NxStage System One®
first-of-its-kind
CLEARANCE FOR HOME
nocturnal
HEMODIALYSIS THERAPY

#### IMPROVING *lives.*





#### INSPIRING everyone.



# HOME HEMODIALYSIS CLINICAL EVIDENCE

PART 3: HOME DIALYSIS COMPARATIVE OUTCOMES AND PATIENT SELECTION



#### 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.

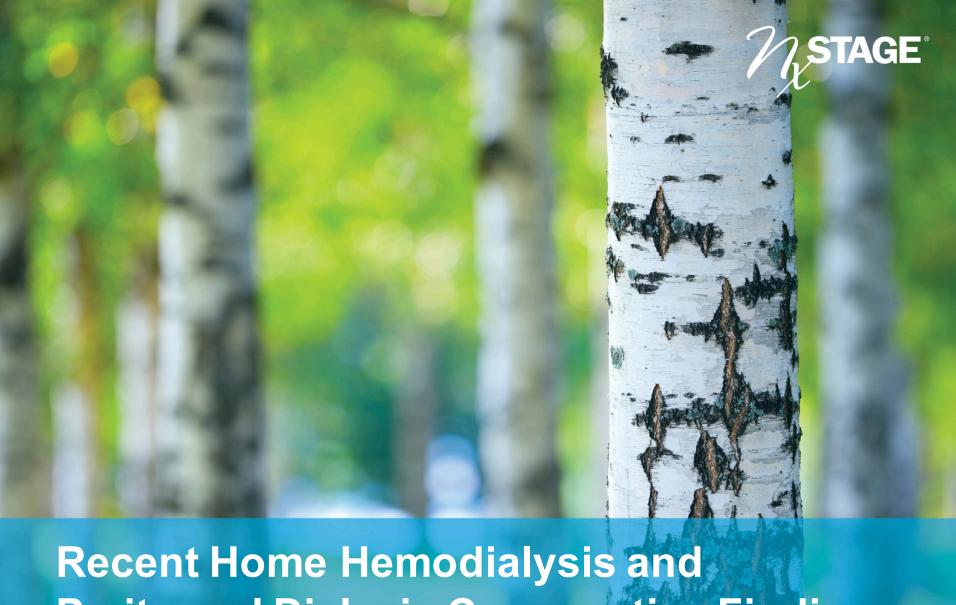
The NxStage System One is a prescription device and, like all medical devices, involves some risks. The risks associated with hemodialysis treatments in any environment include, but are not limited to, high blood pressure, fluid overload, low blood pressure, heart-related issues, and vascular access 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 noctumal 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.

#### **Agenda**

- Recent Home Hemodialysis and Peritoneal Dialysis Comparative Findings
- What if Peritoneal Dialysis Fails?
- Keeping Patients Home
- Talking to Patients About Modality Transitions



**Peritoneal Dialysis Comparative Findings** 

# The Changing Landscape of Home Dialysis

- Both more frequent home hemodialysis (HHD) and peritoneal dialysis (PD) have recently grown in popularity in the US.
- However, PD has been growing at a faster rate than HHD comparatively (10.1% vs. 8.4%, 2012 vs. 2013)
- Recently, studies report differentiated outcomes, for both incident and prevalent patients, and findings include:
  - Survivability
  - Hospitalizations
  - Hospitalization Days
  - Therapy attrition
  - Transplantation incidence
- Both home therapies are a viable option for appropriate patients

## Home Hemodialysis and Mortality Risk in Australian and New Zealand Populations

Mark R. Marshall, MBChB, MPH(Hons), FRACP,<sup>1,2,3</sup>
Carmel M. Hawley, MB,BS(Hons), MMedSci, FRACP,<sup>4,5</sup>
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**AJKD, 2011** 

#### Survival on Home Dialysis in New Zealand

Mark R. Marshall<sup>1,2,3</sup>\*, Rachael C. Walker<sup>4,5</sup>, Kevan R. Polkinghorne<sup>3,6,7</sup>, Kelvin L. Lynn<sup>8</sup>

PLOS, 2014

# The risk of hospitalization and modality failure with home dialysis

Rita S. Suri<sup>1,2</sup>, Lihua Li<sup>2</sup> and Gihad E. Nesrallah<sup>3,4</sup>

Kidney International, 2015

# An Incident Cohort Study Comparing Survival on Home Hemodialysis and Peritoneal Dialysis (Australia and New Zealand Dialysis and Transplantation Registry)

Annie-Claire Nadeau-Fredette, \*†\* Carmel M. Hawley, \*†\* Elaine M. Pascoe, Christopher T. Chan, Philip A. Clayton, \*\*\* Kevan R. Polkinghorne, \*††\* Neil Boudville, \*\* Martine Leblanc, and David W. Johnson\*†

