



Promoting wellness. Ensuring care.





Building a home hemodialysis program and the role of new and emerging technologies

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Declaration of Conflict

I am currently a member of a Scientific Advisory Board for NxStage Medical Inc.

I have recently completed a tenure with Baxter Global Healthcare

I will not speak about off-label uses of NxStage System One or other products during this talk



Objectives

- To review the benefits of home-based hemodialysis treatments
- To understand the process by which British Columbia built a successful home hemodialysis program, with attention to both intake and maintenance of program numbers
- To consider new technologies that may facilitate home hemodialysis for a wider group of patients by reducing the 'technology barrier'



Why home hemodialysis?





Benefits of intensive hemodialysis

- Reduction of medication utilization
 - Phosphate binders
 - Anti-hypertensives
- Fewer dietary restrictions
- Fewer fluid restrictions
- Improved quality of life measurements:
 - QoL proper
 - Illness intrusiveness scoring



Benefits of intensive hemodialysis



- 32% of BC patients on independent dialysis, at home
- Consistently the highest % in Canada*

If these ~1,000 patients were **not** on home dialysis:

 They would travel to community or hospital units to receive dialysis

3 times a week

 This amounts to a total annual travel distance of:

7.05 - 12.23 million km

 Based on these figures, home dialysis saves

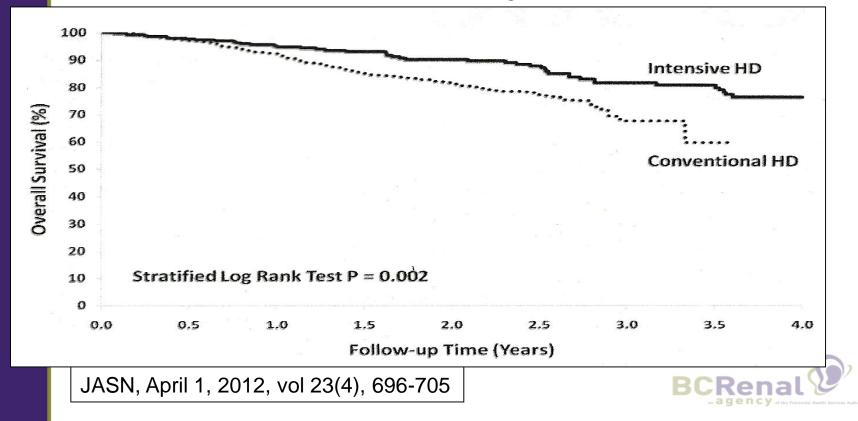
20 - 35 years

