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Improving Dialysis Patient Outcomes Introducing ultrapure water to facilitate HiVOLHDF: An engineer’s perspective

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Improving Dialysis Patient Outcomes
Introducing ultrapure water to facilitate HiVOLHDF:
An engineer’s perspective

Declan P Murray

A Dissertation submitted in part fulfilment of the degree of MSc Leadership Institute of Leadership, Royal College of Surgeons in Ireland

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Abstract

Water quality is fundamental to haemodialysis regardless of the modality; this has two distinct strands namely chemical quality and microbiological quality. However, the water quality is far more critical with the high volume online haemodiafiltration (HiVOLHDF)* modality of treatment. A typical adult will be exposed to approximately fourteen litres of water a week. This is ingested orally, absorbed via the gastrointestinal tract, any excess is removed by the nephron in the kidney and exits the body with other waste products of metabolism in the urine. By contrast, the standard thrice weekly haemodialysis patient is exposed to 576 litres per week via the semipermeable dialyser. In addition, the high volume online HDF patient is exposed typically to an additional 60 L per week which is infused directly into the patient’s blood stream. Furthermore, as the majority of End Stage Renal Disease (ESRD) patients have zero, or very minimal residual renal function, toxins in the blood remain and cannot be ‘renally’ excreted between dialysis sessions.

From the literature review, it has been unequivocally demonstrated that water quality is an essential component to the dialysis process. However, as of 2016 there is not a scientific consensus with regard to whether HiVOLHDF is a superior treatment of ESRD patients with regard to mortality and morbidity. Whilst this may be the current case, it is the author’s belief that this will be forthcoming in due course. In the interim, it should be considered best practice to strive towards implementation of ultrapure water systems in all dialysis units and performing HiVOLHDF, while we await the evidence. This viewpoint is compounded by the fact that there have been no negative reports from the studies reviewed relating to patient outcomes when treatment by HiVOLHDF versus alternative conventional haemodialysis treatments.
In addition, it would definitely seem prudent that when designing new dialysis facilities, ultrapure water should be considered the standard specification.

This organisational development involved the transfer of an existing haemodialysis unit to a new state-of-the-art redeveloped facility within the organisation. This facility would offer ultrapure water to facilitate HiVOLHDF as standard. There were numerous change strands to this project and the author incorporated the HSE change model and the CIPP evaluation framework to evaluate and guide the process.

*The acronym HiVOLHDF has been developed by the author for the purpose of this project.*
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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHU</td>
<td>Air handling unit</td>
</tr>
<tr>
<td>AJKD</td>
<td>American journal of kidney disease</td>
</tr>
<tr>
<td>AKD</td>
<td>Acute kidney disease</td>
</tr>
<tr>
<td>B2M</td>
<td>Beta 2 microglobulin</td>
</tr>
<tr>
<td>BMJ</td>
<td>British medical journal</td>
</tr>
<tr>
<td>CAPD</td>
<td>Continuous ambulatory peritoneal dialysis</td>
</tr>
<tr>
<td>CCDS</td>
<td>Centralised concentrate delivery system</td>
</tr>
<tr>
<td>CIPP</td>
<td>Context input process product</td>
</tr>
<tr>
<td>CKD</td>
<td>Chronic kidney disease</td>
</tr>
<tr>
<td>CONTRAST</td>
<td>Convective transport study</td>
</tr>
<tr>
<td>DMP</td>
<td>Dialysis media panel</td>
</tr>
<tr>
<td>DOPPS</td>
<td>Dialysis outcomes and practice patterns</td>
</tr>
<tr>
<td>EBCT</td>
<td>Empty bed contact time</td>
</tr>
<tr>
<td>EBPG</td>
<td>European best practice guidelines</td>
</tr>
<tr>
<td>EI</td>
<td>Emotional intelligence</td>
</tr>
<tr>
<td>EJMR</td>
<td>European journal of medical research</td>
</tr>
<tr>
<td>EP</td>
<td>European pharmacopeia</td>
</tr>
<tr>
<td>ERBP</td>
<td>European renal best practice</td>
</tr>
<tr>
<td>ESRD</td>
<td>End stage renal disease</td>
</tr>
<tr>
<td>EU</td>
<td>Endotoxin unit</td>
</tr>
<tr>
<td>FMC</td>
<td>Fresenius medical care</td>
</tr>
<tr>
<td>HD</td>
<td>Haemodialysis</td>
</tr>
<tr>
<td>HEPA</td>
<td>High-efficiency particulate arrestance</td>
</tr>
<tr>
<td>HF</td>
<td>Haemofiltration</td>
</tr>
<tr>
<td>HHD</td>
<td>Home haemodialysis</td>
</tr>
<tr>
<td>HIQA</td>
<td>Health information and quality authority</td>
</tr>
<tr>
<td>HIVOLHDF</td>
<td>High volume haemodiafiltration</td>
</tr>
<tr>
<td>HPW</td>
<td>High purity water</td>
</tr>
<tr>
<td>HSE</td>
<td>Health services executive</td>
</tr>
<tr>
<td>IEHG</td>
<td>Ireland east hospitals group</td>
</tr>
<tr>
<td>ISN</td>
<td>International society of nephrology</td>
</tr>
<tr>
<td>ISQSH</td>
<td>Irish Society for Quality and Safety in Healthcare</td>
</tr>
<tr>
<td>JASN</td>
<td>Journal of the American society of nephrology</td>
</tr>
<tr>
<td>JCI</td>
<td>Joint commission international</td>
</tr>
<tr>
<td>KPI</td>
<td>Key performance indicator</td>
</tr>
<tr>
<td>LAL</td>
<td>Limulus amebocyte lysate</td>
</tr>
<tr>
<td>MPO</td>
<td>Membrane permeability outcomes</td>
</tr>
<tr>
<td>NDT</td>
<td>Nephrology dialysis and transplantation</td>
</tr>
<tr>
<td>NEJM</td>
<td>New England journal of medicine</td>
</tr>
<tr>
<td>OD</td>
<td>Organisational development</td>
</tr>
<tr>
<td>OLHDF</td>
<td>Online haemodiafiltration</td>
</tr>
<tr>
<td>PESTE</td>
<td>Political economic social technical environmental</td>
</tr>
<tr>
<td>PW</td>
<td>Purified water</td>
</tr>
<tr>
<td>R2A</td>
<td>Reasoner’s 2A agar</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
</tr>
<tr>
<td>RO</td>
<td>Reverse osmosis</td>
</tr>
<tr>
<td>RRT</td>
<td>Renal replacement therapy</td>
</tr>
<tr>
<td>SWOT</td>
<td>Strengths weaknesses opportunities threats</td>
</tr>
<tr>
<td>TSD</td>
<td>Technical services department</td>
</tr>
<tr>
<td>TVC</td>
<td>Total viable count</td>
</tr>
<tr>
<td>USP</td>
<td>United states pharmacopeia</td>
</tr>
<tr>
<td>WFI</td>
<td>Water for injection</td>
</tr>
</tbody>
</table>
1. Introduction

Kidney failure or disease is predominately defined as a reduction in the glomerular filtration rate within the nephron which leads to inefficient waste product removal (e.g. creatinine, urea) and a reduction or cessation of urine production. This is categorised as being either acute or chronic kidney disease (AKD) or (CKD). There are numerous causes of kidney failure the most common being; diabetes, hypertension, glomerulonephritis and polycystic kidney disease. As seen in figure 1, the two predominant causes of CKD from the United States are diabetes and hypertension.

| Table 7. Prevalence of Persons at Increased Risk for Chronic Kidney Disease* |
|------------------|------------------|------------------|
| Risk Factor       | Estimated         | Prevalence       |
| Diabetes mellitus (23) | Diagnosed: 5.1% of adults age ≥20 y | Estimated, n 10.2 million |
|                   | Undiagnosed: 2.7% of adults age ≥20 y | 5.4 million |
| Hypertension (24)  | 34.0% of adults age ≥18 y | 4.1 million |
| Systemic lupus erythematosus (25) | Approximately 0.05% definite or suspected | Approximately 239 000 |
| Functioning kidney graft (1) | Approximately 0.01% | 88 311 (as of 31 December 1996) |
| African-American (26) | 12.3% | 25.9 million |
| Hispanic or Latino (of any race) (26) | 12.1% | 25.8 million |
| American-Indian and Alaska Native (26) | 0.5% | 2.5 million |
| Age 60–70 y (27) | 7.3% | 20.3 million |
| Age ≥70 y (27) | 9.2% | 25.5 million |
| Acute kidney failure (28, 29) | Approximately 0.14% | Approximately 353 000 nonconfidential hospital stays in 1997 |

*NSAID = nonsteroidal anti-inflammatory drug.

There is no cure for CKD but numerous treatment options exist, from an array of dialysis modalities to transplantation. Writing in the Lancet, Levey and Coresh warn of the significant worldwide health threat stemming from the increased prevalence of CKD and the ever increasing costs associated with both dialysis and transplantation. This coupled with the emerging obesity epidemic and the ageing population provides
significant healthcare challenges to both the developing and developed worlds. (Levey & Coresh, 2012).

In the 2010 Global Burden of Disease report, CKD was ranked 18th as the cause of death compared with 27th in 1990. This rate of increase was second only to HIV and AIDS. In England, the NHS Kidney Care reports that the costs associated with the treatment of CKD exceeds the combined total spent on breast, lung, colon and skin cancer treatments. While in the US, the total annual cost of treatment of CKD patients is circa $48 (US) billion and accounts for 6.7% of the total Medicare budget treating less than 1% of the covered population. In Australia, the predicted cost to treat current and future CKD patients through to 2020 is $12 (AUS) billion. (Jha et al., 2013). In Ireland while 0.03 per cent of the population require dialysis, 2-3 per cent of the overall healthcare budget is consumed by it. (Culliton, 2009).

There are a variety of renal replacement therapies (RRT) available for the treatment of patients with acute or chronic end-stage renal disease (ESRD). These include, but are not limited to, continuous ambulatory peritoneal dialysis (CAPD), low and high flux haemodialysis (HD), home haemodialysis (HHD) nocturnal dialysis, haemofiltration (HF), online haemodiafiltration (OLHDF) and increasingly, high volume OLHDF (HiVOLHDF). For the purpose of this document and project the author has developed the acronym HiVOLHDF.
The focal point of this organisational development is the relocation of inpatient acute haemodialysis services, at a large acute teaching hospital, to a refurbished ultra-modern facility. This new unit will be equipped with state-of-the-art technologies from the water purification plant to the haemodialysis machines and this will facilitate (HiVOLHDF), which may be the best dialysis treatment to date, in terms of mortality and morbidity. As discovered in this document, fundamental to all dialysis treatments is water quality, and with the evolution of therapies from low-flux to HiVOLHDF, stringent purity requirements have become crucial. Additionally, this will enable the treatment of our acute haemodialysis population in a fit-for-purpose environment with increased capacity.

1.1 Rationale

1.1.1 Current Facilities and proposed relocation

There are two units in this organisation providing dialysis treatments. Acute renal inpatients (and some chronic haemodialysis patients) are treated in the 8-bedded acute unit in St. Peter's ward on the 4th Floor. This unit was commissioned in March 1999. The configuration of the ward (4, 2, 2) does not allow for patient isolation requirements. In addition, the unit is now in its sixteenth year and is no longer fit for purpose. The treatment modality performed in this unit was low flux HD owing to limitations of the ageing water purification equipment; this will be addressed in more detail in chapter four. Regarding the latest standards for space between dialysis stations, infection control, fire and safety and patient dignity requirements, updating is required. This acute unit will be re-located to another section of St Peters Ward.
The CAPD and the Pre-Dialysis Programme, currently in St Peter’s ward will be therefore relocated to St Monica’s Ward to facilitate this move.

A new central delivery and water supply system needs to be installed in the acute in-patient haemodialysis unit. The proposed move to a new expanded location on St. Peter’s Ward (with a 4,4,1 configuration) would also offer an area that meets European standards relating to treatment of isolated patients. It would solve space and infection control issues, and improve overall patient care, while fulfilling the Health Information and Quality Authority (HIQA) and Joint Commission International (JCI) recommendations. The new location will provide improved conditions for all and eliminate the overcrowding of corridors with dialysis and related equipment as identified by fire safety officers and JCI.

The second unit is a 9-station chronic haemodialysis unit and is based on the ground floor of the clinical services building and will remain there. This unit operates with ultrapure water and performs HiVOLHDF.

### 1.1.2 Reverse Osmosis (RO) and Pre-treatment

The existing Reverse Osmosis (RO) and Pre-treatment system requires significant on-going maintenance including the replacement of costly RO and Ultrasafe membranes. The proposed relocation of the acute dialysis unit will standardise the RO systems across the hospital and will provide a double-pass reverse-osmosis unit replacing the present single RO/Ultrasafe system.
As the acute dialysis unit provides a six day dialysis service (on call provided on Sundays) which requires constant surveillance and maintenance, the new pre-treatment plant work load will be reduced, as the 4th floor system will be a duty standby system. The new system will be more environmentally friendly and provide heat sanitisation instead of routinely using chemicals.

1.1.3 Central Delivery System

The existing acute dialysis unit does not have a central delivery system for concentrates. Under the proposed relocation, a new central delivery system mirroring the system in place on the chronic haemodialysis unit on the ground floor will be introduced. A centralised delivery system will reduce concentrate waste and storage requirements. In addition, it provides for better manual handling conditions as staff no longer need to carry six kilogram fluid containers.

1.2 Aim and Objectives

1.2.1 Aim

The aim of this organisational development is to relocate and expand the existing acute inpatient haemodialysis service to a new, refurbished and fit-for-purpose location, with a dedicated isolation facility and increased capacity. The new facility will provide ultrapure water to facilitate HiVOLHDF as the treatment modality of choice.
1.2.2 Objectives

This operational development (OD) will incorporate the following SMART objectives (Specific, Measurable, Attainable, Realistic, Timely).

1. By June 3rd 2015, complete and submit a business case to the National Renal Office and the Ireland East Hospitals Group (IEHG) for approval of funding.
2. By August 21st 2015, have the contractors’ schematics for the new unit agreed by all stakeholders.
3. From 5th October 2015, commence installation of water purification plant, centralised concentrate delivery system (CCDS) and associated ring mains.
4. By 7th December 2015, commence quality testing and commissioning of water purification plant and CCDS. This intensive sampling phase will be completed by January 4th 2016 and will incorporate the development of a Key Performance Indicator (KPI).
5. On 8th February 2016, transfer acute haemodialysis services to the new unit and cease services at the current unit.
6. By February 2016, establish a dedicated isolation unit and increase treatment capacity by 12.5%.
7. By February 2016, address fire officer and JCI non compliances.
8. By April 2016, perform and evaluate patient and staff satisfaction surveys to ascertain both cohorts’ experience of the new facilities.
1.3 Organisational context

The Department of Nephrology at this organisation currently has a 9-station chronic haemodialysis unit, an 8-station acute in-patient haemodialysis unit, a CAPD programme and a Pre-Dialysis programme. As well as offering services in nephrology and hypertension, the department is a major contributor to the organisation’s Emergency Services.

