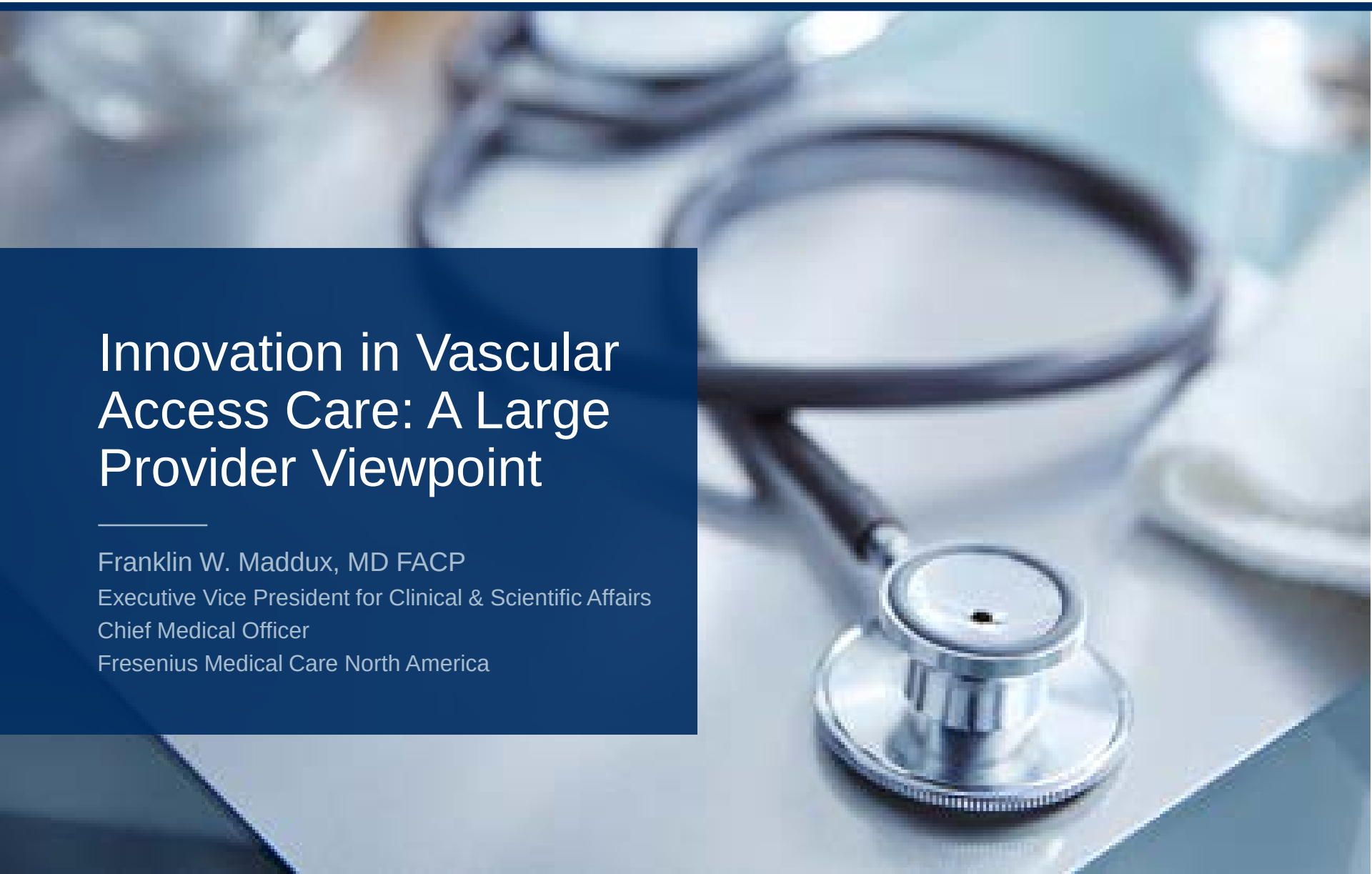
FRESENIUS MEDICAL CARE

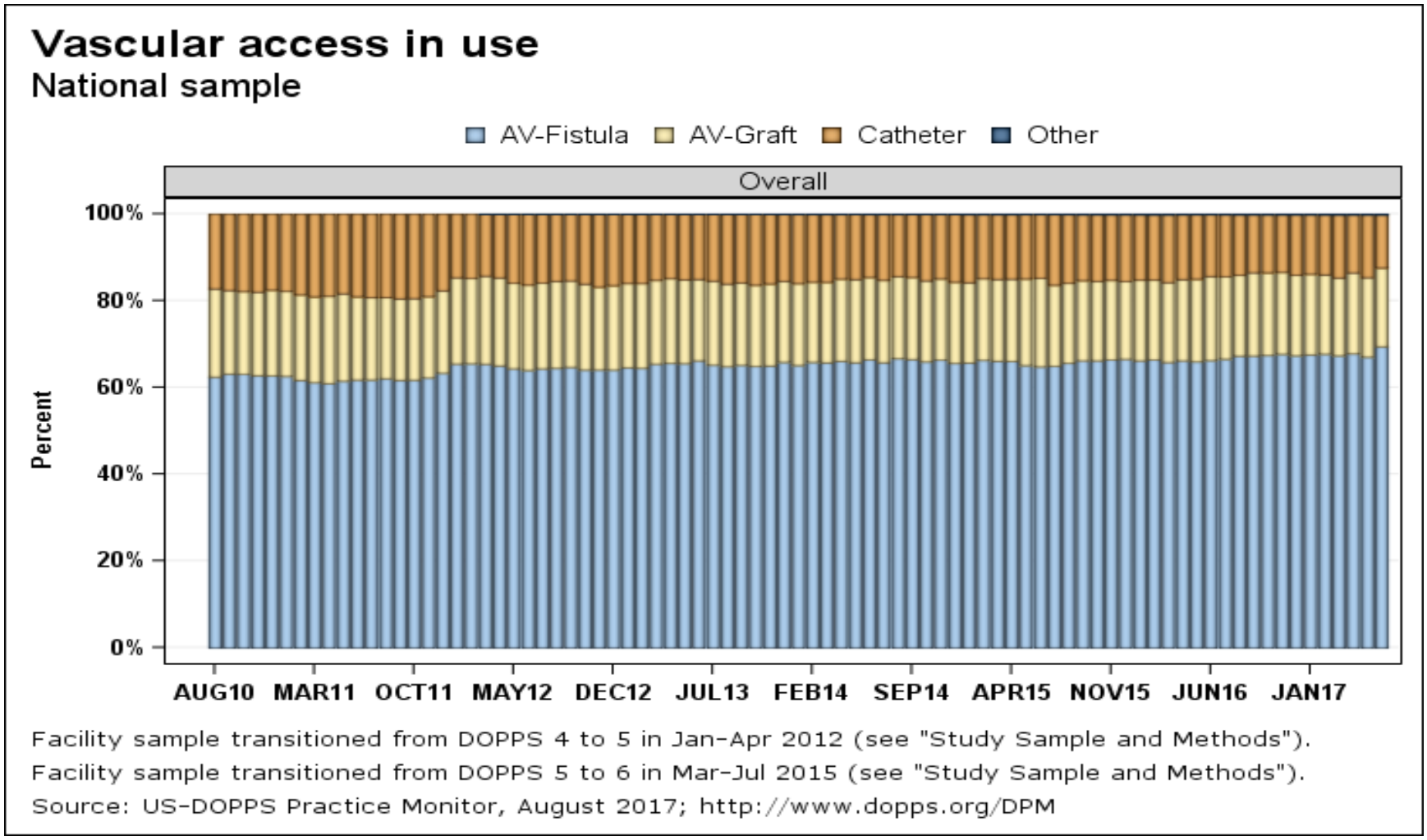
May 11, 2018



Innovation in Vascular Access Care: A Large Provider Viewpoint

Franklin W. Maddux, MD FACP
Executive Vice President for Clinical & Scientific Affairs
Chief Medical Officer
Fresenius Medical Care North America

Distribution of Access Types in the U.S.