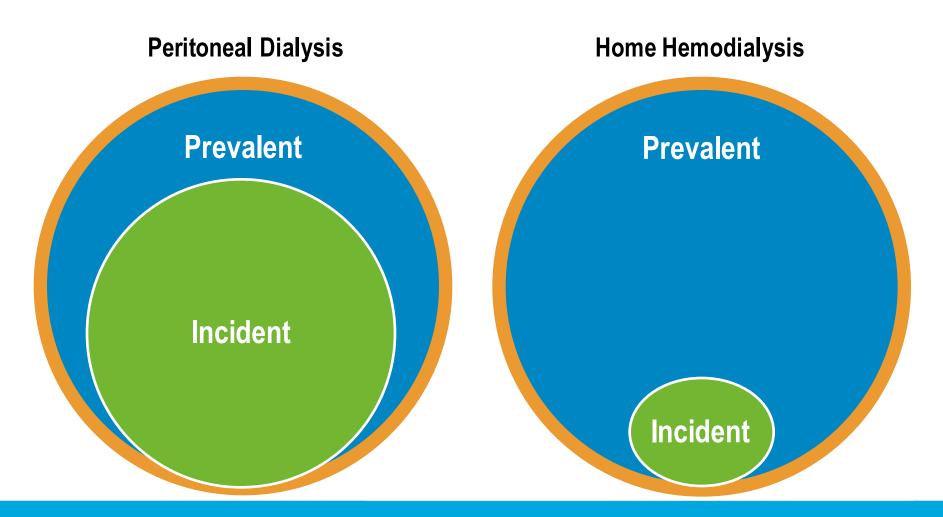
**CJASN, 2015** 

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

Eric D. Weinhandl, PhD, David T. Gilbertson, PhD, and Allan J. Collins, MD1,2

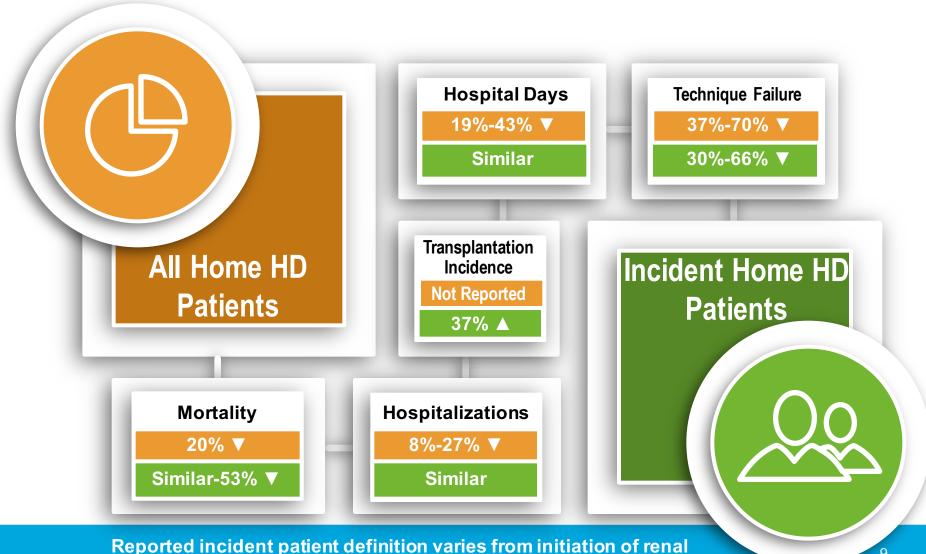
AJKD, 2016

# The Current Home Dialysis Patient Population Differs Significantly



## Home Hemodialysis Associated with Favorable Outcomes as Compared to Peritoneal Dialysis

Summarized Reported Findings for All Patients and Incident Patient Subset



replacement therapy <6 months and <3 months. See appendix for detail.

### **Mortality** Reported Findings

AS COMPARED TO PD



ALL HOME HD PATIENTS



INCIDENT HOME HD PATIENTS

## 20% Lower Risk for All-Cause Mortality (4,201 pts, <4 year follow-up)

Weinhandl ED, Gilbertson DT, 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. 67(1):98-110.

## Similar Mortality Risk as PD (900 pts, <4 year follow-up)

Weinhandl ED, Gilbertson DT, 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. 67(1):98-110.

## 39% Lower Risk for All-Cause Mortality (1,547 pts, <3 year follow-up)

Marshall, M. R., Walker, R. C., Polkinghorne, K. R., & Lynn, K. L. (2014). Survival on Home Dialysis in New Zealand. PLoS ONE, 2014. 9(5), e96847. \*Patients on home HD were younger and healthier

## 53% Lower Risk for All-Cause Mortality (706 pts, <6 year follow-up)

Nadeau-Fredette AC et al. An Incident Cohort Study Comparing Survival on Home Hemodialysis and Peritoneal Dialysis (Australia and New Zealand Dialysis and Transplantation Registry). CJASN. 2015. vol.10 no.8 1397-1407.

#### Hospitalizations Reported Findings

#### As COMPARED TO PD



ALL HOME HD PATIENTS

#### 8% Lower Risk for All-Cause Hospitalizations (4,201 pts, <4 year follow-up)

Weinhandl ED, Gilbertson DT, 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. 67(1):98-110.

## 27% Lower Risk for All-Cause Hospitalizations (1,116 pts, <5 year follow-up)

Suri RS, Lihua L, Nesrallah GE. The risk of hospitalization and modality failure with home dialysis. Kidney International (2015) 88, 360–368.



