### Heimhämodialyse - Barrieren und Perspektiven Lernen von den Kollegen in den USA

Berliner Dialyse Seminar Saturday, December 3<sup>rd</sup>, 2022

Peter Kotanko, MD FASN Renal Research Institute New York, NY





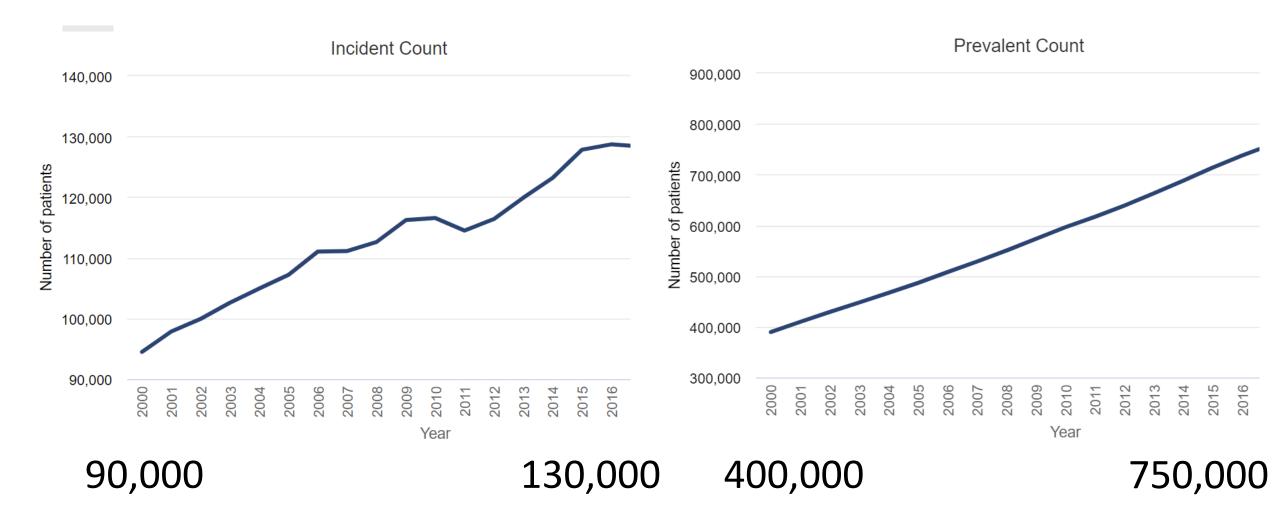
### Potential conflicts of interest declaration

The content of the following speech is the result of efforts to achieve the maximum degree of impartiality and independence.

As a speaker, I wish to point out that there are <u>personal connections</u> to companies whose products are of interest within the context of the following speech. The companies concerned and connections are listed below:

Companies	Connections  (Fee for activities associated with lecturing and in an advisory capacity expert reports and work as an author; fee for preparing training programmes; reimbursement for travel and accommodation costs; reimbursement of participation fees regarding training courses; patents; money from licences and royalties; fee for undertaking commissioned studies; receipt of research funds, etc.)
Fresenius Medical Care (FMC)	I am an employee of the Renal Research Institute, a wholy owned subsidiary of FMC. I hold stock in FMC.

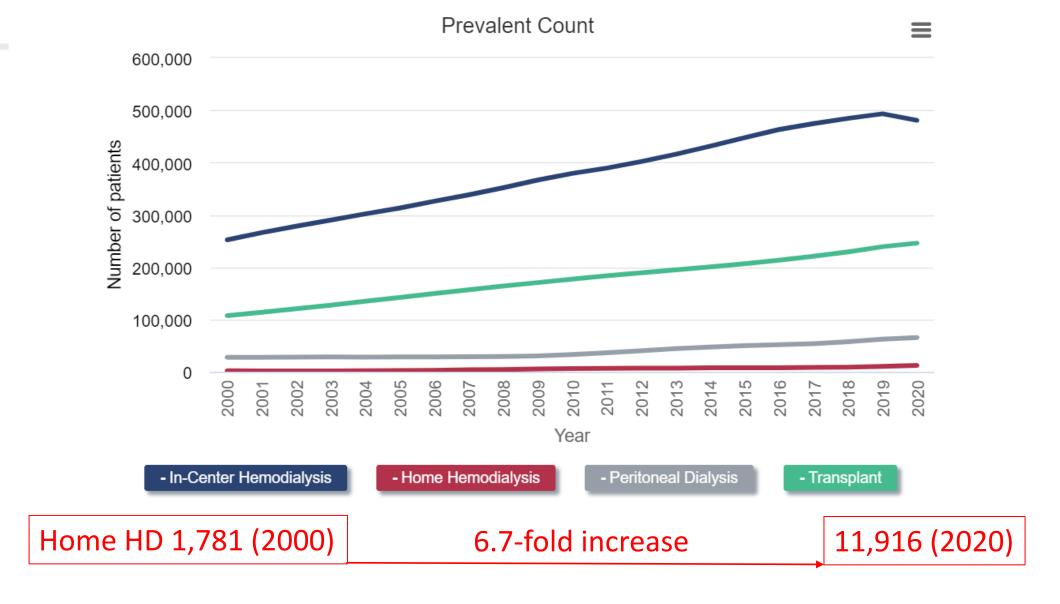
### Incidence and Prevalence of ESKD in the US





