



Proven
**CLINICAL
EVIDENCE**

**Discover the benefits of More
Frequent and Home Hemodialysis**

Let Your Patients Experience the Difference



Prevalence and Barriers of Home Hemodialysis

Across Europe, approximately 36 million people have CKD stages 3-5, and 350,000 people are currently on dialysis.¹ The most popular form of dialysis prescribed in the EU is currently traditional hemodialysis, performed 3 times per week for 4 hours, in a renal unit or satellite.¹

Today, only **3%** of patients are receiving home hemodialysis therapy in the EU.² One study found that **55%** of patients who were informed and educated on their modality options through a Pre-Dialysis Education Program opted for self-care modality options including home hemodialysis.³

Among possible explanations for barriers to home hemodialysis and low program penetration are:

- Misconceptions about safety and efficacy
- Perceived lack of patient capabilities to perform therapy

According to the National Institute of Health and Care Excellence for England and Wales, **“As long as patients are physically and mentally able as well as motivated to perform treatments and related activities, most patients may be candidates for home hemodialysis.”**^{4,5}

Patients performing home hemodialysis can choose therapy schedules from 3 days a week to 6 days a week, but patients who treat more frequently have experienced additional benefits including:



More energy⁶



Ability to continue activities or go back to work^{7,8}



Better sleep⁹



Feeling more in control¹⁰



The NxStage® System One™ is a home-based hemodialysis option that offers freedom and flexibility to dialysis patients. The System One was designed as a simple, portable system without compromising safety, which can provide the growing number of patients with end-stage renal disease a better option for their treatments.

Proven Clinical Benefits

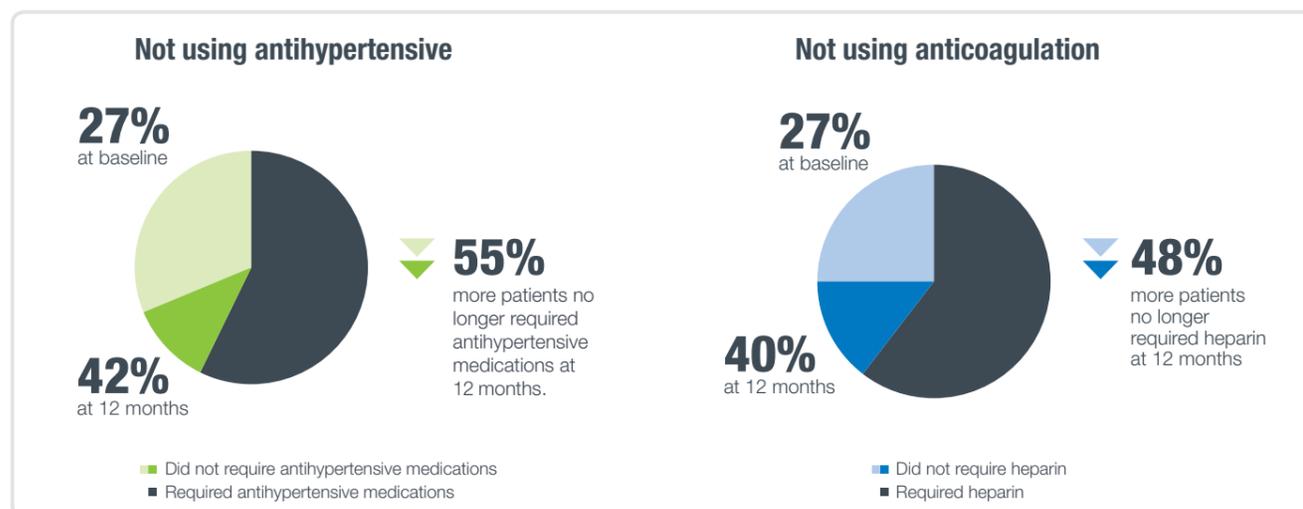
The Knowledge to Improve Home Dialysis Network in Europe (KIHDNEy) cohort* evaluated the effectiveness of more frequent hemodialysis sessions using the NxStage System One. Results from this study showed the NxStage System One is a practical treatment option for home patients and offers significant clinical benefits including:

- Adequate dose of dialysis and above guidelines, based on urea standard Kt/V
- Adequate control of beta-2-microglobulin
- Stable mineral & bone disorders parameters with fewer dietary restrictions, or more patients in the phosphate target range
- Significant improvement in bicarbonate levels from baseline
- Reduction in antihypertensive medications
- Reduction in heparin usage or dose