of transit time for dialysis patients

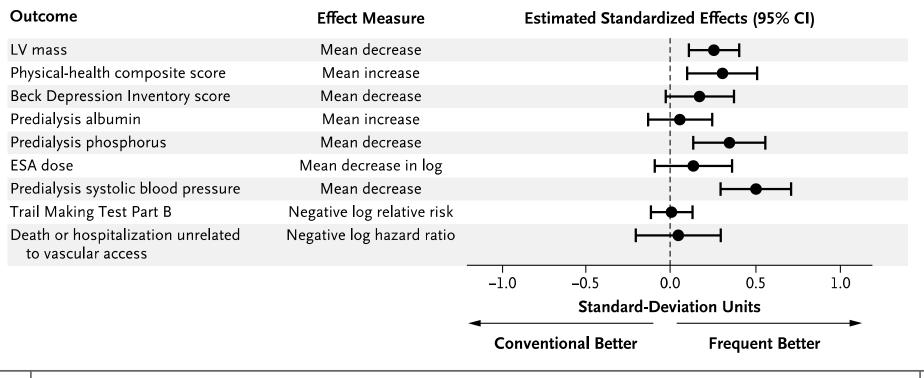




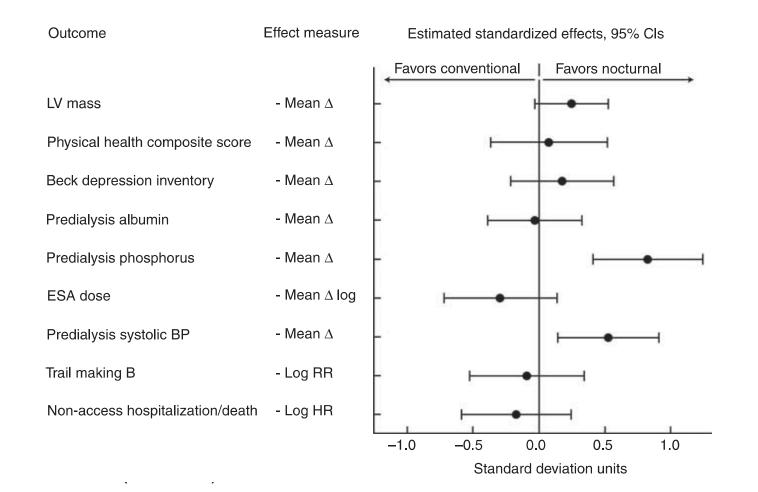
Survival, Intensive vs Conventional Hemodialysis



C Main Secondary Outcomes



N Engl J Med 2010, 363 (24)



Kidney International 2011, 80 (10) November

Based on this....

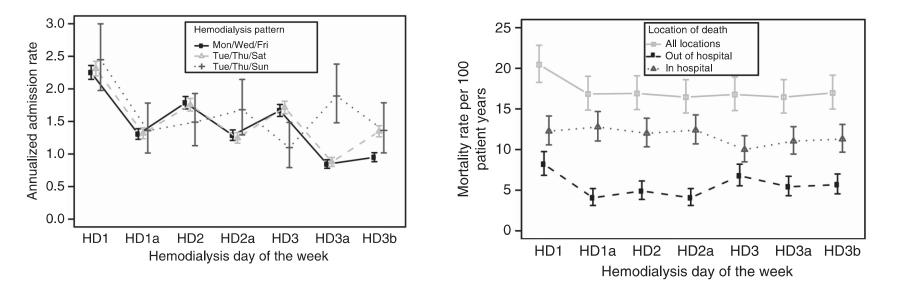
- Evidence suggests benefit of FREQUENCY to be more important than DURATION of dialysis
 - Positive co-primary end-points for SDHD Arm
 - Negative co-primary end-point for NHD Arm
- Rationale for frequency?



The mortality and hospitalization rates associated with the long interdialytic gap in thrice-weekly hemodialysis patients

James Fotheringham^{1,2}, Damian G. Fogarty^{3,4}, Meguid El Nahas⁵, Michael J. Campbell² and Ken Farrington⁶

¹Sheffield Kidney Institute, Northern General Hospital, Sheffield, UK; ²School of Health and Related Research, University of Sheffield, Sheffield, UK; ³UK Renal Registry, Southmead Hospital, Bristol, UK; ⁴Belfast Health and Social Care Trust, Belfast, UK; ⁵Global Kidney Academy, Sheffield, UK and ⁶Renal Unit, Lister Hospital, Stevenage, Herts, UK The mortality and hospitalization rates associated with the long interdialytic gap in thrice-weekly hemodialysis patients

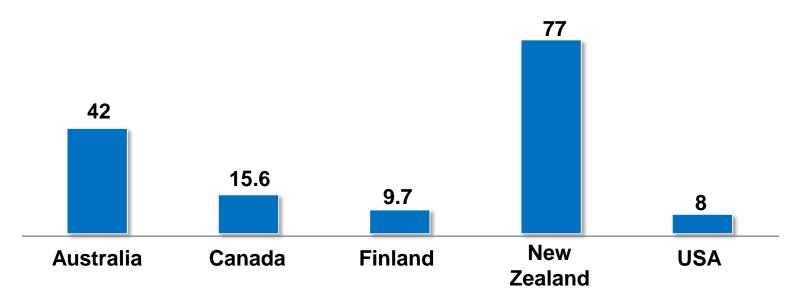




GROWTH OF HOME HD: BRITISH COLUMBIA

International Statistics

Prevalence per million population



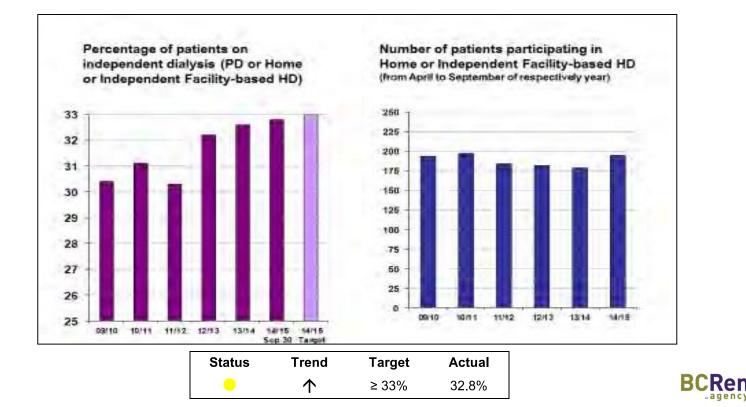
Agar, John. International Variations and Trends in Home Hemodialysis. Advances in Chronic Kidney Disease. 2009:16:205-214

