

NxStage System One®  
**FIRST** and **ONLY**  
CLEARANCE FOR HOME  
**nocturnal**  
HEMODIALYSIS THERAPY

IMPROVING *lives.*



INVENTING *a movement.*

INSPIRING *everyone.*



# HOME HEMODIALYSIS CLINICAL EVIDENCE

PART 2: BREAKING DOWN THE  
PRESCRIPTION BARRIERS TO HOME  
HEMODIALYSIS

*Nx*STAGE®

# Important information

Despite the health benefits that more frequent home hemodialysis may provide to those with chronic kidney disease, this form of therapy is not for everyone. Home hemodialysis with the NxStage System One requires a patient and partner who are committed to being trained on and following the guidelines for proper system operation.

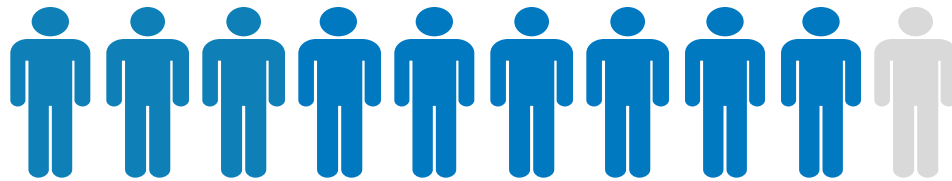
The reported benefits of home hemodialysis may not be experienced by all patients.

The NxStage System One is a prescription device and, like all medical devices, involves some risks. The risks associated with hemodialysis treatments in any environment include, but are not limited to, high blood pressure, fluid overload, low blood pressure, heart-related issues, and vascular access complications. The medical devices used in hemodialysis therapies may add additional risks including air entering the bloodstream, and blood loss due to clotting or accidental disconnection of the blood tubing set. Patients should consult with their doctor to understand the risks and responsibilities of home and/or more frequent hemodialysis using the NxStage System One.

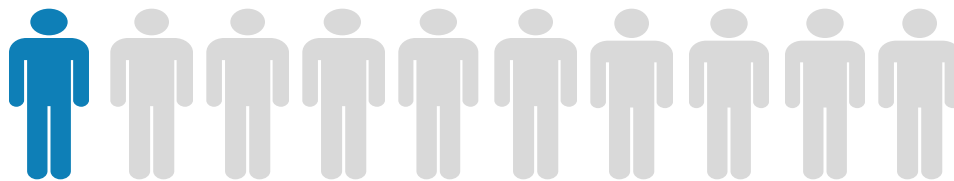
Certain risks are unique to the home. Treatments at home are done without the presence of medical personnel and on-site technical support. Patients and their partners must be trained on what to do and how to get medical or technical help if needed.

Certain risks associated with hemodialysis treatment are increased when performing nocturnal therapy due to the length of treatment time and because therapy is performed while the patient and care partner are sleeping. These risks include, but are not limited to, blood access disconnects and blood loss during sleep, blood clotting due to slower blood flow or increased treatment time or both, and delayed response to alarms when waking from sleep. Patients should consult with their physician to understand the risks and responsibilities associated with home nocturnal hemodialysis using the NxStage System One.

# Current Dialysis Situation by Modality in the United States



**88%** | In-center dialysis treatment

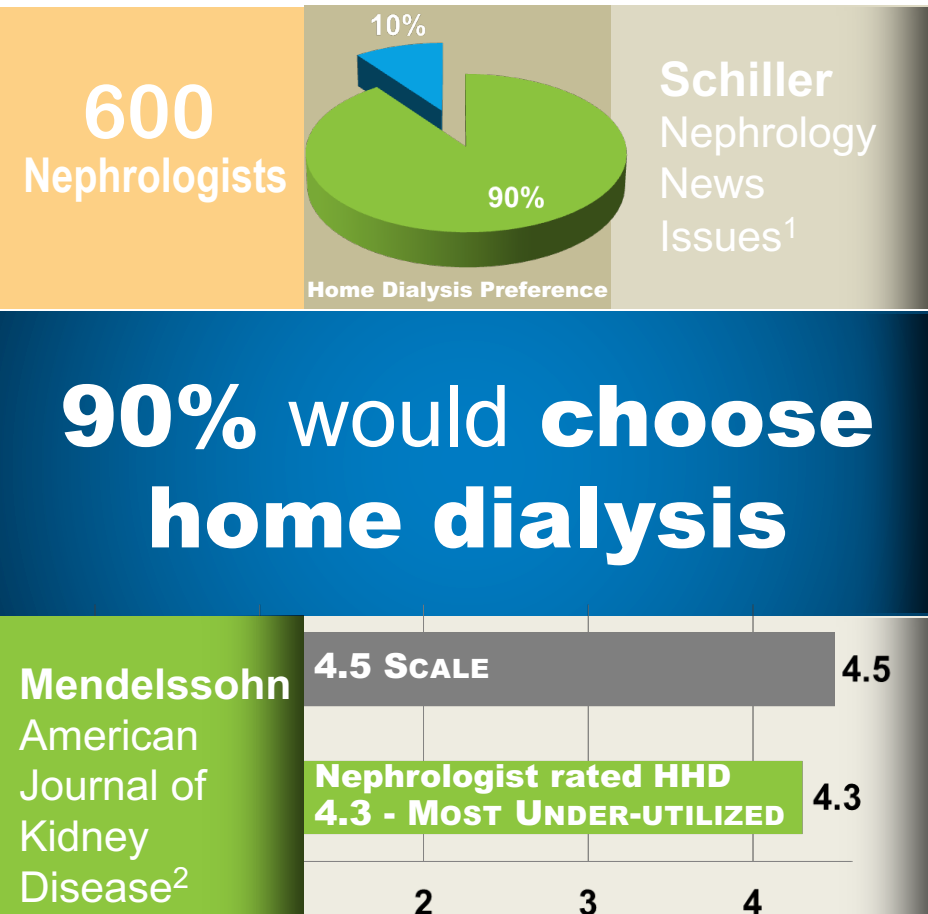


**10%** | Peritoneal dialysis



**2%** | Home hemodialysis

# What Nephrologists Would Choose for Themselves Should be Considered



- A significant majority of nephrologists agree...
  - Home dialysis therapies are an effective alternative to in-center treatments
- Broader access to home therapies is essential
  - 26% of ESRD providers offer home hemodialysis
  - 49% are certified to offer PD<sup>3</sup>

<sup>1</sup>Schiller B, Neitzer A, Doss S. Perceptions about renal replacement therapy among nephrology professionals. Nephrol News Issues. 2010; 24(10):36-44.

