Management of Water Quality for Home Hemodialysis Programs in Canada

by

Sejal Pradeepkumar Dave

A thesis submitted in partial fulfillment of the requirements for the degree of

Master of Science

in

Health Policy Research

School of Public Health

University of Alberta

Thesis Abstract

Background: Hemodialysis (HD) is a life-sustaining treatment for people with end-stage renal disease(ESRD). ESRD patients could experience severe adverse events when the water used during their HD treatments is not of the quality needed for its safe operation. The role of water quality in HD treatments is, therefore, critical. In Canada, home hemodialysis (HHD) as a treatment modality of HD is in great demand, creating the need to understand how water-related aspects influence its wide-scale implementation.

Methods: This thesis included 2 studies: 1) a scoping review (SR) and 2) a qualitative analysis. The SR synthesized and contrasted the existing standards and guidelines on water-related aspects of HHD. The second study collected qualitative data through semi-structured interviews with 18 healthcare professionals from 6 Canadian HHD programs. Participants were asked to comment on the structure and process of managing HD water quality and identify perceived influencing factors to the delivery of safe water within them. A thematic analysis (TA) method was used to analyze interview data related to perceived enablers and barriers to water quality management.

Results: The scoping review found 13 organizations that mandated HHD programs to establish the process surrounding the following 3 main water-related topics: quality criteria, water purification system, and quality management. The included organizations derived their statements based on other organizations, clinical studies, experimental studies, and expert opinions. Organizations varied in their established statements on (1) the number of parameters included in water quality criteria, (2) permissible levels for chemical parameters, (3) the type of microbial grade of water to be used for HD, and the monitoring plan.

The qualitative analysis revealed 4 main themes: current practices for the HHD care process, perceived barriers of and facilitators to water quality management, suggestions discussed to overcome the identified barriers, and approaches to addressing non-compliance. In the first theme, participants identified the HHD care process steps in managing their programs' water-related aspects. Mainly, the differences existed across the participating home programs on their approaches to implementing quality management of water quality.

In the second theme, several factors connected to a built environment that created challenges/barriers were identified. In the third theme, the lack of resources was discussed as a barrier to microbial quality testing and device care, including cost for sufficient staffing, staff travel time, heavy workload requirements for sampling collections and transportation, and patient non-compliance. Participants viewed the requirements of the Canadian Standards Association (CSA) on microbial testing as impractical.

Several facilitators overcoming the challenges of home modifications were identified, including source water suppliers and manufacturers for helping with customization of devices, and patients organizations and tax rebates providing financial help to patients in paying their utility bills. Implementing policies and procedures for tracking data and ensuring timely access to patients' homes helped with device maintenance. The use of point-of-care testing for bacterial counts, when used by patients, was identified as a facilitator for performing testing.

Conclusion: The organizations issuing statements on water-related aspects of HHD have covered all the essential topics needed for the safe delivery of HHD; however, most organizations have left the decision-making on how to implement them in individual dialysis facilities to a large extent. The variations across organizations on their established statements

related to water quality criteria and microbial monitoring could lead to differences in patient outcomes and resource utilization. Therefore, this area needs further exploration. This thesis's qualitative study was conducted with the hope of generating evidence in that direction. It revealed several factors that hindered or created challenges in managing water-related aspects in Canadian HHD programs and implementing the CSA's statements. Such knowledge would provide a basis for HHD programs to initiate their efforts towards improving their implementation process by developing strategies targeted at overcoming them and for which the identified facilitators would be helpful. This research would also benefit the CSA organization to develop contextualized statements on managing HHD water quality by considering and addressing the local implementation issues in subsequent revisions.

Preface

This thesis is an original work by Sejal Dave. The third chapter of this thesis received research ethics approval from the University of Alberta Research Ethics Board, Project Name "Management of Dialysis Water and Dialysate Quality for Home Hemodialysis Programs in Alberta", Study ID Pro000881801, May 30, 2018.

Acknowledgements

I would start writing acknowledgements with the ancient Sanskrit Mantra:

> From ignorance, lead me to truth;
>
> From darkness, lead me to light;
>
> From death, lead me to immortality
>
> Om peace, peace, peace

This mantra is a prayer to God to take a person from ignorance to knowledge. I am thankful to my supervisor Dr. Devidas Menon, and my supervisory committee members, Dr. Tania Stafinski and Dr. Robert Pauly. They played the roles of Gods in my life in last 5 years. I started this project with minimum knowledge and lots of uncertainty on how will I accomplish my goal. But their continued support and their comments have made this work happen. Now, when I look back at my first draft of proposal, I realize that with their continuous guidance I have come a long way. I thank you very much for your patience and trusting my abilities to do this research work. I would like to thanks to the other members of the Health Technology and Policy Unit for their guidance, support, and on top, giving me love and care at work.

I would like to thank all my study participants for giving me their time and sharing their experiences. Without them, this research would not have been possible. I hope I have done a good job in communicating their experiences so that this research can be taken further in helping healthcare professionals in managing water quality in their home programs.

I must acknowledge my family members; without their emotional and financial support, I could not have completed this thesis work. The unconditional love of my daughter Khushi and my niece Aarav was the greatest strength in finishing my project. Thank you, my sister, for saying to me constantly, keep going! I thank my husband and my friends for listening to my worries and giving me their time to discuss what approach I should take in my thesis. I cannot complete this acknowledgment without thanking my parents and in-laws for giving me endless support in taking care of my family in my absence.

I want to thank the pillars of my life, my spiritual guides, and the gurus who gave me the internal power to complete this thesis. I thank you, Shri Rupa Majmundar, Reiki Master, Avdhoot Baba Shivananda, Shri Sadhguru, and Mahant Swami for always sending me positive vibes. I bow down to Lord Shiva-Shakti and Swaminarayan Bhagwan!

Table of Contents

Chapter-1: Introduction **1**
Chapter-2: Scoping Review of Existing Standards and Guidelines for the Quality of Water in Hemodialysis at Home Settings **7**
Introduction **7**
Background 8
Clinical Significance of "Water Quality" in HD 8
Technical Issues with "Water Quality" 9
Scope and Purpose **10**
Approach 11
Methods **11**
Step-1: Identification of Research Questions 11
Step-2: Documents Search 12
Step-3: Documents Selection 13
Step-4: Data Extraction 15
Step-5: Collating, Summarizing, and Reporting the Results 17
Results **17**
Documents Selection 17
Documents Characteristics 18
Topic-1: Quality Criteria 20
Quality Criteria for Source Water 20
Quality Criteria for Dialysis Water 20
Quality Criteria for Dialysate 24
Therapeutic Application of Dialysis Water and Dialysate ....**Error! Bookmark not defined.**
Topic-2: Treatment Systems to Achieve Quality Criteria of Dialysis Water and Dialysate 26
Topic-3: Quality Management 27
Sub-Topic-1: Quality Control 27
Step-1: Sampling Locations (i.e., From Where the Samples Should be Collected?) 29
Step-2: Testing Parameters and Testing Frequency (i.e., Which Parameters Should be Tested and at What Frequency?) 30
Step-3: Testing Parameters (i.e., For What parameters Should Source Water, Dialysis Water, and Dialysate be Tested?) 32
Step-4: Sample Collection, Storage, and Transportation (i.e., How to Collect, Store and Transport Testing Samples?) 33
Step-5: Testing Location and Testing Methods (i.e., Where and How Should the Samples be Tested?) 34
Step-6: Interpretation of Test Results and Remedial Actions (i.e., When Quality Test Results are Considered Unacceptable and What Should be Done About Their Deviations?) 34
Step-7: Stakeholders' Responsibility (i.e., Who Should be Responsible for What?) 40
Sub-Topic-2: Quality Assurance 41
Sub-Topic-2: Quality Improvement 41
Quality of Evidence as Assessed by the Included Organizations 42

Discussion **44**
Chapter-3: Facilitators and Barriers to the Management of Water Quality in Home Hemodialysis Programs in Canada: A Qualitative Approach **51**
Background **51**
Research Aim and Purpose **54**
Research Question **54**
Methods **55**
Research Approach and Study design 55
Study Settings, Participants, and Recruitment 55
Data Collection 56
Ethics 59
Data Analysis 59
Results **61**
Current Practices for Home Hemodialysis Care Process 62
Team Members 63
Guidelines and Standards 63
HHD Care Process Steps: What, How, and When? 63
Perceived Barriers of and Facilitators to Water Quality Management 67
Built Environment 67
Physical Elements in and around Patients' Homes 67
Environmental Conditions 68
Home Modifications 74
Customization of Water-Purification Devices 75
Home Interior Adjustments to Accommodate the Needs of the Placement of Devices 76
Cost to Support Home Modifications and Utility Bills 77
Maintaining Safe Water for Home Hemodialysis 77
Processes for Conducting Testing and Maintenance 77
Knowledge and Skills 77
Resources to Support Appropriate Testing and Maintenance 79
Scheduling Inspection Visits to Patients' Homes 81
Materials and Equipment for Testing and Maintenance 81
Quality Testing Devices 81
Variability in Device Models 82
Recruitment and Ongoing Training 82
Usability of Devices 82
Suggestions for Improvement 83
Identifying a Consistent Process for Microbial Testing 83
Need for more Robust Evidence 83
Innovation to support remote monitoring 84
Approaches to Addressing Non-compliance 85
Discussion **86**
Conclusion **88**
Chapter-4: Thesis Conclusion **91**
References **94**
Appendix 1: Detailed Search Strategy **109**

Appendix 2: Grey Literature Searches 118
Appendix 3: Microbial Monitoring of DW and Dialysate: Sample collection, Storage, and Testing Methods 128
Appendix 4: Invitation Letter 137
Appendix 5: Information Letter and Consent Form 138
Appendix 6: Interview Guide 147
Appendix 7: Process Description of Participating Home Hemodialysis Programs 157
Appendix 8: Illustrative Quotes from Interview Transcripts for the Theme: Perceived Barriers of and Facilitators to Water Quality Management in Home Hemodialysis Programs 232
Appendix 9: Illustrative Quotes from Interview Transcripts for the Theme: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs 279

List of Tables

Table 1: Inclusion and Exclusion Criteria for Documents Selection 13
Table 2: Characteristics of the Included Organizations 46
Table 3: Characteristics of Study Participants 62
Table 4: Perceived Barriers of and Facilitators to Water Quality Management in Home Hemodialysis Programs 69
Table 5: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs 84
Table 6: Approaches to Addressing Non-compliance 85

List of Figures

Figure 1: Schematic Diagram of Hemodialysis Process 2
Figure 2: Prisma Diagram 18
Figure 3: Microbial Quality Criteria for Dialysis Water as Mentioned Across The Included Organizations ..... **Error! Bookmark not defined.**
Figure 4: Chemical Quality Criteria of Dialysis Water Across The Included Organizations 25
Figure 5: Microbial Quality Criteria of Dialysate across the Included Organizations 26
Figure 6: Treatment System Components for Producing Dialysis Water and Dialysate of Required Quality 28
Figure 7: Treatment System Components for Producing Dialysis Water and Dialysate of Required Quality 28
Figure 8: Monitoring of Microbial Quality of Source Water, Dialysis Water, and Dialysate (Validation Testing Frequency, Testing Parameters, and Sampling Locations) 35
Figure 9: Monitoring of Microbial Quality of Source Water, Dialysis Water, and Dialysate (Routine Testing Frequency, Testing Parameters, and Sampling Locations) 37
Figure 10: Monitoring of Chemical Quality of Dialysis Water, Source Water and Dialysate (Testing Schedule, Testing Frequency, Testing Parameters, and Sampling Locations) 39
Figure 11: Basis of Provisions for Quality Criteria of Dialysis Water and Dialysate 43

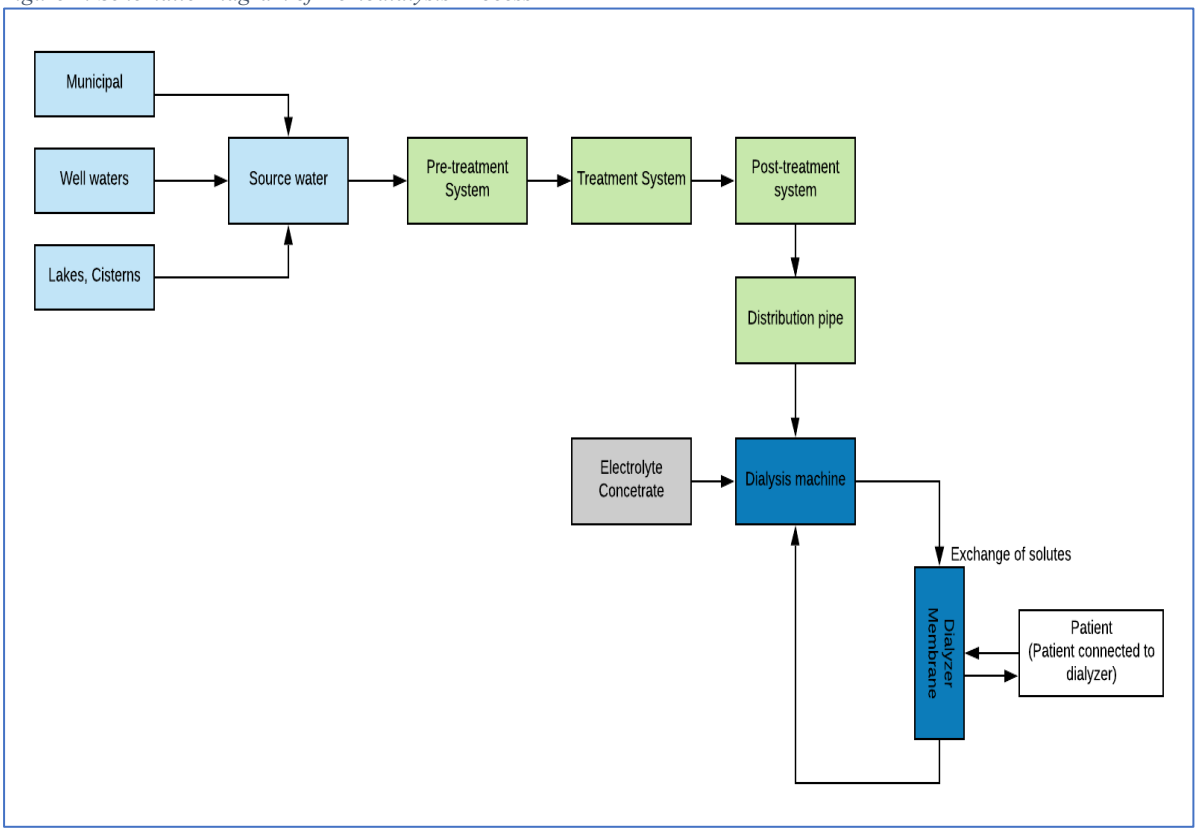
Chapter-1: Introduction

End stage renal disease (ESRD) is a global public health problem. ESRD patients do not have well-functioning kidneys, which leads to electrolytic imbalance, loss of regulation of blood control, and accumulation of toxins. Failure of kidneys, therefore, is a life-critical condition. There are two types of treatments options for an ESRD patient: dialysis and kidney transplantation. While kidney transplants are typically associated with longer and better quality of life, there are more ESRD patients than available kidney donors. In Canada, on average, the number of ESRD patients is growing tremendously; the current estimated ESRD population is more than 40,000, and less than half of this population has received a kidney transplant[(1)]. In Canada, an ESRD patient waits about 2 to 7 years for kidney transplantation. Therefore, the only treatment option available for ESRD patients is either peritoneal dialysis or hemodialysis (HD).

In HD, an ESRD patient is connected to an external medical device that replaces the kidneys' functions. In HD therapy, the external device used is a HD machine that has two primary components: a dialyzer and a dialysate delivery system. A dialyzer is a hollow cylindrical tube consisting of semipermeable membranes that mainly replace the function of kidneys. The role of the second component of the HD machine, the dialysate delivery system, is to prepare a dialysate, by mixing electrolytes and water (called dialysis water), which is filtered water having the quality higher than that of drinking water (Note: the drinking water is referred to as source water (SW) in this thesis). The prepared dialysate is then delivered to the dialyzer compartment of the HD machine. The arrangement is made such that when an ESRD patient is connected to an HD machine, blood enters on one side of the dialyzer and dialysate from the other side, flowing in opposite directions and separated by a semipermeable membrane. With this countercurrent flow, a diffusive phenomenon occurs, allowing the exchange of solutes between an ESRD patient's blood and dialysate. In this process, excess waste is removed from the blood. The electrolyte concentration in the dialysate is set at such a level that a concentration gradient occurs between an ESRD patient’s blood and dialysate to remove the unwanted constituents from an ESRD patient’s blood into the dialysate. After the exchange, the cleaned blood is returned back into an ESRD patient's body and the waste fluid goes into the drain. (Figure-1 shows the schematic diagram of HD process). Since an ESRD patient’s blood is exposed to dialysate,

which is 95% dialysis water (DW) and the remaining 5% electrolytes, the DW quality should be such that it does not contain excess contaminants that can get exchanged into patients' blood and create adverse events. Therefore, water quality, including source water, DW, and dialysate, is crucial for the safe delivery of HD.

Figure 1: Schematic Diagram of Hemodialysis Process



HD therapy can be delivered at healthcare facilities (in a hospital or satellite dialysis unit) or at a patient's home (known as home hemodialysis (HHD)). Evidence suggests that HHD therapy is potentially more beneficial in comparison to facility-based HD to ESRD patients and healthcare system. HHD offers the opportunity of performing intensive HD, which is relatively difficult to perform at facility-based HD mainly due to logistical reasons from patient perspectives. Intensive HD regimes are preferred over conventional HD because they have been potentially shown to be associated with more improvements in clinical outcomes among ESRD patients, such as improved clearance of toxins, better survival, lower hospitalization rates, improved blood pressure, anemia, and nutritional status[2–8]. Additionally, compared to facility based HD, HHD therapy potentially offers more benefits to patients, including freedom, flexible dialysis

schedules, reduced travel, and improved quality of life[2,9–12]. HHD is also preferred over facility based HD for its economical benefits[13–16].

It has been estimated that annual rate of ESRD patients initiating renal replacement therapy on an average would increase by 1.6 % annually in Canada[17]. The care of ESRD patients is associated with significant costs to the healthcare system and increased use of resources[18,19]. Therefore, several provinces across Canada have initiated strategies to increase the use of HHD for all the above mentioned benefits that it offers in comparison to facility-based HD[20]. In recent years, the use of HHD has increased in Canada[17], however, it still remains low in comparison to facility-based HD[21]. Other countries[22–25] also experience the similar ratio of HHD to facility-based HD use. Several research studies have been conducted to identify the determinants of HHD utilization[11,12,20,26–33]. Such knowledge can be useful for decision-makers in developing strategies to overcome specific hindrances that may exist in the use of HHD, and thereby, increasing its expansion to eligible ESRD population. In some of those studies, water quality has been identified as an impediment to the use of HHD[20,26,29–31,33,34]. This calls for gaining a deeper understanding of impact that aspects of water quality and its management could have on the safe delivery of HHD in Canada to support its growth.

Many years ago, when dialysis was still in its infancy, researchers found that the use of drinking water for dialysis was not safe for patients, specifically because of chemical contaminants (such as aluminium and chlorine), so HD therapy began to be conducted using distilled water. With the passage of time, researchers demonstrated that by using a more stringent chemical and microbial criteria for water used in HD, patient outcomes could be improved[35–38]. In Canada, the Canadian Standards Organization (CSA) has laid out the chemical and microbial quality requirements of SW, DW, and dialysate. Although voluntary in nature, these requirements are supposed to be met by home programs for the safe delivery of HD at patients' homes. The implementation of these requirements is affected by various factors. In Canada, individuals in rural communities rely on water that is not sourced from municipal supply; thus, they are responsible for managing drinking water quality on their own. In such cases, research studies have reported that often people do not adequately maintain the quality of water available at their home (i.e. source water)[39–41] resulting in increased levels of inorganic and organic chemical

contaminants, disinfection by-products, and radionuclides. Boil water advisories for drinking water is also evident in several communities of Canada[42]. A similar trend of poor compliance with national regulations for drinking water have been reported for less urban communities in other countries[43]. Also, there are instances of variations in SW delivered from municipal organizations in a way that potentially could affect HD patients[44–47]. All of these factors related to source water (SW) quality increases the risk for HHD patients. Several water purification-related devices are used in HD which filter out undesired elements of SW and produce DW that is safe for HD patients. However, the risk of adverse events persist from unexpected failures of such devices[23,48,49] and the lack of adequate devices to manage the variations in source water quality[49–51]. For all these reasons, home programs should have a process for managing water quality (including SW available at patients' homes, DW, and dialysate) for the protection of HHD patients.

The CSA standards, specifically for HHD[52,53], were developed to promote uniformity in approaches to the management of HHD water quality across various jurisdictions in Canada. The intention was that this would facilitate the delivery of the same quality of care to ESRD patients in various Canadian jurisdictions[54]. Since the Canadian HHD programs are not obliged to adopt the CSA standards, there could be variations in their approaches to the management of HHD water quality. Therefore, the first purpose of this thesis was to understand to what extent the Canadian HHD programs differed in their approaches to managing water-related aspects, and whether their derived approaches differed from those stated in the CSA standards. The second purpose was to explore the experiences of HHD programs with regards to the implementation of approaches that are already in place at various jurisdictions in Canada and mentioned in the CSA standards, specifically, when the home programs' approaches were found to be in discrepancies with them.

The thesis consisted of two studies to achieve its purposes. The objective of the first study was to summarize current and proposed standards and guidelines for the management of water quality for HHD programs across Canada and in different countries. It was addressed using a scoping review method that included systematic searching, reviewing, and synthesizing existing guidelines and standards on the management of DW and dialysate quality for HHD in Canada

and various other countries. The second study directly addressed the purpose of this thesis by comparing the Canadian HHD programs in terms of their organizational structure and processes to achieving and maintaining the required DW and dialysate quality and understand facilitators and barriers/issues to complying with the requirements of DW and dialysate quality as experienced by healthcare professionals.

Together, these studies described 1) the similarities and differences in the requirements of quality of DW and dialysate and for their management in HHD programs across various countries, 2) the similarities and differences across Canadian HHD programs in terms of their organizational structure and processes to manage water-related aspects, and 3) factors perceived as facilitating or challenging/impeding to achieving and managing water-related aspects by healthcare professionals in the Canadian landscape.

Chapter-2: Scoping Review of Existing Standards and Guidelines for the Quality of Water in Hemodialysis at Home Settings

Chapter-2: Scoping Review of Existing Standards and Guidelines for the Quality of Water in Hemodialysis at Home Settings

Introduction

End-stage renal disease (ESRD) is a global public health problem; around 2 million people are estimated to be affected by the disease globally, including approximately 23,000 people in Canada[17]. There remains unacceptably high mortality among ESRD patients, with a 5-year mortality of 75%. There is a heavy cost associated with ESRD patients because they may experience several comorbidities and poor quality of life[18,55,56]. Many patients require dialysis therapy to remain alive. The most common form of this is hemodialysis (HD)[57], whereby patients are connected to a machine at least 3 times per week for the duration of their lives or until they receive a kidney transplant. While most HD treatments occur under the supervision of nursing staff in designated dialysis units (also known as in-center HD or facility-based HD), some ESRD patients are trained to self-administer their treatments at home. Although home hemodialysis (HHD) offers several advantages (e.g., greater treatment flexibility and patient autonomy), it is not free from drawbacks[58,59]. The most significant is that patients perform their HHD treatment in an unsupervised environment. As a result, the burden of care and dialysis equipment maintenance fall upon patients and their family members.

During HD treatments, a patient's blood is cycled through a filter (also known as a dialyzer or an artificial kidney). Within the filter, the movement of waste from blood occurs across a semipermeable artificial membrane. The membrane has a patient’s blood on one side and a clean physiological solution (the dialysate) on the other side. As blood passes through the filter on one side of the membrane, metabolic waste is removed to the dialysate. Thus, adequate dialysis depends on continuous replenishment of clean dialysate for the duration of HD treatment. In most modern HD machines, the dialysate is created by proportioning a chemical concentrate with a water supply, requiring 200 - 500 liters of water per treatment depending on the HD prescription parameters. Over many years of HD therapy, a patient’s bloodstream is exposed to many cubic tons of water, so the quality of that water is paramount to patient safety. This scoping review will assess to what extent there is consistency and variations across the recently developed documents on definition, production, and management of water quality needed for safe delivery of HHD by national and international professionals, standards, and governmental

organizations. The methodology used by organizations in developing their documents will be compared, including the evidence type used and assessed in developing their statements.

Background

Clinical Significance of "Water Quality" in HD

HD therapy uses diffusive, convective, and osmotic processes to replace the normal functions of a kidney, such as blood purification and the maintenance of body fluids, acid-base, and electrolyte balance. During HD, blood and dialysate never directly contact each other (they are, in theory, constantly separated by the membrane). However, the semi-permeable membrane has tiny pores that allow the exchange of solutes between blood and dialysate. Dialysate is a blended mixture of water and a concentrated solution of electrolytes, buffer, and glucose whose purpose is to facilitate the physical process of toxin removal (which would usually be removed in the form of urine in a person with functioning kidneys). The dialysate has chemical constituents set at concentrations essential for creating a concentration gradient across the membrane. This concentration gradient is set at a level allowing the removal of uremic toxins from patients' blood into the dialysate while at the same time retaining essential electrolytes (i.e., calcium, sodium, etc.)[60]. The filtered blood is then returned into a patient's body while the spent dialysate is drained out by the HD machine, ultimately into sewage water. At a minimum, a patient undergoes HD treatment for 3 hours and 3 days a week for survival, which signifies that the quality of dialysate, and thereby water itself, is crucial for patient safety. Serious adverse events have occurred due to inferior chemical quality of dialysate, and the catastrophic examples include methemoglobinemia and hard-water syndrome[49,61,62]. Additionally, microbial growth within the complex chain of dialysate production is an important risk that needs to be contained[63–66]. Microbial contaminants in the dialysate impose risk to patients because it has been shown to lead to adverse events such as pyrogenic reactions and even fatalities in dialysis patients[67,68].

In the 1980s, standards organizations recognized the need to control water quality used in HD therapy to ensure patient safety[69] by specifying maximum allowable levels for chemical and microbiological contaminants and recommendations on meeting them. Over time, the guidelines

and standards have changed as new evidence has emerged on the impact of contaminants on HD patients.

In the last 25 years, several changes have occurred in HD technology to achieve better uremic toxic clearance, including the use of high flux dialyzers (in theory increasing the risk of permeability for microbial contaminants such as endotoxins, exotoxins, and small bacterial DNA fragments)[70–72]. Thus, the microbial impurities of water for HD have to be understood for their chronic impact on patient outcomes and not just for their potential acute effects of pyrogenic reactions. It is speculated that impurities in water used for HD may contribute to chronic inflammation in patients, which is associated with higher mortality[73–76]. In recent years, there has been an increase in research studies investigating the pathophysiological mechanisms by which water quality may alter inflammatory response in ESRD patients[77]. Studies have also investigated its impact on associated comorbidities, including malnutrition, anemia, residual renal function, carpal tunnel syndrome, and patient survival[78–85].

Technical Issues with "Water Quality"

In addition to the HD machine and other dialysis accessories, a complex purification system, including a series of treatment components and distribution lines, is needed to produce water that meets the particular quality criteria for HD[63,86–88]. Studies have shown fluctuations in the quality of water used in HD under several circumstances; therefore, its suitability needs to be ensured at optimum intervals to avoid any adverse events associated with its contamination. The potential areas of vulnerability include: (1) treatment component failure[89], (2) susceptibility of purification system and HD machines to microbial growth[90,91], (3) need to identify an adequate purification system[92], and (4) the need to identify effective means for system maintenance[93]. Dialysis facilities have to adopt quality management specifically dedicated to addressing these issues. In addition, dialysis facilities may have to modify their activities with any variation in source water (SW) quality (geographic or seasonal variations) and be aware of any new emerging contaminants[45,94]. All these issues suggest that, while the need for quality criteria is well recognized, their maintenance is a challenge.

Dialysis facilities may underestimate the need of a monitoring program. Also, they may be unaware of how to design and operationalize a monitoring program so that its main purposes are achieved[95–97]. Some of the purposes of a monitoring program, other than verification of requirements meeting in water used for HD, are: (1) the availability of timely and valuable information (e.g., which parameters are appropriate to test more frequently and which ones at a lesser frequency); (2) transforming such information into knowledge (i.e., understanding reasoning to the declination of water quality); (3) understanding urgent needs; (4) provides a basis of planning management strategies to address such needs; (5) forecasting future threats of contamination; and (6) use of limited resources efficiently. Overall, a reliable monitoring program is necessary for understanding the status quo of water quality and developing effective strategies for its maintenance.

The challenges that may exist for facility-based HD are compounded for patients who perform HD at home in an unsupervised setting, thereby potentially increasing water quality-related risk for three predominant reasons. Firstly, HHD patients dialyze more frequently (i.e., not just 3 times per week but up to 6 times per week); thus, they are potentially exposed to much more water contamination. Secondly, HHD programs often need to manage more than one source of water and purification system for their HHD patients since they use various water sources, including municipal water, well water, or commercially purchased cistern-stored water. Finally, patients themselves are often responsible for several aspects of quality management, thus introducing another variable that may create challenges in managing water quality within home programs compared to facility-based HD(20,29,58,98–100).

Moreover, in practicality, wide variations exist in quality management activities followed by individual HHD programs, raising concerns over determining the best approaches[35,86,87,95,98,101–104] and possibly the quality of care provided. Therefore, there is a need to compile information on the best practices for water quality management in HHD available in various countries.

Scope and Purpose

Peer-reviewed studies[105–107] synthesizing and comparing organizations regarding HHD water quality are limited. In general, guidelines and standards on water quality for HD are based on

literature for facility-based HD and extrapolated to the home setting[36,68,108]. Furthermore, water quality criteria for HD have been synthesized by only a few national and international bodies in the United States, European Union (EU), and the International Organization for Standardization (ISO). The other organizations typically adopt the quality criteria from one of these well-recognized bodies, and they may interpret and implement those criteria based on local legislation and real-world practicality. This scoping review aims to compare and contrast organizations through a specific lens of water quality for HHD. This review intends to provide HHD programs with information on quality criteria available worldwide and guide them in implementing quality criteria.

Approach

A scoping review is a preferred choice of a method when a literature review aims to "examine the extent, range, and nature of research activity"[109(p.4)] in a particular research area and is a mechanism to present findings to policymakers. A scoping review method has been used in scholarly articles[110,111] to collate, compare, and summarize the results of international guidelines in public health, especially to understand similarities and differences in their recommendations and the basis of the evidence used in their development. Based on this proven applicability and relevant need, as discussed above, a scoping review is therefore considered a suitable method to collate, summarize, and contrast organizations that are specifying water quality criteria and means to achieve it for HHD. The methodology as described by Arksey et al. (2005)[109] and other researchers[112,113] guided this review, which followed five steps: (1) identification of the research question for the review, (2) identification of relevant documents, (3) selection of documents, (4) data extraction, and (5) collating, summarizing and reporting results.

Methods

Step-1: Identification of Research Questions

The purpose of the scoping review was to understand the range of documents focusing on defining, producing, and managing water for the safe delivery of HHD in Canada and across different countries. The following 2 research questions guided the scope of the review:

Q-1: What are the current official documents for managing water quality at HHD programs in Canada and other countries?

Q-2: What are the various elements of water quality management being considered, and how do they differ across countries?

Step-2: Documents Search

With the help of a research librarian, the following 7 electronic databases were searched in May 2017 using a structured search strategy to identify relevant peer-reviewed literature: PubMed, EMBASE, Web of Science, CINAHL, Econlit, Center for Research and Dissemination (CRD), and Cochrane Library. This strategy included a combination of controlled vocabulary terms, such as Medical Subject Headings (MESH) and non-MESH terms for the following three different concepts: (1) dialysis modalities (such as HD, HHD), (2) water used for HD (such as dialysis water, dialysate, source water, dialysis fluid), and (3) quality terms (such as purity, guideline, standard, media, quality control, treatment system, testing, chemical, microbiology, legislation) (see Appendix 1). The developed search strategy was piloted on one of the databases and modified as necessary. The first concept of the search strategy included MESH and non-MESH terms related to any dialysis modality. The search was broadened to any study type to identify articles describing relevant organizations' statements since most of their standards or guidelines are not found in the databases. No date restrictions were applied, and all searches were limited to the English language and human subjects.

Country-specific websites of governmental, inter-governmental, standards, and professional organizations were also screened to identify grey literature (i.e., non-peer-reviewed literature). The names of the relevant organizations were identified from the peer-reviewed articles obtained from the electronic search results, and their official website address was obtained from the Google search engine. Various combinations of terms, such as "hemodialysis" and "guidelines or standards," were entered into search tabs available on each organizations' website. Websites' tabs/menus were also searched to gain information on documents' methodological characteristics.

Lastly, hand searches were performed by checking the references of the included full-text peer-reviewed articles. During grey literature and hand searches, if any of the websites or relevant articles found were not in English, best efforts were made to translate them into English using free internet tools. In addition, efforts were made to contact the issuing organizations to verify the latest version.

The articles obtained from electronic databases were imported into Reference Manager.

In July 2021, the current status of the included documents was confirmed by reviewing issuing organization's websites or using the Google search engine. Through this, 6 documents included in the results were replaced with their recently revised versions.

Step-3: Documents Selection

Duplicate citations were removed from the bibliographic search using Reference Manager. One researcher then scanned and assessed the remaining citations for inclusion using the predetermined eligibility criteria (see Table 1) in 3 steps: (1) screening of titles, (2) scanning of abstracts to select documents eligible for full-text reviews, and (3) retrieval and assessment of full texts of selected documents.

Table 1: Inclusion and Exclusion Criteria for Documents Selection

Inclusion Criteria	Exclusion Criteria
• Documents developed by the government, inter-governmental bodies, standards, or professional societies/organizations	• Documents developed by private entities such as hospitals or clinics
• Documents' methodological characteristics: - At least one of the statements formulated based on an informal or formal review of the available evidence, - Documents formulated by a multidisciplinary team, or - Intended to provide guidance or requirements for clinical decision-making	• Adopted another organizations' document in its entirety • Documents meant for device manufacturers
• The current version of a document	• Previously published versions of a document • Documents under revision
• Countries: - The top 25 countries in OECD countries based on healthcare spending[114], - Countries with the universal healthcare system	• Any country other than mentioned in the inclusion criteria

Inclusion Criteria	Exclusion Criteria
(i.e., USA, Norway, Germany, Netherlands, Austria, Sweden, Ireland, Denmark, Belgium, Luxembourg, Canada, France, UK, Iceland, Australia, Japan, Finland, New Zealand, Italy, Slovenia, Spain, Korea, Czech Republic, Portugal, Estonia)	
• Modalities of dialysis: high-flux and low-flux HD. • Settings: Patients' home • Device Type: HD conducted using water	• Modalities of dialysis: Peritoneal dialysis, hemodiafiltration(HDF), and hemofiltration(HF) • Settings: Facility-based (such as hospitals or long term care) and satellite units • Device Type: Sorbent-based technology
• Topics: - Quality requirements (of source water, dialysis water, and dialysate) - Treatment system components (for the production of dialysis water and dialysate of required quality) - Quality management	• Topics: - Dialysate composition - Technical specifications for HD machines and hemodialyzers - Electrical wiring, plumbing, building requirements, site or safety codes for HD machines or purification system
• Articles providing information on the characteristics of the included organizations and other information as related to the scope of this review, when such information was not made available on organizations' websites or their documents	• Articles reporting: - challenges or any issues about any of the statements of interest - the compliance rate achieved by dialysis programs with the statements of interest - adverse events attributed to contaminated dialysis water or dialysate quality

The exact definitions that publishing organizations used in identifying their documents, including standard, guideline, circulaire, or supplementary, were used in this review to classify a document type. A document was considered a standard by a standards organization when it specified permissible values of contaminants for water used in HHD, and test methods for their quantification, except for 1[53] organization. A document was identified as a guideline by professional and standards organizations, when it also consisted of statements on quality management, besides allowable levels and test methods. Exceptionally, 1 organization[115] provided its statements on quality management in a secondary document to a guideline named supplementary. A document with guidance on implementing legislation on water quality used for HD was identified as a Circulaire by the France Ministry of Health. All the document types were advisory unless adopted by government agencies for legal enforcement or reimbursement.

Step-4: Data Extraction

One researcher developed a data extraction form a priori, which was subsequently reviewed and approved by the thesis research supervisor. The following information was extracted from all the included documents: (1) author or the name of an issuing organization, (2) country of origin, (3) document type, (4) year of a recently published version of a document, (5) aim/purpose, (6) stakeholders involved in document development, (7) summary of key statements of interest, (8) methods used to formulate key statements, and (9) limitations or proposed revisions. The rationale for the key statements of interest, including quality and strength of evidence, cost, or other considerations, was extracted. If an organization provided a descriptive rationale, then it was briefly summarized. The supervisor reviewed a sample of the extracted data to verify that they were within the scope of this review. Any disagreements were resolved through discussion and consultation with the thesis supervisory committee when needed.

Upon consultation with a nephrology expert, the key statements concerning the following 3 topics were considered crucial for answering the scoping review question: (1) *quality criteria* of water used in HD, (2) *purification systems to achieve* the quality criteria, and (3) *quality management* for achieving and maintenance of quality criteria. The following briefly describes the elements extracted for these topics:

Topic 1. *Quality Criteria*: In general, water quality refers to (1) suitability of water to be used for a designated purpose (such as healthcare, pharmaceutical production, or drinking) and (2) proper performance of a purification (or treatment) system meant for cleaning the water as needed[116,117]. Allowable levels (or permissible values) for several contaminants (also called parameters), belonging to three main groups of water quality (chemical, physical, and microbiological), are specified for understanding the suitability of water. They are specified usually for two different types of limits, maximum allowable levels, and action level[117]. The former limit indicates the concentration of a parameter beyond which the risk of adverse events is deemed too great[118,119]. In contrast, the latter provides a concentration of a parameter at which there is a need to take corrective action to prevent it from reaching the maximum allowable levels, mainly applicable to microbial quality. Therefore, data on quality parameters, types of limits, and their permissible values were extracted.

Topic 2. *Purification* S*ystems to Achieve the Quality Criteria*: Nystrand (2001)[64] defines systems in dialysis as including "everything from the incoming water to the use of the prepared dialysis fluid. The system does not only refer to the equipment of the clinic but also the maintenance and disinfection actions"[p-135]. Based on this definition, key statements on treatment system components needed to produce dialysis water (DW) and dialysate meeting their quality criteria were extracted. The maintenance practices (e.g., repairs and replacement of parts and types and frequency of disinfection) were not included in this review because they are specific to model classes and manufacturers. However, the statements on the treatment components requiring disinfection were extracted. The drainage aspect of spent dialysate is not within the scope of this review, and therefore its related data were not extracted.

Topic 3. Q*uality Management*: The data extracted for this topic were mainly guided by the literature from industrial engineering[120] and official documents on drinking water quality[116–118,121–128]. Quality management comprises four domains: quality control (QC), quality assurance (QA), quality improvement (QI), and risk management.

In general, the purpose of QC is to ensure that the performance (e.g., quality of products, machine components, or goods) is as required and to take appropriate corrective actions when performance deviates from what is needed. The following definition was used for monitoring of water quality: "the programmed process of sampling, measurement, and subsequent recording or signaling, or both, of various water characteristics [or parameters], often with the aim of assessing conformity to specified objectives [or permissible values set by included documents]"[126](p.10). Therefore, data were extracted on the following monitoring steps and corrective actions as the elements of QC: type and purpose of monitoring, testing parameters, sampling location, sample collection, storage and transportation, location of testing, testing methods, testing frequency, interpretation of test results, remedial or corrective actions, and record keeping[116–118,122–125].

For this review, QA was defined as "part of quality management focused on providing confidence that quality criteria will be fulfilled"[120](p. 59). QA is different from QC in that it does not control quality but ensures that internal policies and procedures are appropriately established and laid out to the extent that confirms or assures that quality is being and will be maintained.

First, information was sought on whether QA was defined separately from QC. Secondly, the types of elements considered for QA were summarized, and for QI and risk management as well. Additionally, statements on the implementation of quality management (e.g., who should be involved and in what aspects) were also extracted.

Step-5: Collating, Summarizing, and Reporting the Results

The data were extracted in Microsoft Excel to analyze the consistency and variations across the included documents. The documents were compared on the following: whether a document stated anything about a topic of interest to this review, a brief description of the established statements along with its supporting explanation for each topic, whether the formulated statements were stated as mandatory or recommended, the assessed level and quality of evidence supporting the established statements, and negative statements (i.e., not recommended or not required) due to a lack of robust evidence. The analysis was then summarized and enumerated according to the above-mentioned main topics and their sub-topics.

Statements that were stated as required to stay in compliance with a particular organization were classified as “mandatory,” “requirements,” or “required”, whereas statements established for guidance were classified as “recommended” or “suggested”. Organizations set their statements meant for recommendations using “should,” “must,” or “may,” and requirements were stated using “shall,” “strongly required,” “highly desirable,” “at least,” or “at a minimum”.

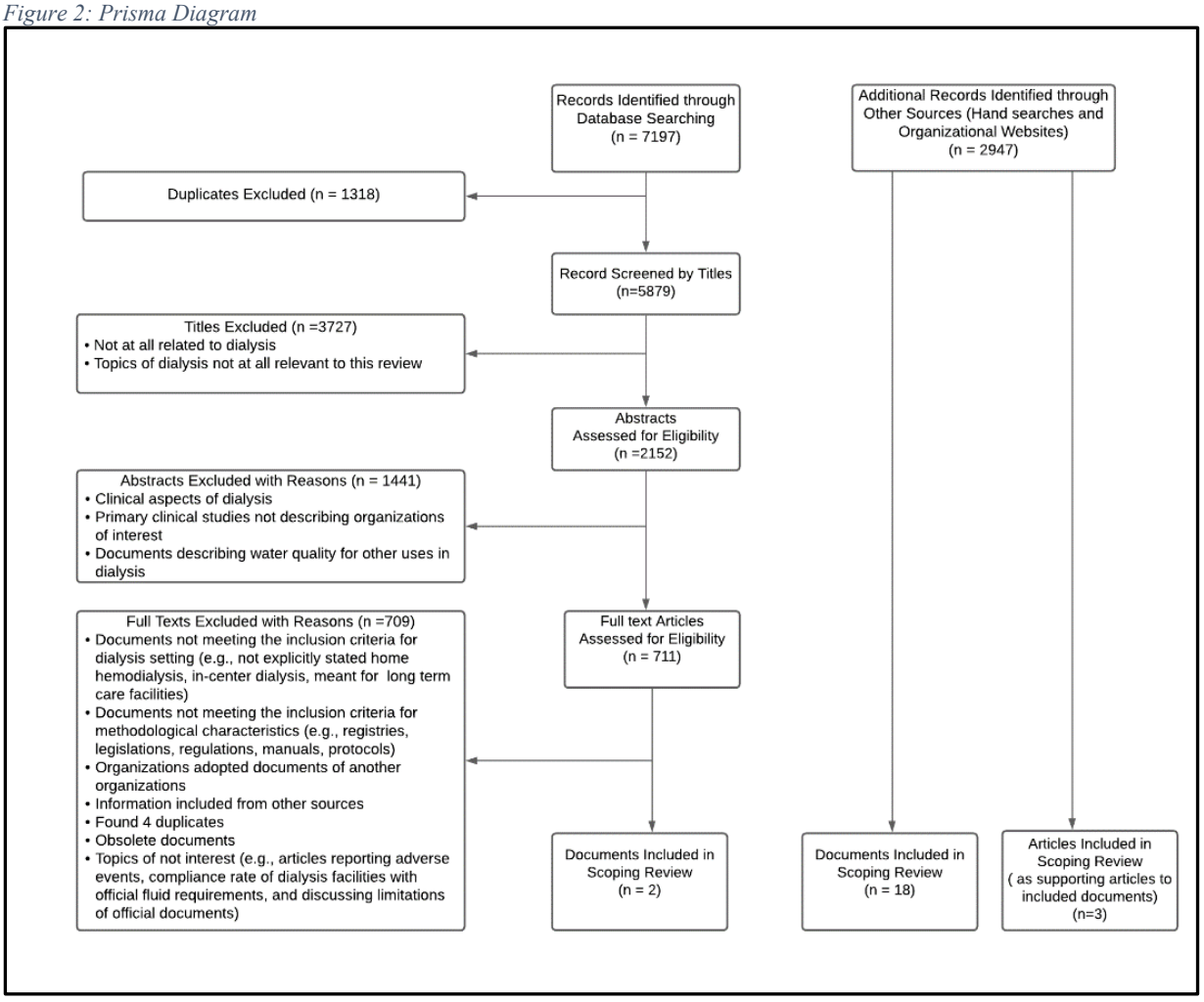
Results

Documents Selection

The searches from various sources, including electronic databases, grey literature, and specific governmental or professional organizations, yielded 10,144 citations. Details of sources of documents and reasons for exclusion are outlined in Figure 1. Documents were excluded mainly for adopting another organization’s document (national standards organizations from USA, NewZealand, The Netherlands, UK, Spain, EU, Norway, and Sweden) or for not including HHD (Japan, Vienna (Austria), and South Korea). Finally, in this review, 20 full-text documents and 3 articles met the inclusion criteria. These documents were developed by 13 organizations: 2 standards organizations, 9 professional organizations, and 2 governmental organizations. Eleven

organizations identified at the national level originated from Canada (1/11) and Europe (10/11), 1 organization at the state level was from Australia, and 1 organization was identified at the international level. The included documents comprised 4 standards, 14 guidelines, 1 supplemental, and 1 circulaire. One of the 3 articles contained information on characteristics[129] of some of the included organizations, and the remaining[100,130] described statements of documents available in non-English languages.

Figure 2: Prisma Diagram



Documents Characteristics

The characteristics of the included organizations are described in Table 2. Documents had their current edition published between 2005 and 2020. Ten organizations[53,115,131–138] had published multiple editions, and their most recent editions ranged from 2nd to 14th. Documents were

retrieved from the websites of their issuing organizations, except 2[139,140] that were obtained from electronic database searches. Documents from 8 organizations[53,131,132,135–137,141,142] were published in English, and those from the remaining 5 were published in languages other than English[115,133,134,138,143].

As commonly stated across included organizations, the 2 primary purposes for publishing documents were to: (1) prevent adverse events from contamination of the water used in HD and (2) help patients and health professionals implement the required quality criteria. The purpose of updates or revisions of documents was: (1) harmonization with another organization; (2) establishing statements addressing local contexts; (3) expanding the scope to home programs; and (4) advancement in dialysis technology (i.e., increase in the use of high-flux dialysis in comparison to low-flux dialysis).

Most organizations[53,115,131–137,143] had development committees or working groups comprised of multidisciplinary experts (12/13). Their members included nephrologists, nurses, technicians, clinical managers, chemical and microbiological analysts, device manufacturers, and academic researchers (specifically from the field of biocompatibility in dialysis). A few documents had specified authorships (3/20). Most documents were approved by external reviewers (19/20). Representatives of other well-known organizations contributing to setting the quality criteria for water used in HD, either as committee members or external reviewers, were included by 5 organizations[53,131,134,139,140,143]. Patient views were sought by 2 standards organizations[53,131]. Five organizations[53,131,135–137] provided information on the methods used in formulating their statements, and 4[53,131,136,137] of these used formal methods (such as voting) for consensus. None of the organizations performed systematic searches to develop their documents, except 1[135] whose search strategy was not provided. Organizations provided references of other organizations that they referred to for creating their documents. A systematic tool to grade the level of studies used as evidence was used by 4 organizations[115,135,137,138]. Two organizations[137,138] used the tool Grading of Recommendations, Assessment, Development, and Evaluate (GRADE), another[135] used an adapted version of GRADE developed by Kidney Disease Improving Global Outcomes (KDIGO)[144], and a fourth[115] developed its own tool. One organization[131] had considered cost in formulating part of its statements; however, no

formalized cost studies were utilized. All of the documents were related to traditional single-pass HD machines; there were none for NxStage devices.

The Results section below compares the included organizations on the three main topics and several sub-topics related to the scope of this review.

Topic-1: Quality Criteria

Dialysate used for HD therapy is manufactured through a production chain. It begins with tap water available at a patient's home. In the middle of the purification system comes a series of treatment components, when combined called a treatment system, and then comes a patient's bedside HD machine, the end-point. For the safe delivery of HD therapy, overall, organizations have laid out specific quality criteria for SW, DW, and dialysate. They are located at the three main junctions of the production chain (entry-point of the production chain, coming out of the middle junction, and at the end-point), respectively. Organizations also specify quality criteria for product water (PW), which comes from various treatment components other than the final treatment component responsible for transforming SW into DW. The following sub-topics compare and contrast the included organizations for their established quality criteria for SW, DW, and dialysate.

Quality Criteria for Source Water

SW meeting applicable local drinking water regulations or legislation on microbial and chemical parameters was required for HHD[53,115,142,143,145,132–138,141]. Organizations suggested following the manufacturer's instructions when SW process parameters' ranges need to be according to a treatment component's specifications. In addition, a specific permissible value for some process parameters was mentioned; however, their details (i.e., types of process parameters) varied across organizations.

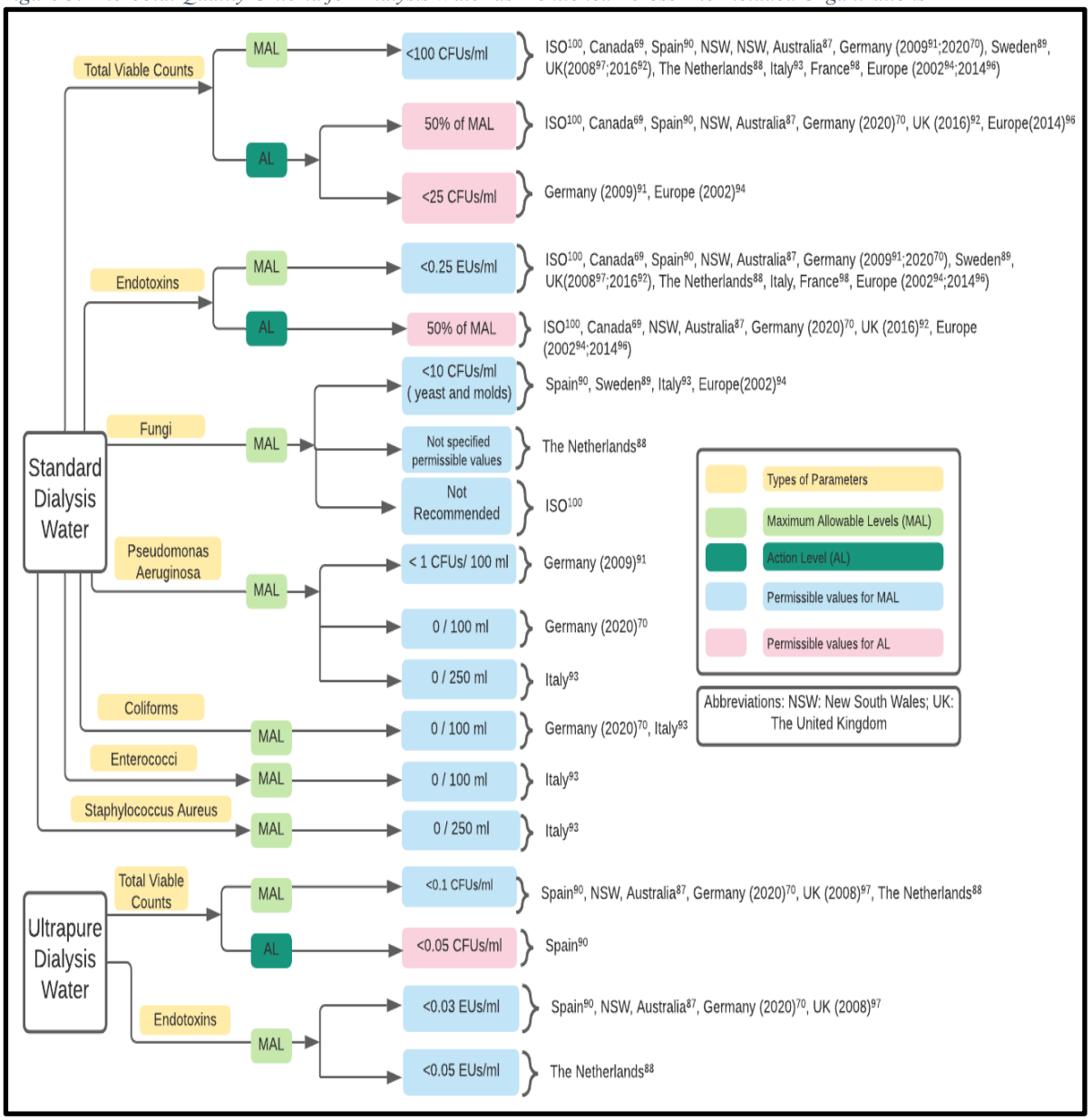
Quality Criteria for Dialysis Water

In total, 7 microbial parameters were specified across the 13 organizations (see Figure 2). Organizations were similar in establishing the maximum allowable level for total viable counts and endotoxins; however, they varied in action level of total viable counts. Three organizations

prescribed isolating specific strains of bacteria from a gram-negative group (total coliforms[115,138], pseudomonas aeruginosa[115,136,138]), and 1[138] from a gram-positive group (enterococci, staphylococcus aureus). There were no significant differences in their permissible

values, except in sample volume for one of these parameters. A significant variation was seen for fungi, where 5 organizations[133–135,138,139] included fungi as one of the

Figure 3: Microbial Quality Criteria for Dialysis Water as Mentioned Across The Included Organizations



microbial parameters, while 1 organization had not[145]. Two grades of DW were specified; standard (13/13) and ultrapure (5/13)[115,132,133,135,142]. The maximum allowable level for total

viable counts and endotoxins were established at a stricter level for ultrapure than for a standard grade.

In total, the maximum allowable and residual levels were established for 37 chemical parameters and 5 chemical disinfectants, respectively, across the 13 organizations[53,115,142,143,145,132–138,141]. Additionally, manufacturers' specifications were suggested to be followed for process parameters, except for 1 organization[135] that specified the safe operating limit for conductivity. Unlike microbial quality, DW was not separated into different grades based on chemical quality[135].

Twenty-two of 37 chemical parameters were stated across several organizations. Figure 3 compares organizations for these parameters in 3 groups, and their categorization is according to ISO. Parameters with evidence of their association with adverse events, such as death, nausea, vomiting, and encephalopathy, due to the diminished chemical quality of DW were listed in the 1st group. The chemicals used in electrolyte concentrate and setting the drinking water quality criteria (by regulatory authorities) were categorized into 2nd and 3rd groups. Organizations were different in establishing the maximum allowable level for 13 of the 22 parameters. Differences also existed in how some of the parameters were specified. Two organizations had not listed all metallic parameters from group-3 but included total heavy metals[134,143]. All organizations stated the parameters related to nitrogen in group-1, but they reported them differently, including nitrate as N[53,115,134,135,137,141,145], nitrate as NO_3^-[132,133,136–138,142,143], and nitrite as NO_2^-[134]. Most organizations stipulated total chlorine, which is the sum of free chlorine and chloramine (11/13)[53,115,145,132–136,138,141,142], and 2 organizations[136,143] individually listed either of these 2 parameters. Additionally, 1 organization[136] also included organic chlorine compounds.

Other than the parameters shown in Figure 3, there were 2 chemical parameters (ammonium and chloride) included by 7 organizations[132–134,136,138,142,143]; the majority of these were from EU member countries[133,134,136,138,142,143] (none of these parameters listed by ISO). Nine chemical parameters (tin[142], trihalomethanes[138], organo-halogen compounds[138], potassium permanganate[134], benzene derivatives[133], halogenated hydrocarbons[133], iron[135], cyanide[136], and chlorine dioxide[137]) were stated by 1 or 2 organizations (organic contaminants, cyanide, and chlorine dioxide stipulated as not required by ISO). Emerging parameters (pesticides,

pharmaceutical products, and radioactive elements) were stated as not required in 2 organizations[143,145].

No differences were seen in the residual levels for disinfectants including bleach[135], ozone[115,135,141,145], peracetic acid[115,141,145], and sodium hypochlorite[115,141,145], except for formaldehyde[115,134,135,141,145] (<3 mg/l[115,135,141,145] vs 0.1 mg/l[134]).

Quality Criteria for Dialysate

Of the 7 parameters that were used in specifying the microbial quality criteria for DW, 4 were also used for dialysate of standard grade, which included total viable counts (11/13)[53,115,146,132–134,136–138,141,143], endotoxin (11/13)[53,115,143,146,132–134,136–139,141], fungi (3/13)[133,134,136], and pseudomonas aeruginosa(1/13)[136]. Furthermore, these parameters for dialysate were established at the same maximum allowable as for DW. Except for endotoxin, which was set at a less stringent level than DW in 4 organizations[53,137,141,146] (i.e., 0.5 vs. 0.25 EU/ml). The action level for total viable counts and endotoxin was established at the same level as DW, except in 1 organization[136].

The quality criteria for ultrapure dialysate were similar across most organizations, except in 4[133,134,138,143]. One of these[138] included total fungi, and, comparatively, 3 organizations[133,134,143] had a less stringent maximum allowable level for endotoxin (0.05[133,134,143] vs 0.03 EUs/ml).

The chemical quality of dialysate remained the same as that mentioned for DW[53,115,137,146].

All organizations incorporated statements on the therapeutic application of dialysate. Most (10/13) agreed on using standard dialysate for HD (making it mandatory[53,115,132–134,137,141,143], recommended[146], or implied as mandatory[136,139]). Among these organizations, 6[53,132–134,143,146] stated ultrapure dialysate as not recommended for HD, 2[139,141] were not clear in their statements, and 4 organizations[53,115,137,142] recommended its use but differed in modality type. One[142] organization stated it for high-flux HD, and the other 3[53,137,142] implicitly stated it for both high-flux and low-flux HD. Conversely, the remaining 2 organizations[135,138] mandated ultrapure dialysate for all dialysis modalities. Seven organizations[53,131,132,134,136,137,143] lacked a description on membrane-type while defining HD in their documents.

Figure 4: Chemical Quality Criteria of Dialysis Water Across The Included Organizations

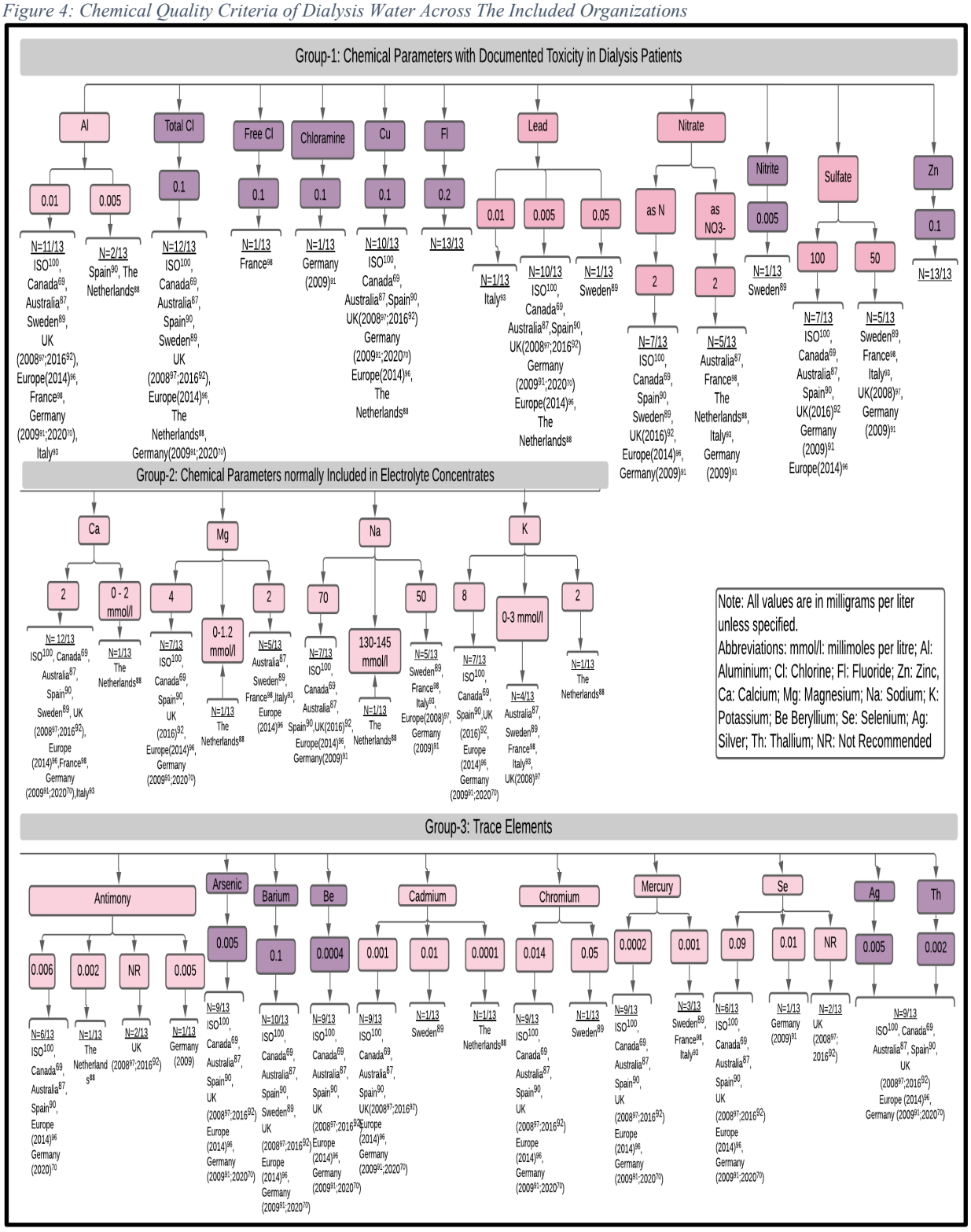
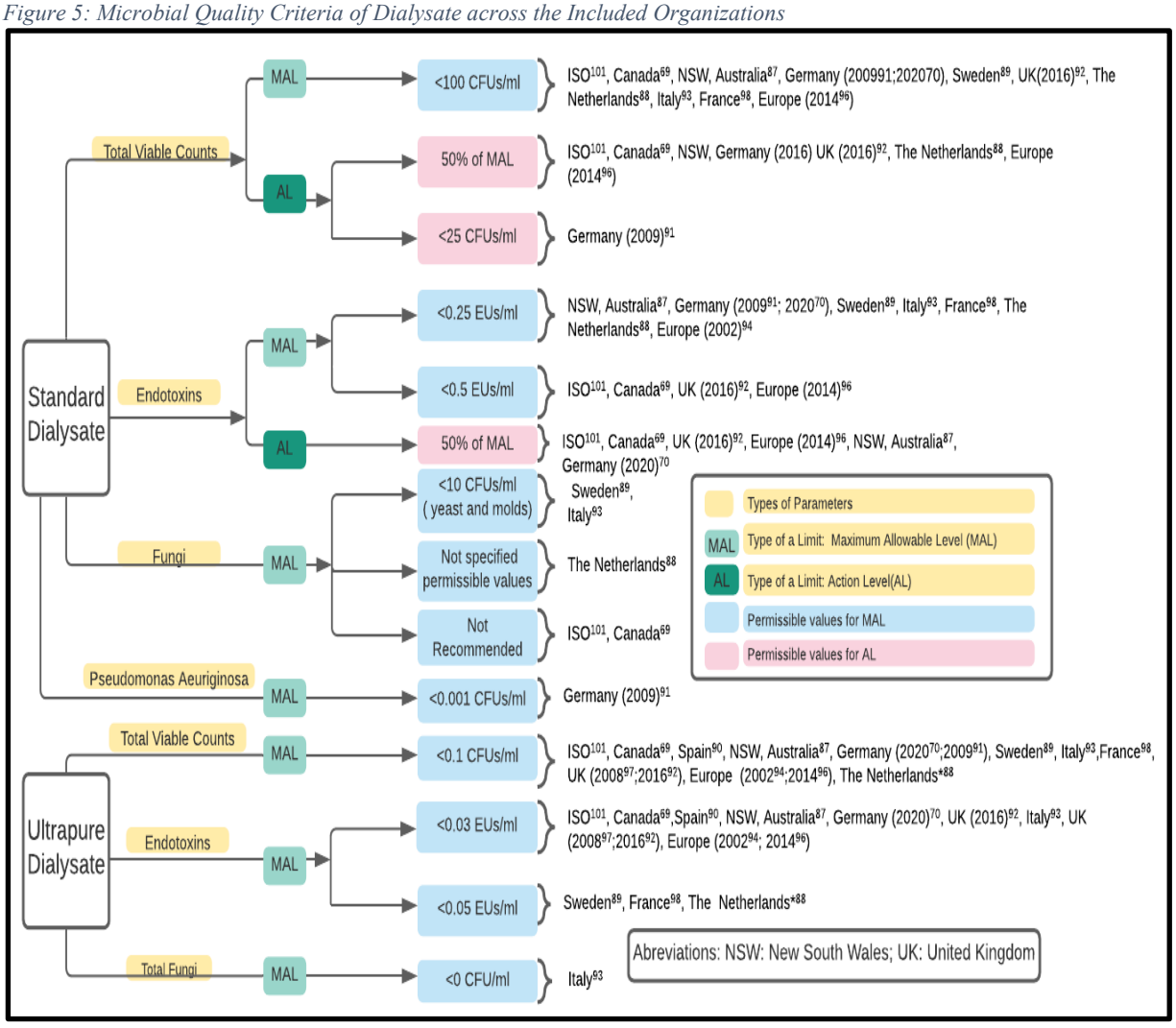


Figure 5: Microbial Quality Criteria of Dialysate across the Included Organizations



Topic-2: Treatment Systems to Achieve Quality Criteria of Dialysis Water and Dialysate

The production of DW and dialysate involves a treatment system (comprised of 4 stages), distribution piping, and the HD machine (see Figure 5). All organizations identified components for pre-treatment (12/12)[115,131,141–143,132–138,140] and main treatment (12/12)[115,131,142,143,132–138,141], but not for the other stages (preparation: 5/12[131–133,137,141], post-treatment: 7/12[131–133,135,137,141,143]) and at HD machine (8/12)[115,131–133,135,137,141,142]. Organizations varied widely in recognizing components as mandatory and recommended (e.g., among the 12 organizations, half of them recommended[131,133–135,137,143] softener for hardness removal, while the remaining[115,132,136,138,141,142] mandated its use). The sequence of components was more or less similar across the organizations, except for softeners and carbon filters[132,135,140,141].

At the pre-treatment stage, minor differences existed across organizations in identifying pre-filters, which is understandable since their selection highly depends on local SW circumstances. Moreover, variations existed concerning achieving chlorine requirements in DW; in contrast to 11 organizations, 1 organization[115] mandated component solely meant for chlorine or chloramine removal when such contaminants are present in SW. Organizations (10/12) were similar in identifying the main treatment component responsible for removing most chemical and microbial contaminants as needed for standard grade, except for 2 organizations[134,143] that also allowed deionizers under certain conditions. Organizations agreed that an ultrapure grade requires more components at main and post-treatment stages than the standard grade, and for which 3 different combinations of components were identified across 2 organizations[135,141]. In contrast, 1 organization[139] recognized point-of-use ultrafiltration at HD machines as sufficient.

Organizations were variable in identifying microbial control components after the final treatment component (7)[131–133,135,137,141,143] but not at HD machines (8)[115,131–133,135,137,141,142]. Among those components, a microbial filter of higher retention capacity had a twofold purpose. One was for achieving a higher grade of DW or dialysate[135,139,141]. Regardless of that, most organizations stated it for adding a layer of protection from microbial contamination for home patients (after final treatment component (1/5)[143], post-treatment and HD machine (7/9)[115,131–133,135,141,142], and either at post-treatment or HD machine[137]).

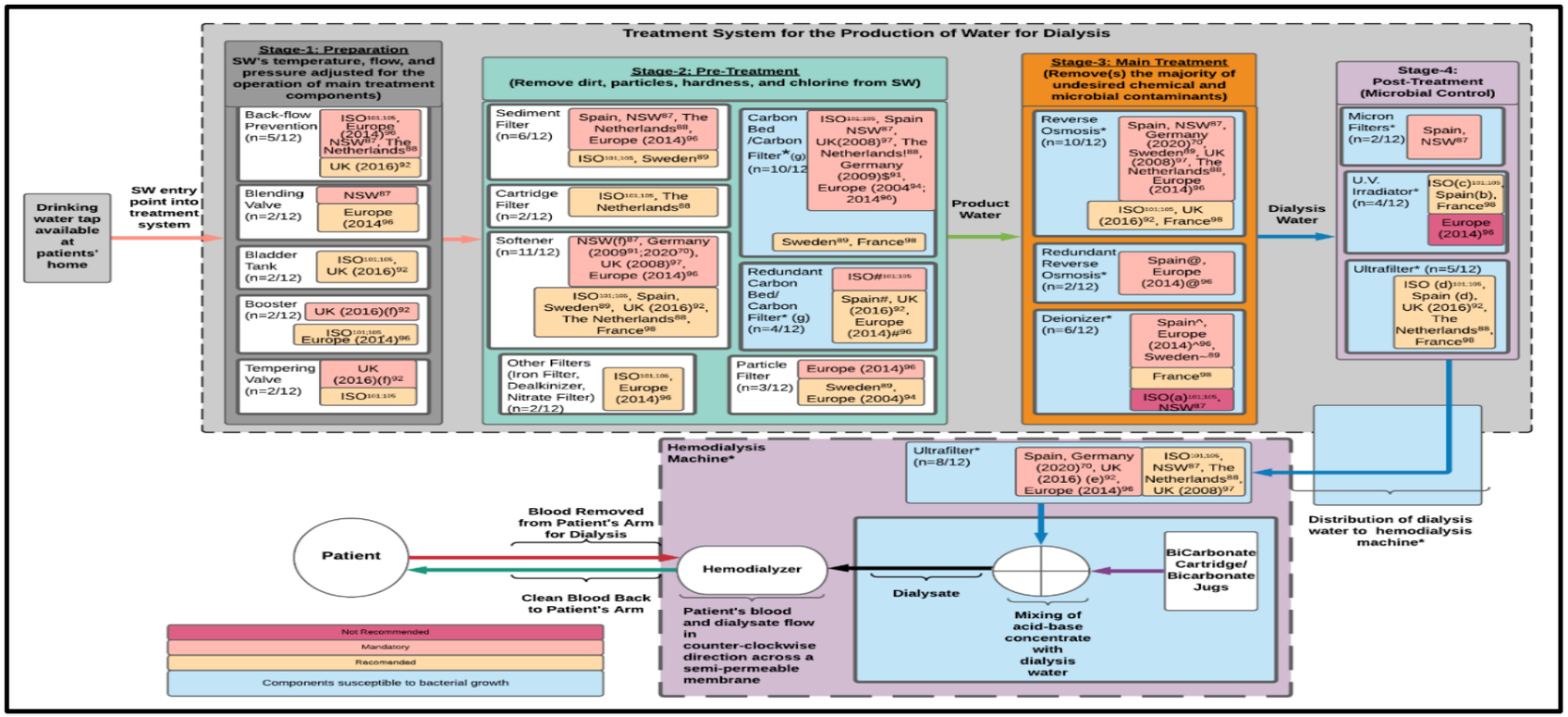
Overall, there was agreement that disinfection is required to prevent microbial growth, even if microbial filters exist within a production chain. Organizations (8/12)[131–133,135,139,140,142,143] discussed crucial parts of the production chain facilitating microbial growth and which parts require disinfection (9/12)[131–135,137,139,140,142]. On these aspects, the major disagreement was concerning the need of disinfecting a carbon filter, where 1 organization[140] was against it (see Figure 5).

