

8

Home Hemodialysis: Infrastructure, Water, and Machines in the Home

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CONTENTS

3	Abstract	13	Water
3	Introduction	18	Machines
4	Infrastructure	23	References
7	Infrastructure in Community House vs Home Hemodialysis		

Abstract

We describe the infrastructure that is necessary for hemodialysis (HD) in the home, focusing on physical requirements, the organization of plumbing and water, and the key features that should guide the selection of machines that are suitable for home use.

Introduction

Hemodialysis (HD) in the home requires specific physical infrastructure, careful organization of plumbing and water, and thoughtful selection of machines that meet the requirements of the patient and his or her environment.

Infrastructure

Technical Requirements Necessary for a Dwelling to be Adapted for Home Hemodialysis

There are few dwellings that cannot be adapted for home HD; however, minimum technical requirements must be met. A checklist of infrastructural considerations for home HD can be found in Appendix 1.

Legal and Financial Requirements

There should be no legal restrictions (either central or local government) concerning the use of the dwelling for home HD. There are multiple different financial responsibilities in home HD, and these should be transparent among stakeholders, and formalized through binding agreements (Table 1).

Building Prerequisites

A sound structure is necessary, which should not be affected by dampness, mold, or excessive environmental pollution.

Electricity Supply

The dwelling must have an appropriate electricity supply to accommodate HD. The supply should be compatible with all equipment, as recommended by the manufacturer, and compliant with local regulations (eg, separate circuit requirements, grounding, trip protection). A stable electricity supply is required,

Table 1. Potential Legal Concerns to Address when Starting Home HD

Issue	Stakeholders
Binding agreements between major stakeholders to establish financial responsibilities (unless mandated by law)	<ul style="list-style-type: none"> • Patient • Provider (hospital and/or dialysis center) • Dialysis machine supplier • Local government authority • Landlord • Tax authorities (some expenses may be deductible)
Compliance with regulations concerning use of land and dwelling, water supply, plumbing, electricity supply, and fluid and solid waste disposal	<ul style="list-style-type: none"> • Provider (hospital and/or dialysis center) • Government authorities • Landlord
Compliance with regulations concerning medical responsibility for treatment in the home, and delegation of medical responsibility to the patient	<ul style="list-style-type: none"> • Provider (hospital and/or dialysis center) • Government authorities

usually via the main power source to the dwelling. Supplemental renewable power supplies, such as solar or wind, can also be considered. If it is likely that there will be frequent power failures, the best option is uninterrupted power supply battery backup, which will bridge the power failure until emergency rinse-back or disconnect procedures can be completed. Some HD machines have built-in battery capacity, and most provide a manual wind-back function. Another option is a stand-by generator installed at the dwelling with associated control equipment, although this is more costly and complicated. For more information on power outages, see the following:

- **Home Dialysis Central, “Disaster Planning for PD and Home HD” (for patients)**
- **“NxStage Home Hemodialysis Patient, Planning Guidebook for Non-Medical Emergencies”**
- Disaster planning discussion in “The Home Hemodialysis Hub: Physical Infrastructure and Integrated Governance Structure” module

Water Supply

The dwelling must have sufficient water supply for HD. In most cases, the feed water for dialysis is sourced from a municipal water supply; occasionally, it is sourced from an alternative supply (eg, tank, bore, or well). Water consumption varies from 500 mL/min to 1500 mL/min, depending on flow rate of dialysate and the percentage of water rejected during the reverse osmosis (RO) process.

In most cases, RO machines require a certain level of water pressure to function. Inadequate water pressure can occur for several reasons. Occasionally, the pressure from water mains is inherently unsatisfactory. In other cases, the HD site may be located above ground floor in a high-rise building, thereby reducing supply pressure. Occasionally, there is transient decrease in pressure when other water-consuming equipment in the house is used (flushing a toilet, running a dishwasher, etc). In these situations, the easiest solution is to install a booster pump on the feed water line. This is seldom necessary for ground floor dwelling installations (~5% of installations), but not uncommon for installations in high-rise buildings. Another option is to install a header tank at the dwelling, although this is more costly and complicated. If transient decreases in water pressure are unavoidable and troublesome, consideration can be given to a “flow-fed” rather than “pressure-fed” RO unit; flow-fed RO units have, in effect, a built-in miniaturized header tank, which allows

for about approximately 60 seconds of reduced supply before inadequate pressure results in RO malfunction.

Water temperatures across the globe are variable and it may be necessary to cool or heat the feed water. Water temperature issues can make RO units inefficient and sometimes inoperative, so it is important to address water temperature problems when planning for home HD. Where the feed water is too cold, it can be heated by mixing hot and cold water with a thermostatic mixing valve. Where it is too hot, it can be cooled through the use of a heat exchanger.

Plumbing Requirements

Reject water from the RO unit is usually disposed of via the dwelling's storm-water drainage system, although reject water can be redirected back to the RO unit for further generation of permeate in areas where there are severe water shortages. Rather than disposing of reject water, strong consideration should be given to its collection and domestic reuse. Reject water is usually potable, but slightly salty, which limits it for some uses. Notwithstanding, there is abundant experience of reject water reuse as high-grade "gray water" for gardening and horticulture, watering of livestock and agriculture, showering, laundry, general cleaning, toilet flushing, etc.¹ For more information, see The Geelong Experiment, available [here](#).

The dwelling will need to have options for environmentally sound disposal of dialysate effluent, which is usually managed

through sewerage systems or septic tanks. The use of septic tanks for drainage of dialysate effluent is, to some degree, a matter of local customary practice and experience. Large volumes of effluent may result in a requirement for emptying of the tank at an unsustainable frequency. Of note, septic tanks are not usually used to collect RO reject water, which will dilute the natural microorganisms in the tank that are required to break down sewerage. Theoretically, such dilution can also occur if the volume of dialysate effluent is very large, as might be the case for a patient on nocturnal or daily HD. Another consideration is the disinfection method used for the dialysis machine. If chemicals are used (eg, bleach), the dialysate effluent will be bactericidal and may drastically reduce the microorganism count in the septic tank. These variations in circumstances lead to corresponding variations in practice. For example, as a generalization, dialysate effluent is not usually drained to the septic tank in Australia, whereas it is in New Zealand.

