CLINICAL CONSIDERATIONS AND THERAPY PRESCRIPTION

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Agenda

- Lifestyle and Clinical Considerations
- Creating a Better Patient Experience
- Prescription Considerations and Management
- Questions

LIFESTYLE AND CLINICAL CONSIDERATIONS

2025 Dialysis Outlook[1,2,3]

650,000
patients

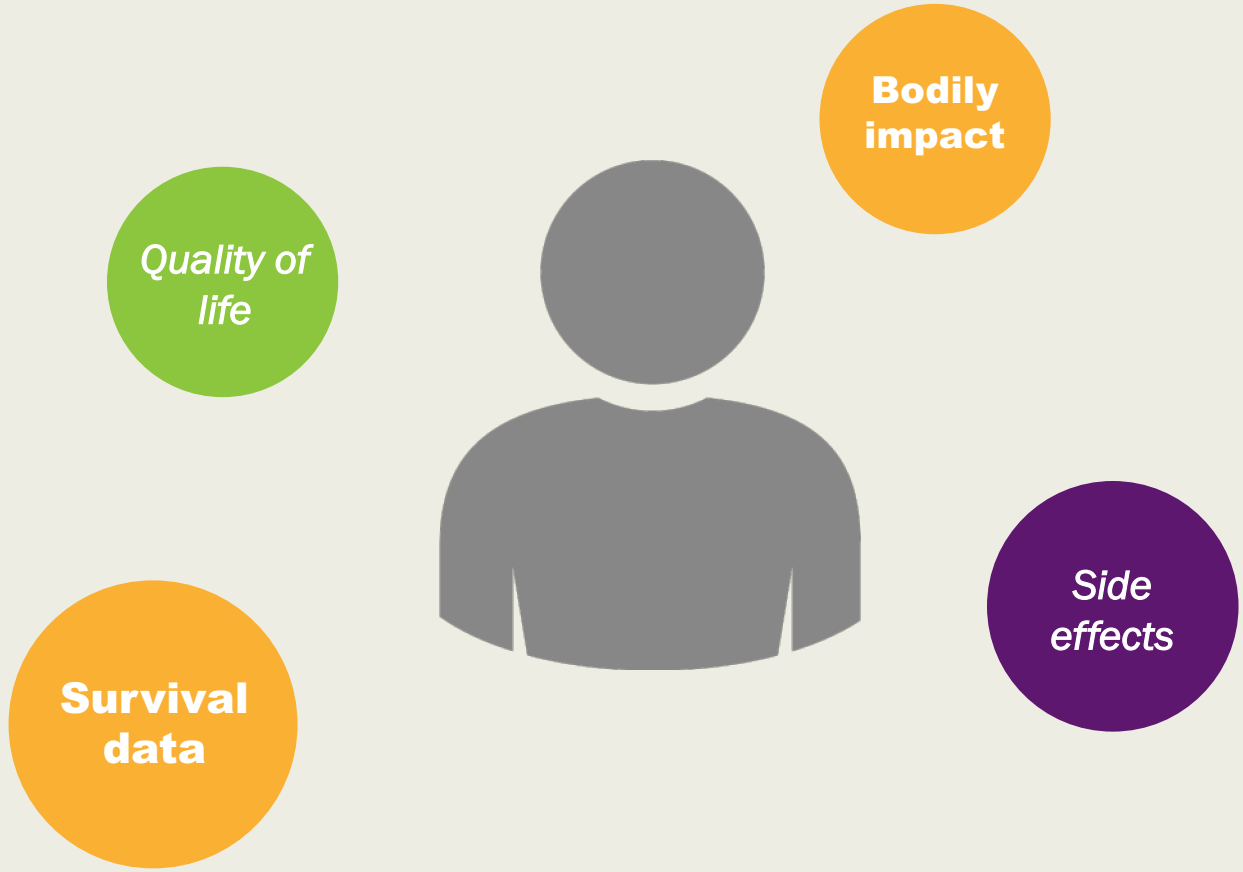
40% more centers

40% more nephrologists

40% more staff

Data sources for calculation: [1]McCullough KP et al. Projecting ESRD Incidence and Prevalence in the United States through 2030. J Am Soc Nephrol 30: 127–135. [2]Census Bureau 2017 National Population Projections Datasets. [3]USRDS 2018 Reference Table D1: Percentages & counts of reported ESRD patients: by treatment modality incident & December 31 point prevalent patients.

Patients Want to Know[1]



[1]Fine A, et al. Nephrologists should voluntarily divulge survival data to Potential dialysis patients: a questionnaire study. Perit Dial Int. 2005;25:269-273.

How You Can Help

Support informed decision making

Educate on benefits

Reinforce engagement

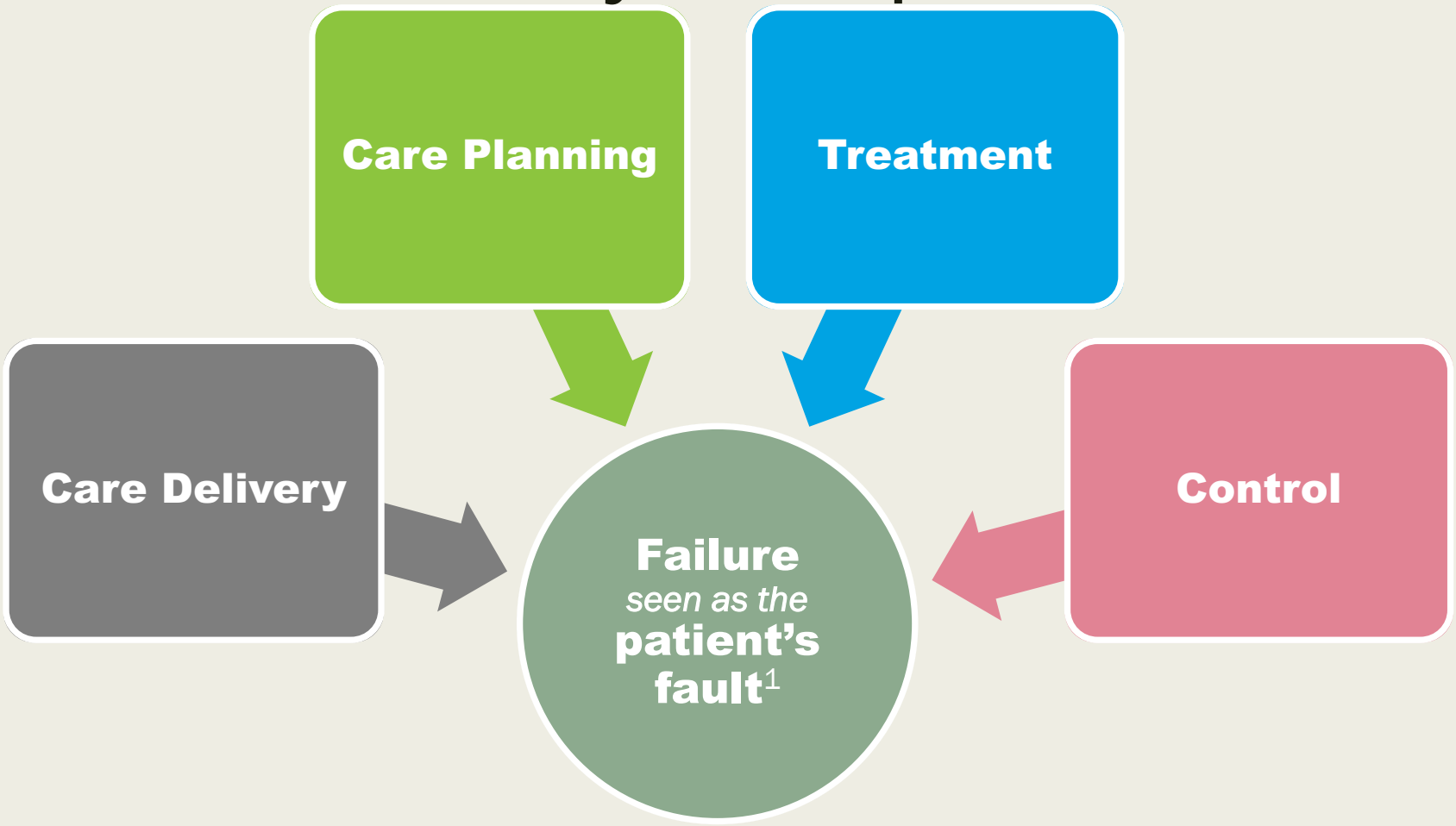
Use positive language

Listen and empathize

Avoid "sick" or "disabled"