Mean parameters at baseline and month 12 in KIHDNEy cohort patients with at least 12 months on home hemodialysis^{11,12}

	Baseline	Month 12	p-value
std Kt/V	2.58	2.61	0.74
Beta-2-microglobulin (mg/L)	23.9	26.2	0.08
Bicarbonate (mmol/L)	22.8	24.1	<0.01
Calcium (mmol/L)	2.29	2.28	0.64
Phosphate (mmol/L)	1.67	1.61	0.22
Phosphate Binders (tablets/day)	3.25	3.08	0.45
Phosphate in target (1.1-1.7 mmol/L)	50%	59%	0.15

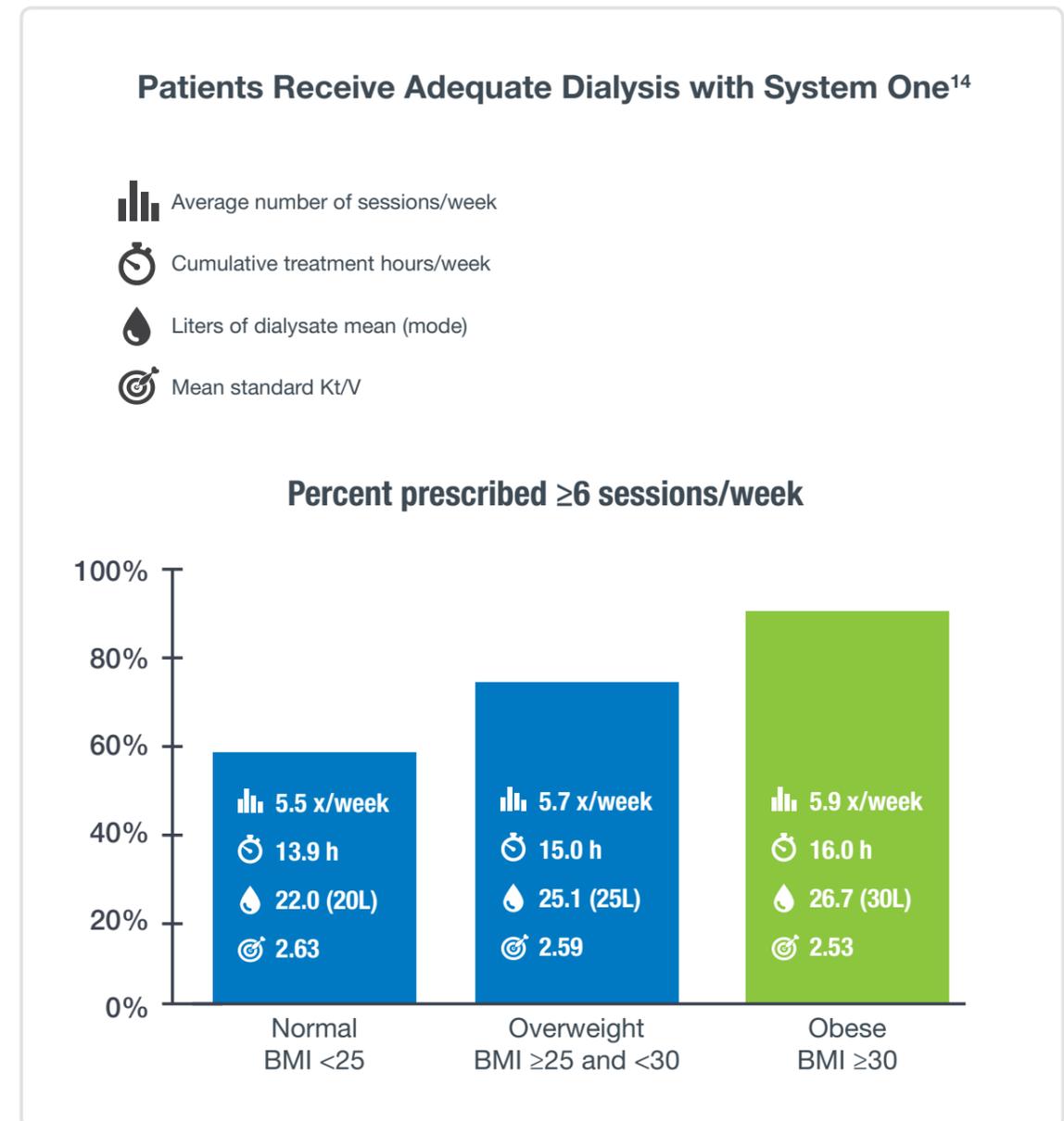
Patients using antihypertensives or anticoagulation saw decreases in usage at 12 months.^{11,13}



