

Risks and wider benefits of haemodialysis

Haemodialysis is a life-sustaining treatment for patients with end-stage renal disease (ESRD) or acute kidney injury (AKI), where the kidneys can no longer perform their essential functions of filtering waste products and excess fluids from the blood. During haemodialysis, blood is diverted from the patient's body to a machine called a dialysis machine, where it passes through semi-permeable membranes. These membranes allow waste products and excess electrolytes to diffuse into a dialysis solution while retaining larger molecules like proteins and blood cells (Daugirdas et al., 2012). The purified blood is then returned to the patient's circulation. Typically, haemodialysis sessions occur three times per week, lasting about 3 to 5 hours each (Johansen et al., 2021).

Safety and Tolerability of haemodialysis

Haemodialysis necessitates frequent, lengthy sessions that can disrupt daily activities. It requires some form of surgical intervention to make vascular access easier and also limitations on fluid and certain nutrients may affect enjoyment of food. Fatigue and weakness are common post-dialysis and can hinder social and occupational functioning. Prevalence of depression is high among dialysis patients, affecting quality of life, as well as adherence and outcomes (Palmer et al., 2013). Overall, haemodialysis is poorly tolerated.

Common Side Effects

- **Hypotension:** Hypotension is the most frequent intradialytic complication, affecting up to 20-30% of sessions (Henrich, 1986). It can result in dizziness, nausea, vomiting, and loss of consciousness. This may be less common in people with normal kidney function.
- **Muscle Cramps:** Fluid and electrolyte shifts during dialysis may cause cramps. Muscle cramps occur in approximately 5-20% of patients (Hossli, 2005). This may be less common in people with normal kidney function.
- **Pruritus (Itching):** It is not clear what the cause of the itching is; it may involve uremic toxins, dry skin, and inflammation. Pruritus affects up to 50-90% of haemodialysis patients (Mathur et al., 2010). This may be less common in people with normal kidney function.
- **Vascular Access Infections:** Infections can occur in arteriovenous (AV) fistulas, grafts, or central venous catheters. Catheter-related bloodstream infections range from 0.5 to 5.5 episodes per 1,000 catheter-days (Lok & Mokrzycki, 2011).
- **Arrhythmias:** Cardiac arrhythmias occur in up to 25% of patients during dialysis (Mavrakanas & Charytan, 2016). They are caused by electrolyte shifts, particularly potassium and calcium levels. This may be less common in people with normal kidney function.

Rare Side Effects

- **Sudden Cardiac Death:** People with underlying cardiac disease, electrolyte imbalances or hypotension are at risk of sudden cardiac death. This accounts for approximately 25% of all deaths in dialysis patients (Mavrakanas & Charytan, 2016). This may be less common in people with normal kidney function.
- **Dialysis Disequilibrium Syndrome:** This results from the rapid removal of urea leading to cerebral oedema. It is characterised by neurological symptoms ranging from headache to seizures and coma (Murdeswar HN, 2023). This may be less common in people with normal kidney function.

- **Haemolysis:** Mechanical stress from dialysis equipment or contamination with disinfectants can lead to haemolysis; the breakdown of red blood cells (Tharmaraj & Kerr, 2017). This may present with back pain, chest pain or dark urine and can have serious sequelae (Murdeswar HN, 2023).
- **Anaphylactic Reactions:** These are rare, severe allergic reactions to dialysis membranes or sterilising agents (potentially also some of the medicines given alongside dialysis). This is a medical emergency.

In addition to this, people receiving haemodialysis are at risk of vitamin and mineral depletion and are likely to require regular blood testing and vitamin and mineral supplementation, particularly iron.

Capital and revenue requirements for establishing and running a haemodialysis service

Necessary Equipment

There are several items needed to deliver dialysis itself (NICE, 2018) and to ensure appropriate water quality for the delivery of dialysis (Coulliette & Arduino, 2013).

- **Haemodialysis Machines:** These are advanced devices that remove waste products and excess fluids from the blood. They are equipped with features like volumetric control, ultrafiltration, and safety alarms. They must be MHRA-approved and capable of performing haemodialysis efficiently and safely.
- **Water Treatment Systems:** These are essential for producing ultrapure water required for dialysis. They include reverse osmosis units, deionizers, and ultrafilters to remove contaminants and toxins.
- **Artificial Kidneys (Dialyzers):** These are disposable units containing semi-permeable membranes for blood purification. They are available in different sizes and membrane types to suit patient needs.
- **Other consumable equipment:** Sterile single-use tubing, fistula needles, personal protective equipment and waste disposal supplies.
- **Dialysate Concentrates:** Acid and bicarbonate solutions mixed with purified water to create dialysate. These allow customised electrolyte composition to match patient requirements.
- **Anticoagulants:** Typically, heparin, administered to prevent blood clotting during dialysis.
- **Saline Solutions:** Used for priming the extracorporeal circuit and managing hypotension.
- **Patient Monitoring Equipment:** Devices to monitor vital signs like blood pressure, heart rate, and oxygen saturation. Scales are also required for pre- and post-dialysis weight measurement to assess fluid removal.
- **Emergency Equipment:** Includes defibrillators, oxygen supplies, and resuscitation kits for immediate response to emergencies.
- **Water Testing Supplies:** Kits and devices to regularly test water quality for contaminants and bacteria.
- **Imaging equipment:** To facilitate vascular access

In addition to this equipment, vascular access would be required, either through a long term indwelling cannula or through the surgical creation of an arteriovenous fistula. Catheters require care and maintenance and both catheters and fistulae are prone to failure.

