Assessment the Efficiency and Safety of Haemodialysis Machine: Case Study

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Abstract— Dialysis is a process for removing waste and excess water from the blood, and is used primarily as an artificial replacement for lost kidney function in people with renal failure. It may be used for those with an acute disturbance in kidney function (acute kidney injury, previously acute renal failure), or progressive but chronically worsening kidney function–a state known as chronic kidney disease stage 5 (previously chronic renal failure or end-stage renal disease). According to the absence or specialized authorities that control and regulate operation of haemodialysis may cause many serious problems because there is no clear Standard Operation Procedure and Policies (SOPs) for haemodialysis (HD) machine applied in Sudan. The objective of this work is to assessment the efficiency and safety of two groups: Group one, six centers of haemodialysis in Khartoum state (Used machines). Group two: twenty Fresenius and twenty Gambro donated machines. This work to protect patient from the risk, Improve the quality of haemodialysis and patient outcomes, provide employers with operational information necessary to perform a job properly, to insure quality for dialysis including prevent risk, correct error, detect deviations, and improve efficiency, and reduce costs. The steps of this work are tested the efficiency and safety for HD machines which include: technical specification, operation requirement, electrical safety, decontamination and the environmental procedures. From group one the total numbers of YES was 160 and total numbers of NO was 26. The percentages are 86.02% and 13.98% for YES and NO respectively. The efficiency and safety for group one is 61.29% and 85% for group two. The result shows that from group one 38.71% is the absence of the efficiency and safety so these centers need to apply The SOPs for HD machine. From group two 15% of the HD machines were rejected. This work is a case study for small sample space which contains two event (group one and group 2) to test the efficiency and safety of the HD machines.It is important for safely healthcare and this it is the beginning step to improve the use of the HD machine to give a better work in Sudan.

Index Terms— Haemodialysis machine; technical specification; electrical safety, decontamination; SOPs

1 INTRODUCTION

Historically, medical devices entered since more than ten decades, and that in its simplest terms of numbers, types and design. Gradually, situation has been developed in eighties of the last century where demands are increased for these devices without presence of mechanisms for controlling and monitoring, which led to the entry of many devices used in very many rubbles of various devices accumulated in hospitals and health institutions [1 and 2]. large numbers and without any controls as those devices which did not serve the purpose for which it brought, then

In the nineties of the last century, operating health institutions began in the acquisition of new appliances, but also without controls to serve the purposes required for ensuring the continuity of these devices and the quality of performance. In that period, there was a big business trade for these devices because the lack of controls. Also many devices imported in form of donations and grants, which have fallen in same fate. At the beginning of this century, attempts began by several agencies to lay foundations and controls to import and manage medical devices. One of those is the Administration of pharmacy and Atomic Energy Authority, Medical Supplies and finally Sudanese Standards and Metrology, which no adequate coordination between its, which create a kind of ideas diverge and conflicts in many cases, leading to failure in achieve hopes for citizens in provision of health services, prompting often to search for therapy abroad country [3].

The formal definition of a standard that should be adopted in the medical device domain is given by the ISO: Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that materials, products, process and services are fit for their purpose [4].

1.1 Types of specifications in standards

Standards can establish a wide range of specifications for products, processes and services; Prescriptive specifications obligate product characteristics, e.g. device dimensions, biomaterials, test or calibration procedures, as well as definitions of terms and terminologies, design specifications set out the specific design or technical characteristics of a product, e.g. operating room facilities or medical gas systems[3], performance specifications ensure that a product meets a prescribed

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test, e.g. strength requirements, measurement accuracy, battery capacity, or maximum defibrillator energy, management specifications set out requirements for the processes and procedures companies put in place, e.g. quality systems for manufacturing or environmental management systems[5 and 6].