### Prevalence by Treatment Modality







# 91% of doctors would choose home dialysis

With home dialysis, people have greater flexibility and may be less restricted by diet, require fewer medications, and experience reduced hospitalizations—so they can stay their healthiest and feel their best.

Home dialysis advertisement by dialysis provider. (Scientific American, December 2022)

### Agenda



Epidemiology and trends of home hemodialysis (HHD) in the U.S.

**Obstacles to HHD** 

Path towards success

### Agenda



Epidemiology and trends of home hemodialysis (HHD) in the U.S.

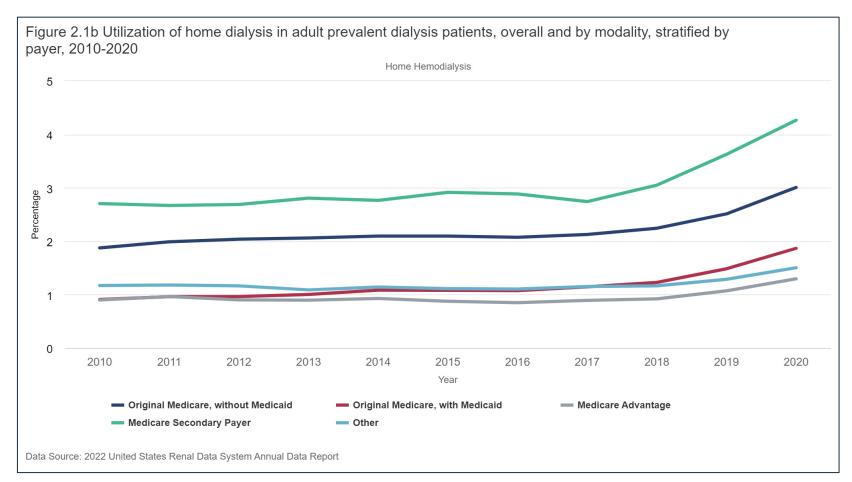
General trends over the past decade
Time to HHD initiation
Conversion from HHD to in-center HD

Obstacles to HHD
Path towards success

### Home hemodialysis (HHD) evolution over time

Over the last decade, HHD has grown in the United States because of

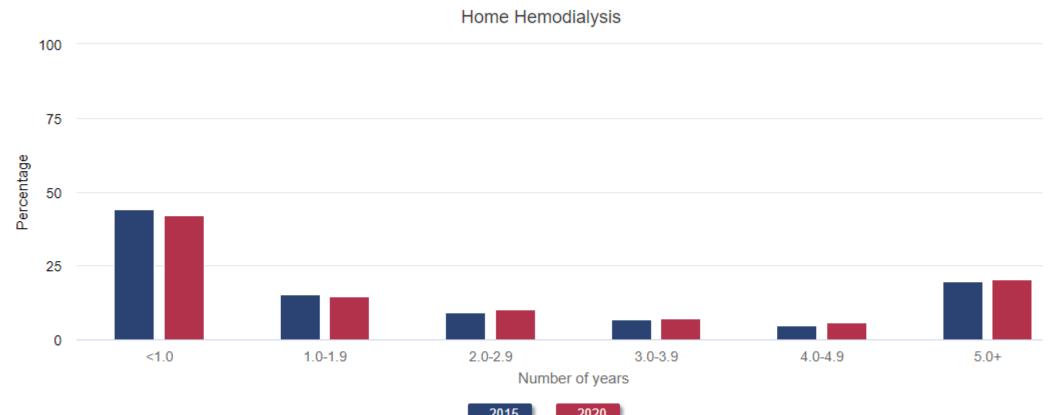
- better dialysis technology,
- transition to valuebased care,
- an increased focus on clinical benefits.