The department also provides a kidney transplant management service in conjunction with Beaumont Hospital (National Renal Transplant centre). There has been an increase of more than 50% in the number of patients receiving post-transplant multidisciplinary care (120 patients in August 2015). New links between this organisation and a large London transplant hospital have resulted in a paired-kidney exchange program in the UK. This has also caused transplant patient numbers to rise by offering alternative routes to kidney transplantation.

The numbers of end-stage renal patients managed by this organisation has expanded considerably in the last decade. This growth has largely been accommodated by the establishment of a satellite dialysis unit.
Haemodialysis Treatments:

<table>
<thead>
<tr>
<th>Year</th>
<th>OPD/Chronic HD Patients</th>
<th>Satellite Chronic Patients under Organisations Governance</th>
<th>Acute Patients</th>
<th>Total HD Patients Treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>79</td>
<td>40</td>
<td>72</td>
<td>12,321</td>
</tr>
<tr>
<td>2010</td>
<td>79</td>
<td>36</td>
<td>96</td>
<td>12,868</td>
</tr>
<tr>
<td>2011</td>
<td>80</td>
<td>39</td>
<td>84</td>
<td>13,173</td>
</tr>
<tr>
<td>2012</td>
<td>80</td>
<td>41</td>
<td>98</td>
<td>12,386</td>
</tr>
<tr>
<td>2013</td>
<td>82</td>
<td>43</td>
<td>162</td>
<td>13,087</td>
</tr>
<tr>
<td>2014</td>
<td>80</td>
<td>47</td>
<td>110</td>
<td>12,082</td>
</tr>
</tbody>
</table>

**Figure 2. Organisational haemodialysis statistics from 2015**

The dialysis treatment of choice for all is HiVOLHDF, a treatment that combines the benefits of conventional haemodialysis, haemofiltration and haemodiafiltration in one therapy and potentially mirrors the function of the natural Kidney. HiVOLHDF has proven beneficial clinical outcomes for long-term haemodialysis patients with a reduced incidence of cardiovascular and rheumatological complications. (Ward, Schmidt, Hullin, Hillebrand, & Samtleben, 2000). It is the intention of the Department of Nephrology to introduce this therapy as its treatment of choice on a phased basis. A significant emphasis on water quality is required as the HiVOLHDF process involves infusing large volumes of ultrapure water directly into the patient’s bloodstream. (J. E. Tattersall & Ward, 2013).

The nephrology department has an active research programme and participates in the Newman Scholarship Programme with the Conway Institute in University College Dublin.
1.4 Role of the student in the organisation and the project

The role of the change agent, the author, is to facilitate and lead-out with this service development. As the author is the head of the clinical engineering department and thereby responsible for the management of medical technologies and their safe deployment for the diagnosis and treatment of patients, this organisational development project provides the platform to exhibit and demonstrate the knowledge and skills gained from participating in the RCSI MSc in Leadership programme. It is sufficiently challenging so as to highlight how the clinical engineer can successfully enact and lead a significant technological organisational development.

The author will use the Health Services Executive (HSE) change model (2009) organisational change model for this development.

“It is, therefore, recommended that change initiatives and restructuring processes should involve careful assessment and evaluation of the health care environment so as to identify critical problem areas such that goals can be effectively set and communicated to all stakeholders and strategies can be designed and aligned to minimize, if not eradicate, these problem areas.” (Volonté, 2013).

In order to execute the implementation plan for all components of this project, the author will perform a literature review and use evaluation tools to evaluate its success. In addition, internal and external stakeholders will be consulted to gain approval for the business case and to successfully deliver on the stated aim and objectives within the proposed timeframes.
1.5 Summary and Conclusion

In summary, this project involves the relocation of existing in-patient acute haemodialysis services to a new fit for purpose dedicated facility. Ultimately, and most importantly, this will facilitate the optimum care environment for patients and ensure the treatment is of the highest quality. In addition, it will expand the service and enable a better facility for clinical staff to operate from. From a clinical engineering perspective, this project has numerous challenges which require a special set of skills, namely vision, leadership, negotiation, patience, technical capability, self and team trust in addition to project management skills.

In the following chapter, the author will detail the literature review relating to various aspects of the treatment modalities and water quality requirements. The subsequent chapters will outline and discuss the change methodology deployed, the evaluations performed and the techniques utilised and finally, complete with a discussion and conclusion.

2. Literature Review

2.1 Introduction

As mentioned in chapter 1 there are a variety of renal replacement therapies available for the treatment of patients with acute or chronic end-stage renal disease. This chapter will outline the search strategy employed, detail the scope of the literature review, introduce the HD, HF and OLHDF modalities, discuss the emerging themes, review in detail the history and the potential clinical benefits (if proven) of
HiVOLHDF and consider the implications for this service development project. Finally, the author will summarise this chapter and highlight any significant conclusions.

2.2 Search strategy

The search methodology consisted of the following search combinations and variations of the same: Haemodialysis vs Online HDF, Haemofiltration vs Haemodialysis, mortality, morbidity and solute removal, water quality haemodialysis and OLHDF. During the search process, ‘Haemo’ was alternated with ‘Hemo’ to reflect international spelling variations.

In total, forty three articles were selected and sourced using Google Scholar, Emerald, PubMed, Medline and Science Direct. The articles were published predominately in; the Journal of the American Society of Nephrology (JASN), Nephrology Dialysis and Transplantation (NDT), American Journal of Kidney Disease (AJKD), European Journal of Medical Research (EJMR), Kidney International, the Journal of the International Society of Nephrology (ISN), The Lancet, the British Medical Journal (BMJ), the New England Journal of Medicine (NEMJ), the Blood Purification Journal and the European Dialysis & Transplant Nurses Association/European Renal Care Association Journal (EDTNA/ERCA). After an initial analysis, ten articles were withdrawn as they had been superseded by later research and publications, leaving thirty three for this review. The date profile of the articles is from 2000 to the present day.
2.3 Scope of Literature Review

During this review, the author will research the differences between the selected modalities and discover any relative strengths and weaknesses in the treatment of patients with ESRD. In addition, the author will attempt to draw on all expert opinion to determine if there is consensus regarding the merits of any dialysis treatment versus another.

2.4 Theme 1 Haemodialysis

Haemodialysis is a clinical process by which urea, excessive water and other waste products of metabolism are removed from the blood by diffusion. Diffusion, a passive process, is defined as the movement of particles from an area of high concentration to an area of low concentration.

Haemodialysis is used to treat patients with either chronic, or acute ESRD and other blood toxicity conditions. Generally, the patients’ blood is accessed via an arteriovenous (AV) fistula and passed through a semi-permeable membrane, the dialyser, where the diffusion of solutes and removal of water by ultrafiltration takes place and is then returned to the patient’s circulation via the AV fistula. On one side of the semi-permeable membrane is the patient’s blood, and on the other is the dialysis fluid which is a combination of purified water and a mixture of acidic chemicals and bicarbonate buffer. These fluids are proportionated by the dialysis machine into an isotonic biocompatible solution of the correct concentration to enable diffusion of predominately small to medium solutes from the patient’s blood. The combination of waste solutes and water is referred to as dialysate and is
dispensed to soil drain by the haemodialysis machine. The pore size of the dialyser dictates the molecular clearance rate for the treatment and this is referred to as the ‘flux’ of the dialyser. With the advancement of water purification technologies facilitating the production of high quality dialysis fluid, most centres routinely use high-flux dialysers in their haemodialysis treatments, thereby enabling better clearance of the low to medium sized solutes. Low molecular weight solutes are typically less than 5 kilodaltons (kDa) whilst the middle molecular weight solutes are typically of the order 5–50 kDa. Later in this chapter the significance of Beta2-microglobulin (ß2M), which has a molecular weight of 11.8 kDa (van der Weerd et al., 2007), will be highlighted.

Conventional haemodialysis uses diffusive forces in the process for the removal of toxins from the patient’s blood stream and secondly, excess fluids are removed using ultrafiltration. Historically, haemodialysis was performed thrice weekly with a typical fixed duration of four hours. Currently, for hospitals performing haemodialysis, it is common practice for the treatment time to be very patient-specific, based on many parameters e.g. the individual patient’s blood chemistry, weight gain and their tolerance of ultrafiltration. Many technological advances, in particular single and blood volume monitoring have facilitated this.

2.5 Theme 2 Haemofiltration

Haemofiltration is primarily used in the intensive care setting for the treatment of patients with acute renal impairment, sepsis and multiple organ deterioration. As with haemodialysis, during hemofiltration the patient’s blood is cleansed by the movement of solutes across a semi-permeable membrane. With haemofiltration,
however, convection rather than diffusion is the process by which the solutes are removed. ‘Convection is bulk-flow of solute across a semi-permeable membrane together with a solvent in a manner that is dependent on transmembrane pressure and membrane characteristics.’ (Ronco, Kellum, & Mehta, 2001). Haemofiltration is an active process whereby a positive hydrostatic pressure is applied which drives the solutes across the dialyser, enabling a very efficient clearance of molecules of a small and medium molecular weight. The defining factor for the clearance is the porosity of the dialyser membrane.

Haemofiltration is more efficient than conventional haemodialysis at removing medium solutes owing to the slower diffusion speed in haemodialysis. As haemofiltration relies on the plasma concentration of the solutes rather than the concentration gradient, as is the case with diffusion, this facilitates the efficient removal of medium to low molecular weight solutes.

With haemofiltration, the conventional dialysis fluid is not prepared by the machine as is the case with conventional haemodialysis; rather the fluids are commercially produced and pumped into the dialyser for the convection process and collected post treatment for disposal. This adds a significant cost to this treatment and, in addition, whilst haemofiltration is efficient at removing solutes of middle molecular weight, when compared to conventional haemodialysis, it does not achieve the same level of low molecular solute clearance as haemodialysis. (Oates, Cross, & Davenport, 2012)
2.6 Theme 3 Online Haemodiafiltration

Online Haemodiafiltration (OLHDF) is a technique associated with high ultrafiltration rates and diffusion across a highly permeable membrane. Blood and dialysate are circulated as in haemodialysis, but in addition, ultrafiltration, in excess of the scheduled weight loss, is provided. Replacement/substitution fluid is used to achieve fluid balance. (Ronco et al., 2001). This renal replacement therapy combines haemodialysis and haemofiltration to achieve the aforementioned benefits of both modalities, namely diffusion and convection. OLHDF involves reinfusion of the replacement fluid which is produced by the machine directly into the patient’s bloodstream. As this treatment modality involves infusing fluid produced by the machine directly into the patient's bloodstream, the quality of the purified water used for the substitution fluid needs to be ‘ultrapure’ i.e. injectable quality as defined by the European pharmacopeia.

The first OLHDF clinical trial was performed in the mid-1980s with a customised prototype Fresenius A2008C dialysis machine. This proved the feasibility, concept and potential of the OLHDF method and over twenty five years later, ‘online HDF has proven to be safe, efficacious and with clinical benefits that justify it becoming a new standard for high-quality care of chronic kidney patients.’ (Bernard Canaud, 2011).
2.7 Haemodialysis versus OLHDF - What are the experts currently saying?

For the purpose of this literature review “Morbidity refers to the state of being diseased or unhealthy within a population,” while “Mortality is the term used for the number of people who died within a population.” (Rossi, Lipsey and Freeman, 2004)

OLHDF first surfaced as a real alternative to traditional haemodialysis in the 1980’s. Initial thinking was that it would provide significant improvement to the outcomes and quality of life for long-term ESRD patients currently being treated by haemodialysis. The author has extensive national and international experience from an engineering perspective and has been involved from the 1990’s in studies and clinical trials of new prototype technologies, relating to adopting existing haemodialysis equipment to meet the stringent technical challenges of OLHDF. The author will outline chronologically the perceived and proven beneficial benefits of this treatment versus conventional HD from all literature and introduce the latest iteration of this high-volume OLHDF modality.

In Montpellier France (B Canaud et al., 2000) published a reflective study of OLHDF versus HD over a thirteen year period involving 242 patients, with the aim of analysing the patients treated and its safety and adequacy as a treatment for ESRD. They concluded that this modality with the online production of substitution fluid offered a safe, efficient and economical means to treat chronic uraemia with a typical standard treatment session of four hours thrice weekly. However, whilst the signs were encouraging it was too early to definitively comment, on a more ‘crucial concern of the nephrologist’, namely how effective is this treatment at preventing beta 2 microglobulin (β2M) related amyloidosis? β2M is strongly associated with the
presence of carpal tunnel syndrome and dialysis-related amyloidosis in chronic HD patients (Van der Weerd et al., 2007). In a similar prospective randomised controlled trial (RCT) in Neuried, Germany (Ward et al., 2000) of 44 patients over a twelve month duration, it was concluded that while there was a superior solute removal over a wide molecular weight with OLHDF versus HD, the improved removal did not result in lower pre-treatment plasma concentrations. This may have been as a result of constraints with the mass solute transfer rates within the body. Although these findings are significant, the sample size and study duration are limiting factors.

In 2002, the results of the US-based HEMO study (Eknoyan et al., 2002), which was only the second RCT of the dialysis prescription on patient outcomes, the previous being the National Cooperative Dialysis Study (NCDS) twenty years beforehand, were published. This was a prospective RCT of 1846 prevalent patients comparing dialysis dose and high-flux with low-flux dialysis on patient’s mortality and morbidity. It involved 72 dialysis units and was the first randomised study on this subject as all previous similar studies were observational. The study concluded that there were no beneficial outcomes for patients receiving thrice weekly treatments with a higher dialysis dose or from the use of high-flux dialysers when compared with current US directives. (Cheung, 2003) concluded in a further observational analysis on the HEMO study that there may be greater benefit for patients who have had prior years of dialysis. This will need to be confirmed by another large randomised study. In agreement with the author is an opinion article on the Hemo study, where it suggested that two potential flaws in this study were that of dialyser reuse and its influence, while noted as having a limited detrimental effect on ß2M clearance, was not considered and also that water quality was not taken into account. (Levin &
Greenwood, 2003). In additional opinion articles on the HEMO study from the US (Rocco, Cheung, Greene, & Eknoyan, 2004) and (Cheung et al., 2003) other fundamental parameters were not part of the study design and would require separate studies including for example, the effects of ultrafiltration and blood pressure control.

Writing on the large European Dialysis Outcomes and Practice Patterns Study (DOPPS) (B Canaud et al., 2006) in relation to the mortality risks for patients receiving either OLHDF or HD, it was observed that OLHDF may improve patient survival independently of its higher dialysis dose but it was noted again that the potential mortality benefits of OLHDF must be tested by further clinical trials. This study involved 4591 patients across five European countries. In addition, (Rayner et al., 2004) stated that the results regarding mortality and morbidity in this study provide an important framework for future investigations that may lead to improvements in dialysis patient outcomes.

