BC KIDNEY DAYS

Hosted by BC Transplant and the BC Renal Agency

2014

Update on NxStage: Is it the Next Stage?

Objectives

- To review the background on the NxStage system
- To provide an overview of the experience in British Columbia with NxStage
- To look at next steps for the NxStage system in British Columbia

Why did we want to look at a different system?

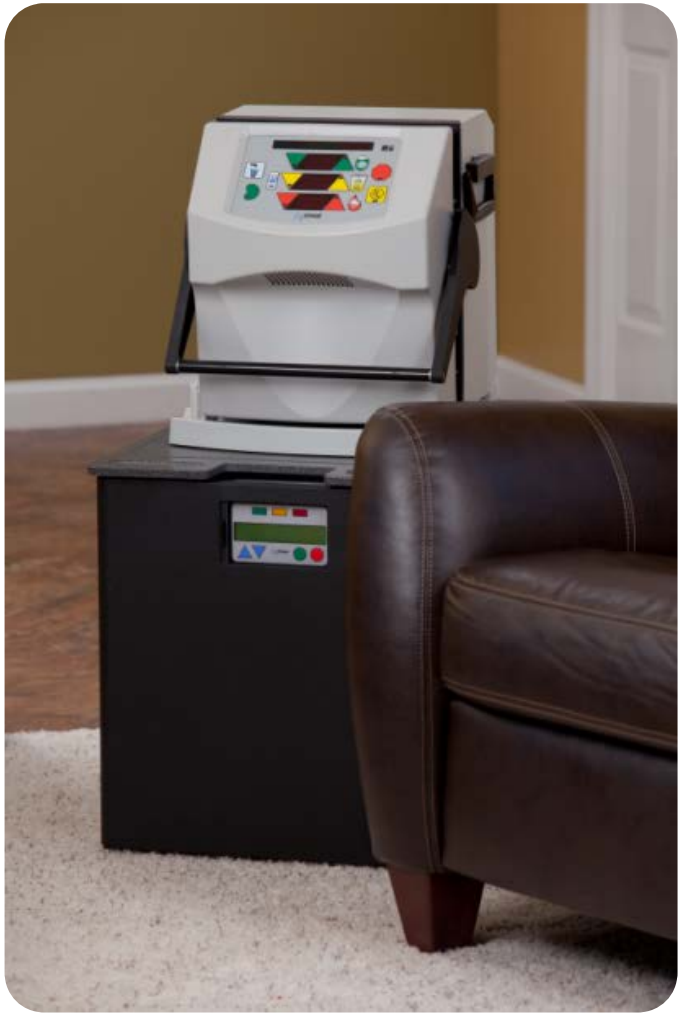
Current state of equipment

Ideal State…

History revisited…

- 2001…Industry sponsored advisory board
  - Home HD physicians from across Canada in attendance
  - Asked to define our ‘ideal HHD system’
- Criteria identified at that time:
  - System able to fit in a suitcase
  - System which takes 10 minutes to set up and 10 minutes to clean up
  - System which requires no interaction / maintenance between dialysis treatment sessions
  - System which is light enough to carry for the average patient
  - System which doesn’t look like a dialysis machine to minimize ‘medicalization’ of the home
  - System which is simple to operate – a big friendly ‘green = go’ button and a obvious ‘red stop sign shaped’ stop button

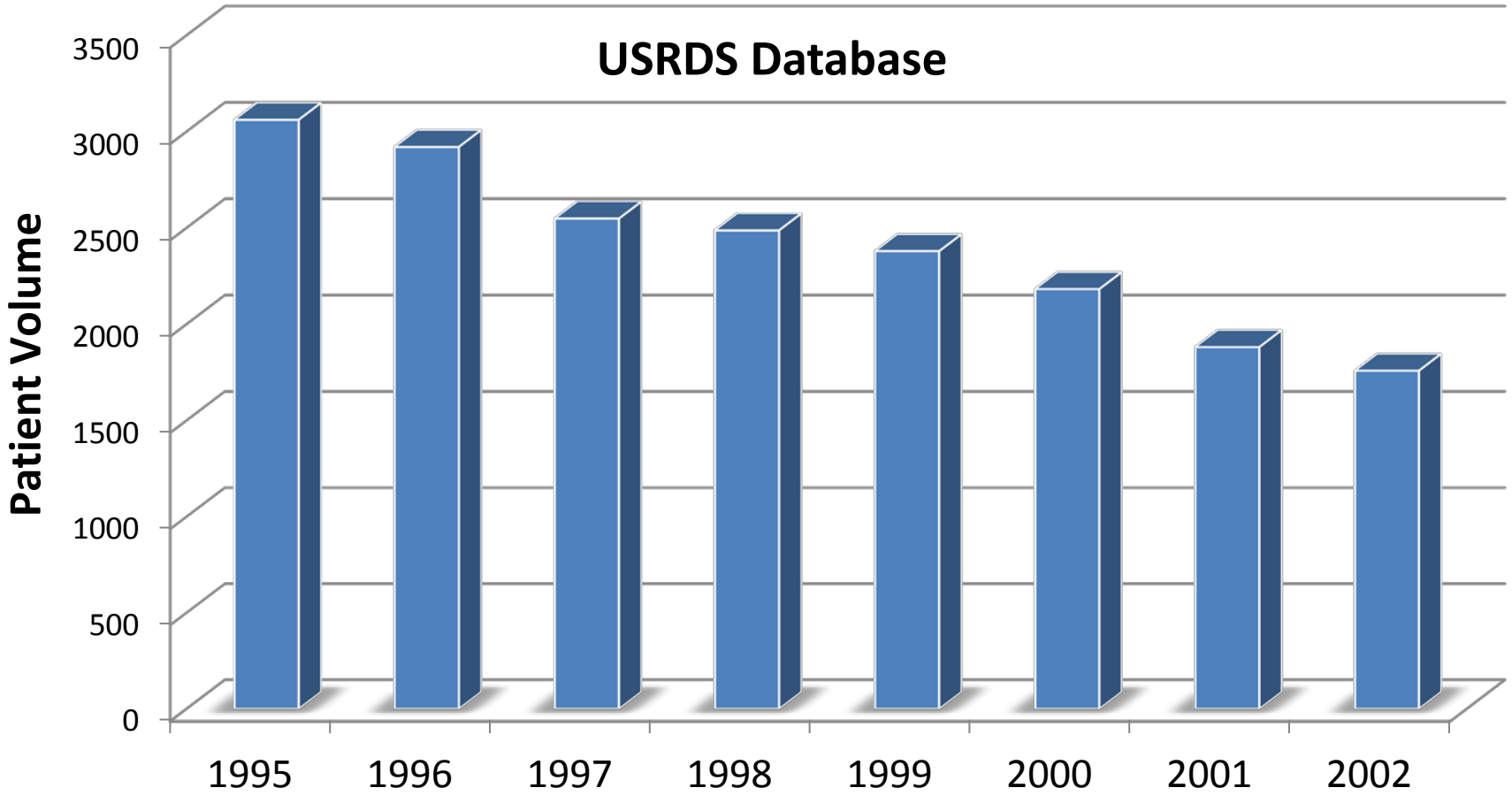
Were we describing the NxStage system?