https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/2-home-dialysis



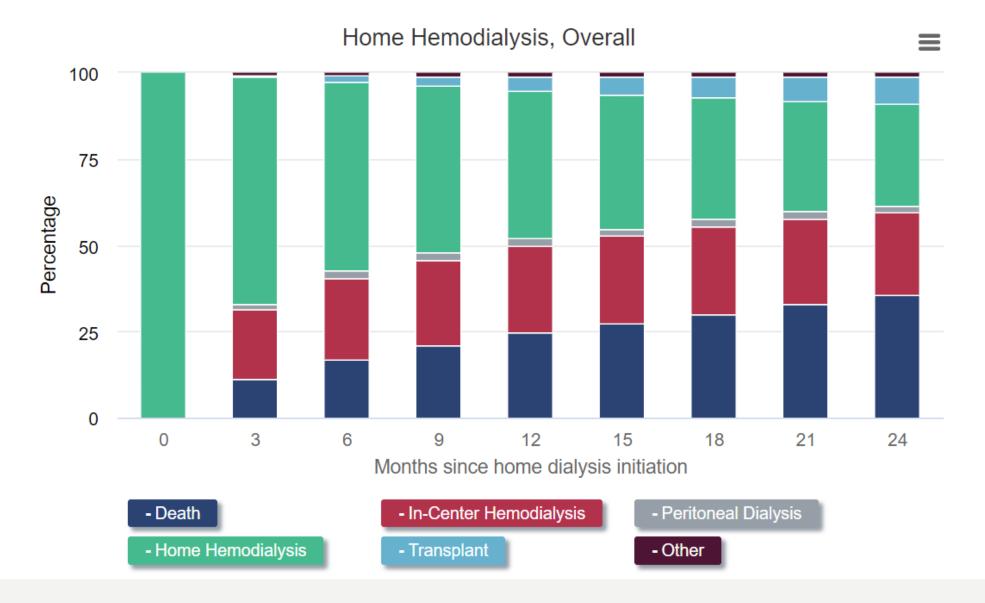
### Years between ESRD incidence and HHD initiation in adult patients (2015-20): "early" vs. "late" HHD



Data source: USRDS ESRD Database. ESRD patients aged ≥18 years initiating home dialysis in 2015 and 2020.