Prevalent Treatment Modality, Canada

Total		1	1	1							
•	%	39.0	38.9	39.2	39.7	40.1	40.4	40.9	41.3	41.8	42.5
Γ	RPMP	377.5	390.8	405.8	423.6	437.5	451.4	464.9	478.1	491.6	506.8
Transplant	N	12,061	12,610	13,238	13,951	14,581	15,230	15,864	16,485	17,146	17,817
	%	6.2	6.4	6.6	6.6	6.6	6.6	6.6	6.4	6.6	6.6
Γ	RPMP	59.9	64.5	68.1	70.3	71.7	74.3	75.1	74.1	77.8	78.4
APD	N	1,915	2,081	2,221	2,315	2,389	2,508	2,563	2,556	2,714	2,757
•	%	5.4	5.0	4.6	4.5	4.4	4.2	3.9	3.7	3.6	3.6
	RPMP	51.9	49.9	47.6	47.9	48.1	46.6	44.6	42.7	42.1	42.4
CAPD	N	1,659	1,611	1,553	1,576	1,602	1,573	1,523	1,472	1,469	1,492
•	%	48.3	48.2	48.0	47.4	46.9	46.8	46.3	46.3	45.6	44.9
Institutional	RPMP	467.9	483.8	496.7	505.3	511.2	523.0	526.2	536.6	536.5	535.4
HD	N	14,949	15,614	16,205	16,642	17,038	17,646	17,957	18,504	10,712	10,025
	%	1.2	1.5	1.7	1.8	2.0	2.1	2.2	2.3	2.4	2.5
	RPMP	11.6	15.0	17.5	19.4	21.5	23.3	24.7	26/5	27.8	29.6
HD Home	N	369	485	572	638	717	785	842	925	000	1,042
Type of Treat	ment [†]	2004	2005	2006	2007	2008	2009	2010	2011*	2012*	2013*



British Columbia (PD and Home Hemodialysis)





BARRIERS TO HHD PROGRAM GROWTH

Preferred modality and training...

- 2362 patients with progressive CKD followed by Kidney Clinics began renal replacement therapy between October 1, 2010 and September 30, 2014 in BC.
 - Reviewed 'Preferred Modality' noted in PROMIS prior to initiation

Modality	Number (Percentage)		
Hemodialysis	785 (33.2)		
Home Hemodialysis	44 (1.9)		
Peritoneal Dialysis	901 (38.2)		
Pre-emptive transplantation	80 (3.4)		
Conservative care	34 (1.4)		
Undecided	518 (21.9)		



Preferred modality and training...

- 44 patients (1.9%) indicated HHD as their preferred modality.
 - However, only 25 (57%) actually started home hemodialysis training.
- Where did the other 19 patients end up?

 Hospital hemodialysis:
 5 (26.3%)

 Satellite hemodialysis:
 9 (47.4%)

 Died:
 2 (10.5%)

 Transplanted:
 3 (15.8%)



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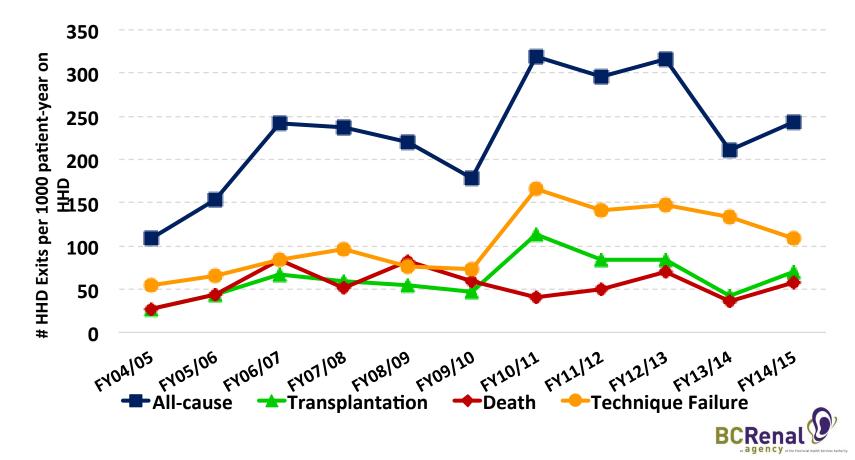
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HHD Annual Attrition Rate Overtime



