

**AL-RAZI UNIVERSITY  
GRADUATE STUDIES  
COLLEGE OF MEDICAL SCIENCES  
APPLIED MEDICAL SCIENCEA DEPARTMENT**



**PREVALENCE OF HEPATITIS B AND C VIRUS AMONG  
HEMODIALYSIS PATIENTS AND INFECTION CONTROL IN  
DIALYSIS UNITS IN SANA'A CITY, YEMEN**

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## معدل انتشار فيروس التهاب الكبد البائي والسي عند مرضى الاستصفااء الدموى ومكافحة العدوى في وحدات الاستصفااء في صنعاء-اليمن

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## **DECLARATION**

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The work provided in this thesis, unless otherwise referenced, is the researcher's own work, and has not been submitted elsewhere for and other degree or qualification.

**Student name**

## ***CERTIFICATE***

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This is to certify that the thesis entitled" *Prevalence of Hepatitis B and C Virus Among Hemodialysis Patients and Infection Control in Dialysis Units in Sana'a City, Yemen*" is submitted to Applied Medical Sciences, College of Medical Sciences, Al-Razi University for award of master's degree in *Epidemiology*. It is a record of the original and confides research work carried out by *Murad Abudlhadi Qassem Al-Yousofi* under our supervision. Such material as has been obtained from other sources has been duly acknowledged in the thesis. This thesis embodies the work of the candidate himself and no part thereof has been submitted for any other degree or diploma. The candidate has put adequate number of terms of research work under our supervision.

*Supervisor*

*Professor Dr. Nabil Ahmed Ahmed Al-Rabeei*

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## **DEDICATION**

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*To my Parents, who I owe my life and success*  
*To my Wife, who has been a great source of support*  
*To my daughters for their hopeful smiles.*  
*To my Brothers and Sisters*

*With Love and Respect*

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## ABBREVIATIONS

AAMI	Association for the Advancement of Medical Instrumentation
ACIP	Advisory Committee on Immunization Practices
AMI	Advancement of Medical Instrumentation
Anti-HCV	Hepatitis C Antibodies
APIC	Association for Professionals in Infection Control
BSI	Bloodstream Infection
CANNT	Canadian Association of Nephrology and Technology
CDC	Centre for Disease Control and Prevention
CDC	Centers for Disease Control and Prevention
CfC	Conditions for Coverage
CFU	Colony Forming Units
CKD	Chronic Kidney Disease
CMS	Centers for Medicare & Medicaid Services.
DNA	Deoxyribonucleic Acid
DOPPS	Dialysis Outcomes and Practice Patterns Study
EBPG	European Best Practice Guidelines
EIA	Enzyme Immunoassay
ELISA	Enzyme-Linked Immune Sorbent Assay
EPA	Environmental Protection Agency
ERBP	A European Renal Best Practice
ESRD	End Stage Renal Disease
FDA	Food and Drug Administration
GFR	Low glomerular filtration rate
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B Virus
HBV DNA	Hepatitis B virus deoxyribonucleic acid.
HCC	Hepatocellular carcinoma
HCPs	Healthcare Personals
HCV	Hepatitis C Virus
HCV RNA	Hepatitis C virus ribonucleic acid.
HCWs	Healthcare Workers
HD	Hemodialysis
HIV	Human Immune Deficiency Virus
HIV	Human Immunodeficiency virus
IgM	Immunoglobulin M
IHDF	Intermittent on-line hemodiafiltration
IPC	Infection prevention and control
KDOQI	Kidney Disease Outcome Quality Initiative

MDROs	Multidrug-Resistant Organisms
MI	Medical Instrumentation
NHANES	National Health and Nutrition Examination Survey
NHS	National Health Survey
PCR	Polymerase Chain Reaction
PPE	Personal Protective Equipment
RNA	Ribonucleic Acid
RO	Reverse Osmosis
RRT	Renal Replacement Therapy
TSN	Turkish Nephrology Society
USA	United States of America
VRE	Vancomycin-resistant enterococci.
WHO	World Health Organization

## ABSTRACT

**Background of the study:** Patients on hemodialysis are at high risk of viral hepatitis B and C due to high number of blood transfusion sessions, prolonged vascular access, and high exposure to infected patients and contaminated equipment, or cross contamination from the dialysis circuits.

**Objective of the study:** The objective of this study was to investigate the prevalence of HBV & HCV among hemodialysis patients and infection control in dialysis units in Sana'a City, Yemen

**Research Methodology:** A descriptive cross-sectional study of 349 patients with HD and 58 staff nurses working in the HD units in three hospitals in Sana'a city, Yemen. A stratified random sampling method was administered to select 349 hemodialysis patients. Data were collected through self-administered questionnaire and retrospectively from patients' files from 1 May to 30 July 2018. The questionnaire includes Part 1: the demographic data of the patients, medical history of patients (Frequency of HD sessions, duration of dialysis and history of HBV vaccination) and history of HBV&HCV infection among patients: at screening stage and at follow-up stage which includes. Socio-demographic characteristics of staff nurses and history of HBV vaccination were also collected. Part 2: Principles of infection prevention and control in dialysis unit. A pilot study was conducted and validity and reliability of the questionnaire was also tested. The data were analyzed using SPSS and measured using frequency and percent for categorical variables and Means and SD for quantitative variable. Student's t-test,  $\chi^2$  test and McNamee test were used. Spearman Coefficient and Phi correlation were used to measure correlation between variable. Cronbach's Alpha Coefficient and Spearman-Brown Coefficient were used to test reliability of questionnaire. A P-value  $\leq 0.05$  (2-tailed) was considered statistically significant. Approval from Al-Razi University was obtained. Oral consent was obtained from patients and nurses to participate in the study.

**Results:** A total of 349 patients undergoing hemodialysis, aged 13 to 85 years with Mean $\pm$ SD was 31.9 $\pm$ 7.3 and 59.3% were males. Most of the patients undergo two HD sessions per week (93.4%). As regards to duration of hemodialysis (69.1%) of the patients the duration of HD was less than 6 years. The overall prevalence of positive HBsAg among HD patients was found to be 2.9% before HD and 14.3% during HD at follow-up stage while positive anti-HCV was 2% before HD and 17.2% during HD at follow-up stage and (5) cases was mixed infection with HBV and HCV. A statistically significant differences in prevalence of HBV was found by HD units (p-value  $<0.05$ ). No statistically association in prevalence of HBV and HCV by patients demographic data (p-value  $>0.05$ ). A statistically correlation between the prevalence of HBV and HCV by frequency of HD sessions was not observed (p-value  $>0.05$ ). The study found a strong correlation between prevalence of HBV and HD duration (p-value=0.000). On the other hand, a strong correlation was found between prevalence of HCV and duration of HD (p-value=0.000). Out of 58 staff nurses the age mean and SD was 31.5 $\pm$ 7.3. 56.9% of the nurses were male. A total responses 64.8% of the staff nurses did not applied screening, immunization and routine testing in dialysis units, 51.2% were practiced standard and transmission-based precaution, 41.8% were practiced environmental, cleaning and disinfection, 61.4% were cleaned and disinfected equipment and 60.7% of the nurses were practiced safe medication in all HD units. 64.6% of the nurses were not familiar with these policies and program in all HD units. 56.9% of the nurses were not tested and treated water of HD machine in all HD units.

**Conclusion and Recommendations:** The study concluded that, the prevalence of HBV and HCV infection in patients who received HD 14.3% for HBV was and 17.2% for HCV. The study recommended that, in each HD unit, policies and practices should be applied.

## الخلاصة

**خلفية الدراسة:** يتعرض مرضى الفشل الكلوي الذين يتلقون الاستشفاء الدموي (التحال الدموي) إلى الإصابة بالتهابات الكبد البائي والسي و نتيجة لزيادة جلسات نقل الدم ووجود فتحة القسطرة الوريدية لفترة طويلة وكذلك تعرضهم العالي لخطورة انتقال العدوى من المرضى والادوات الملوثة التي تنتقل عبر توصيلات جهاز الاستشفاء.

**هدف الدراسة:** تهدف هذه الدراسة إلى فحص معدل انتشار عدوى فيروس الكبد البائي والسي بين مرضى الاستشفاء الدموي ومكافحة العدوى في وحدات الاستشفاء الكلوي في المستشفيات في صنعاء-اليمن.

**طرائق البحث :** دراسة وصفية مقطعية عرضية اجريت على 349 من مرضى الفشل الكلوي اللذين يخضعون للاستشفاء الدموي و58 ممرض وممرضه يعملون في وحدات الاستشفاء الكلوي في المستشفيات في صنعاء. استخدم الباحث العينة العشوائية الطبقيّة لاختيار 349 مريض. قام الباحث بجمع البيانات بواسطة استبيان مكتوب وكذلك من ملفات المرضى خلال الفترة من 1 مايو الى 30 يوليو 2018م. شمل الاستبيان على جزئين: الجزء الاول تكون من البيانات الشخصية للمرضى والتاريخ المرضي (عدد مرات الغسيل في الاسبوع-مدة الغسيل ولقاح فيروس الكبد البائي) , و التاريخ المرضي للعدوى بفيروس الكبد بي وسي وشملت ايضا مرحلة التحري والمتابعه للمرضى. شمل كذلك البيانات الاجتماعية والشخصية للكادر التمريضي واللقاحات ضد فيروس الكبد البائي. الجزء الثاني من الاستبيان شمل على اسس الوقاية ومكافحة العدوى في وحدات الاستشفاء الدموي. تم اخذ الموافقة على اجراء الدراسة من المششفيات وكذا المرضى والكادر التمريضي العاملين في وحدات الاستشفاء الكلوي. قام الباحث باجراء اختبار قبلي لاداة جمع البيانات وكذا قام باختبار المصدقية والثبات للاستبيان قبل جمع البيانات.

تم تحليل البيانات بواسطة برنامج الحزمه الاحصائية (SPSS) واستخدام التكرار والنسب للمتغيرات النوعية والمتوسط الحسابي والانحراف المعياري للمتغيرات الكمية. كذلك تم قياس العلاقات بين المتغيرات الاحصائية بواسطة المقاييس الاحصائية مربع كاي واختبار تي وكذا اختبار مك نيمر- وتم استخدام معامل سيرمان لقياس العلاقات بين متغيرات الدراسة عند مستوى دلالة  $0.05 \leq$  و الفا كرومبج لاختبار ثبات الاستبيان.

**النتائج :** 349 مريض شاركوا في الدراسة وتراوح اعمارهم من 13 الى 85 سنة ومتوسط اعمارهم 31.5 وبانحراف معياري  $7.3 \pm$  سنة ونسبة الذكور 56.9%. معظم المرضى 93.4% ياخذون جلسات استشفاء دموي في الاسبوع و 69.1% من المرضى مدة الاستشفاء الدموي اقل من 6 سنوات. اظهرت الدراسة ان نسبة انتشار فيروس الكبد البائي عند المرضى قبل الاستشفاء 2.9% بينما نسبة الانتشار خلال فترة الاستشفاء الدموي 14.3%. وكانت نسبة الانتشار لفيروس الكبد سي 2.9% قبل الاستشفاء بينما نسبة الانتشار خلال فترة الاستشفاء الدموي 17.2%. اظهرت الدراسة ان 5 حالات مصابة بفيروس بي وسي معا. اظهرت الدراسة وجود فرق ذو دلالة احصائية تجاه انتشار عدوى التهاب الكبد البائي والسي بحسب وحدات الاستشفاء الدموي ( $p\text{-value} < 0.05$ ). لا توجد علاقة ذات دلالة احصائية بين معدل انتشار فيروس الكبد بي وسي والبيانات الديموجرافية ( $p\text{-value} > 0.05$ ) وايضا لا توجد علاقة ذات دلالة احصائية بين معدل انتشار فيروس الكبد سي وبي وعدد جلسات الاستشفاء ( $p\text{-value} > 0.05$ ). اظهرت الدراسة ان هناك علاقة قوية بين معدل انتشار فيروس الكبد بي والفترة الزمنية لجلسات الاستشفاء الدموي ( $p\text{-value} = 0.000$ ) وكذلك علاقة قوية بين انتشار فيروس الكبد سي والفترة الزمنية منذ بداية جلسات الاستشفاء الدموي ( $p\text{-value} = 0.000$ ).

اظهرت الدراسة ان 64.8% من الممرضين اجابوا بعدم وجود تحري وتلقيح وفحوصات دورية يتم عملها في وحدات الاستشفاء, 51.2% من الممرضين يمارسون الاحتياطات المعيارية ومحاذير انتقال العدوى, 41.8% يمارسون الاجراءات الخاصة بالنظافة البيئية في وحدات الاستشفاء الكلوي 61.4% منهم يمارسون تعقيم ملحقات الاجهزة الخاصة بالاستشفاء الدموي 60.7% يمارسون اعطاء الحقن بشكل امن وكذا حفظ الادوية كما هو موصى به. نسبة

64.6% من ممرضي وحدات الاستصفاء اجابوا بعدم وجود سياسات واجراءات خاصه بالوقاية ومكافحة العدوي بوحدة الاستصفاء الكلوي.

**الاستنتاجات والتوصيات:** استنتجت الدراسة ان معدل انتشار عدوي فيروس التهاب الكبد البائي عند مرصي الاستصفاء الدموي كانت 14.3% وفيروس سي 17.2%. توصي الدراسة بتطبيق السياسات والاجراءات الخاصه بالوقاية ومكافحة العدوي بوحدة الاستصفاء الكلوي في المستشفيات.



## Chapter one: Introduction

### 1.1 Background of the Study

Viral hepatitis prevails all over the world and is a key global public health issue. It is the inflammation of the liver resulting in hepatic diseases such as liver cirrhosis, hepatocellular carcinoma (HCC) and acute liver failure. Hepatitis B virus (HBV) and hepatitis C virus (HCV) are the most common viral causes of hepatic diseases universally (*Xing et al., 2013*). HBV causes hepatitis of altering severity and remains in 95% of children and 10% of adult patients (*Muhammad et al., 2007*). HBV and HCV both share a common mode of transmission through parenteral, sexual and perinatal means. (*Geberemicheal et al., 2013; Yami & Alemseged, 2011*).

Viral hepatitis is a global public health challenge, are major communicable public health problem diseases worldwide. Despite the significant burden it places on communities across all global regions, hepatitis has been largely ignored as a health and development priority until recently. The viral hepatitis pandemic takes a heavy toll on lives, communities and health systems. According to the World Health Organization (WHO), it is responsible for an estimated 1.4 million deaths per year from acute infection and hepatitis-related liver cancer and cirrhosis – a toll comparable to that of HIV and tuberculosis. (*WHO, 2016*). In Yemen, HCV prevalence in the general population was estimated to be 1.8% (*Chaabna et al., 2016*).

HBV and HCV infections are more prevalent in renal failure patients than in the general population (*Al Hijazat & Ajlouni, 2008*). Viral hepatitis is an important cause of morbidity and mortality of renal failure patients on chronic dialysis and after renal transplantation. The association between viral hepatitis and renal failure is largely due to the high number of blood transfusion session in patients with end-stage kidney disease and to the multiple invasive medical procedures to which these patients are exposed (*Boulaajaj et al., 2005*). HBV and HCV infections have a wide range in prevalence rates in different regions of the world, ranging from 1% in the UK to more than 90% in Eastern Europe in hemodialysis patients (*Reddy et al., 2005*).

In Arab countries, the prevalence of chronic hepatitis B surface antigen (HBsAg) positivity among hemodialysis (HD) patients ranged from 2% in Morocco to 11.8% in Bahrain (*Boulaajaj, et al, 2005; Almawi et al, 2004*). Also in Arab countries, the prevalence of HCV antibodies among HD patients has been reported to range from 27%

in Lebanon to 75% in Syria (*WHO, 2015a; WHO, 2015b*). However, there are strong indications that studies of HD patients which rely solely on serological screening could underestimate the prevalence of HCV infection (*Chandra et al., 2004*).

The overall prevalence of HBsAg among hemodialysis patients in Yemen according to the publications of the last decade was estimated at 48.83% (*Al-Hegami et al., 2015*) while the overall prevalence of HCV infection among hemodialysis patients in Yemen according to the publications of the last decade was estimated as in 2010, 62.7% (*Selm SB, 2010*). In 2014, 22.5% (*Baghza, 2014*). In 2015, it was reported as 40.2% (*Aman et al., 2015*) and 46.01% (*Al-Hegami et al., 2015*) and (5.16%) mixed infection with HBV and HCV (*Al-Hegami et al., 2015*).

## **1.2 Problem Statement**

Hemodialysis (HD) is routinely used as renal replacement therapy for end-stage renal disease (ESRD) patients (*Geoffrey, 2011*). Chronic hemodialysis patients are at increased risk for both HCV and HBV infections associated with contaminated blood and blood product transfusion and exposure to contaminated hemodialysis equipment during treatment (*Lavanchy, 2009*). Viral hepatitis are an important cause of morbidity and mortality of renal failure patients on chronic dialysis and after renal transplantation. The association between viral hepatitis and renal failure is largely due to the high number of blood transfusion session in patients with end-stage kidney disease and to the multiple invasive medical procedures to which these patients are exposed (*Al-Hegami et al., 2015*).

In 2012, 2.1 million patients worldwide were estimated to require hemodialysis and this number is expected to increase by 7% annually (*Fresenius Medical Care, 2012*). Viral hepatitis continues to be a significant health problem in HD patients, in particular in developing countries with limited resources (*Ramia et al., 2002*). Patients on maintenance HD are strikingly vulnerable to infection for many reasons, including the immune-depressed state intrinsic to end-stage renal disease (ESRD), the high prevalence of diabetes, exposure to other patients in the HD facility three times per week, frequent hospitalization, and the invasiveness of the HD procedure (*USA, 2008*). New diagnostic tools allow early diagnosis and better control of hepatitis in the dialysis units. Optimizing the HBV vaccination in predialysis care, the strict adherence to the universal precaution measures, and segregation of HBV-positive patients in an isolated area and use of the modern therapies are the mainstays in controlling HBV infection in

HD units. (*Ghany et al., 2009*). The issue is more complicated for HCV in the absence of a specific vaccine, the nosocomial transmission of the virus, the controversy of isolation and the bad tolerance for the currently available treatment (*Ramia et al., 2002; Schwarz-Zander et al., 2006*).

Maintenance HD is the most frequent mode of renal replacement therapy in end-stage renal disease (ESRD) worldwide. Though this treatment increases the quality of life of these patients, it predisposes them to infections, especially blood-borne infections, among which hepatitis B and C virus infections (*Fabrizi et al., 2010*). In HD unit, HBV has been identified as a prominent blood-borne infection with significant morbidity and mortality among these patients (*Fabrizi et al., 2008*).

Patients receiving maintenance HD therapy are at increased risk for acquiring these infections and have a higher prevalence of HBV and HCV than the general population (*Taal et al., 2000; Fabrizi et al., 2010; Fabrizi, et al., 2002*). Patient to patient transmission in HD units is also reported. HBV infection is usually due to the patient to patient transmission within HD units (*Ozer et al., 2011*).

Recognition of the risk of nosocomial infection has resulted in recommendations that strict infection control procedures should be followed on HD units; patients with blood-borne virus infections should be isolated from seronegative patients during dialysis and patients as well as staff should be vaccinated against hepatitis B (*Fabrizi et al., 2008; Taal, et al., 2001*). The introduction of blood screening and a reduction in blood transfusions due to the availability of recombinant erythropoietin has significantly reduced the incidence of new HCV infections among HD patients in many countries (*Mohamed, 2010; Patel et al., 2010; Saune et al., 2010*).

It is well known that patients undergoing dialysis treatment, and in particular HD are at increased risk for contracting viral infections. This is due to their underlying impaired cellular immunity, which increases their susceptibility to infection. In addition, the process of HD requires blood exposure to infectious materials through the extracorporeal circulation for a prolonged period. Moreover, HD patients may require blood transfusion, frequent hospitalizations, and surgery, which increase opportunities for nosocomial infection exposure (*Karkar et al., 2006*). HBV and HCV infections are more frequent in HD patients compared to the general population and are known to cause chronic liver disease (*Alavian et al., 2008*). This arises as a consequence of sharing dialysis machines or lack of inadequate infection control methods in hemodialysis centers (*Elamin & Abu-Aisha et al., 2011*).

Chronic hemodialysis patients are at high risk for infection because the process of hemodialysis requires vascular access for prolonged periods. In an environment where multiple patients receive dialysis concurrently, repeated opportunities exist for person-to-person transmission of infectious agents, directly or indirectly via contaminated devices, equipment, and supplies, environmental surfaces, or hands of personnel. Furthermore, hemodialysis patients are immunosuppressed which increases their susceptibility to infection (*Alavia et al., 2008*).

### **1.3 Justification of the study**

There is a high prevalence of hepatitis viruses among HD patients all over the world. Serious sequelae may occur due to the absence of effective treatment for hepatitis viruses. Lack of data on the prevalence of these viruses and their risk factors among HD patients in Yemen would increase the incidence rate of these viruses. Infection with HBV and HCV causes serious mortality, morbidity, and financial burden and therefore they constitute a major global health problem. Reports of increased prevalence in persons treated with blood and blood products have suggested parenteral transmission as a frequent route of infection (*Kristian et al., 2006; Rivanera et al., 2009*).

Exposure to bloodborne pathogens, specifically HBV and HCV is a serious risk for HD patients and employees. There is always the risk of transmission of these pathogens and hence, standard Precautions (formerly Universal Precautions) need to be rigidly observed in the HD facility. The risk of HBV acquisition in HD facilities remains despite the dramatic fall in HBV carriers because of the widespread use of HBV vaccine, the testing of blood transfusions HBsAg and the reduced need for transfusion in the CKD population because of erythropoietin (*Shepard et al., 2008*). Patients with CKD tend to become life-long carriers of HBV if infected, and therefore special care is taken to prevent the spread of infection to other patients and those staff who are susceptible to HBV infection because they either have not been vaccinated or did not respond to HBV vaccine. HBsAg positive individuals may have a very high load of circulating virus, and the virus can survive on environmental surfaces for greater than 1 week in dried blood. (*Barril et al., 2008*).

HD centers or units have characteristics unique among healthcare facilities. Treatment is generally in the same center for months or years on a repetitive basis and is not curative but life-sustaining. Patients are treated in three or four shifts per day so

that the staff is subject to periods of intense activity, during which one shift of patients must have their treatment terminated and the next shift have their treatment initiated. Most of the care is provided by certified dialysis technicians under the supervision of dialysis trained registered nurses. A typical staffing ratio is one nurse to every 12 patients on a shift, and one patient care technician for every 4 patients (*Concepcion, 2008*).

Epidemiologic investigations have indicated substantial deficiencies in recommended infection control practices, as well as a failure to vaccinate hemodialysis patients against HBV. These practices apparently are not being fully implemented because staff members a) are not aware of the practices and their importance, b) are confused regarding the differences between standard (i.e., universal) precautions recommended for all health-care settings and the additional precautions necessary in the hemodialysis setting, and c) believe that hepatitis B vaccine is ineffective for preventing HBV infection in chronic hemodialysis patients (*Edey et al., 2010*). There are no national dialysis practice guidelines or infection control policies enforced by health care authorities, there is general agreement that patients on HD should be screened for HBV and HCV infection before the initiation of HD and monitored every 6-12 months thereafter. Sero-positive patients are dialyzed on dedicated machines either in an isolated area or alongside seronegative patients if space does not allow isolation. There is almost no much data about the situation in these hospitals regarding hepatitis infection in HD, while infection control measures are not applied and/or not strictly followed. In addition, the recommendation for the prevention of bloodborne infection which includes infection control practice specifically designed for the HD setting, routine serologic testing and immunization; surveillance; and training and education programs are not available in most of these centers. Few studies have been reported about the prevalence of hepatitis B & C virus among HD patients in Yemen (*Al-Hegamet et al, 2015; Baghza, 2014; Selm, 2010*). Therefore, the main objective of this study was to investigate the prevalence and infection control of hepatitis B and C in the entire HD units in Sana'a city.

## **Chapter Two: Literature Review**

### **2.1 HBV and HCV infection**

### 2.2.1 Epidemiology of HBV and HCV infection

HBV is a major cause of liver disease morbidity and mortality worldwide, affecting more than 2 billion people, responsible for more than 240 million cases of chronic hepatitis and greater than 780,000 deaths per year of complications such as acute liver failure, liver cirrhosis and hepatocellular carcinoma (*Sagnelli et al., 2012; Sagnelli et al., 2014*). It is the most common cause of liver cancer worldwide, and it is unevenly distributed throughout the world. (*Trepo et al., 2014; WHO, 2015a*). Patients with end-stage kidney disease and that hemodialysis, in particular, have a higher prevalence of hepatitis virus infections, ranging from 0 to 22% for B virus infection (*Schiller et al., 2015*).

Hepatitis B virus infection results in substantial human morbidity and mortality, predominantly through the consequences of chronic infection. Recent estimates of the number of people chronically infected with HBV have ranged from 240 million to 350 million with more than two billion humans globally ever having been infected (*Schweitzer et al., 2015*). In the Global Burden of Disease Study 2010, HBV was estimated to have resulted in 786,000 deaths, the vast majority being attributable to liver cancer (341,000 deaths) and cirrhosis (312,000 deaths). As a result, HBV infection was ranked 15th among all causes of human mortality (*MacLachlan & Cowie, 2015*). The prevalence of HBsAg carrier rate is higher in Yemen 48.83% (*Al-Hegami et al., 2015*) compared to other countries such as Egypt 4.3% (*Abu El Makarem et al., 2012*) and the Kingdom of Saudi Arabia 1.5% (*Almawi et al., 2004*).

Hepatitis C is the second most prominent viral infection globally after hepatitis B and its importance is associated with the occurrence of hepatic diseases (*Craxi et al., 2008*). About 130-150 million people universally are chronically infected with hepatitis C infection (*WHO, 2015b*) and about 500000 people die every year of hepatitis C-associated liver infections (*Lozano et al., 2012*). Globally, about 71 million people have chronically infected hepatitis C virus and are at risk of developing cirrhosis and liver cancer (*WHO, 2015b*). These infections have been the cause of 1.34 million deaths in 2015 (*Cordeiro et al., 2018*).

Patients with end-stage kidney disease and that hemodialysis in particular, have a higher prevalence of hepatitis virus infections, ranging from 2 to 25% for C virus infection (*Schiller et al., 2015*). The prevalence of HCV infection among HD patients

is generally much higher than the general population due to underlying impaired cellular immunity, which increases their susceptibility to infection. In addition, HD requires prolonged vascular access and exposure to contaminated equipment. In addition, HD patients required a blood transfusion, frequent hospitalization, and surgery, which increase opportunities forgetting nosocomial infection exposure (*Khan et al., 2011*).

HCV is more prevalent in some nations in sub-Saharan Africa and Asia. Egypt observed the maximum seroprevalence of 13.9% in the healthy general population and this is lower than that reported in western nations (*Chemaitelly et al., 2013*).

The prevalence of asymptomatic HCV is much lower in Yemen (1.1, 2.2, and 1.56%) comparing with other Arabic countries (*Alodini, 2012*). We also presented estimates for the national population-level HCV prevalence and for the prevalence among various at-risk categories. The results suggest that the national population-level HCV prevalence is at about 1% in Somalia, Sudan, and probably Djibouti, but seems twice as high in Yemen at about 2%. High prevalence estimates were identified in these countries among clinical populations at high risk of infection such as HD and hemophilia patients (*Chaabna et al., 2016*).

HD staff was found also to be an important factor in the transmission of HCV infections among HD patients. The prevalence of HCV infection among HD patients in developed countries ranges from 3.6% to 20% and is higher in the developing countries and in Egypt, it ranges from 49% to 64% (*Mohamoud et al., 2016*).

From Center for Liver Research and Diagnostics, Hyderabad, India has reported that, among the patients of CKD and of either renal transplant or hemodialysis, 7% had HBV infection alone, 46% were infected with HCV alone (*Bhaumik & Debnath, 2012*). While, it is seen that the pooled prevalence of HBV infection among hemodialysis patients in China was 11.9% and HCV infection was 41.1% (*Xing et al., 2013*).

### **2.2.2 Causative agents of HBV and HCV**

Hepatitis is an inflammation of the liver, most commonly caused by a viral infection. Of these viruses, HBV and HCV infections account for a substantial proportion of liver diseases worldwide (*K. Park, 2015; David, 2010*).

### **2.2.3 Risk Factors for HBV and HCV Infection in HD Units**

It should be emphasized that outbreaks of HBV infection in dialysis facilities in the USA and other developed countries occur as a result of clear violations of standard practice (*CDC, 1996*). In a review of outbreaks with patient-to-patient transmission between 1992 and 2007 in the USA and Europe, 30% of 33 outbreaks occurred in HD facilities, the largest single setting identify (*Lanini et al., 2009*). Risk factors for HBV infection in HD facilities include the presence of HBsAg positive patients within the dialysis unit, the use of the same dialysis machines for HBsAg positive and negative patients (i.e., HBsAg patients not being isolated), a relatively low prevalence of HBV vaccination in unit patients, and multiple entries into single or multidose medication vials. The preparation of injectable medications within the HD treatment area has also been associated with a higher incidence rate for HBV infection compared to centers that used a dedicated medication room (2002 incidence rates of 0.27% and 0.06%, respectively) (*Shepard et al., 2008*).

It is important to note that a negative HBsAg test does not preclude the presence of occult HBV infection (HBsAg-negative, HBV DNA positive). In a study from a Canadian dialysis center, 2 of 241 patients were HBsAg positive, while nine (3.8%) of the 239 HBsAg negative patients were positive for HBV DNA in the serum by real-time polymerase chain reaction (PCR) (*Minuk et al., 2004*) and in a study of 188 HD patients from Turkey overt HBV infection was found in 25 patients (13.3%) and occult HBV infection in 5 (2.7%) (*Yakaryilmaz et al., 2006*).

Several factors are known to be associated with increased risk of HCV infection. Duration on HD is well recognized as a predisposing factor for HCV infection (*Ansar & Kooloobandi, 2002; Ben Othman et al., 2004; Ahmetagic et al., 2006*). A relatively large study in Brazil demonstrated that patients on HD for more than 3 years had a 13.6 fold greater risk of HCV positivity compared with subjects with less than 1 year of HD treatment (*Carneiro et al., 2001*). Historically, the number of blood transfusions received was consistently reported in the literature to be associated with an increased prevalence of HCV-positive dialysis patients (*Elamin & Abu-Aisha et al., 2011*). However, several recent reports could not recognize blood transfusion as an



independent risk factor in HCV spread among HD subjects. (*Ben Othman et al., 2004; Rahnavardi et al., 2008*). Other risk factors include older age (*El-Amin et al., 2007; Hmaied et al., 2006*), dialysis in multiple centers (*Carneiro et al., 2001; El-Amin et al., 2007; Petrosillo et al., 2001*), a history of organ transplantation (*Schneeberger et al., 2000; Salama et al., 2000; Sypsa et al., 2005*), and hepatitis B infection (*Salama et al., 2000*).

### 2.2.3 Structure/ Description of HBV and HCV

- **Structure/ Description of HBV**

HBV is a DNA virus with important traits similar to that of retroviruses (*Ganem et al., 2001*). It is in the family Hepadnaviridae. HBV can be categorized into eight genotypes, A to H based on sequence similarity. Each of the genotype has a varying geographic allocation. Three kinds of viral particles can be found in the serum by electron microscopy. The spheres and filaments consist of HBsAg and lipids (*Zhang & Cao, 2011*). The virion of HBV has a round, double structure 42 nm in diameter of a lipid envelope consisting of HBsAg that surrounds an inner nucleocapsid composed of hepatitis B core antigen (HBcAg) complexed with virally encoded polymerase and the viral DNA genome (*Gerlich & Robinson, 1980*).

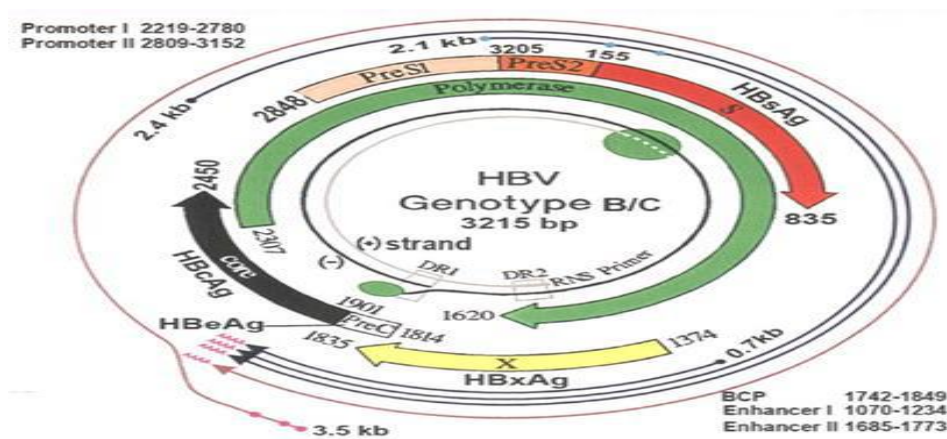


Figure 1. Genomic structure organization of HBV (*Zhang & Cao, 2011*)

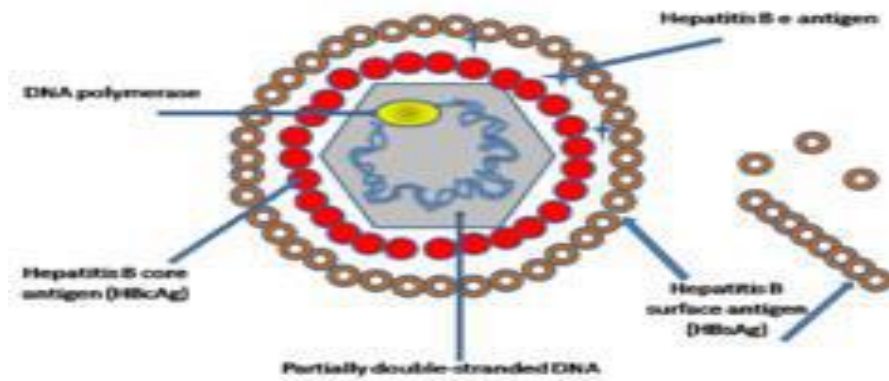


Figure 2. Structure of nuclear genome of Dane particle. (Nuclear genome of the Dane particle (*Wikipedia, 2016*)).

- **Structure / Description of HCV**

HCV is an RNA virus in the genus Hepacivirus and the family Flaviviridae. The genome of HCV is made up of a single-stranded RNA of positive polarity. The genome sequence codes for a lengthy polyprotein (*Simmonds, 1995*) which is processed co-translationally and posttranslationally to produce several structural proteins and non-structural proteins (*Lindenbach et al., 2001*). E1 and E2 envelope proteins are the outward surface of the viral particles responsible for viral entry into the host cell.

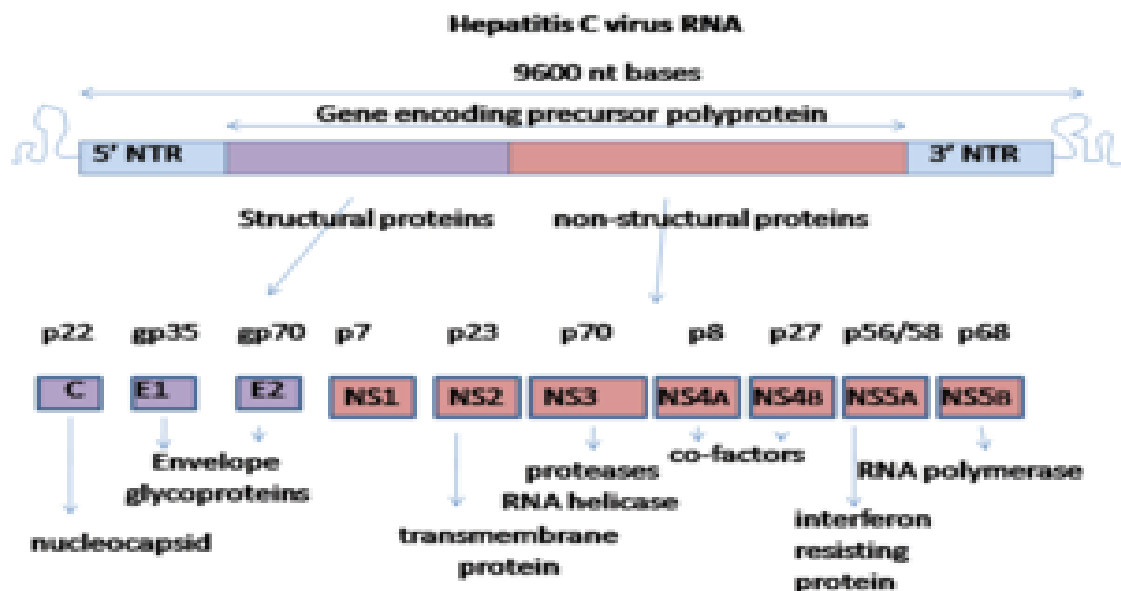


Figure 3. Summary of HCV genomic organization. (Genomic organization of HCV. In *Wikipedia*. Retrieved on 23rd July (*Wikipedia, 2016*)).