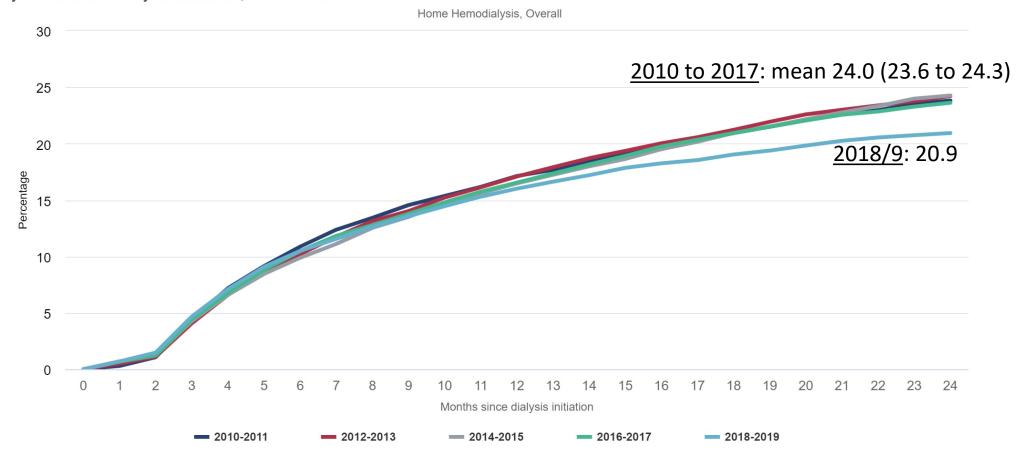
#### Outcomes after HHD initiation





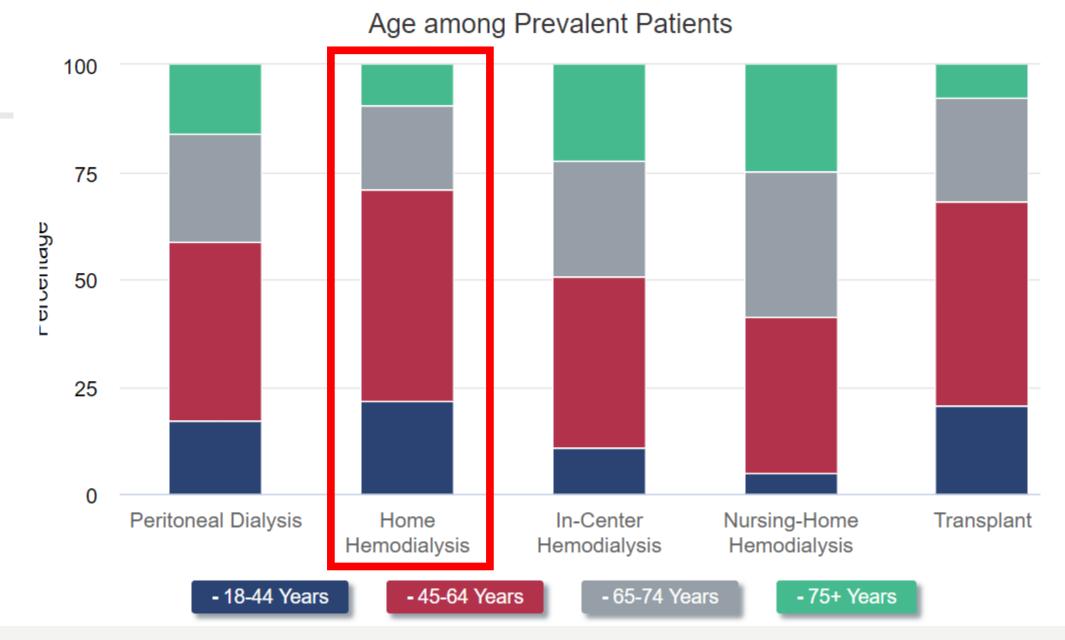
### Less conversion from HHD to ICHD, Overall

Figure 2.14 Cumulative incidence of conversion from home dialysis to in-center hemodialysis, by modality and year of home dialysis initiation, 2010-2019



Data Source: 2022 United States Renal Data System Annual Data Report







### Less conversion from HHD to ICHD, by Age



Data source: USRDS ESRD Database. ESRD patients aged ≥18 years initiating home dialysis in 2010-2019. In subgroups defined by age, sex, race/ethnicity, and primary cause of ESRD, only patients who initiated home dialysis in 2018-2019 are included in the figure. Estimated using the cumulative incidence function with death and kidney transplantation treated as competing risk events.



### Agenda

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Epidemiology and trends of home hemodialysis (HHD) in the U.S.