<sup>2</sup>Mendelssohn DC, et al. What do American Nephrologists think about dialysis modality selection? Am J Kidney Dis. 2001;37(1):22-29.

<sup>3</sup>Dialysis Facility Compare Website provided by the Centers for Medicare & Medicaid Services. Updated July 14, 2014.

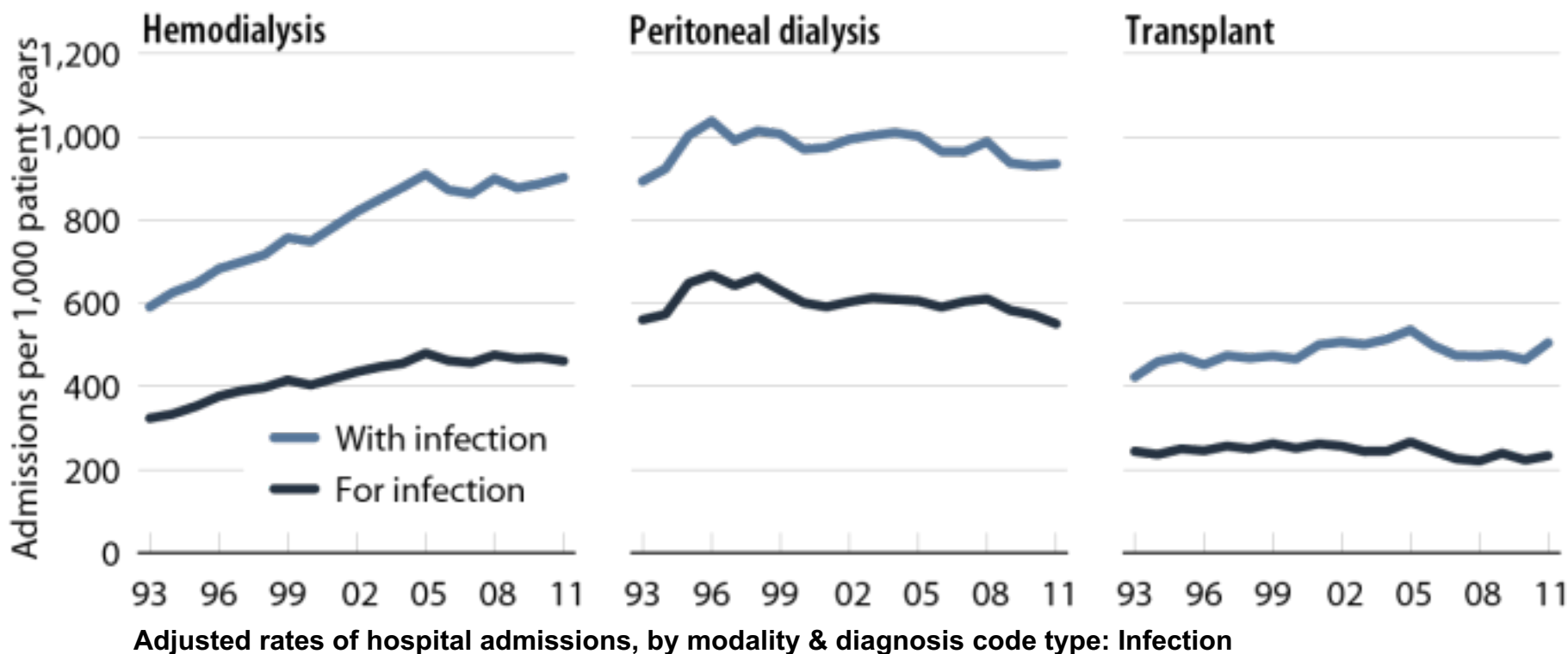


# Possible Explanations for Low Home Dialysis Penetration

- Misconceptions about safety and efficacy across dialysis modalities
- Perceived patient capabilities to perform therapy
- Lack of fair and equal patient education about therapy options

# Making Strides Towards Infection Prevention

# Infection Rates Are Prevalent Across Continuum of ESRD Care



***Infection risk should be appropriately discussed with respect to modalities***

USRDS 2013 ADR. Figure 3.4 (Volume 2)

Period prevalent ESRD patients. Adj: age/gender/race/primary diagnosis; ref: ESRD patients, 2010.

# Lower All-cause Mortality Risk

## Compared to Thrice-weekly In-center Hemodialysis

### JASN Clinical Research:

Survival in Daily Home Hemodialysis and  
Matched Thrice-weekly In-center Hemodialysis  
Patients

	HR (95% CI)
All-cause mortality	0.87 (0.78–0.97)
Cause-specific mortality	
cardiovascular disease	0.92 (0.78–1.09)
infection	1.13 (0.84–1.53)
cachexia/dialysis withdrawal	0.63 (0.41–0.95)
other specified cause	1.06 (0.81–1.37)
unknown cause	0.59 (0.44–0.79)

- Overall, more frequent home hemodialysis (HHD) was associated with a 13% lower risk for all-cause mortality
- However HHD infection-related mortality risk was 13% higher than in-center therapy

# Mitigating Infection Risk

- Historically, peritoneal dialysis had been linked to concerns of increased infection rates
- Implement to improve
  - Standardized infection control procedures
  - Best accepted practices
  - Technological advancements
- Apply learnings from hospitals and outpatient care settings

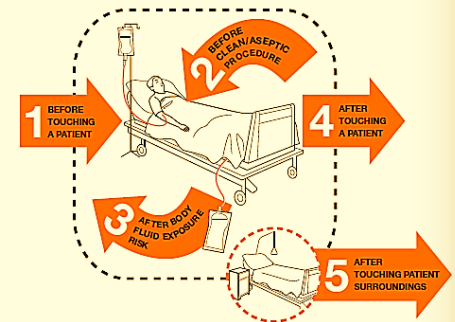
***Appropriate technique helps reduce infection-related risk factors***