Where did HHD patients go? Attrition

Transplantation

Deceased

Complications -> death

Discontinuation of dialysis

Medical deterioration

Family and/or patient demands

Geographical reasons

Moving out of province

Recovery of renal function

Other causes: Hygiene, etc:

Non-modifiable

Potentially modifiable







Efforts to increase uptake of home dialysis PD and Home HD

"Broad" interventions, by era

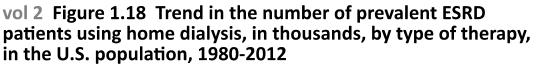
Era	Years	Interventions
1	2002 - 2005	 Established working groups (PD et HD) Funding model revision
2	2007 - 2011	 Uptake (Nurse navigators; educational materials) Attrition (Home services funding; respite provison)
3	2011 - present	 Uptake (NxStage™ Implementation) Attrition ("PD Assist")

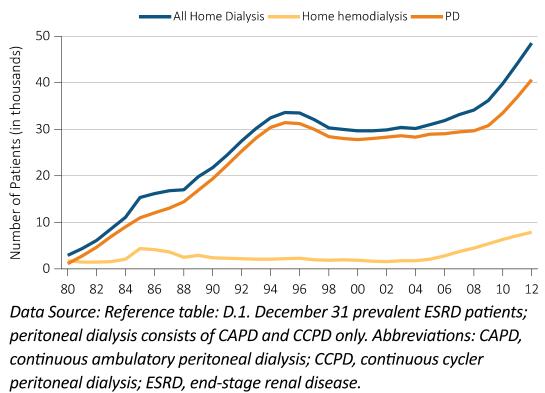


NEW TECHNOLOGIES: NXSTAGE SYSTEM ONE





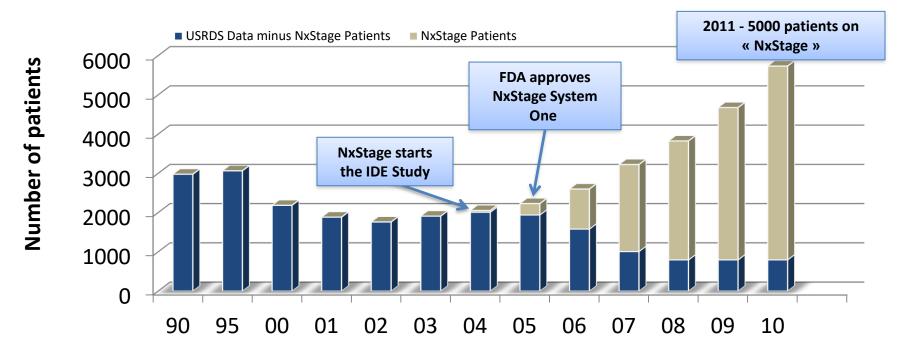






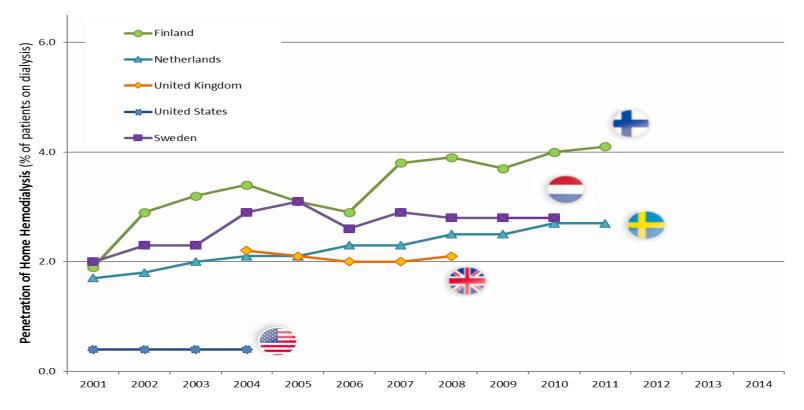
USRDS Report, 2014

Impact of NxStage on Home HD in the USA

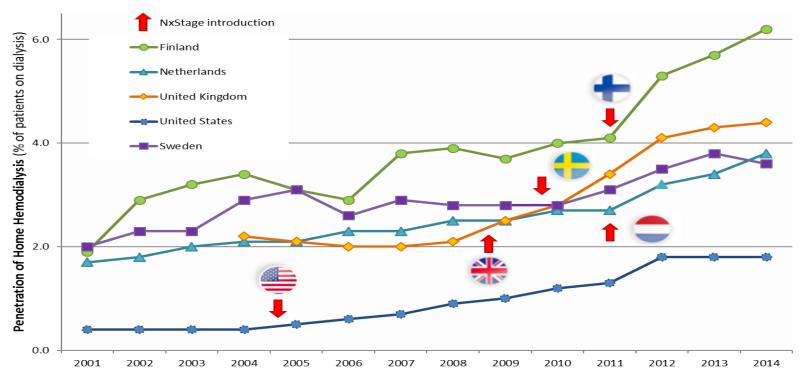


Based on 2010 USRDS Annual Data Report (containing data through 2008) and NxStage data on file as of February 2011. USRDS patient data for 2009-2010 not yet available until actual data is published.

