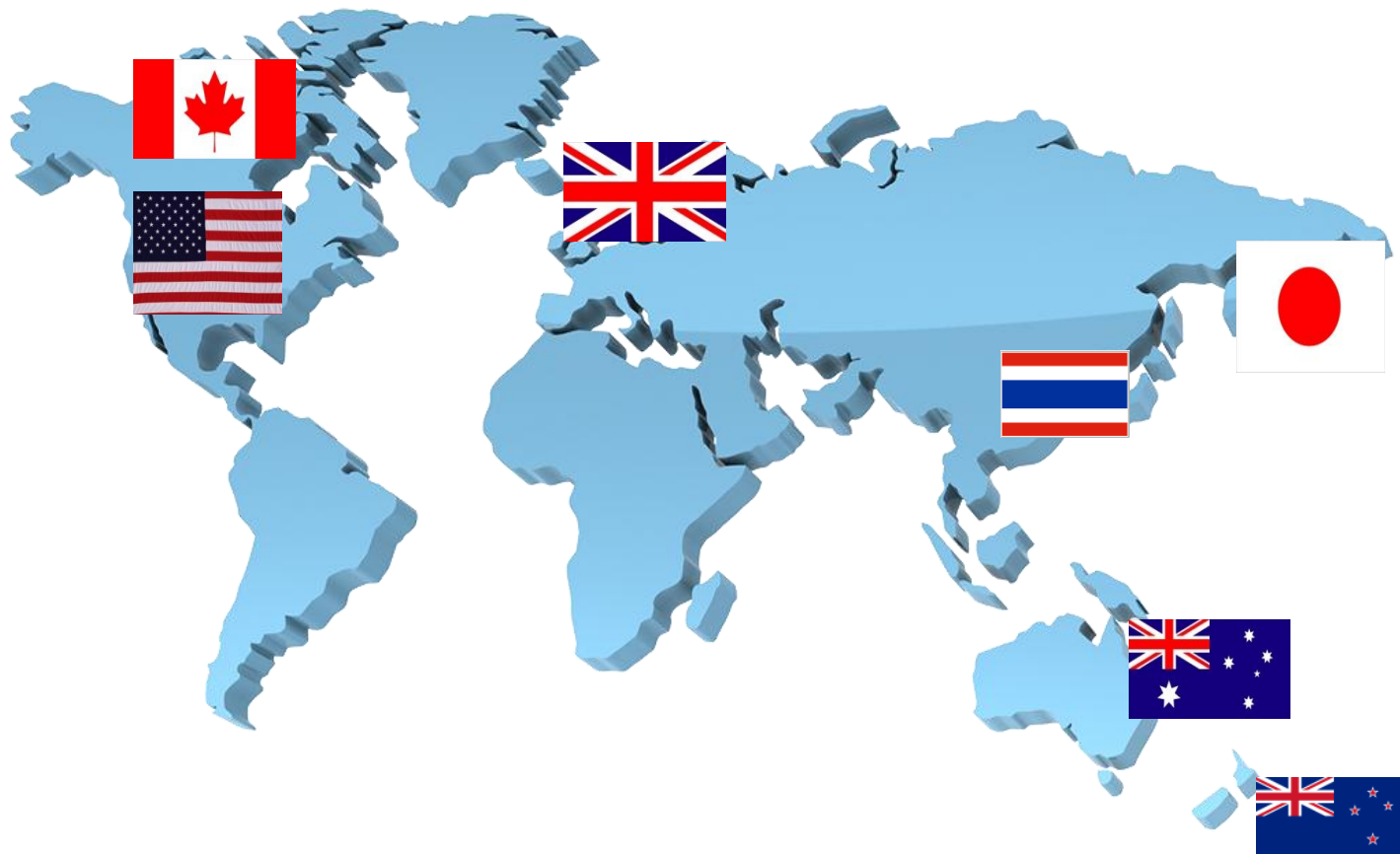
Patient-reported outcomes

PDOPPS Recruitment Status

Country	Site Recruitment Target (N)	Sites Recruited (N)	Census Patients (N)	Patients Consented (N)
United States	105	104	4670	2889
Canada	20	20	2749	845
Japan	32	32	1537	795
Australia	20	20	1598	317
United Kingdom	20	19	1027	201
New Zealand	2	2	272	53
Thailand	22	22	792	100
Total	221	219	12,645	5200