PD THEN	➔	1:12 MONTHS
PD NOW	➔	1:36 MONTHS

***Implement to  
Improve***



## My 5 Moments for Hand Hygiene

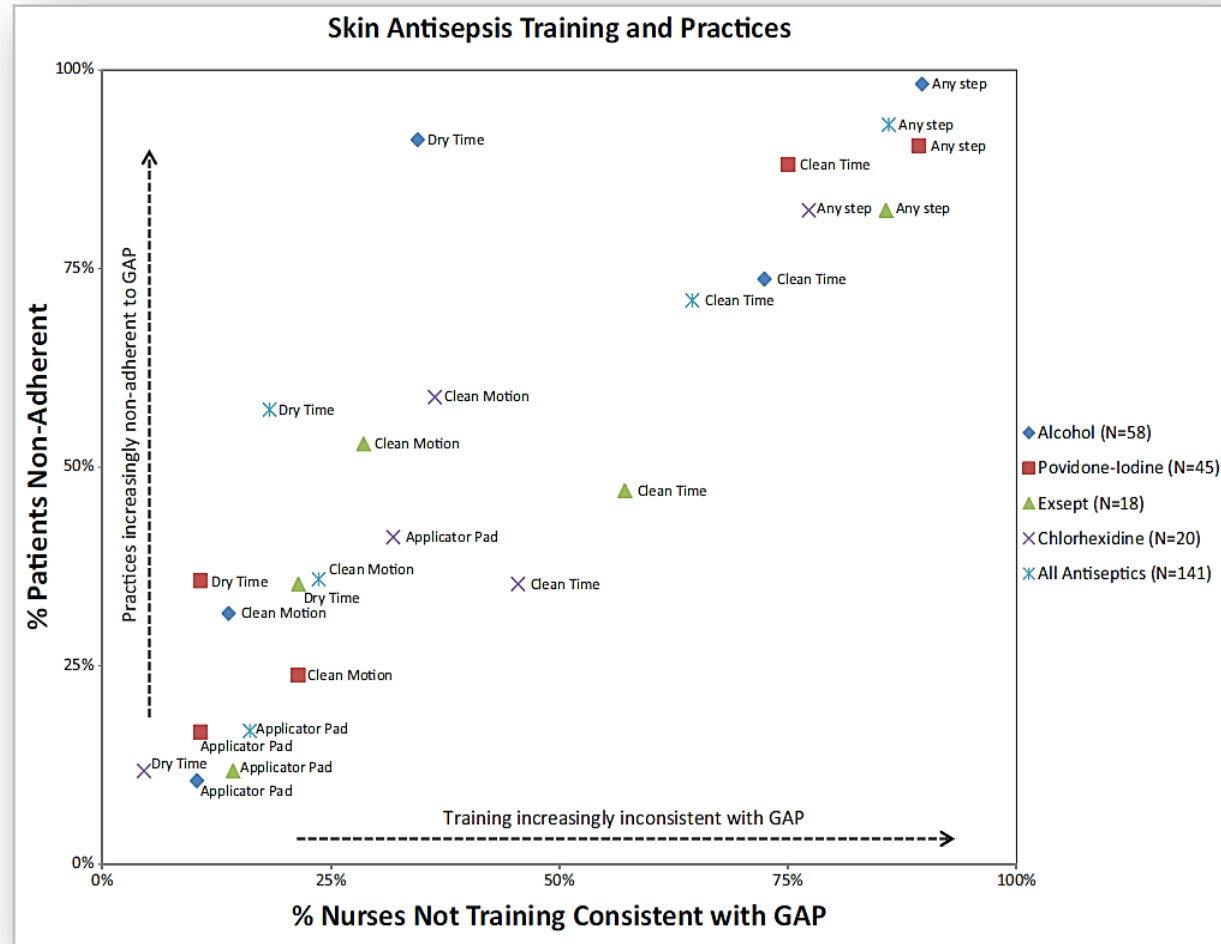




# Consistency of Home Hemodialysis Training and Practice Adherence

**Hemodialysis International:**  
Survey of home hemodialysis patients and nursing staff regarding vascular access use and care

*When aggregating all access cannulation steps surveyed, **not a single patient OR nurse** reported performing **ALL steps in accordance WITH Generally Accepted Practices.***



# Addressing Consistent Training and Patient Protocol Adherence

## Home hemodialysis education programs

- More consistently applied training
- Further uniformity in infection control adherence at home

## NxStage efforts

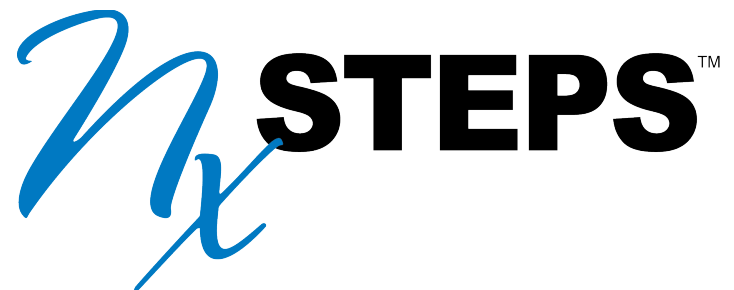
- Expanded infection prevention materials
- Nx2me<sup>®</sup> Connected Health
- Enhanced home hemodialysis nurse training curriculum