1.2 Types of standards

There are two types of standards, the Mandatory standards when a standard is mandated by a government or an international trade agreement, it normally becomes legally obligatory based on regulations or a law established by the government or the contracts between international bodies. Countries that are considering making standards mandatory should take into account the potential consequences under international agreements on technical barriers to trade [5]. the Voluntary standards are preferred in medical devices field for these advantages; They are normally developed by experts with access to the vast resources available in the professional and industrial communities, by taking advantage of such existing resources, the government can overcome its own limited resources for providing product specific technical requirements and characteristics, conformity to standards can also be assessed by an accredited third party (such as a notified body in Europe), which is a well-established industrial practice around the world, the use of international standards facilitates harmonized regulatory processes and world trade, and thus improves global access to new technology, as technology advances, it is much easier to update standards than to change regulations. Timely development and periodic revision by expert groups make medical device standards effective and efficient tools for supporting health care and manufacturers have the flexibility to choose appropriate standards or other means to demonstrate compliance with regulatory requirements [7]. The objectives of the SOPs are to provide UN Country Teams, provide information for program countries that are considering adopting the "Delivering as one" approach, presenting the approach simply and clearly and where appropriate, identify and recommend critically important policy and procedural [8].

1.3 Objectives of the Standard Operating Procedures

SOPs detail the regularly recurring work processes that are to be conducted or followed within an organization. They document the way activities are to be performed to facilitate consistent conformance to technical and quality system requirements and to support data quality. They may describe, for example, fundamental programmatic actions and technical actions such as analytical processes, and processes for maintaining, calibrating, and using equipment. SOPs are intended to be specific to the organization or facility whose activities are described and assist that organization to maintain their quality control and quality assurance processes and ensure compliance with governmental regulations [9]. The development and use of SOPs minimizes variation and promotes quality through consistent implementation of a process or procedure within the organization, even if there are temporary or permanent personnel changes. SOPs can indicate compliance with organizational and governmental requirements and can be used as a part of a personnel training program, since they should provide detailed work instructions. It minimizes opportunities for miscommunication and can address safety concerns. When historical data are being evaluated for current use, SOPs can also be valuable for reconstructing project activities when no other references are available. In addition, SOPs are frequently used as checklists by inspectors when auditing procedures. Ultimately, the benefits of a valid SOP are reduced work effort, along with improved comparability, credibility, and legal defensibility [8]. Technical SOPs can be written for a wide variety of activities. Examples are SOPs instructing the user how to perform a specific analytical method to be followed in the laboratory or field (such as field testing using an immunoassay kit), or how to collect a sample in order to preserve the sample integrity and representativeness (such as collection of samples for future analysis of volatile organic compounds or trace metals), or how to conduct a bioassessment of a freshwater site. Technical SOPs are also needed to cover activities such as data processing and evaluation (including verification and validation), modeling, risk assessment, and auditing of equipment operation. [10]. Technical SOPs need to include the specific steps aimed at initiating, coordinating, and recording and/or reporting the results of the activity, and should be tailored only to that activity. Technical SOPs should fit within the framework presented here, but this format can be modified, reduced, or expanded as required [11].

1.4 Previous works

It concentrated here according to comparisons between some countries around Sudan about the possibility of entering the used the HD machine.

1.4.1 Egypt

Import Regulations for Used and Refurbished Medical Equipment According to a 1997 Ministry of Health (MOH) Technical Committee Decree, the importation of used and refurbished medical equipment and supplies to Egypt is banned without the prior approval of the MOH. The ban does not differentiate between the most complex computer-based imaging equipment and the most basic of supplies. At present, even new medical equipment must be tested in the country of origin and proven safe before it will be approved for importation into Egypt. The importer must submit a form requesting the MOH's approval to import used medical equipment. The importer must also present the following documents in addition to proving that imported used medical equipment has a service center that can provide after sales support including spare parts and technical maintenance [12]. Documents required approving medical devices/equipment: Free Sales Certificate issued by official health authorities in the country of origin, indicating that the medical equipment, subject to importation, is safely used there, copy of Pro-forma Invoice, copy of FDA approval (Certificate to Foreign Government) signed and sealed by the Egyptian Embassy/Consulate in the U.S. The importer may be required to show the original certificate for confirmation, copy of legalized Agency Agreement, certificate of Origin (in case of exporting components to a factory for local manufacture/assembly), declaration of Conformity (in

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case of class 1 non-sterile, non-measuring product or equipment) and catalog or literature (hard copy or CD). The MOH's Technical Committee will examine and review the technical specifications of the equipment before granting an approval to admit it into Egypt. These regulations also apply to medical equipment that is being donated, not sold for profit [12].