#### **2.2.4 Types of HBV infection**

- **Acute HBV infections**

Acute HBV infections occur in teenagers and young adults. Half of these youth never develop symptoms, and only about 20% or one in five infected patients develop severe symptoms and yellowing of the skin (jaundice). Jaundice occurs when the infected liver is unable to get rid of certain colored substances, or pigments, as it normally does. The remaining 30% of patients have only “flu-like” symptoms and will probably not even be diagnosed as having hepatitis unless certain tests are done ( *Liang et al., 2000*).

- **Chronic HBV infection**

Chronic HBV infection lasting longer than six months is said to be chronic. After this time it is much less likely for the infection to disappear. Not all carriers of the virus develop chronic liver disease; in fact, a majority have no symptoms. But, about one in every four HBV carriers develop liver disease that gets worse over time, as the liver becomes more and more scarred and less able to carry out its normal functions. A badly scarred liver is called cirrhosis. Patients are likely to have an enlarged liver and spleen, as well as tiny clusters of abnormal blood vessels in the skin that resemble spiders. Patients with chronic hepatitis B who drink or smoke are more likely to develop liver cancer. The most serious complication of chronic HBV infection is liver cancer ( *Liang et al., 2000*).

#### **2.2.5 Hepatitis B virus genotype**

Ten genotypes of HBV have been identified labeled A through J. The prevalence of HBV genotypes varies geographically. HBV genotypes A through H have been found in the United States, with genotypes A, B, and C being most prevalent. HBV genotypes may play an important role in the progression of HBV-related liver disease as well as response to interferon therapy (*Lin and Kao, 2017*). Genotype A (vs. B-D) is associated with significantly higher rates of hepatitis B e antigen (HBeAg), and HBsAg loss with IFN therapy (*Marcellin et al., 2016*).

Studies from Asia found that HBV genotype B is associated with HBeAg seroconversion at an earlier age, more sustained remission after HBeAg seroconversion, less active hepatic necro-inflammation, a slower rate of progression to cirrhosis, and a lower rate of HCC development compared with genotype C. Studies

from Alaska also show that HBeAg seroconversion occurs on average 2 decades later in persons infected with HBV genotype C than in those infected with HBV genotypes A, B, D, or F. In addition, a significantly higher incidence of HCC has been reported in persons infected with genotypes C or F in Alaska compared with the others (*Terrault et al., 2018*).

HBV is typically transmitted vertically, i.e. from mother to newborn or among siblings at younger ages in endemic areas such as Asia and Africa. In low-risk areas, horizontal transmission, i.e. via sexual and parenteral routes, is more the norm in the adulthood (*Terrault et al., 2018*).

### **2.2.6 Hepatitis C virus genotype**

Hepatitis C virus is divided into the seven main genotypes and more than 100 different subtypes. Genotypes have more than 30% differences in their nucleotide sequences; in most similar species (Quasi-species) differences between nucleotide sequences is 20% (*Moosavy et al., 2017*). Prevalence and distribution of HCV genotyping is different in several geographic regions (*Khedmat et al., 2014*). Genotype -1 is more present in developed countries such as European or North American countries, for instance; HCV-1 (subtype A1-B1) is common in 60% to 70% of patients in United State of America (USA). HCV-2 was more prevalent among middle and west of Africa, and HCV-3 is most prevalent in Far East countries and India. Genotypes 4, 5, and 6 have more prevalence in specific endemic geographical regions. HCV-4 is more prevalent in Egypt and sub-Sahara region, HCV-5 in South Africa and HCV-6 is more prevalent in China and Southeast Asian countries (*Wantuck et al., 2014*).

On the other hand, HCV-1, HCV-2, and HCV-3 have global prevalence around the world, and HCV- 4, HCV-5, and HCV-6 have limited prevalence; for example, HCV-4 is more prevalent in Arabic countries such as Saudi Arabia, Egypt, Syria, and recently in specific parts of Europe. HCV-5 is limited to South Africa, and HCV-6 is more prevalent in southeast countries, including China, Hong Kong, and Taiwan. HCV-3 in Pakistan and HCV-1 and HCV-3 in Iran were more common. In one study on Iranian peoples in South of Iran, 1a (62.1%), 1b (23%), and 3a (14.9%) had more prevalence, respectively ( *Jahanbakhsh et al., 2013; Moosavy et al., 2017*). genotype 7 HCV infection reported from Canada that isolated from central immigrant (*Messina et al., 2015*).

### **2.2.7 Co-infections**

HBV and HCV co-infection was related to a longer time on hemodialysis, longer duration of infection and history of blood transfusion (*Bhaumik and Debnath, 2012*). Persons at risk for HCV infection are also at risk for HBV infections. About 30% to 40% of HIV-infected patients also have HCV. This high rate of co-infection is primarily related to Intravenous drug use. Co-infection with HCV places the patient at greater risk for progression to cirrhosis (*Lewis et al., 2014*).

### **2.2.8 Reservoir of infection of HBV and HCV**

The reservoir of HBV is humans. Chimpanzees are susceptible, but an animal reservoir in nature has not been recognized. Closely related hepadnaviruses are found in woodchucks, ducks, ground squirrels and other animals such as snow leopards and German herons; none cause disease in humans. In HCV is humans; virus has been transmitted experimentally to chimpanzees (*David, 2010*).

### **2.2.9 Modes of transmission of HBV and HCV**

HBV can be transmitted via direct contact with blood, transfusion of blood and blood products, intravenous injections, and unprotected sex, the prevalence of risk factors differs from a society to another according to the norms and traditions of that society. Therefore, for the establishment of public health plan to combat HBV infection, determining the risk factor of infection transmissions in a society is of great importance (*Hussein & Daniel, 2017*). It can be transmitted parentally by mothers infected with HBV (*Jonas 2009; Ranger-Rogez & Denis, 2004*) percutaneous (e.g., IV drug use, accidental needle-stick punctures); or by mucosal exposure to infectious blood, blood products, or other body fluids (e.g., semen, vaginal secretions, saliva) (*David, 2010*).

In dialysis units, both patient-to-patient and patient-to staff transmission of the virus have been recognized since the 1960s. Before the advent of vaccination, some success in limiting the spread of HBV was achieved by dialyzing seropositive patients separately from those who were seronegative (*Bassam, 2015*) This followed the publication in the UK of the Rosenheim Report in 1972 (*Rosenheim Advisory Group, 1972*)

HBV in HD is transmitted by contact of infectious blood or other body fluids with skin or mucous membranes with impaired integrity. HBV can survive on

environmental surfaces for up to 7 days at room temperature. In studies conducted at centers for HD, HBV was detected on surgical equipment, control buttons of HD machines, and on door handles (*Favero et al., 1973*). Transmission from environmental surfaces, equipment, and healthcare workers plays a major role in transmission of HBV (*Kizilates, 2016; Lavanchy, 2004; CDC, 2001*).

Transmission of HCV infection is mainly by exposure to infected devices and tools despite rigid hygienic control, infected blood or blood products, hemodialysis, intravenous drug abuse, and organ transplantation. The estimation of national prevalence and ways of transmission of HCV should be completed in order to allow the national authorities to prioritize preventive measures and have the best and most appropriate use of available resources (*Ashkani-esfahani et al., 2017*). Hepatitis C virus transmission among hemodialysis patients is mainly nosocomial. Possible risk factors include sharing hemodialysis equipment and instruments and the lack of adherence to standard precaution measures and equipment sterilization (*Monsalve-Castillo et al., 2012*).

Like HBV, HCV is also transmitted percutaneously, but horizontal transmission is also possible in HD units from environmental surfaces, equipment, and healthcare workers (*Kizilates, 2016; Elamin&Abu-Aisha, 2011*). The nosocomial pathway plays a primary role in HCV transmission in HD units. There is also the knowledge that HCV is not transmitted from dialysis membrane directly (*Lavanchy, 2004; Kizilates, 2016; Elamin & Abu-Aisha, 2011*).

HBV and HCV are efficiently transmitted parenteral and these viruses have been a historical cause of comorbidities among hemodialysis patients. High prevalence of viral hepatitis B and C have been observed in hemodialysis centers worldwide. In general, these individuals are exposed to several risk factors for viral hepatitis B and C, including blood transfusion, invasive medical procedures and sharing of infected patients' environments (*Cordeiro et al., 2018*).

Moreover, due to the great variety of human activities with potential exposure to blood, several possible biologic transmission models exist, such as from tattoos, piercings, barber shops, scarification rituals, circumcisions and acupuncture (*Monsalve-Castillo et al., 2012*).

The most common ways of transmitting HCV are through sharing needles (almost 60% of infections), accidentally being exposed to contaminated blood (about

10% of cases), or receiving a tattoo done with a contaminated needle. Less frequent methods of transmission are from infected mother to child during childbirth, and a rare method is from sexual intercourse with an infected person. Transmission may take place with either heterosexual or homosexual behavior (*K. Park, 2015; David, 2010*).

#### **2.2.10 Incubation period of HBV and HCV**

HBV has a long incubation period. It replicates in the liver and remains in the serum for relatively long periods, allowing transmission of the virus. HBsAg appears in the circulation in 80% to 90% of infected patients 1 to 10 weeks after exposure to HBV and 2 to 8 weeks before the onset of symptoms or an increase in transferase levels. Patients with HBsAg that persists for 6 months or longer after acute infection are considered to be HBsAg carriers (*Smeltzer & Bar, 2013*). HBV can live on a dry surface for at least 7 days; it is much more infectious than human immunodeficiency virus (*Lewis et al., 2014*). The incubation period for HCV infection varies from 14 to 180 days. Following acute infection, which is usually asymptomatic or occurs as a mild clinical disease, chronic HCV infection develops in 75%–85% of patients (*K. Park, 2015; David, 2010*).

#### **2.2.11 Period of communicability of HBV and HCV**

All persons who are HBsAg-positive are potentially infectious. Blood from experimentally inoculated volunteers has been shown to be infective weeks before the onset of first symptoms and to remain infective through the acute clinical course of the disease. The infectivity of chronically infected individuals varies from high (HBeAg-positive) to modest (anti-HBe-positive). In HCV is from one or more weeks before onset of the first symptoms; may persist in most persons indefinitely. Peaks in virus concentration appear to correlate with peaks in ALT activity (*K. Park, 2015; David, 2010*).

#### **2.2.12 Host susceptibility of HBV and HCV**

In HBV the susceptibility is general. Disease is often milder and anicteric in children; in infants it is usually asymptomatic. Protective immunity follows infection if antibodies to HBsAg (anti-HBs) develop and HBsAg is negative. Persons with Down syndrome, lymphoproliferative disease, HIV infection and those on hemodialysis appear more likely to develop chronic infection. In HCV the susceptibility is general. The degree of immunity following infection is not known; repeated infections with

HCV have been demonstrated in an experimental chimpanzee model (*K. Park, 2015; David, 2010*).

### **2.2.13 Clinical Manifestations of HBV and HCV**

Clinical signs and symptoms of HBV infection during the acute phase are the same as those of HAV infection. Arthralgia, high fever, and rash are hallmark signs of an acute HBV infection (*Morton & Fontaine, 2017*). The patient may have loss of appetite, dyspepsia, abdominal pain, generalized aching, malaise, and weakness. Jaundice may or may not be evident. If jaundice occurs, light-colored stools and dark urine accompany it. The liver may be tender and enlarged to 12 to 14 cm vertically. The spleen is enlarged and palpable in a few patients; the posterior cervical lymph nodes may also be enlarged. Subclinical episodes also occur frequently (*K. Park, 2015; David, 2010*).

Occasionally patients with HBV infection will develop joint swelling and pain (arthritis) as well as hives or a skin rash before jaundice appears. The joint symptoms usually last no longer than three to seven days. Typically, the symptoms of acute hepatitis B do not persist longer than two or three months. If they continue for four months, the patient has an abnormally long-lasting acute infection (*David, 2010*).

Patients with chronic hepatitis C infection are usually asymptomatic, the disease being discovered only following a routine biochemical test when mild elevations in the aminotransferases (usually ALT) are noticed (50%). The elevation in ALT may be minimal and fluctuating and some patients have a persistently normal ALT (25%), the disease being detected by checking HCV antibodies (e.g. in blood donors). Severe chronic hepatitis (25%) and even cirrhosis can be present with only minimal elevation in aminotransferases, but progression is very uncommon in those with a persistently normal ALT (*Caruntu & Benea, 2006*). Fatigue is the commonest symptom with sometimes nausea, anorexia and weight loss, which do not correlate with disease activity (*Kumar & Clark, 2016*). In most patients, HCV can still be found in the blood six months after the start of acute infection, and these patients are considered to be carriers

### **2.2.14 Complications of HBV and HCV**

Chronic HCV infection, which affects 130–150 million people worldwide, is one of the leading causes of liver cirrhosis and hepatocellular cancer, as well as a



leading indication for liver transplantation in developed countries. In addition, several extra-hepatic complications, such as dermatologic, rheumatologic and hematologic disorders, are also associated with chronic HCV. Renal complications, such as albuminuria, cryoglobulinemia-induced membranoproliferative glomerulonephritis and other glomerulonephritides, are also well documented in patients with chronic HCV. However, it is not clear whether and to what extent chronic HCV infection affects the development and progression of CKD at a population level (*Li & Lo, 2015*).

Hepatitis may lead to fulminant (sudden, severe), acute or chronic liver failure. Chronic infection can develop in those with HBV or HCV. Some people are asymptomatic carriers of HBV or HCV and never have an active illness. However, they can infect others and have a greater risk of developing cancer of the liver (*Linda & Paula, 2011*). HBV infection is a major clinical problem, as it can lead to many serious consequences, including acute and chronic hepatitis, cirrhosis, hepatocellular carcinoma and hepatic failure (*Joukar et al., 2011*). Chronic HBV infection may predispose to liver cirrhosis, liver failure, and hepatocellular carcinoma. It is estimated that more than half a million subjects worldwide die annually from HBV and its complications (*Hussein & Daniel, 2017*).

HBV causes acute or chronic infection. Adults with normal immunity experience infection at a rate of 94%–98% after exposure to the virus and acquire permanent immunity with neutralizing antibodies. However, immunosuppressed individuals, such as patients who are infected often develop a chronic infection (*Kizilates et al., 2016*).

### **2.2.15 Diagnosis of HBV and HCV**

The diagnostic criteria of HBV include serologic markers, biochemical markers of liver disease (including elevated liver enzyme levels), and histologic changes in the liver. Incorrect interpretation of HBV serologic markers is common. Familiarity with the serology testing is important for the nurse who is assisting in the diagnostic evaluation of a suspected case of viral hepatitis to prevent inappropriate laboratory testing and patient discomfort (*Morton & Fontaine, 2017*).

Hepatitis B is diagnosed by detecting one of the viral antigens—called HBsAg—in the blood. Later in the acute disease, HBsAg may no longer be present, in which case a test for antibodies to a different antigen—hepatitis B core antigen—is used. If HBsAg can be detected in the blood for longer than six months, chronic hepatitis B is diagnosed. A number of tests can be done to learn how well, or poorly, the liver is working. They

include blood clotting tests and tests for enzymes that are found in abnormally high amounts when any form of hepatitis is present (*WHO, 2015a*).

Diagnostic evaluation for HCV infection includes an HCV enzyme-linked immune sorbent assay (ELISA); ordered when the aminotransferase levels are elevated and for screening patients on hemodialysis), an anti-HCV recombinant strip immune blot assay (RIBA; ordered to confirm a positive HCV test or if a patient presents with symptoms of hepatitis), or an HCV RNA test (ordered when HCV RIBA findings are indeterminate, but there remains a high index of suspicion for HCV. (HCV RNA, which tests for the presence of the virus RNA in the blood (rather than antibodies against the virus), is the gold standard for detecting HCV. HCV RNA levels are used to gauge response to treatment, but they are not serially checked because viral load has no correlation to the degree or rate of liver injury progression (*Caruntu & Benea, 2006; WHO, 2015a*).

A blood test is available to detect the HCV antibody, a substance that the body makes to combat HCV. The test is about 97% accurate, but does not distinguish between acute and chronic infection. Several other blood tests are available to test for HCV RNA (the genetic material of the virus). These tests can be performed in early infection before the antibody is measurable. Simpler blood tests can be done to show how much jaundice-causing pigment is in a patient's blood, or to measure the levels of certain enzymes (proteins) made by the liver. High levels of these liver enzymes (called ALT and AST) indicate that the liver is inflamed. Rising levels could suggest that the infection is getting worse. A liver biopsy (removing a small amount of tissue with a thin needle) can also be used to diagnose hepatitis C (*Kalantar-Zadeh et al., 2005*).

#### **2.2.16 Treatment of HBV and HCV**

In the past, there was no treatment available for hepatitis B. But developments have been made in recent years on drugs that suppress the virus and its symptoms. In early 2003, a drug called adefovir was reported as an effective treatment. Another drug called tenofovir was demonstrated as effective in patients infected with both hepatitis B and HIV. Two studies also reported on the effectiveness of a drug called Preveon, which was more expensive than others were. Patients also should rest in bed as needed, continue to eat a healthy diet, and avoid alcohol. Any non-critical surgery should be

postponed. A large majority of these patients will recover within three months (**WHO, 2015a**).

Guidelines for treatment of chronic hepatitis B and update the previous hepatitis B virus (HBV) guidelines from 2009. The 2018 updated guidance on chronic hepatitis B (CHB) includes (1) updates on treatment since the 2016 HBV guidelines (notably the use of tenofovir alafenamide) and guidance on (2) screening, counseling, and prevention; (3) specialized virological and serological tests; (4) monitoring of untreated patients; and (5) treatment of hepatitis B in special populations, including persons with viral co-infections, acute hepatitis B, recipients of immunosuppressive therapy, and transplant recipients (**Terrault *et al.*, 2018**).

The primary goal of the management of patients with HCV is to reduce or eliminate the complications of chronic HCV infection, such as the development of cirrhosis, hepatic decompensation, hepatocellular carcinoma (HCC), extrahepatic manifestations, and death (**Goossens *et al.*, 2016**). The National Institutes of Health recommend that anyone who has a positive test for the HCV virus in their blood, a liver biopsy that indicates liver damage or an elevated amount of the liver enzyme ALT receive treatment (**Poordad & Dieterich, 2012**).

Drug therapy involves treatment with pegylated interferon alfa combined with twice-daily oral doses of ribavirin (Rebetol), an antiviral agent. As of 2007, three different genotypes (variants) of the hepatitis C virus had been identified. Individuals with genotype 1 usually given 48 weeks of drug treatment, while those with genotypes 2 and 3 are given a 24-week treatment. If this regimen does not eradicate the virus, it may be repeated once. Treatment lasted 24–48 weeks depending on the viral genotype and severity of liver disease. This regimen led to SVR rates of approximately 40–50% in patients with genotype 1 and 4, and higher SVR rates in patients with genotype 2, 3, 5, and 6 (**Sandeep & Dhawan, 2012; Goossens *et al.*, 2016**).

These drugs may have unpleasant flu-like side effects and may cause extreme fatigue, skin irritation, anemia (too few red blood cells) problems with memory and concentration, depression and suicidal behavior, especially in people who have a history of depression. When hepatitis destroys most or all of the liver, the only hope may be a liver transplant (**Poordad and Dieterich 2012**). Side effects of this regimen are substantial and include anemia, neutropenia, thrombocytopenia, fatigue,

neuropsychiatric effects, flu-like symptoms, and multiple other symptoms (*Goossens et al., 2016*).

HCV is no benefit from rest, diet, or vitamin supplements. Studies have demonstrated that a combination of two antiviral agents, interferon (Intron-A) and ribavirin (Rebetol), is effective in producing improvement in patients with hepatitis C and in treating relapses. Some patients experience complete remission with combination therapy (*Smeltzer &Bar, 2013; WHO, 2015b*).

Treatment should be given priority in patients with stage 4-5 chronic kidney disease because: 1). HCV increases the incidence and prevalence of renal disease, ESRD and ESRD-related mortality in the general population. Association of hepatitis C virus infection with risk of ESRD: a population-based study (*Pol &Vallet-Pichard, 2017*), 2). Despite the introduction of screening, improved hygiene and prevention measures, HCV prevalence is higher than in the general population in candidates for transplantation (*Saune et al., 2010*), 3). HCV increases the risk of mortality in dialysis patients in whom survival is lower than in renal transplant recipients, 4). HCV is associated with reduced survival in HCV infected versus HCV non-infected transplant recipients, mainly for liver disease or septic complications due to cirrhosis and/or immunosuppressive therapy, 5). HCV impairs renal allograft survival due to de novo membrano-proliferative glomerulonephritis and may even perhaps favour chronic allograft rejection, 6). HCV antibody positivity increases the incidence of hepatocellular carcinoma in kidney recipients (*Chhatwal et al., 2015*).

The major effort against chronic HBV infection on patients receiving hemodialysis should be directed at prevention. The introduction of HBV immunization has significantly lowered the HBV incidence in several endemic regions, although these patients often have poor responses to vaccination, even after intensified protocols and booster doses.<sup>20</sup> Additional hygiene-preventive measures and lifestyle modifications, such as avoiding alcohol use, quit smoking, and keeping normal body mass index, are also very important and should be always recommended in order to minimize patient-to-patient HBV transmission, slow the progression of liver disease, and reduce the risk of HBV-related complications (*Chan et al., 2016*).

For the management of patients undergoing hemodialysis, physicians should also take into account that these patients may often present with moderate or no

elevations of serum aminotransferases owing to altered inflammatory response, lower serum HBV DNA levels due to its removal by hemodialysis, higher risk of occult HBV infection (detection of viral genome in liver tissue and, in some instances, in serum in HBsAg-negative patients), and a lot of comorbidities such as cardiovascular disease, diabetes mellitus, and anemia. All these parameters may affect the clinical and laboratory presentation and course of chronic HBV infection and the patients' response to antiviral therapy (*Pipili et al., 2013*).

The optimal therapy for chronic HBV infection on hemodialysis may involve observation, IFN- $\alpha$ , or NAs. Among patients who are not candidates for renal transplantation, antiviral treatment should be reserved for those with active or fibrotic liver disease. A limited literature exists on.

IFN therapy on patients with chronic HBV infection receiving hemodialysis. The experience in this patient group comes mostly from treatment of hepatitis C. Although IFN- $\alpha$  administration was related to HBe seroconversion and improvement of liver biochemistry, the exacerbation of IFN side effects (mostly myelosuppression and malnutrition) hampers its use in clinical practice (*Chan et al., 2016*).

There are three reports including five HBV patients undergoing hemodialysis who were treated with adefovir for 12–30 months. Both liver and renal function improved in parallel with the serum HBV DNA clearance. There are no data for telbivudine together with its safety in such patients (*Pipili et al., 2013*). Long-term entecavir therapy seemed to be safe and effective in nine patients on maintenance hemodialysis. Given its high potency and high genetic barrier in NA-naïve patients profile, entecavir is the most promising anti-HBV agent for patients undergoing hemodialysis and/or candidates for renal transplantation (*Fabrizi et al., 2005*). As long-term entecavir therapy is not so effective in patients with lamivudine resistance, tenofovir may be required in such cases, but with caution and dose adjustment for patients with estimated glomerular filtration rate  $\leq 50$  ml/min (*Chan et al., 2016; Pipili et al., 2013*).

### **2.2.17 Method of Control of HBV and HCV**

Infection control measures have been responsible for a decline in the prevalence of hepatitis B virus (HBV) and hepatitis C virus (HCV) infections in hemodialysis patients (*K.Park, 2015; Devid, 2010; Cordeiro et al., 2018*). HBV infection is a preventable disease and can be prevented by 3 doses of vaccination. Furthermore, it can

be prevented by educational programs by teaching the population about the risk factors of acquiring the infection and how to avoid them (*Hussein & Daniel, 2017 ; Plotkin et al., 2011*).

The best way to prevent any form of viral hepatitis is to avoid contact with blood and other body fluids of infected individuals. The use of condoms during sex also is advisable. If a person is exposed to hepatitis B, a serum preparation containing a high level of antibody against HBV may prevent infection if given within three to seven days of exposure. Babies born of a mother with HBV should receive the vaccine within 24 hours. An effective and safe vaccine is available that reliably prevents hepatitis B. Vaccination is suggested for most infants and for children aged 10 and younger whose parents are from a place where hepatitis B is common. Teenagers not vaccinated as children and all adults at risk of exposure also should be vaccinated against hepatitis B. Three doses are recommended (*K. Park, 2015; David, 2010*).

Isolation of HBsAg seropositive patients and the equipment used for patients with susceptibility for HBV may decrease prevalence of HBV infection by up to 70%–80%. Vaccination programs and limitation of blood transfusion may also play an important role in the decreased prevalence. Vaccination at 0, 1, and 6 months is recommended as routine HBV prophylaxis before HD, whereas one scheme for post exposure prophylaxis is vaccination at 0, 1, 2, and 6 months. Some centers recommend a high dose of 40 µg vaccine for HD patients at 0, 1, 2 and 6 months (*Kizilates et al., 2016*).

Universal precaution measures should be strictly observed and the segregation of HBsAg- positive patients on HD should be practiced. Early vaccination against HBV before the start of ESRD remains the best way to secure immunological protection against HBV infection in dialysis patients (*Joukar et al., 2011*).

Risk increase to get hepatitis B, and who therefore should be vaccinated, include; household contacts of a person carrying HBV. Healthcare workers who often come in contact with patients' blood or other body fluids. Patients with kidney disease who periodically undergo hemodialysis removal of waste products from the blood.

Homosexual men who are sexually active and heterosexuals who have multiple sex partners. Persons coming from areas where HBV infection is a major problem. Prisoners and others living in crowded institutions. Drug abusers who use needles to inject drugs into their veins (*Joukar et al., 2011*).

Several infection prevention strategies that are effective in reducing the acquisition of blood borne virus by patients in high resourced healthcare settings includes erythropoiesis stimulating agents which has reduced the need of blood transfusion, HBV vaccination and the adherence by hemodialysis services to specific hemodialysis infection control guidelines (*Duong et al., 2015*).

HCV prevention policy in Yemen should focus mainly on prevention and infection control in settings of exposure such as in medical care and among people who inject drugs (*Chaabna et al., 2016*).

Hemodialysis patients are at high risk for infection because they are immunocompromised and require a vascular access site to remove and replace blood. The vascular access could be an implanted access (fistula or graft), catheter, or port. However, rates of selected adverse events are highest for catheters and, possibly, for ports. Because of frequent infections and need for antimicrobial therapy, resistance to antimicrobials (particularly vancomycin) is high in hemodialysis patients. Surveillance is the first step toward improving patient safety and quality of health care (*Klevens et al., 2005*).

Infections in patients undergoing hemodialysis have adverse consequences for the individual patient, including increased morbidity and mortality, and for society, including increased costs, hospitalization rates, and need for antimicrobials. As a result of their frequent receipt of antimicrobials, particularly vancomycin, antimicrobial resistance has been common in patients undergoing dialysis (*Tokars et al., 2002*).

There are, however, many ways in which HCV and HBV infection may be avoided: those who inject drugs should never share needles, syringes, swabs, spoons, or anything else that is exposed to bodily fluids. They should always use clean equipment. Hands should be washed before and after contact with another person's blood or if the skin is penetrated. The sharing of personal items should be avoided, particularly those that can puncture the skin or inside of the mouth, such as razors, nail files and scissors, and even toothbrushes (*Jacqueline, 2010*). If a person does develop hepatitis C, its spread may be prevented by: not donating blood and sharing personal items with others. Wiping up any spilled blood while using gloves, household bleach, and disposable paper towels. Carefully covering any cut or wound with a band-aid or dressing. Practicing safe sex, especially during the acute phase of the infection (*Jacqueline, 2010*).

## **2.2 Hemodialysis**

### **2.2.1 Introduction to HD**

The primary purpose of the renal system is to maintain the body's state of homeostasis by carefully regulating fluid and electrolytes, removing wastes, and providing other functions. Dysfunction of the kidneys is common and may occur at any age and with varying degrees of severity. CKD is an umbrella term that describes kidney damage or a decrease in the glomerular filtration rate lasting for three or more months. CKD is associated with decreased quality of life, increased health care expenditures, and premature death. Untreated CKD can result in ESKD which is the final stage of renal failure (*Al Zabadi et al., 2016; Beauger et al., 2015*).

ESRD has become a public Health problem worldwide, as the total number of patients was increasing due to the increased prevalence of hypertension and diabetes mellitus. Also ESRD patients are requiring different modality of renal replacement therapy (RRT), which put more burdens on health budget especially in developing countries (*El-Tantawy, 2017*). ESKD results in retention of uremic waste products and the need for renal replacement therapies, dialysis, or kidney transplantation. The cause of renal failure may be a primary kidney disorder or secondary to a systemic disease or other urologic defects. Hemodialysis is used for patients who are acutely ill and require short-term dialysis ranging from days to weeks until kidney resumes its function as well for patients with advanced CKD and ESKD who require long-term or permanent renal re- placement therapy (*Hinkle & Cheever, 2017*).

In hemodialysis, blood is removed from the patient with needles and plastic tubing and pumped past the dialysis membrane. Poisons and toxins cross the dialysis membrane into the dialysate, which is then discarded, and the blood is returned to the patient. Viral hepatitis and human immunodeficiency virus infection are lead causes of mortality and morbidity in patient's with hemodialysis (*Al Zabadi et al., 2016*).

Viral hepatitis has a special relationship to renal disease. HBV and HCV infections are more prevalent in renal failure patients than in the general population. Viral hepatitis is an important cause of morbidity and mortality of renal failure patients on chronic dialysis and after renal transplantation. The association between viral hepatitis and renal failure is largely due to the high number of blood transfusion session in patients with end-stage kidney disease and to the multiple invasive medical procedures to which these patients are exposed. These patients are often anemic, require prolonged vascular access, have high possibility of exposure to infected patients and



contaminated equipment, and cross contamination from the dialysis circuits (*Al-Hegami et al., 2015*).

Hemodialysis patients are at high risk of infection by HCV. Such factors as blood transfusion, partial immunosuppression, and frequent parenteral interventions have been associated with an increased risk for infection. The duration of hemodialysis treatment, and the possibility of nosocomial HCV transmission have also been suggested as additional contributing elements (*Carneiro et al., 2001*).

CKD is a general term for heterogeneous disorders and defined based on the presence of kidney damage or decreased kidney function for 3 months or more. Several risk factors for CKD have been identified, including diabetes, hypertension, older age, tobacco smoking, obesity, cardiovascular diseases, and nephrotoxic drugs or toxins (*Joo et al., 2019*). Renal disease is defined by damaged or decreased kidney function. Renal damage can result from any disease potentially able to reduce the functional capacity of the kidneys. It is a multifactorial disease that represents a serious public health problem due to the increasing percentage of patients who become chronically ill, and to the numerous comorbidities that often accompany it.

There are several treatment forms, including hemodialysis. The disease can be controlled for some time, but it is progressive, incurable and has high morbidity and mortality rates. Renal patients that undergo hemodialysis are particularly prone to contamination by HCV due to the several risk factors they are exposed to. Among these factors, we may draw attention to treatment duration, blood transfusions and the virus prevalence in the hemodialysis unit (*Bastiani et al., 2014*).

### **2.2.2 Definition of HD**

Hemodialysis is a process of purifying the blood of a person whose kidneys are not working normally (*Mowatt et al., 2003*). This type of dialysis achieves the extracorporeal removal of waste products such as creatinine and urea and free water from the blood when the kidneys are in a state of kidney failure. Hemodialysis is one of three renal replacement therapies (the other two being kidney transplant and peritoneal dialysis). An alternative method for extracorporeal separation of blood components such as plasma or cells is apheresis.

Hemodialysis circulates the blood through an artificial disposable dialyzer. The Dialyzer is attached to a big dialysis machine, and the purpose of this machine is to pump the blood and dialysate, which will pass to the artificial dialyzer that maximizes

the diffusion process because the machine can pump more amounts of blood at a time. The haemodialysis machine can also monitor vital signs, blood chemistry and control the access flow and dialysis dosage (*National Kidney & Urologic Diseases, 2018*). The duration of haemodialysis treatment depends on how well the status of the kidneys, the fluid weight gain in between treatments, the size of the patient and which type of artificial kidney they are using. The haemodialysis treatment lasts about three to four hours per session, and is done about three times per week (*National Kidney & Urologic Diseases, 2018*).

Hemodialysis uses an artificial membrane (dialyzer) to remove wastes and extra fluid from the blood. It also restores proper electrolyte balance in the blood. The fluid used to filter or clean the blood is called dialysate. Hemodialysis is usually done in a hospital or dialysis center. In hemodialysis, an access is made for the dialysis, which then carries the blood to and from the dialysis machine. A fistula between an artery and a vein in the forearm is made. Another option is to use a graft to connect the artery and a vein. In some cases a central venous catheter is used (*sfaw & Tuokoniitty, 2012*).

Hemodialysis can be an outpatient or inpatient therapy. Routine hemodialysis is conducted in a dialysis outpatient facility, either a purpose built room in a hospital or a dedicated, stand-alone clinic. Less frequently hemodialysis is done at home. Dialysis treatments in a clinic are initiated and managed by specialized staff made up of nurses and technicians; dialysis treatments at home can be self-initiated and managed or done jointly with the assistance of a trained helper who is usually a family member (*National Kidney & Urologic Diseases, 2018*).

### **2.2.3 Indications of Dialysis**

These can be divided into acute or chronic indications (*National Kidney & Urologic Diseases, 2018*).

- ***Acute indications for dialysis:***
  - Acidemia from metabolic acidosis in situations in which correction with sodium bicarbonate is impractical or may result in fluid overload.
  - Electrolyte abnormality, such as severe hyperkalemia.
  - Overload of fluid not expected to respond to treatment with diuretics.
  - Uremia complications, such as pericarditis, encephalopathy, or gastrointestinal bleeding.
- ***Chronic indications for dialysis:***

- Symptomatic renal failure.
- Low glomerular filtration rate (GFR) (renal replacement therapy often recommended to commence at a GFR of less than 10-15 ml/min/1.73m<sup>2</sup>).
- Difficulty in medically controlling fluid overload, serum potassium, and/or serum phosphorus when the GFR is very low.

#### **2.2.4 Medical uses of HD**

Hemodialysis is the choice of renal replacement therapy for patients who need dialysis acutely, and for many patients as maintenance therapy. It provides excellent, rapid clearance of solutes. A nephrologist decides when hemodialysis is needed and the various parameters for a dialysis treatment. These include frequency (how many treatments per week), length of each treatment, and the blood and dialysis solution flow rates, as well as the size of the dialyzer. The composition of the dialysis solution is also sometimes adjusted in terms of its sodium and potassium and bicarbonate levels. In general, the larger the body size of an individual, the more dialysis he/she will need. In North America and the UK, 3–4 hour treatments (sometimes up to 5 hours for larger patients) given 3 times a week are typical. Twice-a-week sessions are limited to patients who have a substantial residual kidney function (*Venkat et al., 2006*).

Four sessions per week are often prescribed for larger patients, as well as patients who have trouble with fluid overload. Finally, there is growing interest in short daily home hemodialysis, which is 1.5 – 4 hr sessions given 5–7 times per week, usually at home. There is also interest in nocturnal dialysis, which involves dialyzing a patient, usually at home, for 8–10 hours per night, 3–6 nights per week. Nocturnal in-center dialysis, 3–4 times per week, is also offered at a handful of dialysis units in the United States (*Venkat et al., 2006*).

#### **2.2.5 Adverse Effects of HD**

- **Fluid shifts**

Hemodialysis often involves fluid removal (through ultrafiltration), because most patients with renal failure pass little or no urine. Side effects caused by removing too much fluid and/or removing fluid too rapidly include low blood pressure, fatigue, chest pains, leg-cramps, nausea and headaches. These symptoms can occur during the treatment and can persist post treatment; they are sometimes collectively referred to as

the dialysis hangover or dialysis washout. The severity of these symptoms is usually proportionate to the amount and speed of fluid removal. However, the impact of a given amount or rate of fluid removal can vary greatly from person to person and day to day. These side effects can be avoided and/or their severity lessened by limiting fluid intake between treatments or increasing the dose of dialysis e.g. dialyzing more often or longer per treatment than the standard three times a week, 3–4 hours per treatment schedule (*Daugirdas et al., 2007*).

- **Access-related**

Since hemodialysis requires access to the circulatory system, patients undergoing hemodialysis may expose their circulatory system to microbes, which can lead to bacteremia, an infection affecting the heart valves (endocarditis) or an infection affecting the bones (osteomyelitis). The risk of infection varies depending on the type of access used (see below). Bleeding may also occur, again the risk varies depending on the type of access used. Infections can be minimized by strictly adhering to infection control best practices (*Kishimoto et al., 2008*). .

- **Anticoagulation-related**

Heparin is the most commonly used anticoagulant in hemodialysis, as it is generally well tolerated and can be quickly reversed with protamine sulfate. Heparin allergy can infrequently be a problem and can cause a low platelet count. In such patients, alternative anticoagulants can be used. In patients at high risk of bleeding, dialysis can be done without anticoagulation (*Ayus et al., 2005*).