As of 7/5/2016

PDOPPS Map in 2016



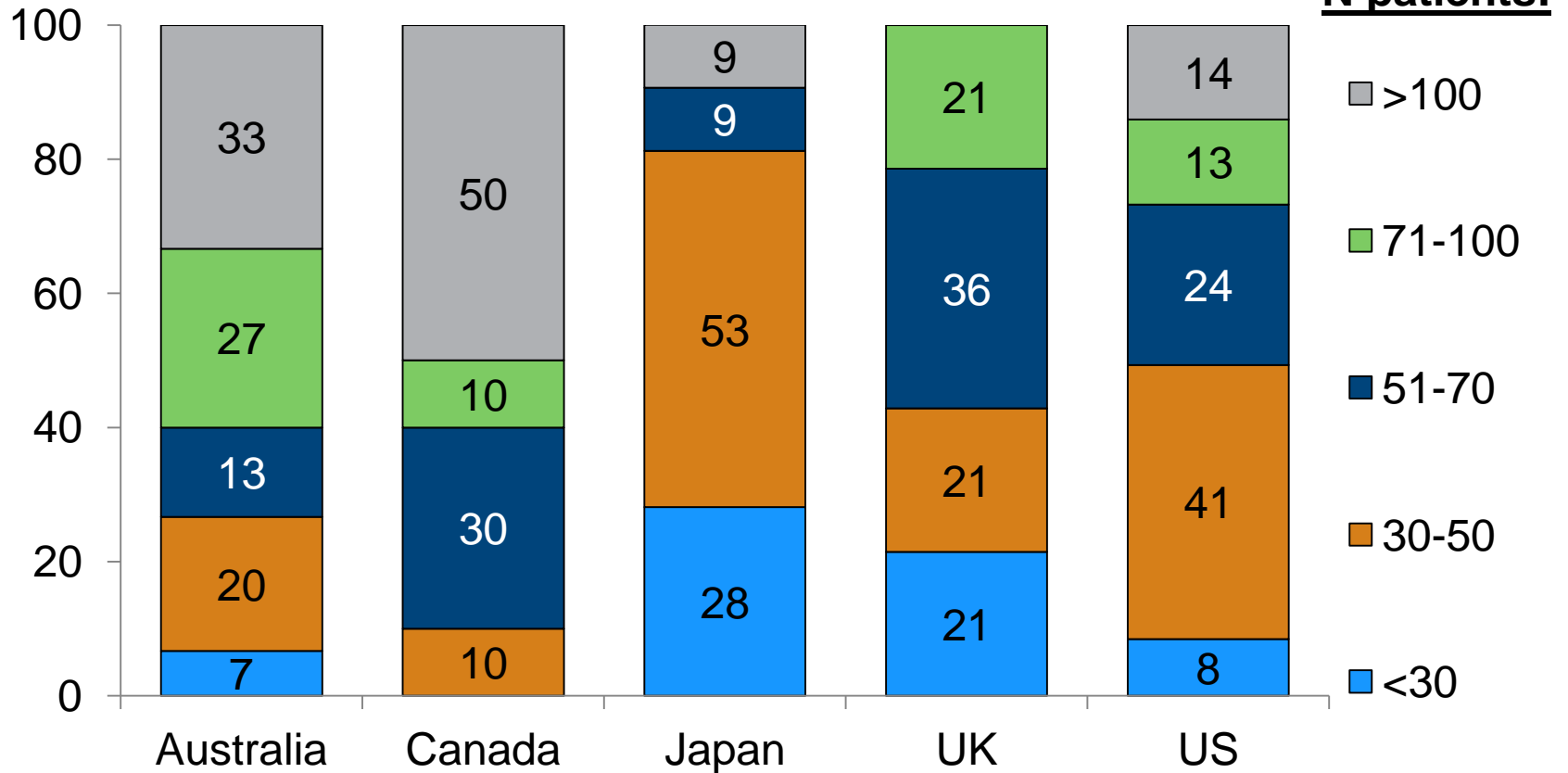
PD PPS

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Research Directions and Early Data