NxStage

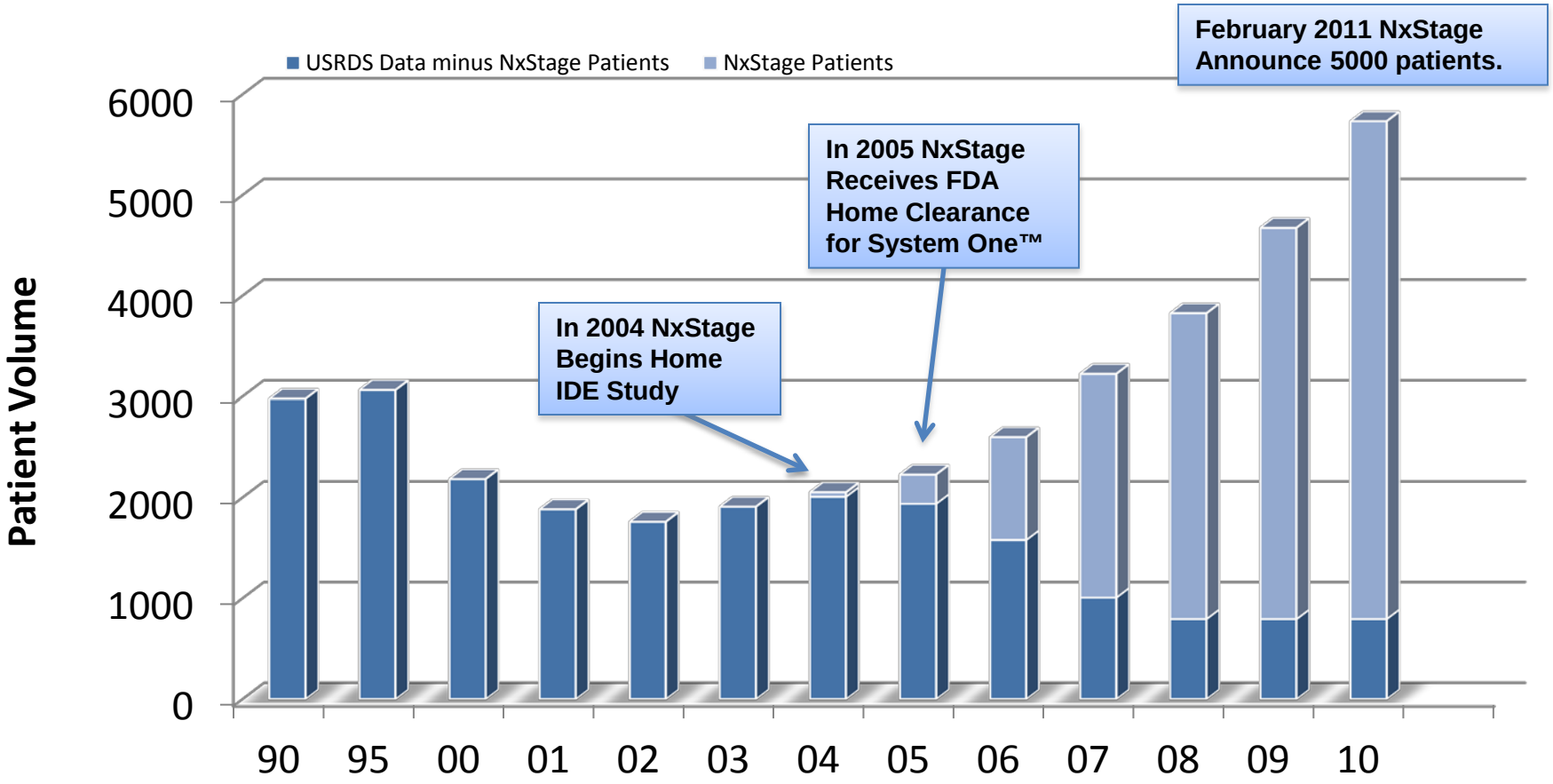
- New technology designed specifically for the home
- New clinical evidence supporting benefits of more frequent and home hemodialysis
- Patients seeking greater independence and alternatives to traditional dialysis schedules