- **First-use syndrome**

First-use syndrome is a rare but severe anaphylactic reaction to the artificial kidney. Its symptoms include sneezing, wheezing, shortness of breath, back pain, chest pain, or sudden death. It can be caused by residual sterilant in the artificial kidney or the material of the membrane itself. In recent years, the incidence of first-use Syndrome has decreased, due to an increased use of gamma irradiation, steam sterilization, or electron-beam radiation instead of chemical sterilants, and the development of new semipermeable membranes of higher biocompatibility. New methods of processing previously acceptable components of dialysis must always be considered. For example, in 2008, a series of first-use type of reactions, including deaths, occurred due to heparin contaminated during the manufacturing process with over sulfated chondroitin sulfate (*Weinreich et al., 2006*).

- **Cardiovascular**

Long-term complications of hemodialysis include hemodialysis-associated amyloidosis, neuropathy and various forms of heart disease. Increasing the frequency and length of treatments have been shown to improve fluid overload and enlargement of the heart that is commonly seen in such patients. Due to these complications, the prevalence of complementary and alternative medicine use is high among patients undergoing hemodialysis (*Heydari et al., 2013*).

- **Vitamin Deficiency**

Folate deficiency can occur in some patients having hemodialysis (*Birdee et al., 2013*).

### **2.2.6 Risk Factors of HBV and HCV Infections in Hemodialysis Patients**

The understanding of the risk of transmission of hepatitis B and C among haemodialysis patients is essential to undertake the appropriate measures to prevent its transmission (*Alkhan, 2015*). A number of risk factors are implicated including blood transfusion, duration of dialysis, dialysis machine sterilization and preparation and the use of common medication carts. Studies conclude that the transmission of Virus to haemodialysis patients is generally nosocomial with possible risk factors being failure to disinfect devices between patients, sharing of single-use vials for infusion, poor sterile technique, poor cleaning of dialysis machines, and poor distance between chairs (*Parande et al., 1986*).

- **General Hygiene Violation**

The number one attributed risk factor for reduction of incidence is general hygienic measures. In April 1994 an outbreak of HBV occurred in 5 hemodialysis centers in California, Nebraska and Texas, US. The cause of the outbreak was thought to be due to failure of identification and isolation of a patient with HBV (*Alkhan, 2015*).

- **Blood Transfusion**

It is the most important risk factors. a retrospective study in Sweden with 236 patients in dialysis center and 23 patients who became sero-positive HCV in the period of study, 80% of them had blood transfusion. In other study in Gaza they found strong relationship between the number of transfused blood units and HBV and HCV infections, results showed that the more units of blood the patients received, the higher the incidence of hepatitis infection (*Ramia et al., 1986*).

- **Duration of Dialysis**

One of the most challenging things is to separate that if the long duration of the dialysis is a risk factor by it is own or because the longer the period the more blood transfusion the patient will have. It was found in a study done by CDC (center for disease control) that patient who had dialysis less than 5 years 12% of them has hepatitis C and 37% of the patient who had the dialysis more than 5 years (**Alkhan, 2015**).

### **2.2.7 Mechanism and technique of HD**

The principle of hemodialysis is the same as other methods of dialysis; it involves diffusion of solutes across a semipermeable membrane. Hemodialysis utilizes counter current flow, where the dialysate is flowing in the opposite direction to blood flow in the extracorporeal circuit. Counter-current flow maintains the concentration gradient across the membrane at a maximum and increases the efficiency of the dialysis. Fluid removal (ultrafiltration) is achieved by altering the hydrostatic pressure of the dialysate compartment, causing free water and some dissolved solutes to move across the membrane along a created pressure gradient.

The dialysis solution that is used may be a sterilized solution of mineral ions. Urea and other waste products, potassium, and phosphate diffuse into the dialysis solution. However, concentrations of sodium and chloride are similar to those of normal plasma to prevent loss. Sodium bicarbonate is added in a higher concentration than plasma to correct blood acidity. A small amount of glucose is also commonly used. Note that this is a different process to the related technique of hemofiltration (**Mayo clinic, 2017**).

- Three primary methods are used to gain access to the blood for hemodialysis: an intravenous catheter, an arteriovenous fistula (AV) and a synthetic graft. The type of access is influenced by factors such as the expected time course of a patient's renal failure and the condition of his or her vasculature. Patients may have multiple access procedures, usually because an AV fistula or graft is maturing and a catheter is still being used. The placement of a catheter is usually done under light sedation, while fistulas and grafts require an operation (**Mayo clinic, 2017**).

### **2.2.8 Types of HD**

There are three types according to the time of hemodialysis

#### **1. Conventional hemodialysis**

Conventional hemodialysis is usually done three times per week, for about three to four hours for each treatment (Sometimes five hours for larger patients), during which the patient's blood is drawn out through a tube at a rate of 200–400 mL/min. The tube is connected to a 15, 16, or 17 gauge needle inserted in the dialysis fistula or graft or connected to one port of a dialysis catheter. The blood is then pumped through the dialyzer, and then the processed blood is pumped back into the patient's bloodstream through another tube (connected to a second needle or port). During the procedure, the patient's blood pressure is closely monitored, and if it becomes low, or the patient develops any other signs of low blood volume such as nausea, the dialysis attendant can administer extra fluid through the machine. During the treatment, the patient's entire blood volume (about 5000 cc) circulates through the machine every 15 minutes. During this process, the dialysis patient is exposed to a week's worth of water for the average person (*TOH, 2008*).

## **2. Daily HD**

Daily hemodialysis is typically used by those patients who do their own dialysis at home. It is less stressful (more gentle) but does require more frequent access. This is simple with catheters but more problematic with fistulas or grafts. The "buttonhole technique" can be used for fistulas requiring frequent access. Daily hemodialysis is usually done for 2 hours six days a week (*TOH, 2008*).

## **3. Nocturnal HD**

The procedure of nocturnal hemodialysis is similar to conventional hemodialysis except it is performed three to six nights a week and between six and ten hours per session while the patient sleeps (*TOH, 2008*).

### **2.2.9Types of HD access sites**

In Hemodialysis, a fistula is created through surgery, and these serve as the communication of the artery and vein inside an extremity to the dialysis machine. A direct communication is called a native arteriovenous fistula (*Fresenius Medical Care, 2012*). According to Fresenius, a fistula is considered as the first and ideal choice for hemodialysis access; this is because this method has the lowest chance of infection. This method is created by connecting one of the arteries to a vein under the skin of the upper lower arm. The Fistula is created at least 2 to 3 months before a person begins a dialysis to make time for it to develop and mature depending on the doctor's order.

Another method is the use of a catheter attached to large vein in the neck (*Fresenius Medical Care, 2012*).

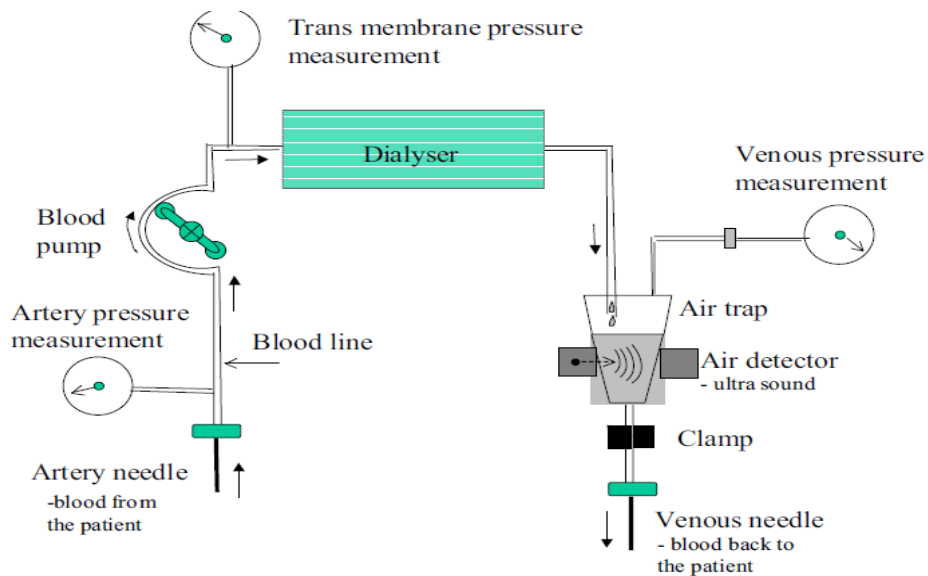
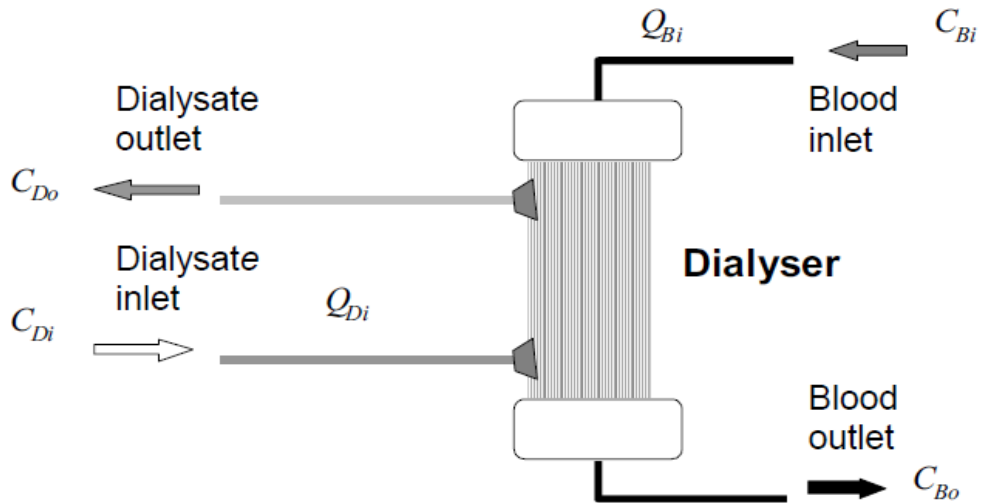


Figure 4: the blood port of the dialysis machine schematically

### 2.2.10 Equipment of HD

The hemodialysis machine pumps the patient's blood and the dialysate through the dialyzer. The newest dialysis machines on the market are highly computerized and continuously monitor an array of safety-critical parameters, including blood and



dialysate flow rates; dialysis solution conductivity, temperature, and pH; and analysis of the dialysate for evidence of blood leakage or presence of air. Any reading that is out of normal range triggers an audible alarm to alert the patient-care technician who is monitoring the patient (*TOH, 2008*).

- **Water system**

An extensive water purification system is absolutely critical for hemodialysis. Since dialysis patients are exposed to vast quantities of water, which is mixed with dialysate concentrate to form the dialysate, even trace mineral contaminants or bacterial endotoxins can filter into the patient's blood. Because the damaged kidneys cannot perform their intended function of removing impurities, ions introduced into the bloodstream via water can build up to hazardous levels, causing numerous symptoms or death. Aluminum, chloramine, fluoride, copper, and zinc, as well as bacterial fragments and endotoxins, have all caused problems in this regard(*TOH, 2008*).

For this reason, water used in hemodialysis is carefully purified before use. Initially it is filtered and temperature-adjusted and its pH is corrected by adding an acid or base. Then it is softened. Next the water is run through a tank containing activated charcoal to adsorb organic contaminants. Primary purification is then done by forcing water through a membrane with very tiny pores, a so-called reverse osmosis membrane. This lets the water pass, but holds back even very small solutes such as electrolytes. Final removal of leftover electrolytes is done by passing the water through a tank with ion-exchange resins, which remove any leftover anions or cations and replace them with hydroxyl and hydrogen ions, respectively, leaving ultrapure water. Even this degree of water purification may be insufficient. The trend lately is to pass this final purified water (after mixing with dialysate concentrate) through a dialyzer membrane. This provides another layer of protection by removing impurities, especially those of bacterial origin that may have accumulated in the water after its passage through the original water purification system (*Eknoyan et al., 2002*).

Once purified water is mixed with dialysate concentrate, its conductivity increases, since water that contains charged ions conducts electricity. During dialysis, the conductivity of the dialysis solution is continuously monitored to ensure that the water and dialysate concentrate are being mixed in the proper proportions. Both excessively concentrated dialysis solution and excessively dilute solution can cause severe clinical problems (*Eknoyan et al., 2002*).

- **Dialyzer**

The dialyzer is the piece of equipment that actually filters the blood. Almost all dialyzers in use today are of the hollow-fiber variety. A cylindrical bundle of hollow fibers, whose walls are composed of a semi-permeable membrane, is anchored at each end into potting compound (a sort of glue). This assembly is then put into a clear plastic cylindrical shell with four openings. One opening or blood port at each end of the cylinder communicates with each end of the bundle of hollow fibers. This forms the "blood compartment" of the dialyzer. Two other ports are cut into the side of the cylinder. These communicate with the space around the hollow fibers, the "dialysate compartment." Blood is pumped via the blood ports through this bundle of very thin capillary-like tubes, and the dialysate is pumped through the space surrounding the fibers. Pressure gradients are applied when necessary to move fluid from the blood to the dialysate compartment (*Kidney Disease Outcome Quality Initiative (KDOQI), 2006*).

#### **2.2.11 Membranes and Flux**

Dialyzer membranes come with different pore sizes. Those with smaller pore size are called "low-flux" and those with larger pore sizes are called "high-flux." Some larger molecules, such as beta-2-microglobulin, are not removed at all with low-flux dialyzers; lately, the trend has been to use high-flux dialyzers. However, such dialyzers require newer dialysis machines and high-quality dialysis solution to control the rate of fluid removal properly and to prevent backflow of dialysis solution impurities into the patient through the membrane. Dialyzer membranes used to be made primarily of cellulose (derived from cotton linter). The surface of such membranes was not very biocompatible, because exposed hydroxyl groups would activate complement in the blood passing by the membrane. Therefore, the basic, "unsubstituted" cellulose membrane was modified. One change was to cover these hydroxyl groups with acetate groups (cellulose acetate); another was to mix in some compounds that would inhibit complement activation at the membrane surface (modified cellulose). The original "unsubstituted cellulose" membranes are no longer in wide use, whereas cellulose acetate and modified cellulose dialyzers are still used. Cellulosic membranes can be made in either low-flux or high-flux configuration, depending on their pore size (*KDOQI, 2006*).

Another group of membranes is made from synthetic materials, using polymers such as polyarylethersulfone, polyamide, polyvinylpyrrolidone, polycarbonate, and polyacrylonitrile. These synthetic membranes activate complement to a lesser degree than unsubstituted cellulose membranes. Synthetic membranes can be made in either low- or high-flux configuration, but most are high-flux (*Cheung et al., 2003*).

- **Membrane flux and outcome**

Whether using a high-flux dialyzer improves patient outcomes is somewhat controversial, but several important studies have suggested that it has clinical benefits. The NIH-funded HEMO trial compared survival and hospitalizations in patients randomized to dialysis with either low-flux or high-flux membranes. Although the primary outcome (all-cause mortality) did not reach statistical significance in the group randomized to use high-flux membranes, several secondary outcomes were better in the high-flux group (*Macleod et al., 2005*). A recent Cochrane analysis concluded that benefit of membrane choice on outcomes has not yet been demonstrated (*Macleod et al., 2005*). A collaborative randomized trial from Europe, the MPO (Membrane Permeabilities Outcomes) study, comparing mortality in patients just starting dialysis using either high-flux or low-flux membranes, found a nonsignificant trend to improved survival in those using high-flux membranes, and a survival benefit in patients with lower serum albumin levels or in diabetics (*Locatelli et al., 2009*).

- **Membrane flux and beta-2-microglobulin amyloidosis**

High-flux dialysis membranes and/or intermittent on-line hemodiafiltration (IHDF) may also be beneficial in reducing complications of beta-2-microglobulin accumulation. Because beta-2-microglobulin is a large molecule, with a molecular weight of about 11,600 daltons, it does not pass at all through low-flux dialysis membranes. Beta-2-M is removed with high-flux dialysis, but is removed even more efficiently with IHDF. After several years (usually at least 5–7), patients on hemodialysis begin to develop complications from beta-2-M accumulation, including carpal tunnel syndrome, bone cysts, and deposits of this amyloid in joints and other tissues. Beta-2-M amyloidosis can cause very serious complications, including spondyloarthropathy, and often is associated with shoulder joint problems (*KDOQI, 2006*). Observational studies from Europe and Japan have suggested that

using high-flux membranes in dialysis mode, or IHDF, reduces beta-2-M complications in comparison to regular dialysis using a low-flux membrane (*Koda et al., 1997*).

### **2.2.12 Dialyzer size and efficiency**

Dialyzers come in many different sizes. A larger dialyzer with a larger membrane area (A) will usually remove more solutes than a smaller dialyzer, especially at high blood flow rates. This also depends on the membrane permeability coefficient  $K_0$  for the solute in question. So dialyzer efficiency is usually expressed as the  $K_0A$  – the product of permeability coefficient and area. Most dialyzers have membrane surface areas of 0.8 to 2.2 square meters, and values of  $K_0A$  ranging from about 500 to 1500 mL/min.  $K_0A$ , expressed in mL/min, can be thought of as the maximum clearance of a dialyzer at very high blood and dialysate flow rates (*Locatelli et al., 1996*).

- **Reuse of dialyzers**

The dialyzer may either be discarded after each treatment or be reused. Reuse requires an extensive procedure of high-level disinfection. Reused dialyzers are not shared between patients. There was an initial controversy about whether reusing dialyzers worsened patient outcomes. The consensus today is that reuse of dialyzers, if done carefully and properly, produces similar outcomes to single use of dialyzers (*KDOQI, 2006*).

Dialyzer Reuse is a practice that has been around since the invention of the product. This practice includes the cleaning of a used dialyzer to be reused multiple times for the same patient. Dialysis clinics reuse dialyzers to become more economical and reduce the high costs of “single-use” dialysis which can be extremely expensive and wasteful. Single used dialyzers are initiated just once and then thrown out creating a large amount of bio-medical waste with no mercy for cost savings. If done right, dialyzer reuse can be very safe for dialysis patients (*National Kidney and Urologic Diseases, 2018*).

There are two ways of reusing dialyzers, manual and automated. Manual reuse involves the cleaning of a dialyzer by hand. The dialyzer is semi-disassembled then flushed repeatedly before being rinsed with water. It is then stored with a liquid disinfectant for 18+ hours until its next use. Although many clinics outside the USA use this method, some clinics are switching toward a more automated/streamlined process as the dialysis practice advances. The newer method of automated reuse is achieved by means of a medical device which began in the early 1980s. These devices

are beneficial to dialysis clinics that practice reuse – especially for large dialysis clinical entities – because they allow for several back to back cycles per day. The dialyzer is first pre-cleaned by a technician, then automatically cleaned by machine through a step-cycles process until it is eventually filled with liquid disinfectant for storage. Although automated reuse is more effective than manual reuse, newer technology has sparked even more advancement in the process of reuse. When reused over 15 times with current methodology, the dialyzer can lose B2m, middle molecule clearance and fiber pore structure integrity, which has the potential to reduce the effectiveness of the patient's dialysis session. Currently, as of 2010, newer, more advanced reprocessing technology has proven the ability to completely eliminate the manual pre-cleaning process altogether and has also proven the potential to regenerate (fully restore) all functions of a dialyzer to levels that are approximately equivalent to single-use for more than 40 cycles. (CANNT, 2008). As medical reimbursement rates begin to fall even more, many dialysis clinics are continuing to operate effectively with reuse programs especially since the process is easier and more streamlined than before (Mowatt et al., 2003).

### 2.2.13 Nursing Care for HD patients

Adapted from nephrology nursing practice recommendations developed by Canadian Association of Nephrology and Technology (CANNT) based on best available evidence and clinical practice guidelines, a nephrology nurse should perform (CANNT, 2008).

- **Hemodialysis Vascular Access:** Assess the fistula/graft and arm before, after each dialysis or every shift: the access flow, complications. Assess the complication of central venous catheter: the tip placement, exit site, complications document and notify appropriate health care provider regarding any concerns. Educates the patient with appropriate cleaning of fistula/graft and exit site; with recognizing and reporting signs and symptoms of infection and complication.
- **Hemodialysis adequacy:** Assesses patient constantly for signs and symptoms of inadequate dialysis. Assesses possible causes of inadequate dialysis. Educates the patient on the importance of receiving adequate dialysis.
- **Hemodialysis treatment and complications:** Performs head to toe physical assessment before, during and after hemodialysis regarding complications and

access's security. Confirm and deliver dialysis prescription after review most update lab results. Address any concerns of the patient and educate patient when recognizing the learning gap.

- **Medication management and infection control practice:** Collaborate with the patient to develop a medication regimen. Follow infection control guidelines as per unit protocol.

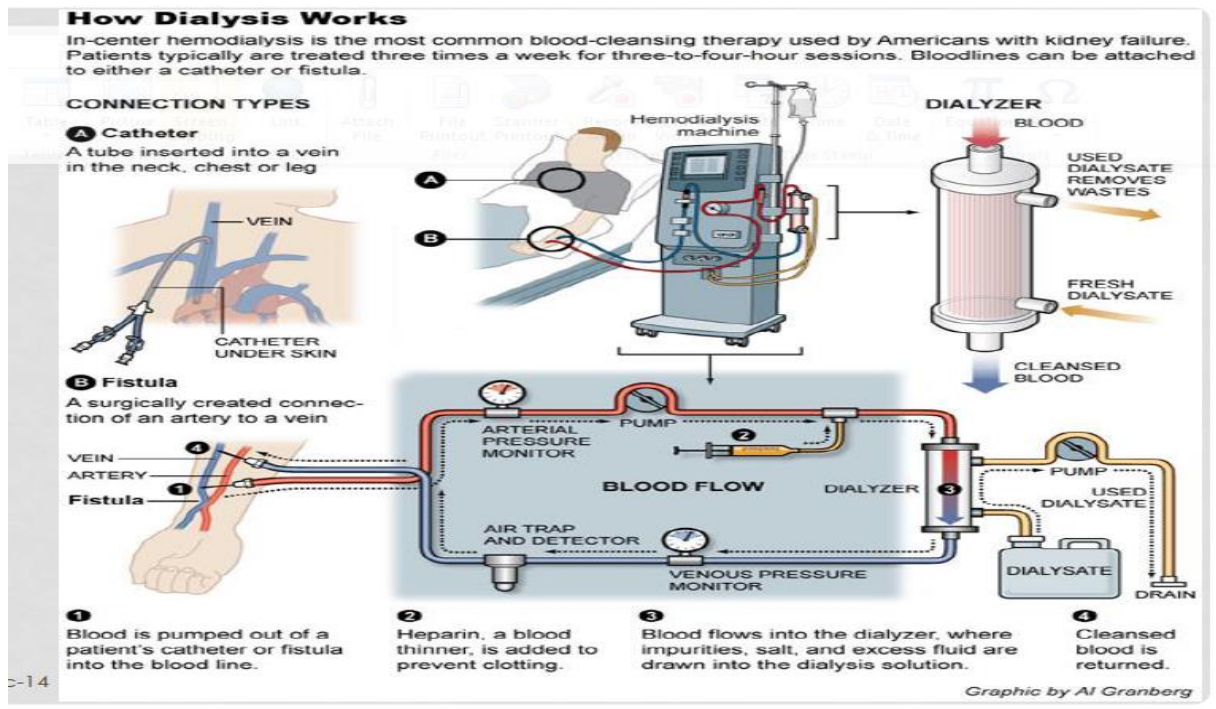


Figure 5: How dialysis works

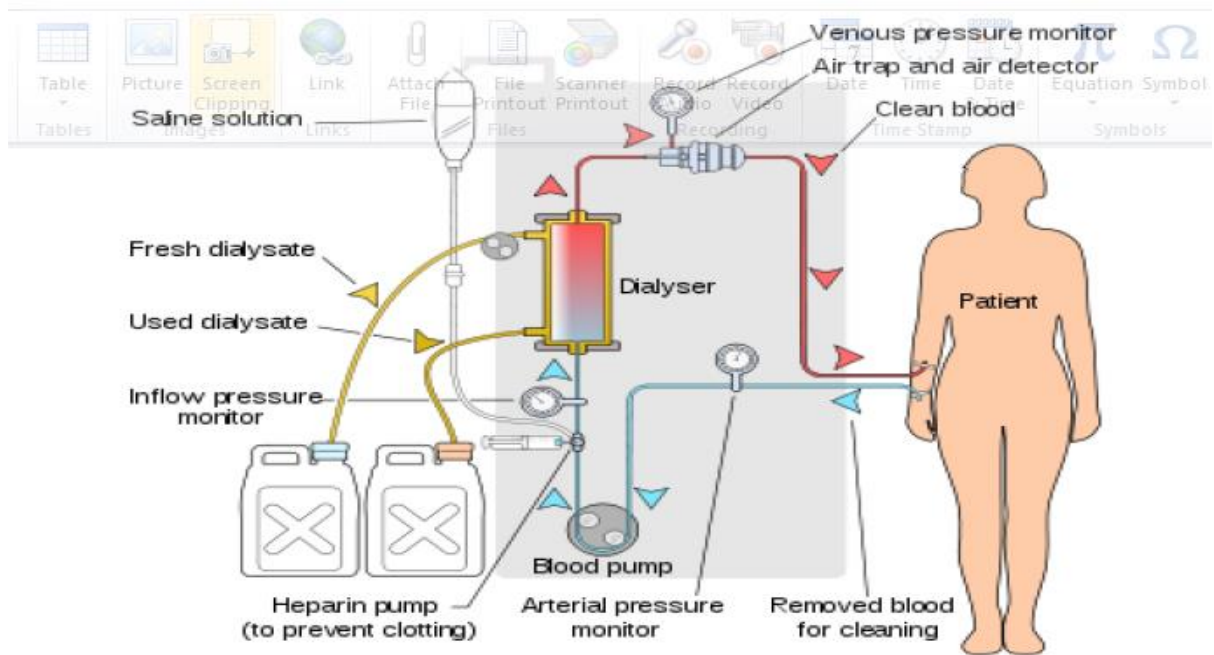


Figure 6: Process of hemodialysis

## 2.3 Infection Prevention and Control in HD Units

### 2.3.1 Introduction

A listing of key infection prevention measures included in this guide follows (Association for Professionals in Infection Control (APIC), 2010; NHS, 2018):

Basic Measures—Category I Level Evidence Supports These Measures	Plus Measures—Level of Evidence Supporting These Measures is Less Than Category I Level
<p><b>1. Environmental and equipment cleaning/disinfection</b></p> <ul style="list-style-type: none"> <li>Use USA. Environmental Protection Agency (EPA)-registered hospital disinfectants labeled tuberculocidal or with specific label claims for HIV or HBV in accordance with label instructions to decontaminate spills of blood and other body fluids.</li> <li>Use standard cleaning and disinfection protocols and EPA-registered hospital disinfectants for confirmed or suspected antibiotic-resistant Gram-positive cocci (e.g.,</li> </ul>	<p><b>1.Environmental and equipment cleaning/disinfection</b></p> <ul style="list-style-type: none"> <li>Because no EPA-registered products are specific for inactivating <i>C. difficile</i> spores, use hypochlorite-based products for disinfection of environmental surfaces in those patient-care areas where surveillance and epidemiology indicate ongoing transmission of <i>C. difficile</i>.</li> <li>Use microfiber cloths and mops if possible (more effective cleaning products than regular cotton cleaning cloths).</li> </ul>

methicillin-resistant *S. aureus* (MRSA), vancomycin intermediate-resistant *S. aureus*, or vancomycin-resistant *Enterococcus* [VRE]).

- Using friction, clean and disinfect high-touch surfaces in patient-care areas (e.g., HD chairs, HD machines, tables, carts, bedside commodes).
- When contact precautions are indicated for patient care, use disposable patient-care items (e.g., blood pressure cuffs) whenever possible to minimize cross-contamination with multiple-resistant microorganisms.
- Items taken into a patient station should be disposed of after use, dedicated for use on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.
- Non disposable items that cannot be comprehensively cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use on a single patient.
- External pressure transducer filters/protectors should be changed after each patient treatment. Items taken into an individual HD patient station should be disposed of after use, dedicated for use on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.
- External venous and arterial pressure transducer filters/protectors should be changed after each patient treatment and should not be reused. Internal transducer filters do not need to be changed routinely between patients.
- The internal HD machine dialysate pathway should be subjected to heat disinfection at the end of each treatment day.
- In the event of a blood leak, disinfection of the internal HD



<p>machine pathway must be performed prior to on a successive patient.</p>	
<p><b>2. Hand hygiene</b></p> <ul style="list-style-type: none"> <li>• To improve hand hygiene adherence among personnel who work in areas in which high workloads and high intensity of patient care are anticipated, make an alcohol based hand rub available at the entrance to the patient's room or at the bedside, in other convenient locations, and in individual pocket-sized containers to be carried by healthcare workers (HCWs).</li> <li>• Perform hand hygiene before and after contact with patient or patient environment.</li> <li>• Remove gloves after caring for a patient. Do not wear the same pair of gloves for the care of more than one patient, and do not wash gloves between uses with different patients.</li> <li>• Perform hand hygiene after glove removal.</li> <li>• If hands are not visibly soiled, use an alcohol-based hand rub for routinely cleaning hands instead of soap and water.</li> <li>• Do not wear artificial fingernails or extenders when having direct contact with patients.</li> </ul>	
<p><b>3. Immunizations screening</b></p> <ul style="list-style-type: none"> <li>• Vaccine status of all patients should be assessed at the start of dialysis. Eligible HD patients should be immunized against HBV, tetanus, pneumococcal disease, and influenza.</li> <li>• CDC recommends one-time baseline screening of HD patients for TB (plus anytime an exposure is suspected).</li> <li>• Employees in HD settings must receive immunization for</li> <li>• measles, mumps, rubella, pertussis, diphtheria, tetanus,</li> <li>• MMR (measles, mumps, rubella), be offered HBV and influenza immunization, and be screened for TB per local regulations (usually annual).</li> </ul>	

<p><b>4. Medication/injection safety:</b></p> <ul style="list-style-type: none"> <li>• Single-dose vials should be dedicated to one patient only and should not be re-entered.</li> <li>• Parenteral medications should be prepared in a designated clean area away from patient treatment stations.</li> <li>• Do not use medication carts to transport medications to patient stations.</li> <li>• Scrub the hub of intravenous tubing and medication vials prior to accessing.</li> <li>• Use aseptic technique when preparing/handling parenteral medications/fluid.</li> <li>• Never use infusion supplies such as needles, syringes, flush solutions, administration sets, or IV fluids on more than one patient.</li> </ul>	<p><b>4. Medication/injection safety:</b></p> <ul style="list-style-type: none"> <li>• Avoid use of multidose vials</li> </ul>
<p><b>5. Pre- and postsurgical infection prevention</b></p> <ul style="list-style-type: none"> <li>• Presurgical hair removal should be performed with clippers instead of a razor.</li> </ul>	<p><b>5. Pre- and postsurgical infection prevention</b></p> <ul style="list-style-type: none"> <li>• Antiseptic impregnated postoperative dressings for fistulas/grafts</li> <li>• Active surveillance testing for MRSA and decolonization should be performed as indicated (e.g., preoperatively).</li> <li>• Preoperative antiseptic bathing/showering</li> </ul>
<p><b>6. Standard/transmission based precautions</b></p> <ul style="list-style-type: none"> <li>• Respiratory etiquette should be employed routinely.</li> <li>• Standard Precautions should be practiced routinely.</li> <li>• Patient identified with a suspected airborne disease should be masked immediately and geographically separated from other patients, preferably in a single room.</li> <li>• HBV isolation should be employed routinely on all patients known to be HBsAg positive.</li> </ul>	<p><b>6. Standard/transmission based precautions</b></p> <ul style="list-style-type: none"> <li>• Contact precautions in HD facilities should be employed in the event of known or suspected MDRO.</li> </ul>
<p><b>7. Vascular Access:</b></p> <ul style="list-style-type: none"> <li>• Support transition from temporary (e.g., CVC) to permanent (e.g., arteriovenous fistula or graft) vascular access whenever possible.</li> </ul>	<p><b>7. Vascular access</b></p> <ul style="list-style-type: none"> <li>• Routine use of CHG impregnated bathing cloths.</li> </ul>

<ul style="list-style-type: none"> <li>• Full barrier precautions and skin antiseptics with chlorhexidine (CHG) alcohol prep prior to insertion of HD CVC.</li> </ul>	<ul style="list-style-type: none"> <li>• Application of CHG impregnated insertion site dressing for HD central catheters.</li> <li>• Prophylactic use of antimicrobial catheter locking solution.</li> <li>• Soak the hub of HD catheters in povidone-iodine solution or wrap with gauze saturated with povidone-iodine solution for 5 minutes prior to removing the cap (<i>Beathard, 2003</i>).</li> <li>• Application of povidone-iodine or triple antibiotic ointment for HD catheter exit site dressings after dialysis session.</li> </ul>
<p><b>8. Water treatment</b></p> <ul style="list-style-type: none"> <li>• Adhere to current Association for Advancement of Medical Instrumentation (AAMI) standards for quality assurance performance of devices and equipment used to treat, store, and distribute water in HD centers and for the preparation of concentrates and dialysate.</li> <li>• Conduct microbiological testing specific to water in dialysis settings.</li> <li>• Disinfect water distribution systems in dialysis settings on a regular schedule.</li> </ul>	<p><b>8. Water treatment</b></p> <ul style="list-style-type: none"> <li>• Ultrapure dialysate</li> </ul>

### 2.3.2 Environmental Cleaning and Disinfection

The outpatient HD setting presents a unique set of challenges related to environmental cleaning and disinfection because of the spatial cohort of patients and the temporal demands of multiple shifts. This setting is one in which patients are typically not segregated from one another by physical barriers, such as walls or privacy curtains. Conditions common to HD settings can also interfere with environmental cleaning, such as the typical 1:4 staff - to-patient ratio for dialysis technicians, the fast turn-around between patient treatments, and the procedurally intensive process of the dialysis treatment (*APIC, 2010; NHS, 2018*).

In the outpatient HD setting, each “patient station” contains a dialysis chair, the dialysis machine, and any other ancillary equipment/supplies necessary to provide the treatment. It may also include a bedside television set and phone. The space for each

patient dialysis station or seating must be considered as the patient's exclusive treatment area, and sharing of equipment between patients should be avoided. Any equipment or item used for the patient must not be shared from patient to patient without prior cleaning and disinfection (*NHS, 2018*).

In a typical hospital setting, environmental cleaning and surface disinfection is performed by trained housekeeping staff dedicated to ensuring that the room is completely cleaned and disinfected between patients. A typical outpatient dialysis unit has no such luxury. The nurse or dialysis technician must perform surface cleaning and disinfection (machine, chair, phone, table, etc.) in the short gap between patient treatments. Sufficient time between the completion of one patient's treatment and post dialysis care and the initiation of the next patient's care is important for permitting reliable and consistent cleaning and disinfection of the patient station (*NHS, 2018*).

### **2.3.2.1 Cleaning and Disinfection of Environmental Surfaces**

The process of physical cleaning of environmental surfaces using detergent (soap), water, and friction is the critical step required prior to surface disinfection. The combination of the cleaning and disinfection processes is designed to remove and kill vegetative microorganisms on surfaces (*APIC, 2010*). Disinfection will not be effective in the presence of dirt, blood, or other bioburden. The goal of the cleaning step is to remove bioburden and with it, the majority of pathogens. Disinfection is designed to be a synergistic and somewhat redundant step to ensure comprehensive removal/kill of pathogens on surfaces. The CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, states that, "noncritical surfaces (e.g., dialysis bed or chair, countertops, external surfaces of dialysis machines) should be disinfected with an EPA-registered disinfectant unless the item is visibly contaminated with blood. In that case, an EPA registered tuberculocidal agent with specific label claims for HBV and HIV should be used (*Rutala et al., 2008*). One commonly used disinfectant for blood contaminated environmental surfaces is a 1:100 dilution of bleach (500–600 parts per million [ppm] free chlorine).

The environmental surfaces in HD settings at highest risk of transmitting germs are described using different terms. From the perspective of the patient, the term "patient zone" is used to refer to the surfaces which the patient can touch, or can touch the patient, including the chair, armrests, bedside table top/counter, and drawer/cupboard handles. From the HCW or dialysis staff perspective, the term "high touch surfaces" is

used to describe surfaces which are frequently touched by HCWs. These include the same surfaces in the patient zone in addition to others such as the exterior surfaces of the HD machine, computer screens, and keyboards.

Cleaning and disinfection of these surfaces (patient zone/high touch surfaces) should be performed between all patient treatments, no matter what the patient diagnosis is, in order to prevent spread of environmentally transmitted pathogens including MDROs (e.g., MRSA, VRE, *C. difficile*) and blood borne pathogens (e.g., HBV, HCV). Of note, microorganisms can live for varying periods of time in the environment. MRSA has been documented as viable at 38 weeks on external sterile packaging and VRE at 6 months on a wheelchair. HBV can survive for 7 days in dried blood (*APIC, 2010; NHS, 2018*).

There are certain products and principles which are recommended in order to optimize environmental cleaning in healthcare settings, including HD facilities. These include the following tasks which are typically performed by the dialysis nurse or technician (*APIC, 2010*).

