Dialysis water quality for renal nurses

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Abstract

This paper aims to overview information related to quality of dialysis fluid, water quality and standards of patient care. This article may assist in learning more about the importance of appropriate water treatment, water testing and the implications to the patient of water and dialysate quality.

Key Words
Water, quality, haemodialysis, testing, nurse

Aim

To identify the technical aspects water treatment system used for dialysis and the importance of following appropriate water quality standards.

Learning Outcomes:

- To understand the importance of water testing to determine water quality.
- Compare the components of the water system at your renal unit.
- Understand the clinical effects of exposure to contaminants when inadequately treated water is used to create dialysate.
- Describe the monitoring of the water treatment system and dialysate.

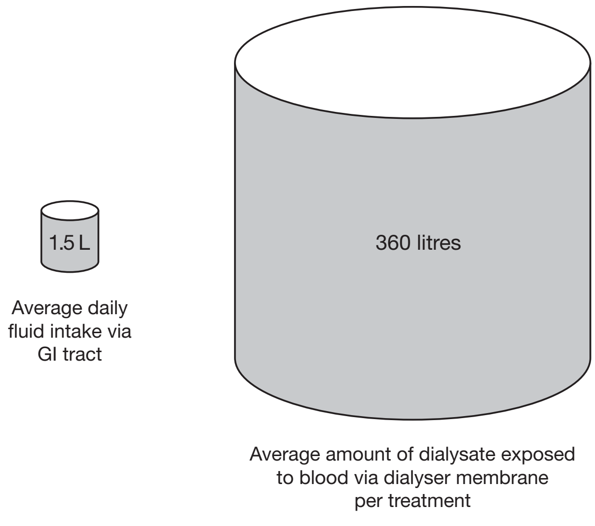
Introduction

The average dialysis patient is exposed to more water in one year than the average person drinks in a lifetime (Figure 1) and although the provision of water supply free from pathogenic organisms is an important factor in the protection of public health it is multiplied for the person on dialysis. The recommendations of the World Health Organisation (WHO 1992) and European Commission (EC Council 1980) relating to potable water aim to provide water that is physically, bacteriologically and chemically safe to drink. To achieve these standards, the water supplied to our homes undergoes several stages of treatment. This treatment often involves the addition of chemicals to facilitate the removal of suspended compounds and other constituents. In addition to this, chemicals are added as disinfection agents to control bacteriological contaminants. Whilst these standards usually ensure a safe drinking water supply they need to be increased for dialysis as even low levels of bacteriological or chemical contaminants could represent a health risk. For this reason, and knowledge gained over time, further treatment of the water supply needs to be undertaken if used for dialysis purposes.

Risks and Hazards

The medical literature contains many reports of patient injury or death associated with inadequately treated or monitored water supplies used in dialysis. Adverse patient reactions caused by chemicals or their residuals that may contaminate water used for dialysis exhibit a wide range

Figure 1: Comparing fluid intake and dialysis fluid exposure



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of symptoms including headache, hypotension, haemolysis, or even death.

With aluminium sulphate being used to treat public supplies, reports of severe bone disease and fatal dialysis encephalopathy have been associated with high levels of aluminium in the water supply (Platts, 1977; Ganzi, 1984; Serrano-Arias, 1995; Ismail, 1996). In 1993, 25 patients in southern Portugal died from severe encephalopathy linked to aluminium intoxication (Stragier 1999).

