TDC
Demonstration
Initiative

Transitional Dialysis Care

Operational Guidance

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Transitional Dialysis Care (TDC) is a patient-centric approach to gently easing a patient into dialysis, and addressing their clinical and emotional needs while in transition. While the clinical benefits to patients may be clear, you may be in search of operational guidance for how to implement a TDC Unit.

This TDC Operational Guidance Resource was built based on the experiences and best practices of several thought-leaders in the renal industry that have either implemented or are in the process of implementing a TDC Unit at their center.

This Transitional Dialysis Care Operational Guidance Resource details:

- Clinical and Economic Considerations
- Implementation Strategies
- Infrastructure and Logistical Planning
- Staffing and Internal TDC Training
- Patient Education
- Marketing Considerations

Acknowledgement

The Transitional Dialysis Care (TDC) Demonstration Initiative, facilitated by NxStage Medical, worked in collaboration to create the content incorporated in this Transitional Dialysis Care Operational Guidance resource.

Members of the TDC Demonstration Initiative include:

TDC Demonstration Initiative

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*"Stacy Cigliana is an employee of NxStage Kidney Care."

Optimize Your Experience

- Within this TDC Operational Guidance resource, there are some Transitional Dialysis Care related documents that can be downloaded.
- In order to download these documents, **you must have internet access** as the documents are stored in a resource library webpage.
- Optionally, you can download all resources packaged into a single folder via the resource library webpage to ensure you have everything you need to implement your TDC Unit.

Click to download all TDC Resources

What are the Core Elements of a TDC Unit?

- All appropriate patients start in a TDC Unit
  - » New to dialysis, failed PD, or transplant
- More frequent treatments prescribed to stabilize patients (eg, No 2-Day Treatment Gap)
- Existing in-center staff and infrastructure utilized
- Thorough education on all renal replacement options provided to patients, including transplantation
- Treatments performed using a home hemodialysis system (such as the NxStage system)

Why Transitional Dialysis Care

Designed to:

- **Ease patients into dialysis**
  - » TDC offers patients in transition:
    - Time to recover medically
    - Time to adjust emotionally
    - Time to receive modality education of their dialysis options
    - Time to choose the modality that fits their unique clinical and life needs
- **Opportunity for patients to experience treatments with a home hemodialysis device.**

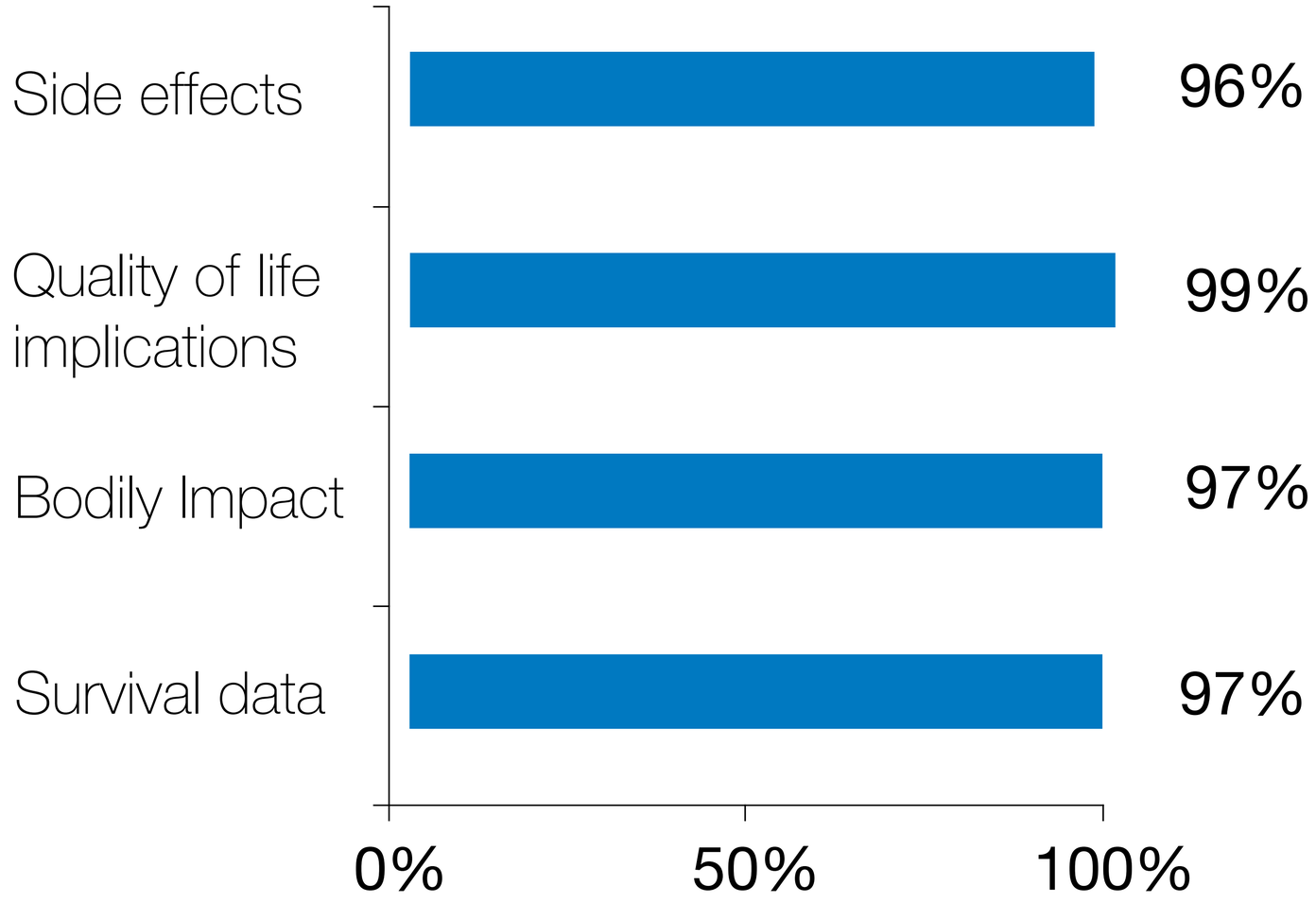
Patient Unawareness of Modality Options

- Emotionally, new dialysis patients may be frightened, confused, anxious, lost[1]
- Clinically, these patients are at a “heightened” risk of mortality and hospitalization[2]
- Survey of new dialysis patients in one ESRD network showed[3]
  - » **66%** were NOT presented the option of PD
  - » **88%** were NOT presented the option of HHD
  - » **74%** were NOT presented the option of transplantation

References: 1. A “New Normal”: Life on Dialysis – The First 90 Days. National Kidney Foundation. **2.** Chan KE, Maddux FW, Tolkoff-Rubin N, Karumanchi SA, Thadhani R, Hakim RM. Early outcomes among those initiating chronic dialysis in the United States, Clin J Am Soc Nephrol 6: 2642-2649, 2011. **3.** Mehrota R, Marsh D, Vonesh E, Peters V, Nissenson A. Patient education and access of ESRD patients to renal replacement therapies beyond in-center hemodialysis. Kid Int. 2005; 68(1): 378-90

Patients Want to be Informed

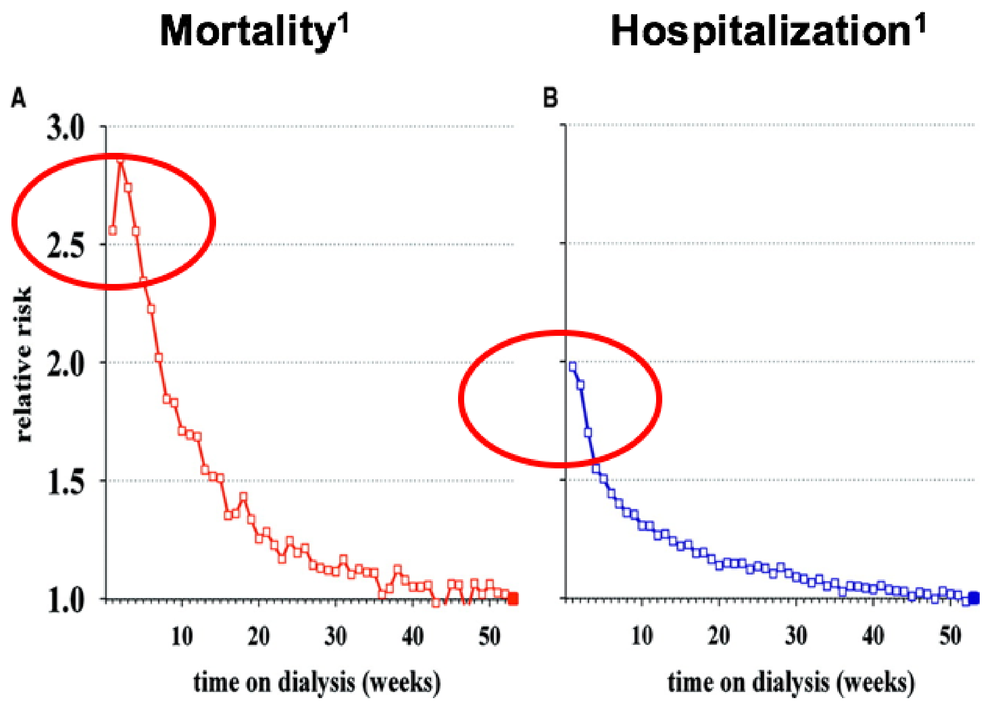
Patients want to be informed on modality options[1]



References: 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.

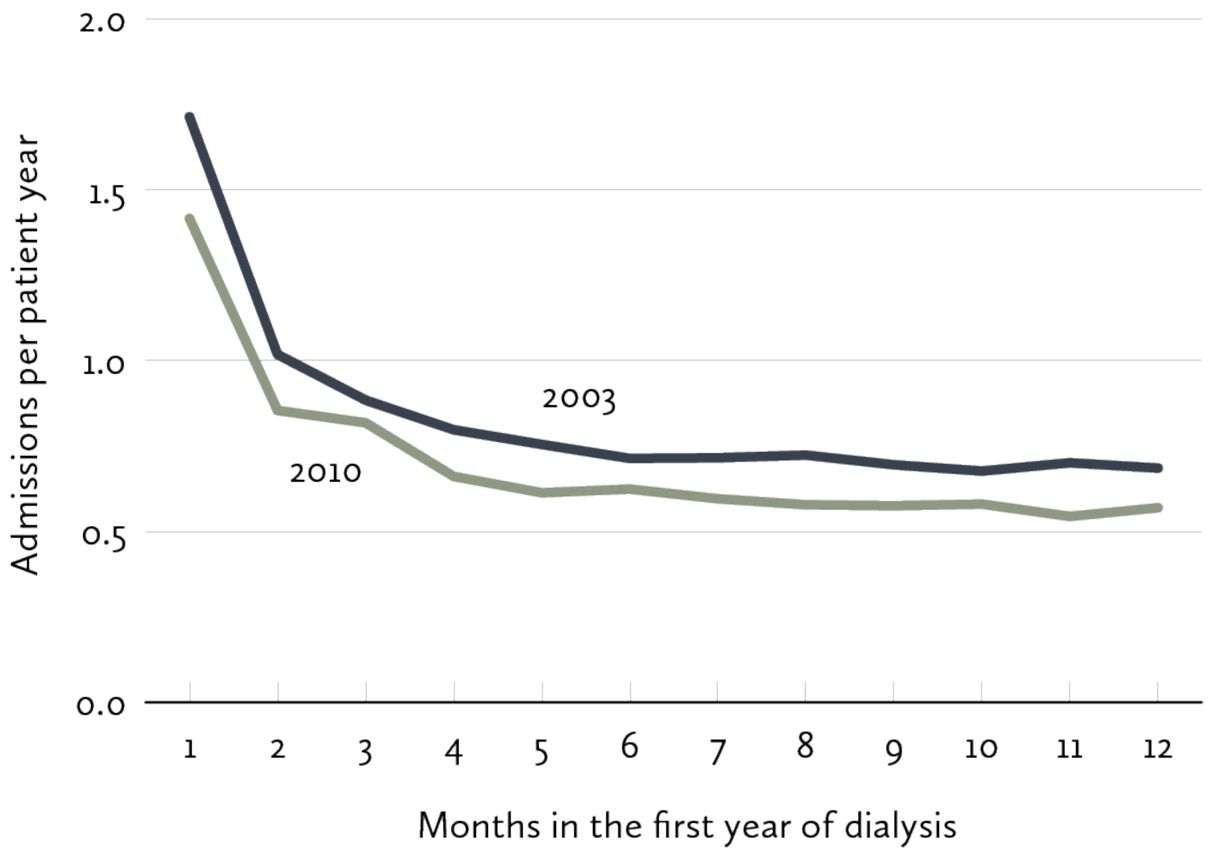
The “Heightened” Period: First 90 Days

- The first two weeks of dialysis are associated with a heightened mortality and hospitalization risk.
- In the second week of being on dialysis, an incident patient is **2.86** times more likely to expire than a patient who survived the first year of dialysis.
- In the first week of being on dialysis, an incident patient is 2 times more likely to be hospitalized than a patient who survived the first year of dialysis.