- Store cleaner/disinfectant separately from skin antiseptics/patient supplies (separate shelves and below patient supplies to avoid potential contamination).
- Perform hand hygiene before and after cleaning the patient station.
- Don gloves when using cleaner/disinfectants.
- Use one set of cleaning cloths or disposable germicidal wipes for each patient station.
- Use microfiber cloths and mops if possible (more effective cleaning products than regular cotton cleaning cloths).
- Clean all frequently touched or “high touch” surfaces in the “patient zone” between patient treatments (chair, armrests, counters, drawer/cupboard handles, exterior surface of the HD machine)—please note that some of these high touch surfaces may be right outside the patient zone (e.g., computer stations), and must also be cleaned between patient treatments.
- Clean the top of an object first and work down to avoid soiling surfaces just cleaned.
- If using cleaning cloths instead of disposable germicidal wipes:
- When using a disinfectant cleaner, wet the surface, use friction to clean, and allow to air dry.

- Fold the cleaning cloth in a series of squares to provide a number of potential cleaning surfaces. A wadded cloth does not clean efficiently.
- Replace cloth as needed. More than one cloth may be required for a patient station.
- Never use the same cleaning cloth for more than one patient unit.
- Never re-dip used cloth into clean disinfectant solution.

***Additional cleaning functions, typically performed by housekeeping staff in HD facilities, should include:***

- At the end of the day:
- Wet mop the floor
- Clean patient/staff bathrooms and restock paper products/hand hygiene supplies
- Check and refill all hand hygiene product dispensers in nursing stations and at patient stations (soap, paper towels, lotion, alcohol-based hand sanitizer).
- On a routine basis, walls and high dusting should be performed (*APIC, 2010*).

### **2.3.2.2 Multidrug-Resistant Organisms Cleaning and Disinfection**

Many health care workers (HCWs) believe the environment of patients with Multidrug-Resistant Organisms (MDROs) require special cleaning. HCWs in HD facilities should clean the environment of the MDRO patient as they would for any patient, as many more patients than are known are colonized/infected with an MDRO. Cleaning involves the use of friction on environmental surfaces to physically remove the soil and germs. The wet contact time of the germicide on the surface helps kill or inactivate any remaining microorganisms. The exception is *C. difficile*, which requires removal by friction and is not inactivated by any surface disinfectant except bleach (*APIC, 2010; NHS, 2018*).

### **2.3.3 Equipment Cleaning and Disinfection**

HD equipment includes HD machines, dialyzers, water supply/treatment/distribution systems, component parts such as tubing and filters, acid and bicarbonate concentrate solutions, and instruments including blood pressure cuff, stethoscope, hemostats, scissors, and clamps. Sterile and clean supplies are also integral to the provision of HD. Infections caused by contamination of supplies/equipment with blood-borne viruses and pathogenic bacteria have been reported. Cleaning and disinfection of equipment and proper handling of reusable and disposable supplies is critical to the safety of patients in this high risk area (*APIC, 2010; Shepard et al., 2005*).

The following pictures are offered as examples only. They are not representative of equipment used in every dialysis center. For instance, some dialysis centers use machines with a waste handling option. This requires extreme care not to cross contaminate, as well as maintenance and testing of check valves. Others use one-time use containers (sometimes called “urinals”) to prevent cross-contamination from priming waste buckets (*APIC, 2010*).

Key principles related to equipment cleaning/disinfection that should be adhered to in order to reduce the risk of cross-contamination in HD settings follow (*APIC, 2010; Rutala et al., 2008*).

- Items taken into an individual HD patient station should be disposed of after use, dedicated for use on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.
- Non-disposable items that cannot be comprehensively cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use on a single patient.
- External venous and arterial pressure transducer filters/protectors should be changed after each patient treatment, and should not be reused. Internal transducer filters do not need to be changed routinely between patients.
- When reprocessing or disposing of dialyzers, dialyzer ports should be capped and tubing clamped. The used dialyzer should be placed in a leak proof container for transport from the patient station to the reprocessing area. Gloves should be worn at a minimum. Gowns are required if there is any risk of contamination of clothing.
- All equipment, including the front of the dialysis machine, should be considered contaminated after a patient dialysis session.
- Non-disposable instruments (scissors, hemostats, clamps, etc.) which have no contact with sterile tissue or mucous membranes may become contaminated during the procedure. To facilitate thorough cleaning of the hinges and joints, these instruments should be first submerged and cleaned (e.g., with enzymatic detergent, rinsed thoroughly, then soaked in an appropriate disinfectant according manufacturer’s instructions-typically low level disinfectant unless visibly contaminated with blood-then tuberculocidal disinfectant).
- The alternative would be to send the instruments to the Sterile Processing Department, if available, for reprocessing. Wiping with a cloth saturated with disinfectant may not be adequate to thoroughly clean hinged or jointed instruments.

### **2.3.3.1 Exterior Cleaning and Disinfection of Dialysis Machine**

Exterior (surface) cleaning and disinfection of dialysis machine can be accomplished between each treatment using any approved EPA-registered disinfectant labeled for use in healthcare settings and in accordance with facility policy and procedure. In a typical HD setting, dialysis technicians and registered nurses generally perform the process of cleaning of the patient station between dialysis sessions. Dialysis schedules and pace must accommodate comprehensive cleaning between patient treatments (*APIC, 2010; CDC, 2001*).

### **2.3.3.2 Interior Disinfection of Dialysis Machine**

Disinfection of the internal pathways of the dialysis machine between patient uses is not required. Dialysis machines are engineered so that the pathways segregate blood and dialysate. The pathways further segregate clean (affluent) dialysate from effluent dialysate (that which has passed through the dialyzer). The term used to describe the flow schematic of HD machines is “single-pass.” This means that the dialysate solution passes through the hemodialyzer once, where it picks up renal waste from the blood through a one way membrane, and then is routed to drain without contaminating any fresh dialysate being introduced into the hemodialyzer. When a single machine is used in succession by patients, cross-contamination via the internal pathways of the machine is prevented by the single-pass feature of the HD machine (*APIC, 2010*).

The exception is if a blood leak event occurs. In the event of a blood leak outside of the blood pathway, the CDC recommends internal disinfection before the dialysis machine is used on a successive patient. A blood leak results when the hemodialyzer fiber membrane is compromised and allows blood to enter the dialysate pathway. In this event, disinfection of this pathway must be performed prior to use of the HD machine on a successive patient (*APIC, 2010; Shepard et al., 2005*).

There are two methods of disinfecting the dialysate pathways (internal) of the HD machine: heat and chemical. The standard as recommended by HD machine manufacturers is to perform disinfection of the dialysate pathways at the end of each treatment day using heat disinfection. Heat disinfection is an auto-cycle that subjects the pathway to an 80o+ centigrade water temperature for approximately 30 minute exposure time. The process is convenient and excludes the use of any chemicals to achieve disinfection for the purpose of bacterial control (*APIC, 2010; CDC, 2001*).



Alternatively, chemical disinfection can be accomplished using a variety of solutions including sodium hypochlorite (bleach) and per oxyacetic acid (compound comprised of per acetic acid and hydrogen peroxide). When using a chemical disinfectant, it is important to follow the manufacturer's recommendation regarding concentration and dwell time. In the acute setting where dialysis may not be performed on a daily basis, HD machines may be inactive for prolonged periods of time and could potentially develop bacterial growth. In this situation, inactive machines must be chemically disinfected prior to patient use (*APIC, 2010; CDC, 2001*).

### **2.3.3.3 Monitoring Dialysis Machine Disinfection**

The effectiveness of disinfection for the internal pathways of the dialysis machine can be validated by routine bacteriologic and endotoxin analysis. Testing of HD machine dialysate and reverse osmosis (RO) water (a central system) for bacteria and endotoxin assay are required at least monthly. This should involve testing of at least two HD machines each month. The sampled machines must be rotated so that each machine in the facility is tested at least annually. Testing of dialysate should be performed at the end of the treatment day. The process of sampling versus testing all machines each month is practiced for two reasons. First, the testing of every machine every month can be labor intensive and costly. Secondly, since all outpatient machines receive the same water via a single distribution loop and each machine is disinfected on the same frequency and same procedure, testing two machines randomly on a rotating basis provides a comprehensive testing model. Dialysate testing for a dialysis machine using portable RO or in a home setting should be performed on a quarterly basis at a minimum (*APIC, 2010; CDC, 2001*).

The maximum allowable level for dialysate bacteria is 200 colony forming units (CFU)/mL, with an action level of 50 CFU/mL. An action level of 50 CFU/mL has been established so that corrective measures are performed to prevent bacteria proliferating to higher levels. The maximum allowable level for dialysate endotoxin is 2 endotoxin unit (EU)/mL, with an action level of 1 EU/mL. As with bacteria, the action level for endotoxin has been established so that corrective measures are performed as an early intervention, preventing endotoxin proliferating to the maximum allowable levels. A decision tree that is published in Association for the Advancement of Medical Instrumentation (AAMI) RD52 is attached and can be used to guide the analysis and action taken in response to test results (*APIC, 2010; Shepard et al., 2005*).

### **2.3.3.4 Auxiliary Equipment**

Additional or auxiliary equipment in an HD setting can include jugs for acid concentrate, sodium bicarbonate concentrate, a priming bucket, and the transducer protector (disposable). Bicarbonate powder can be mixed with processed water in a centralized vat, in individual jugs, or via automated process on the individual machines. All disposable equipment is to be used for only one patient and then must be discarded. Acid concentrate and sodium bicarbonate concentrate can be delivered to the dialysis machine via a distribution loop similar to the RO water loop. Acid, because of its high salt concentration and low pH, is not conducive to bacterial growth and therefore this system would not require routine bacterial control strategies (*APIC, 2010*).

Sodium bicarbonate can support bacterial growth, and this system (which includes the mixing tank, distribution tank, pipe loop, and outlet connectors) must be disinfected at least weekly, using the same process as that used for the RO loop. For facilities that do not use central delivery for concentrate solutions, the use of disposable or reusable jugs is the alternative. For these facilities, each dialysis treatment would utilize two jugs: one for acid and one for sodium bicarbonate. Disposable jugs must be discarded after each use. “Topping off” or adding additional sodium bicarbonate solution to single use jugs is not permitted. The growth of bacteria can occur with prolonged use of the sodium bicarbonate solution in an opened container. Consequently, sodium bicarbonate jugs should not be used 24 hours or more after opening (*APIC, 2010*).

Reusable jugs for sodium bicarbonate must be treated as all other reusable dialysis equipment and subjected to cleaning and disinfection (exterior of jug) prior to removal from the machine after each patient session. With the acid concentrate, it is not necessary to empty, rinse, clean, and disinfect the jug. Sodium bicarbonate reusable jugs must be emptied and rinsed with AAMI quality water (RO water) after use. Tap water should not be used for the cleaning and rinsing of the container. Water that is of AAMI quality water (dialysis quality) should be used. Disinfection of the inside of the sodium bicarbonate jugs must be performed at least weekly. The new Centers for Medicare & Medicaid Services. (CMS) regulation references the use of bleach at 1:100 dilution as an example of an acceptable disinfectant for this purpose (*CMS, 2010*).

This container serves to collect the solution used for preparing the extracorporeal system (blood lines and dialyzer). The procedure for use of the priming buckets may vary from facility to facility. Consequently, the initiation of the dialysis session may or may not introduce blood into the priming bucket. Regardless of the procedure, the

priming bucket should be emptied, cleaned, and disinfected after the initiation of each treatment. Cleaning and disinfection of the priming bucket should follow the same procedure used for the sodium bicarbonate jug. The arterial segment of the blood line is connected to the patient's arterial access and removes blood from the patient. The venous segment of the bloodline is connected to the patient's venous access and returns blood to the patient. The transducer is a component within the electronic modules of the dialysis machine which monitors the condition of these blood pathways by measuring the flow pressure in both venous and arterial segments of the pathway in the dialysis machine. Transducer protectors serve as an additional barrier between the dialysis machine and the patient's blood. Internal transducer filters do not need to be changed routinely between patients. External transducer protectors need to be changed after each dialysis session (*APIC, 2010*).

In addition, during the dialysis session, if the external transducer protector filter becomes wet with blood or fluid, it must be replaced immediately and the transducer inspected. If blood or fluid is visible on the side of the filter that connects to the machine, inspection of the internal hardware of the dialysis machine must be performed prior to use on subsequent patients. A qualified biomedical engineer or a trained and qualified dialysis HCW must inspect the external and internal hardware for blood or fluid intrusion. If the equipment has been contaminated with either blood or fluid, the internal lines and filter must be replaced and the external machine connector port disinfected with an intermediate-level disinfectant such as 1:100 bleach solution (*APIC, 2010; Rutala et al., 2008*).

#### **2.3.3.5 Reprocessing and Reuse of Hemodialyzer**

The practice of reusing dialyzers (for the same patient) has been performed in the USA since the 1960s. The USA Food and Drug Administration (FDA) published "Guidance for Hemodialyzer Reuse Labeling" on October 6, 1995. The document requires that dialyzers labeled for multiple uses must include instructions for their safe and effective reuse. This means that instructions for cleaning, rinsing, disinfecting, and testing the dialyzer as well as instructions for preparation before use (priming) must be included in the labeling package (*APIC, 2010; Rutala et al., 2008*).

Warnings must be included regarding the use of any reprocessing agents or processes known to adversely affect the manufacturer's dialyzer. The percentage of centers practicing reuse declined after 1997 to 63% in 2002 (*Shepard et al., 2005*) and in 2005,

it was estimated that 61% of patients were being treated with single-use dialyzers. The terms reprocessing and reuse have often been used interchangeably within the dialysis community. In fact, the two terms describe different aspects of the multiple use practice. Reprocessing is the act of cleaning, testing, and filling dialyzer with germicidal solution. This is performed outside of the dialysis treatment area. Reuse is performed in the treatment area and refers to verification of germicide, rinsing and testing to ensure the comprehensive removal of all germicide, and “reusing” the reprocessed dialyzer for the designated (same) patient. Reuse and reprocessing must follow all applicable AAMI standards to receive CMS reimbursement (*APIC, 2010; Rutala et al., 2008*).

### **2.3.4 Hand Hygiene**

Hand hygiene is the single most important intervention in preventing infections in healthcare. The challenge, however, is to achieve compliance. Poor hand hygiene compliance has been well documented across the continuum of care, including dialysis facilities. (*WHO, 2012; Arenas et al., 2005; Shimokura et al., 2006*). There are a number of factors that affect compliance. The large number of times that hand hygiene must be performed is one impediment. Other challenges include frequent movement of dialysis staff between patients and between machines and the urgency associated with patient incidents and machine alarms.

It is important to make hand hygiene as simple and expeditious as possible to encourage compliance. The use of alcohol-based hand sanitizer (i.e., gels, wipes, or foams with an alcohol concentration of greater than 60%) for hand hygiene is preferred over hand washing with soap and water, unless the caregiver’s hands are visibly soiled. This is because of the superior efficacy of alcohol sanitizer over soap and water, as well as less time required for use (*APIC, 2010*).

Dispensers can and should be placed at each patient station so that the caregiver can quickly and easily perform hand hygiene without having to leave the chairside to walk to a sink. Sinks with soap dispensers should be available as well, as alcohol sanitizer should supplement instead of replace soap and water washing. The most critical times for performance of hand hygiene are just before touching a patient and before leaving a patient station. Other important times include after gloves are removed; after touching blood, body fluids, secretions, excretions, and contaminated items (including front of the HD machine); and before accessing or restocking supplies (*APIC, 2010*).

Fingernails should be kept short and clean for several critical reasons, including that the subungual region (underside portion of nail that extends beyond fingertip) harbors the majority of microorganisms found on the hand. Removing debris from fingernails requires vigorous cleaning and running water. Additional effort is necessary for longer nails. Also, the risk of tearing gloves increases if fingernails extend past the fingertips, and long fingernails may scratch or gouge patients during patient care (*APIC, 2010; Arenas et al., 2005; Shimokura et al., 2006*).

CDC states that artificial nails are prohibited for direct patient care providers. Bacteria, viruses, and fungus adhere more readily to the material used to make artificial nails. Consequently, artificial nails may harbor organisms which may remain despite hand hygiene. Studies report higher number of Gram-negative microorganisms on artificial finger nail surfaces, both before and after handwashing, and infection transmission has been reported in inpatient environments. Although there have been no studies specific to the HD setting, the method of contamination described in inpatient accounts would theoretically create the same risk in any patient care setting including HD (*Arenas et al., 2005; Shimokura et al., 2006*).

Patients must also be instructed in the importance of hand hygiene including before and after dialysis sessions.

Glove use is an integral aspect of hand hygiene. Gloves must be worn in HD facilities whenever caring for a patient or touching the patient's medical equipment, handling lab specimens or used dialyzers, cleaning machines, cleaning stations, and wiping up blood or other body fluid spills. They must be changed whenever moving from one patient or machine to another. Gloves must be changed after cannulation. Clean disposable gloves are provided for this type of routine use. Sterile gloves must also be available and used during procedures requiring aseptic technique such as central line insertion (*APIC, 2010; Shimokura et al., 2006*).

### **2.3.5 Patient Immunization**

For reasons illuminated previously, HD patients are at increased risk for a variety of infections including HBV and a number of vaccine preventable diseases.

- 3 HBV: full series of three vaccinations (HBV vaccine may be a four dose series rather than three dose series, depending on the vaccine preparation being provided). Serologic testing of HD patients is recommended 1–2 months after administration of the final dose of the primary vaccine series to determine the need

for revaccination. For HD patients, the need for HBV vaccine booster doses should be assessed by annual testing for antibody to HBV surface antigen (anti-HBs). A booster dose should be administered when anti-HBs levels decline to less than 10 mIU/ml (*APIC, 2010; CDC, 2001*).

All new patients should receive a full course of HBV vaccine. A higher dose than normal is recommended (Table 1) since the immune response is impaired in ESRD patients and both the antibody response and the rate of seroconversion in these patients is lower than in non-ESRD population (*CDC, 2006*). Patients should receive HBV vaccine in the pre dialysis phase when the immune response is better preserved. This practice maybe uncommon, often because the patient has not seen a nephrologist prior to initiation of maintenance dialysis. In the case of failure of the patient to reach the desired titer of antibody ( $\geq 10$  mIU/mL), a repeated course is recommended. If the patient still does not respond, he or she should be considered susceptible and screened monthly for HBsAg. No additional doses of vaccine are warranted for those who do not respond to a full second series (*APIC, 2010*).

HD centers must be careful not to send blood for testing for HBsAg within 2–3 weeks of HBV vaccine administration, as during this time HBsAg may be detected. This is referred to as transient antigenemia, which can lead to an erroneous diagnosis of acute HBV infection and unnecessary concern. Additionally, there is potential risk to the patient if they are inappropriately treated in an HBV isolation area (*CDC, 2001*). Although sufficient time must be allowed between the vaccine administration and the testing of the surface antigen, it is imperative not to skip the monthly antigen blood draw. Ideally, the monthly blood is drawn immediately before giving the vaccine. This way, no matter what dose of the vaccine in the series is administered, sufficient time will have been allowed avoiding transient antigenemia (*APIC, 2010*). Patients who do achieve the anti-HBs level of at least 10 mIU/mL should be screened annually, since patients with ESRD tend to lose their protective level at a much higher rate than normal. If the anti-HBs level falls below 10 mIU/mL, the patient should be given a booster dose of vaccine. Patients who are both anti-HBs and anti-HBc positive do not require such follow-up screening (*CDC, 2001*).

**Table 1. Doses and Schedules: Hepatitis B Vaccines for Hemodialysis Patients**

Group	Recombivax HB			Engerix B		
	Dose	Volume	Schedule	Dose	Volume	Schedule

≥20 years of age: pre dialysis*	10µg	1.0 mL	Three doses at 0,1, and 6 months	20 µg	1.0 mL	Three doses at 0,1, and 6 months
≥20 years of age: Dialysis-dependent	40µg	1.0 mL	Three doses at 0,1, and 6 months	40 µg	Two 1.0 MI doses at one site	Four doses at 0, 1, 2, and 6 months
<20 years of age‡	5 µg	5.0 mL	Three doses at 0,1, and 6 months	10 µg	5.0 mL	Three doses at 0,1, and 6 months

- \*Immunogenicity might depend on degree of renal insufficiency, †Special formulation.
- ‡Doses for all persons aged <20 years approved by the U.S. FDA. For HD patients, higher doses might be more immunogenic.
- Note: All doses should be administered in the deltoid by the intramuscular route.

### 2.3.6 Medication Safety and Injection Practices (APIC, 2010).

The transmission of bloodborne viruses and other pathogens during routine healthcare procedures continues to occur. Root causes include improper injection, infusion, and medication vial practices within various clinical settings throughout the USA. Over 35 outbreaks of hepatitis have occurred in a wide range of settings in the USA. in the past 10 years because of these and other unsafe practices. These outbreaks have resulted in the transmission of hepatitis B or C to more than 500 patients. The unsafe practices that were reported in these outbreaks include (USA, 2009).

- Syringe reuse between patients during medication administration;
- Contamination of medication vials or IV bags
- Failure to follow basic injection safety practices when preparing and administering parenteral medications to multiple patients such as “scrub the hub.”

#### 2.3.6.1 General Principles (APIC, 2010).

The following general principles are recommended in all patient care settings, including HD, in order to reduce the risk of infection transmission between patients and between employees and patients.

#### 2.3.6.2 Aseptic Technique (APIC, 2010).

- Perform hand hygiene prior to accessing supplies, handling vials and IV solutions, and preparing or administering medications.
- Use aseptic technique during all aspects of parenteral medication administration, medication vial use, injections, and glucose monitoring procedures.
- IV medications should be prepared in a clean area away from the patient treatment area to avoid contamination.

- Discard all opened vials, IV solutions, and prepared or opened syringes that were used in an emergency situation.

#### **2.3.6.3 IV Solutions (APIC, 2010).**

- Never use IV solution containers (e.g., bags or bottles) for the purpose of IV flush solutions (or other purposes) for more than one patient.
- Never use infusion supplies such as needles, syringes, flush solutions, administration sets, or IV fluids on more than one patient.
- Complete infusion of lipid containing solutions within 24 hours, lipid emulsions with 12 hours, and blood/ blood products within 4 hours.
- Disinfect IV ports prior to accessing, using friction and 70% alcohol, iodophor, or chlorhexidine/alcohol agent. Allow to dry prior to accessing.

#### **2.3.6.4 Flushing**

- Use single-dose containers for flush solutions (Infusion Nurses Society 2006).

#### **2.3.6.5 Syringes (APIC, 2010).**

- Never use medication in a syringe for more than one patient even if the needle is changed between patients.
- Changing the needle but not the syringe is unacceptable.
- Utilize sharps safety devices whenever possible.
- Discard syringes, needles, and cannulas after used on a patient or in the IV administration system.
- Dispose of used needles at the point of use in an approved, puncture resistant sharps container.

#### **2.3.6.6 Vials (APIC, 2010).**

- Use single-use or single-dose vials whenever possible.
- Always use a sterile syringe and needle/cannula when entering a vial.
- Never enter a vial with a syringe or needle/cannula that has been used on a patient.
- Cleanse the access diaphragm of vials using friction and 70% alcohol. Allow to dry before inserting a device into the vial.
- Discard single-dose vials after use. Never reuse for another patient.
- Use multidose medication vials for a single patient whenever possible and access all vials using a new sterile syringe and needle/cannula with adherence to aseptic



technique. The risk of transmission posed by multidose vials has been clearly demonstrated and mandates a practice of one vial per one patient whenever possible.

- Infection transmission risk is reduced when multidose vials are dedicated to a single patient.
- Never store vials in clothing or pockets.
- Never pool or combine leftover contents of vials for later use.
- Never leave a needle or cannula inserted into a medication vial rubber stopper because it leaves the vial vulnerable to contamination.
- Dispose of opened multidose medication vials 28 days after opening (*USA Pharmacopeia, 2008*).
- .2 Date vial to reflect date opened and date of expiration. CDC Immunization Program states vaccines are to be discarded per manufacturer's expiration date.
- Examine the vial for any particulate matter, discoloration, or turbidity. If present, do not use and discard immediately.
- All vials used during an emergency should be discarded as sterility cannot be guaranteed.
- Do not use medication carts to transport medications to patient stations in HD settings

### **2.3.7 Patient and Employee Education**

Staff education and oversight of compliance with infection prevention practice is mandatory in all direct care areas including HD settings. HD facilities should designate an individual responsible for oversight of the Infection Prevention program under the supervision of the medical director. This role could be fulfilled by the clinic manager or other designee. The scope of this position must include education of employees and patients related to infection prevention and control in the HD setting. Most of the care in the dialysis facility is delivered by patient care technicians who are under the supervision of registered nurses (*CDC, 2001*).

In some states, prior to the new Conditions for Coverage (CfC) implemented by CMS in October 2008, there were no required qualifications for patient care technicians. Some states such as Arizona, Oregon, and Ohio required patient care technician certification prior to the new CfC and certified clinical HD technician certifications. Most HD facilities have always had defined training programs in place. As a result of frequent turnover among HD caregivers, training of new staff can be

particularly challenging. HD staff assigned to be in charge of infection prevention and control typically do not have experience in this area. HD facilities should consider seeking assistance from a certified IP to assist with education and training of staff (*CMS, 2010*).

Patient involvement in any effective infection prevention and control program is critical. Dialysis staff should ensure patients are involved and understand their role in the infection prevention and control program. This can be supported via education regarding the patient role in infection prevention and control including hand hygiene, access and wound cleaning, respiratory etiquette, and understanding/reporting signs and symptoms of infection (*Splaine, 2008; APIC, 2010*).

Caregivers and patients should be educated by HD staff regarding what infection prevention measures they should expect to see taken by their dialysis team. An informed patient can make an important contribution to infection prevention efforts (*APIC, 2010*).

### **2.3.8 Standard Precautions**

#### **2.3.8.1 Introduction**

Standard Precautions (formerly Universal Precautions) refers to the practices that are designed to prevent transmission of infection by contact with bodily fluids. The concept of Standard Precautions is based on the principle that all blood, body fluids, secretions, and excretions of all patients may contain transmissible infectious agents, and involves the use of Personal Protective Equipment (PPE) such as masks, face shields, gowns, and gloves. In HD settings, in addition to Standard Precautions, more stringent measures are recommended because of the increased potential for contact with blood and bloodborne pathogens including HBV, and HCV. The risk of exposure is increased because accessing the bloodstream is required during the dialysis session, there is close proximity of patients, and staff have frequent contact with numerous patients and equipment. Exposure to blood and potentially contaminated items can be routinely expected during the process of HD. As a result, dialysis healthcare personnel must take more rigorous steps to protect their patients as well as themselves, as follows (*APIC, 2010*).

- **Use dedicated equipment:** A risk of transferring infectious material between patients is created when moving equipment or disposables from patient station to station. Any single-use disposable item must be used for only one patient and then discarded. Items such as adhesive tape should be dedicated for use on a

single patient and discarded. Blood pressure cuffs should be made or covered with a material that can be cleaned and disinfected between patient uses. Items such as pillows and blankets are sometimes supplied by the facility and sometimes the patient. Patients bringing items from home to the unit for each treatment must take them home afterwards to prevent use by other patients. Unused medications or supplies (e.g., syringes, alcohol swabs) taken to the patient's station should not be returned to a common clean area or used on other patients (*APIC, 2010*).

- Prohibit use of shared mobile supply or medication carts.
- Gloves must always be worn for any contact with the patient or a patient's equipment.
- Isolation of HBsAg-positive patients

#### **2.3.8.2 PPE Guidelines for Standard Precautions in HD Settings**

The following guidelines for PPE use should be followed for all patients in all HD settings (*APIC, 2010*).

- ***Patients***
  1. Wear a mask during initiation and discontinuation of dialysis treatment if vascular access is a catheter.
  2. Wear a mask in an HD facility when experiencing symptoms of an upper respiratory illness.
- ***Employees***
  - 1. Lab-style cover coats:**
    - Regular cotton, non-fluid resistant lab coats are *not* considered PPE and should be removed or worn under an isolation or fluid resistant gown when needed.
    - Fluid resistant lab coats *are* considered PPE.
    - Either type of lab coat must be removed if it becomes soiled or wet.
    - Either type of lab coat must be removed prior to leaving the unit and for breaks and lunch.
  - 2. Full isolation or fluid resistant gowns should:**
    - Be worn when caring for an isolation patient with HBV.
    - Cover arms and be closed in front.

- Be worn when there is likelihood of blood contact, especially when initiating and removing patients from dialysis.
- Be worn when there is a likelihood of body fluid contact especially with diarrheal illnesses, uncontrolled secretions, draining wounds, stool incontinence, and ostomy tubes and bags.
- Be worn during reprocessing of dialyzers.

### **3. Gloves should be:**

- Worn whenever caring for a patient.
- Worn when touching the patient's medical equipment or handling lab specimens or used dialyzers.
- Worn when cleaning machines, cleaning stations, or wiping up blood or other body fluid spills.
- Changed whenever moving from one patient or machine to another.
- Changed when moving from a dirty to a clean site/task on the same patient (i.e., new gloves should be
- donned after touching the HD machine, prior to touching the same patient's vascular access)
- Changed after cannulation.
- Removal of gloves should always be followed with hand hygiene.

### **4. Mask should be:**

- Worn if experiencing mild cold or cough illness in order to protect patients and other employees.

### **5. Face protection (mask with eye protection [goggles, face shield]) should be:**

- Worn during initiation and discontinuation of dialysis.
- Worn during reprocessing dialyzers or cleaning equipment in a sink.
- Worn when within 6 feet of an unmasked coughing patient.
- Discarded between patients or if reusable, cleaned and disinfected between uses as indicated.

## **2.3.9 HBV Isolation/Precautions**

### **2.3.9.1 Introduction**

In addition to Standard Precautions, isolation (separate room) for HBsAg positive patients is standard of practice in HD facilities, for several reasons (*APIC, 2010; Lanini et al., 2009*).

1. Environmental stability: HBV can persist on surfaces and equipment and remain infectious at ambient room temperature for up to 7 days. HBsAg has been detected on clamps, machine control surfaces, doorknobs, and other surfaces in dialysis facilities. These blood-contaminated surfaces can serve as a reservoir for HBV transmission, creating the potential for contamination of healthcare personnel hands, equipment, and supplies.
2. High viral titer: Persons with HBV infection tend to have high concentrations of virus in their blood. This, along with its environmental stability, makes the risk of HBV transmission from blood contaminated items in this setting greater than would be expected for other common blood borne viruses. While HCV and HIV also pose potential infection risk to employees and patients, the risk is significantly less than that related to HBV:
  - HIV infection from an exposure occurs at a rate of 0.2%–0.4%.
  - HCV infection from an exposure occurs at a rate of less than 1%.
  - HBV infection from an exposure occurs at a rate of up to 30%.

#### **2.3.9.2 HBV Isolation/Precautions (*KDOQI, 2006; Valsamakis, 2007*).**

- Patients are placed in a private room or segregated area.
- Dedicated dialysis machine is used for HBV-positive patients.
- Dialyzers are discarded in biomedical waste after treatment.
- Dialyzers cannot be reprocessed/reused.
- Gown and gloves are required for each entry into room.
- Mask with eye protection is required for cannulation and decannulation.
- Staff caring for HBV patients cannot care for HBV susceptible patients at the same time (*CDC, 2001; CMS, 2010*)
- Staff caring HBV patients should be HBV-immune.
- Required when the surface antigen is positive and not required when the surface antigen is not detectable.

Since the introduction of universal HBV vaccination in 1991 in the USA, the prevalence of chronic HBV infection in the general population including dialysis patients has decreased. In the 1999–2004 National Health and Nutrition Examination Survey (NHANES), (*Glynn et al., 2000*) the prevalence was reported to be 0.27%. However, it must be remembered that certain racial groups have much higher prevalence of positivity. A survey of the general population in Rochester County,

Minnesota, showed a prevalence of 2.1% among Asians, 1.9% among African-Americans, and 0.02% among Caucasians. A total of 86% of the population with chronic HBV infection were born outside the USA (*Kizilisik et al., 2004*) Other groups at high risk include men who have sex with men and IV drug users (*Frenette et al., 2009*).

### **2.3.9.3 HCV Positive Patients**

Standard Precautions recommended for all HD patients are sufficient to prevent HCV transmission between patients. Patients who are anti-HCV positive (or HCV RNA positive) do not have to be isolated from other patients or dialyzed separately on dedicated machines. According to CDC recommendations, dialyzers can be reused (for same patient) with HCV infection (*CDC, 2001*). Case series have not shown that the risk of transmission is higher in centers that practice such reuse (*Fabrizi et al., 2008*). HCV is not transmitted as efficiently as HBV, and the HCV conversion rate for HD patients is low. In one report, the rate of seroconversion of known negative patients was 0.34%. However, this disease still remains a risk to HD patients and employees since there is no vaccine to confer immunity, and the prevalence of persons with chronic HCV infection is currently much higher than that of HBV infection. Adding to the severity of the risk is that the incidence of chronic persistent infection after an acute episode of HCV is high: 80%–100% of patients remain HCV-RNA positive, and 60%–80% have persistently elevated liver enzymes. Data derived from NHANES suggest that the prevalence of HCV infection in the general population is only about 1.6%. The prevalence of anti-HCV in patients in the various ESRD networks during the last National Surveillance of Dialysis-Associated Diseases in the United States in 2002 ranged from 5.5% to 9.8%, (*CDC, 2001*) significantly higher than in the general population. The CDC and the KDOQI recommends screening HD patients for anti-HCV at 6-month intervals; however, CMS does not reimburse for this. Fortunately, there is a very low conversion rate of patients to HCV positivity when Standard Precautions are rigorously followed (*CDC, 2001; KDOQI, 2006*).

### **2.3.10 Respiratory Hygiene**

Respiratory illnesses which cause coughing include but are not limited to influenza, upper/lower respiratory illnesses, pertussis, strep throat, and MRSA pneumonia. To prevent the transmission of all respiratory infections in HD settings, the

following measures should be implemented year-round at the first point of contact with a coughing or potentially infected person. HD facilities should have adequate signage and supplies (tissue, waterless alcohol hand sanitizer (i.e., gels, wipes, or foams with an alcohol concentration of greater than 60%) to support the following prevention efforts (*CDC, 2010a; CDC, 2010b*).

1. Cover the nose/mouth when coughing or sneezing with tissues or masks to contain respiratory secretions and dispose of them in the nearest waste receptacle after use.
2. Persons unable or unwilling to use tissue or wear a mask should be spatially separated from others by at least 6 feet.
3. HCWs who care for individuals who are coughing or have a respiratory illness should don a mask with eye protection when within 6 feet of the individual (microorganism contact with conjunctiva can cause illness).
4. Patients and HCWs should perform hand hygiene after having contact with respiratory secretions and contaminated objects/materials.

### **2.3.11 Transmission-Based Precautions**

Transmission-Based Precautions are recommended in addition to Standard Precautions by the CDC when the route(s) of transmission is (are) not completely interrupted using Standard Precautions alone. There are three categories of Transmission-Based Precautions: Contact Precautions, Droplet Precautions, and Airborne Precautions (*Sehulster & Chinn, 2010; Siegel et al., 2007; Siegel et al., 2006*).

**1. Airborne Precautions:** Transmissible airborne illnesses include varicella, disseminated varicella, TB, and measles. Microorganisms can remain airborne for up to 2 hours.

- **Inpatient Setting:** Patients are placed in a negative airflow room. Respirators are required for TB and for anyone not immune to varicella, measles, or other airborne disease. It is recommended that those individuals who are not immune be reassigned to prevent exposure to vaccine preventable diseases.

***Hospital policies should be followed:***

- **Ambulatory Setting:** Patient identified with a suspected airborne disease should be masked immediately and geographically separated from other

patients, preferably in a single room. Arrangements should be made for HD treatments at a facility that can provide a negative pressure isolation room.

- **Droplet Precautions:** Illnesses transmitted by large respiratory droplets include pertussis, influenza, mumps, strep throat, rubella, diphtheria, Mycoplasma pneumonia, adenovirus, Neisseria meningitidis, Haemophilus influenzae type b, and acute respiratory infections with MRSA/VRE/other MDRO.
- **Inpatient:** Hospital policies should be followed.
- **Ambulatory Setting:** Respiratory Hygiene/Cough Etiquette Precautions should be followed. If hospitalization is required, the patient should be spatially separated by at least 6 feet from other patients and a mask worn until transport can be arranged. In HD facilities, dialysis center exposure management and follow-up policies should be followed in the event of a vaccine preventable disease exposure or meningitis. Only immune staff should care for patients with a vaccine preventable disease (i.e., mumps, rubella, diphtheria).
- **Contact Precautions:** Illnesses transmitted via contact include *C. difficile*, adenovirus, rotavirus, impetigo, scabies, pediculosis, and MDROs (e.g., MRSA, vancomycin intermediate-resistant *S. aureus*, VRE, and other MDROs).
  - **Inpatient Setting:** Hospital policy should be followed.
  - **Ambulatory Setting:** Routine contact precautions are not required in HD units for patients infected or colonized with pathogenic bacteria for several reasons. First, although contact transmission of pathogenic bacteria is well-documented in hospitals, similar transmission has not been well-documented in HD centers. Transmission might not be apparent in dialysis centers, possibly because it occurs less frequently than in acute-care hospitals or results in undetected colonization rather than overt infection. Also, because dialysis patients are frequently hospitalized, determining whether transmission occurred in the inpatient or outpatient setting is difficult. Second, contamination of the patient's skin, bedclothes, and environmental surfaces with pathogenic bacteria is likely to be more common in hospital settings (where patients spend 24



hours a day) than in outpatient HD centers (where patients spend approximately 10 hours a week).