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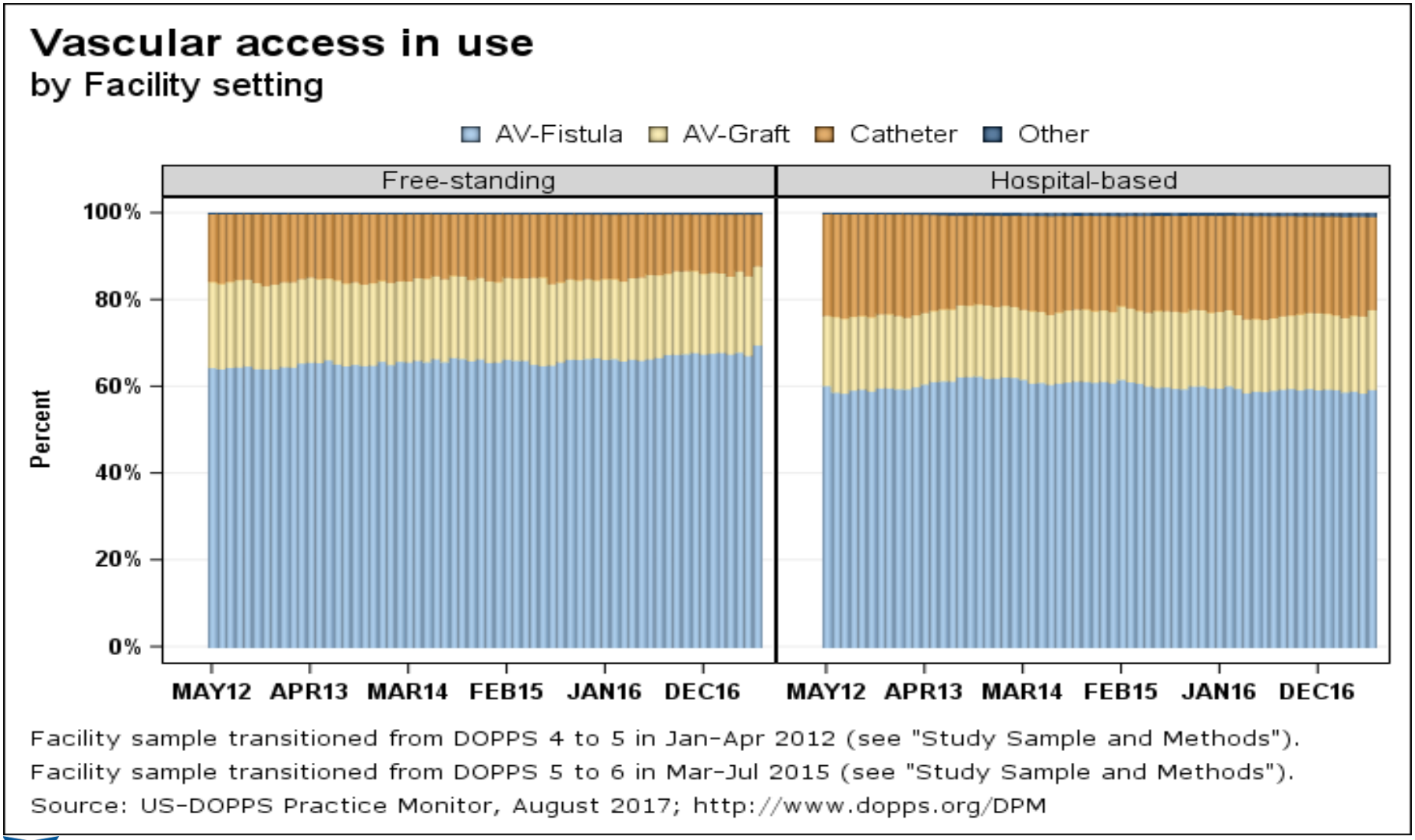

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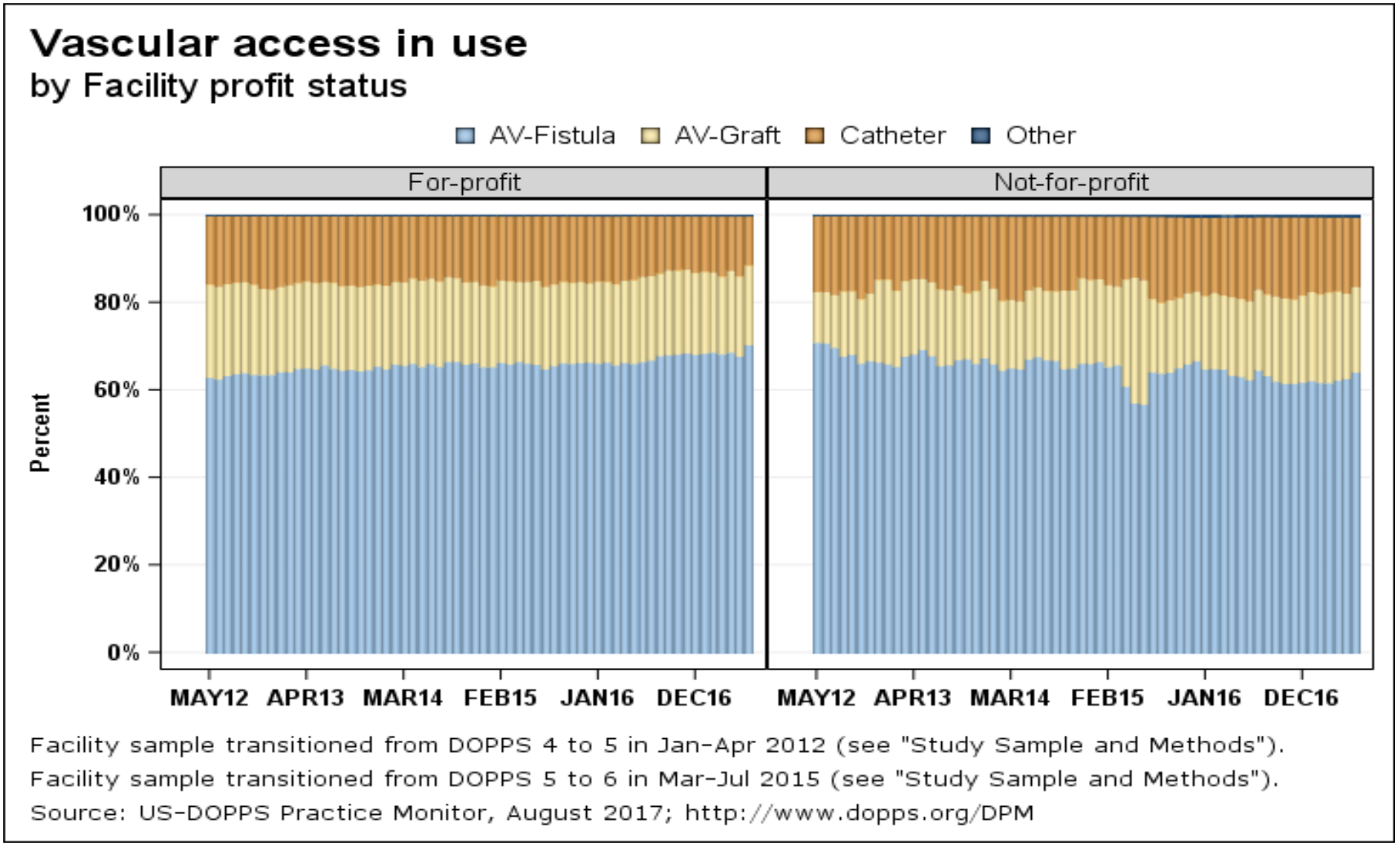