References: 1. Chan KE, Maddux FW, Tolkoff-Rubin N, Karumanchi SA, Thadhani R, Hakim RM. Early outcomes among those initiating chronic dialysis in the United States, Clin J Am Soc Nephrol 6: 2642-2649, 2011.

Admission Rates in the 1st Year, By Month



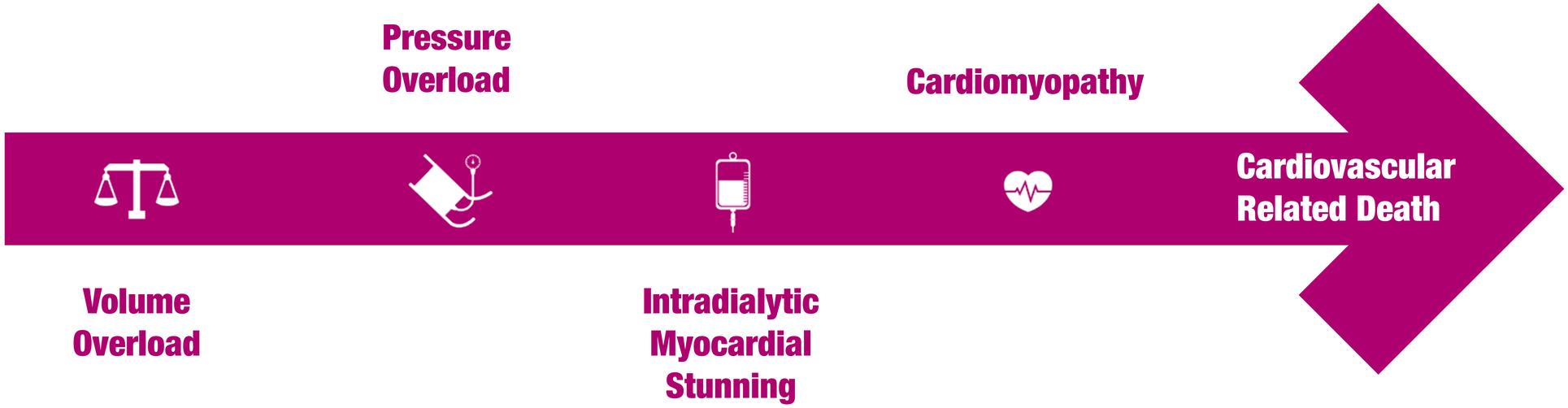
Increases in hospitalization in the first 90 days is also seen in:

- Acute Coronary Care
- Arrhythmia
- Heart failure/Cardiomyopathy
- Fluid overload/Pulmonary Edema

References: 1. Peer Report: Dialysis Care & Outcomes in the US, 2014 Hospitalization

Fluid Management and Cardiovascular Outcomes

- Cardiovascular Disease Causes ~50% of incident patient deaths[1]
- Effective fluid management is associated with better cardiovascular outcomes[2-5]
- Effectiveness varies by modality[6]

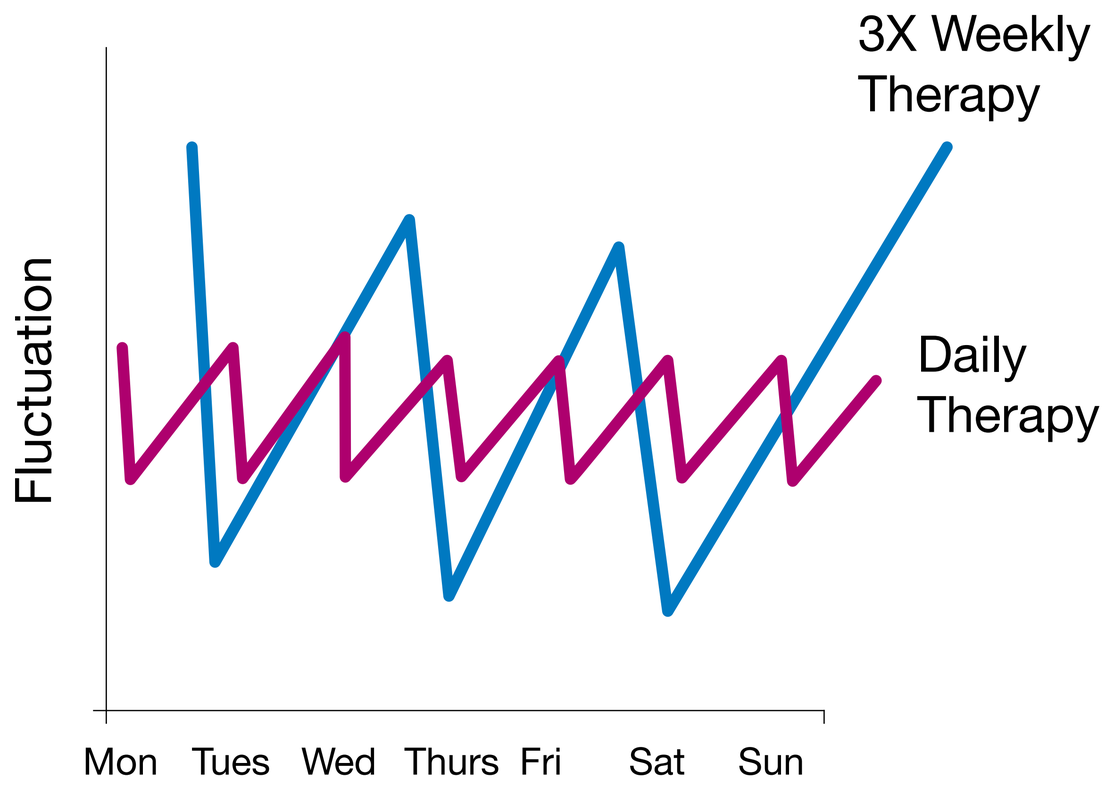


References: 1. Lukowsky LR, Kheifets L, Arah OA, Nissenson AR, Kalantar-Zadeh H. Patterns and predictors of early mortality in incident haemodialysis patients: new insights. Am J Nephrol 2012;35:548-58. **2.** Spanner E, Suri R, Heidenheim AP, Lindsay RM. The impact of quotidian hemodialysis on nutrition. Am J Kidney Dis. 2003;42(1 suppl):30-35. **3.** Galland R, Traeger J, Arkouche W, Cleaud C, Delawari E, Fouque D. Short daily hemodialysis rapidly improves nutitional status in hemodialysis patients. Kidney Int. 2001;60(4):1555-1560. **4.** Traeger J, Galland R, Delawari E, Arkouche W, Hadden R. Six years' experience with short daily hemodialysis: do the early improvements persist in the mid and long term? Hemodial Int. 2004;8(2):151-158. **5.** Buoncristiani U. Fifteen years of clinical experience with daily haemodialysis. Nephrol Dial Transplant.1998;13(suppl 6):148-151. **6.** Daugirdas et al.: Effect of frequent hemodialysis on residual kidney Function. Kidney International- 2013.

Cardiovascular Benefits of More Frequent Therapy

More frequent dialysis can help manage fluid fluctuations[1-4]

- Less stress on the heart[5,6]
- Better blood pressure control with fewer medications[5,7]



References: 1. Spanner E, Suri R, Heidenheim AP, Lindsay RM. The impact of quotidian hemodialysis on nutrition. Am J Kidney Dis. 2003;42(1 suppl):30-35. **2.** Galland R, Traeger J, Arkouche W, Cleaud C, Delawari E, Fouque D. Short daily hemodialysis rapidly improves nutitional status in hemodialysis patients. Kidney Int. 2001;60(4):1555-1560. **3.** Traeger J, Galland R, Delawari E, Arkouche W, Hadden R. Six years' experience with short daily hemodialysis: do the early improvements persist in the mid and long term? Hemodial Int. 2004;8(2):151-158. **4.** Buoncristiani U. Fifteen years of clinical experience with daily haemodialysis. Nephrol Dial Transplant.1998;13(suppl 6):148-151. **5.** FHN Trial Group. In-center hemodialysis six times per week versus three times per week. N Engl J Med. 2010;363(24):2287-2300. **6.** Ayus JC, Mizani MR, Achinger SG, et al. Effects of short daily versus conventional hemodialysis on left ventricular hypertrophy and inflammatory markers: a prospective, controlled study. J Am Soc Nephrol. 2005;16(9):2778-2388. **7.** Kotanko P, Garg AX, Depner T, et al. FHN Trial Group. Effects of frequent hemodialysis on blood pressure: results from the randomized frequent hemodialysis network trials. Hemodial Int. 2015; 19:386–401.

Clinical Benefits of More Frequent HHD

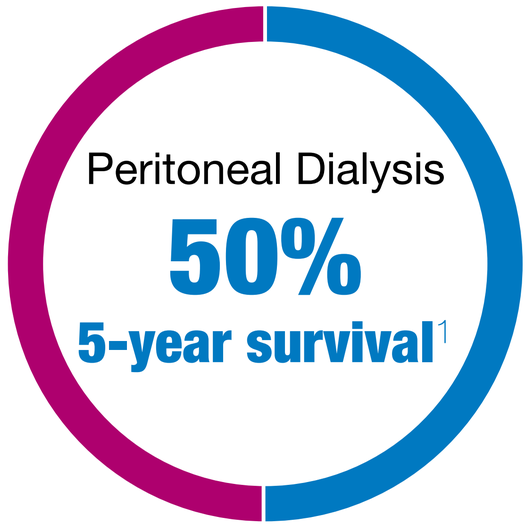
Compared to conventional three-times-weekly therapy, more frequent hemodialysis may provide:

- Less stress on the heart[1,2]
- Better blood pressure control with fewer medications[1,3]
- Quicker recovery time after treatment[4,5]
- More energy[6-9]
- Improved sleep quality[4,8]
- Liberalized diet and fluid intake restrictions[10]

References: 1. FHN Trial Group. In-center hemodialysis six times per week versus three times per week. N Engl J Med. 2010;363(24):2287-2300. **2.** Ayus JC, Mizani MR, Achinger SG, et al. Effects of short daily versus conventional hemodialysis on left ventricular hypertrophy and inflammatory markers: a prospective, controlled study. J Am Soc Nephrol. 2005;16(9):2778-2388. **3.** Jaber BL, Collins AJ, Finkelstein FO et al. Daily Hemodialysis (DHD) Reduces the Need for Anti-Hypertensive Medications. Abstract presented as poster at American Society of Nephrology Renal Week, 2009. **4.** Jaber BL, Lee Y, Collins AJ, 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(3):531-539. **5.** 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. Clin J Am Soc Nephrol. 2006;1(5):952-959. **6.** Finkelstein F, Gehr T, Kraus M, et al. Daily hemodialysis (DHD) improves quality of life (QofL): interim results from the FREEDOM study. Abstract presented as poster at Annual Dialysis Conference, 2011. **7.** Heidenheim PA, Muirhead N, Moist L, Lindsay RM. Patient quality of life on quotidian hemodialysis. Am J Kidney Dis. 2003;42(S1)(S1):S36-S41. **8.** Ting GO, Kjellstrand C, Freitas T, Carrie BJ, Zarghamee S. Long-term study of high-comorbidity ESRD patients converted from conventional to short daily hemodialysis. Am J Kidney Dis. 2003;42(5):1020-1035. **9.** Goldfarb-Rumyantzev AS, Leypoldt JK, Nelson N, Kutner NG, Cheung AK. A crossover study of short daily haemodialysis. Nephrol Dial Transplant. 2006;21:166-175. **10.** Spanner E, Suri R, Heidenheim AP, Lindsay RM. The impact of quotidian hemodialysis on nutrition. Am J Kidney Dis. 2003;42(1 suppl):30-35.