Distribution of Facility Size

% of facilities



N facilities: 71 15 20 32 14

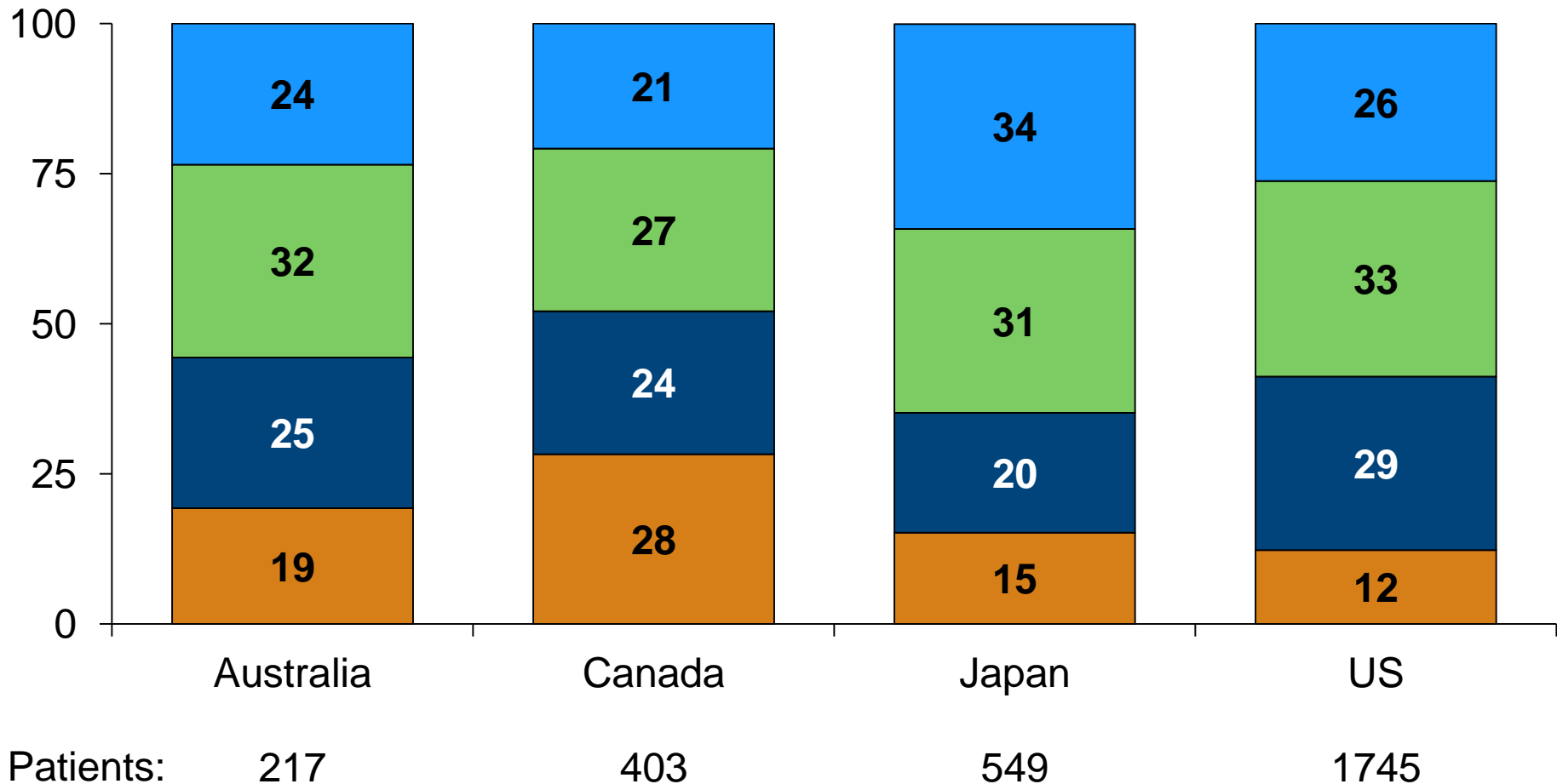
Patient Characteristics*

Characteristic	Australia	Canada	Japan	US
# of facilities	15	20	28	68
# of Selected patients	217	403	549	1745
Demographics				
Male	65%	57%	62%	54%
Age, years				
<45	10%	13%	8%	18%
45-59	22%	28%	25%	30%
60-74	44%	39%	44%	38%
75+	24%	20%	23%	15%
Body Mass Index	28.0(5.3)	26.9(5.5)	23.1(3.2)	28.8(6.7)
Comorbidities				
Primary Cause of ESRD				
Diabetes	29%	36%	31%	36%
Glomerulonephritis	22%	21%	34%	13%
Other	49%	43%	35%	51%
Coronary Heart Disease	30%	29%	17%	25%
Diabetes	42%	44%	37%	49%

* Preliminary data as of May, 2016; results are shown as mean (standard deviation), %. FRN 0 only.