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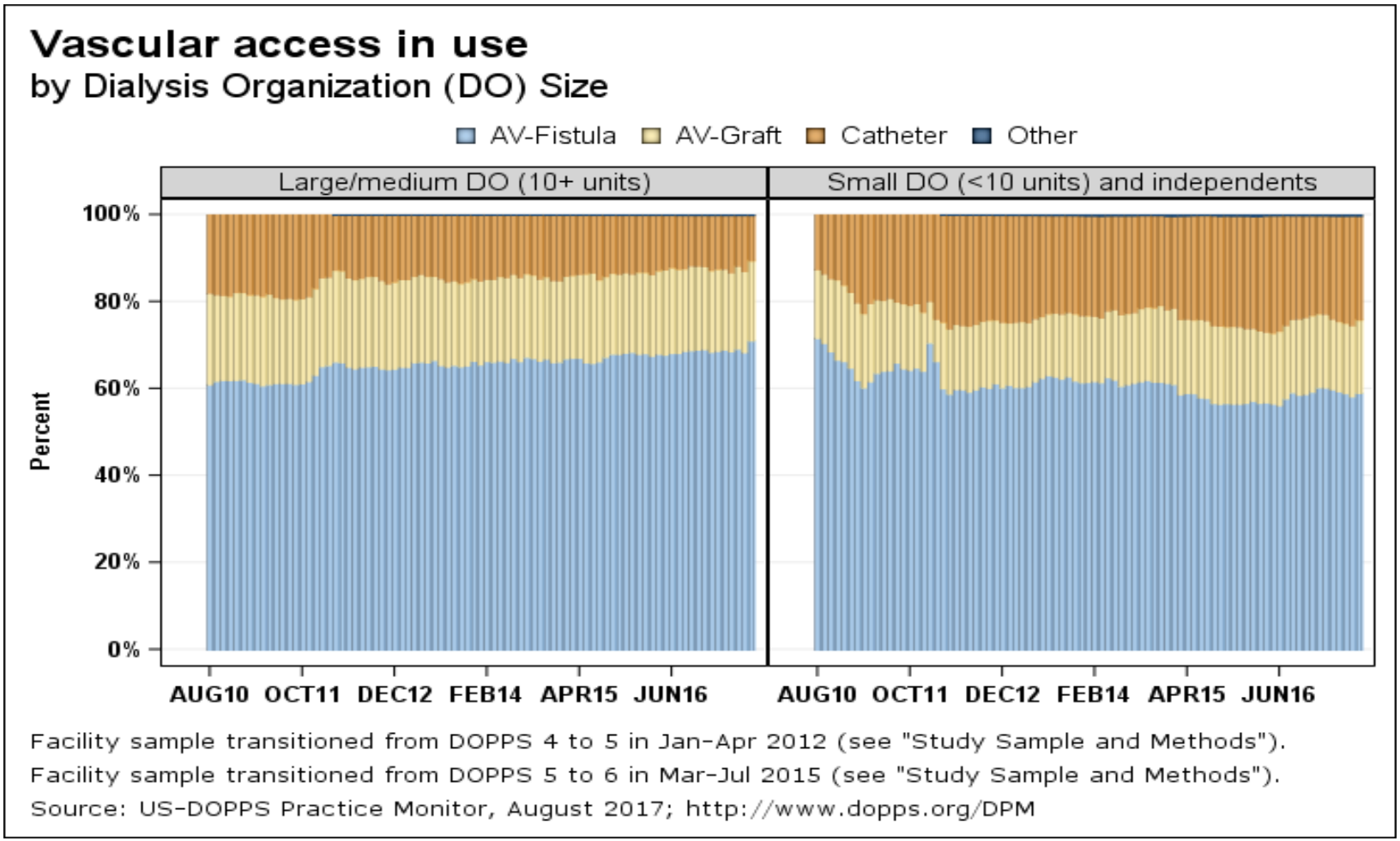

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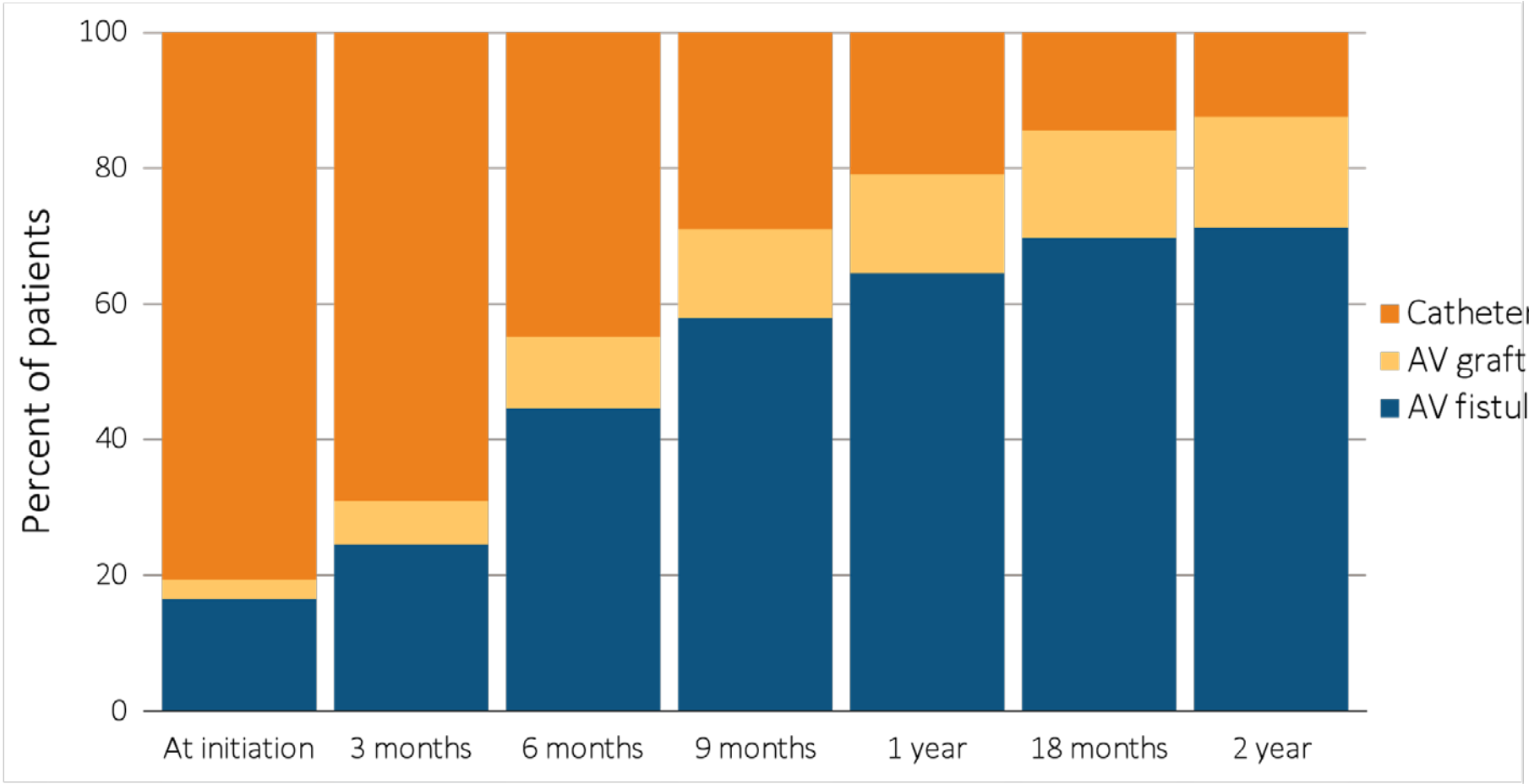
Change in Access During the First Year of Dialysis Among Patients Starting ESRD in 2013



USRDS 2017 ADR: Special analyses, USRDS ESRD Database. Data from January 1, 2013 to May 30, 2016: (a) Medical Evidence form (CMS 2728) at initiation and CROWNWeb for subsequent time periods. (b) ESRD patients initiating hemodialysis (N =101,453). Patients with a maturing AV fistula / AV graft with a catheter in place were classified as having a catheter. Abbreviations: AV, arteriovenous; CMS, Centers for Medicare & Medicaid; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis.