Required Personnel

- **Lead clinician:** Probably a consultant nephrologist with expertise in haemodialysis. Role includes oversight of medical procedures, assessing patient therapeutic and diagnostic needs, and compliance with medical standards.
- **Specialist nurses:** To perform vein punctures, operate dialysis machines, and monitor patients during the procedure. They need to be certified in the delivery of dialysis and trained in the use of specific dialysis equipment.
- **Dialysis Technicians:** To prepare machines and monitor equipment
- **Surgical staff:** To obtain vascular access
- **Maintenance and Cleaning Personnel:** To ensure cleanliness of the facility and proper functioning of equipment. This is critical for infection control and meeting health standards.

Maintenance and Regulatory Compliance

- **Regular Servicing of Equipment:** Haemodialysis machines and water purification units require routine checks and servicing by qualified technicians.
- **Calibration of Equipment:** Medical devices must be calibrated regularly to ensure accuracy (ISO, 2022).
- **Facility Cleaning Protocols:** Adherence to strict cleaning schedules for donor areas, equipment, and common spaces.
- **Infection Control:** Implementation of standard precautions to prevent cross-contamination
- **Licensing and Accreditation:** Obtain necessary licenses from health regulatory organisations.
- **Standard Operating Procedures (SOPs):** Develop and maintain SOPs for all processes, aligning with MHRA, FDA and European Medicines Agency (EMA) guidelines.
- **Staff Training and Certification:** Ongoing education to keep staff updated on best practices and regulatory changes.
- **Audits and Inspections:** Regular internal audits and readiness for external inspections.
- **Documentation:** Comprehensive record-keeping for patient care and adverse event tracking (Lundin et al., 2008).

Offering a haemodialysis service involves more than just cleansing blood; it requires a robust infrastructure of specialised equipment, skilled personnel, and stringent maintenance protocols.

Cost of a Haemodialysis Service for Human Use

Capital cost

The cost of a new haemodialysis machine in the UK ranges from approximately **£15,000 to £30,000** per unit, depending on the manufacturer, model, and features (Roberts et al., 2022). Advanced models with additional capabilities such as online hemodiafiltration or biofeedback systems may be at the higher end of the price range. It should be noted that, in order to maintain continuity of service, at least two machines would be required. Because the potential use here is for the removal of PFAS, rather than to replace renal function, it is difficult to predict how many treatments might be needed. It is unlikely that it would be anywhere near the number needed to offer renal replacement therapy in Jersey.

In addition, a Water Treatment System is essential to provide ultrapure water for dialysis. Costs range from **£10,000 to £20,000**, depending on capacity and technology (ISO, 2024). Installing such a system may require modifications to existing facilities to accommodate the machine, including water supply, drainage, and dedicated electrical circuits. Estimated cost: **£5,000 to £10,000**.

Additional Costs to Consider

- **Maintenance and Service Contracts:** Essential for the safe and effective operation of the machine and the water treatment system, there will be regular maintenance and calibration, carried out by facility staff. In addition to that there would be a requirement for a service contract with the manufacturers. These can be of the order of **£10,000-£20,000** per annum (assuming two dialysis machines and one water treatment system).
- **Consumables:** Artificial kidneys cost approximately **£10 to £20**. Assuming ten treatments required, that equates to **£100 to £200** per patient per year, or **£5,000 - £10,000** overall. Tubing sets cost **£5 to £10**, so calculating on a similar basis, the total cost would be **£2,500 - £5,000** overall. Dialysate solutions cost approximately **£3** per treatment, or **£1,500** overall. Vascular access costs, if using a tunnelled cannula, would be approximately **£800** per cannula, cannulae last up to six months, so the cost is **£1,600** per patient per year. Cannula care, blood testing and vitamin/electrolyte replacement can be reasonably estimated to cost around **£5,000** per patient per year. Taking all those together, consumable costs would potentially be up to **£23,100** per annum.
- **Training and Staffing:** In addition, the salary costs of the staff described above, staff must be trained to operate the machine safely. Some manufacturers offer training programs, which may be included or charged separately. Assuming the consultant nephrologist is half time, the surgical staff are 0.1 WTE and all other staff are full time, staff costs (excluding on costs) are likely to be between **£200,000 and £250,000** per annum.
- **Regulatory Compliance:** Compliance with the Medicines and Healthcare products Regulatory Agency (MHRA) regulations may involve fees and/or modifications to the facility.

In summary

Bring all this together, a haemodialysis service would have set up costs, assuming two machines, and the necessary water treatment infrastructure and installation, of the order of

£100, 000. Running the service for one year, assuming 50 patients receiving 10 sessions each, would cost around **£1,380,000 per annum.**

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