Vascular Access Checklist



Fistula or Graft Access Preparation / Cannulation

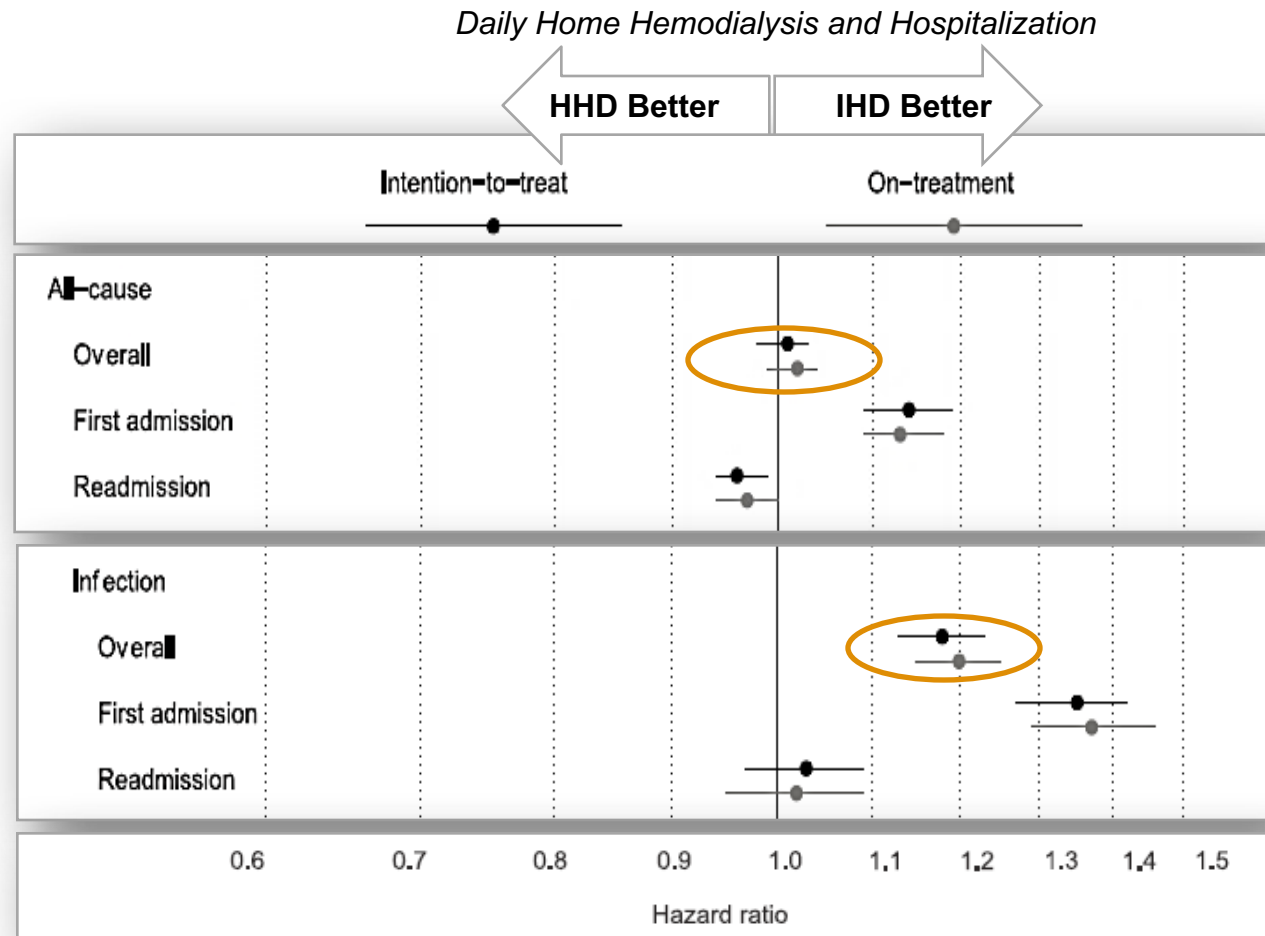
Catheter Connection



# Added Efforts Should Improve Infection Rates

**AJKD Original Investigation:**  
Hospitalization in Daily Home Hemodialysis and Matched Thrice-weekly In-center Hemodialysis Patient

*All-cause hospitalization rates for home hemodialysis are similar as compared to in-center hemodialysis*

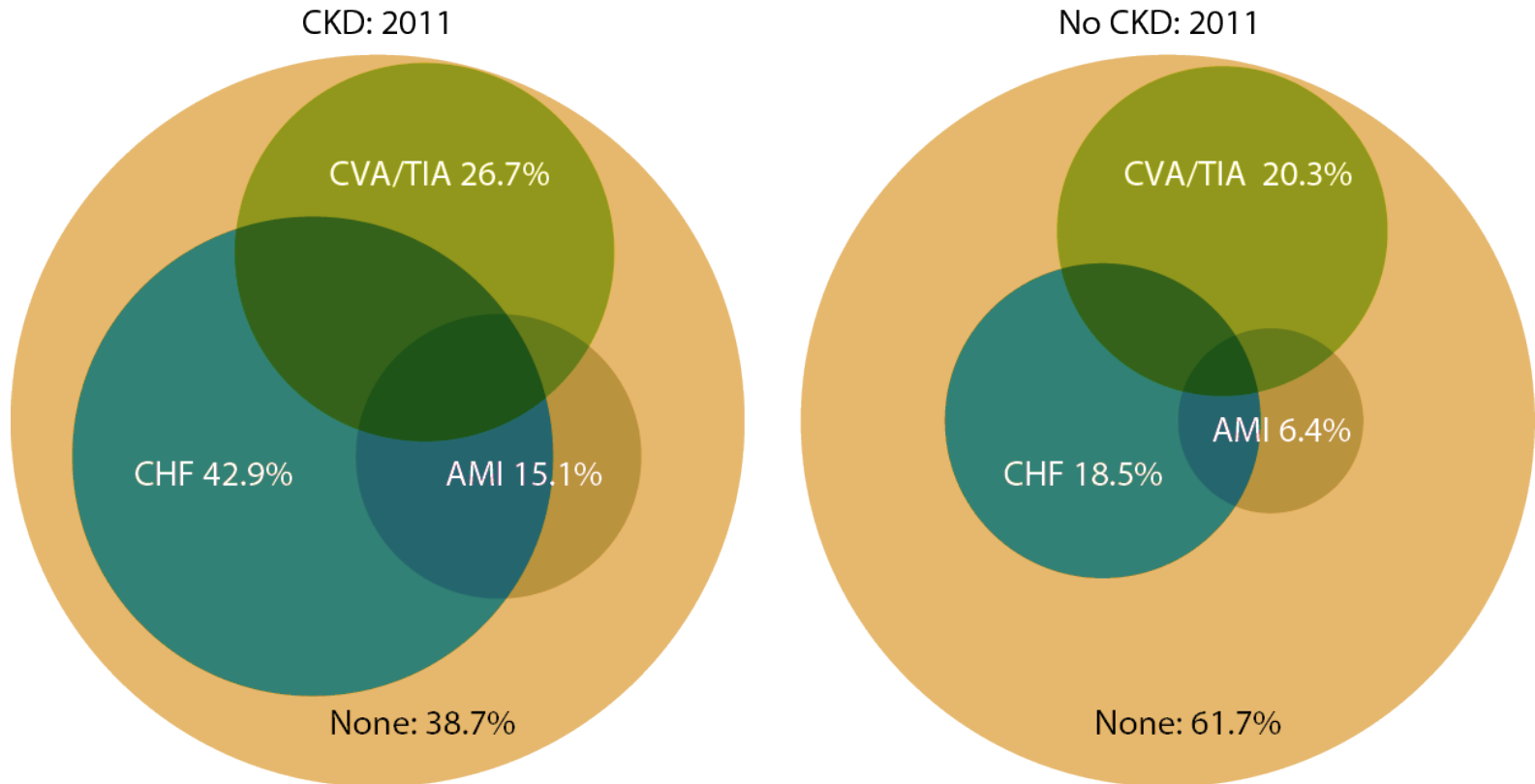


HHD=More frequent home hemodialysis  
IHD=Conventional, thrice-weekly in-center hemodialysis

E.Weinhandl, K.Nieman, D.Gilbertson, A.Collins. American Journal of Kidney Disease; Hospitalization in Daily Home Hemodialysis and Matched Thrice- Weekly In-Center Hemodialysis Patient. 2014.