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Dialysis Access Services by Place of Service

TABLE III - Distribution of outcomes by matched population: FOC versus HOPD

Outcome measures	FOC (n = 80,831)	HOPD (n = 133,965)	Difference[a]
Health indicator			
Mortality per year	14.6%	17.2%	-2.6%[†]
21-day infection episodes per year (count)	0.16	0.20	-0.04[†]
Vascular access related services (count) (per year, unless otherwise noted)			
Fistula	0.11	0.14	-0.03[†]
Graft	0.05	0.06	-0.01[†]
Catheter placement	0.35	0.44	-0.09[†]
Catheter exchange	0.10	0.11	-0.01[†]
Ultrasound of vein and artery	0.41	0.49	-0.09[†]
Vessel mapping	0.06	0.05	0.01[†]
Catheter removal	0.22	0.23	-0.01[†]
Thrombectomy	0.00	0.00	0.00
Dialysis (per week)	2.91	2.99	-0.08[†]

JVA
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ORIGINAL RESEARCH ARTICLE
ASDIN

What is the best setting for receiving dialysis vascular access repair and maintenance services?

Audrey M. El-Gamil[1], Al Dobson[1], Nikolay Manolov[1], Joan E. DaVanzo[1], Gerald A. Beathard[2], Terry Foust Litchfield[2], Brook Cowin[2]

[1] Dobson DaVanzo and Associates, LLC, Vienna, VA - USA
[2] Lifeline Vascular Access, a DaVita Healthcare Partner ®, Vernon Hills, IL - USA

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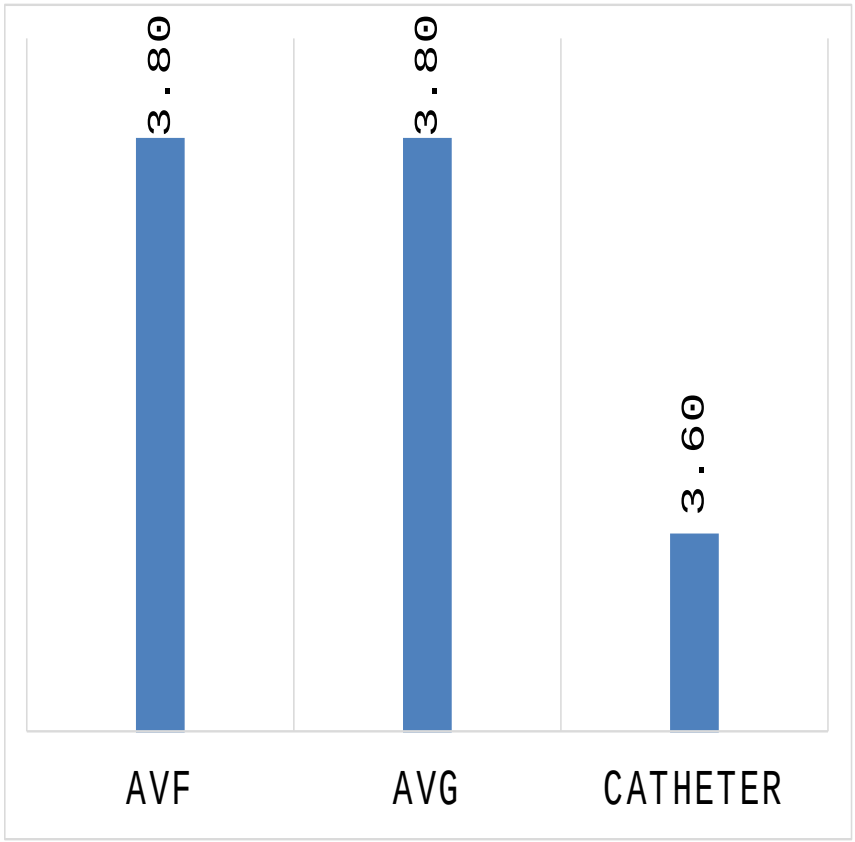
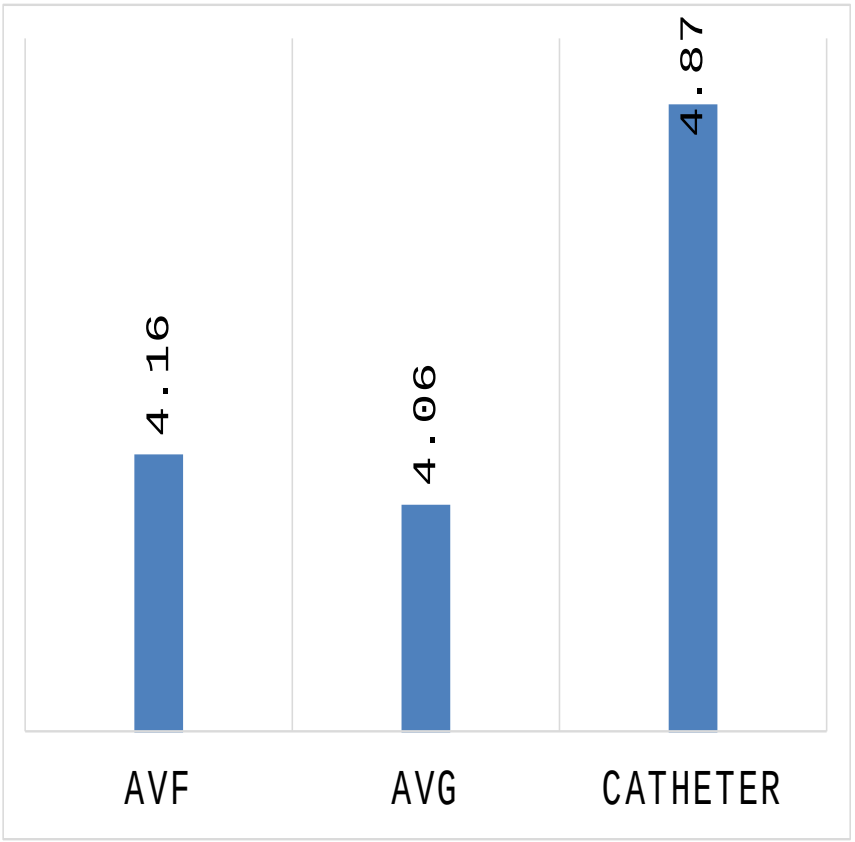
Inflammatory Markers by Access Type in the FMCNA Patients