(Schiffl, 2007) published the results of a German randomised controlled trial of a four-year duration with 76 patients and concluded that OLHDF and HD, both employing ultrapure water, offered sustained reductions in β2M, however the reduction was more significant with OLHDF. Also, removal of urea and phosphate was significantly greater for OLHDF. It is noted at this time that the uptake of OLHDF is still quite low, but it is postulated that this will change once the results of on-going large scale studies become available. Whilst the observational studies are reporting mixed findings in relation to the patient benefits detected regarding mortality outcomes, there is a total consensus with regard to the need for large randomised controlled trials as highlighted in numerous articles (Santoro et al., 2008), (Feliciani et al., 2007) & (Vilar et al., 2009).
Following a prospective randomised controlled trial of 648 incident haemodialysis patients from 57 European centres, the Membrane Permeability Outcome (MPO) was published. The MPO study looked at the survival rate of patients randomly assigned to low-flux or high-flux dialyses and having a serum albumin ≤40 g/l on enrolment. One of the conclusions was that high-flux dialysis showed better survival rates in patients at risk for worse outcome, defined by serum albumin ≤40 g/l. In a position statement on the MPO study (J. Tattersall et al., 2009) stated that the study provided high grade evidence of improved survival for high risk patients i.e. serum albumin ≤40 g/l (grams per litre) using high-flux and also high grade evidence of the beneficial effect on serum β2M.

The European Best Practice Guidelines (EBPG) guidelines of 2007 stated that use of synthetic high-flux dialysis membranes should be considered to delay long-term complications of haemodialysis therapy specifically relating to; dialysis-related amyloidosis, improved control of hyperphosphatemia, to reduce the cardiovascular risk and to improve the control of anaemia. This recommendation was rated level 2B (weak recommendation) based on moderate quality evidence, for all patients. (J. Tattersall et al., 2007). However, in light of the MPO study, combined with the subgroup analysis of the HEMO study, the European Renal Best Practice (ERBP) Advisory Board in 2010 issued a ‘position statement’ on the original EBPG specifically relating to guideline 2.1., in relation to the use of hi-flux dialysers to delay long-term complications in high-risk patients (serum albumin <40 g/l). The rating was changed to level 1A (strong recommendation, based on high-quality evidence). Additionally, owing to the observation of reduced β2M, the use of synthetic high-flux dialysers is recommended for low-risk patients at level 2B (J. Tattersall et al., 2009).

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From Thailand in South East Asia (Tiranathanagul et al., 2009) results of a three year single-centre prospective observational non-randomised study were published. Its purpose was to compare numerous patient outcomes of twenty two patients on HD versus OLHDF. It concluded OLHDF was well tolerated with a lower incidence of intradialytic symptoms. Additionally, they concluded an improved nutritional status, a lower inflammatory state and effective clearance of higher molecular weight toxins. As this study included only twenty two patients, its influence is lessened. It was also non-randomised which can introduce bias (Britton et al., 1998), therefore its findings would require confirmation with a large ‘gold standard’ RCT.

The Convective Transport Study (CONTRAST) was a RCT and involved 589 patients in twenty six dialysis centres in three European countries (Penne et al., 2010). In its findings, using phosphate as the marker, it reported that pre-dialysis phosphate levels in patients dialysed with OLHDF compared with HD, were reduced which resulted in a decrease phosphate binder usage. Whilst these results offer hope of improved patient outcomes in pre-dialysis phosphate levels and the associated potential cardiovascular benefits, the true benefit to improved patient mortality/morbidity outcomes, have still to be established.

From 2010, the literature focused more on solute removal. Increasingly, this focus is on the convective forces required and the volume of replacement fluid used in OLHDF to enable effective clearance of solutes with a medium to large molecular weight. (Ledebo & Blankestijn, 2010) postulates that in order to get acceptable clearance of the medium and larger uremic solutes, it is not sufficient to rely on high-flux membranes alone. In addition, we must add large amounts of convection by performing high volume OLHDF (HiVOLHDF). This concurs with the DOPPS study which provided observational evidence as to the beneficial outcomes for patients
with a higher convection volume. (B Canaud et al., 2006). A prospective Turkish RCT of 782 patients (Ok et al., 2012), agreed with the observational findings of the DOPPS study for patients receiving OLHDF with substitution volumes greater than 17.4 L per session. In an Italian prospective RCT study (Pedrini et al., 2011) involving sixty nine patients from eight centres randomly assigned to HD or OLHDF for six months, the findings concluded that when compared with HD, OLHDF may contribute to improved patient survival by increased removal of small and medium protein bound solutes. This study, albeit small in the number of patients and short in duration, adds to the growing consensus relating to the potential benefits of HiVOLHDF. However, as this study combined pre and post dilution (mixed dilution) for the substitution fluid, a direct correlation to the previous studies is not possible. (Pérez-garcía, 2014).

While results of the further analysis of the European CONTRAST prospective RCT of 714 patients (Grooteman et al., 2012) reported no significant survival benefits in patients treated with OLHDF versus HD, they did hypothesise on the perceived benefits on patient outcomes with total delivered convection volumes >20.7 L/treatment, HiVOLHDF. Again, it was recommended that this observation would require confirmation by further trials.

(Maduell et al., 2013) and the Catalanian Estudio de Supervivencia de Hemodiafiltración On-Line (ESHOL) study was a RCT of 906 patients in 27 Catalanian dialysis units, with a remit to compare patient survival of OLHDF over standard haemodialysis and 456 patients versus 450 respectively. The ESHOL study concluded that patients assigned to HiVOLHDF had a 30% lower risk of all-cause mortality and a 55% lower risk of infection-related mortality when compared with patients who received standard haemodialysis. They also concluded that this
would correlate to the possible prevention of one annual all-cause death by switching eight patients to OLHDF. This was a relatively large RCT and of potential significance is the fact that the replacement volume of substitution fluid ranged between 20.8 to 21.8 litres per treatment session and possibly adds proof to previous studies relating to the importance of HiVOLHDF.

(Mercadal et al., 2015) reporting on a French study of 28,407 patients 2008-2012 from the findings of the French National Renal Epidemiology and Information Network’s (REIN) observational study of 28,407 patients were published in 2015 and concluded that the OLHDF therapy, compared to standard HD was associated with better patient survival, when accounting for all-cause mortality in the French patient population receiving one or the other of these treatment modalities. A prospective observational study in the UK (Davenport et al., 2015) of pooled data from 2753 patients offered additional promise for the HiVOLHDF modality when the convective volume is individualised to the patient. It concluded that while there appears to be a statistically significant reduction in all-cause mortality and morbidity with the cohort of patients treated with HiVOLHDF versus standard dialysis, further studies are required to consider individualised substitution volumes relating to patients BSA and weight. Whilst all of the indicators are outlining the possible link to beneficial patient outcomes relating to morbidity and mortality when treated by HiVOLHDF, this is very encouraging and offers promise, the science is still not totally conclusive. Further large RCT’s to prove and consolidate the emerging evidence on the effect of HiVOLHDF in improving patient survival are required. (Locatelli, Violo, Longhi, & Del Vecchio, 2015).
While the evidence may not be totally complete regarding HiVOLHDF, in the meantime a reflective article by Canaud should be considered; “So why not offer OLHDF to all end-stage kidney disease patients? It is a promising wager on a future of renal replacement therapy with improved patient survival and enhanced quality of patient life.” (Bernard Canaud, 2011).

### 2.8 Implications for the project

Whilst we currently do not have complete consensus regarding the beneficial morbidity/mortality outcomes for patients being treated by HiVOLHDF, it is the author’s belief that it is only a matter of time before this evidence will be available. In the meantime, it should be considered best practice to strive towards implementation of ultrapure water. Achieving water of the best quality possible, namely ‘ultrapure water’, should be the standard specification for all new dialysis units in 2016. For the scope of this project, that is the specification that is been used (J. Tattersall et al., 2009). While this offers an additional complexity to the design phase and certain additional cost, this is offset by the fact that the system has a degree of future proofing for any revision to quality standards which may occur. With the capital expenditure required when installing a new water purification plant for dialysis, which is typically a twenty year investment it seems prudent that the best possible specification of the day is used especially whilst been aware, that regulatory standards for online haemodialysis therapies are almost certainly going to become more stringent and obligatory. (J. E. Tattersall & Ward, 2013).
2.9 Summary and conclusion

Although the nephrology world is not still totally convinced by proven factual data, it would appear that HiVOLHDF has the potential to offer scientifically proven, significantly better patient outcomes in the near future. In this context, one must be cognisant of the fact that at the heart of the dialysis process is the water purification system. Its design and specification will have implications regarding the future dialysis modalities a hospital can offer, in the short, medium and long term. In this context, it is financially prudent to invest in the best possible system when purchasing new water purification equipment, that meets all current and any proposed future standards, as such capital reinvestment may take twenty years to be readdressed.
3. Methods and methodology

“There is nothing more difficult to take in hand, more perilous to conduct, or more uncertain in its success, than to take the lead in the introduction of a new order of things.” (Machiavelli, 1532).

3.1 Introduction

In this chapter the author will introduce and explain the various approaches to organisational change. This will involve discussing the various models that exist and their particular characteristics, merits and demerits. Following this, the subjects of organisational culture, resistance and the importance of leadership will be introduced and discussed. In the next section, the rationale for the selected change model for this organisational change project will be discussed and the various phases defined in the context of this organisational development.

3.2 Approaches to Organisational change

Various models exist which can provide a logical process to guide one through the process of change. One must be cognisant of the fact that there is not a one size fits all in relation to organisational change. The change agent/leader must be cognisant of the distinct factors within change namely planned, emergent and spontaneous change and be adaptable to change and flexibility within the change process. Planned change traditionally follows a rigid set of interconnected steps in a strict almost choreographed order. Planned change rarely achieves a radical cultural or
systemic change within an organisation, and is often referred to as been ‘structural change’. Emergent and spontaneous change generally exude a nonlinear, flexible approach and with numerous concurrent components. It is the authors opinion that there is an analogy between planned/emergent change and transactional/transformational leadership styles. In order to enact successful change the leader must adapt to prevailing changes and circumstances to achieve the vision and aim within the organisational context, which may be a reconceptulisation of the historical definition of leadership (Liebhart & Garcia-Lorenzo, 2010). The leader must exhibit and perform the best attributes of all the current leadership skills, which will be further addressed in section 3.3 and in relation to this organisational development in 3.4.

3.2.1 Lewin

In the 1950’s Kurt Lewin a physicist and social scientist explained the process of organisational change by using a quite simplistic analogy to changing the shape of a block of ice. This process known as the Lewin model consists of three distinct phases. Phase one is called the ‘unfreezing’ phase and this is where there is admission that a process or system is not efficient and requires changing. This is the phase where all influencing factors are considered, especially factors which may hinder or obstruct the process and thereby the potential of the change implementation. Lewin considered communication to be very important to successfully unfreeze the existing conditions and to highlight the discrepancies between the current and desired future state. (McAuliffe & Vaerenbergh, 2006).
Phase two of this process is known as the ‘Change’ phase and is where the organisational change is implemented. This can be the most precarious phase. To use the ice analogy, this is where the process is in liquid form and where the process can unravel. The final phase is what Lewin called ‘Refreezing’ where the change has been enacted and incorporated into the daily way of business.

3.2.2 Kotter

This model consists of eight distinct steps which can be divided into three distinct groupings namely ‘creating a climate for change’, ‘engaging and enabling the whole organisation’ and finally ‘implementing and sustaining change’. Within the first grouping the stages are firmly based around the foundations; ‘creating a sense of urgency’, having a ‘guiding team’ and having the ‘uplifting vision’. The urgency, guiding team and vision combined add dynamism to the organisational change and create the bedrock for the subsequent groupings. The second grouping again comprises of three distinct stages namely; ‘communicate for buy-in’, ‘empower action’ and ‘create short-term wins’. All this builds on group one and consolidates the complete process. Excellent communication combined with empowerment and short term wins makes the ultimate goal more achievable and attainable. Communication must be clear, heartfelt, concise and accurate, not complex and technocratic. This has the effect of diminishing fear and mistrust. (Kotter & Cohen, 2002). The final grouping in Kotter’s organisational change model comprises two stages ‘don’t let up’ and ‘make change stick’ and has similarities with Lewin’s refreezing stage. Its importance cannot be understated in order to prevent the implementation unravelling. The organisational change must be embedded into the
culture of the organisation for change to succeed and its implementation will then become firmly the new normality. (Kotter & Cohen, 2002).

3.2.3 Senior and Swailes
Barbara Senior and Stephen Swailes developed their five stage model in 2010 and describe projects as been ‘Hard and difficult’ or ‘Soft and messy’. ‘Hard’ projects are described as being tangible, easily defined and for which a logical solution generally exists. On the other hand ‘Soft’ projects are more difficult to define and are less tangible and hence ‘messy’ (Senior, 2002). Stage one of this model involves two phases, diagnosis of the present situation and a vision development to get to the future state by change.

They use the Paton and McCalman from 2000 TROPICS rating (timescale, resources, objectives, perception, interest, control and source) to quantify the scale of the problem. The remaining four stages involve ‘gaining commitment to the vision’, ‘developing an action plan’, ‘implementing the change’ and finally ‘assessing and reinforcing the change’. The Senior and Swailes model is active and employs a continuous feedback mechanism between all stages unlike the passive Lewin and Kotter models.

3.2.4 Health Service Executive (HSE) Change Model 2009
This organisational change model comprises of four distinct phases with seven separate steps. The initiation phase is the preparatory phase and involves the leader determining the key components of the organisational change e.g. defining the aim and objectives, identifying all stakeholders, determining the urgency and the resources required. It is at this initiation phase that the business case is developed.
Planning is the second phase and involves ‘building commitment’, ‘detailing the change’ and ‘developing the implementation plan’. In building the commitment the leader is selling the vision to stakeholders and staff. Unrelenting communication is a fundamental requirement to achieving total commitment. A communication plan should be established to facilitate this. (HSE, 2008). By ‘determining the detail of the change’ the leader and key stakeholders clearly outline the precise specifics for the required change. By having the key stakeholders and staff involved at this early stage facilitates maximum buy-in. The final step of the planning phase involves developing the implementation plan.

The third phase of the HSE change model is the implementation phase consisting of a single step, namely ‘implementing change’. This is where the change is enacted and we transition from the old to the new way of doing things. Yet again, communication is critical for the leader and the team to successfully achieve the aim and objectives. Leaders must be adaptable and open to fine tuning actions as dictated by the prevailing conditions. It is the leader’s responsibility to keep the agreed vision on track and within the agreed resources.

The final phase consists of two steps and is known as ‘Mainstreaming’. By ‘making it the way we do business’ we are normalising the new reality and we embed the change into the new organisational structure. It is important that the leader is observant of the achievement by all, and that time is taken to celebrate this. This should be the case at ‘all stages and key milestones’. Finally, with the ‘evaluating and learning’ step is the opportunity to assess the effectiveness of the organisational
change and its implementation. Fine tuning may be required to ensure a live change is implemented efficiently, from the theoretical change outlined pre implementation.

### 3.2.5 Critical review of organisational change models

“When you're finished changing, you're finished.” Benjamin Franklin

In 2005, in a critical review of change management argues that the fact that up to seventy percent of all change management initiatives fail (Balogun & Hope, 2008), may be as a result of the fact that there is a lack of a valid framework or model. It goes on to criticise the available models as being based on “unchallenged hypotheses and lacking empirical evidence”. (Todnem By, 2005). In a 2015 review Bartunek and Woodman discuss the increasing complexities relating to organisational change models when compared to Lewin’s model, as it approaches seventy years since its development. They describe Lewin’s model as having isolated phases with no interconnection or feedback. Using an orchestral analogy, they compare the monophonic Lewin’s method with current organisational change which has evolved into a complex polyphonic process. To reflect this evolution, change models need to move away from the linear three step model outlined by Lewin into a broader interlinked, temporal model with iterative components. (Bartunek & Woodman, 2015).