#### **Obstacles to HHD**

Workforce related

Patient and caregiver related

Finances and administration

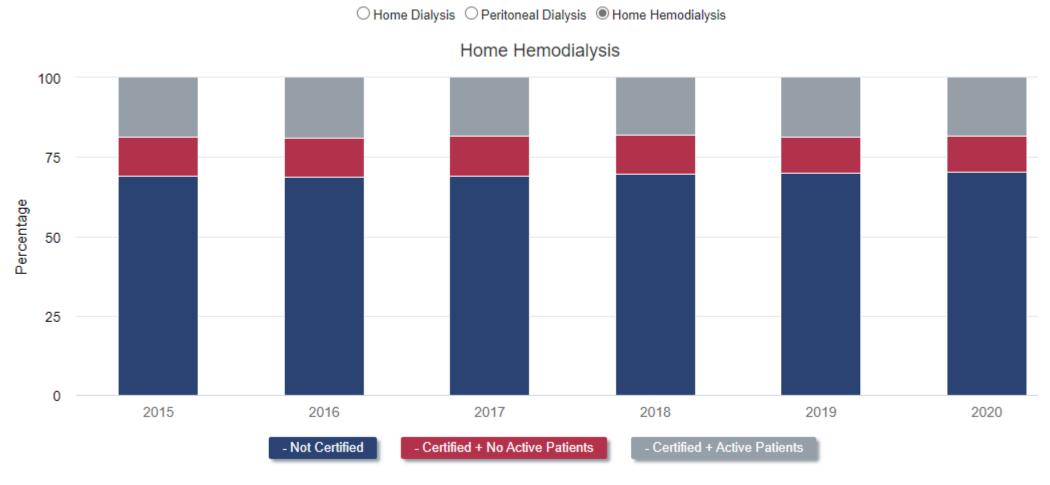
Path towards success

### Barriers: The workforce perspective

Barriers	<b>Opportunities</b>
Lack of physician training (education)	<ol> <li>Mandate exposure to home therapies in fellowship</li> <li>HHD questions on American Board of Internal Medicine (ABIM) exams</li> <li>Project ECHO (Extension for Community Healthcare Outcome): virtual platform that connects HHD experts to less experienced clinicians</li> <li>3rd year special fellowship focused on home therapies</li> </ol>
Difficulties with HHD nurse recruitment	<ol> <li>Cross training of home modalities</li> <li>Increase application of virtual care</li> </ol>
Lack of nurse education	<ol> <li>Mandatory webinars (e.g., Advanced Renal Education Program)</li> <li>Attendance at conferences focused on home therapies, e.g., ADC</li> <li>Payment for more education days</li> </ol>



### Facility certification to offer HHD and delivery of HHD (2015-2020): still many non-certified centers

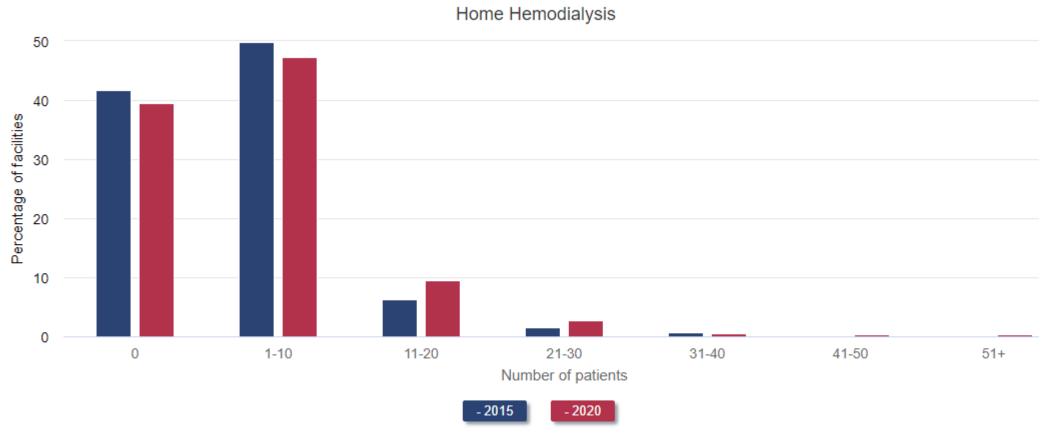


Data source: Dialysis Facility Compare (April 2022) and Dialysis Facility Report (Fiscal Year 2022) data.



Number of HHD patients per certified facility (2015-20): Most centers are small (less than 10 patients).

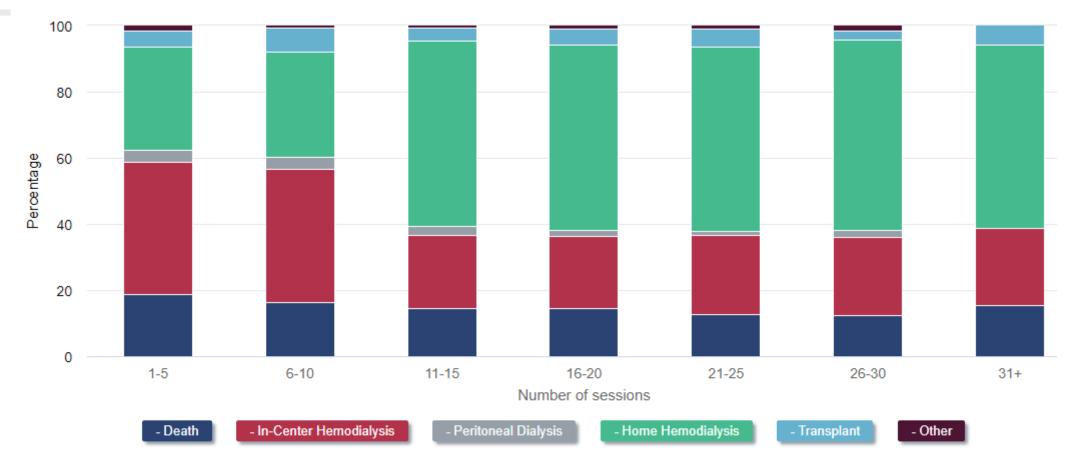
A slight upward trend of facilities with > 20 patients in 2020.