In the US, Home Hemodialysis Hit a Peak in 1995



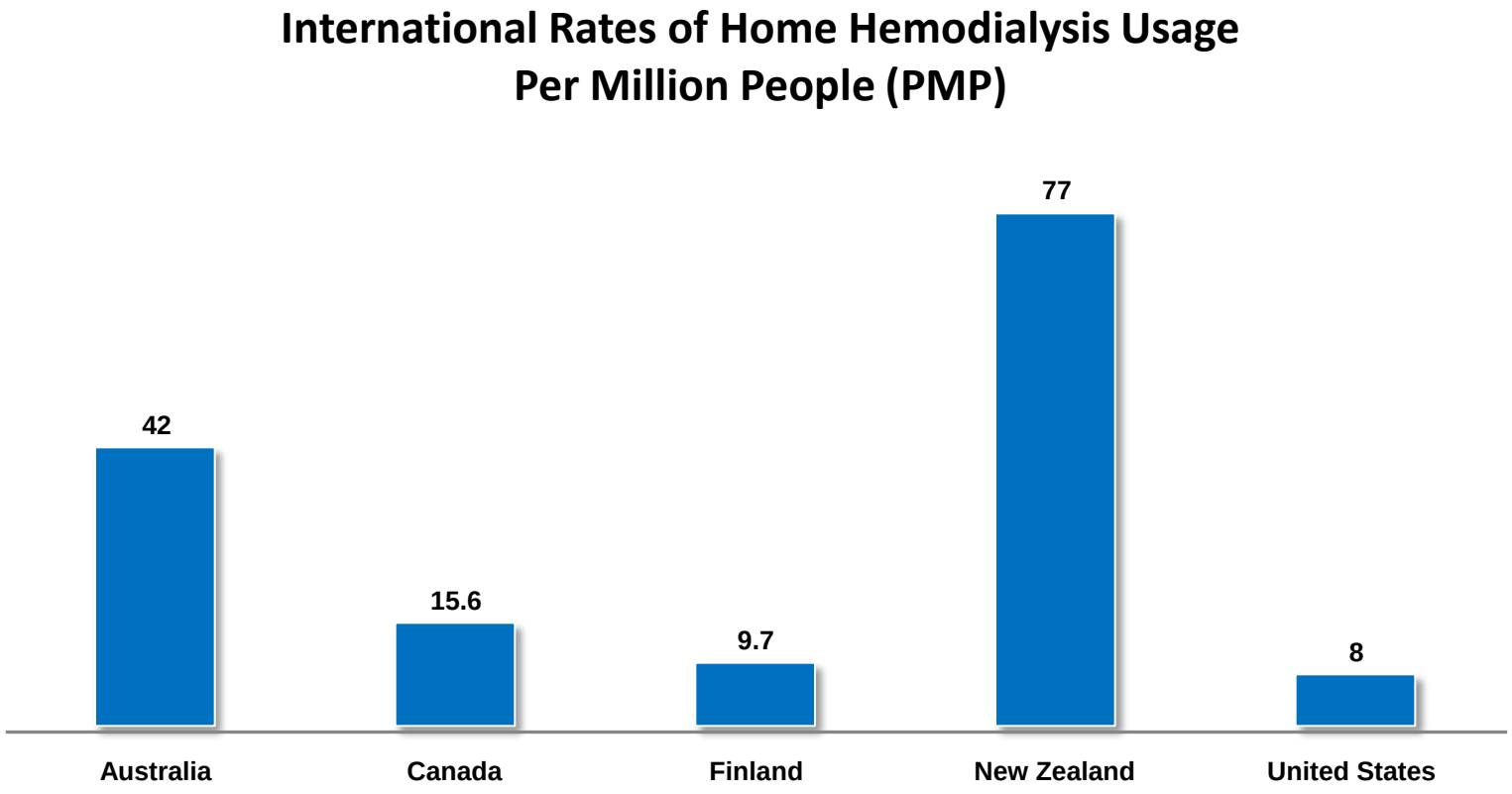
Data from 2010 USRDS Annual Data Report

System One Enters Market and Changes the HHD Picture in the US



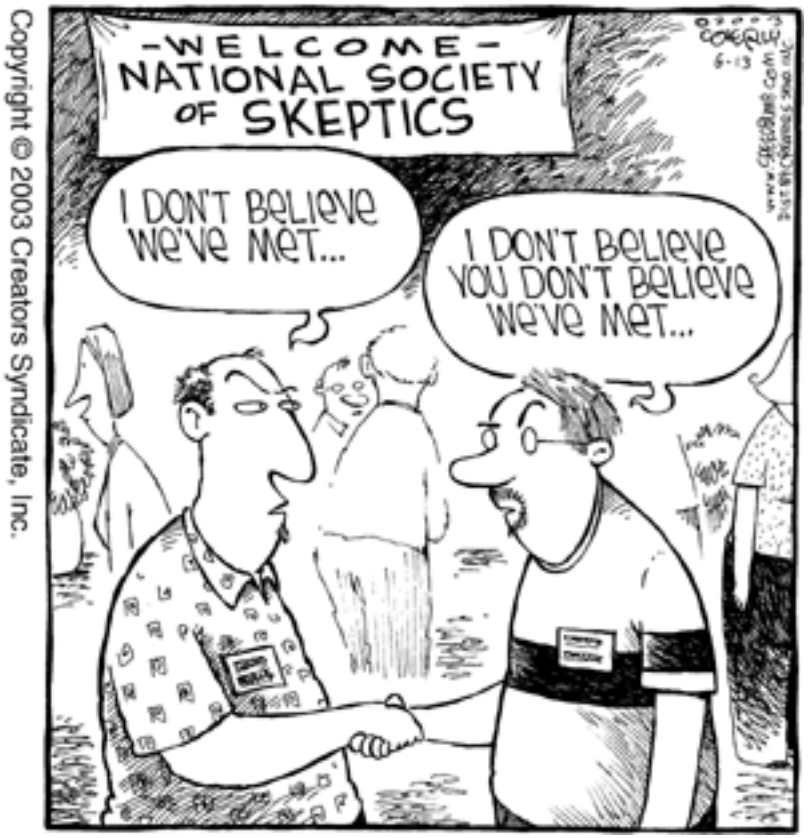
Based on 2010 USRDS Annual Data Report (containing data through 2008) and NxStage data on file as of February 2011. USRDS patient data for 2009-2010 not yet available until actual data is published.

International Rates of HHD Usage



Agar, John. International Variations and Trends in Home Hemodialysis. Advances in Chronic Kidney Disease. 2009:16:205-214

What is the evidence for NxStage?



NxStage Home Indication Study

Overview

Objective

- To demonstrate the NxStage System One is as safe and effective on a per treatment basis in the home setting as in the in-center setting

Type of Study

- 32 patient, crossover study of NxStage hemodialysis therapy in the center vs. at home at 6 clinical sites
  - 8 weeks in center
  - 2 weeks “wash-out”
  - 8 weeks at home

Primary Endpoints

- Efficacy: dose delivery
- Safety: adverse events

Kraus, Hemodialysis Int, 2007; 11:468-77

NxStage Home Indication Study Findings

Consistent dose delivery

	Conventional (in-center prior to NxStage)	In-Center NxStage	Home NxStage
Frequency	3 times weekly	6 times weekly	6 times weekly
Time (hr)	3.7 ± 0.7	2.8 ± 0.6	2.8 ± 0.6
Dialysate Volume (L)	n/a	18.8 ± 2.9 (12.5-24.0)	19.2 ± 3.0 (12.5-24.0)
Dry Weight (kg)	81 ± 15 (49-107)	82 ± 15 (48-112)	79 ± 17 (49-115)
spKt/V	1.7 ± 0.3 (1.2-2.4)	0.53 (CI: 0.50-0.57)	0.54 (CI: 0.51-0.57)
stdKt/V	**2.4**	**2.3**	**2.3**