Chlorine and chloramines are used as bactericidal agents in public supplies and by the 1970's chlorine along with aluminium, fluoride and copper were noted to be toxic to haemodialysis patients. Low levels of these contaminants can cause dementia, osteomalacia, nausea and vomiting, so the water used to create dialysate needs to contain low levels of these contaminants (Alfrey, LeGendre and Kaehny 1976; Ward 2007). Contaminant exposure to blood can cause denaturing of haemoglobin. In 1988, the FDA reported 44 cases of haemolysis due to inadequate chloramine removal in Philadelphia. (FDA, 1988). In Madrid due to a failure in the water treatment system 66 patients were affected by severe haemolysis, 15 of whom needed blood transfusions, the remaining needed extra erythropoietin (Lorenzo et al 1996). Also in 1996 60 haemodialysis patients in Brazil died due to the presence of cyanobacteria (blue-green algae) in water treatment supplies (Pouria et al 1998). Adverse effects related to chemical contaminants also result from nitrates, copper, calcium and potassium, fluoride and sodium azide. (Arduino et al 1989)

Dialysis Water System

Water for haemodialysis requires additional treatment to remove contaminants that may be present in drinking water (Hoenich and Levin 2003). The typical water treatment system for dialysis will depend upon the quality of the incoming supply. Different contaminants require different treatment processes for their removal. The desired end quality will have a bearing upon the design of the system, with higher quality necessitating further treatment processes.

To choose the water treatment system most appropriate for the needs of the unit is important. A series of logical steps are required that identifies the uses to which the purified water will be put. The purpose is to reach a configuration for the final system. Knowledge of this is not intended to make renal nurses a design engineer; however, it should help to develop a perception for a system, including the purification processes to be used and their sequence in the system. All dialysis water standards assume that the feed water adheres to a drinking level standard. In Australia some communities do not have this level of quality water.

Defining Water Quality

Various bodies and associations, such as CARI, KDOQI, AAMI and EDTNA/ERCA have produced standards and guidelines for haemodialysis systems which include water used to prepare dialysate. The Association for the Advancement of Medical Instrumentation (AAMI) standards have represented a worldwide reference since 1980, which have been recently updated (AAMI, 2001; 2004). In Europe most standards are defined by the European Pharmacopoeia (2002) or suggested by national guidelines. The maximum contaminant levels allowed are stated and it has recognized that some applications impose additional water purity criteria. These additional criteria mainly relate to microbiological contamination and are necessary because of developments in therapy that have taken place over the years.

Compliance with the general standard is adequate for water used in the preparation of dialysate with conventional low permeability membranes. This is sufficient because the membrane acts as a final filter for microbiological contaminants, due to limited permeability to large solutes and particles. The use of highly permeable membranes and ultrafiltration control systems may result in transfer of dissociated endotoxins and endotoxin fragments from dialysate to blood (Hoenich and Levin 2003). As a consequence water used to prepare dialysate for high-flux haemodialysis, needs to have a level of microbiological contamination less than suggested for low flux.

Evaluation of feed water quality

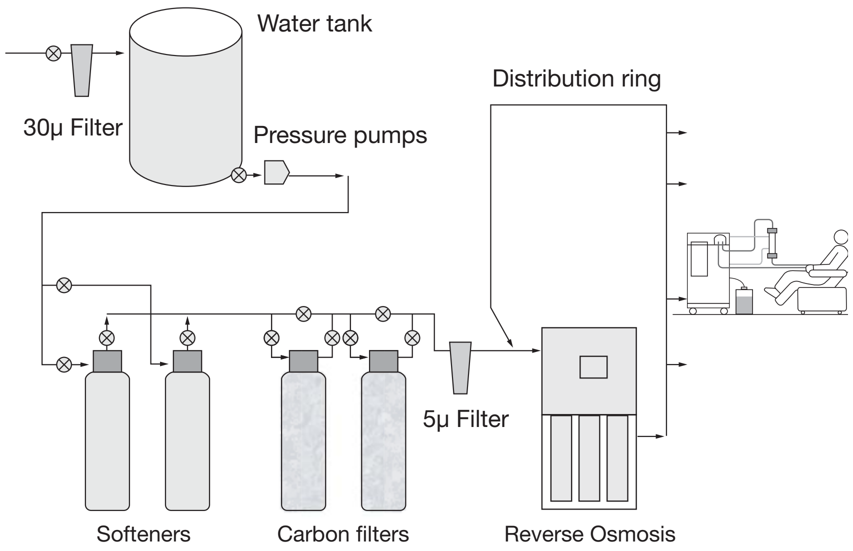
The public water supplier should be contacted to establish the characteristics and seasonal variations of water leaving the water treatment plant. The supply can vary widely by both region and nature of the water source. It is therefore important for the haemodialysis unit to know the source and quality of the supply and potential problems related to seasonal variations and water treatment practices.