Home HD Penetration is Limited



With more options Home HD can grow



Baxter (Gambro) AK95S/AK96S







NxStage System One





2001...Industry sponsored advisory board: "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

....can fit in a suitcase

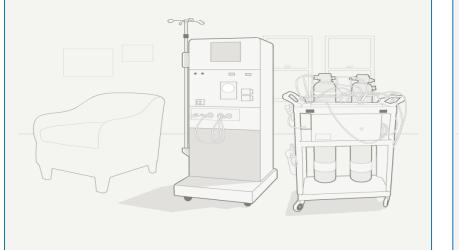
PureFlow[®] SL Package

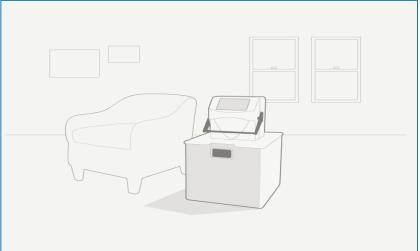
Express Package





....can fit in a suitcase





Traditional system (dialysis machine and RO)

NxStage System One with PureFlow[®] SL

...can be quickly set-up and cleaned-up The Cycler and Cartridge





... can be quickly set-up and cleaned-up





... can be quickly set-up and cleaned-up

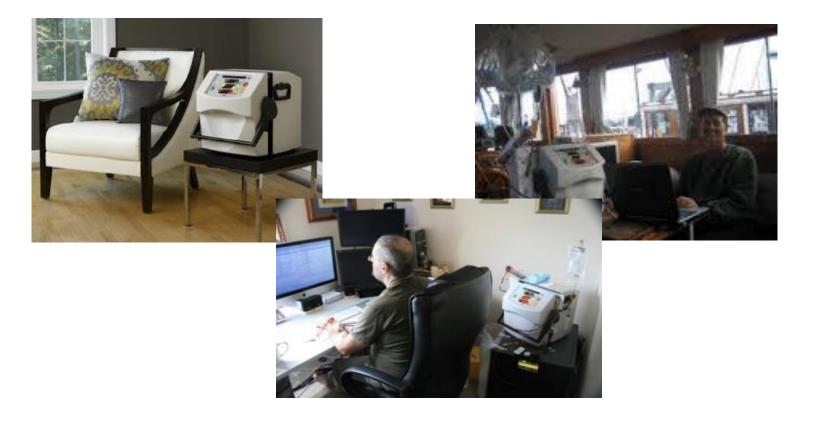
- Cycler requires simple wipe-down of any visible blood
- PureFlow does require interactions of creating dialysate
 - May last 2 dialysis sessions



...small enough to transport



...doesn't look like a dialysis machine to minimize 'medicalization' of the home



...friendly 'green to go' and 'stop sign to stop'



Additional advantages of NxStage[®]