In relation to Kotter’s model, Appelbaum et al in 2011 revisited John Kotter’s 1996 change model in an attempt to ascertain what the pros and cons of each of the eight steps are and concluded that whilst it is a good starting point, it’s rigidity regarding following the steps in sequence was negative. They suggested that it may be best to
use in conjunction with other models. (Appelbaum, Habashy, Malo, & Shafiq, 2012). While Kotter’s model has been one of the most widely used it lacks academic literature that analyse its use in practice. This model is often portrayed as a linear sequence of steps but (Pollack & Pollack, 2014) state that to manage anything but a small organisational change requires “the change team to facilitate multiple concurrent instances of Kotter’s process throughout the organisation”. (Pollack & Pollack, 2014). Pollack, in a research article on the Kotter model indicates that a disconnect exists between the change management academia and the practitioners of change. The academics emphasis was based on theory, models and frameworks while this was not apparent with the change practitioners. This was based on a three-stranded study; ‘an analysis of highly cited change management articles, most cited articles in the specialist change management publications and interviews with change management practitioners.’ (Pollack, 2015).

Similarly, in a 2015 article by Mark Hughes he states that both Kotter’s article and book would ‘have gained legitimacy’ if they had been backed up by research. He goes on to say that whilst Kotter’s book ‘Leading Change’ remains a testament to leadership studies, it is out of date and “paradoxically today discourages change”. A disconnect between leadership studies and practice is alluded to by Hughes and is described as needing to be challenged. (Hughes, 2015).

### 3.3 Change Leadership, Resistance and Culture

The key attributes of a leader who is embarking on an organisational change are persuasion, trust, emotional intelligence (EI), vision, a sense of urgency and a dedication to the vision. (Garvin & Roberto, 2005) & (Appelbaum, Degbe,
MacDonald, & Nguyen-Quang, 2015b) Stonehouse 2013 highlights the importance for the change agent, to be seen to have the managers’ support and the organisations buy in where possible right to CEO level. (Stonehouse, 2013). In relation to persuasion, in separate articles Cialdini & Conger refer to persuasion as having scientific and artistic components respectively. Furthermore the scientific component is described as been a cocktail of six parts namely; liking, reciprocity, social proof, consistency, authority and scarcity. (Cialdini, 2001). Similarly, the artistic element is described as having the following stages for the effective change agent; establishing credibility, framing the vision, providing evidence to substantiate the vision and finally, the change agent must connect emotionally. (Conger, 1998).

Whilst the aforementioned attributes are essential for the change agent to enact a successful organisational change, it is the author’s belief that trust and EI provide the foundation. In order to avoid the possible deceptive or coercive influences of the scientific and artistic components, trust can be the guardian.

Writing in the Harvard Business Review Jeanie Daniel Duck emphasises the importance of trust within change management, and alludes that this needs to be established prior to change enactment as it is more difficult to establish in the midst of change. (Duck, 2000). In addition, the change agent is required to be politically astute. By being astute, an individual shows an understanding of others actions and their motivations. Therefore a politically astute person is a person who is aware of the political dynamics within an organisation and of the external influencing effects. They knowledge is not used in a manipulative manner or for personal gain, but for the overall benefit of the team’s, or the organisation’s goal or vision. (Hartley, Alford, Hughes, & Yates, 2013). The leader must be cognisant of power which can have the
following manifestations, coercion, manipulation, domination and subjectification. “Power not only represses and controls, but also produces behaviour both desirable and undesirable, depending on the political lens through which one views it.” (Fleming & Spicer, 2014) & (Senior, 2002). In order to effectively achieve successful management of change, the leader must be aware of the organisational context within which they are trying to implement the change, whilst been totally cognisant of their personal leadership style and the necessity of changing from transformational (Phipps, Prieto, & Verma, 2011) and transactional in sympathy with the prevailing circumstances of the change cycle. (Appelbaum, Degbe, MacDonald, & Nguyen-Quang, 2015a). & (Ford, Ford, & D’Amelio, 2008).

For many resistance tends to conjure up negative connotations. The change agent should consider countering this by considering it as a potentially powerful resource to validate and fine tune the vision. Resistance to change should not be construed as a negative or an obstructive force by the change agent but rather as a strengthening attribute for the change process, and a self-check for the leader/change agent. Resistance, albeit with negative connotations, should be considered as something more dynamic and positive and, as described by Ford et al should consist of three components, namely ‘change recipient action’, ‘change agent/leader sense-making’ and lastly ‘change agent recipient relationship’. It is recommended that the leader should lead the conversations and communicate effectively to identify the root of possibly misplaced or perceived resistance (Ford et al., 2008). Resistance can stem from genuine concerns within an individual or group, internal or external and the successful change agent should embrace and use as leverage to improve overall
commitment to the change rather than use it as a criticism of perceived opponents. (Appelbaum et al., 2015a) & (Ford et al., 2008).

In an interesting article on organisational culture in relation to healthcare performance, Scott et al. 2003 postulate that the intricacies of culture and performance require further conceptual and empirical work to determine the true definition of both concepts and their true interdependencies. (Scott, Mannion, Marshall, & Davies, 2003). From a national study of clinical governance managers in acute and primary care trusts throughout England, Mannion et al. comment that whilst there are an overabundance of culture assessment tools they tend to be predominately focused on the assessment of safety cultures rather than quality and performance. (Mannion, Konteh, & Davies, 2009). In a special article Davies et al. observe that the roots of organisational culture has its roots in ‘anthropological literature’ and that organisational culture evolves from shared beliefs, values, attitudes and goals between colleagues from within an organisation. (Davies, Nutley, Mannion, & Davies, 2000).

Organisational psychologists Weick and Quinn compare and contrasts ‘episodic’ and ‘continuous’ change methodologies and their impact. Episodic organisational change tends to be infrequent and only happens sporadically within an organisation. From the current equilibrium, a change is applied to reach the desired vision, the new equilibrium. This category is generally very closely aligned with Lewin’s three stage change model. By contrast ‘continuous’ change, as the name suggests, is an ongoing process. This type of organisational change can benefit from the synergy of cumulative, concurrent small changes. Organisations which operate in this manner are in a continual state of mini change. (Weick & Quinn, 1999).
3.4 Rationale for the selected change model

The HSE Change model (figure 5) was selected for this organisational development project as it was deemed the best fit for a development of this scale and as it facilitates numerous episodes of change. This model incorporates a nonlinear cyclical approach and treats the process in an adaptive manner. It recognises that the Irish health services are involved in a perpetual process of change at all levels and also facilitates multiple instances of concurrent change. The model is based around best practice and is evidence based. As mentioned in section 3.3 there are key attributes that the change agent must exhibit in order to successfully enact a change, in addition he/she must be cognisant of the various components involved in the organisational development; people, culture, structures, processes, organisational and individual behaviours. (HSE 2008). As a means of a reminder, the existing dialysis unit is not fit for purpose from numerous critical aspects. While the water quality is sufficient for standard and high flux dialysis the existing purification equipment does not have the capability of meeting the stringent requirements proven as necessary for HiVOLHDF without been totally dependent on the on-board additional filtration of the dialysis machine. In addition, the current environment is not best suited to the treatment of dialysis patients in a setting that is in sympathy with best care surroundings. Finally, the current facility does not comply with best practice guidelines for the treatment of isolated patients, accreditation and fire regulations. The HSE change model and some of its parts will now be applied to this organisational development with its various instances of concurrent change.
3.4.1 Initiation

‘Preparing to lead the change’

The objective of this stage was to scope out the scale of the organisational development, add flesh to the vision and make it a tangible potential reality as opposed to a theoretical concept.

The author performed a force field analysis (figure 4) to determine the scale of the forces supporting and opposing the changes. Lewin developed his force field theory as an assessment tool to highlight the driving and resisting forces for the change initiative and with this tool the leader is better equipped to implement the organisational change.
The force field analysis showed significant supporting forces, predominately from within the organisation but most importantly from the HSE and the National Renal office. The main potential for resistance was identified as being the current occupants of the identified preferred location namely the pre dialysis and peritoneal dialysis services. Whilst the scale of this resistance was numerically small when compared with the supporting forces, it was still significant and required close management and monitoring by the change agent (Ford et al., 2008). A secondary channel of resistance emerged during this initiation phase when the proposed location for the water purification plant room met with opposition as this location had been assigned previously for the ICT servers.

The author focused on these potentially very significant restraining forces to reduce their impact. This was achieved by negotiation during a series of separate meetings with the ICT department and the pre dialysis and peritoneal dialysis services. In relation to the ICT requirements, numerous possibilities were explored unsuccessfully but with the change agents further exploration and intervention, a larger more suitable location was identified and agreed upon on a different floor.
within the block. This location surpassed the current ICT requirements but also facilitated a degree of future proofing to meet and host future expansions. In relation to the relocation of the CAPD and pre-dialysis services this was harmoniously enabled by the relocation to the refurbished and partially vacant St Monica’s ward.

Following the force field analysis, the author performed a stakeholder analysis, (appendix 1) in order to identify the range of stakeholders, both within the organisation and external to it. The stakeholder’s power and influence were determined in order to highlight their impact on the project and its implementation. This enabled the author to develop the most appropriate communication avenues from the beginning thereby developing relationships and facilitating stakeholder buy-in from the outset.(Fleming & Spicer, 2008).

The author analysed the various stakeholder groupings and developed a communication strategy around this. Meetings were scheduled commencing with the low interest high influence group. The author deemed this necessary because whilst their interest was low their influence within the organisation may prove very important particularly in relation to unseen resistance. Communication involved sharing the vision and the proposed implementation programme. With regards to the high interest/low influence group communication was channelled through existing established forums. For instance, the project updates were included on agendas of the regular nephrology management team meetings and the clinical engineering department meetings. In relation to the high interest/influence stakeholder’s communications during the initiation stage, these were frequent and formal. It involved using Ancona's four components of leadership, 'sensemaking ', 'visioning ', 'inventing ' and 'relating' (Ancona, Malone, Orlikowski, & Senge, 2009) in order to prepare for the planning and implementation stages. Finally, the low
interest/influence group were then defined as requiring, minimal but important key communications, as this group may transition to high interest and then potentially high influence in the later stages of planning and implementation. This transition will potentially manifest itself once the successful initiation phase is complete. A PESTE (Political, Economic, Social, Technical, Environmental) analysis is a powerful framework or tool that the change agent/leader can use to assess influences and their importance relating to a change management project and its implementation. In the initiation stage of an organisational change project, current thinking is that best practice is to perform a PESTE analysis and allow this to feed into the threats section of the SWOT analysis (Strengths, Weaknesses, Opportunities & Threats). (Jacobs, van Witteloostuijn, & Christe-Zeyse, 2013).

In relation to this organisational development project the PESTE analysis and its relevant influences/challenges are as follows:

• Political influences: If these are not managed there is risk of failure to get approval to relocate to the required locations

• Environmental: The proposed water purification system as mentioned will be a dual reverse osmosis system with the capability of operating in a duty standby configuration if required. It will offer economies in water usage as RO1 waste is recycled and feeds RO2 and this will result in a 15% reduction in total water wastage. As mentioned, the system will perform heat sanitisation thereby reducing the routine use of caustic chemicals. In addition, a centralised concentrate delivery system (CCDS) will eliminate the current use and disposal of 6 litre polyethylene canisters.
• Social: For the scope of this organisational development the proposed social change will mean that patients will be treated in a new state of the art modern facility.

• Technical: Technologically, this project proposal will present many challenges in order to achieve the water quality specification required to offer the preferred treatment modality HiVOLHDF. In addition, there will be technical challenges while trying to implement the best patient environment within the proposed location.

• Economic: Failure to get approval for funding of the infrastructural works and the high specification water purification plant.

SWOT (appendix 3)

• Strengths: This project offers the capability to perform HiVOLHDF in a fit for purpose environment while achieving patient isolation requirements.

• Weakness: There is a possibility of not expanding the facility sufficiently to future-proof for service requirements.

• Opportunities: The opportunity to create a state of the art haemodialysis unit offering HiVOLHDF as the optimum treatment.

• Threats: The proposed location is currently occupied by the PD and pre-dialysis services. There may be resistance to the relocation of these services. There is also a potential threat relating to the proposed location for the water purification plant. There is a dependence on the external political environment in relation to funding.
During the course of this project, a new potential threat emerged. One of the key internal stakeholders left the organisation which left a significant void in relation to implementation of this organisational development, potentially it could have 'unfrozen', lost impetuous and unravelled. For the change agent, this required revisiting the SWOT and stakeholder analysis specifically relating to threat (appendices 2 & 4). This potential threat did not materialise, however it does highlight the importance for the change agent/leader being cognisant and responsive to all perceived and actual threats and adjusting the programme and his/her leadership style accordingly.

3.4.2 Planning

The planning phase of this organisational development was multi factorial and involved all three steps of this phase of the HSE model i.e. 'Building commitment, determining the detail of the change and developing the implementation plan' (HSE 2008).

In order to gain and 'build commitment', the author engaged with the key stakeholders in the previously defined high influence/interest group. In addition, the high influence low interest group were included as their influence was critical to ensure corporate and financial commitment at this critical juncture. This was achieved by a combination of one-on-one and group meetings where the vision was reiterated and the projected implementation outlined. Also, these meetings offered a forum for the change agent to voice any significant developments or concerns relating to the progression of the organisational development. These meetings proved extremely beneficial for the change agent, when in particular confronted with the previously mentioned potential threat to the project from the departure of a key internal stakeholder. It was through this medium that this individual’s responsibility in
relation to the project was transferred to another key stake holder, who already had high interest but low influence in the project. Appendix 4.

In ‘determining the detail of the change’ the author was predominately involved with the engineering specification of the technological requirements to ensure the reliable routine production of ultrapure water. This involved the lead clinical engineer for dialysis, the technical services department and the water purification equipment vendor. During this series of meetings, the details of the proposed technical solution were discussed, fine-tuned and advanced towards a final solution. This group were particularly cognisant of the limiting infrastructural restrictions which prevailed, owing to the fact that the intention was to retrofit this modern system within an existing functioning hospital. The logistical aspects of this will be addressed in the next paragraph. The change agent was also involved in planning the transfer of the existing service to the new facility. This involved initial exploratory meetings with the nephrology team (both medical and nursing), clinical engineering, portering and security. From these initial meetings the consensus was to plan for a phased transfer. To this end, it was agreed once go live date was agreed the second treatment of that day would be performed in the new unit. This approach offered numerous benefits; firstly, pressure on commencing all treatments at 8am was abated, offering the opportunity to meet, assess and debrief on the effectiveness of the change. Finally, it afforded the opportunity to provide full technical assistance for the phased trial transition.

‘Developing the implementation plan’ provided the change agent and stakeholders the opportunity to focus on the details of the infrastructural redevelopment and its schedule, the water purification plant installation programme and the transfer of services in a coordinated manner. From the change agent’s perspective, at this
point the water purification vendors had traversed to the status of high influence/interest, in the stakeholder’s analysis, as their installation plan would directly influence the key milestones in relation to the new unit going live. Their schedule of work necessitated out of hours and weekend work owing to the fact that these works had to be completed in a live functioning hospital. Significantly and importantly, this did not accrue any additional expenditure as it had been clearly highlighted in the initial scope of works within the specification document. In conjunction, the change agent was actively engaged with the key stakeholders in relation to the physical logistical transfer of services from the existing unit to the new. This engagement was deemed essential at this stage by the change agent in order to alleviate or address any potential issues.