ESRD Vintage (study participants)*

% of Patients ■ <3 months ■ 3 months - 1 year ■ 1-3 years ■ 3 years+

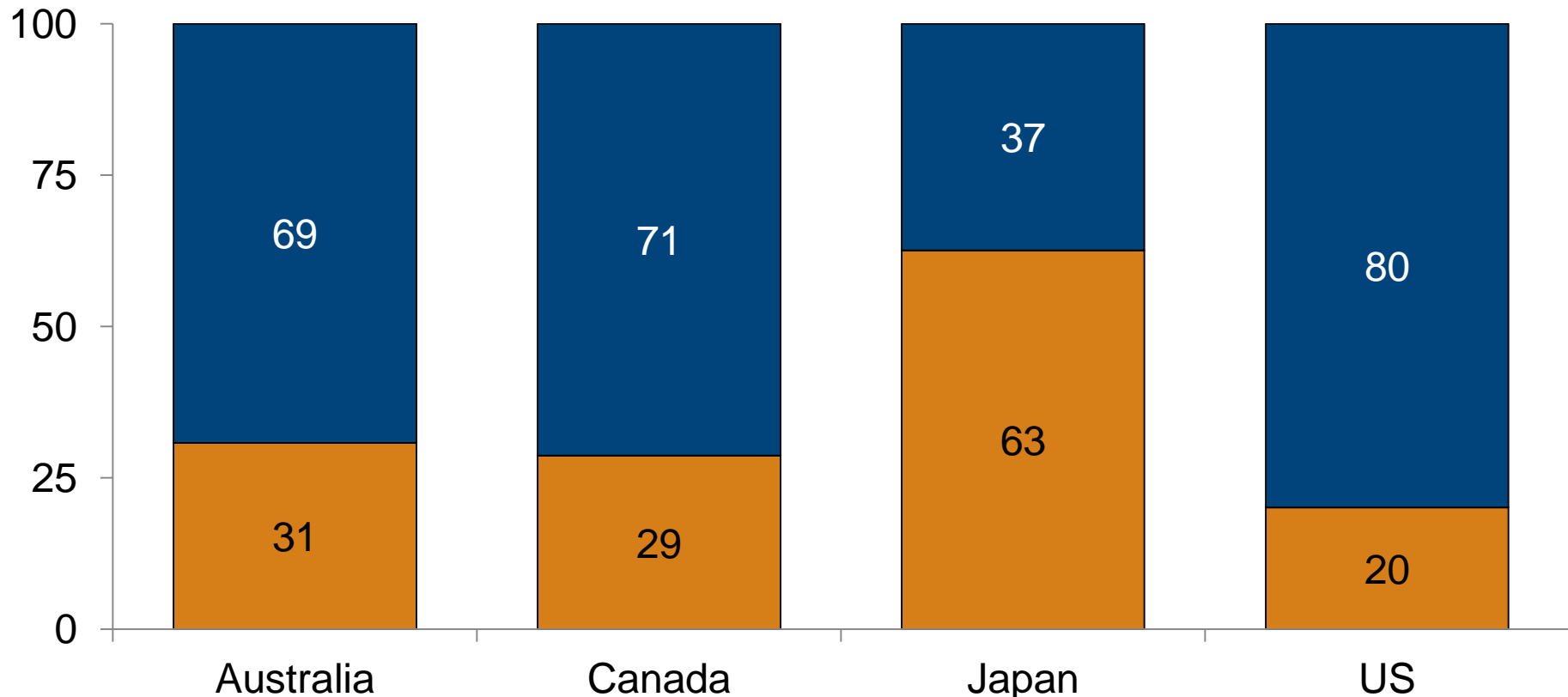


PD Type

% of Patients

■ CAPD

■ APD



N Patients: 198

380

522

522

* Preliminary data as of May, 2016;