# Getting to the Heart of the Matter

# Cardiovascular Disease in Patients With or Without CKD





# Cardiovascular Benefits of More Frequent Therapy are Significant

## JASN Clinical Research:

Survival in Daily Home Hemodialysis and Matched Thrice-Weekly In-Center Hemodialysis Patients

	HR (95% CI)
All-cause mortality	0.87 (0.78–0.97)
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unknown cause	0.59 (0.44–0.79)

- Overall, more frequent home hemodialysis was associated with a 13% lower risk for all-cause mortality as compared to thrice-weekly in-center therapy
- 8% lower cardiovascular-related mortality risk

# More Frequent Hemodialysis Improves Fluid Control

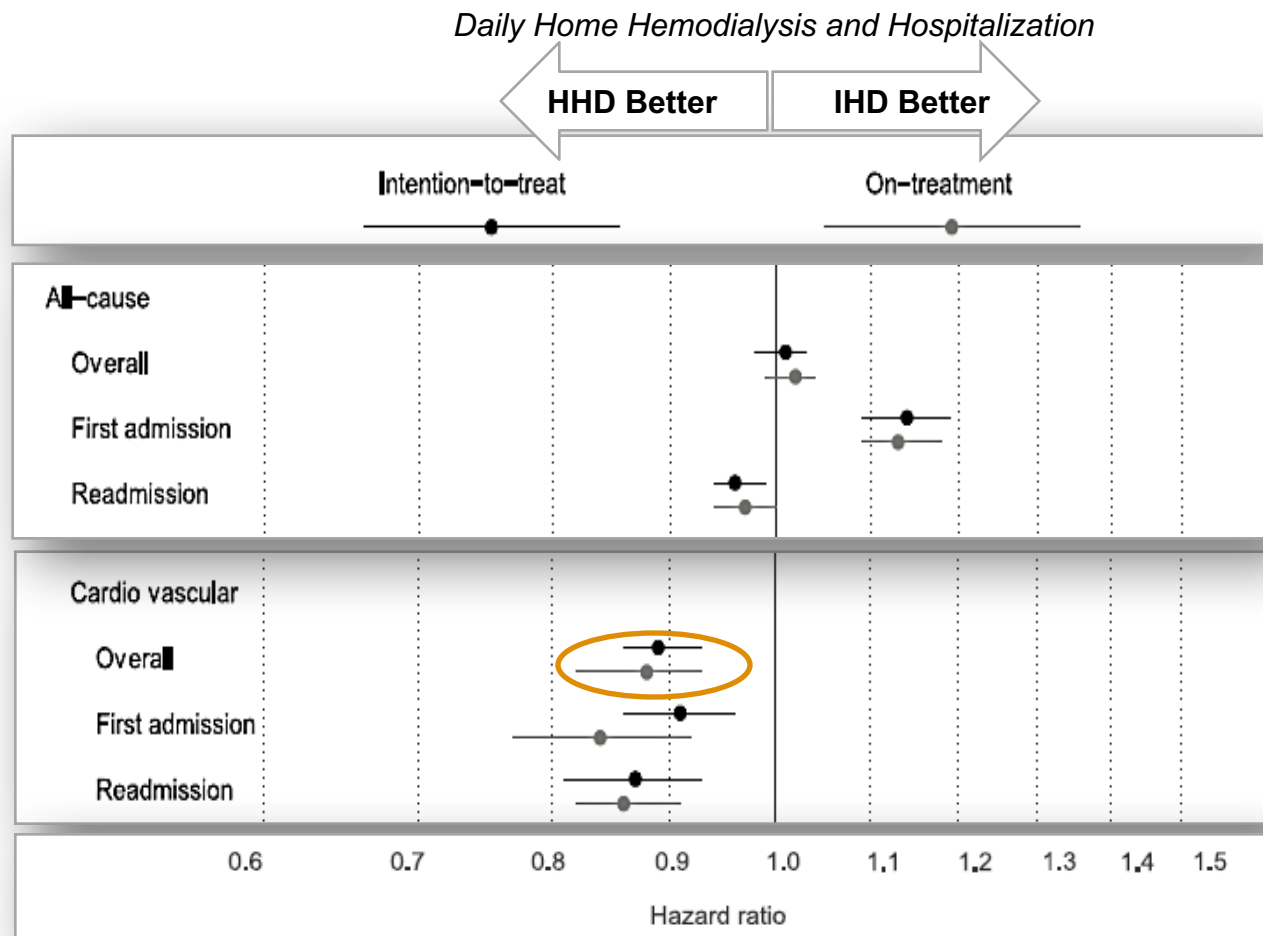
“Frequent hemodialysis, as compared with conventional hemodialysis, was associated with favorable results with respect to the composite outcomes of death or change in left ventricular mass and death or change in a physical-health composite score but prompted more frequent interventions related to vascular access.”

The FHN Trial Group. In-Center Hemodialysis Six Times per Week versus Three Times per Week. The New England Journal of Medicine. 2010;363:2287-2300.

# Lower Cardiovascular-related Hospitalization Risk Compared to Thrice-weekly In-center Hemodialysis

**AJKD Original Investigation:**  
Hospitalization in Daily Home Hemodialysis and Matched Thrice-weekly In-center Hemodialysis Patient

**More frequent home hemodialysis associated with an 11% lower risk of cardiovascular-related hospitalization**



HHD=More frequent home hemodialysis  
IHD=Conventional, thrice-weekly in-center hemodialysis

E.Weinhandl, K.Nieman, D.Gilbertson, A.Collins. American Journal of Kidney Disease; Hospitalization in Daily Home Hemodialysis and Matched Thrice-weekly In-center Hemodialysis Patient. 2014.