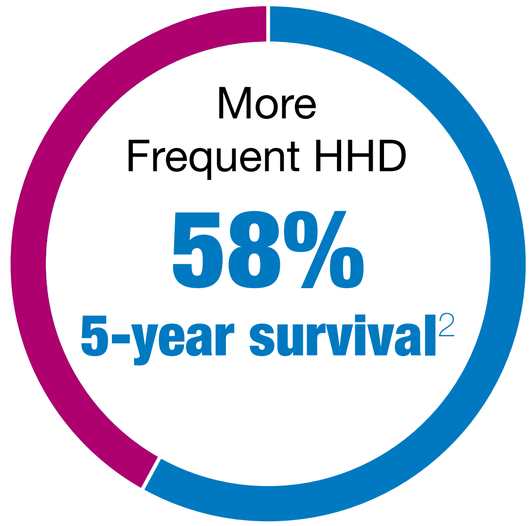
5-Year Survival By Modality

>420,000
Conventional HD Patients[1]



>45,000
PD Patients[1]

More frequent HHD is associated with better 5-year relative survival



>9,000
HHD Patients[2]

References: 1. U.S. Renal Data System, USRDS 2015 Annual Data Report: 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) Abbreviation: ESRD, end-stage renal disease. **2.** Data source: NxStage patient data on file.

Economic Considerations

The below financial considerations are important to keep in mind when trying to assess the economic impact of a TDC Unit compared to traditional In Center.

New ESRD patients that start each month

Medicare/Commercial payer mix for home and in-center patients

Medicare ESRD Adjuster for first 120 days (1.327 x bundle)

TDC patients are more likely to choose a home modality[1]

~$96 Training Add-On for Medicare patients that choose home

References: 1. NxStage Data on File. Internal Customer Information. June 2017.

Pros and Cons of TDC

There are some potential pros and cons of implementing a TDC Unit compared to traditional in-center:

POTENTIAL PROS

- Increased Revenue
- Improved Gross Margin*
- Increased home census
- Minimized need to build new clinics
- Reduced costs as a result of improved quality of care

POTENTIAL CONS

- Higher Treatment Costs
- Initial increase in labor to provide patient education

*Total gross margin is often higher over time with Transitional Dialysis Care because more total treatments are billed, overcoming the increased cost of supplies.

Assess all operational, staffing, and billing factors when comparing a TDC and traditional in-center model

TDC Champion

- Prior to implementing a TDC Unit, it is essential to identify one representative in your practice that has a vested interest in both your In Center and Home Training units to champion your TDC Unit
- This person does not need to be a physician
- The TDC Unit Champion should drive the behavior that all appropriate new to dialysis patients as well as failed PD, and transplant patients begin in the TDC Unit

Creating a TDC Planning Team

- The TDC Champion plays an important role in creating a TDC Planning Team
- The TDC Champion should engage key members of the dialysis center to participate in the early stages of implementation planning
- Below are recommendations for center team members that should be part of the TDC Planning Team:
  - » Physician Champion
  - » Nurse Overseeing TDC Unit
  - » Patient Care Techs (PCTs) / Licensed Practical Nurse (LPN)
  - » Social Worker
  - » Dietician
  - » Patient Financial Advisor
  - » Home Nurses (HHD & PD, if applicable)
  - » Provider Cost Analysis Personnel
  - » Materials Management / Supply Chain Representative
  - » In-Center Operations Representative

Roles of the TDC Planning Team

- **In Center RN** – Oversees TDC treatments, assesses patients (pre and post treatment), coordinates patient vascular access plan, administers medication and provides education to patients, responsible for the schedule of all
- **PCT / LPN / LVN** – Performs the treatments, troubleshoot alarms, and reinforce education provided by the RN
- **Home Therapy RN** – Provides in-depth PD and HHD modality education
- **Social Worker** – Shares relevant financial information with patients regarding their insurance coverage entitlements as well as other economic aspects related to dialysis, assists in transplant referral as needed, and provides emotional support to patients and their families
- **Dietician** – Educates patients on their dietary and fluid requirements for each modality
- **Physician** – Prescribes therapy, adjusts medications and treatments based on patient needs, reinforces education provided by care team, informs patients of survival, data, and risks of each modality
- **Patient Financial Advisor** – Advises patient on economic related topics such as insurance, transportation, and Medicare/Medicaid regulations (Can be done by Social Worker if necessary)

Roles of the TDC Planning Team (cont)

- **Provider Cost Analysis Personnel** – Responsible for ensuring a financial analysis comparing the flow of patients in a TDC model vs a traditional in center model is completed
- **Materials Management / Supply Chain Representative** – Ensures all TDC equipment and supplies that will be required by the center to order are setup within the center's ordering system
- **In Center Operations Representative** – Ensures both TDC Unit and In Center are run efficiently and optimizes capacity

Internal Alignment

- The TDC Champion should ensure that everyone on the TDC Planning Team understands the intent and framework of a TDC Unit.
- Anyone on the TDC Planning Team that is relatively unfamiliar with what a TDC Unit entails should be presented with the concept of TDC.
- A recommended best practice to keep everyone on task is for the TDC Planning Team to meet on a weekly basis and to establish a target start date to work toward.

Goal Setting

To implement a successful TDC Unit, it's important to determine your center's goals before the implementation process begins.

Examples of Goals

- Achieve patient blood pressure control by end of the first month on therapy
- Reduce patient mortality and hospitalizations
- Reduce patient treatment recovery time by end of the first month
- Increase home penetration
- Better educate patients on dialysis modality choices
- Increase % of patients on the active transplant list
- Differentiate services to potentially increase referral stream
- Reduce patient LVH by end of first year on therapy

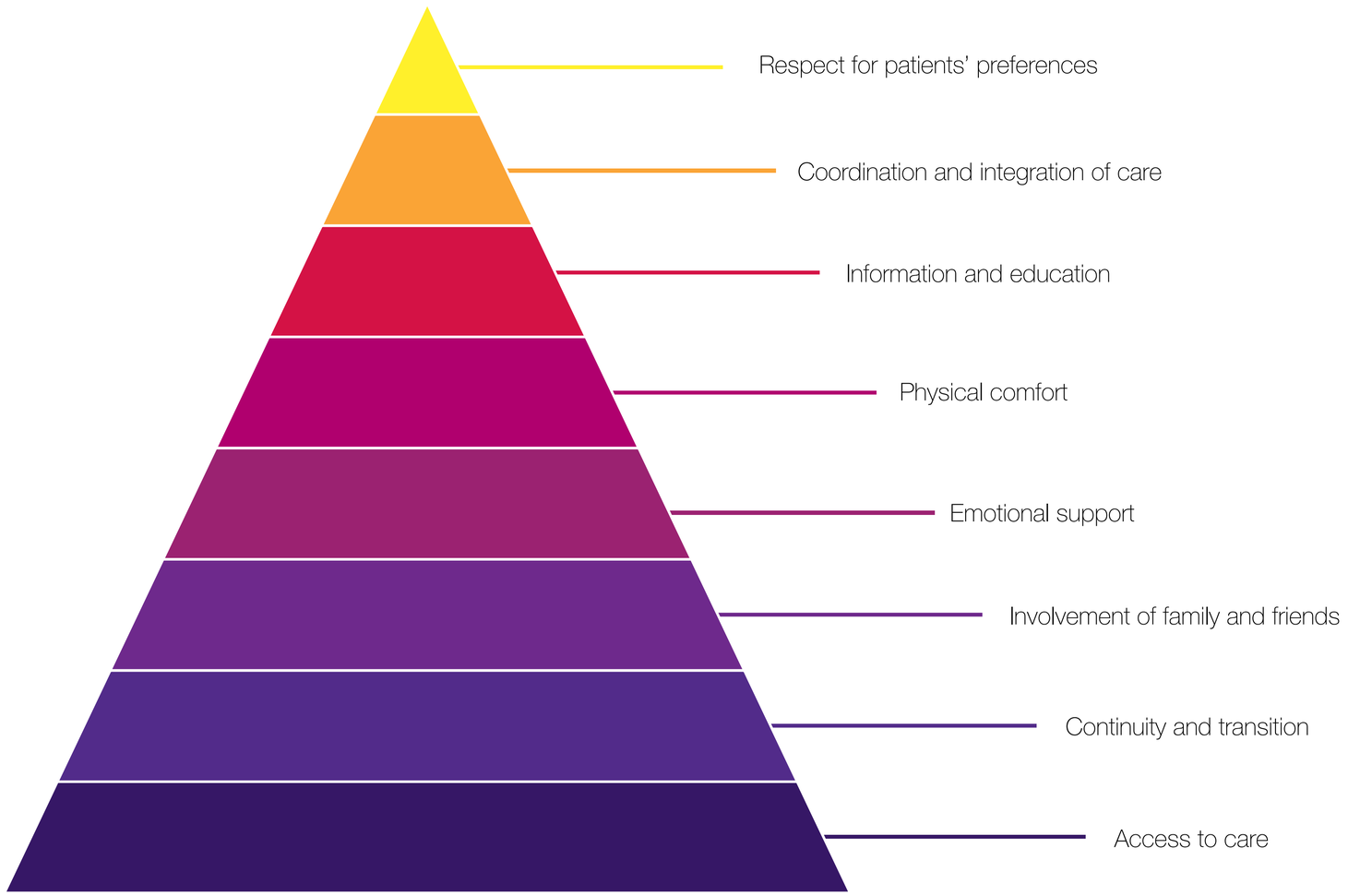
Once the goals are established, the TDC Champion will need to collaborate with the appropriate administration personnel to ensure there is alignment on business goals and objectives.

Strategies for Gaining Buy-in

Organizational change often runs into resistance due to different assessments or opinions, misunderstandings, or low-tolerance for change.

- Dealing with resistance, education, and communication are key
  - » Provide information and education about TDC through supportive literature or study data (Refer to pages 7 & 8)
- Make sure to allow and encourage involvement and participation
  - » To encourage adoption, include the wider team and listen to any concerns or arguments against the change
- Facilitate support
  - » Change can be difficult for many people so make sure to facilitate support by offering additional education or team meetings to talk through potential concerns or problem areas.

Principles of Patient-Centered Care



Picker's Eight Principles of Patient Centered Care[1]

References: 1. Picker Institute and Harvard Business School. The Eight Principles of Patient Centered Care. Oneview. May 15, 2015.

Achieving Physician Buy-in

- To implement an effective TDC Unit, it is important that all physicians support the concept and center goals
- It helps to have a “Physician Champion” who is enthusiastic about TDC and motivated to start patients in the program
- Have the Physician Champion present the concept and goals of a TDC Unit to all physicians that refer patients to the clinic
  - » It is recommended to consistently follow-up with these physicians
- If there is pushback about starting patients in the TDC Unit, try using the following questions as discussion items:
  - » Which of your patients would benefit from:
    - Better ultrafiltration management at the start of dialysis?[1-4]
    - Thorough education of all dialysis modality options?
    - Making an informed choice on the dialysis modality that best fits their life goals?

References: 1. Spanner E, Suri R, Heidenheim AP, Lindsay RM. The impact of quotidian hemodialysis on nutrition. Am J Kidney Dis. 2003;42(1 suppl):30-35. **2.** Galland R, Traeger J, Arkouche W, Cleaud C, Delawari E, Fouque D. Short daily hemodialysis rapidly improves nutritional status in hemodialysis patients. Kidney Int. 2001;60(4):1555-1560. **3.** Traeger J, Galland R, Delawari E, Arkouche W, Hadden R. Six years’ experience with short daily hemodialysis: do the early improvements persist in the mid and long term? Hemodial Int. 2004;8(2):151-158. **4.** Buoncristiani U. Fifteen years of clinical experience with daily haemodialysis. Nephrol Dial Transplant.1998;13(suppl 6):148-151.

Attaining Nurse Buy-in

- Based on the patient selection of dialysis modalities from centers that have implemented TDC Units, it's likely your home program will grow
- It's important to consider as the home program grows, the home training nurses' workload will expand
- Investing in the appropriate resources ensures home programs are staffed to provide quality patient training and care
- It is recommended to engage the nursing team early in the TDC implementation process to make them feel more as an owner of the program rather than just taking orders from management.
- Potential ways to maximize job satisfaction include:
  - » Consider hiring an additional nurse to account for additional workload
  - » Provide appropriate administrative resources and support

External Healthcare Partner Buy-in

- It's also essential to educate external healthcare partners about TDC and its benefits.
- Provide information about the TDC Unit and benefits to ESRD patients by educating the following:
  - » Hospital Discharge Planners & Social Workers
  - » Primary Care Physicians
  - » Acute Dialysis Staff
- Inform the center's business development team and explain how the TDC Unit may improve the volume of new patients

Other Buy-in Considerations

- If you are part of a LDO, it's vital to reach out to the regional directors and present the concept and goals of a TDC Unit to gain their support
- In addition, if you are part of a LDO, it is recommended to achieve buy-in from other important stakeholders such as renal care coordinators and kidney care advocates.