Topic-3: Quality Management

Sub-Topic-1: Quality Control

All organizations agreed that QC mainly comprises 1) monitoring quality parameters and 2) undertaking corrective actions as required in response to monitoring results, although some had

Figure 6: Treatment System Components for Producing Dialysis Water and Dialysate of Required Quality



Abbreviations: ISO: International Standards Organization; NSW: New South Wales, Australia; SW: Source Water; mg/l: millligrams per litre. !: Mandatory only when SW contains chlorine or chloramine (Note: not specified specific concentration), and if not, then cartridge filter is adequate; #: Mandatory (by ISO) and recommended (by Spain and Europe (2014))when SW contains greater or equal to 1mg/l of chloramine or organic content of industrial wastes; $: Mandatory even when SW contains <1 mg/l of chlorine;@: Mandatory for the production of ultrapure grade of DW or dialysate; ^: The combination of single reverse osmosis and de-ionizer is required when double reverse osmosis is not used for the production of ultrapure grade of DW or dialysate; ~: mandatory to use deionizer when reverse osmosis is not used as primary treatment system; *: components that require disinfection; (a): ISO strongly discourages to use deionizer as the primary treatment system; (b): U.V. Irradiator is used only when double RO is not used for the production of ultrapure grade of DW. Also, U.V. irradiator is required to be followed by ultrafilter, if used; (c): U.V. Irradiator can also be placed after carbon filter as pre-treatment.; (d): Ultrafilter placed after de-ionizer or U. V. irradiator, when they are used for water purification. Spain mandates use of ultrafilter when the combination of single RO and U.V. Irradiator is used for the production of ultrapure grade of DW; (e): UK mandates ultrafilter, either as post-treatment or at HD machines.; (f): Mandatory for patients' home whose drinking water is not supplied from municipal authorities; (g) disinfection is not required

used other terminology for QC. The monitoring objectives identified across the organizations included 1) verification (13/13), 2) operational, and 3) trends analysis (10/13)[115,131,132,134,137,139–143]. Seven steps in a monitoring process were identified across the included organizations. However, compared to others, 2 documents had limited scope; 1 did not include statements on testing of chemical parameters[139], and the other on testing of dialysate[132]. The following sub-sections evaluate similarities and differences across organizations for all 7 steps of the monitoring process, organized in 4 phases (i.e., before HD machine's and treatment system's installation, at the time of installation validation, during routine operation, at the time of revalidation, and for special circumstances). Such statements apply to treatment components assembled from various vendors and not for an integrated treatment system. For the integrated treatment system, 2 organizations[131,137] mandated following manufacturers' instructions. Moreover, organizations generally acknowledged that manufacturers' instructions and applicable local laws or regulations take precedence over their documents, irrespective of treatment type.

Additionally, organizations were assessed to understand whether any of the following factors had been considered in establishing statements on a monitoring process: source type of SW, dialysis modalities, and treatment components.

Step-1: Sampling Locations (i.e., From Where the Samples Should be Collected?)

Several organizations addressed a specific sample location for DW (10[115,131,143,132–136,138,139,141]/13) and dialysate (6[131,134,135,138,139,141] /11[53,115,142,131,133–135,137–139,141]), however, none for SW.

Validation differed from routine operation in that it required sampling from each newly installed treatment component (8/10)[115,131–133,135,139,141,143]. During the routine operation, the most commonly stated sampling point for microbial testing of DW was the last component in the treatment system (usually post-RO) (7/10)[115,132–135,143]. Several other sampling points were identified for testing DW across 7 organizations[115,133–136,139,141], and variations existed across them. One organization[135] specified the criteria warranting sample collection from pre-treatment. No differences were noted across organizations in selecting sample locations for chemical testing of DW and microbial testing of dialysate (see Figures 6 & 7).

Several organizations with statements on ultrafilter required its sampling (6[131–133,135,137,141]/9[115,131–133,135,137,139,141,142]), and some of them[131–133,135], stated it with a proper location (i.e., pre-post)—none of the organizations mentioned sample location for an ultrafilter at HD machine.

Step-2: Testing Parameters and Testing Frequency (i.e., Which Parameters Should be Tested and at What Frequency?)

The included organizations' testing parameters and frequencies for physio-chemical and microbial quality verification are shown in Figures 6 & 7, respectively. All organizations had statements concerning DW testing, but not for SW (11/13)[53,115,142,143,131–134,137,138,140,141] and dialysate (10/13)[53,115,131,133–135,137,139,141,142]. Organizations agreed on testing samples of DW and SW for their microbial and physio-chemical quality and dialysate for ensuring microbial quality alone. The statements concerning when to test, from where to test, and how frequently are described below according to 4 phases.

Organizations specified the testing of SW (microbial: 3/11[53,132,141]; physio-chemical: 10/11[53,115,131,132,134,136,137,141–143]) to approve the installation of a treatment system and HD machine at patients' homes. After that, their validation would be initiated.

With 2[133,139] exceptions, organizations mandated obtaining a single sample of DW (microbial: 10/13[53,115,131,132,134,137,141,142,147]; chemical: 10/13[53,115,131–135,137,142,143]; process: 6/13[53,115,131,133,137,143]), and dialysate (microbial: 8/10[53,115,131,134,135,137,141,148] for approving the use of the installed treatment system and an HD machine). Two organizations[133,139] recommended more than a single microbial sample for DW. Some organizations recommended verifying SW during validation (microbial: 4/11[134,135,142,143]; chemical: 3/11[53,131,137]; process: 3/11[53,131,137]). Wide variations were noted in how the statements were laid out across these organizations (i.e., mandatory vs. recommended). Additionally, 5 organizations[131,133–135,139] recommended microbial testing for a longer period; specifically, 2[133,135] organizations stated a validation period of 1 month. However, variations were noted in their specified sampling locations and testing frequencies. Additionally, a detailed validation process was described for dialysis facilities.

All of the included organizations supported testing beyond the validation phase, that is, during routine operation; however, there were considerable disagreements across them. Eleven organizations mandated SW testing but they differed in parameter types (microbial: 6/11[53,115,132,134,137,142]; chemical: 9/11[53,115,131,132,134,137–139,143]; process: 1/11[135]). Nine specified testing frequency for guidance (note: 1[132] had not specified testing frequency for SW supplied from municipal source), while 1 stated it[53] as a requirement. Two organizations[133,142] recommended the criteria for when to test SW instead of providing a specific testing frequency. Among 8 organizations with specific routine testing frequency, all but 2 organizations had set the annual testing frequencies for SW's microbial quality[53,137] and chemical quality[53,115,131,137,138,141] when supplied from municipal sources. Irrespective of SW source type, 2 organizations specified[133,134] bi-annually for microbial quality, and 1[134] for chemical quality. Almost half of the organizations specified a different testing frequency for SW supplied from sources other than municipal (microbial: 2/4[53,137]; chemical: 5/8[53,115,131,132,137]), including bi-annually[53,137], more than yearly[115,131], and annually[132]. Overall there was an agreement among the organizations that SW supplied from private sources requires more frequent testing than SW supplied from municipal sources. Concerning process parameters, 1 organization[135] mandated their monthly verification.

Most of the organizations mandated testing of both DW and dialysate during routine operation (9/13)[53,115,133–135,137–139,141,142]. However, specific to ensuring microbial quality, 1 organization[131] required sampling from dialysate only. Three organizations[132,136,143] mandated DW testing; however, they did not include statements on dialysate testing. Of the organizations mandating DW or dialysate testing, all but 1[132] provided a specific testing frequency (DW: 11/11[53,115,143,133–135,137–139,141,142]; dialysate: 8/10[53,115,133–135,137,138,141]); however, they differed on DW's parameters types (microbials: 11/11[53,115,142,143,133–139,141]; chemicals: 11/12[53,115,143,131,133–135,137,138,141,142]. Four organizations mandated their testing frequency (microbial: 2/4[53,135]; chemicals: 4/4[53,135,138,142]), but it varied across them (see Figures 6, 7 & 8). The routine testing frequency also varied depending on the source types of SW (for chemical)[53,115,131,137], dialysis modalities (for microbial)[137], parameters type, and treatment components[115,131]. Specifically, 7 organizations recommending the use of ultrafilters were not in agreement concerning dialysate testing. Of these, 2 organizations[115,131] did not require testing, 2 organizations[135,143] required

testing, and 1[137] was not clear in its statement. However, having such filters on an HD machine or a treatment system did not impact downstream testing (i.e., DW)[115,132,133,135,137,142,143], except in 1 organization[142] that allowed reducing the testing frequency from monthly testing.

Overall, microbial quality must be verified more frequently than chemical quality, except for chlorine. Moreover, specific parameters required testing during each dialysis session, including chlorine, operational parameters, and chemical disinfectants. Only 1 organization[132] did not need patients to perform testing.

Organizations (9/13)[53,115,131,133–136,142,143] provided various scenarios under which revalidation may be required, along with recommendations from where to obtain samples.

In addition to the three phases, as mentioned above, organizations mandated testing when clinical symptoms appear[131,136,139,143] and recommended adjusting testing frequency depending on geographical locations and seasonal variations[53,131,132,143].

Organizations (8/13) also encouraged dialysis facilities to develop a customized testing frequency. Methods to determine a testing frequency included the estimated annual dialysis sessions[143], local validation test results[115,131,134], trends analysis[115,131,133,134,142], SW quality[132,134,143], sampling DW and dialysate in alternate months[135], degree of disinfection[136], or when clinicians request it[132].

Step-3: Testing Parameters (i.e., For What parameters Should Source Water, Dialysis Water, and Dialysate be Tested?)

All organizations had statements related to testing parameters for different phases, including validation and routine operation. Specifically, 1 organization[143] recommended using a risk assessment method to identify parameters that may require testing based on geographical locations and seasonal variations. The decision on what to test is up to dialysis facilities during revalidation and special circumstances.

All but 2 mandating SW, DW, and dialysate testing during validation and routine operation agreed to include their required microbial and process quality parameters as testing parameters; 1[139] organization was different since it preferred testing of endotoxin over total viable counts.

While organizations recommended routine testing for pseudomonas aeruginosa in DW[136,138], 1 organization[115] did not.

All organizations mandating chemical testing of SW and DW were similar in including all their specified chemical and process quality parameters as testing parameters for validation. However, other than chlorine, there were wide variations in their specified routine chemical testing parameters. While 5 organizations[53,132,134,138,141] mandated testing of all their stipulated chemical quality parameters during routine operation, the remaining organizations restricted testing to specific parameters. Five[115,131,133,135,143] required off-site testing of those parameters with evidence of toxicity in dialysis patients while using online meters for trace elements, and 1 organization[133] selected 3 parameters out of its 11 prescribed quality parameters for routine testing. Three organizations[134,137,142] omitted those parameters rarely seen above their required maximum allowable level in SW. All these options were provided for dialysis programs facing budget and resource constraints. However, such restricted testing was allowed when SW and operational parameters of the treatment system were within the safe limits.

Step-4: Sample Collection, Storage, and Transportation (i.e., How to Collect, Store and Transport Testing Samples?)

Ten of the 13 organizations[53,131–137,139,142] had recommendations on sampling procedures to avoid sample contamination. These included cleaning the port with disinfectants that can evaporate rapidly, ensuring absence of disinfectant residuals at the time of sample collection, collecting samples before any disinfection, draining out the water before final sample collection, and collecting the second sample after discarding the first one. Assaying samples immediately after their collection was preferred; however, organizations acknowledged the limitations of home programs in following such a recommendation. Therefore, documents included recommendations on proper sample storage conditions to be followed after their collection and during their transportation to the examining laboratory. Organizations[53,131–137,139,142] varied in specifying sample storage temperature during its transit (range: 1 to 10 degrees Celsius), but they were similar in specifying time duration for assaying a sample after it had been collected (i.e., within 24 hours). One organization[133] addressed the process of sending samples to the laboratory. Detailed recommendations as established by the relevant organizations for this

section are provided under Appendix 2. In terms of chemical contaminants, no such major precautions were indicated except for chlorine and hardness measurements.

Step-5: Testing Location and Testing Methods (i.e., Where and How Should the Samples be Tested?)

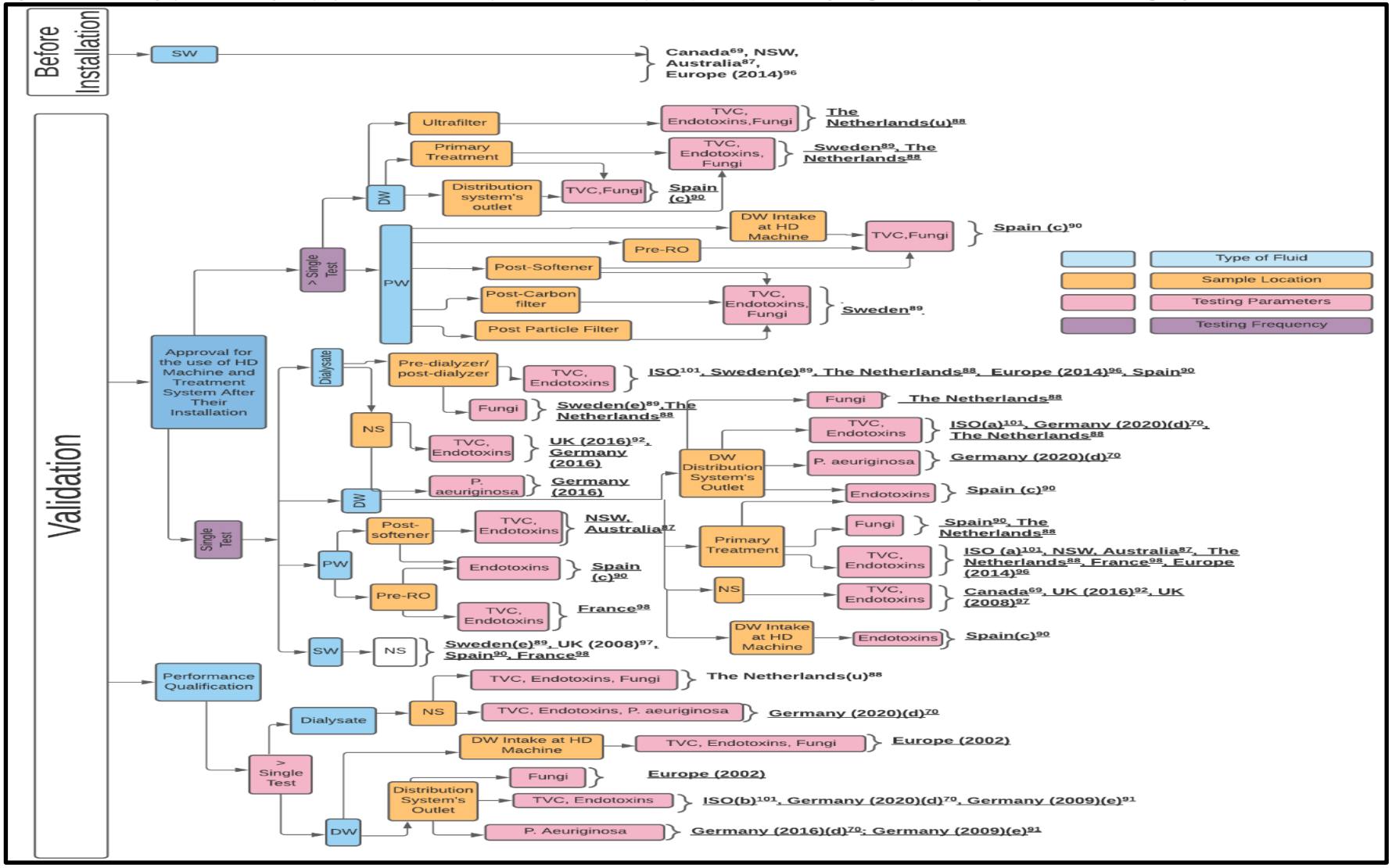
No significant issues were discussed in listing types of tests for chemical contaminants (5/10)[53,131,135,137,140] and microbial parameters (other than total viable counts) (10/10)[53,131–137,139,142].

Overall, significant differences were noted across the organizations for testing techniques, incubating conditions, and testing media for assessing total viable counts. Additionally, testing methods differed according to quality grades. Membrane filtration (9/10)[53,131–135,137,139,142] was the most preferred recommended testing method for assessing total viable counts for both the grades of DW and dialysate. Additionally, standard plate (8/10)[53,131–133,135,136,139,142] and pour plate (6/10)[53,131,132,136,139,142] were also recommended, but for standard grade only. The dip-sampler technique was not recommended except by 1 organization[132]. Reasoners' 2A (R2A) is the testing media recommended by most of the organizations (9/10)[53,131–134,136,137,139], followed by tryptone glucose extract agar (TGEA) (6/10)[53,131,133,136,137,139] and tryptone soy agar (TSA) (4/10)[53,131,132,134]. The former 2 were recommended for both the grades of DW and dialysate, and the latter for standard grade only. Organizations differed in their recommended incubation temperature while using these testing media, but not for incubation days. Half of the organizations (5/10)[131,135,137,141,142] had recommendations on inoculation volume. The details of testing methods are provided in Appendix 2.

Step-6: Interpretation of Test Results and Remedial Actions (i.e., When Quality Test Results are Considered Unacceptable and What Should be Done About Their Deviations?)

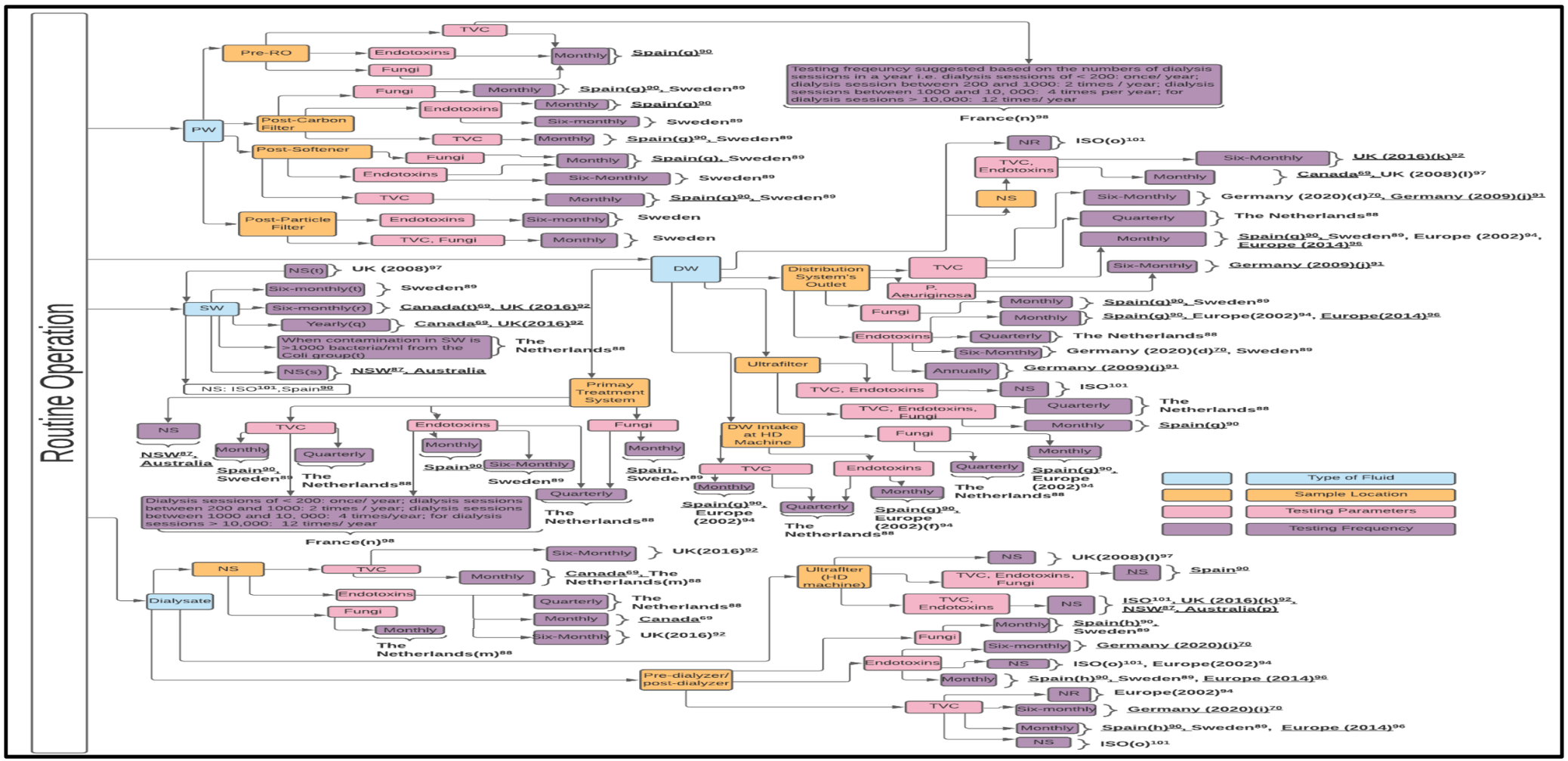
All of the organizations had suggested remedial actions when results were not acceptable for their prescribed quality parameters. They agreed that the stipulated values under the action level have operational significance, whereas the maximum allowable level is related to patient safety. The action level was provided only for microbial contaminants as an indicator for rising microbial growth or development of a biofilm.

Figure 8: Monitoring of Microbial Quality of Source Water, Dialysis Water, and Dialysate (Validation Testing Frequency, Testing Parameters, and Sampling Locations)



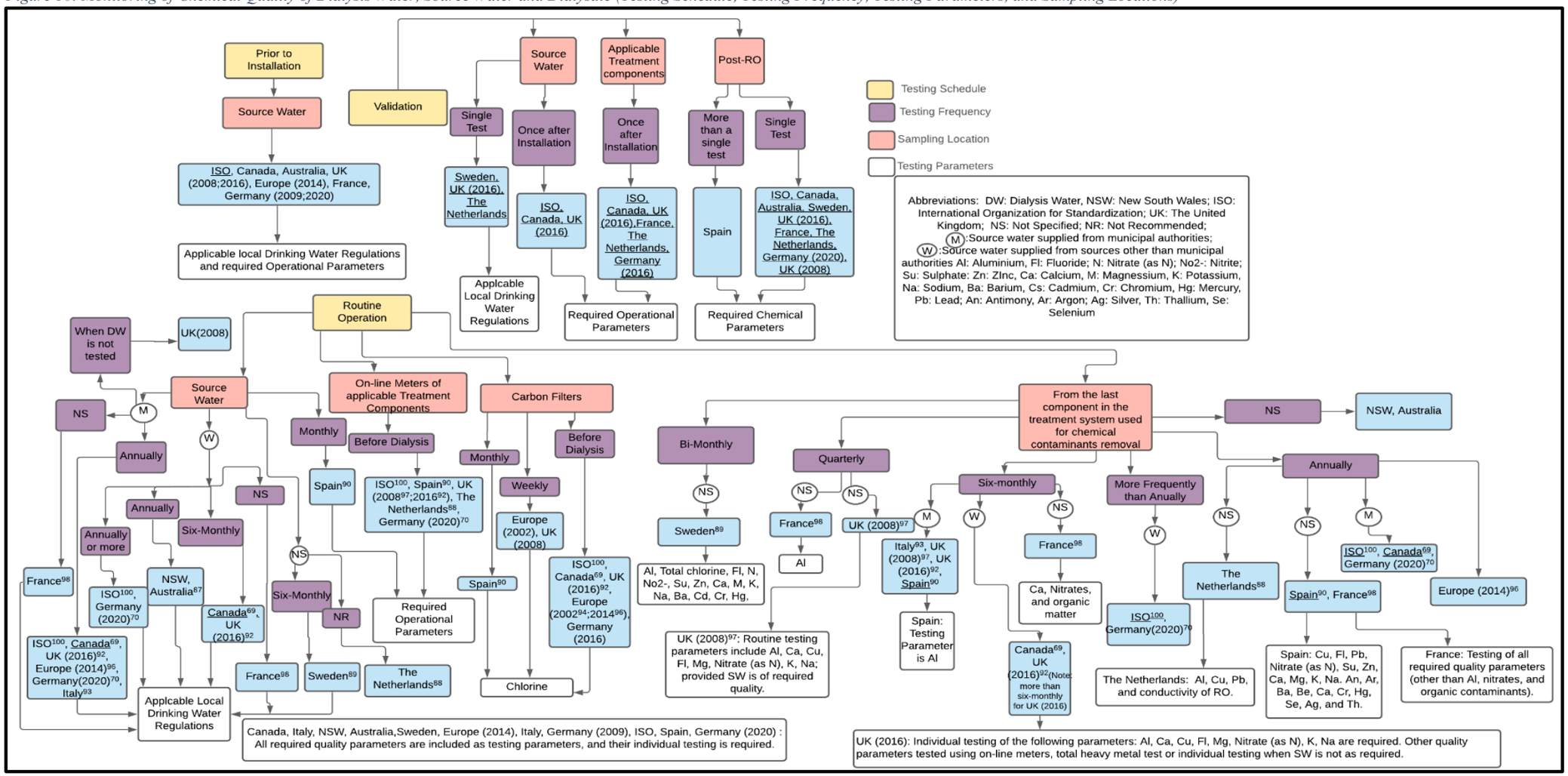
Abbreviations for Figure-8: SW: Source Water; PW: Product Water; DW: Dialysis Water; NR: Not Recommended; NS: Not Stated; NSW: New South Wales; TVC: Total Viable Counts; RO: Reverse Osmosis; P. Aeuriginosa: Pseudomonas Aeuriginosa; HD: Hemodialysis; Note: Post-RO was specifically stated as the primary treatment by Spain (2016), NSW, Australia, Sweden, and France. (a): Recommended sampling from the component used as a primary treatment, which is usually RO, and less frequently, de-ionizer; (b) Alternatively, ISO recommends sampling from HD machine as part of performance qualification(PQ). ISO does not specify for how long the PQ should be conducted. However, states that single test from HD machine and treatment system is required for the initiation of HD therapy. ISO does not recommend testing of dialysate, if HD machine is fitted with ultrafilter. (c) Spain (2016) requires validation period of 1 month. Spain mandates the testing of dialysate without specifying a testing frequency during validation. There is no clear statement on testing requirement for initiating dialysis after the installation of treatment system and HD machine. (d) Sampling locations for DW were implied, as the stated sampling locations seemed not specific to HHD. The sampling point related to DW distribution system is from the connectors on DW distribution pipe and not at outlet. A specific location for dialysate sampling was not provided. (e): Germany (2009) had no statement on testing requirement for initiating dialysis after the installation of treatment system and HD machine. The testing of DW had been mandated for endotoxins during validation without providing a testing frequency. Further, some of the stated sampling point were not specific to HHD (i.e., transfer point from the water treatment plant, in the middle and at the end of distribution pipe). Identifying additional sampling points by a dialysis facility was recommended.

Figure 9: Monitoring of Microbial Quality of Source Water, Dialysis Water, and Dialysate (Routine Testing Frequency, Testing Parameters, and Sampling Locations)



Abbreviations for Figure 9: SW: Source Water; PW: Product Water; DW: Dialysis Water; NR: Not Recommended; NS: Not Stated; NSW: New South Wales; TVC: Total Viable Counts; RO: Reverse Osmosis; P. Aeuriginosa: Pseudomonas Aeuriginosa; HD: Hemodialysis; (f): Europe (2002): Does recommends validating the system as part of performance qualification (PQ) by testing the system once a week after it has been installed, without specifying a validation period. Furthermore, there was no clear statement on when the system could be put into use after its installation. A testing frequency was not specified for fungi during routine operation. (g) Testing from a post-carbon filter and a pre-RO was mandatory when their disinfection are not being performed during routine operation. The sampling point for DW also included from the begining of DW distribution system and from pre and post of an ultrafilter. (h) When monthly testing of DW and dialysate is not possible, then their testing was recommended to be conducted in alternative months. The sampling point for dialysate was from pre-dialyzer. (i) Dialysate testing was stated as mandatory upon not meeting any of the following three conditions: ultrafilter on an HD machines, ultrafilters not operated in accordance to manufacturers' instructions, and DW of required quality. (j) Sampling points were implied, since the specifed sampling points did not seem applicable to HHD, and they were: transfer point from the water treatment plant and from middle of distribution system. Testing frequency and sampling location was not provided in relation to HHD for fungi. (k) The guideline stated that the recommended dialysate testing frequency would not be sufficient for daily dialysis regime. Further, recommended following manufacturer's intructions for testing of ultrafilters. (l) Acknowledged that the recommended DW testing frequency would be impractical to implement at home programs, and therefore, recommended using ultrafilter on HD machine. (m) Recommended to reduce the testing frequency from monthly to quarterly for TVC in dialysate, when it is shown to be within the required permissible values over a certain period. (n) Testing of DW is mandatory even when HD machines are fitted with ultrafilters, (o) The testing of DW was not recommended when dialysate quality is as required. The testing of dialysate was not required when HD machines have ultrafilters (Note: Not clear whether this statement is applicable to home settings). (p) Testing frequency for SW supplied from sources other than municipal is required to set at a higher frequency than that for SW supplied from municipal authorities. The sampling points for an ultrafilter (HD machine) is from pre-post ultrafilter. (q) SW supplied from municipal authorities. (r) SW supplied from sources other than municipal authorities. (s) SW supplied from municipal authorities and from sources other than municipal authorities. (t) Source type for SW was not specified (u) Mandated the period of PQ of a year, however, no specific frequency had been provided for PQ. Further, system could be put into use after having obtained compliant microbial results for 1 month, and during that time, the recommended testing frequency for DW and dialysate was weekly. In contrast, a single dialysate test was mandated to initiate the use of HD machines. In Figure 9, a country name is underlined to showcase that an organization from that country had specified its statements as mandatory, and a country name is not underlined when an organization from that country had specified its statements as recommended.

Figure 10: Monitoring of Chemical Quality of Dialysis Water, Source Water and Dialysate (Testing Schedule, Testing Frequency, Testing Parameters, and Sampling Locations)



Organizations recommended similar subsequent steps when the action level has not been fulfilled (resampling and then disinfection of the system or HD machine). After that, more profound investigative actions are required to identify sources of microbial contamination. Although these would depend upon the type of treatment system, some general guidelines were provided. These included: (1) evaluating dead spaces within the treatment system[131], (2) identifying components that are not getting disinfected (e.g., distribution pipe between RO and HD machine) and are more susceptible to contamination (carbon filters, ultrafilters)[133], (3) replacement of components majorly responsible for microbial filtering (RO, ultrafilters)[131,133,139], and (4) revalidation of disinfection strategy[131,139]. Organizations generally agreed that the implementation of disinfection as suggested by manufacturers is the only strategy for keeping microbial growth in control.

All organizations had generally stated that DW must be within the maximum allowable level for their prescribed chemical quality; this also applies to operational parameters. Additionally, 1 organization[135] noted that RO conductivity is an indicator of chemical contamination in DW, and subsequently, chemical testing of DW was required.

When results go above the maximum allowable level for microbial, 1 organization[135] mandated terminating dialysis. However, 3 organizations[131–133] suggested leaving the decision to the individual medical directors. No specific quality criteria for stopping dialysis were provided for results above the maximum allowable level for chemical contamination.

Step-7: Stakeholders' Responsibility (i.e., Who Should be Responsible for What?)

Nine organizations[52,131–137,143] mandated having suitable personnel for the performance of each quality management activity. The stakeholders from various disciplines crucial for the implementation of various management activities were mentioned across these organizations. They included technologists, a clinical manager, patients and/or their helpers, nephrologists, laboratory personnel, medical directors, a quality control manager, hygienists/ microbiologists, infection control committee, and external vendors. However, detailed guidance was lacking across the organizations[131–135,137,139,143] on who should be involved in specific activities. These included technical maintenance of treatment components (e.g., involving either in-house

technical staff or external vendors), sample collection, sample transportation, coordination with laboratory personnel for test results, and who dialysis patients should contact upon failure of results). Only 1 organization[132] stated that patients should not be involved in routine quality checks. Organizations recommended having either a clinical manager[115,131,132,134,135,137] or a quality manager[52,115,132,134,135,137,143] for higher-level management tasks, such as approval of validation/revalidation of treatment components, the establishment of quality management activities and providing oversight, performing trend analysis, and conducting internal audits.

Further, a working group or a committee specifically for HHD was recommended for quality management and a higher level of decision-making using audit results[52,132,133,137,143]. One organization suggested having a risk management team for establishing QI[137]. Although the activities are delegated among the varied stakeholders as per their expertise, organizations agreed that the ultimate responsibility rests on the medical director[133,135,139,145]. Organizations differed in how they specified the accountability of the medical director for the final chemical and microbial quality of DW and dialysate[135,139,145].

Sub-Topic-2: Quality Assurance

The following were mandatory activities underlying QA as mentioned across the 10 organizations[52,115,131,132,134–137,140,143]: (1) record keeping, (2) scheduling training programs when required, (3) performing and documenting trend analysis of quality results, (4) internal auditing[52,115,131,132,135–137,140,143], (5) external auditing[115,134], and (6) conducting quality meetings. Organizations made similar recommendations on how each of these activities should be completed and how frequently. Two organizations[132,140] had additional requirements for auditing patient outcomes to ensure the safe delivery of HD. Home programs were required to have written policies and procedures on each QC activity.

Sub-Topic-2: Quality Improvement

The internal audit or trend analysis results were suggested to be critically analyzed to identify areas of improvement[132,133,136,137]. The QI tools, as mentioned across the organizations, but without details on their methods, included the plan-do-check-act (PDCA) cycle[136], root cause analysis[137], and risk analysis[131,143].

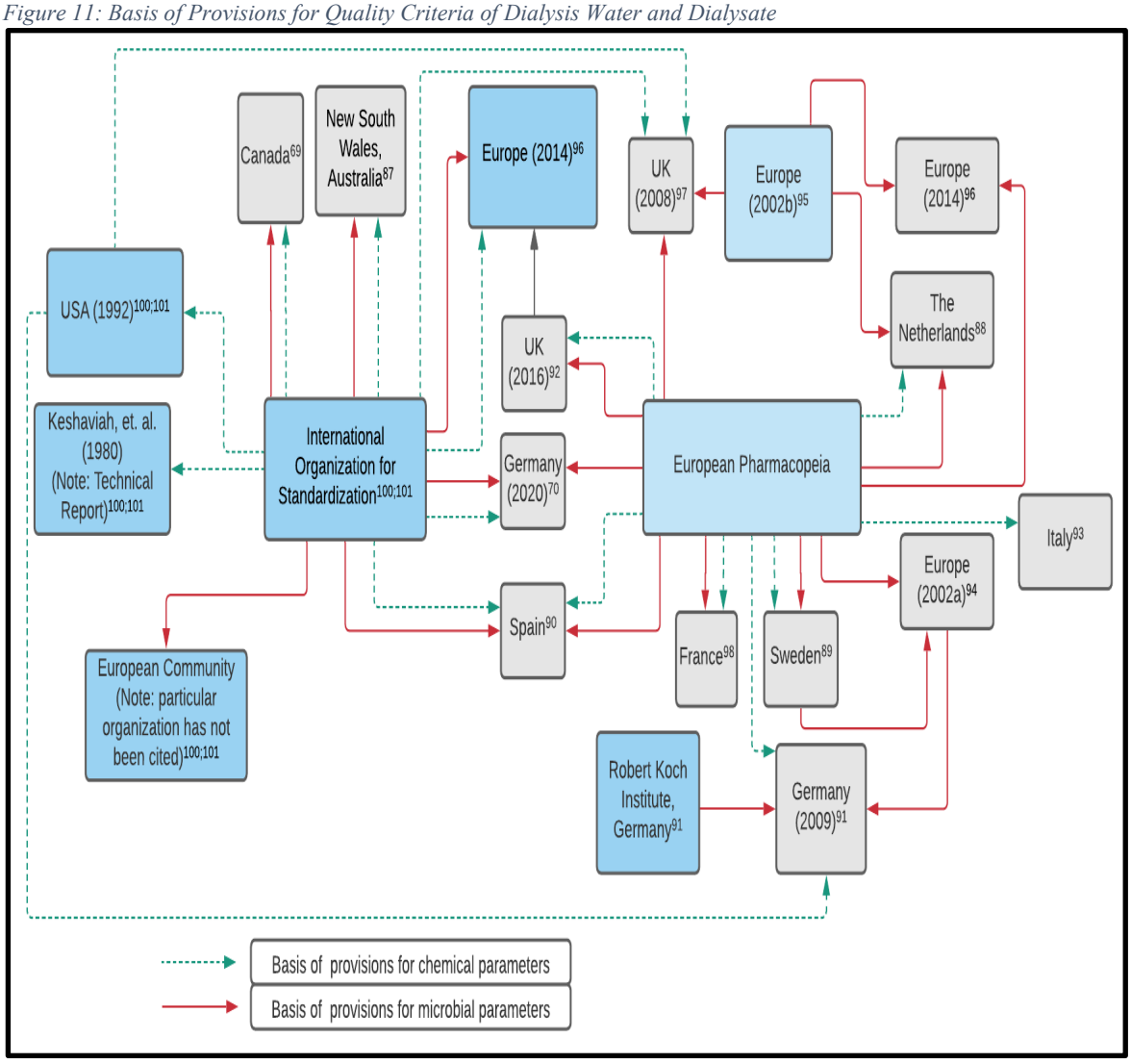
Quality of Evidence as Assessed by the Included Organizations

This section analyzed the rationale provided by the organizations to establish their requirements or recommendations for each topic and sub-topic included in this review.

Thirteen organizations[53,115,141–143,132–139] cited one or more of the primary organizations as a rationale behind their established permissible values for chemical and microbial quality parameters of DW and dialysate (see Figure 8). In addition, 4 organizations[131,135,137,142] cited clinical studies, in-vitro studies, or reviews. They were used as evidence for the pathway of contaminants entering into patients' blood from DW and dialysate. The cited studies also reported contaminant types that led to adverse events among dialysis patients in the past and at what concentration in DW or dialysate.

The evidence used to support microbial parameters, except for fungi and chemical requirements, is of moderate quality as assessed by 2 organizations[137,138]. In contrast, the other organizations[53,115,133,134,138,139,141–143] relied on expert opinion. The same evidence (i.e., primary studies) of fungi was assessed differently across 3 organizations, including moderate quality[138], low quality[135], and not substantial enough to be used as evidence[146]. The disagreements existed across organizations in assessing the quality of evidence used for the ultrapure grade of DW or dialysate. The organizations favoring ultrapure grade DW or dialysate based their statements on the level of evidence ranging from expert opinion to high quality[135,137,142]. Two organizations[131,133] did not favor using the ultrapure grade of dialysate because of budgetary and resources constraints. Only 2 organizations[135,137] rated the strength for their recommendations on quality parameters as strong, except for aluminum which was rated as weak[135].

Figure 11: Basis of Provisions for Quality Criteria of Dialysis Water and Dialysate



The statements on treatment components were based on expert opinion[53,115,149,132–135,137,141–143], except for ultrafilter use, which was supported by a moderate quality of evidence but rated as a strong recommendation[135,137]. Two organizations[53,115] cited the ISO as their only evidence source for treatment components. Eight organizations[132–135,137,141,143,149] additionally provided references to clinical studies or a descriptive rationale.

All but 1[53] provided a rationale for monitoring DW and dialysate quality using clinical studies or descriptive reasoning. Still, none justified their established testing frequency. The statements on testing frequency were based on expert opinion[53,115,141,143,145,132–136,138–140], and 2 organizations[115,141] also cited ISO. Two organizations rated the strength of their statements

differently, strong[137] and weak[135]. Most organizations[53,133–137,139,145,146] that specified microbial testing methods cited one or more primary organizations as rationale, except one[132], which did not provide any justification. Four organizations[131,135,137,139] used experimental studies as a source of information to derive their statements on incubation media, time, and temperature; however, none of them graded the quality of evidence.

Discussion

To our knowledge, this is the first international comparison of standards and guidelines for dialysis delivered in the home setting, where there are unique logistical challenges compared to facility-based HD.

Although the benefits of HHD seem to be clear, they have not translated into an increase in its adoption. The provision of water that is safe for HD may serve as one of the impediments to recruiting and retaining clinically eligible ESRD patients in HHD programs[20,29,30,32,34,150]. Dialysis programs may face challenges in managing water quality[100,151,152] when both initiating and maintaining patients on HHD, and thus they will need to identify the best approaches to support decision-making. This scoping review evaluated similarities and differences in statements on microbial and physicochemical quality parameters and their permissible values in water used for HHD, the means of achieving the defined quality, and quality management for the safe delivery of HHD across 13 organizations. The results indicate that there are heterogeneities across them.

Previously published reviews of HD standards and guidelines[153–156] have attributed these heterogeneities to (1) use of different assaying conditions for quantifying total viable counts, and (2) water quality used for HHD varies from region to region. This review findings revealed that organizations have identified ways of addressing the first heterogeneity, however, not the second one. It may not be important to reach agreement on the desired chemical quality of DW (except for parameters that have evidence linking them to adverse effects) since various factors, including natural geographic conditions, local drinking water regulations, patients' home conditions, local activities threatening contamination in SW, and electrolyte composition for dialysate could vary from region to region. However, establishing universal microbial

requirements for DW and dialysate quality is desirable, since the pathway of dialysate production, which is an intrinsic factor for microbial growth in DW and dialysate remains similar for all dialysis patients, regardless of region. This review suggests that heterogeneity likely arises from the interpretation of the primary literature. However, the patients not performing their dialysis using identical microbial DW and dialysate quality does not seem to be an issue unless such differences produce variability in patient outcomes. In this context, further research on understanding the impact of DW and dialysate quality on outcomes that are clinically relevant to healthcare professionals and patients would be helpful to organizations in understanding the need for harmonization.

Heterogeneity also exists around the means of achieving desired water quality for HD and quality management. Therefore, there is a need for research on (1) determining the minimal configuration and management strategies that can deliver HD water of the desired level of quality, and (3) identifying the practical challenges that may arise in standards implementation.

This scoping review has some limitations. Since professional services were not utilized to translate non-English documents, there could be errors in their translation. However, it does not significantly affect the overall results since most of the extracted information was numerical, and only a few of them were descriptive (e.g., statements on the basis of evidence and therapeutic application of different grades of DW and dialysate) which may have a higher likelihood of being misinterpreted. Organizations were not contacted to clarify the applicability of their documents to home programs. Therefore, it is possible that some organizations for whom the statements used for facility-based HD remain applicable to home settings at ground-level may have been missed. This scoping review did discuss the methodological quality of guidelines but they were not evaluated individually using appraisal tools for the quality assessment of practice guidelines. However, since the purpose was to inform organizations on improving their development process, this was not inappropriate.

Table 2: Characteristics of the Included Organizations

Sr. No.	Organization	Year	Organization type	Document type (numbers)	Country, Level	Aim/Purpose	Multidisciplinary development group (Yes/No)	Source of funding	List of reviewed documents from other organizations (Yes/No)	Formalized search strategy (Yes/No)	Quality appraisal of evidence used to formulate directives (Yes/No)	Formal method to formulate directives (Yes/No) / Authorship
1.	ISO	2019	Standards	• Standards (n=2)[145,146] • Guideline (n=2)[131,149]	International	• To specify quality criteria of water used in HD and treatment components for the prevention of adverse events in dialysis patients • To provide guidance on implementing quality criteria of SW, DW, and dialysate • Documents revised to harmonize with ANSI/AAMI (2014)	• Yes	• NM	• No	• No	• No	• Yes • Organizational
2.	CSA	2017	Standards	• Standards (n=2)[52,53]	Canada, National	• To resolve inconsistencies in the outcomes arising from practice variations (other than clinical) that may exists across home dialysis providers in Canada	• Yes	• From industry and CSA` s health care group	• Yes	• No	• No	• Yes • Organizational
3.	ACI	2018	Professional	• Guideline (n=1)[132]	New South Wales, Australia, State	• To specify quality criteria of water used in HD and of treatment components for the prevention of adverse events in dialysis patients • To provide guidance on implementing the quality	• Yes	• NM	• Yes	• No	• No	• NM • Committee

Sr. No.	Organization	Year	Organization type	Document type (numbers)	Country, Level	Aim/Purpose	Multidisciplinary development group (Yes/No)	Source of funding	List of reviewed documents from other organizations (Yes/No)	Formalized search strategy (Yes/No)	Quality appraisal of evidence used to formulate directives (Yes/No)	Formal method to formulate directives (Yes/No) / Authorship
						criteria of water used in HD						
4.	SSN	2015	Professional	• Guideline (n=1)[135]	Spain, Europe, National	• Guideline was revised to a) unify with ISO's directives where possible, and b) establish provisions for HHD and high-flux modality of dialysis	• Yes	• NM	• Yes	• Yes	• Yes	• Yes • Authors
5.	ISN	2005	Professional	• Guideline (n=1)[138]	Italy, Europe, National	• Guideline was revised to provide detailed directives on implementing the quality criteria of water used in HD, with the purpose of minimizing practice variations across dialysis programs in Italy	• Information could not be extracted+	• Information could not be extracted+	• Information could not be extracted+	• Information could not be extracted+	• Yes	• Information could not be extracted+
6.	The Renal Association and The 92 of Renal Technologists	2016	Professional	• Guideline (n=1)[137]	UK, Europe, National	• To specify quality criteria of water used in HD and of treatment components • To provide guidance on implementing quality criteria by considering local situations, with the purpose of facilitating dialysis technicians in performing their tasks and promote patient safety	• Yes	• NM	• Yes	• Yes	• Yes	• NM • Authors
7.	Working Group for	2009	Professional	• Guideline • (n=1)[136]	Germany, Europe, National	• To summarize quality criteria existing in Germany for water used in HD	• Yes	• NM	• Yes	• No	• No	• Yes • Organizational

Sr. No.	Organization	Year	Organization type	Document type (numbers)	Country, Level	Aim/Purpose	Multidisciplinary development group (Yes/No)	Source of funding	List of reviewed documents from other organizations (Yes/No)	Formalized search strategy (Yes/No)	Quality appraisal of evidence used to formulate directives (Yes/No)	Formal method to formulate directives (Yes/No) / Authorship
	Applied Hygiene in Dialysis Units					• To provide guidance on implementing such quality criteria						
8.	German Society of Nephrology	2020; 2019	Professional	• Guideline (n=1)[115] • Supplementary (n=1)[157]	Germany, Europe, National	• To provide guidance on implementing quality criteria of water used in HD	• Yes	• Information could not be extracted+	• Yes	• No	• Yes	• Yes • Committee •
9.	SMPA	2020	Regulatory Agency	• Guideline • (n=1)[134]	Sweden, Europe, National	• Guideline updated a) to incorporate latest editions of Eu. Ph. and b) provide guidance on implementing quality criteria of water used in HD	• Information could not be found+	• Information could not be found+	• Yes	• No	• No	• Information could not be found+ • Organizational
10.	The Dutch Federation for Nephrology (NfN)	2020	Professional	• Guideline (n=1)[133] • Supplementary[158]	The Netherlands, Europe, National	• Guideline updated to a) incorporate the section on legal requirements, b) provide directives for HHD and high-flux modality of HD, and c) clarify the status of existing ISO standards in the Netherlands.	• Yes	• NM	• Yes	• No	• No	• Information could not be found+ • Organizational

Sr. No.	Organization	Year	Organization type	Document type (numbers)	Country, Level	Aim/Purpose	Multidisciplinary development group (Yes/No)	Source of funding	List of reviewed documents from other organizations (Yes/No)	Formalized search strategy (Yes/No)	Quality appraisal of evidence used to formulate directives (Yes/No)	Formal method to formulate directives (Yes/No) / Authorship
11.	The Ministry of Health in France	2000	Government	• Circulaire (n=1)[143] •	France, Europe, National	• To provide guidance on implementing quality criteria of water used in HD	• Yes •	• NM	• Yes	• No	• No	• NM • Organizational
12.	EDTNA-ERCA	2002; 2004; 2014	Professional	• Guideline (n=3)[139–141]	Europe, National	• To provide guidance on implementing quality criteria of water used in HD •	• Yes (2002,2014) • NM (2004) •	• Educational grant from industry(141) • NM(139,140)	• Yes	• No	• No	• NM • Organizational (2002) (139) • Authors (2004 & 2014) (140,141)
13.	BAPN	2008	Professional	• Guideline (n=1)[142]	UK, Europe, National	• Guideline developed to provide directives on clinical care aspects of dialysis for children, and water quality has been considered as one of the domain of clinical care	• No	• NM	• Yes	• No	• No	• No • Authors

Abbreviations: ISO: International Organization for Standardization; CSA: Canadian Standards Association; ANSI/AAMI: American National Standard Institute/Association for the Advancement of Medical Instrumentation; ACI: The Agency for Clinical Innovation; EDTNA/ERCA: The European Dialysis and Transplant Nurses Association/European Renal Care Association; ISN: Italian Society of Nephrology; BAPN: British Association for Pediatric Nephrology; Eu. Ph.: European Pharmacopeia; [+]Information not available in English language; NM: Not mentioned

Chapter-3: Facilitators and Barriers to the Management of Water Quality in Home Hemodialysis Programs in Canada: A Qualitative Approach

Chapter-3: Facilitators and Barriers to the Management of Water Quality in Home Hemodialysis Programs in Canada: A Qualitative Approach

Background

End-stage renal disease (ESRD) patients need dialysis therapy for their survival. Since ESRD patients have to wait to receive a transplant, which is the only alternative treatment, many spend years receiving dialysis. Dialysis is a costly therapy; therefore, the growing number of ESRD patients is a considerable concern to the healthcare system[159]. Identifying cost-effective alternative approaches is crucial to reducing the economic burden of dialysis.

Healthcare expenses from different dialysis modalities vary dramatically[13–15] with home hemodialysis (HHD) being less expensive than in-center hemodialysis (HD). ESRD patients can have a frequent dialysis schedule with HHD, which could be challenging to achieve with in-center HD, partly due to logistical reasons. Such dialysis schedules are more beneficial in improving clinical outcomes than conventional HD typically performed at the in-center[160]. From patients' perspectives, HHD offers benefits of greater freedom and flexibility. ESRD patients can perform the treatment as per their schedule, and the need to travel to a hospital or dialysis unit for their treatment is eliminated[15]. Therefore, it has been receiving increasing interest in recent years[20]. In Canada, even though patients and healthcare professionals realize the benefits of HHD, its utilization remains low compared to in-center HD[57]. The situation is similar in several other parts of the world[19,22,23].

HHD therapy can be divided broadly into two main components: clinical and technical. The former mainly involves improving patient outcomes (e.g., increased blood purification) through improving different ways of doing HD sessions (e.g., HD dose and frequency). The latter relates to understanding how devices and their accessories, materials, and organizational processes, could influence the safe and effective delivery of HD and the user experience in performing HD. The implementation of the technical component of HHD programs takes over several stages. These include (1) pre-assessment (that begins even before a patient is accepted on a home program), (2) preparing patients' homes for HD, (3) transferring devices from hospital premises to patients' homes, and (4) quality management. Moreover, the implementation of the technical component of HHD is described as complex in literature, as it requires considerable support at

varying levels, including the healthcare system, patients, and organizational levels(26). Therefore, to support the growth of HHD in Canada, it is essential to understand healthcare professionals' experiences with favorable and unfavorable factors at these levels.

When patients receive home care, the technology needed to perform their treatment remains at home. Specifically for HD, moving technology to patients' homes is not simple. A patient with a safely running HD machine and accessories is not enough to initiate HD therapy. HD therapy puts forward unique demands, which are rarely seen in other home-based treatments. They are (1) the availability of safe water supply and quality at patients' homes as defined by the Canadian Standards Association (CSA) (or other national organizations), and (3) the availability of water-purification devices that produce and deliver water meeting those requirements[52,53].

Furthermore, setting up HD-related devices: including HD machines, water-purification devices, and their accessories, is insufficient for the safe delivery of HHD; technical support is needed to manage these devices, which continue over the entire period while patients receive HHD. The inherent nature of any device and water is to decay over time, which is also applicable to HD, and, again, HD-related devices may not be easy to manage. Technical support for HHD could be complex because of the number of devices needing management and its periodicity. Unexpected device failure and water quality fluctuations are potential areas of concern[48,161], demanding the need for a systematic approach to device monitoring and maintenance[162]. The consequences of improper care and maintenance of devices and water used for HD could be as severe as death[163]. In this respect, technical aspects immensely influence HD's safe delivery–no safe water, no dialysis.

When treatment is moved from a hospital environment to patients' homes, there is an expectation from healthcare professionals that patients should receive the same level of care as they would receive in a hospital environment. However, it could be challenging to achieve. The reason is that the same level of support for implementing quality management in a hospital environment may not be available within patients' homes, including trained users to take care of the devices, the availability of replacement devices within hospital premises, and a clean environment[164–166]. The CSA, the national standards organization in Canada, has defined safe levels for water quality to avoid devastating situations, along with provisions on water-related devices and their quality

management in their published standards[52,53]. Therefore, healthcare professionals have the additional responsibility of planning and implementing how patients in their homes would be supported in taking care of their HD-related devices as per the CSA requirements[52,53] (or other national organizations specific to a country). Secondly, healthcare professionals must also ensure that the need for a safe water supply within patients' homes has been met. Therefore, understanding health professionals' views on how and what factors are helping and creating challenges in managing the technical aspects of HHD when compared to in-center HD becomes crucial.

Although not mandated by legislation, the CSA's requirements are well recognized by healthcare professionals in Canada. As stated earlier, in Canada, healthcare professionals are supposed to follow the CSA's requirements on water-related aspects in HHD. To the author's knowledge, no study exists to understand healthcare professionals' perceptions towards implementing the existing CSA requirements for HHD. Studies have raised concerns over difficulties in achieving adherence to water-related recommendations from other organizations, and these recommendations were similar to those stated by CSA[53]. Since most studies were conducted within hospital settings[95,104,130,151,152,167–170], their results may not be generalizable to home settings. However, the question indeed arises of whether a similar situation exists within HHD programs. Additionally, the CSA standards require stricter water purity levels for HHD, which is a matter of concern because this aspect of HD is highly debated in the dialysis literature regarding its contribution to improving patients' outcomes and the feasibility of its delivery in a home setting[171]. The existing literature on this topic mainly arises from European Union (EU) member countries, Japan, and the USA, which warrants the need to fill the literature gap from a Canadian perspective. Therefore, there is a need to explore the characteristics of HHD programs in Canada and healthcare professionals' views of facilitators for and barriers to delivering HHD.

The management of water-related aspects can be easily overlooked amid various other aspects of HD, possibly because other HD areas could be more problematic than water-related aspects due to the relatively higher occurrence of complications arising from them[172–175]. Also, adverse events from water used in dialysis have dramatically decreased over time[173]. However, this does not lessen the need to manage water-related aspects in HD. The reason is that the fluctuations in

HD water quality from what is required by national organizations to deliver HD safely are possible[48,161]. Recently, the risk of water-related adverse events is low[173]; however, if such an event occurs, its impact could be devastating[48,49].

Prior studies have identified that the provision of safe water for HD could be problematic in a home environment[20,23,29–31,33,34,59,100,172,173,176,178–185], and a few[34,100,150,182,183] of them have explored this topic in detail, which includes understanding the factors influencing monitoring, maintenance and quality assurance (e.g., documentation and auditing). These aspects of quality management are crucial because they are fundamental to maintaining desired water quality and are delineated either as requirements or recommendations by several national organizations for the safe delivery of HHD[53,137,146]. Also, such studies have several limitations, including being opinion-based[182], lacking healthcare professionals' views[31,176], being limited to a single-center study[34,150], and occurring outside of Canada[100,183]. Therefore, for all the limitations mentioned above, research on healthcare professionals' views on common issues and facilitating factors they experience while implementing water-related aspects is needed to identify opportunities for better delivery of HHD in Canada.

Research Aim and Purpose

The growing trend of HHD in Canada is likely to continue in the coming years due to the rising numbers of ESRD patients and the need to provide care to them in an affordable way. Therefore, this research study aims to compare HHD programs across Canada and examine various factors that facilitate or challenge/impede the management of the water-related aspects of HHD.

Research Question

The research questions of this study were:

- What approaches and means are being utilized to implement the water-related aspects by various Canadian home hemodialysis programs?
- What are the facilitators and barriers/challenges to managing water-related aspects for home hemodialysis programs as perceived by healthcare professionals in Canada?

Methods

Research Approach and Study design

A pragmatic qualitative approach is applicable for research requiring interpretation of events, views, or experiences as described or shared by study participants, which aligns with the research questions being studied[186]. Therefore, a pragmatic qualitative approach was utilized to gain in-depth insight into healthcare professionals' perspectives on what and how water-related aspects influence the delivery of HHD programs in the Canadian landscape. Also, for a deeper understanding of how home settings can enable and challenge the safe delivery of water used for HHD.

A multicentre cross-sectional study design using a qualitative semi-structured interview method was utilized to answer the stated research questions. This study was conducted and has been reported following the Consolidated Criteria for Reporting Qualitative Research (COREQ)[187].

Study Settings, Participants, and Recruitment

Home dialysis programs were eligible to participate in this study if they were located in Canada and offered HD (or any other modality of HD) at patients' homes. Specifically, an attempt was made to recruit HHD programs covering a broader geographical scope because it was thought to be beneficial in gaining information on diversified water-associated problems that may exist in different Canadian provinces. No restrictions were applied on how many HHD programs could be selected from a given Canadian province. Usually, a multidisciplinary team is involved in water quality management. Therefore, the recruitment goal was to include at least 6 healthcare professionals in different roles and responsibilities related to water quality management from each participating HHD program, including medical directors, renal nurses, biomedical engineering technologists, clinical managers/chief biomedical engineers (with the background as engineering technologists), unit managers, and any other personnel involved in quality assurance (specifically performance adherence and management).

A purposive sampling method was used for this study. The home programs and participants for this study were recruited using a combination of "gate-keeper" and "snowball sampling"

methods. The “gate-keeper” method is a helpful technique for making initial contacts with organizations that are otherwise hard to reach for researchers. The medical director of a specific HHD program, Alberta Kidney Disease – North (AKD-N), contacted medical directors from 7 different HHD programs across Canada (whom they thought as probably interested in participation), introducing the researcher (SD) and providing a brief overview of the research study. After that, the researcher (SD) approached medical directors from 7 different HHD programs with a formal invitation letter (Appendix 4) by email to seek their support and request they facilitate access to individuals responsible for water quality management within their respective programs. If a response was not received, the medical director’s (AKD-N) help was sought again, and follow-up emails (maximum of 3 attempts) were sent.

After receiving the initial support of “gate-keepers” (i.e., medical directors in this case) from HHD programs and research ethics approval, the researcher (SD) contacted them to schedule interviews and distribute information sheets and consent forms (Appendix 5). The “gate-keepers” then provided the names of other key informants from their programs whom they thought had the necessary experience and involvement in water-related aspects needed to conduct this research. Additionally, snowball sampling was applied by asking the initial interviewees to help identify other relevant healthcare professionals within their programs who met the study criteria.

Data saturation was achieved when the study participants of a home program interviewed last did not identify any new information regarding water-related issues and approaches to water quality management. Data saturation was also achieved within the home program, meaning the last participant interviewed from a given home program did not share any new information from what other fellow participants from the same home program had shared.

Data Collection

One-on-one semi-structured interviews were conducted over 13 months, from June 2018 to July 2019, except for 1 interview that involved two participants (a medical director and a clinical manager). Before any interview, a signed informed consent form was obtained by the primary researcher (SD). Interviews were conducted over the telephone or in person by the primary researcher (SD) using an interview guide. Each lasted from 30 minutes to 2 hours. All interviews

were audio-recorded and transcribed verbatim by one researcher (SD), except for 1 interview where the primary researcher (SD) noted down the participant's responses using a pen and a paper.

The interview guide was developed based on (1) the scoping review conducted as part of this thesis research (See Chapter 2) and (2) reviewing existing peer-reviewed studies discussing the issues surrounding water-related aspects in HD therapy and their implementation in the home settings[20,29,31,34,59,100,130,133,150,151,161,179,183,188,189].

The interview guide (Appendix 6) contained questions related to the following 4 sections:

(1) Section-1: Existing HHD care process steps that involve water-related aspects and their underlying activities, to understand whether the activities within each process step are conducted following CSA requirements when such requirements exist;

(2) Section-2: Perceived barriers, challenges, and facilitators in implementing activities within each identified HHD process steps (Note: if participants discussed issues with the implementation of any of the CSA requirements, then they were probed using What? Why? questions)

(3) Section-3: Suggestions to overcome the perceived challenges and barriers, and

(4) Section-4: Perception of the clinical significance of water quality as per the CSA requirements

The interview guide was reviewed by the thesis supervisor (DM) for clarity and content, specifically to ensure that the questions were sufficient to gather the information needed to answer the study research question and purpose. Additionally, the interview guide was pilot tested with an experienced registered nurse employed at HHD-1 to understand the estimated interview time, content clarity, and interview question flow. Following the pilot testing, there were no significant changes made to the interview guide.

The interview guide was refined iteratively as data collection progressed. A significant change was made concerning the Ishikawa diagram, which was developed as part of the interview guide,

using the instructions laid out by Health Quality Ontario[190] and the Institute for Healthcare Improvement[191]. Initially, it was thought that showing the Ishikawa diagram to study participants would help to facilitate the discussion about identifying issues associated with achieving and maintaining water quality as per the internal protocol or CSA requirements at their respective HHD programs. An Ishikawa diagram (also called a cause and effect diagram or a fish-bone diagram) is a handy tool in structuring a brainstorming session meant for quality improvement initiatives, including investigating factors underlying an undesired event or performance improvement (e.g., improving adherence to clinical practice guidelines)[192]. Notably, in public health, there is a range of practical examples where it has been used to conduct barriers assessment or identify multiple causes or factors giving rise to a problem being studied, with an intention to identify root causes and thereby focus on improving them[161,193,194]. For this study, the quality problem (i.e., water quality management) being researched was stated on the right of the Ishikawa diagram (as shown in Appendix 6), and different HHD process care steps were shown on the left of the diagram. Participants were asked to identify possible causes under each laid out HHD process care step on the diagram that they considered contributing to the stated quality problem. After using the diagram with some participants whose interviews were conducted in person, it was realized that its use was not adding any value in facilitating interview discussion. Also, using such a diagram was not possible with participants whose interviews were conducted over the phone. Therefore, the use of the Ishikawa diagram for data collection was discontinued.

Moreover, using a semi-structured in-depth interview with open-ended questions for data collection allowed the researcher to probe deeper into participants' responses which were beneficial in understanding the underlying root causes or supportive factors to water quality management. Therefore, it was preferred over other methods of data collection (e.g., structured interviews). This approach aligned with the underlying research aims as it allowed the participants to share their experiences, opinions, and complexities around their roles and responsibilities. The other advantage of using the semi-structured method for data collection is that it provided the flexibility to switch the sequence of questions, modify the questions, and use probes in response to participants' responses during interviews, which helped further clarify the study participants' responses.

Ethics

Data collection started after receiving ethical approval from the University of Alberta's (UofA) Research Ethics Board (ARISE) on May 13, 2018 (Study Application ID: Pro00081801). The approval for study renewal was received on May 13, 2019 (Pro00081801_REN1). The operational approval for research from Northern Alberta Clinical Trials Research Centre, Alberta Health Services, was sought and obtained on May 29, 2018. The study was conducted in accordance with the approved research protocol.

Data Analysis

Thematic Analysis (TA) was used to analyze the interview data. It consisted of the following six steps as developed by Braun and Clarke (2006)[195]: (1) become familiar with data, (2) generate initial codes, (3) search for themes, (4) review themes, (5) define themes, and (6) write a report. The TA was managed using Microsoft Word. Before initiating the analysis, the names of the participants and HHD programs were de-identified from the transcripts by assigning them with a unique number, such as P-1 and HHD-1, respectively.

The TA was conducted inductively, meaning that the interview data drove the process of labeling codes and grouping codes showing similar concepts into larger sub-themes and themes. First, all the transcripts were read thoroughly to have a deep sense of key concepts about how HHD water quality was being managed and participants' perceptions of barriers and facilitators in implementing tasks related to HHD water quality management by the primary researcher (SD). Other than that, transcripts were also read thoroughly to capture any new concepts that could emerge from interview data related to HHD water quality. In this study, the following definitions related to facilitators, barriers, and issues/challenges were used for data analysis:

1) Barriers: A factor was considered a barrier when expressed as a hindrance in implementing the program's internal protocol, CSA's requirements, or recruiting eligible ESRD patients on HHD programs.
2) Challenges: A factor or a situation was considered a challenge when expressed as not impeding but as adding complications or difficulties in initiating HHD and providing

continuing care of devices to HHD patients, such as creating the need for extra efforts or delays in the timely completion of a task.

3) Facilitators: A factor was considered a facilitator when expressed as currently or in the future envisioned as helping to achieve the program's internal protocol or CSA requirements on water used in HHD.

The data analysis began with line-by-line open coding within and across all the interview transcripts by the primary researcher (SD). In this process, key textual segments were labeled with codes (i.e., the naming of codes) in a way that they captured the essence of their underlying textual segment in the transcript. The same codes were applied repeatedly to other textual segments within and across the remaining transcripts as deemed suitable (i.e., when repetitive concepts occurred). When new textual segments from the remaining transcripts were seen as highlighting concepts that were not aligned with previously derived codes, then new codes were developed. Further, transcripts were reread continuously to ensure that previously coded textual segments had been adjusted according to the newly developed codes. After completing the initial coding of all transcripts following the iterative process, a finalized list of codes was created.

The initial codes showcasing recurring patterns and similar concepts were organized and grouped into larger sub-themes and themes independently by the primary researcher (SD). The process of identifying prominent emerging themes was conducted at two levels. First, the codes were combined to identify emerging themes addressing the approaches to managing water quality across the participating HHD programs. Secondly, the codes were analyzed to capture emerging themes about factors influencing the implementation of HHD water quality management (i.e., perceived barriers to water quality management and perceived facilitators to water quality management) and other key concepts related to HHD water quality.

To ensure rigor, the entire preliminary TA was independently reviewed by the supervisory committee member (TS), an expert in qualitative research methods, and the thesis supervisor (DM). Before producing the final results, the TA was modified following the discussions with the supervisory committee member (TS) and the thesis supervisor to ensure that the emerging themes were coherent and distinct. At this stage, the TA analysis was reviewed and revised, including removed, remerged, renamed, and reorganized, based on the discussion between the

primary researcher, one of the supervisory committee members (TS), and the thesis supervisor. The refinement of initial coding and themes occurred several times until the consensus was reached through discussion among the research team members. All research team members agreed upon the final produced themes and sub-themes.

The focus of the TA was to compare and contrast within themes and sub-themes (a) the approaches used for water quality management across participating HHD programs and (b) participants' responses to barriers/challenges and facilitators to water quality management with reasoning when their responses differed. The TA showcased how participants' responses about barriers and facilitators signify the interdependency of varied aspects of water quality management which is discussed in more detail in the Results section.

Results

A total of 7 HHD programs were approached for participation, and in response, 6 HHD programs showed interest and were successfully recruited in the study; with 4 HHD programs [HHD-3, 4, 5, and 6] situated in distinct Canadian provinces and 2 HHD programs [HHD-1 and 2] from the same province. The study participants included 18 health professionals from diverse backgrounds (see Table 3) and were employed across 6 HHD programs, including 6 participants from HHD-1, 5 from HHD-2, 2 from each of the 2 HHD programs; HHD-4 and 5, and 1 participant from HHD-6. The recruited HHD programs all represented different geographical regions of Canada (including the west, north, and central). Except for medical directors, the recruitment goal of interviewing allied health professionals (i.e., nurses, unit managers, clinical managers, or dialysis technicians) from each participating HHD program was not possible. The reasons for non-participation included lack of interest in participation, no response to a request for scheduling an interview, and "gate-keepers" and "initial interviewees" identified other healthcare professionals in their programs as not valuable to add further new information.

Table 3: Characteristics of Study Participants

	Home Hemodialysis (HHD) Programs						Total /Range
	HHD -1	**HHD -2**	**HHD-3**	**HHD-4**	**HHD-5**	**HHD-6**	
Program Size	90 - 100	90-100	Information could not be collected	Information could not be collected	Information could not be collected	Information could not be collected	**Range: 90 to 100**
Numbers of Study Participants according to their Roles							
• Medical Director	1	1	1	1	1	1	**N= 6**
• Technical Manager (Note: Technical Manager was also called Clinical Manager or Chief BioMedical Engineer in some programs)	1	1	1	1	1	0	**N= 5**
• Unit Manager	1	1	0	0	0	0	**N= 2**
• Nurses	2	1					**N= 3**
• BioMedical Engineering Technologist	1	1	0	0	0	0	**N= 2**
Total Study Participants	6	5	2	2	2	1	**N= 18**

Four themes emerged from the interview data, including (1) current practices for the HHD care process, (2) perceived barriers of and facilitators to water quality management, (3) suggestions discussed to overcome the identified barriers to water quality management, and (4) approaches to addressing non-compliance. In the next section, these themes and their underlying sub-themes have been described.

Current Practices for Home Hemodialysis Care Process

This theme relates to the interview questions about current practices for the HHD care process in water quality management. This theme is divided into three sub-themes: team members, guidelines and standards, and HHD care process steps: what, how, and when?. The description of this theme is mainly based on 5 HHD programs [HHD-1, 2, 3, 4, and 5], as all the required information could not be collected from HHD-6. The direct quotations from transcripts for the current practices being followed for various HHD care process steps across 6 HHD programs are provided in Appendix 7.

Team Members

A multidisciplinary team was involved in delivering safe water for HHD. An in-house technical team comprised of biomedical engineering technologists [range: 3 to 5] and a technical manager provided technical support to manage devices and water quality in 4 home programs [HHD-1, 2, 4, and 5]. In comparison, external vendors offered technical support in the remaining 2 home programs [HHD-3 and 6] (Note: External vendors were employed for NxStage and not for traditional HD machines in HHD-6). In addition to the technical team, unit managers, nurses, educators, patients, and medical directors played a crucial role in the HHD care process. Home programs varied concerning how these team members and to what extent they were involved, which is discussed in the next sub-theme on the HHD care process steps.

Guidelines and Standards

All study participants were aware of the CSA standards. According to participants' responses, all programs had internal protocols concerning the HHD care process, except for 1 HHD program that did not have them in a written format [HHD-4]. All programs derived their internal protocols based on the requirements laid out by the national CSA standards, provincial laboratories, and HD-related device manufacturers. However, 1 program did not follow the criteria specified in the CSA on how often to verify the levels of endotoxins in HHD water [HHD-4]. The unit managers [HHD-1, 2, and 3] and technology managers [HHD-2 and 5] were mainly responsible for drafting policy documents (e.g., organizational flow charts) in collaboration with other team members.

HHD Care Process Steps: What, How, and When?

The overall HHD care process, as described by the participants, can be divided into three main sequential stages: (1) Stage-1: preassessment, (2) Stage-2: preparation, and (3) Stage-3: support for quality management. The following paragraphs describe the HHD care process according to these 3 stages. The description is focused on what, how, and who within each HHD care process step. The HHD care process was complex, specifically for stage 3. In stage 3 (support for quality management), participants mentioned numerous care process steps (e.g., performance measures). Again, within each process step (e.g., performance measures), there were multiple tasks (e.g.,

microbial water quality testing) and their underlying activities (e.g., collecting and sending samples) to manage device and water quality. The illustrative quotations supportive of this sub-theme have been provided in Appendix 7.

The first two stages of the HHD care process were almost similar across all programs. Two process steps were discussed by participants under pre-assessment, including assessing patients and their homes for HHD. First, patients were assessed by nurses and educators to understand whether they were physically and mentally capable of doing HHD independently. After that, patients' homes were assessed to understand their suitability for HHD by a technical team, including water available for drinking and home infrastructure (such as plumbing, electrical, access to homes, etc.). In the process step of assessing patients' homes, 1 home program [HHD-1] differed from others as it did not perform actual drinking water testing at patients' homes.

If patients' pre-assessment results met the required criteria, they were identified as eligible for HHD. Then they moved to the preparation stage, which included preparing patients and their homes for HHD. After being selected for home programs, patients were required to attend a training program, for which they had to wait until a spot was available. The training sessions were conducted by nurses in 1 home program [HHD-3], while biomedical engineering technologists were also involved in the remaining home programs [HHD-1, 2, 4, and 5]. Patients were taught how to use and take care of devices they were expected to operate for HHD and all other safety instructions and mitigation plans if something goes wrong with the devices or water quality. Except in 1 program [HHD-3], those devices that were considered additional were not covered in the training sessions [HHD-3]. Patients were required to showcase their proficiency in performing HHD independently through an assessment at the end of the training. If patients could complete the training assessment, home programs would then get involved in preparing patients' homes for HHD. The preparation included renovations, adjustments, providing necessary supplies, installation of devices as deemed essential for HHD, and verifying installed devices and water quality to ensure they are safe for patients. After patients' homes have been set-up for HHD, patients would perform their first dialysis session under the close supervision of a nurse and a biomedical engineering technologist.