Data source: USRDS ESRD Database and Dialysis Facility Compare (April 2022) data. Point prevalent ESRD patients receiving dialysis on December 31, 2015 and 2020.



### Outcomes at one year after HHD training, by number of training sessions (2019): <u>higher drop-out rate with < 10 sessions</u>



Data source: USRDS ESRD Database. ESRD patients aged ≥18 years, with Medicare FFS coverage (Parts A and B), initiating home hemodialysis in 2019, and with last training session in 2019.



### **Barriers**: the Patients and Caregivers Aspect

Barriers	Opportunities
Lask of mations arranges	1. In-hospital education
	2. Transitional care units/ETD
Lack of patient awareness	3. Expand Kidney Dialysis Education, drop co-pay
	4. Standardized HHD training curriculum
Cognitive / Physical barriers	1. Assisted HHD – allow staff other than registered nurses
	2. Learning assessment/increased training period
Patient Fear	In-center self-care training ("Experience the Difference")
Inappropriate home setting	Community house dialysis
Reducing Burden	1. Caregiver mental health support HHD respite
	2. Device innovation to decrease burden



### Patient and Caregiver Concerns

- Lack of adequate training
- Feeling of isolation after transitioning to home
- Lack of confidence
- Fear of harming self / patient in treatment
- Afraid to ask for help
- Not familiar with assistance offers



### **Barriers**: Finances and Administration

Barriers	Opportunities
Financial reimbursement	<ol> <li>Incentive to hospitals: increase length of stay for in-hospital education and permanent access creation</li> <li>Incentive to nursing homes: increased payment for each HHD patient</li> <li>Implement HDPA (ESKD Treatment Choices model) to provide physicians with capital to develop home therapy infrastructure</li> <li>Revise Medicare, so cost savings in one part can be applied to another Part</li> <li>Implement Kidney Care Choices model to allow greater payment for CKD care coordination</li> <li>Rebate for length on HHD</li> </ol>
Medicare Administrative Contractor / Local Coverage Determinations	<ol> <li>Centers for Medicare and Medicaid Services (CMS) provides one national Local Coverage Determinations to cover more frequent dialysis (MFD)</li> <li>Standardize documentation/frequency required for MFD</li> <li>Establish national registry of MFD patients to follow</li> </ol>



### Agenda

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Epidemiology and trends of home hemodialysis (HHD) in the U.S.

**Obstacles to HHD** 

Path towards success

**Political will** 

Interdisciplinary, patient-centric team

**Technology** 

Workforce

**Patient awareness** 

### Political & Societal Support: The Advancing American Kidney Health Initiative (AAKHI)

Enacted as an executive order on July 10<sup>th</sup>, 2019, the AAKHI has focused much needed attention on patients with CKD and ESKD.

Specifically, one of the goals of the initiative is for 80% of patients with incident ESKD to receive either home dialysis or kidney transplantation by the end of year 2025.





### Incentives to dialyze at home



The bundled payment also includes a training add-on payment adjustment for home and self-dialysis modalities. The base rate for one HD is \$265.57.

CMS announcing the **ESRD Treatment Choices** (ETC) Model that went into effect January 1, 2021.

The ETC promotes greater use of home dialysis and kidney transplants for Medicare beneficiaries with ESRD in order to preserve or enhance their quality of care while reducing Medicare expenditures.

payment adjustment for new and innovative equipment and supplies (TPNIES)

Expansion of the TPNIES to Include Capital-Related Assets that are Home Dialysis Machines
When Used in the Home for a Single

Patient: CMS is expanding eligibility for the
TPNIES to include certain capital-related assets that are home dialysis machines when used in the home for a single patient.



### **Technology: HHD Platforms in the U.S.**

#### Three HHD platforms approved by the FDA:

- NxStage System One
- Fresenius 2008K@home
- Tablo Hemodialysis System

The NxStage system has a specific approval for nocturnal dialysis and does not require a partner.