Regulatory Considerations

- When implementing a TDC Unit, CMS Certifications should be considered.

- If you have licensure or certification questions, it is recommended to reach out to your regional director and/or state for guidance.

TDC Implementation Timeline

Working collaboratively with your center team, it's very important to agree on an initial TDC Kickoff Date that your first patient will begin in order to determine the dates that key milestones must be completed by.

1.

Center Name:	
Main Center Contact:	
Project Name:	Transitional Dialysis Care Unit
Current Date:	

Action	Owner	Start	Finish	Note(s)
Pre-Implementation Approval Process				
Initiate Budget Approval Process	Center Leadership			Once you've decided to implement a TDC Unit, initiate a budget approval process.
Strategic & Leadership Considerations				
Identify Transitional Dialysis Care Unit Champion	Center Leadership			Champion drives behavior and has holistic interest in all center modalities
Select Staff Members for TDC Planning Team	TDC Unit Champion			Key members of the Interdisciplinary Care Team (IDT) should participate
Review TDC Framework & Best Practices with Planning Team	TDC Unit Champion			The entire Interdisciplinary Care Team (IDT) should be familiar with concept
Set Goals to Achieve by Implementing a TDC Unit	TDC Unit Champion			Solicit input from the IDT as necessary
Establish Key Clinical & Financial Performance Indicators to Track	TDC Unit Champion & Planning Team			
Establish a Plan to Gain Staff Buy-In	TDC Unit Champion & Planning Team			Incorporate RVP / Director of Operations, if applicable
Financial Considerations				
Conduct an Economic Analysis (if not already done so)	TDC Unit Champion & Center Financial Manager			Important to compare economic differences between TDC and In Center models
Logisitical & Infrastructure Considerations				
Determine Location of TDC Unit	TDC Unit Champion & Planning Team			
Assess regulatory and certification requirements based on TDC location	TDC Unit Champion & Center Legal Team			
Determine Patient Treatment Schedule	TDC Unit Champion & Planning Team			
Evaluate Number of Stations & Shifts Required	TDC Unit Champion & Planning Team			
Finalize Supply Order Management Process	TDC Unit Champion & Planning Team			
Establish a Solution for Medical Record and Billing Integration	TDC Unit Champion, Planning Team & IT			
Determine equipment and supplies storage requirements	TDC Unit Champion & Planning Team			
Determine required frequency of supplies deliveries	TDC Unit Champion & Planning Team			
Establish a Service & Repair Plan	TDC Unit Champion & Planning Team			
Patient Education & Care Plan Considerations				
Create a TDC Patient Education Curriculum & Care Plan	TDC Unit Champion & Planning Team			
Determine the Hemodialysis Prescription for hemodialysis patients	TDC Unit Champion & Planning Team			
Staffing & Training Considerations				
Define the Roles of the Interdisciplinary Care Team (IDT)	TDC Unit Champion & Planning Team			
Define Staffing Requirements	TDC Unit Champion & Planning Team			
Define Staff Training Plan	TDC Unit Champion & Planning Team			
Marketing Considerations				
Finalize Marketing Plan for Promoting Your TDC Unit	TDC Unit Champion & Marketing			
Budget Approval & Equipment Purchase				
Administration/Budget Approval	Center Leadership / TDC Unit Champion			Leadership approves project
Final Decision | Approval Process	Center Leadership/Purchasing			Center Leadership
Purchase Order | Process & Review	Center Leadership/Purchasing			Center Leadership
Submittal | Signed Purchase Agreement or A La Carte Addendum Added	Center Leadership/Purchasing			Verify signed agreement is in place. If no agreement, then a signed agreement is required. If agreement is in place then an a la carte addendum should be considered with manufacturer.
Review | PO & Signed Agreement if not completed	Center Leadership/Purchasing			
Delivery/Install of NSOs if needed | Provided by Manufacturer	NxStage Field Service			
Site Prep | In Center Config. Planning For TDC	NxStage Field Service			
Disposables Ordering | Cartridges & Fluids	Chronic HD Unit Manager			Customer orders through designated ordering process
Training| In-Center Staff	NxStage Training Manager			
Patients Start in TDC Unit				
GO-LIVE | 1st Patient Therapy	HD Chronic and Home Team			
Education | Continuing Support	NxStage Manager/Educator			Clinical Education Support collaboration with Home Team/NxStage.

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Tracking TDC Clinical and Operational Success

- Prior to your first patient starting in a TDC Unit, think through how you will track your clinical or operational goals
- Some examples may include:
  - » Mortality & Hospitalization rates of TDC patients vs. In Center patients
  - » Patient dialysis modality choice after completing program
- Beyond achieving your goals, there are a few other reasons why tracking this data is essential such as:
  - » To evaluate if your TDC Unit is benefiting patients
  - » To evaluate trends that your center may need to adjust to
  - » To potentially publish a paper in a journal about your TDC Unit

Location of TDC Unit

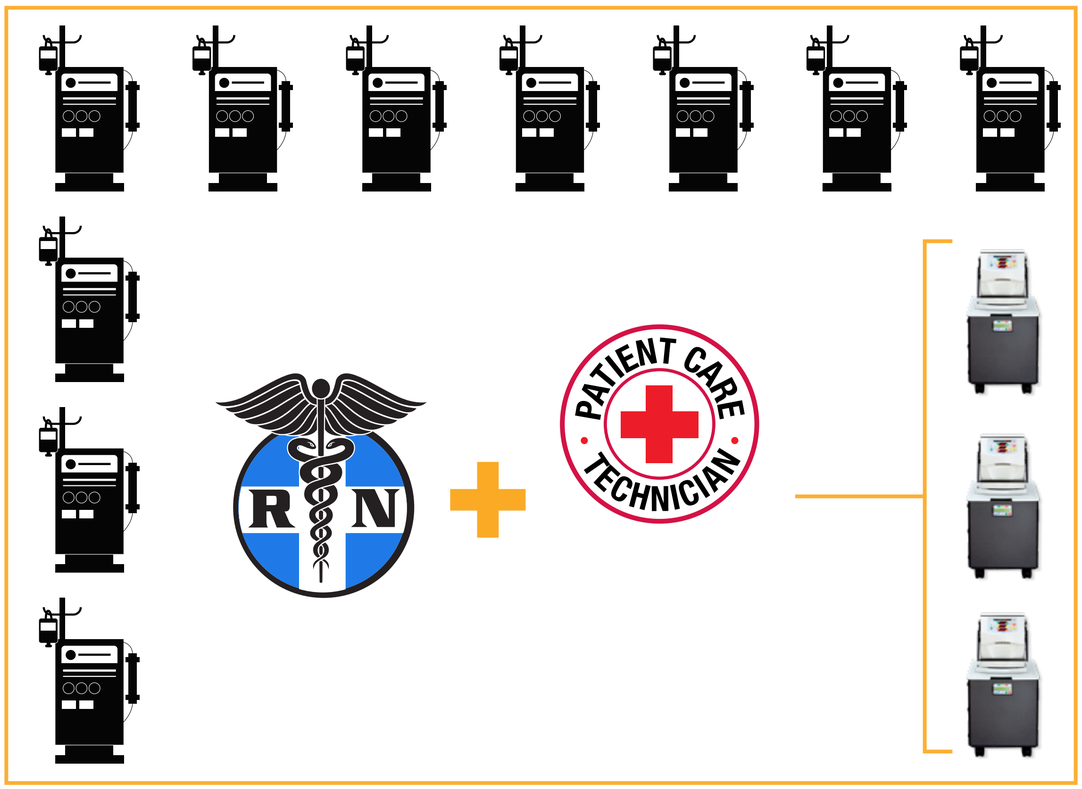
- Based on best practices, the 2 most common models for a TDC Unit are:
  - » The In-center floor
  - » A stand-alone area affiliated with a Home Training Unit

- When implementing a TDC Unit, the following should be considered:
  - » Capacity of both your In-center and Home Training Units
  - » Staff Availability
  - » Number of new monthly ESRD patients
  - » Number of shifts per day
  - » How to best eliminate the 2-day treatment gap with more frequent treatments

For guidance related to certification and regulatory requirements, visit: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/esrdpgmguidance.pdf*

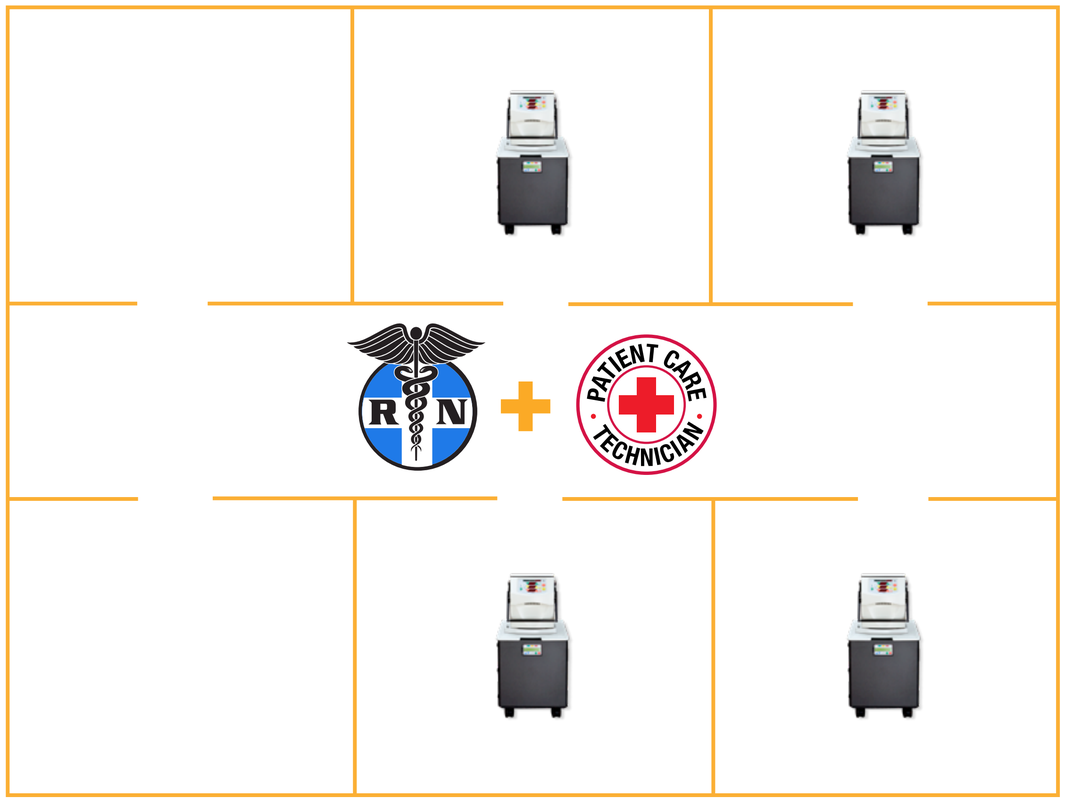
Model #1: In-Center Floor

- Several NxStage systems (or other home system) on the in-center floor
  - » The NxStage HHD system is cleared for use on the in-center floor
- Dedicated square footage for the TDC Unit
- PCT or LPN dedicated to treat patients
- RN provides education



Model #2: Stand-Alone Unit Affiliated with a Home Training Unit

- Several NxStage systems (or other home system) in the stand-alone (or dedicated) area affiliated with a home training unit
- Provides more frequent treatments (No 2-day treatment gap)
- PCT or LPN dedicated to treat patients
  - » RN provides education
- Several shifts



Patient Capacity Planning

- Determine the approximate number of new to dialysis patients as well as failed PD, and transplant patients that start dialysis in your center each month.
- After determining the number of new patients per month, calculate the number of shifts and stations needed to accommodate the volume of TDC patients
  - » Example, if you have 6 new to dialysis patients that start on a monthly basis, you could utilize 3 stations for 2 shifts (4 or 5 treatments per week) or you can do 2 stations for 3 shifts (4 or 5 treatments per week).
- If at or near capacity, here are some creative suggestions of how to potentially add a TDC station on the in center floor.
  - » Add an additional shift
  - » Evaluate current patient situations as some may be receiving a transplant, moving to a home therapy, etc.
  - » Find additional space, especially if tap water is readily available, to add new stations (additional certification may be required)
  - » Remember, the flow of patients that start dialysis each month is the same whether they start TDC or In Center

Patient Treatment Schedule

- Determine the number of treatments that will be provided per week for each patient
  - » Emphasis is on eliminating the 2-day treatment gap
    - 4 treatments per week (M, W, F & Sat) or (M, Tue, Thu & Sat)
    - 5 Treatments per week (ex. M, Tue, Thu, Fri, Sat)

- More frequent therapy offers both clinical and quality of life benefits to patients[1]

References: 1. Finkelstein FO, Schiller B, Daoui R, et al. At-home short daily hemodialysis improves the long-term health-related quality of life. Kidney Int. 2012;82(5): 561-569.