In-Center Treatment Considerations

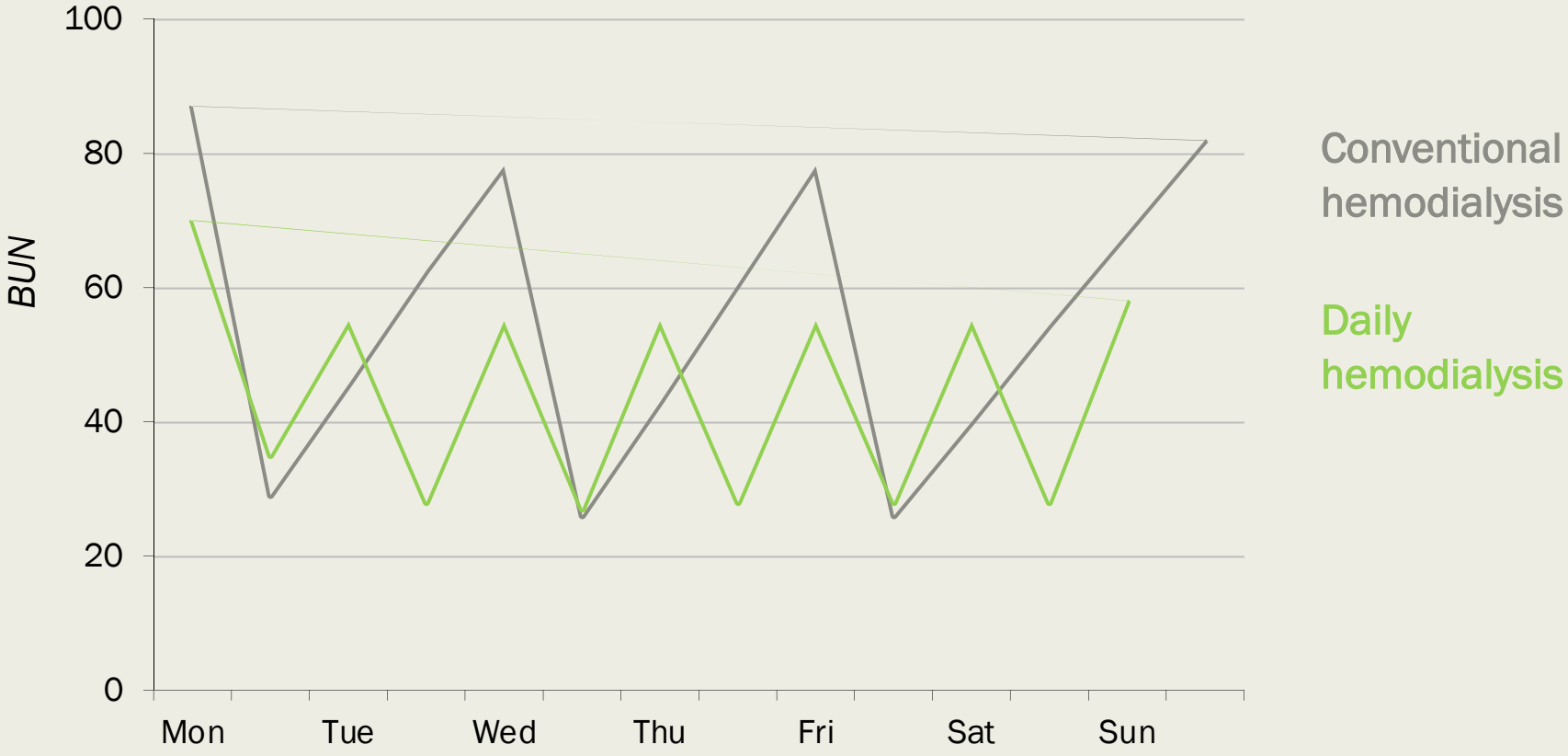
How Can We Improve the Current Dialysis Experience?



1"World as we know it" concept by Ellen Balovlenkov RN, MS, CHN, Technical Lead, Dialysis Facility Compare. Patient and Family Engagement … Exploring Avenues for Change. Presented May, 20,2014. 2014 Renal Network 4 Annual Meeting.

CREATING A BETTER PATIENT EXPERIENCE

More Frequent Hemodialysis is Physiologically More Tolerable



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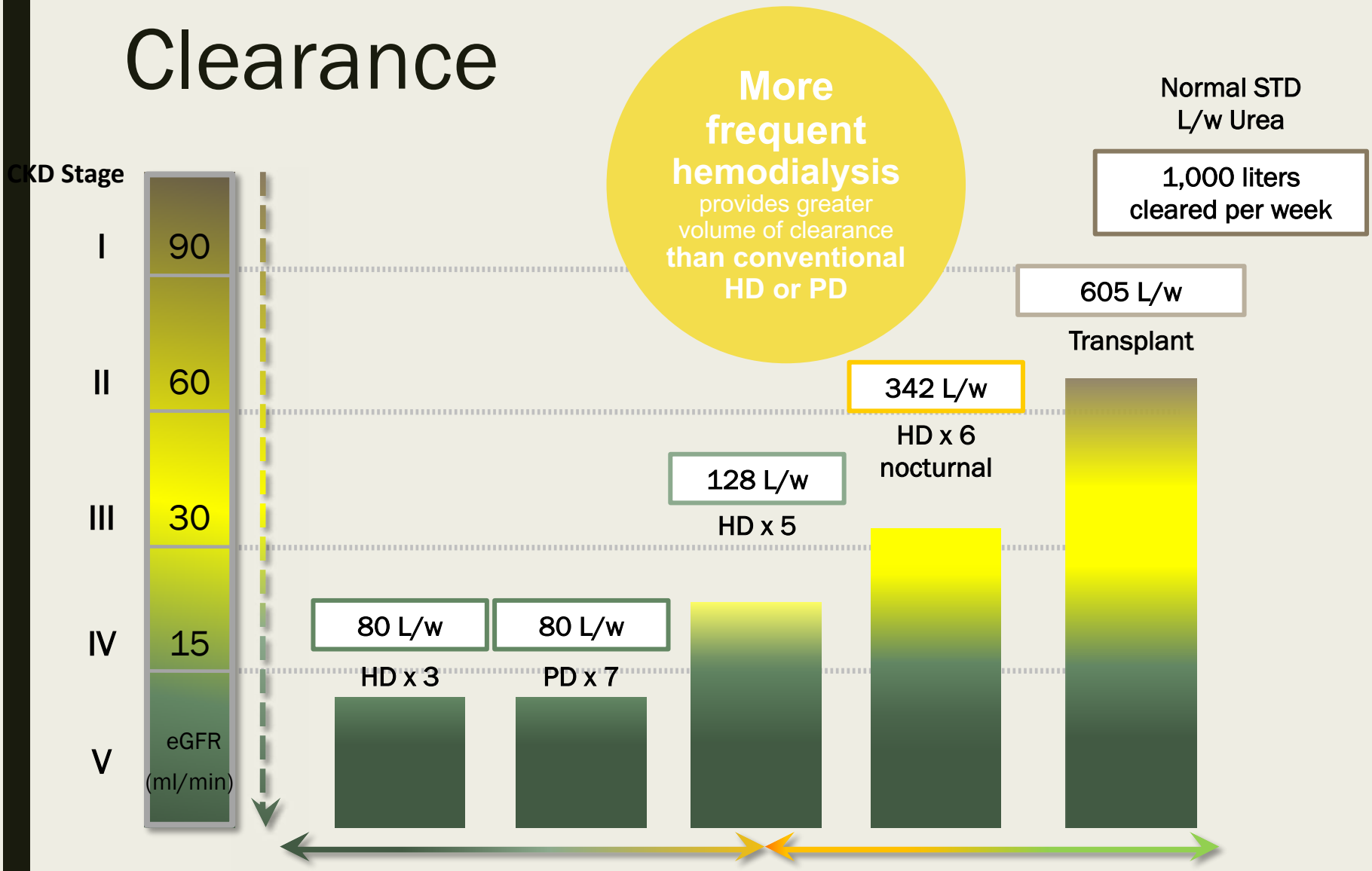
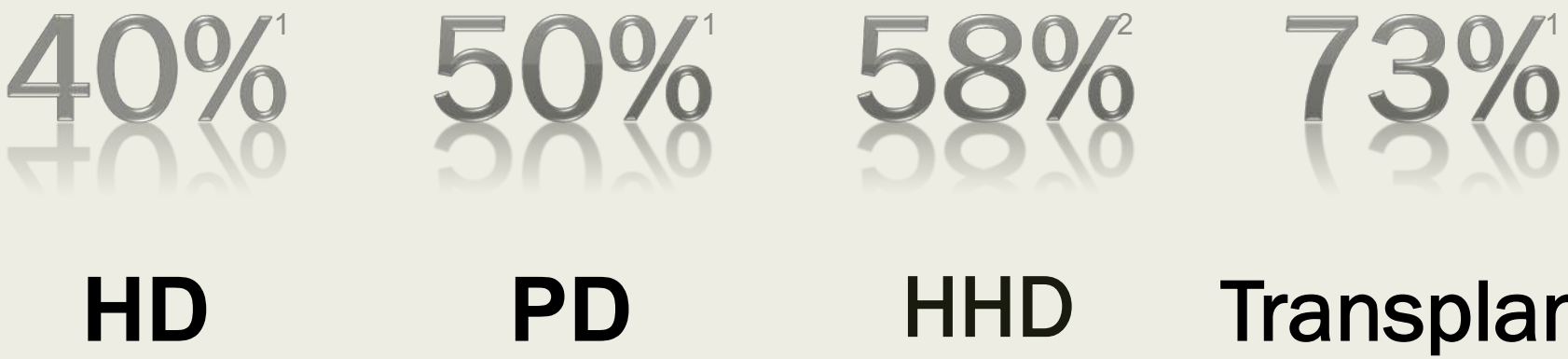
Provides Greater Renal Clearance



Five-Year Relative Survival

Home Dialysis Associated with Better Patient Survival[1,2]

More Frequent Nocturnal HD Similar Survival to Deceased Donor Transplant[3]



[1]USRDS 2015 Annual Data Report: Data Source: Reference Table 6.3. Adjusted survival (%) by (a) treatment modality and incident cohort year (year of ESRD onset), and (b) age, sex, race, and primary cause of ESRD, for ESRD patients in the 2008 incident cohort (initiating ESRD treatment in 2008).