As stated and demonstrated, the HSE change model readily facilitates multiple concurrent changes within the remit of a singular organisational development. Whilst it is achievable, it requires flexible, adaptable, hands on approach by the leader/change agent. He/she must be prepared to continually revisit, reassess, and alter as necessary to progress the vision and ensure there is a readiness for the change. (Rafferty, Jimmieson, & Armenakis, 2012).

3.4.3 Implementation

The implementation phase for this particular organisation development consisted of three distinct but closely interlinked components; the infrastructural redevelopment, installation of the water purification plant and the transfer of the existing dialysis service to its new location. The author shall now outline the implementation of these components, highlighting overlap and interdependencies as appropriate.
The infrastructural redevelopment

As with any medium to large size construction project within a live functioning hospital, there are numerous safety and environmental concerns. A major benefit to this project was that this component was coordinated through the organisation's technical services department (TSD), so no third party contractors had to be managed. The site was locked down and isolated from the main hospital for the demolition phase of the works in late August 2015. This required significant alteration to existing wayfinding on a temporary basis. Additionally, a separate entrance to facilitate the ingress and egress of construction personnel and materials was created. The primary role of the change agent during this stage was to monitor the progress of the redevelopment in relation to the predefined plan. This was achieved by having regular meetings with the assistant head of technical services who project managed the redevelopment. This close collaboration was essential in order to achieve the overall implementation on target with the agreed schedule. One potentially very significant matter arose in relation to the delivery and installation of the high-efficiency particulate arrestance (HEPA) air handling unit (AHU). The AHU was to be manufactured near Frankfurt in Germany and was due for delivery and installation mid-October. However, owing to a communication breakdown this was not achievable and estimated installation had to be rescheduled for mid-November. The significance of this was that it directly impacted on the validation schedule of the water purification plant, pushing out the go-live date to March, which would directly impact on plans for the vacated old dialysis unit. Following a series of meetings, this issue was alleviated with a compromise solution. All of the enabling works for the installation of the AHU would be completed as per schedule and capped off in the ceiling void and a new location for the installation of the AHU was located and
agreed. This compromise solution facilitated the scheduled water plant implementation as planned and did not impact on the HEPA air quality. While this example demonstrates the importance of adaptability and flexibility, it also demonstrates the necessity for the change agent to keep to the agreed deadlines in achieving the shared vision.

**Installation of the water purification plant**

Once the demolition stage of the infrastructural redevelopment and the rebuilding phase had started, the initial stages of the water plant installation commenced. Many stages of these two critical components of the organisational development were performed simultaneously and were interdependent. The highly specialist nature of the water plant installation was managed directly by the equipment manufacturer Whitewater. Stage one of the water plant installation involved assembly of the plant in its dedicated plant room which is situated adjacent to the dialysis unit. This was scheduled to be completed over six weeks and was completed within this timeframe. Following this, the Clean-Pex™ circulating ring main was installed. This circulates the ultrapure water to the dialysis media panel (DMP) at each treatment bay. The DMP is a service delivery panel which facilitates the delivery of electrical power, ultrapure water, data and dialysis concentrates. This is currently considered best practice from both an aesthetic and ergonomic perspective. This was followed by the commissioning of all the individual plant components of the purification process and then the complete system. Once commissioned, the intensive period of heat disinfection of the complete ring main commenced, followed by the detailed quality validation. Again the role of the change agent was to monitor the progress of all components in line with the project plan. This required detailed analysis of the scheduled works in relation to key milestones.
With respect to the CCDS and its installation, it became apparent in late October that this would not be achievable within the timeframe of this development. This resulted from a manufacturing fault identified by the manufacturer Fresenius Medical Care (FMC) which impacted the manufacture of all CCDS systems. FMC notified their client, this organisation, that the new estimated delivery would be January 2016. Following meetings with FMC, Whitewater and TSD it was agreed to proceed with CCDS ring main installation and connection to the DMP’s. This would facilitate a minimally intrusive installation of the CCDS on a Sunday after the new dialysis unit went live. It would also negate the need for a deep clean of the unit post installation of the CCDS as there would be no requirement to enter the roof void or the DMP’s.

**Transfer of the dialysis service**

As mentioned in the planning phase a ‘trial transfer’ was agreed with all the relevant stakeholders prior to the complete transfer of the service. This involved the nephrology team, clinical engineering, portering and security but in addition at this stage dietetics, catering and pharmacy were also included. It was deemed prudent at this stage to include these additional service providers to gain reassurance that the relocation from a practical perspective did not present any unforeseen issues for the provision of their services. The trial was agreed for the second set of treatments on February 9\textsuperscript{th} 2016 with a complete transfer of services scheduled for the 11\textsuperscript{th}, subject to a satisfactory trial. At a meeting on the 10\textsuperscript{th} it was agreed that the trial had been a resounding success and presented no impediment to the scheduled complete transfer of services the following day. As planned, all the new dialysis machines were transferred from the existing unit at the end of treatment on the 10\textsuperscript{th}, and reprogrammed for automated heat sanitisation to commence before the unit opened on the 11\textsuperscript{th}. This is performed in addition to the weekly pre-programmed
automated disinfection of the ultrapure water ring main. With the service now successfully transferred to its new location with its dedicated isolation facility and HiVOLHDF with ultrapure water a reality, the author formally handed over the day to day running, from a technical perspective, to the lead clinical engineer for dialysis services. For the departments of nephrology, clinical engineering and the organisation, this is the ‘new way we do our dialysis business’.

3.5 Summary and conclusion

The author used the HSE change model for this organisational development as it provides a logical approach during the process, while affording the change leader certain flexibility when compared with the more regimented and linear Lewin and Kotter models. It is a cyclical model which benefits the change agent as one can move back and forth between stages. There were numerous challenges to this change project owing in part to its highly technical nature, its three distinct components as highlighted in 3.4.3 but also the array of stakeholders both internal and external.
4.0 Evaluation

“The only man who behaves sensibly is my tailor; he takes my measurements anew every time he sees me, while all the rest go on with their old measurements and expect me to fit them”

George Bernard Shaw

4.1 Introduction

This chapter will focus on the evaluation of the implementation of this organisational change project and will comprise two distinct components; the quantitative analysis of the production of ultrapure water and the development of a KPI and secondly, the qualitative analysis from the patients’ perspective on their experience of the new versus the old unit. Firstly, the author will outline the background to healthcare evaluation and introduce some frameworks. In addition, the aim and objectives of this organisational change project will be revisited and discussed. This will be followed by a detailed explanation of the evaluation results of this organisational change. Finally, this chapter will conclude with a summary of the evaluation and a reflection on the chosen methodology.

4.2 Evaluation and Healthcare

As alluded to in chapter three, all aspects of Irish healthcare are in a continuous state of concurrent change. This is again multi-factorial, with numerous
predominately positive aspects e.g. technological advances, socio-political influences, and financial constraints and despite current public opinion, the continuously improving services which facilitate better patient outcomes. To embrace and enact these changes successfully requires evaluation, ensuring the patient experience is therapeutically beneficial and delivered in a sympathetic caring environment, with patient satisfaction to the fore (Conry et al., 2012) & (HSE, 2008). As a result of historical inconsistencies in the delivery of care, the need for evaluation and standardisation of practice based on these evaluations is now of paramount importance. As recommended by the HSE evaluation should be resourced and funded correctly for all stages of the change programme. (HSE, 2008).

4.3 Evaluation Frameworks

An evaluation programme is a logical systematic process used to assess the effectiveness of a project or programme, from the inception stage to the completion stage. It can be an iterative process requiring the evaluator to continually assess and modify the process to achieve the desired aim and objectives. According to Rossi, Lipsey and Freeman (2004) the following distinct stages may be involved, which may also require different evaluation methodologies and the evaluation may be conducted at several stages during a project’s lifetime.

- Assessment of the need for the programme
- Assessment of the programme design and logic/theory
- Assessment of how the programme is being implemented (i.e., is it being implemented according to plan? Are the programme's processes maximizing possible outcomes?)

- Assessment of the programme's outcome or impact (i.e., what it has actually achieved)

- Assessment of the programme's cost and efficiency

(Rossi, Lipsey and Freeman, 2004)

There is a whole array of evaluation frameworks e.g. the ADDIE, DECIDE, ‘Logic framework’, the CIPP (Context, Input, Process and Product), Kirkpatrick’s and the Miller framework. Most of the frameworks have evolved from three theories namely; system, complexity and reductionism. These theories assist the evaluator when selecting a framework. There is no hierarchy of good or bad framework and it is best to select an evaluation framework that is most suitable for the particular project. (Frye & Hemmer, 2012). In some instances, it may be more appropriate to combine components from different frameworks depending on the particular nature of the evaluation.

It is the authors opinion that the DECIDE framework offers a concise and meaningful introduction to the whole concept of evaluation in the context of an organisational development. This framework consists of six steps which are defined as follows:

- **Determine** the aims and objectives the evaluation addresses

- **Explore** the specific criteria to be answered
Choose the evaluation paradigm and framework or frameworks to answer the criteria

Identify the practical issues

Decide how to deal with the ethical issues

Evaluate, interpret and present the data

4.4 Aims & Objectives

As outlined in chapter one the aim of this operational development is to relocate and expand the existing acute inpatient haemodialysis service to a new, refurbished and fit-for-purpose location, with a dedicated isolation facility and increased capacity. The new facility will provide ultrapure water to facilitate HiVOLHDF as the treatment modality of choice.

Objectives

1. By June 3rd 2015, complete and submit a business case to the National Renal Office and the Ireland East Hospitals group (IEHG) for approval of funding.
2. By August 21st 2015, have the contractors’ schematics for the new unit agreed by all stakeholders.
3. From 5th October 2015, commence installation of water purification plant, centralised concentrate delivery system (CCDS) and associated ring mains.
4. By 7th December 2015, commence quality testing and commissioning of water purification plant and CCDS. This intensive sampling phase will be completed by January 4th 2016 and will incorporate the development of a KPI.
5. On 8th February 2016, transfer acute haemodialysis services to the new unit and cease services at the current unit.

6. By February 2016, establish a dedicated isolation unit and increase treatment capacity by 12.5%

7. By February 2016, address fire officer and JCI non compliances

8. By April 2016, perform and evaluate patient survey to ascertain their experience of the new facilities.

For the purpose of this evaluation, the objectives will be divided into two distinct groupings; quantitative 1-4 and qualitative 5-8.

4.5 Evaluation and this organisational development

There were two significant aspects to the evaluation of this organisational development project. The primary evaluation was of the ultrapure water quality which facilitates the HiVOLHDF treatment modality. This was a quantitative evaluation, involving the development of a KPI, a performance measurement instrument that acts as an early warning indicator that foresees any deviation in the water quality, both chemically and microbiologically. It also facilitates early preventative intervention, to ensure HiVOLHDF can remain the haemodialysis treatment of choice. The secondary evaluation, which was more qualitative in nature, incorporated a patient satisfaction survey to ascertain the patient experience in the new refurbished unit when compared with the existing, old unit.

While being cognisant of all the aforementioned frameworks and their potential benefit to this evaluation, the author feels the CIIP framework (Figure 5) offers the best and most appropriate methodology. It is the author’s belief that it offers the
most logical route to evaluate this organisational development through all of its strands; initiation, planning, implementation and mainstreaming. In relation to a project of this scale, systematic evaluation was required for all stages of each component to ensure the overall agreed vision was realised, and that none of the individual components had a debilitating influence on the overall outcome.

![Context Evaluation Diagram](image)

**Figure 5**

**Context Evaluation**

Within the ‘context evaluation’, the ‘what needs to be done’ phase of the CIPP model requires the change agent to focus on the vision, goals, the planning of its implementation and its evaluation. During this phase it is critical to concentrate on making the change a best fit for the organisation while identifying all the resources, political and cultural issues. In conjunction with this, it is imperative for the change agent to ensure that all key stakeholders are identified and engaged with. In essence, this stage provides the opportunity for the change agent to take soundings, verify if the change is achievable within the current structure and identify what additional resources may be required. (Mertens & Wilson, 2012). In effect this phase correlates directly with the initiation stage of the HSE change model. According to
Stufflebeam, for context evaluation to be effective it must ‘delineate, obtain and provide’ the correct information in a timely efficient manner to fine tune the planning process. (Stufflebeam, 2001).

**Input Evaluation**

The ‘input evaluation’ phase is where fine tuning is addressed. In this phase the change agent and stakeholders determine the use of resources, develop strategies to achieve the objectives and focus/define the implementation strategy. This phase concurs with the planning stage of the HSE change model.

**Process Evaluation**

During ‘process evaluation’ we have the opportunity to access how well we are progressing in accordance with the predetermined plan. The purpose of this phase is to give the change agent the opportunity to make changes to the implementation, based on the circumstances and realities of implementation and couldn’t have been foreseen in the preparatory design stages. It requires close monitoring of the project, possibly on a daily basis, which will guide and assist any alterations required to the project delivery.

**Product Evaluation**

‘Product evaluation’ offers the opportunity to evaluate the outcomes when compared with the objectives of the organisational change. This requires having clearly defined criterion or standards to be achieved. This evaluation should continue throughout the complete implementation, particularly at key milestones, and finally an overall evaluation on completion. The essence of product evaluation is to determine whether the specific outcomes of the project were achieved.
4.6 Results: Ultrapure water quality

“Those medical directors who learn, know, and embrace the requirements for providing high-quality dialysis water will be most successful.”

(Kasparek & Rodriguez, 2015)

Water quality is fundamental to haemodialysis regardless of the modality; this has two distinct strands namely chemical quality and microbiological quality. However the criticality of the quality is far more stringent with the HiVOLHDF modality of treatment. A typical adult will be exposed to approximately fourteen litres of water a week. This is ingested orally, absorbed via the gastrointestinal tract, any excess is removed by the nephron in the kidney and exits the body with other waste products of metabolism in the urine. By contrast, the standard thrice weekly haemodialysis patient is exposed to 576 litres per week via the semipermeable dialyser. In addition, the high volume online HDF patient is exposed typically to an additional 60 litres per week which is infused directly into the patient’s blood stream. Furthermore, as the majority of ESRD patients have zero, or very minimal residual renal function, toxins in the blood remain and cannot be ‘renally’ excreted between dialysis sessions.

Evidently, the requirement for stringent water quality standards for patients requiring dialysis is imperative versus those merely reliant on drinking water, both chemically and microbiologically for the aforementioned reasons. Many of the constituents naturally found in potable water e.g. calcium, aluminium, zinc, etc., and those added to make water suitable for human consumption e.g. fluoride, chlorine, chloramine,
etc. are at toxic levels for the dialysis patient. These are cumulatively known as the chemical constituents and, as with drinking water, must achieve a different set of stringent quality standards. (Appendix 5).