CMS - Pre-Configured System Guidelines

- Guidance provided on in-center use of preconfigured hemodialysis systems
  - » Designed, tested, and validated to yield AAMI quality water and dialysate
  - » FDA cleared labeling adhered to for machine use and monitoring of water and dialysate quality
- For more information on CMS regulations:
  https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/esrdpgmguidance.pdf

Supply Order Management

- Work with your home training team to create a supply list
- If using a NxStage system:
  - » Determine whether you will be utilizing bagged dialysate or PureFlow
    - If you select to use PureFlow, below are some helpful time-related considerations:
    - A PAK lasts up to 12 weeks depending on incoming water quality
    - It takes 2.5 hours to prime a new PAK
    - It takes 5-7 hours to make a batch depending on the batch size
  - » PureFlow requires additional water testing (see **Policies & Procedures** for additional details)
  - » Incorporate the NxStage supply list into your in-center supply order routine
  - » Consider the amount of storage space needed to support the number of TDC stations and patients
  - » Ask your NxStage Area Manager how a la carte supply pricing and ordering may benefit your center.
  - » Check with your corporate office to determine if an agreement may already be in place for a la carte

NxStage Dialysate Ordering

If using NxStage, below is the catalogue for ordering NxStage dialysate

2.

APPENDIX A:
DIALYSATE CATALOG

Premixed Dialysate Bag Formulations

Constituents (mEq/L)	RFP-204	RFP-205	RFP-207	RFP-209	RFP-211
Lactate	40 mEq/L (40 mmol/L)	35 mEq/L (35 mmol/L)	45 mEq/L (45 mmol/L)	45 mEq/L (45 mmol/L)	40 mEq/L (40 mmol/L)
Potassium	1 mEq/L (1 mmol/L)	3 mEq/L (3 mmol/L)	1 mEq/L (1 mmol/L)	2 mEq/L (2 mmol/L)	2 mEq/L (2 mmol/L)
Sodium	140 mEq/L (140 mmol/L)				
Calcium	3 mEq/L (1.5 mmol/L)	3 mEq/L (1.5 mmol/L)	3 mEq/L (1.5 mmol/L)	3 mEq/L (1.5 mmol/L)	3.5 mEq/L (1.75 mmol/L)
Magnesium	1 mEq/L (0.5 mmol/L)				
Chloride	105 mEq/L (105 mmol/L)	112 mEq/L (112 mmol/L)	100 mEq/L (100 mmol/L)	101 mEq/L (101 mmol/L)	106.5 mEq/L (106.5 mmol/L)
Glucose	1.1 g/L				
Osmolar–ity (calculated)	294 mOsmol/L	298 mOsmol/L	294 mOsmol/L	296 mOsmol/L	296 mOsmol/L

All RFP-2XX fluids are packaged in 5.0 liter bags and will typically have up to 1.5% overfill.

Dialysate Concentrates

The PureFlow SL System prepares batches of dialysate in the following formulations and volumes:

Constituents (mEq/L)	SAK-301/401	SAK-302/402	SAK-303/403	SAK-304/404	SAK-305/405	SAK-306/406	SAK-307/407
Lactate	45 mEq/L (45 mmol/L)	40 mEq/L (40 mmol/L)	45 mEq/L (45 mmol/L)	45 mEq/L (45 mmol/L)	45 mEq/L (45 mmol/L)	45 mEq/L (45 mmol/L)	40 mEq/L (40 mmol/L)
Potassium	1 mEq/L (1 mmol/L)	1 mEq/L (1 mmol/L)	1 mEq/L (1 mmol/L)	2 mEq/L (2 mmol/L)	1 mEq/L (1 mmol/L)	2 mEq/L (2 mmol/L)	1 mEq/L (1 mmol/L)
Sodium	140 mEq/L (140 mmol/L)						
Calcium	3 mEq/L (1.5 mmol/L)	3 mEq/L (1.5 mmol/L)	3 mEq/L (1.5 mmol/L)	3 mEq/L (1.5 mmol/L)	3 mEq/L (1.5 mmol/L)	3 mEq/L (1.5 mmol/L)	3 mEq/L (1.5 mmol/L)
Magnesium	1 mEq/L (0.5 mmol/L)						
Chloride	100 mEq/L (100 mmol/L)	105 mEq/L (105 mmol/L)	100 mEq/L (100 mmol/L)	101 mEq/L (101 mmol/L)	100 mEq/L (100 mmol/L)	101 mEq/L (101 mmol/L)	105 mEq/L (105 mmol/L)
Glucose	100 mg/dL						
Batch Size	60 L	60 L	50 L	60 L	40 L	50 L	50 L

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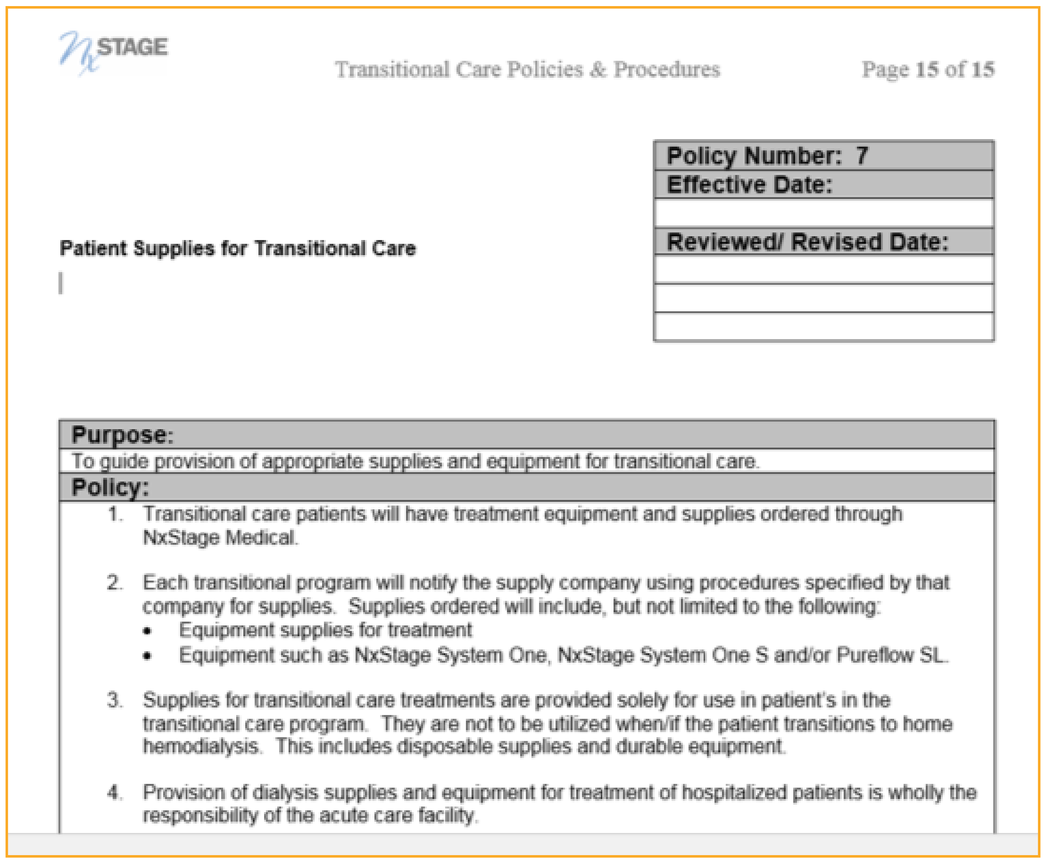
NxStage Supply Order Management Policies and Procedures

If using NxStage, below is a template of a TDC Patient Supplies Ordering Policies & Procedure (P&P)

3.



NxSTAGE

Transitional Care Policies & Procedures Page 15 of 15

Policy Number: 7
Effective Date:
Reviewed/ Revised Date:

Patient Supplies for Transitional Care

Purpose:
To guide provision of appropriate supplies and equipment for transitional care.
Policy:

1. Transitional care patients will have treatment equipment and supplies ordered through NxStage Medical.
2. Each transitional program will notify the supply company using procedures specified by that company for supplies. Supplies ordered will include, but not limited to the following:
   - Equipment supplies for treatment
   - Equipment such as NxStage System One, NxStage System One S and/or Pureflow SL.
3. Supplies for transitional care treatments are provided solely for use in patient's in the transitional care program. They are not to be utilized when/if the patient transitions to home hemodialysis. This includes disposable supplies and durable equipment.
4. Provision of dialysis supplies and equipment for treatment of hospitalized patients is wholly the responsibility of the acute care facility.

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Equipment and Supplies Storage

- It is important to consider where you will store equipment and supplies.
- Ensure the storage area you decide on has enough space to accommodate the amount of supplies required.
- If using the NxStage HHD system, consider having a second PureFlow system for each station to provide a second shift
- Consider a dedicated room for PureFlow

Supplies Delivery Frequency

- Where you will be storing your equipment and supplies will determine your ordering frequency.
- Based on the number of TDC patients and available storage space you may consider weekly to bi-weekly deliveries (additional fees may apply).

Medical Record and Billing Integration

- If using the NxStage system for your TDC Unit as opposed to a traditional in-center machine, you will need to determine how treatments will be documented and ordered by the physician in your electronic medical record.
- Consider that in most cases a machine interface to your EMR will not exist.

Patient : **Date:____/____/____**

Cartridge Lot #	Cycler Serial #	PF SL Serial #	PAK Lot #	SAK Lot #	SAK Type

PF SL / PAK Product Water Sample Sent for Analysis: Yes / No

PF SL Dialysate Sample Sent for Analysis: Yes / No

Alarms Test Passed Yes / No

New PureFlow SL Batch? Yes / No **Chloramines ≤ 0.1 ppm (mg/l) Yes / No / n/a**

Pre-Treatment Assessment

Today's weight - dry weight + oral fluid = UF Volume Goal (Kg)	BP sitting	BP standing	Pulse sitting / standing	Temp	Liters of Dialysate / Max FF
- = + =	/	/	/		/

Medications: Time / Drug / Dose — Initials

/ Heparin /

Any nausea / vomiting / diarrhea?	/	/
Any difficulty breathing / edema?	/	/
Any chest pain / palpitations?	/	/
Any other medical complaints?	/	/
Any change in medications?		

Labs

Access: Any access problems?

Time	Blood Pressure	Pulse	RATES			VOLUMES		PRESSURES			Alarms / FF Changes / Comments	Initials
			Dialysate	UF	Blood Flow	Dialysate	UF	Venous	Effluent	Access		
	/											
	/											
	/											
	/											

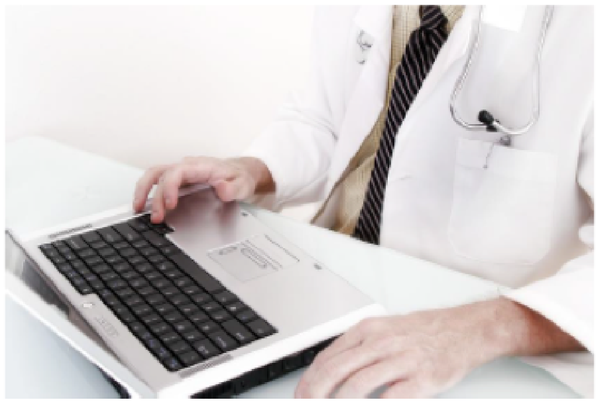
NxStage paper flowsheet

Medical Record and Billing Integration (cont'd)

- NxStage treatment prescriptions will contain these therapy elements and should be incorporated into the physician order and the patient's medical record.