of overnight changes for APD patients

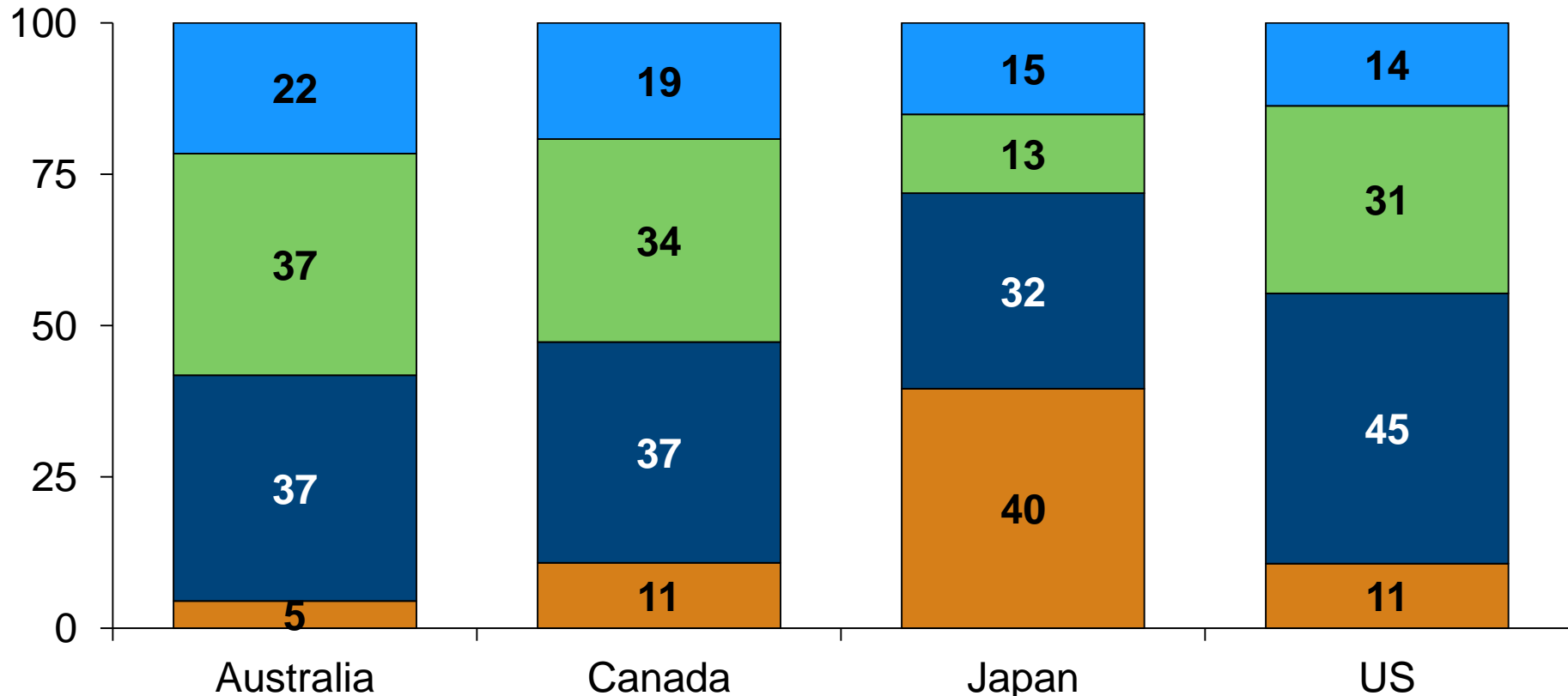
% of Patients

■ ≤3

■ 4

■ 5

■ ≥6



N Patients: 137

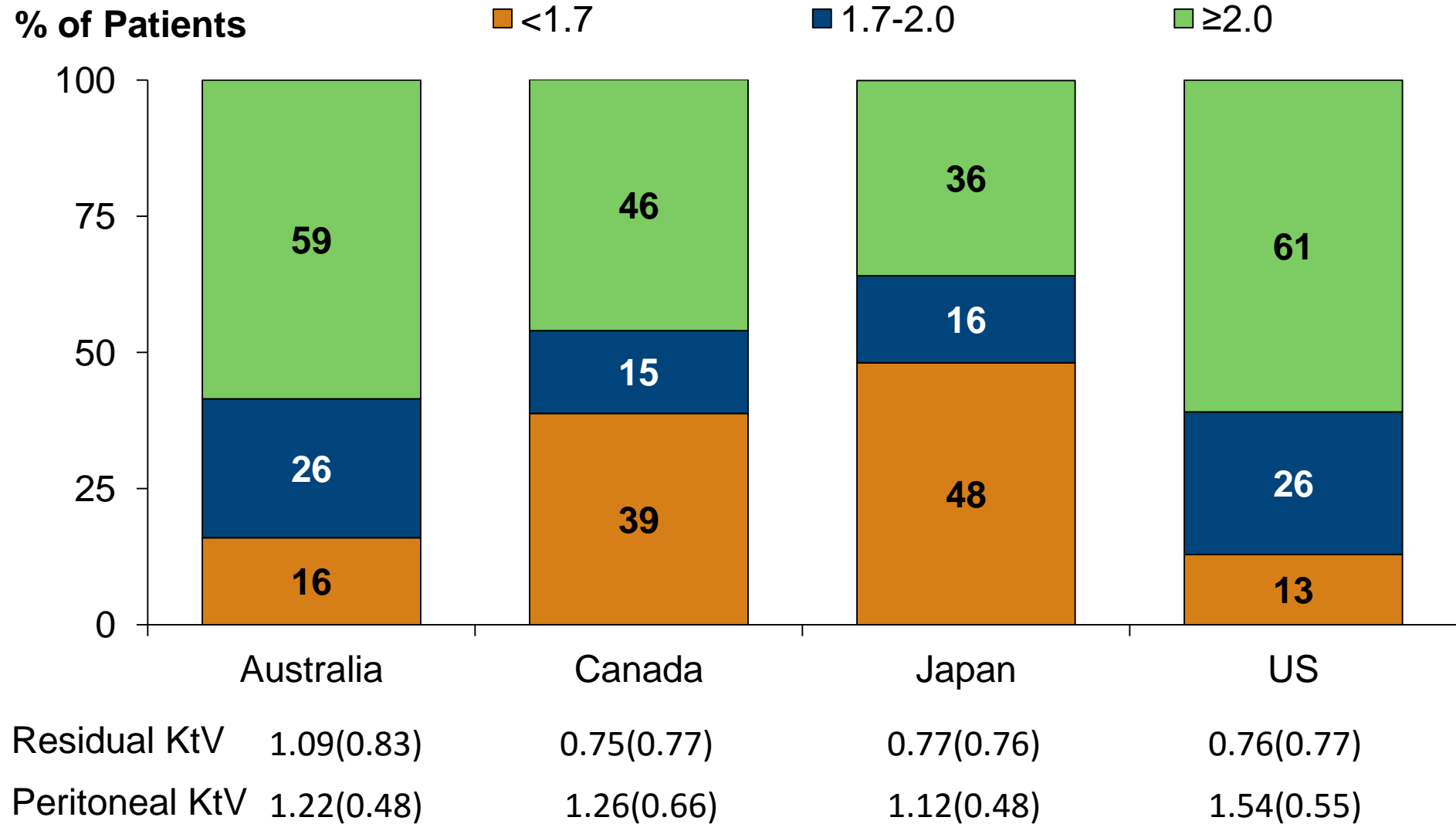
271

195

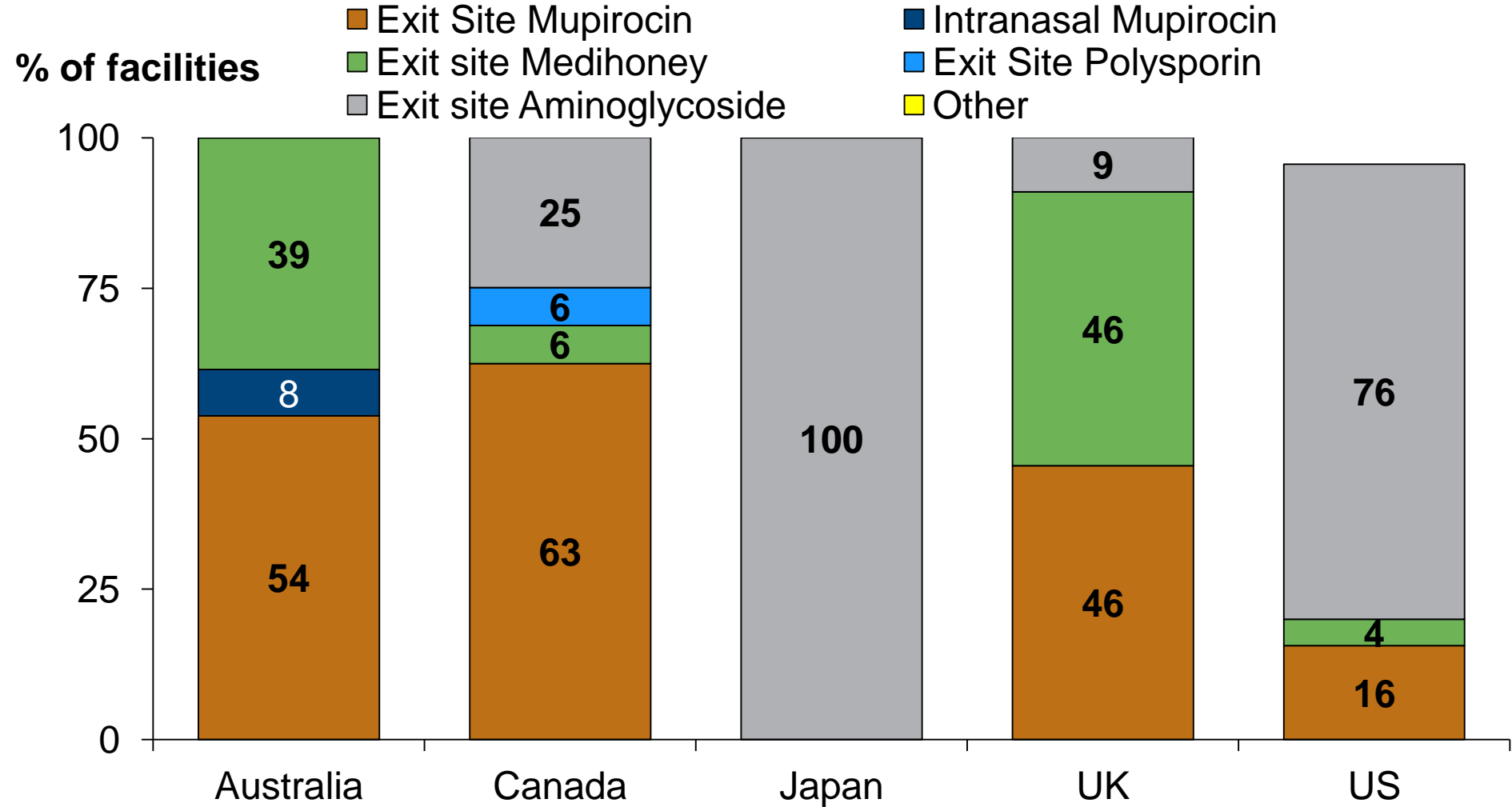
417

* Preliminary data as of May, 2016;

Distribution of Total KtV



Exit Site Antimicrobial Prophylaxis



N facilities: 13 20 28 17 51

* Preliminary data as of May, 2016;

International Variations of Patient-Reported Quality of Life from the PDOPPS (Unadjusted)

	Japan (n=472)	Canada (n=227)	US (n=627)	p- value ^a
Kidney Disease Quality of Life (KDQOL) Measures				