The disposal of waste into municipal storm water or sewerage systems usually requires a tundish (Figure 1), which is a standard plumbing fitting that provides a point of physical separation ("air break") between a machine and/or patient and municipal drains. This prevents the accidental back-siphoning of drain waste into dialysis machinery, which can occur with cyclical changes in pressure in directly connected drain lines.

In most locations, a device to prevent back-flow from the intake of the RO unit into the municipal potable water supply is required.



Figure 1. Tundish (photo courtesy of John Agar).

This device is called a back-flow preventer and it functions as a one-way valve on the feed water line. Back-flow preventers are installed to eliminate the potential risk of back-pressure forcing contaminants (eg, bleach) from the dialysate circuit into potable water piping. The device is not merely a check valve, but a complex and expensive technical assembly involving test cocks and shut-off valves. The back-flow preventer requires careful installation and regular calibration. For dialysis facilities, these devices are mandatory. For home HD, the consequences of back-flow are somewhat mitigated by the more prevalent use of heat disinfection rather than chemical disinfection. Some countries do not require installation of a back-flow preventer, although it is still the default practice and recommended in a guideline established by the International Organization for Standardization (ISO) 23500:2014.²

Plumbing requirements are complex, and the plumber used for installations should be familiar with dialysis systems. The plumbing should be nontoxic with an internally smooth surfaces (with no grooves or sharp corners) and no dead space. In addition, unattractive and circuitous plumbing is unacceptable, and the layout should as aesthetically pleasing and as efficient as possible. Plumbing services are usually provided to patients in 2 main ways: via an independent commercial provider whose services have been contracted by the patient, or plumbing professionals who have been contracted through the patient's dialysis provider. In both cases, it is important to ensure reliable, expert service from the vendor. Table 2 contains a checklist of plumbing questions that should be considered before beginning home HD.

Solid Waste Disposal

HD produces large amounts of waste, primarily plastic products, and those that have had blood contact (dialyzer, lines, etc) are considered biohazardous. The dwelling is usually required to have an extra waste bin exclusively for dialysis-generated wastes, which should be secured but accessible for pick-up and disposal. All sharps waste should be collected in dedicated containers; disposal arrangements and costs are usually the responsibility of the caring home HD program. For other solid waste, options will vary depending on local regulations. For some, dialysis solid waste can be double bagged and thrown in the regular household

garbage. For others, local authorities require extra payment for medical waste disposal. Home HD programs should understand local regulations around storage and disposal of medical (and particularly biohazardous) waste and the recycling of plastics.

Communication

The dwelling must have options for adequate communication, and at a minimum should have access to a fixed or cellular telephone network, and ideally connection to the Internet as well.

Table 2. Necessary Plumbing Questions Checklist

Questions	Done/Not Done
Is the chosen site accessible to plumbing? • Site assessment • By whom?	<input type="checkbox"/> <input type="checkbox"/>
What are the requirements for dialysate effluent and reverse osmosis reject water drainage? • Sewer • Septic tank	<input type="checkbox"/> <input type="checkbox"/>
What external/internal connections are required? • List of required connections (eg, tundish, back-flow preventer)	<input type="checkbox"/>
Is the installation on the ground floor or on a higher floor? • Ground • Second floor or higher	<input type="checkbox"/> <input type="checkbox"/>
If elevated (second floor or above), consider water pressure and the requirement for: • Pump system • Header tank • Additional plumbing complexity and cost	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Infrastructure in Community House vs Home Hemodialysis

Two options may be available to patients desiring to undergo independent HD. HD can be performed in either an unstaffed community-based setting (“community house” HD) or in a residential dwelling (home HD). A community house setting is not as common, so it will be discussed only briefly here.

Community house HD is performed in a home-like setting that is adapted from a previous residential dwelling or dialysis facility.^{3,6} The community house is shared by a group of patients who come and go as they choose and are responsible for their own HD, just as they would if they were performing home HD. Each patient has a space with a machine bay and other dialysis equipment and consumables. A key requirement for successful operation of community house HD is the ability to create a home-like, noninstitutional atmosphere with flexible scheduling that is comparable to home HD. For those patients who dialyze 5 or more times per week at a community HD location, it is best that they have their own dedicated machine and space, while those who dialyze 3 times per week or perform alternate-day HD can usually share a machine. The home HD program is responsible for the infrastructure of the HD system and maintenance of the equipment in the community house.

Patients using the community house for HD have their own secure access, as do maintenance and professional staff from the caring dialysis center.

The technical details of HD are common to both the community house and home HD, although community house HD requires consideration of the following issues related to infrastructure and processes within the house:

- Demarcation of operational tasks. There should be clear agreement by all participating patients that define responsibility for specific tasks. This process is usually implemented through “community house rules” and “patient contracts”; these responsibilities include:
 - » Cleaning of the house: Performed by either participating patients themselves or by a contracted cleaning staff
 - » Care of machinery: Patients should leave machines in a suitable condition for the next user. The caring center is responsible for technical machine maintenance
 - » Patient rostering: Performed by internal agreement among patients
 - » Communication arrangements for both routine and emergency situations:
 - At a minimum, a landline telephone is required

- Explicit and agreed to arrangements should exist so that patients know who, how, when, and where to call in the case of clinical, technical, or emergency problems, or when there are concerns about the building or the machines

- Financial and legal responsibilities: Home HD programs will need to give consideration to the payment and/or provision of the following services for an affiliated community house:

- » Insurance of the building and contents
- » Building rent and taxes
- » Building maintenance
- » Property security
- » Supply and payment of electricity, water, and other utilities

Although content can often be applied to community house HD, the remainder of this module is concerned with HD performed in the patient’s personal residence.