INCIDENT HOME HD PATIENTS

## Similar All-Cause Hospitalization Risk (900 pts, <4 year follow-up)

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

#### Hospitalization Days Reported Findings

As Compared to PD



ALL HOME HD PATIENTS

### 19% Fewer Hospitalization Days (4,201 pts, <4 year follow-up)

Weinhandl ED, Gilbertson DT, 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. 67(1):98-110.

#### 43% Fewer Hospitalization Days

(1,116 pts, <5 year follow-up)

Suri RS, Lihua L, Nesrallah GE. The risk of hospitalization and modality failure with home dialysis. Kidney International (2015) 88, 360–368



INCIDENT HOME HD PATIENTS

### Similar Number of Hospitalization Days (900 pts, <4 year follow-up)

Weinhandl ED, Gilbertson DT, 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. 67(1):98-110.

## Technique Failure Reported Findings

As COMPARED TO PD



ALL HOME HD PATIENTS

#### 37% Lower Risk for Technique Failure (4,201 pts, <4 year follow-up)

Weinhandl ED, Gilbertson DT, 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. 67(1):98-110.

## 70% Lower Risk for Technique Failure (1,116 pts, <5 year follow-up)

Suri RS, Lihua L, Nesrallah GE. The risk of hospitalization and modality failure with home dialysis. Kidney International (2015) 88, 360–368.



HOME HD PATIENTS

## 30% Lower Risk for Technique Failure (900 pts, <4 year follow-up)

Weinhandl ED, Gilbertson DT, 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. 67(1):98-110.

## 66% Lower Risk for Technique Failure (706 pts, <6 year follow-up)

Nadeau-Fredette AC et al. An Incident Cohort Study Comparing Survival on Home Hemodialysis and Peritoneal Dialysis (Australia and New Zealand Dialysis and Transplantation Registry). CJASN. 2015. vol.10 no.8 1397-1407.

# Transplantation Incidence Reported Findings

AS COMPARED TO PD



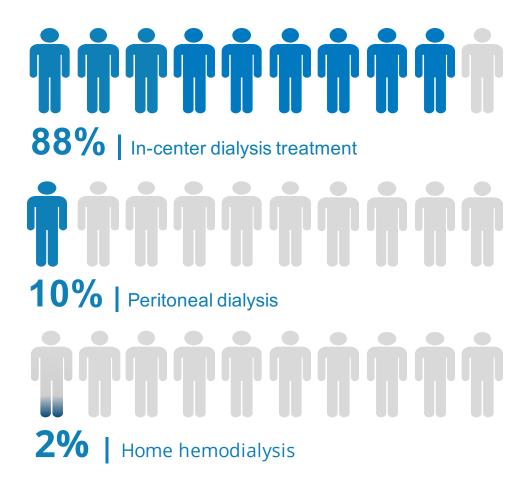
INCIDENT HOME HD PATIENTS

## 37% Greater Transplantation Incidence (1,368 pts, <4 year follow-up)

Weinhandl ED, Collins AJ. Incidence of Kidney Transplant in Daily Home Hemodialysis, Peritoneal Dialysis, and In-Center Hemodialysis Patients. 2015 NKF Spring Clinical Meeting Poster Session.



# **Current Dialysis Situation by Modality** in the United States



Data source: 2013 Census Data by MAC and State, 2013 ESRD Network Annual Report

# Commonly Reported Peritoneal Dialysis Drop Reasons

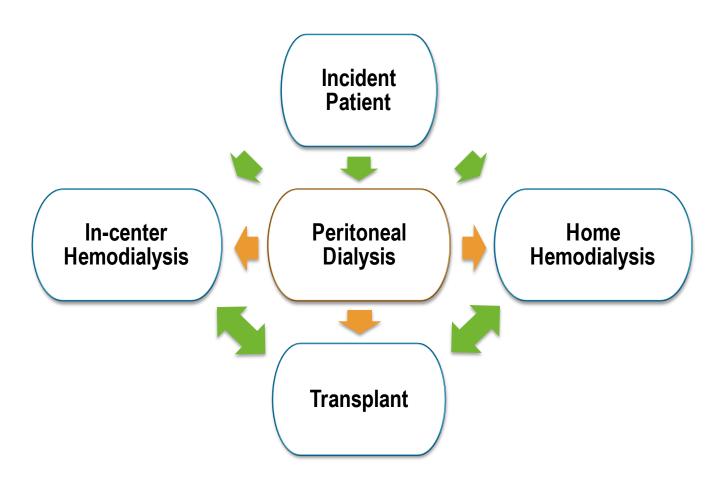
Peritonitis and/or Catheter Related Infections