Routinely, patients were required to perform their dialysis sessions independently but with ongoing support from home programs (i.e., stage-3). Home programs were needed to make arrangements for continuously sending supplies to patients, which was mainly coordinated by nurses. According to participants' descriptions of what comprises quality management and how it was implemented, the following four process steps were identified: measuring the performance of devices (online and offline testing) and water quality (laboratory-based testing for chemical and microbial quality of water), taking care of devices, documenting results, and evaluating and communicating results.

The first two process steps for quality management, including performance measures and device care, occurred parallelly. So, beginning with what participants shared on how the tasks related to performance measures were implemented. Some tasks under the performance measures were conducted daily, including visual checks to ensure the safe operation of devices and a strip-based chlorine test, and they were performed by patients. Comparatively, other tasks under the performance measures were conducted less frequently (ranging from monthly to annually), including testing water's microbial and chemical quality. There were variations across home programs in how they implemented these tasks. First of all, 1 program [HHD-5] tested water quality for more numbers of microbial parameters than others. Secondly, 1 program [HHD-4] used point-of-care (PoC) testing to ensure water's microbial quality as a primary method, and the remaining relied on the laboratory. Third, patients were responsible for microbial sampling except in 1 program [HHD-5] that involved in-house biomedical engineering technologists. Moreover, chemical testing was performed by biomedical engineering technologists in most programs and by external vendors in 1 program [HHD-3].

Next, regarding device care, patients were responsible for the task of filter replacements in 2 home programs [HHD-3 and 4], whereas in-house technical performed such tasks in 3 programs [HHD-1, 2, and 5]. However, there were no differences across home programs in terms of how frequently filter replacements were performed. Moreover, the task of cleaning devices was achieved by patients, and the pace at which it was needed remained similar across home programs. Technical on-call support was provided by all programs to support patients if they faced any unexpected problems with devices; however, they varied in its availability and

involved stakeholders - most of these programs did not offer in-person weekend support [HHD-2, 4, and 5].

After performance measurements and device care, the following process step was documentation. A person responsible for performing any tasks related to device care or performance measurements had to enter the information in a relevant record sheet (For example, a patient was responsible for entering when the chlorine test was performed and its result in the log sheet). However, variations existed across home programs on who was primarily responsible for documenting water quality test results, including nurses [HHD-3], biomedical engineering technologists [HHD-1], and technical managers [HHD-2,4, and 5]. In 1 program, there was a lack of clarity concerning who was primarily responsible for documenting the chemical quality test results [HHD-1].

Now comes the last process step under quality management: evaluation and communication. According to participants' responses, home programs evaluated the documented test results to understand whether they were as required and the need to take follow-up actions in case of failure in achieving the desired results. The patients' documented results (concerning water quality and device care) were reviewed by technologists when they visited their homes for device servicing in most programs [HHD-1, 2, 4, and 5]. Additionally, in 1 program [HHD-1], nurses reviewed them during patients' visits to in-center clinics and by making follow-up phone calls with patients. There were variations across home programs concerning who was involved in the evaluation of microbial quality results, including a technical manager [HHD-2, 4, and 5], unit manager [HHD-1], nurses [HHD-3 and 6], technology manager in conjunction with external vendors [HHD-3], and biomedical engineering technologists [HHD-1]. A collaborative team effort was involved in reviewing whether device care (when the in-house technical team was responsible) was performed as planned. Specifically, when external vendors were involved, a technical manager played the lead role of coordinating and reviewing their work. Moreover, whoever evaluated microbial quality results, the same person was also responsible for chemical quality results, except in 1 program with no clear protocol for them (routine tests).

In 1 home program, a formal report showcasing the results of all the quality management tasks was prepared by a technical manager and submitted to the medical director for review. Such an

elevated reporting structure was not seen in other home programs. However, an acknowledgment was made by other programs' participants that water quality test results were accessible (through shared drives and emails) to all team members, including medical directors, and discussed in meetings conducted on a routine basis. Also, in other programs, medical directors reviewed water quality results in case any issues were detected.

Perceived Barriers of and Facilitators to Water Quality Management

This theme is based on analyzing participants' responses about barriers and facilitators to water quality management. The identified barriers, challenges, and facilitators emerged into two sub-themes: the built environment and maintaining safe water for home hemodialysis. A thematic table showcasing themes and sub-themes related to perceived barriers and facilitators is provided in Table 4. The illustrative quotes from transcripts to support this theme are provided in Appendix 8.

Built Environment

This sub-theme is related to how and which built environment factors could impact patient selection in HHD programs and the implementation of various quality management tasks. Barriers and facilitators connected to the built environment could be summarized in three sub-themes: physical elements in and around patients' homes, environmental conditions, and home modifications.

Physical Elements in and around Patients' Homes

The physical elements in and around patients' homes that could make the safe installation and operation of HHD challenging were described by study participants in almost all HHD programs. These elements included inadequate heating and electrical requirements, plumbing requirements (piping quality and drain), entranceways, and improper pavements. The characteristics of housing associated with such poor conditions were discussed by some participants, including older homes, apartments, and houses in remote locations.

> "Mainly in an apartment where piping cause problems, not in houses. I had one issue where there was extra aluminum or something in the water. So, it is something to do with home piping of apartment." [HHD-2_P11_BioMedical Engineering Technologists]

There was also a discussion surrounding how some of the physical elements were found in entirely unacceptable conditions at patients' homes. Due to this, patients were not accepted into home programs. However, there was an acknowledgment that such extreme incidents occasionally occurred. Remarkably, an incident when a patient was not allowed to be on HHD as their home was not accessible by a vehicle was shared by 1 participant.

> "We had one challenge recently. I just tell you one story. We had a home patient who lived on an island here about an hour from [Name of a city]. The island is accessible by [a] ferry. There are no stairs on this ferry. So, the problem was not a patient's house or patient, [but] the problem was to get to the patient's house in a timely manner. You know, [the] ferry only runs on a certain schedule. We can not make the machine through the island. And then how do we get it from the island to the house? Of course, home dialysis patient needs a lot of supplies, and that was the big stopper. So, we got all the equipment out there, [but] how we [are] going to [send] supplies over there regularly. You know, in the winter months, a ferry can stop running because of ice and weather and [so] now what. So, we had to reject that patient mainly because that would come down to the safety of the patient. It would not be possible for us to do that because, you know what if we can't get to that guy, and so let us pull him off. So, the patient was upset about it, but hey, you know, in the end, it is for his betterment. So sadly, he had to move." [HHD4_P14_Chief BioMedical Engineer]

In 2 home programs [HHD-1 and 2], the inadequate physical space at patients' homes was discussed as creating challenges in identifying a suitable place for placing devices (per the requirements) and storing extra testing supplies.

> "Ahh…I am sure we have had challenges. So, a lot of would be space issues. So, like where do you locate the RO [reverse osmosis], and then you have to separate the RO and the pre-treatment media or anything like that. And then how long is the pipe from the RO to the [hemodialysis] machine. I think those would be problems." [HHD-2_P8_Technical Manager]

Environmental Conditions

Two factors related to environmental conditions were discussed as creating difficulties. First, the source water was considered a barrier to patients' selection in HHD when its quality failed to meet the Canadian drinking regulations. Also, patients could not continue their HD at home when its quality did not meet the manufacturer's requirements for HD-related devices. Further discussing the underlying reasons for failure in source water quality, factors that influenced its quality were identified by some participants, including wells and cisterns as the

Table 4: Perceived Barriers of and Facilitators to Water Quality Management in Home Hemodialysis Programs

Theme: Perceived Barriers of and Facilitators to Water Quality Management in Home Hemodialysis Programs				
Theme	**Sub-theme**	**Sub-sub-theme**	**Barriers (B) / Challenges (C)**	**Facilitators**
Built environment	Physical elements in and around patients' homes		• Patients' homes did not meet the requirements to support the installation, operation, and maintenance of hemodialysis (HD) machines and water-purification devices. (B/C)	• None were mentioned.
			• Patients' homes were not accessible by vehicle. (B)	
			• Some patients' homes did not have sufficient space, which created challenges for the placement of devices (per the requirements) and storage of extra supplies for water quality testing. (C)	
	Environmental Conditions		• There was a lack of a clean home environment which impacted microbial sampling. (C)	
			• There was a lack of adequate quality and supply of source water at patients' homes to support the initiation and maintenance of home hemodialysis programs (HHD). (B/C)	
	Home Modifications	Customization of water-purification devices	• There was a need for customizing water-purification devices according to source water issues at patients' homes. (C)	• External vendors helped identify water-purification devices for removing contaminants found in the source water occasionally and not mentioned by the CSA standards. (F)
			• There were concerns about uncertainty in determining which devices should be considered necessary and which should not. (C)	
		Home interior adjustments to accommodate the needs of placement of devices	• The adjustments made to patients' homes to accommodate devices disturbed them. (C)	
			• The noise generated from the devices was bothersome for patients. (C)	
		Cost to home modifications	• In one home program, the lack of reimbursement for the source water quality testing (before a patient was selected for home programs) was identified as a challenge for the planning of water-purification devices. In contrast, all other programs covered the cost of such testing. (C)	• The program's coverage for installing additional water-purification devices helped maintain water-purification devices. (F)

Theme: Perceived Barriers of and Facilitators to Water Quality Management in Home Hemodialysis Programs				
			• The cost for some aspects of home modifications was incurred by patients. (C)	• There was financial support provided to patients from patients' organizations and through tax rebates. (F)
Maintaining safe water for home hemodialysis	Processes for conducting testing and maintenance	Knowledge and skills	• There were difficulties in achieving consistency in the method used for sampling and verifying the microbial quality of HHD water. (B)	• Local drinking water suppliers and testing laboratories helped identify the types of testing parameters needed for ensuring water quality for HHD, in addition to those mentioned by the CSA standards. (F)
			• Guidelines and manufacturers' recommendations on some aspects of HHD water quality management were contradictory. (C)	
		Resources to support appropriate testing and maintenance	• *Staff time* for traveling to each patient's home and the *cost of keeping sufficient staffing* were barriers to performing water quality management tasks, precisely for the tasks requiring the number of inspection visits to patients' homes more often. (B)	• For efficiency purposes, maintenance services were scheduled according to the patient's geographic location.
			• Patients' non-compliance was mentioned as a barrier to performing quality testing and device maintenance, potentially leading to unsafe conditions (e.g., development of microbial growth in devices) and increased cost of device care. Patients' non-compliance also created challenges in gaining information needed to ensure the safety of devices for an extended period. Several factors potentially leading to non-compliance were mentioned, which could be majorly divided into patient-related and process-related. (B)	• The procedures (e.g., entering microbial quality test results into excel sheets) and processes (including dedicated personnel) for tracking quality test results and maintenance schedules were considered beneficial. (F)
			• The heavy workload from other tasks, involving or not involving water quality aspects, was also a barrier to keeping up with maintenance schedules. (B)	
			• The microbial sample storage and transportation requirements were difficult to achieve, leading to increased sample rejection or false negatives. As a result, there was a delay in receiving microbial test results and an increase in the cost of testing. (B)	

Theme: Perceived Barriers of and Facilitators to Water Quality Management in Home Hemodialysis Programs				
			• Sampling from two locations within the chain of devices helped gain information on the source of microbial contamination but was not performed in all programs due to financial constraints.	
			• The use of device performance data (e.g., disinfection history and operational parameters) was considered beneficial for the quality improvement process and optimizing device maintenance; however, the lack of data, staff time constraints, and staff attitude were identified as barriers. (B)	
			• Communication failure was identified as an issue in some home programs, potentially leading to delays in prompt actions related to device care. (e.g., when the information on patients being away from their homes for extended days had not been passed on to a staff member, then delays in making alternative arrangements for managing their devices in their absence were inevitable.)	
		Scheduling inspection visits to patients' homes	• Scheduling visits for preventive maintenance with patients was challenging. (C)	• Policies were established to ensure timely access to patients' homes. (F)
	Materials and equipment for testing and maintenance	Quality testing devices		• The point-of-care testing device for verifying microbial water quality (bacterial and endotoxins) was introduced to improve access and efficiency of testing. However, such devices were criticized for their accuracy (bacterial testing) and pricing (for endotoxin testing).
		Variability in device models	• The make and model of devices varied, creating difficulties for technicians who had to help patients resolve problems over the phone or at their homes. (C)	

Theme: Perceived Barriers of and Facilitators to Water Quality Management in Home Hemodialysis Programs				
		Recruitment and ongoing training	• Resources were required to retrain patients when issues relating to compliance with water quality testing and daily device maintenance were identified. (C)	• The steps for using and maintaining devices were mentioned as doable by patients at the time of their recruitment training (F), but there was a contrasting view. Moreover, comments were made that patients could be worrisome during the initial learning period and that the time taken to complete the learning process could vary depending on individual abilities. (C)
			• When a new technology was introduced, staff training was required. (C)	
		Usability of devices	• There could be difficulties in cleaning and disinfecting the devices because of their design. (C)	• Devices with built-in reminders, safety alarms, and the ability to self-lock (when a patient fails to perform a task related to device maintenance) were seen as helping improve patients' compliance and increase safety.
			• The size and weight of some devices could act as a hindrance to performing device maintenance among patients with co-morbid conditions. (C)	• The use of ultrafilters on HD machines was seen as protecting patients from microbial contamination, specifically for those patients who were non-compliant with disinfection and testing; however, the clarification was made that its use does not eliminate the development of microbial growth.
			• The pre-programmable feature of a device was seen as not usable in a home environment due to patients' unfixed schedules for performing their HD. (C)	• The capability of devices to store information on when tasks related to maintenance were performed was considered beneficial in assessing

Theme: Perceived Barriers of and Facilitators to Water Quality Management in Home Hemodialysis Programs				
				patients' compliance to varied aspects of device maintenance.
Abbreviations: HHD: Home hemodialysis; HD: Hemodialysis; B: Barriers; C: Challenges				

source of supply to drinking water at patients' homes and when advisories were issued by municipal suppliers.

> "Municipal drinking water is usually fine. I am not, none other than the occasional boil water advisory. What we [can] do if a patient can not use water any more". [HHD3_P15_Medical Director]
>
> "And then contaminants, actually there is one case, where it looked like the septic field or another local septic field was actually leaking into the well. And so the well would continually sort of failed its quality test." [HHD2_P8_Unit Manager]
>
> "Ya, there could be many other [contaminants in source water]. There are many other [such as] extra mercury. There could be other things as well, [due to] which we then [have to] say no we cannot dialyze there." [HHD2_P11_BioMedical Engineering Technologist]
>
> "They [referring to well waters in a particular city of Canada] presented other issues too, like lack of water. You know, that is one of the unique things." [HHD4 _P14_Chief BioMedical Engineer]

Second, the lack of maintenance of a clean environment in patients' homes was considered a challenge for device care and testing validity. Specifically, several conditions at patients' homes that could potentially lead to the contamination of the samples taken for verifying microbial quality testing were identified by 1 participant [HHD2_P9_Clinical Manager].

> "Some patients' homes are not conducive for testing. There is just so much in the air that could contaminate that sample. We had a [an incident], we were wondering like for some patients we had multiple failures. We just don't know if it is the sampling method that the patient uses or even [when] the techs [technologists] have it, and they [samples] failed. We just don't know what was causing that and just wondering if there is stuff in the air if you stir up like if they got carpet and if you just move and that stirs up microparticles on the carpet that could contaminate the sample. So it [referring to sampling] is sensitive." [HHD2_P9_Clinical Manager]

Home Modifications

Based on participants' responses on their experiences about modifying patients' homes to support HHD, influencing factors related to customization of purification devices, home interior adjustments to accommodate the needs of placement of devices, and cost to home modifications were identified.

Customization of Water-Purification Devices

The provision of customized purification devices according to source water quality that varied at each patient's home depending on their geographic locations and home conditions was considered challenging by several participants, mainly because it was time-consuming and complex.

> "(…) so we ended up putting a scavenger in front as pre-treatment and as soon as we did that we are getting the actual 3 months life span of those filters now. But, it took a little bit of digging in and analysis of that water. So, certain areas you get a kind of know what the ..what the area is like..if it is high alkaline area or something else." [HHD2_P9_Technical Manager]

> "(…) and also the machine and the equipment and the service is quite individualized right. So, if someone is on a well, then the technicians would have already talked to them about what are the filters that they might need [and] what the water pressures are. [HHD1_P6_Unit Manager]

There were several examples of source water issues described by participants when they could not figure out how to fix them using an appropriate purification device in 2 home programs [HHD-2 and 3]. The remark was also made by 1 participant that there was no official guidance available in the context of dialysis on managing some of the source water issues identified at patients' homes [HHD-3_P15_Medical Director]. In those cases, seeking the help of external vendors who were experts in water purification for drinking water and dialysis was considered a facilitator.

> "We had to tell them [referring to patients] we can't provide you a system that can take care of these contaminants [referring to contaminants found in patients' source water]. So, we do go to the water treatment company and find out whether they can engineer a system [i.e., water-purification system]. Because we have a set system right and [if] that set system is not capable [to remove contaminants of source water], so we had to provide [additional things]. So, we go to manufacturers of water system to tell us if you can give us extra help." [HHD2_P11_BioMedical Engineering Technologist]

> "There are not any guidelines on how to deal with radioactive elements in particular, but we have been able to resample with dialysate side and now we have almost undetectable levels of radioactive elements". [HHD-3_P15_Medical Director]

Although vendors' help was available, participants felt that deciding on device selection was still challenging (particularly regarding pre-treatment and posttreatment filters). There was an

acknowledgment that modern purification devices had capabilities in resolving most of the water-related issues in dialysis by several participants. On the other hand, specific examples showcasing difficulties in determining the usefulness of a device to resolve a particular water-related problem were shared by some participants. The concern over using additional devices was mainly discussed from a resource standpoint which would be needed for managing them, considering there were restrictive budgets.

> "Not really for quality [of source water available at patients' homes]. In my experience, I know that the technology is available, no matter how dirty the water supply is, to make it suitable for dialysis." [HHD4_P13_Medical Director]

> "Yes, from cost point of view. But, then, softener would be more costlier to run rather than changing the membrane. Softener, then monitoring softener [and] maintaining softener could be much more work, [and] then going for filter change [referring to BioMedical Engineering Technologists would have to go at patients' homes for filter changes]. Instead of 5 years, it [referring to reverse osmosis membrane] will be every 4 years, something like that. I am talking about the main membrane." [HHD2_P9_Clinical Manager]

> "We have got no evidence right. Now, the companies would tell you this is what the potential. But, we have got no evidence that anybody is ever tested and proven that it was endotoxin or bacterial issue that cause the problem to the patient. I just pulled up a minute ago a really good presentation. I wonder if I still have it, ya its right here. So, this is the vendor propaganda to sell their filters. [HHD_P1_Clinical Manager]

Home Interior Adjustments to Accommodate the Needs of the Placement of Devices

The noise of devices was cited as challenging for patients by some participants because it disturbed them. Additionally, patients' disliking about making adjustments to their homes' interiors as needed to meet the requirements of placement of devices was also cited by some participants.

> "It happens all the time [referring to challenges in the placement of devices], that happens. This people are so finicky that they want the water system down in the basement so that they do not see it or hear the noise. Sometimes, they want it somewhere in another room. But, we have to, since quality of the water is very important, we have to make sure that [the] line between the dialysis machine and [the] water also get[s] disinfected." [HHD2_P11_BioMedical Engineering Technologist]

Cost to Support Home Modifications and Utility Bills

Cost availability was discussed as an essential facilitator in implementing various aspects of home modifications, while its unavailability was considered a barrier. Particularly, cost availability for source water testing at the time pre-assessment was described almost by all participants as helpful in planning ahead of the type of devices that would be needed for the safety of HHD patients. On the top of purification devices generally used for HHD, the reimbursement for additional devices to manage source water issues was seen as helpful by participants for avoiding increased device failure and, thereby, visits to patients' homes.

The comment that out-of-pocket costs for some aspects of home modifications were burdensome to patients was mentioned by all participants, specifically in the context of those patients who were at an economic disadvantage. The patients' organizations and tax rebates were discussed as facilitators for providing financial support to patients in paying their utility bills in home programs not covering such costs [all programs except HHD-6].

Maintaining Safe Water for Home Hemodialysis

The barriers and facilitators connected to maintaining safe water for HHD emerged into two main sub-themes: processes for conducting testing and maintenance (knowledge and skills, resources to support appropriate testing and maintenance, and scheduling inspection visits to patients' homes) and materials and equipment for testing and maintenance (quality testing devices, variability in device models, and recruitment and ongoing training).

Processes for Conducting Testing and Maintenance

Knowledge and Skills

The difficulties in figuring out the appropriate method for sample collection and storage as part of verifying the microbial quality of water used in HHD were emphasized by participants in 2 home programs [HHD-1 and 2]. However, an acknowledgment was made that such things were later improved in the program after gaining knowledge through practical experience.

> "So, we experiment from time to time the length [and] the volume of flushing prior to taking a sample. So, the things are improving. But, we have to do this quite a few time[s]

> using trial and error. That's how we do working." [HHD1_P2_BioMedical Engineering Technologist]

Another challenge was difficulties in interpreting the microbial test results. Notably, the difficulty in figuring out the issues when two samples taken from the same device had different results was expressed by 1 participant [HHD1_P2_BioMedical Engineering Technologists]. However, difficulties in interpreting and maintaining validity in microbial sampling were not noted in other programs by biomedical engineering technologists (here on referred to as BioMed).

> "And, so we have also been playing with sterilize the testing devices prior to taking samples. We [have] tried with different types of chemicals. One chemical will pass all the endotoxins and will not pass microbiology CFUs. And another chemical will pass all of the CFUs but will fail the endotoxins. So we always find that challenge to come up with a chemical that is consistent. So, some of our technicians get frustrated from one day to the next. You know I used this chemical, and everything passes on the Endotoxins, but the CFUs are not passing. Next time we will try different chemicals…all CFUs will pass but not the endotoxin. So this is [an] ongoing challenge for us." [HHD1_P2_BioMedical Engineering Technologists]

It was noted by several participants that having timely awareness of issues associated with each patient's source water was critical for understanding what needs to be tested to determine whether water available at patients' homes is safe for their dialysis. The local water suppliers and provincial water testing laboratories were identified as facilitators because they provided knowledge on the type of testing required according to each patient's water source.

Another challenge about following official organizations' recommendations was discussed in 2 home programs [HHD-3 and HHD-6]. There were some examples shared by participants on how the official organizations' had conflicting recommendations on some aspects of water quality management. It was considered challenging because there remained confusion among participants as to which recommendation needed to be implemented.

> "Well, it involves what the standard wants to see and what the manufacturers provide related to drain. So, CSA standards says drain should be X and NxStage does not need that X and so that's either we ignore it and treated as guideline or not?" [HHD3_P15_Medical Director]

Resources to Support Appropriate Testing and Maintenance

The lack of resources was cited by several participants as a barrier and challenge to performing water-related tasks. The lack of resources was discussed regarding staff time to travel long distances, financial constraints, heavy workload from other tasks, inability to meet the requirements for sample collection and transportation, communication failure, and lack of patient compliance. The improvement in planning the route to making visits to patients' homes was identified as a facilitator in 1 home program [HHD-1]. Also, tracking of quality test results to understand their compliance with the requirements was identified as a facilitator by several participants.

A lack of staff time to travel to patients' homes at far physical distances and a lack of cost to keep sufficient staffing were identified as barriers in almost all home programs. These barriers were specifically discussed when the frequency of visits to patients' homes' was needed monthly or quarterly. These were discussed as barriers to adhering to the maintenance schedules [HHD-1 and 2]. Another aspect affected by these barriers was that the home program did not employ biomed to perform water quality management tasks, including microbial testing [in several programs] and device maintenance [HHD- 3, 4, and 6]. In 1 home program [HHD-5] that employed BioMed for microbial sampling, there was a remark made by a medical director that it creates financial strain on the system.

A second time lack of cost emerged as a barrier to testing, due to which the implementation of the CSA standards on sampling from two different locations within the chain of purification devices was not followed in 2 programs [HHD-1 and 2] during routine testing of water quality. Moreover, this requirement of the CSA standards was not implemented in any of the participating programs.

The heavy workload from several other water quality management tasks was considered a barrier to performing device maintenance in 1 program [HHD-1]. Moreover, it was also cited as a reason for asking patients to perform filter replacements in other programs [HHD-3 and 4]. There was a remark made by several participants that there was a heavy volume of work for BioMed, including the need to manage spare devices, perform patients' pending tasks, make

visits to patients' homes for repairs, and provide support to the in-center dialysis program. Therefore, if not a barrier, managing heavy workload was cited as challenging by several participants.

Patients were given various responsibilities related to managing devices and water quality for HHD in all programs. Therefore, patient compliance was considered a critical component in implementing activities related to water quality management. Lack of patient compliance was considered a barrier to the performance of various water-related tasks, including microbial sampling, disinfection, and documentation by several participants. According to participants' responses, patients' compliance was influenced by factors related to process (e.g., need for sample drop-off at a courier service center, overburdened with other dialysis-related tasks) and patients' characteristics (e.g., behavioral). Additionally, it was noted by several participants that patients' compliance was affected because they were not experiencing any adverse events from water quality.

Sending samples to the laboratory was commonly cited as challenging for conducting microbial quality testing because of sample storage and transportation requirements. Additionally, such requirements were identified as a barrier by several participants, specifically in the context of patients located in remote locations. Two significant consequences for not meeting the requirements of sending samples for testing were identified by participants in 2 home programs [HHD-1 and 2], including lack of information on the status of microbial quality of patients' devices and burden on resources created by making arrangements for resampling.

Effective communication between responsible stakeholders was considered an influencing factor in coordinating several tasks of water quality management by several participants. The task of sending supplies to patients was interrupted in 1 home program [HHD-1] because of a lack of communication between the HHD team and the provincial healthcare agency's warehouse. Another aspect identified as affected due to infective communication was a delay in making arrangements for device maintenance at patients' homes when they were away from their homes for vacation or seeking care at one of the hospital facilities. In those scenarios, a lack of communication between (1) the HHD team and patients and (2) the HHD team and staff at a hospital emerged as barriers. Moreover, good communication within the HHD team was

identified as a facilitator by some participants for taking prompt actions following any failures in performing any quality management tasks as desired.

There were two main facilitators discussed that were identified as potentially overcoming the barriers related to resources. Scheduling the service visits for patients living nearby was considered a facilitator for reducing staff time spent on traveling. Implementing processes and procedures for tracking quality test results was identified as helpful for improving compliance with the schedule of microbial testing and maintenance services. There was also a discussion surrounding the significance of tracking device maintenance data with participants. Some participants projected its potential use in quality improvement and data-driven maintenance. However, lack of data and staff time were identified as barriers.

Scheduling Inspection Visits to Patients' Homes

Several participants identified scheduling preventive maintenance visits with patients as challenging because they were not available at their homes when BioMed would like to schedule an appointment. Another reason cited was that patients would not keep their devices available for service, creating a waste of time for BioMed. Implementing policies that allow maintenance services at patients' homes even in their absence was considered a facilitator for scheduling inspection visits in 2 home programs [HHD-1 and 4].

Materials and Equipment for Testing and Maintenance

Quality Testing Devices

The use of *PoC* testing device by patients for verifying bacterial counts was considered a facilitator in 1 home program [HHD-4], specifically to overcome the barriers connected to resources for testing. However, using a PoC testing device was criticized for its accuracy (bacterial testing) in other programs. The use of a PoC device for endotoxins was identified as a facilitator for reducing the cost associated with testing and obtaining quicker test results in 2 programs [HHD-1 and 2].

Variability in Device Models

The use of varied make and models of devices was described as challenging by 2 participants [HHD1_P6_Unit Manager; HHD-5_P19_Retired Technical Manager]. This issue was raised for two reasons. The first one was that troubleshooting was complex for BioMed over the phone because, based on the information provided by patients, it takes time for them to figure out which device the patient is asking for help with. The second reason was that there were too many things to remember regarding preventive maintenance with the increased use of different types of devices.

Recruitment and Ongoing Training

It was seen that the purification and HD devices were difficult for patients to learn at the start of the training, but gradually patients became comfortable using them independently. Also, the design and steps involved in using those devices were considered by several participants as not difficult to learn for patients. On the other hand, the need for longer training time to learn how to use the device and remember numerous steps was considered challenging for patients by 1 participant [HHD-5_P18_Medical Director].

The need for training every time a new technology was introduced in the program was considered challenging from a resource point of view (staff time and patient time). This challenge was also seen by some participants in 2 home programs [HHD-1 and 2] when patients had to provide retraining to patients if they were identified as having issues in following any of the given instructions.

Usability of Devices

There were several features of devices identified as facilitators for increasing patient safety. First, built-in reminders for filter replacements were considered beneficial for improving patients' compliance. Second, having safety alarms at different levels was helpful in protecting patients from devastating events. Third, the feature of the HD machine to self-lock itself until the disinfection had not been performed as needed and to store data on when past disinfections were performed were considered helpful in improving patients' compliance with disinfection. Lastly,

using ultrafilters on HD machines was deemed protective to patients, since achieving microbial testing and disinfection as needed was a common problem across several programs.

Suggestions for Improvement

The following three sub-themes emerged based on participants' responses on strategies that they thought were useful for HHD programs: identifying a consistent process for microbial testing, the need for more robust evidence, and innovation to support remote monitoring (See Table 5). The illustrative quotes from transcripts to support this theme are provided in Appendix 9.

Identifying a Consistent Process for Microbial Testing

There were several challenges and barriers identified related to performing microbial testing compared to chemical testing. Therefore, solutions to overcome this challenge were brainstormed with participants. The use of home program staff to perform microbial testing-related activities was considered a future facilitator by several participants. There was a remark made that employing professionals instead of patients for collecting and sending samples would help eliminate non-compliance. Also, it was noted by 1 participant that reducing the burden on patients by not involving them in testing was suitable for their quality of life. [HHD2_P7_Medical Director]. There was a remark made by some participants that there could be a less financial burden on the system if a non-technical staff or a paramedical nurse was employed for microbial testing-related activities.

Another future facilitator noted by several participants was identifying an alternative testing method for the verification of microbial quality. The existing laboratory-based method used for microbial testing was considered a barrier to obtaining timely microbial results by several participants. The use of a PoC testing device for microbial testing was seen as beneficial in providing quicker test results compared to the existing laboratory-based method in 2 home programs [HHD-1 and 2].

Need for more Robust Evidence

The need for monthly microbial testing as required by the CSA standards was questioned by several participants. There were two main arguments noted in participants' responses. First,

several participants deemed such a requirement impractical given local factors making its implementation difficult. Second, it was pointed out by some participants as unnecessary since devices used for microbial filtration provide an additional layer of protection to patients from microbial contamination. Therefore, the need to generate more robust evidence for microbial water quality testing frequency was identified for better use of resources in HHD programs.

Another potential area of research discussed was to understand better how water quality impacts patient outcomes and identify better ways to conduct this research. This need was also put forward by participants to understand the benefits of using stricter microbial quality for HHD patients.

Innovation to support remote monitoring

Enhancing the design of devices by making them remotely accessible by BioMed was identified as a future facilitator. It was seen as beneficial to overcome the barrier of staff travel time, optimize device maintenance schedule, and better serve patients in resolving their machine-related problems.

Table 5: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs

Theme: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs	
Sub-themes	**Summary of Sub-themes**
Identifying a consistent process for microbial testing	• The need to identify a better process for microbial quality verification was identified, and some programs made the following suggestions: • Instead of relying on patients, using home program staff for sample collection and sending it to a laboratory was a potential solution for achieving the Canadian Standards Association's (CSA) required testing frequency and avoiding false positive samples. • The affordable point-of-care testing device was perceived as a future facilitator (for testing microbial and endotoxins) to overcome the drawback of the extended time taken to produce microbial test results by the existing laboratory-based testing method.
Need for robust evidence	• There was a need identified for more research on how water quality impacts patient outcomes, but there was an acknowledgment that clinical studies on that aspect would be difficult to conduct.

	• The need to generate more robust evidence for microbial water quality testing frequency was identified for better use of resources in HHD programs.
	• The consideration of local operational factors when making the requirements on the frequency of inspections for microbial verification of water used in HHD was suggested, including home environment and device modernization.
Innovation to support remote monitoring	• There was a suggestion to make improvements in the design of devices by enabling remote monitoring of operational parameters to ensure their safe operation and planning inspection visits for preventive or corrective maintenance.

Abbreviations: HHD: Home hemodialysis; CSA: Canadian Standards Association

Approaches to Addressing Non-compliance

Based on participants' responses, a recurring theme of the types of approaches used by home programs to manage the non-compliance of patients emerged (See Table 6). Since non-compliance was not affecting patients' health, a policy of not removing them from HHD was seen in all programs. There were several efforts made by participants to improve patient behavior, including having a one-on-one discussion with participants by medical directors, re-education, reminder telephone calls, and sending warning letters to patients to make them understand the risk of improper device care and testing.

While commenting on the consequences, home programs were not worried not about being legally responsible if something went wrong due to patients' non-compliance because they have been provided enough resources and opportunities to learn and understand the risk of poor maintenance.

Table 6: Approaches to Addressing Non-compliance

Theme: Approaches to Addressing Non-compliance	
Content	**Quotes**
• The warning letters were sent to non-compliant patients	• And if we don't see results from patients, we will send a letter saying that it is recommended that they do the sampling and etc..They identify the risks associated with not doing the sample in the letter format and so it is kind of up to

	patients to meet those or not. [HHD3_P15 _Medical Director]
• Patients were not removed from the home hemodialysis program even if they were non-compliant with tasks related to water quality management.	• If they are so non-compliant on the way that they are not doing dialysis, then we have take them off, because they are not doing their dialysis. We have never taken them off because they are not compliance in sending a sample. [HHD4_P13_Medical Director]

Discussion

The analysis of this study showed the status of HHD programs in the Canadian landscape concerning how they achieve and maintain water-related aspects and the barriers/challenges and facilitators that health professionals face in implementing them. The analysis revealed that the HHD care process related to managing water quality is complex, and its implementation needs adequate resources and policies. Moreover, HHD care process steps are interlinked, highlighting that addressing issues in maintaining and achieving water quality would need a multilevel approach.

This study highlighted barriers and facilitators (current and future) that were connected to specific process steps, such as pre-assessment, home modifications, routine monitoring, and communication and evaluation. Additionally, themes related to strategies to overcome the identified barriers and how HHD programs dealt with the non-compliance of patients also emerged in the study analysis.

Unsuitable built environment factors, patients' non-compliance, managing sampling for microbial quality testing, financial constraints, constrained staff time due to increased traveling, a heavy burden of work for BioMed, and devices to deliver safe water were found as influencing factors in several home programs. The findings of this study suggest that strategies developed to address these barriers will help better manage water-related aspects in home programs.

The management of water-related aspects in a home environment is very different compared to a hospital environment. Therefore, the CSA organization developed a specific standard for HHD, specifically to lay out the requirements for managing all those aspects of HHD that are different

from in-center HD. The standards were also developed to promote a consistent approach to how Canadian home programs manage their water-related aspects to avoid variations in how the care is provided to home patients across the provinces[54]. However, participants of this study felt that that the organization had not utilized an evidence-based approach, specifically to manage the microbial water quality of water used in HHD; instead extrapolated what is known for water quality in facility dialysis to the home setting. Additionally, the CSA had not considered the local context in developing their requirements. The study findings were similar to other studies conducted across European Union member countries that have shown that managing water-related aspects in home programs puts a heavy workload on BioMed[100,183]. Therefore, there is a need to identify the best approaches to managing those water-related aspects of HHD that are different from what is usually not experienced in the hospital environment (e.g., increased traveling to patients' homes for device management).

The analysis of this study revealed participants' views on strategies to overcome some of the barriers that were identified. Several suggestions were made at the structure level (e.g., need of staffing, virtual monitoring of devices' performance, PoC testing), process level (e.g., who should be involved in testing, need to reduce the frequency for verifying microbial quality), and at outcomes levels (e.g., availability of operational data to develop evidence-based approach to water quality monitoring). However, all of these suggestions were not without their limitations. Some research has been done on alternative approaches to managing water quality in home programs. Prior published studies have shown that a risk-based assessment approach can help derive program-specific management processes, such as failure mode effects analysis, root-cause analysis[161], and risk assessment[196]. Since the analysis of this research study revealed a need for an individualized approach to managing HD and water-related devices, exploring how these management tools will help develop processes will indeed be helpful in better care delivery from a technical perspective.

This study shows that there is a need for discussion on what should be the water quality requirements in the Canadian landscape. Since the existing CSA standards have become stricter over the years, parallel to some of the guidelines available in some European countries, participants were concerned about its actual benefits on HHD patient outcomes. Moreover, as

highlighted in the findings of this study, home programs could face ground-level challenges and barriers to delivering stricter quality water. The medical directors interviewed in this study had conflicting views on the benefits of using more stringent water quality for HHD. Still, they did agree on the need for future studies to identify how delivering the microbial quality at a stricter level (i.e., ultrapure grade) would benefit home programs from a clinical and technical perspective.

This study is not without its limitations. First, this study could have collected more information on barriers to identifying challenges in providing technical support to patients living in remote locations by recruiting participants from home programs with such a cohort of patients. In this respect, it can be said that saturation in data analysis has not been achieved. Secondly, the interviews were conducted with healthcare professionals only, so this study lacked the perspective of patients and third-party vendors, who are also essential stakeholders. However, this limitation was managed by having the participants' views on the barriers from a patient perspective. Since several barriers from the patient side were perceived as contributing to degraded microbial quality in some of the participating home programs, including them in future barriers assessment studies on home programs would be beneficial.

Conclusion

Several aspects of quality management that could be improved to better manage water delivery in Canadian home programs were highlighted. However, improving the implementation of quality management would require solutions that address multiple factors; any changes at a structure level will also have to be supported by improving the process of managing them (e.g., insufficient device design leads to improper disinfection, which affects water quality). Since water needs to be managed in a home program at each patient's home, the environmental and geographical factors add more complexity to its implementation. Therefore, considering these factors when deriving solutions to improve quality management is essential.

Along with barriers, the proven facilitators connected to processes of testing and device care and practical design features of devices were identified, which could be used as a future reference for home programs aiming at improving their delivery of care.

It was recognized by healthcare professionals that the level of care should remain the same irrespective of where a patient performs dialysis. At the same time, the approaches to deliver care should be tailored according to the environment where it is being delivered was considered crucial. Therefore, future research on the impact of varied approaches used for quality management and the existing CSA's water quality requirements on patient outcomes was deemed essential for home programs to serve their patients better and manage resources.

Chapter-4: Thesis Conclusion

Chapter-4: Thesis Conclusion

This thesis was comprised of 2 studies. The first study was about understanding the significance of water quality and the organizations involved in developing its requirements for home hemodialysis (HHD). A scoping review of existing standards and guidelines revealed that organizations involved in issuing the requirements for water in HHD had extensive variations. They developed documents to enhance safety and avoid inflammatory triggers among end-stage renal (ESRD) patients. The scoping review revealed that Canada's approach to the requirements of microbial water quality for HHD is similar to that of some of the European Union (EU) member countries, particularly for the use of ultrapure dialysate to improve the chronic conditions of the ESRD population. Regarding the chemical quality of dialysis water (DW) and dialysate for HHD, EU member countries have laid out more water quality parameters than Canada, specifically by including organic contaminants. In that sense, Canada is comparatively less strict regarding chemical requirements for DW and dialysate in HHD. The scoping review revealed an interesting variation across the reviewed guidelines and standards. Several organizations provided recommendations by providing statements on how to manage water quality that meets the requirements. However, in Canada, the statements provided were mandatory. In the management aspects (i.e., when to test and from where to test), Canada took a stricter approach than the other countries.

In the second chapter of this thesis, the results revealed that implementation of the national standards on water quality as developed by the Canadian Standards Association (CSA) is highly challenging to healthcare professionals. Decision-makers aiming at improving quality management in HHD should consider developing practical multifactorial approaches to improving the process for sending microbial samples to a laboratory, timely receiving of microbial test results, compliance with CSA's required microbial testing frequency, compliance with device care schedule, documentation of data, scheduling inspection visits at patients' homes, and enhancing communication. Several factors identified acted as barriers and challenges in these areas of quality management. The need to address the barrier of lack of resources in terms of the cost of maintaining sufficient staffing, patient compliance, and adequate devices was cited in many home programs to improve the process of testing and device maintenance. The need for monthly testing as required by the CSA standards was considered unnecessary by

several participants. Overall, it was perceived by health professionals that the local context and home care environment were not considered by the CSA standards, which created issues in their implementation mainly from a resource standpoint (cost, patients, and staff travel time).

In addition to the barriers and facilitators related to process and equipment for testing and device care, participants identified several factors connected to the built environment. Moreover, the use of well water or cistern as the source of supply for drinking water at patients' homes and the poor construction of patients' homes were the most prominent barriers to selecting patients for home programs.

Furthermore, there were conflicting views among medical directors regarding the use of ultrapure dialysate. A lack of convincing evidence on the clinical effectiveness of ultrapure dialysate among ESRD patients was cited as an argument for not supporting its use in HHD. Moreover, some biomedical engineering technologists did not support its use due to inadequate resources to support its testing requirements. The work of quality management was described as burdensome by biomedical engineering technologists since they were involved in numerous tasks, including installation, decommissioning, and managing quality of each patients' source water quality and devices, which require long-distance traveling.

There were several facilitators identified by participants that helped in managing water quality in their home programs. The facilitators that improved the testing and device care process were: policies to ensure timely access to patients' homes and adequate policies and procedures for auditing quality test results. The use of guidance from organizations involved in manufacturing purification devices for HD, diagnostic laboratories, and source water suppliers was considered helpful in understanding variability in water quality according to patients' geographic locations. Additionally, the usability of devices was regarded as a crucial factor in enhancing patient safety and improving patient compliance. Several factors connected to device design were identified as helping achieve desired water quality: the use of ultrafilters and the use of integrated heat disinfection.

The findings of this thesis revealed several areas for future research. First, there is a need for research into identifying a consistent process for microbial testing. Second, there is a need to

evaluate the impact of the requirements within the CSA standards (including quality requirements and testing frequency) on patient outcomes. Third, patients and vendors should be consulted to understand their perceptions on what challenges they face in conducting activities related to the maintenance of water quality in HHD programs.

References

1. Canadian Institute for Health Information. Annual statistics on organ replacement in Canada: dialysis, transplantation and donation, 2010 to 2019 [Internet]. Ottawa, Ontario; 2020. Available from: https://www.cihi.ca/sites/default/files/document/corr-dialysis-transplantation-donation-2010-2019-snapshot-en.pdf
2. Culleton BF, Walsh M, Klarenbach SW, Mortis G, Scott-Douglas N, Quinn RR, et al. Effect of frequent Nocturnal Hemodialysis vs Conventional Hemodialysis on Left Ventricular Mass and Quality of Life. JAMA [Internet]. 2007 Sep 19;298(11):1291. Available from: http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.298.11.1291
3. Walsh M, Culleton B, Tonelli M, Manns B. A systematic review of the effect of nocturnal hemodialysis on blood pressure, left ventricular hypertrophy, anemia, mineral metabolism, and health-related quality of life. Kidney Int [Internet]. 2005 Apr;67(4):1500–8. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0085253815506066
4. Rydell H, Ivarsson K, Almquist M, Segelmark M, Clyne N. Improved long-term survival with home hemodialysis compared with institutional hemodialysis and peritoneal dialysis: a matched cohort study. BMC Nephrol [Internet]. 2019 Dec 13;20(1):52. Available from: https://bmcnephrol.biomedcentral.com/articles/10.1186/s12882-019-1245-x
5. Weinhandl ED, Nieman KM, Gilbertson DT, Collins AJ. Hospitalization in Daily Home Hemodialysis and Matched Thrice-Weekly In-Center Hemodialysis Patients. Am J Kidney Dis [Internet]. 2015 Jan;65(1):98–108. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0272638614009731
6. Bakris GL, Burkart JM, Weinhandl ED, McCullough PA, Kraus MA. Intensive Hemodialysis, Blood Pressure, and Antihypertensive Medication Use. Am J Kidney Dis [Internet]. 2016 Nov;68(5):S15–23. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0272638616302645
7. Eloot S, Van Biesen W, Dhondt A, Van de Wynkele H, Glorieux G, Verdonck P, et al. Impact of hemodialysis duration on the removal of uremic retention solutes. Kidney Int [Internet]. 2008 Mar;73(6):765–70. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0085253815530718
8. Schulman G. Nutrition in daily hemodialysis. Am J Kidney Dis [Internet]. 2003 Mar;41(3):S112–5. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0272638603000192
9. Eneanya ND, Maddux DW, Reviriego-Mendoza MM, Larkin JW, Usvyat LA, van der Sande FM, et al. Longitudinal patterns of health-related quality of life and dialysis modality: a national cohort study. BMC Nephrol [Internet]. 2019 Dec 8;20(1):7. Available from: https://bmcnephrol.biomedcentral.com/articles/10.1186/s12882-018-1198-5
10. Finkelstein FO, Schiller B, Daoui R, Gehr TW, Kraus MA, Lea J, et al. At-home short daily hemodialysis improves the long-term health-related quality of life. Kidney Int [Internet]. 2012 Sep;82(5):561–9. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0085253815555944
11. Walker RC, Howard K, Morton RL, Palmer SC, Marshall MR, Tong A. Patient and caregiver values, beliefs and experiences when considering home dialysis as a treatment option: a semi-structured interview study. Nephrol Dial Transplant [Internet]. 2016

Jan;31(1):133–41. Available from: https://academic.oup.com/ndt/article-lookup/doi/10.1093/ndt/gfv330
12. Walker RC, Hanson CS, Palmer SC, Howard K, Morton RL, Marshall MR, et al. Patient and Caregiver Perspectives on Home Hemodialysis: A Systematic Review. Am J Kidney Dis [Internet]. 2015 Mar;65(3):451–63. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0272638614014358
13. Mcfarlane PA, Pierratos A, Redelmeier DA. Cost savings of home nocturnal versus conventional in-center hemodialysis. Kidney Int [Internet]. 2002 Dec;62(6):2216–22. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0085253815487915
14. Beaudry A, Ferguson TW, Rigatto C, Tangri N, Dumanski S, Komenda P. Cost of Dialysis Therapy by Modality in Manitoba. Clin J Am Soc Nephrol [Internet]. 2018 Aug 7;13(8):1197–203. Available from: https://cjasn.asnjournals.org/lookup/doi/10.2215/CJN.10180917
15. Walker RC, Howard K, Morton RL. Home hemodialysis: a comprehensive review of patient-centered and economic considerations. Clinicoecon Outcomes Res [Internet]. 2017;9:149–61. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28243134
16. Komenda P, Gavaghan MB, Garfield SS, Poret AW, Sood MM. An economic assessment model for in-center, conventional home, and more frequent home hemodialysis. Kidney Int [Internet]. 2012 Feb;81(3):307–13. Available from: https://linkinghub.elsevier.com/retrieve/pii/S008525381555285X
17. Canadian Institute for Health Information. Trends in end-stage kidney disease in Canada,2019 [inforgraphic] [Internet]. Ottawa, Ontario; 2020. Available from: https://www.cihi.ca/en/trends-in-end-stage-kidney-disease-in-canada-2019
18. Canadian Institute for Health Information (CIHI). High Risk and High Cost: Focus on Opportunities to Reduce Hospitalizations of Dialysis Patients in Canada. 2016.
19. Saran R, Robinson B, Abbott KC, Agodoa LYC, Bhave N, Bragg-Gresham J, et al. US Renal Data System 2017 Annual Data Report: Epidemiology of Kidney Disease in the United States. Am J Kidney Dis [Internet]. 2018 Mar;71(3):A7. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0272638618300428
20. Canadian Agency for Drugs and Technologies in Health. Dialysis programs in Canada: implementation considerations and funding practices. 2017;(March):1–47. Available from: https://www.cadth.ca/sites/default/files/pdf/ES0304_Dialysis_Programs.pdf
21. Canadian Institute for Health Information (CIHI). Treatment of End-Stage Organ Failure in Canada, Canadian Organ Replacement Register, 2010 to 2019: End-Stage Kidney Disease and Kidney Transplants — Data Tables [Internet]. Ottawa, Ontario; 2020. Available from: https://www.cihi.ca/en/organ-replacement-in-canada-corr-annual-statistics-2020
22. Hajj JJ, Laudanski K. Home Hemodialysis (HHD) Treatment as Effective yet Underutilized Treatment Modality in the United States. Healthc (Basel, Switzerland) [Internet]. 2017 Nov 28;5(4). Available from: http://www.ncbi.nlm.nih.gov/pubmed/29182543
23. Masakane I, Hanafusa N, Kita T, Maeda K. Recent Trends in Home Hemodialysis Therapy in Japan. In 2017. p. 54–60. Available from: https://www.karger.com/Article/FullText/450671
24. Walker DR, Inglese GW, Sloand JA, Just PM. Dialysis Facility and Patient Characteristics

Associated with Utilization of Home Dialysis. Clin J Am Soc Nephrol [Internet]. 2010 Sep;5(9):1649–54. Available from: https://cjasn.asnjournals.org/lookup/doi/10.2215/CJN.00080110
25. European Renal Association - European Dialysis Transplantation Association. ERA-EDTA Registry: ERA-EDTA Registry Annual Report 2019 [Internet]. Amsterdam, The Netherlands; 2021. Available from: https://www.era-online.org/registry/AnnRep2019.pdf
26. Mehrabian S, Morgan D, Schlaeper C, Kortas C, Lindsay RM. Equipment and water treatment considerations for the provision of quotidian home hemodialysis. Am J Kidney Dis [Internet]. 2003 Jul;42:66–70. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0272638603005419
27. Jacquet S, Trinh E. The Potential Burden of Home Dialysis on Patients and Caregivers: A Narrative Review. Can J Kidney Heal Dis [Internet]. 2019 Jan 18;6:205435811989333. Available from: http://journals.sagepub.com/doi/10.1177/2054358119893335
28. Jones LA, Gordon EJ, Hogan TP, Fiandaca CA, Smith BM, Stroupe KT, et al. Challenges, Facilitators, and Recommendations for Implementation of Home Dialysis in the Veterans Health Administration: Patient, Caregiver, and Clinician Perceptions. Kidney360 [Internet]. 2021 Dec 30;2(12):1928–44. Available from: https://kidney360.asnjournals.org/lookup/doi/10.34067/KID.0000642021
29. Purves CS. Patient's experience with home hemodialysis: A qualitative study [Internet]. ProQuest Dissertations and Theses. University of Ontario Institute of Technology; 2015. Available from: https://search.proquest.com/docview/1696771060?accountid=14660
30. Forbes SH, McCafferty K, Lawson T, Stoby-Fields M, Raftery M, Yaqoob MM. Is lack of suitable housing a barrier to home-based dialysis therapy for patients with end-stage renal disease? A cohort study. BMJ Open [Internet]. 2013;3(2). Available from: http://www.ncbi.nlm.nih.gov/pubmed/23396574
31. Diebel L, Jafari M, Shah S, Day C, McNaught C, Prasad B. Barriers to Home Hemodialysis Across Saskatchewan, Canada: A Cross-Sectional Survey of In-Center Dialysis Patients. Can J Kidney Heal Dis [Internet]. 2020 Jan 10;7:205435812094829. Available from: http://journals.sagepub.com/doi/10.1177/2054358120948293
32. Régimbald J, Gill C, Ottawa T, Riverside H. Psychosocial barriers to home hialysis : A literature review. 2012;7–17. Available from: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/viewer.html?pdfurl=https%3A%2F%2Fwww.kidney.org%2Fsites%2Fdefault%2Ffiles%2Fv36a_a1.pdf&clen=77653&chunk=true
33. Nesrallah G. DETERMINANTS OF HOME DIALYSIS USE: A MIXED-METHODS STUDY. McMaster University; 2013.
34. Zacharias J, Komenda P, Olson J, Bourne A, Franklin D, Bernstein K. Home hemodialysis in the remote Canadian north: treatment in Manitoba fly-in communities. Semin Dial [Internet]. 24(6):653–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22098423
35. Singh SK, Loucaidou M, Power A, Beagle S, Nevin M, Edwards C, et al. Pre-emptive replacement of water treatment components improves responsiveness to erythropoiesis-stimulating agents in maintenance haemodialysis patients: A quality improvement report. Blood Purif. 2014;36(3–4):265–73.
36. Favero, M.; Petersen, N.; Boyer, K.; Carson, L.; Bond W. Microbial contamination of renal dialysis systems and associated health risks. Trans Am Soc Artif Intern Organs [Internet]. 1974;(20A):175–83. Available from:

https://pubmed.ncbi.nlm.nih.gov/4450335/
37. Hoshino J, Yamagata K, Nishi S, Nakai S, Masakane I, Iseki K, et al. Significance of the decreased risk of dialysis-related amyloidosis now proven by results from Japanese nationwide surveys in 1998 and 2010. Nephrol Dial Transplant [Internet]. 2016 Apr;31(4):595–602. Available from: https://academic.oup.com/ndt/article-lookup/doi/10.1093/ndt/gfv276
38. Davison AM, Oli H, Walker GS, Lewins AM. Water supply aluminium concentration, dialysis dementia, and effect of reverse-osmosis water treatment. Lancet [Internet]. 1982 Oct;320(8302):785–7. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0140673682926782
39. Munene A, Lockyer J, Checkley S, Hall DC. Exploring Well Water Testing Behaviour Through the Health Belief Model. Environ Health Insights [Internet]. 2020 Jan 11;14:117863022091014. Available from: http://journals.sagepub.com/doi/10.1177/1178630220910143
40. Abraham Munene DCH. Factors influencing perceptions of private water quality in North America: a systematic review. Syst Rev. 2019;8(1):111.
41. Kennedy GW, Drage J. A Review of Private Well Contaminants, Testing, and Mitigation Behaviours in Nova Scotia. Geosci Mines Branch, Engergy Mines Geol Surv Halifax, Nov Scotia. 2020;(April):23.
42. Eggertson L. Canada has 1838 drinking-water advisories. CMAJ [Internet]. 2015 Apr 21;187(7):488. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25780055
43. Allaire M, Wu H, Lall U. National trends in drinking water quality violations. Proc Natl Acad Sci [Internet]. 2018 Feb 27;115(9):2078–83. Available from: https://pnas.org/doi/full/10.1073/pnas.1719805115
44. Cribb, Robert; Cohen, Ben; Keogh Declan; Buckley, Charles; Mutis J. Is there lead in your tap water? Canada-wide investigation exposes dangerous levels of toxic metal. 2019 Nov; Available from: https://www.thestar.com/news/investigations/2019/11/04/is-there-lead-in-your-water-canada-wide-investigation-exposes-chronic-extreme-exceedances-of-toxic-metal.html
45. Layton L. Water analysis raises safety issues. 2010 Dec;1–2. Available from: https://www.washingtonpost.com/wp-dyn/content/article/2010/12/20/AR2010122005875.html
46. Charron DF, Thomas MK, Waltner-Toews D, Aramini JJ, Edge T, Kent RA, et al. VULNERABILITY OF WATERBORNE DISEASES TO CLIMATE CHANGE IN CANADA: A REVIEW. J Toxicol Environ Heal Part A [Internet]. 2004 Oct;67(20–22):1667–77. Available from: http://www.tandfonline.com/doi/abs/10.1080/15287390490492313
47. Salvadori MI, Sontrop JM, Garg AX, Moist LM, Suri RS, Clark WF. Factors that led to the Walkerton tragedy. Kidney Int [Internet]. 2009 Feb;75:S33–4. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0085253815536120
48. Leonard H, Pile T. Hard water syndrome: a case series of 30 patients from a London haemodialysis unit. Clin Kidney J [Internet]. 2020 Feb 1;13(1):111–2. Available from: https://academic.oup.com/ckj/article/13/1/111/5488492
49. Junglee NA, Rahman SU, Wild M, Wilms A, Hirst S, Jibani M, et al. When pure is not so pure: chloramine-related hemolytic anemia in home hemodialysis patients. Hemodial Int

[Internet]. 2010 Jul;14(3):327–32. Available from: http://www.ncbi.nlm.nih.gov/pubmed/20618875
50. Davenport A, Murcutt G, Whiting S. Cross-sectional audit of blood lead levels in regular outpatient haemodialysis patients dialysing in north London. Nephrology. 2009;14(5):476–81.
51. Azevedo SMFO, Carmichael WW, Jochimsen EM, Rinehart KL, Lau S, Shaw GR, et al. Human intoxication by microcystins during renal dialysis treatment in Caruaru - Brazil. Toxicology. 2002;181–182:441–6.
52. The Canadian Standards Association Group. Z364.6-17 quality management for kidney dialysis providers [Internet]. 2017. Available from: https://www.csagroup.org/store/product/2704193/
53. Canadian Standards Association. CSA Z364.5-17Safe installation and operation of hemodialysis and peritoneal dialysis in a home setting [Internet]. 2017. Available from: https://www.csagroup.org/store/product/2703162/
54. Ouji M. HHD_rationale_CSANews_googlesearch. 2010;
55. Manns BJ, Johnson JA, Taub K, Mortis G, Ghali WA, Donaldson C. Dialysis adequacy and health related quality of life in hemodialysis patients. ASAIO J [Internet]. 48(5):565–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12296580
56. Molnar AO, Moist L, Klarenbach S, Lafrance J-P, Kim SJ, Tennankore K, et al. Hospitalizations in Dialysis Patients in Canada: A National Cohort Study. Can J kidney Heal Dis [Internet]. 2018;5:2054358118780372. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29900002
57. Canadian Institute for Health Information. Final treatment modality for end-stage kidney disease (ESKD) patients on December 31 [indicator] [Internet]. 2020. Available from: https://www.cihi.ca/en/indicators/final-treatment-modality-for-end-stage-kidney-disease-eskd-patients-on-december-31
58. Walker R, Howard K, Morton R. Home hemodialysis: a comprehensive review of patient-centered and economic considerations. Clin Outcomes Res [Internet]. 2017 Feb;Volume 9:149–61. Available from: https://www.dovepress.com/home-hemodialysis-a-comprehensive-review-of-patient-centered-and-econ-peer-reviewed-article-CEOR
59. Masakane I, Hanafusa N, Kita T, Hasegawa T, Maeda K. The present status of and perspectives on home hemodialysis therapy in Japan. Contrib Nephrol. 2015;185:32–41.
60. Locatelli F, La Milia V, Violo L, Del Vecchio L, Di Filippo S. Optimizing haemodialysate composition. Clin Kidney J [Internet]. 2015 Oct;8(5):580–9. Available from: https://academic.oup.com/ckj/article-lookup/doi/10.1093/ckj/sfv057
61. Alfrey, C., LeGendre, G., Kaehny W. The dialysis encephalopathy syndrome. Possible aluminum intoxication. N Engl J Med [Internet]. 1976;4(294):184–8. Available from: https://pubmed.ncbi.nlm.nih.gov/1244532/
62. Levin NW. Adequacy of dialysis. Am J Kidney Dis [Internet]. 1994 Aug 15;24(2):308–15. Available from: http://theprofesional.com/index.php/tpmj/article/view/390
63. Favero MS, Carson LA, Bond WW, Petersen NJ. Factors that influence microbial contamination of fluids associated with hemodialysis machines. Appl Microbiol [Internet]. 1974 Nov;28(5):822–30. Available from: http://www.ncbi.nlm.nih.gov/pubmed/4216291
64. Nystrand R. Dialysis fluid contamination of pathways and life of microbes. EDTNA ERCA J [Internet]. 2001;27(3):135–9. Available from:

http://www.ncbi.nlm.nih.gov/pubmed/11868995
65. Schiavano GF, Parlani L, Sisti M, Sebastianelli G, Brandi G. Occurrence of fungi in dialysis water and dialysate from eight haemodialysis units in central Italy. J Hosp Infect [Internet]. 2014 Mar;86(3):194–200. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24556142
66. Lonnemann G. When good water goes bad: how it happens, clinical consequences and possible solutions. Blood Purif [Internet]. 2004;22(1):124–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/14732820
67. Hindman SH, Favero MS, Carson LA, Petersen NJ, Schonberger LB, Solano JT. Pyrogenic reactions during haemodialysis caused by extramural endotoxin. Lancet (London, England) [Internet]. 1975 Oct 18;2(7938):732–4. Available from: http://www.ncbi.nlm.nih.gov/pubmed/52769
68. Favero MS, Petersen NJ, Carson LA, Bond WW, Hindman SH. Gram-negative water bacteria in hemodialysis systems. Health Lab Sci [Internet]. 1975 Oct;12(4):321–34. Available from: http://www.ncbi.nlm.nih.gov/pubmed/1236620
69. Vichek DL, Pressly N. Quality assurance guidelines for hemodialysis devices. [Internet]. Medical device technology. 1991. Available from: https://www.fda.gov/files/medical devices/published/Quality-Assurance-Guidelines-for-Hemodialysis-Devices.pdf
70. Lonnemann G, Behme TC, Lenzner B, Floege J, Schulze M, Colton CK, et al. Permeability of dialyzer membranes to TNFα-inducing substances derived from water bacteria. Kidney Int. 1992;42(1):61–8.
71. Vanholder R, Van Haecke E, Veys N, Ringoir S. Endotoxin transfer through dialysis membranes: small- versus large-pore membranes. Nephrol Dial Transplant [Internet]. 1992;7(4):333–9. Available from: https://academic.oup.com/ndt/article/1813199/Endotoxin
72. Ronco C. Fluid mechanics and crossfiltration in hollow-fiber hemodialyzers. Contrib Nephrol [Internet]. 2007;158:34–49. Available from: https://www.karger.com/Article/FullText/107233
73. Ekdahl KN, Soveri I, Hilborn J, Fellström B, Nilsson B. Cardiovascular disease in haemodialysis: role of the intravascular innate immune system. Nat Rev Nephrol [Internet]. 2017 May 27;13(5):285–96. Available from: http://www.nature.com/articles/nrneph.2017.17
74. Akchurin OM, Kaskel F. Update on inflammation in chronic kidney disease. Blood Purif [Internet]. 2015;39(1–3):84–92. Available from: https://www.karger.com/Article/FullText/368940
75. Zhang W, He J, Zhang F, Huang C, Wu Y, Han Y, et al. Prognostic role of C-reactive protein and Interleukin-6 in dialysis patients: a systematic review and meta-analysis. J Nephrol [Internet]. 2013;26(2):243–53. Available from: http://www.jnephrol.com/article/prognostic-role-of-c-reactive-protein-and-interleukin-6-in-dialysis-patients-a-systematic-review-and-meta-analysis
76. Sun J, Axelsson J, Machowska A, Heimbürger O, Bárány P, Lindholm B, et al. Biomarkers of cardiovascular disease and mortality risk in patients with advanced CKD. Clin J Am Soc Nephrol [Internet]. 2016 Jun 7;11(7):1163–72. Available from: https://cjasn.asnjournals.org/lookup/doi/10.2215/CJN.10441015
77. Berland Y, Brunet P, Ragon A, Reynier JP. Dialysis fluid and water: their roles in

biocompatibility. Nephrol Dial Transplant [Internet]. 1995;10 Suppl 1:45–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/8825432
78. Schiffl H. Ultrapure dialysis fluid slows loss of residual renal function in new dialysis patients. Nephrol Dial Transplant [Internet]. 2002 Oct 1;17(10):1814–8. Available from: https://academic.oup.com/ndt/article-lookup/doi/10.1093/ndt/17.10.1814
79. Schiffl H, Lang SM, Stratakis D, Fischer R. Effects of ultrapure dialysis fluid on nutritional status and inflammatory parameters. Nephrol Dial Transplant [Internet]. 2001 Sep 1;16(9):1863–9. Available from: http://academic.oup.com/ndt/article/16/9/1863/1863077
80. Baz M, Durand C, Ragon A, Jaber K, Andrieu D, Merzouk T, et al. Using ultrapure water in hemodialysis delays carpal tunnel syndrome. Int J Artif Organs [Internet]. 1991 Nov 13;14(11):681–5. Available from: http://journals.sagepub.com/doi/10.1177/039139889101401101
81. Arizono K, Nomura K, Motoyama T, Matsushita Y, Matsuoka K, Miyazu R, et al. Use of ultrapure dialysate in reduction of chronic inflammation during hemodialysis. Blood Purif [Internet]. 2004;22(2):26–9. Available from: https://www.karger.com/Article/FullText/81870
82. Hasegawa T, Nakai S, Masakane I, Watanabe Y, Iseki K, Tsubakihara Y, et al. Dialysis fluid endotoxin level and mortality in maintenance hemodialysis: A nationwide cohort study. Am J Kidney Dis [Internet]. 2015 Jun;65(6):899–904. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0272638614015418
83. Lederer SR, Schiffl H. Ultrapure dialysis fluid lowers the cardiovascular morbidity in patients on maintenance hemodialysis by reducing continuous microinflammation. Nephron [Internet]. 2002;91(3):452–5. Available from: https://www.karger.com/Article/FullText/64286
84. Go I, Takemoto Y, Tsuchida K, Sugimura K, Nakatani T. The effect of ultrapure dialysate on improving renal anemia. Osaka City Med J [Internet]. 2007 Jun;53(1):17–23. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17867630
85. Schiffl H. High-flux dialyzers, backfiltration, and dialysis fluid quality. Semin Dial [Internet]. 2011 Jan;24(1):1–4. Available from: http://doi.wiley.com/10.1111/j.1525-139X.2010.00786.x
86. Gorke A, Kittel J. Routine disinfection of the total dialysis fluid system. EDTNA-ERCA J [Internet]. 2002 Jul 9;28(3):130–3. Available from: http://doi.wiley.com/10.1111/j.1755-6686.2002.tb00226.x
87. Hoenich NA, Levin R. The implications of water quality in hemodialysis. Semin Dial [Internet]. 2003 Nov 17;16(6):492–7. Available from: http://doi.wiley.com/10.1046/j.1525-139X.2003.16106.x
88. Cross J. The development of water treatment technology for hemodialysis. Dial Transplant. 1997;26(9):596–609.
89. Tipple MA, Shusterman N, Bland LA, McCarthy MA, Favero MS, Arduino MJ, et al. Illness in hemodialysis patients after exposure to chloramine contaminated dialysate. ASAIO Trans [Internet]. 37(4):588–91. Available from: http://www.ncbi.nlm.nih.gov/pubmed/1768494
90. Vorbeck-Meister I, Sommer R, Vorbeck F, Hörl WH. Quality of water used for haemodialysis: bacteriological and chemical parameters. Nephrol Dial Transplant.

1999;14(3):666–75.
91. Oumokhtar B, Ouali A El, Mahmoud M, Berrada S, Arrayhani M, Houssaini TS. Prevent infection linked to the dialysis water in a hemodialysis center in Fez city (Morocco). Pan Afr Med J [Internet]. 2013 May;16(5):534–43. Available from: http://www.ncbi.nlm.nih.gov/pubmed/4021988
92. de Torres JP, DeTorres JP, Strom JA, Jaber BL, Hendra KP. Hemodialysis-associated methemoglobinemia in acute renal failure. Am J Kidney Dis [Internet]. 2002 Jun;39(6):1307–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12046046
93. Laurence RA, Lapierre ST. Quality of hemodialysis water: a 7-year multicenter study. Am J Kidney Dis [Internet]. 1995 May;25(5):738–50. Available from: http://www.ncbi.nlm.nih.gov/pubmed/7747728
94. Baldwin D. Water officials urge dialysis registration. 2010 Mar; Available from: https://oklahoman.com/article/3450220/water-officials-urge-dialysis-registration
95. Lindley EJ, Lopot F, Harrington M, Elseviers MM. Treatment of water for dialysis - A European survey. EDTNA-ERCA J. 2000;26(4):34–40.
96. Almodovar AAB, Buzzo ML, Silva FP de LE, Hilinski EG, Bugno A. Effectiveness of the monitoring program for ensuring the quality of water treated for dialysis in the state of São Paulo. J Bras Nefrol [Internet]. 2018 Dec;40(4):344–50. Available from: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0101-28002018000400344&tlng=en
97. Hilinski EG, E Silva FP de L, Pinto T de JA, Bugno A, Almodovar AAB, Silva FP de L e, et al. Is dialysis water a safe component for hemodialysis treatment in São Paulo State, Brazil? Brazilian J Pharm Sci [Internet]. 2020;56:1–9. Available from: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S1984-82502020000100542&tlng=en
98. Marshall MR, Chan CT. The global forum for home hemodialysis: A new open-source practical manual. Hemodial Int. 2015;19(S1):S1–3.
99. Institute of Health Economics. Innovative kidney care policy options for the future [Internet]. 2015. Available from: https://www.google.ca/search?source=hp&ei=7IkdYLTlOYzc-gTTrraYCg&q=+Innovative+funding+models+kidney+care+policy+options+for+the+future.&oq=+Innovative+funding+models+kidney+care+policy+options+for+the+future.&gs_lcp=CgZwc3ktYWIQA1B6WHpg3QJoAHAAeACAAWGIAW
100. Ponson L, Arkouche W, Laville M. Home hemodialysis: the technical overview. A 2010 survey. Nephrol Ther [Internet]. 2012 Apr;8(2):81–6. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22341646
101. Kerr PG, Agar JWM. Keeping home dialysis patients at home. Am J Kidney Dis [Internet]. 2016 Apr;67(4):542–4. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0272638616000093
102. Dialysis JRC, Ren S, Aust S. Dialysis water quality for renal nurses. Society. 2008;4(March):13–20.
103. Penne EL, Visser L, Van Den Dorpel MA, Van Der Weerd NC, Mazairac AHA, Van Jaarsveld BC, et al. Microbiological quality and quality control of purified water and ultrapure dialysis fluids for online hemodiafiltration in routine clinical practice. Kidney Int. 2009;76(6):665–72.