Most U.S. HHD patients (98%) use the NxStage platform



**NxStage System One** 



Fresenius 2008K@home



Tablo Hemodialysis
System



### Successful HHD requires an interdisciplinary, patient-centric team

Successful HHD is a consequence of an interdisciplinary dialysis team, consisting of

- "at home" team; it comprises the patient and close family member or friend (the care partner),
- technicians,
- social service,
- dieticians,
- subspecialty HHD nurses and physicians



#### Vascular access

Catheters remain an important and significant access for HD; acceptable access to initiate HHD while AV access planning, creation, and cannulation training are in process

**Cannulation training** of the patient or caregiver needs to be implemented after access creation. AV access cannulation is the rate-limiting step for transition to HHD

Natural fear of cannulation that needs to be alleviated to avoid complications.

Choose a correct needle size according to dialysis prescription.

**AVF cannulation techniques**: "rope-ladder"; "buttonhole technique"; avoid "Area" cannulation.

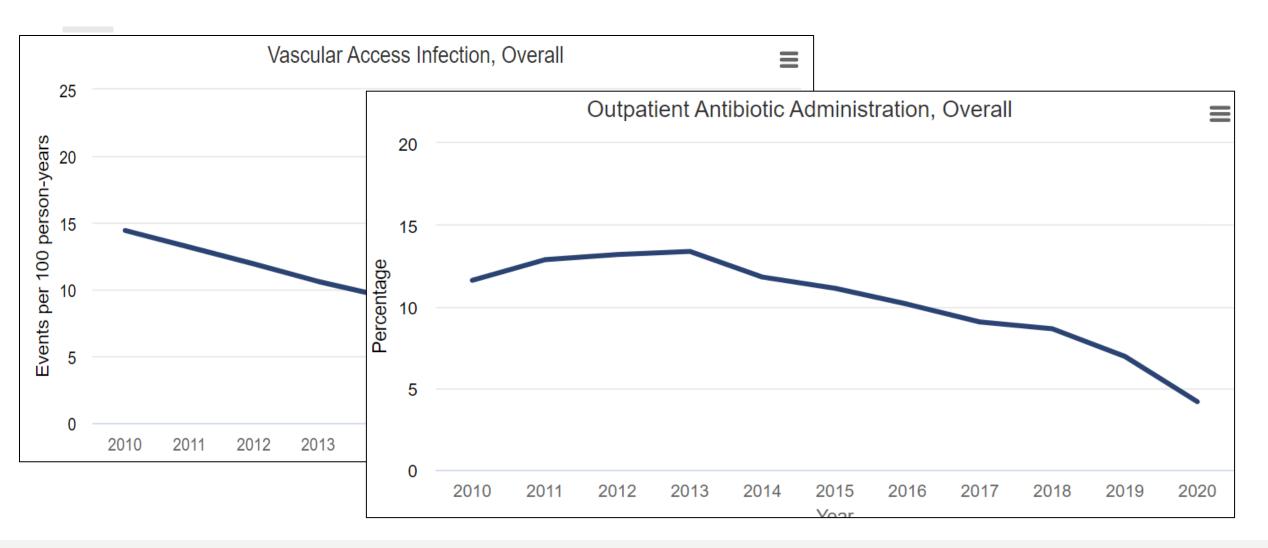
The use of a constant site, angle, depth, and direction of a sharp needle are essential when creating a buttonhole. Generally, 8-10 initial sharp cannulations are required for adequate development of the track that would accommodate the blunt needle.

Often, a second set of buttonholes is recommended, but without regular use

Another important aspect of cannulation of buttonhole is **removal of the scab** with a separate needle before blunt needle cannulation.



### Complication rate is declining





### HHD Retention analysis (Blankenship, ASN 2022)

**Cohort:** 3,434 adult FKC patients who started training for HHD from 2016 through 2019 and completed training with ≥ 1 recorded treatment at home.

Outcome: Time to transition to in-center hemodialysis (IHD).