Ground water (underground streams or caverns) is usually less contaminated with organic substances, but may be high in ionic contaminants. Surface water (dams or rivers on the earth's surface) can be contaminated with organic compounds, naturally occurring substances as well as man made pollutants. Ground water is generally less subject to seasonal variations than surface water. However, suppliers may alternate between surface and ground water sources.

Public water suppliers generally use free chlorine or chloramines to suppress bacterial growth. Sometimes potassium permanganate is used to control algae or yeast contamination. Free chlorine or chloramines in the water supply to the haemodialysis facility must be removed because of their haemolytic effects and susceptibility of certain types of reverse osmosis (RO) membranes to

Activity 1: Find out whether ground water or surface water is the major source. What antibacterial agent is used at the water treatment plant? What methods are used to clarify water? What contaminant concentrations can be expected?

Figure 2: Basic Direct Feed water treatment system



damage by free chlorine (AAMI, 2004). Chloramine is derived from chlorine by adding ammonia to make it last longer, so bacteria is controlled in long runs of feed distribution pipes. The disadvantage of this in dialysis is that it is more potent at our dialysis sites.

A number of clarification techniques are used, some of which are detrimental to haemodialysis water quality. If the supplier uses ferric chloride flocculation, iron oxide may precipitate and pose a problem as a foulant. If the water treatment plant uses alum, the aluminium concentration of the water supply may be high enough to require extensive treatment to bring it to safe levels. Peak concentration data should be requested from the water supplier for contaminants listed in the standards. In addition data on the alkalinity/acidity of the water supply and the total organic carbon should be requested.

The dialysis treatment system

Purified water for dialysis must meet the requirements for ionic and organic chemical purity and must be protected from microbial proliferation. It is usually prepared using drinking or potable water as feed water and is purified using operations that may include ion-exchange, RO, filtration, or other suitable procedures. A feed water tank is quite often used to provide a buffer from the supply and allow pressure booster pumps to be used to give a constant supply.

Filtration

Particle filtration is used primarily to protect downstream equipment including RO membranes from becoming clogged with dirt. Filtration is generally achieved by using what is basically an ultra-fine sieve capable of removing fluid borne particles which are larger than the pore size of the filter membrane. There are two general types of cartridge filter which are routinely used: 'depth filters' and 'membrane filters'. With depth filters the water flows through the thick wall of the filter, where the particles are trapped throughout the media. The most important factor in determining effectiveness of depth filters is the porosity throughout the media. Filters with a graded density, i.e. lower on the outside and increasingly higher toward the inside, have a higher dirt holding capacity than single density filters. The effect is to trap larger particles toward the outside and finer particles toward the inside. This type of filter is usually employed as coarse filters (typical rating 5 - 30 micron) in the incoming water stream to remove larger particulate matter.

Absolute or membrane particle filters typically use a flat sheet media, membrane or specially treated non-woven material to trap the particles. The media is usually pleated to provide a larger surface area. These filters are usually positioned after all the pretreatment components and immediately before the RO pump and membranes.

Activated carbon

The main purpose of using activated carbon is to remove chlorine and chloramines from the water. The term 'activated' refers to the process by which the carbon is processed in order to enlarge its pore structure. Activated carbon removes chlorine and chloramines by attracting and holding the chlorine onto the carbon granules. The ability of activated carbon to remove contaminants is determined not by its weight or volume, but its adsorption capacity. Adsorption is a process where a solid is used for removing a soluble substance from the water, where the substance is attached to a surface. The adsorptive capacity is calculated in contact time of the water to the carbon, therefore the more water required and the bigger the carbon tank. Granular activated carbon (GAC) is commonly used in dialysis water treatment systems. Carbon is often rated in terms of iodine numbers for absorbency, the higher the number, the more chlorine and chloramines will be adsorbed. An iodine number of 900-1000 is recommended for dialysis purposes. (AAMI, 2001).