Kraus, Hemodialysis Int, 2007; 11:468-77

NxStage Home Indication Study Findings

Stable labs

	Baseline	In-center (Week 8)	Home (Week 8)
BUN (mg/dL)	60.4 ± 3.0 (32-110)	57.5 ± 3.6 (22-98)	55.4 ± 3.0 (23-83)
Creatinine (mg/dL)	10.3 ± 0.5 (6-15)	10.6 ± 0.6 (5-18)	10.3 ± 0.6 (4-17)
Potassium (mEq/L)	4.6 ± 0.1 (3.3-6.2)	4.4 ± 0.1 (2.7-5.8)	4.3 ± 0.1 (3.1-5.7)
CO2 (mEq/L)	21.4 ± 0.7 (12-28)	22.7 ± 0.5 (17-27)	22.2 ± 0.6 (18-29)
Calcium (mg/dL)	9.1 ± 0.2 (5.4-10.2)	9.3 ± 0.2 (7.8-11.3)	9.0 ± 0.1 (7.7-9.9)
Phosphorus (mg/dL)	5.7 ± 0.3 (3.3-9.5)	5.3 ± 0.3 (2.7-10.7)	5.1 ± 0.3 (2.3-8.1)
Hemoglobin (g/dL)	12.7 ± 0.3 (10.1-16.9)	12.7 ± 0.3 (9.8-16.3)	11.9 ± 0.3 (9.0-14.5)

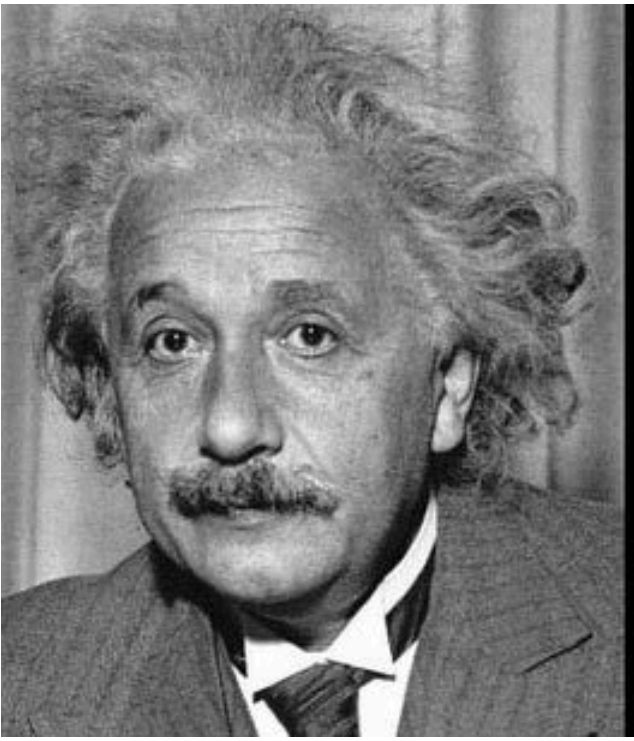
Kraus, Hemodialysis Int, 2007; 11:468-77

Conclusions from IDE Study

"Daily home hemodialysis with the System One hemodialysis device is a safe and viable option for select ESRD patients capable of home/self-care dialysis. This represents a novel device that provides a simplified process compared with traditional dialysis machines."