Ultrafiltration
Failure and
Volume
Overload

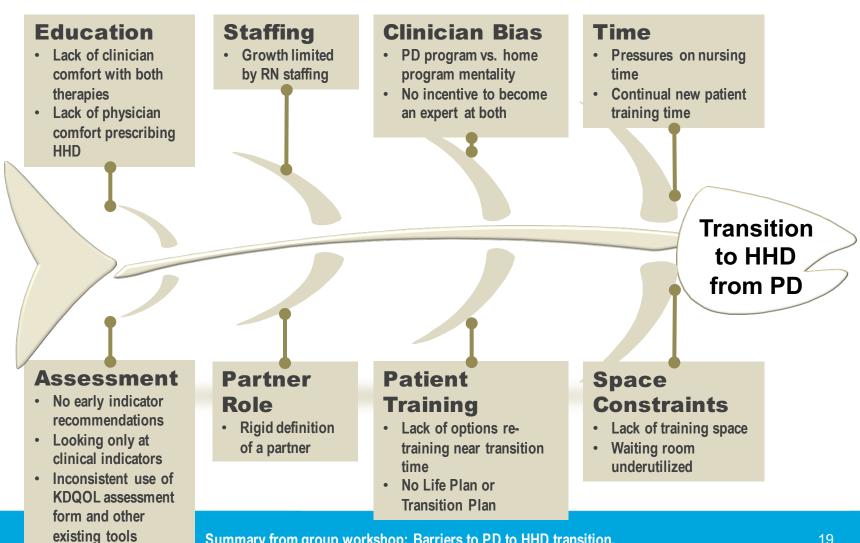
Inadequate Solute Clearance

Psychosocial Issues

## Dialysis is a Life Journey

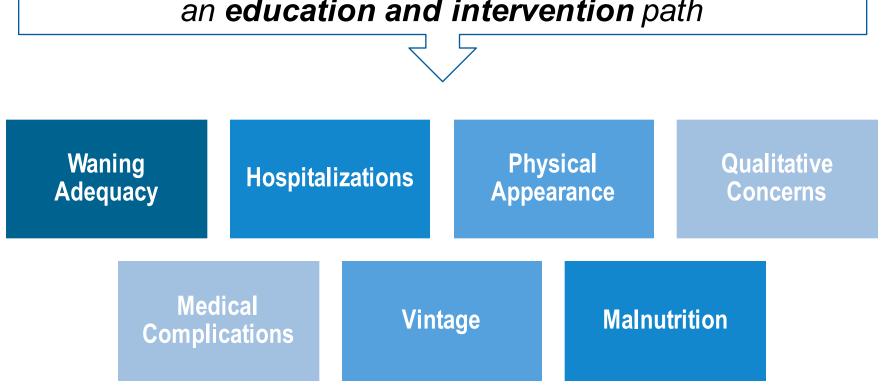


## Why do Few Peritoneal Dialysis (PD) Patients Transition to Home Hemodialysis (HHD) When Modality Change is Necessary?

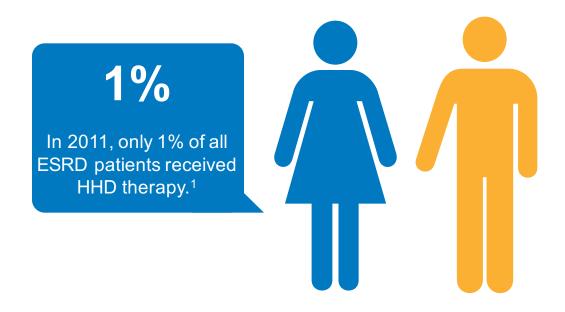


# Addressing the Need for a Peritoneal Dialysis to Home Hemodialysis Transition Plan Overview of PD@Risk Methodology

Clinical criteria and profile attributes that place patients on an education and intervention path



#### **Effects of Education**



A large study demonstrated that patients who chose their therapy were significantly more likely to live longer and to receive a transplant.<sup>2</sup>

#### Patient Knowledge of Treatment Options



31%

#### Not equally presented as option

The AAKP Survey showed that approximately 31% of respondents felt the therapies were not equally and fairly presented as treatment options and



32%

#### Not educated about HHD

32% responded they were not educated regarding home HD.\*

# PD@Risk Transition Planning PD Transition Education Timing Analogous to CKD Education





**CKD Stage 4** 



CKD Stage 5











#### **Healthy PD**

50% survival over 36 months.

Start Modality
Options Education



50% technique failure within 6-9 months.

Continued Modality Education, with Urgency

## Precipitous PD Decline

Analogous to acute renal failure
Continued Education & Modality Training

#### PD@Risk

#### PATIENT PROFILES AND CLINICAL INDICATORS



#### **Healthy**

- Peritonitis episode
- Albumin level < 3.5
- Life changing events (family, change in social support, depression)
- PD vintage > 5 yrs
- Transplant waiting list > 2 yrs



#### At Risk

- Declining or loss of Residual Renal Function
- Albumin level < 3.0 or decrease of .2 every 2 mos</li>
- Infections (peritonitis, ES, tunnel) 3 or more with a year; 1 very severe episode (fungal, sclerosing)
- <1 L/Day of UF combined with residual and therapy)</li>
- Increasing number of exchanges
- Use of Icodextran
- Declining adequacy (Kt/V<1.7 after RX adjustments)</li>
- Decline in physical appearance and or abilities



#### **Imminent Transition**

- 3 or more of the above indicators plus:
- Medical complications (CV, Fractures, hernias, leaks)
- > 3 hospitalizations in 1 year (ICU)