Overview Physician Order

Element
Target: stdKt/V/spKt/V
Treatment Schedule
Dialysate Volume
Dialysate Rate (Qd)
Dialysate Composition: Lactate Potassium
Blood Flow Rate (Qb)
Maximum Ultrafiltration Rate (UFR)
Anticoagulation



Medical Record and Billing Integration (cont'd)

- Ensure that your physician ordering system can accommodate prescribing with NxStage on the in-center floor for the following:

NxStage HHD system

Appropriate dialysate

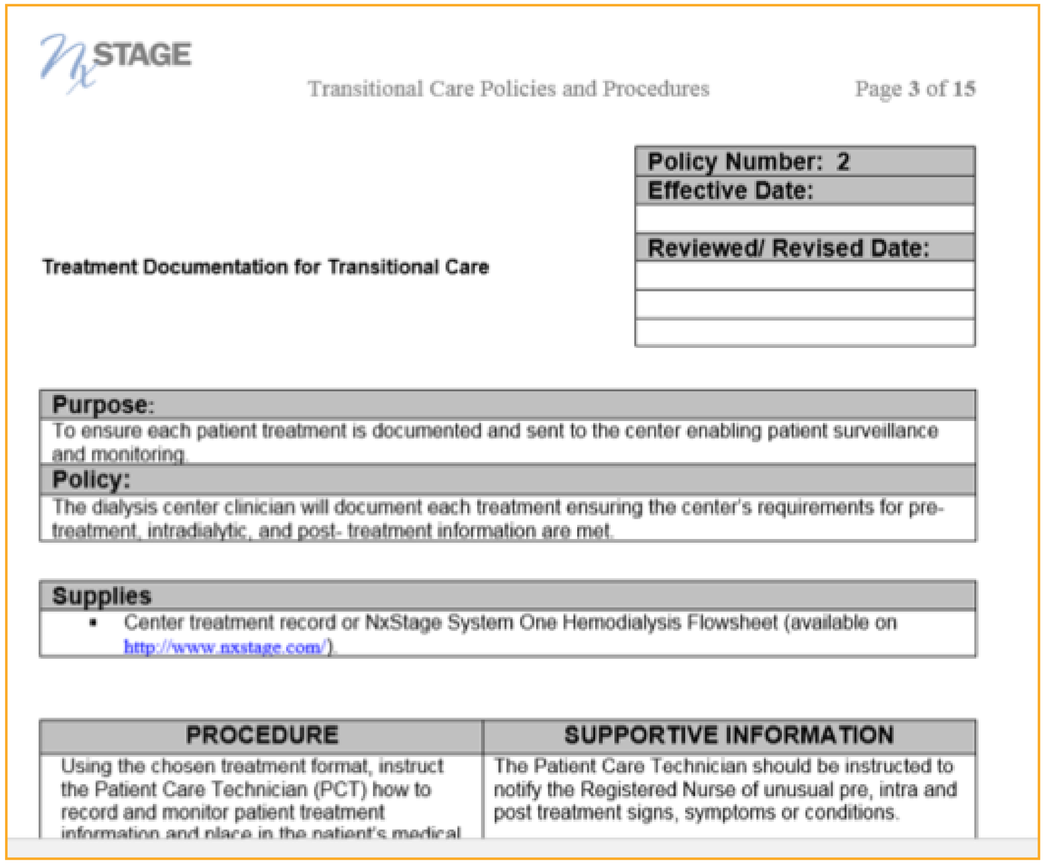
Sacks vs. bags

Cartridge type (includes pre-attached dialyzer)

Medical Record and Billing Integration (cont'd)

- If using a NxStage system, below is a template of a TDC Treatment Documentation Policies & Procedure (P&P).

4.



NxSTAGE

Transitional Care Policies and Procedures Page 3 of 15

Policy Number: 2
Effective Date:
Reviewed/ Revised Date:

Treatment Documentation for Transitional Care

Purpose:
To ensure each patient treatment is documented and sent to the center enabling patient surveillance and monitoring.
Policy:
The dialysis center clinician will document each treatment ensuring the center's requirements for pre-treatment, intradialytic, and post- treatment information are met.

Supplies
▪ Center treatment record or NxStage System One Hemodialysis Flowsheet (available on http://www.nxstage.com/)

PROCEDURE	SUPPORTIVE INFORMATION
Using the chosen treatment format, instruct the Patient Care Technician (PCT) how to record and monitor patient treatment information and place in the patient's medical	The Patient Care Technician should be instructed to notify the Registered Nurse of unusual pre, intra and post treatment signs, symptoms or conditions.

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TDC Ordering & Billing Questions

Please contact your Director of Operations (DO), Regional Vice President (RVP) or VP of Home Therapy if you have the following questions:

- How do I order TDC treatments with a NxStage system within my electronic medical record?
- How do I bill for treatments on a NxStage system within my electronic medical record?

Service and Repair Plan

- The NxStage HHD system is cleared for in-center use and services and repairs are done via a system swap
- Swaps are usually done within 24-48 hours
  - » You may want to consider having additional equipment on-site to ensure no interruption in patient care
- No biomedical technicians in your facility are required to perform routine preventative maintenance or repairs.
- Your biomedical technicians can perform re-deployment procedures as necessary.

5. *Learn more about equipment redeployment*

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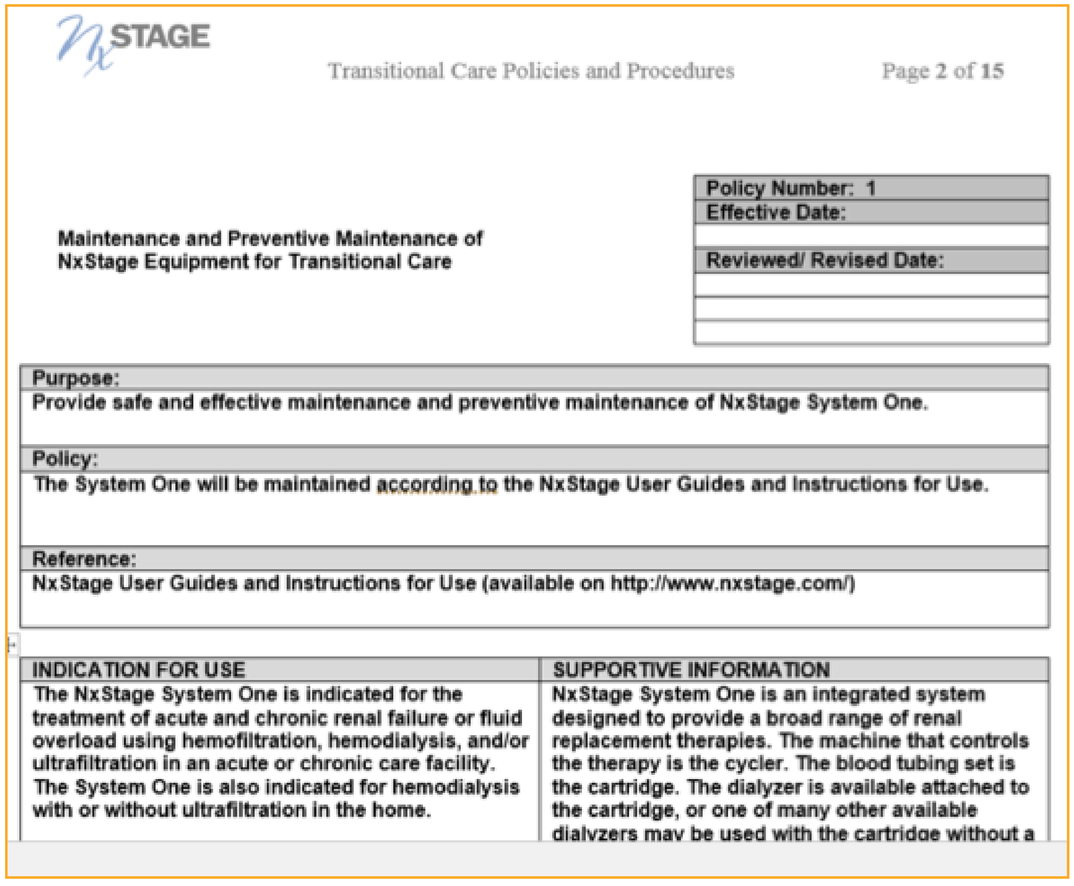
Maintenance Policies and Procedures (P&P)

- If using a NxStage system, below is a template of a TDC Maintenance & Preventative Maintenance P&P.

6.



NxSTAGE

Transitional Care Policies and Procedures Page 2 of 15

Maintenance and Preventive Maintenance of NxStage Equipment for Transitional Care	Policy Number: 1 Effective Date: Reviewed/ Revised Date:

Purpose:
Provide safe and effective maintenance and preventive maintenance of NxStage System One.
Policy:
The System One will be maintained according to the NxStage User Guides and Instructions for Use.
Reference:
NxStage User Guides and Instructions for Use (available on http://www.nxstage.com/)

INDICATION FOR USE	SUPPORTIVE INFORMATION
The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration in an acute or chronic care facility. The System One is also indicated for hemodialysis with or without ultrafiltration in the home.	NxStage System One is an integrated system designed to provide a broad range of renal replacement therapies. The machine that controls the therapy is the cycler. The blood tubing set is the cartridge. The dialyzer is available attached to the cartridge, or one of many other available dialyzers may be used with the cartridge without a

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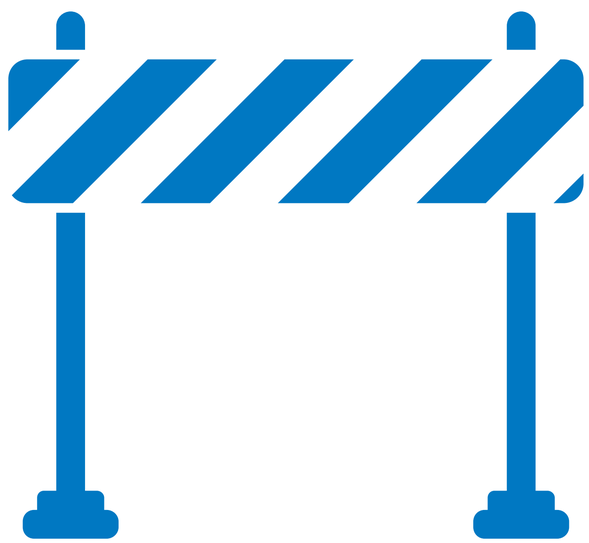
Transitional Dialysis Care Staffing Requirements

- It is important to assess the time requirements that each team member will need to allocate to the TDC Unit
- Based on the topics covered within the **4 week "Patient Education Curriculum"** section, the following illustrates the time allotment for each team member

Labor Considerations for Delivering TDC Treatments



It is recommended that…

- The PCT or LPN perform treatments at a 1 to 3 patient ratio (maximum)
- A RN should oversee all TDC treatments and should be staffed at a 1 to 6 patient ratio (maximum) so that additional patient education can be accommodated
- Other members of the Interdisciplinary Team (IDT) may assist in patient education as deemed appropriate (see next page for further detail)

Resource and Staffing Considerations

(Per Patient in Transitional Dialysis Care Unit)

Staff Member	Week 1	Week 2	Week 3	Week 4	Total
PCT	30 Min.	30 Min.	15 Min.		**1 Hr. & 15 Min.**
In Center RN	55 Min.	3 Hr. & 30 Min.	1 Hr.	30 Min.	**5 Hr. & 55 Min.**
Dietitian				1 Hr. & 30 Min.	**1 Hr. & 30 Min.**
Social Worker	1 Hr. & 25 Min.	30 Min.	30 Min.		**2 Hr. & 25 Min.**
Home RN			2 Hr. & 35 Min.	5 Min.	**2 Hr. & 40 Min.**
Physician				50 Min.	**50 Min.**
TOTAL	2 Hr. & 50 Min.	4 Hr. & 30 Min.	4 Hr. & 20 Min.	2 Hr. & 55 Min.	**14 Hr. & 35 Min.**

Staffing model to educate 4-6 patients for Transitional Dialysis Care is 1 RN to 2 PCTS

- If a Modality Nurse Educator is on staff, they can provide in-depth education for their area of expertise
- If a Financial Advisor is on staff, they may assume some responsibilities of the social worker
- If a Transplant Coordinator is on staff, they can assume physician responsibilities for transplant center information
- If LPNs are on staff, they can assume responsibilities of PCTs

Staff Training Plan

- Having a staff training plan is crucial to ensuring your clinical staff is prepared and helps to optimize the patient experience in a TDC Unit
- Below is a template of a staff training plan.

7.