[2]USRDS 2015 Annual Data Report: Table 6.3. & NxStage patient data on file.

[3]Pauly RP, et al. Survival among nocturnal home haemodialysis patients compared to kidney transplant recipients. Nephrol Dial Transplant (2009) 24: 2915–2919.

Reported Benefits of More Frequent Home Hemodialysis

Improving fluid management[1]

Mitigating the two-day "killer gap"[2,3]

Lessening cardiovascular injury[4-9]

Reducing cardiovascular hospitalizations and mortality[3,10,11]

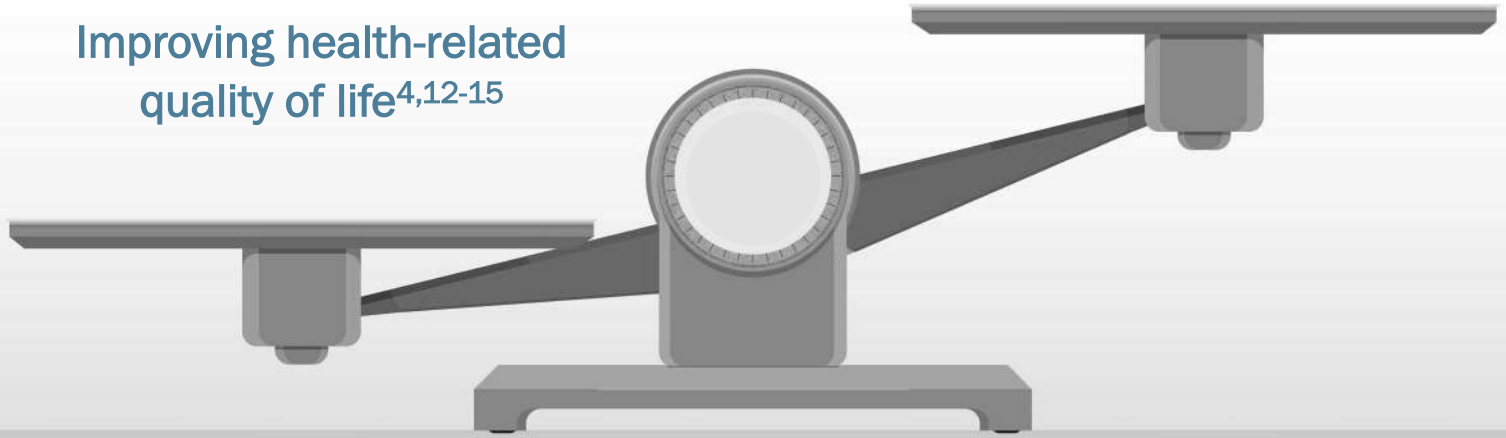
Improving health-related quality of life[4,12-15]

Vascular access complications[3,4,10,11,16]

Technique survival[10,11]

Infection risk[3,4,10,11,16]

Burden of therapy[4,10,11,15]



See slides 24-25 for references

PRESCRIPTION CONSIDERATIONS AND MANAGEMENT

Dialysis Prescription Objectives

- Avoid volume and pressure overload
- Target appropriate phosphorous clearance
- Achieve acceptable fluid removal rates
- Schedule to fit patient lifestyle

Avoid Volume and Pressure Overload

Problem	Evidences	Adjustments
• Elevated pre-dialysis blood pressure[1]	• Positive effect on blood pressure[2] • Reduced need for antihypertensive agents[2]	• Closely monitor fluid balance, weight, blood pressure throughout patient stay on treatment

[1]The DOPPS Practice Monitor. http://www.dopps.org/DPM/. Accessed May 20, 2015.

[2]Kotanko P, Garg AX, Depner T, et al. Effects of frequent hemodialysis on blood pressure: Results from the randomized frequent hemodialysis network trials.Hemodial Int Int Symp Home Hemodial. 2015;19(3):386-401.

Target Appropriate Phosphorus Clearance

Problem	Evidences	Adjustments
• Dietary intake versus phosphorus clearance leads to high pill burden[1,2,3]	• Decrease in pills per day (7.17 to 5.70)[4] • With more frequent nocturnal, fewer patients using phosphate binders (97% to 27%)[4]	• Closely monitor phosphorus levels throughout patient stay on treatment

[1]Noori N, Kalantar-Zadeh K, Kovesdy CP, et al. Dietary potassium intake and mortality in long-term hemodialysis patients. Am J Kidney Dis. 2010;56(2):338-347

[2]Hou SH, Zhao J, Ellman CF, et al. Calcium and phosphorus fluxes during hemodialysis with low calcium dialysate. Am J Kidney Dis. 1991;18(2):217-224.Adv Chronic Kidney Dis. 2007;14(1):3-12.

[3]Navaneethan SD, Palmer SC, Craig JC, Elder GJ, Strippoli GFM. Benefits and harms of phosphate binders in CKD: a systematic review of randomized controlled trials. Am J Kidney Dis.2009;54(4):619-637.

[4]Daugirdas JT, Chertow GM, Larive B, Daugirdas JT, Chertow GM, Larive B, et al. Effects of frequent hemodialysis on measures of CKD mineral and bone disorder. J Am Soc Nephrol JASN. 2012;23(4):727-738.

Achieve Acceptable Fluid Removal Rates

Problem	Evidences	Adjustments
• Intradialytic hypotension[1] • Long recovery times[1,2]	• Significant reductions in intradialytic hypotension and recovery times[3,4]	• Intravascular volume contraction may occur if fluid removed >5–6 mL/kg/hour[5] • Reduced organ perfusion risked if fluid removed >10 mL/kg/hour[5] • Likely if fluid removed >13 mL/kg/hour[5]

[1]Flythe JE, Brunelli SM: The risks of high ultrafiltration rate in chronic hemodialysis:implications for patient care.Semin Dial. 2011;24(3):259-265.

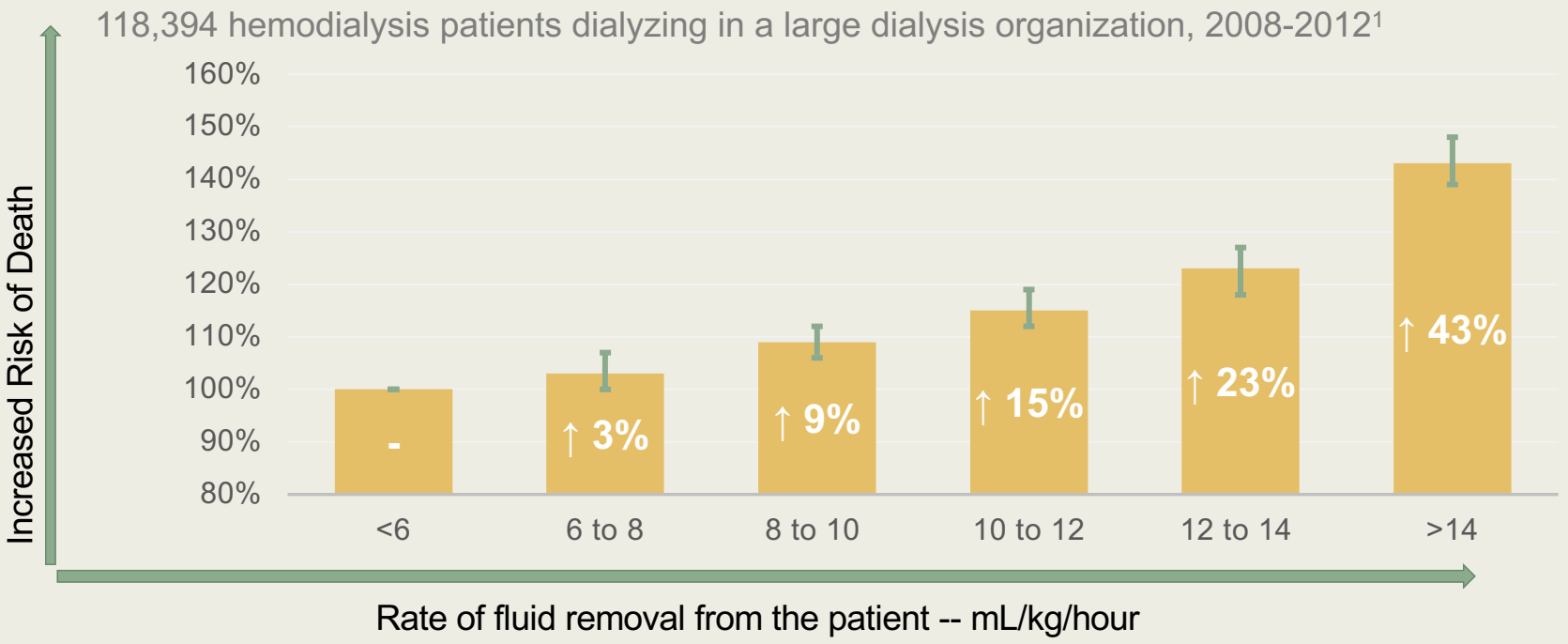
[2]Flythe JE, Kimmel SE, Brunelli SM. Rapid fluid removal during dialysis is associated with cardiovascular morbidity and mortality. Kidney Int. 2011;79(2):250-257

[3]FHN Trial Group, Chertow GM, Levin NW, et al. In-center hemodialysis six times per week versus three times per week. N Engl J Med. 2010;363(24):2287-2300.