- Reduced renovation requirements:
 - Standard household amperage
 - Garden hose connection



- Simplicity for rural patients on wells / septic fields:
 - 20 60 L dialysate per session



NxStage®: "Peritoneal Dialysis of the Blood"

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



Clearance data:

British Columbia Data Freedom Study Data European Cohort data

British Columbia Pilot Project Data

(n = 20)



	Baseline	6 months	Variability
Hemoglobin	109.4	109.93	0.50
(g/L)	± 14.2	± 13.1	± 19/1
Potassium	4.8	4.6	-0.2
(mmol/L)	± 0.8	± 0.6	± 0.7
Bicarbonate	26.5	26.7	0.2
(mmol/L)	± 4.8	± 4.3	± 5.8
Urea	14.7	16.5	1.8
(mmol/L)	± 7.9	± 7.6	± 8.4
Creatinine	587.2	698.4	111.2
(umol/L)	± 208	± 309.3	± 266.7
Phosphate	1.46	1.52	0.06
(mmol/L)	± 0.4	± 0.5	± 0.6
Albumin	38.1	38.9	0.8
(g/L)	± 4.7	± 5.9	± 5.4

Freedom One study

(n=247)

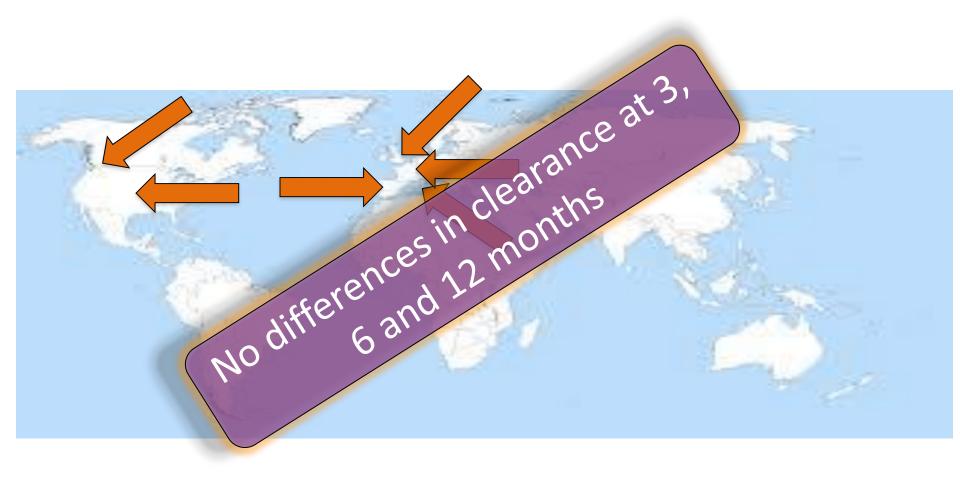


Parameter	Units	Baseline	6 month	12 month	P-value
Creatinine	umol/L	796	804	804	0.24
Blood urea	mmol/L	20.3	20.6	20.9	0.27
K+	mmol/L	4.8	4.5	4.5	<0.001
Bicarbonate	mmol/L	23	23.8	23.9	<0.001
Calcium	mmol/L	2.22	2.25	2.25	0.14
Phosphate	mmol/L	1.81	1.71	1.71	0.03
iPTH	pmol/L	46.1	62.3	54	0.23
Albumin	g/L	39	40	40	0.001
Hemoglobin	g/L	117	111	110	<0.001

KIDHNEy Cohort (n = 127)



Parameter	Units	Baseline	3 month	6 month
Creatinine	umol/L	760	708	712
Urea	mmol/L	20.0	19.1	19.0
К+	mmol/L	4.81	4.64	4.61
Bicarbonate	mmol/L	23.2	24.0	24.0
Calcium	mmol/L	2.29	2.30	2.28
Phosphate	mmol/L	1.72	1.68	1.71
Albumin	g/L	37.1	37.6	37.9
Hemoglobin	g/L	113	111	111







Summary...

- Home hemodialysis provides a cost-effective treatment modality which offers a number of health outcome advantages
 - Likely due to ability to increase dose of dialysis rather than 'home' per se
- New technologies with simplified user interface provide the opportunity to:
 - increase uptake
 - reduce program losses
 - And do so without adversely affecting dialytic clearances



Thank you!