NxSTAGE **Transitional Care Staff Education Plan**

Day	Topic	Resources Used	Additional Notes	Date Completed
	Pre Training Preparation			
	· **Confirm Site and Staff readiness**	**Ensure all equipment and resources are on site and staff ready for training**	SalesForce Portal User-Enter contacts- done by NxStage CE/CM/Dir RN or Admin only; NxRx- Equipment report	
WEEK 1	**On - site Training**	**Using the NSO and the Dialysis Process**		
Day	**Topic**	**Resources**	**Additional Notes**	**Date Completed**
1	· NxStage Overview	TM0472 Rev E		
1	· Overview of NxStage and NxSTEPS resources	NxStage User Guides- 5 1. System One Cycler - NC4012 Rev D 2. NxStage Pureflow User Guide - NC5342 Rev A 3. NxStage Express Fluid Warmer User Guide- NC1760 Rev F 4. NxStage Fluid Detection System NC6532 Rev A and NC2323 Rev C 5. NxStage System One Jewel Box and ConNxBox Computer Removal and Installation Instructions- NC3382 Rev C NxSTEPS User's Quick References Guides, TM0532 Rev F (5 QRGs) 1 Nurse Guide per facility TM0537 Rev C How to contact Technical Support		
1	· Cartridge Labeling · Flowpath · Use of LockSite and /or heparin line (if used)	NxStage IFUs for Cartridges: 1. CAR 170C - NC45-0403 Rev B 2. CAR 172C - NC45-0501 Rev A 3. CAR 124C - NC45-0364 Rev D CAR 172 Identification Tool - TM0420 Rev B	Located on NxDx Discuss the CAR 124-C but just to describe the features May want to add CAR 172	

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TM1147 Rev A

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Patient HD Prescription for TDC

Based on best practices experienced by members of the TDC Demonstration Initiative that have implemented TDC Units, below are suggestions regarding a TDC patient HD prescription.

- Emphasis is on eliminating the 2-day treatment gap
  - » 4 treatments per week (M, W, F & Sat) or (M, Tue, Thu & Sat)
  - » 5 Treatments per week (ex. M, Tue, Thu, Fri, Sat)
- Perform treatments using the NxStage HHD system (or home machine of choice)
- Standard blood flow at the discretion of physician, based on patient vascular access.
- Time: Approximately three hours per treatment (or between a total of 14-16 hours per week)
- Access: AVF, AVG or CVC
- Heparin bolus per unit protocol at the beginning of treatment
- Recommended fluid removal not to exceed 10 mL/kg/hour
- Consider additional treatments if required ultrafiltration goal exceeds 10 mL/kg per hour

The NxStage dosing calculator can assist in making prescription recommendations.
To access the dosing calculator click here

*Ultimately, hemodialysis prescriptions are at the discretion of the treating nephrologist and can be modified based on individual patient needs.

Patient HD Prescription for TDC (cont'd)

Based on best practices experienced by members of the TDC Demonstration Initiative that have implemented TDC Units, below are suggestions regarding a TDC patient HD prescription.

- Check pre and post vital signs
- During treatment, check BP every 30 minutes on dialysis
- Obtain weight pre & post treatment
- Baseline monthly lab at beginning of the TDC

*Ultimately, hemodialysis prescriptions are at the discretion of the treating nephrologist and can be modified based on individual patient needs.

Patient HD Prescription for TDC (cont'd)

Based on best practices experienced by members of the TDC Demonstration Initiative that have implemented TDC Units, below are suggestions regarding a TDC patient HD prescription.

- Dose Erythropoiesis-stimulating agent (ESA) and iron based on monthly lab and in center ESA and iron protocols
- Monitor BP medications and target weight closely, adjusting to prevent hypotension during and after treatments per in-center protocols

*Ultimately, hemodialysis prescriptions are at the discretion of the treating nephrologist and can be modified based on individual patient needs.

Patient HD Prescription for TDC (cont'd)

Based on best practices experienced by members of the TDC Demonstration Initiative that have implemented TDC Units, below are suggestions regarding a TDC patient HD prescription.

When using a NxStage system in a TDC Unit, use the dialysate volume per treatment based on the below table[1]:

	Female			Male		
Treatment	<=80 kgs	80-100 kgs	>100 kgs	<=80 kgs	80-100 kgs	>100 kgs
4	30L	30L	40L	30L	40L	40L
5	25L	25L	30L	25L	30L	30L
6	20L	20L	25L	20L	25L	25L

- Set dialysate flow at an hourly rate.

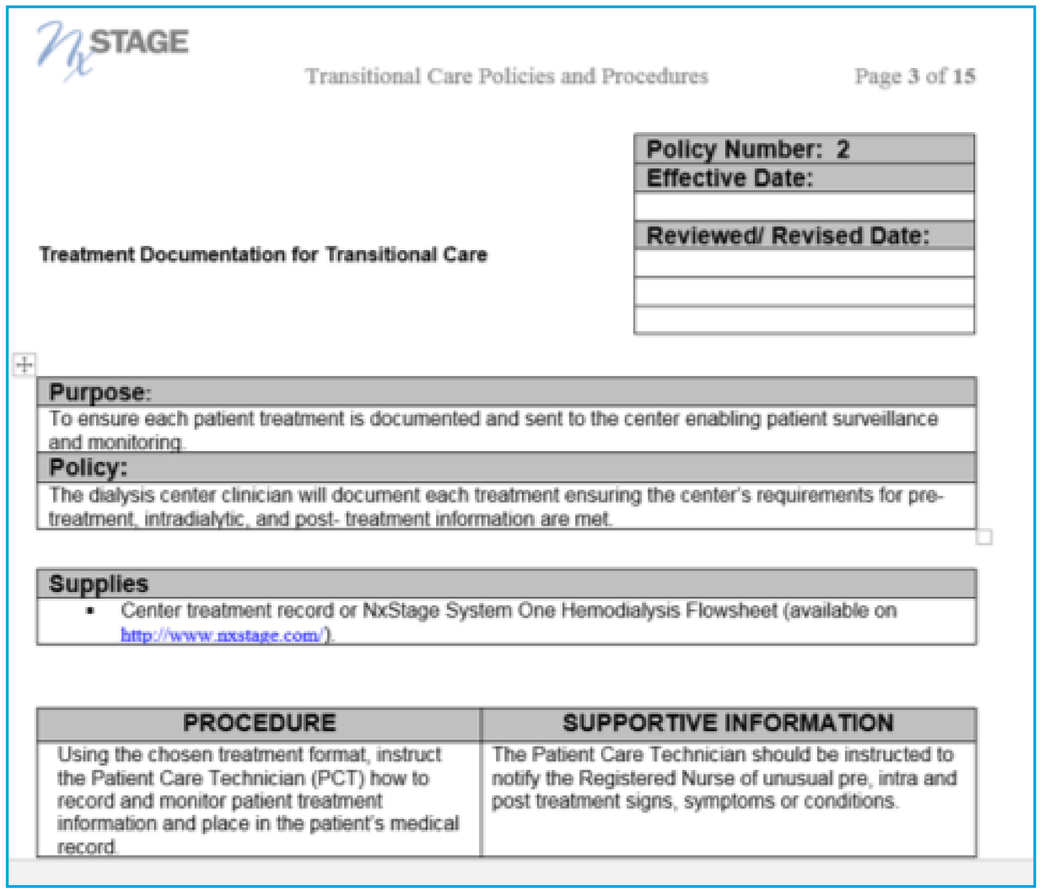
*Ultimately, hemodialysis prescriptions are at the discretion of the treating nephrologist and can be modified based on individual patient needs.

Reference: 1. NxStage Data on File. Prescribing Home Hemodialysis with NxStage: A Physcians Quick Reference Guide.

Hemodialysis Dosing P&P

Below is a template of a TDC Hemodialysis Dosing Policies & Procedures.

8.



NxSTAGE

Transitional Care Policies and Procedures Page 3 of 15

Policy Number: 2
Effective Date:
Reviewed/ Revised Date:

Treatment Documentation for Transitional Care

Purpose:
To ensure each patient treatment is documented and sent to the center enabling patient surveillance and monitoring.
Policy:
The dialysis center clinician will document each treatment ensuring the center's requirements for pre-treatment, intradialytic, and post- treatment information are met.

Supplies
▪ Center treatment record or NxStage System One Hemodialysis Flowsheet (available on http://www.nxstage.com/).

PROCEDURE	SUPPORTIVE INFORMATION
Using the chosen treatment format, instruct the Patient Care Technician (PCT) how to record and monitor patient treatment information and place in the patient's medical record.	The Patient Care Technician should be instructed to notify the Registered Nurse of unusual pre, intra and post treatment signs, symptoms or conditions.

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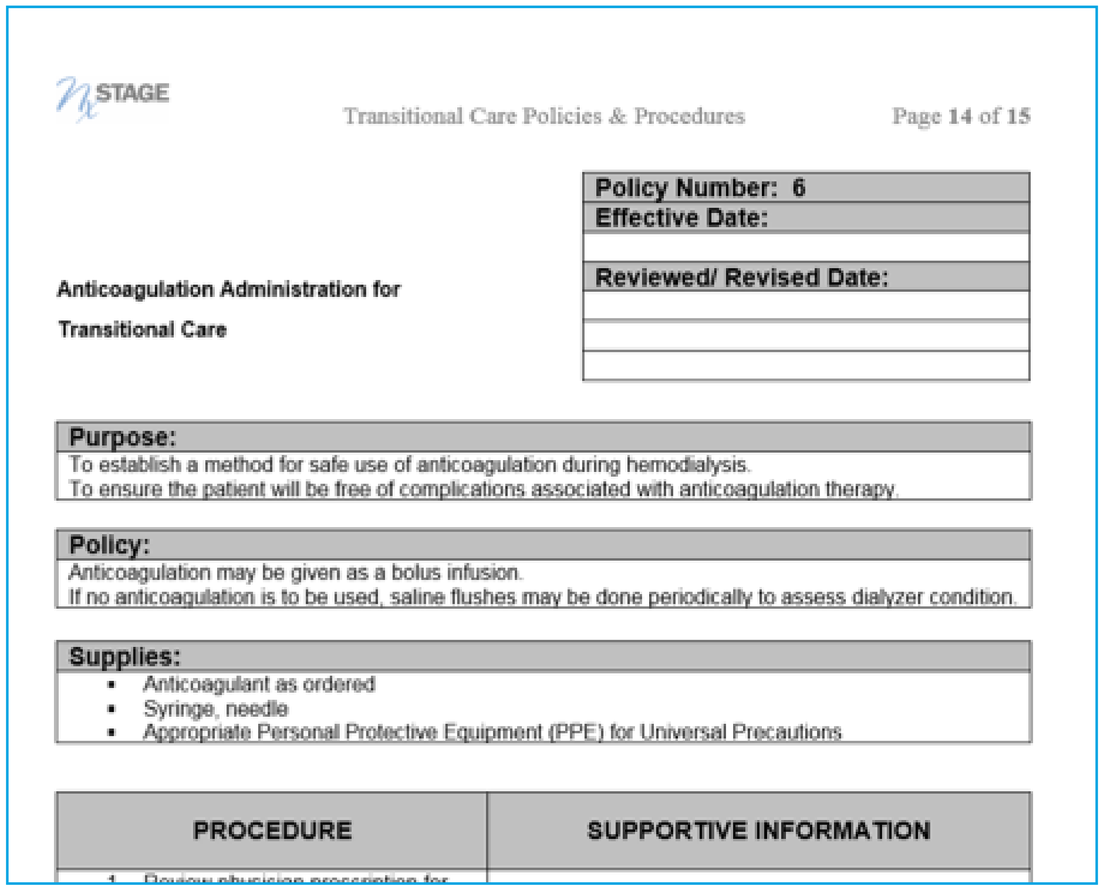
Anticoagulation Administration

Below is a template for a TDC Anticoagulation Administration Policies & Procedures.

9.



STAGE

Transitional Care Policies & Procedures Page 14 of 15

Policy Number: 6
Effective Date:
Reviewed/ Revised Date:

Anticoagulation Administration for

Transitional Care

Purpose:
To establish a method for safe use of anticoagulation during hemodialysis. To ensure the patient will be free of complications associated with anticoagulation therapy.

Policy:
Anticoagulation may be given as a bolus infusion. If no anticoagulation is to be used, saline flushes may be done periodically to assess dialyzer condition.