# Home Hemodialysis Outcomes Favorable to More Established Home Therapies

# **JKKD Original Investigation:** Mortality, Hospitalization, and Technique Failure in Daily Home Hemodialysis and Matched Peritoneal Dialysis Patients: A Matched Cohort Study

***Suggests there are improved mortality and hospitalization outcomes with more frequent home hemodialysis as compared to peritoneal dialysis.***

2016 AJKD Original Investigation

## Home Dialysis Therapies Compared

### Home Hemodialysis vs. Peritoneal Dialysis



Mortality Risk:  
20% Lower



Infection-related  
Hospitalization Risk:  
11% Lower



Cardiovascular-related  
Hospitalization Risk:  
15% Lower

Weinhandl ED, Gilbertson DT, Allan J. Collins AJ. Mortality, Hospitalization, and Technique Failure in Daily Home Hemodialysis and Matched Peritoneal Dialysis Patients: A Matched Cohort Study. *Am J Kidney Dis.* 2016 Jan;67(1):98-110.



# Identifying the *Right* Patient



# Many Centers Identify Home Dialysis Candidates Based on Varying Factors



# Embracing a Home First Philosophy

Best practices used by many programs in Europe, Canada, Australia and New Zealand...

- Nearly all patients attend home hemodialysis training programs

*The training process itself can assist in determining a patient's ability to perform hemodialysis effectively at home*



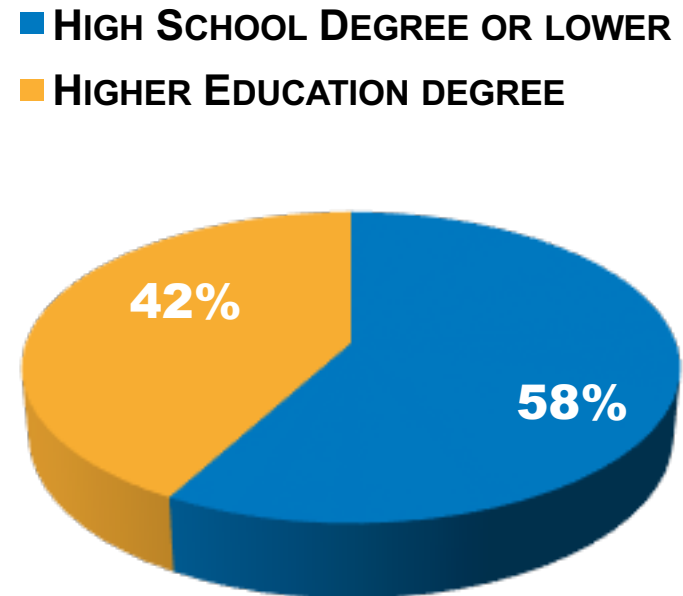
# Patients with Varying Levels of Resources Can Thrive on Home Hemodialysis

Studies show that patients of various demographics and with varying levels of resources can “learn” home hemodialysis

- Dialysis Center of Lincoln revealed that 58% of patients on home therapy had high school degrees or lower
- Similar findings at Northwest Kidney Centers (Seattle, WA) and Regional Kidney Disease Program (Minneapolis, MN)

***Patient capabilities should not be underestimated***

Dialysis Center of Lincoln  
Home Hemodialysis patient census  
EDUCATION LEVEL



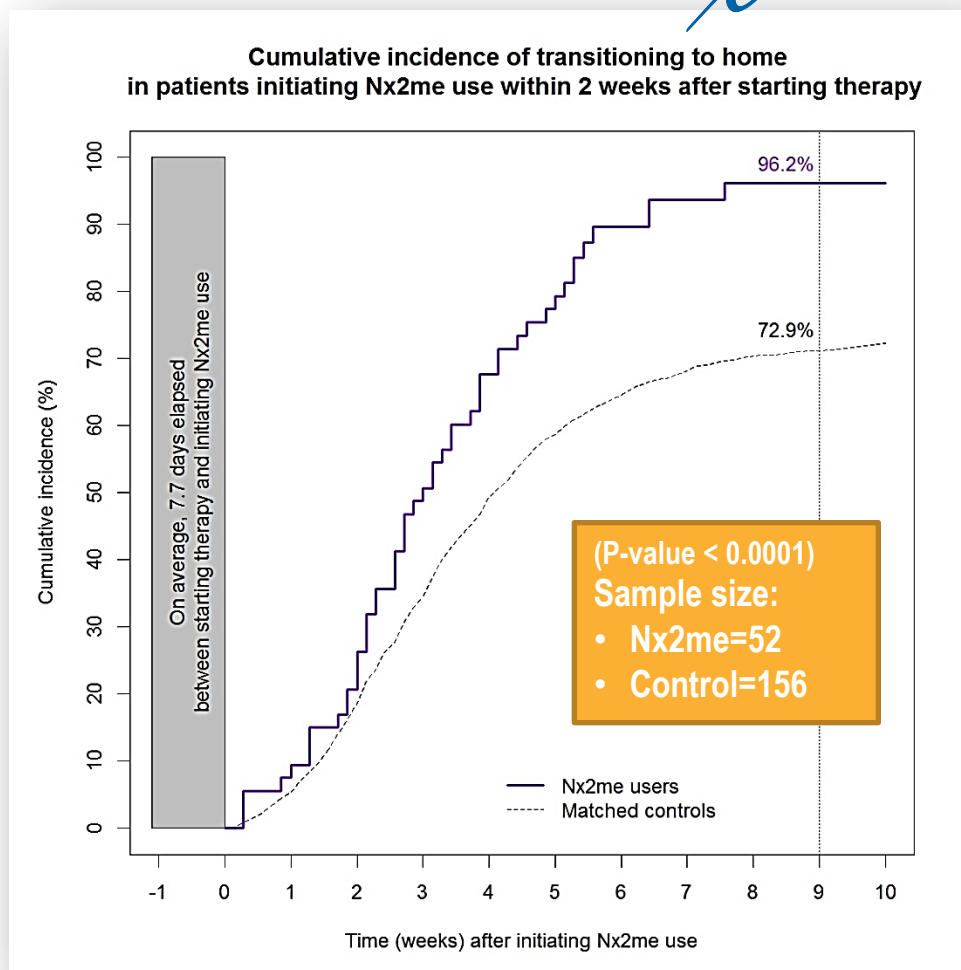
# Training Tools to Help Patients Succeed

## Nx2me<sup>®</sup> Connected Health Pilot Program Analysis



Results from patients trained with Nx2me connected health as compared to a 3:1 matched control group:

- More effective training
  - Only 3.8% failing to graduate by week 10 (vs. 27.1%)
- Faster transitions to home:
  - 50% patients graduated by week 4 (vs. week 5)
  - 68% patients graduated by week 5 (vs. week 7.5)





# Patient Care



# Many Causes of Home Therapy Under-utilization Can be Attributed to Education

- Access to home dialysis is limited
  - 26% of ESRD providers offer home hemodialysis
  - 49% are certified to offer PD<sup>1</sup>
- CMS Conditions of coverage
  - Patients need to be provided with complete and balanced education, on the broadest set of modality options

<sup>1</sup>Dialysis Facility Compare Website provided by the Centers for Medicare & Medicaid Services. Updated July 14, 2014.