### 2.3.12 Water Treatment and Testing

#### 2.3.12.1 Bacteriology of Water and Dialysate

Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse shall contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration lower than 2 EU/mL. The action level for the total viable microbial count in the product water shall be 50 CFU/mL, and the action level for the endotoxin concentration shall be 1 EU/mL.” “Action level” indicates that once these are measured in the product water, corrective measures shall promptly be taken to reduce the levels of bacteria/endotoxin (*APIC, 2010*).

<b>Fluid</b>	<b>Bacteria CFU/mL</b>	<b>Endotoxin EU/mL</b>
Water used for dialysate, reprocessing of hemodialyzer, germicide production	200/50 action level	2/1 action level
Dialysate	200/50 action level	2/1 action level
Minimum frequency	monthly	monthly

Bacteriologic and endotoxin assay are performed to validate the adequacy of the dialysis machine disinfection process and frequency, not to determine when disinfection is needed. If an HD facility’s monthly testing results are below the action levels and disinfection frequency is monthly, this suggests that process and frequency of dialysis machine disinfection is effective. If monthly testing results are above acceptable levels for bacteria/endotoxin, this would suggest that either the machine disinfection process or frequency is not sufficient to control bacterial growth. An adjustment to the frequency or process of disinfection would be indicated in order to keep bacteria/endotoxin below action levels (*APIC, 2010*).

#### 2.3.12.2 When Bacteria and Endotoxin Levels are Exceeded

Measures must be performed promptly when results exceed the action level or the maximum allowable level. Dialysis may continue when bacteria/endotoxin is found to be at the action level, but retesting and/or disinfection of the system should be performed promptly. “Promptly” has been defined by CMS regulation as within 48 hours of receiving the report (*CMS, 2010*). For bacteria/endotoxin levels exceeding the maximum allowable levels, the medical director must determine the course of action. The medical director must assess the impact to the patient and determine which option

would result in a more detrimental outcome for the patient: not receiving the treatment or using a dialysate which contains greater than the allowable CFU and EU limits. When limits exceed the maximum allowable, regulations require that cultures be performed weekly for at least a month until a stable trend has been reestablished demonstrating control of the bacteria/endotoxin levels which does not exceed the maximum allowable (*APIC, 2010*).

The sampling source has also been defined within the new regulations for *central* RO systems (RO that produces and supplies product water for three or more dialysis machines) and individual portable RO systems (mobile systems that produce and supply product water for one or two machines and are typically used in home or acute settings). For central RO systems, the recommended sampling location for bacteria/endotoxin samples are the first point of use, last point of use, and an auxiliary point such as the reprocessing machine or concentrate mixing system. The recommended sampling frequency is monthly, when repairs to the RO system result in intrusion to the membrane and dialysate pathways, and when pyrogenic reactions are suspected. For portable systems, the recommended sampling frequency is quarterly, when repairs are performed and during suspected pyrogenic reactions (*APIC, 2010*).

### **2.3.12.3 Bacteriologic Monitoring of Water and Dialysate**

The bacteriologic levels permitted for dialysate is very low. Consequently, the sensitivity of the culturing methods used must be sufficient to detect bacteria at these low levels. Testing can be done through an accredited laboratory or on site at the dialysis facility using commercially available dip samplers. Water samples should be collected directly from outlet taps. Sample taps should be flushed for at least 60 seconds before the sample is collected (*APIC, 2010*).

Collection containers must be sterile/endotoxin-free. All new sterile plastic ware is endotoxin-free because of the high temperatures involved in the manufacturing process. Disinfection of the sample taps is not recommended as residual disinfectant may contaminate the sample and affect the result. If users insist on disinfecting the sample taps, sterile gauze saturated with alcohol may be used. Caution must be followed so that collection of the sample is performed after sufficient time has elapsed that would ensure that alcohol has evaporated so as to leave no disinfectant residual in the sample. Bleach or other disinfectant solutions should not be used. A minimum of 50 mL of water, or the volume specified by the laboratory performing the test, should be collected (*APIC, 2010*).

According to the regulations and AAMI recommendations (*AAMI, 2001*), samples that cannot be cultured within 1 to 2 hours can be refrigerated for up to 24 hours. Membrane filtration technique is the reference method used. The method involves a known volume or sample or diluted sample filtered through a 0.45 µm membrane filter; the membrane filter is transferred aseptically to the surface of an agar plate. Trypticase soy agar is the medium of choice for culturing water and dialysate. (*APIC, 2010*).

## **Chapter Three: Objectives and Hypothesis of the study**

### **3.1 Objectives of the Study**

#### **3.1.1 General Objective**

To investigate the prevalence of hepatitis B and C virus and infection control measures among hemodialysis patients in public hospitals in dialysis units in Sana'a City, Yemen.

#### **3.1.2 Specific Objectives**

1. To identify the demographic characteristics, medical and vaccination history among hemodialysis patients and staff nurses.
2. To verify the periodical testing for HBV&HCV infection among HD patients before and during HD
3. To determine the prevalence of HBV& HCV infections before and during HD in relation to medical history of HD patients.
4. To find out the association between the prevalence of hepatitis B and C viral infections and infection control measures in dialysis unit.
5. To explore the prevalence of hepatitis B and C viral infections in relation to demographic characteristics of hemodialysis patients.
6. To assess the prevalence of HBsAg &Anti-HCV among patients during HD by dialysis units
7. To examine the principles of infection prevention and control in dialysis units

### **3.2 Hypothesis of the Study**

1. There is no a statistical significant differences between prevalence of hepatitis B and C viral infections according to demographic characteristics of hemodialysis patients.
2. There is no a statistical significant differences before and during hemodialysis regarding prevalence of HCV among hemodialysis patients

3. There is no a statistical significant differences in prevalence of hepatitis B and C viral infections according to medical history of hemodialysis patients.
4. There is no statistical significant correlation between prevalence of hepatitis B and C viral infections and frequency of hemodialysis.
5. There is no a statistically significant correlation between prevalence of hepatitis B and C viral infections and duration of hemodialysis.
6. There is no statistical significant differences in principles of infection prevention and control in dialysis units in relation to hospitals

## Chapter Four: Research Methodology

### 4.1 Study design

A descriptive cross-sectional study was performed to investigate the prevalence of hepatitis B and C virus among hemodialysis patients and principles of infection prevention and control in dialysis units in Sana, a City, Yemen from 1 May to 30 June 2018.

### 4.2 Study Setting

This study was conducted at the dialysis units in hospitals in Sana a city, Yemen (Al-Thowrah, Military and Al-Jomhury Hospital). All hospitals provide primary, secondary and tertiary health care and referee hospitals to all Yemeni patients.

### 4.3 Study population and sample

All patients who received hemodialysis and staff nurses who working in dialysis units in all hospitals in Sana a city during the study period were enrolled to this study. Three hundred forty-nine patients with HD were enrolled to this study. We undertook a review over the period from 1 May to 30 June 2018 and extracted and analyzed the data from the records of 349 patients undergoing maintenance HD in the three hospitals. Therefore, this study finally included a total of 349 patients' records who underwent HD and 58 staff nurses provided supplementary data.

### 4.4 Sample size determination

*4.4.1 The sample size for hemodialysis patients was calculated by used the EpiCalc program and based on the following criteria:*

- The proportion was 9% (based on a study conducted by *Abdalhafeez. et al. (2015: Prevalence of HBV infections in hemodialysis patients in Khartoum State, Sudan).*

- Precision was 3%
- Confidence level = 95%.

*The final sample size was 349 HD patients.*

**Also used the following equation:**

$$\text{Sample size} = z^2 * (1-P*q) / d^2$$

- Where: **Z**: statistic for a level of confidence,
- **P**: is the estimated prevalence rate
- **d**: precision, the confidence level 95% and percentage of error 2%
- The estimated sample size is 349 dialysis patients.

#### **4.4.2 Sample size for staff nurses:**

Due to a small number of staff nurses working in a dialysis unit the researcher was enrolled all nurses presented during field work were enrolled in the study they were 58 nurses.

### **4.5 Sampling Technique**

A stratified random sample was administered to select 349 HD patients from dialysis units in 3 hospitals. The researcher obtained the lists of HD patients undergoing HD in dialysis units. The list was reviewed and patients meeting the inclusion criteria were included in the study to obtain from the total study population n= 1065 HD patients. Then, the sampling frame was divided into 3 strata (hospital); Al-Thowrah hospital (n= 490), Al-Jomhury hospital (n= 245) and Military hospital (n= 330).

*The procedure for selecting a stratified sample was:* 1). identified all sampling units in the sampling population, 2) decided upon the different strata into which we want to stratify the population, 3) placed each element into the appropriate stratum, 4) Number every element in each stratum separately, 5) decided the total sample size, 6) administered the proportionate stratified sampling, 7) determined the proportion of each stratum in the study population, 8) determined the number of elements to be selected from each stratum and 9) selected the required number of element from each stratum with systematic random sample technique.

To calculate the number of HD patients to be drawn at random from each of the 3 strata (hospitals) were used the following formula:

$$\frac{n}{N} * K = \text{sample size to each hospital}$$

- n = Sample size
- N= Total study population
- k= Population of each hospital

<b>Stratum/hospital</b>	<b>Population of each stratum/hospital</b>	<b>The study sample for each stratum/hospital</b>
Al-Thowrah hospital	490	160
Al- Jomhury hospital	245	81
Military hospital	330	108
<b>Total study Population</b>	<b>1065</b>	<b>349</b>

According to these characteristics, a systematic random sample of a pre-determined size was obtained from each stratum (hospital). For example, the sampling fraction is  $k=N/n$ . For Al-Thowrah hospital the Population (N) = 490 HD patients and sample size (n) = 160, so  $k =490/160= 3$ . With a list of the 490 HD patients in the sampling frame, the researcher went to the starting point and selected every 3<sup>rd</sup> name on the list until the sample size was reached.

#### **4.6 Inclusion and Exclusion Criteria**

- ***The Inclusion criteria were included:***
  1. All patients receiving maintenance HD during the study period and agree to participate in the study.
  2. All nurses who working in dialysis units and agree to participate in the study.
- ***The exclusion criteria was included:***
  - All patients and nurses do not fulfillment the above criteria.

#### **4.7 Data Collection Technique and Tools**

The researcher developed his own tool to assess the prevalence of HBV and HCV infection among patients and principles of prevention and infection control in HD Units environment. The tools consisted of two-part, which all had been constructed based on the international guidelines of the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) for environmental infection control, and Association for Professionals in Infection Control (APIC) (*WHO, 2016; CDC, 2016;*

*CDC, 2012a; APIC, 2017*) and other literature review (*Khalid, 2013; Eltagi et al., 2017; CDC, 2011; Ayman et al., 2014; Department of Health, 2010*).

A close-ended based questionnaire was developed in english language and translated to Arabic and completed by the researcher via patient and staff nurses' interview to ensure proper data collection and prevent any misunderstanding. The questionnaire had been administered after being translated into the Arabic language to be easily understood by the respondents. In each questionnaire, an explanatory letter was attached to facilitate questionnaire filling. The questionnaire was clear with no complex terms, no jargons, and no leading questions. All questions follow a binary scale.

Medical history of HD patients was taken by access to the patients' medical record files to validate the provided data. When there were discrepancies between data sources, the data in the medical record files were used. In case, some data were not available in the patient's medical record files, the researcher was taken data from the physician or nurse who responsible for the care and treatment of the case. The questionnaire included the following (*Appendix-A*):

- **Part one:** includes;
  1. Demographic characteristics of the patients (age, sex, marital status, level of education, occupation, and place of residence)
  - Medical history of patients (Frequency of HD sessions, duration of dialysis and history of HBV vaccination)
  2. History of HBV&HCV infection among patients: at the screening stage and at the follow-up stage which includes (HBsAg and anti-HCV).
- **Part two:** includes:
  1. Socio-demographic characteristics of staff nurses (age, sex, marital status, level of education, duration of working, monthly income and course training in infection control in dialysis unit).
  2. . History of HBV vaccination.
  3. Principles of infection prevention and control (IPC) in the dialysis unit, which included :
    - Screening, immunization, and routine testing, which included: Routine testing / or documentation for HBV &HCV as soon as, it is anticipated that



dialysis is required & every 3 months, for HBsAg, HCV & HIV antibody and patient's vaccination (e.g. HBV).

- Standard and transmission based-precaution which include: Segregation of HBsAg-positive patients and their equipment and supplies from those used for non-HBV-infected patients, patients with either HCV or HIV infection also require a dedicated machine, contact precautions, proper hand hygiene (as WHO's 5 moments), staff must wear a mask and gloves and the patient must wear a mask while the site is being accessed, wash the access site using an antibacterial soap/scrub and water, cleanse the skin by 2% chlorhexidine gluconate/70% isopropyl alcohol, 70% alcohol, or 10% povidone iodine, Access lines used for HD must not be used for other purposes.
- Environmental cleaning and disinfection, which included: Hospital grade disinfectant is used for all patient areas, Special attention to high-touch items or surfaces likely to be contaminated with blood or body fluids, prompt containment and cleaning of spills of blood or body fluids, prevention of mould contamination resulting from water damage or wetting of permeable walls, furniture, etc, strict adherence to IPC precautions for construction and renovation activities, used supplies and dialyzers disposed of to prevent contamination of patients and environmental surfaces.
- Equipment cleaning and disinfection, which included: policies and procedures for correct care and maintenance of, dialysis systems, including the water treatment system, distribution system, and dialysis machines, reusable dialyzers must be cleaned, receive high-level disinfection, and be thoroughly rinsed and dried prior to reuse and adequate cleaning and disinfection of dialysis machines and equipment and reusable supplies between all patient uses. Safe medication and injection practices which included: Avoid contamination of multi-dose vials, the stopper should be disinfected with alcohol before accessing the vial, A single-use sterile needle and syringe for each access, single-use vials are preferable, Needles should not be recapped, used sharps should to be discarded sharps containers and safety-engineered medical devices (e.g., self-retracting or self-sheathing needles) when possible.
- Health care workers training, which included: The staffs initial and on-going education on the basic principles and practices of dialysis, infectious

risks, and potential adverse events, and IPC practices and the patient education on access site and dressing care, signs and symptoms of infection, and the importance of reporting potential infections.

- Finally water treatment and testing which included: Testing of dialysis water and dialysate, Water quality; both microbial and chemical components should also be monitored, Water used to prepare dialysate or to process dialyzers and dialysate should contain a total viable microbial count of no more than 200 CFU/ml and an endotoxin concentration lower than 2 EU/ml, If the total viable microbial count reaches 50 CFU/ml or the endotoxin concentration reaches 1 EU/ml, corrective measures should be taken promptly).

**Blood sample collection and processing:** A blood sample (5mL) was taken by hospitals laboratories from each patient through venipuncture using a vacutainer device. The sample was allowed to clot naturally to separate the serum for analysis and was stored upright in an ice box/refrigerator at a temperature of 2–8 °C (for up to 3 days).

***Serological detection of viral hepatitis:*** Patients, HBsAg and anti-HCV antibody status was investigated by serological testing. HBsAg and anti-HCV antibodies were assessed using third generation enzyme linked immunoassay kit (ULTRA kit, bioMerieux, France).

## **4.8 Pilot Study**

A pilot study was conducted before starting the data collection as a pretest to point out weaknesses in wording, translation to Arabic, predict response rate, determine the time needed to fill the questionnaire and identify areas of vagueness and to test the validity and suitability of the questionnaire. A total of 10% of staff nurses out of a total population of 70 nurse is represents 7 nurses were chosen from the study target population to conduct the pilot study. However, at the end of this process, one small change has been conducted. Because this modification didn't affect its important content of the questionnaire and didn't make a significant change, the researcher not include the pilot study in the total data.

## **4.9 Validity and Reliability of the Questionnaire**

- **Validity**

Validity is the extent to which an instrument accurately reflects the abstract construct (or concept) being examined (*Burns & Grove 2011*). To maximize validity, representative questions for each category were designed and evaluated against the desired outcome. To establish the validity of the instrument, a pilot study was conducted on 7 nurses, that is, 10% of nurses.

- **Face validity:**

It is achieved by clarity and organizing the instruments in categories with a logical sequence. An expert panel were agreed on the face and content validity of the questionnaire. The questionnaire was validated because the same questionnaire was used to during the pilot study and it measured what it was supposed to measure.

- **Content validity:**

Is the extent to which the method of measurement includes all the major elements relevant to the construct being measured (*Burns & Grove 2011*). The contents of the instrument included best practices from the Infection Control Guidelines, CDC guidelines (*CDC, 2012a & 2012b*) as well as WHO guidelines in the prevention of Hospital Acquired Infections (*WHO, 2001, 2012 & 2015*) and other literature review.

The instruments were sent to 3 panels of expert persons to assess the clarity and relevance of the questionnaire to the objectives of the study. All comments on the instruments were taken into consideration, as a result, some modification for some items were done. In addition, a pilot study was conducted before starting the data collection of the questionnaire.

- **Construct validity:**

To maximize validity, representative questions for each category of questionnaire were designed and evaluated against the desired outcome of infection prevention and control.

- **Reliability**

Reliability is defined as the extent to which an instrument consistently measures a concept (*Burns & Grove 2011*). For the most purposes reliability coefficient  $\geq 0.7$  are considered satisfactory. The statistician's explained that, overcoming the distribution of the questionnaire to measure the reliability can be achieved by using Cronbach's Alpha through the SPSS software (*Eisinga et al., 2012*).

- ***Internal consistency reliability:***

Is a measure of reliability used to evaluate the degree to which different test items that probe the same construct produce similar results. Determining how all items on the test relate to all other items. In internal consistency reliability estimation we use our single measurement instrument administered to a group of people on one occasion to estimate reliability. In effect we judge the reliability of the instrument by estimating how well the items that reflect the same construct yield similar results. We are looking at how consistent the results are for different items for the same construct within the measure (*Eisinga et al., 2012*). This method depends on finding of Cronbach's Coefficient Alpha. The normal range of Cronbach's coefficient alpha value between 0.0 and + 1.0, with  $r=0.7$  or greater considered as sufficiently reliable and the higher values reflects a higher degree of internal consistency (*Eisinga et al., 2012*). The results were in the range from 0.8391 and 0.9215, and the general reliability for all items equal 0.8991. This range is considered high; the result ensures the reliability of the questionnaire.

#### **4.10 Data Processing and Statistical Analysis**

Data processed, tabulated and statistically analyzed using the Statistical Package of Social Sciences (SPSS) version 20. Descriptive analysis was performed and the results were expressed as frequency and percentages. Means and standard deviations were calculated for quantitative variable and proportions for categorical variables. Multiple responses set was applied to calculate total responses of variables.

Student's *t*-test was used to test the difference in means if data were normally distributed and Mann-Whitney *U* test was used otherwise. Chi-square ( $\chi^2$ ) test was used to analyze association among variables and McNamee test was used to analyze differences in proportions pre-posttest. Spearman coefficient was used to measure the correlation between variable and Phi correlation for dichotomous variables.

The overcoming the distribution of the questionnaire to measure the reliability can be achieved by using Cronbach's Alpha coefficient and Spearman Brown

correlation coefficient. Cronbach Alpha for measuring the reliability of the items of the questionnaires (internal consistency).

The basis for the decision in the reliability coefficient  $\geq 0.7$  are considered satisfactory. A P-value  $\leq 0.05$  (2-tailed) was considered statistically significant.

#### 4.11 Study Variables/ Operational Definition

- **Study variables:**
  - **Independent variables:** Demographic characteristics, medical history of HD patients, history of HBV vaccination and principles of infection prevention and control in dialysis unit among staff nurses.
  - **Dependent variables:** Prevalence of HBV and HCV infection.
  
- **Operational definition:**
  - **Hemodialysis:** is a process of purifying the blood of a person whose kidneys are not working normally. This type of dialysis achieves the extracorporeal removal of waste products such as creatinine and urea and free water from the blood when the kidneys are in a state of kidney failure. Hemodialysis is one of three renal replacement therapies (the other two being kidney transplant and peritoneal dialysis). An alternative method for extracorporeal separation of blood components such as plasma or cells is apheresis. (*Mowatt et al., 2003*).
  - **Hemodialysis Unit:** refers to a special area in a hospital, where critically ill patients or highly dependent patient, who need HD, can be cared for by qualified and special trained staff working under the best possible condition.
  - **HD nurse:** Any nurse working in HD units or centers at the hospital.
  - **Acute hepatitis B:** Newly acquired symptomatic hepatitis B virus (HBV) infection (*Fabrizi et al., 2008*).
  - **Acute hepatitis C:** Newly acquired symptomatic hepatitis C virus (HCV) infection (*Fabrizi et al., 2008*).
  - **Chronic (persistent) HBV infection:** Persistent infection with HBV; characterized by detection of HBsAg >6 months after newly acquired infection (*Fabrizi et al., 2008*).

- **Chronic (persistent) HCV infection:** Persistent infection with HCV; characterized by detection of HCV RNA >6 months after newly acquired infection (*Fabrizi et al., 2008*).
- **Chronic hepatitis B:** Liver inflammation in patients with chronic HBV infection; characterized by abnormal levels of liver enzymes.
- **Chronic hepatitis C:** Liver inflammation in patients with chronic HCV infection; characterized by abnormal levels of liver enzymes (*Fabrizi et al., 2008*).
- **Prevalence:** Prevalence is a frequently used epidemiological measure of how commonly a disease or condition occurs in a population. Prevalence measures how much of some disease or condition there is in a population at a particular point in time. The prevalence is calculated by dividing the number of persons with the disease or condition at a particular time point by the number of individuals examined (*Le & Boen, 1995*).
- **Infection:** It is defined as the transmission of microorganisms into a host after evading defense mechanisms, resulting in the organism's proliferation and invasion within the host tissues (*CDC, 2007*).
- **Infection prevention and control:** Evidence-based practices and procedures that, when applied consistently in health care settings, can prevent or reduce the risk of transmission of microorganisms to health care providers, other clients, patients, residents and visitors (*Ontario Ministry of Health and Long-Term Care, 2011*).
- **Principles/Protocol:** a formal set of rules and procedures to be followed during a particular research experiment, course of treatment, etc. (*Your dictionary, 2011*).
- **Personal Protective Equipment:** Clothing or equipment worn for protection against hazards. (*Ontario Ministry of Health and Long-Term Care, 2011*).
- **HD training:** this is a specialized/formal HD Unit training for nurses working under the best possible condition to a care-dependent patient who needs close and frequent observation.

#### 4.12 Ethical Considerations

Approval from the college of medical sciences of Al-Razi University was obtained prior to carrying out this study. A cover letter was issued from the college of

medical sciences of Al-Razi University to the general administration of the hospitals, Sana`a, City, in order to obtain approval to conduct this study. (*Appendix-B*). The purpose and benefits of the study were explained to patients and nurses and were assured that their responses would not influence their care.

The participants have assured the confidentiality of their data and they were asked to sign a consent form, which describes the study and indicated that the participants could withdraw from the study at any time. Oral consent was obtained from patients and nurses to participate in the study. The study was conducted according to the declaration of Helsinki principles (*Appendix-A*).

## Chapter Five: Results

### 5.1 The Results Among Hemodialysis Patients

#### 5.1.1 Demographic characteristics of the patients

A total of 349 patients undergoing hemodialysis, aged 13 to 85 years was recruited for the study. Table 1 summarizes the demographic characteristics of the patients. Age mean± SD was 42.8±15.6 and 207 representing 59.35% were males. Among the patients, 281 were married, 58 were single. One hundred twenty-five patients representing 36.1% had no formal education (illiterate), followed by 105 representing 30.1% had a basic education background. Concerning the occupational status of the patients, 38.9% were housewife followed by 30.9% were unemployed. Regards to the place of residence of the patients, 68.8% were from urban and 31.2% from a rural area.

**Table 5.1: Demographic characteristics of the patients (n=349).**

<b>Demographical characteristics</b>						
<b>Items</b>	<b>F</b>	<b>Minimum</b>	<b>Maximum</b>	<b>Mean</b>	<b>S.D</b>	
<b>Age in years</b>	349	13	85	42.79	15.619	
<b>Sex</b>					<b>F</b>	<b>%</b>
• Male					207	59.3
• Female					142	40.7
<b>Marital status</b>						
• Married					281	80.5
• Single					58	16.6
• Divorced					5	1.4
• Widowed					5	1.4
<b>Level of education</b>						
• Illiterate					126	36.1
• Basic Education					105	30.1
• Secondary Education					70	20.0
• Diploma Degree					14	4.0
• B.Sc. Degree					32	9.2
• Master Degree					1	0.3
<b>Occupation</b>						
• Un-employee					108	30.9
• Governmental employee					55	15.8
• Self-employee					50	14.3
• Housewife					136	38.9

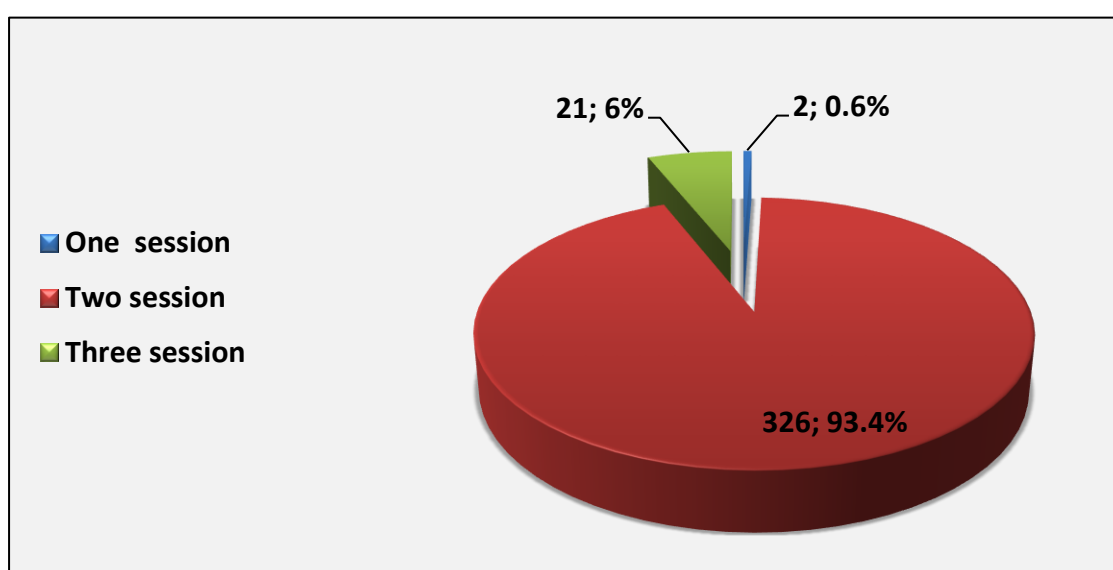


Place of resident		
• Urban	240	68.8
• Rural	109	31.2

### 5.1.2 Medical history of hemodialysis patients

- **Frequency of HD sessions**

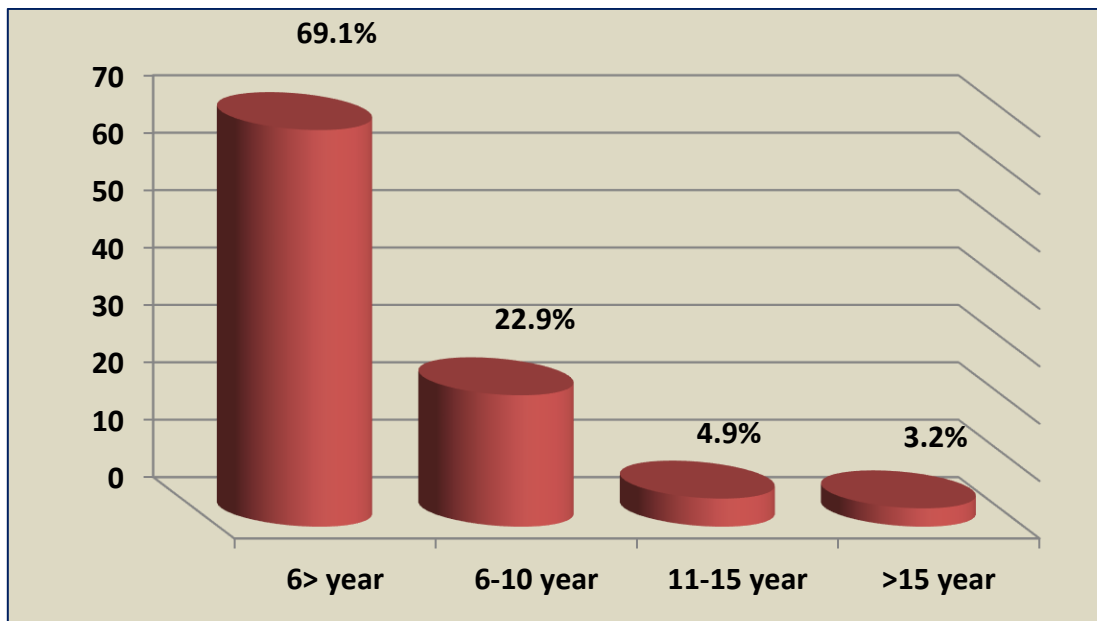
The frequency of HD sessions for each patient according to the patient's condition. Most of the patients undergo two HD sessions per week 326 (93.4%), followed by three HD session 21(6.0%) and the minimum number of sessions was one per week 2(0.6%). Figure 5.1.



**Figure 5.1: Frequency of HD sessions among patients (n=349)**

- **Duration of HD 90**

As regards to duration of hemodialysis, the findings of the study showed that more than half (69.1%) of the patients the duration of HD was less than 6 years followed by (22.9 %) from 6-10 years and the minimum duration of hemodialysis was (4.9 %) from 11-15 years and (3.2%)>15 years. Figure 5.2 illustrates the duration of HD among patients.



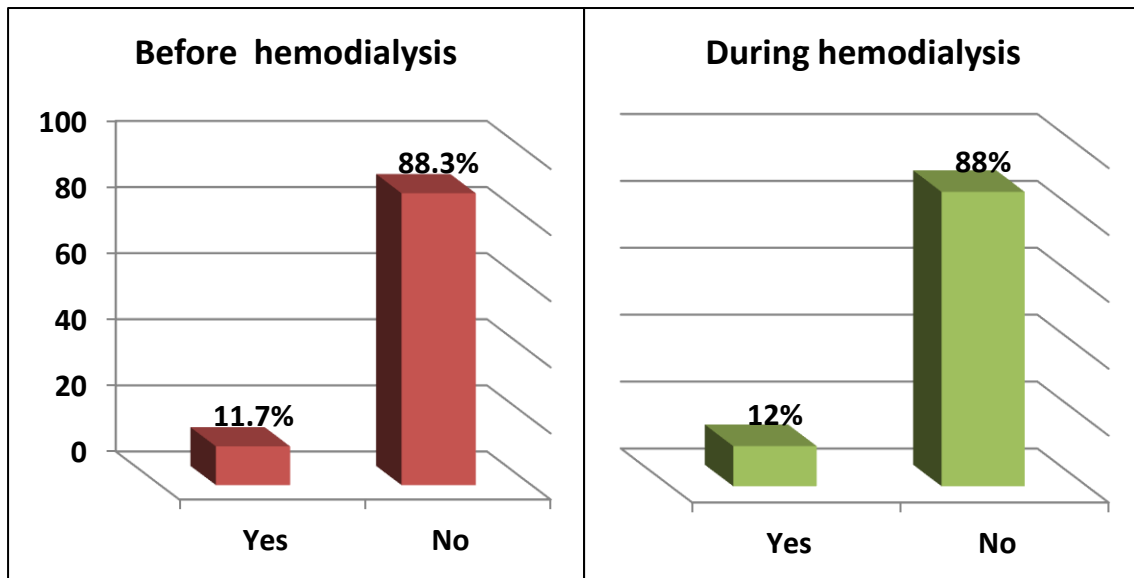
**Figure 5.2: Duration of HD among patients (n=349)**

- **Vaccination against HBV**

The results of the present study showed that 308(88.3%) of participants did not received HB vaccine before HD while only 41(11.7%) of participants received HB vaccine.

During HD only 42 (12%) of participants received HB vaccine in contrast 307(88%) did not received HB vaccine.

Figure 5.3 presents the history of vaccination against HBV among patients before and during HD.



**Figure 5.3: Distribution of patients by HB vaccine before and during HD (n=349)**

### 5.1.3 Periodical Testing for HBV&HCV infection among HD patients before and during HD

According to CDC recommendation, negative HBV patients must be tested for the presence of HBsAg each month and negative anti-HCV patients must be tested for anti-HCV semiannually.

By investigating these criteria we found that 349 patients representing 100% were tested for hepatitis B and C viruses before first commencing to HD. Regarding regular testing of HD patients for hepatitis B and C virus infections at follow-up the stage during HD showed that, three hundred and ninety-four patients representing 100% were tested at all but not tested periodically since the first test at the beginning of HD. Table 5.2.

**Table 5.2: Periodical testing of HBsAg and anti-HCV among HD patients before and during HD (n=349)**

Periodical testing of HBsAg and anti-HCV	Yes		No	
	F	%	F	%
<b>At Scanning stage before HD</b>				
• HBsAg test	349	100	0	0
• Anti-HCV test	349	100	0	0
<b>At follow-up stage during HD</b>				
• HBsAg test	349	100	0	0
• Anti-HCV test	349	100	0	0

### 5.1.4 Prevalence of HBV&HCV among patients before HD and during HD

The overall prevalence of HBV among HD patients was found to be 2.9% at the scanning stage before HD and 14.3% during HD at the follow-up stage. The prevalence of HCV was 2% at the scanning stage before HD and 17.2% during HD at the follow-up stage. Table 5.3.

Out of them 5 cases were identified as positive for both HBV and HCV.

**Table 5.3: Prevalence of HBV & HCV among patients before and during HD (n=349)**

Results	Positive		Negative	
	F	%	F	%
<b>Before HD</b>				
• HBsAg	10	2.9	339	97.1
• Anti-HCV	7	2	342	98
<b>During HD</b>				
• HBsAg	50	14.3	299	85.7
• Anti-HCV	60	17.2	289	82.8

### 5.1.5. Differences in prevalence of HBV&HCV before and during HD

There was a statistically significant difference before and during HD regarding the prevalence of HBV among HD patients (McNemar test;  $P$ -value=0.000).

Also, there was a statistically significant difference before and during HD regarding the prevalence of HCV among HD patients (McNemar test;  $P$ -value=0.000).

Table 5.4.

**Table 5.4: Prevalence of HBV&HCV among patients before and during HD (n=349)**

Results of HBsAg & Anti-HCV							P-value
HBsAg before HD	HBsAg during HD						
	Positive		Negative		Total		
	F	%	F	%	F	%	
• Positive	10	2.9	0	0.0	10	2.9	0.000
• Negative	40	11.4	299	85.7	339	97.1	
<b>Total</b>	<b>50</b>	<b>14.3</b>	<b>299</b>	<b>85.7</b>	<b>349</b>	<b>100</b>	
Anti-HCV before HD	Anti-HCV during HD						P-value
	Positive		Negative		Total		
	F	%	F	%	F	%	
• Positive	7	2.0	0	0.0	7	2.0	0.000

• Negative	53	15.2	289	82.8	242	98	
<b>Total</b>	<b>60</b>	<b>17.2</b>	<b>289</b>	<b>82.8</b>	<b>34</b>	<b>100</b>	<b>9</b>

### 5.1.6 Prevalence of HBV&HCV among patients during HD by dialysis units in hospitals

A statistically significant association was found in the prevalence of HBV by dialysis units in hospitals (Chi-square test;  $p=0.018$ ). For HBV the highest prevalence of positivity was found at Al-Thowrah hospital 9.2%, while both Al-Jomhury and Military hospitals 2.6%.

For HCV the highest prevalence was found at Al-Thowrah hospital 9.5%, followed by Military hospital 4.6%, then Al-Jomhury hospital 3.2%. No statistical significant association in the prevalence of HCV and dialysis units in hospitals (Chi-square test;  $P\text{-value}=0.287$ ).Table 5.5.

**Table 5.5: Prevalence of HBV&HCV among HD patients during HD by dialysis units in hospitals**

Hospital name	Results during HD							
	HBV				HCV			
	Positive		Negative		Positive		Negative	
	F	%	F	%	F	%	F	%
• Al-Thowrah	32	9.2	128	36.7	33	9.5	127	36.4
• Al-Jomhury	9	2.6	72	20.6	11	3.2	70	20.1
• Military	9	2.6	99	28.4	16	4.6	92	26.4
<b>Total</b>	<b>50</b>	<b>14.3</b>	<b>299</b>	<b>85.7</b>	<b>60</b>	<b>17.2</b>	<b>289</b>	<b>82.8</b>
<i>Chi-square- test</i>	<b>p-value=0.018</b>				<b>p-value=0.287</b>			

### **5.1.7 Prevalence of HBV&HCV among patients during HD by demographic data**

- **Prevalence of HBV& HCV by the patients' age**

The mean age for HBV positive patients was  $39 \pm 13$  year, while for HBV negative patients was  $43 \pm 16$  year, statistically significant differences in the prevalence of HBV by age of patients was not found (t-test;  $p=0.103$ ). On the other hand, no statistically significant differences in the prevalence of HCV by the age of the patients (t-test;  $p=0.192$ ). The mean age for HCV positive patients was  $40 \pm 13$  and for HCV negative patients was  $43 \pm 16$  year. Table 5.6.