104. Lindley EJ, Lopot F, Harrington M, Elseviers MM. Treating and monitoring water for dialysis in Europe. Nephrol News Issues [Internet]. 2001 Jan;15(2):27, 30, 33–6. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12098832
105. Glorieux G, Neirynck N, Veys N, Vanholder R. Dialysis water and fluid purity: more than endotoxin. Nephrol Dial Transplant [Internet]. 2012 Nov 1;27(11):4010–21. Available from: https://academic.oup.com/ndt/article-lookup/doi/10.1093/ndt/gfs306
106. Ward RA. Worldwide water standards for hemodialysis. Hemodial Int. 2007;11(SUPPL. 1):18–25.
107. Dheda S, Van Eps C, Hawley C, Johnson DW. Water treatment for centre and home-based haemodialysis. In: Updates in Hemodialysis [Internet]. InTech; 2015. Available from: http://www.intechopen.com/books/updates-in-hemodialysis/water-treatment-for-centre-and-home-based-haemodialysis
108. Bek MJ, Laule S, Reichert-Jünger C, Holtkamp R, Wiesner M, Keyl C. Methemoglobinemia in critically ill patients during extended hemodialysis and simultaneous disinfection of the hospital water supply. Crit Care. 2009;13(5):1–4.
109. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol [Internet]. 2005 Feb;8(1):19–32. Available from: http://www.tandfonline.com/doi/abs/10.1080/1364557032000119616
110. Kraicer-Melamed H, Doll MK, Boikos C, Winters N, Frimer L, Stirling R, et al. A scoping review of existing guidelines and recommendations for the use of influenza antiviral medications. Off J Assoc Med Microbiol Infect Dis Canada [Internet]. 2017 Dec;2(2):16–32. Available from: https://jammi.utpjournals.press/doi/10.3138/jammi.2.2.04
111. Knowles L, Luth W, Bubela T. Paving the road to personalized medicine: recommendations on regulatory, intellectual property and reimbursement challenges. J Law Biosci [Internet]. 2017 Dec 1;4(3):453–506. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29868182
112. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. Implement Sci [Internet]. 2010 Dec 20;5(1):69. Available from: http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-5-69
113. Peters MDJ, Godfrey CM, Khalil H, McInerney P, Parker D, Soares CB. Guidance for conducting systematic scoping reviews. Int J Evid Based Healthc [Internet]. 2015 Sep;13(3):141–6. Available from: https://journals.lww.com/01787381-201509000-00005
114. OECD. Health at a Glance 2019 [Internet]. Organización para la Cooperación y el Desarrollo Económicos. Paris: OECD Publishing; 2019. 2–4 p. (Health at a Glance). Available from: https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance_19991312
115. German Society for Nephrology A of GKC and TS for PN. Dialysis standard [Internet]. 2020. Available from: https://www-dgfn-eu.translate.goog/dialyse-standard.html?_x_tr_sl=de&_x_tr_tl=en&_x_tr_hl=en&_x_tr_pto=nui,sc
116. Canadian Council of Ministers of the Environment-Water Quality Task Group. A Canada-wide framework for water quality monitoring [Internet]. Winnipeg - Manitoba; 2006. Available from: https://publications.gc.ca/site/eng/9.690835/publication.html
117. World Health Organization. Guidelines for drinking water quality: :fourth edition incorporating the first addendum [Internet]. Fourth. Geneva; 2017. Available from:

https://www.who.int/publications-detail-redirect/9789241549950
118. New Zealand Ministry of Health (NZMOH). Guidelines for drinking-water quality management for New Zealand [Internet]. 2013. 1–729 p. Available from: https://www.moh.govt.nz/notebook/nbbooks.nsf/0/B97E4331F0C1F869CC257C2E0072BAB9/$file/guidelines-drinking-water-quality-management-for-new-zealand-oct13.pdf
119. World Health Organization. Guidelines for drinking water quality- 2nd ed. [Internet]. Vol. 3. Geneva; 1997. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15806952
120. Hoyle D. International Standards Organization (ISO) 9000: quality systems handbook [Internet]. 2001. Available from: https://pqm-online.com/assets/files/lib/books/holye2.pdf
121. World Health Organization. Guidelines for drinking water quality, 3rd Edition [Internet]. Vol. 1. 2004. Available from: https://www.who.int/water_sanitation_health/dwq/GDWQ2004web.pdf
122. Olsen AR, Robertson DM. Monitoring Design [Internet]. Available from: https://acwi.gov/monitoring/final_4_monitoringdesign_0605.pdf
123. Government of Saskatchewan. Quality assurance and quality control for water treatment utilities standard – drinking water quality management [Internet]. 2012. Available from: http://www.saskh20.ca/pdf/epb542.pdf
124. National Health and Medical Research Council, National Resource Management Ministerial Council, Common Wealth of Australia C. Australian drinking water guidelines Paper 6 national water quality management strategy [Internet]. 2018. Available from: https://www.nhmrc.gov.au/about-us/publications/australian-drinking-water-guidelines
125. Cook C, Prystajecky N, Ngueng Feze I, Joly Y, Dunn G, Kirby E, et al. A comparison of the regulatory frameworks governing microbial testing of drinking water in three Canadian provinces. Can Water Resour J [Internet]. 2013 Sep;38(3):185–95. Available from: http://www.tandfonline.com/doi/abs/10.1080/07011784.2013.822186
126. Bartram J, Pedley S. Water quality monitoring- A practical guide to the design and implementation of freshwater quality studies and monitoring programmes [Internet]. United Nations Environment Programme; World Health Organization. 1996. 1–27 p. Available from: http://www.who.int/water_sanitation_health/resourcesquality/wqmchap10.pdf
127. Burke A. Water quality in the south SK river basin [Internet]. 2013. Available from: https://southsaskriverstewards.ca/projects/water-quality-assessment/
128. Canadian Council of Ministers of the Environment. Guidance manual for optimizing water quality monitoring program design [Internet]. 2015. Available from: https://ccme.ca/en/res/guidancemanualforoptimizingwaterqualitymonitoringprogramdesign_1.0_e.pdf
129. Mactier R. Renal association clinical practice guideline development policy manual. Nephron Clin Pract [Internet]. 2011;118 Suppl:c13-25. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21555892
130. Totaro M, Casini B, Valentini P, Miccoli M, Giorgi S, Porretta A, et al. Evaluation and control of microbial and chemical contamination in dialysis water plants of Italian nephrology wards. J Hosp Infect [Internet]. 2017;97(2):169–74. Available from: http://dx.doi.org/10.1016/j.jhin.2017.05.011
131. International Organization for Standardization. ISO 23500-1: 2019 Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: general

requirements [Internet]. Switzerland. 2019. Available from: https://www.iso.org/standard/67610.html
132. Network Dialysis Working Group of the Agency for Clinical Innovation Renal. Water for dialysis: A guide for in-centre, satellite and home haemodialysis in NSW [Internet]. 2018. Available from: https://aci.health.nsw.gov.au/__data/assets/pdf_file/0007/306088/water-for-dialysis2018.pdf
133. Dutch Federation for Nephrology. Water treatment for HD and online HDF, 2020 [Internet]. 2020. Available from: https://www-nefro-nl.translate.goog/richtlijnen/waterbehandeling-voor-hd-en-online-hdf-2020?_x_tr_sl=nl&_x_tr_tl=en&_x_tr_hl=en&_x_tr_pto=nui,sc
134. Swedish Pharmacopoeia Committee and the Swedish Medical Products Agency. Manufacturing and handling of hemodialysis fluids and hemofiltration fluids in health care [Internet]. 2021. Available from: https://translate.google.ca/translate?hl=en&sl=sv&u=https://lakemedelsverket.se/sls&prev=search
135. Pérez-García R, García Maset R, Gonzalez Parra E, Solozábal Campos C, Ramírez Chamond R, Martín-Rabadán P, et al. Guideline for dialysate quality of Spanish Society of Nephrology (second edition, 2015). Nefrologia [Internet]. 2016;36(3):e1–52. Available from: http://dx.doi.org/10.1016/j.nefroe.2016.03.004
136. Working Group for Applied Hygiene in Dialysis Units. Guideline for applied hygiene in dialysis units. Pabst Science Publishers; 1st edition (September 1, 2009); 2009. 192 p.
137. Hoenich, Nicholas; Mactier, Robert; Morgan, Ian; Boyle, Gerard; Rylance, Paul; Thompson C. Guideline on water treatment systems, dialysis water and dialysis fluid quality for haemodialysis and related therapies [Internet]. 2016. Available from: https://www.renaltech.net/educationcpd.html
138. Alloatti S, Bolasco P, Canavese C, Cappelli G, Pedrini L, Pizzarelli F, et al. Guidelines on water and solutions for dialysis. Italian Society of Nephrology. G Ital Nefrol [Internet]. 2016;22(3):246–73. Available from: http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L612311506%0Ahttp://dx.doi.org/10.1097/MCG.0000000000000594
139. The European Dialysis and Transplant Nurses Association/European Renal Care Association. EDTNA/ERCA guidelines: technical section. EDTNA-ERCA J [Internet]. 2002 Jul 9;28(3):107–15. Available from: https://onlinelibrary.wiley.com/doi/10.1111/j.1755-6686.2002.tb00221.x
140. Morgan ITSIGRB of the E. Quality assurance for dialysis-quality water and dialysis fluid. Guidelines for the control of chlorine and chloramine in water for haemodialysis using activated carbon filtration. EDTNA ERCA J [Internet]. 2004;30(2):106–12. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15368889
141. Pancirova, Jitka; Davidson A. A guide to implementing renal best practice in haemodialysis [Internet]. Switzerland; 2014. Available from: https://www.edtnaerca.org/resource/edtna/files/Clinical_Guidelines.pdf
142. Rees, Lesley; Feather, Sally; Shroff R. Haemodialysis clinical practice guidelines for children and adolescents [Internet]. British Association for Paediatric Nephrology. 2008. Available from: https://www.erknet.org/fileadmin/files/user_upload/British_Association_for_Paediatric_N

ephrology._Haemodialysis_clinical_practice_guidelines_for_children_and_adolescents..pdf
143. Ministry of Social Affairs and Health. Circulaire DGS / DH / AFSSAPS n ° 2000-337 of 20 June 2000 on the dissemination of a guide for the production of water for hemodialysis of patients with renal insufficiency [Internet]. 2000. Available from: https://solidarites-sante.gouv.fr/fichiers/bo/2000/00-29/a0292111.htm
144. Uhlig K, MacLeod A, Craig J, Lau J, Levey AS, Levin A, et al. Grading evidence and recommendations for clinical practice guidelines in nephrology. A position statement from Kidney Disease: Improving Global Outcomes (KDIGO). Kidney Int [Internet]. 2006 Dec;70(12):2058–65. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0085253815519030
145. International Organization for Standardization. ISO 23500-3: 2019 Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: water for haemodialysis and related therapies [Internet]. Switzerland. 2019. Available from: https://www.iso.org/standard/67612.html
146. International Organization for Standardization. ISO 23500-5: 2019-Preparation and quality management of fluids for haemodialysis and related therapies — Part 5: quality of dialysis fluid for haemodialysis and related therapies [Internet]. Switzerland. 2019. Available from: https://www.iso.org/standard/67614.html
147. Muirhead N, Mitton R. Use of bone char as an adsorbent in preparation of water for dialysis. ASAIO J [Internet]. 1992;38(3):M334-7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/1457876
148. van der Linde K, Lim BT, Rondeel JMM, Antonissen LPMT, de Jong GM. Improved bacteriological surveillance of haemodialysis fluids: a comparison between Tryptic soy agar and Reasoner's 2A media. Nephrol Dial Transplant [Internet]. 1999 Oct;14(10):2433–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/10528669
149. International Organization for Standardization. ISO 23500-2: 2019 Preparation and quality management of fluids for haemodialysis and related therapies — Part 2: water treatment equipment for haemodialysis applications and related therapies [Internet]. Switzerland. 2019. Available from: https://www.iso.org/standard/67611.html
150. Mehrabian S, Morgan D, Schlaeper C, Kortas C, Lindsay RM. Equipment and water treatment considerations for the provision of quotidian home hemodialysis. Am J Kidney Dis [Internet]. 2003 Jul;42(1 Suppl):66–70. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12830447
151. James R. Monitoring of dialysis water systems - is there a need for increased sampling? EDTNA-ERCA J [Internet]. 2006 Apr 6;32(2):74–7. Available from: http://doi.wiley.com/10.1111/j.1755-6686.2006.tb00454.x
152. Pizzarelli F, Cerrai T, Biagini M, Malaguti M, Bargagna R. Dialysis water treatment systems and monitoring in Italy: Results of a national survey. J Nephrol. 2004;17(4):565–9.
153. Ledebo I, Nystrand R. Defining the microbiological quality of dialysis fluid. Artif Organs. 1999;23(1):37–43.
154. Ward RA. Worldwide guidelines for the preparation and quality management of dialysis fluid and their implementation. Blood Purif. 2009;27(SUPPL. 1):2–4.
155. James R. Microbiological monitoring of dialysis water systems - Which culture method? J

Ren Care. 2007;33(2):66–9.
156. Garcia PR. Quality of dialysis fluid and its components: water and concentrates. Nefrologia [Internet]. 2020; Available from: https://nefrologiaaldia.org/es-articulo-calidad-del-liquido-dialisis-sus-322
157. Girndt, Matthias; Backus, G; Biege, J; Bruns, S; Herget-Rosenthal, S; Cleophas, W; Kruger, B; Leidig, M; Lemmen, S; Riegel, W; Ross, S; Westphalen W. Guideline to infection prevention and hygiene (as a supplement to the dialysis standard) [Internet]. 2019. Available from: https://www-dgfn-eu.translate.goog/dialyse-standard.html?_x_tr_sl=de&_x_tr_tl=en&_x_tr_hl=en&_x_tr_pto=nui,sc
158. Dutch Federation for Nephrology. Appendices to water treatment directive for hemodialysis and online hemodiafiltration [Internet]. 2020. Available from: https://www.nefro.nl/sites/www.nefro.nl/files/richlijnen/Appendices richtlijn Waterbehandeling 2020.pdf?_x_tr_sl=nl&_x_tr_tl=en&_x_tr_hl=en&_x_tr_pto=nui,sc
159. Saran R, Li Y, Robinson B, Abbott KC, Agodoa LYC, Ayanian J, et al. US Renal Data System 2015 Annual Data Report: Epidemiology of Kidney Disease in the United States. Am J Kidney Dis [Internet]. 2016 Mar;67(3 Suppl 1):Svii, S1-305. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26925525
160. Miller BW, Himmele R, Sawin D-A, Kim J, Kossmann RJ. Choosing Home Hemodialysis: A Critical Review of Patient Outcomes. Blood Purif [Internet]. 2018;45(1–3):224–9. Available from: https://www.karger.com/Article/FullText/485159
161. Yadav P, England D, Vanderkolk C, Iroh Tam P-Y. Improving water quality in a dialysis unit using root cause analysis. Am J Infect Control [Internet]. 2017 Jul;45(7):799–804. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0196655317301074
162. Vala S, Chemweno P, Pintelon L, Muchiri P. A risk-based maintenance approach for critical care medical devices: a case study application for a large hospital in a developing country. Int J Syst Assur Eng Manag [Internet]. 2018 Oct 12;9(5):1217–33. Available from: http://link.springer.com/10.1007/s13198-018-0705-1
163. de Wolff FA, Berend K, van der Voet GB. Subacute fatal aluminum poisoning in dialyzed patients: post-mortem toxicological findings. Forensic Sci Int [Internet]. 2002 Aug;128(1–2):41–3. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0379073802001597
164. Taylor C. Home care devices: a new challenge for the profession. Biomed Instrum Technol [Internet]. 42(5):351–6. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18925807
165. National Research Council (US) Committee on the Role of Human Factors in Home Health Care. The Role of Human Factors in Home Health Care [Internet]. Washington, D.C.: National Academies Press; 2010. Available from: http://www.nap.edu/catalog/12927
166. Kaufman-Rivi D, Collins-Mitchell J, Jetley R. Design considerations for medical devices in the home environment. Biomed Instrum Technol [Internet]. 2010;Suppl Home:21–6. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22049603
167. Okunola O, Olaitan J. Bacterial contamination of hemodialysis water in three randomly selected centers in South Western Nigeria. Niger J Clin Pract [Internet]. 2016;19(4):491. Available from: http://www.njcponline.com/text.asp?2016/19/4/491/183293
168. Rao CY, Pachucki C, Cali S, Santhiraj M, Krankoski KLK, Noble-Wang JA, et al. Contaminated Product Water as the Source of Phialemonium curvatum Bloodstream

Infection among Patients Undergoing Hemodialysis . Infect Control Hosp Epidemiol. 2009;30(9):840–7.
169. Leigh Thompson W. Epidemic Parenteral Exposure to Volatile Sulfur-Containing Compounds at a Hemodialysis Center. Infect Control Hosp Epidemiol. 2004;25(11):899–900.
170. Oie S, Kamiya A, Yoneda I, Uchiyama K, Tsuchida M, Takai K, et al. Microbial contamination of dialysate and its prevention in haemodialysis units. J Hosp Infect [Internet]. 2003 Jun;54(2):115–9. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0195670102004024
171. Ouseph R, Ward RA. Ultrapure Dialysate for Home Hemodialysis? Adv Chronic Kidney Dis [Internet]. 2007 Jul;14(3):256–62. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1548559507000511
172. Paterson B, Fox DE, Lee CH, Riehl-Tonn V, Qirzaji E, Quinn R, et al. Understanding Home Hemodialysis Patient Attrition: A Cohort Study. Can J Kidney Heal Dis [Internet]. 2021 Jan 13;8:205435812110221. Available from: http://journals.sagepub.com/doi/10.1177/20543581211022195
173. Schachter ME, Tennankore KK, Chan CT. Determinants of training and technique failure in home hemodialysis. Hemodial Int [Internet]. 2013 Jul 17;17(3). Available from: https://onlinelibrary.wiley.com/doi/10.1111/hdi.12036
174. Pauly RP, Maximova K, Coppens J, Asad RA, Pierratos A, Komenda P, et al. Patient and Technique Survival among a Canadian Multicenter Nocturnal Home Hemodialysis Cohort. Clin J Am Soc Nephrol [Internet]. 2010 Oct;5(10):1815–20. Available from: https://cjasn.asnjournals.org/lookup/doi/10.2215/CJN.00300110
175. Trinh E, Hanley JA, Nadeau-Fredette A-C, Perl J, Chan CT. A comparison of technique survival in Canadian peritoneal dialysis and home hemodialysis patients. Nephrol Dial Transplant [Internet]. 2019 Nov 1;34(11):1941–9. Available from: https://academic.oup.com/ndt/article/34/11/1941/5486187
176. Pauly RP, Komenda P, Chan CT, Copland M, Gangji A, Hirsch D, et al. Programmatic variation in home hemodialysis in Canada: Results from a nationwide survey of practice patterns. Can J Kidney Heal Dis. 2014;1(1):1–13.
177. Ward RA. New AAMI standards for dialysis fluids. Nephrol News Issues. 2011;25(13):33–6.
178. AGAR JWM. Home hemodialysis in Australia and New Zealand: Practical problems and solutions. Hemodial Int [Internet]. 2008 Jul;12:S26–32. Available from: http://doi.wiley.com/10.1111/j.1542-4758.2008.00292.x
179. Fortnum AD, Dialysis H, Manager P. A Model for Home Dialysis. 2012.
180. Davenport A. Complications of hemodialysis treatments due to dialysate contamination and composition errors. Hemodial Int [Internet]. 2015 Oct;19:S30–3. Available from: https://onlinelibrary.wiley.com/doi/10.1111/hdi.12350
181. Davenport A. Selecting Patients for Home Haemodialysis Modality. In 2017. p. 46–53. Available from: https://www.karger.com/Article/FullText/450670
182. Lloyd J. The dialysis technologist: what is our role? CANNT J.
183. Wright J, Harrington M, Picavet L, De Vos JY, Elseviers M. Technical aspects of haemodialysis treatment: Comparative results of Scotland and Belgium. EDTNA-ERCA J. 2006;32(1):24–6.

184. NHS National Services Scotland/Crown Copyright November. Scottish Renal Registry Report 2008. World. 2008.
185. Masakane I, Nakai S, Ogata S, Kimata N, Hanafusa N, Hamano T, et al. An Overview of Regular Dialysis Treatment in Japan (As of 31 December 2013). Ther Apher Dial. 2015;19(6):540–74.
186. Kelly LM, Cordeiro M. Three principles of pragmatism for research on organizational processes. Methodol Innov [Internet]. 2020 May 1;13(2):205979912093724. Available from: http://journals.sagepub.com/doi/10.1177/2059799120937242
187. Booth A, Hannes K, Harden A, Noyes J, Harris J, Tong A. COREQ (Consolidated Criteria for Reporting Qualitative Studies). In: Guidelines for Reporting Health Research: A User's Manual [Internet]. Oxford, UK: John Wiley & Sons, Ltd; 2014. p. 214–26. Available from: https://onlinelibrary.wiley.com/doi/10.1002/9781118715598.ch21
188. Ouseph R, Ward RA. Ultrapure Dialysate for Home Hemodialysis? Adv Chronic Kidney Dis. 2007;14(3):256–62.
189. Murcutt G, Shaldon S, De Vos JY, Lindley E, Greening R, Hansen SK, et al. Should we provide ultrapure dialysis fluid? Summary of the EDTNA/ERCA Journal Club discussion: Winter 2006. J Ren Care. 2007;33(2):92–6.
190. Health Quality Ontario. Quality improvement guide [Internet]. Queen's Printer for Ontario. 2012. Available from: https://www.hqontario.ca/portals/0/documents/qi/qi-quality-improve-guide-2012-en.pdf
191. Institute for Healthcare Improvement. QI Essentials Toolkit: Cause and Effect Diagram. Institute for Healthcare Improvement. 2017.
192. Harel Z, Silver SA, McQuillan RF, Weizman A V., Thomas A, Chertow GM, et al. How to diagnose solutions to a quality of care problem. Clin J Am Soc Nephrol. 2016;11(5):901–7.
193. Campbell DJ, Brown FG, Craig JC, Gallagher MP, Johnson DW, Kirkland GS, et al. Assessment of current practice and barriers to antimicrobial prophylaxis in peritoneal dialysis patients. Nephrol Dial Transplant. 2016;31(4):619–27.
194. Pasricha S, Valiquette CR, Singh M, Pasricha R, Jimal D, Khurshid F. Neonatal intensive care unit hand hygiene: Exploring current practice and adherence barriers in a Canadian hospital. Can J Infect Control [Internet]. 2021;36(2):77–85. Available from: https://search.ebscohost.com/login.aspx?direct=true&db=c8h&AN=152064695&amp%0Alang=pt-br&site=ehost-live
195. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol [Internet]. 2006 Jan;3(2):77–101. Available from: http://www.tandfonline.com/doi/abs/10.1191/1478088706qp063oa
196. Chemweno P, Pintelon L. A comparative risk assessment of dialysis care processes in the home and hospital care contexts. Int J Syst Assur Eng Manag [Internet]. 2020 Oct 5;11(5):985–1002. Available from: https://link.springer.com/10.1007/s13198-020-01032-4

Appendix 1: Detailed Search Strategy

Limits: English Language only, Human Studies
No Restrictions applied on Search Date
Search Date: May 12, 2017
Databases:

1. PubMed
2. Embase
3. Web of Science
4. Cochrane
5. Cumulative Index to Nursing and Allied Health Literature (CINAHL)
6. Centre for Reviews & Dissemination (CRD)
7. EconLit

(1) PubMed

#79 **Search** ((((((((((((((((((((((((((((((((((((("sampling frequency") OR "testing frequency") OR sample*) OR "testing method") OR criteria) OR framework*) OR strateg*) OR monitor*) OR purification) OR purity) OR "water testing") OR "fluid testing") OR "dialysate purification") OR "dialysate treatment") OR "fluid disinfection") OR "water disinfection") OR "fluid treatment") OR OR Statute*) OR Law*) OR legislation) OR "management process*") OR manage*) OR parameter*) OR regulation*) OR directive*) OR recommendation*) OR guid*) OR standard*) OR guideline*) OR "Legislation, Medical"[Mesh]) OR "Practice Guideline" [Publication Type]) OR "Policy"[Mesh]) OR "Water Purification"[Mesh]) OR "Disinfection"[Mesh]) OR "Quality Control"[Mesh])) AND ((((((((((("source water") OR "feed water") OR "product water") OR "hemodialysis fluid") OR concentrate) OR "electrolyte concentrate") OR ultrapure) OR dialysate) OR "dialysis fluid") OR "dialysis water") OR "Hemodialysis Solutions"[Mesh]) OR "Dialysis Solutions"[Mesh])) AND (((((dialysis) OR hdd) OR "Peritoneal Dialysis"[Mesh]) OR "Renal Dialysis"[Mesh]) OR "Hemodialysis, Home"[Mesh]) Filters: Humans; English **Result-3874**

#78 Search ((((((((((((((((((((((((((((((((((((("sampling frequency") OR "testing frequency") OR sample*) OR "testing method") OR criteria) OR framework*) OR strateg*) OR monitor*) OR purification) OR purity) OR "water testing") OR "fluid testing") OR "dialysate purification") OR "dialysate treatment") OR "fluid disinfection") OR "water disinfection") OR "fluid treatment") OR "water treatment system") OR "system design") OR "performance quality") OR validation) OR quality) OR Statute*) OR Law*) OR legislation) OR "management process*") OR manage*) OR parameter*) OR regulation*) OR directive*) OR recommendation*) OR guid*) OR standard*) OR guideline*) OR "Legislation, Medical"[Mesh]) OR "Practice Guideline" [Publication Type]) OR "Policy"[Mesh]) OR "Water Purification"[Mesh]) OR "Disinfection"[Mesh]) OR "Quality Control"[Mesh])) AND ((((((((((("source water") OR "feed water") OR "product water") OR "hemodialysis fluid") OR concentrate) OR "electrolyte concentrate") OR ultrapure) OR dialysate) OR "dialysis fluid") OR "dialysis water") OR "Hemodialysis Solutions"[Mesh]) OR "Dialysis Solutions"[Mesh])) AND (((((dialysis) OR hdd) OR "Peritoneal Dialysis"[Mesh]) OR "Renal Dialysis"[Mesh]) OR "Hemodialysis, Home"[Mesh]) Filters: Humans **Result -5007**

#77 **Search** ((((((((((((((((((((((((((((((((((("sampling frequency") OR "testing frequency") OR sample*) OR "testing method") OR criteria) OR framework*) OR strateg*) OR monitor*) OR purification) OR purity) OR "water testing") OR "fluid testing") OR "dialysate purification") OR "dialysate treatment") OR "fluid disinfection") OR "water disinfection") OR "fluid treatment") OR "water treatment system") OR "system design") OR "performance quality") OR validation) OR quality) OR Statute*) OR Law*) OR legislation) OR "management process*") OR manage*) OR parameter*) OR regulation*) OR directive*) OR recommendation*) OR guid*) OR standard*) OR guideline*) OR "Legislation, Medical"[Mesh]) OR "Practice Guideline" [Publication Type]) OR "Policy"[Mesh]) OR "Water Purification"[Mesh]) OR "Disinfection"[Mesh]) OR "Quality Control"[Mesh])) AND ((((((((((("source water") OR "feed water") OR "product water") OR "hemodialysis fluid") OR concentrate) OR "electrolyte concentrate") OR ultrapure) OR dialysate) OR "dialysis fluid") OR "dialysis water") OR "Hemodialysis Solutions"[Mesh]) OR "Dialysis Solutions"[Mesh])) AND (((((dialysis) OR hdd) OR "Peritoneal Dialysis"[Mesh]) OR "Renal Dialysis"[Mesh]) OR "Hemodialysis, Home"[Mesh]) **Result-7418**

#76 **Search** ((((((((((((((((((((((((((((((((((("sampling frequency") OR "testing frequency") OR sample*) OR "testing method") OR criteria) OR framework*) OR strateg*) OR monitor*) OR purification) OR purity) OR "water testing") OR "fluid testing") OR "dialysate purification") OR "dialysate treatment") OR "fluid disinfection") OR "water disinfection") OR "fluid treatment") OR "water treatment system") OR "system design") OR "performance quality") OR validation) OR quality) OR Statute*) OR Law*) OR legislation) OR "management process*") OR manage*) OR parameter*) OR regulation*) OR directive*) OR recommendation*) OR guid*) OR standard*) OR guideline*) OR "Legislation, Medical"[Mesh]) OR "Practice Guideline" [Publication Type]) OR "Policy"[Mesh]) OR "Water Purification"[Mesh]) OR "Disinfection"[Mesh]) OR "Quality Control"[Mesh] **Result-8714881**

#75 **Search** "sampling frequency" **Result-1157**

#74 **Search** "testing frequency" **Result-220**

#73 **Search** sample* **Result-1441759**

#72 **Search** "testing method" **Result-1406**

#71 **Search** criteria **Result-1159864**

#70 **Search** framework* **Result-194498**

#69 **Search** strateg* **Result-808725**

#68 **Search** monitor* **Result-784643**

#67 **Search** purification **Result-954947**

#66 **Search** purity **Result-32067**

#65 **Search** "water testing" **Result-139**

#64 **Search** "fluid testing" **Result-165**

#63 **Search** "dialysate purification" **Result-4**

#62 **Search** "dialysate treatment" **Result-9**

#61 **Search** "fluid disinfection" **Result-952**

#60 **Search** "water disinfection" **Result-832**

#59 **Search** "fluid treatment" **Result-180**

#58 **Search** "water treatment system" **Result-189**

#57 **Search** "system design" **Result-2622**

#56 **Search** "performance quality" **Result-240**

#55 **Search** validation **Result-201126**

#54 **Search** quality **Result-926249**

#53 **Search** Statute* **Result-4446**

#52	**Search** Law*	**Result-230222**
#51	**Search** legislation	**Result-354920**
#50	**Search** "management process*"	**Result-990**
#49	**Search** manage*	**Result-1272210**
#48	**Search** parameter*	**Result-816775**
#47	**Search** regulation*	**Result-1224071**
#46	**Search** directive*	**Result-18743**
#45	**Search** recommendation*	**Result-195003**
#44	**Search** guid*	**Result-690329**
#43	**Search** standard*	**Result-1561896**
#42	**Search** guideline*	**Result-360062**
#41	**Search** "Legislation, Medical"[Mesh]	**Result-16396**
#39	Search "Practice Guideline" [Publication Type]	**Result-22545**
#36	Search "Policy"[Mesh]	**Result-137315**
#31	**Search** "Water Purification"[Mesh]	**Result-24456**
#29	**Search** "Disinfection"[Mesh]	**Result-12259**
#27	**Search** "Quality Control"[Mesh]	**Result-44603**
#25	**Search** ((((((((((("source water") OR "feed water") OR "product water") OR "hemodialysis fluid") OR concentrate) OR "electrolyte concentrate") OR ultrapure) OR dialysate) OR "dialysis fluid") OR "dialysis water") OR "Hemodialysis Solutions"[Mesh]) OR "Dialysis Solutions"[Mesh]	**Result-45539**
#23	**Search** "source water"	**Result-928**
#22	**Search** "feed water"	**Result-243**
#21	**Search** "product water"	**Result-122**
#20	**Search** "hemodialysis fluid"	**Result-21**
#19	**Search** concentrate	**Result-27179**
#18	**Search** "electrolyte concentrate"	**Result-3**
#17	**Search** ultrapure	**Result-1075**
#16	**Search** dialysate	**Result-15766**
#15	**Search** "dialysis fluid"	**Result-1312**
#14	**Search** "dialysis water"	**Result-135**
#13	**Search** "Hemodialysis Solutions"[Mesh]	**Result-1494**
#11	**Search** "Dialysis Solutions"[Mesh] 5683	
#9	**Search** ((((dialysis) OR hdd) OR "Peritoneal Dialysis"[Mesh]) OR "Renal Dialysis"[Mesh]) OR "Hemodialysis, Home"[Mesh]	**Result-164969**
#8	**Search** dialysis	**Result-164728**
#7	**Search** hdd	**Result-250**
#6	**Search** "Peritoneal Dialysis"[Mesh]	**Result-24287**
#4	Search "Renal Dialysis"[Mesh]	**Result-102248**
#2	Search "Hemodialysis, Home"[Mesh]	**Result-1779**

(2) EMBASE

1. monitor*.mp.	1153699
2. criteria.mp.	75294

3. framework.mp.	1107960
4. strateg*.mp.	1107960
5. statute.mp.	2052
6. exp law/ or law.mp.	195215
7. legislation.mp.	201016
8. parameter.mp.	1382331
9. regulation.mp.	1382331
10. directive.mp.	13808
11. recommendation.mp.	50935
12. practice guideline.mp.	441819
13. guideline*.mp.	602363
14. policy.mp. or exp policy/	365120
15. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14	5405316
16. "source water".mp.	1296
17. "feed water".mp.	674
18. "product water".mp.	268
19. "hemodialysis fluid".mp. or exp hemodialysis fluid/	1440
20. "electrolyte concentrate".mp.	4
21. ultrapure.mp.	1434
22. dialysate.mp. or exp dialysate/	14815
23. "dialysis fluid".mp. or exp dialysis fluid/	7123
24. "hemodialysis solution".mp. or exp hemodialysis fluid/	1428
25. "dialysis solution*".mp.	1759
26. 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25	24396
27. hdd.mp.	390
28. exp dialysis/ or dialysis.mp.	162654
29. "peritoneal dialysis".mp. or exp peritoneal dialysis/	42822
30. "renal dialysis".mp.	2567
31. "home hemodialysis".mp. or exp home dialysis/	2398
32. 27 or 28 or 29 or 30 or 31	163084
33. 15 and 26 and 32	3712

(3) Web of Science

#35	#39 AND #32 AND #17	802
#34	#37 OR #36 OR #35 OR #34 OR #33	108323
#33	TOPIC: ("home hemodialysis")	877

#32	TOPIC: ("renal dialysis")	1509
#31	TOPIC: ("peritoneal dialysis")	26369
#30	TOPIC: (dialysis)	105740
#29	TOPIC: (hdd)	2339
#28	#31 OR #30 OR #28 OR #27 OR #26 OR #25 OR #23 OR #22 OR #20 OR #19 OR #18	20447
#27	TOPIC: ("dialysis solution*")	1294
#26	TOPIC: ("dialysis water")	123
#25	TOPIC: ("dialysis fluid")	1140
#24	TOPIC: ("hemodialysis solution")	20
#23	TOPIC: (dialysate)	10039
#22	TOPIC: (ultrapure)	2830
#21	TOPIC: ("electrolyte concentrate")	3
#20	TOPIC: ("hemodialysis fluid")	32
#19	TOPIC: ("product water")	891
#18	TOPIC: ("feed water")	2672
#17	TOPIC: ("source water")	2582
#16	#16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1	9274644
#15	TOPIC: (policy)	66351
#14	TOPIC: (guideline*)	403780
#13	TOPIC: ("practice guideline*")	33672
#12	TOPIC: (guidance)	196941
#11	TOPIC: (recommendation)	308821
#10	TOPIC: (directive)	35819
#9	TOPIC: (regulation)	1054957
#8	TOPIC: (parameter)	2729114
#7	TOPIC: (legislation)	65374
#6	TOPIC: (law)	625453
#5	TOPIC: (statute)	10876
#4	TOPIC: (strateg*)	1737712
#3	TOPIC: (framework)	963065
#2	TOPIC: (criteria)	862710
#1	TOPIC: (monitor*)	1169062

(4) Cochrane

#37	#39 and #33 and #21	52
#36	#34 or #35 or #36 or #37 or #38	12573
#35	MeSH descriptor: [Hemodialysis, Home] explode all trees	65
#34	MeSH descriptor: [Renal Dialysis] explode all trees	5131
#33	dialysis	12460
#32	hdd	54
#31	MeSH descriptor: [Peritoneal Dialysis] explode all trees	917
#30	#22 or #23 or #24 or #25 or #26 or #27	

	or #28 or #29 or #30 or #31 or #32	4395
#29	MeSH descriptor: [Dialysis Solutions] explode all trees	512
#28	MeSH descriptor: [Hemodialysis Solutions] explode all trees	151
#27	dialysis solution	585
#26	dialysis fluid	933
#25	dialysate	1103
#24	ultrapure	44
#23	electrolyte concentrate	18
#22	hemodialysis fluid	444
#21	product water	991
#20	feed water	270
#19	source water	1489
#18	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17	237404
#17	MeSH descriptor: [Practice Guideline] explode all trees	16
#16	MeSH descriptor: [Legislation, Medical] explode all trees	7
#15	MeSH descriptor: [Policy] explode all trees	935
#14	guideline*	9904
#13	“practice guideline”	4801
#12	guidance	8462
#11	recommendation	5352
#10	directive	1020
#9	regulation	16618
#8	parameter	9417
#7	legislation	1120
#6	law	2374
#5	statute*	21
#4	strateg*	60031
#3	criteria	5456
#2	framework	113465
#1	monitor*:ti,ab,kw	57717

(5) CINAHL

S1	monitor*	125480
S2	criteria	107628
S3	framework	80608
S4	strateg*	194102
S5	law	25085
S6	legislation	131312
S7	parameter	74873
S8	regulation	66283
S9	directive	7597

S10	recommendation	75518
S11	guidance	28714
S12	“practice guideline*”	64180
S13	guideline	136110
S14	“practice guideline*’	2235
S15	guideline*	136510
S16	policy	147565
S17	S1 OR S2 OR S3 OR S5 OR S6 S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16	841356
S18	“source water”	31
S19	“feed water”	11
S20	“product water”	3
S21	“hemodialysis fluid”	3
S22	“electrolyte concentrate”	10
S23	ultrapure	43
S24	dialysate	632
S25	"dialysis fluid"	81
S26	“dialysis water”	140
S27	“hemodialysis solution”	2
S28	S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27	841
S29	hdd	62
S30	dialysis	20049
S31	“peritoneal dialysis”	3685
S32	“renal dialysis”	231
S33	S29 OR S30 OR S31 OR S32”	24941
S34	S33 AND S28 AND S17	745

(6) CRD

1	(practice guideline)	195
2	(framework)	869
3	(law)	171
4	(guidance)	2943
5	(recommendation)	1003
6	(regulation)	282
7	(guideline)	1047
8	(directive)	109
9	(criteria)	59941
10	(monitor*)	3503
11	(parameter)	1460
12	(policy)	3028
13	(legislation)	241
14	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12	

	OR #13	63118
15	("source water")	0
16	("feed water")	0
17	("product water")	0
18	("hemodialysis fluid")	0
19	("electrolyte concentrate")	0
20	(ultrapure)	1
21	(Dialysate)	19
22	("dialysis fluid")	1
23	("dialysis water")	0
24	("hemodialysis solution")	0
25	MeSH DESCRIPTOR Hemodialysis Solutions EXPLODE ALL TREES	6
26	MeSH DESCRIPTOR Dialysis Solutions EXPLODE ALL TREES	14
27	#20 OR #21 OR #22 OR #25 OR #26	28
28	(hdd)	2
29	(dialysis)	906
30	MeSH DESCRIPTOR Peritoneal Dialysis EXPLODE ALL TREES	79
31	MeSH DESCRIPTOR Renal Dialysis EXPLODE ALL TREES	485
32	MeSH DESCRIPTOR Hemodialysis,	18
33	#28 OR #29 OR #30 OR #31 OR #32	918
34	#14 AND #27 AND #33	23

(7) EconLit

S1	monitor*	35929
S2	criteria	3554
S3	framework	73061
S4	strateg*	120532
S5	law	94024
S6	legislation	9191
S7	parameter	32420
S8	regulation	110571
S9	directive	2051
S10	recommendation	10772
S11	guidance	3115
S12	“practice guideline*”	11
S15	guideline*	4796
S16	policy	541760
S17	S1 OR S2 OR S3 OR S5 OR S6 S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16	764123
S18	“source water”	40
S19	“feed water”	118

S20	“product water”	1035
S21	“hemodialysis fluid”	0
S22	“electrolyte concentrate”	0
S23	ultrapure	0
S24	dialysate	0
S25	"dialysis fluid"	1
S26	“dialysis water”	140
S27	“hemodialysis solution”	0
S28	S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27	45
S29	hdd	35
S30	dialysis	20049
S31	“peritoneal dialysis”	3685
S32	“renal dialysis”	231
S33	S29 OR S30 OR S31 OR S32	122
S34	S33 AND S28 AND S17	15

Appendix 2: Grey Literature Searches

Sr. No.	Source	Link	Search Date	Search Terms	Hits	Selected (reasons for exclusion)
International Organizations						
1.	National Kidney Foundation	www.kidney.org	May 8, 2017	Hemodialysis, dialysis, Peritoneal dialysis, standard*,guideline	8	0
2.	Kidney Disease: Improving global outcomes (KDIGO)	http://kdigo.org/home/	May 8, 2017	Hemodialysis, dialysis, Peritoneal dialysis, standard*,guideline sis	15	0
3.	International organization for standardization (ISO)	www.iso.org https://www.iso.org/search/x/query/dialysis%2520and%2520water%2520and%2520dialysis%2520fluid	Aug 25,2017	dialysis and water and dialysis fluid	20	4(131,145,146,149) (not related to dialysis water (DW) or dialysate quality, standards on hemodialysis (HD) machines and hemodialyzers)
4.	NY Academy of Medicine, Grey literature collection	Greylit.org	May 8, 2017	Hemodialysis, Dialysis, Peritoneal dialysis, Standard*, Guideline*	11	0
5.	ISPOR Health Technology Assessment Special Interest Group (HTA)	https://www.ispor.org/sigs/HTAEBD.asp		Hemodialysis	36	0
6.	INAHTA	www.inahta.org	May 8, 2017	Hemodialysis, Peritoneal dialysis, dialysis, standard*, guideline*	31	0
7.	Health Technology Assessment International (HTAI)	www.htai.org		Hemodialysis, dialysis, Peritoneal dialysis, standard*,guideline*	0	0
8.	International Society for Hemodialysis	http://www.ishd.org/manual/	Nov. 23, 2017		1	0 (Adopted documents from ISO)
U.S.A						
9.	American National Standards Institute (ANSI)/Association for the Advancement of Medical	ansi.org	August, 25, 2017	Dialysis water or dialysis fluid	22	0 (adopted documents from ISO (n=4)), not related to DW or dialysate quality, obsolete standards, standards on hemodialysis (HD) machines and hemodialyzers)

Sr. No.	Source	Link	Search Date	Search Terms	Hits	Selected (reasons for exclusion)
	Instrumentation (AAMI)					
10.	Centers for Medicare & Medicaid Services (CMS)	https://www.cms.gov/site-search/search-results.html?q=dialysis%20water%20 https://search.cms.gov/search?affiliate=cms-new&commit=Search&dc=&page=1&query=dialysis+water&utf8=%C3%A2%C5%93%E2%80%9C	August 28,2017	Dialysis water	About 146	0 (legislation on DW and dialysate quality, guidance on topics of water quality management not related to this review (such as national surveillance system))
11.	Google	https://www.google.ca/search?q=dialysis+water+and+guidelines+and+USA&ei=sEEfWt3cOYLO0gSP4Y8Y&start=0&sa=N&biw=1920&bih=971	dialysis water and guidelines and USA	November 19, 2017	First 25 selected	0 (not meeting the definition of a guideline as specified in the inclusion criteria)
Canada						
12.	Canadian Standards Association	http://shop.csa.ca/en/canada/health-care-and-medical-devices/kidney-dialysis/icat/kidneydialysis?sort=name&parentCategoryRef=kidneydialysis&order=asc&q=*&bklist=icat%2C5%2Cshop%2Cpublications%2Chealthcare%2Ckidneydialysis&bklist=icat%2C5%2Cshop%2Cpublications%2Chealthcare%2Ckidneydialysis&setpagenum=1&perpage=10	Oct 29, 2017		12	2(52,53) (standards on technical specifications for HD machines, hemodialyzers, hemodiafliters and hemofilters, safety standards, electrical standards)
13.	Canadian Institutes of Health Research (CIHR)	http://recherche-search.gc.ca/rGs/s_r?cdn=irsccihr&st=s&num=10&langs=eng&st1rt=0&s5bm3ts21rc	Oct 29, 2017	Dialysis water quality	2	0 (not related to DW and dialysate quality)

Sr. No.	Source	Link	Search Date	Search Terms	Hits	Selected (reasons for exclusion)
		h=x&q=dialysis+water+quality				
14.	Public Health Agency of Canada	https://www.canada.ca/en/sr.html?st=s&q=dialysis+water+quality&_charset_=UTF-8&num=10&st1rt=1&s5bm3ts21rch=x&wb-srch-sub=&as_q=&langs=en&cdn=canada	Oct 29, 2017	Dialysis water quality	About 41	0 (obsolete standards on DW and dialysate quality, drinking water standards, recreational water standards, standards related to HD prescription, and technical specifications for HD machines)
15.	British Columbia Renal Agency	http://www.bcrenalagency.ca/bc-renal-agency-search-results#k=dialysis%20water%20quality%20or%20dialysis%20fluid%20quality	Sept 2, 2017	Dialysis water quality OR dialysis fluid quality	Around 55	0 (not meeting the definition of a guideline as specified in the inclusion criteria)
16.	British Columbia Renal Agency	http://www.bcrenalagency.ca/bc-renal-agency-search-results?k=dialysis%20water#314d98da-5fab-4a8d-a6de-86e86bbee20e=%7B%22k%22%3A%22dialysis%20water%22%7D#k=NXstage	Jan 22, 2020	Nxstage	First 25	0 (not meeting the definition of a guideline as specified in the inclusion criteria)
17.	Manitoba Renal Program	http://www.kidneyhealth.ca/wp/healthcare-professionals/resources/mrp-policy-and-procedure-manual/	Sept 2, 2017		Around 157	0 (not meeting the definition of a guideline as specified in the inclusion criteria)
18.	Ontario Renal Network	http://www.renalnetwork.on.ca/search/default.aspx?q=dialysis+water+quality+guidelines&sortby=Relevance&type=-1,256223-78|0,97964-40484&pg=0#.WayZRbpFzIU	Sept 2, 2017	dialysis water quality guidelines	388	0 (guidance on topics of water quality management not related to this review (such as province wide surveillance system))
19.	Nova Scotia Renal Program	http://www.cdha.nshealth.ca/search/apachesolr_search/dialysis%20water%20%20quality	Oct 29, 2017	Dialysis water quality	About 30	0

Sr. No.	Source	Link	Search Date	Search Terms	Hits	Selected (reasons for exclusion)
20.	Canadian Society of Nephrology	csnscn.ca	https://www.csnscn.ca/component/search/?searchword=dialysis%20water%20quality&ordering=newest&searchphrase=all&limit=20	dialysis water quality	0	0
21.	The kidney foundation of Canada	https://www.kidney.ca/page.aspx?pid=195&txtSearch=home+hemodialysis	August 2017	home hemodialysis	650	0 (not at all relevant to DW and dialysate quality)
22.	Canadian Association of Nephrology Nurses and Technologists	http://www.cannt.ca/en/misc/search.html	August 2017	Dialysis water guidelines	128	0 (Standards adopting another organizations) Individual research studies (quantitative or qualitative) for clinical outcomes, continuous quality improvement, and home hemodialysis programs. Best practice guidelines for decision-making on clinical outcomes, guidelines related to dialysis procedure)
23.	Health Canada	http://www.hc-sc.gc.ca	Oct 29, 2017	Dialysis water quality	Same results as obtained with the website of Public Health agency of Canada	0 (obsolete standards on DW and dialysate quality, drinking water standards, recreational water standards, standards related to HD prescription, and technical specifications for HD machines)
24.	Alberta Health Services	http://www.albertahealthservices.ca/Search.aspx?client=ahs-external&site=ahs-external&getfields=keywords:description&entqr=0&output=xml_no_dtd&filter=0&q=dialysis water&sort=date:D:L:d1&start=0	Oct 29, 2017	Dialysis water	111	0 (emergency preparedness for acute care settings, status on number of patients on HHD, educational material on management of nutrition, and other comorbid conditions such as BP, diabetes, , news related to expansion of HD or HHD services, Not related to dialysis water or dialysate quality, patients/volunteer experiences, information on renal units services, related to collection of

Sr. No.	Source	Link	Search Date	Search Terms	Hits	Selected (reasons for exclusion)
						sample for blood, drinking water or recreational water issues, news about home hemodialysis improved patient satisfaction and quality of life, dialysis waste disposal)
Australia						
25.	Standards Australia	http://www.standards.org.au/search/Results.aspx?k=dialysis%20water	Oct 30, 2017	dialysis water	5	0 (adopted documents from ISO (n=4)), not related to dialysis, safety standards for HD machines)
26.	Australian Government Department of Health	https://search.tga.gov.au/s/search.html?collection=tga-websites-web&query=dialysis+and+quality+and+water	Nov 17, 2017	Dialysis and quality and water	335	0 (risk management analysis for therapeutic drugs for dialysis, analysis of drugs for regulatory purpose, microbial analysis of drugs)
27.	Australian government department of health	http://search.health.gov.au/s/search.html?collection=health&profile=health&query=dialysis+water+quality+guideline+	Nov 17, 2017	dialysis water quality guideline	907 (only first 200 results scanned)	0 (drinking water quality guidelines, infection prevention at healthcare facilities, not related to dialysis water or dialysate quality)
28.	Kidney Health Australia	http://kidney.org.au/search?query=dialysis%20water%20quality	Oct 30, 2017	Dialysis water quality	49	0 (costing of water, recycling of water, not provided enough details to extract info on water quality criteria, patient experiences, economic evaluation of dialysis procedure, educational material on treatment options, fact sheet on hhd benefits, identification of research priorities mostly for clinical outcomes)
29.	Caring for Australians with Renal Impairment (CARI)	cari.org.au http://www.cari.org.au/archived_guidelines.html	July 11, 2017	Note: Looked at Archived Guidelines		0 (obsolete standards)
30.	Government of South Australia	http://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/Search/Search+Results?query=dialysis+water+testing&s=1	July 11, 2017	dialysis water testing	104	0 (in-center or satellite dialysis units, drinking water guidelines, nothing related to DW or dialysate quality, electricity reimbursement information, range of services by health centers, training manual for infection prevention, patient referral guidelines, not

Sr. No.	Source	Link	Search Date	Search Terms	Hits	Selected (reasons for exclusion)
						related to dialysis, infection not from contaminated DW)
31.	Australia and New Zealand Horizon Scanning	http://search.health.gov.au/s/search.html?collection=health&profile=horizonscanning&query=dialysis+	Nov. 20, 2017	Dialysis	25	0(Technology assessment of dialysis machines, not including water quality, technology assessment for emerging technologies related to kidney transplant)
32.	New South Wales Agency for Clinical Innovation (ACI)	https://www.aci.health.nsw.gov.au/ https://www.aci.health.nsw.gov.au/search?page=0&q=dialysis	July 7, 2017	Dialysis	34	1(132) (evaluation of HHD model of care, evaluation of renal care pathways, evaluation for barriers to utilization of HHD(but does not include water management))
33.	Australian Clinical Practice Guidelines	https://www.clinicalguidelines.gov.au/ https://www.clinicalguidelines.gov.au/advanced_search?field_computed_ngp_filter_value=dialysis+&field_nhmrc_approved_value=All&field_sys_lit_review_value=All&field_publication_date_value%5Bmin%5D%5Byear%5D=&field_publication_date_value%5Bmax%5D%5Byear%5D=&field_ngp_pop_sub_groups_value=All&field_ngp_guideline_status_value=All	November 23, 2017	Dialysis	1	0(Dialysis adequacy)
NewZealand						
34.	Kidney Health New Zealand (KHNZ)	https://www.kidneys.co.nz/search.php	Nov. 23, 2017	Dialysis	70	0(guideline not related to dialysis, educational material for nutrition, and information webpages for management of clinical outcomes, renal statistics).
35.	Standards NewZealand	https://shop.standards.govt.nz/search/ed?q=dialysis&fq=&sort=&start=0	Nov. 23, 2017 & Revised 8th August 2019	Dialysis	35	0 (adopted documents from ISO(n=4))

Sr. No.	Source	Link	Search Date	Search Terms	Hits	Selected (reasons for exclusion)
36.	Google search Keyword: standards newzealand and dialysis water and committee	https://www.google.ca/search?q=standards+newzealand+and+dialysis+water+and+committee&ei=f_pDX5K9Hcb_-gSczpLgAg&start=40&sa=N&ved=2ahUKEwjS-K6osLTrAhXGv54KHRynBCw4HhDy0wN6BAgMEDY&biw=1920&bih=926	Aug 24, 2008		First 30	0
European Union (EU) and EU member countries						
37.	Google	https://www.google.ca/search?q=european+pharmacopoeia+and+dialysis+water&ei=CB5EX9m-EtGc-gSU4LLoAw&start=30&sa=N&ved=2ahUKEwjZ4oia0rTrAhVRjp4KHRSwDD04FBDy0wN6BAgLEDQ&biw=1920&bih=926	August 24, 2020	European pharmacopoeia and dialysis water	First 30	0
38.	Scottish Renal registry	https://www.srr.scot.nhs.uk/	August 24, 2020	Screened entire website	First 30	0 (none related to DW, report on compliance of home programs with required DW and dialysate quality)
39.	Google	https://www.google.ca/search?q=scottish+renal+registry+and+dialysis+water&ei=UUNEX821BMHn-wSjx6KYCw&start=0&sa=N&ved=2ahUKEwiNoq_h9bTrAhXB854KHaOjCLM4FBDy0wN6BAgMEC8&biw=1920&bih=926	August 24, 2020	scottish renal registry and dialysis water		
40.	European Committee for Standardization (CEN)	https://www.cen.eu/news/brief-news/Pages/News-2019-016.aspx	April 18, 2019	Dialysis	13	0 (adopted documents from ISO (n=4))

Sr. No.	Source	Link	Search Date	Search Terms	Hits	Selected (reasons for exclusion)
		https://standards.cen.eu/dyn/www/f?p=204:105:0:::::				
41.	Svensk Lakemedelsstandard SLS 2007 (Sweden)	https://www.google.ca/search?q=svensk+L%C3%A4kemedelsstandard&ei=kHIJXfTpO5qBk-4P7-msyAU&start=0&sa=N&ved=0ahUKEwj08ZLDlvTiAhWawMQHHe80C1k4ChDy0wMIfw&biw=1920&bih=929	July 25, 2019	svensk Läkemedelsstandard	First 30 hits	0 (adopted documents from ISO (n=4))
42.	The Renal Association (UK)	http://www.renal.org http://www.renal.org/search-results/page/2?indexCatalogue=global&searchQuery=quality+and+dialysis+water+and+dialysis+fluid+and+guideline&wordsMode=0#sthash.2ydl0Deg.dpbs	August 15, 2017.	quality and dialysis water and dialysis fluid and guideline	43	3(129,137,142) (obsolete guidelines and DW and dialysate quality guidelines not for HHD).
43.	Spanish Society of Nephrology	http://www.revistanefrologia.com/en-buscar?txtBuscador=dialysis+water+guideline&buscar_en=AND&cmbRevista=20132514&txtVolumen=&txtPagIni=&cmbResultados=20&cmbOrden=itemFecha&txtDesde=&txtHasta=&txtPalabras=&txtTitulo=&txtContenido=&txtAutores=&apartado=0	Oct 30, 2017	dialysis water guideline	51	1(135) (clinical practice guidelines on topics other than DW and dialysate quality)
44.	German Society of Nephrology	https://www-dgfn-eu.translate.goog/dialyse-standard.html?_x_tr_sl=de&_x_tr_tl=en&_x_tr_hl=en&_x_tr_pto=nui,sc				2(115,157)

Sr. No.	Source	Link	Search Date	Search Terms	Hits	Selected (reasons for exclusion)
45.	Working Group for Applied Hygiene in Dialysis Units					Guideline obtained in hard copy.
46.	Google	https://www.google.ca/search?q=dialysis+and+water+and+quality+and+germany&dcr=0&ei=GZ0YWqaXJITsjwOhhpuIAw&start=10&sa=N&biw=1920&bih=971	November 24, 2017	dialysis and water and quality and germany	First 100 selected	0
47.	Google	https://www.google.ca/search?q=dialysis+and+germany&ei=CMoYWpHPGdKSjwOSzKL4AQ&start=0&sa=N&biw=1920&bih=971	November 24, 2017	Dialysis and Germany	First 19 selected	0
48.	Italian Society of Nephrology	http://sinitaly.org/	Nov. 27, 2017	-	-	Website not in English
49.	Dutch Federation of Nephrology (DfN)	http://www.nefro.nl https://www-nefro-nl.translate.goog/richtlijnen/waterbehandeling-voor-hd-en-online-hdf-2020?_x_tr_sl=nl&_x_tr_tl=en&_x_tr_hl=en&_x_tr_pto=nui,sc	Nov. 27, 2017			2(133,158)
50.	Google	https://www.google.ca/search?ei=fUsJXabQFqeD0wK83Ij4Aw&q=The+Italian+Society+of+Nephrology+%28ISN%29+and+guideline+and+dialysis+&oq=The+Italian+Society+of+Nephrology+%28ISN%29+and+guideline+and+dialysis+&gs_l=psy-	-	The Italian Society of Nephrology (ISN) and guideline and dialysis	First 10 selected	2(130,138)

Sr. No.	Source	Link	Search Date	Search Terms	Hits	Selected (reasons for exclusion)
		ab.3...10464.14392..14700...0.0..0.140.2526.22j6.....0....1..gws-wiz.....0i71j33i160j33i21j33i10.1EsoeKaACbM				
51.	The Health Council of The Netherlands	https://www.gezondheidsraad.nl/en/search/dialysis%20water	Sept 6, 2017	Dialysis water	20	0 (none related to DW or dialysate quality, related to kidney transplant wait times, albumin dialysis, water quality for recreational waters)
52.	*Swedish Agency for Health Technology Assessment and Assessment of Social Services*	http://www.sbu.se/en/search/?q=dialysis	Nov 24, 2017	dialysis	1	0 (not related to renal failure patients)
53.	Japanese Society of Dialysis Therapy	http://www.jsdt.or.jp/guideline.html	Sept 5, 2017		13	0 (not related to home hemodialysis)
54.	Norway Standards	https://www.google.ca/search?ei=bfwxXu_CGvXK0PEP142B8Ao&q=Norway+Standards+&oq=Norway+Standards+&gs_l=psy-ab.3..0i22i30l10.73010.77631..78132...2.2..0.97.1367.19.....0....1..gws-wiz.....0i71j0i273j0i131j0i67j0i131i67j0j0i10.U4_Z-mzu4uQ&ved=0ahUKEwivrfPP46nnAhV1JTQIHddGAK4Q4dUDCAo&uact=5	Jan 29, 2020	Water hemodialysis https://www.standard.no/en/webshop/search/?search=water+hemodialysis		0 (adopted documents from ISO (n=4))

Appendix 3: Microbial Monitoring of DW and Dialysate: Sample collection, Storage, and Testing Methods

Organization	Things to consider before sample collection	Sample collection technique	Sample analysis, storage and transportation conditions	Sample volume	Testing technique	Testing Conditions	Biofilm (Y/N)	Nature of Recommendation	Not permitted	Testing Location	Rationale	Comments (sampling issues, transportation)
ISO*	Sample collected when: a) no disinfectant residual is present b) before disinfection	Sample containers: sterile and endotoxin free. DW: Sample ports cleaned either using sterile gauze or cotton swab. Drain DW for 60s before sample collection. Dialysate: Dialysate sample port disinfected with alcohol. First sample discarded, of at least 10 ml taken using sterile syringe. Second sample taken again using a new sterile syringe.	• Analysis of samples in <4hrs after they have been collected. • If not possible, then samples stored at <10 °C until their analysis. No freezing allowed. • The storage of samples for >24hrs after their collection should be avoided.	Standard: • Ranged from5 ml to 1000 ml. • It depends upon the testing technique and colony counts. Ultrapure: • 10 ml to 1000 ml	Standard: • MF (preferred) • PP • SP Ultrapure • MF	Media: • R2A • TGEA • TSA (only for standard) Incubating conditions: • Incubation at 17 to 23 for 7 days (TGEA and R2A) • Incubation at 35 to 37 for 48 hours (TSA) Counting of colonies: • Not mentioned (NM)	NM	• Mandatory. Note: Use of other testing methods are allowed only if they have been validated by showing their results are comparable to those obtained using the recommended methods.	•Bleach or other disinfectant solutions for port cleaning •Blood and chocolate agars (PP) •Dip samplers technique (DS)	NM	• Referenced several studies that showed incubation media with poor nutrient, longer incubation time and lower incubation temperature facilitates better recovery for most environmental bacteria found in purified water to support their recommendations. TSA media mainly recommended for its advantage of recovery of bacteria lesser time (48 hrs). Evidence not graded.	• Provides criteria for the selection of testing methods. • Sample contamination at the time of sample collection and sample storage has been recognized as major issue for false positive results. • Nothing mentioned about who is involved in sample transportation, and preferable days for sample collection.
CSA (CSA/ISO 23500)*	Sample collected when: a) no disinfectant residual is present b) before disinfection	Sample containers: sterile and endotoxin free. DW: Sample ports cleaned either using sterile gauze or cotton swab. Drain DW for 60s before sample collection.	• Analysis of samples in <4hrs after they have been collected. • If not possible, then samples stored at <10 °C until their analysis. No freezing allowed. • The storage of samples for >24hrs after their	Standard: • Ranged from5 ml to 1000 ml. • It depends upon the testing technique and colony counts. Ultrapure: • 10 ml to 1000 ml	Standard: • MF (preferred) • PP • SP Ultrapure • MF	Media: • R2A • TGEA • TSA (only for standard) Incubating conditions: • Incubation at 17 to 23 for 7 days	NM	• Mandatory. Note: Use of other testing methods are allowed only if they have been validated by showing their results are comparable to those obtained using the	•Bleach or other disinfectant solutions for port cleaning •Blood and chocolate agars (PP) •Dip samplers technique (DS)	NM	• Referenced several studies that showed incubation media with poor nutrient, longer incubation time and lower incubation temperature facilitates better	• Provides criteria for the selection of testing methods. • Sample contamination at the time of

Appendix 3: Microbial Monitoring of DW and Dialysate: Sample collection, Storage, and Testing Methods

Organization	Things to consider before sample collection	Sample collection technique	Sample analysis, storage and transportation conditions	Sample volume	Testing technique	Testing Conditions	Biofilm (Y/N)	Nature of Recommendation	Not permitted	Testing Location	Rationale	Comments (sampling issues, transportation)
		Dialysate: Dialysate sample port disinfected with alcohol. First sample discarded of least 10 ml using sterile syringe. Second sample taken again using new sterile syringe.	collection should be avoided.			(TGEA and R2A) • Incubation at 35 to 37 for 48 hours (TSA) Counting of colonies: • Not mentioned (NM)		recommended methods.			recovery for most environmental bacteria found in purified water to support their recommendations. TSA media mainly recommended for its advantage of recovery of bacteria lesser time (48 hrs). Evidence not graded.	sample collection and sample storage has been recognized as major issue for false positive results. • Nothing mentioned about who is involved in sample transportation, and preferable days for sample collection.
Spain*	• Samples to be collected before start of a dialysis session. • Two people should be involved in sample collection. • Use of sterile gloves recommended for minimizing cross-contamination.	Sample containers: sterile and endotoxin free. DW: Only alcohol as disinfectant is permitted for cleaning the sampling port, and not others such as hypochlorite, pera-acetic acid or acetic acid. Prior to sampling, the disinfectant should be allowed to be evaporated and DW drained out for 1 min.	• The containers containing the sample should be kept on ice or refrigerated at 4 °C (between 3 °C and 6 °C) until processing for culture. • The storage of samples for >24hrs after their collection should be avoided.	Standard: • NM Ultrapure: • 100ml– 1000 ml	Standard: • MF (preferred) • SP Ultrapure • MF	Standard: Testing Media: • R2A (MF, SP) Incubating conditions: • Inoculation volume of 100 – 1000ml for MF and 1 ml for SP. • Incubation temperature between 20 and 25 degrees C for 7 days (MF).	• NM	• Mandatory	• Blood and chocolate agars (MF) • Calibrated loop technique (SP).	• NM	The proposed assay methods are based on Spanish Royal Pharmacopoeia R2A, which is nutrient poor media, has been recommended for its superiority in detecting microorganisms in water in comparison to other culture media TSA, TGEA, etc. which are richer media. This	• Shorter days for incubation permitted if it is validated to show that results are similar to those obtained using recommended incubation period.

Appendix 3: Microbial Monitoring of DW and Dialysate: Sample collection, Storage, and Testing Methods												
Organization	**Things to consider before sample collection**	**Sample collection technique**	**Sample analysis, storage and transportation conditions**	**Sample volume**	**Testing technique**	**Testing Conditions**	**Biofilm (Y/N)**	**Nature of Recommendation**	**Not permitted**	**Testing Location**	**Rationale**	**Comments (sampling issues, transportation)**
		Dialysate: Dialysate sampled using either a syringe or a container. Sample containers to be properly labelled for ease in identifying the type of sample.				• Incubation temperature between 23 and 27 degrees for 7 days (SP) Ultrapure: • R2A (MF) Incubating conditions: • Incubation temperature between 20 – 25 degrees C for 7 days. Inoculation volume: 100 – 1000 ml (MF). Colonies counting: • Magnifying glass along with a tally counter or a punch while counting the colonies. If the mass dilution method is used, they can be marked with a marker pen on the underside of the plate.					recommendation is based on studies comparing recovery of bacteria between three media R2A, TGEA and TSA when culturing conditions remained same for all of them. Evidence cited is not graded. The other reason mentioned is to unify with international standards (ISO 13959: 2014 and ISO 11663: 2014), so that comparison of contamination levels could be done legitimately at international level. This is because, the culturing of colonies depend on the volume of water inoculated, the composition of the culture medium,	

Appendix 3: Microbial Monitoring of DW and Dialysate: Sample collection, Storage, and Testing Methods

Organization	Things to consider before sample collection	Sample collection technique	Sample analysis, storage and transportation conditions	Sample volume	Testing technique	Testing Conditions	Biofilm (Y/N)	Nature of Recommendation	Not permitted	Testing Location	Rationale	Comments (sampling issues, transportation)
											temperature and incubation time.	
New South Wales, Australia (NSW)!	• NM	• NM	• Samples shall be assayed within 30 minutes of collection • If not, the collected samples have to be stored at a temperature between 1–5 °C until they have been analysed. • The collected samples should not be stored for >24hrs.	• NM	• DS • MF (preferred) • SP • PP	Testing Media: • R2A • TSA (preferred) Incubating conditions: • Inoculation volume of 500–1000 mL. Incubating at 28–32 °C for 5 days or longer (R2A). • Inoculation volume: NM; Incubation temp at 35–37 °C. Colonies counted at 48 hours and then recounted after another 48 hrs. (TSA) Counting of Colonies: • NM	• NM	• Mandatory	• Blood and chocolate agars (MF) • Calibrated loop technique (SP).	• NM	• NM	• NM
Working Group for Applied Hygiene in Dialysis Units (2009)!	• NM	• Aseptic conditions maintained during sample collection. • Internal protocols required on steps to be followed	• Samples after they have been collected should be stored at 4 °C until they have been analyzed. • The collected samples should not be stored for >24hrs.	• NM	• SP • PP	Testing Media: • R2A • TGEA Incubating conditions: • Inoculation volume: NM; incubation	• NM	• NM	• NM	•Laboratory	• NM	• NM

Appendix 3: Microbial Monitoring of DW and Dialysate: Sample collection, Storage, and Testing Methods

Organization	Things to consider before sample collection	Sample collection technique	Sample analysis, storage and transportation conditions	Sample volume	Testing technique	Testing Conditions	Biofilm (Y/N)	Nature of Recommendation	Not permitted	Testing Location	Rationale	Comments (sampling issues, transportation)
		during sample collections.				temperature of 20 – 24 °C for 7 days. Colonies counted at 3rd day and then again counted on 7th day. (R2A, TGEA)						
Sweden (2019)+	• NM	• NM	• Sample container: appropriate for the type of test conducted. • Samples refrigerated until they have been analyzed.	• NM	• MF	Testing Media: • R2A • TSA Incubating conditions: • Innoculation volume: 100ml; Incubated temperature at 20-25 degrees for 5- 7 days. (R2A) • Inoculation volume: 100ml; Incubated temperature at 30-35 degrees for 3 days. (TSA) Counting of Colonies: • NM	• NM	• Mandatory Note: Other cultivation and bacterial counting methods are allowed only if they have been shown to be equivalent to the methods that have been recommended. Other media used should be nutrient-poor and salt-free.	• NM	•In-house (by trained experts such as hygienist) or at labs.	• NM	• NM
The Renal Association and	• Sampling done prior to disinfection of	Sample containers: sterile and endotoxin free.	• No specific recommendations	• NM	Standard: • MF Ultrapure:	Testing Media • R2A • TGEA	• NM	• Mandatory	• Bleach or other disinfectants for port cleaning	•NM	Guideline has referenced several studies, which showed	• Sample contamination at the time of

Appendix 3: Microbial Monitoring of DW and Dialysate: Sample collection, Storage, and Testing Methods

Organization	Things to consider before sample collection	Sample collection technique	Sample analysis, storage and transportation conditions	Sample volume	Testing technique	Testing Conditions	Biofilm (Y/N)	Nature of Recommendation	Not permitted	Testing Location	Rationale	Comments (sampling issues, transportation)
The Association of Renal Technologists (2016)*	system and HD machines	DW: Ports being cleaned either using sterile gauze or cotton swab. Drain DW for 60s. Dialysate: Dialysate sample port disinfected with alcohol. First sample discarded of least 10 ml using sterile syringe. Second sample taken again using new sterile syringe.			• MF	Incubating conditions: • Inoculation volume: NM; Incubated at temperature of 17-23ºC for at least 7 days. (MF) Ultrapure: • Inoculation volume: 100ml; Incubated at temperature of 17-23ºC for at least 7 days. (MF)			• Blood and chocolate agars (PP) • DS		that incubation media with poor nutrient, longer incubation time and lower incubation temperature facilitates better recovery for most environmental bacteria found in purified water to support their recommendations. Majority of the recommendations are based on the recommendations by EDTNA/ERCA and ISO.	sample collection and sample storage has been recognized as major issue for false positive results.
British Association for Paediatric Nephrology (2008)*	Sampling done prior to disinfection of system and HD machines	same as EBPG and EDTNA/ERCA	same as EBPG and EDTNA/ERCA	same as EBPG and EDTNA/ERCA	same as EBPG and EDTNA/ERCA	same as EBPG and EDTNA/ERCA	same as EBPG and EDTNA/ERCA	same as EBPG and EDTNA/ERCA	same as EBPG and EDTNA/ERCA	same as EBPG and EDTNA/ERCA	Guideline has referenced several studies which showed that incubation media with poor nutrient, longer incubation time and lower incubation temperature facilitates better recovery for most environmental bacteria found in purified water to support their recommendations. Majority of	same as EBPG and EDTNA/ERCA

Appendix 3: Microbial Monitoring of DW and Dialysate: Sample collection, Storage, and Testing Methods

Organization	Things to consider before sample collection	Sample collection technique	Sample analysis, storage and transportation conditions	Sample volume	Testing technique	Testing Conditions	Biofilm (Y/N)	Nature of Recommendation	Not permitted	Testing Location	Rationale	Comments (sampling issues, transportation)
											the recommendations are based on ERA-EDTA and EDTNA/ERCA.	
Dutch Federation for Nephrology, NfN water committee (2016)+	• NM	• NM	• Samples have to be analyzed immediately for culture after they have been collected. • If not then, samples have to be refrigerated until they have been analyzed. • The collected samples should not be stored for >24hrs.	• NM	• MF • SP	Media: • R2A • TGEA Incubating conditions: • Inoculation volume of 100ml for colonies expected is < 5 CFU per ml. With smaller number of colonies, higher volume is required. The incubation temperature at 17-23 ºC for 5-7 days. Colonies counted after 2-3 days and then again at 7th day. (R2A) • Inoculation volume depends on the numbers of colonies expected. If between 5 - 5000 CFU/ml expected,	• NM	• Mandatory Note: Alternative analysis methods could be use given that they have been validated against methods recommended by Eu. Ph.	• NM	• Laboratory	• Based on Eu. Ph.	• Suggested three options for sample collection and transportation: a) if patients are allowed to take samples (e.g. in a cooling bag) they should bring it along with them at the time of their medical check up, b) healthcare professionals take samples during their visit to patient homes (such as supply of dialysis materials), or c) to have the samples transported and processed by an external organization

Appendix 3: Microbial Monitoring of DW and Dialysate: Sample collection, Storage, and Testing Methods

Organization	Things to consider before sample collection	Sample collection technique	Sample analysis, storage and transportation conditions	Sample volume	Testing technique	Testing Conditions	Biofilm (Y/N)	Nature of Recommendation	Not permitted	Testing Location	Rationale	Comments (sampling issues, transportation)
						then 0.2 ml. With smaller number of colonies, higher volume is required. The incubation temperature at at 17-23 ºC for 5-7 days. Colonies counted after 2-3 days and then again at 7th day. (TGEA) Counting of Colonies: • NM						• Sample contamination at the time of sample collection (from skin bacteria) recognized as major issue for false positive results.
EDTNA-ERCA *	• NM	DW: First, the sampling port cleaned using flame sterilization or disinfectant. 70% ethanol or 80-90% isopropyl alcohol and allowing the alcohol to evaporate). Drain out 2 litres of DW from the sampling port before sampling. DIALYSATE: Sampling technique depends on the sample port available at a particular HD machine. Preferred is	• Samples analyzed immediately after they have been collected. • If not then, store samples at temperature below 10 degrees Celsius, but not frozen. • When testing has to be delayed for more than 6 hours, the storage conditions should be validated.	• NM	Standard: • MF (preferred) • SP • PP Ultrapure: • MF	Testing Media • R2A (MF) • TGEA (MF and PP) Incubating conditions: • Inoculation volume depends on expected colonies count. Incubation temperature and days are not mentioned. (R2A)	• NM	• Mandatory	• The general technique for "microbiological examination of non-sterile product" described in EU Ph. is not appropriate for DW.	•In-house (provided procedure validated by an accredited Lab) or Laboratory	• Comparisons of different test methods indicate that the recovery of bacteria from water used for dialysis is highest when a low nutrient agar, a longer incubation time and a low temperature is used. (Evidence cited , but not graded).	• Recognizes the issue of sample contamination if storage conditions have not been met as required.

Appendix 3: Microbial Monitoring of DW and Dialysate: Sample collection, Storage, and Testing Methods

Organization	Things to consider before sample collection	Sample collection technique	Sample analysis, storage and transportation conditions	Sample volume	Testing technique	Testing Conditions	Biofilm (Y/N)	Nature of Recommendation	Not permitted	Testing Location	Rationale	Comments (sampling issues, transportation)
		collecting samples using syringe from septum port in the line between the machine and the dialyser.				• Inocculation volume of 1 – 5ml. Incubation temperature and days are not mentioned. (TGEA) Ultrapure: • Inoculation volume of 100ml. Incubation temperature and days are not mentioned (MF) Counting of Colonies: • Manually						

Abbreviations: DW: Dialysis water; MF= membrane filtration technique; PCA=plate count agar; PP=pour plate technique; R2A= Reasoner's 2A medium; SMA= standard methods Agar; SP= spread plate technique; TGEA= tryptone glucose extract agar; TSA= trypticase (tryptic) soy agar; DS= dip samplers technique; NM= Not mentioned; * = sample type includes standard dialysis water, standard dialysate and ultrapure grade; ! = standard DW; + = standard dialysis water and standard dialysate

Appendix 4: Invitation Letter

We are writing to invite you to participate in the research study which we hope will generate information that will be use to home hemodialysis centers across Canada. “Management of dialysis water and dialysate quality at home hemodialysis programs (HHD) in Alberta” is the project that is being conducted by Ms. Sejal Dave, an Msc student in health policy research at our School of Public Health. Drs. Robert Pauley (Nephrology) and Medical Director of the Northern Alberta home hemodialysis program, Dev Menon and Tania Stafinski (Public Health), are supervising Sejal’s research program.