#### PD@Risk

#### INTERVENTIONAL STRATEGIES AND EDUCATIONAL MESSAGING



#### **Healthy**

- Discuss average survival on Peritoneal Dialysis can be successful for several years; on average, 50% technique survival at 24 – 36 months
  - "It is possible to remain at this stage for years"
- Create Life Plan and continually re-educate patients about other therapy options available to them

"If and when therapy is needed, there are options"



#### **At Risk**

- May begin to see clinical signs "Transition is coming. It might be immediate, in months or in a year"
- Be proactive about access plans "It varies from person to person"
- Re-educate on other modality options that fit within lifestyle "Revisit your Life Plan, get re-trained on your therapy choices and discuss your transition"



#### **Imminent Transition**

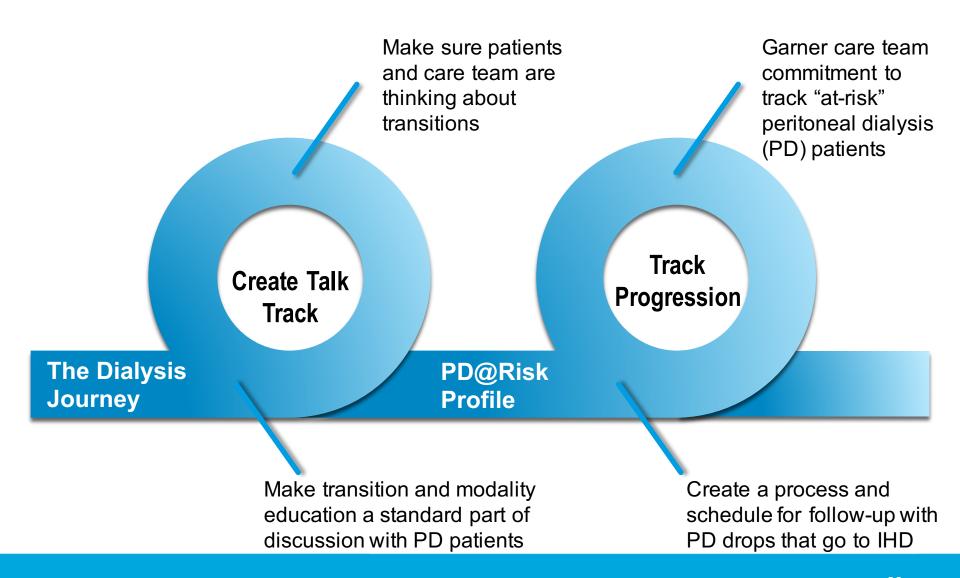
- · Vascular Access placed
- Determine best therapy option; Home Hemodialysis or In-center Hemodialysis
- Encourage patients to Experience the Difference
   "Access will be critical. Get stable and revisit options once stabilized"



# Getting Started How to Build Your Modality Transition Education Program

Indoctrinate PD@Risk Procedures **Mandate Continuing Transition Ed Require Patient Life Plan Forms Profile PD@Risk Patients Create Talk Track** 

# Outline a process for direct transition to Home Hemodialysis or for follow-up with patients that go to in-center HD (IHD)



# Implementing your PD@Risk Program Process

Life Plan

Form

Require patients to complete a Life Plan form

Continuing Modality

education a standard part of discussions with peritoneal dialysis (PD) patients

**Education** 

Life Plan Form

Transition Options

Program

Make ongoing transition and

alternative modality

PD@Risk

Revisit patient Life Plan forms regularly to measure whether patients are meeting their goals

Establish a process and schedule for follow-up with PD drops that go to in-center HD



# Talking to Patients About Modality Transitions

# When Should Therapy Options be Discussed? ...Follow Your PD@RISK PROGRAM PROCEDURES

#### Goals should be reviewed yearly, if not more frequently

- Care team should be keenly aware of how patients are responding to current therapy both clinically and emotionally
  - Patient shows signs of therapy disillusionment
  - Lack of positive outcomes
  - Patient or family shows signs of stress

#### Overcoming Training Intimidation

- Start a "slow ramp" training process to avoid in-center HD
- Hybrid Peritoneal Dialysis (PD)/Home Hemodialysis (HHD) for a few weeks if fistula is maturing
- Education on how HHD works; compare and contrast PD and HHD processes, training and benefits from PD patient perspective

#### Continuing PD Drop Patient Education

 Offer Experience the Difference and patient-to-patient support resources to patients that have gone to in-center HD

# Opportunities to Discuss Transition Planning with Patients

- Patient Care conferences
- Monthly CQI/QA meetings
- Patient educational or support group meetings
- Lobby Days
- HCP rounds
- Clinic visits

# Embrace Continuing Modality Transition Education

#### This is a Philosophical Change

- Position modality selection as a journey from onset
- Make sure patients are always thinking about transitions and matching modalities to their goals
  - "Most patients will try multiple modalities over time"

#### How You Can Help

- Make ongoing transition and alternative modality education a standard part of discussion with peritoneal dialysis (PD) patients
- Continuing education on how home hemodialysis (HHD) works;
   compare and contrast PD and HHD process, training and
   benefits from PD patient perspective
- Create a Life Plan form for patients to measure whether they are meeting their goals



## Home Hemodialysis and Mortality Risk in Australian and New Zealand Populations

Mark R. Marshall, MBChB, MPH(Hons), FRACP,<sup>1,2,3</sup>
Carmel M. Hawley, MB,BS(Hons), MMedSci, FRACP,<sup>4,5</sup>
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AJKD, 2011

### Home Hemodialysis and Mortality Risk in Australia and New Zealand

Marshall MR., et al: AJKD – 2011

#### **Study Design:**

Observational cohort study using the Australia and New Zealand Dialysis and Transplant Registry.