Albumin



Neutrophil to Lymphocyte Ratio



Active FMCNA In-Center Patients as of 04/02/2018

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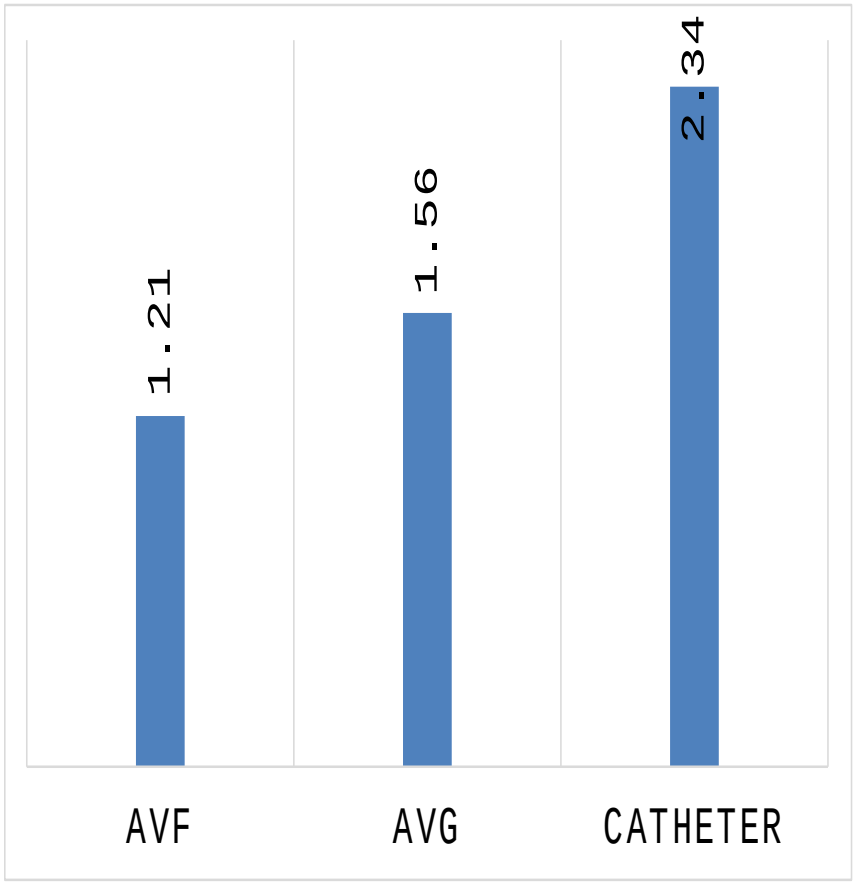
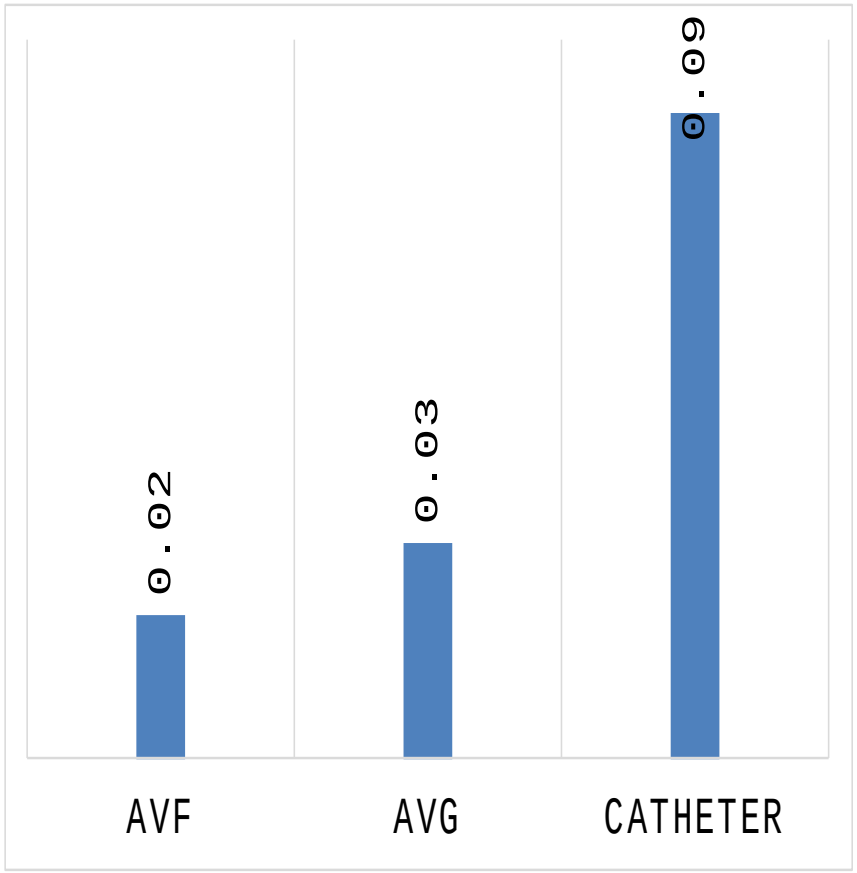
Outcomes by Access Type in the FMCNA Patients

Hospital Admissions
Per Patient Year



Blood Stream Infections
Per Patient Year



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Active FMCNA In-Center Patients as of 04/02/2018

Hospitalization and Catheter Related BSI Rates by Vascular Access Type

Table 1 Hospitalization and CRBSI rates by vascular access type

Rate	Fistula	Graft	Tunneled catheter	Nontunneled catheter
Hospitalization (Per 100 patient-months)	7.7	9.2	15.7	34.7
CRBSI (Per 100 patient-months)	0.5	0.9	4.2	27.1

Notes: Pooled mean data from the National Health and Safety Network allows for quantification of the rate of infection as it relates to access type. Adapted with permission from John Wiley and Sons from Klevens RM, Edwards JR, Andrus ML, et al. Special Report: Dialysis surveillance report: national healthcare safety network (NHSN)-data summary for 2006. *Semin Dial*. 2007;21(1):24–28.[5] Copyright © 2007 Blackwell Publishing.[5]
Abbreviation: CRBSI, catheter-related bloodstream infection.

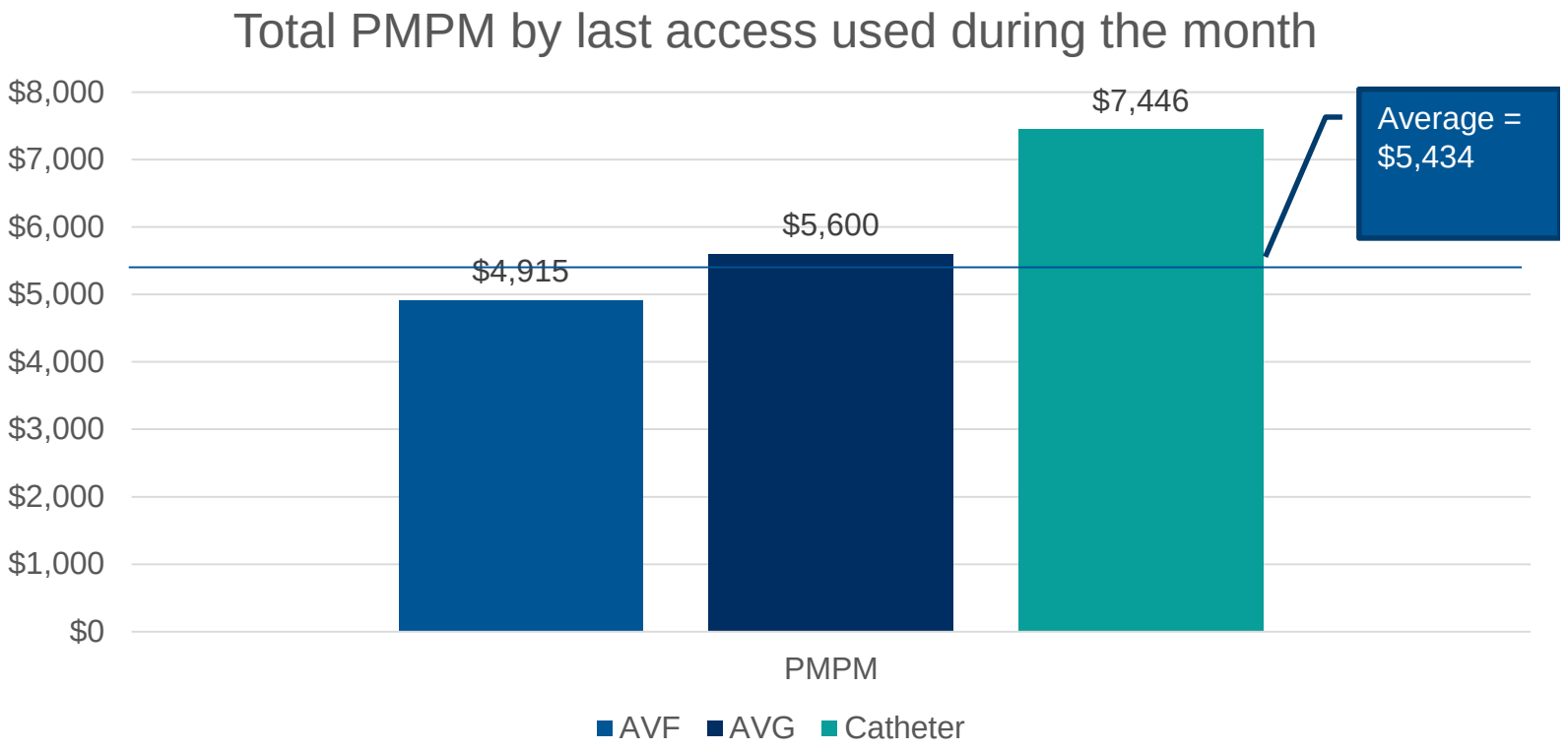
International Journal of Nephrology and Renovascular Disease Dovepress
REVIEW