- **Prevalence of HBV& HCV by the patient's sex**

There were no statistically significant association in the prevalence of HBV by sex of patient (Chi-square test;  $p=0.466$ ). Male patients were found to be more susceptible to HBV than female patients. On the other hand, for HCV no significant association were found by patient sex (Chi-square test;  $p=0.455$ ). Table 5.6.

- **Prevalence of HBV& HCV by the patients' educational level**

A statistical significant association was found in the prevalence of HBV by the level of education (Chi-square test;  $p=0.000$ ). Most patients with HBV were educated (11.1%). On the other hand in contrast no statistical significant association in the prevalence of HCV by the level of education (Chi-square test;  $p=0.169$ ), most patients with HCV were found in education category (52.4%).Table 5.6.

- **Prevalence of HBV& HCV by the patients' occupation**

There were no statistically significant association in the prevalence of HBV by the occupation of the patient (Chi-square test;  $p=0.250$ ). On the other hand, a statistically significant association in the prevalence of HCV by occupation was not found (Chi-square test;  $p= 0.184$ ). Table 5.6.

- **Prevalence of HBV& HCV by the patients' place of resident**

There was no statistically significant association in the prevalence of HBV by a resident of the patient (Chi-square test;  $p=0.233$ ). On the other hand, no statistically significant association in the prevalence of HCV by a resident of the patient (Chi-square test;  $p= 0.402$ ). Table 5.6.

**Table 5.6: Prevalence of HBV&HCV among patients during HD by demographic data (n=349).**

Demographic data	Results during HD							
	HBsAg				Anti-HCV			
	Positive		Negative		Positive		Negative	
	F	%	F	%	F	%	F	%
<b>Age</b>	<b>p-value=0.103</b>				<b>p-value=0.192</b>			
• <18 year	0	0.0	8	2.3	1	0.3	7	2.0
• 18-24 year	6	1.7	27	7.7	5	1.4	28	8
• 25-31 year	12	3.4	43	12.3	9	2.6	46	13.2
• >31 year	32	9.2	221	63.3	45	12.9	208	59.6
<b>Sex</b>	<b>p-value=0.466</b>				<b>p-value=0.455</b>			
• Male	32	9.2	175	50.1	33	9.5	174	33
• Female	18	5.2	124	35.5	27	7.7	115	27
<b>Marital status</b>	<b>p-value=0.628</b>				<b>p-value=0.123</b>			
• Married	39	11.2	242	69.3	44	12.6	237	44
• Unmarried	11	3.2	57	16.3	16	4.6	52	16
<b>Level of education</b>	<b>p-value=0.000</b>				<b>p-value=0.169</b>			
• Uneducated	11	3.1	115	32.9	21	6.0	105	30.2
• Educated	39	11.1	183	52.4	39	11.1	183	52.4
<b>Occupation</b>	<b>p-value=0.250</b>				<b>p-value=0.184</b>			
• Unemployed	17	4.8	85	24.5	21	6.0	81	23.2
• Governmental employee	8	2.3	47	13.5	12	3.4	43	12.3
• Self-employed	8	2.3	47	13.5	5	1.4	56	16.0
• Housewife	17	4.9	119	34.1	21	6.0	115	33.1
<b>Place of resident</b>	<b>p-value=0.233</b>				<b>p-value=0.402</b>			
• Urban	38	10.9	202	57.9	44	12.6	169	48.2
• Ruler	12	3.4	97	27.8	16	4.6	93	26.6



### 5.1.8 Prevalence of HBV&HCV by medical history of HD patients

- **Prevalence of HBV&HCV in relation to the frequency of HD sessions**

. A statistically significant correlation between the prevalence of HBV and the frequency of HD sessions was not observed (Spearman correlation=0.009; p-value=0.866). The mean frequency for negative HBV patients was 2±0 session and for HBV positive patients was 2±0 session.

On the other hand, a statistically significant correlation was not found between the prevalence of HCV and frequency of HD (Spearman correlation =0.004; p-value=0.944). The mean frequency of HD sessions for negative HCV patients was 2±0 session and for HCV positive patients was 2±0 session. Table 5.7.

**Table 5.7: Prevalence of HBV & HCV by frequency of HD per week (n=349).**

Frequency of HD session per week	HBsAg				Anti-HCV			
	Positive		Negative		Positive		Negative	
	F	%	F	%	F	%	F	%
• Once	0	0.0	2	0.6	0.0	0.0	2	0.6
• Twice	47	13.5	279	79.9	57	16.3	26	77.1
• Three	3	0.9	18	5.2	3	0.9	18	5.2
<b>P-value</b>	<b>0.866</b>				<b>0.944</b>			

- **Prevalence of HBV & HCV in relation to the duration of HD**

Varying duration on HD is spent by patients, ranging from 1 year to 25 years. The study found a strong correlation between the prevalence of HBV and HD duration (Spearman correlation=0.189; p-value=0.000). The mean duration for negative HBV patients was a 5±4 year and for HBV positive patients was 7 ±4 years.

On the other hand, a strong correlation was found between the prevalence of HCV and duration of HD (Spearman correlation= 291; p-value=0.000). The mean time duration for HCV negative patients was 4±3 years while for positive HCV was 8±5 years. Table 5.8.

**Table 5.8: Prevalence of HBV&HCV by duration of HD (n=349)**

Duration of HD	HBsAg				Anti-HCV			
	Positive		Negative		Positive		Negative	
	F	%	F	%	F	%	F	%
• <6 years	27	7.7	214	61.3	19	5.4	22	63.6
• 6-10 years	17	4.9	63	18.1	25	7.2	55	15.8
• 11-15 year	4	1.1	13	3.7	8	2.3	9	2.6
• >15 year	2	0.6	9	2.6	8	2.3	3	0.9
<b>P-value</b>	<b>0.000</b>				<b>0.000</b>			

- **Prevalence of HBV according to HB vaccine**

Table 5.9 presents a history of vaccination against HBV among HD patients in relation to the prevalence of HBV. The results showed that all patients who received a vaccine against HBV 42 (12%) were HBsAg negative in contrast 50 (14.3%) who did not receive a vaccine against HBV was positive. A statistically significant correlation was found between the prevalence of HBV and vaccination against HBV during HD (Phi- test= 0.145; p-value=0.007).

**Table 5.9: Prevalence of HBV by HB Vaccine among HD patients (n=349).**

Vaccination against HBV	HBsAg during HD				P-value
	Positive		Negative		
	F	%	F	%	
• Yes	0	0.0	42	12.0	<b>0.007</b>
• No	50	14.3	257	73.7	
<b>Total</b>	<b>50</b>	<b>14.3</b>	<b>299</b>	<b>85.7</b>	

## 5.2. The Results Among Staff Nurses

### 5.2.1 Demographic characteristics of the nurses

Table 5.10 shows that the age means and SD was  $31.5 \pm 7.3$ . 56.9% of the nurses were male and 43.1% were female. Regarding the marital status of the respondents, the table revealed that married respondents constituted 69% of the study population and the single population represented 25.9% of the study population. The majority of the respondents 79.3% have a diploma in nursing and 20.7% have BSc degree in nursing. Regarding the experience as shown in table nearly 48.3% of the participants have less than 5 years of experience working while 51.7% have more than 5 years. 74.1% of the participants were not received any education and training programs regarding infection control.

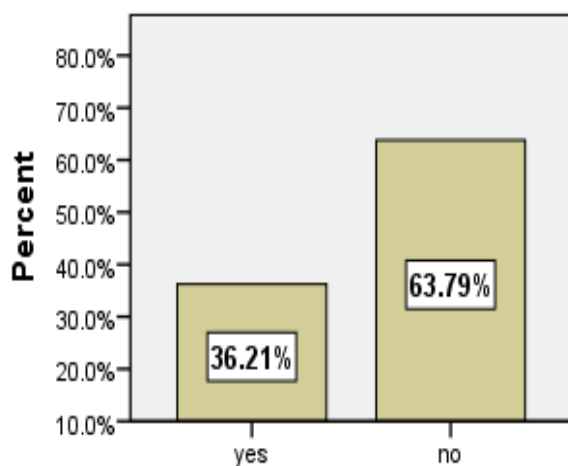
**Table 5.10: Demographic characteristics of the nurses (N=58)**

<b>Demographic data</b>						
<b>Age in years</b>	<b>N</b>	<b>Minimum</b>	<b>Maximum</b>	<b>Mean</b>	<b>S.D</b>	
	58	22	60	31.45	7.29	
<b>Hospital name</b>						
• Al-Thowrah					33	56.9
• Al-Jomhury					15	25.9
• Military					10	17.2
<b>Sex</b>						
• Male					33	56.9
• Female					25	43.1
<b>Marital status</b>						
• Married					40	69.0
• Single					15	25.9
• Divorced					2	3.4
• Widowed					1	1.7

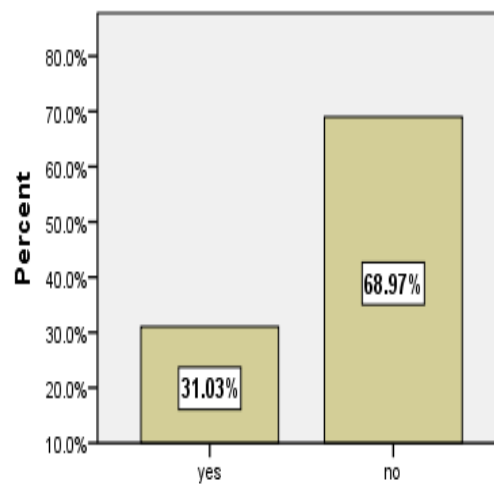
<b>Level of education</b>		
• Diploma degree	46	79.3
• BSc degree	12	20.7
<b>Duration of working</b>		
• <5	28	48.3
• ≥5	30	51.7
<b>Course Training in infection control</b>		
• Yes	15	25.9
• No	43	74.1

### 5.2.2 History of HB vaccine among nurses

Figure 5.4 shows that 37 (63.79%) of nurses did not receive HB vaccine prior to the period of employment in the dialysis unit while 21(36.2%) were received HB vaccine. In contrast, about 40 (68.9%) of the nurses did not receive HB vaccine during the period of employment in dialysis unit while 18(31.03%) were received HB vaccine. Figure 5.5.



**Table 5.4: Vaccination against HBV prior the period of employment in dialysis unit**



**Table 5.5: Vaccination against HBV during the period of employment in dialysis unit**

### 5.2.3 Principles of infection prevention and control in dialysis units

- **Screening, immunization and routine testing of HBV and HCV**

As regards to screening policy for HBV and HCV among patients' prior to dialysis and at follow-up stage, the findings of the study showed that 72.4% of the nurses answered yes there is while 27.6% were answered no screening policy for HBV and HCV of patients' prior to dialysis. In contrast, screening policy for HBV and HCV of staff nurses prior to employment showed that 39.7% of the nurses answered yes there is while 60.3% were answered no screening policy for HBV and HCV for staff nurses prior to employment.

Regarding to regular testing of HD patients for hepatitis B and C virus infections at follow-up stage, more than half 56.9% of the nurses stated that no regular testing of HD patients for hepatitis B and C virus infections at follow-up stage and 93.1% of the nurses were stated that no regular testing of staff nurses for HBV and HCV at regular intervals during employment. On another hand 60.3% of the nurses have answered no routine vaccination for HD patients against HBV before commencing dialysis and 86.2% were answered no routine vaccination for staff nurses against HBV prior to employment in a dialysis unit. Sixty-nine percent (69%) of the nurses were answered no standard precaution and post-exposure prophylaxis for patients and staff nurses in the hospital.

**Table 5.11: Screening, immunization and routine testing for HBV&HCV (N=58)**

Statement	Yes		No	
	F	%	F	%
Screening policy for HBV and HCV of patients' prior to dialysis	42	72.4	16	27.6
Screening policy for HBV and HCV of staff member prior to employment	23	39.7	35	60.3

Regular testing of dialysis patients for hepatitis B and C virus infections at follow-up stage	25	43.1	33	56.9
Regular testing of a staff member for HBV and HCV infections at regular intervals during employment	4	6.9	54	93.1
Routine vaccination of dialysis patients against HBV before commencing dialysis	23	39.7	35	60.3
Routine vaccination of staff members against HBV Prior to employment in the dialysis unit	8	13.8	50	86.2
Standard precaution post-exposure prophylaxis for patients and staff members	18	31.0	40	69.0

- **Standard and transmission-based precaution**

Table 5.12 reveals standard and transmission-based precaution, more than two-third (79.3%) were separated patients with HBV&HCV in a separate room and their equipment and supplies from those used for non-HBV&HCV-infected patients, two-third (69.0%) were performed hand hygiene before and after contact with patient or environment.

63.8% did not wear disposable gloves, masks, gowns, and eye protection when caring for the patient or touching the patient's equipment at the dialysis station, half (50.0%) of the staff were not cleaned & disinfection the access site using an antiseptic solution soap/scrub and water and most of them (82.8%) were not cleansed and disinfection the skin by (2%) chlorhexidine gluconate/70% isopropyl alcohol, 70% alcohol, or 10% povidone-iodine.

**Table 5.12: Standard and transmission-based precaution (N=58).**

Statement	Yes		No	
	F	%	F	%
Separate patients with HBV&HCV in a separate room and their equipment and supplies from those used for non-HBV&HCV-infected patients	46	79.3	12	20.7
Perform hand hygiene before and after contact with a patient or environment	40	69.0	18	31.0
Wear disposable gloves, masks, gowns, and eye protection when caring for the patient or touching the patient's equipment at the dialysis station	21	36.2	37	63.8
Clean & disinfection the access site using an antiseptic solution soap/scrub and water	29	50.0	29	50.0
Cleanse and disinfection the skin by 2% chlorhexidine gluconate/70% isopropyl alcohol, 70% alcohol, or 10% povidone iodine	10	17.2	48	82.8

Statement	Yes		No	
	F	%	F	%
Hospital-grade disinfectant is used for all patient areas	44	75.9	14	24.7
Cleaning of spills of blood or body fluids	19	32.8	39	67.2
Prevent of mould contamination resulting from water damage or wetting of permeable walls, furniture, etc	37	63.8	21	36.2
Disposed used supplies and dialyzers to prevent contamination of patients and environmental surfaces	35	60.3	23	39.7

- **Environmental cleaning and disinfection**

Table 5.13 presents the environmental cleaning and disinfection, more than two-third (75.9%) were disinfected all patients areas, more than half (67.2%) did not cleaned of spills of blood or body fluids, more than half (63.8%) were prevented of mould contamination resulting from water damage or wetting of permeable walls, furniture, and more than half (60.3%) of the staff were disposed used supplies and dialyzers to prevent contamination of patients and environmental surfaces.

**Table 5.13: Distribution of responses toward environmental cleaning and disinfection (N=58)**



- **Equipment cleaning and disinfection**

As regards to equipment cleaning and disinfection, the results of the study

Statement	Yes		No	
	F	%	F	%
Disinfect of non-disposable items (clamps, scissors, and blood pressure cuffs) before use on another patient	26	44.8	32	55.2
Clean and disinfection of hemodialyzer port caps	29	50.0	29	50.0
Clean and disinfection of interior pathways of the dialysis machine	33	56.9	25	43.1
Clean and disinfection of water treatment and distribution system	41	70.7	17	29.3
Clean and disinfection of environmental surfaces include exterior surfaces of the hemodialysis machine	35	61.4	21	38.6

showed that (55.2%) of staff nurses were not disinfected of non-disposable items (clamps, scissors, and blood pressure cuffs) before use on another patient, half (50.0%) of them were not cleaned and disinfected of hemodialyzer port caps, (56.9%) were cleaned and disinfected of interior pathways of dialysis machine, most of them (70.7%) were cleaned and disinfected water treatment and distribution system and (61.4%) were cleaned and disinfected environmental surfaces include exterior surfaces of hemodialysis machine. Table 5.14.

**Table 5.14: Distribution of responses toward equipment cleaning and disinfection (N=58).**

Statement	Yes		No	
	F	%	F	%
Disinfected the stopper with alcohol before accessing the vial	35	60.3	23	39.7
Use a single sterile needle and syringe for each access	42	72.4	16	27.6
Recapped Needles	41	70.7	15	25.9
Discarded used sharps in sharps containers	23	39.7	35	60.3

- **Safe medication and injection practice**

Regarding responses toward safe medication and injection practice, the results of the study showed that more than half (60.3%) of staff nurses were disinfected the stopper with alcohol before accessing the vial, more than two-third (72.4%) were used a single sterile needle and syringe for each access, most of them (70.7%) were recapped needles, and (60.3 %) did not discard used sharps in sharps containers. Table 5.15.

**Table 5.15: Distribution of responses toward safe medication and injection practice (N=58).**

- **Hospital infection control polices, program, team, and training**

Table 5.16 presents the hospital infection control polices, program, team, and training. The results of the study showed that (69.0%) had not infection control program at hospital, (63.8%) had not infection control policies or guidelines in unit at hospital, most of the staff nurses (70.7%) did not receive some form of training or orientation about infection prevention and control in hospitals and most of the hospitals (75.9%)

Statement	Yes		No	
	F	%	F	%
The present of infection control program at dialysis units in the hospital	18	31.0	40	69.0
The present of infection control policies or guidelines in dialysis units	20	34.5	37	63.8
Staff received some form of training on infection prevention and control	16	27.6	41	70.7
The present of active infection control team at the hospital	13	22.4	44	75.9
Staff received initial and on-going education on the basic principles and practices of dialysis	34	58.6	23	39.7

had not active infection control team at hospital.

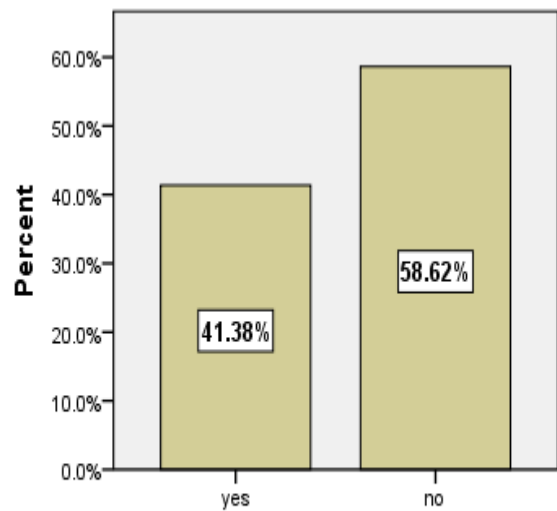
As regards to if staff received initial and on-going education on the basic principles and practices of dialysis, the findings showed that more than half (58.6%) of the staff nurses were received initial and on-going education on the basic principles and practices of dialysis answered yes.

**Table 5.16: Distribution of hospital infection control polices, program, team, and training**

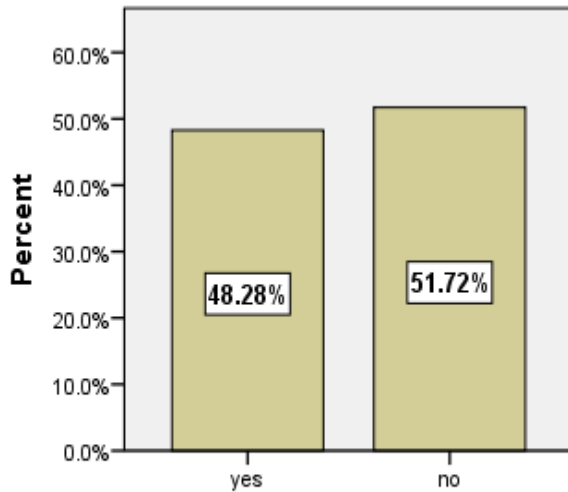
- **Water treatment and testing**

Figure 5.6 reveals the distribution of test of dialysis water and dialysate at least monthly. The findings of the study showed that 28(48.28%) were tested the dialysis water and dialysate at least monthly and 34(51.7%) did not test the dialysis water and dialysate at least monthly.

As regards monitor water quality; both microbial and chemical components 24(41.38%) were monitored water quality; both microbial and chemical components at the hospital and 34(58.6%) did not monitor water quality. Figure 5.7.



**Table 5.7: Monitor water quality; both microbial and chemical components**



**Table 5.6: Test of dialysis water and dialysate at least monthly**

#### **5.2.4 Principles of infection prevention and control in dialysis units in relation to hospitals**

- **Vaccination of nurses against HBV by hospitals**

Table 5.17 indicates the HB vaccine among nurses prior to the period of employment in dialysis units by hospitals. The finding of the study showed that 36.2% of nurses were vaccinated against hepatitis B virus prior the period of employment in dialysis units (17.2% in Al-Thowrah hospital, 12.1% in Al-Jomhury and 6.9% in Military hospital).

A statistically significant association was not found in relation to HB vaccine according to the hospitals (Chi-square test: p-value=0.530).

**Table 5.17: HB Vaccine among nurses prior to the period of employment in dialysis by hospitals (N=58)**

Hospital name	HB vaccine prior to employment				P-value
	Yes		No		
	F	%	F	%	
• Al-Thowrah	10	17.2	23	39.7	<b>0.530</b>
• Al-Jomhury	7	12.1	8	13.8	
• Military	4	6.9	6	10.3	
<b>Total</b>	<b>21</b>	<b>36.2</b>	<b>37</b>	<b>63.8</b>	

Table 5.18 indicates the HBV vaccination among nurses during the period of employment in dialysis units by hospitals. The finding of the study showed that 31.0% of nurses were vaccinated against hepatitis B virus during the period of employment in dialysis units (24.1% in Al-Thowrah hospital, 6.9% in Al-Jomhury and 0.0% in Military hospital).

A statistically significant association was observed in relation to HB vaccine according to the hospitals (Chi-square test: p-value=0.036).

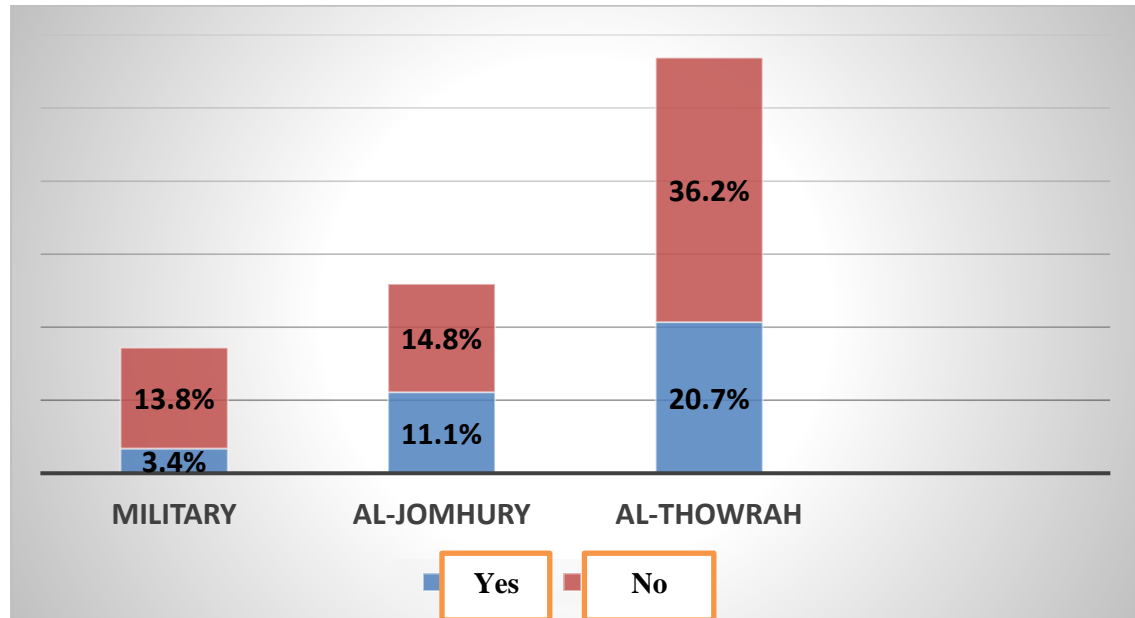
**Table 5.18: HB vaccine among nurses during the period of employment in dialysis by the hospitals (N=58)**

Hospital name	HB vaccine during employment				P-value
	Yes		No		
	F	%	F	%	
• Al-Thowrah	14	24.1	19	32.8	<b>0.036</b>
• Al-Jomhury	4	6.9	11	19.0	
• Military	0	0.0	10	17.2	
<b>Total</b>	<b>18</b>	<b>31.0</b>	<b>40</b>	<b>69.0</b>	

• **Screening, immunization and routine testing by hospitals**

Figure 5.8 shows the total responses among staff nurses toward screening, immunization and routine testing by the hospital. The findings of the study showed that the total responses was 35.2% ( Al-Thowrah hospital 20.7%, Al-Jomhury 11.1% and Military hospital 3.4%) were applied screening, immunization and routine testing in dialysis units in hospitals while 64.8% (36.2% in Al-Thowrah hospital, 14.8% in Al-Jomhury, and 13.8% in Military hospital) did not applied screening, immunization and routine testing in dialysis units in hospitals.

The finding of the study showed that no statistically significant association in screening, immunization, and routine testing according to the hospitals (Chi-square test: p-value=0.076).

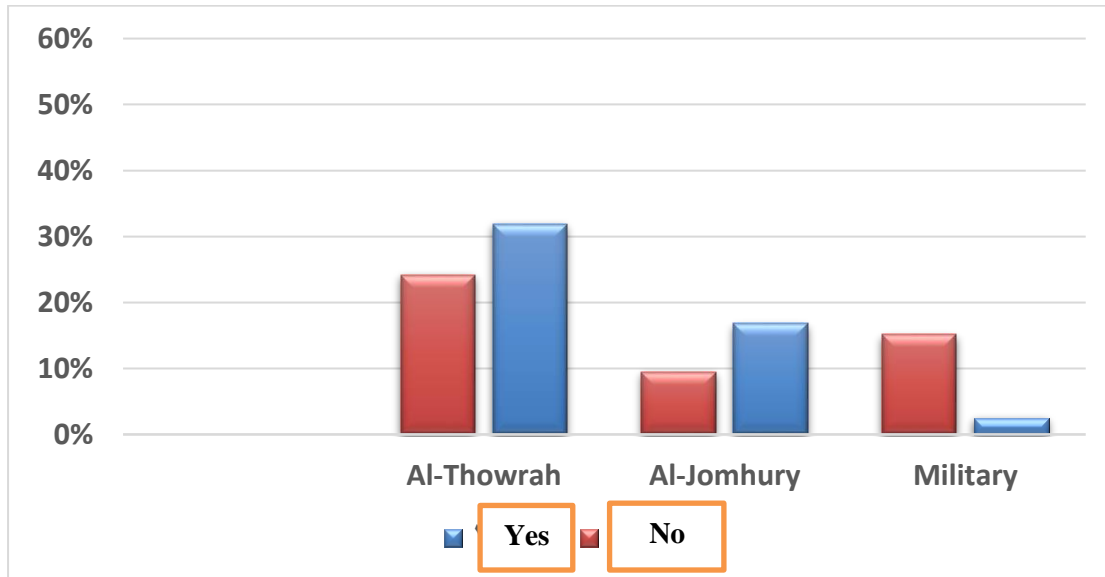


**Figure 5.8: Total responses toward screening, immunization and routine testing by the hospital (N=58).**

- **Standard and transmission-based precaution**

Figure 5.9 presents the total responses among staff nurses toward standard and transmission-based precaution among staff nurses by hospitals. The total responses 51.2% (Al-Thowrah hospital, 31.9%, Al-Jomhury 16.8% and Military hospital 2.5%) were practiced standard and transmission-based precaution in HD units in hospitals while 48.8% (24.2% in Al-Thowrah hospital, 9.5% in Al-Jomhury and 15.1% in Military hospital) did not practiced standard and transmission-based precaution in HD units in hospitals.

The results of the study showed that a statistically significant association was found between standard and transmission-based precaution and the hospitals (Chi-square test: p-value=0.000).



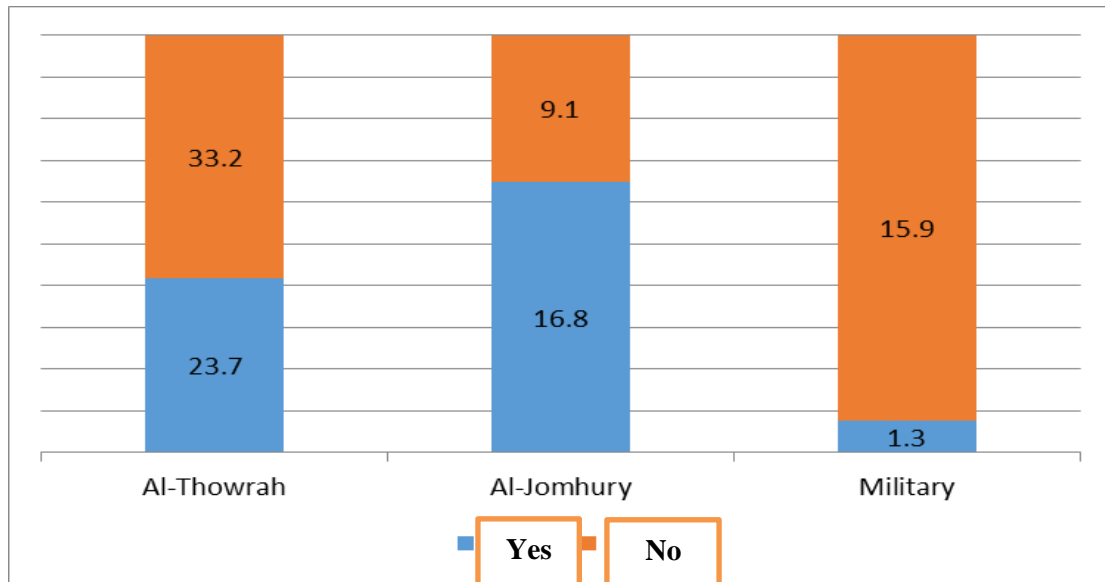
**Figure 5.9: Total responses toward standard and transmission-based precaution by hospital (N=58).**

- **Environmental cleaning and disinfection by hospitals**

Figure 5.10 presents the total responses among staff nurses toward environmental cleaning and disinfection by the hospital. The result of the study showed that the total responses among staff nurses was 41.8% (Al-Thowrah hospital 23.7%, Al-Jomhury 16.8% and Military hospital 1.3%) were cleaned and disinfected of environmental surfaces in HD units in hospital while 58.2% (33.2% in Al-Thowrah hospital, 9.1% in Al-Jomhury and 15.9% in Military hospital) did not cleaned and disinfected of environmental surfaces in HD units.



The finding of the study showed that a statistically significant association was found between environmental, cleaning and disinfection and hospitals (Chi-square test: p-value=0.000).

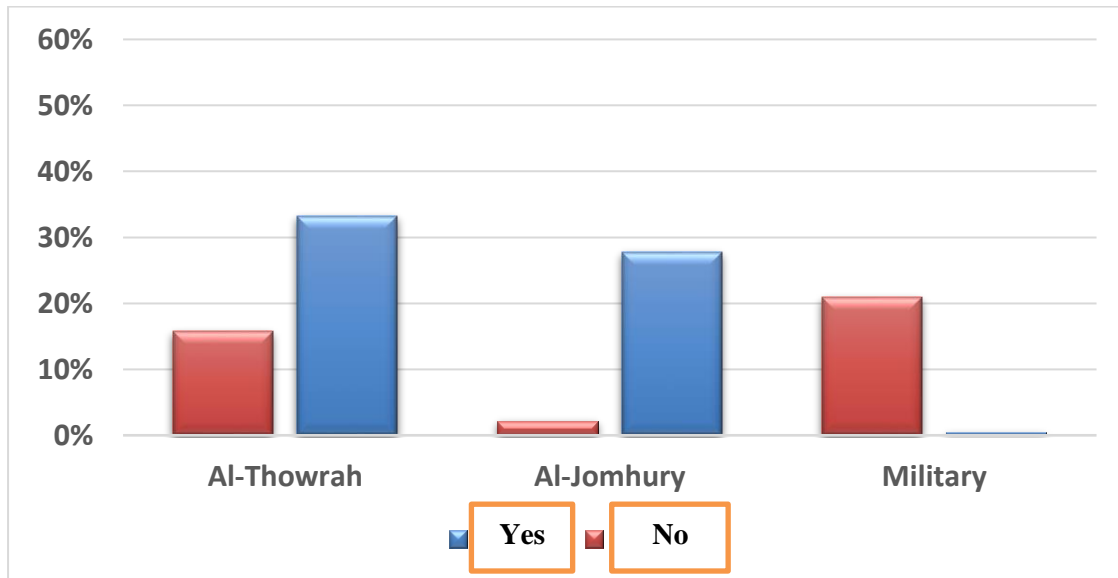


**Figure 5.10: Total responses toward environmental cleaning and disinfection by the hospital (N=58).**

- **Equipment cleaning and disinfection by hospitals**

Figure 5.11 reveals the total responses among staff nurses toward equipment cleaning and disinfection by the hospital. The total responses among staff nurses was 61.4% (Al-Thowrah hospital 33.2%, Al-Jomhury 27.7% and Military hospital 0.4%) were cleaned and disinfected equipment in HD units while 38.7% (15.7% in Al-Thowrah hospital, 2.1% in Al-Jomhury and 20.9% in Military hospital) did not cleaned and disinfected equipment in HD units in hospitals.

The finding of the study showed that a statistically significant association was found in relation to total responses toward equipment cleaning and disinfection according to the hospitals (Chi-square test: p-value=0.000).

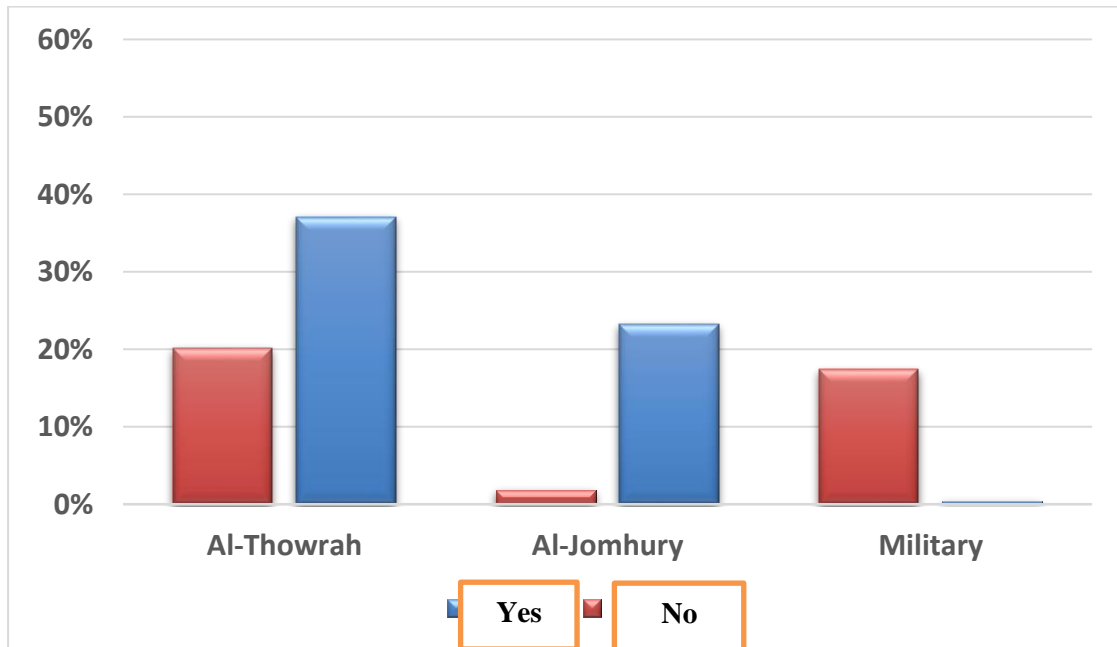


**Figure 5.11: Total responses toward equipment cleaning and disinfection by the hospital (N=58)**

- **Safe medication and injection practice by hospitals**

Figure 5.12 reveals the total responses among staff nurses toward safe medication and injection practice by the hospital. The total responses among staff nurses was 60.7% (Al-Thowrah hospital 37.1%, Al-Jomhury 23.2% and Military hospital 0.4%) were practiced safe medication and injection in HD units while 39.3% (20.1% in Al-Thowrah hospital, 1.8% in Al-Jomhury and 17.4% in Military hospital) of the staff nurses were did not practiced safe medication and injection in HD units.

The results of the study showed that a statistically significant association was seen in relation to total responses of safe medication and injection practice according to the hospital (Chi-square test: p-value=0.000).