[4]Rocco MV, Lockridge RS, Beck GJ, et al. The effects of frequent nocturnal home hemodialysis: the Frequent Hemodialysis Network Nocturnal Trial. Kidney Int. 2011;80(10):1080-1091.

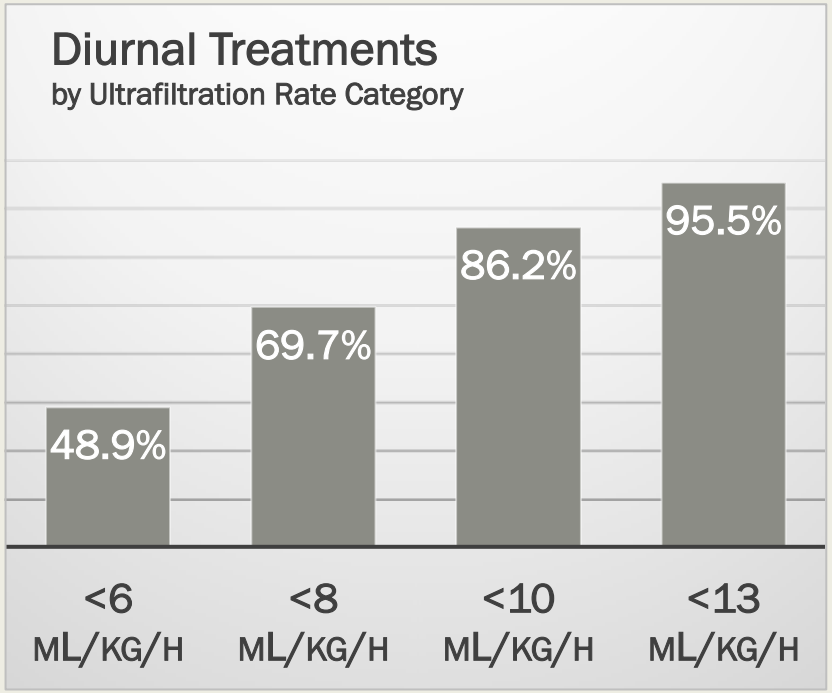
[5]Burton, JO et al., Hemodialysis-Induced Cardiac Injury: Determinants and Associated Outcomes. *Clin J Am Soc Nephrol.*2009;4: 914–920.

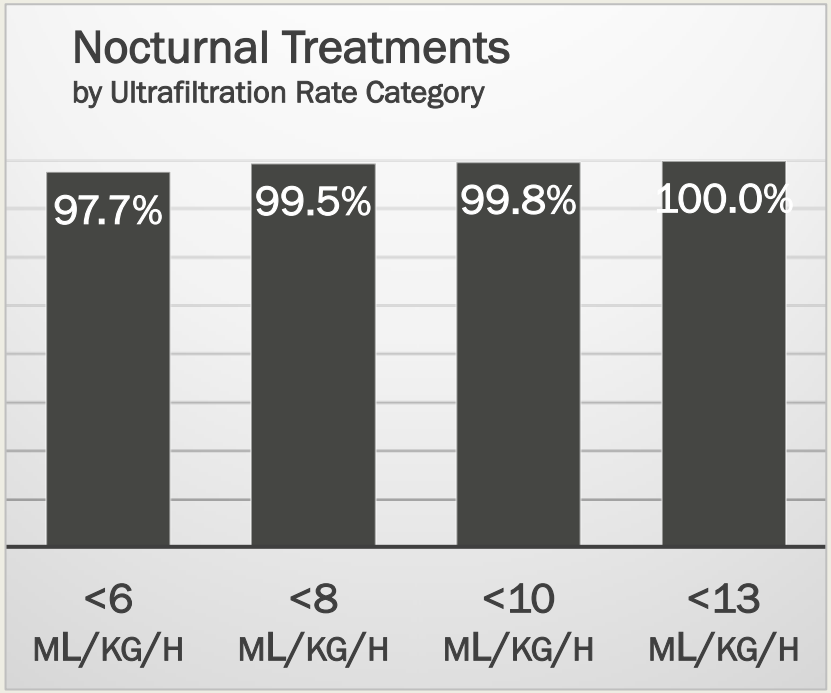
Newer Data Suggest Even Lower Thresholds Linked to Increased Risk of All-cause Mortality[1]



1. Assimon, M.M. et al. Ultrafiltration Rate and Mortality in Maintenance Hemodialysis Patients. Am J Kidney Dis. 2016;68(6):911-922. 2. Weinhandl, Collins and Kraus Ultrafiltration Rates with More Frequent Home Hemodialysis. Oral presentation, ADC, 2017. 3. Flythe, J.E., Curhan, G.C., Brunelli, S.M. Clin J Disentangling the Ultrafiltration Rate–Mortality Association: The Respective Roles of Session Length and Weight Gain. Clin J Am Soc Nephrol. 2013 Jul;8(7):1151-61.

Frequency and Duration Positively Addresses Aggressive Ultrafiltration Rates[1]





[1]Analysis of NxStage Nx2me Flowsheets During Patient-Weeks with ≥4 Prescribed Treatments

Chronic Fluid Overload and Mortality Risk:

Increased Mortality Risk ≥1kg Over Dry Weight

Flythe[1]

- 30-day follow-up
- ≥50 percent of treatments leaving patients >1kg "heavy"
  - → 35% increased risk for mortality

Zocalli[2]

- 1-year follow-up
- Average 1.6kg removed
  - ~1Kg "heavy"
    - → 62% increased risk for mortality

Dekker[3]

- 1-year follow-up
- 1.1 L to 2.5 L – considered moderate fluid overload
  - → 64% increased risk of death

[1]Flythe JE, Assimon MM, Overman RA. Target weight achievement and ultrafiltration rate thresholds: potential patient implications. BMC Nephrol. 2017; 18: 185.

[2]Zocalli C et al. Chronic Fluid Overload and Mortality in ESRD. J Am Soc Nephrol. 2017 Aug; 28(8): 2491–2497.

[3]Dekker MJE et al. Impact of fluid status and inflammation and their interaction on survival: a study in an international hemodialysis patient cohort. Kidney International (2017) 91, 1214–1223.

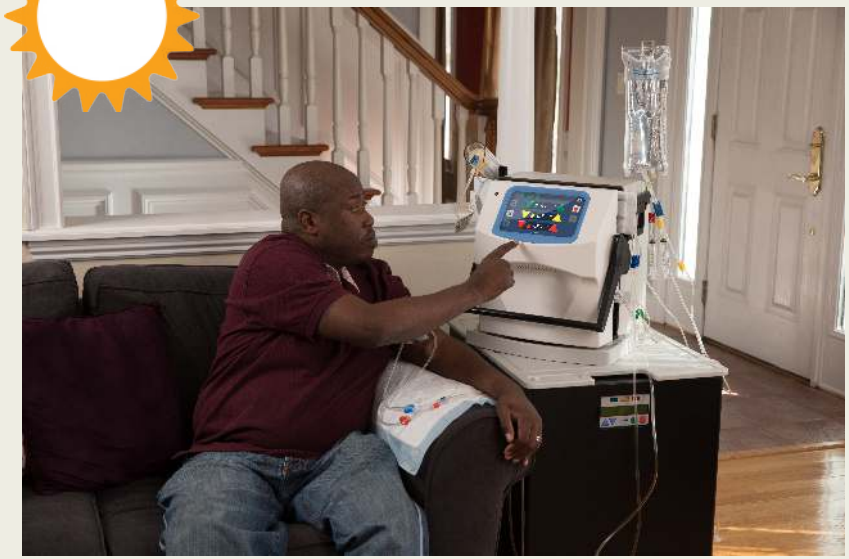
Recovery Time Matters

- Each 1-hour increment in chronic, post-dialysis recovery time associated with significantly increased risk of death[1]
- 68% of hemodialysis patients reported chronic, post-hemodialysis recovery time ≥ 2 hours

32% Reported **<2 hours**	41% Reported **2-6 hours**	17% Reported **7-12 hours**	10% Reported **>12 hours**
5-10% increased risk of death	**10-34%** increased risk of death	**41-80%** increased risk of death	**?** increased risk of death not studied

1. Rayner HC, Zepel L, Fuller DS, et al. Recovery time, quality of life, and mortality in hemodialysis patients: the Dialysis Outcomes and Practice Patterns Study (DOPPS). Am J Kidney Dis. 2014.