Kraus, Hemodialysis Int, 2007; 11:468-77

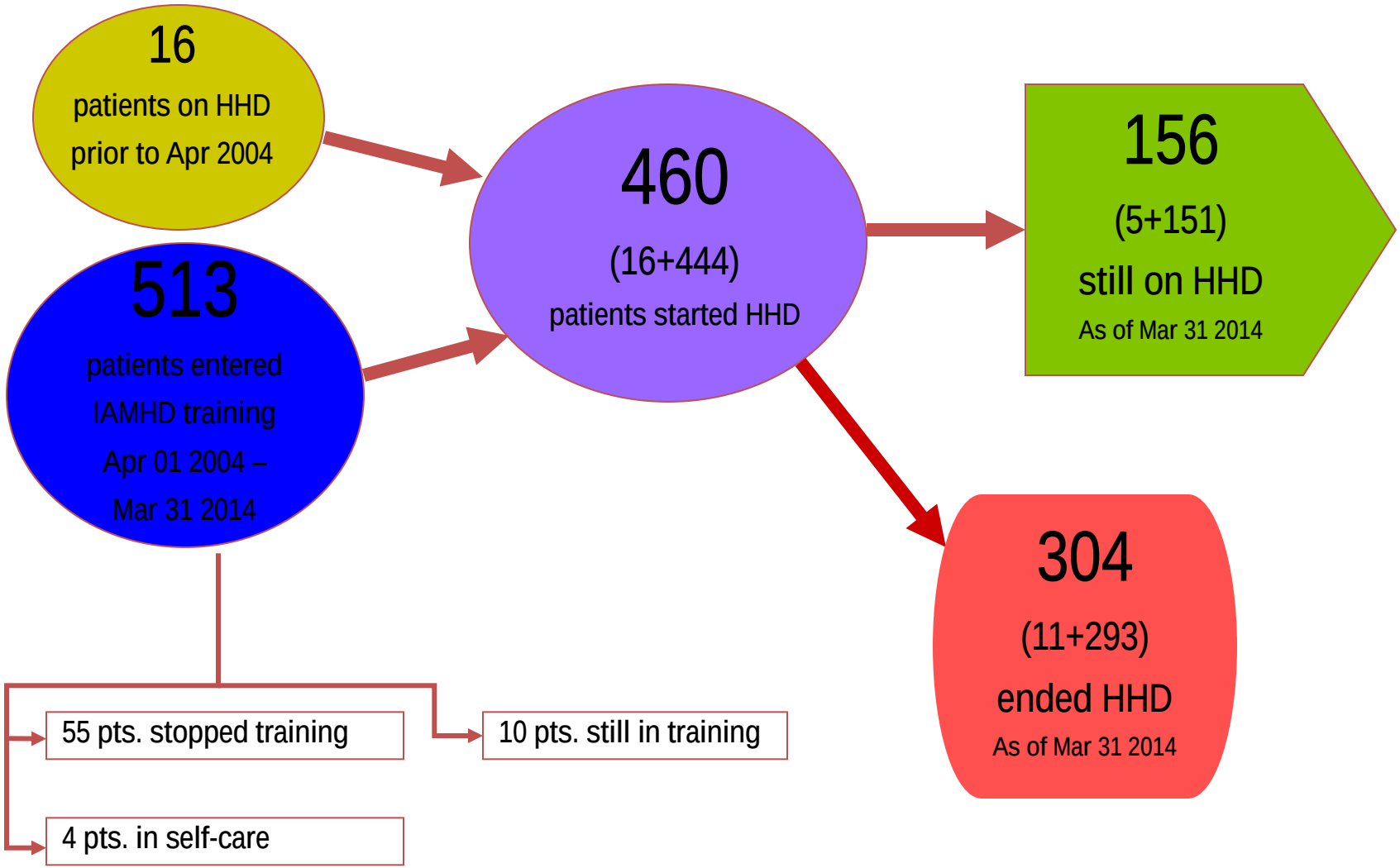
Think differently…



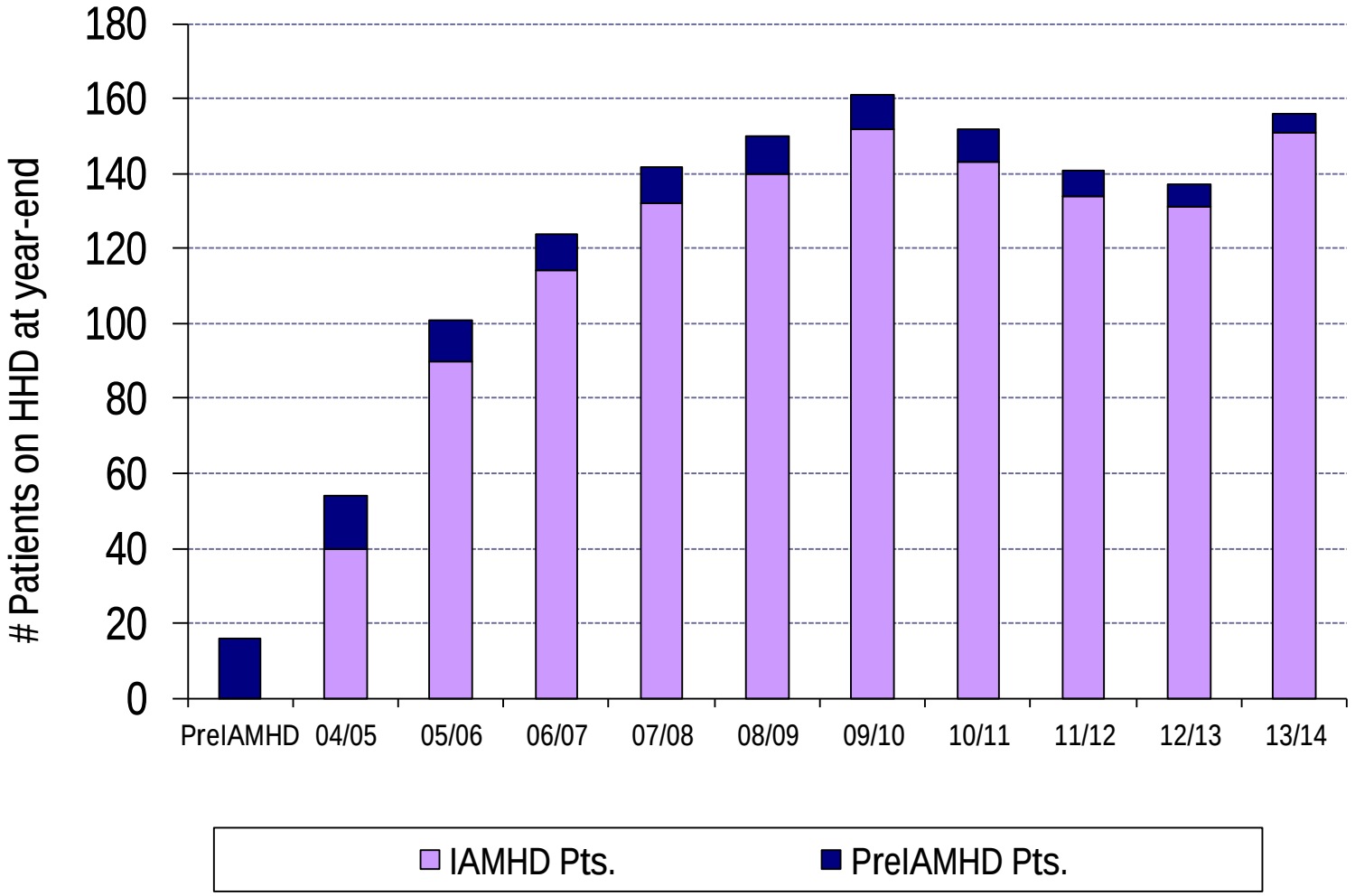
The purest form of insanity is to leave everything the same and the same time hope that things will change.