Ion exchange softening

Ion exchange can be defined as the reversible interchange of ions between a solution and an ion exchanging material. In water treatment, the principle of ion exchange is used to remove unwanted ionic impurities, and the main use to which ion exchange is put is in the softening of water. This is achieved by passing hard water containing calcium and magnesium ions through a vessel containing an exchange resin of the sodium form. The calcium and magnesium ions are exchanged for sodium ions, and it is the sodium ions which give the water its 'softness'.

The resin is ion specific so only calcium and magnesium ions are removed and


NOT
EVERYB


Roche
ODY HURTS[1*]
CAMPAIGN
AGAINST
PAIN
NeoRecormon®
Epoetin Beta
SC NeoRecormon: fortnightly
Hb control,[2] with significantly
less injection site pain than
darbepoetin alfa[3–8]

replaced by sodium. Once all of the sodium ions have been exchanged, the softening process ceases. The resin then needs to be regenerated by flushing with a strong brine solution containing large amounts of sodium chloride, enabling the reverse exchange to occur. The calcium and magnesium are disposed of by flushing to drain.

The point of exhaustion of sodium ions will depend upon the levels of calcium and magnesium in the feedwater. The hardness of the feedwater is usually ascertained by testing and is often quoted in degrees of hardness or parts per million CaCO3. Most dialysis facilities use a permanent softener that incorporates a brine tank and control head that automatically executes the regeneration cycle.

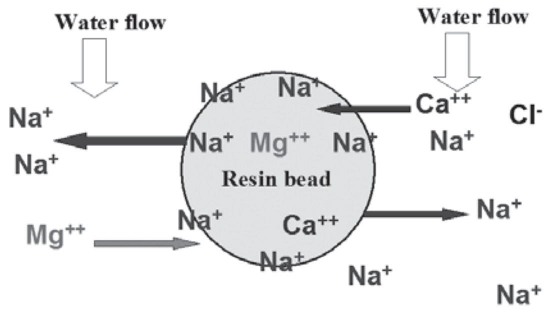


Figure 3: Ion Exchange Softening.

Reverse osmosis

RO filter systems involve the transport of water through a membrane which acts as barrier to the constituents to be removed from solution. Originally developed for removal of inorganic salts, they also have the capacity to remove some organic material. Typically, only organic compounds above a certain weight are removed by a given membrane composition, and this is achieved by a straining type of process.

RO will generally remove any molecular compounds smaller in size than water molecules. Such compounds include salt, manganese, iron, fluoride, lead, and calcium (Binnie et al, 2002). Feed water under pressure is pumped into a module containing a semi-permeable membrane. Provided the applied pressure exceeds the natural osmotic pressure of the impure water, a proportion of the feed will pass through the membrane, which rejects most of the contaminants, to form the "permeate." The contaminants accumulate in the residual "concentrate" stream which is discharged to drain.

Thin-film composite RO membranes can remove up to 99.5% of the inorganic ions from the feed water, together with virtually all the colloids, micro-organisms, pyrogens, and other organic macromolecules. Thus, water purified by RO will be essentially free from endotoxins and from inorganic toxins, such as aluminium, irrespective of their chemical form (Cross, 1997).RO membrane performance is measured by percent rejection. Final product water quality is measured by either conductivity in micro Siemens/cm (µS/cm) or total dissolved solids (TDS) displayed as mg/L or parts per million (PPM).