In addition to the chemical quality standards are the microbiological quality standards, which comprise two distinct markers namely the total viable count (TVC) and the endotoxin level (EU), the latter measured traditionally by the limulus amebocyte lysate (LAL) test or increasingly Reasoner's 2A (R2A) but less frequently the Tryptic soy agar (TSA) (Appendix 6). As seen from this, the standards relating to water quality for ultrapure water are sufficiently stringent but, as a result of significant technological advances readily achievable, for all modern dialysis facilities. The introduction of ultrapure can help in preventing dialysis treatment related complications. (Pontoriero, Pozzoni, Andrualli, & Locatelli, 2003) & (Coulliette & Arduino, 2013). Whilst this is a requirement for all haemodialysis treatments, the use of ultrapure water is of utmost importance for patients undergoing HiVOLHDF. (Kasparek & Rodriguez, 2015), (Bernard Canaud & Lertumrongluk, 2012), (Ward et al., 2000) & (Ward and Tattersall, 2015). Appendix 7 tabulates the differences between the United States and European pharmacopoeias (USP and EP respectively) in relation to water quality standards under the purified water (PW) and water for injection (WFI) classifications. In 2002, with the publication of the fourth edition of the EP, highly purified water (HPW) was introduced. HPW is applied in the production of medicinal products which sets high standards to be met in the field of microbiology, but where WFI is not mandatory.

The business case was submitted and gained approval in May 2015. Following this, there was the initial engagement with the water treatment plant supplier regarding the water quality and system specification. This was a lengthy process involving
numerous meetings and clarifications relating to the engineering design and installation logistics. Appendices 8 & 9 schematically represent the agreed facility layout and plant components.

The specified water purification system for this project comprises the key components below, with the requirement to produce product water quality in compliance with the standards outlined in appendix 5 and appendix 6. In addition, the system design took countenance of the fact that this organisation has two differing raw water supplies and many seasonal variations in water supply quality, particularly relating to nitrate levels and chlorination. (Fluck et al., 1999) & (Casey, Kearney, & Kerr, 2012).

- Depth filtration
- Organic scavenging
- Duplexed water softening
- Carbon adsorption with an EBCT (Empty Bed Contact Time) of > 10 mins
- Dual pass reverse osmosis
- Ultrafiltration
- UV irradiance
- Heat sanitisation module

In conjunction with the infrastructural component of this project, as described in chapter three, the plant installation commenced as agreed, in October 2015. This phase was completed ahead of schedule and was concluded on November 27th 2015, thereby enabling the early commencement of the commissioning, validation and quality testing.
Validation commenced in December 2015 and was completed at the end of the second week in January 2016. This consisted of monthly sampling and chemical analysis of the incoming raw water and the product water (V 20). Additional mid process samples were taken post softening, post-carbon adsorption and mid-reverse osmosis (V19). The purpose of this additional sampling was to facilitate evaluation of the individual component stages of the complete purification process and to confirm its correct performance. These results are tabulated in appendix 10 and confirm that this water purification design consistently provides water that surpasses the chemical standards for ultrapure water. The microbiological quality validation followed a similar regime with samples for total viable count (TVC) and Endotoxin units (EU) being analysed on a weekly basis and again, consistently complied with the standard TVC < 0.1cfu per ml and < 0.03 EU per ml. (Appendix 11).

Additionally, daily chlorine and water hardness testing is performed whilst dialysis machine product dialysis fluid is sampled monthly for TVC and EU (appendix 13). This latter test confirms that the individual flow paths through each dialysis machine are not contaminated and validates the complete process as producing sterile pyrogen-free dialysis and HiVOLHDF substitution fluid. (Ward and Tattersall, 2015). This provides a major step forward in reducing dialysis related complications by improving the biocompatibility of the total process. (Bernard Canaud & Lertdumrongluk, 2012).

Previously at this dialysis facility standard low flux dialysis was the predominant modality, with only limited high flux and zero HiVOLHDF performed. Water
purification consisted of a centralised water softening system and a carbon adsorption stage. The softened and dechlorinated water was then delivered to each dialysis machine, where a built in reverse osmosis unit provided further purification. Whilst this met the standards of the day relating to water quality for standard dialysis, it was unable to achieve the current more stringent microbiological standards required for HiVOLHDF. Appendix 14 outlines the typical water quality results achieved under this regime while figure 7 indicates the thresholds for dialysis water, standard dialysis fluid and ultrapure dialysis fluid. When comparing chemical quality, this was consistently achieved. However, in relation to the microbiological quality, the TVC/ml were typically > x 100 and EU/ml > x 10 than that achieved by the new plant. It must be reiterated that while this would be totally unacceptable for HiVOLHDF it was in compliance with the requirements for standard HD.

Figures 6 & 7 compare the microbiological count for standard dialysis results achieved over a typical six month period versus the new ultrapure plant over the past six months. As can be seen the ultrapure system has consistently returned results of TVC < 0.1 cfu per ml. In relation to microbiological quality there is no degree of tolerance from the standard TVC < 0.1 cfu per ml and < 0.03 EU per ml. In the event of a failed result all treatments are reverted to standard or high flux and a daily sampling frequency is introduced. Nightly, as opposed to the routine weekly heat sanitisations, are performed until two consecutive sets of samples are returned negative. It is only at this stage that HiVOLHDF is reintroduced.
Meanwhile, figure 8 portrays that, from a chemical quality perspective charting nitrate and fluoride as markers over a six month interval, the ultrapure plant routinely produces water which is compliant with standards.
4.6.1 KPI Water quality

A KPI is a quantitative, measurable value, whereby an organisation can rate a component against a defined standard over a period of time. It can facilitate an early warning mechanism where slight deviations from the desired outcome can trigger corrective action. In selecting KPI’s it is important to choose ones that are relevant to the particular subject matter. In relation to this organisational development project and the production of ultrapure water, the critical factor is to consistently achieve and maintain the required level of quality. Historically there has been a slightly laissez-faire approach to quality of dialysis fluids. However, with the increasing body of evidence indicating a possible relationship between long-term morbidity of patients and dialysis fluid contamination, the consensus now is to reduce contamination to the absolute minimum. (Pontoriero et al., 2003). Reassurance for the clinical team in relation to this was given by the creation of a KPI on chemical components of the water. Four key chemical components of water were selected, aluminium, calcium,
fluoride and nitrate as the markers for use in this KPI. They were selected based on their proven toxic effects on the dialysis patient; dialysis dementia, muscle weakness, bone disease and haemolysis respectively and due to the significant degree of variation in levels found in source raw water.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Normal</th>
<th>Warning (Action)</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminium ug/L</td>
<td>&lt;1</td>
<td>2.5</td>
<td>10</td>
</tr>
<tr>
<td>Calcium ug/L</td>
<td>&lt;400</td>
<td>500</td>
<td>2000</td>
</tr>
<tr>
<td>Fluoride mg/L</td>
<td>&lt;0.02</td>
<td>0.05</td>
<td>0.2</td>
</tr>
<tr>
<td>Nitrate mg/L</td>
<td>&lt;0.75</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Figure 9 highlights the normal, warning/action and the standard levels for each of the four components. The warning/action levels are designed to give an early indication that some component of the water purification process may be deteriorating and requires technical intervention. In the case of aluminium and fluoride, this would indicate that the reverse osmosis stages require attention as this process removes both. As calcium and nitrates are removed by an ion exchange process, an elevation in their levels would indicate a problem relating to the water softening stage.

In figure 10, we see the sampling frequency schedule agreed and adapted by this organisation. This schedule is based on the UK RA/ART (Renal Association/Association of Renal Technologists) clinical practice guideline (Hoenich et al., 2011).
<table>
<thead>
<tr>
<th>Contaminant</th>
<th>Recommended frequency</th>
<th>Actual frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorine</td>
<td>at least weekly</td>
<td>online 24/7</td>
</tr>
<tr>
<td>Hardness</td>
<td>daily</td>
<td>online 24/7</td>
</tr>
<tr>
<td>TVC</td>
<td>at least monthly</td>
<td>monthly</td>
</tr>
<tr>
<td>EU</td>
<td>at least monthly</td>
<td>monthly</td>
</tr>
<tr>
<td>Chemical except chlorine</td>
<td>at least every three months</td>
<td>three monthly</td>
</tr>
</tbody>
</table>

While this guideline is considered best practice Hoenich et al. state that deviations are acceptable but they need to be evidence based, documented and reflect local trends.

4.6.2 Patient Satisfaction Survey Evaluation

At the time of writing, there is a dearth of published information on the benefits, either perceived or scientifically proven, on the merits of HiVOLHDF from the patient’s perspective. However, there is plenty of anecdotal evidence where patients describe better quality of life, higher energy levels and less intradialytic symptoms. It is the author’s belief that many of the inefficiencies of standard conventional haemodialysis are not instantaneously observed, but are rather more cumulative in nature e.g. amyloid deposition and the delayed onset of carpel tunnel syndrome, and can take eight to ten years to clinically present. The corollary may also be that the true benefits of HiVOLHDF may be masked and will require a lot of time to manifest. (Merkus et al., 1999). In the continuing absence of definitive scientific evidence, it is interesting that in a survey of 6595 nephrology professions (57% physician and 28% nursing) on the subject of the best form of ‘extracorporeal dialysis’ HiVOLHDF was rated best amongst the European responses, and high-flux for the Asian and
American respondents. Significantly, only 7% had a preference for low-flux. (Ledebo & Ronco, 2008).

An anonymised patient satisfaction survey, based on the Irish Society for Quality & Safety in Healthcare (ISQSH) 2010 Hospital Inpatient Survey, was created by the author in April 2016 and issued to all patients. The primary purpose of this survey was to ascertain whether the patient experience was significantly different in the new dialysis unit versus the old. The selection criteria for inclusion were based on the fact that each patient must have been dialysed in the old unit for a minimum of two months, prior to their transfer to the new unit. This was important to ensure they had a significant experience of the old unit. Also, as the survey was performed in April, the patient’s experience of the new unit was based on use of the new facility for two months. The questionnaires were issued on a Wednesday and a Thursday which represented the second weekly treatment for all patients on a thrice weekly treatment plan. A sample of the questionnaire is included as appendix 15. and uses a one to five point scale often referred to as Likert scaling.

In total, 40 patient satisfaction surveys were completed from a total possible maximum of 44. For the purpose of this evaluation, the following questions were identified as the best criterion to gain an insight into the patient’s perspective, in relation to the environment and the overall impression.
The dialysis environment:

Chart 1

In relation to the new unit been too quiet (chart 1) almost three quarters 73% of respondents either disagreed or strongly disagreed and when asked in relation to how sociable it is (chart 2) 56% disagreed or strongly disagreed that it was less sociable when compared with the old unit. What is interesting is the close correlation with those who agreed with the statements, 18% and 20% respectively. There are two potential reasons for this; the new unit offers larger treatment areas and greater separation between patients and the background noise is dramatically reduced in the new unit.
Overall impression

Charts three and four outline the patients direct responses to a comparison of both units from an overall impression perspective. A highly significant 95% thought the new unit was excellent or good while just over half 53% had the same impressions of the old unit.

Patient wellbeing

Overall I feel better on my non dialysis days now, when compared with when I was dialysed in the old unit?

Chart 5
What the author finds significant with the results in chart 5 are that while they are not scientific and are anecdotal they do, albeit in a very small sample size, concur with the hypotheses of HiVOLHDF being perceived as offering better patient outcomes.

4.7 Dialysis and the environment

During the water purification process, water consumption is very high when creating ultrapure fluid. With technological advances, the current process of reverse osmosis has a rejection rate (concentrate) of approximately 35%. This equates to the requirement for 135 litres to create 100 litres of ultrapure water, which is approximately 300 litres per week is concentrate (reject water) in the treatment of a single patient. With previous technologies, this has been as high as 60% or approximately 500 litres for a single patient treatment. The significant efficiencies achieved have in part resulted from membrane design but also from the double pass concept.

![Diagram of water purification process](image)

With double pass reverse osmosis the reject water from the second reverse osmosis unit is fed back to the input of the first (Figure 11). The reject water from
the process of reverse osmosis is classified as ‘greywater.’ For green-field dialysis unit developments, greater efficiencies can be achieved by rerouting and using this reject water for irrigation systems and flushing of toilets etc.

4.8 Conclusion

On reflection, the author found that the adaption of the evaluation frameworks to the various components of this operational development was not an exact science. As most of the frameworks are very educational and training focused, their relevance and applicability to engineering type projects are more tenuous. However, the author did find that the ‘Logic’ and components of DECIDE and CIPP approaches were easier to apply and appeared more relevant to this organisational development. This highlights the benefit of the mixed method approach when considering both quantitative and qualitative data.
5 Conclusion

5.1 Introduction

Through the journey of this thesis, the author has introduced the technical complexities pertinent to the treatment of renal patients by dialysis. This organisational development involved applying an engineering solution to address one of the key requirements to facilitate HiVOLHDF; high quality injectable grade water i.e. ultrapure water. In addition, this involved relocation of the existing inpatient acute dialysis unit to a fit for purpose, and technically state-of-the-art facility. This also addressed issues of non-compliance with recommended best practice in a number of areas, notably the introduction of a dedicated isolation zone for patients requiring isolation.

5.2 Project Impact

From the literature review, it has been unequivocally demonstrated that water quality is an essential component to the dialysis process. However, as of 2016, there is not a scientific consensus with regard to whether HiVOLHDF is a superior treatment of ESRD patients with regard to mortality and morbidity. Whilst this may be the current case, it is the author’s belief that this will be forthcoming in due course. In the interim, it should be considered best practice to strive towards implementation of ultrapure water systems in all dialysis units and in particular, whilst performing HiVOLHDF, while we await the evidence. This viewpoint is compounded by the fact that there have been no negative reports from the studies reviewed, relating to patient outcomes with HiVOLHDF versus alternative conventional haemodialysis treatments. In addition, it would definitely seem prudent that when designing new dialysis facilities, ultrapure water should be the standard specification.
5.2.1 Culture
The author has, and benefits from, working in an organisation where a culture of continually striving for excellence in both patient care and patient outcomes predominately prevails. The culture was evident during this organisational development project from its initial conceptual stage in 2011 with all internal stakeholders, through to its implementation in 2016. Working in this environment adds synergy to projects of this nature, and in such a large organisation there is a continual evolving process of change and a corporate buy-in exists, adding momentum and traction to the change management. (Weick & Quinn, 1999).

5.2.2 Theory
"Change is the law of life and those who look only to the past or present are certain to miss the future." (John. F. Kennedy).

In relation to organisational change we have discovered that various theories and models exist. From the initial, quite restrictive linear three step model by Lewin to the extended Kotter’s eight step model, which again, as discovered, proved quite restrictive, limited and lacking in comparison to the more applicable and relevant Senior & Swailes and HSE models. These latter two models incorporate feedback and an interconnected system of interconnectivity between the phases. This enables a fine tuning and continuous monitoring of all phases but in addition facilitates the change agent to modify phases mid process. While the author is of the belief that there is not a one size fits all model in relation to organisational change, the HSE model was the best fit for this particular organisational development. It’s clearly defined phases of IPIM (Initiation, Planning, Implementation & Mainstreaming) offered a clearly logical process to implement and monitor this
project from inception to delivery. We also explored the significance of resistance, power, influence, culture and the importance of leadership from the change agent.