Albert Einstein

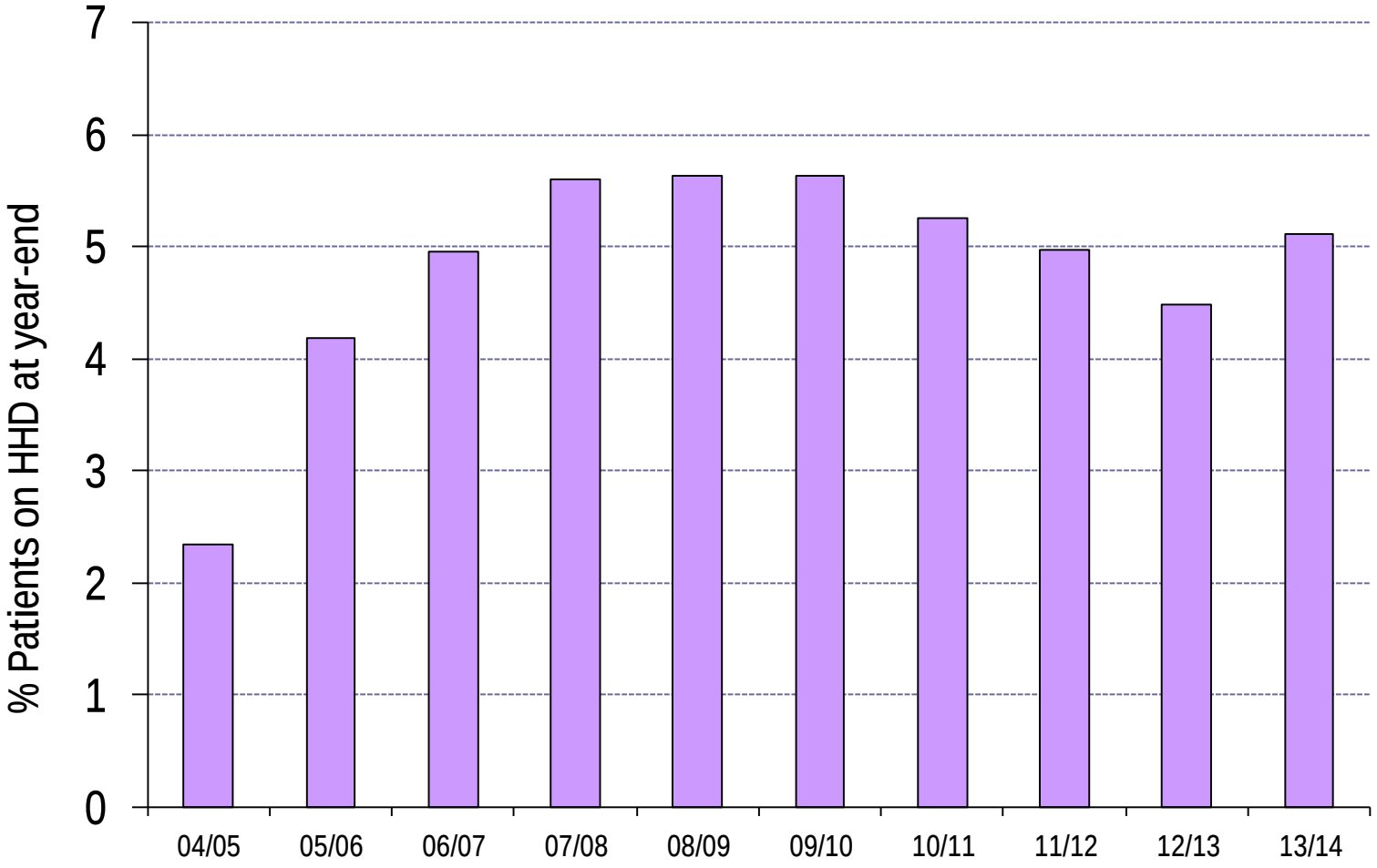
IAMHD Patients



Home HD Growth

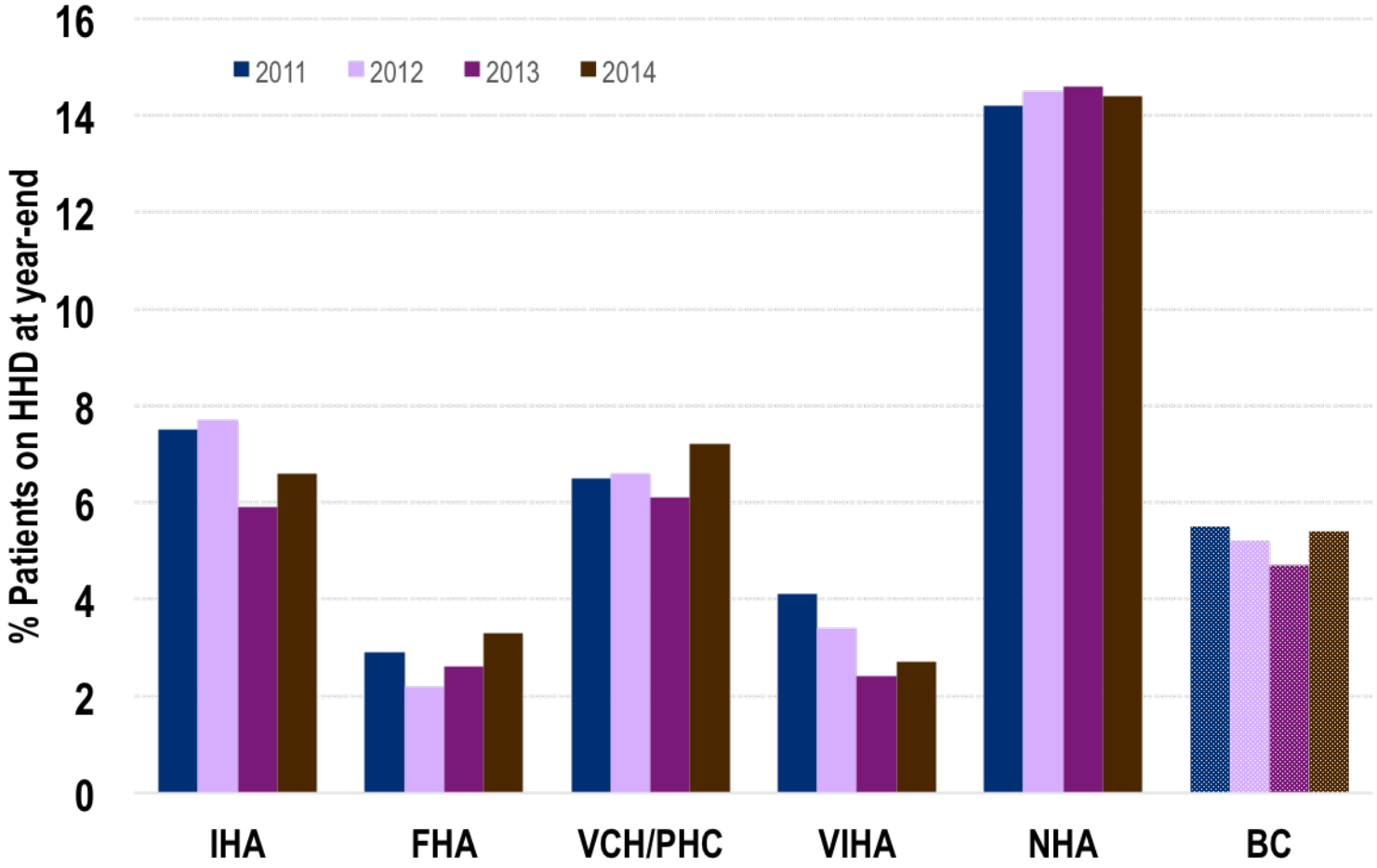


Prevalent Rate of Home HD Over Time



Prevalent Home HD Over Time by HA

(as of March 31 of respective years)



Think differently…

…what can NXSTAGE OFFER?