Mean physical component summary (PCS) score	46.1	37.2	37.6	<0.01
Mean mental component summary (MCS) score	46.6	48.7	48.6	0.02
% with a lot of limitation doing moderate activities	11.7	28.7	26.0	<0.01
% with a lot of limitation climbing several flights of stairs	14.1	39.6	39.3	<0.01
% who accomplish less than they would like (physically) all the time	6.6	14.0	14.3	<0.01
% for whom pain does not interfere with their normal work	55.3	29.0	31.8	<0.01
% with a lot of energy all the time	8.5	3.2	2.5	<0.01
Self-reported Depression				
Mean CES-D ^b score	8.66	7.44	7.20	<0.01
% with CES-D ^b score ≥ 10	39.7	31.5	29.2	<0.01

Preliminary data as of May, 2016;

- Testing the null hypothesis that all three countries have the same crude patient reported outcome measures.
- Center for Epidemiologic Studies Depression (CES-D)

Summary

- **PDOPPS is already the largest international study of PD practice**
- **It represents an unprecedented degree of international cooperation in PD research**
- **Its focus is Technique Failure**
- **Early data provides ample evidence of significant practice pattern variation**
- **It provides the opportunity of ancillary studies – e.g. UK catheter study and GWAS investigation of determinants of membrane function**