#### Methods:

The main predictor was dialysis modality (conventional facility HD, conventional home HD, frequent/extended facility HD, frequent/extended home HD, and PD) adjusted for the confounding effects of patient demographics and comorbid conditions. 26,016 patients with 856,007 patientmonths of follow-up. Censored for death with 4 year follow-up period.

#### **Outcome:**

Mortality

#### **Findings:**

More frequent/extended HD hazard ratio indexed to conventional in-center HD was 0.49 (0.32-0.76, P<.05) and 1.10 (1.06-1.16, P<.05) for PD.

#### **Noteworthy:**

This analysis didn't exclude extended patients as a subset of home hemodialysis patient set which has reportedly been a common home hemodialysis therapy offered and utilized in Australia and New Zealand.

### Survival on Home Dialysis in New Zealand

Mark R. Marshall<sup>1,2,3</sup>\*, Rachael C. Walker<sup>4,5</sup>, Kevan R. Polkinghorne<sup>3,6,7</sup>, Kelvin L. Lynn<sup>8</sup>

PLOS, 2014

### Survival on Home Dialysis in New Zealand

Marshall MR., et al: PLOS – 2014

#### **Study Design:**

Observational cohort study using the Australia and New Zealand Dialysis and Transplant Registry.

#### Methods:

Time-varying dialysis modality in New Zealanders over a 15-year period to 31-Dec-2011, adjusting for patient co-morbidity by Cox proportional hazards multivariate regression to determine if home dialysis associates with better survival than facility HD by simultaneous comparisons of the three modalities. Model consisted of 6,419 patients with 3,254 deaths over 20,042 patient-years of follow-up.

#### **Outcome:**

Survival

#### Findings:

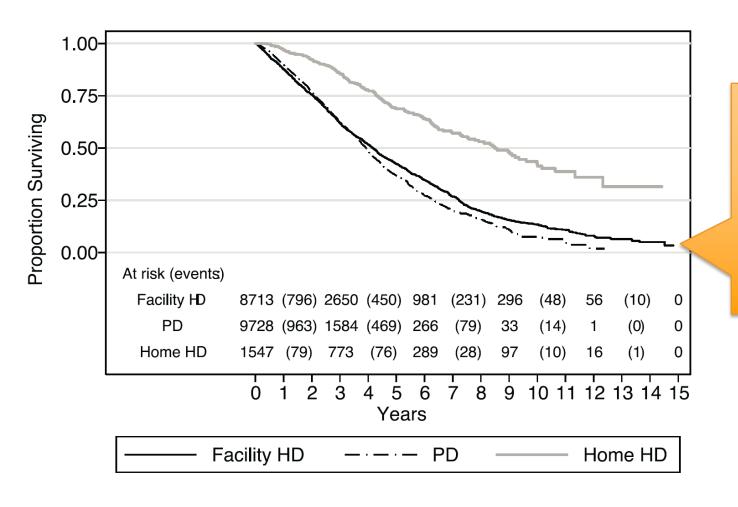
Peritoneal Dialysis (PD) and Home Hemodialysis (HHD) as compared to conventional in-center HD (CHD) and home dialysis with the following results (P<.05):

- No significant difference in mortality risk between PD and CHD
- 52% lower mortality risk associated with home HD

#### **Noteworthy:**

HHD patients studied were reported as "younger and healthier" than the PD and facility HD patients.

### Patient Survival Significantly and Positively Associated with Home Hemodialysis



Little Difference in Survival with Peritoneal Dialysis as Compared to Conventional Thrice-Weekly HD

# An Incident Cohort Study Comparing Survival on Home Hemodialysis and Peritoneal Dialysis (Australia and New Zealand Dialysis and Transplantation Registry)

Annie-Claire Nadeau-Fredette,\*<sup>†‡</sup> Carmel M. Hawley,\*<sup>†§</sup> Elaine M. Pascoe,<sup>||</sup> Christopher T. Chan, <sup>¶</sup> Philip A. Clayton,<sup>†</sup>\*\* Kevan R. Polkinghorne,\*<sup>††‡†§§||</sup> Neil Boudville,\*<sup>¶</sup> Martine Leblanc,<sup>‡</sup> and David W. Johnson\*<sup>†§</sup>

**CJASN, 2015** 

### An Incident Cohort Study Comparing Survival on Home Hemodialysis and Peritoneal Dialysis

(Australia and New Zealand Dialysis and Transplantation Registry) Nadeau-Fredette AC., et al: CJASN – 2015

#### **Study Design:**

Observational cohort study using the Australia and New Zealand Dialysis and Transplant Registry.