Patient-Centered Ease of Use



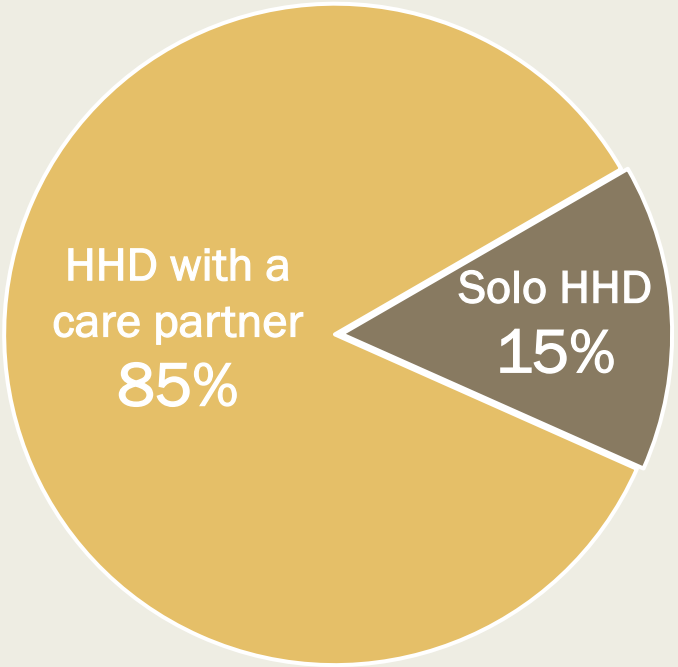
87% improvement
with more frequent
home hemodialysis[1]

98% improvement
with more frequent
nocturnal hemodialysis[2]

1. Jaber BL, Lee Y, Collins AJ, et al. Effect of daily hemodialysis on depressive symptoms and post-dialysis recovery time: interim report from the FREEDOM (Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements) Study. Am J Kidney Dis. 2010;56(3):531-539. 2. Lindsay RM, Heidenheim PA, Nesrallah G, Garg AX, Suri R, Daily Hemodialysis Study Group London Health Sciences Centre. Minutes to recovery after a hemodialysis session: a simple health-related quality of life question that is reliable, valid, and sensitive to change. *CJASN*. 2006;1(5):952-959. .

Home HD Patient Preference Survey Results

NxStage System One Cleared in 2017 for solo home hemodialysis without a care partner during waking hours

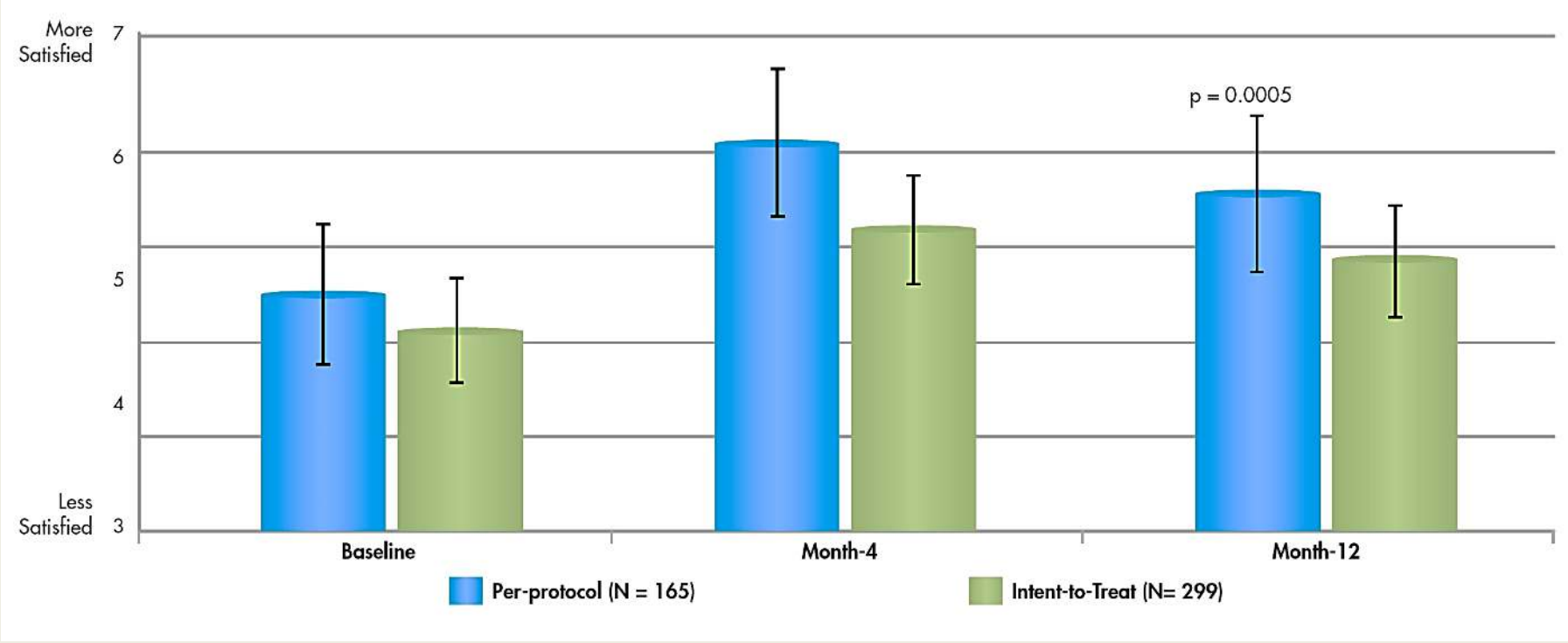


15% of **patients** confidently and competently perform **Solo Home Hemodialysis**[1]

1 Weinhandl E, Collins AJ. Consistent preferences for solo home hemodialysis vs. incenter hemodialysis across hypothetical relative risks of Death. Hemodialysis International 2018; 22:A22–A23

Improved Sexual Satisfaction

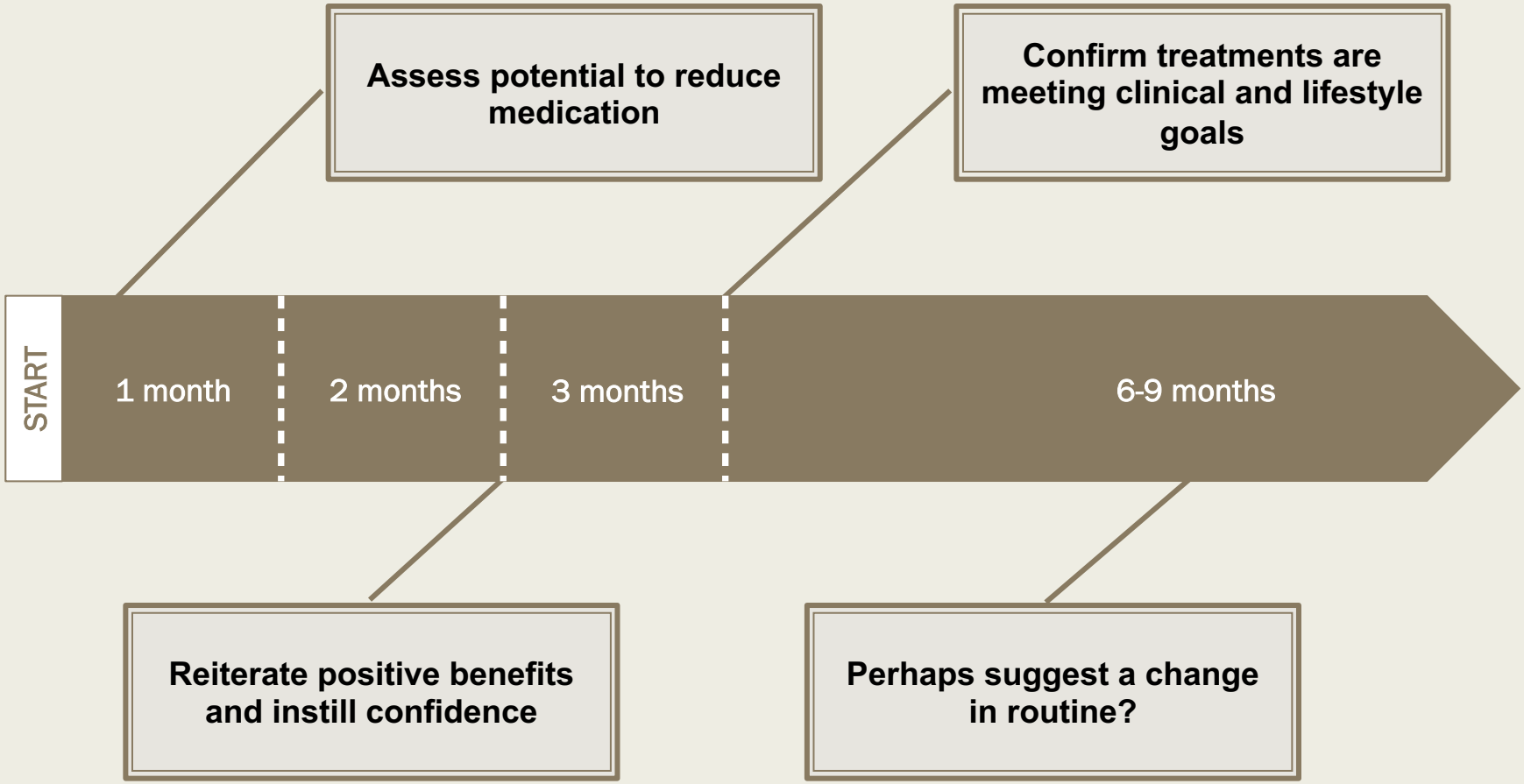
Satisfaction with physical intimacy increased after initiation of more frequent home hemodialysis[1]



1. Kraus M, Finkelstein FO, Daoui R, et al. Short Daily Hemodialysis (SDHD) improves overall Quality of Life (QOL) and physical intimacy: interim results from the FREEDOM study. Abstract presented at the American Society of Nephrology Conference, 2011.