One objective of Sejal’s research is to understand the existing challenges in implementation and monitoring of standards for dialysis water and dialysate quality across Canadian home hemodialysis centers. In particular, this study will look into what is regarded as acceptable quality for dialysis water and dialysate quality, understand approaches to and challenges with adherence to standards, and existing decision-making processes with regards to testing.

Clearly, in order to be successful in this study, we would need the participation of health professionals involved in the management of dialysis water and dialysate quality. Therefore we are planning to interview key personnel of home hemodialysis centers, and would therefore welcome your participation. We expect that the interview will take approximately 45 minutes, and will be conducted via telephone. It is also expected that in addition to yourself, there may be staff of your center who would have information pertinent to this study; therefore, we would be grateful if you could let us know how they may be contacted.

We will provide you and other interviewees with preliminary analyses of the interviews for validation and feedback, before final reports and manuscripts are prepared and distributed.

We hope that you are able to participate in this study. Our intentions are not just to have the results published in the peer-reviewed literature, but communicated to policy-makers as well.

Sincerely ,

Dr. Robert Pauly Dr. Devidas Menon

Appendix 5: Information Letter and Consent Form

Study Title: Management of Dialysis Water and Dialysate Quality for Home Hemodialysis Programs in Alberta

Research Investigator

Sejal Dave

MSc. Health Policy Research

School of Public Health, University of Alberta

3021 Research Transition Facility

8308 – 114 Street

Edmonton, AB, T6G 2V2

Phone: (780) 710-1706

Email: sejal@ualberta.ca

Supervisor

Dr. Devidas Menon

Health Technology & Policy Unit

School of Public Health, University of Alberta

3021 Research Transition Facility

8308 – 114 Street

Edmonton, AB, T6G 2V2

Phone: (780) 492-9020

Email: menon@ualberta.ca

Supervisory Committee

Dr. Robert Pauly

Medical Director & Associate Professor of Medicine,

Home Hemodialysis Program,

Northern Alberta Renal Program

University of Alberta

11-107 Clinical Sciences Building

8440 112th Street

Edmonton, AB, T6G 2G3

Phone: (780) 407 – 3218

Email: rpauly@ualberta.ca

Dr. Tania Stafinski

Director

Health Technology & Policy Unit

School of Public Health, University of Alberta

3021 Research Transition Facility

8308 – 114 Street

Edmonton, AB, T6G 2V2

Phone: (780) 492-4791

Email:tstafinski@ualberta.ca

Dear Participant,

You are being invited to take part in one of the study for the research project, "*Management of Dialysis Water and Dialysate Quality for Home Hemodialysis Programs in Alberta"*. We would request you to carefully read and understand this informed consent form that provides information on the research study background, purpose, procedure, benefits, risks, and confidentiality. This form also declares that the participation is voluntary and you may wish to declare withdrawal anytime during the interview. Please go through this entire form to make an informed decision regarding participation. If you may require any further clarification for any part of this form, then please do not hesitate to contact either researcher, supervisor or supervisory committee. By signing this consent form, you declare your wish to participate in this study and are satisfied with the provided information.

Background

Dialysis patients are at the risk of adverse events associated with the poor quality of dialysis water and dialysate quality. The quality of water is susceptible to fluctuations and its maintenance is a complex process that involves treatment system, disinfection, testing, and quality management. Moreover, ensuring the quality of dialysis water and dialysate at home hemodialysis programs (HHD) is particularly challenging. HHD is meant for more intensive regimes, such programs need to manage more than one source of water and treatment system, and patients need to manage the process themselves on routine basis. So, it is important to understand how water-related problems may affect the HHD programs and the specific areas of challenges in the entire process of the quality management as experienced by health professionals.

Purpose

The purpose of this research study is to understand the existing barriers/challenges in implementation and monitoring of standards for dialysis water (DW) and dialysate quality as experienced by health professionals across Canadian HHD programs. In particular, this study will look into what is regarded as an acceptable quality for DW and dialysate, understand approaches to and challenges with adherence to standards, and existing decision-making processes with regards to testing. The results of this research study will be used towards fulfillment of requirements for the masters' thesis program.

Clearly, in order to be successful in this study, we would need your participation as you have rich insight on the process involved for the management of DW and dialysate quality and related problems at your HHD program.

Study Procedures

We would like to interview health professionals including nurses, technologists, clinical managers, nephrologists, medical directors and others involved in the management of DW and dialysate quality at HHD programs. The researcher, *Sejal Dave,* will conduct one-on-one interviews, and the duration of interview will last approximately 45-60 minutes. Depending upon the availability of time, interviews will be arranged either in-person or from distance at participants' preferred time and location. In the case of distance interviews, the participants will be requested to get connected via phone, "Skype" or "Adobe Connect Meetings". Before each interview, the researcher will explain the study purpose and overview of interview discussion,

and will provide this consent form. After you are satisfied with the provided information, you will be asked to sign the consent form and then the interview process will start. Interviews will use a semi-structured interview guide and will particularly focus on questions related to the DW and dialysate quality management policies and procedure, and the identification of challenges as perceived by health professionals. The whole session will use a root-cause analysis technique to identify barriers, facilitators and needs as experienced by you in your field of expertise of quality management. The interviews (in-person or distance) will be audio-recorded to ensure the accuracy of data collected and will be transcribed verbatim using Microsoft Word. Interviews conducted using "Skype" or "Adobe Connect Meetings" will be recorded using the available features within the respective software. Depending on your willingness, the transcript will be made available to you for content verification. Transcripts will be stored in the password protected computer at Health Technology and Policy Unit, School of Public Health (SPH), University of Alberta (UofA), and will be accessible only to the researcher, supervisor, and supervisory committee of this project. The transcript will be analyzed based on thematic and content analysis technique of qualitative research by the researcher, *Sejal Dave*, and we hope to identify common themes of barriers, facilitators, and needs in the quality management of dialysis water and dialysate. The analyzed results will be made available to you by email as part of validation of findings.

Benefits

There are no direct benefits involved with the participation, but we anticipate that the information you provide will help us to generate the list of challenges/barriers involved in the management of DW and dialysate quality at HHD programs in Canada. We hope that this

information will be useful to policy-makers on prioritizing the areas of quality improvement and building suitable recommendations. We are grateful for your precious time and helping us to explore this important area of research.

Risk

There are no known risks involved with the participation in this project. All the steps will be taken to protect the confidential information that is shared during the discussion. Your identity will not be declared in any report developed based on the information collected. The results will be discussed at the provincial level and will use direct quotes from the transcripts. However, the names of the provinces will be anonymized (such as "province-1") and the direct quotes will be described using codes instead of disclosing your names such as "participant-1", "Nurse-1" or "HHD-1". Only researchers, supervisor, and supervisory committee involved in this project will know about this coding. You can deny to answer any question that you may feel uncomfortable or you may think that something confidential is involved at the time of interview.

Voluntary Participation

The participation in this research study is completely voluntary. You may choose to opt out at any time during the entire interview process and can request to withdraw the data within 2 months of review of transcript and draft final report. If you are not willing to review the transcript or draft final report, then you can withdraw data within 3 months after the interview. In such case, please contact the researcher using the contact information provided on page-1 of this form. You are not obliged to answer any questions that you may feel is confidential or could affect your organization's policies.

Confidentiality & Anonymity

The results of this study will be used towards fulfilling the thesis requirement of masters' research program. As part of knowledge translation, the results may be presented at relevant conferences or published in academic journals. The qualitative research analysis will use direct quotes from the transcript, but will not use your names. The analysis and compilation will be done using the number format ("participant-1", "nurse-1", or "HHD-1") and any results discussed at the provincial level will be anonymized using codes such as "province-1". The audio recorded data from the interview or any other information collected, such as photographic images (of charts) and hard copies of charts, field notes or transcripts, during this research study will be stored at secured location (using locked cabinets) at Health Technology & Policy Unit, SPH, UofA. The recordings of interviews conducted using "Skype" or "Adobe Connect Meetings" and computer files related to research data collection (such as transcripts and charts) will be stored on password protected computer at Health Technology & Policy Unit, SPH, UofA. Before any related publication or thesis presentation, you will be provided with a transcript as well as final results for reviewing direct quotes and originality of the content by emails, and you can ask to either modify or remove any portion that you may feel that has not conveyed your message appropriately within 2 months. All the relevant paper data, recorded audio-tape and computer files will be stored with necessary protection for 5 years following completion of research project at Health Technology and Policy Unit, SPH, UofA.

If we plan to use the data from this study for any future research purpose, then we will follow the applicable Research Ethics Board procedure.

Further Information

If you have any questions or concerns during the entire study period , please feel free to contact the researcher , supervisor or supervisory committee using the contact information provided at page-1 of this consent form.

If you have any specific questions regarding data collection and reporting, please contact Sejal Dave at 780-710-1706.

The plan for this study has been reviewed by a Research Ethics Board at the University of Alberta. If you have questions about your rights or how research should be conducted, you can call (780) 492-2615. This office is independent of the researchers.

Consent Statement

Please tick (√) if you agree with the following statements:

	Yes	No
I have read and had explained to me the information provided on the research project.	❑	❑
I understand that the results will be analyzed and presented using direct quotes from my interview but will not use my names. (i.e. I remain anonymous).	❑	❑

I understand that the results discussed at the provincial level will be coded to maintain confidentiality and anonymity.	❑	❑
I understand that the data will be safely stored for five years following the completion of the research.	❑	❑
	❑	❑
I understand the possible risks and benefits of participating in this research.		
I will be willing to participate in reviewing the transcript of my interview and draft final report.	❑	❑
I understand that the information I provide will be used towards the completion of masters' program and results may be presented at conferences or academic journals.	❑	❑

I have been given the opportunity to ask questions and my questions have been answered. If I have additional questions, I have been told whom to contact. I agree to participate in the research study described above and will receive a copy of this consent form. I will receive a copy of this consent form after I sign it.

_____	_____
Participant's Name (printed) and Signature	Date
_____	_____
Name (printed) and Signature of Person Obtaining Consent	Date

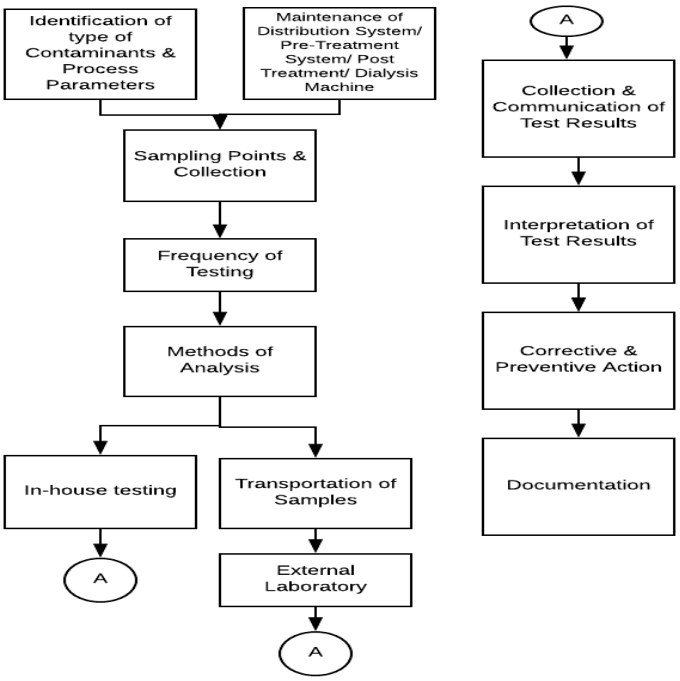
Appendix 6: Interview Guide

Introduction

The purpose of the study is to investigate barriers, needs and facilitators as experienced by health professionals for the management of dialysis water and dialysate quality for home hemodialysis programs in Canada. For this, it is important that we understand current monitoring process of DW and dialysate quality at your HHD program, what systems exist that support you for the management of DW and dialysate quality, barriers to the management of DW and dialysate quality and your needs to overcome the identified barriers. Your response will help us to prepare a taxonomy of barriers/facilitators/needs and then prioritize the identified barriers and needs. This research is important for guiding policy-makers in improving the quality of DW and dialysate quality for HHD program.

Section-I: How quality of dialysis water or dialysate is measured and assessed by your organization?

1. Tell me about your role and responsibilities for the management of dialysis water or dialysate quality for home hemodialysis (HHD) program. Please comment on your involvement at the various stages of the management of dialysis water and dialysate quality at your HHD program.



2. What type of contaminants and process parameters are measured and assessed? How do you decide whether indicators are good enough to assess the quality for DW and dialysate?

3. What are the various sampling points (locations) for testing source water, product water, dialysis water and dialysate? How do you decide to increase or decrease the sampling points?

4. What is the frequency of testing for each contaminants, process parameters or any other parameters? Is it same for all HHD patients?

5. Do you prioritize parameters or it remains same every time the test is conducted?

6. Under which circumstances the frequency of testing is altered i.e. increased/decreased in comparison to routine measurement?

(Prompts: depends on any season, type of source water, commissioning period, in case of contamination or in response to clinical results)

7. What is the process followed for water sampling, collection and transportation of samples? Does it vary depending upon the type of test?

8. Which tests are performed in-house and at external laboratory? (For both, chemical and microbiological)? Who is involved at this stage?

9. How do you decide the appropriateness of water treatment system or HD machine? How do you ensure proper operation of water treatment systems and HHD machine from the time of installation to the actual operation? Who is involved at this stage ? (Prompts: Technology: need of special post-treatment or pre-treatment equipment such as ultrafilters, or endotoxin filters, any special features of HHD machine, etc. Validation and process verification to ensure proper operation of treatment systems. Note: This is with respect to dialysis water or dialysate quality)

10. At what steps (as shown in above figure) you rely on patients for measurement and assessment of dialysis water and dialysate quality? (Note: This question will be asked only if the participant does not say anything about patient involvement in above questions)

11. How did your organization come up with the current monitoring process? (Prompts: input from drinking water supply organization, input from water treatment suppliers, based on any guidelines, other factors at your organization such as organic contaminant, source water disinfectants that may demand unique monitoring requirements. etc.)

Section-II: Decision-Making

12. What is considered as success or failure of results for chemical, microbiological, process parameters or any other indicators? Who is responsible for the interpretation of results?

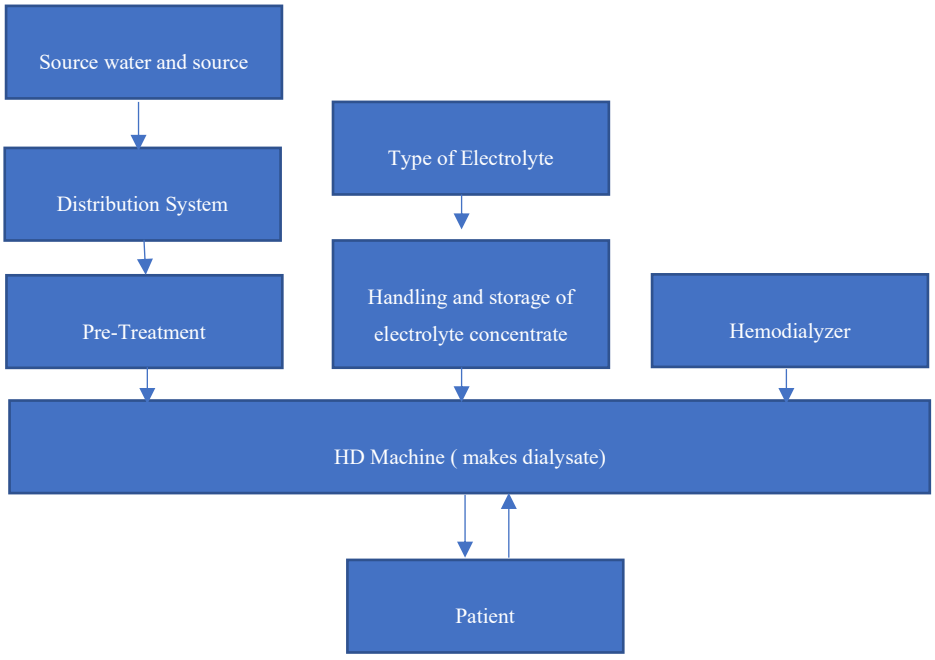
(Prompt: when do you take precautionary actions such as disinfection, replacement of any part of water treatment components, or others?)

13. What process is followed in the case of failure of results? Please elaborate with any of your past experiences. If not, then what are the main reasons?

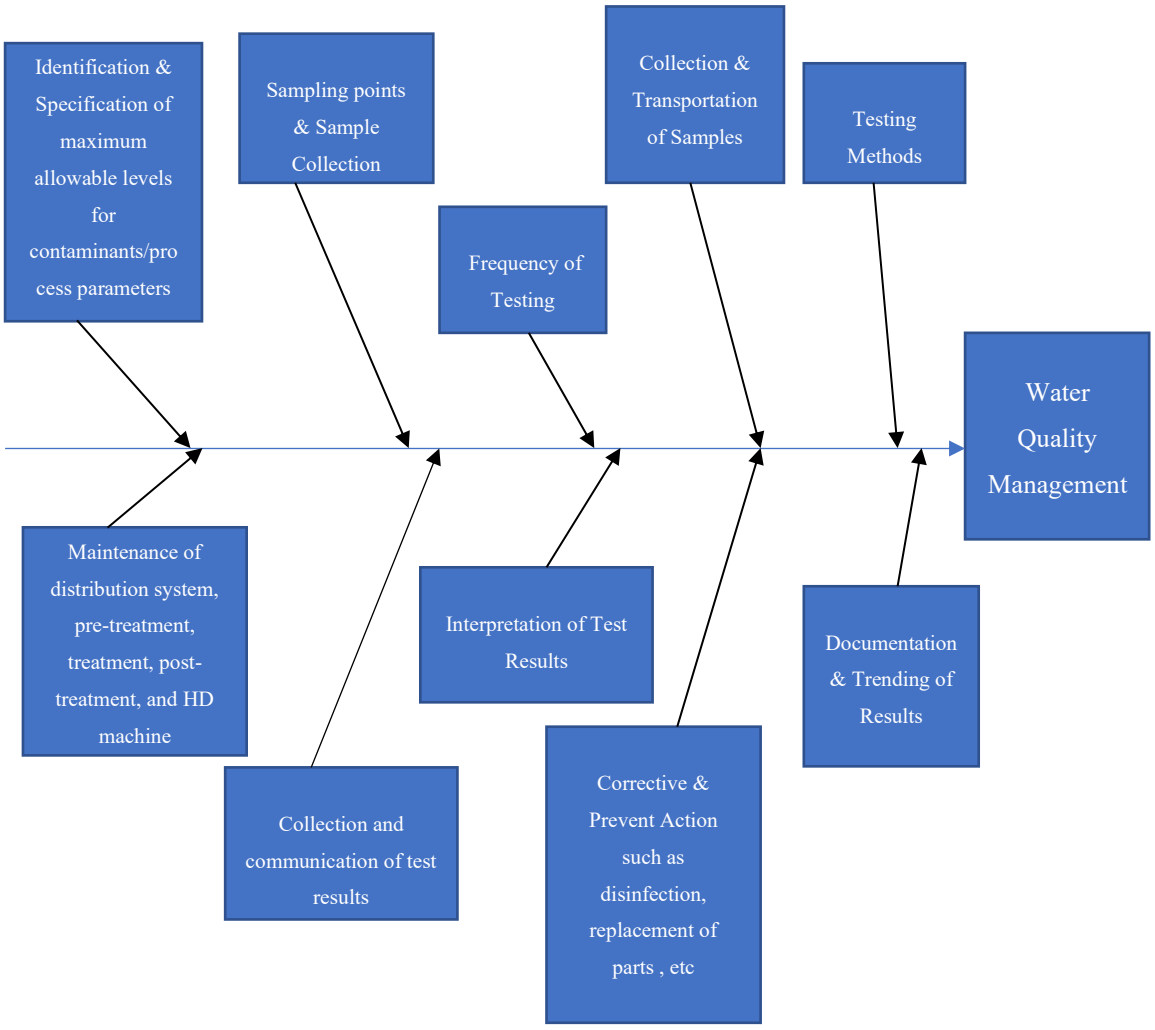
14. How do you communicate results to patients and within the organization?

Section-III: Barriers, Needs & Facilitators

15. What are the major contributing factors for the water quality issues from the entry point of source water to dialysate production?
    (Prompts: fluctuating temperature and water pressure, disinfection not properly performed by patients, log sheets incomplete, improper handling of concentrates, etc.)



16. What do you see as barriers in the process of planning and implementation of your current monitoring process? (Prompts: Barriers could be financial, inadequate testing methods, distance monitoring of water treatment systems, lack of knowledge, bad weather conditions, co-ordinating with laboratory, appropriate test methods, lab results may take longer time, etc.). Please enlist the barriers and rank them.



17. Are there any experiences in the past that led to any major changes in the monitoring process? What source of information did you used or consulted? What benefits you achieved with the change?

18. Has there been any requirements or recommendations to improve DW or dialysate quality in the past? What barriers have you experienced in implementing the recommendations? (Prompts: any technological change not possible due to budget constraints, difficulties experienced in educating staff or patients, etc.)

19. What factors you see as barriers to maintenance of patients for HHD programs (in regards to quality of source water, DW or dialysate quality)?
(Prompts: recruitment of patients due to infrastructure problem, source water not appropriate, patients not interested in testing water quality, training of HHD not sufficient enough to educate patients, etc.)

20. Are you aware of any specific circumstances or situations when patients complain more about water quality issues?
(Prompts: depends on any season, type of source water, commissioning period, patient education level, patient support at home, in case of contamination or in response to clinical outcomes, patients have very old distribution system)

21. What do you see as barriers in the overall management at your HHD program? How they are different from in-center Hemodialysis (HD)?. Please enlist the barriers and rank them.
(Prompts: difficult to maintain microbiological or chemical indicators, inability to establish whether a particular contaminant at a particular level will cause harm to dialysis patients, well water as source water, lack of awareness among staff members, not able to rationalize the need for monitoring of certain contaminants as recommended by CSA, remote monitoring, patient may not follow instructions properly, inadequate water treatment components and distribution system, communication with other staff members

and patients, preventive maintenance, disinfection, communication with external agencies such as source water supplier, water treatment supplier, reprocessing of dialyzers, etc.)

22. Are you able to identify any gaps in your current process for the management of dialysis water or dialysate quality?
    (Prompts: lack of information for guiding patients on telephone, lack of remote monitoring technology, lack of staff for scheduled and preventive maintenance, patient unable to troubleshoot with phone information, lack of process on follow-up with failure results, lack of process for un-compliance patients)

23. In your current role and responsibilities, what are your needs for the management of dialysis water or dialysate quality?
    (Prompts: Needs could be any tools/technology/training that can enhance or help with better management of dialysis water or dialysate quality, need of any resources for testing of chlorine or any other indicator, need of on-line monitoring)

24. Specifically, what do you think that you require in better responding to patients' complaints related to water quality or treatment equipment ? (Ask this question only if a participant does not say anything about needs for managing patients' complaints in Q-24)

25. In your current role and responsibilities, what do you see as facilitators for the management of DW or dialysate quality?

26. Is there anything I have missed that you would like to add?

Section IV: Quality Management System

27. What are the components of quality control/quality assurance (in regards to quality of source water, product water, dialysis water, dialysate and water used for reprocessing of dialyzers) at your HHD program?
    (Prompts: written protocols, policies and procedures, documentation of results, schedule of maintenance, clearly outlined roles and responsibilities of staff for testing and maintenance, SOPs for sampling, frequency, and methods of monitoring, recording and reporting, etc.)

28. Do you have any process for performance measurement at your HHD program as part of quality control/quality assurance?
    (Prompts: trending and analysis of results of water quality and water treatment equipment, monitoring of patient outcomes that are associated with water quality, audit by internal or external committee

29. Does your organization have quality improvement process or how do you plan to improve DW or dialysate quality at your HHD program? Ex: monthly meetings with staff to identify opportunities, etc.

30. Does your organization use risk management or any other tools (such as “process verification”) for the management of quality of DW and dialysate?

31. What effect do you think such programs could have on maintaining or improving the quality of DW or dialysate and thereby patient outcomes? If you do not foresee any positive outcomes with such programs, then what are the main reasons?

32. What do you think that needs to be done to ensure that water quality management is being conducted within the policies and is appropriate at your HHD program? (Ask this question only if there is no reply to answer to Q.30 and 31)

33. Are there any provincial or federal legal obligations for dialysis water or dialysate quality?
    (Prompt: legal requirements for certification or training of staff/patients, recording and monitoring of patient outcomes, requirements for maintaining indicators for DW or dialysate quality)

34. Is it possible to identify any barriers you experienced in fulfilling the legal requirements for maintenance of DW or dialysate quality? (Note: Ask this question only if there is positive answer to Q-34)
35. Is there anything I have missed that you would like to add?

Section-V: Guideline Related Questions

36. In past few years, how frequently and why have you referred to guidelines/standards by CSA or other organizations for the management of DW or dialysate quality?

37. What kinds of problems do you face in the implementation of recommendations by guidelines at your settings? Please elaborate with any scenario or specific recommendations that you were not able to implement.
    (Prompts: Such as lack of agreement, not practical in terms of cost, not enough evidence, time constraints, vague language)

38. Do you think any resources you need to use guidelines/ evidence more effectively?
    (Prompts: training consultants, dedicated staff, allocated time apart from your routine work, preferred documents in certain format, delivery or language?)

39. Is there anything I have missed that you would like to add?

Thank-you for your precious time and helping me to identify the challenges associated with the management of dialysis water and dialysate quality. I will provide you the transcript of our

today's discussion for content verification. Please feel free to add or modify any part of the transcript, if you feel that I have misinterpreted any of your thoughts. After I finish all the interviews, I will be analyzing results based on thematic and content analysis. If you are willing to participate for the verification of analysis, I will send you the preliminary results of analysis. At this stage you could ask to modify or add the content as necessary within 2 months. If you would like to add any other comments or require any clarification regarding the study, please feel free to contact me at sejal@ualberta.ca or at 780-710-1706. I would like to remind you that you can either modify or withdraw data within 3 months after the interview. If you are willing to participate for data verification, please submit your comments within 2 months of reviewing of transcripts and draft final report. It could be possible that during my analysis I may need to contact you once again, if I am stuck with the missing information. In such case, may I ask what is the best possible way to contact you? .

Appendix 7: Process Description of Participating Home Hemodialysis Programs

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
Program Characteristics		
Numbers of Nurses	**HHD-1**	• "We do case management. So, each nurse has about 20 [HHD] patients right now." (P6_Unit Manager) • "We have only 4 nurses. We actually had 6 [nurses] but we have got 2 [nurses] off right now." (P6_Unit Manager)
	HHD-2	• "Like 0.8 nurse in [name of a city], there is 0.8 nurse in [HHD program name], and then here in [name of a city] we have 7 nurses." (P8_Unit Manager)
	HHD-3	• Note: Information could not be obtained from the participants of HHD-3.
	HHD-4	• "I believe there are 7 nurses [who] do home training and they do share home on-call." (P14_Chief BioMedical Engineer)
	HHD-5	• Note: Information could not be obtained from the participants of HHD-5.
	HHD-6	• Note: Information could not be obtained from the participants of HHD-6.
Numbers of Technicians	**HHD-1**	• "We have technicians in [city name] who supports the home program in patients that is fairly a new thing. But, he also supports [city name] and the units in the [city name]. So, he has those units plus the home patients right, and that is what we find in the [city name], [where] he [a dialysis technician] is looking after [city name] which is a big unit there plus the home hemo [HHD program]." (P6_Unit Manager)
	HHD-2	• "In the [city name] area, there are three technicians who are dedicated to the home hemo [hemodialysis] program. They also do some support for other programs, but mainly home hemo [home hemodialysis program]. Then, there is a technician in [city name] who splits, I think, between home hemo [HHD program] and the regular program…and then there is one I think in, new one now [referring to a HHD program], in [town name] who splits between the home hemo [HHD program] and a regular program." (P8_Unit Manager)
	HHD-3	• Not applicable (Note: HHD-3 has outsourced the tasks related to water quality to third party vendors)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-4	• "8 of us [talking about dialysis technicians] cover home programs and satellites. There is 8 of us who do all home repairs and maintenance. But, there are only about 4 [dialysis technicians], 4 [dialysis technicians] only [who] in the home program [who does] initial home installations. There is no point in having all 8 [to] do that. We only need about 4 [dialysis technicians]. They are the ones who go for initial [assessment] to check space, electrical, plumbing and what not." (P14_Chief BioMedical Engineer)
	HHD-5	• "We [referring to the technical program that supports HHD program]…actually our technical program is blended. We [referring to technical program to support HHD program] will be at in-centre HD program. So, I don't have a certain number of techs [referring to dialysis technicians] that are just [supporting] home hemo [HHD program]." (P18_Medical Director) • "Our staff works on 12 hour shifts. So, at any given time we always have 2 technologists assigned to home programs plus one on extra shift. So, at any given time we have 3 technologists assigned to the home program. They would do service call but in between they would do the monthly visits as well." (P19_Retired Technical Manager)
	HHD-6	• "We have in our program got [a] technology manager. The technology manager directs a number of dialysis technicians who go out to patients' homes to do a patient assessment on the home for water quality. And then they also assess again plumbing capacity, and so on. They also subsequently arrange monthly water testing for endotoxins and things like that in nature. Sometimes, I think they go out, I think more often times they shipped to central location and then they have third party to do most water testing for us." (P17_Medical Director)
Technical/Clinical Manager/ Chief technologist	**HHD-1**	• 1
	HHD-2	• 1
	HHD-3	• 1
	HHD-4	• 1
	HHD-5	• 1
	HHD-6	• 1
Unit Manager	**HHD-1**	• 1

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-2	• 1
	HHD-3	• Note: Information could not be obtained from the participants of HHD-3.
	HHD-4	• Note: Information could not be obtained from the participants of HHD-4.
	HHD-5	• Note: Information could not be obtained from the participants of HHD-5.
	HHD-6	• Note: Information could not be obtained from the participant of HHD-6.
Numbers of Patients	**HHD-1**	• "We have got 80 patients." (P6_Unit Manager) • "Yes, we have got 85 [patients]." (P2_BioMedical Engineering Technologist)
	HHD-2	• "82 [patients] or something." (P7_Medical Director) • "I think 85 patients." (P8_Unit Manager)
	HHD-3	• "I think there are 50 patients [referring to total numbers of HHD patients on NxStage machine]." (P16_Technical Manager) • "100 [referring to total numbers of HHD patients on Baxter HD machine]." (P16_Technical Manager)
	HHD-4	• "Right now, I think the number is about 30 [referring to HHD patients] and that is just for central zone home program which is basically administered out of [city name]. But, it covers most of mainland [name of the city]." (P14_Chief BioMedical Engineer) • "We [referring to technical program that supports HHD program] cover most of [name of the city] except [name of the city] which is a separate facility and they have their own home programs. I think they have about 5 patients." (P14_Chief BioMedical Engineer) • "But, we don't work for hemodialysis group [referring to HHD program]. We [referring to dialysis technicians] are dedicated to their program, but we work for biomedical engineering department. But our techs [technicians] only do dialysis stuff and any equipment related to dialysis equipment, oh sorry the clinic. For example, the infusion pump they use in the clinic, or you know [unclear] that are always in clinic, we also do maintenance and repairs on those. We are all fully qualified BioMedical techs [technicians]." (P14_Chief BioMedical Engineer)
	HHD-5	• "We only right now…we only have about 30 [HHD patients]." (P18_Medical Director) • "We had about 60 at the most home hemo [hemodialysis] patients." (P19_Retired Technical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-6	• "We are stuck in around with 30 patients on Bellco [and others are using NxStage]. Now in the province we have 100 home hemo [hemodialysis] patients." (P17_Medical Director)
Geographical Spread	**HHD-1**	• "So, they [referring to numbers of dialysis technicians in HHD program] are based on the needs and the patient population and proximity to dialysis depends how you get funding for new units and there was determine there was need in the [city name] for home program. So, there is a home program in [name and location of HHD program] and they take patients all the way up to [city name]. But, [city name] itself is a very fast growing municipality so they do have all the outline in [home program location]. They have quite a few patients so there was just deemed the need." (P6_Unit Manager)
	HHD-2	• "So, we have got [HHD patients] at [city name] and then we have also got [referring to HHD patients] [at] [city name] and [city name]. So, we have three big cities in [province name]. We have [the home program] spread into three cities, but we all run as a single program." (P7) • "Ya,...its (referring to HHD program name) not as big as the one is here. But, there is a support so that we can train at [city name] and [city name] as well as in [city name]." (P9_Clinical Manager) • "So, at [HHD program name], we [referring to dialysis technicians] look everything right from [city name] and all the way down to [province name] border with US. Right, east and west, all the way to [city name] to [city name]. So, means we have patients everywhere. So 2 hours up and 2 hours down, 3 hours east and 2 hours west. So, that is the whole geographical areas." (P11_BioMedical Engineering Technologist)
	HHD-3	• "It [referring to HHD-3] has got all of [name of the province] so, it is…" (P16_Technical Manager)
	HHD-4	• "We [referring to HHD program] cover what is known as [name of the zone in the province]. In our portfolio, we [referring HHD-4] have 200 machines, 8 clinics and 30 home patients. That is over mainland [name of the province]. It is about 200 kms. That's about where our territory is. But, we don't work for hemodialysis group, we are dedicated to their program, but we work for biomedical engineering department." (P14_Chief BioMedical Engineer)
	HHD-5	• "When it was difficult, it was mostly not with in-center like in the city patients but the patients ..because we patients that we have to drive upto 3 hours to visit." (P19_Retired Technical Manager)
	HHD-6	• "NxStage is probably is not for everyone but it does allow us in our especially rural areas patient access where they would not have before." (P17_Medical Director)
Process for Home Assessment		

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
Source Water (SW) Analysis	**HHD-1**	• "Before they [referring to HHD patients] are accepted into the program, the technicians do talk to them about their water, source of their water…well, cistern or city water or the rural facilities, and they do a quick assessment based on the information from the patient." (P6_Unit Manager) • "During the home assessment we do look at water supply. Normally, if it is a municipal supply we do not ask any further question, because whatever the information we need we can usually ask from the municipal suppliers of what is in the water. The municipal facilities have usually a weekly or monthly report on what their water sampling has been. They usually do their own chemical analysis. So, we can get a report from them whenever we are ready to send a patient home." (P1_Clinical Manager) • "When we [technicians] go to patients' home that has a well, we [technicians] normally try to ask if the patient has any paper work for the well, and 99% of the time they don't [have it]. Nobody does anything for the water. So, the only thing we can do at that particular time is to see what the incoming conductivity of the water is, the supply that will be going into our water treatment carts. So, we just look at that and that gives us an idea roughly whether our equipment would be able to process the incoming water." (P1_Clinical Manager) • "The [unclear] all we do is…we [referring to technicians] do check on the water. We make sure [source water] pressure is good. We ask patient if it [referring to source water] is potable water. We do a quick check with the conductivity on the water as well, so we can know whether our RO or pre-treatment water system can handle it [referring to source water]. Other than that, we don't do the actual chemical analysis until the patient actually is on the home program." (P2_BioMedical Engineering Technologist) • "So, a person [who] comes into the program from a referral, that referral can come from either pre-dialysis clinic or from one of the dialysis unit. The referral can be made from anyone and patients can even self-refer. They [referring to patients] undergo evaluation by one of our staff members in the home dialysis unit, and the patient will be reviewed by one of the nursing staff and a technologist. Usually nursing interview happens face to face. The technologist, we like to have that [referring to review of patients] happen face-to-face, but it could also be that it happen by a telephone. If there are no immediate red flags to the patient coming and the red flags don't really refer to the technical aspects. They are more on the social side of things, the biomedical and psychosocial barriers rather than the logistical ones ..ahhmm…If none of those have been identified, then our technologists would go and kind of do site visit at the patient's home…and that's what they have to look at the infrastructure of the home. They would discuss with the patients [that] where would you do this, in the living room, in the bedroom, [or] in the spare room, etc. They would look at the electrical and the water at that time just to see if there is any immediate red flags anything that kind of is obviously would need to get dealt with. So, if, somebody sees if there is well water or cistern then there is a frank conversation about you know the quality and the quantity of water and how that needs to get monitored. Ahhmm…and then they identify at that time you know where there is something specific that needs to happen with respect to the water. So, you know likely need of extra filters likely need for more water than what is available through their cistern or well or what not." (P5_Medical Director)
	HHD-2	• "And then we do have our technicians. So, once they [referring to HHD patients] met certain basic criteria and at the point where we think that he [referring to a patient] be a good candidate physically, mentally, then we have the techs [technicians] go and look at the home and take samples." (P8_Unit Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "On installation we measure. When we are installing our equipment we take a source water sample." (P8_Unit Manager) • "Primarily, my part is to go and assess before even they [referring to HHD patients] start training, whether the incoming water [at patients' home] is suitable [or not]. So, that is where I take my kit to [take a sample and] send it [referring to source water sample] to lab [lanoratory]." (P11_BioMedical Engineering Technologist) • "Yes, for chemical and microbial, everything, is part of that kit. Everything we check for before we even say yes to patient. So, the idea is that water should meet Canadian potable water standard." (P11_BioMedical Engineering Technologist) • "We [referring to HHD-2 program] still measure SW [referring to source water supplied from municipal sources]." (P11_BioMedical Engineering Technologist) • "Yes, 90% of time, this [refers to source water testing] is before the patient starts training." (P11_BioMedical Engineering Technologist) • "When we [referring to HHD-2 program] get patients will go and do inspection of the home to see if they [referring to a patient] are suitable for the home hemo [HHD]. So, when we do that we do an actual source water sample and we send that to the lab. We use [name of the water testing laboratory] for that and that just test the quality of source water." (P9_Clinical Manager) • "Ya, so for municipal anybody in town. Rurals, if they [patients] are on well water, [then] we have different parameters that we [technicians] test. They [referring to testing parameters for source water supplied from private sources] are much more stringent than just municipal." (P9_Clinical Manager) • "So, we are looking for organics in that [referring to source water, either supplied from municipal sources or private sources]. If it does not meet Canadian drinking guidelines, then really we cannot install their [at a patient's home]. Because, it [source water] is not fitting the base parameters that we need to start with." (P9_Clinical Manager) • "When I get those results [referring to the analysis of source water], I will review it. I will run it through an analysis. I have got spreadsheet, so I have got all my parameters from the Canadian drinking water guidelines and [the] CSA [Canadian Standards Association] standards that what we [technical staff of HHD program] need to [do to] meet for dialysis quality water." (P9_Clinical Manager)
	HHD-3	• "We [referring to someone from HHD-3 program] arrange them [third party vendors] to go and do the initial water assessment, so potability for chemical analysis [and] for microbiology." (P15_Medical Director) • "Ensuring that the feed water is [at a] potable level, irrespective of source water [type]. We [referring to HHD-3 program's internal protocol] sample feed water initially." (P15_Medical Director) • "Traditionally, let us say with Baxter set-up, if, the water is coming from municipal source, then it [is of] drinking water [quality], potable water and so what each manufacturer, Baxter or NxStage, requires is that the water meets the Canadian drinking water standards. And so if the feed water is [from] municipal source, then the water treatment system that Baxter uses would be sufficient to produce the water quality required to do hemodialysis." (P16_Technical Manager) • "Researcher: So, before installation [of treatment system at patients' home] when the vendors do [home] assessment, do they test the source water?; Participant: Yes; Researcher: even if it is municipal or do they just take municipal records; Participant: They [referring to third party vendors] test the source water." (P16_ Technical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "Yes, the water sample is sent by the vendor to a lab." (P16_Technical Manager)
	HHD-4	• "The inorganic substances are measured certainly prior to the [patients'] training." (P14_Chief BioMedical Engineer)
	HHD-5	• "So, for the chemical testing, it [referring to the analysis of source water at patients' home] is done before we send people [referring to patients] out for home hemo [HHD." (P18_Medical Director) • "At that time [referring to home assessment] then, we [referring to HHD-5 program] even before the decision was made by the patient to go home dialysis or not, we [referring to dialysis technicians] will take water sample of the feed water. Not only [the testing of] metal or organic contaminants, but we would also test microbiology." (P19_Retired Technical Manager)
	HHD-6	• We have in our program got [a] technology manager. The technology manager directs a number of dialysis technicians who go out to patients' homes to do a patient assessment on the home for water quality. And then they also assess again plumbing capacity, and so on. They also subsequently arrange monthly water testing for endotoxins and things like that in nature. Sometimes, I think they go out, I think more often times they shipped to central location and then they have third party to do most water testing for us." (P17_Medical Director)
Infrastructure Assessment	**HHD-1**	• "So, a person [who] comes into the program from a referral, that referral can come from either pre-dialysis clinic or from one of the dialysis unit. The referral can be made from anyone and patients can even self-refer. They [referring to patients] undergo evaluation by one of our staff members in the home dialysis unit, and the patient will be reviewed by one of the nursing staff and a technologist. Usually nursing interview happens face to face. The technologist, we like to have that [referring to review of patients] happen face-to-face, but it could also be that it happen by a telephone. If there are no immediate red flags to the patient coming and the red flags don't really refer to the technical aspects. They are more on the social side of things, the biomedical and psychosocial barriers rather than the logistical ones ..ahhmm…If none of those have been identified, then our technologists would go and kind of do site visit at the patient's home…and that's what they have to look at the infrastructure of the home. They would discuss with the patients [that] where would you do this, in the living room, in the bedroom, [or] in the spare room, etc. They would look at the electrical and the water at that time just to see if there is any immediate red flags anything that kind of is obviously would need to get dealt with. So, if, somebody sees if there is well water or cistern then there is a frank conversation about you know the quality and the quantity of water and how that needs to get monitored. Ahhmm…and then they identify at that time you know where there is something specific that needs to happen with respect to the water. So, you know likely need of extra filters likely need for more water than what is available through their cistern or well or what not." (P5_Medical Director) • "Before they [referring to patients] are accepted into the program, the technicians do talk to them [referring to patients] about their water [referring to source water quality]." (P6_Unit Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "My team has been doing it [referring to management of water quality for HHD] for years. I might not actually do the testing, [but] I trust it that assessment of marking." (P1_Clinical Manager)
	HHD-2	• "When we [referring to dialysis technicians] get patients, we [referring to dialysis technicians] will go and do inspection of the home to see if they [referring to patients] are suitable for the home hemo [HHD]." (P9_Clinical Manager) • "Before, I get those results [referring to test results of source water quality available at patients' home], and then I will review it. I will run it through an analysis. I have got [a] spreadsheet, so, I have got all my parameters from the Canadian drinking water guidelines and the Canadian Standards Association (CSA) standards that what we [referring to HHD-2 program] need to meet for dialysis quality water. So, I run it [referring to source water quality test results] through that [referring to excel sheet] and if it [referring to source water quality] does not meet that [referring to CSA standards and Canadian drinking regulations], then I will go to one of our vendors and get them to run it again, and then see what we can do for pre-treatment to treat that water [referring to source water available at patients' home] if possible." (P9_Clinical Manager)
	HHD-3	• "So, the dialysis provider which is at we [HHD-3 program] handle the patients starting at home. We [HHD-3 program] arrange them [third party vendors] to go [at patients' home] and do the initial water assessment. So, potability [of drinking water] for chemical analysis and for microbiology." (P15_Medical Director) • "and then we would actually sort of convene a panel of water treatment experts which generally speaking that does not include me to be honest." (P15_Medical Director) • "Again, we are working pretty closely with our partner Baxter." (P15_Medical Director) • "If there are any challenges, [then] we would discuss those. Normally, the vendors would do the home assessment and if there are no problems then we would proceed to [training]. And we have two vendors to contract that we go with. But, both of those vendors are responsible for recommending the renovations required to the home in order to set it up for home hemodialysis." (P16_ Technical Manager) • "I would get involve is once when the patient is selected for going home and doing home hemodialysis and their home is assessed." (P16_Technical Manager) • "So, routine things in the nutshell would be are home set up electrically where the patients want to plug in the system and so we have as I said two contracts one is with Baxter following Gambro, and it is more of traditional hemodialysis set up. The other contract we have is with NxStage." (P16_Technical Manager) • "Ya, they [third party vendors] would look at electrical requirements, plumbing requirements, feed water, where the patients would get their feed water from whether say municipal source or well source, and those types of things. They [third party vendors] would make the recommendations based on that. They would also look at supply storage areas, [such as] where the patients would keep their supplies and how much room they have. So, those types of things." (P16_Technical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-4	• Note: Patients' home is assessed to determined their suitability for HHD by the program. However, the details on the process for home assessment were not discussed during interviews with the participants of HHD-4.
	HHD-5	• "We [referring to HHD-5 program] had a policy…technical policy ….basically dictated what needed to get done during the pre, what we called is home dialysis pre-assessment visit. So, the [pre-assessment] visit would involve a nurse, our clinical specialist and a technologist. They would meet with the patients to look at different things within the home to make sure that the home is adequate. During that time the technologists would assess the electrical and plumbing system as well, would take [a] note of what set up is in place already. At that time then we, even before the decision was made on patients' to go home dialysis or not, we [referring to dialysis technicians] will take water sample of the feed water. Not only from metal or organic contaminants, but we would also test microbiology. And then, we would use this result to decide on what kind of water treatment system would be required for the home patients." (P19_ Retired Clinical Manager)
	HHD-6	• "So, we have a tech, we have in our program got technology manager and the technology manager directs a number of dialysis technicians who go out to patients' homes to do a patient assessment on the home for water quality. And then they also assess again plumbing capacity." (P17_Medical Director)
Patients' Training	**HHD-1**	• "Patient training takes place in our facility and it is [for] 4 to 6 weeks…and we review everything from infection control, set-up of the machine to there is water cart reverse osmosis machine that patients trained to use." (P6_Unit Manager) • "So, they [referring to patients] are given the information, there have multiple demonstrations and then they practice how to test the water(P6)"; • "Nurses and the technicians [are involved in the training]." (P6_Unit Manager) • "Yes. So they [teach about] set up the machine, supply management, cleaning and disinfection of both dialysis machine and the RO machine and then patient care, complication, and safety." (P6_Unit Manager) • "a written demonstration [after training]" (P6_Unit Manager) • "You can quickly see that if we have a few people on the waiting list … ahh…you know in order to get through as 6 weeks training period you can sometimes accumulate some people on waiting list. Because, you know turn over isn't that fast. So, that can be anywhere from kind of weeks to few months. Then, whenever there is an opening available then you know we call the patient up and say look on Monday you are going to come to the unit we are ready to start teaching you. It is typically 6 week training period, where patient will learn everything about conduct of self-managing their dialysis. As part of the process, the technologists spent some time on one-on-one time with patients teaching them about some of the logistics around the machinery, the technical aspects of the dialysis equipment and inclusive in that is water monitoring and how often and how frequently etc. etc. and how to perform that." (P5_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-2	• "We have one nurse for one patient for the training for the 4 to 6 weeks in the program. And they go through everything including the water sampling." (P7_Medical Director) • "So, the technologist they work with the nursing staff to train the patient on how to use the portable RO [reverse osmosis] and then what to test on the portable RO. So, we teach patients to look at there are pressure gauges, temperature gauges that help us to monitor the filters and that. Temperature we want to monitor that because the RO runs between 5 degrees and 25 degrees Celsius. The optimum [operating temperature] is probably around 18 degrees, and that is where you are going to get your best quality water from your RO, and so we want to monitor that. And then pressure gauges we teach them to read those. Because we got pressure gauges before and after the carbon filters. If the carbon filters start plug up then we know that we need to go and change them and then we also do residual chlorine testing for the patients…we train them how to do that so that if there is a breakthrough on those carbon filters they can let us know and not to proceed with dialysis if they have breakthrough and then we need to go and replace those filters." (P9_Clinical Manager)
	HHD-3	• "Yes, [we train patients for how to do microbiological sampling]." (P16_Technical Manager) • "It is not the part of home hemodialysis training [to train patients on maintenance of softeners]." (P16_Technical Manager) • "No, I am not. Everything patients need to do that training nurse would go through to train a patient." (P16_Technical Manager)
	HHD-4	• "The nurses train them how to do the [microbiological] sampling." (P14_Chief BioMedical Engineer) • "Yes, what our role for technical for home patient training we basically only speak to them [referring to patients] only about water system how it operates, how they have to monitor, remember I spoke about logging we trained them how to do that, we trained them on how to disinfect properly, and how many times we want them to do it. But, for everything else from dialysis machine strictly meaning the nurses are doing that. But, we do speak to them about general care of the dialysis machine like you know don't put your cup of coffee on top of it, how to keep it clean, how to keep it operational, and that for the technical that would be our role in home training." (P14_Chief BioMedical Engineer)
	HHD-5	• "The patient learn about the importance of water quality during their original training. Our technical team does come and talk to them about the water." (P18_Medical Director) • "When I led the program, I think we trained patients for 5 weeks at in-center before they went on [for home hemodialysis]. But, during the training towards the end when the nurses would include the water treatment component into the training at that time then I would visit the in-center. I would go at home units and meet with home patients and spend sometime with them and talk about water quality and the importance of reporting problems. You know, like generally speaking in terms of what to do for them, but what we need them to do for us in order to be successful. You know like in other words if you are explaining things like it is important for you to test chloramine and this is why it is important that then. And if you have the machine malfunction you need to call it right away and this is why it is important to be

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		reported and so on. Even myself and one of my staff would spend like couple of hours with home patients in the home units talking to them about equipment." (P19_Retired Technical Manager)
	HHD-6	• Note: Information could not be obtained from the participant interviewed from HHD-6.
Patients Selection on Home Programs	**HHD-1**	• "Once that home assessment is completed and they have been accepted then they go on the list to go onto the program. But, whether they can go right away or whether there is a waitlist depends on the time of the year what's going on." (P6_Unit Manager)
	HHD-2	• "We have like technical criteria in terms of making sure that they have access to reliable water." (P7_Medical Director) • If that [referring to source water] is within the Canadian drinking water guidelines, then we move forward with installing for that patient.. Like, we get to know that the water is treatable with our portable RO [reverse osmosis] system, [and] that's what we are going to install. So, that's why we are doing that sample [for source water]." (P9_Clinical Manager)
	HHD-3	• "The way we try to organize at in [name of the province] is that we have sourced our water management to our dialysis provider. So the dialysis provider we handle the patients starting at home. We arrange them to go and do the initial water assessment…..so portability for chemical analysis [and] for microbiology." (P15_Medical Director) • "I probably don't have a lot involvement with patient selection. Where I would get involve is once the patient is [clinically] selected for going home and doing home hemodialysis, their home is assessed. If there are any challenges, we would discuss those. Normally the vendors would do the home assessment and if there are no problems, then we would proceed to [device installation]." (P16_Technical Manager) • "Yes, they would look at electrical requirements, plumbing requirements, feed water, where the patients would get their feed water from whether say municipal source or well source, those types of things. They would make the recommendations based on that. They would also look at supply storage areas, where the patients would keep their supplies, how much room they have and those types of things." (P16_Technical Manager)
	HHD-4	• "We check it [quality of source water] on the initial set up [of devices] and if we determine the softener is to be needed, [then] we would put one in." (P14_ Chief BioMedical Engineer) • "Yes, we had a few [referring to problems with home infrastructure and water quality at patients' home]. For plumbing not too many sometimes mainly for not getting water, but for getting drainage out. There is no grounding at all in houses." (P14_ Chief BioMedical Engineer)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-5	• "So, whatever is for home or in-center we followed CSA [Canadian Standards Association] standards as much as we could, so the publish standards, in our practice." (P19_Retired Technical Manager)
	HHD-6	• Note: This topic was not discussed in detail during the interview with the participant from HHD-6.
Treatment Components and Hemodialysis (HD) Machine Installation	**HHD-1**	• "So, for very first home visit a nurse and a technician is present to make sure that transition and machine is smooth at home." (P6_Unit Manager) • "That is where we are testing water, the technicians test the water when they install that machine into the home." (P6_Unit Manager) • "Then, there is telephone follow-up as well. As they [referring to patients] come in to the clinic after the first month at home where we can reiterate some more training and review some of the things that they may have forgotten. Then, they come in to the clinic every three months." (P6_Unit Manager) • "Before we [referring to in-house technicians] do an install [device installation], we take a water sample [referring to chemical testing] and according to CSA standards. Of course, sure we have got here, these are all of the elements that are tested for according to the standard. The sample of water is shipped here in the town to [name of the laboratory]." (P1_Clinical Manager) • "Not, until we get our device in place [referring to microbial testing for source water], that [referring to installed devices] is supposed to eliminate all of that [unwanted microbial contaminants in source water]." (P1_Clinical Manager) • "That is usually when they start training. So, after that point any testing that we do is covered by our program." (P1_Clinical Manager) • "The equipment that we take to the patient's home, we already test it and validate it before we take it to the patient home." (P2_BioMedical Engineering Technologist) • "On that very first dialysis treatment in the home, the patient is always accompanied by the nurse who has trained them and one of the technologist as well. So, that first home run is always done at the patients' home, but in a very supervised kind of manner. (P5_Medical Director) • "Normally, if it is a municipal supply we [referring to in-house technicians] do not ask any further question for the [source water], because whatever the information we need we can usually ask from the municipal suppliers of what's in the water. The municipal facilities have usually a weekly or monthly report on what their water sampling has been. They usually do their own chemical analysis. So, we can get a report from them whenever we are ready to send a patient home. The issues we have some time the process that we have is that when we go to patients' home that has a well. There we normally try to ask if the patient has any paper work for the well, and 99% of the time they don't. Nobody does anything for the water. So, the only thing we can do at that particular time is to see what the incoming conductivity of the water is. The supply that will be going into our water treatment carts. So, we just look at that and that gives us an idea roughly where our equipment would be able to process the incoming water." (P2_BioMedical Engineering Technologist)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-2	• "Yes, for the first run. So, the machine would be set up. The technicians, I think, would actually do may be the like first sample and then the nurse would come out for the in the first week. They organize to be there for I think it is the first run typically." (P7_Medical Director) • "So, after we do those source waters [testing], we install [devices at patients' home].On that installation, we do our post-RO [reverse osmosis] water sample that goes to the same lab [laboratory] and that's again testing the water to make sure that our RO [reverse osmosis] is treating the way we wanted to. So, it is just really a verification process. But at that time, then we do our microbiology and endotoxins as well. And that goes to a different lab [laboratory]." (P9_Clinical Manager)
	HHD-3	• "They [referring to vendors] would test source water as part of the drinking water standards. When they test the RO [reverse osmosis] water, they would make sure that they would do more microbiology testing of actual water used for HD." (P16_Technical Manager)
	HHD-4	• "We check it [quality of source water] on the initial set up [of devices] and if we determine the softener is to be needed, [then] we would put one in." (P14_ Chief BioMedical Engineer) • Note: The quality of source water before and after device installation was assessed by the program. Also, after device installation their ability for delivering required water quality for dialysis was also assessed. However, the other details related to the first run of dialysis at patients' home had not been discussed during interviews with the participants interviewed from HHD-4.
	HHD-5	• "That is whole done in advance. So the technical team, we usually install the machine the week before the patients would go to home and that's obviously include all of the water treatment system and our technical team does that." (P18_Medical Director) • "So, let us say we did the home assessment visits and then we perform water taps and patient decided I want to go home. The nephrology program, physicians team were satisfied with setting up home dialysis. On the day of the set up of the equipment, the technologists would take again a full water sample [unclear] on the feed water and then they would do this on the product water once when the equipment is set up." (P19_Retired Technical Manager) • "So, when they [referring to patients] do their first treatment at home, we usually have a nurse who goes to their home and supports them through their first treatment. Our technical people are not their for that first treatment. It is our nurses that are their to support our patient." (P18_Medical Director)
	HHD-6	• Note: The details on the kind of testing being conducted before and after installation were not discussed in the interview with the P17.
Support for Dialysis	**HHD-1**	• "We do not send nurses out to the patient. Family members are only [with patients] that have been trained with the patients." (P6_Unit Manager)
	HHD-2	• Staff-assisted HHD is not available in HHD-2.

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-3	• Staff-assisted HHD is not available in HHD-3.
	HHD-4	• Staff-assisted HHD is not available in HHD-4.
	HHD-5	• "So, in the province, they did have a program where we had a PSW [personal support worker]. If we had a patient who just wasn't quite capable of doing the treatment on their own, then they could get support from our personal support worker that is currently on hold. I did have some people still at home who do have a personal support worker , but moving forward at least for right now there is no additional [funding]. We won't be sending people home with personal support worker." (P18_Medical Director)
	HHD-6	• "No we do not have assisted home program at this point." (P17_Medical Director)
Permissible Values of Quality Parameters for SW and Water used in Dialysis		
	HHD-1	• "So, part of my responsibility is to make sure that patients that are dialyzing at home they are getting clean dialysis type water for their dialysis. And that water has to meet Canadian standards to be able to dialyze patients at home." (P2_BioMedical Engineering Technologist)
	HHD-2	• "If that [referring to source water] is within Canadian drinking water guidelines then we move forward with installing [of devices]for that patient." (P9_Clinical Manager) • "I mean really we are following CSA standards for that [referring to water for dialysis]." (P9_Clinical Manager)
	HHD-3	• "If, the water is coming from municipal source then it is drinking water, potable water and each manufacturer [of hemodialysis machines] requires is that the water meets the Canadian drinking water standards." (P16_Technical Manager) • "But essentially what we do is we follow the CSA [Canadian Standards Association] and AAMI [American Association of Medical Instrumentation] guidelines for the water quality. Ensuring that the feed water is portable level irrespective of source water." (P15_Medical Director)
	HHD-4	• "Our standard practice is CSA [Canadian Standards Association] standards." (P13_Medical Director)
	HHD-5	• "So, whatever is for home or in-center we followed CSA standards as much as we could, so the publish standards, in our practice." (P19_Retired Technical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-6	• As per the local drinking water regulations (for source water) and as per Canadian Standards Association(CSA) for water used in dialysis
Types of Treatment Components used in Home Programs and Reimbursement		
	HHD-1	• 'The equipment and the first time install and the renovations and all the supplies are paid by the program." (P6_Unit Manager) • "They [referring to patients] don't pay to drop the water sample off at Purolator." (P6_Unit Manager) • "We [referring to in-house technicians] do the chemical testing [referring to the testing of source water quality] and then will give the results to patient. We [referring to in-house technicians] will make a recommendation but not very often do we enforce that recommendation. If the patient feels cannot afford to do something they may not do it." (P1_Clinical Manager) • "The only thing that our program provides is the reverse osmosis which is a charcoal filtering system, microbial filtering, and reverse osmosis membrane that prepares the water for use. But we [referring to home program] don't provide water softeners or iron filters or anything like that." (P1_Clinical Manager) • "We [referring to in-house technicians] do the testing [referring to the testing of source water] and identify the failures. We will say that this has to be dealt with before we can proceed if there is a huge failure." (P1_Clinical Manager) • "[The] testing samples cost all are covered by the program and all of our [referring to in-house technicians] service." (P1_Clinical Manager) • "Dialysis equipment that is required for set up at home, [including] the water cart which contains filters, carbon tanks, [and] reverse osmosis, that is covered by the program. Any maintenance required on that thing[s] is covered by the program as well. Other than that dialysis machine, centrifuge, [and] any supplies that patient needs for dialysis is covered by the program." (P1_Clinical Manager) • "Basically, it [referring to water-related devices] is a cart that comes with carbon filter, pre and post carbon filters. Sorry, there is a carbon filter, there is [a] pre-micro 0.5-micron pre-filter and then the post-carbon filter [and then a] 1-micron filter. So, those [components] are on the cart itself. After the 1-micron filter, [the] water goes to the RO [reverse osmosis]." (P2_BioMedical Engineering Technologist) • "So, we [referring to home program] do not pass on any fees to the patient. So, if somebody needs something it is us who provide as the program. It is not, we have never asked the patient to pay for extra filters or things, that does not happen. [But,] what does happen is if the patient water quality from, you know for example, there well was insufficient or inadequate or not appropriate or they have to pay for the cistern water they have to pay for the road. We do not actually pay for the water but we don't ask people to pay for anything equipment or filter related." (P5_Medical Director) • "Right, so everybody has the same baseline equipment and then on occasion in our program we have had patient who have required extra filters something, something a little bit different, and that is decided on a case by case basis. But again, I would be…I have never heard that our program charges [to patients] for anything." (P5_Medical Director) • "We [referring to home program] have AK 98 [referring to the model of a hemodialysis machine]. We have bought about 45 AK98 for 89 patients. So, about half way for replacement." (P1_Clinical Manager) • "Actually, its one it is the not the heat, and the one that does not do heat." (P1_Clinical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "We [referring to home program] only use the 300 [referring to the model of hemodialysis machine] and this is a chemical disinfected device only. It does not use heat [disinfection]." (P1_Clinical Manager) • [The in-house technicians] are going to do trials with them [referring to ultrafilters on hemodialysis machines]. So, lot of the patient[s] have them but it [referring to ultrafilters on hemodialysis machines] is not a standard just yet." (P6_Unit Manager) • "[The program] is not using endo [endotoxin] micron filters [referring to ultrafilters on hemodialysis machines]." (P1_Clinical Manager) • "So, over [the] last year and a half, so, we have started a study [about] giving patients the filters [referring to ultrafilters]." (P2_BioMedical Engineering Technologist) • "The equipment and the first time install and the renovations and all the supplies are paid by the program." (P6_Unit Manager)
	HHD-2	• "We [referring to the home program] fund the machines and fund the necessary renovations that required for meeting plumbing requirements and water requirements. Sorry, not water [and] electrical requirements for the machine, and the treatments the Ros [reverse osmosis]. So, ya, funding is really part of it. Although, you could argue that you know we do not pay in our program we do not pay for the water bills or the electricity bills. So, that can be an issue for certain patients definitely." (P7_Medical Director) • "Depending on what the source water sample is we have to decide what we have to install (referring to water related devices)." (P8_Unit Manager) • "We [referring to home program] have in [name of the province] covered with all the costs. Whatever it needs to be done is done by [name of the healthcare agency] everything, so [that] patient[s] can dialyse at home." (P11_BioMedical Engineering Technologist) • "If a patient meets the Canadian drinking water guidelines, [then] we will install [the devices at patients' home]. But, if they like may be the town is treating more with chlorine or ammonia or something. It includes water, but then it creates some, it might go through more carbon filters. So, we [referring to home program] will put more pre-treatment [filters] and to protect the RO [reverse osmosis] on that. That cost comes like we pay for that cost." (P9_Clinical Manager) • "So, on the portable RO [reverse osmosis], there is a ten-micron filter, [and it] takes out sediment particles. Then, it [referring to source water] goes to two carbon filters, one we call it as worker and one as a polisher. Then, it [referring to source water] goes to another one-micron filter. Actually, the first one is 5 micron and then [they] taking [take] all particles [away from source water]. So, post [of the] carbon [-filter], you can get particles coming out from the carbon. So, we want to capture that too before it [referring to particles] goes into the RO and then the RO does it job and it takes out 99% of bacteria and all the other metals and contaminants that are in there." (P9_Clinical Manager) • "Well, actually, Gambro [referring to the manufacturer of a hemodialysis machine] is the manufacture, and Baxter is the company that sells it [referring to hemodialysis machine]. Gambro used to be the company on its own, but Baxter bought Gambro so you will see Gambro on that. It is actually Baxter [and] this [Note: participant shows the picture of the model to the researcher] is the AK 98 [referring to the model of a hemodialysis machine]." (P9_Clinical Manager) • "The cartridge, so it is disposable. So, it is one treatment thing. They use that cartridge and the acid that is in a container. Once the treatment is done and they [referring to patients] throw it [away]." (P9_Clinical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "No, no. We used to [provide Deionizer] and then we [referring to the home program] changed to these portables [referring to reverse osmosis]." (P9_Clinical Manager)
	HHD-3	• "And, so we sort of adding another layer of protection [referring to putting ultrafilters on hemodialysis machines] to bring it to ultrapure." (P15_Medical Director) • "With Baxter system that we are using it is pretty much possible. We also have the NxStage system that we are using, and that is a different technology that uses de-ionization system as opposed to RO [reverse osmosis]." (P15_Medical Director) • "Yes, all [water-related devices] covered [by the program]." (P15_Medical Director) • "So, that would involve the filtration component, carbon or other filters and then reverse osmosis unit to produce water that is the machine would accept." (P16_Technical Manager) • "Let us take traditional system, when a patient is on a municipal well we would pay the vendor to do home assessment [and] set up their equipment. We [referring to the home program] pay for the equipment in terms of water treatment equipment system for hemodialysis. And we pay for all the supplies that patient uses." (P16_Technical Manager) • "If that patient has to have some treatment of feed water first, like water softener or some other treatment, then we would probably pay for the initial installation for the patients of those treatment. But, patients would be responsible for maintaining that." (P16_Technical Manager) • "For carbon filters, we [referring to the HHD-3] would provide." (P16_Technical Manager) • "It is required and this is all disposable but there is called a PAK [Pure Flow SL Purification]. PAK is an acronym for it. So, it is different than reverse osmosis system. But, that requires some prefiltration with deionization [and] UV." (P16_Technical Manager) • "They [referring to ultrafilters] are on the machine itself." (P16_Technical Manager) • "It is [referring to the model of hemodialysis machine] called WROs 300H, and probably goes through heat disinfection every time and then they do integrated disinfection of chemical once a week. So, what we have been buying WRO 300H so Gambro product that is matched that is matched to the AKM 95 96 machines." (P16_Technical Manager)
	HHD-4	• "We use two different types of system in our home program. One system is based on our RO [reverse osmosis] with pre-filters and carbon filtration. The other system that we use is a deionization system. And that is deionization plus ultrafiltration." (P13_Medical Director) • "Yes, they [water-related devices] are all [paid by the program and] patients do not [have to] pay for those." (P13_Medical Director) • "Testing will be covered as well." (P13_Medical Director) • "Yes, we have two different models [of hemodialysis machines] here. We have Phoenix machine made by Baxter, [and] the model is called Phoenix that do not have an extra filter on. But we also have other half of our fleet is the Fresenius 5008 and they do have bacteria filters on them." (P14_Chief BioMedical Engineer)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-5	• "But, with the Fresenius machine and the RO [reverse osmosis] and our charcoal filter and stuff that is currently within the home hemo budget." (P18_Medical Director) • "We [referring to the home program] do, with the electrical and minor renovations are paid for by the program." (P18_Medical Director) • "We [referring to the home program] have two machines right now we have the Bellco [the manufacturer of hemodialysis machine] machine and the Fresenius machine [the manufacturer of hemodialysis machine]. With the Bellco, we are phasing out and our major machine will be the Fresenius machine." (P18_Medical Director) • "There is an additional ultrafilter at the back of that machine [referring to hemodialysis machine made by Fresenius], and so all of our patient has those." (P18_Medical Director) • "We [referring to the home program] always install a portable, like the basic standards component were always there like pre-filters, pre-carbon filters, and water treatment systems like reverse osmosis. But different sometimes would be the need to add sometimes U.V. light and ultrafilter depending on the water quality or additional pre-treatment equipment at times would be require to lower the conductivity in the feed water." (P19_Retired Technical Manager) • "In home environment, all of our hemodialysis machines were equipped with ultrafilter like pre-dialyzer just before the patient. All of our concentrate that we use in our home environment is dry bicarbonate cartridges." (P19_Retired Technical Manager) • "I think when I was leaving [referring to leaving the home program], we [referring to the home program] started purchasing Gambro heat disinfection. I don't know if they have actually implemented those yet so they might have, because it has been over a year." ((P19_Retired Technical Manager) • "In [name of the province], would be [healthcare agency] as the technical advisory committee, we were able to achieve that and [name of the healthcare agency] provided adequate funding for all the tests at the frequency that the standards [referring to the Canadian Standards Association] was calling for. So, there was a cost to the system, to healthcare system, but no cost to the program, because we are getting members by the ministry." (P19_Retired Technical Manager) • "like I said the U.V. light [ultraviolet light] and D.I [Deionizer] tanks, ultrafilters, and so on." (P19_Retired Technical Manager) • "No, we [referring to the home program] don't except there are a few set ups if the conductivity of feed water because of contaminants is too high. What we do is we use DI [Deionizers] as polishers. So, what we do is we have like an industry coins we have pre-filters, carbon filters, RO systems [reverse osmosis], and then we install DI tanks [Deionizer], and then we install UV lights [ultraviolet] and then ultrafilters." (P19_Retired Technical Manager) • "No, no. The only time when we had to install a water softener [referring to reimbursement of components]." (P19_Retired Technical Manager) • "But, when the patient, if it was feasible for the patient, then we you know we would show them how to make sure that there is enough salt in the softener and so on. But, when we had a home patient sometime when we install them they already had a water softener so in that case then we did not provide them with a salt. Because, they already had a salt provider going to their home." (P19_Retired Technical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-6	• "Mainly, 95% of our patients are on NxStage." (P17_Medical Director) • "Researcher: In terms of water treatments system, [whether] everything is reimbursed by the program.; Participant: Yes.; Researcher: Do you provide softeners [to patients]; Participant: Yes." (P17_Medical Director)
Ordering Supplies for Testing		
	HHD-1	• "They [referring to patients] have to order their supplies." (P6_Unit Manager) • "They [referring to patients] get supplies once a month through [name of the healthcare agency]. But, this water sample kits are in addition to the warehouse. So, warehouse does not keep them [referring to sample kits]. [Instead], we [referring to the home programs] have to have them [referring to sample kits] deliver to the warehouse." (P6_Unit Manager) • "[Name of the healthcare agency] puts them [sample kits] together. So, we [referring to the home program] have got the supplies. But, we have to get them to warehouse. The nurses are not always doing that, it is one of the … we have a supply clerk that does that." (P6_Unit Manager) • "[Name of the healthcare agency] supplies them [referring to testing kits] using local trucking companies." (P6_Unit Manager) • "Generally, the technicians, when they go for their home visits, they do take water sample kits [with them]." (P6_Unit Manager)
	HHD-2	• "Supplies, we [referring to the home program] deliver every 6 weeks." (P8_Unit Manager) • "Patients store [testing kits]. They [referring to patients] have these supplies. They order a lot of things already so this is under check list. All they have to do is, there is a computerized form they ship it. They check it and then shipped out to them [referring to the home program] every month and a half. So, supply is never a problem in here. There is a system in place. They sometimes over stocked [the testing kits]. They order more. They use less and they keep ordering every month." (P11_BioMedical Engineering Technologist)
	HHD-3	• Note: Patients were responsible for sampling of microbiological testing. However, the specific discussion on the process of sending the testing supplies to patients and its related issues did not came up during the interviews with the participants of HHD-3.
	HHD-4	• Note: Patients were responsible for sampling of microbiological testing. However, the discussion on the process of sending the testing supplies to patients' home and its related issues did not came up during the interviews with the participants of HHD-4.
	HHD-5	• Note: This topic is not applicable for HHD-5. The reason being that in-house technicians were responsible for microbial and chemical testing. However, specific discussion on ordering of supplies for chlorine testing, for which patients were responsible, did not occur during the interviews with the participants of HHD-5.