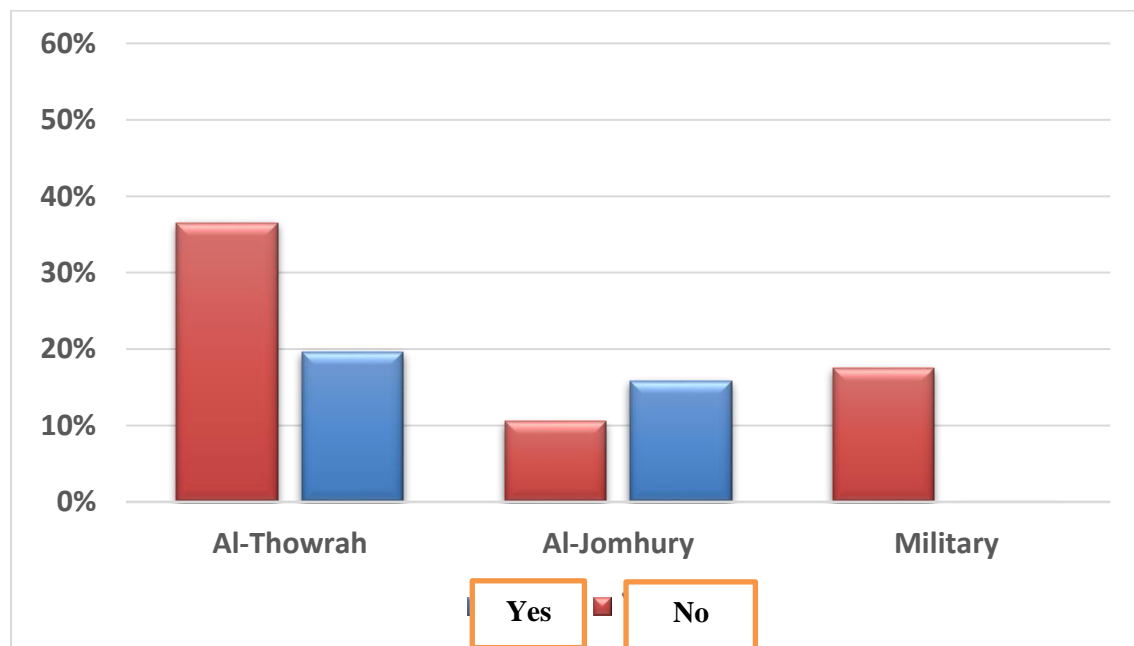
**Figure 5.12:** Total responses toward safe medication and injection practice by hospitals (N=58)

- **Hospital infection control policies, program and training by hospitals**

Figure 5.13 shows the total responses among staff nurses toward infection control policies, program and training by the hospital. The overall responses toward hospital infection control policies, program, team, and training presented that only 35.4% (Al-Thowrah hospital 19.6%, Al-Jomhury 15.8% and Military hospital 0.0%) of the nurses were answered yes there is a hospital infection control policies, program, team and training while 64.6% (36.5% in Al-Thowrah hospital, 10.5% in Al-Jomhury and 17.5%

in Military hospital) of the nurses were not familiar with these policies, program, and training in HD units.

The results of the study showed that a statistically significant association was observed in relation to infection control policies, program and training according to hospitals (Chi-square test: p-value=0.000).

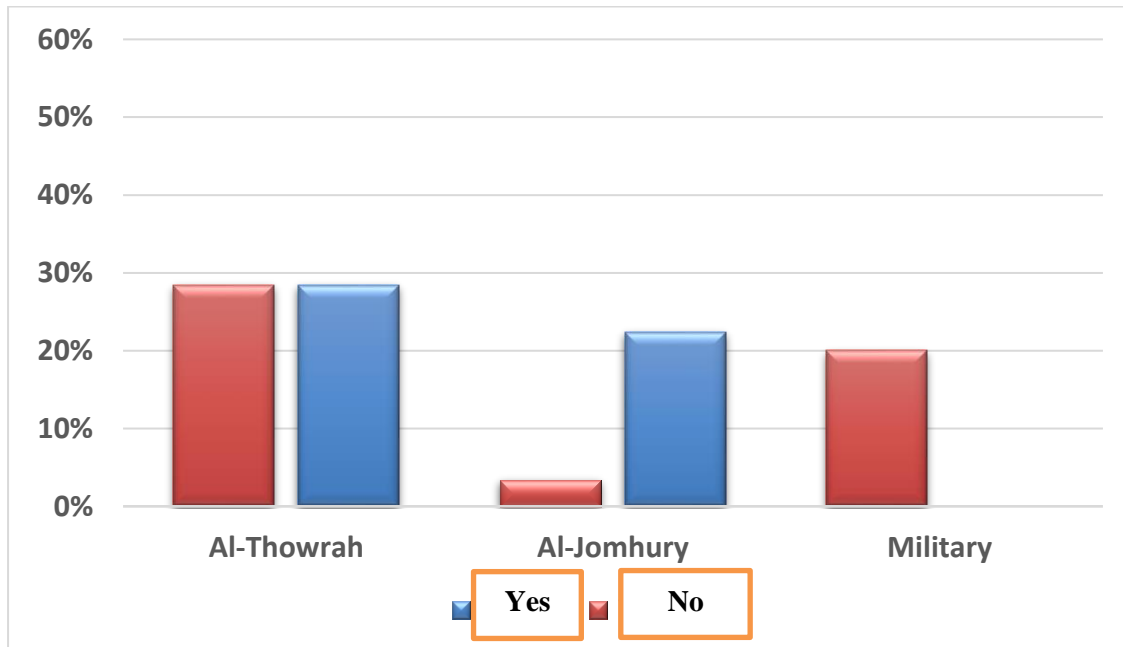


**Figure 5.13: Total responses toward infection control policies, program and training by hospitals (N=58)**

- **Water treatment and testing by hospitals**

Figure 5.14 reveals the total responses among staff nurses toward water treatment and testing by the hospital. The total response was 50.9% (Al-Thowrah hospital 28.4%, Al-Jomhury 22.4% and Military hospital 0.0% of the nurses were applied water tested and treated for HD machine in HD units. while 49.1% (28.5% in Al-Thowrah hospital 3.4% in Al-Jomhury and 17.2% in Military hospital) were did not applied water tested and treated for HD machine in HD units.

The results of the study showed that a statistically significant association was found in relation to total responses toward water treatment and testing according to the hospitals (Chi-square test: p-value=0.000).



**Figure 5.14:** Total responses toward water treatment and testing by hospitals (N=58)

## Chapter Six: Discussion

This present study was aimed to investigating the prevalence of hepatitis B and C virus among hemodialysis patients and infection control in dialysis units at hospitals in Sana'a City, Yemen.

### *6.1 Discussion on prevalence of HBV and HCV infection*

Viral hepatitis remains a major hazard for both patients and medical staff of HD units (*Feher & Ambuhi, 2004; Sammy, 2001; Fabrizi et al., 2003*). HBV & HCV became the major form of viral hepatitis among HD patients especially after the decline in the incidence of HBV infection due to several factors including vaccination and screening of transfused blood for HBV (*Fabrizi et al., 2005; El-kader et al., 2010*).

Hemodialysis is a major risk factor for HBV and HCV infection among HD patients. Knowing the prevalence of this infection may help the health policymakers and care providers plan for better screening, management, and treatment of the infection. It has been reported that hemodialysis increases the possibility of blood-borne viral infection but the prevalence is variable from hemodialysis center to center, region to region and country to country and high-cost hemodialysis center vs low-cost hemodialysis center. It is not well understood whether this variability has got any relationship with the basic prevalence of the disease in the community (*El-kader et al., 2010*).

HBV and HCV infections are important causes of morbidity and mortality in patients who undergo HD (*Chan, 2016; Fissell et al., 2004*). These infections may lead to acute or chronic hepatitis, cirrhosis, or hepatocellular carcinoma. Patients who undergo HD are vulnerable to and at risk for HBV and HCV infections because of the immunosuppressive effects of renal failure, increased exposure to blood transfusion, and breakdown of standard infection control and isolation rules (*Chan, 2016*). In addition, insufficient antibody response against infections leads to diagnostic problems in these patients.

Early diagnosis is important to identify nosocomial transmission and damage to the liver can be prevented by early treatment of acute infection. Since 1982, we have an effective vaccine for HBV, yet over 350 million people worldwide are estimated to be chronic HBV carriers. The majority of these carriers live in undeveloped or developing countries (*Chan, 2016*). Chronic HBV infection is seen as highly endemic (>8%) in Southeast Asia, Sub-Saharan Africa, Central Asia, and some Eastern European countries. In these regions, the incidence of HBV infection before the age of 40 years remains high (*Elamin & Abu-Aisha, 2011; Lavanchy, 2004*). In developed countries like North America, Western and Northern Europe, Australia, and some parts of South America, HBV seroprevalence is below 2% (*Elamin & Abu-Aisha, 2011*).

In this study, the overall prevalence of HBsAg in HD patients was 14.3%. This prevalence is higher than that in the USA (0.9%), Switzerland (1.63%), Casablanca

(2%), Iran (4.6%), Jordan (5.9%), Saudi Arabia (Najran) (10%), Bahrain (11.8%), Pakistan (12.4%), and India (14.2%) but lower than Greece (20.4%), Spain (20.9%), Turkey (25%) and Brazil (29.8%) (*Tokars et al., 2004; Ambuhl et al., 2000 ; Boulaajaj et al., 2005; Taremi et al., 2005; Al Hijazat & Ajlouni, 2008; Khan, 2003; Almawi et al., 2004; Khokhar et al., 2004; Chattopadhyay et al., 2005; Siagris et al., 2006; Loza et al., 2005; Yakaryilmaz et al., 2006; Ferreira et al., 2006*).

In this study, the prevalence of HBsAg in HD patients was much higher than that reported in developed countries, HBV prevalence among patients who undergo HD is low (0–10%), whereas the prevalence is higher in developing countries (2%-20%) (*Fabrizi et al., 2008*). The present study result was not similar than reported in Turkey, according to national data from the Turkish Society of Nephrology's, HBsAg seropositivity in HD patients was, 6.8% in 2006, and 4.3% in 2011 (*Erek et al., 2006; Suleymanlar et al., 2011*).

In this study, the overall prevalence of positive anti-HCV 17.2%, positive HBsAg (14.3%) and 5 had mixed infection with HBV and HCV among HD patients with  $P$ -value=0.000. The prevalence of HBV infection within dialysis units in Gaza strip appears lower (8.1%) (*El-kader et al., 2010*). In other neighboring countries like Jordan (5.9%), in Saudi Arabia (10%) and Bahrain (11.8%) (*Al Hijazat & Ajlouni, 2008; Qadi et al., 2004*). This prevalence was lower than the results in the present study.

A similar study conducted in India has reported a high prevalence of HBV of 55% and HCV of 25.8% in patients with HD (*Alavian et al., 2008; Ozer et al., 2011*), which are higher than the results of the present study. The HBV prevalence rate varies from one dialysis unit to another.

The prevalence rate in Europe is reported to be 23% - 43%, in USA 16% - 18%, in Tunisia 18%, in France 2.2%, in Russia 39% - 50%, and in South Africa 17% (*Abu El Makarem et al., 2012*).

In addition, the appearance of serological markers for HBV may be delayed by as long as 6-12 months. Some dialysis centers have reported outbreaks of fulminant HBV infection indicating that immunocompromised hosts, such as end-stage kidney disease patients on dialysis, may develop severe disease from HBV infection (*Joukar et al., 2011*). In India (*Bhaumik & Debnath, 2012*) reported the prevalence of HBV and HCV infection among hemodialysis patient is variable which agree to the results of our study.

On the other hand, studies carried out in various centers worldwide among HD patients have shown a prevalence of HCV as 8% - 36% in North America, (*Zahedi et al., 2012*), 25% - 39% in South America (*Santos et al., 1998*), 1% - 36% in Europe, (*Wang et al., 2010*), 17% - 51% in Asia (*Dentico et al., 1992*), 1.2% - 10% in Iran (*Zahedi et al., 2012*) and 7% - 85% in South Africa (*Boulaajaj et al., 2005*) have reported that among patients on hemodialysis While, 1.4% of patients had HBV infection (*Alavian et al., 2008*).

*Chandra et al. (2004)* have reported that among the patients of chronic kidney disease, renal transplant or hemodialysis, HBV, HCV and infection of both viruses were 7.46% and 37.10% respectively these results are not an agreement to the results of our study. Overall, the prevalence and incidence of HBV and HCV infections in HD patients reflect the prevalence of these infections in the general population, the quality of healthcare services in a community and the standards of infection control practices in HD units are related.

The risk of acquiring HBV infection has been apparent since HD was first performed in the 1960s. In the USA, a large survey of HD centers in 1974 found HBV incidence rates of 6.2% (*CDC, 2001*). Contaminated dialysis machines, other equipment, and environmental surfaces were accused of spreading of HBV among HD patients (*Souza et al., 2003*). Furthermore, HD patients are immunosuppressed; which may lead to increase their susceptibility to infections and could explain the observed high frequency among HD patients (*Al-Sohaibani et al., 1995*). As a result of segregation, universal precautions, vaccination, reduced blood transfusions, and screening of organs before transplantation, the incidence of HBV infection decreased to 0.08% for patients and 0.05% for staff within dialysis units in the USA by 1996 (*CDC, 2001*). These achievements were also supported by better blood bank screening-measures, the introduction of which dramatically decreased the risk of transfusion-associated HBV infection (*Schreiber et al., 1996*). In spite of the reduction of HBV spread within dialysis centers, some isolated outbreaks of HBV infection continue to be reported among HD patients in developed countries (*Lindh et al., 2000*).

In the present study, the rate of 14.3% was higher than the in Turkey (2.37%) and another study including 201 HD patients from Turkey (2.5%) (*Daglar et al., 2014*). The high prevalence of HBsAg in present study may be the result of the absent of the strict rules by the HD units at hospitals regarding to prevention and control measures which includes: precautions such as isolation of HBsAg positive HD patients in



separate rooms, segregation of dialysis machines of anti-HCV positive patients, infection control programs and surveillance of chronically hepatitis B and C disease with vaccination of the susceptible patients' mandatory.

In the present study, the prevalence of HCV was 17.2%, which is higher than reported in Turkish (5.9%) by *Daglar et al.* in 2014. The prevalence of HCV in the present study was higher than reported in other countries which reported that the prevalence of HCV among HD patients was 9% in Lebanon, and Iran (12%) but lower than reported in Syria 54% (*Othman and Monem, 2001*). In Saudi Arabia (19%), Iraq (20%), Turkey (23%), and Palestine (18%) (*Ashkani-Esfahani et al., 2017*). In Saudi Arabia before 2000, prevalence reports ranged from 15% to 90% among different hemodialysis centers (*Karkar, 2007*). Afterward, the study showed a range of 14.7% to 43.9% (*Saxena et al., 2001*). Many of these studies suggested that the duration of the dialysis session was more related to the chance of infection than the repeated blood transfusions (*Saxena et al., 2001; Qadi et al., 2004*). Despite the further increase in dialysis services, the prevalence did not have a significant change during the recent years in Saudi Arabia which may be due to better implementation of infection-control policies and also the screening methods in certain hemodialysis units (*Karkar, 2007*). However, the studies on the epidemiology of HCV infection related to hemodialysis are noticeably insufficient. Our estimated prevalence in Iran is also lower than the previously reported 13.57% was conducted by *Alavian et al., 2010*.

In Yemen, sensitivity analyses suggest that there may be an underestimation for HCV prevalence since measured HCV prevalence in Yemen increased from 1.9% in baseline analysis to 2.8% and 2.4% in the two sensitivity analyses, respectively (*Chaabna et al., 2016*). HCV prevalence among hemodialysis patients increased from 40% in 1999 to 62.7% in 2007 (*Selm, 2010; Chaabna & Abu Raddad, 2014*). Insufficient data on the prevalence of HCV infection, particularly among the patients on maintenance hemodialysis is a barrier for determining the alterations in the trend and risk factors of transmission; thus, present literature show an increase in the overall prevalence in Yemen. Moreover, in Syria, the higher rates of infection ranged from 48.9% to 75% (*Othman et al., 2001*), seems to be continued during the past two decades as well as our present evaluation (54.4%). This might be due to less than the optimal screening of blood and blood products and poor sterilization of equipment in these patients (*Moukeh et al., 2009*). Studies in Jordan showed a decline in the rates of HCV infection among hemodialysis patients (from 49.8% to 16.5%) though the overall rate

was high (35%) (*Bdour et al., 2002; Ghunaimat et al., 2007; Al-Jamal et al., 2009; Batchoun et al., 2011*).

Standardized infection control protocols including the use of disposable gloves, kits, needles, dialyzers, and single-use vials as well as disinfection of surfaces and dialysis machines between hemodialysis sessions with appropriate solutions were the reasons for the decline in the prevalence rates (*Ghazzawi et al., 2015*). In Kuwait, Qatar, and UAE, non-nationals comprise more than three-fourths of the population (*Fent, 2008*).

Documents depict a high prevalence of HCV infection before 2006 among hemodialysis patients in Kuwait, ranging between 27% and 71% (*El-Reshaid et al., 1995; Wreghitt et al., 1999; Sadeghi et al., 2016; Mohamoud et al., 2016*). Those results were higher than results in the present study. Obviously, studies on the prevalence of HCV infection and the possible changes in its trend are not well investigated in Kuwait country during the last decade, even the reports of the health ministry revealed no data in this case (*Sadeghi et al., 2016*). In UAE, it seems that the medical care providers still do not take HCV infection as a major concern, especially among patients undergoing dialysis treatment, and studies are lacking and the changes in the trend are not measurable. In Qatar, HCV prevalence was as high as 44.6% in hemodialysis patients according to a recent systematic review (*Mohamoud, 2013*). A study reported the prevalence of HCV infection among the Bahraini hemodialysis patients, a rate of 7.4% among 81 patients recruited from tertiary health centers of the country (*Qadi et al., 2004*). .

Latest reports depicted the prevalence of HCV infection in the United States hemodialysis centers to be in a range of 8% to 16.8% (*Finelli et al., 2002; Chaabna, & Abu Raddad, 2014*) which was about 5 times greater than the prevalence within the country's general population (1.6%) (*Armstrong et al., 2006*) this results in line with the present study.

The prevalence of HBV in the present study also higher than reported in Europe, a prevalence of 11.5% was reported in 2003, while Japan's HCV infection prevalence among hemodialysis patients was 13.4% (*Goodkin et al., 2003*). In some other reports from European developed countries such as Belgium, Germany, Spain, Sweden, United Kingdom, and Italy, prevalence rates of 6.8%, 6%, 12%, 9%, 15%, 3%, and 16% were reported, respectively (*Jadoul et al., 2004*) but lower than reported in France 30% and Poland, Hungary 44% (*Johnson et al., 2009*). .

As it is demonstrated, in contrast with the developed countries, some Middle-East countries such as Iran, Turkey, Lebanon, Palestine, and Saudi Arabia may have had better hygienic condition; however, the lower rates of infection can be due to the lower number of patients and the sample population and also the number of dialysis units in the country, for example in areas like Iraq and Palestine, specifically Gaza strip (*El-kader et al., 2010; Abumwais & Idris, 2010; Al Zabadi et al., 2016*). The mechanisms responsible for HCV infection transmission in hemodialysis services in the Middle-East countries has not been recognized properly yet. However, some investigations have reported that cross-infection through hemodialysis machines may be in charge of the transmission which necessitates more attention on sterilization and control of infection in dialysis units (*Alavian, 2009*).

Diagnosis and treatment of all hemodialysis patients who are infected with the virus, education of nurses and all health care providers involved with these cases, and organizing prevention programs regarding the natural characteristics of each country and its population are suggested as prevention programs which can be initiated in Middle-East countries for better evaluation and reduction of HCV infection (*Alavian, 2009; Alavian, 2008*). Nevertheless, successful control of the infection needs further investigations to assess the effectiveness of different preventive and diagnostic policies. Preventive programs vary in different regions and various societies. Several studies are focused on isolating hemodialysis patients while some others attempted to use specified equipment and services for these patients and disinfection of the devices and the environment infection (*Alavian et al., 2010; Barril and Traver., 2003; Alter et al., 2001*).

HCV seroprevalence in HD patients differs among countries and among HD units in the same country between 4–60% (*Elamin & Abu-Aisha, 2011; Agarwal, 2011*). HCV seroprevalence was reported as 1%–5% in Brasil, Eastern Europe, Mediterranean countries, India, and some Asian and African countries (*Wasley & Alter, 2000*). In Dialysis Outcomes and Practice Patterns Study (DOPPS) HCV seroprevalence among HD patients in countries including France, Germany, Italy, Japan, Spain, United Kingdom, and the USA was reported between 2.6% and 22.9% with a mean value of 13.5% (*Johnson et al., 2009*). In another registry study in 2009, the seroprevalence was reported as 7.9% in Asia-Pacific countries; below 5% in Australia, New Zealand, Korea, Japan, and Thailand; 5%–15% in Hong Kong, Taiwan and Malaysia and over 15% in China (*Fissell et al., 2004*).

Similar results were found in Turkish Nephrology Society (TSN) reported that HCV seroprevalence among HD patients was 15.9% in 2006 and 7.9% in 2011 (*Erek et al., 2006; Suleymanlar et al., 2011*).

The prevalence of HBV/HCV co-infection among hepatitis patients was reported in 5 patients of the total HD population which is low when compared with other studies in developed and developing countries: (Moldavia (10%), Venezuela (41%), Japan (54.8%), Poland (92.3%)) (*Covic et al., 1999; Muller et al., 1992; Oguchi et al., 1993; Hurby et al., 1993*). The prevalence of HBV/HCV co-infection among hepatitis patients in the current study was in agreement with that conducted by (*Abed El-kader, 2008*). Co-infection with both HBV and HCV was reported in 4 patients (1.6%) of the total HD population. The prevalence of HBV/HCV co-infection in the study may suggest that the two viruses share a common mode of transmission with increased risk of developing into hepatic diseases.

## **6.2 Discussion on HBV vaccination among HD patients**

The present study revealed that most of the patents nearly 88.3% were not vaccinated against hepatitis B virus before HD and 88% were not received a vaccine against HBV during HD. 31% of staff nurses unvaccinated against HBV during the period of employment in dialysis by the hospital. According to literature, on the one hand of hepatitis B vaccination these results were not consistent with previous studies in Gaza, the first was the study of *Awad* (2009) which revealed that 85.6% of respondents have received hepatitis B vaccination and the second was the study of *El-Dalow* (2011), which reported that 84.7% of the participants have received hepatitis B vaccination and 63.2% of them received three doses, the third was *Elmadhoun* (2011) which revealed that 90.8% of respondents have received hepatitis B vaccination and 79.3% of them received three doses . The research results are better than the results of a research conducted in Jordan which revealed that only 36% of Healthcare Personals (HCPs) were vaccinated (*Al-Omari & Al-Dwairi, 2005*), while 11.3% of the respondents had received three doses in Egypt (*Ismail et al., 2007*). Another study conducted in Iran revealed that 61.5% had received complete vaccination against HBV (*Askarian and Assadian 2009*). Another study conducted in India revealed that 61.2 percent of the dental students had not been vaccinated with hepatitis B (*Singh et al., 2011*).

### 6.3 Discussion on HBV and HCV by demographic characteristics

**Distribution of HBV and HCV by age:** A statistical difference was not found between HBV infection and age of the patients, the patients >31 years old were found more susceptible to HBV than other patients. The present study disagreed with study conducted by Hou et al, the reported that the high number of patients who had HBV infection were between the ages group of 18-45 years (*Hou et al., 2005*). This was an agreement with a study done in Gaza among the general population, which found that the highest percentage of HBsAg among the age group of 30 to 39 years (*Yassin et al., 2002*). On the other hand, other studies showed no statistically significant differences in ages between HBV positive and negative patients (*Covic et al., 1999*). Also no statistically significant differences was found between HCV prevalence and patient's age; this finding is supported by other studies in a different region of the world (*Alavian et al., 2003; Lopes et al., 2006*).

In accord with *Alavian et al. (2008) & Abu El Makarem et al. (2012)* studies results which did not show significant differences in regard to age between hemodialysis patients with HBV or HCV infection compared with hemodialysis patients without HBV or HCV infection whereas, this does not comply with *Taal & van Zyl-Smit (2000)* study that reported a statistically significant relationship between HBV infection and age of the patients in a way that patients aged less than 40 years were found to be more susceptible to HBV than older patients. This observation is in agreement with a previous report from Libya showing that the highest prevalence of HCV antibodies was observed in HD patients aged 36 – 55 years (*Santos, et al., 1998*).

The present study results are showed that age >31 years were found to be more susceptible than older patients but statistically significant differences was not found between HBV and patients aged, this results in contrast with other studies conducted by *Otedo et al. (2003)*, *Wang, et al. (2010)*, *Almawi et al (2004)* and *Patel & Brinsley-Rainisch (2017)* have reported a higher prevalence of HBV or HCV sero-positivity in older patients.

**Prevalence of HBV and HCV by sex:** The results also showed that males HD patients had higher HBV prevalence than females with no statistical association. This may be related to the fact that males in Yemen are more socially active than female. Furthermore, they are more exposed to male-related risk factors for HBV than female. This result was disagreement with that conducted by (*Abed El-kader, 2008*) and with

another study in general populations (*Kalaajieh et al., 2002*). Males recorded a high number of HBV infection than females (*Khosravani et al., 2012*). In this study, no differences were not found between HCV prevalence and sex of the patients. This was disagreement with other studies (*Alavian et al., 2003; Lopes EPA et al., 2006*) while some studies showed that anti-HCV was detected in female more commonly which could be due to females being more exposed particularly during labor (*AlGhamdi et al., 2002; Khattab et al., 2008*). In contrast, HCV was found to be more prevalent in males (*Huraib et al., 1995; Dentico et al., 1992*). The results of *Te and Jensen* (2010) showed that male hemodialysis patients had higher HBV prevalence, whereas *Abu El Makarem et al.* (2012) study showed that male hemodialysis patients had higher HCV prevalence.

These results are in disagreement with the results of study of *Alavian et al. (2008)*. The results of the present study showed that the prevalence of HBV and HCV infection among males was (9.2%) and (9.5%) respectively while in females was (5.2%) and (7.7%) respectively in patients on hemodialysis. The present study results showed that no significant association in regard to sex and prevalence of HBV or HCV infection ( $p>0.05$ ).

***Distribution of HBV and HCV by educational level, marital status, occupation and residence:*** The present study found a statistical association between HBV prevalence among HD patients and education level in which most of HBV positive patients were educated. This result was an agreement with that conducted by (*Abed El-kader, 2008*). On other hand no statistical significant association in prevalence of HBV and HCV and residence and marital status. These findings were similar to those found by *Hou et al., (2005)*. A previous study among the HD in Taiwan showed that HBV is more prevalent among married (*Wang et al., 2002*) similar results were found in our study. A statistically significant relationship was not found between HCV and education level. Currents study result was an agreement with that conducted by *Abed El-kader (2008)*. Previous studies showed that HCV is prevalent among high educated level people (*Wang et al., 2002; El-Sadawy et al., 2004*). The study found a statistical association between HBV and HCV prevalence among HD patients and occupation.

#### ***6.4 Discussion on prevalence of HBV & HCV by hospitals and the duration of HD***

***Prevalence of HBV and HCV by hospitals:*** A statistically significant association in the prevalence of HBV was found by HD hospitals ( $p=0.018$ ). For HBV but no statistically significant association in prevalence of HCV by HD hospital ( $p=0.287$ ).

Regarding prevalence of HBV and HCV by the duration of HD, the current study showed that the mean duration for HBV positive patients was ( $7 \pm 4$  years) and for HCV was ( $7 \pm 4$  years) seropositivity was a strong statistical correlation ( $p=0.000$  and  $p=0.000$  respectively). This is consistent with nosocomial transmission related to dialysis since the longer duration of dialysis represents a longer period at risk of acquiring an infection. Similar observations have been reported by other authors (*Qadi et al., 2004; Elzouki et al., 2006; Reddy et al., 2005; Telaku et al., 2003*).

In the present study a statistically significant relationship was found between HBV and duration of HD, this observation was in disagreement with a previous report in Moldavia (*Covic et al., 1999*) while other studies in Jordan and Brazil showed a direct relationship between HBV and duration on HD (*Al Hijazat & Ajlouni, 2008; Carrilho et al., 2004*). The risk of HBV infection increased with increasing the time duration. In HD patents under investigation, the duration time for HBV negative patients was found to be  $4.4 \pm 4.0$  year and for HCV positive patients was  $6.5 \pm 3.7$  year.

Duration on HD was found to be a statistically significant risk factor for HCV infection in HD setting. The risk of HCV infection increased with increasing the time duration. In HD population under investigation, the duration time for HCV negative patients was found to be a  $3.9 \pm 3.4$  year and for HCV positive patients was  $8.4 \pm 4.9$  year. Other studies from different regions in the world have shown similar results (*Oguchi et al., 1992; Hardy et al., 1992; Okuda et al., 1995; Pujol et al., 1996; Huraib et al., 1995; Jadoul et al., 1993*). This effect may be due to nosocomial transmission of HCV as indicated by other studies (*Allander et al., 1994; Allander et al., 1995*). Epidemiological and molecular studies have shown the role of HD environment for dissemination of HCV between patients (*Bdour et al., 2002; Sartor et al., 2004; Almoroth et al., 2002*). A previous study showed that HCV RNA was resistant to drying at room temperature for at least 48 hours (*Froio et al., 2002*). A statistically significant relationship was not found in the prevalence of HBV and HCV and frequency of HD. The time spent on dialysis therapy has been suggested as an independent risk factor for the infection (*Patel & Brinsley-Rainisch, 2017*).

The present study is in line with what was found by others studies where the risks of HCV infection increase with long duration. In Sudan by *El-Amin et al. (2007)*, in

Egypt by *Sabry et al.* (2007) in Palestine by *Abumwais and Idris* (2010), in Kosovo by *Telaku et al.* (2009) and in China by *Han & Shi-xiang* (2010). Prevention of nosocomial transmission is of vital importance in the Yemen Republic as HCV antiviral treatment is expensive and its availability is limited to only a few centers.

### ***6.5 Discussion on prevalence of HBV&HCV by frequency of HD sessions***

A statistically significant correlation between the prevalence of HBV/HCV and frequency of HD sessions was not observed ( $p\text{-value}>0.05$ ). Similar results were found by *Wiam et al.* (2012) they reported that there were no correlations between a number of HD patients treated in each center and the prevalence or incidence of seropositivity to HBV or HCV ( $p\text{-value}>0.05$ ).

### ***6.6 Discussion on infections prevention and control in HD Units***

Unlike the conditions in general hospital wards, the typical layout and associated conditions in most HD units, wherein multiple patients receive extracorporeal treatment with prolonged blood exposures in the same area and usually with one health-care worker (HCW) caring for more than one patient at the same time, are potential factors that may increase the transmission of infections. Therefore, stricter measures are specifically recommended in this setting in addition to standard precautions, which include but are not restricted to, the following:

***Vaccination of patients and health-care personnel:*** Vaccination against HBV is recommended for all patients with ESKD (ideally before starting HD) and all staff members (*Anonymous, 2001*). Hepatitis B surface antigen (HBsAg) and hepatitis B surface antibody (HBsAb) titers should be obtained before starting dialysis, and HBsAg titers should be checked monthly if HBsAb titers are not at the desired level. If patients are HBsAg positive, they should be dialyzed in an isolation room with dedicated equipment (*Anonymous, 2001*). It is recommended that a staff member be dedicated to the care of these patients for that shift, but this is cost-prohibitive.

The finding of the study showed that 36.2% of nurses were vaccinated against hepatitis B virus prior the period of employment in dialysis units and 31.0% of nurses were vaccinated against hepatitis B virus during the period of employment in dialysis units. Recommended immunization of HD patients, especially those that are dialysis-dependent, include at a minimum (a) hepatitis B vaccine, (b) (*CDC, 2012b*).



Other vaccines recommended for healthy individuals may be used if otherwise indicated, except for any live attenuated vaccines that are generally contraindicated in patients who are immune-compromised (*CDC, 2012b; ACIP, et al., 2013; NCIRD, 2011*). Hepatitis B vaccination is specifically recommended for susceptible healthcare workers at risk for exposure to blood and body fluids (e.g., hemodialysis personnel) (*CDC, 2012b; ACIP et al., 2011*). Most facilities will ensure that the nearby dialysis stations are assigned to patients with high HBsAb titers, and the same staff member may care for them as well. For those patients who were immunized, HBsAb levels should be checked 1–2 months after the third dose and annually. A booster dose may be required if HBsAb levels decline to, 10 mIU/ml (*CDC, 2013*). Baseline and routine (annual or biannual) HCV antibody screening is beneficial for early diagnosis and possible treatment, thus reducing transmission risk (*Anonymous 2001; Mbaeyi and Thompson, 2013*).

**Screening, immunization and routine testing:** As regards to screening policy for HBV and HCV among patients' prior to dialysis and at follow-up a stage, the findings of the study showed that 72.4% of the nurses answered yes. In contrast, screening policy for HBV and HCV of staff nurses prior to employment showed that 39.7% of the nurses answered yes. Regular testing of HD patients for hepatitis B and C virus infections at follow-up stage showed that more than half of the nurses stated that no regular testing of HD patients for hepatitis B and C virus infections. On another hand 60.3% of the nurses have answered no routine vaccination for HD patients against HBV before commencing dialysis and 86.2% were answered no routine vaccination for staff nurses against HBV Prior to employment in a dialysis unit. Sixty-nine percent of the nurses were answered no standard precaution and post-exposure prophylaxis for patients and staff nurses in the hospital (*Malaysian Society of Nephrology, 2018*).

The international bodies unanimously recommended that all HD patients should be screened for HBV and HCV infection on admission, and routinely tested thereafter. However, they differ with regard to testing for HIV infection. Testing for HBV is required for the purpose of isolating the HBV-infected patient and for vaccination and monitoring of susceptible patients. To avoid an erroneous diagnosis of acute HBV infection, which may put the patient at risk when inappropriately taken for treatment in an HBV isolation room, care should be taken to ensure that blood sample for HBsAg testing is not drawn within two to three weeks after the administration of an HBV

vaccine because, during this time, HBsAg may be detected (known as “transient antigenemia”) (*APIC, 2010; Singh, 2007; Ly D, 2002; Mohan et al., 2011*).

The testing for HCV is to identify infected patients, who may be considered as treatment candidates, and to monitor any occurrence of seroconversion to HCV is also recommended by the APIC, CDC, Kidney Disease: Improving Global Outcomes (KDIGO) and ERBP, which should be done at baseline and whenever exposure is suspected, using the blood test (*APIC, 2010; CDC, 2005; ERA/EDTA, 2002a; KDIGO, 2008*). Except for HBV isolation, the APIC, CDC, and KDIGO did not recommend the segregation/ isolation of HCV- and HIV-infected patients during HD treatments (*APIC, 2010; Singh, 2007; KDIGO, 2008*). due to the following reasons: (a) HCV and HIV are not transmitted as efficiently as HBV (viral titer in the infected patients’ blood and the virus’ viability on environmental surfaces are much less as compared with HBV) and (b) standard precautions and the specific measures of infection control recommended for HD units are considered to be sufficient to prevent their transmission. However, treatment of HCV positive patients in separate areas with dedicated staff is recommended by the EBP in 2002 in units with a high prevalence of HCV infection, which has been reiterated in the 2009 A European Renal Best Practice (ERBP) position statement treatments (*ERA/EDTA, 2002a; Covic, 2009*).

These viral diseases, however, remain a potential risk to both HD patients and staff for the following reasons: (a) there is no vaccine as yet to confer immunity for HCV and HIV, (b) the incidence of chronic persistent infection after an acute episode is high in both HCV (80–90%), (c) the prevalence of patients with chronic HCV is currently higher than that of HBV and is much higher among the HD population, (d) the consequence of having a chronic infection with either HCV or HIV can be severe and/or fatal and (e) of utmost significance is the fact that implementation of standard precautions and stricter measures of infection control recommended for HD units cannot always be guaranteed to be consistently and reliably adhered to. Even in HD units with an “ideal set-up,” unintentional breach of recommended infection control practices (i.e., as hand hygiene) do occur, especially at times when urgent interventions are required (*Malaysian Society of Nephrology, 2018*).

Many studies have proven that segregating HD patients according to their virology status have resulted in a decrease in the incidence and prevalence of infections (*Karkar et al., 2014; Mohamed, 2010; Hussein & Mooji, 2010; Yang et al., 2003; Alavian, 2009; Huraib, 2003; Thompson et al., 2011*). By simple logic, this can be

attributed to the physical barrier that prevents exposure of susceptible patients to patients who have identified infection/colonization with pathogenic microorganisms. The staff movements between susceptible and infected patients will definitely be prevented, as well as the sharing of possibly contaminated equipment and other items. Another strategy that can be used is the “temporal segregation,” wherein patients who are suspected of being infectious are dialyzed in the last shift (*Hotchkiss et al., 2007*).

**Standard and transmission-based precaution:** A statistically significant differences were found in relation to standard and transmission-based precaution according to hospitals (p-value=0.000).

As regards to performing hand hygiene before and after contact with patient or environment, there was 69.0% of nurses in HD units were practiced hand hygiene before and after contact with patient or environment. Studies showed that the main route of transmission of hospital acquired infections is via the transiently contaminated hands of the HCW (*Pittet, 2001; Bhalla et al., 2004; Duckro et al., 2005; Kampf & Kramer, 2006*). Therefore, hand hygiene is singled out as the most important infection prevention intervention. However, the compliance rates of HCWs in hand hygiene is very poor, with an overall average of only 40% (*Boyce & Pittet, 2002*). Based on hand hygiene indications as per recommendations from the *APIC* (2016), *CDC* (2011) and *WHO* (2012).