Figure 2. The dialysis room. The dialysis room should feel like “home” (photo courtesy of James Heaf).

The Dialysis Room

The room chosen for HD should be functional and conducive to safe and convenient home HD (Figure 2). The room should also be comfortable and allow for the room’s other social requirements (eg, family activities). Safety should also be a prominent consideration in all decisions around infrastructure and machinery choice and placement. The room should have or offer the following:

- Adequate lighting (ie, 900 lumens)
- A low humidity and comfortable temperature
- No overt safety risks or hygiene hazards (eg, no open fireplace, drafts, frequent through traffic, clutter), with restricted access to small children and pets during HD
- Surfaces and furnishings that are easy to clean. Curtains and carpets are generally undesirable and, if possible, should be replaced with wet-wipe surfaces (plastic/synthetic blinds, tiles, linoleum, hard flooring)
- In-room telephone access
- Easy access to washbasins, which ideally should have hands-free elbow taps or an automatic sensor system for turning water on and off

Safety

Safety should be a prominent consideration in decisions regarding infrastructure and choice of HD machines for the home.

Exsanguination

Exsanguination is a rare complication of home HD and has the potential to be life-threatening. Full discussion of prevention and management of this and other complications is provided in the “Ensuring Patient Safety During Home Hemodialysis” module, although the following points are relevant to a discussion of infrastructure and machinery for home HD:

- All dialysis machines should be equipped with monitors for exact measurement of venous and arterial pressure, which should be set to appropriately narrow alarm bands. Importantly, there are limitations of pressure-based safety systems to detect line separation. The core methods to guard against that hazard involve adherence to standard operating procedures on securing and taping of needles, closed connector devices for tubing connections, and wetness detectors to detect blood and dialysate leaks (see “The Care and Keeping of Vascular Access for Home Hemodialysis Patients” module)
- Real-time monitoring of home HD treatments has been provided by some centers in the past, but is not generally recommended⁷
- An automatic alarm (“panic button/alarm”) to contact the local paramedic unit may be an appropriate option available for some patients

Intradialytic Hypotension

Intradialytic hypotension (IDH) is a common complication which, in extreme situations, can lead to loss of consciousness and serious consequences. In the home setting, the absence of onsite staff makes IDH a potentially more sustained and therefore threatening event. To help prevent and mitigate IDH, each dialysis treatment should be arranged to permit rapid administration

of therapy (eg, intravenous [IV] fluid administration and reduction in blood flow and ultrafiltration rate). Also, patient seating should permit rapid adjustment to a supine position.

Intravenous Drugs

Treating clinicians are responsible for prescribing IV therapy in the home. Secure (and sometime refrigerated) storage is required for such medications. Some drugs have the potential to cause anaphylaxis; therefore, patients should have their first administration of these drugs performed in the dialysis center to ensure that no problems will occur with the prescription.

The following drugs are typically *not* problematic:

- Erythropoietin-stimulating agents
- Vitamin D analogues
- Albumin

Machinery Breakdowns

The most common malfunctions leading to machine shutdown include power failure and interruptions in water supply. If a shutdown does occur, a patient should terminate his or her dialysis session and as soon as possible contact the dialysis center for service.

Configuration of the HD Space

The location and configuration of the home HD space will be determined by the size of machinery and the available space in the home. In some home HD programs, a choice of different HD machines with different size specifications is available. In most programs, choice is limited. The size of the available dialysis machine will often dictate where the home HD space will be located within the home.

Water Treatment Units

Water treatment units do not require a large amount of space. In choosing and situating these types of units, the following are important considerations:

- Noise and vibration
- Adequate servicing access
- Leakage protection with wet-resistant flooring
- Adequate drainage access

For systems using home dialysate batch generation, the size of the dialysate bath should also be included in the space calculation. At present, the only available batch dialysate home HD machine has a unit that contains 60 L of dialysate (see section on “Low-flow Systems”).

Storage

Patients need a cupboard or a closet for storing dialysis equipment (scales, tubing, needles, plaster, filters, etc), with additional space for their dialysis machines, should they choose to store it as well (Figure 3). Depending on the logistics of the dialysis program and the type of dialysis being performed, a single cupboard or closet may not be adequate for supply storage and this should be carefully assessed.

Placement and Location of Dialysis Machinery and Peripherals

Choosing the appropriate location for the dialysis machine within the residence is a key issue. Substantial dwelling alterations are sometimes required to accommodate machinery. Before home modifications are made, there should be a clear agreement between parties (preferably based on a unit policy) about who is financially responsible for making the required alterations.

There are several factors and requirements that may be relevant to machine placement. Some questions patients may wish to consider include the following:

- Where is the best place to perform dialysis?
 - » The bedroom is the only option for patients who choose nocturnal HD. Despite this, some patients choose to sleep in reclining chairs due to fear of moving too much while asleep and disconnecting needles (Figure 4)



Figure 3. Home HD storage (photo courtesy of James Heaf).

- » Patients who choose HD during daytime hours can perform dialysis in the bedroom or another dedicated space within the home
- » Many patients find HD equipment unattractive and clinically sterile looking, and will therefore prefer to keep their HD equipment out of view
- » The HD machine should be placed close to the patient and oriented to permit ease of adjustment. Some machines have mobile control panels that provide more flexibility



Figure 4. Placement of the home HD machine. This patient initially chose the living room, but changed his mind because the armrest on his sofa was too wide (photo courtesy of James Heaf).