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)		Chunks from Transcripts
	HHD-6		• Information could not be obtained from the participants of HHD-6. However, the technical tasks related to water quality had been outsourced to third party vendors.
Routine Monitoring Process (Microbial)			
Testing Parameters	**SW**	**HHD-1**	• "So, part of my responsibility is to make sure that patients that are dialyzing at home they are getting clean dialysis type water for their dialysis. And that water has to meet Canadian standards to be able to dialyze patients at home." (P2_BioMedical Engineering Technologist)
		HHD-2	• "Yes, of course, the Canadian drinking water guidelines." (P8_Unit Manager) • "Researcher: Do you measure any other microbiological parameters like fungi, algae or any other? Participant: No not for that. We will do that in a source water sample and you know like if it is well water then that is done again at the source water every six months." (P9_Clinical Manager)
		HHD-3	• "I can not say on the top of my head what those parameters are. If you go to the drinking water standards, the requirements are in there and they (vendor) talk with the lab and lab matches those. I don't [know] which. But, the testing matches what has been required to be met [by] Canadian drinking standards." (P16_Technical Manager)
		HHD-4	• "Our standard practice is CSA [Canadian Standards Association] standards." (P14_Chief BioMedical Engineer)
		HHD-5	• "So, whatever is for home or in-center, we followed the CSA [Canadian Standards Association] standards as much as we could, so the publish standards, in our practice." (P19_Retired Technical Manager)
		HHD-6	• "So, we follow the CSA [Canadian Standards Association] standard." (P17_Medical Director)
	Water used in Dialysis (Microbial)	**HHD-1**	• "So, part of my responsibility is to make sure that patients that are dialyzing at home they are getting clean dialysis type water for their dialysis. And that water has to meet Canadian standards to be able to dialyze patients at home." (P2_BioMedical Engineering Technologist)
		HHD-2	• "So, we would test for endotoxins. And then of course the samples culture." (P8_Unit Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)		Chunks from Transcripts
			• "I mean really we are following the CSA [Canadian Standards Association] standards for that [referring to water for dialysis]." (P9_Technical Manager)
		HHD-3	• "But essentially what we do is we follow the CSA [Canadian Standards Association] and AAMI [American Association of Medical Instrumentation] guidelines for the water quality. Ensuring that the feed water is portable level irrespective of source water." (P15_Medical Director)
		HHD-4	• "Our standard practice is CSA [Canadian Standards Association] standards." (P14_Chief BioMedical Engineer)
		HHD-5	• "When I started in [name of the province] in 2004, actually, endotoxin testing was not being performed at all." (P19_Retired Technical Manager) • "Currently, [testing parameters are] as per the CSA." (P19_Retired Technical Manager)
		HHD-6	• "So, we follow the CSA [Canadian Standards Association] standard." (P17_Medical Director)
	Water used in Dialysis (Chemical)	**HHD-1**	• "So, part of my responsibility is to make sure that patients that are dialyzing at home they are getting clean dialysis type water for their dialysis. And that water has to meet Canadian standards to be able to dialyze patients at home." (P2_BioMedical Engineering Technologist)
		HHD-2	• "I mean really we are following the CSA [Canadian Standards Association] standards for that [referring to water for dialysis]." (P9_Technical Manager)
		HHD-3	• "But essentially what we do is we follow the CSA [Canadian Standards Association] and AAMI [American Association of Medical Instrumentation] guidelines for the water quality. Ensuring that the feed water is portable level irrespective of source water." (P15_Medical Director)
		HHD-4	• "Our standard practice is CSA [Canadian Standards Association] standards." (P14_Chief BioMedical Engineer)
		HHD-5	• "So, whatever is for home or in-center we followed CSA [Canadian Standards Association] standards as much as we could, so the publish standards, in our practice." (P19_Retired Technical Manager)
		HHD-6	• "So we follow the CSA [Canadian Standards Association] standard." (P17_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)		Chunks from Transcripts
	Parameters other than stated in the Canadian Standards Association	HHD-1	• No
		HHD-2	• "If we [referring to the home program] are testing for rural. So, [if] we are testing well water, then we have an expanded test group. So, we would include things like in addition to the regular spectrum we also include hydrocarbons. Some other stuff, like, [name of the province] has lot of agriculture lands so agricultural run-off, pesticides, etc." (P8_Unit Manager) • "Ya, so for municipal anybody in town. [In] rural [areas], if they [referring to patients] are on well water we have different parameters that we test that they are much more stringent then just municipal." (P9_Clinical Manager) • "Now, if we [referring to the home program] are doing well water samples, [then] there is [are] a couple of tests that [name of the city] lab [laboratory] cannot handle. So, they (referring to the laboratory) send it [referring to water samples for chemical analysis of water for dialysis] off to [name of the city], and I am not sure if it is for petroleum or pesticides, herbicides, [and] stuff like that." (P9_Clinical Manager) • "Participant: Well, when we went to [name of the laboratory] labs to get the chemical analysis done, we sat down and we went through everything that we think we need to go through. Like our [name of the laboratory] lab testing is following the CSA and the Canadian drinking guidelines. But, it is much more even than that so we are bringing in. Like, we are testing lots of stuff, and [all those] stuff that are not even in the CSA and the ISO [International Standards Organization] or Canadian drinking guidelines.; Researcher: Can you give us some examples; Participant: Ohh..like there is just so many elements that we are testing for them. Ya, I am not sure if we are doing municipal testing say from for the city of Calgary we are doing pretty extensive testing on that. But, we do not do on that packing we are not doing herbicides or pesticides or petroleum. We are not testing that. But, we do that on rural patients for well water. So, like we are going for hydrocarbons like that in there. So, we do reference Canadian drinking guidelines for a lot of that. But, there are even stuff that are not even in the Canadian drinking guidelines that we are testing them. I don't know what [name of the laboratory] lab is referencing those tests." (P9_Clinical Manager)
		HHD-3	• "The testing matches [with] what is required to meet Canadian drinking standards, [and] chemicals that are being looked for are radionucleotides." (P116_Technical Manager)
		HHD-4	• "Occasionally, [name of the Chief BioMedical Engineer] and I were chatting that there are requests to do some specific microbiologic testing." (P13_Medical Director) • "For example, here we have to test for radon and uranium in some locations." (P14_Chief BioMedical Engineer) • "We worked a little bit close to [name of the government department related to drinking water quality], because they monitor [drinking water quality]. So, they have a good idea of [different regions' water quality in the province]. If I am going into one region and patient is on a well, I can call the department of environment and they can give me a good idea of things to look out for because of what is naturally occurring in the area. Like here in [name of the province] one of the problem is uranium. There is [a] lot of uranium in the ground where [name of the

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)		Chunks from Transcripts
			province] sits on. So, it is something the CSA does not require us to test for. But, it [referring to Radon] is just something that we learned over time through the department of environment that perhaps something you might want to check for and we do. And that is why we do if they [referring to patients] are in that region. If they [referring to patients] are on a municipal supply, [then] we do not ask for uranium test." (P14_Chief BioMedical Engineer) • "Radon, yes, [we measure it]. Radon can be in the form of gas that's a bigger problem. I mean we were in the situation where radon was detected in people's basement in the air. It is something to be aware of." (P14_Chief BioMedical Engineer)
		HHD-5	• "Certainly, not Legionella. We [referring to the home program] are not testing specifically for any type of microorganism." (P19_Retired Technical Manager) • "Volatile organic and semi-volatile organic like pesticides, herbicides, and so on" (P19_Retired Technical Manager) • "But, they [referring to patients] tested for chloramine before the [dialysis] treatment on water treatment system." (P19_Retired Technical Manager) "Now, apart from that on a yearly or every 6 months depending on the water system set up in the home program the water sample for microbiology was also taken to a private lab to validate our internal testing. So, we [referring to the in-house technicians of the home program] took down to the [name of the provincial] lab where they did E. coli [Escherichia coli], total coliforms, and plate counts as well for us. And these was done at the same time as we did the environmental water test for other contaminants like feed water, organics and so on. If they were on water well, if home patients were on water well we would do complete feed and product analysis once every 6 months and that was including total coliforms, E. coli [Escherichia coli], and plate counts. We did for city water as well except for city water we did them as once a year as oppose to once in every 6 months." (P19_Retired Technical Manager)
		HHD-6	• "So, we follow the CSA [Canadian Standards Association] standard." (P17_Medical Director)
Sample Locations	**HHD-1**		• "No, they do one sample." (P6_ Unit Manager) • "They [referring to patients] collect it [referring to the sample] from the dialysate water, which has, which be the end point." (P6_ Unit Manager) • "When the technicians go out [to patients' home], they test [from] both the RO [reverse osmosis] and the machine." (P6_ Unit Manager)
	HHD-2		• "We take it [referring to the sample] from the treated water from the dialysis machine." (P7_Medical Director) • "So, we [referring to the home program] use dialysate as a proxy for the system. So, we would take a dialysate sample." (P8_ Unit Manager) • "So, on the blue dialysate line [of hemodialysis machine], we have a sample port and that is where we take the water sample from." (P9_Clinical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-3	• "The water quality piece they [referring to patients] would check [from reverse osmosis]." (P16_Technical Manager) • "Yes, [from post-deionizer]." (P16_Technical Manager)
	HHD-4	• "We just do the product water, but we take it from [a] dialysis machine. What we do is we are running the RO [reverse osmosis], and will run the dialysis machine just in a rinse mode just processing the water. We would sample from the sample port of dialysis line. So, that way we are covering most of the plumbing." (P14_Chief BioMedical Engineer)
	HHD-5	• "From the dialysis machine what we did is we did the microbiology [and] endotoxin testing on the day of the sampling as well. On the water treatment system, the microbiology including endotoxin testing on the water treatment system, we did that post-installation, [and then] we did [that] once per month. We did [sampling] both product water and dialysis machine as well [during routine operation]." (P19_Retired Technical Manager) • "That is right. What they [referring to the home program] did is they basically they took the water sample from one of the dialysate line[s] on HD machine." (P19_Retired Technical Manager) • "If we talk about microbiology, we [referring to the home program] took two samples." (P19_Retired Technical Manager) • "For the product water we [referring to the home program] would collect it, we had a quick connection between the RO [reverse osmosis] and dialysis machine. So, my [in-house technical] staff disconnected [the] line before it got into dialysis machines. They could disconnect it right at the output of dialysis machine and then we would wash this into a bucket for like 60 secs and then they [referring to in-house technical staff] would take the sample." (P19_Retired Technical Manager)
	HHD-6	• "So, number one we test the water going in to the system, once it goes into the system. NxStage, the system, will let the patient dialyse, once the PAK [Pure Flow SL Purification] is quality checked for dialysate which it generates." (P17_Medical Director)
Sample Collection	**HHD-1**	**<u>The below quotations are related to the internal protocol of HHD-1 that existed before 2019:</u>** • "So, they [referring to patients] are provided with all the equipment they need to do the sample [for assessing microbial quality of water for dialysis]." (P6_Unit Manager) • "Patients at home take samples of water and send it in to lab for analysis." (P2_BioMedical Engineering Technologist) • "The sampling process is to [first] clean the ports and then withdraw 20 mls [millilitres] and discard [that]. Then, they [patients] would need a new clean syringe to get [an] another sample." (P6_Unit Manager) • "They [referring to in-house technicians] go into the home to service the machine and they usually do their own water samples at that point as well to verify and they reiterate [the significance of sampling] with patient[s]. So, water sampling at that point as well." (P6_Unit Manager) • "In addition, at around 3 months [of] interval our technologists are also on the road going into the patients' home to do preventative

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		maintenance. So, at that time they may do water sampling themselves, if the patient has not done it [referring to sampling] the way the otherwise they are asked to do it. [The in-house technicians] might troubleshoot the machines [and] do whatever needs to happen for their routine preventative maintenance." (P5_Medical Director) • "We [referring to in-house technical team] are now committed just recently to taking a water sample [for those] patients that are not in-compliance and are ensuring that we get a minimum water sample every 3 months instead of every month." (P1_Clinical Manager) **<u>The below quotations are related to the internal protocol of HHD-1 being followed after 2019:</u>** • "Now, the last time when we [referring to the interview with the researcher] met our patients were sampling their water on monthly basis. Since then we made a change to them. We do not ask patients to sample water samples anymore." (P2_BioMedical Engineering Technologist)
	HHD-2	• "We [referring to the HHD-2] expect our patients to do the water quality monitoring right so they have to do sampling." (P7_Medical Director) • "The [in-house] technicians will go out every three months to change the ultrafilters on the back of the dialysis machine. And when they do that the techs will then get the samples." (P7_Medical Director) • "We [referring to the home program-2] depend on our patients to do [microbial sampling]." (P8_Unit Manager) • "We ask patients to do their own samples. But, we [referring to in-house technicians] change carbon filters on the portable RO [reverse osmosis] systems every three months. So, we are trying to, the techs will take a sample when they go out and do those filters so we have at least one water sample every three months from patients." (P9_Clinical Manager) • "Ya, there is a whole procedure that the nursing staff [and in-house] technicians go over with patients for obtaining a sample. So, [a] part of that is cleaning that sample port and then you know once you clean it you use alcohol to clean it. Then you flush it [referring to the water coming out from the reverse osmosis] and then you take your sample." (P9_Clinical Manager) • "We want to do our sampling that is far away from a disinfection as possible, right. [So,] you do not want to do a sample right after your disinfection." (P9_Clinical Manager) • "Well, if there are some patients on the program that are just physically unable to do their samples, whether [it is] due to an age factor or physical limitations right, [then] we would look at that and would say ok for this patient we need to be out there on monthly basis doing monthly samples. We [referring to the home program] do that. There are probably may be 6 or 8 patients that we do have like that. We have identified those patients, [and] say ok they cannot do their samples on monthly basis so we need to go and do for them. So, we [referring to the HHD-2] do look at that." (P9_Clinical Manager)
	HHD-3	• "Patients are taught to sample their own microbiology at monthly basis and again all is centrally managed through Baxter." (P15_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "We are partnering with them [third party vendors] so that they are providing us with the expertise. They are making their recommendations, we implement it, and we go back and we follow-up to make sure that it is working and ultimately it is us who as the provincial renal program signing off .. the local health authority program that are signing off on it." (P15_Medical Director) • "So, they [referring to vendors] go once or twice a year, depending upon where the patient lives and does the sampling for us." (P16_Technical Manager)
	HHD-4	• "Sample collection that patient does really come from us from the home program. We are using just really indicator bacteria not full proof count that what do you see in the lab [laboratory]. You know bacteriology lab [laboratory]. So, they [referring to patients] use what is called red pallet that is a bacterium medium. They [referring to patients] soak the medium in the water and let it sit for 24-hour period." (P14_Chief BioMedical Engineer)
	HHD-5	• "So, every month we had a group of technologists that would go around and visit a home patient and then they would have a quick look at the equipment. But, at the same time they would pull water sample for micro [microbials] and endo [endotoxins] testing." (P19_Retired Technical Manager) • "These samples were taken into specific containers that the lab provided to us and they were put into a cooler with ice pack. Then, they [referring to in-house technicians] would be taking them right to the lab once they are back in the city." (P19_Retired Technical Manager)
	HHD-6	• "They [referring to in-house technicians] also subsequently arrange monthly water testing for endotoxins and things like that in nature ..hmm sometimes I think they [referring to in-house technicians] go out. I think more often times they shipped to central location and then they have third party to do most water testing for us." (P17_Medical Director) • "Patients send it [referring to microbial samples] in. I am not sure they send it to third party tester or us [referring to the home program]. But, patients have to do it. Although we keep a log of it." (P17_Medical Director)
Sample Transportation	**HHD-1**	• "So as part of the training we have them [referring to patients] research where is the closest Purolator to drop off their sample. So, they are provided with all the equipment [that] they need to do the sample and a thermal kit to put it [referring to samples] in and then the Purolator's bags and the labels." (P6_Unit Manager) • "It [referring to microbial samples] is get sent by UPS to [name of a city]." (P6_Unit Manager) • "[Name of a courier company] will pick it [referring to microbial samples] up in some places." (P6_Unit Manager) • "The patient can drop it [referring to microbial samples] off at the [name of a courier company] or can have [name of a courier company] come pick it up at their home." (P1_Clinical Manager) • "Normally, actually we did try that courier service will go to patients' home. We didn't find them reliable enough and so we ended up having to teach patients to take it to drop/pick up location rather than wait for courier company to come by." (P2_BioMedical Engineering Technologist)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "We [referring to in-house technicians] get the samples from the patient's home. We take a kit to the patient's home and in that kit [there will be] all the sample bottles, the shipping bag, and an icepack. So, when the samples are taken they are placed in the bag with an ice pack and we use the [name of a courier company] to ship the stuff over to [name of a city]." (P2_BioMedical Engineering Technologist) • "Usually, we [in-house technicians] try to if there is a [name of a courier company] drop off point near the patient's place, [then] we just drop it there. Most of the time that is how we do it in [name of a city]. Even when we are doing outside of [name of a city], if we know of a [name of a courier company] drop-off point then we drop them. Because, otherwise it takes too long to bring it [referring to the collected sample] here [at the healthcare facility] and then get the [name of a courier company] pick it up from here [referring to a healthcare facility]." (P2_BioMedical Engineering Technologist)
	HHD-2	• "Then, they [referring to patients] basically [name of a courier company] or [name of a courier company] the samples to a laboratory [located] in [name of a city] that does the analysis." (P7_Medical Director) • "The courier [service] is supposed to pick up at their [referring to patients] location." (P8_Unit Manager) • "When they [referring to patients] get their dialysate supplies from [name of a laboratory], there is a kit for the water samples that go out. So, in that kit there are instructions [on how] to call the courier to pick up the [collected] samples. They [referring to the collected sample] goes into a cooler bag, [then] there is an ice pack that goes in there and then sample too as well. So, patients take a sample in the tube, [it] goes into the ice pack or into the cooler pack, ice pack goes in there [referring to the sampling bag]. And [then], they call, I think, we [referring to the HHD-2] are using or [name of a laboratory] uses [name of a courier company]. [They] pick it up and deliver directly it to the [name of a laboratory]." (P9_Clinical Manager) • "If the techs [referring to in-house technicians] are out and doing the filter changes, then the techs will pick [up] the sample and deliver it to [name of a laboratory] themselves." (P9_Clinical Manager) • "We [referring to HHD-2] going to have those samples delivered it to the lab [laboratory] within 24 hours." (P9_Clinical Manager)
	HHD-3	• "So, the sample would go from patients to a third party laboratory organized by [name of a third party vendor]." (P15_Medical Director) • "We are trying to transport the samples in a timely manner, where we have up to 24 hours turn around time for the microbiology." (P15_Medical Director) • "The patient's responsibility is to take the sample and get it to a courier office. And then courier [office] will send it to the lab [laboratory]." (P16_Technical Manager) • "It [referring to microbial samples] has to be in labs [laboratory] within 24 hours." (P16_Technical Manager)
	HHD-4	• Note: Patients were responsible for the testing of total viable counts using a point-of-care testing, which eliminates the need of sample transportation. In routine times, endotoxins sampling were not collected monthly. Technicians were involved in microbiological sampling

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		during their preventive maintenance visits at patients' home. However, details were not discussed how the technicians specifically transport samples from patients' home to the laboratory.
	HHD-5	• "If we talk about microbiology, we [referring to HHD-5] took two samples. One [of the samples] they [referring to in-house technicians] took on the ice pack and then they took [it] as soon as they were back in the city they took [it] to our lab [laboratory] at the [name of the hospital campus]. And the endotoxins water sample, this sample was taken back to our lab [laboratory], our technical lab [laboratory] and technologists used the kit and did testing themselves. They were trained and they were shown how to do the LAL [limulus amebocyte lysate] testing." (P19_Retired Technical Manager) • "These samples were taken into specific containers that the lab [name of the provincial laboratory] lab provided to us [referring to HHD-5] and they were put into a cooler with an ice pack. Then, they [referring to in-house technicians] would be taking them right to the lab [laboratory] once they were back in the city." (P19_Retired Technical Manager) [Note: In this quotation, the participant is talking about the sample collection and transportation process for the testing of Escherichia coli and total coliforms]
	HHD-6	• "They [referring to in-house technicians] also subsequently arrange monthly water testing for endotoxins and things like that in nature ..hmm sometimes I think they [referring to in-house technicians] go out. I think more often times they shipped to central location and then they have third party to do most water testing for us." (P17_Medical Director) • "Patients send it [referring to microbial samples] in. I am not sure they send it to third party tester or us [referring to the home program]. But, patients have to do it. Although we keep a log of it." (P17_Medical Director)
Testing Site	**HHD-1**	• "Samples that [were taken by] patients on monthly basis, we [would] just do CFUs [colony forming units] and endotoxins testing on that only. We have the lab [laboratory] in [name of a city] that does the testing for us." (P1_Clinical Manager) • "Actually, we [referring to in-house technicians] started doing some of that [referring to in-house testing of endotoxin using a point-of-care testing device] ourselves. We have invested in finding that endotoxin testing ourselves. Therefore, what we started, we only started doing it recently. So, what we do is that when we find [any] issues with endotoxin [samples], [then at that time] rather than taking the samples and sending it to the laboratory [and] wait for the test results, we would do it on the spot." (P2_BioMedical Engineering Technologist) • "We can do a pre-test before we send the [endotoxin] samples in [name of a city], but it does not eliminate [us from] sending the samples to the laboratory." (P2_BioMedical Engineering Technologist)
	HHD-2	• "We [referring to HHD-2] got a handheld endotoxin meter that we can use if we need to [for endotoxin testing]." (P8_Unit Manager) • "But, most of our samples go to [name of a laboratory] and it is actually located in [name of a city]." (P8_Unit Manager) • "No, we send the samples to the lab [laboratory]. We have outsourced it [referring to the testing of water samples]. Therefore, it is all going to the company called [name of a laboratory]. So, we are sending all the water samples there." (P11_BioMedical Engineering Technologist)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "So, we [referring to HHD-2] use the [name of a laboratory] is the lab [laboratory]. We do our micro [microbiological] and endotoxin testing at that lab [laboratory]." (P9_Clinical Manager) • "Well, if we [referring to in-house technicians] have questions, [then] will take the meter [referring to point-of-care testing device] with us. If it [referring to the endotoxin sample] is failed couple of times, then we can do it on the spot. But, we do rely on the lab [laboratory] for that [endotoxin sampling]." (P9_Clinical Manager)
	HHD-3	• "I think it [referring to sample for microbiological testing] is going to [name of a city] [and] not in [name of a province]. Yes, there is a lab [laboratory] in [name of a province] where we do the microbiology. But, the endotoxins is challenge and so…But, I believe that it [referring to the laboratory] is in [name of a city] where it has to get tested." (P16_Technical Manager) • "I think they [referring to sample for the testing of endotoxin and colony forming units] both go to a same place in [name of a city]." (P16_Technical Manager)
	HHD-4	• "So, our patients actually have [point-of-care testing device called as] pattels that they use to assess for CFU [colony forming units] and they do [the CFU testing] once a month." (P13_Medical Director) • "However, we do a lab [laboratory] check of CFU [colony forming units] and endotoxin whenever the machine is serviced, which could be minimum once a year." (P13_Medical Director) • "No, we use our own provincial laboratory and it is adjacent to our home dialysis facility." (P14_Chief BioMedical Engineer) • "We are using just really indicator bacteria really not full proof count that what do you see in the lab [laboratory]. You know bacteriology lab [laboratory]. So, they [referring to patients] use what is called red pallet that is a bacterium medium. They [referring to patients] soak the medium in the water and let it sit for 24-hour period." (P14_Chief BioMedical Engineer)
	HHD-5	• "If we talk about microbiology, we [referring to HHD-5] took two samples. One [of the samples] they [referring to in-house technicians] took on the ice pack and then they took [it] as soon as they were back in the city they took [it] to our lab [laboratory] at the [name of the hospital campus]. And the endotoxins water sample, this sample was taken back to our lab [laboratory], our technical lab [laboratory] and technologists used the kit and did testing themselves. They were trained and they were shown how to do the LAL [limulus amebocyte lysate] testing." (P19_Retired Technical Manager) • "Now, apart from that [referring to chemical testing parameters], on a yearly or every 6 months depending on the water system set up in the home program, the water sample for microbiology was also taken to a private lab to validate our internal testing [laboratory located within the hospital premises]. Therefore, we took down to the [name of a laboratory] lab [referring to the external laboratory] where they did E. coli [Escherichia coli], total coliforms and plate counts as well for us. And these was done at the same time as we did the environmental water test for other contaminants like feed water, organics and so on." (P19_Retired Technical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-6	• "They [referring to in-house technicians] also subsequently arrange monthly water testing for endotoxins and things like that in nature ..hmm sometimes I think they [referring to in-house technicians] go out. I think more often times they shipped to central location and then they have third party to do most water testing for us." (P17_Medical Director) • "Patients send it [referring to microbial samples] in. I am not sure they send it to third party tester or us [referring to the home program]. But, patients have to do it. Although we keep a log of it." (P17_Medical Director)
Testing frequency		
Source Water	**HHD-1**	• Source water is not tested during the routine operation
	HHD-2	• "We will do that [referring to testing of fungi and other microbiological parameters] in a source water sample and you know like if it is well water, then that is done again at the source water every six months." (P9_Clinical Manager)
	HHD-3	• "We sample feed water initially and then do it annually for chemical analysis and then dialysate on monthly basis ..or at least recommended on monthly basis." (P15_Medical Director)
	HHD-4	• "Well, what we do is for using a RO [reverse osmosis] system, we test their [referring to reverse osmosis device] water, [including] their feed water and their product water, the water for the dialysis machine, we check that once a year for the full CSA [Canadian Standards Association] requirement." (P14_Chief BioMedical Engineer) • "Yes, we collect feed water. We [also] collect product water [and] that [is] the water for dialysis machine." (P14_Chief BioMedical Engineer)
	HHD-5	• "At that time then we even before the decision was made to by the patient to go home dialysis or not we will take water sample of the feed water. Not only from the normally from metal or organic contaminants, but we would also test microbiology." (P19_Retired Technical Manager) • "On the day of the set up of the equipment, the technologists would take again a full water sample on the feed water and then they would do this on the product water once when the equipment is set up." (P19_Retired Technical Manager) • "If they [patients] were on water well, if home patients were on water well, [then] we [referring to in-house technicians] would do complete feed and product analysis once every 6 months and that was including total coliforms, E. coli, and plate counts." (P19_Retired Technical Manager) • "They [referring to in-house technicians] were trained and they were shown how to do the LAL [Limulus Amebocyte Lysate] testing. Now apart from that, on a yearly or every 6 months, depending on the water system set up in the home program, the water sample for microbiology was also taken to a private lab to validate our internal testing so we took down to the [name of the laboratory] laboratory

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		where they did E. coli [Escherichia coli], total coliforms, and plate counts as well for us. And these was done at the same time as we did the environmental water test for other contaminants like feed water, organics and so on." (P19_Retired Technical Manager)
	HHD-6	• Note: Information on sample locations could not be obtained during interview with the P17 of HHD-6.
Water for dialysis	**HHD-1**	• "They [referring to patients] definitely submit a water sample monthly [for microbial quality]. That is what we [referring to HHD-1] are expecting." (P1_Clinical Manager) • "They [referring to patients] only do endotoxins and bacterial testing, which is just a water sample." (P1_Clinical Manager) • "[The testing of] water quality, which is endotoxins and microbial test is done monthly." (P1_Clinical Manager) • "Samples that [are taken by] patients on monthly basis, we just do CFU [colony forming units] and endotoxins on that only. We have the lab. [laboratory] in Calgary that does the testing for us." (P1_Clinical Manager) • "Because the technicians goes to their [referring to patients] house every 3 months, so now we [referring to in-house technicians] are sampling at every 3 months. This thing started right after we started using the ultrapure filter on the dialysis machine." (P2_BioMedical Engineering Technologist)
	HHD-2	• "We expect them [referring to patients] to do it [sampling for microbial and endotoxin] monthly." (P7_Medical Director) • "If a patient is not doing this [referring to the sampling for microbial and endotoxin] on repeated basis, then the technicians put that patient on a schedule. They make sure that they collect the samples themselves for that patient at least quarterly, so that we have results quarterly for that patient." (P8_Unit Manager) • "[The testing of] microbiology, we [referring to HHD-2] are doing it monthly." (P9_Clinical Manager)
	HHD-3	• "For bacteriology, samples would be collected on monthly basis." (P15_Medical Director) • "So, they [referring to third party vendors] go once or twice a year, depending on where the patient lives and does the sampling for us." (P16_Technical Manager)
	HHD-4	• "We [referring to in-house technicians] do a lab check of CFU [colony forming units] and endotoxins whenever the machine is serviced, which could be minimum once a year." (P13_Medical Director) • "So, our patients actually have [point-of-care testing device called as] pattels that they use to assess CFU [colony forming units] and they do [its testing] once a month." (P13_Medical Director) • "We do monitor them [referring to Deionizers] twice as much as the RO [reverse osmosis] system; whereas compared to monthly." (P13_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-5	• "The [in-house] technical team would go once a month [for microbiological sampling]." (P19_Retired Technical Manager) • "If during the service call if we had to change an important component of water treatment system, let us say the RO [reverse osmosis] membrane became defective and needed to be replaced. Any of the major pre-treatment component, if we change them, we would redo a product and not the feed, but we will redo the product water analysis complete to external lab as well." (P19_Retired Technical Manager)
	HHD-6	• "They also subsequently arrange monthly water testing for endotoxins and things like that nature." (P17_Medical Director) • "The micro [microbial sampling] is dealing with water coming in to the system. So, we [referring to HHD-6] do that testing again on monthly basis." (P17_Medical Director)
Communication of Test Results	**HHD-1**	• "I guess it is [name of a laboratory] which is based in [name of a city] and then anytime there is an immediate fail we would get an alert or email from the lab [laboratory] that says there is fail and then usually week after that we get the printed report or the result [from the laboratory]. We usually get the preliminary alert [from the laboratory] about whether the system is failed or not." (P4_Nurse Practitioner) • "They [referring to the microbial test results received from the laboratory] go directly to the technicians and to [person responsible for quality within the hospital], and then I get copies after she has reviewed them." (P6_Unit Manager) • "I do get the [microbiological quality test] results. So, [name of the person responsible for quality within the hospital], is part of our quality and she will send the results to us [referring to HHD-1]. And we do and technicians will get copies of the results and so we do review which [samples] are positive and which [ones] are negative." (P6_Unit Manager)
	HHD-2	• So, it is me, but we have a distribution list. So, on that [list], there is myself, medical director, manager, all the technicians, and then it goes to I believe the nurse clinicians. But, they got their address set up for [name of the HHD-2 center] and then we also have a two nurse trainers in [name of a city] and [name of a city] so they are all on that list as well. So, you know one of us is in here [referring to the main centre of HHD], somebody is getting that result and can act on it." (P9_Clinical Manager) • "The [name of the provincial laboratory] sends me [the microbiological quality test results]. Every time, I get spreadsheet from [name of the laboratory] that shows results and they will tell me if there is any failures on that." (P9_Clinical Manager)
	HHD-3	• "So, the way the information would then flow is that it would come to the provincial working groups and largely if it is …We would only get engage with our water sample if they are all normal and everything…is you know if acceptable we would not really talk about it." (P15_Medical Director) • "The information [about the microbial test results] will then be returned to the training nurse who is the primary point of contact for it." (P15_Medical Director) • "Lab [laboratory] would just send the reports." (P16_Technical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-4	• "We do not do that regularly in our quarterly meetings. I think our technician side do that." (P13_Medical Director) • "At technical room, we [referring to in-house technical team] are the front line for [receiving] the [quality test] results. We draw the samples and we review results directly from the lab [laboratory] and it is up to me to interpret the results whether they are safe or not. If I find something that is at wack then I would contact the home hemo program and [name of the medical director of HHD-4]." (P14_Chief BioMedical Engineer) • "The way it works for us [is that] they [referring to the laboratory] email results. If there is a high count, [then] we do a 7-day [incubation] count, [then] we [referring to in-house technical team] ask them to report anything about 50 [colony forming units] after 2 days [of the first day of the analysis]." (P14_Chief BioMedical Engineer)
	HHD-5	• "The lab [laboratory] would process the sample and send us the [test] report." (P19_Retired Technical Manager)
	HHD-6	• "No, I don't review [water quality test results]. I outsource it to a technology manager. If there is problem with water quality it does get raised to me and the nursing staff." (P17_Medical Director)
Documentation of Test Results	**HHD-1**	• "Ya, we have one of our [in-house] technician that enters the [quality test results] data on the charts…on [excel] spreadsheets." (P2_BioMedical Engineering Technologist)
	HHD-2	• "So, I do have [the test results]. When it [referring to test results] comes, and I get the results from [name of the testing laboratory], so I have done a spreadsheet where I track all my [microbiological quality test] results in here." (P9_Clinical Manager) • "So, our test results, on chlorine and microbiology, they are on that spreadsheet and the results are send to our group of people. I enter all the results on the spreadsheet and that is on the network drive that anybody [from the HHD-2 team] can access [them]." (P9_Clinical Manager)
	HHD-3	• "The nurses will capture the microbiological data and enter into our system." (P15_Medical Director) • "The nurses would enter that into our central provincial renal database on our system." (P15_Medical Director) • "And we have, sitting on our group one of the biomedical engineer who would sort of largely take the lead in conjunction with the logistic supervisor from Baxter." (P15_Medical Director) • "I think, we are more confident in terms of our chemical because that is coming in more formally. So, we are having and that are signed off by the home training nurses and that becomes the part of their records. Again, the microbiological data as they come they are entered into our provincial database. So, they are going to be captured quite well. But, I think the "point-of-care" testing that is done is not and are not robustly reported." (P15_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-4	• "Record retention is the big problem. Where we can see some record retention is that they [referring to patients] are supposed to mark their monthly CFUs [colony forming units] tracks with those petals [referring to point-of-care testing device]. They are supposed to mark those petals and bring them to clinic. I don't look at those records, I will be honest. Usually, nurses review that information and if there is any big gap or anything that they are concern about, then they will bring it to my attention." (P13_Medical Director) • "So, they [referring to patients] keep regular logs for their monthly checks that accompanies them to their regular clinical visits and where it is reviewed by nurses." (P13_Medical Director) • "Yes, it is all part of BioMed Package. All our medical equipment we [referring to in-house technical team] have a recorded data base where we record all the equipment. We can upload water sample results, everything. The system is called [name of a software program]. It is dedicated for Biomedical, and it is designed for BioMedical equipment. Either dialysis machine or any other device. It is a wonderful database because we have access to history of machine from day it entered the building to the day we retire it. And we know everything that was done to it. It is a good system. Most BioMedical departments in the country would do something like that." (P14_Chief BioMedical Engineer)
	HHD-5	• "I think the role as a technical practice committee that we have set up in [name of a province] part of its role was to review like every time we met one is the technologist was responsible for showing a report that we produced on water results. So, we can have audited [test results] ourselves internally if we wish doing it this way. And on a quarterly basis, what I did is I would produce two types of reports one for microbiology testing and endotoxins, and one was on equipment maintenance. And these were like completion way of tasks as well as results and I would share these reports with physicians as well and the program lead like clinical director and clinical managers. I wanted to make sure we had [one word unclear] as much as possible with everybody. So, we shared those reports with them and they could keep it with them [unclear]. It was not like an internal audit, [but] just there needs to be more auditing you know at provincial level. But yes absolutely, there needs to be more auditing you know at the provincial level." (P19_Retired Technical Manager) • "One of the technologists in my team was Chair as committee as technical practice. And you know my role as technical manager was to co-ordinate the sharing of information across the program including infection control. They were always copied on our reports as well." (P19_Retired Technical Manager) • "Well, every month we have to provide to them [referring to the provincial healthcare agency], as part of our statistics, we needed to provide them the numbers of home visits that we perform, the number of carbon exchange tanks, DI [Deionizer] exchange tanks and the testing we did." (P19_Retired Technical Manager)
	HHD-6	• "Patients send it [microbial samples] in. I am not sure they send it to us or third party tester. But, patients have to do it. Although, we keep a log of it." (P17_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
Review of Test Results & Follow-ups	**HHD-1**	• "They [referring to patients] come in to the clinic every three months. But, there is monthly telephone visits as well. Then one of the questions on that, we have a questionnaire, one of them is when did you last do your water samples, any issues with the machines. So, that is usually we do have it once in a month, and nurses does that." (P6_Unit Manager) • "I do get the [microbiological quality test] results. So, [person responsible for quality within the hospital], is part of our quality and she will send the results to us [referring to HHD-1]. And we do and technicians will get copies of the results and so we do review which [samples] are positive and which [ones] are negative." (P6_Unit Manager) • "I don't know. I know there is a frequency of testing on the units and satellite units. But, I really don't know what the patient is doing." (P1_Clinical Manager) • "We get our [microbiological test] results back from our lab [laboratory]. They sent to us [referring to in-house technical team]. So, we know who has done the testing and what the results are for the testing. So, that is the overall process." (P2_BioMedical Engineering Technologist) • "Actually, it [microbiological test results] does come to us [referring to the technical team of the home program]. I don't deal with it myself anymore. But, somebody else from our department deals with that. But, it does come to us. I see it in my emails every weekend, we do get that ourselves….to us directly…and so we don't as a rule follow-up on patients that have not taken any samples. Because, in the past we found that to be just time wasting more than anything else." (P2_BioMedical Engineering Technologist) • "I have a list of patients that are coming to the clinic. I will have a look and see they have been doing water testing or not. Usually, I speak to them that hey you have been not doing your water testing …do you want me to go over through it to refresh your memory on how to do everything." (P2_BioMedical Engineering Technologist) • "Technicians are doing the follow-up, yes." (P2_BioMedical Engineering Technologist) • "So, now every month we do review of you know how many patients were sampling, [then] inform the units. If it [referring to microbiological test result] is a fail result, [then] we inform the unit." (P4_Nurse Practitioner) • "So, we have got the spread sheet on the shared drive. So, that is accessible to the home hemo technicians. So, [name of a technician] who is the BioMed has taken the lead into the water quality. So, any action that he does, for example, if it is fail, [then] it is highlighted [on the excel sheet]. If he has any actions from the BioMed, then they go into the spreadsheet along with a comment on what was done. So that we [referring to other technicians in the program] know whether it was addressed or not." (P4_Nurse Practitioner) • "Not really. We do not really make any report to send it somebody. They [referring to quality test results] are available on a shared drive. So, anybody manager or whoever wants to look, can have a look at it. We share with everybody, but do not actually prepare in particular just for the manager." (P2_BioMedical Engineering Technologist) • "So, I have really ever heard about water quality management issues when I am told about it from the technologist or the nurses." (P5_Medical Director) • "I only hear about it [microbiological quality results], if somebody has problems with learning some aspects of the procedure and you know it would not be necessarily be flagged or something specific for water treatment. If somebody was unable to master the management of water,

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		then they also could not master most of the other things related to the dialysis. So, water specifically would never really come to my attention to begin." (P5_Medical Director) • "I actually have never seen any of those test results. Now, I am sure if there were some you know really horrific things that have happened, that there is bacteria growing in somebody's water that made it unsafe for them [referring to patients] to dialyze, [then] somebody would tell me about that. But, I have not come across that." (P5_Medical Director)
	HHD-2	• "We [referring to HHD-2] kind of have a protocol. So, basically the sampling goes out, the [name of the laboratory] emails me and the head technician of the home hemo [hemodialysis] program. [Also], we [other staff of HHD-2] all get the results right away." (P7_Medical Director) • "Yes, I am copied on all of those results." (P7_Medical Director) • "I do not think that as the physicians looking after my patient I never have seen that here is the copy of last three months of water quality. I am wondering. Actually, I have never seen that. I see it as a director of the whole program." (P7_Medical Director) • "I think we ask them on a bi-monthly basis [that] whether they [referring to patients] are doing their microbiology. I think we follow up with that." (P8_Unit Manager) • "Again, their [referring to patients] microbiological results are all tracked on the spreadsheet and part of that is to actually help us to figure out who is not doing their testing [and] who do we need to put on the schedule so that we get a sample at least every three months." (P9_Clinical Manager) • "Yes, [name of the technical head of HHD-2], he does that [and] he is very good [in keeping the track of microbiological results]. He sits in his office all day. The input goes to him [and] he sees he does all data analysis. All the water quality results are going to him. He has got snapshot of everything [and] he is very good at record keeping. One thing he does is he has got excellent spread sheets for this [referring to microbiological test results], [and] so we [can] know who is doing what, what is the trend, [and] what is the data analysis. Basically, we [can] know everything [we need to know]." (P11_BioMedical Engineering Technologist) • "So, I do have, when it [referring to the microbiological results] comes. I get the results from [name of the laboratory]. I have done a spreadsheet to track all my results in there." (P9_Clinical Manager)
	HHD-3	• "So, the way the information would then flow is that it would come to the provincial working groups and largely if it is …We would only get engage with our water sample if they are all normal and everything…is you know if acceptable we would not really talk about it." (P15_Medical Director) • "But, basically we [referring to the team managing water-related aspects in HHD-3] would come together only if there was challenging water issue." (P15_Medical Director) • "We [referring to the HHD-3] have sitting on our group one of the biomedical engineers. [He] would sort of largely take the lead in conjunction with the logistic supervisor from Baxter." (P15_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "Not specifically. We have what is called quarterly business review meeting with vendors. Because we have two vendors we have two meetings and they have specific format measures to keep track of [the results]. The format measures are presented at the initial meetings. If water quality was a problem or an issue, [then] we would talk about it. But, not specifically we do not talk about water quality." (P16_Technical Manager)
	HHD-4	• "We [referring to the HHD-4] do not have [a] regular matrix in place to evaluate or assess water quality as a service standing item per se." (P13_Medical Director) • "They [referring to patients] are supposed to mark those petals and bring them to [the] clinic. I don't look at those records, I will be honest. Usually, nurses review that information and if there is any big gap or anything that they are concern about then they will bring it to my attention." (P13_Medical Director) • "When they [referring to patients] come in, they come in every 3 months, what they call as clinical visit. [At that time], nurse would review with them all their responsibilities, [such as] are you doing this and when did you do this." (P14_Chief BioMedical Engineer) • "They are supposed to bring it with them [referring to whether patients bring their point-of-care testing results during their clinical visit] and present it to nurse." (P14_Chief BioMedical Engineer)
	HHD-5	• " [Name of the retired technical manager of HHD-5] and I, when I originally became responsible for the home hemo program [as medical director], we sat down at that time and that was before the standards [referring to the home hemodialysis standards by the Canadian Standards Association] has been done. We talked about our water quality and what we were doing and each of the different patient's home to try and ensure their safety. Then, as we moved forward, if there were concerns based on well testing or whatever, [name of the retired technical manager] always included me on any of those email conversations about you people's well water. Also, whether or not any other sample have come back you know testing outside of the CSA [Canadian Standards Association] guidelines. So that was basically my …my oversight and being involved if we had values that were outside of the recommended ranges." (P18_Medical Director) • "I think the role as a technical practice committee that we have set up in [name of a province] part of its role was to review like every time we met one is the technologist was responsible for showing a report that we produced on water results. So, we can have audited [test results] ourselves internally if we wish doing it this way. And on a quarterly basis, what I did is I would produce two types of reports one for microbiology testing and endotoxins, and one was on equipment maintenance. And these were like completion way of tasks as well as results and I would share these reports with physicians as well and the program lead like clinical director and clinical managers. I wanted to make sure we had [one word unclear] as much as possible with everybody. So, we shared those reports with them and they could keep it with them [unclear]. It was not like an internal audit, [but] just there needs to be more auditing you know at provincial level. But yes absolutely, there needs to be more auditing you know at the provincial level." (P19_Retired Technical Manager) • "One of the technologists in my team was Chair of technical practice committee. And you know my role as technical manager was to co-ordinate the sharing of information across the program including infection control. They were always copied on our reports as well." (P19_Retired Technical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "Well every month we have to provide to them [provincial healthcare renal agency], as part of our statistics, we needed to provide them the numbers of home visits that we perform the number of carbon exchange tanks, DI exchange tanks and the testing we did." (P19_Retired Technical Manager)
	HHD-6	• "No, I do not review [water quality test results]. I outsourced [it] to a technology manager." (P17_Medical Director) • "No, if there is a problem with water quality, [then] it does get raised to me and the nursing staff." (P17_Medical Director) • "As a physician that [referring to reviewing of water quality results] is not my domain, and that is more technology manager domain. They delegate responsibility to ensure that patients' dialysis equipment generates high quality dialysate and that is really same as in-center. If there is any issue with [water quality], [then] technicians will raise it to the clinical team for the patient to stop dialysis until they have high quality dialysate so its really no different than any other aspect of our renal program here." (P17_Medical Director) • "We are not tracking [referring to water quality test results]. We [referring to HHD-6] try to develop a better a comprehensive quality improvement plan. We do have weekly patients rounds. For home hemo patients we try to establish a more of quality improvement program specifically, but we do not have anything formally in place which is a bit of a deficiency in the province right now." (P17_Medical Director) • "No, [I do not audit water quality test results]." (P17_Medical Director)
Trends Analysis	**HHD-1**	• "That is how we [referring to HHD-1] did the analysis of capturing how many patients have not tested. [We also look at reasons for] the water quality results that have failed [to understand] is it due to poor water quality or because of sampling technique." (P4_Nurse Practitioner)
	HHD-2	• "I know that our technical manager does a good job of trending microbiological results. So, we have a spread sheet that will do some of the work for us. It [is] posted and available to the teams both the technical and clinical teams." (P8_Unit Manager)
	HHD-3	• Note: The program collects and store information on quality test results, but it seems from the interview discussion that the program does not perform trends analysis. • "Not specifically. We have what is called quarterly business review meeting with vendors. Because we have two vendors we have two meetings and they have specific format measures to keep track of [the results]. The format measures are presented at the initial meetings. If water quality was a problem or an issue, [then] we would talk about it. But, not specifically we do not talk about water quality." (P16_Technical Manager)
	HHD-4	• "We [referring to the HHD-4] do not have [a] regular matrix in place to evaluate or assess water quality as a service standing item per se." (P13_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "They [referring to patients] are supposed to mark those petals and bring them to [the] clinic. I don't look at those records, I will be honest. Usually, nurses review that information and if there is any big gap or anything that they are concern about then they will bring it to my attention." (P13_Medical Director) • "When they [referring to patients] come in, they come in every 3 months, what they call as clinical visit. [At that time], nurse would review with them all their responsibilities, [such as] are you doing this and when did you do this." (P14_Chief BioMedical Engineer) • "They are supposed to bring it with them [referring to whether patients bring their point-of-care testing results during their clinical visit] and present it to nurse." (P14_Chief BioMedical Engineer) • "Yes, it is all part of BioMed Package. For all our medical equipment, we [referring to in-house technical team] have a recorded data base where we record all the equipment. We can upload water sample results, everything. The system is called [name of a software program]. It is dedicated for Biomedical, and it is designed for BioMedical equipment. Either dialysis machine or any other device. It is a wonderful database because we have access to history of machine from day it entered the building to the day we retire it. And we know everything that was done to it. It is a good system. Most BioMedical departments in the country would do something like that." (P14_Chief Biomedical Engineer) • "What we do is when we go every time we go for service, maintenance or repair maintenance, we will ask the patient for this charts [of process parameters and disinfection] that he fills out. Then, we will review it right on site. Basically, we see that RO [reverse osmosis] can measure the quality of the feed water and that's mainly what we are interested in. Because, we know that feed water can change. It does [change] over seasons and what not. And this helps us tell if something is going wrong in the feed water and also by following the trend of the product water quality we can judge the quality of the membranes within the RO [reverse osmosis] because we can see like in over 8 months it targeted 4 micro-Siemens and now we are around 9 micro-Siemens. Ok, so membranes are getting either dirty or they are wearing out." (P14_Chief BioMedical Engineer)
	HHD-5	• "Well every month we have to provide to them [provincial healthcare renal agency], as part of our statistics, we needed to provide them the numbers of home visits that we perform, the number of carbon exchange tanks, DI [Deionizer] exchange tanks, and the testing we did." (P19_Retired Technical Manager)
	HHD-6	• "No, I do not review [water quality test results]. I outsourced [it] to a technology manager." (P17_Medical Director) • "No, if there is a problem with water quality, [then] it does get raised to me and the nursing staff." (P17_Medical Director) • "As a physician that [referring to reviewing of water quality results] is not my domain, and that is more technology manager domain. They delegate responsibility to ensure that patients' dialysis equipment generates high quality dialysate and that is really same as in-center. If there is any issue with [water quality], [then] technicians will raise it to the clinical team for the patient to stop dialysis until they have high quality dialysate so its really no different than any other aspect of our renal program here." (P17_Medical Director) • "We are not tracking [referring to water quality test results]. We [referring to HHD-6] try to develop a better a comprehensive quality improvement plan. We do have weekly patients rounds. For home hemo patients we try to establish a more of quality improvement

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		program specifically, but we do not have anything formally in place which is a bit of a deficiency in the province right now." (P17_Medical Director) • "No, [I do not audit water quality test results]." (P17_Medical Director)
Routine monitoring (chemical)		
Sample Locations	**HHD-1**	• Post-reverse osmosis
	HHD-2	• "So, after we [referring to in-house technicians] install, we do annual testing on the source water, but we do it on post-RO [reverse osmosis] for the patients on municipal water supplies. If patients [are] on well water, [then] we do it twice a year, and we will do a both pre-RO and post-RO because we want to make sure that well water is still usable for the patients." (P9_Clinical Manager)
	HHD-3	• "Yes, it is achievable and the chemical analysis is of really feed water and also [of] the RO [reverse osmosis] quality." (P16_Technical Manager)
	HHD-4	• "We test their water, [which is] their feed water and their product water. So, the water for the dialysis machine we check that once a year for the full CSA requirement." (P14_Chief BioMedical Engineer) • "Yes, we collect feed water and we collect product water that is the water for dialysis machine." (P14_Chief BioMedical Engineer) • "We just do the product water, but we take it from dialysis machine. What we do is we are running the RO [reverse osmosis], and will run the dialysis machine just in a rinse mode just processing the water. We would sample from the sample port of dialysis line. So, that way we are covering most of the plumbing." (P14_Chief BioMedical Engineer)
	HHD-5	• "Any of the major pre-treatment component, if we change them, we will redo a product and not the feed, but we will redo the product water analysis complete to external laboratory as well." (P19_Retired Technical Manager)
	HHD-6	• Note: Information on sample locations could not be obtained during interview with the P17 of HHD-6.
Sample Collection	**HHD-1**	• "So, each of those chemical collections are done by [in-house] technicians. So, they are then sent to labs [laboratory] by ourselves." (P2_Biomedical Engineering Technologist)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-2	• "That is right, we [referring to in-house technicians] collect it [referring to chemical quality test results]." (P8_ Unit Manager)
	HHD-3	• "….and then they [referring to third party vendors] co-ordinate for the annual testing thereafter for chemical analysis. They co-ordinate and they plug-in those samples and analyze those samples." (P15_Medical Director) • "We are partnering with them [third party vendors] so that they are providing us with the expertise. They are making their recommendations, we implement it, and we go back and we follow-up to make sure that it is working. Ultimately, it is us who as the provincial renal program signing off, the local health authority program that are signing off on it." (P15_Medical Director)
	HHD-4	• "Exactly that's right [referring to testing of chemical quality of water for dialysis annually and bi-annually depending on the source origin of source water]." (P13_Medical Director) • "When we [referring to in-house technicians] give the sample for the lab [laboratory], when they do the yearly sample for all the metals and everything it's a 1 litre sample and there is a separate bottle for mercury. Because, for mercury, the collected water has to be in a brown glass bottle." (P14_Chief BioMedical Engineer)
	HHD-5	• " [In-house] technical guys do that [referring to microbiological and chemical testing and maintenance]." (P18_Medical Director)
	HHD-6	• "So, we have in our program got technology manager and the technology manager directs a number of dialysis technicians who go out to patients' homes to do a patient assessment on the home for water quality. And then they also assess again plumbing capacity, and so on. They also subsequently arrange monthly water testing for endotoxins and things like that nature. I think they go out I think more often times they shipped to central location and then they have third party to do most water testing for us." (P17_Medical Director) • "Patients send it [referring to microbial test results] in. I am not sure they send it to us or third party tester, but patients have to do if. Although we keep a log of it [referring to microbial test results]." (P17_Medical Director)
Sample Transportation	**HHD-1**	• "So, each of those chemical collections are done by technicians. So, they are then sent to labs [laboratory] by ourselves." (P2_BioMedical Engineering Technologist)
	HHD-2	• Note: Samples are sent to the laboratory, located near the in-center, by in-house technicians. Technicians collect the samples and send them to the laboratory in their own vehicle. However, transportation of samples to the laboratory by technicians in their vehicle may not be applicable for the patients who are located at far distance from the in-center facility. • "You get to make sure that those samples are refrigerated before you get [them] to the laboratory. Because, if they are not, winter time should not be a big problem, but summer time it gets hot in the vehicles." (P9_Clinical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-3	• Note: Third party vendors are responsible for arranging the sample collection for ensuring chemical quality and sending them to laboratory. No information available on how the vendors send the samples to the laboratory. • "Yes, the water sample is sent by the vendor to a lab [laboratory] and the lab [laboratory] tests it for all of those contaminants [referring to chemical contaminants]." (P16_Technical Manager)
	HHD-4	• Note: In-house technicians were involved in the sampling for the verification of chemical quality of source water and water for dialysis. However, details were not discussed how the technicians specifically transport samples from patients' home to the laboratory. • "Exactly that's right [referring to testing of chemical quality of water for dialysis annually and bi-annually depending on the source origin of source water]." (P13_Medical Director) • "When we [referring to in-house technicians] give the sample for the lab [laboratory], when they do the yearly sample for all the metals and everything it's a 1 litre sample and there is a separate bottle for mercury. Because, for mercury, the collected water has to be in a brown glass bottle." (P14_Chief BioMedical Engineer)
	HHD-5	• "We (referring to in-house technical team] use the lab [laboratory] in [name of the province] called [name of the laboratory]." (P19_Retired Technical Manager)
	HHD-6	• Note: Information could not be obtained from the participant of HHD-6. • "So, we have in our program got technology manager and the technology manager directs a number of dialysis technicians who go out to patients' homes to do a patient assessment on the home for water quality. And then they also assess again plumbing capacity, and so on. They also subsequently arrange monthly water testing for endotoxins and things like that nature. I think they go out I think more often times they shipped to central location and then they have third party to do most water testing for us." (P17_Medical Director)
Testing Site	**HHD-1**	• "So, each of those chemical collections are done by technicians. So, they are then sent to labs [laboratory] by ourselves." (P2_BioMedical Engineering Technologist)
	HHD-2	• So [name of the laboratory] has a laboratory at [name of the city]. So, their lab [laboratory] [is located] in [name of the city]. So, my understanding is that they can do basic tests in [name of the city]. There are bunch of tests they are not going to test for with respect to rural stuff. My understanding is that the [name of the laboratory] actually has a lab [laboratory] in [name of the city] and they send that those samples to [name of the city] because they don't have the capacity to do so [name of the city]. So, they would do that in [name of the city]." (P8_Unit Manager) • "Ya, the [name of the laboratory] is in [name of the city]. Now, if we are doing well water samples there are a couple of tests that [name of the city] lab [laboratory] cannot handle. So, they to send it off to [name of the city]. I am not sure if it is for petroleum, pesticides, or

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		herbicide and stuff like that. So, it is just that [name of the city] lab [laboratory] cannot handle it. So, there is a [delay in getting results]. I think we get our results within 7 days, but for those well water samples it could take over a week before we get them. [The reason being that] we get to wait once it comes from [name of the city]. But, we just deliver them to the lab [laboratory] in [name of the city] and then the [name of the city] lab sends it to the [name of the city] lab [laboratory].” (P9_Clinical Manager)
	HHD-3	• “So, typically, vendor takes the sample and send it to labs. I think the laboratory is located in [name of the province].” (P16_Technical Manager)
	HHD-4	• “When we [referring to in-house technicians] give the sample for the lab [laboratory], when they do the yearly sample for all the metals and everything it’s a 1 litre sample and there is a separate bottle for mercury. Because, for mercury, the collected water has to be in a brown glass bottle.” (P14_Chief BioMedical Engineer)
	HHD-5	• “We [referring to HHD-5] use the lab [laboratory] in [name of the province] called [name of the laboratory].” (P19_ Retired Technical Manager)
	HHD-6	• “Patients send it in [referring to microbial quality test results]. I am not sure they send it to us or third party tester, but patients have to do it.” (P17_Medical Director)
Testing Frequency	**HHD-1**	• “On the well water we test their [referring to patients] water twice a year for chemical analysis.” (P1_Clinical Manager) • “We are doing chemical samples at the time of installation. Thereafter, every year in the patients that have municipal supply, and every 6 months on patients that have well water or cisterns. So, we are doing every 6 months in those patients. And the technicians are doing all that.” (P2_BioMedical Engineering Technologist)
	HHD-2	• “We take the product water every year and send it to analysis. [We take sample] from reverse osmosis.” (P11_BioMedical Engineering Technologist) • “We do measure quite often every six months. We also measure incoming as well, tap water as well because their ground chemical changes, everything changes. [Therefore,] we measure twice a year both product and incoming [for patients living in rural areas].” (P11_BioMedical Engineering Technologist) • So, after we install we do annual testing on the source water….. If patients on well water we do it twice a year….(P9_Clinical Manager)
	HHD-3	• “and then do it annually for chemical analysis.” (P15_Medical Director) • “For well water, we do it every six months.” (P15_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-4	• "[The chemical quality testing of water for dialysis is done] annually in individuals who are having municipal water. We aim for twice a year in individuals who are having private water systems like wells." (P13_Medical Director)
	HHD-5	• "If feed water came from water wells then we would test on 6 months basis and if the city water was provided to home patients than we would test once a year." (P19_Retired Technical Manager) • "During the service call, if we had to change an important component of water treatment system, let us say the RO [reverse osmosis] membrane became defective and needed to be replaced. Any of the major pre-treatment component, if we change them, we would redo a product and not the feed, but we will redo the product water analysis complete to external lab as well." (P19_Retired Technical Manager)
	HHD-6	• Information could not be obtained from the participant of HHD-6.
Documentation of Test Results	**HHD-1**	• "The chemical analysis we still working on right now, such as where we have been stored [storing its results]. We have it stored, but we are not sure who is actually monitoring it [and] who is actually analyzing it. We are still working on that because there has been a little bit of a change. So, we are trying to re-work on how it is going to be done." (P2_BioMedical Engineering Technologist) • "So, at the moment we had an incident last week where one of the chemical analysis was above allowable limits and the lab [laboratory] called me and we re-sampled. So, I am waiting for the result to come back from the resampling. We just file everything [referring to chemical quality test results] and we have it on computer. But, I don't think we are keeping a good record so that we can trend it and see what is going on with that so we are not doing that yet. But, I know it is being stored. We have not just got somebody designated to look after that properly." (P2_BioMedical Engineering Technologist)
	HHD-2	• Not clear whether the procedure followed for the documentation and tracking of microbiological results is also being followed for the chemical quality test results. • "We don't have lot failures when we are testing the source water especially in Calgary or any municipality when its already treated water we do have ahhhh..couple of patients on well …before even we even I get those results and then I will review it …I will run it through an analysis I have got spreadsheet so I have got all my parameters from the Canadian drinking water guidelines and CSA standards that what we need to meet for dialysis quality water. So, I run it through that and if it does not meet that then I will go to one of our vendors and get them to run it again. And then see what we can do for pre-treatment to treat that water if possible. Sometimes, it is not just possible to treat the water so then we let the patient know and they are not suitable for the home program" (P9_Clinical Manager) • Yes, he [clinical manager of HHD-2] does that [referring to the data analysis of quality results]. He is very good. He sits in his office all day. The input goes to him, see he does all data analysis. All the water quality results are going to him. He knows everything. He has got [a] snapshot of everything. He is very good at record keeping. One thing he does is he has got excellent spread sheets for this, so we know

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		who is doing what and what is the trend [and] what is the data analysis. So we know everything." (P11_BioMedical Engineering Technologist)
	HHD-3	• "The information would then be returned to the training nurse who is the primary point of contact for it. For the chemical analysis, it is really just kept on record and as long as it needs to be as per requirements." (P15_Medical director) • "I think we are more confident in terms of our chemical, because that is coming in more formally. So, we are having and that are signed off by the home training nurses and that becomes the part of their records. Again, the microbiologic data as they come they are entered into our provincial database. So, that is going to be captured quite well. But, I think the "point-of-care" testing that is done are not robustly reported." (P15_Medical Director)
	HHD-4	• "Yes, for the RO [reverse osmosis]. We have them [referring to patients] check. We have them log the RO [reverse osmosis]. We have log in chart. So, what the patient does each week that he runs the RO [reverse osmosis] and he records the bunch of numbers for us. So he is trained to how to get to access these number. [It is] just the matter of scaling up and down some menus on the RO [reverse osmosis] and with that we get water quality, temperature, flow, and the whole bit. They record for us every week." (P14_Chief BioMedical Engineer) • "Yes, it is all part of BioMed Package. For all our medical equipment, we [referring to in-house technical team] have a recorded data base where we record all the equipment. We can upload water sample results, everything. The system is called [name of a software program]. It is dedicated for Biomedical, and it is designed for BioMedical equipment. Either dialysis machine or any other device. It is a wonderful database because we have access to history of machine from day it entered the building to the day we retire it. And we know everything that was done to it. It is a good system. Most BioMedical departments in the country would do something like that." (P14_Chief Biomedical Engineer)
	HHD-5	• "I think the role as a technical practice committee that we have set up in [name of a province] part of its role was to review like every time we met one is the technologist was responsible for showing a report that we produced on water results. So, we can have audited [test results] ourselves internally if we wish doing it this way. And on a quarterly basis, what I did is I would produce two types of reports one for microbiology testing and endotoxins, and one was on equipment maintenance. And these were like completion way of tasks as well as results and I would share these reports with physicians as well and the program lead like clinical director and clinical managers. I wanted to make sure we had [one word unclear] as much as possible with everybody. So, we shared those reports with them and they could keep it with them [unclear]. It was not like an internal audit, [but] just there needs to be more auditing you know at provincial level. But yes absolutely, there needs to be more auditing you know at the provincial level." (P19_Retired Technical Manager) • "One of the technologists in my team was Chair as committee as technical practice. And you know my role as technical manager was to co-ordinate the sharing of information across the program including infection control. They were always copied on our reports as well." (P19_Retired Technical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "Well, every month we have to provide to them [referring to the provincial healthcare agency], as part of our statistics, we needed to provide them the numbers of home visits that we perform, the number of carbon exchange tanks, DI [Deionizer] exchange tanks and the testing we did." (P19_Retired Technical Manager)
	HHD-6	• "No, I do not review [water quality test results]. I outsourced [it] to a technology manager." (P17_Medical Director) • "No, if there is a problem with water quality, [then] it does get raised to me and the nursing staff." (P17_Medical Director) • "As a physician that [referring to reviewing of water quality results] is not my domain, and that is more technology manager domain. They delegate responsibility to ensure that patients' dialysis equipment generates high quality dialysate and that is really same as in-center. If there is any issue with [water quality], [then] technicians will raise it to the clinical team for the patient to stop dialysis until they have high quality dialysate so its really no different than any other aspect of our renal program here." (P17_Medical Director) • "We are not tracking [referring to water quality test results]. We [referring to HHD-6] try to develop a better a comprehensive quality improvement plan. We do have weekly patients rounds. For home hemo patients we try to establish a more of quality improvement program specifically, but we do not have anything formally in place which is a bit of a deficiency in the province right now." (P17_Medical Director) • "No, [I do not audit water quality test results]." (P17_Medical Director)
Review of Test Results	**HHD-1**	• "If we got a failure in anyone of those tests [referring to chemical quality test results], then you [need to] have to somebody that follows up on that too. So, we have in [someone] for [reviewing of] the bacterial microbiological testing [results]. We do have somebody that follows up on that. So, like I said [earlier], we are working through the process of who is assigned for the responsibility to follow-up through chemical testing." (P2_BioMedical Engineering Technologist) • "Not really. We do not really make any report to send it somebody. They [referring to quality test results] are available on a shared drive. So, anybody, manager or whoever wants to look, can have a look at it. We share [that] with everybody, but do not actually prepare in particular [a report] just for the manager." (P2_BioMedical Engineering Technologist) • "So, I have really ever heard about water quality management issues when I am told about it from the technologist or the nurses." (P5_Medical Director) • "I only hear about it [microbiological quality results], if somebody has problems with learning some aspects of the procedure and you know it would not be necessarily be flagged or something specific for water treatment. If somebody was unable to master the management of water, then they also could not master most of the other things related to the dialysis. So, water specifically would never really come to my attention to begin." (P5_Medical Director) • "I actually have never seen any of those test results. Now, I am sure if there were some you know really horrific things that have happened, that there is bacteria growing in somebody's water that made it unsafe for them [referring to patients] to dialyze, [then] somebody would tell me about that. But, I have not come across that." (P5_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-2	• Not clear whether the procedure followed for the documentation and tracking of microbiological results is also being followed for the chemical quality test results. • "We don't have lot failures when we are testing the source water especially in Calgary or any municipality when its already treated water we do have ahhhh..couple of patients on well …before even we even I get those results and then I will review it …I will run it through an analysis I have got spreadsheet so I have got all my parameters from the Canadian drinking water guidelines and CSA standards that what we need to meet for dialysis quality water. So, I run it through that and if it does not meet that then I will go to one of our vendors and get them to run it again. And then see what we can do for pre-treatment to treat that water if possible. Sometimes, it is not just possible to treat the water so then we let the patient know and they are not suitable for the home program" (P9_Clinical Manager) • Yes, he [clinical manager of HHD-2] does that [referring to the data analysis of quality results]. He is very good. He sits in his office all day. The input goes to him, see he does all data analysis. All the water quality results are going to him. He knows everything. He has got [a] snapshot of everything. He is very good at record keeping. One thing he does is he has got excellent spread sheets for this, so we know who is doing what and what is the trend [and] what is the data analysis. So we know everything." (P11_BioMedical Engineering Technologist)
	HHD-3	• "So, the way the information would then flow is that it would come to the provincial working groups and largely if it is …We would only get engage with our water sample if they are all normal and everything…is you know if acceptable we would not really talk about it. But, basically we would come together only if there was challenging water issue." (P15_Medical Director) • "We have the biomedical engineer in our group who would sort of largely take the lead in conjunction with the logistic supervisor from Baxter." (P15_Medical Director) • "We do every time we see the patients at clinic every 3 months. We really try to push them about please having the samples when they come in clinic. "But really, we are ensuring that we advise them that what they need to be doing and we check with them what we can get." (P15) • Not me specifically [review quality test results], mostly because I did not want them. But, the nurse the training nurse would get a copy of all those results." (P16_Technical Manager) • "Not specifically. We have what is called quarterly business review meeting with vendors. Because we have two vendors we have two meetings and they have specific format measures to keep track of [the results]. The format measures are presented at the initial meetings. If water quality was a problem or an issue, [then] we would talk about it. But, not specifically we do not talk about water quality." (P16_Technical Manager)
	HHD-4	• "We [referring to the clinical team] do not do that regularly in our quarterly meetings. I think our technician side do that." (P13_Medical Director) • "At technical room, we [referring to in-house technical team] are the front line for [receiving] the [quality test] results. We draw the samples and we review results directly from the lab [laboratory] and it is up to me to interpret the results whether they are safe or not. If I find

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		something that is at wack, then I would contact the home hemo program and [the medical director of HHD-4].” (P14_Chief BioMedical Engineer) • “We [referring to the HHD-4] do not have [a] regular matrix in place to evaluate or assess water quality as a service standing item per se.” (P13_Medical Director) • They [referring to patients] record for us every week. So, when the tech arrives [at patients’ home] for servicing, [then] he can take those charts and he can track trends. Right, he can tell oh you the water is getting worse. Right, he can just tell by the trending.” (P14_Chief BioMedical Engineer)
	HHD-5	• “I think the role as a technical practice committee, that we have set up in [name of the province], part of its role was to review like every time we met. One is the technologist was responsible for showing a report that we produced on water results. So, we can have audited [test results] ourselves internally if we wish doing it this way. And on a quarterly basis, what I did is I would produce two types of reports one for microbiology testing and endotoxins, and one was on equipment maintenance. And these were like completion way of tasks as well as results and I would share these reports with physicians as well and the program lead like clinical director and clinical managers. I wanted to make sure that we had shared this with as much as possible with everybody. So, we shared those reports with them and they could keep it with them [unclear]. It was not like an internal audit, [but] just there needs to be more auditing you know at the provincial level. But yes absolutely, there needs to be more auditing you know at the provincial level.” (P19_Retired Technical Manager) • “One of the technologists in my team was Chair in the technical practice committee. And you know my role as technical manager was to co-ordinate the sharing of information across the program including infection control. They were always copied on our reports as well.” (P19_Retired Technical Manager) • “Well every month we have to provide to them [referring to provincial healthcare renal agency], as part of our statistics, we needed to provide them the numbers of home visits that we perform, the numbers of carbon exchange tanks, DI exchange tanks and the testing we did.” (P19_Retired Technical Manager)
	HHD-6	• “No, I do not review [water quality test results]. I outsourced [it] to a technology manager.” (P17_Medical Director) • “No, if there is a problem with water quality, [then] it does get raised to me and the nursing staff.” (P17_Medical Director) • “As a physician that [referring to reviewing of water quality results] is not my domain, and that is more technology manager domain. They delegate responsibility to ensure that patients’ dialysis equipment generates high quality dialysate and that is really same as in-center. If there is any issue with [water quality], [then] technicians will raise it to the clinical team for the patient to stop dialysis until they have high quality dialysate so its really no different than any other aspect of our renal program here.” (P17_Medical Director)
• **Testing (Process Parameters)**		

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
Testing	**HHD-1**	• "So, they [referring to patients] do have to maintain the machines." (P6_Unit Manager) • "So, when they [referring to patients] set up the machine, they turn it on. Once its done, some of its [referring to process parameters] are self-checks [and] they do a chlorine test everyday." (P6_Unit Manager) • "We [referring to HHD-1] give them [referring to patients] these [chlorine] strips that they use for checking chlorine. So, basically they take a sample of the water from the cart (i.e. post carbon tank) and they use strips to find out [chlorine results]." (P2_BioMedical Engineering Technologist) • "So, prior to starting the dialysis, one of the routine checks is on the water treatment for chlorine and everything. But they do also check for residuals peroxides and residuals chemicals even before they actually start dialysis. So that is done daily at every run regardless of whether chemical disinfection was done or not. It is done all the time." (P2_BioMedical Engineering Technologist)
	HHD-2	• "Yes, we ask them [referring to patients] to do [verification of process parameters]." (P8_Unit Manager) • "Ya, we [referring to HHD-2] test for chlorine before each treatment." (P8_Unit Manager) • "We [referring to HHD-2] don't test for conductivity anymore. If there is anything else, post-disinfection we test…hmm....no…we don't even test for the post-disinfection. We don't even test for that chemical either." (P8_Unit Manager) • "It [referring to process parameters] is all manufacturers' recommended, because it is their system finally. But, we make sure that they [referring to patients] measure incoming water pressure, incoming water temperature, and pressure after first and second filter. Because those filters if [they are] plugging up fast, so we need to know pressure going to the RO [reverse osmosis]. On top of that we measure chlorine [from] first carbon and second carbon. So, [if] the first carbon [filter] is fine, [then the] second [carbon filter] has to be fine right. Chlorine has to be less than 0.1 ppm or g/l as per the CSA [Canadian Standards Association]. If it is more than that, [then] we have to change the filter out. (P11_BioMedical Engineering Technologist) • "Ya, patients do have their run sheet and on that run sheet there is a space to record the chlorine check." (P9_Clinical Manager)
	HHD-3	• "They [referring to patients] do have test strips and they are suppose to check it [referring to chlorine tests] before each dialysis." (P16_Technical Manager) • "Ahh..they [referring to patients] probably do [referring to verification of process parameters]. To be honest, I am not 100% sure what they would need to check in each time as before they run [their dialysis]. If there are challenges, they would be directed to me. But, I don't necessarily do it each time. But, they would need to check that the water treatment system is working [before dialysis]." (P16_Technical Manager)
	HHD-4	• "We [referring to HHD-4] train the patients how to do it [referring to the verification of process parameters and chlorine before dialysis] and also test for residual chemicals." (P13_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-5	• "So, basically, the home patient, before the treatment, like, the only involvement was testing really was the post-disinfection, because they were in charge of disinfecting their dialysis machines and water treatment system. They were in-charge of testing chemicals, if we use chemicals for disinfection. That was pretty much the standard. They used the test strips to confirm the chemical post-disinfection." (P19_Retired Technical Manager) • "So, they [referring to patients] did chemical disinfection once in a while on the system. But they tested for chloramine before the treatment on water treatment system." (P19_Retired Technical Manager) • "Because, in [name of the province], the city uses chloramine in the [drinking] water. So, we have patients testing chloramine. It is very similar test strips. It does job for both, but in [name of the province] we do chloramine." (P19_Retired Technical Manager)
	HHD-6	• Information could not be obtained from the participant of HHD-6.
Documentation of Test Results	**HHD-1**	• "So, every time they [referring to patients] have their dialysis, they keep a track [of process parameters and chlorine test results] on a flowsheet." (P6_Unit Manager) • "We [referring to HHD-1] do have a check list that patients complete on daily basis." (P2_BioMedical Engineering Technologist)
	HHD-2	• "We [referring to HHD-2] ask them [referring to patients] to document…right…then at every run they are supposed to write certain details down." (P7_Medical Director) • "On our treatment record sheet, we have a set of parameters that we ask them [referring to patients] to collect." (P8_Unit Manager) • "You know, it [process parameters and chlorine test results] goes on the treatment record now. We have made another form which is a treatment record form and we write it down. They [referring to patients] have to write down their treatment parameters right, [such as] weight removal, weight of blood pump speed and everything. The chlorine [results] goes on top of the form." (P11_BioMedical Engineering Technologist) • "The conductivity [of reverse osmosis], we ask them [referring to patients] to monitor." (P9_Clinical Manager) • "So, all of our chlorine and microbiology are on that spreadsheet and that results are send to our group of people. I enter all the results on the spreadsheet and that is on the network drive that anybody can access." (P9_Clinical Manager) • "There is no real log information on that [referring to disinfection]." (P9_Clinical Manager)
	HHD-3	• "We are relatively very low at documentation about the pre-testing. They [referring to patients] are supposed to be, but all of the time they do not." (P15_Medical Director) • "I think we are more confident in terms of our chemical, because that is coming in more formally. So, we are having and that are signed off by the home training nurses and that becomes the part of their records. Again, the microbiologic data as they come they are entered into our