Following this, we explored the process of evaluation and its significance in relation to organisational development. As discussed, numerous evaluation frameworks exist and again similar to the change models there is not a one size fits all. Best practice would appear to be a marriage of the best components of many, which can be adapted to the specific organisational change project. In relation to the quantitative analysis, for this operational development, it has been proven that ultrapure water is consistently and reliably reproducible using standard water purification technologies. Regarding the qualitative analysis, in the patient and staff satisfaction surveys it was fascinating to find that the softer ‘feel good’ factors as reported by the patients in the new unit dominated results.

5.3 Strengths
This organisational development project has given the author the opportunity to experience the numerous and intricate aspects of managing change and its many components. A significant achievement was achieving ultrapure water and thereby HiVOLHDF, and a dedicated patient isolation area within this new state of the art facility. It has also highlighted the importance of collaboration, communication and compromise by all stakeholders to achieve a vision under the guidance of the change agent.

5.4 Limitations
As highlighted in the first SWOT analysis, the most pressing limitation of this organisational development project is the increased capacity. From the statistics
quoted in chapter 1, the requirement for dialysis is increasing globally, therefore within five years it is conceivable that this organisation will require greater treatment capacity.

5.5 Recommendations

The possibility of the combination of certain aspects of current treatment modalities appears to be very much a live reality in the near future. In this way, there is a realistic hope that more beneficial patient outcomes particularly in relation to treatment quality, mortality and morbidity, can be provided. The endless possibilities of change coupled with the continuous development of new technologies bode well for all future medical treatments particularly in relation to patients requiring treatment of ESRD. To realise the future and to make all technological innovations a reality for all patients in need of renal replacement therapies, technical acumen and leadership is required to ensure the change is proven, assimilated and becomes the new way 'we do things'.

5.6 Conclusion

Finally, some years ago in 1991 as a recently qualified clinical engineer MSc at one of London’s largest teaching hospitals, I often recall a conversation with a PhD qualified clinical engineering colleague who entered the still emerging profession 15 years previously. He relayed a conversation he had in 1986 with an eminent consultant nephrologist. The consultant questioned the relevance of such a highly skilled and qualified clinical engineer applying himself to the speciality of haemodialysis, as 'all the technical developments associated with the treatment of patients with kidney failure had been accomplished'. I regularly recall this conversation been relayed by my colleague and mentor, with a wry smile. Today, I
also reflect that some thirty years later and with many ground breaking innovative technological advances, we still appear to be a significant distance away from a consensus on some of the highly technical, but fundamental functions of the nephron and more specifically the glomerulus in relation to molecular clearance in the treatment of ESRD patients by any modality of haemodialysis. In the past 25 years alone, examples of technological advancements include moving from acetate-based dialysis to the more biocompatible bicarbonate, closed loop ultrafiltration for fluid removal, the revolution in water purification technologies, urea kinetic modelling, relative and actual blood volume monitoring, real time fistula recirculation monitoring, heparin free dialysis and on-line molecular clearance. There is currently no reason to believe that HiVOLHDF won’t be the next breakthrough.
References


doi:10.1053/j.ajkd.2015.11.016


doi:10.5301/jn.5000046

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doi:10.1093/ndt/gfq761


Schiffl, H. (2007). Prospective Randomized Cross-over Long-term Comparison of


Tiranathanagul, K., Praditpornsilpa, K., Katavetin, P., Srisawat, N., Townamchai, N.,


Hemodiafiltration, pp.41-55.

Appendices

Appendix 1  Stakeholder analysis (1)

KEEP SATISFIED
Board of Management
Finance
Internal Estates department
Director of Scheduled Care

MANAGE CLOSELY
HSE
IEHG
National Renal Office
Medical Director
Director of Unscheduled Care

KEEP INFORMED
Nephrology staff
Clinical Engineering staff
Irish Kidney Association
Patients

MONITOR
(MINIMUM EFFORT)
External Contractors
Specialised Contractors

INFLUENCE

INTEREST
Appendix 2  Stakeholder analysis (2)

<table>
<thead>
<tr>
<th>INFLUENCE</th>
<th>INTEREST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>

- **KEEP SATISFIED**
  - Board of Management
  - Finance
  - Internal Estates department

- **MANAGE CLOSELY**
  - HSE
  - IEHG
  - National Renal Office
  - Medical Director
  - Director of Scheduled Care

- **MONITOR (MINIMUM EFFORT)**
  - External Contractors
  - Specialised Contractors

- **KEEP INFORMED**
  - Nephrology staff
  - Clinical Engineering staff
  - Irish Kidney Association
  - Patients
Appendix 3  SWOT (1)

SWOT Analysis

**Strengths**
- HiVOLHDF
- Isolation requirements

**Weaknesses**
- Limited expansion capabilities

**Opportunities**
- Create state of the art facility
- Ultrapure water

**Threats**
- Pre-dialysis and CAPD
- ICT

Appendix 4  SWOT (2)

SWOT Analysis 2

**Strengths**
- HiVOLHDF
- Isolation requirements

**Weaknesses**
- Limited expansion capabilities

**Opportunities**
- Create state of the art facility
- Ultrapure water

**Threats**
- Pre-dialysis and CAPD
- ICT
- Departure of key stakeholder
### Appendix 5  Chemical constituents of drinking water versus dialysis water

PMC full text:  [Semin Dial. Author manuscript; available in PMC 2015 Oct 7.](#)

## Chemical limits allowable in municipal drinking water and dialysis water (5,11,23)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Municipal drinking water</th>
<th>Health effect</th>
<th>Dialysis water</th>
<th>Health effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxic chemicals (mg/l)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aluminum(^1)</td>
<td>0.05–0.2</td>
<td>Anemia, osteomalacia</td>
<td>0.01</td>
<td>“Dialysis dementia”</td>
</tr>
<tr>
<td>Chloramine(^2)</td>
<td>4.0</td>
<td>Eyes, nose; GI discomfort, anemia</td>
<td>0.1 (^3)</td>
<td>Acute hemolytic anemia</td>
</tr>
<tr>
<td>Chlorine(^2)</td>
<td>4.0</td>
<td>Eyes, nose; GI discomfort, anemia</td>
<td>0.5 (^3)</td>
<td></td>
</tr>
<tr>
<td>Total chlorine</td>
<td>–</td>
<td></td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>Copper(^2)</td>
<td>1.3</td>
<td>GI distress, liver/kidney</td>
<td>0.1</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) EPA 1537.1

\(^2\) EPA 1537.2

\(^3\) FDA 21CFR 1610.10
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Municipal drinking water</th>
<th>Health effect</th>
<th>Dialysis water</th>
<th>Health effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoride</td>
<td>4.0</td>
<td>Bone disease</td>
<td>0.2</td>
<td>Toxicity, bone disease</td>
</tr>
<tr>
<td>Lead&lt;sup&gt;2&lt;/sup&gt;</td>
<td>0.015</td>
<td>Neurological damage, fatal</td>
<td>0.005</td>
<td>GI pain, muscle hemolysis</td>
</tr>
<tr>
<td>Nitrate (as N)</td>
<td>10</td>
<td>Blue-baby syndrome, shortness breath</td>
<td>2.0</td>
<td>Methemoglobinemia</td>
</tr>
<tr>
<td>Sulfate</td>
<td>–</td>
<td></td>
<td>100</td>
<td>Nausea, metabolic acidosis</td>
</tr>
<tr>
<td>Zinc</td>
<td>–</td>
<td>Nausea, vomiting, fever, anemia</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>Trace elements</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antimony</td>
<td>0.006</td>
<td></td>
<td>0.006</td>
<td></td>
</tr>
<tr>
<td>Arsenic</td>
<td>0.010</td>
<td></td>
<td>0.005</td>
<td></td>
</tr>
</tbody>
</table>

<sup>2</sup> Lead is a cumulative toxicant.
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Municipal drinking water</th>
<th>Health effect</th>
<th>Dialysis water</th>
<th>Health effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barium</td>
<td>2</td>
<td></td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>Beryllium</td>
<td>0.004</td>
<td></td>
<td>0.0004</td>
<td></td>
</tr>
<tr>
<td>Cadmium</td>
<td>0.005</td>
<td></td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>Chromium</td>
<td>0.10</td>
<td></td>
<td>0.014</td>
<td></td>
</tr>
<tr>
<td>Mercury</td>
<td>0.002</td>
<td></td>
<td>0.0002</td>
<td></td>
</tr>
<tr>
<td>Selenium</td>
<td>0.05</td>
<td></td>
<td>0.09</td>
<td></td>
</tr>
<tr>
<td>Silver¹</td>
<td>0.10</td>
<td></td>
<td>0.005</td>
<td></td>
</tr>
<tr>
<td>Thallium</td>
<td>0.002</td>
<td></td>
<td>0.002</td>
<td></td>
</tr>
</tbody>
</table>

¹This limit is part of the National Secondary Drinking Water Regulation, which is nonenforceable.

²This is the highest allowable limit in drinking water, defined as the Maximum Residual Disinfectant Level.

³Chloramine and Free Chlorine limits are only listed in the CMS standards, not in the ANSI/AAMI/ISO recommendations.

⁴This limit is the action level if more than 10% of samples exceed this threshold.
Microbial standards for municipal drinking water, dialysis water, and dialysate (standard and ultrapure) \((2, 5–8, 11, 23)\). The heterotrophic bacteria (HPC) and Total Viable Count are comparable when using Reasoners 2A (R2A) for 7 days at 17–23°C.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Municipal drinking water</th>
<th>Conventional dialysis water</th>
<th>Conventional dialysate/Dialysis fluid</th>
<th>Ultrapure dialysate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heterotrophic bacteria (HPC)</td>
<td>(\leq 500) CFU/ml</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Total Viable Count</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMS max allowable limit(^1)</td>
<td>–</td>
<td>(&lt; 200) CFU/ml</td>
<td>(&lt; 200) CFU/ml</td>
<td>(&lt; 0.1) CFU/ml</td>
</tr>
<tr>
<td>CMS action level(^1, 2)</td>
<td>–</td>
<td>50 CFU/ml</td>
<td>50 CFU/ml</td>
<td>–</td>
</tr>
<tr>
<td>ANS max allowable limit(^3)</td>
<td>–</td>
<td>(&lt; 100) CFU/ml</td>
<td>(&lt; 100) CFU/ml</td>
<td>(&lt; 0.1) CFU/ml</td>
</tr>
<tr>
<td>Parameter</td>
<td>Municipal drinking water</td>
<td>Conventional dialysis water</td>
<td>Conventional dialysate/Dialysis fluid</td>
<td>Ultrapure dialysate</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------------</td>
<td>----------------------------</td>
<td>---------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>ANS action level&lt;sup&gt;1,2&lt;/sup&gt;</td>
<td>50 CFU/ml</td>
<td>50 CFU/ml</td>
<td></td>
<td>–</td>
</tr>
</tbody>
</table>

**Endotoxin**

<table>
<thead>
<tr>
<th>CMS max allowable limit&lt;sup&gt;1&lt;/sup&gt;</th>
<th>&lt;2 EU/ml</th>
<th>&lt;2 EU/ml</th>
<th>&lt;0.03 EU/ml</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>CMS action level&lt;sup&gt;1,2&lt;/sup&gt;</th>
<th>1 EU/ml</th>
<th>1 EU/ml</th>
<th>–</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>ANS max allowable limit&lt;sup&gt;1&lt;/sup&gt;</th>
<th>&lt;0.25 EU/ml</th>
<th>&lt;0.5 EU/ml</th>
<th>&lt;0.03 EU/ml</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>ANS action level&lt;sup&gt;1,2&lt;/sup&gt;</th>
<th>0.125 EU/ml</th>
<th>0.25 EU/ml</th>
<th>–</th>
</tr>
</thead>
</table>

<sup>1</sup>The Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services set the regulations for maximum allowable limits and action levels for dialysis facilities to be certified under the Medicare program (<sup>5</sup>); these are currently based upon the 2004 recommendations from the Association for the Advancement of Medical Instrumentation (AAMI) (<sup>6</sup>).<sup>2</sup>The action level is the concentration at which corrective measures are to be immediately conducted to reduce the bacteria and/or endotoxin levels, which are typically 50% of the maximum allowable level.<sup>3</sup>The American National Standard (ANS) published through American National Standards Institute (ANSI)/AAMI/International Organization for Standardization (ISO) are voluntary, recommended practices for dialysis water (<sup>8</sup>,<sup>11</sup>) and dialysis fluid (<sup>7</sup>,<sup>8</sup>).

---

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Appendix 7 United States Pharmacopeia and European Pharmacopeia standards

<table>
<thead>
<tr>
<th></th>
<th>Purified Water</th>
<th>Highly Purified Water</th>
<th>Water For Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process</strong></td>
<td>Distillation, reverse osmosis and any other suitable process</td>
<td>Distillation, ice exchange, reverse osmosis and any other suitable process</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Conductivity</strong></td>
<td>≤ 1.3 µS/cm @ 25°C</td>
<td>≤ 4.3 µS/cm @ 20°C</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Bacteria</strong></td>
<td>100 cfu/ml (suggested)</td>
<td>&lt; 100 cfu/ml</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Endotoxin</strong></td>
<td>N/A</td>
<td>&lt; 0.25 IU/ml (only for bulk water for dialysis)</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>TDC</strong></td>
<td>500 ppb</td>
<td>≤ 0.5 mg/l</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>5.7</td>
<td>5.7</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Nitrates</strong></td>
<td>N/A</td>
<td>≤ 0.2 ppm</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Heavy metals</strong></td>
<td>N/A</td>
<td>≤ 0.1 ppm</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Aluminium</strong></td>
<td>N/A</td>
<td>≤ 10 ppb (if intended for use in the manufacture of dialysis solutions)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

- EP (European Pharmacopoeia); (2002)
- USP (United States Pharmacopoeia).
Appendix 8  New facility schematic
Appendix 9 New plant room schematic
## Sample chemical results