- » The HD machine needs to be close to a water supply and drains, and the room must be able to accommodate extra plumbing, if required
- What if I want to perform dialysis privately or in the same room with family members present?
 - » If the patient prefers more social dialysis, the living area is best; however, machine placement is an issue, and there should be consensus within the family on placement

- » If a patient prefers private dialysis, the machine should be placed in the bedroom or a spare room
- What do I want to do while performing dialysis?
 - » For example, watch television, perform work, talk on the phone, use a computer
 - » Patients with flexible access to telephone and Internet (eg, Wi-Fi) will have an increased choice of placement

No matter where a patient chooses to perform dialysis, access to a landline or cellular telephone is mandatory.

Multiple Placements

Patients who have the larger, more static HD machines may be limited in terms of options for machine placement. However, this is not necessarily true for those patients who use mobile batch dialysis equipment (eg, NxStage). Because these units are considered portable, they can be more easily moved from one location to another, as long as the appropriate outlets and peripheral equipment are in place in the dialysis area. Patients using the portable equipment are able to dialyze in various rooms throughout a house. In addition, patients with the more portable units are able to dialyze at a second dwelling (eg, a weekend cottage or vacation home) or in a travel caravan (recreational vehicle). It is very important to note that each location requires a separate plumbing, drainage, and electrical installation, which can result in added setup costs. It is also important to remember

that water supplies that are not used frequently may lead to water stasis, which, in turn, could result in potential water contamination. This fact must be taken into consideration when planning for dialysis at weekend cottages or vacation homes. Each manufacturer will have special protocols required for water flushing and water connection if a water treatment system has not been used recently.

Convenience

Lighting

In addition to room lighting, a reading light is desirable. A back-lit magnifier can be considered for needle insertion, if appropriate.

Seat/Bed

For nocturnal HD, there are few requirements for the bed used. If the patient wishes to use the bed for HD during the day, a bed with an independent head adjustment can be considered.

Seating requirements for dialysis are more rigorous. A dedicated dialysis chair should be provided. It should be comfortable, easy to clean (ie, vinyl or leather, rather than fabric), and have arm rests and an adjustable back rest. The patient must be able to assume a supine position quickly and without effort if symptomatic hypotension occurs. If possible, consider letting the patient choose his or her own chair.

Noise

Dialysis is generally a quiet process; however, excessive noise can be a problem and a major disincentive to home HD. Noise is a particular issue for patients performing nocturnal HD and for their partners who share the bedroom in the dwelling.

The RO unit usually generates most of the noise that does occur. If the noise is bothersome, one easy solution is to install the RO unit in an adjacent and separate room, and run plumbing through the intervening wall. Alternatively, a purpose-built, insulated cover box for the RO system is an option if it must be located in the same room as the patient and machine. HD machinery with squeaky pumps or other moving parts may also be sources of excess noise. It is important to ensure that all moving parts on the machine are as silent as possible.

Hygiene

A clean environment is necessary to prevent infectious complications associated with home HD. Two problems need to be addressed:

- Home structure and configuration
- Patient and family adherence to standard hygiene procedures

Staff need to be satisfied that both of these elements are satisfactory before home dialysis is allowed.

Patient and Family Requirements

The following applies primarily to the patient, but family members living in the same dwelling should be advised to follow the same hygienic rules, particularly if they help with the dialysis process.

- The home and the dialysis room should be kept clean and dry. Vacuum cleaning and cleaning of all surfaces should be performed regularly. Textiles and upholstered furniture that remain in the room should be deep-cleaned frequently
- Dirty clothing during dialysis should be avoided by both patient and care partner
- The patient and care partner should always practice good hand hygiene when performing any dialysis-related procedures. The value of both soap and chlorhexidine or alcohol washing should be emphasized
- Small children and pets pose a safety and hygiene risk for dialysis. In general, pets should not be present during dialysis. Until it can be established through supervised visits that a pet will not chew, pull, or bat at the dialysis lines, it is recommended to keep pets out of the dialysis room. Even if a pet proves well behaved enough to be present during treatment, it is best to keep it out of the room during cannulation

Environment

The environmental impact of a home HD program should be assessed. A particular area of concern is electricity and water consumption.⁸ Strong consideration ought to be given to:

- Reject water reuse⁹
- “Green” energy, such as solar, wind, etc¹⁰

Responsibility

Ultimately, the home HD program or provider is held accountable for clinical outcomes within the service; however, the provision and undertaking of home HD involves a division and sometimes sharing of responsibilities between the patient and program. It is vital that patients and their care partners understand the responsibilities that are assigned to them, as opposed to those responsibilities that fall under the purview of the home HD program. There should be no ambiguity, and agreement between the 2 parties should be formally documented through either patient contracts, or embedded in unit policies and procedures. These documents should be written in simple, easy-to-understand, nontechnical language so that they are accessible and useful to patients.

Responsibilities should be clear from the time of the initial home feasibility study and site evaluation. Patients and their care partners should understand whether they have a choice of machine and other equipment, and whether they are

responsible for any of the costs or processes involved with building renovations and/or installation. There should be clear understanding and agreement around use and ownership of dialysis machinery, communication and monitoring equipment, and home storage modifications and infrastructure.

In most instances, the program is responsible for home HD equipment costs, although some costs may fall to the patient, depending on the country in question and, occasionally, personal factors. The following factors will affect equipment and financial responsibilities:

- Local, regional, national subsidy schemes
- Public or private insurance arrangements
- Patient preference for a system that is not offered, and whether the patient has the means to pay for or contribute to home care

Communication and monitoring equipment can include home landline or cellular telephone and information technology systems and hardware (eg, email, fax, modem, Wi-Fi). These may be the responsibility of the patient, home HD program, or both. If this equipment is provided, there should be clear understanding of ownership and agreement on appropriate use. Often, shelving and storage facilities are part of the installation for home HD, and the patient and program should be clear about who “owns” these modifications, who is responsible for their maintenance and repair, how maintenance and repairs should be handled, and

who is responsible for removing and/or restoring these home modifications to predialysis status should the patient move or no longer require home HD.