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		provincial database. So, that is going to be captured quite well. But, I think the "point-of-care" testing that is done are not robustly reported." (P15_Medical Director) • "They [referring to patients] would log their treatment parameters more so than water quality levels. It is more of clinical recording. But, they are doing their testing and getting results etc..[and] yes they would log those as well."(P16_Technical Manager)
	HHD-4	• "Yes, we [in-house technical team] look into logs. So, home patients will log. We actually have log charts for RO [reverse osmosis]. We ask home patients to fill out that log each day prior to their treatments. There are series of parameters checks, things like water quality temperature, flow, and conductivity. It is more for the technical department than for anyone else. Later, we can take that log and review it and look at trends." (P14_Chief BioMedical Engineer) • Right, it [referring to recording of process parameters using a log book] is more of a support for the trouble shooting to ask us, we can ask our team what is going on with the water. Because, we are not there everyday, right, we have to have some kind of recording going on. So, patients [have] to do this. It is a very manual thing. It only takes about 5 minutes to do it every week." (P14_Chief BioMedical Engineer) • "Exactly, part of the trending we do is they [referring to patients] have to record all these dinfects [disinfection] as well. Even though we know the equipment is recording it. We don't necessarily tell the patient that. We want to make them pro-active right. We have log sheets for their disinfection, we have log sheets for RO [reverse osmosis] logging. So, basically that is just data from the RO [reverse osmosis] when it is running. And that is all monitoring data for the RO, [such as] seeing for quality, temperature, flow, and everything. That is really helpful for a technical person, actually for a RO [reverse osmosis] system because they do not stay the same. They eventually wear [out and] that is their nature. So, we get an idea where we are at for each RO [reverse osmosis]. So, when the patient finishes the treatment at home we take that log sheet with that RO and upload it to its database. So, we have that information in touch of few buttons. So, I go, that was a patient Jo Jo place, and he had a nasty well. So now, lets pull up the log up on that. So, next time the tech goes, he can go there and hey this used to be his own house so we know that he had water issues and that way we will know may be we should send techs [technicians] there. Let's take a closer look." (P14_Chief BioMedical Engineer) • "Yes, it is all part of BioMed Package. For all our medical equipment, we [referring to in-house technical team] have a recorded data base where we record all the equipment. We can upload water sample results, everything. The system is called [name of a software program]. It is dedicated for Biomedical, and it is designed for BioMedical equipment. Either dialysis machine or any other device. It is a wonderful database because we have access to history of machine from day it entered the building to the day we retire it. And we know everything that was done to it. It is a good system. Most BioMedical departments in the country would do something like that." (P14_Chief BioMedical Engineer)
	HHD-5	• "They [referring to patients] are supposed to put stuff on their records. I mean you can check the machine too obviously and our techs [technicians] do that when they go out to the patient, like you can check the RO [and] you can check the machine. But, they all are supposed to document their, like their chloramine strips were negative and, on this date, they did their disinfection. So, we get that information. [Such information was] brought in to me." (P18_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-6	• Information could not be obtained from the participant of HHD-6.
Review of Test Results	**HHD-1**	• "So, when they [referring to patients] come for their clinic, we ask them to bring their run sheets with them. So, every time, they have their dialysis, they keep a track on a flowsheet. [These include] their BP [blood pressure] and on it there is a safety check list that they check off. One of those things [on the safety check list] is [about] chlorine [test]. We ask if it is you know to tell us if it is positive or negative. Also, on our monthly calls that is one of the things we ask if you had a positive chlorine test in the past month and it just helps trigger the question." (P6_Unit Manager) • "So, we look at the [log] sheets to see if they are filling that piece out." (P6_Unit Manager) • "I don't know. I know there is a frequency of testing on the units and satellite units. But, I really don't know what the patient is doing." (P1_Clinical Manager) • "They [referring to patients] do not bring it in [and] there is no requirement for them to bring it in. It is basically, dialysis technician will go [to patients' home] and have a look and check to see where it is.]" (P2_BioMedical Engineering Technologist) • "We [referring to HHD-1] do not, because when they [referring to patients] are checking their chlorine they are supposed to be doing that every single time before they go on [for dialysis]. So, we do not log in [the chlorine results]. It is a common practice that you teach [them], so we do not log that." (P4_Nurse Practitioner) • "Not really. We do not really make any report to send it somebody. They [referring to quality test results] are available on a shared drive. So, anybody, manager or whoever wants to look, can have a look at it. We share [that] with everybody, but do not actually prepare in particular [a report] just for the manager." (P2_BioMedical Engineering Technologist) • "So, I have really ever heard about water quality management issues when I am told about it from the technologist or the nurses." (P5_Medical Director) • "I only hear about it [microbiological quality results], if somebody has problems with learning some aspects of the procedure and you know it would not be necessarily be flagged or something specific for water treatment. If somebody was unable to master the management of water, then they also could not master most of the other things related to the dialysis. So, water specifically would never really come to my attention to begin." (P5_Medical Director) • "I actually have never seen any of those test results. Now, I am sure if there were some you know really horrific things that have happened, that there is bacteria growing in somebody's water that made it unsafe for them [referring to patients] to dialyze, [then] somebody would tell me about that. But, I have not come across that." (P5_Medical Director)
	HHD-2	• "There is no real log information on that [referring to process parameters]." (P9_Clinical Manager)…
	HHD-3	• "Not specifically. We have what is called quarterly business review meeting with vendors. Because we have two vendors we have two meetings and they have specific format measures to keep track of [the results]. The format measures are presented at the initial meetings. If

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		water quality was a problem or an issue, [then] we would talk about it. But, not specifically we do not talk about water quality." (P16_Technical Manager)
	HHD-4	• "We [referring to the HHD-4] do not have [a] regular matrix in place to evaluate or assess water quality as a service standing item per se." (P13_Medical Director) • " [The in-house] technicians will check the [process parameters] records when the records are available. For example, the machine RO [reverse osmosis] has available records. The machine itself though we cannot back log to see that how often it is has been disinfected with our current old machine." (P13_Medical Director) • "What we do is when we [referring to in-house technicians] go every time we go for service or for the maintenance or repair maintenance, we will ask the patient for these charts that he fills out and then we will review them right on site. Basically, we see that RO [reverse osmosis] can measure the quality of the feed water and that is mainly what we are interested in because we know that feed water can change. It does change over the season and what not." (P14_Chief BioMedical Engineer) • "Exactly, part of the trending we do is they [referring to patients] have to record all these dinfects [disinfection] as well. Even though we know the equipment is recording it. We don't necessarily tell the patient that. We want to make them pro-active right. We have log sheets for their disinfection, we have log sheets for RO [reverse osmosis] logging. So, basically that is just data from the RO [reverse osmosis] when it is running. And that is all monitoring data for the RO, [such as] seeing for quality, temperature, flow, and everything. That is really helpful for a technical person, actually for a RO [reverse osmosis] system because they do not stay the same. They eventually wear [out and] that is their nature. So, we get an idea where we are at for each RO [reverse osmosis]. So, when the patient finishes the treatment at home we take that log sheet with that RO and upload it to its database. So, we have that information in touch of few buttons. So, I go, that was a patient Jo Jo place, and he had a nasty well. So now, lets pull up the log up on that. So, next time the tech goes, he can go there and hey this used to be his own house so we know that he had water issues and that way we will know may be we should send techs [technicians] there. Let's take a closer look." (P14_Chief BioMedical Engineer) • "When they [referring to patients] come in, they come in every 3 months what they call as clinical visit, nurse would review with them all their responsibilities. Are you doing this? Are you doing this? When did you do this?." (P14_Chief BioMedical Engineer)
	HHD-5	• "They [referring to patients] are supposed to put stuff on their records. I mean you can check the machine too obviously and our techs [technicians] do that when they go out to the patient, like you can check the RO [and] you can check the machine. But, they all are supposed to document their, like their chloramine strips were negative and, on this date, they did their disinfection. So, we get that information. [Such information was] brought in to me." (P18_Medical Director) • "I think the role as a technical practice committee, that we have set up in [name of the province], part of its role was to review like every time we met. One is the technologist was responsible for showing a report that we produced on water results. So, we can have audited [test results] ourselves internally if we wish doing it this way. And on a quarterly basis, what I did is I would produce two types of reports one for microbiology testing and endotoxins, and one was on equipment maintenance. And these were like completion way of tasks as well as

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		results and I would share these reports with physicians as well and the program lead like clinical director and clinical managers. I wanted to make sure that we had shared this with as much as possible with everybody. So, we shared those reports with them and they could keep it with them [unclear]. It was not like an internal audit, [but] just there needs to be more auditing you know at the provincial level. But yes absolutely, there needs to be more auditing you know at the provincial level." (P19_Retired Technical Manager) • "One of the technologists in my team was Chair in the technical practice committee. And you know my role as technical manager was to co-ordinate the sharing of information across the program including infection control. They were always copied on our reports as well." (P19_Retired Technical Manager) • "Well every month we have to provide to them [provincial healthcare renal agency], as part of our statistics, we needed to provide them the numbers of home visits that we perform, the number of carbon exchange tanks, DI [Deionizer] exchange tanks, and the testing we did." (P19_Retired Technical Manager)
	HHD-6	• "No, I do not review [water quality test results]. I outsourced [it] to a technology manager." (P17_Medical Director) • "No, if there is a problem with water quality, [then] it does get raised to me and the nursing staff." (P17_Medical Director) • "As a physician that [referring to reviewing of water quality results] is not my domain, and that is more technology manager domain. They delegate responsibility to ensure that patients' dialysis equipment generates high quality dialysate and that is really same as in-center. If there is any issue with [water quality], [then] technicians will raise it to the clinical team for the patient to stop dialysis until they have high quality dialysate so its really no different than any other aspect of our renal program here." (P17_Medical Director) • "We are not tracking [referring to water quality test results]. We [referring to HHD-6] try to develop a better a comprehensive quality improvement plan. We do have weekly patients rounds. For home hemo patients we try to establish a more of quality improvement program specifically, but we do not have anything formally in place which is a bit of a deficiency in the province right now." (P17_Medical Director) • "No, [I do not audit water quality test results]." (P17_Medical Director)
Trends Analysis	**HHD-1**	• Note: Trend analysis of process parameters are not being performed in HHD-1 • "We do the micro [microbiological test results] every three months. So that's what he [person responsible for reviewing microbiological quality test results] is doing right now. The chemical analysis we still working on right now. We have it stored, but we are not sure who is actually monitoring it [and] who is actually analyzing it. We are still working on that because there is been little bit of a change. So we are trying to re-work how it is going to be done." (P2_BioMedical Engineering Technologist)
	HHD-2	• : Well, I think there is always a value in trend analysis but its how we get that information .. a good information for that ..because…I mean you are trying to examine really gonna be as good as the information you are getting…Like if you don't have to track it…

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-3	• Information could not be obtained on whether HHD-3 perform trends analysis of process parameters. But, it seems that HHD-3 does not perform trends analysis of process parameters: • "We are relatively very low documentation about the pre-testing. [Patients] are supposed to do [it], but all of the time they do not. I mean we have troubles with documentation across the board not just with the water quality but also in terms of dialysis parameters. I think we are more confident in terms of our chemical because that is coming in more formally [from vendors and laboratory], so we are having and that are signed off by the home training nurses and that becomes the part of their records and again the microbiologic data as they come they are entered into our provincial database so that's going to be captured quite well . But, I think the "point-of-care" testing that is done is not [and] are not robustly reported." (P15_Medical Director)
	HHD-4	• "What we do is when we [referring to in-house technicians] go every time we go for service or for the maintenance or repair maintenance, we will ask the patient for these charts that he fills out and then we will review them right on site. Basically, we see that RO [reverse osmosis] can measure the quality of the feed water and that is mainly what we are interested in because we know that feed water can change. It does change over the season and what not. And this helps us tell if something is going wrong in the feed water and also by following the trend of the product water quality we can judge the quality of the membranes within the RO [reverse osmosis]. This is because we can see like in over 8 months it targeted 4 micro Siemens and now we are around 9 micro Siemens. Ok, so membranes are getting either dirty or they are wearing out." (P14_Chief BioMedical Engineer) • "Exactly, part of the trending we do is they [referring to patients] have to record all these disinfects [disinfection] as well. Even though we know the equipment is recording it. We don't necessarily tell the patient that. We want to make them pro-active right. We have log sheets for their disinfection, we have log sheets for RO [reverse osmosis] logging. So, basically that is just data from the RO [reverse osmosis] when it is running. And that is all monitoring data for the RO, [such as] seeing for quality, temperature, flow, and everything. That is really helpful for a technical person, actually for a RO [reverse osmosis] system because they do not stay the same. They eventually wear [out and] that is their nature. So, we get an idea where we are at for each RO [reverse osmosis]. So, when the patient finishes the treatment at home we take that log sheet with that RO and upload it to its database. So, we have that information in touch of few buttons. So, I go, that was a patient Jo Jo place, and he had a nasty well. So now, lets pull up the log up on that. So, next time the tech goes, he can go there and hey this used to be his own house so we know that he had water issues and that way we will know may be we should send techs [technicians] there. Let's take a closer look." (P14_Chief BioMedical Engineer)
	HHD-5	• "I think the role as a technical practice committee that we have set up in [name of a province] part of its role was to review like every time we met one is the technologist was responsible for showing a report that we produced on water results. So, we can have audited [test results] ourselves internally if we wish doing it this way. And on a quarterly basis, what I did is I would produce two types of reports one for microbiology testing and endotoxins, and one was on equipment maintenance. And these were like completion way of tasks as well as results and I would share these reports with physicians as well and the program lead like clinical director and clinical managers. I wanted to make sure we had [one word unclear] as much as possible with everybody. So, we shared those reports with them and they could keep it

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		with them [unclear]. It was not like an internal audit, [but] just there needs to be more auditing you know at provincial level. But yes absolutely, there needs to be more auditing you know at the provincial level." (P19_Retired Technical Manager) • "One of the technologists in my team was Chair as committee as technical practice. And you know my role as technical manager was to co-ordinate the sharing of information across the program including infection control. They were always copied on our reports as well." (P19_Retired Technical Manager) • "Well, every month we have to provide to them [referring to the provincial healthcare agency], as part of our statistics, we needed to provide them the numbers of home visits that we perform, the number of carbon exchange tanks, DI [Deionizer] exchange tanks and the testing we did." (P19_Retired Technical Manager)
	HHD-6	• "No, I do not review [water quality test results]. I outsourced [it] to a technology manager." (P17_Medical Director) • "No, if there is a problem with water quality, [then] it does get raised to me and the nursing staff." (P17_Medical Director) • "As a physician that [referring to reviewing of water quality results] is not my domain, and that is more technology manager domain. They delegate responsibility to ensure that patients' dialysis equipment generates high quality dialysate and that is really same as in-center. If there is any issue with [water quality], [then] technicians will raise it to the clinical team for the patient to stop dialysis until they have high quality dialysate so its really no different than any other aspect of our renal program here." (P17_Medical Director) • "We are not tracking [referring to water quality test results]. We [referring to HHD-6] try to develop a better a comprehensive quality improvement plan. We do have weekly patients rounds. For home hemo patients we try to establish a more of quality improvement program specifically, but we do not have anything formally in place which is a bit of a deficiency in the province right now." (P17_Medical Director) • "No, [I do not audit water quality test results]." (P17_Medical Director)
• **Process for Preventive Actions and Maintenance**		
Disinfecting (Components, Type & Frequency) **Note: NxStage Machine does not require disinfection**	**HHD-1**	• "Once a week for RO [reverse osmosis." (P2_BioMedical Engineering Technologist) • "The HD machine is [disinfected] after each treatment [of dialysis]. Well, we [referring to HHD-1] do both heat and chemical [disinfection]. After two treatments [of dialysis], we do heat [disinfection] and after the third treatment we do chemical disinfection." (P2_BioMedical Engineering Technologist) • "Yes, that is right [patients are responsible for chemical disinfection of hemodialysis machine and for] RO [reverse osmosis] as well." (P2_BioMedical Engineering Technologist) • "The integrated [heat] disinfection that would be implemented with the new equipment is that the RO [reverse osmosis] and the dialysis machine will be disinfected together. So, that way the chemical will…every component [of dialysis machine and treatment system] will be disinfected during that integrated heat disinfection [and] which we do not have the capacity to do that in the older equipment. But, the new equipment will have it." (P2_BioMedical Engineering Technologist)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "If we [referring to in-house technician] know a patient has not disinfected, then we will disinfect it [referring to disinfecting HD machine during patients' visit for routine maintenance]." (P2_BioMedical Engineering Technologist) • "They [referring to patients] have to disinfect them [referring to treatment system and dialysis machine]." (P6_Unit Manager) • "Nim: That's right, [answering the question on whether disinfection involves reverse osmosis, carbon filters and an HD machine]." (P2_BioMedical Engineering Technologist)
	HHD-2	• "With our current machine we have Baxter AK 98 and also we have Baxter Ros [reverse osmosis]. So, they integrate the disinfection now." (P8_Unit Manager) • "So, they [referring to patients] are supposed to disinfect [an HD machine] after every treatment. They would do heat disinfect after every second or every treatment depending on how they sorted out. They are supposed to do clean cart C which is a heat citric right. Once a week, they are supposed to do low flow disinfection and low flow means it integrates the disinfection between RO [reverse osmosis] and the machine and what they do is clean cart A which is sodium carbonate that is same as sodium hypochlorite. So, that integrates the disinfection. It disinfects the machine, the RO and the pathway between the two." (P8_Unit Manager) • No, RO [reverse osmosis] once a week and [an hemodialysis] machine everyday. Yes. We have integrate. So, whenever RO [reverse osmosis] gets disinfected, we use integrated heat, so that the line and [and an HD] machine everything gets disinfected in one shot." (P11_BioMedical Engineering Technologist) • "This [referring to disinfection frequency] is based on manufacturers and [the] CSA's [Canadian Standards Association] [requirements]. [They both are] almost aligned, so we are doing exactly the same as per the requirement." (P11_BioMedical Engineering Technologist) • "So, the dialysis machine gets disinfected after each treatment and I think they just do a heat on it. On the RO [reverse osmosis], we ask them [referring to patients] to do a heat disinfection weekly and then I think once a week they are also disinfecting the line that goes between the RO [reverse osmosis] and the dialysis machine. So, that bit of hose gets disinfected too which they call it a low flow heat [and] we set that up through the RO [reverse osmosis]." (P9_Clinical Manager) • "On a monthly basis, they [referring to patients] do a chemical [disinfection]. We [referring to HHD-2] used to use a peracetic acid called [unclear] and Dialox that was used previously. But, now we [have] switched to citric acid. [The] citric acid, we have to adjust [it] on the RO [reverse osmosis]. We adjust the concentrate that like how much it pulls in, so on the peracetic acid I think we are pulling in 100 milli-litres of the disinfectants. The citric acid is not as strong, so we are pulling it like 400 milli-litres." (P9_Clinical Manager) • "It is because of this [hemodialysis] machine, actually with this dialysis machine, we got [the feature of] clean cart. They are just tubes. I do not know if anybody has showed you, but there are tubes about this long going to bicarbonates. You know that may be so very small and compact as opposed to other machines where we have to have jugs of like 4 litres jugs of bleach on the back of that machine or citric acid or both. So, because of that we do not have those jugs any more. And the RO [reverse osmosis] is integrated with this machine, so we can control how the RO [reverse osmosis] operates by the program in the machine." (P9_Clinical Manager) • "There is an actual sequence that goes through [during disinfection]. So, I believe that when we got it [referring to disinfection] hooked up, I think it does dialysis machine first, then the RO [reverse osmosis] and then once a week does the all flow. So, these three things it will do

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		all in sequence, like it is not at all of the same time. You need the water to bring in to the dialysis machine to disinfect that so your RO [reverse osmosis] can be disinfecting at that time. The disinfection time on the machine is I think it is 30 minutes or 40 minutes ….something like that. So, it goes to all cycle first, then the RO [reverse osmosis] will go through its disinfection cycle which is 132 minutes for the heat to do that. Once that cycle goes on low flow and [then] everything shuts off. That is how we got the [disinfection] program." (P9_Clinical Manager)
	HHD-3	• "Baxter has integrated heat disinfection and it is chemical [also]. [The integrated feature] disinfects the water treatment system, RO [reverse osmosis] and the machine. They [referring to patients] do it once a week. There is heat disinfection as part of RO [reverse osmosis] [and] it is probably done weekly as well. I don't think they do it [reverse osmosis] daily for sure." (P16_Technical Manager) • "The NxStage does not require disinfection." (P16_Technical Manager)
	HHD-4	• "They [referring to patients] do something called as integrated disinfection once a month." (P13_Medical Director) • "No, we [referring to HHD-4] do heat [disinfection]. For home patients, the RO [reverse osmosis] is heat disinfected once[in] a week and then once a month we do chemical disinfection." (P13_Medical Director)
	HHD-5	• "No, patients are supposed to do it [referring to disinfection]. They are all trained to do it." (P18_Medical Director) • "Dialysis machine was disinfected through heat cycle and citric. Water treatment system we had most of our system were chemically disinfected using peracetic acid, but newer system were using heat as well." (P19_Retired Technical Manager) • "So they [referring to patients] would disinfect dialysis machine every time they do their treatment." (P19_Retired Technical Manager) • "The water treatment system we actually did disinfection once in every 2 weeks." (P19_Retired Technical Manager)
	HHD-6	• "Yaa, all the lines are disposable with NxStage. So, we do not really have to [do disinfection]." (P17_Medical Director)
Routine Replacement of Treatment Components	**HHD-1**	• "We [referring to in-house technicians] do filter changes and service on the device[s] every 3 months." (P1_Clinical Manager) • "Normally, we [referring to in-house technicians] do maintenance on the home water system every three months, and at that time for now we are changing those filters [referring to ultrafilters on hemodialysis machines]." (P2_BioMedical Engineering Technologist)
	HHD-2	• "We would send the technicians basically anything in the RO like that involves the filter. We do not train the patients to do that. We will train them how to test the, check, and document the pressure drop across the membrane and across the filters, etc." (P8_Unit Manager) • "Our maintenance is set on, it is a set schedule. So, within 3 months if we are not [done with] anything [then] plug it on up that. The three months [maintenance] schedule works really very well." (P9_Clinical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-3	• "We do not actually have a whole lot of technical staff associated with our home program. Because, we made a decision provincially here to outsource it to vendor. So, we are relying on technical support from Baxter and they [referring to patients] have had additional training with water management." (P15_Medical Director) • "They [referring to patients] would do that [referring to changing of filters on routine basis] themselves." (P16_Technical Manager) • "And the filtration system are set up to allow patients to do it relatively easily so they are mostly cartridges that they would have to change." (P16_Technical Manager) • "We [referring to vendors] also do it at least yearly as part of the maintenance." (P16_Technical Manager) • "Patients would change those [referring to cartridges and carbon filters] every 3 months. So, it does not make sense because they are being change on regular basis." (P16_Technical Manager)
	HHD-4	• "We train home patients on how to do that [referring to Deionizer], because they just naturally wear out." (P13_Medical Director) • "Yes, in a home program the home patient is trained to replace the carbon, he is trained to replace particle filter." (P14_Chief BioMedical Engineer)
	HHD-5	• "Participant: and I think they [referring to filters on treatment system] get swapped out every like every three months or something; Researcher: Patients are not involved in that only tech guys do that; Participant: technical guys do that…" (P18_Medical Director) •
	HHD-6	• It implies that patients or vendors are responsible for replacement of filters. • "Again that is the issue right so I had the situations where PAK [Pure Flow SL Purification] had to be replaced every two weeks because water is so hard. The average size is three months but does not work like that." (P17_Medical Director)
Replacement of Ultrafilters of HD machines	**HHD-1**	• "patients change it [referring to ultrafilters on hemodialysis machines] every 60 days." (P2_BioMedical Engineering Technologist) • "On the older machine which we just started using ultrafilters on [them], the technicians are changing them every three months." (P2_BioMedical Engineering Technologist)
	HHD-2	• "The technicians will go out every three months to change the ultrafilters on the back of the dialysis machine." (P7_Medical Director) • "If a patient is not able to change filter ultrafilter we will go and help them." (P11_BioMedical Engineering Technologist)
	HHD-3	• "They [referring to patients] would do that [referring to changing of filters on routine basis] themselves." (P16_Technical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-4	• "Yes, in a home program the home patient is trained to replace the carbon, he is trained to replace particle filter." (P14_Chief BioMedical Engineer) • "Researcher: So, tech guys only goes there [at patients' home] for once a year for one machine for sample collection for chemical and lab microbiology, and at that time you also check the machine,.. am I correct? Participant: That is right." (P14_Chief BioMedical Engineer)
	HHD-5	• Researcher: and I think they [referring to filters on treatment system] get swapped out every like every three months or something; Researcher: And patients are not involved in that….only tech guys does that….Participant: Technical guys do that…" (P18_Medical Director) •
	HHD-6	• It implies that either patients or vendors are responsible for replacement of filters. • "Again that is the issue right so I had the situations where PAK [Pure Flow SL Purification] had to be replaced every two weeks because water is so hard. The average size is three months but does not work like that." (P17_Medical Director)
Maintenance of Treatment Components not Reimbursed by a Home Program	**HHD-1**	• Note: Some components were identified by the participants that were not reimbursed by the program, and patients were recommended to have such components at their own cost. However, no specific discussion occurred with participants on who was ultimately responsible for the maintenance of the components that were not reimbursed by the program. • "We don't. As a program we are not funded to do anything other than that [referring to sediment filters, carbon filters and reverse osmosis]. So we do struggle from time to time where the water is high in iron and high in sodium or something then we end up having more frequent maintenance schedule in those cases." (P2_BioMedical Engineering Technologist)
	HHD-2	• "If a patient meets the Canadian drinking water guidelines, [then] we will install [the devices at patients' home]. But, if they like may be the town is treating more with chlorine or ammonia or something. It includes water, but then it creates some, it might go through more carbon filters. So, we [referring to home program] will put more pre-treatment [filters] and to protect the RO [reverse osmosis] on that. That cost comes like we pay for that cost." (P9_Clinical Manager)
	HHD-3	• "If a patient has to have some treatment of feed water first, like water softener or some other treatment, then we would probably pay for the initial installation for the patients of those treatment. But, patients would be responsible for maintaining that [additional treatment components]." (P16_Technical Manager)
	HHD-4	• Not applicable, because all water-related devices are reimbursed by the program.

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-5	• "If it was feasible for the patient, then you know we would show them how to make sure that there is enough salt in the softener and so on. But, when we had a home patient sometime when we install them they already had a water softener so in that case then we did not provide them with a salt because they already had a salt provider going to their home." (P19_Retired Technical Manager)
	HHD-6	• Not applicable, because all water-related devices are reimbursed by the program.
Repairs Services	**HHD-1**	• "We do filter changes and service on the device every 3 months." (P1_Clinical Manager)
	HHD-2	• "That is [referring to repairs] what we do right." (P11_BioMedical Engineering Technologist)
	HHD-3	• "We do not actually have a whole lot of technical staff associated with our home program. Because, we made a decision provincially here to outsource it to vendor. So, we are relying on technical support from Baxter and they [referring to patients] have had additional training with water management." (P15_Medical Director) • "As part of service, yes, they [referring to vendors for NxStage] would do at least once a year." (P16_Technical Manager)
	HHD-4	• "Our majority is done with our own Bio-Medical Engineers . We do have contract services for repair and replacements. That is it. We [referring to in-house technical team] would do majority of everything." (P13_Medical Director)
	HHD-5	• "Any of the major pre-treatment component, if we [referring to in-house technicians] change them, we will redo a product and not the feed, but we will redo the product water analysis complete to external laboratory as well." (P19_Retired Technical Manager)
	HHD-6	• So, we have a tech ..we have in our program got technology manager and the technology manager directs a number of dialysis technicians who go out to patients' homes to do a patient assessment on the home for water quality. And then they also assess again plumbing capacity, and so on…they also subsequently arrange monthly water testing for endotoxins and things like that nature ..hmm sometimes I think they go out I think more often times they shipped to central location and then they have third party to do most water testing for us..
Documentation & Review of	**HHD-1**	• "They [referring to patients] do. We have a check list that patients do check for every time before they start their dialysis. So they will check things like water pressures at the gauges, they will check the conductivity of the water, and they will check how efficiently the membrane is working on the reverse osmosis and they will check of course chlorine free as well. These are the six things that they will check for prior to going starting dialysis"(P2_BioMedical Engineering Technologist)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
Maintenance Performed		• "They [referring to in-house technicians] do monitor those things [referring to process parameters verification before the onset of dialysis]. They can tell you how often they are changing on what machine and they can tell you which patients are not disinfecting because they have checked that every time they [in-house technicians] go out there." (P6_Unit Manager) • "So, we look at the sheets, [for documenting the process parameters results], to see if they are filling that piece out." (P6_Unit Manager) • "So again that is another one of our monthly calls [by nurses] is have you been disinfecting [and] any issues with disinfection? Right." (P6_Unit Manager) • "They [referring to patients] do not bring it in [and] there is no requirement for them to bring it in. It is basically, dialysis technician will go [to patients' home] and have a look and check to see where it is.]" (P2_BioMedical Engineering Technologist) • "We [referring to in-house technicians] keep record of what we have with each piece of the equipment. So, if we have a machine or water treatment cart with any issues, when we do work on them the record is kept with that piece of equipment. It is all in the computer so anybody can look at it whenever they want it…each medical piece of equipment has a history that we can look up." (P2_BioMedical Engineering Technologist)
	HHD-2	• "I do not think we will specifically ask like excuse me are you doing your disinfection. I do not think that is there." (P8_Unit Manager) • "That is hard, because that [referring to disinfection, maintenance, and process parameters data] is on the machine and that does not get transferred to clinical manager [who managers all the data]. So, it is on us [referring to in-house technicians]. No it does not go that way, because there is no reporting. There is no proper report that goes from machine to clinical manager." (P11_BioMedical Engineering Technologist) • "We have not done such things [referring to trending of maintenance and process parameters results]. It should be done but we are not doing than. Because, it [referring to membrane] has to be changed every 3 to 4 years for RO [reverse osmosis]. So, there is not enough data and it is not worth. Sometimes it needs to be done we just do it. But, there is nothing like this RO [reverse osmosis] is breaking down every 3 years and one of them is required every 2 years, and one of the RO requires every 4 years. (P11_Clinical Manager)
	HHD-3	• "I am not 100% sure. I would say yes, [patients log data related disinfection]. But, I am not sure 100%." (P16_Technical Manager)
	HHD-4	• "Transitioning over to new home machine where we would be able to get an automated log of when the last disinfection actually occurred." (P13_Medical Director) • "I would say we do audit that whether or not patients are doing disinfection properly, when technicians do go and service the machine the opportunity to identify those they may not be properly disinfecting the machine. And any problem that are identified where a patient is not doing properly would be brought to attention of myself." (P13_Medical Director) • "Exactly, part of the trending we do is they [referring to patients] have to record all these disinfects [disinfection] as well. Even though we know the equipment is recording it. We do not necessarily tell the patient that. We want to make them pro-active right. We have log sheets for their disinfection, we have log sheets for RO [reverse osmosis] logging. So, basically that is just data from the RO [reverse osmosis]

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		when it is running. And that is all monitoring data for the RO, [such as] seeing for quality, temperature, flow, and everything. That is really helpful for a technical person, actually for a RO [reverse osmosis] system because they do not stay the same. They eventually wear [out and] that is their nature. So, we get an idea where we are at for each RO [reverse osmosis]. So, when the patient finishes the treatment at home we take that log sheet with that RO and upload it to its database. So, we have that information in touch of few buttons. So, I go, that was a patient Jo Jo place, and he had a nasty well. So now, lets pull up the log up on that. So, next time the tech goes, he can go there and hey this used to be his own house so we know that he had water issues and that way we will know may be we should send techs [technicians] there. Let's take a closer look." (P14_Chief BioMedical Engineer) • "When they [referring to patients] come in, they come in every 3 months what they call as clinical visit, nurse[s] would review with them all their responsibilities. Are you doing this? Are you doing this? When did you do this?." (P14_Chief Biomedical Engineer)
	HHD-5	• "and the techs do follow up with them [referring to patients] [for disinfection] when they go into the home." (P18_Medical Director) • "They [referring to patients] are supposed to put stuff on their records. I mean you can check the machine too obviously and our techs [technicians] do that when they go out to the patient, like you can check the RO [and] you can check the machine. But, they all are supposed to document their, like their chloramine strips were negative and, on this date, they did their disinfection. So, we get that information. [Such information was] brought in to me." (P18_Medical Director) • "At some point in time, you know, because you do all these testing and then you collect data, and some point in time we using excel we created a spread sheet that allowed us to better monitor those non-compliant patients." (P19_Retired Technical Manager) • "My staff would go in to do monthly testing and if the water system has not been disinfected in last two weeks then they would tell the home patient you know they would remind the home patient that this needs get to done." (P19_Retired Technical Manager) • "So, what we did in [name of the province] in 2005, we started in 2005 we used the excel and we created what we called equipment maintenance log sheet. Every time the technologist would come back from a home patient, they would enter into those spreadsheet that the work is done. This spreadsheet will design automatically, they will red flags when things came up to be due for replacement. One of my staff was very good at excel and maintained the system. Every morning my staff would turn the system on and we would look at the equipment maintenance log sheet, and everything that was red, it was an indication that it was due to be replaced. And two weeks prior to the due date, the flag would be pink so that we could see what is coming up in next two weeks. We had those success with using this as well." (P19_Retired Technical Manager)
	HHD-6	• Information could not be obtained from the participant of HHD-6.
• **Emergency Contact & Corrective Actions**		
Communication	**HHD-1**	• "that means I am contacting the nurses and letting them know that this person had a failed sample and we need to have it recollected so then…and then the technicians often would call them as well." (P6_Unit Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "We also always teach them [referring to patients] if it [referring to chlorine tests] is negative. Sorry if it is positive to call us so that we can follow up right." (P6_Unit Manager)
	HHD-2	• "If there is a breakthrough on those carbon filters, they would let us know." (P9_Clinical Manager) • " The [name of the laboratory] sends me, every day I get spreadsheet from [the laboratory] that shows [microbiological] results. They will tell me if there is any failures on that. So, when I get that then I go to technical room and say you need to contact patient. Get them to disinfect." (P9_Clinical Manager) • "We just call the patient. So, if I get the result and it comes in and it is at an actionable level, [then] I send an email out to all the technicians. It will [also] go to the nursing staff like in [name of the city] they got one and then it goes to two nursing in [name of the city] and [name of the city], plus the manager, plus I cc the medical director on it. The instruction is we got this result [and] it's at an actionable level so can you contact the patient [and] get them to disinfect. So, that's our protocol." (P9_Clinical Manager)
	HHD-3	• "Basically, we would come together only if there was challenging water issue. "And we have, sitting on our group one of the biomedical engineer who would sort of largely take the lead in conjunction with the logistic supervisor from Baxter." (P15_Medical Director) • "They [referring to patients] call the vendor and the training nurse. If the training nurses needed help, then they would contact myself or someone else." (P16_Technical Manager)
	HHD-4	• "If a patient is having clinical issues, then they will call home nurses. If they are having technical issues, [then] they call the technical room." (P14_Chief BioMedical Engineer) • "The nurses who do assess the patients on their regular clinic visits, they do review one element of the water examination of the patients do. And, if, there are any problems then they identify those to me." (P13_Medical Director) • "The way it works for us [is that] they [referring to the laboratory] emailed test results. If there is a high count, we do a 7 day count, we ask them to report anything about 50 after 2 days. So that way we will know sooner. Because, we know after 7 days it is going to be higher than that. So, we know it is going to fail. This way we know sooner. We do not have to wait a week. So, the lab [laboratory] is very good at calling us. They actually, they have the full standards for dialysis water testing. They know what they are doing. We have sat down and they understand completely what we are asking for. So, they are good at calling us, they would call us , and would say this year like we identify all our equipment with our own identification number. They will say hey [name of the chief biomedical engineer] here this me the number blabla..after 2 days you have a plate count of 75 ..ok thanks… ok we know faster that we know that we have to get that machine faster to get it. We have to clean up and test it again, instead of waiting 7 days. If we did 7, lab wasted the time and we wasted the time and meanwhile the machine is being used that may be potentiality. So it is better to know in 2 days than 7. If it is not over 50 after 2 days, they will just let the count complete and then send us the report." (P14_Chief BioMedical Engineer)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-5	• "So, what happens with internal lab, well , [there are] two things. From plate count results perspective, when we had a result, we tested at, the maximum count was 100 CFU per ml. When we exceeded 50, then the lab would call me directly to report." (P19_Retired Technical Manager) • "We would take action and this was all laid down in our policy procedures. From endotoxin perspective, because my staff were testing themselves then they would know we exceeded 0.125 then they would know what actions to take by the way." (P19_Retired Technical Manager) • "And if you have the machine malfunction, you [referring to patients] need to call it right away." (P19_Retired Technical Manager)
	HHD-6	• "If there is [a] problem with water quality, [then] it does get raised to me and the nursing staff." (P17_Medical Director)
Emergency Contact at Home Programs	**HHD-1**	• "We have nurse on-call 24 hours a day and 7 days a week and a technician as well." (P6_Unit Manager)
	HHD-2	• "We do not really have an on-call program for the home hemodialysis program in terms of technical. We have a nurse on-call and hmm…and we do sometimes have a technician who is on-call and can be reach by the nurse for the consultation. I am told that sometimes our technicians will answer the phone if there is a patient call over the weekend. But we don't have a formal technical on-call program for home hemo [hemodialysis program]." (P8_Unit Manager) • "We do have a technical on-call support. Typically home patients would call the on—call home hemo [hemodialysis] nurse first. If they can not resolve a problem or if it is a machine problem, then they can call the on-call tech [technician]. Now, typically it is going to be next day service. Most likely, will just have the patient disconnect themselves from dialysis whatever the problem might be whether it is machine or water and will send the tech [technicians] out the next day to service it. On the weekends, a tech [technician] may go out on the weekend or if it is like a long weekend or something like that patient needs to dialyze [unclear]. Now, part of the problem was not all of my technicians were trained on home hemodialysis machine itself. So, I only have like the group of home hemo technicians trained on it so those really on the guys. When they are on on-call they can do it. The other guys when they are on-call not trained they could not answer those calls. But, now I have got pretty much trained up on both the machines in-centre and home hemodialysis." (P9_Clinical Manager)
	HHD-3	• "They call the vendor and the training nurse…and then the training nurse needed help then they would contact myself or someone else [in the program]." (P16_Technical Manager)
	HHD-4	• "We have a telephonic support for clinical and technical related issues. If a patient is having clinical issues then they will call home nurses. If they are having technical issues, they call the technical room. If they are not sure whether it is technical or clinical because sometimes it is kind of grey area, [then] they will typically call the nurse. The nurse will figure out and call the technical guys. Our nurses are on-call 24 hours 7 days a week." (P13_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-5	• "We do have a technical person on-call. Because, again it's the same technical person they are on for the main unit. They are not typically not going to be going out to patient's home on weekend if there is a problem because they are covering the unit. So, if there is a technical problem it will be triaged during the weekend. If the patient needs dialysis and can not do it, then they will have to come in to the centre." (P18_Medical Director)
	HHD-6	• Information could not be obtained from the participant of HHD-6.
First Line of Corrective Action	**HHD-1**	• "The failed microbiological samples, usually, we phone the patient and ask the patient for a recollection to see if there was an issue with the sample itself. So that is the first step." (P6_Unit Manager) • "Usually, with the first fail, the nurses would call the patient, you know resample again. For the system, we sample again. If there is second fail, then there is a more intervention by the BioMed." (P4_Nurse Practitioner) • "I am contacting the nurses and letting them know that this person had a failed sample and we need to have it recollected. Then, the technicians often would call them [referring to patients] as well and make sure that they have done all their disinfection on their machines and then recollect it [referring to sampling for microbiological verification]." (P6_Unit Manager) • " It is recollection (i.e. re-sampling), find out what a patient is doing, find out what is going on. So, sometimes a technician will also change that is some of the filter in the machines and make sure that it is not the issue. Then, they actually test the water cart itself when they go out there [at patients' home]. But, we have the patients tests their dialysis machine." (P6_Unit Manager) • "If we have any issues with the water, then we start breaking it down where to test it." (P2_BioMedical Engineering Technologist) • "We want you [referring to patients] to resample. Before, you resample, we want you to take this precaution, make sure your sampling techniques [are correct such as] wearing gloves, you follow the procedure. So, that is our first course of action." (P2_BioMedical Engineering Technologist)
	HHD-2	• "For example, the CFU [colony forming units] if it is like 100 or more, then it is pretty critical. So, the call would go right away to disinfect and resample." (P7_Medical Director) • "then we will disinfect like the technicians would engage the patients to do whole lot of disinfection and then we resample so we keep disinfecting and resampling until we get a good water." (P7_Medical Director) • "So, if we have multiple failures that we have identified as a problem. Our next step would be to test separately for the product water and so it is part of our troubleshooting process. So we get separate results, is it on RO [reverse osmosis] side that we have the problem or is it with the machine that we have the problem. Then, once we have identified them, we can address the problem that way." (P8_Unit Manager) • "Oh ..ya ..we try to teach them [referring to re-training on how to do sampling]." (P7_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		• "Yes, second [carbon filter] shows more than 0.1 [milli-grams/ litre], then [patients would have to] stop the dialysis. The first one is more than 0.1 [milli-grams/ litre], but the second [carbon filter] is good, [then patients] can still dialyze. But we will have to go and change the filter out." (P11_BioMedical Engineering Technologist) • "Because, if the conductivity starts rising on it [referring to reverse osmosis], then it is an indication that may be the RO [reverse osmosis] membrane is starting to go and we need to replace it and service that RO [reverse osmosis]." (P9_Clinical Manager) • "If it [referring to microbiological sample] passes, then we don't communicate anything. If it fails, then I technically send out an email to the technicians to arrange for disinfection of the equipment and to arrange a re-sample. And sometimes we would ask the patient to actually do the sample [again] and sometimes the technicians will go and grab that sample." (P9_Clinical Manager) • "When I get that [failed microbiological test results], then I go to technical room and say [to technicians that] you need to contact the related patient. Get them to disinfect. If it [the sample test result] is just in that warning stage, so colony forming units is between 50 and 100, that's just a warning and it is actionable. We don't have to really do anything. But, even on a failure we just, our first step is to re-sample." (P9_Clinical Manager) • "We just call the patient. So, if I get the result and it comes in and it is at an actionable level, [then] I send an email out to all the technicians. It will [also] go to the nursing staff like in [name of the city] they got one and then it goes to two nursing in [name of the city] and [name of the city], plus the manager, plus I cc the medical director on it. The instruction is we got this result [and] it's at an actionable level so can you contact the patient [and] get them to disinfect. So, that's our protocol." (P9_Clinical Manager) • "Yes, we re-train them [referring to patients]." (P9_Clinical Manager) • "We will tied up [the re-training] in another service call." (P9_Clinical Manager)
	HHD-3	• "So, the model is, if there is any problem anything related to NxStage system, then it gets swapped our. So you get a patient, they get the new one and they send the old one back. They can fix it over the phone right, but if there is a real problem and so prior to that going to next patient and then they have…what's they called it but a process or procedure everything through ready for the patient. They would do that minimum once a year as part of the maintenance. So, they would check all the conductivity and patients have to do that. They would also send the component of the NxStage system back to the factory and then the factory would hand over the new one and patient can carry on." (P16_Technical Manager) • "If the results are negatives, then we would probably sample again. If we got negative results again, then we would do disinfection or something more drastic." (P16_Technical Manager) • "Now what we will do, when we are concern of contamination…as we do see when patient is having repeat contamination we will often send a technician out to do sampling for us so that we can see if there is actually real water issue or just contamination and most of the time when technician goes out they retrain the patient in terms of what they are doing and more often what we do find is the collection issue and those are big issues." (P15_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-4	• "Exactly, we ask for what we call is heat integrated disinfection so that would be from RO [reverse osmosis] all the way to water lines all the way through the machine." (P14_Chief BioMedical Engineer) • "We did repeated failures we would then investigate and draw our own samples and bring it to the lab [laboratory]." (P14_Chief BioMedical Engineer)
	HHD-5	• "I remember we certainly have to remind people about the stuff that they are supposed to do for water quality. But, I can not say that we have to retrain patients because of the water quality stuff." (P18_Medical Director) • "In case of home programs, our process in home programs is different because of complexity and so on. But, we had created a table. If you have a result over 50 [colony forming units for total viable counts] on home program, on water systems, but not your dialysis machine, it does not mean that dialysate would allow more than 50 to go through. We had establish kind of a guideline in terms of, I will give an example. On water treatment system, if you tested and you had < 50 [colony forming units] and machine < 50 [colony forming units], then no action was required. If on the RO [reverse osmosis] you are sitting at between 100 CFU [colony forming units], the dialysis machine on the same day was testing less than 50 [colony forming units] then we would call home patients and tell them that they needed to disinfect the RO [reverse osmosis]. We would go within 48 hours to retest ourself. If it was I will tell you point in time, if we have more 100 CFU [colony forming units], then patients were not allowed to dialyse and then we would have to go in [at patients' home] and test right away." (P19_Retired Technical Manager) • "That's right. Home patients were not allowed to dialyse, [if] they needed, [then they were required] to either come [to] in-center for their treatment or wait, like in a case of a nocturnal patients or short daily patients. Those patients were easier because if they dialyse almost every day then, and talking with physicians because we would never make that call myself, I would then contact the home program and either talk to [the medical director] or any nephrologist. But, in those case, we would tell the home patient you can skip the treatment we are going to go in tomorrow and meet up." (P19_Retired Technical Manager)
	HHD-6	• "We [would] tell the patients to stop dialysing until the water issue is fixed." (P17_Medical Director)
Re-Sampling Locations as part of Corrective Actions	**HHD-1**	• "If we have any issues with the water, then we start breaking it down where to test it." (P2_BioMedical Engineering Technologist)
	HHD-2	• "If we do have a failure then we will switch and adopt, but we end up taking a sample from the machine itself. But, then we will eliminate the machine and will take just post-RO [reverse osmosis], so that if it fails again we can tell that whether is it the machine that causing a problem or is it the RO [reverse osmosis]." (P9_Clinical Manager)
	HHD-3	• Note: Information could not be obtained from the participants of HHD-3.

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-4	• "[If] we did [get] repeated failures, we would then investigate and draw our own samples and bring it to the laboratory." (P14_Chief BioMedical Engineer) • "What we do is we are running the RO [reverse osmosis], and will run the dialysis machine just in a rinse mode just processing the water. We [referring to in-house technicians] would sample from the sample port of dialysis line." (P14_Chief BioMedical Engineer)
	HHD-5	• "In case of home programs, our process in home programs is different because of complexity and so on. But, we had created a table. If you have a result over 50 [colony forming units for total viable counts] on home program, on water systems, but not your dialysis machine, it does not mean that dialysate would allow more than 50 to go through. We had establish kind of a guideline in terms of, I will give an example. On water treatment system, if you tested and you had < 50 [colony forming units] and machine < 50 [colony forming units], then no action was required. If on the RO [reverse osmosis] you are sitting at between 100 CFU [colony forming units], the dialysis machine on the same day was testing less than 50 [colony forming units] then we would call home patients and tell them that they needed to disinfect the RO [reverse osmosis]. We would go within 48 hours to retest ourself. If it was I will tell you point in time, if we have more 100 CFU [colony forming units], then patients were not allowed to dialyse and then we would have to go in [at patients' home] and test right away." (P19_Retired Technical Manager) •
	HHD-6	• Information could not be obtained from the participant of HHD-6.
Second Line of Corrective Action	**HHD-1**	• "So, sometimes a technician will also change that is some of the filter in the machines and make sure that it is not the issue. Then, they actually test the water cart itself when they go out there [at patients' home]. But, we have the patients tests their dialysis machine." (P6_Unit Manager) • "The techs go out there [at patients' home]. They pull their machines." (P6_Unit Manager) • "When the water is being resampled, and it fails for the second time, that is when we [referring to in-house technicians] go out there and then do sampling ourselves. [We] do have a look at this thing and lets do this, so that's our protocol. I am not saying that happens every time, but that's our protocol to say ok..we have two failures, so we need to go to sampling. Then, we go there with a new RO [reverse osmosis cart], so that if that is the issue we take a known good RO [reverse osmosis] with us and we replace that and resample at that point." (P2_BioMedical Engineering Technologist)
	HHD-2	• "If [the sample] fails [again], [then] we are looking at pulling up equipment again. Because, a failure may be that there was a sampling technique error or something else [may be] causing [the problem]." (P9_Clinical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-3	• "Laboratory would just send the reports. I haven't heard that there is problem with the timing [of receiving the test results]. So, if the results are negatives, then we would probably sample again. If we got negative results again, then we would do disinfection or something more drastic." (P16_Technical Manager)
	HHD-4	• "So, typically in that situation we just swap out the equipment and then bring the stuff back for cleaning and assessing and testing." (P14_Chief BioMedical Engineer)
	HHD-5	• "Any of the major pre-treatment component, if we change them, we will redo a product and not the feed, but we will redo the product water analysis complete to external laboratory as well." (P19_Retired Technical Manager)
	HHD-6	• Information could not be obtained from the participant of HHD-6.
• **Process to Handle Non-Compliant Patients**		
	HHD-1	• "Well we start with re-training right and reinforcement. We don't like to threaten them [referring to patients]. We do not like to take [them off from the treatment]. It is a life sustaining treatment, so we just can not say sorry. But, there have been times when we have to sent specific letters out to patients to say this is a life sustaining therapy that we are happy to provide you, however, the machine will break down when you do not service it correctly." (P6_Unit Manager)
	HHD-2	• "Usually we discuss it as a group, right. So, it has kind of different levels, [including], talking to their primary doctors firs'. And then if there behavior is still present, then the whole group will get involved. Yes, [at] that point we sort of make a decision that so we let them continue or do we take the machine out. Hmm..that's what kind of, it is like a group approach." (P7_Medical Director)
	HHD-3	• "The risk management strategy was that, as long as you have given them [referring to patients] the tools and you have told them the importance to do it and the risks of not doing it [and] if they choose not to do it, [then] that's their own risk. They should not be grounds for pulling them off the program. So we don't pull them off the program for not doing it, but we constantly try to reinforce them to do it." (P15_Medical Director) • "If we don't see results from patients to patients, we will send a letter saying that it is recommended that they do the sampling and etc. They identify the risks associated with not doing the sample in the letter format. So, it is kind of up to the patients to meet those or not." (P16_Technical Manager)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-4	• "I tell our technicians, we don't confront patients. Because, that is not our role, that is not the role of a technical person. We make recommendations, but we don't confront them really. That is up to clinical team. It can cause a bit of a situation we don't want to go there. But we definitely report it absolutely say look if you think this patient is presenting issues physical issues while he is at home he is not disinfecting. Then, we ask the doctor to speak to the patient, and say you need to speak to him [unclear] because we are not doing it. And if they continue [doing that] then they will be threatened to having them pull out from the program." (P14_Chief BioMedical Engineer)
	HHD-5	• "So, we obviously remind them [referring to patients] and reiterate the importance of it for the safety of their water quality at home." (P18) • "If we saw that this was happening on routine basis, that is when I would get in touch with [the medical director of the program] and sometimes we have to talk to patients to remind them of importance of doing that on regular basis." (P19_Retired Technical Manager)
	HHD-6	• "I am actually not quite even aware what happens if they don't [do what they are supposed to do], but we try to keep on top as best as we can." (P17_Medical Director)
• **Communication with Source Water Supplier**		
	HHD-1	• Note: HHD-1 remained in contact with the source water supplier. However, details were not discussed on the process of communication with source water supplier during interviews with the participants of HHD-1.
	HHD-2	• "Ya..we do. That is a good question. I think I did mention that. So, there is actually an email that sort of that is basically water quality for the province of Alberta and they are integrated with public health I believe. Anytime there is water quality alert, myself, the technical manager, the medical director, and I believe the home hemo unit itself is actually on that string, so we would get the notification. For instance, if there is like a blue green algae advisory or you know if there is water shut off or well water advisory, that would be the another one and then we can communicate with our patients as we need to." (P8_Unit Manager)
	HHD-3	• Note: The home program remained in contact with the source water supplier. However, the process of communication with source water supplier were not discussed during the interviews with the participants of HHD-3.
	HHD-4	• "Yes, absolutely. I have [contacts], because I am the chief technologists here and all the water results comes through me. I have direct contact with municipal suppliers pretty much in every region of the province and with the department of environment. Because, they can help me with well water in different areas. I mean they know more than I could possibly know. And they have been very helpful." (P14_Chief BioMedical Engineer)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-5	• "We were in constant contact with water quality engineers with those municipalities." (P19_Retired Technical Manager)
	HHD-6	• The home program remained in contact with the source water supplier, but details were not discussed on their process of communication with source water supplier.
• **Quality Meetings**		
	HHD-1	• "Yes, there is monthly meetings for the home hemodialysis program. I meet with managers, the medical director, directors, educators, and clinical engineering team. I think every 2 months. I will have to check the frequency again . May be we slow down in summer and back up to month now but we meet at least 2 months." (P1_Clinical Manager)
	HHD-2	• "We have weekly Friday meetings where we discuss all this analysis and all this information. All the data recordings we have in the excel file we discuss that. It is very tightly run program." (P11_BioMedical Engineering Technologist)
	HHD-3	• "Basically, we would come together only if there was a challenging water issue." (P15_Medical Director) • "Not specifically. We have what is called quarterly business review meeting with vendors. Because we have two vendors we have two meetings and they have specific format measures to keep track of [the results]. The format measures are presented at the initial meetings. If water quality was a problem or an issue, [then] we would talk about it. But, not specifically we do not talk about water quality." (P16_Technical Manager)
	HHD-4	• " The first and foremost is that we run quarterly home hemodialysis quality meetings." (P13_Medical Director) • "At that meeting our head technician attends and discusses any water issues were they to arrive…..anything had arrived in that period of time prior to that meeting that we have. And if there is any other issue that would have occurred in between , head technicians and I would talk on one-on-one." (P13_Medical Director)
	HHD-5	• "A technical practice committee which is a local group of technologists involved with reviewing best practices and making sure that we move along with the best practices as well." (P19_Retired Technical Manager) • "As the technical manager, I was part of the committee. But, I did not want to lead it. I want to minimize the task related so I was not the chair of the committee I was there just as a regular member. But, the committee was involved and they were making policy and procedures for various tasks within the BioMed Nephrology program and also reviewing and discussing challenges that we face in our daily tasks as well as the working on ways to improve practices. So, when we face a particular challenge with our lets say home dialysis water quality

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
		issue then the committee will take the time to discuss it and see where we could improve practices to prevent them happening again." (P19_Retired Technical Manager) • Yes, [the medical director of the program] came sometimes to our technical practice committee meetings where we had general discussion about home programs. But I had a very close relationship with physicians that work for home programs and we would meet and talk on regular basis when we have challenges and decide to get you know what approach we should take. Whether it was with the challenges in the home program like water set up perspective, the compliance issues on home patients. I would meet with nephrologists on regular basis, it was kind of being done continuously." (P19_Retired Technical Manager)
	HHD-6	• Information could not be obtained from the participant of HHD-6.
• **Risk Management Team**		
	HHD-1	• "No, we don't [have risk management team for home hemodialysis]." (P4_Nurse Practitioner)
	HHD-2	• "So, what would happen is the nurses will raise the concern and I will speak directly with the primary physician. If they can not overcome that concern and it is still present, then it comes to my attention. Then we meet as a group with the [unit] manager. So, I guess I think it is not the official committee. But, yes we do meet as group all of us. We talk about either strategies or you know what we can do to get the patient to get more engaged or if they are worried about the safety risk then we need to remove the machine from home." (P7_Medical Director)
	HHD-3	• "We actually ran that formally through our risk management matrix and essentially the recommendation from my risk management was that as long as the patient has been taught how to do it [referring to microbial sampling], has been advised to do it, and understand the potential implications of not doing it, then it is their decision of whether do it or not do it." (P15_Medical Director)
	HHD-4	• Provincial renal program has a risk management committee. It covers the home program but it also covers everything. It covers renal program. I am a technical representative on that committee. So, they made a point of making sure that biomed technician is on the committee. It is just safety right, and one of our main reasons for being [on the committee] is about safety. If I am not there, then I assign other techs to attend the meeting." (P14_Chief BioMedical Engineer) • "We do have home advocacy for home patients we invite patients to all our committees. We have two patients on risk assessment committee. We just ask patients to volunteer for committee. We certainly get patients to, we want their suggestions." (P14_Chief BioMedical Engineer)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
	HHD-5	• "We have also establish a technical practice committee which is a local group of technologists involved with reviewing best practices and making sure that we move along with the best practices as well." (P19_Retired Technical Manager)
	HHD-6	• Information could not be obtained from the participant of HHD-6.
• **Quality Improvement**		
	HHD-1	• "We have ..we do that…so we always coming up with lets improve this and improve that so we do that ourselves as well." (P2_BioMedical Engineering Technologist)
	HHD-2	• "We have weekly Friday meetings where we discuss all this analysis [of water quality results] and all this information. All the data recordings we have in [clinical manager's] file we discuss that. It is very tightly run program." (P11_BioMedical Engineering Technologist)
	HHD-3	• "You mean constantly trying to improve it [referring to monitoring process]. Ahmm…nothing comes to my mind." (P16_Technical Manager)
	HHD-4	• " [Chief BioMedical Engineer] and I were discussing that we are good at identifying problems. But I don't think we sort of have present any standard operating procedures to tell us what the exact course of action should be if a problem occurs. We have a general idea of what we will do but I don't think we have any SOPs that we go through it . So that is something definitely a value to have or to be part of developing." (P14_Chief BioMedical Engineer)
	HHD-5	• "Yes. The medical director of the program came sometimes to our technical practice committee meetings where we had general discussion about home programs. But I had a very close relationship with physicians that work in terms of home programs and we would meet and talk on regular basis when we have challenges and decide to get you know what approach we should take. Whether it was with the challenges in the home program like water set up perspective, the compliance issues on home patients. I would meet with nephrologists on regular basis, it was kind of being done continuously." (P19_Retired Technical Manager)
	HHD-6	• "We are not tracking [the results]. We try to develop a better a comprehensive quality improvement plan. We do have weekly patients rounds for home hemo patients we try to establish a more of quality improvement program specifically, but we do not have anything formally in place which is a bit of a deficiency in the province right now." (P17_Medical Director)

Categories	Home Hemodialysis (HHD) (The participating HHD programs are de-identified with a number)	Chunks from Transcripts
Abbreviations: HHD: Home hemodialysis		

Appendix 8: Illustrative Quotes from Interview Transcripts for the Theme: Perceived Barriers of and Facilitators to Water Quality Management in Home Hemodialysis Programs

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
Built Environment	Physical elements in and around patients' homes		• Patients' homes did not met the requirements to support the installation, operation, and maintenance of hemodialysis (HD) machines and water-purification devices. (B/C)	• [HHD2_P9_Clinical Manager] • [HHD2_P11_BioMedical Engineering Technologist] • [HHD1_P2_BioMedical Engineering Technologist] • [HHD2_P8_Unit Manager] • [HHD3_P15_Medical Director] • [HHD1_P6_Unit Manager] • [HHD4_P14_Dialysis Technician] • [HHD5_P18_Medical Director] • [HHD5_P19_Retired Technical Manager]/	• [Name of a city] is a very old city. So, we have homes that have very old wiring. Well, believe or not they are not even properly grounded. There is no grounding at all in houses, and when we see that we say oh we got to have grounding. So, it is very important.[HHD4_P14_Chief BioMedical Engineer] • The one I can think of it is they had a home in the north on a lake and it was not insulated completely, so that was not safe. As well as the driveway was very steep and not paved, so we could not get trucks and service the patient and so things like that. But there are a few that we can not do even from an infrastructure. But, there are some [cases] occasionally. I think the biggest problem is they [patients' homes] have to, we had one, again it was only partially insulated and only partial part of the house was safe for dialysis. [Yes], those are the only two [cases], that I can actually think of. [HHD1_P6_Unit Manager] • We, do [referring to home modifications]. The electrical and minor renovations are paid by the program. Having said that we have had the occasional cases that we have been unable to do home hemo just because of, perhaps, the age of the home like some of our old farm houses you know you go out there and it is just not possible with where they want to put the machine to actually renovate the home and a sort of reasonable amount

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					of money. Ya, [referring to patients are responsible for major renovations] or at the end of the day they just they chose just not to go home [HHD5_P18_Medical Director] • Again may be once or twice, a few occasions when we have to replace these lines [connection from well water to tap water] because of the distance sometimes. How far your you know the point of use the feed water line gets into the home from water wells. [HHD5_P19_Retired Technical Manager] • Another occasion I remember we had to say no was patient has no electrical system and was on a generator and well you know we refuse to send a patient on home on a generator because they are too unstable and they could damage the equipment. [HHD5_P19_Retired Technical Manager]
			• Patients' homes were not accessible by vehicle. (B)	• HHD4_P14_Chief BioMedical Engineer	• We had one challenge recently. I just tell you one story. We had a home patient who lived on an island here about an hour from [Name of a city]. The island is accessible by [a] ferry. There are no stairs on this ferry. So, the problem was not a patient's house or patient, [but] the problem was to get to the patient's house in a timely manner. You know, [the] ferry only runs on a certain schedule. We can not make the machine through the island. And then how do we get it from the island to the house? Of course, home dialysis patient needs a lot of supplies, and that was the big stopper. So, we got all the equipment out there, [but] how we [are] going to [send] supplies over there regularly. You know, in the winter months, a ferry can stop running because of ice and weather and [so] now what. So, we had to reject that patient mainly

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					because that would come down to the safety of the patient. It would not be possible for us to do that because, you know what if we can't get to that guy, and so let us pull him off. So, the patient was upset about it, but hey, you know, in the end, it is for the betterment of him. So sadly, he had to move. [HHD4_P14_Chief BioMedical Engineer]
			• Some patients' homes did not have sufficient space, which created challenges for the placement of devices (per the requirements) and storage of extra supplies for water quality testing. (C)	• [HHD2_P8_Unit Manager] • [HHD1_P6_UnitManager]	• Ahh, I am sure we have had challenges. So, a lot of would be space issues. So, like, where do you locate the RO [reverse osmosis], and then you have to separate the RO and the pre-treatment media or anything like that. And then, how long is the pipe from the RO to the machine? I think those would be [the] problems. [HHD2_P8_Unit Manager] • They have to [take one sample], but the sampling process is to clean the ports and then withdraw 20 milliliters and discard it [referring to a syringe]. Then, they need a new clean syringe to get another sample. So that is where some of the errors can happen, whether they don't discard it or whether they don't change that syringe because some patients are very….. they have a lot of space issues. So, they don't want to have extra things if they don't need them, and they don't want to waste [them]. So, sometimes they think, oh well, it's a clean syringe, I will just use it, so those are some of the techniques errors that we might see. [HHD1_P6_UnitManager]
	Environmental conditions		• There was a lack of a clean home environment which impacted microbial sampling. (C)	• [HHD4_P14_Chief BioMedical Engineer] • [HHD2_P9_Clinical Manager]	• Well, if we have questions will take the meter [referring to point-of-care testing device for Endotoxins] with us, and if it [referring to microbial sample] is failed a couple of times, we can do it on the spot. But, we do rely on the lab [laboratory] for

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					that because it is just it is a more controlled environment. Some patients' homes are not conducive for testing. There is just so much in the air that could contaminate that sample. [HHD2_P9_Clinical Manager]
			● There was a lack of adequate quality and supply of source water at patients' homes to support the initiation and maintenance of home hemodialysis programs [HHD]. (B/C)	● [HHD2_P8_Unit Manager] ● [HHD2_P9_Clinical Manager] ● [HHD2_P11_BioMedical Engineering Technologist] ● [HHD3_P15_Medical Director] ● [HHD2_P7_Medical Director] ● [HHD4_P13_Medical Director] ● [HHD4 _P14_Chief BioMedical Engineer] ● [HHD6_P17_Medical Director] ● [HHD1_P5_Medical Director] ● [HHD1_P3_Nurse Practitioner] ● HHD1_P18_Medical Director] ● [HHD1_P19_Retired Technical Manager]	● Our biggest challenge here is not the quality of water but the quantity of water [i.e., source water at patients' homes]. We have some home patients with well water that is very shallow and they do not have [a] lot of water. So, that becomes more of challenge because no water no dialysis.[HHD4_P13_Medical Director] ● There was organic some stuff in that water that we cannot treat. So, once I got those results I took it to the home hemo staff here in [Name of a city] and I said we can not treat this water. [HHD2_P8_Unit Manager] ● Yes…we definitely have to do that when the testing of the feed water is positive ..we had a couple of people that leave out of the country and unfortunately their well have had to be shocked on numerous occasion because of water run – off and problems with the feed water. [HHD5_P18_Medical Director] ● I have to say that if the water quality, it does not happen often, but it did happen the numbers of times, if the water quality of the feed water [i.e., source water] was really way off of our standards, [then] we would decide that the patient ..that's not the patient to go home. We did not install home [for] patients on water that were terrible that we need so much more equipment to just because of the concern of what that could be. So we have to try to

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					be simple. Yes, yes [referring to not recruiting such patients on home programs] and sometimes in my discussion on times. Those discussion would take place with physicians and nursing case manager. But, sometimes it was difficult for me to take this to physicians and sometimes the physicians would… I give you an example. We had a patient home on a lake and was pulling water from the lake in the home. And the program wanted to dialyse this patient at home. You know I had to explain no we could not do it because it is an open source water and we have no control over that water. And could not send the patient home. [HHD5_P19_Retired Technical Manager] ● Municipal drinking water is usually fine. I am not, none other than the occasional boil water advisory. What we [can] do if a patient can not use water any more. [HHD3_P15_Medical Director] ● Yes, more problem for Nxstage patients [referring to boil water advisory issued by suppliers]. Because, Nxstage water treatment system does not necessarily remove all of those boil water advisory bugs and where the traditional system, the patient was on a baxter traditional system with RO, then RO would take out anything that was of concern, but, NxStage does not and so we clinically we don't necessarily allow those patients to continue to use their NxStage system because it has its stand. [HHD3_P16_Technical Manager]
	Home modifications	Customization of water-purificati	● There was a need for customizing water-purification devices according to source water issues at patients' homes. (B/C)	● [HHD1_P2_BioMedical Engineering Technologist] ● [HHD1_P6_Unit Manager]	● I think there are solutions to the problem. I won't say [that] it is more [problems in patients having their drinking water supplied from wells compared to those having their water supplied from

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
		on devices		●HHD2_P11_BioMedical Engineering Technologist] ●[HHD2_P9_Clinical Manager] ●[HHD3_P15_Medical Director] ●[HHD3_P16_Technical Manager] ●[HHD4_P14_Chief BioMedical Engineer] ●[HHD4_P13_Medical Director] ●[HHD6_P17_Medical Director]	municipal]. It is just we have to be very specific about how we do it [referring to maintenance of treatment]. We had no issues with some of the wells. For sure, that's [referring to well water] not necessarily an issue, but we may had to do some troubleshooting before they started on the water system. And once we know that how the well works, then we are fine. It is really very individual, we have people in small towns that are not on wells but they have problems with the water pressure, so it just depends [on patients' source water quality]. Really, going like and say [name of a town] has lot of sediments in their water. So, like you know the pressures in the water system and damage to some of the equipment is little different and it just depends [on patients' source water quality], its quite an individual [referring to need of type of treatment and maintenance services]. [HHD1_P6_Unit Manager] ●..so we ended up putting a scavenger in front as pre-treatment and as soon as we did that we are getting the actual 3 months life span of those filters now. But, it took a little bit of digging in and analysis of that water…so certain areas you get a kind of know what the ..what the area is like..if it is high alkaline area or something else[HHD2_P9_Clinical Manager] ●We certainly ran into problems with some naturally occurring radioactive elements that were not actually clear through the system. And so we had to look at different pre-treatment and [when] we were not able to manage some of those aspects.[HHD3_P15_Medical Director];

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					● .. that's where the NxStage is the beauty right. Because, you have 50 liters in the dialysate equipment batch prepared and you are good to go. So, water supply is not an issue. [HHD6_P17_Medical Director] ● At that time [referring to home assessment] then we even before the decision was made to by the patient to go home dialysis or not we will take water sample of the feed water. Not only from the normally from metal or organic contaminants, but we would also test microbiology. And then, we would use this result to decide on what kind of water treatment system would be require to the home patients. Basically, 1 in 3 every home patients the water treatment set up are different right…like if they are in the city,if they are out in the country, if they have wells, we would use those results and decide based on that what kind of water treatment would be required. what I see the kind I mean we always install a portable…like the basic standards component were always there like you pre-filters, pre-carbon filters, and water treatment systems like reverse osmosis. But different sometimes would be the need to add sometimes U.V. light and ultrafilter depending on the water quality or additional pre-treatment equipment at times would be require to lower the conductivity in the feed water. [HHD5_P19_Retired Technical Manager] ● I don't see that maintenance as a problem…water quality if we had one or two patients where the water quality is a challenge…and better that patient was more on a traditional system so that we can deal with water quality challenges..but patients

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					really wants to be on the Nxstage system…so that becomes a challenge for us. [HHD3_P15_Medical Director] ● Actually, we have one example, actually one thing I am interested that may not quite apply but [name of a Chief BioMedical Engineer] was saying that we were even though our well water patients don't get water supply chlorinated or chloramine, I should say, we do use carbon tanks even for all of our well patients as well. And I mean there is one incident where someone's well dried out and they put municipal water in their with the chloramines added. So, if we not had carbon tanks present then patient could had a hemolytic issues with that chloramine exposure. So, we do have safeguards like that in place. [HHD4_P13_Medical Director]
			● There were concerns about uncertainty in determining which devices should be considered necessary and which should not. (C)	● HHD1_P1_Clinical Manager] ● [HHD1_P6_Unit Manager] ● [HHD2_P7_Medical Director] ● [HHD2_P9_Clinical Manager] ● [HHD2_P11_BioMedical Engineering Technologists] ● HHD5_P18_Medical Director	● We have got no evidence right. Now, the companies [referring to water treatment manufacturing or marketing companies] would tell you this is what the potential. But, we have got no evidence that anybody is ever tested and proven that it was endotoxin or bacterial issue that cause the problem to the patient. I just pulled up a minute ago a really good presentation. I wonder if I still have it, ya its right here. So, this is the vendor propaganda to sell their filters. [HHD_P1_Clinical Manager] ● Well that's would be our ideal situation is that we will provide patients with the filters, but then who would change them on periodic basis. New machines will have a reminder when they need to be changed so the patients would do that. I am not sure that all of our patients are able to change those