# Informing Patients' Decisions

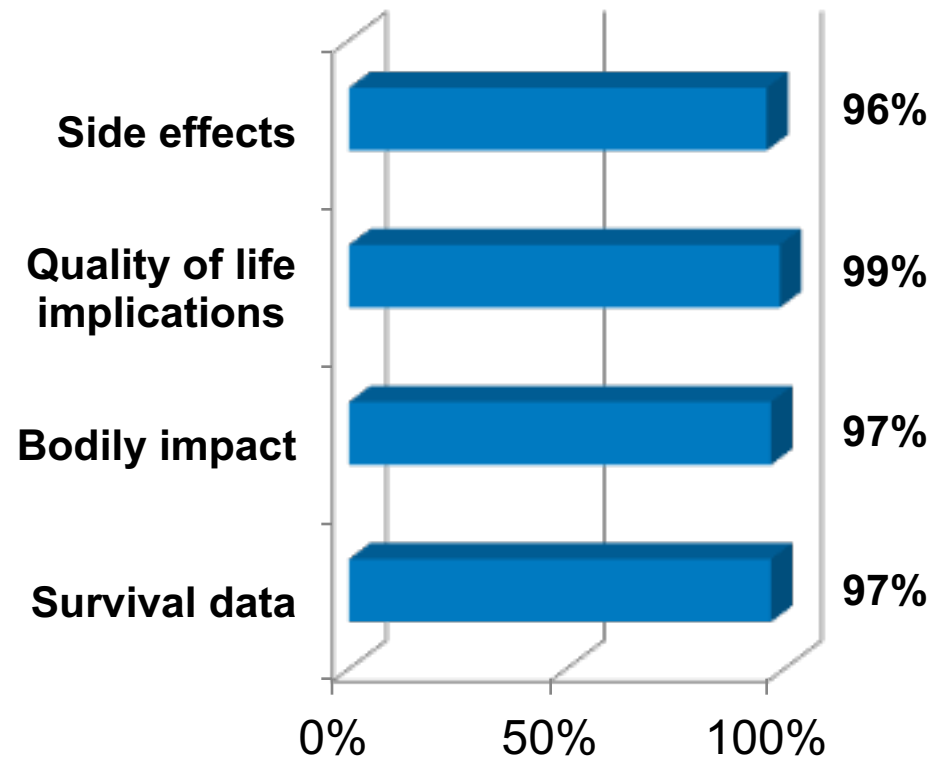
Fine, et.al survey:

- Patients want to be informed about modality options

CMS Conditions for coverage

- Providers need to ensure that comprehensive education is provided **and** that patients' preferences are incorporated into their care plan

**Most patients want to know...**



# Patient Centered Care

*The fact is...*

Dialysis impacts a patient's quality of life

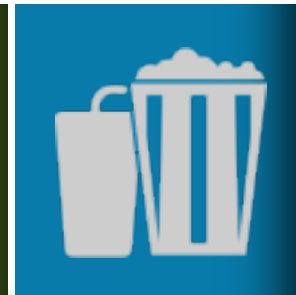
***Patients, their work and their families may sacrifice greatly when adhering to prescribed in-center therapy***