There are numerous responsibilities related to HD machine support and troubleshooting, and maintenance of the supply chain. Patient contracts or unit policies and procedures should clearly define which responsibilities accrue to the patient, the home HD program, and the manufacturer. In general, the costs of HD machine support and troubleshooting will not be borne by the patient; however, the patient and his or her care partner have responsibility for the timely communication of equipment issues, general care and cleaning of the machine’s external surfaces, and performance of some routine maintenance procedures. It is vital to establish what is expected from whom, how, and when.

- Who is responsible for communication of equipment issues, and to whom?
- What is the contractual responsibility of the manufacturer with the program/provider?
 - » Equipment updates
 - » Timely advice regarding equipment issues
- Who is responsible for maintenance of supply chain for consumables and stock control in the home?

Water

Water can contain many different natural and artificial contaminants that can be harmful to humans. The intake of water for a healthy individual is estimated at approximately 2 L per day (14 L/week). An HD patient is exposed to around 360 to 580 L of water per week (depending on dialysate flow rates, dialysis duration, and dialysis frequency), and this water is separated from blood only by a thin, semipermeable membrane. Ensuring that water used in the HD process is of excellent quality is important to reduce the risk of patient exposure to harmful contaminants.

Home HD patients will often be exposed to more water than those patients undergoing conventional dialysis, because they typically dialyze longer and more frequently. As a result, home HD patients depend even more on having excellent water quality. The importance of water quality in HD, regardless of modality, therefore, requires a number of essential water-treatment processes to ensure patient protection by the removal of all contaminants. Because water is an integral part of the HD process and requires frequent review, maintenance, and surveillance, a number of guidelines have been developed to ensure that the water used in the HD process meets best practice standards. ISO guidelines for hemodialysis water quality and treatment can be purchased [here](#). Relevant guidelines include the following:

- ISO 11663:2014, “Quality of dialysis fluid for haemodialysis and related therapies”. Available [here](#).
- ISO 13958:2014, “Concentrates for haemodialysis and related therapies”. Available [here](#).
- ISO 13959:2014, “Water for haemodialysis and related therapies”. Available [here](#).
- ISO 23500:2014, “Guidance for the preparation and quality management of fluids for haemodialysis and related therapies”. Available [here](#).
- ISO 26722:2014, “Water treatment equipment for haemodialysis applications and related therapies”. Available [here](#).

Feed Water

Apart from municipal water, feed water can be sourced from a variety of different places, such as rivers, streams, dams, bores, and wells. Some systems like the NxStage (see the section on “Low-flow Systems”) have the option of using batch dialysate provided by the manufacturer. In this case, the responsibility for water quality lies with the manufacturer. In all other cases, batch or single-pass dialysate preparation requires water that is subjected to properly designed and maintained water treatment systems, such that it meets appropriate chemical and microbiological standards for purity (Figure 5).

Feed water should meet ISO 13959:2014 (“Water for haemodialysis and related therapies”) for maximum allowable levels for certain elements that may be toxic in hemodialysis and those that are normally included in dialysate.¹¹ *A full chemical analysis should be performed on any water that is being considered for use in HD.* This analysis should then be compared with ISO 13959:2014 to ensure safety.

Water Purification Processes

A cascade of processes is required in HD to ensure that water is at a level of purity that is acceptable for use. While not all processes are necessary in all cases, water of lower purity may require additional purification for use in HD (Figure 6). The following equipment and filters may be required to ensure higher water purity:

Water Softeners

- Common purification devices that are used in locations where the local water supply has a high mineral content (“hard water”)
- They are a form of deionizer that exchanges calcium and magnesium ions for sodium ions
- Although calcium and magnesium ions are effectively removed by RO, use of a water softener along with the RO unit will protect the RO membranes from calcification by calcium and magnesium salts, thereby reducing system maintenance costs

14 | Home HD – Setup in the Home

- Water softener tanks have a finite capacity and must be regenerated. Monitoring RO conductivity will indicate when softener tanks should be regenerated
- Water softeners used for HD processes must include a lock-out system to prevent brine from entering the softener's product water stream
- Some jurisdictions do not permit water softeners because of the discharge of salt during regeneration

Activated Carbon

- Activated carbon is the standard method used to remove monochloramine (commonly referred to as chloramine) from water
- Chloramine is toxic. All water treatment systems should include carbon beds, unless it is clear that the water supply is disinfected by a means other than chlorination, such as ozone
- Carbon also provides nonspecific removal of organic contaminants from water
- Carbon beds cannot be regenerated and have a finite capacity for chloramine absorption
- To prevent inadvertent exposure of patients to chloramine as the capacity of the carbon is exhausted, 2 carbon beds are installed in series
- Block carbon filters can offer an alternative to conventional granular activated carbon beds when space is limited



Figure 5. Examples of temporary water configurations. Home HD should not be excluded from those who have rental agreements that prevent permanent installation of fittings and equipment (photos courtesy of Anthony Perkins).



Figure 6. Water purification unit (photo courtesy of James Heaf).