#### Methods:

Registry study assessed all Australian and New Zealand adult patients receiving home dialysis on day 90 after initiation of RRT between 2000 and 2012. The primary outcome was overall survival. The secondary outcomes were on-treatment survival, patient and technique survival, and death-censored technique survival.

#### Outcome:

Mortality

#### Findings:

HHD as compared to PD was associated with the following (P<0.001):

- 53% Lower risk of death
- 66% Lower risk of technique failure (censored for death)

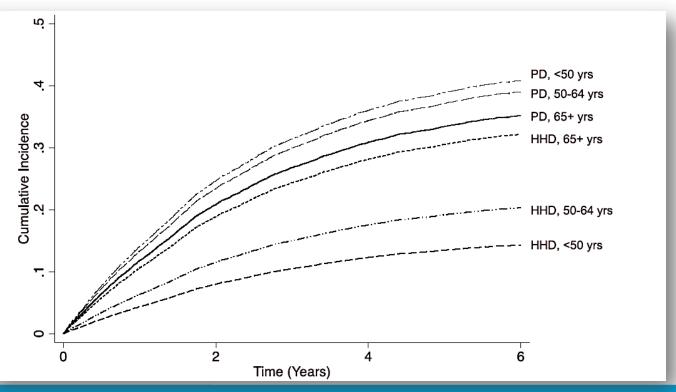
#### **Noteworthy**:

Although not reported for this study, authors have referred that a majority of HHD patients in this region receive >5 hrs therapy, 3x/week.

# HHD Associated with Better Technique Survival, Regardless of Age

As Compared to Peritoneal Dialysis

In the evaluation of death-censored technique survival with death and transplantation as competing events, the protective association between HHD and technique survival was preserved (HR, 0.40; 95% CI, 0.33 to 0.48), and the interaction between age and modality persisted.



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

Eric D. Weinhandl, PhD, David T. Gilbertson, PhD, and Allan J. Collins, MD1,2

AJKD, 2016

# Mortality, Hospitalization and Technique Failure in NxStage Patients and Matched Peritoneal Patient: A Matched Cohort Study

Weinhandl E., et al: AJKD – 2016

#### Study Design:

Retrospective cohort propensity score matched study with subset findings for ESRD Duration ≥ 6 months and ESRD Duration < 6 months.

#### Methods:

Study comparing mortality in 4,201 new daily (5-6 days/week) home hemodialysis (HHD) patients in 2007 to 2010 matched with 4,201 new peritoneal dialysis (PD) patients from the US Renal Data System database to determine observed mortality, hospitalization, and technique failure. Mean time from end-stage renal disease onset to home dialysis therapy initiation was 44.6 months for HHD and 44.3 months for PD patients. ESRD Duration, Medicare Part-D, hospitalizations during preceding 3 months, network and dialysis provider were used as blocking factors.

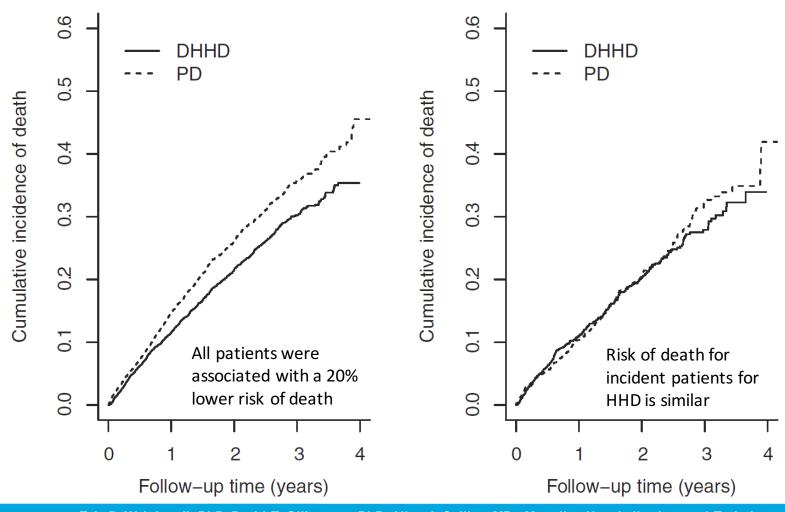
#### Findings:

Overall, as compared to PD, HHD was associated with the following (P<0.001):

- 20% lower mortality risk; Similar mortality risk (<6 months)</li>
- 8% lower risk of hospitalizations; Similar hospitalization risk (<6 months)</p>
- 19% fewer hospital days per 100 patient years; Similar number of hospital days (<6 months)</li>
- 37% lower risk of technique failure; 30% lower risk of technique failure (<6 months)</li>