Prevention of catheter-related bloodstream infections in patients on hemodialysis: challenges and management strategies

Soi V, et al. Int J Nephrol Renovasc Dis. 2016 Apr 18;9:95-103.

Access Type and Total Cost of Care: ESCO Data

ESCOs 1/1/2016-6/30/2016



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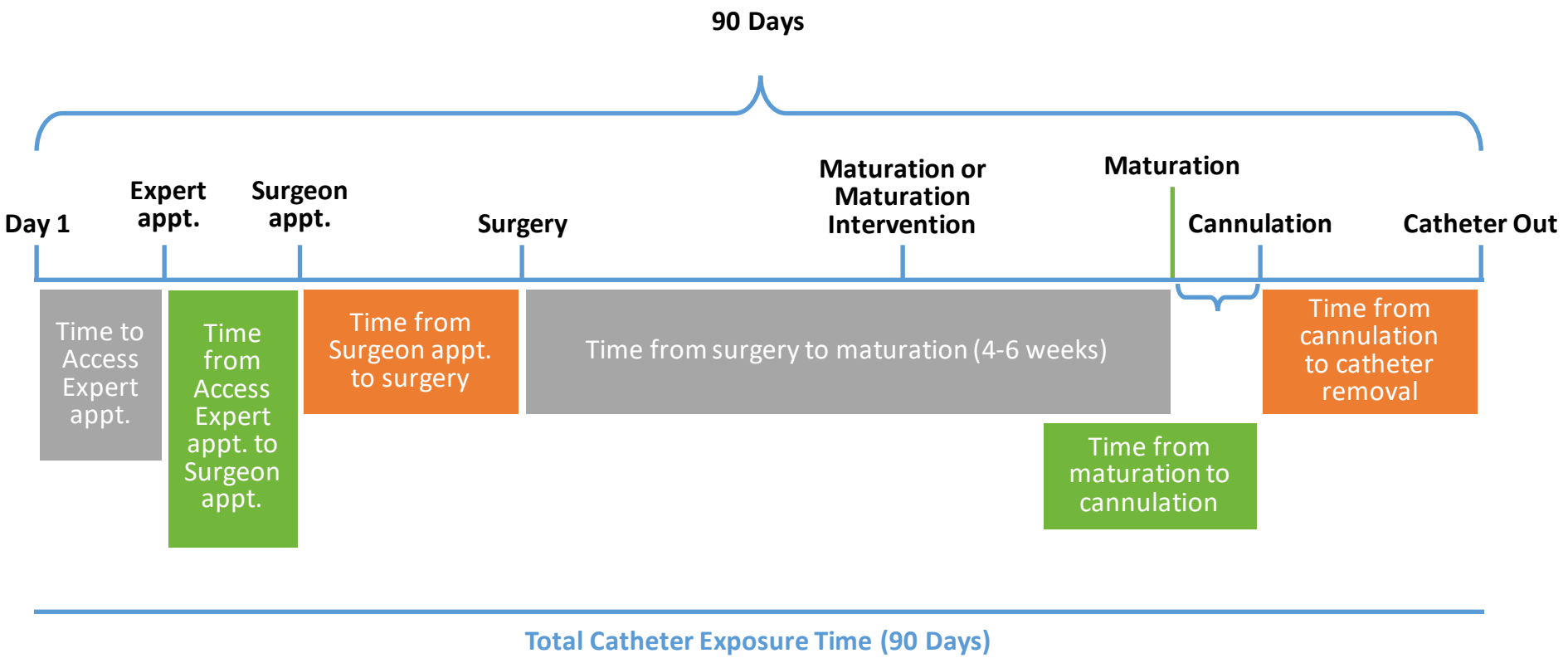
“Time To” Metrics: What Matters?



“Time To” Metrics: Outcomes

VAT Metric	Pilot Month 1 (median days)	Pilot Month 2 (median days)	Pilot Month 3 (median days)
Time from the first HD with CVC to VAE appointment	49	33	28
Time from VAE appointment to surgeon appointment	85	67	67
Time from surgeon appointment to surgery	41	29	29
Time from surgery to maturation	79	79	79
Time from maturation to cannulation	7	7	7
Total clinic CVC exposure time	**221**	**204**	**195**