Success Across Diverse Body Mass Indices

The KIHDNEy Cohort observed patients across three body mass categories, normal, overweight, and obese, where BMI ranged from 13-51 kg/m².¹⁴

Patient dialysate volume ranged from 20 to 30 L but all patients in each tested category achieved clearances above standard guidelines, supporting other study results which state patients of varying size can be successful on System One.¹⁴



*KIHDNEy is a retrospective study of 182 patients, in 9 centers, located in the United Kingdom, France, Italy, Belgium, and Spain. This was the first international cohort evaluating more frequent home hemodialysis therapy over 6 and 12 months of follow-up.

Addressing Patient Training and Adherence

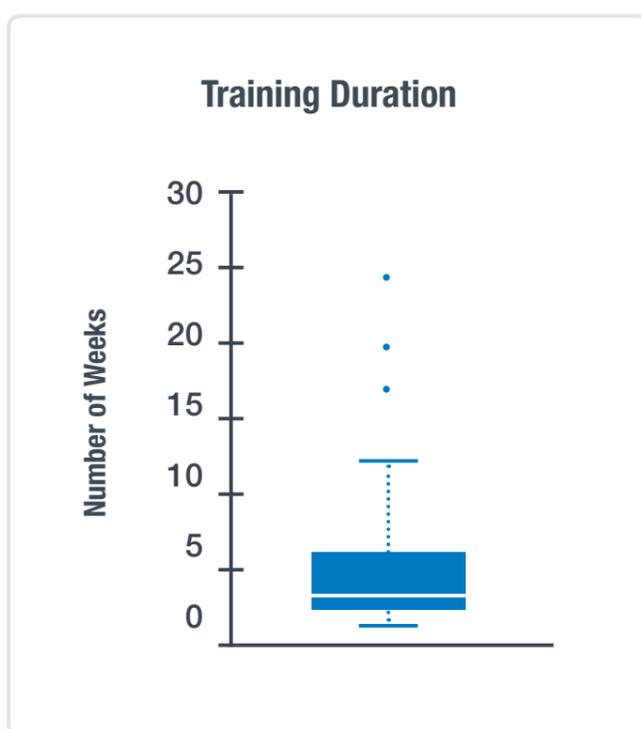
The positive clinical and quality of life outcomes for patients on more frequent home hemodialysis support the need for a home first philosophy and offering home hemodialysis to a wider range of patients.

While patient training and adherence remains a serious challenge for prescribing renal physicians, results from the KIHDNEy study showed rapid patient training and excellent patient retention.^{11,15}

Training

Mean training time for patients, learning the System One, during the KIHDNEy study was **16.9 sessions** compared to 27.7 sessions observed during the FHN Nocturnal Trial, using conventional hemodialysis machines.¹⁵