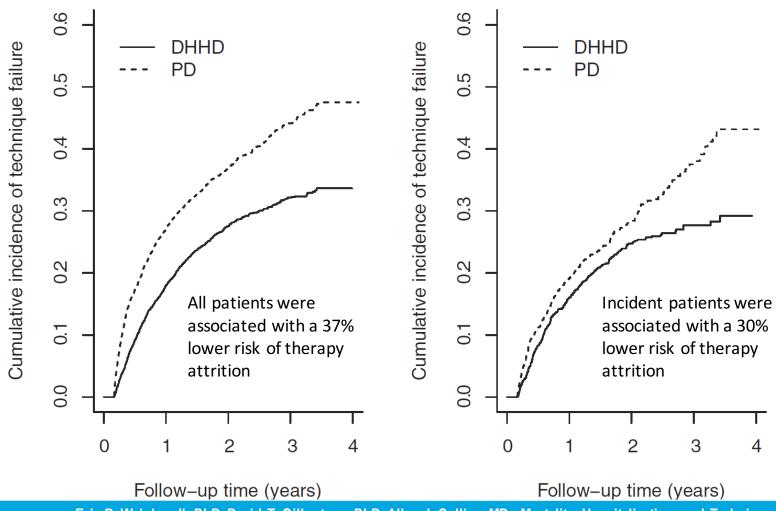
### Cumulative Incidence of Death

AJKD – 2015: All patients and subset of ESRD onset < 6 months



### Cumulative Incidence of Technique Failure

All patients and subset of ESRD onset < 6



## The risk of hospitalization and modality failure with home dialysis

Rita S. Suri<sup>1,2</sup>, Lihua Li<sup>2</sup> and Gihad E. Nesrallah<sup>3,4</sup>

Kidney International, 2015

# The Risk of Hospitalization and Modality Failure with Home Dialysis

Suri RS., et al: Kidney International – 2015

#### **Study Design:**

Matched cohort study of 1,116 daily home hemodialysis (DHD) patients.

#### **Methods**

Using a large US dialysis provider's administrative database, patients were matched by propensity scores to 2,784 contemporaneous USRDS patients receiving home peritoneal dialysis (PD), to compare hospitalization rates from cardiovascular, infectious, access-related or bleeding causes (prespecified composite), and modality failure risk. ). >90% of patients received DHD using low dialysate flows (<300 ml/min). Additionally, a similar analyses for 1,187 DHD patients matched to 3,173 USRDS patients receiving in-center conventional hemodialysis (CHD).

#### Findings:

As compared to PD, DHD was associated with the following:

- 31% lower composite hospitalization rate (P<0.001)</li>
- 43% fewer hospital days per year (P<0.001)</li>
- 63% more DHD patients remained admission-free (P<0.001)</li>
- 70% less likely to switch back to in-center HD

## HHD Associated with Overall Fewer Hospitalizations

As Compared to Peritoneal Dialysis

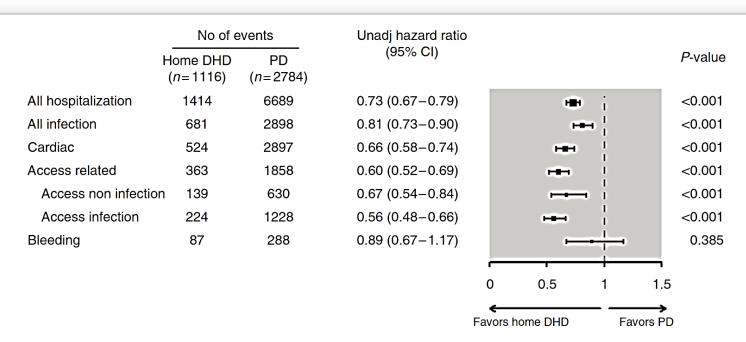


Figure 2 | Relative hazard of hospitalization associated with home daily home hemodialysis (DHD) versus peritoneal dialysis (PD). Cl, confidence interval; No, number.

## HHD Associated with Overall Fewer Hospitalizations

AS COMPARED TO CONVENTIONAL HEMODIALYSIS

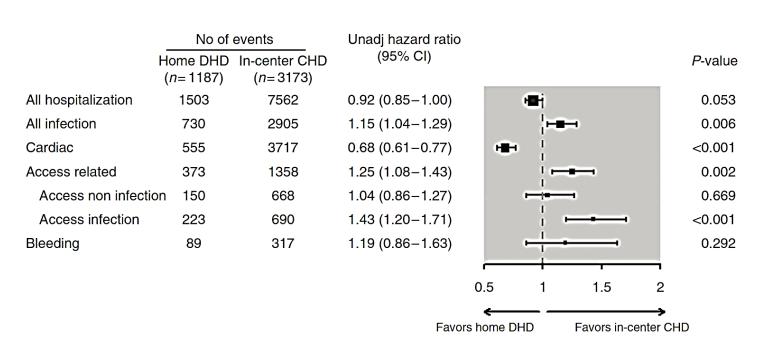


Figure 3 | Relative hazard of hospitalization associated with daily home hemodialysis (DHD) versus in-center conventional hemodialysis (CHD). CI, confidence interval; No, number.

# Home Hemodialysis (DHD) Associated with Lower Modality Failure than Peritoneal (PD) As COMPARED TO PERITONEAL DIALYSIS

- Approximately 1% (9/1162) of DHD patients switched to PD, whereas 25% (691/2784) of PD patients switched to home HD (defined as 'cross-overs')
- During follow-up, 15% (172/1116) of the DHD group compared with 44% (1233/2784) of the PD group switched back to incenter CHD (defined as 'modality failure')











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