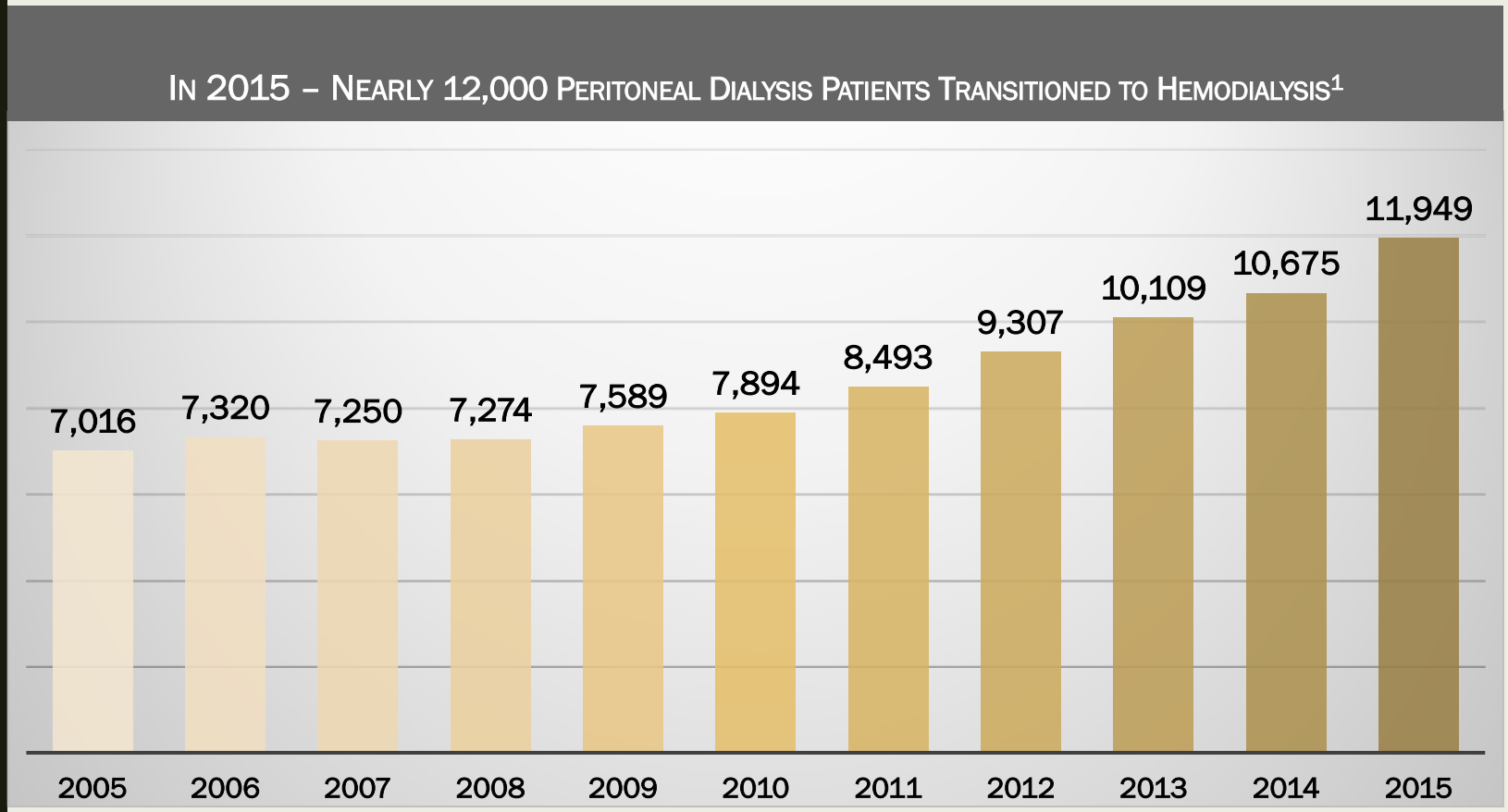
THE FREEDOM STUDY™

Monitor Changes



BUILDING FOUNDATIONS FOR THE FUTURE BY PLANNING AHEAD

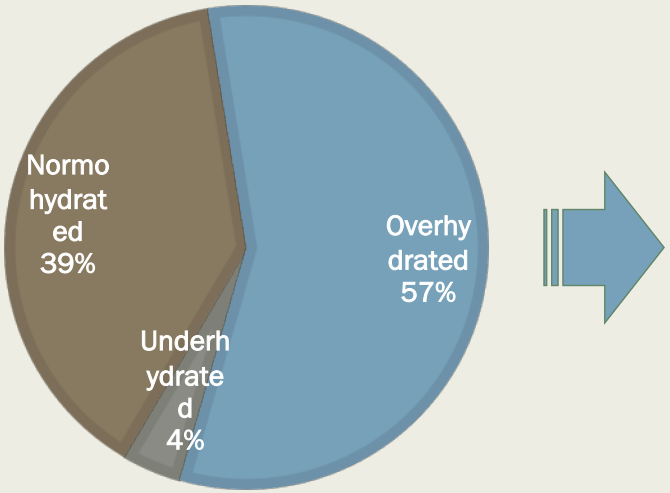
More attention needed to keep patients home



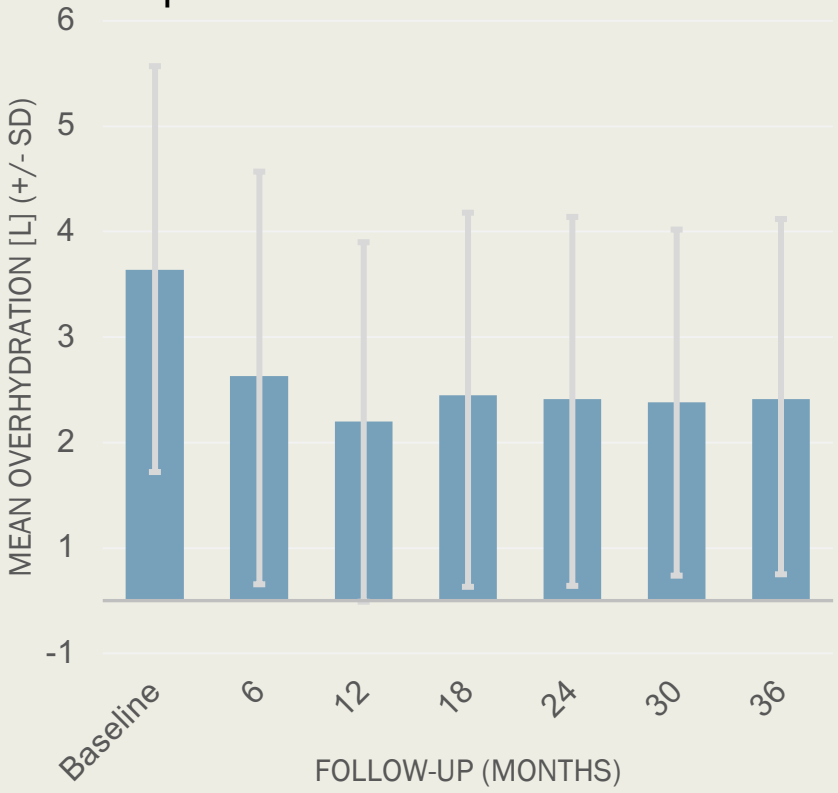
[1]Analysis of United States Renal Data System Standard Analysis Files. PD technique failure defined by at least 30 days of HD immediately following PD.