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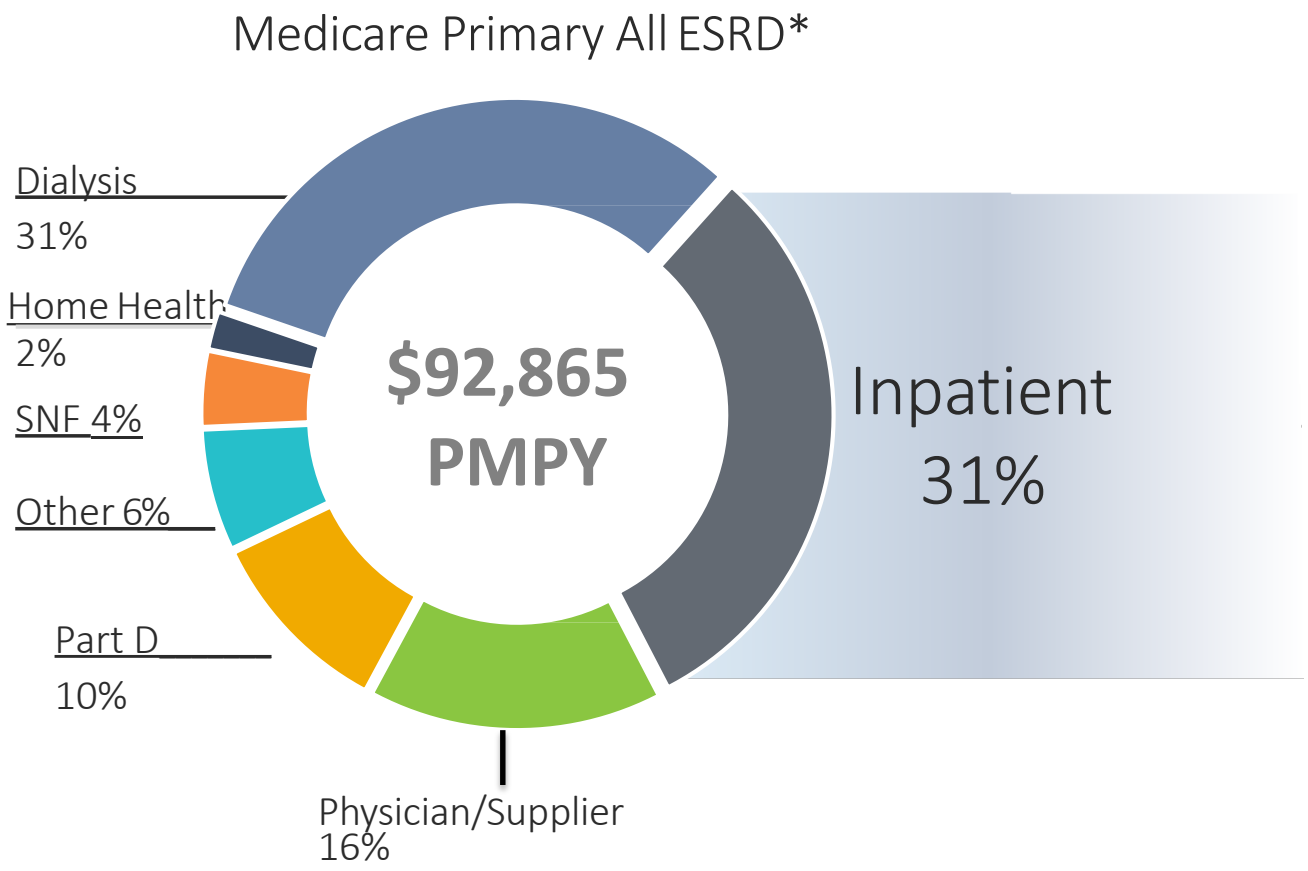
Cost Reduction
Opportunity with ESRD beneficiaries



*Source: 2017 USRDS:
https://www.usrds.org/reference.aspx

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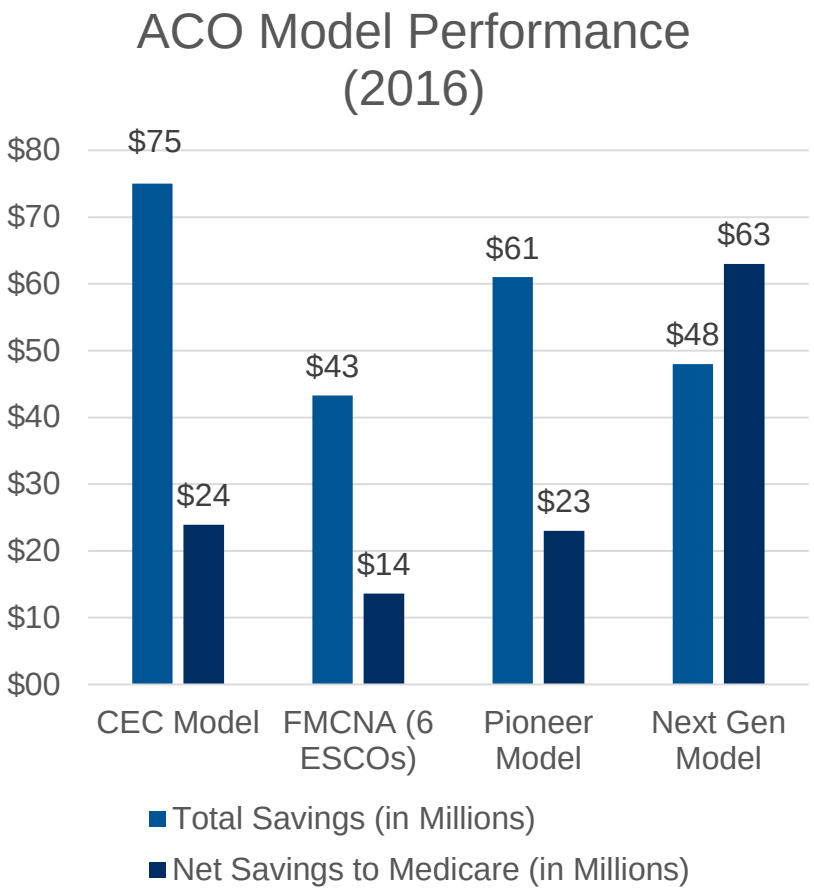
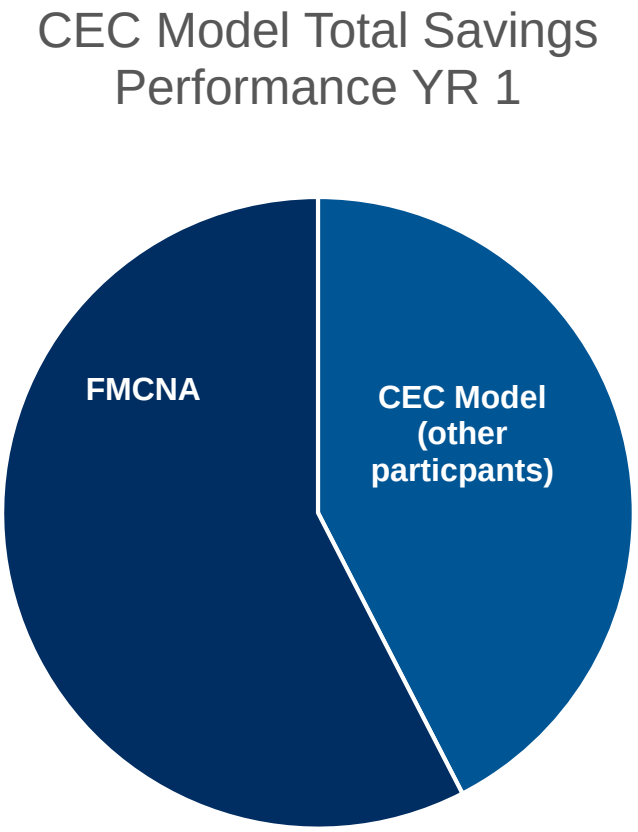
CEC Model Relative Performance

Renal focused value based care has great potential





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Vascular Access Innovation

Graft Material Enhancements

BARD · TERUMO · GORE · MERIT MEDICAL

Biological Grafts

HUMACYTE · Artegraft · LeMaitre VASCULAR · LifeNet Health (Saving Lives. Restoring Health. Giving Hope.) · CryoLife · AZIYO

Percutaneous Fistula Creation

AVENU MEDICAL · TVA medical

Fistula Maturation Enhancers

PROTEON Therapeutics · Vascular Therapies · Laminate Medical Technologies

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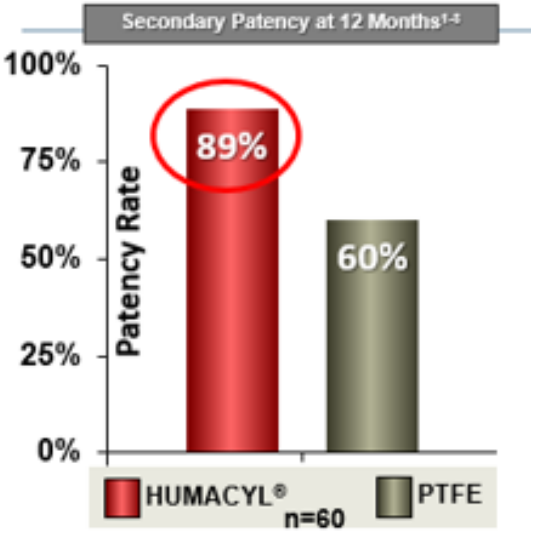
Biologics

- **Banked human vascular smooth muscle cells obtained from FDA-approved tissue banks**
- **Cells are seeded onto a biodegradable scaffold made of polyglycolic acid (PGA)**
- **Cultured in a bioreactor**
- **Cultured cells removed (10 wks.) via proprietary decellularization and wash process**
- **6mm diameter, 42 cm length, shipped in original single use bioreactor to Hospital OR**



- HUMACYL® Phase II Patients Prior Accesses = 2-9, avg. of 4, Published PTFE = 1-2

[2] Humacyte Phase II studies, The Lancet, volume 387, No. 10032, p2026-2034. Published in issue: May 14, 2016.