Lapses in infection control practices, such as hand hygiene and environmental cleaning, have been associated with HBV and HCV infections. The CDC strongly recommends several infection control procedures, including the practice of hand hygiene, appropriate catheter care, use of antiseptic agents, checklists, and staff and patient education, all of which are vital to reducing infections (*Patel & Brinsley-Rainisch, 2017*). Dialysis personnel should be thoroughly trained in Standard Precautions and other infection control measures as outlined by the CDC and other organizations, such as the Association for Professionals in Infection Control and Epidemiology (*APIC, 2017; CDC, 2016*). Hand hygiene is an important measure for preventing vascular access-related and viral infections, and dialysis facilities should ensure the availability of easily accessible handwashing sinks and alcohol-based hand sanitizers. Opportunities for hand hygiene include; 1) before touching a patient, 2) before aseptic procedures, 3) after body fluid exposure risk, 4) after touching a patient, and 5) after touching patient surroundings.

One quality improvement project using an evidence-based intervention package and guidance from the CDC showed that staff training, hand hygiene, vascular access care audits, and staff feedback resulted in a significant reduction in access-related bloodstream infections (*Patel et al., 2013*). Use of checklists and monthly audits of hand hygiene practices as well as feedback to the caregivers are strongly recommended to improve adherence (*Malaysian Society of Nephrology, 2018*).

Although arteriovenous fistulas and grafts make up a majority of vascular accesses in HD facilities, approximately 19% of the prevalent HD population use CVCs. The CDC recommends a set of “Core Interventions for Bloodstream Infection Prevention” that address infection control measures specific to CVCs (*CDC, 2017*). Appropriate exit site skin cleansing with chlorhexidine plus alcohol, routine performance of catheter hub disinfection (“scrub the hub”), and applying antimicrobial ointment or chlorhexidine impregnated dressing to the catheter exit site are essential steps in infection prevention include (*Patel & Brinsley-Rainisch, 2017*). After the CVC caps are removed, the hubs should be scrubbed with an appropriate antiseptic (e.g., alcoholic chlorhexidine, povidone-iodine, or 70% alcohol) every time that the catheter is accessed or disconnected. Antimicrobial barrier caps may also help to reduce catheter-related bloodstream infections and are widely used.

Only 36.2% of the nurses were wearing disposable gloves, masks, gowns, and eye protection when caring for the patient or touching the patient’s equipment at the dialysis station. PPE refers to a variety of barriers and respirators used alone or in combination to protect mucous membranes, airways, skin, and clothing from contact with infectious agents. They include gloves, gowns, masks, eye goggles, face shields and respirators (*Siegel et al., 2007*). In the HD setting, gloves are recommended to be worn whenever caring for a dialysis patient, whether touching patient’s intact skin (e.g., taking blood pressure) or patient’s equipment at the dialysis station. Gloves should be removed and followed by hand hygiene between patients or stations (*Malaysian Society of Nephrology, 2018; CDC, 2001*). The recommended practice of glove use for every contact with the patient(s) and equipment(s) at the dialysis station requires an enormous amount of glove supply, which is not always realistic in many HD units. However, when visible soiling is present and/or contact precautions are indicated, wearing gloves is a must. Sterile gloves must be used during procedures requiring a sterile aseptic technique, such as during catheter insertion or at any time a dialysis

catheter is handled/manipulated (*Vanholder et al., 2010; Tordoir et al., 2007; ERA/EDTA, 2002b*).

Wearing gowns (fluid-resistant with full coverage of the arms and body front and preferably disposable ones) over the uniform and use of a face mask and eye goggles or face shield is recommended when performing procedures wherein splashes of blood can be anticipated, especially during initiation and discontinuation of dialysis (*APIC, 2010; Siegel et al., 2007; CDC, 2001*). If a face shield is used during catheter handling, a surgical mask should be worn underneath to protect the patient from the HCW's respiratory droplets (*APIC, 2010*). Equally important is the fact that the patient should also wear a mask and be asked to turn his/her face away from the catheter site to reduce contamination from infectious droplets (*APIC, 2010; ERA/EDTA, 2002b; National Kidney Foundation, 2006; National Kidney Foundation, 2001*). Furthermore, wearing a mask is important when a staff member, a patient or a visitor is experiencing cold or cough (*Siegel et al., 2007*). A respirator should be used by HCWs only when taking care of a patient with an airborne infection. HCWs uniforms can be colonized with potentially pathogenic bacteria in up to 60% of the situations (*Wiener-Well et al., 2011; Perry et al., 2001; Fijan & Turk 2012; Wilson et al., 2007; Jackson & Cole 2010*) and, therefore, should be washed and changed daily in order to decrease the bacterial load.

***Cleaning and disinfection of environmental surfaces:*** 41.8% were cleaned and disinfected of environmental surfaces in HD units in our study. In the health-care setting, contamination of environmental surfaces with various pathogens and the persistence of these pathogens on surfaces (*Kramer et al., 2006; Dietze et al., 2001; CDC, 2014; Ciesek, 2010*) can be an important and frequent source of transmission of infectious agents through the frequent hand touching of HCWs (*Cataño et al., 2012; Dancer, 2009*). The environment in HD units is particularly prone for contamination with blood-borne pathogens such as HBV and HCV. Microorganisms can survive on environmental surfaces for varying periods of time, ranging from few hours to days and months. Low temperature, high humidity and high inoculums favor the long persistence of pathogens on inanimate surfaces (*Kramer et al., 2006*). In order to prevent and control the spread of environmentally transmitted pathogens, cleaning and disinfection of the external surfaces of equipment (i.e., HD machine, dialysis chair or bed, procedure trolley) and other environmental surfaces inside the HD units, especially those that are frequently touched by patients and staff, should be performed between all patient

treatments (irrespective of the patient diagnosis) (*APIC, 2010; CDC, 2001; ERA/EDTA, 2002b*). The application of *friction* during cleaning is emphasized as some organisms like *C. difficile* are not easily inactivated by most surface disinfectants (except bleach) and require removal by friction (*APIC, 2010; Siegel et al., 2007*).

**Equipment cleaning and disinfection:** The dialysis facility environment may be a source of infection transmission. Inadequately cleaned and disinfected dialysis stations, priming buckets, HD machines, effluent drain wall box, and other equipment have been implicated in the transmission of pathogens in HD facilities (*Nguyen et al., 2016; APIC, 2017*).

The results of this study showed that 61.3% were cleaned and disinfected of external surfaces of HD machines in dialysis units. It is recommended to clean and disinfect the external surfaces of the HD machine after each dialysis session (*APIC, 2010; CDC, 2001; ERA/EDTA, 2002b*). A low-level disinfectant or an EPA-registered disinfectant solution labeled for use in a health-care setting is recommended to be used on non-critical items (including HD machines), and should also be in accordance with the machine manufacturer's recommendations (*Rutala et al., 2008*). The presence of bio-burden will reduce the killing/inactivating effect of disinfectants. Therefore, if visible blood spills or other infectious material is present on the external surface of an HD machine, it should be cleaned separately (not to spread) before applying the disinfectant solution. In such cases, it is recommended to use an intermediate-level disinfectant or tuberculocidal agent (with specific label claims for HBV and HIV) or a 1:100 dilution of a hypochlorite solution (500– 600 ppm free chlorine) (*Rutala et al., 2008*). If using disinfectant wipes, one wipe should be used to exclusively clean the bloodstain followed by another wipe(s) for disinfection. All external surfaces of the machine, especially the frequently touched front panel, including the intravenous pole, the side, back and base, should be thoroughly cleaned and disinfected using *friction* and be allowed to air dry (*APIC, 2010*). All used towels or wipes and gloves that are contaminated with blood should be discarded in a biohazard waste container, and hand hygiene performed after glove removal.

The CDC and APIC guidelines do not suggest the disinfection of internal fluid pathways of “single-pass” HD machines between patient uses, except when a blood leak event occurs. Routine disinfection and rinsing is recommended at the beginning or end of the day (or as recommended by the machine's manufacturer) (*APIC, 2010; CDC, 2001*). The European Best Practice Guidelines (EBPG) recommends

routine disinfection of the HD-proportioning machine after each dialysis session either by heat or a chemical agent (*Rutala et al., 2008; ERA/EDTA, 2002b*). Chemical disinfection prior to patient use is recommended for standby machines, which could be inactive for variable periods of time and potentially develop bacterial growth (*APIC, 2010*). The chemical disinfection protocol should be according to the machine manufacturer's recommendation, including the concentration and dwell time) (*APIC, 2010*).

Auxiliary equipment used in HD may include reusable jugs for mixing bicarbonate solution, transducers. As per recommendation, any reusable item should be cleaned and disinfected prior to being used on another patient, and external pressure transducers should be changed between patients' uses. Nowadays, many units have shifted to using the more hygienic automated process of mixing bicarbonate powder in the cartridge on the individual machines, eliminating the use of reusable bicarbonate jugs. If bicarbonate solution in a jug is used, any "leftover" solution must be discarded and opened jugs should not be used after 24 h because sodium bicarbonate solution constitutes a good media for bacterial growth (*APIC, 2010*).

Reusable priming buckets are now seldom used as most dialysis companies include a disposable prime collection bag in each pack of sterile bloodline set and also with pre-attached external pressure transducers. With improved and better technology in some of the newer models of HD machines, prime collection bags or transducer protectors are not even required, because drainage of priming solutions can be done by connecting the bloodline to a drainage port in the machine and blood pressure sensors are completely non-invasive without using transducer connections and protectors.

Also the handling of disposable supplies and reusable items in HD units both CDC and APIC have recommended specific measures that include the following: (a) items taken into an individual patient's HD station should be used only for that patient and be disposed off after use, (b) unused item(s) should be cleaned and disinfected before returning to a common clean area or used on another patient, or be disposed off if it cannot be disinfected and (c) non-disposable items that cannot be comprehensively cleaned and disinfected (e.g., adhesive tape, cloth-covered blood pressure cuffs) should be dedicated for use on a single patient (*APIC, 2010; CDC, 2001*). In reality, allocating a blood pressure cuff for each patient may not be practical as too frequent detachment and reattachment of the cuff can cause imminent damage to the line connections. Reusable blood pressure cuffs that are covered with waterproof material with a smooth

surface (instead of cloth-covered cuffs) can be an attractive alternative as they can be comprehensively cleaned and disinfected between patient uses. There should also be a clear separation for storage and handling of clean supplies and medications from contaminated items (i.e., used supplies/equipment, blood samples, biohazard containers).

***Safe medication and injections:*** The findings of the study regarding safe injection practices showed that 60.7% of the staff nurses in all hospitals were practiced the safe medication and injection. Aside from the basic principles of aseptic technique, there are specific complementary recommendations for HD published by the CDC and APIC, which include the following: (a) all single-use injectable medications and solutions should be dedicated for use on a single patient and be used one time only, (b) medications packaged as multi-dose should be assigned to a single patient whenever possible, (c) medication preparation should occur in a clean area away from the patient treatment area, and be delivered separately for each patient, (d) to not carry multi-dose vials from station to station or carry medication vials, syringes, alcohol swabs or supplies in pockets, (e) unused medications or supplies taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients, (f) to not use common medication carts to deliver medications to patients and, if trays are used to deliver medications to individual patients, they must be cleaned between patients (*APIC, 2010; CDC, 2001; CDC, 2008*).

Careful use of single-dose and multidose medication vials is also essential in the prevention of infection transmission. Single-use should only be accessed once, and whenever possible, multidose vials should be dedicated to one patient. Medications and saline syringes should be prepared in a dedicated, clean, separate area in the dialysis unit and taken to individual stations by hand. A medication cart should not be used to take medications from station to station, because this has been associated with the transmission of infections, especially HCV. Reuse of dialyzers has been associated with outbreaks of gram-negative bloodstream infections, and reuse facilities must ensure strict adherence to sterilization protocol to mitigate the risk of infection transmission (*Patel & Brinsley-Rainisch, 2017*).

***Hospital infection control policies, program and training:*** Only 35.4% of the hospitals were administered hospital infection control policies, program and training. Education and training in infection prevention and control should be provided to all health-care workers upon hire and should be repeated regularly (at least on a yearly



basis). Basic principles and practices for preventing the spread of infections should be covered and staff competencies should be assessed and documented upon orientation to the facility, and this should be repeated as appropriate for the specific staff and position (*CDC, 2011*). The patient(s) and/or caregiver(s) should also be educated on the care of new access and whenever there is a change in access type, and this should be repeated at least every year (*CDC, 2012a*).

Patient and family engagement is key in our attempt to target 100% infection control. Medical directors and dialysis nursing staff should invite patients in HD facilities to start a conversation about infection prevention (*See et al., 2014*). Patients and their family members should be encouraged to ask questions about infection prevention policies and practices used by the facility and speak up if infection control measures are not being practiced appropriately.

Sample information that patients might ask about includes the dialysis center's policies for the prevention of HBV and HCV; hand hygiene practices; medication safety; disinfection of dialysis stations; alternatives to using dialysis catheters; and whether the unit uses a new disposable dialyzer with each dialysis treatment (*Patel & Brinsley-Rainisch, 2017*).

It is imperative that medical directors play a key role in developing and implementing infection control measures in the dialysis unit because physician leadership is essential in preventing health care-associated infections. Medical directors should help review policies and practices dealing with hand hygiene, vascular access care, medication preparation, disinfection of environmental surfaces and dialysis equipment, and screening and immunization procedures, and they should address these issues during monthly quality assurance meetings (*Kapoian et al., 2015*).

During their dialysis rounds, they should serve as role models by practicing hand hygiene and speak up about infection control practices to the staff. Medical directors should actively collaborate with the nurse manager to perform staff audits of key infection control measures, such as appropriate precautions when accessing the HD catheter and cannulating the vascular access. Physicians should engage their patients in infection control measures and encourage patients to speak up and ask questions without fear of retaliation. Assuring antibiotic stewardship is also a major responsibility of the medical director. Colonization and infection by multidrug-resistant organisms are common among patients on HD, and antibiotic exposure is an independent risk factor for acquisition of multidrug-resistant gram-negative bacteria. Medical directors

can minimize this risk by developing and implementing an antimicrobial stewardship program.

Reducing the number of patients receiving antibiotics or reducing the duration of antimicrobial therapy may reduce both rates of colonization and environmental contamination by multidrug-resistant organisms (*Anitha & John, 2018*).

**Water treatment and testing:** as regards to water treatment: Purity and testing showed that only 50.9% were applied and checked the water treatment and purity and testing. Water quality is an essential component in the provision of good HD and in ensuring patient safety. This is especially the case in the settings of high-flux HD, hemofiltration and/or hemodiafiltration due to the possible entrance of contaminants from the dialysis fluid into the blood by either convective transfer (back filtration) or movements down the concentration gradient (back-diffusion) or the direct infusion of substitution fluid into the circulation. Failure to meet water quality standards has major consequences and may lead to increased patient morbidity and mortality. Studies have demonstrated that ultrapure dialysis fluid is associated with a reduction in inflammatory markers, reduced chronic inflammation, decreased erythropoietin resistance, preservation of residual renal function, a reduction in cardiovascular morbidity, a reduction in  $\beta$ 2-microglobulin amyloidosis and decreased levels of advanced glycation end-products (*Damasiewicz et al., 2012; Susantitaphong et al., 2013*). Both CDC and APIC recommend adherence to the standards set by the Association for the Advancement of Medical Instrumentation (AAMI) for the quality of water used in dialysis. Fluids used for dialysis can be divided into three levels according to microbiological quality: Standard, ultrapure and sterile.

Prepared solutions that are used as substitution fluids and priming solutions (intravenous infusion) during hemofiltration and hemodiafiltration are considered as drugs and, therefore, should be sterile and non-pyrogenic (*AAMI, 2014; Ledebø & Blankestijn, 2010; Nystrand, 2008; Chamney & James, 2008*). The quality of the fluid before the final filter (from the first bacteria- and endotoxin-retentive filter) and the functioning of this filter both determine whether the final fluid can be referred to as sterile and non-pyrogenic (*Ledebø & Blankestijn, 2010*). In this case, the fluid sample for microbiologic testing should be taken from the dialysate sampling port (the fluid that has passed only from the first filter). If the dialysate sample meets the standard for ultrapure water, then the substitution fluid (the fluid that passed the second filter) can be assumed as sterile. Others insist that one other condition must be fulfilled in order

to achieve a sterile fluid: A sterile, single-use filter must be used for the final filtration step, which is according to the definition in pharmacopeias (*Nystrand, 2008*).

Testing of product water of in-center reverse osmosis (RO) for bacteria and endotoxin assay are required at least monthly (*AAM, 2001*) and on a quarterly basis for portable RO or in a home setting. To avoid false-negative results, fluid sampling for microbiological testing should be performed no sooner than 24 h after disinfection and, when disinfection is performed on consecutive days (or more frequently), samples should be taken before and as close as practicable to a disinfection procedure (*AAM, 2001*).

## **6.7 Strengths and Limitations of the Study**

### ***6.7.1 Strengths of the Study***

1. The strength of this study lies in the fact that less time and resources were allocated to investigate HBV and HCV among the study patients on maintenance HD.
2. Few documented data or previous studies have been reported on the prevalence of hepatitis B and C viruses among HD patients in Yemen.
3. No documented data or previous studies have been reported for preventive and infection control measures such as screening on a semi-annual basis for isolation of susceptible patients, proper injection medication practices and cleaning and disinfection in these HD units so this is the first study has been done to investigate infection prevention and control in HD units in Yemen.

### ***6.7 Limitations of the Study***

Medical records were sometimes incomplete, however, additional clinical information was frequently obtained by interviewing staff and patients.

## Chapter Seven: Conclusion and Recommendations

### 7.1 Conclusions

*The study concluded that;*

- Hepatitis B and C virus infection is frequent among HD patients in Sana'a city (HBV was 14.3% and HCV was 17.2%).
- A total percentage of 64.8% of the staff nurses did not practiced screening, immunization and routine testing in all HD units.
- 51.2% of the staff nurses were practiced standard and transmission-based precaution in all HD units.
- 58.2% of the staff nurses did not practiced environmental, cleaning and disinfection in all HD units.
- 60.3% of the staff nurses were cleaned and disinfected equipment in all HD units.
- 60.7% of the staff nurses were practiced safe medication and injection practice in all HD units.
- Responses about infection control policies, education, and training course, the study revealed that 64.6% of the nurses were not familiar with these policies, program and training in all HD units.
- Regarding to water treatment and testing, 48.3% of nurses were tested of dialysis water and dialysate at least monthly and 41.4% were monitored water quality; both microbial and components.

## 7.2 Recommendations

### *The study recommended that;*

1. Implementation of the infection control program, the components of such program include infection control practices specially designed for HD setting, including routine serological testing and immunization, surveillance, training, and education. These practices should be carried out routinely for all patients in the HD units.
2. In each HD unit, policies and practices should be reviewed and updated to ensure that infection control practices recommended for HD are implemented and rigorously followed.
3. Continuous training and education are recommended for both staff and patient or patient family, the training courses must contain information such as proper hand hygiene techniques, proper use of protective equipment, mode of transmission of bloodborne viruses and infection control practices.
4. All susceptible patients must be vaccinated against HBV, vaccinated patients must be tested for anti-HBs (1-2 months after the last dose),
5. Hepatitis positive patients must dialyze in a separate room using separate machines, equipment, instrument, and supplies.
6. Staff members caring for hepatitis positive patients should not care for negative hepatitis virus patients at the same time.
7. Negative HBV patients must be tested for the presence of HBsAg each month, and for negative anti-HCV, patients must be tested for anti-HCV.
8. Further studies should be conducted using a larger sample size. In addition to this, more sensitive and specific diagnostic tools like PCR should be used in diagnoses of viral hepatitis and finally to investigate the risk factors in transmission of hepatitis viruses and nurses practice in transmission of infection among HD patients.

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## Appendix- A: Questionnaire and informed consent

استبانة حول  
معدل انتشار فيروس التهاب الكبد البائي والسي لمرضى الاستصفاء  
الدموي ومكافحة العدوى في وحدات الاستصفاء - صنعاء اليمن

اسم المستشفى:  .....	[REDACTED]
----------------------	------------

رقم الملق: .....	الإخوة الاعزاء انا/ باحث من كلية العلوم
ملاحظات: .....	الطبية-جامعة الرازي.أقوم بعمل بحث في
.....	مجال الوبائيات، ونجري هذا البحث بموافقة
.....	كلية العلوم الطبية-جامعة الرازي. ونهدف
.....	من خلال بحثنا هذا إلى التحري عن معدل
.....	الانتشار ومكافحة العدوى لفيروس التهاب
.....	الكبد البائي والسي لمرضى الاستصفاء
.....	الدموي في المستشفيات في صنعاء اليمن
.....	وندون بعض الملاحظات في الاستبيان رقم الاستبيان
.....	المعلومات التي سنأخذها منك ستحاط
.....	بالسرية التامة وفقاً لأخلاقيات البحث العلمي،
.....	ولن تتأثر في مهنتك أو عملك بما سوف تدلي
.....	به من معلومات..
.....	والآن، هل ترغب بالاستفسار عن أي شيء
.....	في البحث؟
.....	[REDACTED]
.....	هل توافق على المشاركة في هذا البحث؟
.....	<input type="checkbox"/> نعم أو افق ← استكمل <input type="checkbox"/> لا أو افق ← أنهى
.....	التوقيع: .....
.....	المقابلة

شكرا على تعاونكم

### 3. History of HBV & HCV Infection among Patients

البيانات الديمغرافية للمرضى			
الرقم	السؤال	الإجابة المتوقعة	الرمز
1	العمر بالسنة	(.....)	
2	الجنس	• ذكر	1
		• انثى	2
3	الحالة الاجتماعية	• متزوج	1
		• عازب	2
		• مطلق	3
		• ارمل	4
4	المستوى التعليمي	• غير متعلم	1
		• التعليم الأساسي	2
		• التعليم الثانوي	3
		• دبلوم	4
		• بكالوريوس	5
		• ماجستير	6
5	الوظيفة	• لا يعمل	1
		• موظف	2
		• اعمال حره	3

#### 1. التاريخ الطبي للمرضى

الرقم	رقم الفقرة	السؤال	الإجابة المتوقعة	الرمز
7	1	متى بدأت اول غسيل كلوي	.....	
8	2	كم عدد مرات الغسيل في الأسبوع	.....	
9	3	هل أخذت لقاح لفيروس الكبد البائي قبل اول غسيل كلوي	نعم	1
			لا	2
10	4	هل أخذت لقاح لفيروس الكبد البائي خلال فترة الغسيل الكلوي	نعم	1
			لا	2

#### Serologic assays

##### فحوصات الأمصال

OUTCOMES		AT SCREENING STAGE PERIOR DIALYSIS	رقم الفقرة	الرقم
Negative	Positive			
		Hepatitis B surface antigen (HBsAg)	1	11
		Anti-HCV	2	12
		AT FOLLOW-UP STAGE DURING DIALYSIS	C	
		Hepatitis B surface antigen (HBsAg)	1	16
		Anti-HCV	2	17

استبانة حول

معدل انتشار فيروس التهاب الكبد الباني والسي عند مرضى الاستصفاء  
الدموى ومكافحة العدوى في وحدات الاستصفاء في صنعاء-اليمن

الجزء الثاني: خاص بالكادر التمريضي

رقم الاستبيان: | \_\_\_\_\_ |

<p>اسم المستشفى:  ..... </p> <p>ملاحظات: ..... ..... ..... .....</p> <p>أؤكد أن الاستبيان قد عبى بالكامل</p> <p>التاريخ: .....</p> <p>التوقيع: .....</p>	<p><b>Informed</b> الموافقة الرسمية <b>consent</b></p> <p>الإخوة الأعزاء انا/ باحث من كلية العلوم الطبية- جامعة الرازي. أقوم بعمل بحث في مجال الوبانيات، ونجري هذا البحث بموافقة كلية العلوم الطبية- جامعة الرازي. ونهدف من خلال بحثنا هذا إلى التحري عن معدل الانتشار ومكافحة العدوى لفيروس التهاب الكبد الباني والسي لمرضى الغسيل الكلوي في المستشفيات في صنعاء اليمن وندون بعض الملاحظات في الاستبيان..</p> <p>المعلومات التي سنأخذها منك ستحاط بالسرية التامة وفقا لأخلاقيات البحث العلمي، ولن تتأثر في مهنتك أو عملك بما سوف تدلي به من معلومات..</p> <p>والآن، هل ترغب بالاستفسار عن أي شيء في البحث؟</p> <p><b>الموافقة</b></p> <p>هل توافق على المشاركة في هذا البحث؟</p> <p><input type="checkbox"/> نعم أو افق ← استكمل <input type="checkbox"/> لا أو افق ← أنهى المقابلة</p>
--	--

ضع اشارة صح  امام الاجابة المناسبة

البيانات الديمجرافية			
الرمز	الاجابة المتوقعة	السؤال	الفقرة أ
	.....	العمر بالسنة	1
1	• ذكر	الجنس	2
2	• انثى		
1	• متزوج	الحالة الاجتماعية	3
2	• عازب		
3	• مطلق		
4	• ارمل		
1	• دبلوم	المستوى التعليمي	4
2	• بكالوريوس		
3	• ماجستير و أعلى		
		كم فترة العمل بالسنوات	5
1	• نعم	هل لديك دورة في مكافحة العدوى بقسم الغسيل	6
2	• لا		

تاريخ لقاحات فيروس الكبد بي للكادر التمريضي			الفقرة ب
الاجابة المتوقعة	البيان		
لا	نعم	هل أخذة لقاح فيروس الكبد بي قبل مباشرة العمل بالقسم	1
لا	نعم	هل اخذة لقاح فيروس الكبد بي خلال فترة عمك بالقسم	2

مبادئ الوقاية ومكافحة العدوى في قسم الاستشفاء الدموي		
الإجابة المتوقعة		الفحوصات واللقاحات للكادر التمريضي بوحدة الاستشفاء الدموي
لا	نعم	هل توجد سياسات تحري لفحص الفيروسات قبل تسجيل المرضى في قسم الغسيل
لا	نعم	هل توجد سياسات تحري لفحص الفيروسات للموظفين عند مباشرة العمل بالقسم
لا	نعم	هل تعمل فحوصات للفيروسات للمرضى بشكل منتظم وتتابع باستمرار
لا	نعم	هل تعمل فحوصات للفيروسات للعاملين في القسم بشكل منتظم وتتابع باستمرار
لا	نعم	هل يتم عمل إجراء لقاح فيروسات الكبد قبل تسجيل المرضى بالقسم للغسيل
لا	نعم	هل يتم عمل إجراء لقاح فيروسات الكبد قبل مباشرة الموظفين للعمل في القسم
لا	نعم	هل لديكم إجراءات وقائية في حالة تعرض الموظفين او المرضى للإصابة بفيروس سي
الإجابة المتوقعة		الفقرة ج
معايير ومحاذير تحد من انتقال العدوى		
الإجابة المتوقعة		البيان
لا	نعم	هل يتم فصل المرضى المصابين والأدوات المستخدمة عن الغير مصاب
لا	نعم	هل تقوم بغسل الأيدي قبل وبعد الاتصال مع المرضى
لا	نعم	هل تلبس كمام ,جونتي ,جاون ,واقي للعين , عند العناية بالمرضى في قسم الاستشفاء الكلوي
لا	نعم	هل تستخدم عند غسل الأيدي معقمات وصوابين ضد البكتيري
لا	نعم	هل تستخدم في تنظيف الجلد سائل كلوروهكسادين 2% والكحول 70% وبوفدين ايودين 10%
الإجابة المتوقعة		الفقرة د
النظافة والتعقيم البيئي		
الإجابة المتوقعة		البيان
لا	نعم	هل تستخدم درجات لمكافحة العدوى عند كل المرضى
لا	نعم	هل يتم تنظيف الدم او سوائل الجسم المنسكب حالا
لا	نعم	هل يتم عمل وقاية من التلوث للقوالب او الجدران او الأثاث نتيجة المياه المتسخة او الرطوبة للأثاث وللجدران
لا	نعم	هل تستخدم مستلزمات ذات الاستخدام الواحد للوقاية من التلوث المرضى والبيئة
الإجابة المتوقعة		الفقرة ر
تعقيم ونظافة الادوات		
الإجابة المتوقعة		البيان
لا	نعم	هل يتم اعادة تعقيم الادوات التي تستخدم مرة واحدة
لا	نعم	هل يتم تنظيف وتعقيم قنوات تصريف الغسيل
لا	نعم	هل يتم تنظيف وتعقيم امام ممرات جهاز الغسيل
لا	نعم	هل يتم تنظيف وتعقيم ومعالجة المياه المستخدمة بقسم الغسيل
لا	نعم	هل يتم تنظيف وتعقيم الأسطح الخارجية لجهاز الغسيل
الإجابة المتوقعة		الفقرة س
ممارسات الحفظ الامن للادوية والحقن		
الإجابة المتوقعة		البيان
لا	نعم	هل يتم تعقيم السدادة قبل إدخال الحقن
لا	نعم	هل تستخدم شرنقة معقمة لكل مريض قبل كل إدخال علاج
لا	نعم	هل تعيد تغطية رأس النيدل الحادة
لا	نعم	هل تستخدم اناء لتجميع المخلفات الحادة
الإجابة المتوقعة		الفقرة ص
تدريب الكادر التمريضي والمرضى		
الإجابة المتوقعة		البيان
لا	نعم	هل لديكم برنامج لمكافحة العدوى في مؤسستك
لا	نعم	هل لديك سياسات وإرشادات لمكافحة العدوى في وحدت
لا	نعم	هل سبق وان حصلت على توجيه من القسم بالتدريب حول مكافحة العدوى
لا	نعم	في مؤسستك هل يوجد فريق نشط في مكافحة العدوى
لا	نعم	هل يتم تدريب الموظفين حول مبادئ ممارسات الاستشفاء الدموي
الإجابة المتوقعة		الفقرة ع
معالجة وفحص المياه		
الإجابة المتوقعة		البيان



لا	نعم	هل يتم فحص مياه الغسيل على الاقل شهريا	1
لا	نعم	هل يتم مراقبة جودة المياه كيميائيا وبيولوجيا	2

**English version**

**QUESTIONNAIRE ABOUT  
PREVALENCE OF HEPATITIS B AND C VIRUS AMONG  
HEMODIALYSIS PATIENTS AND INFECTION CONTROL  
IN DIALYSIS UNITS IN SANA'A CITY, YEMEN**

**Part two: Staff Nures**

Questionnaire No. | \_\_\_\_\_ |

<p align="center"><b>Informed consent</b></p> <p><i>Dear Respondent,</i></p> <p>I am <i>Murad Abudlhadi Qassem Al-Yousofi</i> master's student from Al-Razi University, College of medical sciences, Department of Applied medical sciences, conducting a research on the topic <i>“prevalence of hepatitis b and c viral infections among hemodialysis patients and infection control in dialysis in Sana,a City-Yemen.</i> We kindly ask you to answer this questionnaire as part of study. This study will help you to improve your knowledge and practices on nosocomial infection and its control measures.</p> <p>We guarantee that information provided would be kept confidential and this is only for academic purposes. Participation in this study is completely voluntary; any participant is at liberty to withdraw at any time without prejudice or negative consequences In the near future you. We hope you are willing to collaborate with this research.</p> <p align="center"><b>Consent</b></p> <p><b>New, do you agree to participate in this study?</b></p> <p>Yes _____ No-----</p>	<p>Name of hospital :.....</p> <p>Notes:.....</p> <p>Date: .....</p> <p>Signature:.....</p>
--	---

Please write down or tick (✓) in the box that corresponds to your response unless otherwise asked.

<b>SECTION 1: Demographic characteristics of staff Nurses</b>			
<b>NO.</b>	<b>Statement</b>	<b>Expected answer</b>	<b>Code</b>
<b>1</b>	Age (Year)		
<b>2</b>	Sex	• Male	1
		• Female	2
<b>3</b>	Marital status	• Married	1
		• Unmarried	2
		• Divorced	3
		• Widowed	4
<b>4</b>	Level of education	• Diploma degree	1
		• BSc degree	2
		• Master degree and above	3
<b>5</b>	Duration of working (Year)		
<b>6</b>	Course Training in infection control of Dialysis	• Yes	1
		• No	2

<b>Section 2: History of vaccination among staff Nurses</b>			
<b>No.</b>	<b>Items</b>	<b>Responses</b>	<b>Code</b>
<b>7</b>	Vaccination against HBV prior to employment	• Yes	1
		• No	2
<b>8</b>	Vaccination against HBV during the time of employment	• Yes	1
		• No	2

<b>Section 3: Principles of infection prevention and control (IPC) in Dialysis Unit</b>			
<b>NO.</b>	<b>Statement</b>	<b>Expected answer</b>	<b>Codes</b>
<b>A SCREENING, IMMUNIZATION, AND ROUTINE TESTING</b>			
<b>9</b>	Do you have screening policy for HBV and HCV of patients' prior to dialysis?	• Yes	1
		• No	2
<b>10</b>	Do you have screening policy for HBV and HCV of staff member prior to employment?	• Yes	1
		• No	2
<b>11</b>	Do you have regular testing of dialysis patients for hepatitis B and C virus infections at the time of dialysis?	• Yes	1
		• No	2
<b>12</b>	Do you have regular testing of staff member for HBV and HCV infections at regular intervals during employment?	• Yes	1
		• No	2
<b>13</b>	Do you have routine vaccination of dialysis patients against HBV before commencing dialysis?	• Yes	1
		• No	2
<b>14</b>	Do you have routine vaccination of staff Members against HBV Prior to employment?	• Yes	1
		• No	2
<b>15</b>	Do you administer Post-exposure prophylaxis of patients and staff Members?	• Yes	1
		• No	2
<b>B STANDARD AND TRANSMISSION-BASED PRECAUTIONS</b>			
<b>16</b>	Does the facility separate patients with HBV &HCV in separate room and their equipment and supplies from those used for non-HBV&HCV-infected patients?	• Yes	1
		• No	2
<b>17</b>	Do you perform hand hygiene before and after contact with patient or patient environment?	• Yes	1
		• No	2
<b>18</b>	Do you wear sterile gloves, a mask, and protective eyewear?	• No	2
		• Yes	1
<b>19</b>	Do you wash the access site using an antibacterial soap/scrub and water?	• Yes	1
		• No	2
<b>20</b>	Do you cleanse the skin by 2% chlorhexidine gluconate/70% isopropyl alcohol, 70% alcohol, or 10% povidone iodine?	• Yes	1
		• No	2
<b>C ENVIRONMENTAL CLEANING AND DISINFECTION</b>			
<b>21</b>	Does the hospital grade disinfectant is used for all patient areas?	• Yes	1
		• No	2
<b>22</b>	Do you cleaning of spills of blood or body fluids?	• Yes	1
		• No	2
<b>23</b>	Do you prevent of mould contamination resulting from water damage or wetting of permeable walls, furniture, etc?	• Yes	1
		• No	2
<b>24</b>	Do you disposed used supplies and dialyzers to prevent contamination of patients and environmental surfaces?	• Yes	1
		• No	2
<b>D EQUIPMENT CLEANING AND DISINFECTION</b>			
<b>25</b>		• Yes	1

	Do you disinfect of non-disposable items (clamps, scissors, and blood pressure cuffs) before use on another patient?	• No	2
26	Do you clean and disinfection of Hemodialyzer port caps?	• Yes	1
		• No	2
27	Do you clean and disinfection of Interior pathways of dialysis machine?	• Yes	1
		• No	2
28	Do you clean and disinfection of Water treatment and distribution system?	• Yes	1
		• No	2
29	Do you clean and disinfection of Environmental surfaces include exterior surfaces of hemodialysis machine?	• Yes	1
		• No	2
<b>E</b>	<b>SAFE MEDICATION AND INJECTION PRACTICES</b>		
30	Do you disinfected the stopper with alcohol before accessing the vial?	• Yes	1
		• No	2
31	Do you use a single sterile needle and syringe for each access?	• Yes	1
		• No	2
32	Do you recapped Needles?	• Yes	1
		• No	2
33	Do you discarded used sharps in sharps containers?	• Yes	1
		• No	2
<b>F</b>	<b>PATIENT AND HCWS TRAINING</b>		
34	Do you have infection control program at your institution?	• Yes	1
		• No	2
35	Do you have infection control policies or guidelines in your unit?	• Yes	1
		• No	2
36	Have your staff received some form of training or orientation about infection prevention and control?	• Yes	1
		• No	2
37	At your institution, do you have active infection control team?	• Yes	1
		• No	2
38	Have your staff received initial and on-going education on the basic principles and practices of dialysis?	• Yes	1
		• No	2
39	Have your staff received initial and on-going education on the basic principles and practices of dialysis?	• Yes	1
		• No	2
<b>H</b>	<b>WATER TREATMENT AND TESTING</b>		
40	Do you test of dialysis water and dialysate at least monthly?	• Yes	1
		• No	2
41	Do you monitor water quality; both microbial and chemical components?	• Yes	1
		• No	2

*Thanks*

## **Appendix-B: Approval to conduct this study**