For many home installations, the only equipment needed for quality water is a carbon filter and RO. This is especially true in relatively clean water areas. All the other equipment is there to reduce maintenance. A softener will reduce the number of times you need to chemically clean the RO membranes. Pre treatment filtration will improve the life of the softener, carbon, and RO membranes, although not required to meet AAMI water quality. A break tank or backflow prevention device at the start of the dialysis water treatment system is required to meet most local plumbing codes.

Distribution pipe work

The final element is the distribution pipework, the design of which minimises dead space and uses non-toxic materials. The distribution pipework is usually constructed in a loop, allowing surplus water to be returned to the input side of the RO and the dialysis machine connection points are also designed to have minimum dead space. As water treatment systems are susceptible to microbial contaminations, periodical disinfection is mandatory to obtain levels expected by international water quality standards (Cappelli et al 2006).

Developments in materials and design of the distribution system enable options for different disinfection methods. The materials are less susceptible to bacterial colonisation. The level of microbiological contamination can increase due to biofilm being present in the water system. These bacterial fragments can cross the dialysis membrane and simulate an inflammatory patient response, which has been implicated in mortality and morbidity of haemodialysis patients (Hoenich and Levin 2003).

As quality issues are addressed, future systems will need to meet more exacting standards, including the full integration of disinfection procedures with those of

Activity 2: Look at the water treatment system in your unit. Does it have the same components outlined above? Also, consider how a home HD set-up may differ from that of a dialysis centre.

the dialysis machines and also further improvements in microbiological and chemical aspects. This is particularly so with the development of systems which use the water to produce infusate, such as 'on-line' haemodiafiltration.

Evaluation and monitoring of hemodialysis water quality

There are numerous guidelines that can be followed, and most guidelines concur on the majority of issues. Routine testing should form part of unit policy and the frequency of testing should not be less than monthly, and be sufficiently frequent to detect trends. Guidelines suggest samples for microbiological and endotoxin analysis should be taken from the water treatment outlet plant and points expected to have the highest bacterial load, normally where the flow is at its lowest. (EDTNA/ERCA, 2002) Samples should be taken from the machine connection points as these can harbour bacteria that are not detected at other sample points, potentially leading to a false impression of quality (James, 2006). Current guidelines suggest that samples for microbiological analysis should be cultured using a low nutrient media but vary in recommending temperature and time. A commonly accepted method of culturing samples is at 22°C for 7 days (ERA-ERCA, EDTNA-ERCA), and this provides for a greater recovery rate than at other temperatures and times (James, 2007). Endotoxin analysis is usually carried out using the Limulus Amoebocyte Lysate (LAL) assay.

Routine monitoring of the feed water and permeate is the best way to ensure that a water system operates under optimal conditions. Variables such as hardness levels, chlorine, conductivity, flow rates and operating pressures should be monitored. Testing frequency depends on the items being tested. More intense testing is recommended in the initiation phases or after any break in the closed circuit for repair or maintenance (CARI, 2005).

The user is responsible for developing a monitoring plan, including testing frequency, that would keep the microbial and endotoxin levels within the standard. Operational data should be recorded frequently; this data can be used to spot trends in operating conditions and alert to impending maintenance issues such as membrane replacement or cleaning.

If a softener is used a hardness test is recommended. This is to ensure that the softener is regenerated before it is exhausted, therefore protecting downstream equipment. Is an RO is used then the patient is still protected if the softener is exhausted. A hardness test using an ethylenediaminetetracetic acid (EDTA) titration test, or dip and read test strips on the effluent softened water should be done at least once at the end of the day and recorded (AAMI, 2004). Testing at the end of the day proves the softener performed adequately all day in removing hardness. The salt level in the brine tank should be inspected daily and be at least half-full with salt (AAMI, 2004).