Supplies:
▪ Anticoagulant as ordered ▪ Syringe, needle ▪ Appropriate Personal Protective Equipment (PPE) for Universal Precautions

PROCEDURE	SUPPORTIVE INFORMATION
1. Review physician prescription for	

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Speaking With a New ESRD Patient

- A patient that has been newly diagnosed with ESRD may likely experience:
  - » Depression
  - » Anxiety
  - » Confusion
- As a result, new ESRD patients are often unable to comprehend important information and choices that may be presented to them
- When speaking with an ESRD patient, do not overwhelm them with too much detail instead, only offer small, digestible, and concise information
- In addition, speak slower and have a compassionate, supportive tone

Patient Education Curriculum

Best practices indicate that offering a 4 week education curriculum will provide patients in transition with sufficient time to:

- Recover medically
- Adjust emotionally
- Become educated on all dialysis modality options, including transplantation
- Make an informed modality decision best suited for their future and lifestyle

Week 1 Plan

Patient Education

Clinical Stabilization & Emotional Support

- Provide emotional support and comfort patient
- Determine if patient would like a family member involved in the educational process
- Briefly introduce how dialysis works
- Address patient/family member initial questions, fears & concerns
- Educate patient/family member on the cause of their ESRD
- Address pre-conceived ideas about dialysis & introduction to staff
- Review patient insurance benefits

Patient Care Plan

Initiate & Optimize Therapy

- Initiate therapy with the transition team
- Stabilize the patient clinically
- Evaluate target weight & blood pressure medications
- Begin to establish plan for dialysis access (venous mapping & surgical appointment, if applicable)

10.

Click to download full 4 Week Curriculum

Week 2 Plan

Patient Education

Basic Modality Education

- Allow patient/family member to ask questions prior to week 2.
- Educate on fluid, infection, and medication management
- Discuss patient short & long-term lifestyle goals
- Provide basic modality and access education: PD, HHD, transplant and in-center
- Present outcomes data, quality of life data
- Review patient insurance benefits

Patient Care Plan

Begin Long-Term Care Plan

- Discuss vascular access options in detail
- Monitor blood pressure and adjust antihypertensive medications, as needed
- Prepare and present patient with potential benefit-related documentation

Week 3 Plan

Patient Education

In-Depth Modality Education

- Allow patient/family member to ask questions prior to week 3
- In-depth education (including access) on:
  - » PD
  - » HHD
  - » In-Center
  - » Transplant
- Patient/family member discusses modalities with a PD, HHD, In-Center, & Transplant patient
- Financial education regarding dialysis therapy (water consumption, transportation to In-Center, etc..)

Patient Care Plan

Ensure Clinical & Emotional Stability of Patient

- Finalize dialysis access plan and CVC exit plan
- Assess target weight, RRF, & medication regiment
- Evaluate delivered dose of dialysis

Week 4 Plan

Patient Education

Patient Modality Choice

- Allow patient/family member to ask questions prior to week 4
- Determine patient's modality preference
- Reassure patient that all options remain available
- Teach patient dietary restrictions
- If patient is interested in transplant, refer to appropriate transplant centers
- If patient chooses a home modality, refer them to helpful resources

Patient Care Plan

Complete Patient Care Planning

- Ensure patient comprehends their vascular access plan
- Refer to PD or HHD training program or In-Center facility closest to home and schedule visit
- Re-evaluate transportation needs
- Schedule home visit, if appropriate
- Ensure necessary documentation is completed and signed by physicians (such as 2728 FORM)

10.

Click to download full 4 Week Curriculum

Marketing Your TDC Unit

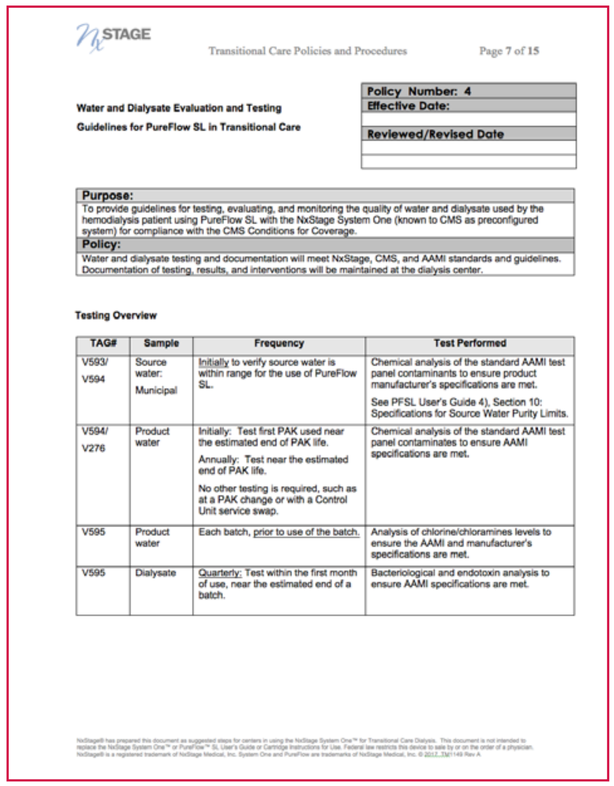
Below are a few best practices for promoting your unique competitive advantage:

- Create a brochure for prospective patients and hospital discharge planners
- Host an educational event with hospital discharge planners explaining TDC
- Create a section on your website articulating the benefits of your TDC Unit
- Create a video of your program and include patient stories and experiences
- Execute an email campaign highlighting the TDC Unit
- Partner with a local newspaper to create an article about your unique offering
- Utilize social media channels to advertise your TDC Unit
- Publish clinical or operational outcomes in a peer-reviewed journal (AJKD, CJASN, etc.)
- Showcase a TDC banner in your center highlighting the benefits of the TDC Unit

TDC Policies and Procedures

Besides the TDC Policies & Procedures already included within the TDC Operational Guidance, there are 2 other Policies & Procedures that can also be downloaded. See below:

11.
Water and Dialysate Evaluation and Testing Guidelines for PureFlow SL in Transitional Care



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Transitional Care Policies and Procedures Page 7 of 15

Water and Dialysate Evaluation and Testing Guidelines for PureFlow SL in Transitional Care	**Policy Number: 4** **Effective Date:** **Reviewed/Revised Date**

Purpose:
To provide guidelines for testing, evaluating, and monitoring the quality of water and dialysate used by the hemodialysis patient using PureFlow SL with the NxStage System One (known to CMS as preconfigured system) for compliance with the CMS Conditions for Coverage.

Policy:
Water and dialysate testing and documentation will meet NxStage, CMS, and AAMI standards and guidelines. Documentation of testing, results, and interventions will be maintained at the dialysis center.

Testing Overview

TAG#	Sample	Frequency	Test Performed
V593/ V594	Source water: Municipal	Initially to verify source water is within range for the use of PureFlow SL.	Chemical analysis of the standard AAMI test panel contaminants to ensure product manufacturer's specifications are met. See PFSL User's Guide 4), Section 10: Specifications for Source Water Purity Limits.
V594/ V276	Product water	Initially: Test first PAK used near the estimated end of PAK life. Annually: Test near the estimated end of PAK life. No other testing is required, such as at a PAK change or with a Control Unit service swap.	Chemical analysis of the standard AAMI test panel contaminates to ensure AAMI specifications are met.
V595	Product water	Each batch, prior to use of the batch.	Analysis of chlorine/chloramines levels to ensure the AAMI and manufacturer's specifications are met.
V595	Dialysate	Quarterly: Test within the first month of use, near the estimated end of a batch.	Bacteriological and endotoxin analysis to ensure AAMI specifications are met.

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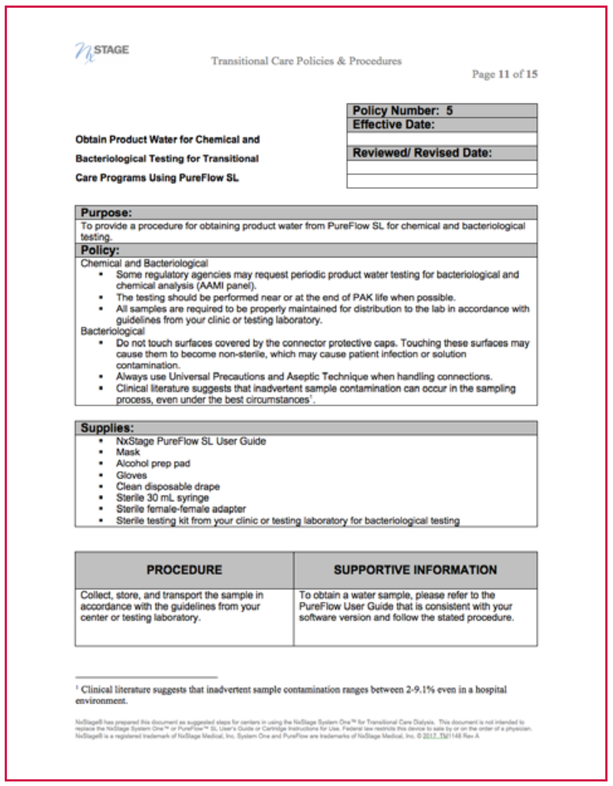
12.
Product Water for Chemical and Bacteriological Testing for Transitional Care Programs Using PureFlow SL



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Transitional Care Policies & Procedures Page 11 of 15

Obtain Product Water for Chemical and Bacteriological Testing for Transitional Care Programs Using PureFlow SL	**Policy Number: 5** **Effective Date:** **Reviewed/ Revised Date:**

Purpose:
To provide a procedure for obtaining product water from PureFlow SL for chemical and bacteriological testing.

Policy:
Chemical and Bacteriological
- Some regulatory agencies may request periodic product water testing for bacteriological and chemical analysis (AAMI panel).
- The testing should be performed near or at the end of PAK life when possible.
- All samples are required to be properly maintained for distribution to the lab in accordance with guidelines from your clinic or testing laboratory.

Bacteriological
- Do not touch surfaces covered by the connector protective caps. Touching these surfaces may cause them to become non-sterile, which may cause patient infection or solution contamination.
- Always use Universal Precautions and Aseptic Technique when handling connections.
- Clinical literature suggests that inadvertent sample contamination can occur in the sampling process, even under the best circumstances[1].

Supplies:
- NxStage PureFlow SL User Guide
- Mask
- Alcohol prep pad
- Gloves
- Clean disposable drape
- Sterile 30 mL syringe
- Sterile female-female adapter
- Sterile testing kit from your clinic or testing laboratory for bacteriological testing

PROCEDURE	SUPPORTIVE INFORMATION
Collect, store, and transport the sample in accordance with the guidelines from your center or testing laboratory.	To obtain a water sample, please refer to the PureFlow User Guide that is consistent with your software version and follow the stated procedure.

[1] Clinical literature suggests that inadvertent sample contamination ranges between 2-9.1% even in a hospital environment.

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Other Relevant Resources

Beyond the information included in this TDC Operational Guidance Resource, there are other documents that can provide support in implementing a TDC Unit. These resources are listed below:

- Using a Transitional Start Dialysis Unit to Improve Modality Selection (Dr. Robert Lockridge)
  https://www.nephrologynews.com/using-a-transitional-start-dialysis-unit-to-improve-modality-selection/
- Transitional dialysis care units: A new approach to increase home dialysis modality uptake and patient outcomes
  https://doi.org/10.1111/sdi.12651
- Improving Incident ESRD Care Via a Transitional Care Unit
  https://doi.org/10.1053/j.ajkd.2018.01.035

For additional resources, policies, and procedures, please visit: *http://ww3.nxstage.com/tdc-resources*

Risks and Responsibilities

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

The NxStage System 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. When vascular access is exposed to more frequent use, infection of the site, and other access related complications may also be potential risks. 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.

Home hemodialysis with the NxStage System during waking hours may not require a care partner, provided a physician and a qualified patient agree that solo home hemodialysis is appropriate. Patients performing nocturnal treatments are required to have a care partner. Care partners are trained on proper operation and how to get medical or technical help if needed.

Certain risks associated with hemodialysis treatment are increased when performing solo HHD because no one is present to help the patient respond to health emergencies. If patients experience needles coming out, blood loss, or very low blood pressure during solo HHD, they may lose consciousness or become physically unable to correct the health emergency. Losing consciousness or otherwise becoming impaired during any health emergency while alone could result in significant injury or death. Additional ancillary devices and training are required when performing solo HHD

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 and/or increased treatment time, and delayed response to alarms when waking from sleep.

Patients should consult their doctor to understand the risks and responsibilities of performing these therapies using the NxStage System.

Best of luck in implementing your TDC Unit!

Introduction

Clinical and Economic Considerations

Implementation Strategies

Infrastructure and Logistical Planning

Staffing and Internal TDC Planning

Patient Education

Marketing Considerations

Additional Resources

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TDC Demonstration Initiative

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