Particle Filters

- Particle filters remove coarse particulate matter from the water, and can also remove finer particles from washed out carbon beds (Figure 7). This also helps protect the RO membrane from clogging and fouling

Ultraviolet Irradiation

Ultraviolet (UV) irradiation is a common water purification process for facility-based systems, but is less commonly used in current



Figure 7. Water filter (photo courtesy of James Heaf).

home-based systems. This method involves a low-pressure mercury vapor lamp enclosed in a quartz sleeve that emits a germicidal 254-nm wavelength and provides a dose of radiant energy of $30 \text{ mW} \cdot \text{sec}/\text{cm}^2$ to kill bacteria.¹¹ UV irradiation penetrates bacteria, which alters their DNA such that they are neutralized or unable to replicate. It has also been suggested that UV could be used for dechlorination, as it has been successfully implemented for this purpose in the food and pharmaceutical industry.¹²

- Of note, some bacteria are or can become resistant to UV irradiation, and the presence of biofilm will reduce its effectiveness
- UV irradiation does not destroy endotoxin, and the levels of endotoxin may even increase as a result of the release of bacterial fragments. Therefore, UV irradiation should be followed, at some point, by ultrafiltration
- The UV irradiation device should be sized for the maximum anticipated flow rate according to the manufacturer's instructions
- Regular maintenance of the UV irradiation device includes continuous monitoring of radiant energy output that activates an audible and visual alarm, routine cleaning of the quartz sleeve, and replacing the lamp at least annually or sooner if recommended by the manufacturer

Reverse Osmosis

- RO is a common, but not mandatory, process used to produce water of quality suitable for HD. RO uses a high transmembrane water pressure gradient to force water across a membrane to create permeate, the product water
- Small and portable RO machines are customary for home installations, where space is at a premium. These machines require a routine maintenance and disinfection program
- Heat disinfection is the best method to prevent the formation of biofilm and keep microorganisms within allowable limits

Deionizers

A secondary purification step after RO may be required where RO alone is not sufficient to provide water of the required quality.

A deionizer is a device that can be added to aid in the water purification process.

- Deionizers can produce water of very high purity. They are effective in removing ionic contaminants; however, they do not remove microbiological contaminants. In fact, they provide a good environment for bacterial proliferation and often worsen the microbiological quality of water passing through them
- It is necessary to incorporate bacterial control equipment after the application of a deionizer

Ultrafilters in the Dialysate Pathway

- Work by using adsorption of endotoxin; they have a finite capacity
- These filters are the last line of defense against endotoxin and the potential contamination of the HD machine fluid pathway
- Ultrafilters need regular replacement per manufacturer specifications

Water Quality

ISO has developed easily adaptable guidelines pertinent to HD water quality. Adherence to these guidelines will help in setting up an appropriate water program for home HD.

• Guidelines

- » ISO 13959:2014, “Water for haemodialysis and related therapies”
- » ISO 26722:2014, “Water treatment equipment for haemodialysis applications and related therapies”
- » ISO 23500:2014, “Guidance for the preparation and quality management of fluids for haemodialysis and related therapies”

• Frequency of sampling and testing

- » Many guidelines recommend monthly testing and sampling of dialysate for microbiological contamination; however, the frequency of testing should be dependent on the quality of feed water. Feed water of poorer quality (eg, from rivers, streams, dams, bores, and wells [public and private]) may need more frequent testing to ensure the best quality of dialysate is produced
- » Biochemical analysis should also be performed frequently. In most cases, analysis may only need to be performed annually, but in areas where there is poor water quality, or areas where there is a higher usage of chemicals in agriculture, industry, or the environment, more frequent testing will be necessary to ensure a suitable water supply used for dialysis

• Bacteria

- » The maximum allowable levels are at 100 cfu/mL¹¹
- » Low-nutrient agar (R2A) at room temperature (22°C [71°F]) is the best medium for culturing bacteria

• Endotoxins

- » The maximum allowable levels are at 0.25 EU/mL¹¹
- » Endotoxin levels can be tested using the Limulus amoebocyte lysate (LAL) test, which can be performed by either the quantitative turbidimetric assay (most sensitive and expensive) or the qualitative gel-clot assay (less sensitive but also less costly). The most common method used in dialysis quality assurance programs is the latter

• Biofilm

- » Bacteria are extremely difficult to remove from a water distribution system once they have had an opportunity to colonize, especially if they form a mature biofilm on the interior surfaces of the water distribution system. To minimize biofilm formation, all water distribution systems should be disinfected on a regular basis using a schedule designed to limit bacterial proliferation, rather than to eliminate bacteria once proliferation has occurred. Regular heat disinfection of the water distribution system is recommended to prevent the formation of biofilm

- Prevention is better than cure
- Disinfection with hypochlorous acid/hypochlorite or bleach has been shown to be inadequate for disinfection of fluid pathways to remove biofilm¹³
- Frequent heat disinfection

- Maintenance

- » Regular maintenance and cleaning processes should be scheduled to prevent contamination of the water pathways within the equipment. Heat disinfections can help prevent the formation of biofilm, but hard-to-reach areas within water equipment needs to be manually cleaned. In some cases, harsh chemicals, such as peracetic acid, need to be used
- » Annual replacement of inflow hoses between the RO unit, HD machine, and dialysate hoses can help prevent the formation of biofilm problem areas

- Relationships

- » Building relationships with microbiology experts goes a long way in setting up appropriate water quality surveillance programs. Good relationships with municipal water providers should also be established

Pure vs Ultrapure

Clinical trial and observational evidence suggest that ultrapure water or dialysate may have beneficial clinical outcomes, particularly in relation to inflammation and the reduction of inflammatory markers in patients exposed to high-quality/ultrapure water.¹⁴⁻²² To achieve ultrapure water, stringent considerations need to be adhered to, including:

- Design of the water distribution system to avoid areas of stagnation
- Attention to the preparation of concentrates
- Frequent disinfection of the treated water distribution system and dialysis machines
- Regular surveillance and microbiological analysis of water

Machines

Which Machine Is Most Appropriate?

The choice of machine is commonly the single greatest per-patient capital outlay for home HD. It is also the most problematic to discuss without commercial bias, as this is the chief domain of commercial competition between dialysis equipment providers. Many of the currently available systems have been designed for facility-based dialysis and are over-engineered and unnecessarily complex for home HD. The easier and more intuitive the machine is to operate, the better it will be for a home HD program. However, 1 fact is paramount: *any currently available HD machine is capable of providing home HD. No particular machine is, or should be considered to be, a requisite for good, sustained and effective home hemodialysis.* Thus, the answer to the question “which machine?”, the response is “any machine”, as long as it meets the patient’s specific needs and requirements.