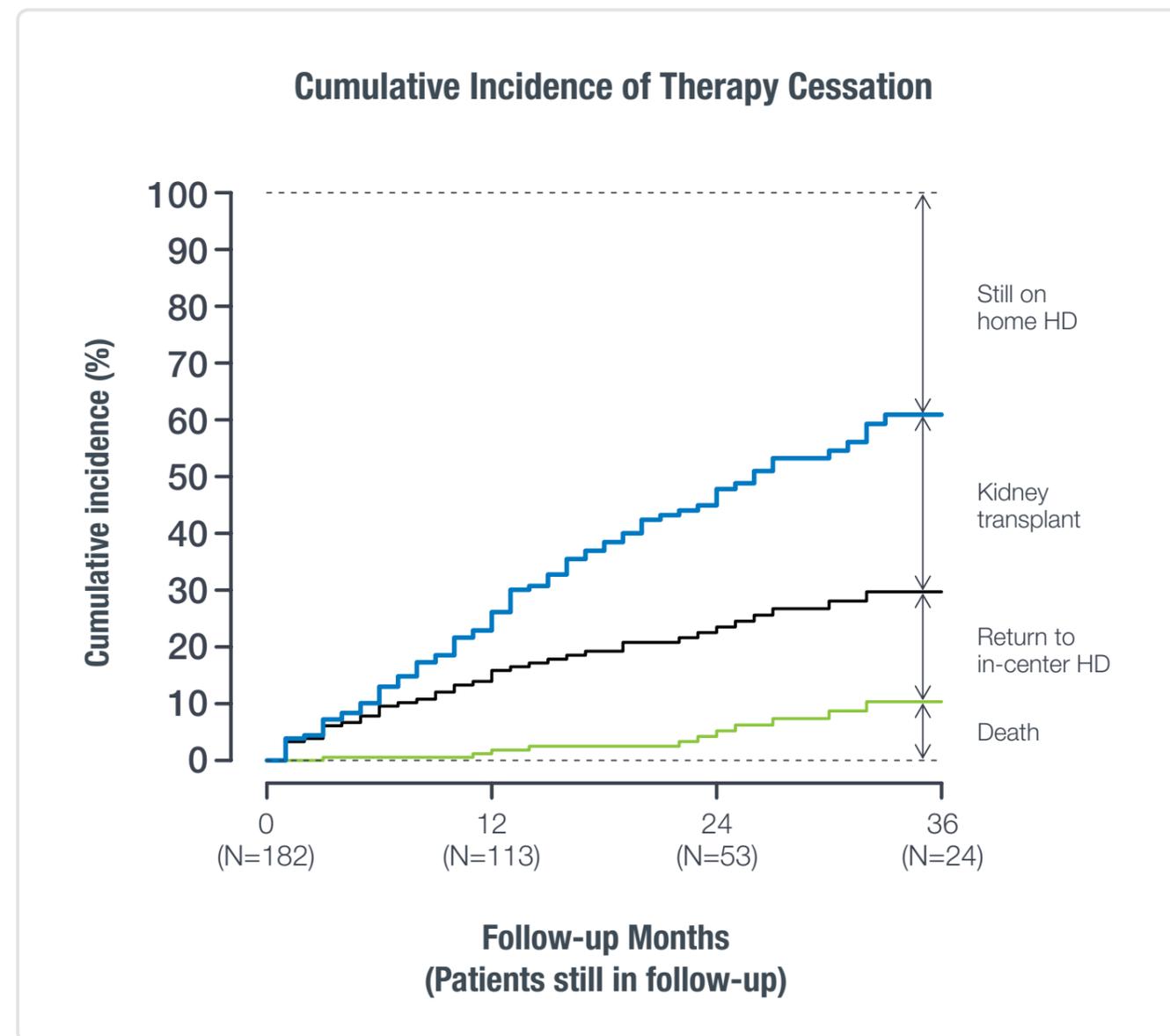
55.6% and **91.9%** of patients begin treatments at home after 3 and 6 weeks respectively¹⁵



Patient Retention

Therapy cessation results were also positive showing¹¹

- **74%** of patients continuing on home hemodialysis therapy with the System One after the 1st year
- Among discontinuation causes, transplant is dominant with 31% and death is only 10% after 3 years



For more information on the KIHdNEy Cohort, or how the System One can help your patients, contact your Local Area Representative or visit www.nxstage.co.uk.

Despite the health benefits that more frequent home hemodialysis may provide to those with chronic kidney disease, this form of therapy is not for everyone. Home hemodialysis with the NxStage System One requires a patient and partner who are committed to being trained on and following the guidelines for proper system operation.

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

The NxStage System One is a prescription device and, like all medical devices, involves some risks. The risks associated with hemodialysis treatments in any environment include, but are not limited to, high blood pressure, fluid overload, low blood pressure, heart-related issues, and vascular access complications. The medical devices used in hemodialysis therapies may add additional risks including air entering the bloodstream, and blood loss due to clotting or accidental disconnection of the blood tubing set. Patients should consult with their doctor to understand the risks and responsibilities of home and/or more frequent hemodialysis using the NxStage System One.

Certain risks are unique to the home. Treatments at home are done without the presence of medical personnel and on-site technical support. Patients and their partners must be trained on what to do and how to get medical or technical help if needed. When vascular access is exposed to more frequent use, infection of the site, and other access related complications may also be potential risks.

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 or increased treatment time or both, and delayed response to alarms when waking from sleep. Patients should consult with their physician to understand the risks and responsibilities associated with home nocturnal hemodialysis using the NxStage System One.

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