Factor	Level	Hazard Ratio
Age	<45 Years	Reference
	45-54 Years	1.19
	55-64 Years	1.16
	65+ Years	1.46
Dialysis vintage	<6 Months	Reference
	6 Months-1 Year	0.89
	1-3 Years	0.69
	3+ Years	0.59
Gender	Female	Reference
	Male	1.55
Race	White	Reference
	Black	0.69
	Other	0.97
	Unknown	0.77
Ethnicity	Hispanic or Latino	Reference
	Not Hispanic or Latino	0.89
	Unknown	0.89
ВМІ	<25	1.02
	25-29.9	Reference
	30-34.9	1.05
	35+	1.40
	Unknown	1.44
Dual Medicare/Medicald	No	Reference
Enrollment at baseline	Yes	0.93
Year of first training	2016-17	Reference
	2018	1.03
	2019	1.32

Factor	Level	Hazard Ratio
Vascular access at baseline	Fistula	Reference
	Catheter	0.88
	Graft	1.24
Diabetes/HbA1c at baseline	No diabetes at baseline	Reference
	Diabetes, HbA1c <6	1.20
	Diabetes, HbA1c 6 to <7	1.25
	Diabetes, HbA1c 7 to <8	0.99
	Diabetes, HbA1c 8+	1.12
	Diabetes, w/o HbA1c	0.87
Heart fallure at baseline	No	Reference
	Yes	0.87
Employment	Employed	Reference
	Unemployed	1.24
	Disabled	1.21
	Other	0.73
	Unknown	0.77
Education	High school or less	Reference
	Some college	1.16
	College or vocational or graduate school	0.96
	Unknown	0.91
Relationship	Partnered	Reference
	Single (single, widowed, divorced, separated) or Unknown	1.45
PHQ	3+	0.77
	<3	Reference
	Not collected	1.26

### Color Legend Protective Effect (p<0.05) Risk Factor (p<0.05)

Factor	Level	Hazard Ratio
Albumin	<3.5	Reference
	3.5-3.9	1.17
	4+	0.75
Phosphorous	5.5 or Less	Reference
	>5.5	1.28
Dialysis frequency	<4 sessions/week	Reference
	4 to <5 sessions/week	0.73
	5 to <6 sessions/week	0.96
	6 to 7 sessions/week	0.75
Frequency change	No	Reference
	Yes	0.90
Dialysate volume	<40L	Reference
	40L+	0.79
Kru	0 Kru	Reference
	>0 to <2	0.84
	2+	0.62
Standardized Kt/V	<2.1	1.01
	2.1 - 2.3	0.93
	2.3+	Reference
	Unknown	0.42
Number of training sessions	<15	0.82
	15 - 25	Reference
	>25	1.04
Any hospitilizations in last	No	Reference
quarter	Yes	1.18
Cumulative BSIs	0	Reference
	1	0.89
	2+	1.35
Number of ICHD treatments per	0	Reference
quarter	>0	2.70
Technical support calls per	0	Reference
quarter	0-1	0.67
	2-5	0.53
	6+	0.38



### Factors related to HHD Drop-out (Blankenship, ASN 2022)

#### **Risk Factors**

- Male sex
- Single household (single, divorced, widowed, separated, or unknown)
- Previous in-center dialysis

#### **Protective Factors**

- Dialysis vintage > 5 years
- African American
- Technical support calls > 0 per week



### Outlook

#### HHD is expected to grow though

a) Higher enrollment rates

"Home first" mindset

Transition clinics

b) Sophisticated retention strategies

Al-driven early attrition warning system

24/7/365 call center support

Outbound, open-ended check-up calls to validate patients are experiencing the benefits of HHD and to address and resolve any concerns

Outreach calls to create a sense of "we care" (in contrast to passive inward calls)

c) Workforce recruitment and retention:

Specialized home dialysis nephrologist

Virtual training; online courses



### Acknowledgements

Dr. Michael Kraus (NxStage & Indiana University Health North Hospital)

**Contact** 

Peter.Kotanko@rriny.com





### Backup slides

## Prescribed number of treatments per week in adult patients performing HHD (2015-20) – Overall: <u>less than 4 sessions / week is declining</u>



Data source: Centers for Medicare & Medicaid Services End Stage Renal Disease Quality Reporting System. Period prevalent ESRD patients aged ≥18 years receiving home hemodialysis in 2015 and 2020.



### Prescribed number of treatments per week in adult patients performing HHD (2015-20) – By Age



Data source: Centers for Medicare & Medicaid Services End Stage Renal Disease Quality Reporting System. Period prevalent ESRD patients aged ≥18 years receiving home hemodialysis in 2015 and 2020.