Design of The NxStage System One

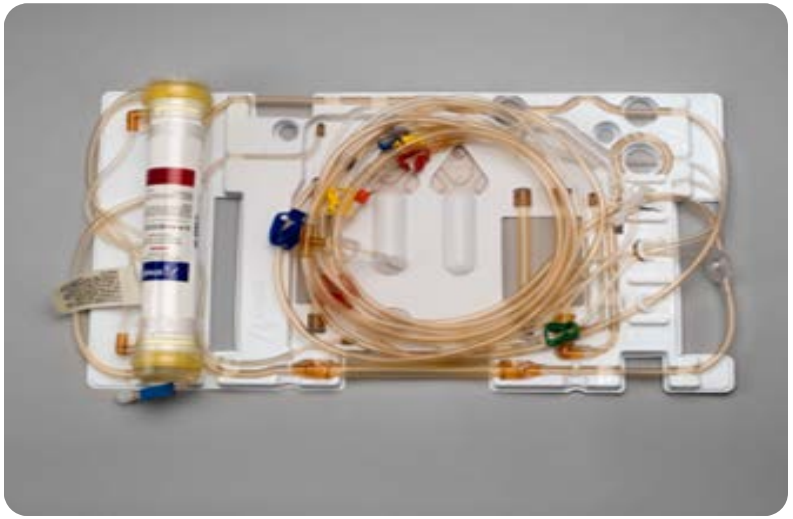
- Designed specifically for the home
  - A standard electrical outlet and a simple faucet or undersink connection are all that are required to operate the NxStage System One and PureFlow SL
  - PureFlow SL's integrated water treatment, dialysate mixing, and heating prepares ultra-pure water and high-purity dialysate from tap water
- Designed to fit patients' lifestyles
  - Portability gives patients freedom to travel or dialyze throughout their home
  - Easy-to-use drop-in cartridge allows for easy, wipe-down disinfection after each use

See NxStage User Guide for environmental requirements for treatment
See NxStage User Guide for source water purity requirements.

The Cycler and Cartridge

Simple interface using shapes, colors, and diagrams to aid in operation of system

Color coded cartridge clamps to match fluid pathways



Cycler

- Controls and displays volumes and rates
- Displays treatment pressures and treatment time remaining
- Displays operating conditions
- Monitors all safety systems
- Routine Maintenance limited to external surface cleaning after each treatment and monthly cleaning of the blood leak detector

Flexible Treatment Options

PureFlow™ SL Package

Express Package

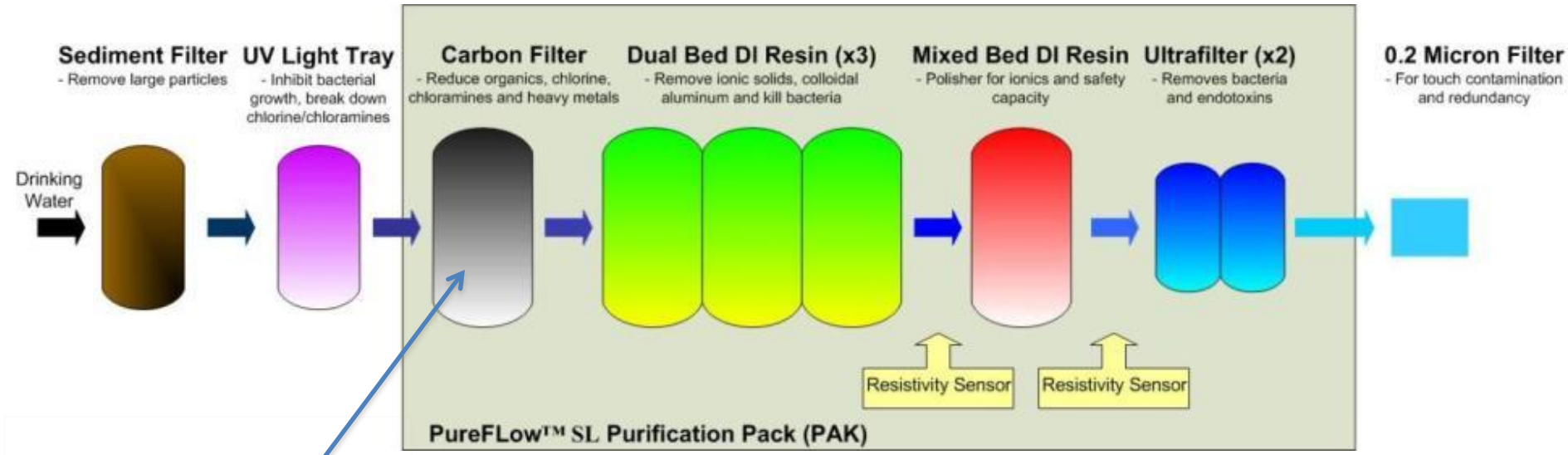
System One™ – Travel Option

NxStage can support travel only within the USA

PureFlow SL Dialysate Preparation

- Designed for simplicity, ease of use, and patient safety
  - Compact, self-contained, disposable deionization (DI) water filtration system
  - Reduces monthly supply needs when compared to using premixed bagged dialysate
- Simple faucet or under sink connection and standard electrical outlet are all that are required to operate

Water Purification System in a Box (PAK)



Disposable Dialysate Sack (SAK)

Disposable Dialysate Sack (SAK)

Contains dialysate concentrate

PureFlow SL vs. Express Supply Needs

Example of typical weekly supply needs for System One with pre-mixed bagged dialysate

Example of typical weekly supply needs for System One with PureFlow SL

Back to our ideal system…

Variable	Present
System able to fit in a suitcase	✔
System which take 10 minutes to set up and clean up	✔*
System which requires no interaction / maintenance between treatment sessions	✔*
System which is light enough to carry	✔*
System which doesn't look like a dialysis machine	✔
System which is simple to operate – green button go; red button stop	✔

BRITISH COLUMBIA EXPERIENCE

Based on a review of:

- Care team perspective
- Time spent with aspects of training time
- Monitoring of clinical parameters / lab work
- Specific focus groups meetings for feedback with patients:
  - Incident patients – no direct comparator of equipment; mainly focusing on learning experience / time to confidence
  - Prevalent patients – looked at timing to competence but especially ‘compare and contrast’ experience

A VERY DIFFERENT WAY TO THINK ABOUT DIALYSIS!