An AAMI chemical analysis should be performed at least once a year to validate the removal of contaminants by the water treatment system. The AAMI recommendation for bacteria is less than 200 CFU/ml for all water used in dialysis, including the water in the distribution system, with an action level of 50 CFU/ml. If 50 CFU/ml is reported, then an action should be taken such as disinfecting the RO and/or loop and re-sampling. For endotoxins, the AAMI recommendation is less than 2.0 IU/ml with an action level of 1.0 IU/ml. The European recommendations are more stringent. The European Pharmacopoeia suggests a limit of 100 CFU/ml for bacteria, with an action level of 25 CFU/ml. For endotoxins, the limit is 0.25 IU/ml, with an action level of 0.125 IU/ml.

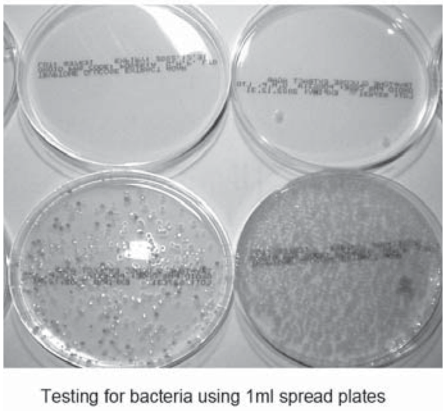


Figure 4: Cell culture plates.

Dialysis professionals should understand that the above-mentioned bacteria testing measures may underestimate the bacterial burden in the water system due to the nature of biofilm (AAMI, 2001). The required testing methods may not show all organisms growing in the system because testing measures for planktonic (free-floating) bacteria and not sessile (attached) bacteria. Therefore, it is highly recommended to disinfect on a routine basis and not just when unacceptable microbial samples dictate. Where systems have a large amount of downtime (system off) or poor flow through the system, biofilm can be present even with samples indicating no growth.

Dialysate

Dialysate is a continuously produced blend of treated tap water and a concentrated electrolyte solution. This water originates as drinking water but via several processes becomes usable for haemodialysis (Hoenich, Ronco and Levin, 2006). Dialysate is a solution intended to exchange solutes and/or water with blood during haemodialysis or haemodiafiltration (definition from IEC 60601-2-16 2.107). Dialysate is generally made up of three components

Activity 3: **Find out what the microbiological limits are in your unit? Do they follow unit guidelines, National & International guidelines?**

– water, 'A' concentrate and 'B' concentrate. The 'A' concentrate contains some acid in the form of acetate, which is why it is sometimes referred to as the 'acid bath' or concentrate. "B" is the bicarbonate concentration and it is the dilution of the 'A' and 'B' concentrates in water that gives the conductivity of the dialysis fluid. More than 95% of the dialysate is water, so the more pure the water, the more accurate the dialysate prescription.

Ultrapure dialysis fluid

With the increasing use of high flux dialysers, there is also the increased risk of backfiltration and so the water used in therapy needs to have stricter levels of acceptable microbes as contamination can lead to septicaemia, headache or malnutrition in the longer term. This is imperative with online haemodiafiltration as the dialysate is infused directly into the patient's blood stream (Brunet and Berland 2000).

The desire to improve treatment outcomes has led to stringent standards for microbiologic purity of the dialysis fluid (Hoenich and Levin 2003). Ultrapure dialysis fluid is highly purified dialysis fluid that can be used in place of conventional dialysis fluid. The definition of ultrapure fluid varies, but the +recommendation used in the ERA/EDTA Guidelines is <0.1 cfu/ml and <0.03 IU/ml. These standards are usually achieved by point of use filtration of the water and dialysis fluid at the dialysis machine. Most current systems pass the water and final dialysis fluid through at least two ultrafilters. Ultrapure dialysis fluid may be further purified to produce on-line substitution fluid for haemodiafiltration.

Conclusion

Water quality for dialysis is a fundamental quality process that requires attention by both technical and nursing staff. If quality processes are inadequate people receiving dialysis may suffer serious poor health outcomes.

Activity 4: Ask your renal technician to guide you through the water treatment process and testing. Take some water samples from both the RO machine and the dialysis port.

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