**Chemical Analysis Laboratories Ltd Confidential Report No. W21863**

<table>
<thead>
<tr>
<th>Semi Quant Screen</th>
<th>Whistwater V19 RO 2 New Plant Lab No. 53830</th>
<th>Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Sulphur (mg/l)</td>
<td>&lt;0.11</td>
<td></td>
</tr>
<tr>
<td>Total Cadmium (µg/l)</td>
<td>&lt;0.006</td>
<td>1.0</td>
</tr>
<tr>
<td>Total Mercury (µg/l)</td>
<td>0.68</td>
<td>0.2</td>
</tr>
<tr>
<td>Total Zinc (µg/l)</td>
<td>&lt;2.2</td>
<td>100</td>
</tr>
<tr>
<td>Total Potassium (µg/l)</td>
<td>&lt;900</td>
<td>2,000</td>
</tr>
<tr>
<td>Total Magnesium (µg/l)</td>
<td>&lt;0.2</td>
<td>2,000</td>
</tr>
<tr>
<td>Total Nickel (µg/l)</td>
<td>0.20</td>
<td></td>
</tr>
<tr>
<td>Total Aluminum (µg/l)</td>
<td>&lt;1.90</td>
<td>10</td>
</tr>
<tr>
<td>Total Calcium (µg/l)</td>
<td>&lt;900</td>
<td>2,000</td>
</tr>
<tr>
<td>Total Iron (µg/l)</td>
<td>&lt;5.60</td>
<td></td>
</tr>
<tr>
<td>Total Chromium (µg/l)</td>
<td>&lt;3.51</td>
<td>14</td>
</tr>
<tr>
<td>Total Boron (µg/l)</td>
<td>1.2</td>
<td>100</td>
</tr>
<tr>
<td>Total Tin (µg/l)</td>
<td>&lt;0.16</td>
<td>100</td>
</tr>
<tr>
<td>Total Cobalt (µg/l)</td>
<td>&lt;0.07</td>
<td></td>
</tr>
<tr>
<td>Total Lead (µg/l)</td>
<td>&lt;0.01</td>
<td>5.0</td>
</tr>
<tr>
<td>Total Arsenic (µg/l)</td>
<td>&lt;0.18</td>
<td>5.0</td>
</tr>
<tr>
<td>Total Antimony (µg/l)</td>
<td>&lt;0.033</td>
<td>6.0</td>
</tr>
<tr>
<td>Total Manganese (µg/l)</td>
<td>&lt;2.60</td>
<td></td>
</tr>
<tr>
<td>Total Barium (µg/l)</td>
<td>&lt;0.5</td>
<td>100</td>
</tr>
<tr>
<td>Total Beryllium (µg/l)</td>
<td>&lt;0.14</td>
<td>0.4</td>
</tr>
<tr>
<td>Total Molybdenum (µg/l)</td>
<td>&lt;0.480</td>
<td></td>
</tr>
<tr>
<td>Total Strontium (µg/l)</td>
<td>&lt;0.39</td>
<td></td>
</tr>
<tr>
<td>Total Vanadium (µg/l)</td>
<td>0.08</td>
<td></td>
</tr>
<tr>
<td>Total Selenium (µg/l)</td>
<td>&lt;0.31</td>
<td>500</td>
</tr>
<tr>
<td>Total Thallium (µg/l)</td>
<td>0.24</td>
<td></td>
</tr>
<tr>
<td>Total Phosphorus (µg/l)</td>
<td>&lt;21.0</td>
<td></td>
</tr>
<tr>
<td>Total Sodium (µg/l)</td>
<td>&lt;5.10</td>
<td>50,000</td>
</tr>
<tr>
<td>Total Silver (µg/l)</td>
<td>&lt;0.4</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix 11  Ultrapure water standards

<table>
<thead>
<tr>
<th>Contaminant</th>
<th>Drinking water standards: mg/l&lt;sup&gt;10&lt;/sup&gt;</th>
<th>Standard dialysis water mg/l&lt;sup&gt;11,12&lt;/sup&gt;</th>
<th>Ultrapure dialysis fluid</th>
<th>Symptoms and disease associations:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminium</td>
<td>0.1</td>
<td>0.01</td>
<td></td>
<td>Anaemia, neuropathy, bone disease</td>
</tr>
<tr>
<td>Total chlorine</td>
<td>5</td>
<td>0.1</td>
<td></td>
<td>Haemolysis</td>
</tr>
<tr>
<td>Chloramine&lt;sup&gt;3&lt;/sup&gt;</td>
<td>3</td>
<td>0.1</td>
<td></td>
<td>Haemolysis</td>
</tr>
<tr>
<td>Copper</td>
<td>2</td>
<td>0.1</td>
<td></td>
<td>Haemolysis</td>
</tr>
<tr>
<td>Fluoride</td>
<td>1.5</td>
<td>0.2</td>
<td></td>
<td>Bone disease</td>
</tr>
<tr>
<td>Lead</td>
<td>0.01</td>
<td>0.005</td>
<td></td>
<td>Haemolysis, neuropathy, goitre&lt;sup&gt;14&lt;/sup&gt;</td>
</tr>
<tr>
<td>Nitrate</td>
<td>50 - 100</td>
<td>2</td>
<td></td>
<td>Hypotension, Haemolysis</td>
</tr>
<tr>
<td>Sulphate</td>
<td>250</td>
<td>100</td>
<td></td>
<td>Acidosis</td>
</tr>
<tr>
<td>Zinc</td>
<td>3</td>
<td>0.1</td>
<td></td>
<td>Anaemia</td>
</tr>
<tr>
<td>Antimony</td>
<td>0.003</td>
<td>0.006</td>
<td></td>
<td>Encephalopathy, cancer&lt;sup&gt;15,16&lt;/sup&gt;</td>
</tr>
<tr>
<td>Arsenic</td>
<td>0.01</td>
<td>0.005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barium</td>
<td>2</td>
<td>0.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beryllium</td>
<td>0.06</td>
<td>0.0004</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cadmium</td>
<td>0.002</td>
<td>0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chromium</td>
<td>0.05</td>
<td>0.014</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mercury</td>
<td>0.001</td>
<td>0.0002</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selenium</td>
<td>0.01</td>
<td>0.09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Silver</td>
<td>0.1</td>
<td>0.005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thallium</td>
<td>NS</td>
<td>0.002</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Copper</td>
<td>2</td>
<td></td>
<td></td>
<td>Anaemia</td>
</tr>
<tr>
<td>Calcium</td>
<td>200</td>
<td>2 (0.05)</td>
<td></td>
<td>Muscle weakness</td>
</tr>
<tr>
<td>Magnesium</td>
<td>TDS (600)</td>
<td>4 (0.15)</td>
<td></td>
<td>Muscle weakness</td>
</tr>
<tr>
<td>Sodium</td>
<td>180</td>
<td>70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potassium</td>
<td>TDS</td>
<td>8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Microbiological criteria:**

- **Microbial count (CFU/ml)<sup>11</sup>**
  - Individuaal bacterial levels, eg Ecoli: < 100 CFU/ml
  - <0.1 CFU/ml<sup>11</sup> Hypotension, inflammation

- **Endotoxin Concentration EU/ml**
  - NS < 0.25 EU/ml
  - <0.03 EU/ml Hypotension, inflammation

---

1. ISO 2009 standards for haemodialysis water recommend ultra pure water for routine dialysis, defined as a microbial count < 0.1 cfu/ml and an endotoxin concentration <0.03EU/ml.
2. Total dissolved solids (TDS) consist of inorganic salts and small amounts of organic matter that are dissolved in water. The palatability of drinking water has been rated according to TDS concentrations. High TDS values, apart from taste, may also be associated with excessive scaling in pipes, fittings and household appliances.
Appendix 12  Sample microbial results

Final Chemical Analysis Laboratories Ltd Confidential Report No.W21846

<table>
<thead>
<tr>
<th>Lab. No.</th>
<th>Your ID</th>
<th>Total Viable Count (c.f.u./ml)</th>
<th>Bacterial Endotoxin (EU/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>53814</td>
<td>Whitewater V19</td>
<td>&lt;0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td></td>
<td>RO 2 New Plant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>53815</td>
<td>Whitewater No. 2 Plant</td>
<td>&lt;0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td></td>
<td>End of Line</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CAL Ltd
Hudson Road
Sandyoeve
Co. Dublin
Ireland
Tel: Dublin = 353 1 286 0755
Tel: Dunboy = 353 1 286 0781
Fax: Dunboy = 353 1 286 0781
VAT No: IE 6326425L

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### Final Chemical Analysis Laboratories Ltd Confidential Report No. W22014

<table>
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<tbody>
<tr>
<td>Invoice Number</td>
<td>22014</td>
</tr>
<tr>
<td>Laboratory Number(s)</td>
<td>54073-54081</td>
</tr>
<tr>
<td>Your Order Number</td>
<td>161000999</td>
</tr>
<tr>
<td>Number of Samples</td>
<td>9</td>
</tr>
<tr>
<td>Sample Description</td>
<td>Water from Fresenius OLV HDF DC 29/02/16. Received 29/02/16</td>
</tr>
<tr>
<td>Date Reported</td>
<td>11/03/16</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lab. No.</th>
<th>Your ID</th>
<th>Total Viable Count (c.f.u./ml)</th>
<th>Bacterial Endotoxin (EU/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>54073</td>
<td>No. 15</td>
<td>&lt;0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td>54074</td>
<td>No. 17</td>
<td>&lt;0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td>54075</td>
<td>No. 18</td>
<td>&lt;0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td>54076</td>
<td>No. 24</td>
<td>&lt;0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td>54077</td>
<td>No. 26</td>
<td>&lt;0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td>54078</td>
<td>No. 27</td>
<td>&lt;0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td>54079</td>
<td>No. 29</td>
<td>&lt;0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td>54080</td>
<td>No. 32</td>
<td>&lt;0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td>54081</td>
<td>No. 34</td>
<td>&lt;0.1</td>
<td>&lt;0.03</td>
</tr>
</tbody>
</table>

---

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### Chemical Analysis Laboratories Ltd Confidential Report No. W15871

<table>
<thead>
<tr>
<th>Laboratory Number</th>
<th>Your ID</th>
<th>Total Viable Count (c.f.u./ml)</th>
<th>Bacterial Endotoxin (EU/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>37981</td>
<td>No. 3 Fresenius Post Diasafe</td>
<td>0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td>37982</td>
<td>No. 6 Fresenius Post Diasafe</td>
<td>&lt;0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td>37983</td>
<td>No. 7 Fresenius Post Diasafe</td>
<td>0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td>37984</td>
<td>No. 8 Fresenius Post Diasafe</td>
<td>&lt;0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td>37985</td>
<td>No. 11 Fresenius Post Diasafe</td>
<td>&lt;0.1</td>
<td>&lt;0.03</td>
</tr>
<tr>
<td>37986</td>
<td>Loan No.1 Fresenius Post Diasafe</td>
<td>5.4</td>
<td>&gt;0.03</td>
</tr>
<tr>
<td>37987</td>
<td>Loan No.14 Fresenius Post Diasafe</td>
<td>0.3</td>
<td>&lt;0.03</td>
</tr>
</tbody>
</table>

Invoice Total: €660.65
Appendix 15  
Patient satisfaction survey

Dear Patient, here at XXXXXXX we continuously strive to ensure our patients experience is the best possible whilst you use our facilities. We would be delighted if you would complete this short anonymous questionnaire on your experience and opinions of the new dialysis facility when compared to the old.

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
<th>Not relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am always treated with dignity and respect.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The new dialysis unit offers a better patient experience when compared to the old.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In the new unit I have more privacy.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If I had to choose I would prefer to be dialysed in the new unit.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The level of background noise I experience in the new unit is more acceptable than the old unit.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The new unit is less sociable.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Members of my healthcare team make sure that they explained what they are going to do before they did it.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The purpose of tests/procedures/new medication are always explained to me.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The new unit is a better environment to be dialysed in compared to the old.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>During my treatment sessions I can relax more in the new unit when compared to the old.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I would recommend this new unit to a friend or family member if they needed similar treatment.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall I feel better on my non dialysis days now when compared with when I was dialysed in the old unit.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The new unit is too quiet.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If I needed assistance it was always given in a timely manner by staff in the unit.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Overall impression [please tick one for the new unit and the old unit]

<table>
<thead>
<tr>
<th></th>
<th>New Unit</th>
<th>Old Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fair</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

111
Appendix 16 Poster abstract

Abstract

Water quality is fundamental to haemodialysis regardless of the modality; it has two distinct strands namely chemical quality and microbiological quality. However, the water quality is far more critical with the high volume online haemodialfiltration (HIVOLHDF)* modality of treatment. A typical adult will be exposed to approximately fourteen litres of water a week. This is ingested orally, absorbed via the gastrointestinal tract, any excess is removed by the nephron in the kidney and exits the body with other waste products of metabolism in the urine. By contrast, the standard thrice weekly haemodialysis patient is exposed to 678 litres per week via the semipermeable dialysate. In addition, the high volume online HDF patient is exposed typically to an additional 60 L per week which is infused directly into the patient’s blood stream. Furthermore, as the majority of End Stage Renal Disease (ESRD) patients have zero, or very minimal residual renal function, toxins in the blood remain and cannot be renally excreted between dialysis sessions.

From the literature review, it has been unequivocally demonstrated that water quality is an essential component to the dialysis process. However, as of 2016 there is not a scientific consensus with regard to whether HIVOLHDF is a superior treatment of ESRD patients with regard to mortality and morbidity. Whilst this may be the current case, it is the author’s belief that this will be forthcoming in due course. In the interim, it should be considered best practice to strive towards implementation of ultrapure water systems in all dialysis units and performing HIVOLHDF while we await the evidence. This viewpoint is compounded by the fact that there have been no negative reports from the studies reviewed relating to patient outcomes when treatment by HIVOLHDF versus alternative conventional haemodialysis treatments. In addition, it would definitely seem prudent that when designing new dialysis facilities, ultrapure water should be considered the standard specification.

*The acronym HIVOLHDF has been developed by the author for the purpose of this poster and the accompanying thesis.
Appendix 16 Poster

Improving Dialysis Patient Outcomes
Introducing ultrapure water to facilitate HiVOLHDF: An engineer’s perspective
Dean P. Murray  Student number: 11600084

Introduction & Background

The existing acute dialysis unit is sub-standard (circa 1995) from numerous critical aspects. The water quality is sufficient for standard and high flux dialysis but the existing purification equipment does not have the capability of meeting the stringent requirements proven as necessary for HiVOLHDF. The current environment is not suited to the treatment of dialysis patients in a setting that is in sympathy with best care surroundings. Finally, the current facility does not comply with guidelines for the treatment of isolated patients accreditation and fire regulations.

Aim & Objectives

Aim:
Relocate and expand the existing acute inpatient haemodialysis service to a new refurbished and fit-for-purpose location. This new facility will provide ultrapure water to facilitate HiVOLHDF.

Objectives:
- By June 30th 2015, complete and submit a business case to the National Renal Office for approval of funding.
- By August 21st 2015, have the contractors’ schematics for the new unit agreed by all stakeholders.
- From 6th October 2015, commence installation of water purification plant and associated ring mains.
- By 7th December 2015, commence commissioning and validation of water purification plant.
- By 6th February 2016, transfer acute haemodialysis services to the new unit.

Methodology

The HSE change model (Fig 1) was chosen as a framework for the implementation of this OD

Fig 1: HSE Change model

Initiation stage
- Stakeholder analysis
- PESTLE
- SWOT

Planning stage
- Communication
- Agreement on water plant specification
- Prepare for implementation

Implementation stage
- Commission and validate water plant

Mainstreaming stage
- Evaluating and maintaining the ultrapure water quality

Evaluation

For the evaluation on water quality the CIPP framework was used.

Fig 2: CIPP Evaluation framework

Evaluation
- Content Evaluation
- Context Evaluation
- Impact Evaluation
- Outcome Evaluation

Evaluation Table

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Normal</th>
<th>Desired</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminium (μg/L)</td>
<td>&lt;25</td>
<td>25</td>
<td>30</td>
</tr>
<tr>
<td>Calcium (mg/L)</td>
<td>100</td>
<td>90</td>
<td>100</td>
</tr>
<tr>
<td>Magnesium (mg/L)</td>
<td>1.35</td>
<td>1.2</td>
<td>1.6</td>
</tr>
<tr>
<td>Chloride (mg/L)</td>
<td>98</td>
<td>90</td>
<td>120</td>
</tr>
</tbody>
</table>

Evaluation Table

Organisational Impact

- HiVOLHDF using ultrapure water is performed.
- Compliant with JCI standards for dialysis patients in isolation.

Conclusion

As demonstrated in the organisational development, ultrapure water is readily achievable using current technologies. With the known benefits and the emerging potential future benefits, it should be considered the standard for all haemodialysis treatments.

References