Crossover therapy

Similarities to PD

- Lactate based fluids
- Saturation of dialysate (dwell time)
- Dosing (prescribed clearance volume)
- Weekly Kt/V

Similarities to HD

- Blood flow rate dependent
- Monitor blood and fluid circuit pressures
- Any vascular access (graft, fistula, catheter)
- Anticoagulation

New patients training

- Training time remains about 5 – 6 weeks
  - Comfort in machine management within 2 – 3 weeks
  - Remainder of time in training mainly related to needling comfort

Prevalent patients

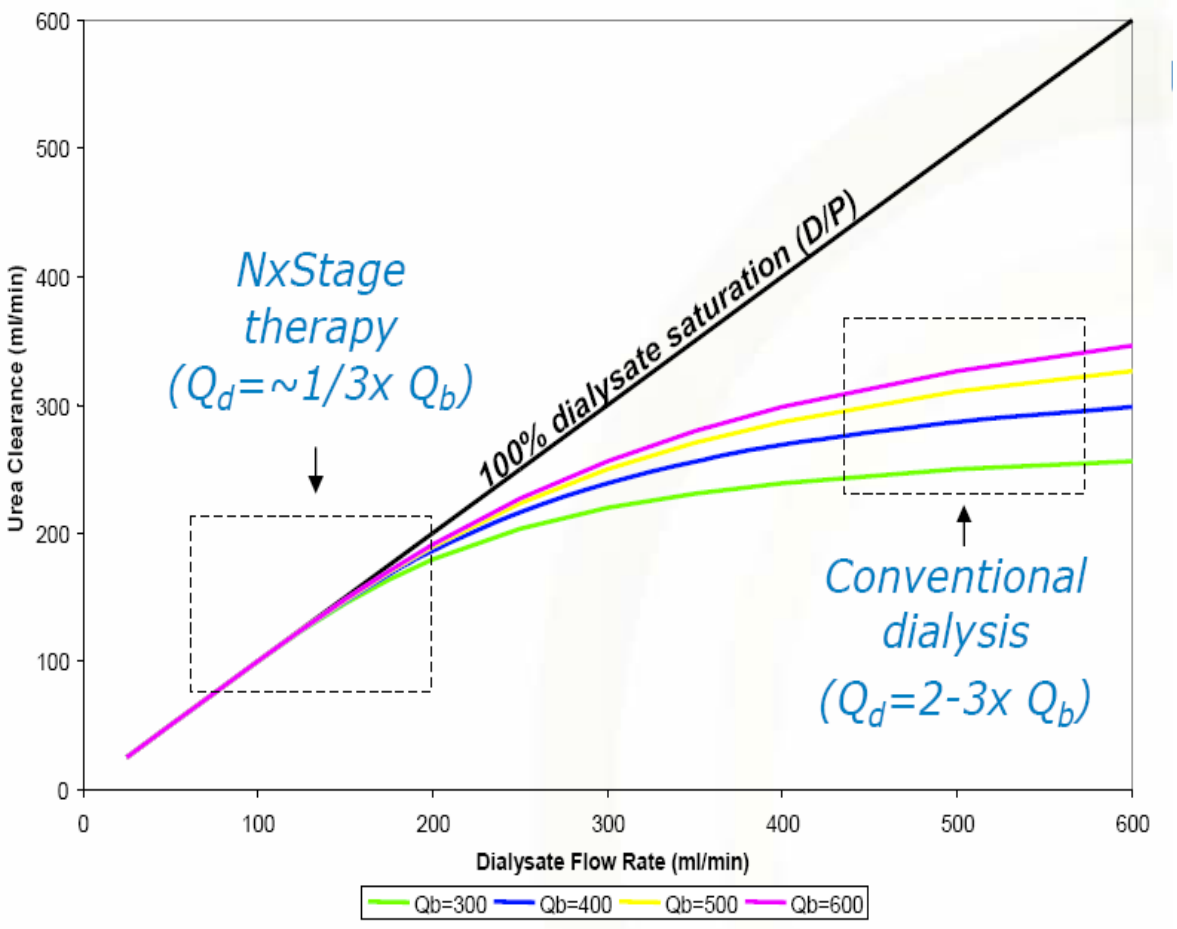
- Time to convert from conventional machine to NxStage machine 1 – 2 weeks
  - “very easy and intuitive to learn”
  - “a very simple machine”
- Ease of use:
  - “so easy to use when I am feeling tired”
  - Easier to run at minimal fluid removal

Clearances / metabolic parameters

- Consistent with what was observed in published studies, could see no systematic differences in adequacy of dialysis

Dialysate Saturation:

Time Efficiency (conventional) vs. Fluid Efficiency (NxStage)



Conventional Dialysis

- Fluid-inefficient
- Time efficient
- High Qd (2 to 3 times Qb)
  - Dialysate saturation & urea clearance decrease as Qd increases

NxStage Approach

- Fluid-efficient
- Time-efficient via:
  - Similar range of weekly avg. dialysis hours (3x4 hrs vs. 6x2.5 hrs)
- Low Qd (1/3 that of Qb) supports use of bag or batch systems
- ***Equivalent dose delivery with much less fluid use***

Clearances / metabolic parameters

- Consistent with what was observed in published studies, could see no systematic differences in adequacy of dialysis
- Some ‘learning points’
  - Detectable lactate post-dialysis
  - Paradigm shift for phosphate supplementation
  - Restriction in dialysis parameters

Themes of patient feedback…

- NxStage customer and technical support:
  - Extremely positive feedback from all patients
  - 24/7 service; same technical advisor follows through entire call issue
  - 2 patients required ‘switch-out’ of control units – completed within 24 hours and time to replace actual unit ~5 minutes

Themes of patient feedback…

- Time spent interacting with machine away from dialysis:
  - When considering time spent for:
    - Machine set up
    - Machine clean up
    - Disinfection
  - Agreement from patient that weekly time savings ranged from 3 – 5 hours

Drop outs

- 2 patients dropped out:
  - One due to machine noise
  - One due to moving away (goal to remain on home hemodialysis in Nova Scotia)

Themes of patient feedback…

- Frustrations….
  - Some patients found that DI PAK expired much more quickly (due to feed water chemistries)
  - Time limits on making up dialysate batch
  - Greater degree of waste generated with NxStage

Where do we go from here?

NxStage Patient Characteristics

- 64% are male
- Average age: 53 ½ yrs
- Average weight: 88kg
- Vascular Access:
  - 60% fistula
  - 15% catheter
- >90% patients doing 5-6 treatments per week

NxStage Data on File as of June 2011

British Columbia will have a 2-machine model

- Successfully managed in other jurisdictions
  - In discussions with program in Leiceter, UK
- Allocation planning to be determined, but likely ‘next machine available’ philosophy
- Certain characteristics may suggest one vs the other

Favours conventional HD

- Not willing to dialyze greater than 3 x per week
- Goal weight greater than 100 kg

Favours NxStage

- Water supply from well or other reason for limited water access
- Rental property where landlord will not approve plumbing / electrical upgrades
- ?? Role for travel ??

Next Steps…

- Detailed cost analysis and business case will be developed by early 2015 for consideration at BC Renal Agency Executive Committee level

- Contract discussions and planning 2015 (if approved by PRA / PHSA)

THANK YOU!