**Patient sacrifices may include:**



**Control**

**Unable to work or go to school**



**Freedom**

**No longer able to enjoy the activities they used to**



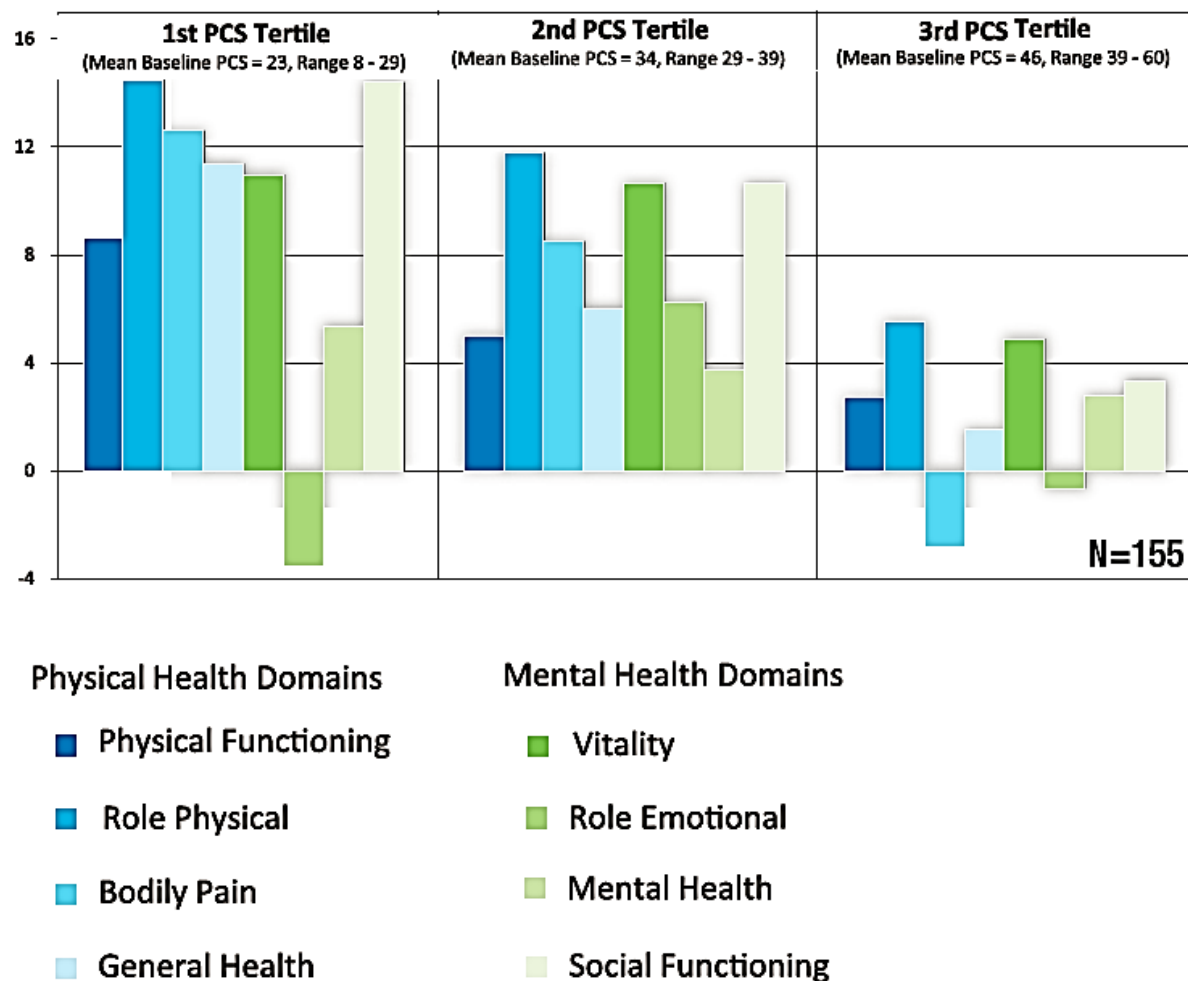
**Vitality**

**Too “washed out” for social and family interaction**

# Dialysis Outcomes and Quality of Life

As reported in the DOPPS study, lower health related quality of life scores in dialysis patients have been strongly associated with death and hospitalizations.

**Dialysis Outcomes and Practice Patterns Study (DOPPS)**



# Studies Show More Frequent Treatment May Improve Vitality and Overall Quality of Life

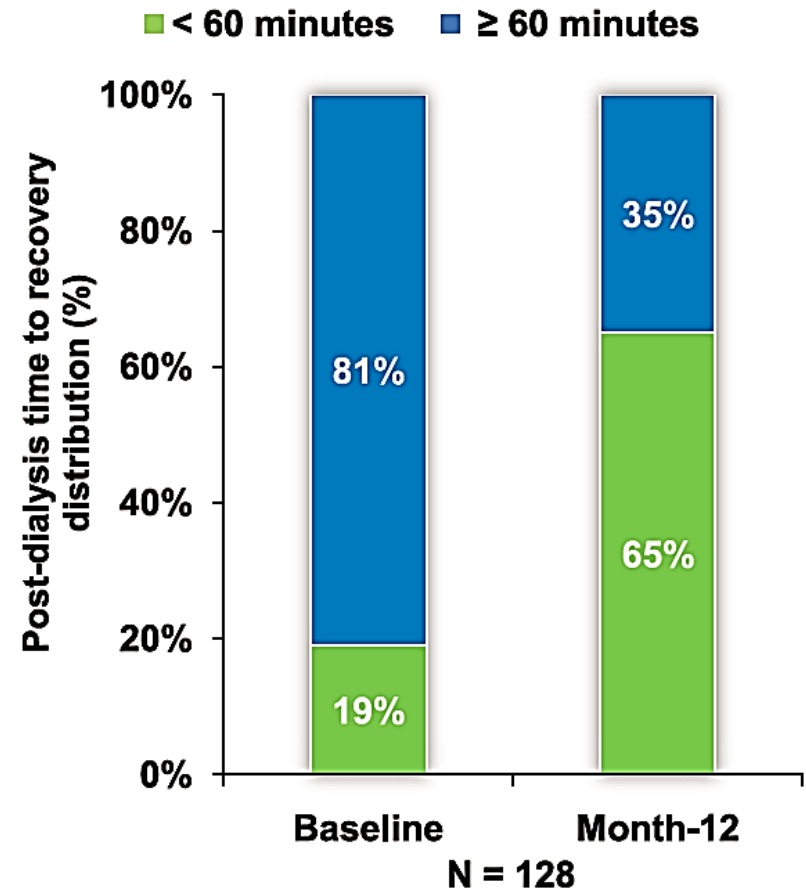


Study of Medicare patients starting more frequent home hemodialysis with NxStage System One

- Results captured at baseline, month 4 and month 12

## Key Findings:

***87% improvement in time to recovery and significant improvement in quality of life measures***





# Outcomes and Quality of Life



## Key Finding:

*More Frequent  
Home  
Hemodialysis  
may improve  
Mental &  
Physical Health*

SF-36 Domain (N = 155)	Baseline	Month-4	Month-12	Global P value
Physical component scale (PCS)	34	38	38	<0.0001
Mental component scale (MCS)	50	52	52	0.01
Physical Functioning	51	57	56	0.002
Role-Physical	45	56	56	<0.0001
Bodily Pain	57	61	64	0.03
General Health	44	51	49	<0.0001
Vitality	44	55	54	<0.0001
Role-Emotional	77	78	78	0.86
Mental Health	73	76	77	0.04
Social Functioning	63	73	73	<0.0001

# Review Findings

# What We've Found

## Home Hemodialysis Therapy

- More frequent home hemodialysis (HHD) has been associated with improved cardiovascular benefits compared to in-center and peritoneal dialysis (PD)

## Infection Risk

- While infection risk associated with HHD has been noted as higher compared to in-center hemodialysis, HHD infection risk has been reported as lower than PD, thereby placing HHD in between in-center and PD for infection risk
- Added efforts should improve upon HHD infection rates

# Providers

- Providers should have a broader view of home hemodialysis candidates
- The training process itself can assist in determining a patient's ability to perform hemodialysis effectively at home
- Nx2me® Connected Health has been associated with increased home hemodialysis training effectiveness, better graduation rates and faster transitions home

# Patients

- CDRG studies report
  - 13% lower mortality risk associated with home hemodialysis (HHD) as compared to conventional in-center therapy
  - 20% lower mortality risk as compared to peritoneal dialysis
- Most patients want to know the side effects of therapy options, quality of life implications, bodily impact and survival data
  - Patients, their work and their families sacrifice greatly adhering to prescribed in-center therapy
- Patients of various demographics and resources can thrive on HHD
- The FREEDOM study shows that HHD is associated with:
  - 87% improvement in time to recovery
  - Significant improvements in quality of life measures
  - Improved mental and physical health





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