All machines have strengths and weaknesses, whether they are used in facilities or in the home. Key considerations are differences in size, and also differences in the way that dialysate is delivered. Some machines require water treatment systems to generate on-line or batched dialysate, and others come with prepackaged dialysate in bags.

As with the dialysis machines themselves, each of the generative options for creating suitable dialysate has strengths and weaknesses. These include: purity of water, ease of manufacture,

availability, handling, and cost. The choice of machine and the fluid delivery pathway will depend on a range of individual factors that will vary between countries, services (and sometimes, within a service), and patients.

Single-pass Systems

Single-pass systems (SPS) have been the HD standard around the world for over 50 years. SPS are well understood and widely used systems, where dialysate is produced within the machine. This production is performed by proportionally mixing a purified water source with a pair of acid and base concentrates, the buffer component of which is now commonly bicarbonate. The reconstituted dialysate is tested for conductivity, which is a check system to ensure correct proportioning, and then is heated, deaerated, and pressurized. The dialysate is then directed as a single-pass, high-flow, pure or ultrapure fluid to the dialyzer for transmembrane contact with the patient's blood. Common examples of SPS for home HD include, but are not limited to, systems manufactured by Baxter, Braun, Fresenius, Gambro, Jihua, Nikkiso, and Nipro.

SPS machines have a number of advantages:

- Physician and nursing dialysis staff everywhere are familiar with operating characteristics of SPS. This also applies to unit technical staff who are familiar with the strip-down and replacement practices required for machine maintenance

- Although SPS machines are complex, most current systems have on-screen instructions for nurses (and, in the situation of home HD, the patients) to follow
- On-screen instructions are commonly matched by a number of fail-safe warning systems to alert the user to any missteps made during the set up process
- SPS systems allow for multiple variations in dialyzer and dialysis fluid parameters, for example, dialyzer surface area, and the sodium concentration of the dialysate
- A wide range of commercially available dialysis fluid concentrates permits individualization of fluid component electrolytes, in particular, potassium and calcium, allowing customization of the dialysis prescription
- The high dialysis fluid-to-blood-flow ratio of SPS machines allows higher clearance rates, particularly for small molecular solutes

SPS systems also have a number of disadvantages:

- SPS machines are often large and heavy. This limits—indeed, effectively prevents—portability and, in addition, introduces a range of occupational health and safety (OH&S) issues. This is particularly pertinent to home HD, where current SPS machines are of such bulk that OH&S rules usually prevent a single technician alone being sent to maintain (and especially move) the system

- Importantly, the maintenance requirements for SPS machines are extensive. The systems are “wet” systems—this means that a fluid circuit exists within the machine. O-rings wear or leak; electrical circuits are exposed to the risk of moisture; and internal dialysis fluid pathways must be sterilized, de-scaled, and decalcified to properly maintain the system
- As equipment failures and maintenance requirements introduce additional cost, most HD services will be well aware that machine maintenance and servicing comprise a significant component, both in time and money, of the provision of their services

Low-flow Systems

The only currently available example of a low-flow system (L-FS) is the NxStage system. This system is currently the most frequently used within the United States, although it is not as widely available or used as frequently outside the United States.

An L-FS machine depends on a quite different clearance concept when compared to SPS systems. In some ways it is more akin to peritoneal dialysis (PD), where dwell time allows a greater equilibration between blood and dialysate across a semipermeable membrane. SPS systems use a dialysate flow to blood flow (Qd:Qb) ratio of 2:1, but the low-flow dialysate rate used by L-FS reverses this ratio, so Qd:Qb is between 1:2 and 1:3. As a result, an L-FS operates at a different site on the diffusion curve, allowing far greater transmembrane

dialysis fluid equilibration with blood than occurs in the more rapid pass profile of an SPS. A good peer-reviewed discussion of the principles of L-FS dialysis is given by Kohn et al.²³ Home HD prescriptions using L-FS are discussed in the “Prescriptions for Home Hemodialysis” module. There are 2 current options for the NxStage L-FS:

1. Using dialysis fluid that is bagged in a clear 5-L plastic bag (similar to that provided to patients for PD) and which provides a travel-suitable option
2. Using an on-line dialysis fluid generator (PureFlow™, NxStage Medical, Inc., Lawrence, MA) that provides 60-L batched dialysis fluid that is manufactured on-line by an additional on-line, ultrapure fluid generator. The PureFlow™ is not intended to be a travel-suitable dialysate source, but is intended for a permanent or semipermanent installation.

The NxStage L-FS system has several advantages. All blood and dialysis fluid, dialysate, and wet flow systems are disposable and attached to the external surfaces of the machine such that the machine has no internal wet contact areas, which makes the machine safe from corrosion and its electronic circuitry is protected. The machine weighs 32 kg (71 lb) and is therefore potentially portable. This weight lies within single technician and O&HS handling parameters, which makes servicing simpler and relatively inexpensive. Finally, it uses a preformed plastic cartridge that incorporates all lines, the dialyzer, and fluid pathway ports. The patient need only

insert the cartridge into the machine, after which all pathways are opened and engaged automatically.

The NxStage machine also has disadvantages. At 32 kg, the machine still demands significant organization and commitment from patients in terms of planning travel logistics. In addition, patients must travel with or ensure that adequate quantities of dialysate will be available throughout their trip. In addition, only 1 dialyzer option is available in the preformed cartridge, which limits individualization of prescription. Finally, the maximum volume of dialysate that can be used during a single treatment is 60 L. This may be inadequate for some patients with high generation of uremic toxins, without substantial increases in treatment frequency to essentially daily dialysis.