Percutaneous Creation

TVA medical

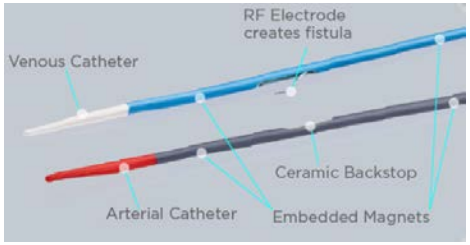
Technology: radio frequency ablation of tissue to create AVF

- **Endovascular device, utilizes two 6Fr magnetic catheters and a radiofrequency (RF) energy generator**
- **Received CE Mark, pending FDA**

Product: everlinQ endoAVF System

Headquarters: Austin, TX

Founded in 2008



AVENU MEDICAL

Technology: forearm catheter based fistula creation through heat annealing

- **Minimally invasive intravascular access, image-guided catheter system**
- **Received CE Mark, pending FDA (Phase III)**

Product: Ellipsys Vascular Access System

Headquarters: Orange County, CA

Founded in 2010

Ellipsys Power Controller

Ellipsys Catheter

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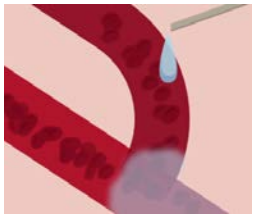
Vascular Maturation Enhancers

PROTEON Therapeutics

Technology: elastase inhibitor

- **One-time local application to the external surface of the blood vessel during creation of fistula**
- **Elastase applied externally on a fistula anastomosis to lyse elastin, promote outward remodeling, and reduce intimal hyperplasia**
- **Recent Phase III clinical trial failed to meet endpoint of improved primary patency, and had no reported impact on time to, or rate of, maturation**

Product: Vonapanitase

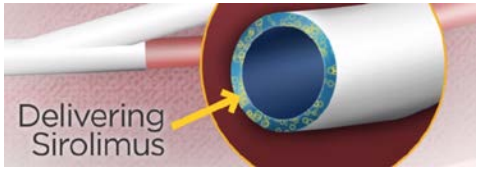


Vascular Therapies

Technology: sirolimus applied to anastomoses

- **Sirolimus in a collagen wrap, that is applied externally on a fistula anastomosis at implant, with the goal of aiding maturation**
- **Phase II study demonstrated an average 7-week maturation time, but still need to test whether treated vessels become suitable for cannulation and sustained use. Catheter use would be required during this extended maturation timeframe**

Product: Sirolimus Wrap

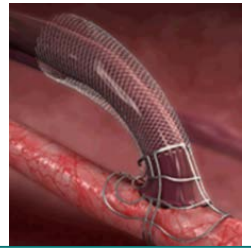


Laminate Medical Technologies

Technology: nitinol external support device

- **Nitinol external support device that is placed around the anastomosis and adjacent short segment of vein during AVF creation to constrain geometry and regulate flow, with the goal of aiding maturation (received CE Mark, pending FDA)**
- **This technology focuses only on the peri-anastomotic region, and the maturation process requires a biological process as well**

Product: VasQ



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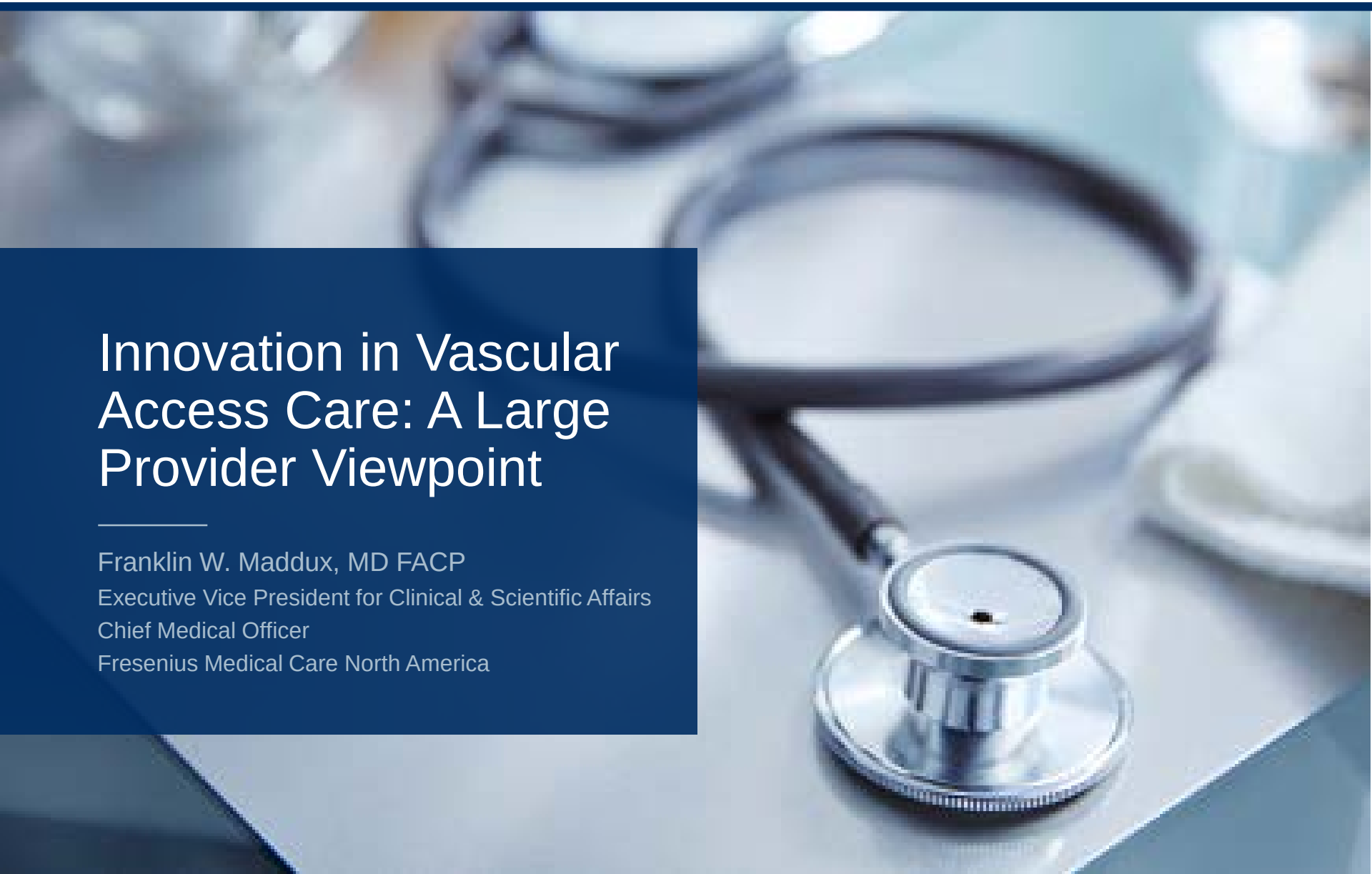

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