57% of Participants Initiating Dialysis ≥1L Over Dry Weight

Hydration status in a cohort of 1,054 participants initiating PD



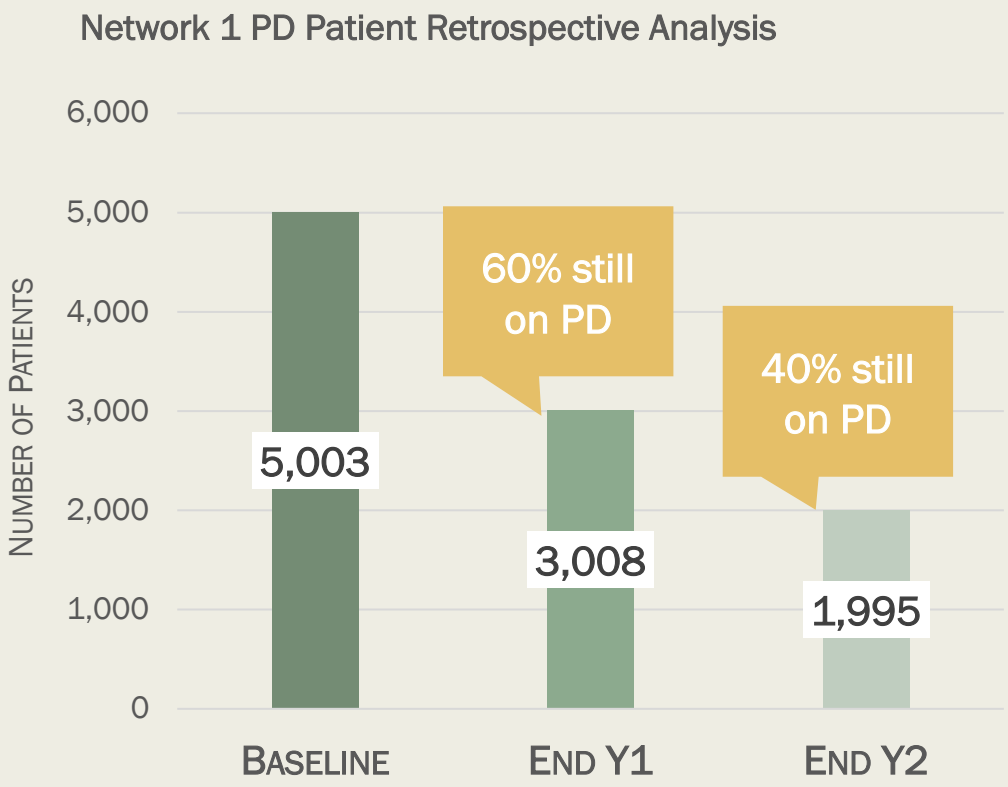
Volume status in overhydrated participants averaged ≥2L during 3-year follow-up



High Peritoneal Dialysis Therapy Attrition Rates Commonly Reported

Reported 1-year Peritoneal Dialysis (PD) therapy attrition rates over 35%[1]

Similar attrition rates for mortality and transition to hemodialysis[1]



[1]Bayode Afolalu, Laura Troidle, Osasu Osayimwen, Jaya Bhargava, Jenny Kitsen4 and Fredric O. Finkelstein. Perit Dial Int May-June 2009 vol. 29 no. 3 292-296

Educational Plans and Interventions to Prepare Patients for Home Modality Transitions

Experiences and Considerations comprised of the Medical Directors and Clinician Teams at the six largest Peritoneal Dialysis (PD) programs in the U.S.[1]

STAGE 1

Adjustment

Prepare for the future even as they begin PD at home

TRANSITION OVERVIEW

Watch For:

How well are they adjusting to this life-changing event?

Action:

- Help them understand the different stages of PD therapy
- Identify their goals and aspirations for the next week, month, year
- Create a life plan to address how therapy can meet their needs
- Educate on modality options for their future, including home hemodialysis (HHD)

CLINICAL INDICATORS

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

INTERVENTIONAL STRATEGIES & EDUCATIONAL MESSAGING

- Discuss average survival on PD—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 a Life Plan and continually re-educate patients about other therapy options available to them

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

STAGE 2

Re-evaluation

Closely monitor for signs of decline as the journey continues

TRANSITION OVERVIEW

Watch For:

Have they stopped engaging in hobbies or activities because they aren't feeling well?

Action:

- Re-assess if therapy is meeting their needs, referring to their life plan
- Re-educate on modality options, knowing that they're used to the freedom of home dialysis

CLINICAL INDICATORS

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

INTERVENTIONAL STRATEGIES & EDUCATIONAL MESSAGING

- 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."

STAGE 3

Imminent Transition

Proactively plan a modality transition to keep them at home, if that's what they want

TRANSITION OVERVIEW

Watch For:

Does their health and quality of life appear to be deteriorating?

Action:

- Discuss their modality options, including the clinical and lifestyle benefits of HHD
- Establish access—their PD access can no longer be used
- Train on their chosen modality

CLINICAL INDICATORS

- 3 or more of the Stage 2 indicators plus the following:
  - —Medical complications (CV, fractures, hernias, leaks)
  - —> 3 hospitalizations in 1 year (ICU)

INTERVENTIONAL STRATEGIES & EDUCATIONAL MESSAGING

- 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."

Examining Ways to Address Patient Anxiety and Depression

Intradialytic Laughter Therapy

Intradialytic laughter therapy is a safe and feasible therapy that can improve perceptions of mood in dialysis patients and dialysis staff and has implications for patient stress, anxiety and adherence to treatment and staff satisfaction.[1]

Intradialytic Meditation

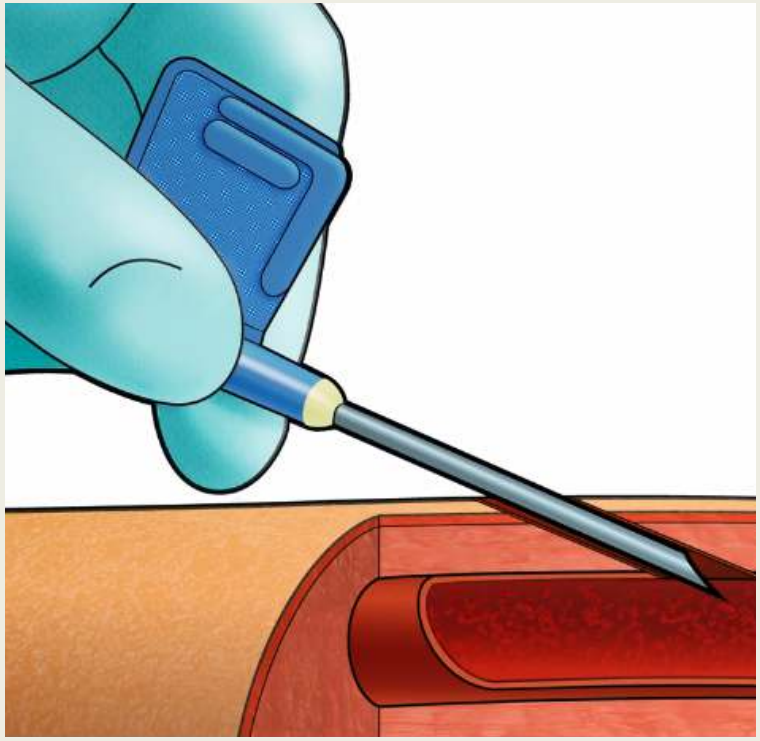
Meditation during HD does not improve pain during cannulation. However, overall PHQ-4 scores improved significantly due to decreased anxiety and feelings of depression. PROMs suggest an improvement with washed out feelings after meditation.[2]

1 Bennett PN, Cunanan J, Luckett T, Grant A, Cabrera R, Schiller B. Hemodialysis International 2018;22:A8

2 Ngo T, Bennett PN, Hordagoda M, Penny J, Chang R, Schiller B. Hemodialysis International 2018;22:A6.

Other Resources to Help Address Needle Phobia

ButtonHole® with SteriPick®



ISHD: HHD Practical Manual

REFERENCES

Reported Benefits of More Frequent Home Hemodialysis **References**

[1]Morfin, J.A., Fluck, R.J., Weinhandl, E.D., Kansal, S., McCullough, P.A., and Komenda, P. Intensive hemodialysis and treatment complications and tolerability. Am J Kidney Dis. 2016; 68: S43–S50.

[2]Chan, C.T., Greene, T., Chertow, G.M. et al. Determinants of left ventricular mass in patients on hemodialysis: Frequent Hemodialysis Network (FHN) Trials. Circ Cardiovasc Imaging. 2012; 5: 251–261.

[3]Weinhandl, Leypoldt, Collins. Application of Extended Home Hemodialysis with the NxStage System One. Oral Presentation. 2017 ASN Kidney Week.

[4]FHN Trial Group, Chertow, G.M., Levin, N.W., Beck, G.J. et al. In-center hemodialysis six times per week versus three times per week. N Engl J Med. 2010; 363: 2287–2300.

[5]Stefánsson, B.V., Brunelli, S.M., Cabrera, C. et al. Intradialytic hypotension and risk of cardiovascular disease. Clin J Am Soc Nephrol. 2014; 9: 2124–2132.

[6]Jaber, B.L., Lee, Y., Collins, A.J. et al. Effect of daily hemodialysis on depressive symptoms and postdialysis recovery time: interim report from the FREEDOM (Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements) Study. Am J Kidney Dis. 2010; 56: 531–539.

[7]McCullough, P.A., Chan, C.T., Weinhandl, E.D., Burkart, J.M., and Bakris, G.L. Intensive hemodialysis, left ventricular hypertrophy, and cardiovascular disease. Am J Kidney Dis. 2016; 68: S5–S14.

[8]Bakris, G.L., Burkart, J.M., Weinhandl, E.D., McCullough, P.A., and Kraus, M.A. Intensive hemodialysis, blood pressure, and antihypertensive medication use. Am J Kidney Dis. 2016; 68: S15–S23.