Other Systems

Among many, 4 other home HD systems are in advanced stages of development; however, they are not yet commercially available. These include the Fresenius Portable Artificial Kidney (PAK) (United States), the Baxter Vivia system (United States), the Quanta SC+ System (United Kingdom), and the Physidia home HD/HDF system (France).

- The Fresenius PAK is a sorbent-based system for reprocessing and regenerating dialysis fluid online and during dialysis
 - » Sorbent systems, once commercially competitive in the 1970s and 1980s as the REDY dialysis system, fell from popularity in the 1990s

- » Many newer dialysis systems in development seeking portability and/or wearability will depend on sorbent dialysis principles

- » More information on sorbent principles is given by Agar²⁴

- The Baxter Vivia machine is an SPS with integrated water treatment that allows multiple uses of its dialyzer and blood sets
- The Quanta SC+ is a small SPS machine that is RO-dependent, but designed to be portable
- The Physidia system will have the capacity to provide either HD or hemodiafiltration (HDF) treatment options, which is in line with the growing European preference for HDF
 - » As HDF is a process that combines diffusive and convective principles and necessitates the reinfusion of 20 to 30 L of water back into the patient, the water that is produced on-line must be ultrapure
 - » While the requirement for ultrapure water has placed potential practical and financial limitations on HDF in the home, HDF has been used successfully for home dialysis in the United Kingdom, Australia, New Zealand, and in Europe

The Concept of Portability

The NxStage system is a portable system and, indeed, many patients travel with it; however, traveling with any current dialysis system available is not easy, nor is it for the uncommitted. The machine remains heavy and cumbersome for travel, and requires 25 to 30 L of bagged dialysate per treatment. While bagged dialysis fluid can be delivered to most regions and sites, multisite delivery for during travel is difficult and costly. Newer dialysis systems based on recirculating sorbent regeneration of dialysis fluid (currently in development) will potentially reduce the total water requirements for dialysis fluid generation to ≥ 6 L of tap water, and may make genuinely portable HD machines a reality in the future.

In some places, “portable” HD is available in the form of fitted mobile vans for hire. In particular, for more than 30 years, New Zealand has offered vacation vans for subsidized public hire that are fitted with dialysis machines and RO systems, which are supported by various New Zealand dialysis services (see [this website](#)). However, because the machines that have been fitted and built into the vans may not be familiar to all patients—a patient trained on 1 system may be unable to manage a different, unfamiliar machine or RO system—care must be taken when arranging a van for hire to ensure that the equipment fitted in the van is suitable for the patient-vacationer. Patient-vacationers

will also need to ensure that a stable power supply will always be available at their selected destination. Effluent drainage is, by and large, tank-captured for later disposal at a suitable drainage site.

What Machine Features Are the Most Important for Successful Home Dialysis?

The choice of machine should be tailored to meet the individual requirements of the patient and his or her home circumstances, and the capacity of the home HD program to provide support and maintenance.

A key issue determining choice is that of space. Ideally, the home HD machine should take up as little space as possible (Figure 8). In general, large machines do not provide sufficient technological superiority to justify their use, but price will ultimately be a deciding factor. Most HD machines have NOT been designed for home installation. In many bedrooms, such as in Europe and Asia, bed-to-wall space is narrow and limits the installation of large-based systems. In this regard, the current best options are those machines with narrower width/depth footprints.

Purchasers should be aware of 2 methods of assessing size:

- Gross size = maximum breadth \times maximum length \times maximum height. Determining size requirements is probably the most important factor, because many patients place their machines in a cupboard or closet when not in use



Figure 8. Practical and accessible home HD room (photo courtesy of John Agar).

- Net size, or how many cubic centimeters the machine will fill. Smaller units will have an aesthetic advantage. Often, the problem for home dialysis machines is not the size requirements, but the necessity of having a broad base on the machine to prevent accidents

A second key issue determining machine choice is that of ergonomics. The features of the machine should be chosen such that the system is well suited to the intended dialysis site. Ultimately, the most significant challenge in home dialysis is one that must be directed toward the manufacturers, namely, to create a dialysis system that meets the needs of potential home HD patients. The ideal home HD machine should be:

- Compact enough to meet space requirements
- Reliable
- Quiet
- Accessible
- Easy to learn and use
- Simple for patients with limited dexterity to use
- Simple and quick to set up and take down
- Easy to clean
- Able to be hidden when not in use
- Affordable

Currently, no available machine fits all these criteria, so the choice of machine should be such that it meets as many as possible.

Environmental Considerations

Environmental issues are important to consider in any home HD program for several reasons:

- Utility costs are generally borne by the dialysis service in facility-based care, but are transferred to the patient in most home HD models
 - » While some countries offer variable water and power subsidies to patients, this is not applicable to all. As an example, the subsidies offered by the Australian government are available at the [Kidney Health Australia website](#).
 - » As a result, water and power usage can be a paramount financial consideration for many patients who wish to pursue home HD where subsidies either do not exist or fall short of the amount required to cover water and power costs
 - » Waste disposal—both at practical levels of volume and type and, potentially, from a cost perspective as well—may also present significant environmental and cost problems for the patient

- » Governments are placing an increasing emphasis on carbon generation and carbon footprints—a growing concern for health systems worldwide—and the carbon footprint of dialysis is particularly large. The carbon footprints of several dialysis systems in relation to the duration and frequency of prescriptions and associated wastes have been calculated by Connor et al.²⁵
- » Machine systems and prescriptions can generate a 4-fold increase in the carbon footprint, which becomes a potential area of concern for patients wishing to undergo home HD. Carbon issues are fast becoming government policy platforms that affect subsidies, and this in turn can impact directly on the program costs for patients

With these issues in mind, machines that are water and/or power efficient, and systems that minimize waste generation, can be important considerations for the home HD patient and his or her support network.

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