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					filters. So, in some cases, we may still be required to change them when we are going their for routine maintenance. We go there every three months. [HHD1_P6_Unit Manager] ● Yes, from cost point of view…but then, softener would be more costlier to run rather than changing the membrane…softener than monitoring softener…maintaining softener could be much more work…than going for filter change. Instead of 5 years it will be every 4 years…something like that…I am talking about the main membrane…[HHD2_P9_Clinical Manager]
			● External vendors helped identify water-purification devices for removing contaminants found in source water occasionally and not mentioned by the Canadian Standards Association [CSA]. (F)	● [HHD2_P11_BioMedical Engineering Technologists] ● [HHD3_P15_Medical Director] ● [HHD2_P9_Clinical Manager]	● Yes exactly. Certainly it has created some challenges with couple of our patients. Again, we are working pretty closely with our partner Baxter. We really gone back to them that we need to recreate in terms of how we are going to manage these systems and they have been successful. There are not any guidelines on how to deal with radioactive elements, in particular. But, we have been able to resample with [the] dialysate side and now we have almost undetectable levels of radioactive elements, certainly within the acceptable guidelines for it. [HHD3_P15_Medical Director]
		Home interior adjustments to accommodate the needs of	● The adjustments made to patients' homes to accommodate devices disturbed them. (C)	● [HHD2_P11_BioMedical Engineering Technologist] ● [HHD3_P16_Technical Manager] ● [HHD4_P14_Chief BioMedical Engineer]	● So it [referring to the distance in-between devices and from the source water] has to be at certain distance. We do provide patient no when they commit these problems. We say no, because of this reason [referring to the significance of keeping the line between RO and the HD machine free from contamination] we need to have everything close

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
		placement of devices			by. Sometimes that's why I go for pre-assessment always go that ok what is your idea. They say oh I want this I want that…I say no …I know you have started training but this is where the things will go you need to move this this and this from your apartment. No they [referring to patients] do mind. Oh I like the dresser I do not want to move this…or you know…[But], my job is to tell them [that] we got to move these things out because this will go here..and this will go here. I need to make sure safety of the patient and efficacy of the machine, both right. [HHD2_P11_BioMedical Engineering Technologist]
			●The noise generated from the devices was bothersome for patients. (C)	●[HHD2_P7_Medical Director] ●[HHD2_P11_BioMedical Engineering Technologist]	●It happens all the time [referring to challenges in the placement of devices], that happens. This people are so finicky that they want the water system down in the basement so that they do not see it or hear the noise. Sometimes, they want it somewhere in another room. But, we have to, since quality of the water is very important, we have to make sure that [the] line between the dialysis machine and [the] water also get[s] disinfected. [HHD2_P11_BioMedical Engineering Technologist] ●I don't know about the quality, if I can say if the quality is creating problem. But I think water in general can be a problem, you know, it is one more system or machine that patient have to look after. One more thing that can go wrong, right. I remember before we switched to these ROs [referring to integrated heat disinfection], we used to have Ros [that were] very loud and patient

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					complained and they still do complain actually about the noise of the machine
		Cost to home modifications	● In one home program, the lack of reimbursement for the source water quality testing before a patient was selected for home programs was identified as a challenge for planning of water-purification devices. In contrast, all other programs did covered the cost of such testing.	● [HHD1_P2_BioMedical Engineering Technologist] ● [HHD2_P9_Clinical Manager] ● [HHD2_P11_BioMedical Engineering Technologists]	●Before they become our patients we have an issue with doing the testing. The testing of chemical samples and taking and sending samples for testing is expensive. So, if we do the initial assessment on patients and that's the long way way for them to actually becoming our patients for this program. So, if we take samples, that's going to cost that program has to bear. And we cannot charge that against the patient and we cannot charge that cost to anybody until they actually become the patient of this program. So, that's how kind I would a hindrance to be able to do the sampling initially. [HHD1_P2_BioMedical Engineering Technologist] ●We know what our water treatment system will do, and if it cannot take care of the incoming water, then we have to provide extra filtration or extra specific kind of filters to tackle that contaminant. So, all those contaminants that are that may be there. We do measure them using our special rural kit and then we design system based on that. So all for designing the system. [HHD2_P9_Technical Manager] ●Basically, one in three every home patients the water treatment set up are different right. Like, if they are in the city, if they are out in the country, if they have wells, we would use those results and decide based on that what kind of water treatment would be required. [HHD5_P19_Retired Technical Manager]
			●The program's coverage for installing additional water-	●[HHD1_P2_ BioMedical Engineering Technologist]	●Ya, I talked to my team about this, recently. We do the chemical testing [referring to testing after

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
			purification devices helped maintain water-purification devices. (F)	●[HHD1_P4_Nurse Practitioner] ●[HHD1_P5_Medical Director] ●[HHD2_P9_Clinical Manager] ●[HHD2_P11_BioMedical Engineering Technologist] ●[HHD3_P15] ●[HHD3_P16_ Technical Manager] ●[HHD4_P14_Chief BioMedical Engineer] ● [HHD5_P19_Retired Technical Manager]	patient is selected on home program] and then will give the results to patient. And will make a recommendation but not very often do we enforce that recommendation. If the patient feels [that he] cannot afford to do something they may not do it. The only thing that our program provides is the reverse osmosis which is a charcoal filtering system, microbial filtering, and reverse osmosis membrane that prepares the water for use. But we don't provide water softeners or iron filters or anything like that. The RO [reverse osmosis] will eliminate a lot of that, but it is just harder on the RO. So, harder on our device and we end up going to membrane [a] lot more if we don't enforce that they get water softeners and those sort of things. So, that's hard to enforce that. [HHD1_P2_BioMedical Engineering Technologist] ●Yes, we pay for everything except…So, if a patient on a well..So I don't know how to answer this. Lets take traditional system when a patient is on a municipal well we would pay the vendor to do home assessment set up their equipment..we pay for the equipment in terms of water treatment equipment system for hemodialysis..and we pay for all the supplies that patient uses. If that patient has to have some treatment of feed water first like water softener or some other treatment then we would probably pay for the initial installation for the patients of those treatment, but patients would be responsible for maintaining that. [HHD3_P16_ Technical Manager]

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
			● The cost for some aspects of home modifications was incurred by patients. (C)	● [HHD1_P1_Clinical Manager] ● [HHD1_P5_Medical Director] ● [HHD1_P6_Unit Manager] ● [HHD2_P8_Clinical Manager] ● [HHD2_P9_Clinical Manager] ● [HHD4_P14_Chief BioMedical Engineer] ● [HHD6_P17_Medical Director] ● HHD2_P7_Medical Director ● [HHD5_P18_Medical Director] ● HHD1_P2_BioMedical Engineering Technologist	● But, they are paying for water usage and there is some rebate they get for taxes for water usage and I know the Kidney foundation is looking into ways to help them more with the water. [HHD1_P6_Unit Manager] ● Yes, they do. It is not only about electricity that they complain about, it is water consumption [also]. Especially, when you are on municipal supply, you are paying for water right. [HHD4_P14_Chief BioMedical Engineer] ● Oh water wise we have been going on going battles because [the] CSA [Canadian Standards Association] requires patients on home hemo [hemodialysis] machine to have a separate dedicated, a breaker panel, circuit breaker for electricity. Most of the patients don't have room for that on their breaker panel. So, patients have to pay for that. [HHD6_P17_Medical Director] ● So, we do that once a year for home patients, [and] then they can submit that [referring to calculation for water consumption and electricity spect on home hemodialysis] and they get tax return on that and they get it done. Before they go home, we warn them your power bill and water bill are going to go up, you have no choice you are adding to your system. So, we warn them we do not want surprises and it is sometimes some of our home patients, patients [who] are not doing economically that great, the little things like that could be a problem. But we also work with Kidney Foundation and you know. [HHD4_P14_Chief BioMedical Engineer] ● So, we don't pass on any fees to the patient. So, if somebody needs something it is on us who provide

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					as the program. We have never asked the patient to pay for extra filters or things, that does not happen. What does happen is if the patient water quality from you know for example there well was insufficient or inadequate or not appropriate, they have to pay for the cistern water, or they have to pay for the road. We don't actually pay for the water but we don't ask people to pay for anything equipment or filter related. [HHD1_P5_Medical Director] ● Most of our home patients, it [referring to water hardness in source water] is not an issue.We check it on the initial set up and if we determine the softener is to be needed, then we would put one in. But what we found is our the patient already have one, you know what I mean. They already known their water that they have some hardness to it. [HHD4_P14_Chief BioMedical Engineer] ● I have certainly heard people you know occasionally complain about it [referring to electricity bills]. I think the bigger issue is actually is water you know these machines use more electricity. But, does it actually cost more than having to come in to in-centre for dialysis 3 times a week? I don't think so. [HHD5_P18_Medical Director]
			● There was financial support provided to patients from patients' organizations and through tax rebates. (F)	● [HHD1_P6_Unit Manager] ● [HHD4_P14_Chief BioMedical Engineer] ● [HHD5_P18_Medical Director]	● But, they are paying for water usage and there is some rebate they get for taxes for water usage and I know the Kidney foundation is looking into ways to help them more with the water. [HHD1_P6_Unit Manager] ● We actually do that. So, there we actually had Kidney foundation lobbies, so we [referring to

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					home programs] will reimburse patients fully for all utilities. We have been doing that now for several years. With NxStage again because water is so much less it becomes quite a normal amount, [but] we still reimburse people with NxStage with all utilities and power and water. We had government funded things for several years ya..[HHD6_P17_Medical Director] ● So, we do that once a year for home patients, [and] then they can submit that [referring to calculation for water consumption and electricity spect on home hemodialysis] and they get tax return on that and they get it done. Before they go home, we warn them your power bill and water bill are going to go up, you have no choice you are adding to your system. So, we warn them we do not want surprises and it is sometimes some of our home patients, patients [who] are not doing economically that great, the little things like that could be a problem. But we also work with Kidney Foundation and you know. [HHD4_P14_Chief BioMedical Engineer] ● Not completely true. Years ago with the help of one of our patients we did ahh we meet with city council in Ottawa and so for the Ottawa residents for years they have been able to get a 500 dollars rebate if they are on home hemo dialysis and many of our patients also qualify. Now there is a subsidy for low income families for their electricity bills and ofcourse many of our patients are on low income and so they do qualify. But, it is certainly not like it is not paid for. [HHD5_P18_Medical Director]

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
Maintaining safe water for HHD	Processes for conducting testing and maintenance	Knowledge and skills	● There were difficulties in achieving consistency in the method used for sampling and verifying the microbial quality of HHD water. (C)	● [HHD1_P2_ BioMedical Engineering Technologist] ● HHD2_P9_Clinical Manager ● HHD1_P6_Unit Manager	● We should find a consistent way of testing [microbial testing of HHD water], because [if] we test a device one day it will pass and the same device the next day will fail or vice versa and we have done nothing different. So, that kind of thing worries us from time to time. [HHD1_P2_BioMedical Engineering Technologist]
			● Local drinking water suppliers and testing laboratories were helpful in identifying the types of testing parameters as needed for ensuring water quality for HHD, in addition to those mentioned by the CSA standards. (F)	● [HHD1_P2_ BioMedical Engineering Technologist] ● [HHD1_P6_Unit Manager] ● [HHD2_P9_Clinical Manager]/ ● [HHD3_P15_Medical Director] ● [HHD4_P13_Medical Director]/ ● [HHD4_P14_Chief BioMedical Engineer]/ ● [HHD5_P19_Technical Manager]	● Well, when we went to [name of a provincial laboratory] to get the chemical analysis done, we sat down and we went through everything that we think we need to go through. Like the lab testing is following the CSA [Canadian Standards Association] and the Canadian drinking guidelines. But, it's much more even than that. So, like we are testing lots of stuff, [and] stuff that is not even in the CSA and ISO [International Organization for Standardization], or Canadian drinking guidelines…[HHD2_P9_Clinical Manager]
			● Guidelines and manufacturers' recommendations on some aspects of HHD water quality management were contradictory. (C)	● HHD3_P15_Medical Director	● Well it involves what the standard wants to see and what the manufacturers provide related to drain. So, CSA standards says drain should be X and NxStage does not need that X and so that's either we ignore it and treated as guideline or not? [HHD3_P15]
		Resources to support appropriate testing and maintenance	● Staff time for travelling to each patients' home and the cost of maintaining sufficient staffing were barriers to performing water quality management tasks, precisely when the number of inspection visits to patients' homes was required more often. (B/C)	● [HHD1_P1_Clinical Manager]/ ● [HHD1_P2_BioMedical Engineering Technologist]/ ● [HHD1_P3_Nurse Practitioner] ● [HHD1_P6_Unit Manager]/ ● [HHD1_P4_Nurse Practitioner]/ ● [HHD3_P15_Medical Director]/ ● [HHD2_P7_Medical Director]/	● If they [referring to in-house BioMedical Engineering Technologists] are going out they often stay out so that they can capture more than one patient in a trip, [and] that includes over time travel time right so there is lot of cost. [HHD1_P6_Unit Manager]If we are going on in the program and if we are expanding it out to more rural sides and ya..its personnel, you need more people to be able to service that. Right now I have got three

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
				●[HHD2_P8_Unit Manager]/ ●[HHD2_P9_Clinical Manager]/ ●[HHD2_P11_BioMedical Engineering Technologist]/ ●[HHD4_P13_Medical Director] ●[HHD4_P14_Chief BioMedical Engineer] ●[HHD5_P18_Retired Technical Manager] ●[HHD5_P19_Retired Technical Manager] ●[HHD6_P17_Medical Director]	technicians in [name of a city], one in [name of a city], and one in [name of a city]. I just hired a tech in [name of a city], because previously the tech in [name of a city] is covering [name of three cities] home patients and now that is quiet a bit of travel for him to go. It is 2 hours [name of two cities] and it is gonna be overnight and hopefully it is not big issues. But, now having a tech guy at those locations, it certainly cuts down on that. But, we are still growing the home program here in [name of a city] we are getting more patients so even another tech could be helpful, because what we are finding just hard keeping up all the filters changes and all that. [HHD2_P9_Clinical Manager] ●We can't do [microbial water quality testing] once a month, because some of our patients lives 8 hours away. So, operationally we would not be able to up taking that ok right. Because they have to go out every 3 months service anyway so that's what we thought every 3 months would be sustainable. We just don't have money to send someone out every month to do sample. Healthcare system don't have the money. [HHD1_P4_Nurse Practitioner] ●Ofcourse, it will help [referring to technologists doing microbial sampling will help in getting more consistent way of sampling], but it comes the issue of manpower resources. As it is, we got it to 2 months. And when we go out in three months we do all that work. If we know a patient has not disinfected, then we will disinfect it. If a patient has not taken any monthly samples, [then we will] take samples. So, we do all that. But it is difficult to say that well ok if the patient doesn't do anything in 3

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					months, we are going to go there every months- every 2 months. It just becomes much more you know labor intensive to be able to do that. In perfect world we send everybody every week to do it. [HHD1_P2_BioMedical Engineering Technologist] ● Something like that once in three to four months [referring to delay in keeping up with preventive maintenance schedule for every 3 months], because we are still short staffed. The staffing in [name of a province] is always a problem, so because [there is] thin population [and] longer distances. So, staffing is a problem. [HHD2_P11_BioMedical Engineering Technologists] ● Yes, in a home program the home patient is trained to replace the carbon, he is trained to replace particle filter. It wouldn't be practical to have a technical person do that, because they will be travelling all the time. It is not practical, it will make program a lot more expensive to run. You got to send staff all the time for change filters. We train the patient how to do that. [HHD4_P14_Chief BioMedical Engineer] ● And probably you will find practices across the country in different programs have different approaches. In Ottawa we try to limit as much as possible the demand on the home patient by having the staff. So, basically, the home patient, before the treatment, like, the only involvement was testing really was the post-disinfection, because they were in charge of disinfecting their dialysis machines and water treatment system. They were in-charge of testing chemicals, if we use chemicals for

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					disinfection. [HHD5_P19_Reitred Technical Manager] ● Oh it has..so whole testing has tremendous impact on the budget and it is one of the things that we need to sit down. Now that [name of a retired technical manager] has left we do need to sit down and look at all of this again, because having the techs [BioMedical Engineering technologists] go out and do the water sampling obviously has implications for cost. And even the test themselves can be quite expensive. It has huge implications for the program when you are…you know when you are trying to stay within the budget constraints. [HHD5_P18_Medical Director] ● Definitely, the home program is more demanding from that perspective[referring that during seasonal variations devices in home programs need more maintenance compared to in-center]. I mean in-center we tested at same frequency as home patients on a city water. But, it is just that it is easier because it is right there, [but,] with home patients obviously [there is a] challenge of travelling. [HHD5_P19_Retired Technical Manager] ● For sure….I think that's ..when you look at from a financial point of view it makes absolute sense to have the patients do this, [but] the challenge is getting them to do it. So, [name of a Retired Technical Manager] felt very strongly about the importance of water quality and that they just needed to do it. [HHD5_P18_Medical Director] ● You know resources are an issue with those folks who are on well waters, [but] they really need our program anyway. I mean we haven't had to make

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					this difficult choices but the folks on well waters are the ones that we have the biggest challenge. Ya..we have patients who are couple of hours from the centre and those are often obviously the ones who are on well. Oh it is, it does create challenges. [HHD5_P18_Medical Director]
			●Patients' non-compliance was mentioned as a barrier to performing quality testing and device maintenance, potentially leading to an unsafe condition (e.g., development of microbial growth in devices) and increased cost of device care. Patients' non-compliance also created challenges in gaining information needed to ensure the safety of devices for an extended period. Several factors leading to non-compliance were mentioned, which could be majorly divided into patient-related and process-related. (B)	●[HHD2_P9_Clinical Manager] ●[HHD1_P6_Unit Manager] ●[HHD5_P19_Retired Technical Manager] ●[HHD4_P14_Chief BioMedical Engineer] ●[HHD2_P8_Unit Manager] ●[HHD2_P7_Medical Director] ●[HHD1_P5_Medical Director] ●[HHD1_P3_registered Nurse] ●[HHD1_P4_Nurse Practitioner] ●[HHD1_P2_BioMedical Engineering Technologist] ●[HHD2_P9_Clinical Manager] ●[HHD1_P1_Clinical Manager] ●[HHD2_P11_BioMedical Engineering Technologist] ●[HHD3_P15_Medical Director] ●[HHD5_P18_Medical Director] ●[HHD4_P14_Chief BioMedical Engineer] ●[HHD1_P2_BioMedical Engineering Technologist] ●[HHD5_P19_Retired Technical Manager]	●I would say significant proportion greater than 50 % I would say probably don't do what they are supposed to do. [HHD2_P8_Unit Manager] ●It is usually source water is not the issue, [but] it is usually a patient not disinfecting [participant referring to reasons for microbial contamination] [HHD1_P2_BioMedical Engineering Technologists] ●We certainly have the recommendations for them to do it, but the majority of them I would say do not do it on monthly basis. [HHD3_P15_Medical Director] ●Well, that is challenging now right because if they [referring to patients] don't sample…if they don't send the samples for 4 months, [then] we don't know if they are disinfecting the system regularly. Because, at the end of the day sending a sample give us a snap shot of how well they are keeping the system clean, right. If we don't know for 4 months, then we have to go in before 4 months right. [HHD2_P9_Clinical Manager] ●Are they changing their ultrafilters as required on 60 days basis?…hmm.. I think those are things for me [that] is really where the problem is. [HHD2_P8_Unit Manager] ●It is getting patients buy-in to convince that monitoring is important. We have one patient that said, he swear that he would never take a sample

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					ever. So, it is up to our techs to do the sampling. [HHD2_P9_Clinical Manager] ● I think there are many opportunities where they [patients] could go wrong, because it [referring to the microbial sampling process] is more complicated procedure. So, we certainly hear grumbling from our patients about how complicated it is and sometimes it is challenge to get the water and I think where you start to see is that you do get fair number of what you will see is false positives results where they see it is microbiologic contamination, but it is not really a water problem. So, I think they [referring to technical team of a home program] do see technical errors in terms of sampling and that's probably introducing patients frustration. [HHD3_P15_Medical Director] ● Now what we will do [is that] when we are concern of contamination, as we do see one patient is having repeat contamination, we will often send a technician out to do sampling for us so that we can see if there is actually real water issue or just contamination. Most of the time when technician goes out they retrain the patient in terms of what they are doing and more often what we do find is the [sample] collection issue and those are big issues. [HHD3_P15_Medical Director] ● Not easy. So, patient will sometime find it difficult then they will work around it. It might be [a] little bit more time consuming so that might be a problem. If there is automatic ok..I press the valve here and machine dispense the water I close it. Somebody, comes and take it off, then they will do it. [They have to] wait for the machine and then

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					they have to connect the syringe [referring to microbial sampling process]. [HHD2_P11_BioMedical Engineering Technologist] ● It is a small thing, but it is one more thing on top of everything else they do. It is because it [referring to microbial sampling] is only once a month, it is so easy to forget it. [HHD1_P6_Unit Manager] ● There are certain patients say for carbon filters, if they are changing their carbon tanks. A carbon tank is heavy. So, we know right away. So, you are not changing the carbon tanks, because I don't want to break your arm right. So we often have home patients say oh I have got my neighbour he is going to come over and change the tank for me that's one situation we had. Sometimes, family members do it even sometimes a person who delivers the tanks he does not work for us he is just a contractor we train him how to do it in case that's needed.. but we make things work out. If a patient is physically able then they will do it, otherwise me make other arrangements. Some aren't physically able to do with anything too heavy and we don't want them to do it. [HHD4_P14_Chief BioMedical Engineer] ● Patients do not notice any difference. So, they are not going to worry about it. If it comes about 100 [CFUs], [then] we call a patient, "hey can you do this , do this, do this…for testing." But, [a] patient says, "I don't feel any problem I am not going to test it." So, we are very stuck in the situation we are trying to meet this Canadian Standards but the standards are set in a way that I don't know. So, if you fail what are the consequences for the patient. I

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					don't see that, [pause] our patients don't see that. So, then what is the motivation for the patient to do something about it. I mean if you give a prescription to the patient they don't take it, [but] they have adverse effect, so they take it. In this case, if it is at 150 [CFUs] and tell the patient that, "hey your CFU was 150, can you re-do this, re-do this. The patient then says, "I am fine why I am doing this?" So, those kinds of questions I wonder about from time to time. It is hard to convince a car owner to bring the car and change the engine when he is not having any problems for that your car has not stopped, he never had any problem and he takes it to service…and why I am not having any problem. And patients say the same thing when we say you do this, you do this, it is like what are we doing? It is difficult to convince some patients I will say you do this, you do this. And I think that people who set the standards should be able to answer too. [HHD1_P2_BioMedical Engineering Technologist] ● Absolutely, [nodding to the question whether noncompliant to disinfection increases cost of maintenance]. So we actually take pictures of how clogged up some of the filters are and trying to show the patient that if you don't disinfect this is what happens. [HHD1_P6_Unit Manager] ● ..and also on our monthly calls that's one of the things we ask if you had a positive chlorine test in the past month and it just helps trigger the question so [name of a patient] will say, "oh I ran out of those or I don't have the chlorine test strips."[HHD1_P6_Unit Manager]

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					● If you are disinfecting, ya, we want to do our sampling that is far away from a disinfection as possible right. You don't want to do a sample right after your disinfection typically you don't want to do that. Because, it is not giving you a really good idea of what is going on. That sample better pass right. Well, it is possible [referring to patients may be sampling after disinfection] because there is nobody there to [see them] and they are not probably not going to tell you if they just disinfected and sample. [HHD2_P9_Clinical Manager] ● The cost of our maintenance are quite high because if routine cleaning and disinfection is not done the cost, once if bacteria and endotoxins get into the system, is quite expensive to remove them. Yes, pretty, we get it quite often [referring to development of biofilms in patients' devices]. We had one this morning that had biofilm developed we can tell. [HHD1_P2_BioMedical Engineering Technologist] ● Some of them are good and some are not. One home patient one time told me he is a real IT guy [and] works a lot with computer. He works for RIM, the blackberry company. We were training him on technology. He was looking at the network technology of the machine where the machine can be hooked up to a central software system. Ok machines can be monitored from central station. So, he had spoken to me that, "you know what I am going to do [name of the Chief BioMedical Engineer of HHD-4], I am going to write a software program and hook up my laptop to this dialysis

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					machine. I hope he is not dead serious and I am looking at him, "No you are not." You are not attaching anything like that. Before we send the machine home, I would disconnect that. Because he was curious, I was sure he going to write a software and could have damaged machine. I know probably he wouldn't have gone anywhere, but just for safety. [HHD4_P14_Chief BioMedical Engineer]
			● Heavy work-load from other tasks involving and not involving water quality aspects was a barrier to keeping up with the quality testing and maintenance schedule. (B)	● [HHD1_P2_BioMedical Engineering Technologists] ● [HHD1_P6_Unit Manager] ● [HHD1_P3_Nurse Practitioner] ● [HHD1_P14_Chief BioMedical Engineer] ● [HHD2_P11_BioMedical Engineering Technologists] ● [HHD4_P14_Chief BioMedical Engineer] ● [HHD2_P9_Clinical Manager]	● That's right. Well the technicians, when the patient gets trained they go out there and install but they are also involved doing when the patients come off the program and so we have probably 48 percent of our population comes off the program in any given year. So, we have lots of transplants or then they change the modality so they are not able to do it at home anymore. So, we train and we take them off as fast as we train them. It is a good thing that we are losing them to transplant and that's most of our patients. However, that's [a] lot of workload for the technicians. They have to go to their homes and bring the equipment out after they install and do all the servicing they have to monitor that as well that's right. …that's most of our patients. So, water sampling is just always that an extra thing for everybody involved. It is important but it is extra [HHD1_P6_Unit Manager] ● But, we don't work for hemodialysis group, we are dedicated to their program, but we work for biomedical engineering department. But our techs we only do dialysis stuff and any equipment related to dialysis equipment oh sorry the clinic, for example, the infusion pump they use in the clinic, or you know deregulators crash carts that are always in

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					clinic, we also do maintenance and repairs on those. We are all fully qualified bioMeds techs. [HHD4_P14_Chief BioMedical Engineer] ● The time ..patients get admitted to a hospital and sometimes we even don't know about it. Sometimes patients travel we try and tell them you have to let us know when you are travelling, so we have to have a plan for disinfection of your machine. So, they might say ya ..I am travelling here so the technicians would have to go and pull the machine or make a plan. [HHD1_P6_Unit Manager] ● Just two other major challenges I think so number one is storage of equipment and the microbiological purity of the equipment that we are storing. So, take for instance..reverse osmosis machines. So, I think if you let them sit for any period of time they just start to grow bacteria…we have lot of this…right ..because we need a stock…to be able to send to patients as the program grows…and so being able to hook them up and disinfect them on routine basis is actually very challenging. [HHD2_P9]
			● For efficiency purposes, maintenance services were scheduled according to patient's geographic location (F)	● [HHD1_P2_BioMedical Engineering Technologist]	● We have already made some improvements to [referring to inspection visits]. We just don't, when we go out, we just don't go out to one patient and come back. We have patients that are clustered together, so we can do more than one patient when the technician is out on the road. So, they can do two to three patients in one trip, rather than making separate trips to each patient. We kind of maximize that way so we reduce the travel time and it is more efficient that way. So, we have done that already. So, I am not sure what else we can do it to

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					maximize our time. [HHD1_P2_BioMedical Engineering Technologists]
			● The microbial sample storage and transportation requirements were difficult to achieve, creating issues with testing validity. As a result, there was a delay in receiving microbial test results and an increased cost of testing. (B)	● [HHD1_P1_Clinical Manager] ● [HHD1_P4_Nurse Practitioner] ● [HHD1_P6_Unit Manager] ● [HHD2_P11_BioMedical Engineering Technologists] ● [HHD2_P9_BioMedical Engineering Technologists] ● [HHD3_P15_Medical Director] ● [HHD4_P13_Medical Director] ● [HHD4_P14_Chief BioMedical Engineer] ● [HHD_P18_Medical Director]	● The next problem is timing distance. We have got people that are eight hours away from [name of a city], but that's another four hours away from [name of a city] where the tests needs to get by vehicle. The test isn't viable unless it has been in with a frozen pack for a certain period. [HHD1_P1_Clinical Manager] ● That's what I am saying. That is why we don't take sample sometimes when we go far, because it will fail for sure next day when we bring it right. So, there are problems, we have to properly ice it you know and it has to be transported properly. If there is a little bit of breaking the chain of the things, then sample will fail and then we have to you know ..it is a bigger problem. [HHD2_P11_BioMedical Engineering Technologists] ● Ya, then there is sample storage. I don't wanted to first start this even with the techs. They were taking samples, but then they were driving house to house for hours and the sample is sitting in the car. In summer time even if you put ice bags in there [it] well eventually that warms up and then drop by [the] time you drop the sample off ..it is now no good. [HHD2_P9_BioMedical Engineering Technologists] ● Sometimes Purolator takes it [referring to samples], but they don't give it right away. [HHD2_P11_BioMedical Engineering Technologist]

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					● ..that's why we have cut off for Thursday because if it [referring to microbial samples] is sent on Friday, [then] the lab is closed on the weekends so they don't get the sample back until Monday. I mean receive until Monday and that would have been too late, and that's why we have cut off for Thursday. [HHD1_P4_Nurse Practitioner] ● when they [referring to patients] have everything, if they do it too late in the week so it is not going to get to [location of laboratory] and they might have done it and they might have used good technique and they may have completed it and then it is just too late in the week for them to get to [name of a laboratory]. So, it is just a waste. So there is a lot of samples that do get out there but they don't get processed and so there is a lot of recollection which is a problem for our patients. [HHD1_P6_Unit Manager] ● So they have to send it, that's why they send it via UPS. But, we have patients that are 8 hours [name of a city]. So, they are all over [name of a province] and so for those rural places to find a place and to get there on the right day sometimes the more rural they are they don't get UPS daily where they have to send it to you know the local staples or wherever they can get that the sample picked and if they live way out on a farm then UPS wont pick it up ..right it will pick it up in some places but we have lot of farmers and things like that so the remoteness of some of that communities makes that a little harder. So, I think that's why sometimes they have to go out of their way to take the samples so then to have to go to the way to drop it off and so by the time

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					they do that sometimes they are not getting to [location of laboratory] on time. [HHD1_P6_Unit Manager] ● So, to do a monthly water sample they [patients or in-house BioMedical Engineering Technologists] can't do it on Friday, so it depends on when they are dialyzing when they remember to do it and fit it in with all the other things that they [referring to patients] have to do. [HHD1_P6_Unit Manager] ● Yes, cost is the big issue [for testing ultrapure water for HD]. Certainly doing endotoxin testing, and transportation challenges of getting the endotoxins in for testing has been a big issue. So definitely there are more technical challenges. [HHD3_P15_Medical Director] ● So, it varies right. A patient's responsibilities is to take the sample and get it to courier office. And then courier will send it to labs and you know because there is [a] timing issue there. It has to be in labs within 24 hours that's how we have bit of challenge to get it in there within 24 hours..so. [HHD3_P15_Medical Director] ● We probably get about half doing it and half don't for reasons either it is hard for them or they don't necessarily care that much or they can't just it is impossible for them to get the sample to lab withing 24 hour period so they don't even bother. HHD3_P15_Medical Director] ● The other challenge we definitely have from our remote locations is that we are trying to transport the samples in a timely manner, where we have up to 24 hours turn around time for the microbiology, and many of our very remote communities have

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					very hard time of getting samples out and we have not done particularly successful getting into our hospital labs to actually run the environmental cultures for us because the set-up is quite different than clinical culture.[HHD3_P15_Medical Director] ● Usually, because of the transportation problems ..the lab requires the sample to be within the lab within 24 hours of the sample being drawn. If the sample needs to be refrigerated in there for 24 hours as well. Often, that becomes the challenge depending upon where our home patient is located. It is not a challenge if the patient is located here in the city not a problem because the lab is here in the city. But if a patient is several hours away it can be a problem. [HHD4_P14_Chief BioMedical Engineer] ● Oh yes, often, it is most of the time the sample was either contaminated by the lab itself. They are very good in doing that. They will call us that we have messed up with the samples and give us another. Samples can be rejected by the lab if they are not within 24 hours. And if they are not refrigerated then they can be rejected as well. [HHD4_P13_Medical Director] ● Our lab is pretty good, but you know we are subject to their [referring to laboratory] schedules. They are not open, they are only open 6 days a week. So, now like please do not submit and don't submit a sample on Saturday. Because, it will sorry late Friday or Saturday, because it will get rejected that they would not have anyone to actually sample it. Because, it will sit there and come in on Monday, and they will throw it out. Because, they know it

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					has gone 24 hours. So, we know that and lab communicates with us very closely with us. We give warnings all the time [that] no samples no samples please because may be [there could be a] long weekend coming up [so] people would be on vacation. [HHD4_P14_Chief BioMedical Engineer] ● I don't think from the system point of view we would view that [referring cost of re-sampling for microbial testing] as a huge cost driver. Yes there are some, the chemical analysis is much a larger cost driver than the microbiology, you know 1500 dollars to do a chemical analysis so that's the bigger cost driver.. and even that is once a year so it is just a small overall cost component.[HHD3_P15] ● The lab would know .. they will charge us for anything… so we can get a contaminated sample and it will go out of the lab..you that's…200 bugs…60 dollars for endotoxins samples and 160 for chemical…but its 60 for the water…so every water sample is 60 bugs…they don't care about whether its contaminated or not…there are gonna bill us …[HHD1_P1] ● Ya, because, once it [talking with respect to false positives] happens you have get to submit tech out [for resampling]. [HHD2_P9] ● Chemical is more expensive but we do it only once a year. Or we do it if we change out the system. If we are putting the new system on. But the water quality that is the endotoxins and microbials test is done monthly, 60 dollars per sample, that's where the cost is. But not all our patients are compliant so not paying the full price what we should be

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					anyways. So there has been a discount in that sense. [HHD1_P1] ● And even the test [referring to microbial testing] themselves can be quite expensive. It has huge implications for the program when you are you know when you are trying to stay within the budget constraints. [HHD5_P18_Medical Director]
			● Sampling from two locations within the chain of devices was helpful in gaining information on the source of microbial contamination, but was not performed due to financial constraints by some programs. (B)	● [HHD2_P9_Clinical Manager]	● It is ..it is cost prohibitive sometimes…like…we are not doing dialysate on home patients…we are just doing on water …some programs just do dialysate and that's it. There is a cost to it…the thing with the CSA [Canadian Standards Association] is that they are recommendations for you to follow…it is not the law. It is just the guidelines and they want you to attain to that. We are doing our best to get to that CSA standards…if you are not…[HHD2_P9_Clinical Manager]
			● The procedures (e.g., entering microbial quality test results into excel sheets) and processes (including dedicated personnel) for tracking quality test results and maintenance schedules were considered beneficial. (F)	● [HHD1_P2_BioMedical Engineering Technologists] ● [HHD1_P4_Nurse Practitioner] ● [HHD1_P6_Unit Manager] ● [HHD2_P8_Unit Manager] ● [HHD2_P9_Clinical Manager] ● [HHD-2_P9_Clinical Manager] ● [HHD4_P13_Medical Director]	● I think my main challenge in [the] past two years is really getting someone to do the data piece. Because, I was doing all of that. So, now that have been passed on. So, we do have a data person now two years later [and] that was probably the biggest challenge [to] get someone on board [HHD1_P4_Nurse Practitioner] ● And over the years, I know who is doing their water samples because I do track which patients actually submit samples and when the techs submit samples and I get [participant showed the excel file to the researcher].So, back in July I have probably twenty to thirty-two percent of the samples by the patients, [and] 17 % of samples were done by the techs. But, we only have 50 % of all the patients submitted

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					samples for that month…so [HHD2_P9_Clinical Manager] ● That's right, if something is overdue [referring to preventive maintenance] that we have missed, [then] we have [the] computer set-up in a way that says, there is a flag, these things are coming up for due. These are overdue and that kind of things. [So,] there is a schedule that shows up on regular basis. [HHD1_P2_BioMedical Engineering Technologist] ● Well, I don't think [that] would be a full time position. But, someone to monitor [results], that would be helpful for sure. [HHD1_P6_Unit Manager] ● There was no process in place of monitoring, who was capturing, [and] we don't know who was sending samples. [This is] because they didn't had a spread sheet [and] they didn't [knew] when patient do send it [or] you know samples we checked were pass/fail but there was no follow up if in case it fails. There was no process in place. [HHD1_P4_Nurse Practitioner] ● We do the micro [microbial testing] every three months so that's what he is doing right now. The chemical analysis we still working on right now, [like] where we stored. We have it stored, but we are not sure who is actually monitoring it [referring to laboratory results] who is actually analyzing it, [and] we are still working on that because there is been little bit of a change. So, we are trying to rework how it is going to be done. So, at the moment we had an incident last week where one of the chemical analysis was above allowable limits

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					and the lab [laboratory] called me and we re-sampled. So, I am waiting for the result to come back from the re-sampling…hmm…But, other than that we don't. We just file everything and we have it on computer. But, I don't think we are keeping a good record so that we can trend it and see what is going on with that so we are not doing that yet. But, I know it is being stored we haven't just got somebody designated to look after that properly. [HHD1_P2_BioMedical Engineering Technologists]
			● The use of device performance data (e.g., disinfection history and operational parameters) was considered as beneficial for quality improvement process (e.g., auditing to identify better ways of doing things) and optimizing device maintenance (e.g., predicting when a particular device is more likely to have a breakdown); however, the lack of data, staff time constraints, and staff attitude were identified as barriers. (B)	● [HHD1_P1_Clinical Manager] ● [HHD1_P6_Unit Manager] ● [HHD1_P5_Medical Director] ● [HHD2_P7_Medical Director] ● [HHD2_P8_Unit Manager] ● [HHD2_P9_Clinical Manager] ● [HHD4_P13_Medical Director] ● [HHD2_P11_BioMedical Engineering Technologist] ● [HHD4_P13_Medical Director] ● [HHD4_P14_Chief BioMedical Engineer] ● [HHD3_P15_Medical Director] ● [HHD6_P17_Medical Director]	● Trend analysis is always of value, but what happens is that in this we need more staff for that. We need more people to actually gather that kind of data.[HH2_P11_BioMedical Engineering Technologist] ● So, that's a big gap right. We are dependent on patient reporting and they don't ..they don't have time …they don't do it or they you know some people actually fill out their paper work on the way to the clinic and they just make it up numbers [and then] there is no way for us to prove otherwise. [HHD1_P6_Unit Manager] ● It can be done with proper service records, if there is proper software where all the data is logged [in], all the hours, then we would know what is happening why this RO [reverse osmosis] is. So, it all depends on how powerful your database is, right, how well your database inputs are. Even a person who is doing trend analysis will depend on data for trend analysis right and database has to be powerful. Now your database should be able to, when I

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					change the filter I would be able to put in RO hours, all the information has to be there and then every time it has to be there, then there is a trend analysis. Then you can do failure mode analysis and everything. But, this database is not powerful what we using. [HHD2_P11_BioMedical Engineering Technologist] ● That can occur [referring to patients not filling up their logs for conductivity and chlorine measurements]. But, we kind of impose upon them to do as much as possible. It is very helpful for maintaining the RO [reverse osmosis]. Because, then it will show us trends in its performance. [HHD4_P14_Chief BioMedical Engineer] ● Because my typical failure rate [referring to microbial sampling] is about 2% every month. Like back in April I have 1.27% failure rate, [and in] May [it] jumped up almost double like 3.8 percent failure rate. Ya, but I think when it really spiked up it was like close to 5% that's huge. So, that was special when you see like 1-2% percent failure rate a month [and] when it jumped off to five percentage, [then] it's crazy. So, something could be going wrong. In, [the months of] February [and] March we jumped it to like opps 7.4 percent to 7.3 percent in those two months and that was double for the month before. So, I don't know whether sample tubes from manufacturing that just more a sterile one inside cause that failure. I don't know. But that's the advantage of tracking it and looking at the stuff like this because when I see that so why are we spiking up here like this because I can start

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					questioning techs and stuff. [HHD2_P9_Clinical Manager] ● I brought it up with my technicians like how do we audit this from our point of view just amongst the technicians how do we audit this. As soon as I bring up the word audits …technicians are always…now you are monitoring what I am doing this. No it is not, I am trying to figure out what we are not doing so we can do it. [HHD2_P9_Clinical Manager]
			● Communication failure was identified as an issue in some home programs, potentially leading to delays in prompt actions related to device care. (e.g., when the information on patients being away from their homes for extended days had not been passed on to a particular staff member, then delays in making alternative arrangements for managing their devices in their absence were inevitable. (B)	●[HHD1_P4_Nurse Practitioner] ●[HHD1_P6_Unit Manager] ●[HHD4_P14_Chief BioMedical Engineer] ●[HHD2_P11_BioMedical Engineering Technologists] ●[HHD2_P9_Clinical Manager]	●We had one issue, we do run into occasionally, is patients stop dialysing at home. They do not communicate back to us. Equipment sits there for couple of weeks and nothing has happened [referring to device maintenance]. Patients then says I am going back to dialysis at home, [then] we will step in and say no no no we have to test and we have to check that equipment because it has been sitting and we know bacteria is growing. So, typically in that situation we just swap out the equipment and then bring the stuff back for cleaning and assessing and testing. We are just being safe. Again, it is just communication. You know home patients sometime fail to communicate with us and that can become problem too. But, again it is working with home programs mostly. Remind them [the] master key for technical is to work, I mean, the critical, it is really important to know what each others are doing otherwise there is going to be [a] problem. [HHD4_P14_Chief BioMedical Engineer] ●We can always. No we can easily miss it, because we always don't know which patient is in the

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					hospital so taken by the ambulance and they are in ICU [intensive care unit] and they are not able to tell us. [A] lot of times, people don't think to tell the home program…oh..this is your patient…they know they need dialysis so they get the dialysis in the hospital so we have been working a lot with them to make sure that they tell us if you have one of our patients because we cannot have if we do not know…we have to have our machine and sometimes will pull the machine because they are going to be in the hospital for long time and then they say oh we are discharging…but you cannot discharge until we put up a machine in their home…right so now we have taken it…we need to put it back and they can't get the dialysis…so you have to co-ordinate that…so that's often we are juggling with that….[HHD1_P6_Unit Manager] ● Well, the nurses are not always doing that. It is one of the, we have a supply clerk doing that [referring that a supply clerk of home hemodialysis program is responsible for sending the testing supplies to a warehouse, which are then delivered to patients' home by a provincial healthcare agency] . But, it seems to me that something that often missed. And we won't know about it until we are like, "we have haven't seen water samples from you [referring to a patient], where is it?. Oh I didn't get a water sample kit. "Ok, we will get you one." So, generally the technicians, when they go for their home visits, they do take water sample kits because it is something that always forgetting it and they do sample themselves when they are there and bring it back and send it so..[HHD1_P6_Unit Manager]

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
		Scheduling visits to patients' homes	●Scheduling of preventive maintenance visits with patients was challenging (C).	●[HHD1_P2_BioMedical Engineering Technologists] ●[HHD-2_P11_BioMedical Engineering Technologists] ●[HHD4_P14_Chief BioMedical Engineer]	●Patients are not available all the time. So, we have to go with their schedules. So, it is not always easy even if I want to go somewhere and call him and he is not there. So, now I have to go somewhere else and then I call him later on. So, our scheduling is also not easy like I want to do the XYZ patient. I am not able to go there because that patient is not available or has no access to us to their homes. So, those are the problems. Yes, big problem, so half of the time is gone and if they are not available, then we have to reschedule and then we get busy with some other people so ..[HHD-2_P11_BioMedical Engineering Technologists]
			●Policies were established to ensure timely access to patients' homes. (F)	●[HHD1_P2_BioMedical Engineering Technologists] ●[HHD1_P6_Unit Manager] ●[HHD4_P14_Chief BioMedical Engineer]	●Usually, the technicians call and make sure that someone is going to be at home. A lot of them would have a lockbox, so it is not just for the supplies, [but] it is also for the technicians so that they can access the home if they need to. For most part they don't have too much problems that is a piece of education before they go home is that the technicians must need to have access. [HHD1_P6_Unit Manager]
	Materials and equipment required for testing and maintenance	Quality testing devices	● The point-of-care testing for verifying microbial water quality (bacterial and endotoxins) was introduced to improve access and efficiency of testing. However, such devices were criticized for their accuracy (bacterial testing) and pricing (for endotoxin testing).	●[HHD4_P13_Medical Director] ●[HHD2_P11_BioMedical Engineering Technologist] ●[HHD2_P9_Clinical Manager] ●[HHD1_P1_Clinical Manager] ●[HHD1_P2_BioMedical Engineering Technologist] ●[HHD6_P17_Medical Director]	●So our patients actually have pattels [missed the correct spelling of the testing device] that they use to assess for CFU [colony forming units] and they do once a month. They don't give endotoxins measurements monthly. However, we do a lab [laboratory] check of CFU and endotoxins whenever the machine is serviced, which could be minimum once a year. But, probably in [a] lot of patients it approaches to twice a year. I am less concerned with the fact that it is saving us money but it is more allowing us to somewhat bridge a gap

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					where if we won't have that then we would have really nothing that was being done regularly on monthly basis with our patients. [HHD1_P13_Medical Director] ● It [point-of-care testing device used for bacterial testing] is not allowed ..it has …[The] CSA [Canadian Standards Association] has said no. It is not reliable and it is not approved method. [HHD2_P11_BioMedical Engineering Technologist] ● We have invested in endotoxin testing ourselves. So, what we started, we only started doing it recently, is that when we find issues with endotoxins, rather than taking the samples and sending it into the laboratory wait for the test to come, we can do it on the spot. We can get the results in 15 minutes oh ya there is a problem here ..then there is no point of sending the samples right now because it is going to fail. So, we can do a pre-test before we send the samples in [name of a city]. So, it does not eliminate sending the samples in, but what it does is we can attend and correct the problem faster [rather] than waiting for results to come back to us. If we can do on-site testing and get a result. If it fails we know [that] we got to do something. [HHD1_P2_BioMedical Engineering Technologist]
		Variability in device models	● The make and model of devices varied, creating difficulties for technicians in routine preventive maintenance or who had to help patients resolve problems over the phone or at their homes. (C)	● [HHD1_P6_Unit Manager] ● [HHD5_P19_Retired Technical Manager]	● When we are dealing with the patients you have to be keep track of which machine they are on so that you can make sure that they [referring to BioMedical Engineering Technologists] give the right information about collection, right. They collect it at slightly different ports so we need to

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					know which machine they are using, so ya it's a bit challenge and then technicians too need to know hmmm which machines the patient is calling about and what kind of service we are doing and what filters the different machines have …so ……[HHD1_P6_Unit Manager] ● And ya they use slightly different disinfectants in their on the different machines they have different consumables for the different disinfectants. [HHD1_P6] ● I wanted to keep things simple so that we don't make mistakes because we have too many different products and if we forget to do something. So, we treated them the same. [HHD5_P19_Retired Technical Manager]
		Recruitment and ongoing training	● Resources were required to retrain patients when issues relating to compliance with water quality testing and daily device maintenance were identified. (C)	● [HHD1_P4_Nurse Practitioner] ● [HHD1_P6_Unit Manager] ● [HHD2_P8_Unit Manager] ● [HHD2_P9_Clinical Manager] ● [HHD4_P14_Chief BioMedical Engineer] ● [HHD3_P15_Medical Director]	● It is very challenging because we usually implement something and implementation of that takes a long time to do. Just because there are ninety patients, so 85 patients, and they spread out all over the [name of the province]. So, the logistics of being able to go to each patient, putting even say ultrafilters and then showing them how to change it or the other way is to bring them in here in the institution of how to change it which is not really not feasible. So, that takes time…and that's why it is little bit more cumbersome and slower than say in-center or satellite centers. Because there you can install twenty-five to thirty machines so quickly because they are all available to you. And yes [in the] same location [and] same room. So, there it is much much faster so implementing something like this is much quicker, whereas in home patient program it takes

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					[a] little bit longer to do.[HHD1_P4_Nurse Practitioner] ● Hmm. I think the time that we spend saying the same thing over and over again, definitely is costly for the program from a like you know time management of the nurses they are the people who are doing this education generally and ya it's the pain in the butt…right if you have to say the same thing until you blew in the face and yet nowhere. [HHD2_P8_Unit Manager] ● and ya then making the phone calls… so it definitely takes ….I mean its patient safety right …. so we can't just not do it (26: 46)…but it does takes lot of nursing time…[HHD1_P6]
			● When a new technology was introduced staff training was required. (C)	● [HHD1_P6_Unit Manager]	● Well it's a bit challenge for us now because the nurses need to be comfortable with the new equipment as well.. ….[HHD1_P6_Unit Manager]
			● The steps for using and maintaining of devices were mentioned as doable by patients at the time of their recruitment training (F), but there was a contrasting view. Moreover, comments were made that patients could be worrisome during the initial learning period and that the time taken to complete the learning process could vary depending on individual abilities. (C)	● [HHD1_P6_Unit Manager] ● [HHD5_P18_Medical Director]	● So, it is overwhelming only at first and after a while they are like ok I can do this [HHD1_P6_Unit Manager] ● You know the nice thing about ….what all we looking? we are looking for something that is little bit easier. Can it take little bit less time for patient? Our current home hemo machines that are really being adapted from the in-center machines are hard they are just difficult you know what are the technologies that takes weeks to train somebody to be able to go home. So, the biggest advantage of the NxStage machine is inclusively and the potential opportunity again to decrease the training time or be able to train folks who are just having a bit more about a challenge in learning. Currently because of budget constraints and some of the challenges with

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					the NxStage machine atleast in the short term future it will not be part of my program.[HHD5_P18_Medical Director] • We usually do not deny many people …hmm..once they are motivated they usually find somebody or if they are by themselves they can do it we just have to train them to do it. Sometimes they might need a little longer training but we rarely deny a patient and they usually always have an opportunity to try it and occasionally fail based on their well-being or some other functions. [HHD1_P6_Unit Manager]
		Usability of devices	• There could be difficulties in cleaning and disinfecting the devices because of their design.	• [HHD1_P1_Unit Manager] • [HHD1_P2] • [HHD3_P15] • [HHD2_P9] • [HHD5_P19_Retired Technical Manager] • [HHD4_P14] • [HHD1_P4] • HHD2_P8 • HHD2_P9 • HHD1_P6	• We know that the dialysis machines are disinfecting because they have the heat cycle they disinfect on themselves. The RO [reverse osmosis] machine are not and there is [a] tube between the two devices there [which is] right now is not being disinfected. So, that too is an issue .And we take a look at tube, [and] if there is a dark spot in it we replace the tube. With the new dialysis machines for home, they [referring to reverse osmosis, tube between reverse osmosis and hemodialysis machine, and hemodialysis machine] are going to be connected together and that cycle is going to be through chemical is gonna be disinfected through chemical. But, still we are not doing heat through the RO. [HHD1_P1_Unit Manager] • Every part of the machine cannot be get disinfected. So, there are some components cannot get disinfected. The first incoming valve that on any machine, the machine that we have never actually get disinfected. So, that is where we see some of the biofilms.[HHD1_P4_BioMedical Engineering Technologist]

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					• We sometimes have removed certain aspects and brought in something better. Like removed some of the chemicals that we were using. At a great length we have removed lot of chemicals that were harmful that we do not have to monitor not. Right, like peracetic acid. So, we have removed those things from patient environments and then you have to take special precautions for that…as well.. so we do not have to do it anymore. [HHD2_P11_BioMedical Engineering Technologists] • It's once a month on the RO machine and it takes time. So, patients will have a dialysis at night time, and then they will either throw their machine in the disinfection or just do a rinse. They [referring to patients] have to go to work so they may [have] to shut the water off, because you do not want to leave the water on to do the disinfection because it takes you know an hour and a half to disinfect the RO machines and someone has to be around. So they often have the best intentions and then they run out of the time to go or interrupted somehow so depends on how busy their life is …[HHD1_P6_Unit Manager]
			• Devices with in-built reminders, safety alarms, and the ability to self-lock (when a patient fails to perform a task related to device maintenance) were seen as helping improve patients' compliance and increase safety.	• [HHD4_P14] • [HHD1_P1] • [HHD2_P11] • [HHD4_P14] • [HHD2_P9] • [HHD2_P8] • [HHD1_P4] • [HHD3_P15]	• We have noticed with new machine [that] the machine itself requires more disinfection and new technology really locks the user as compared to older model the user can actually ignore it [referring to patients' noncompliance to disinfecting hemodialysis machines]. I don't have time to disinfect right now I am going to dialyze anyway where the new machines will lock you out. Say, I have not been disinfected for so many hours and

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
				• [HHD6_P17] • [HHD5_P19_Retired Technical Manager]	they lock the dialysis machine until they do it disinfection. So, technology is getting better. It is telling me you cannot ignore them anymore. Some of the users would get upset oh now I cannot use it for an hour. Well, too bad, but it is safer. [[HHD4_P14_Chief BioMedical Engineer] • Yes, [it] drops and sometimes too warm [referring to source water's physical properties], then the quality of the water goes down. Because RO [reverse osmosis] membrane becomes porous and then the RO will start alarming that my output RO water quality is low. [HHD2_P11_BioMedical Engineering Technologist]
			• The size and weight of some devices could act as a hindrance to performing device maintenance among patients with co-morbid conditions.	• HHD2_P9] • [HHD4_P14] • HHD3_P15	• There are certain patients say for carbon if they are changing their carbon tanks. A carbon tank is heavy. So, we know right away. So, you are not changing the carbon tanks.. because I don't want to break your arm right. So we often have home patients say oh I have got my neighbour he is going to come over and change the tank for me.. that's one situation we had ..sometimes family members do it.. even sometimes a person who delivers the tanks he does not work for us he is just a contractor we train him how to do it in case that's needed.. but we make things work out. If a patient is physically able then they will do it, otherwise me make other arrangements. Some aren't physically able to do with anything too heavy and we don't want them to do it. [HHD4_P14_Chief BioMedical Engineer] • And so it is more [about] cartridges [that] patients would need to change. But, they are smaller and easier to handle. [HHD3_P15_Medical Director]

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
			• The pre-programmable feature of a device was seen as not usable in a home environment due to patients' unfixed schedules for performing their HD. (C)	• [HHD1_P2_BioMedical Engineering Technologist]	• Basically their reverse osmosis which are quite a large size central system. They have central water system …so the reverse osmosis are planned programmed so that at midnight the system comes on it does heat disinfection for the whole system…so they do it automatically…so they don't have to come across these problems…and we even try to program our machines to say ok…we want them to the RO and the machine to disinfect at such certain time ..we can't even do that…even though the we have the capacity to do it. [HHD1_P2_BioMedical Engineering Technologist]
			• The use of ultrafilters on HD machines was seen as protecting patients from microbial contamination, specifically for those patients who were non-compliant to performing disinfection and testing, however, the clarification was made that its use does not eliminate the development of microbial growth. (F)	• [HHD1_P2_BioMedical Engineering Technologist]. • [HHD1_P1] • [HHD4_P14] • [HHD3_P15] • HHD1_P4	• That was the reason we put it [ultrafilters] in, because it was just so unpredictable and we were getting some positive results and we were in some cases not getting any testing at all [referring to patient not sending samples for testing]. With ultrapure filter, we have been able to kind of still guarantee ourselves that the patient safety is not compromised, that's the main thing…[HHD1_P2] • That's exactly what has happened since we have started using ultrafilters we haven't had any issue where the dialysate samples failing so because of that we have been able to agree on three months interval [referring to microbial testing frequency] for now. If we didn't have these ultrafilters, [then] I am sure that we would be risking by going to three months [for microbial testing]. [HHD1_P2_BioMedical Engineering Technologist]. • This ultrafilter will help us with the end product i.e. the water that goes to the patient, because the ultrafilter will take that all out. But, biofilm is still there in those pre-ultrafilter part. And there is no

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					way we can remove that [participant is here talking in the context of lack of disinfection]. That's what we have to understand. [HHD1_P4_BioMedical Engineering Technologist] • And I think we did that with presumption that we are going to anticipate patients making errors and not doing their sampling and so we sort of adding another layer of protection to bring it to ultrapure …So I do believe that it is important. Particularly when you are exposing patients more frequently and for longer dialysis treatments potentially when they are doing at home their contact time of that water potentially at much worse consequences than in-center.[HHD3_P15]
			• The capability of devices to store information on when tasks related to maintenance were performed was considered as beneficial assessing patients' compliance to device maintenance.	• [HHD1_P1_Clinical Manager] • [HHD1_P2_BioMedical Engineering Technologist] • [HHD1_P4_Nurse Practitioner] • [HHD1_P6_Unit Manager] • [HHD2_P8_Unit Manager] • [HHD2_P9_Clinical Manager] • [HHD2_P11_BioMedical Engineering Technologist] • [HHD4_P13_Medical Director] • [HHD4_P14_Chief BioMedical Engineer] • [HHD3_P15_Medical Director] • [HHD6_P17_Medical Director]	• Technicians will check the records when the records are available. For example, the machine RO [reverse osmosis] has available records. The machine itself though we cannot back log to see that how often it is has been disinfected with our current old machine. With our new machine, we would be able to do that a bit more formally. That is new Fresenius machine. We just went through procurement, so we will be adopting those machines for our home patients over the next several months. [HHD4_P13_Medical Director] • One of the nice things about going to newer technology we have is that equipment itself monitors how often it has been disinfected. In the past, you are right, patients …I would be blunt they would lie to us..and we suspected but we could not prove it..so we would now have the equipment that

Theme	Sub-theme	Sub-sub theme	Barriers (B)/ Challenges (C)/ Facilitators (F)	Home programs_Participants' details	Quotes
					does not lie… software record everything… so I can go in and tell…[HHD4_P14]

Appendix 9: Illustrative Quotes from Interview Transcripts for the Theme: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs

Theme: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs		
Sub-themes	**Summary of Sub-themes**	**Quotes**
Identifying a consistent process for microbial testing	• The need to identify a better process for microbial quality verification was identified, and the following suggestions were made by some programs: • Instead of relying on patients, using home program staff for sample collection and sending it to a laboratory was seen as a potential solution for achieving the CSA's required testing frequency and avoiding false positive samples. • The affordable point-of-care testing device was perceived as a future facilitator (for testing of microbial and endotoxins) to overcome the drawback of the elongated time taken to produce microbial test results by the existing laboratory based testing method.	• I think if there is more proper staff to do this [referring to microbial sampling], then yes you can probably avoid this [referring sample contamination from improper sampling]. We somebody can run around monthly and do all these things, so that patient does not have to do anything. [HHD2_P11_BioMedical Engineering Technologist] • So, it would be nice to be able to do that if we had somebody that could do even on monthly basis they could go and take water samples monthly basis at the same time as well. So, there is no reason why we could not train those same people [referring to non-technical person] to do the water samples monthly instead of technicians doing it every three months. [HHD1_P2_BioMedical Engineering Technologist] • Somebody can run around monthly and do all these things so that patient does not have to do anything. [It] improves patient life [and] improves patient confidence. So, you just hire somebody at a technician level not as high pay have him run couple of people around and job is done. Seriously, and I have been recommending that since five years, but they [referring higher management staff of a home program] don't listen here. [HHD2_P11_BioMedical Engineering Technologist] • The only challenge right now facing us the biggest one is microbial, 7 day incubation period. We don't know for 7 days whether [a] patient can dialyse or not that's the only challenge. [Regarding], endotoxins we can say .ok ..endotoxins is good in one hour [referring to time taken for endotoxin testing]. But, what about microbial, is it important is it not. If it is not important why are we checking and if it is important then should not patient wait for 7

Theme: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs		
Sub-themes	**Summary of Sub-themes**	**Quotes**
		days till he hears the result and in that ..that is the question nobody wants to answer…yes nobody knows. Nobody wants to answer. [HHD2_P11_BioMedical Engineering Technologist] • Are there..I think I last time I talked to Charles River, they were looking at getting something [referring to point-of-care testing device]. But, it is still probably the size. May be bigger than a printer but you know about that kind of foot print may be little bigger and that's still…it is still not…you would probably not get the results quickly but it would be definitely quicker than 7 days sending to the labs. [HHD2_P9_Clinical Manager] • I know there are some kits out there. But, I don't know what there accuracy is on it, like may be it might give an idea but I don't know. It is certainly not going to be anything close to what the lab tests. But, I think that would be one improvement across the board just having may be better portable testing. [name of a province] is probably a prime example because they have lot of patients that are in such remote areas like how do you monitor them, I don't know. [HHD2_P9] • Ya, for sure like patients who are afraid of not initiating home therapy or may want to come off the program, I think it will help in that. I mean [name of a province] has done quite a good experiment with that [referring to staff-assisted HHD program] and was quite successful. Ya, it is not the requirement of the program. They have somebody at home, but I would say most of them do. Just in terms of like a family member or you know somebody living in the house with them. We don't have like a nurse right when a patient is hired…I don't know if any of our patients that have that. We have talked about it as a program so like assisted home dialysis just like for PD, we have a nurse go out or a LPN [licensed practitioner nurse] go to patients and help them connect and disconnect for PD. [So,] why don't we use something similar for home right? But I guess it is the cost problem because then it adds to the cost and then

Theme: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs		
Sub-themes	**Summary of Sub-themes**	**Quotes**
		you are back at the same price at the in-center or more patients so there is no appetite for that. [HHD2_P7] • So, absolutely I think that we have been able to send a few people home that otherwise would not be able to dialyze at home because you know the equipment is still difficult right doing home hemo is difficult…there is a lot to learn…and especially for older folks I think it's a bit overwhelming. And so we definitely worried about send some people home without the support of PSW that I don't think we otherwise would have gotten [them] there. But, as you can imagine it's an expensive model…and so I think predominantly for those reasons it is on hold. [HHD5_P18_Medical Director]
Need for more robust evidence	• There was a need identified for more research on how water quality impacts patient outcomes, but there was an acknowledgment that clinical studies on that aspect would be difficult to conduct.	• I mean it is not an area that many people really talk about …and so my guess is all of that is also not particularly evidence based…its clear that whatever we are doing is not causing a tremendous amount of harm if any at all because other wise we will be seeing people have adverse consequences that we couldn't otherwise attribute to a more obvious cause and then we say Jes may be it is at the water…but that just…hasn't happened so you know I am not suggesting that stricter standards aren't reasonable it is just that how do we actually know whether the stricter standards serve any real purpose[HHD1_P5_Medical Director] • And again the whole data around ultrapure dialysate I am not sure like in the context of everything if you look at relative risk reduction of like any bad outcomes with ultrapure vs regular dialysate you know may there may be problems with the activation of CRPs [C-reactive proteins] little higher than like that. But, at the end of the day, I am not sure how that translates to much more meaningful benefits for patients. [HHD6_P17_Medical Director] • There are so many other things that are happening as well, because just they have heart disease so they all are at high risk of some devastating event to occur anyway. So, I think it will be really hard

Theme: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs		
Sub-themes	**Summary of Sub-themes**	**Quotes**
		to tease out the impact of the water on a clinical outcome. I would be honest. [HHD2_P7_Medical Director] • Because the people have water samples that have failed various tests. [and then] you wait another month until test that again to confirm. You know by then it is very difficult to link any kind of clinical scenarios to abnormality in a lab value. That takes weeks to get back to us and then you repeated that will take more weeks and then you know before you get those results it is yet more weeks and so it is very difficult to somehow link a clinical scenario with a water related problem. [HHD1_P5_Medical Director] • I would like to see you know a systematic review on water quality and patient outcomes. I like to see patients weigh their interest in that in terms like what is really true patient outcomes since we are spending resources and I am not sure we are getting any good value for money. Frequently testing and that kinds of things. Probably why are we doing this. I think that's the good priority to look at. [HHD6_P17_Medical Director] • The water testing ya that area of endotoxins of water but really relative to all the other things how bad is that going to cause and really if certain counts I think it is quite arbitrary and not scientific, because it is not balanced in the context of all the other risks that patient is assuming [in a home program]. But, yes I want relatively pure dialysate but I think every you know once you have a couple of tests we can call you back off on frequency of testing without much increase harm to patients. [HHD6_P17_Medical Director] • and this is the question if there is no clinical outcome that we can measure and see right now and we are not getting compliance and it is [a] big cost [and] what is the benefit. So, are we testing for the sake of testing. We change filters and we do what we can, but I think that's the big question for… ofcourse we assume that water is important..and we know it is important…and endotoxins and you

Theme: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs		
Sub-themes	**Summary of Sub-themes**	**Quotes**
		know…but you know people are exposed to things in their homes everywhere…everywhere they go right…so they hasn't been a lot of long term studies on ..so you have positive endotoxins ..what's the clinical result……and without that people [referring to patients] don't see the significance of it [HHD1-6]. • So we pose the question is it necessary to do the water question we are just playing the devils advocate because we assume so but we have done all of this and have we made any changes to the patient's quality of life???. Because, people are exposed to the things all the time and we can isolate and make sure its not in the dialysis machine but they are exposed everywhere else…so how do we measure their exposure to endotoxins where are they getting their endotoxins from? If we ..the machine is fine great…but if we measure whether they still have the exposure we don't know right…so we can worry about it and it sounds worse…it sounds bad…but in the end we are still not sure ..right. [HHD1_P6_Unit Manager] • The big issue is going to be the sample size….like whether or not if you can vision let's say that somebody goes home and may be their B2 [B2-Microglobulins] level goes up a little bit compare to when they were in in-centre. But, if you don't actually have big enough numbers to see if that increase makes any difference to their outcomes then all you have done is measured a number or surrogate that may or may not have impact on how well they do overall. [HHD5_P18_Medical Director] • Of course, anything you increase [referring to ultrapure grade of dialysis water] it is going to have financial increase on it right, which is fine. I mean, I am sure there is [a] very good reason to use ultrapure water for dialysis. But, the study should be the patients that don't use ultrapure water and who use it what the difference is? [HHD1_P2_BioMedical Engineering Technologist]

Theme: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs		
Sub-themes	**Summary of Sub-themes**	**Quotes**
		• I think ..it is really quality of life from patient perspective and if we start to end pipe all our requirements and start ask even more of them I think then it affects the reason that they are at home right. Like they want to be at home for quality of life and so I think we have to be aware of that as a program. And honestly I think being at home gets so much better benefit than ultrapure in-center. You know we do offer ultrapure at our in-center that's all we use as ultrapure but I really don't think that is an advantage to come back to in-center because the water quality might be different at home. I think its so much better to be just at home for all the other psycho-social reasons and so ya…we would end it up and request for more ..even more monitoring…once a month is a lot already…..we already have like a percentage even who can't or refuse to maintain that…so I can't imagine being more aggressive.[HHD2_P7_Medical Director]

Theme: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs		
Sub-themes	**Summary of Sub-themes**	**Quotes**
	• The need to generate more robust evidence for microbial water quality testing frequency was identified for better use of resources in HHD programs.	• Not worth enough to spend time and cost on microbial testing due to lack of adverse events [HHD1_P1_Clinical Manager] • So, it would be ideal if we had a better system of verification and checking yet on the other hand you can also see it from the perspective of a program and from the patients perspective too…..if someone's been on dialysis for a years and years and nothing has ever happened then you can get the perception that these are theoretical problems rather than actual problems…because the serious adverse event that you could legitimately trace back to a water and water quality issue is so uncommon that you can see that in the big picture is it really a problem that people would expend so much energy trying to address by all the sampling. I am not advocating for that but you can quickly see something that is so rare does not consume tremendous amount of attention. [HHD1_P5_Medical Director] • True…and I have been that why too big time …that's why you should…or somebody should come out with some kind of research.. But nobody is willing to take that risk of doing less [referring to microbial testing frequency]. [HHD2_P11_BioMedical Engineering Technologist] • I would also like to see if frequency of testing for catching anything that is actually life threatening to patients. All the tests that we do I would like to see any intervention based on the testing like you know we have situations where we have routinely boil water advisory, we tell people to stop dialysing at that point and wait till the water advisory group is lifted. There is a couple of situations with water going on, mainly why there is monthly they have to decided on god knows why right. Should we getting doing that daily, should we doing it hourly, should we be doing yearly, really I am not sure what the frequency why that in a world was decided

Theme: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs		
Sub-themes	**Summary of Sub-themes**	**Quotes**
		upon. And I don't think that is really patient centered. [HHD6_P17_Medical Director] • I think they are important. But, I think that there has to be some realization of human factors when you are dealing with patient doing that I think it is important to have it as our baseline expectation to guide what we are teaching to patients. Honestly, in a hospital environment, [it] is much easier to enforce those things because you have army people paid to do that. That's where patients service self-manage their disease and I think there is a philosophy about management that comes in with home therapies that you can teach patients to do …really teach people to do whatever you want but they would they can choose what they actually do. And again I think its important to have the right set of recommendations that we can say this is why we are recommending it to you. [HHD3_P15_Medical Director] • I am just trying to think in which sort of scenario it [clinical outcomes] would change what we do given that we are focussed so much in this program on water quality mostly because of [name of a Retired Technical Manager], so I think probably a whole lot of expense without any guarantee change in outcomes. [HHD5_P18_Medical Director] • Absolutely, we have done this in [name of a province] at different levels over the years. I think if you are unable to achieve the monthly before moving before moving away from the standards in any way definitely I would do validation and see once every 2 months is sufficient. I mean seriously standards are I mean they are important they are great but they are not mandated..they are not legislated so it is ..there is so what as recommended practice but they are not like obligated. [HHD5_P19_Retired Technical Manager]

Theme: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs		
Sub-themes	**Summary of Sub-themes**	**Quotes**
	• The consideration of local operational factors when making the requirements on the frequency of inspections for microbial verification of water used in HHD was suggested, including home environment and device modernization.	• We are definitely looking for that sort of option…we are trying to find whats the right balance is and a big dilemma there is that the standards that exist for monitoring of home dialysis water…presumably have simply been carried over in-center dialysis..and are not perhaps not related to any real data that would suggest a rationale reason for monitoring water for home hemodialysis environment at any particular frequency…[HHD1_P5_Medical Director] • We can say that if the filters in place doing a monthly test is really a waste of money. We can say that…but the standards says it has to be done or recommends that it should be done. I guess. And that's the problem is it should or must. [HHD1_P1_Clinical Manager] • and basically you know we even don't know why are we doing this .now we have ultrafilter at the back of the machine ..so that is suppose to take care of all these things..ya..they do guarantee that our filter will always work to provide zero endotoxins and bacteria ..always…they guarantee you that. So, there was a debate in CSA [Canadian Standards Association] community that should we even check for water quality anymore. [HHD2_P11_BioMedical Engineering Technologist]
Innovation to support remote monitoring	• There was a suggestion to make improvements in the design of devices by enabling remote monitoring of operational parameters to ensure their safe operation and planning inspection visits for preventive or corrective maintenance.	• So, if we did have a remote monitoring of the machine we will be able to see that. What we like to see is keeping track on the dialysis machine how often they are running that's often something that we can't control [and] the water system itself can record the last disinfection that's helpful ..but it would be better if it was automated. [HHD1_P6_Unit Manager] • Well there might be, we might be able to see if the carbon filters are starting to exhaust sooner or sediment filters if they starting to clog up if they are losing pressures ..so there is …[HHD2_P9_Clinical Manager]

Theme: Suggestions Discussed to Overcome the Identified Barriers to Water Quality Management in Home Hemodialysis (HHD) Programs		
Sub-themes	**Summary of Sub-themes**	**Quotes**
		• Yes..if we are at patients' home that's the time we do our testing…but the technology that's involved in looking it up so that we can monitor from our own laptops I don't believe that I have come across that. Yet, it may be there and it would be really ideal. Ofcourse, it will be ideal, perfect for us. [HHD1_P4_Nurse Practitioner] • If there was a way to check in whether people has done their disinfection, and what the status of various part of the equipment was, I think that would be something we would be certainly be interested in if it was affordable. [HHD1_P5_Medical Director] • that would be so cool…if you could have ….like one technician looking after 100 machines..and then they all are being monitored and that you get the signal like oh…Mr John's filter is starting to wear down….and better get out there….you know that would be cool[HHD2_P7_Medical Director] • Ya, it can help. But, it is very difficult to implement. [The] RO [reverse osmosis] and the machine, they both have to be logged in remotely. So, you need [a] modem at home, you need some kind of wireless. Unless there is idea is that company should provide wireless data communication on all these ROs and everything, if they provide transporting chip in there then all can be hooked up to [a] central device and we can monitor them all the time. So, ROs and the dialysis machines they both have some kind of wireless transmission capacity where wires are not involved then it is easy. Because, otherwise, [it would] not [be] easy. Wireless communication..something [like that] has to be there. [HHD2_P11_BioMedical Engineering Technologist]
Abbreviations: HHD: Home hemodialysis; HD: Hemodialysis; B: Barriers; C: Challenges; F: Facilitators		