[9]Copland, M., Komenda, P., Weinhandl, E.D., McCullough, P.A., and Morfin, J.A. Intensive hemodialysis, mineral and bone disorder, and phosphate binder use. Am J Kidney Dis. 2016; 68: S24–S32.

Reported Benefits of More Frequent Home Hemodialysis **References** ***(continued)***

[10]Weinhandl, E., Constantini, E., Everson, S. et al. Peer Kidney Care Initiative 2014 report: dialysis care and outcomes in the United States. (S1-140)Am J Kidney Dis. 2015; 65: Svi.

[11]Kotanko P, et al. Effects of frequent hemodialysis on blood pressure: Results from the randomized frequent hemodialysis network trials. Hemodial Int. 2015 Jul;19(3):386-401. doi: 10.1111/hdi.12255.

[12]Daugirdas JT, Chertow GM, Larive B, et al. Effects of frequent hemodialysis on measures of CKD mineral and bone disorder. JASN. 2012;23(4):727-738.

[13]Lowrie, E.G., Curtin, R.B., LePain, N., and Schatell, D. Medical Outcomes Study Short Form-36: a consistent and powerful predictor of morbidity and mortality in dialysis patients. Am J Kidney Dis. 2003; 41: 1286–1292.

[14]Lacson, E., Xu, J., Lin, S.-F., Dean, S.G. Lazarus, J.M., and Hakim, R.M. A comparison of SF-36 and SF-12 composite scores and subsequent hospitalization and mortality risks in long-term dialysis patients. Clin J Am Soc Nephrol. 2010; 5: 252–260.

[15]Finkelstein, F.O., Schiller, B., Daoui, R. et al. At-home short daily hemodialysis improves the long-term health-related quality of life. Kidney Int. 2012; 82: 561–569.

[16]Jaber, B.L., Schiller, B., Burkart, J.M. et al. Impact of short daily hemodialysis on restless legs symptoms and sleep disturbances. Clin J Am Soc Nephrol. 2011; 6: 1049–1056.

[17]Culleton BF, Walsh M, Klarenbach SW, et al. Effect of frequent nocturnal hemodialysis vs conventional hemodialysis on left ventricular mass and quality of life: a randomized controlled trial. JAMA. 2007;298(11):1291-1299.

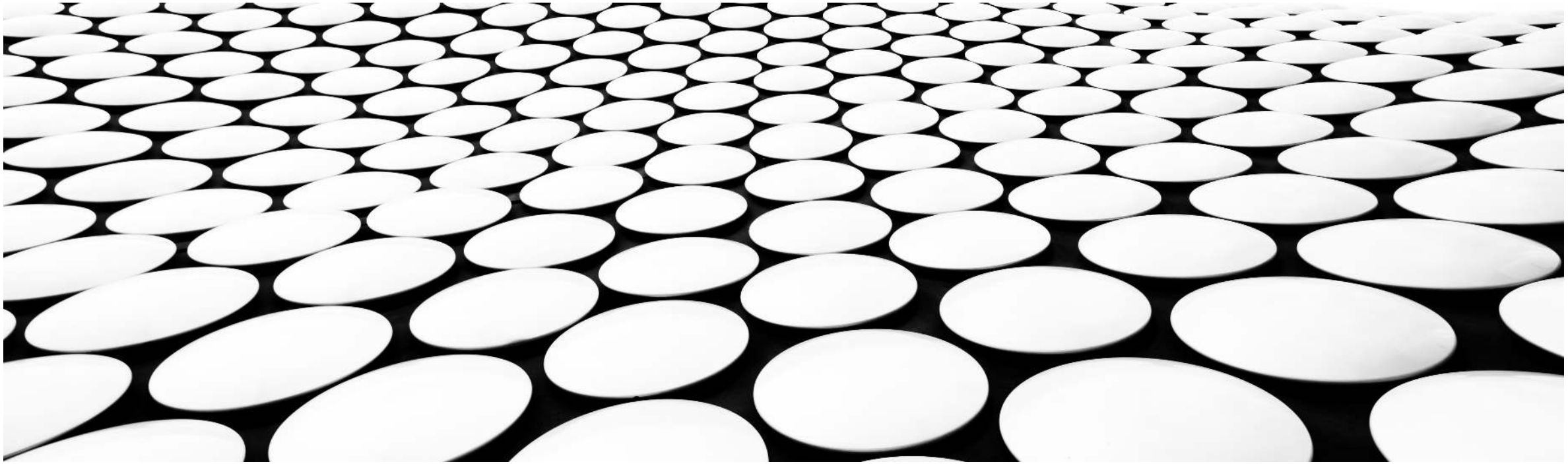
QUESTIONS?

WORKFORCE DEVELOPMENT AND MODELS OF CARE IN HEMODIALYSIS

MICHAEL A KRAUS, MD FACP

EMERITUS CLINICAL PROFESSOR OF MEDICINE, INDIANA UNIVERSITY

ASSOCIATE CHIEF MEDICAL OFFICER, FRESENIUS KIDNEY CARE



CONFLICTS OF INTEREST

- Full time employee (Associate Chief Medical Officer) – Fresenius Kidney Care, Inc

ITS NOT YOU MOTHERS HOME DIALYSIS ANY MORE

How do we staff? Who is on the team?
How do we ensure adequate resources and space?
All Modalities - Training and retention
Growth

1 nurse in a small space

Focus on staffing ratio, Nurse heavy staffing

Changes needed

More PD nurses
Separate HHD programs starting fresh

WHAT WE WILL NOT DISCUSS

- Staffing ratios
- Staffing ratios
- Staffing ratios

MODELS ARE DEPENDENT ON SETTING AND MISSION

- Academic Versus Private
- Is home a priority for you?
- What are your goals of growth
  - Set Targets, measure results and meet targets
- Size matters
  - Associated with quality, retention and resources
- Part of a dialysis organization versus standalone

FUTURE OF HOME IS DEPENDENT ON ABILITY TO GROW AND IMPROVE QUALITY AND VALUE

- Home dialysis is a program regardless of model.
  - Not a “unit” anymore
  - Home therapies is teamwork
  - “Everyone” must share some responsibility in growth of home – Same with transplant

EDUCATION

Physicians and Nurses

Incenter staff

- Educators –
  - Physician champion
  - Nurse Champions
  - Education team
  - Dialysis Organization Medical Office
  - Academic Centers
  - Educational programs, virtual and in person
  - NKF, ASN, ANNA, RPA…

EDUCATION (PRE HOME THERAPY PATIENT)

Patient, Family and Care Partners

- Home dialysis nurses
- Nephrologist
- CKD education classes
- Advocates for kidney care teams
- Patient navigators
- In-center staff/ IDT
- Peer groups
- Marketing
  - Development of patient facing materials
    - Print, Video, social media…
    - Pre patients, training material, follow up

TRAINING

Patients and Care partners

- Education Team
- Home Nurses are primarily responsible
  - Larger Programs MAY consider Nurses who are primarily trainers only
- Dieticians and Social work have their own content
- Non licensed personnel (NLP) have value
  - Home PCT could be cannulation expert
  - NLP can reinforce education, support training
  - PCT assist in performing treatments (particularly HD)
- Training must also be part of QAPI, reevaluate frequently
  - Balance between duration and assurance
  - Monitor training “graduation” and technique attrition – especially first 90 days

PATIENT CARE/ CLINICS AND DAILY CARE

- Nurses
  - PD an/or HHD only. Dual trained AND responsible
  - Training versus “Clinic” Nursing
  - 24/7 coverage is necessary
    - Can (should) remote Telehealth play a part in the future?
  - Did I mention role of telehealth and nurses' responsibilities
  - Telehealth should also assist in daily care
  - Review of flow sheets/alarms and trouble shoot (dialysis device info and RPM)

- Entire IDT should participate
  - Did I mention telehealth (all members should try to attend virtual and in-person clinic)
  - IDT role in daily care – social work and Dietician visits are essential
    - In person or telehealth
  - Telehealth should also assist in daily care
  - Review of flow sheets/alarms and trouble shoot (dialysis device info and RPM)
  - Role in growing transplant waitlist

- NLP have great value in clinics
  - Intake and rooming patients
  - Phlebotomy
  - Assist in scheduling – Patient reminders
  - Telehealth “rooming” and reminders
  - Follow up phone calls, reminders of labs, other specialty visits, tests etc

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ENSURING QUALITY AND VALUE

Measure results

Not only “usual” QIP

Measure and follow volume/ BP

Infection control

Monitor training success

Monitor retention

Monitor optimal transition between therapies

Monitor Hospitalizations

- Medical Director
- All Nephrologists
- Entire IDT
- IT support
  - Telehealth
  - Remote patient Monitoring
- Artificial intelligence, data analysis
- PDSA – entire team

WORKFORCE DEVELOPMENT AND MODELS OF CARE IN HEMODIALYSIS

- Consider all the needs
- Determine which staff and which responsibilities
- Ideally work to license
- Requires an entire team
- Models will vary but needs are the same
  - Cannot give ideal staffing ratios because that is not a known variable and dependent on model variations