1.4.2 South Africa

According to the Department of Health, South Africa does not make a distinction between refurbished / used and new medical equipment. Medical equipment—other than electro medical devices including disposable or single use devices—is not regulated. The South African Department of Health is currently in the process of drafting the necessary policy documents and has indicated that these may become available sometime in the future. As mentioned, there are, however, exceptions with regard to specific electro medical products (as listed at the end of this document). Although there is no distinction between new and refurbished / used equipment, all importers—whether the product is destined for commercial or personal use—must apply for a license in terms of Section 4 (1)(b) of the Hazardous Substances Act, 1973 (Act 15 of 1973) from the Department of Health, Directorate: Radiation Control [12].
Potential importers must apply for a license for each model and must supply the following documentation: Completed application form 41BM-1, obtainable from the Radiation Directorate, a color brochure (including technical specifications) from the manufacturer, a letter of appointment as authorized representative of the original manufacturer, EC Certificate(s) issued by a Notified Body in terms of EC Directive and EC Declaration of Conformity by the manufacturer in terms of EC. If the intention is to conduct clinical trials with a listed electro medical product, before it has been licensed to be imported or manufactured in South Africa, the importer must supply the following documentation [12]:

- Completed application form 41BM-1, obtainable from the Radiation Directorate
- Color brochure (including technical specifications) from the manufacturer
- A letter of appointment as authorized representative of the original manufacturer.
- List of medical institutions where the clinical trials will be conducted.
- List of the medical practitioners who will supervise the clinical trials.
- Copy of the letter in which the medical ethics committee of a medical institution gives approval for the clinical trials to be performed at that particular medical institution.
- Copy of the approved research protocol for the clinical trials.
- Copy of the "informed consent" form.

This product must be re-exported to the original manufacturer after completion of the clinical trials and may not be re-sold in South Africa. However, if the model is to be offered for local sale then Documentation (as outlined in Point 3 and 4) must be submitted. Further, the date of importation or manufacture of units of that model may not precede the dates of the documentation required under Points3 and 4. There are no special tariffs or restrictions reserved for used / refurbished equipment, as there is no distinction made between new and refurbished / used medical devices [12]. No third party may legally import the same device in used / refurbished condition without the used device being subjected to new safety inspections, since each importer must obtain a license for each model that they import. There are no restrictions on the number of licensed importers allowed per model at present [12,13,14,15].

1.4.3 Kenya

Key competitive factors that serve to limit the potential for the sale of U.S. electro-medical equipment include price, promotion and after-sales service. Many of the industry stakeholders identified promotion as a major limitation that resulted in their lack of knowledge and awareness of medical technologies from the United States. Unlike the U.K, German and Dutch medical equipment suppliers who have over the years actively promoted their products to the Kenyan market, only a few U.S. suppliers such as G.E. Medical systems were identified but still accused of not being as active as their European counter parts. Secondary to promotion is the issue of after-sales service backup. Many of the health institutions that had purchased U.S. medical equipment cited poor after-sales service as a major problem. The lack of locally available spares and parts was attributed to the absence of local representative offices for the U.S. companies. It is recommended that U.S. companies consider appointing local agents or representatives to facilitate this after-sales service component that could also be used to promote U.S. medical equipment technology. This is the path, which successful European suppliers have chosen. Aggressive promotion campaigns can only be successful if they are not limited by the lack of a perpetual presence in any market of interest. Considering the dynamism of medical science, a number of Kenyan health institutions would like U.S. medical equipment suppliers to consider the sale of used and refurbished equipment as well as leasing options for new upgradeable equipment as enviable marketing strategy. Import Climate: Medical equipment imports into Kenya require an import license, as is the case with all other health sector inputs. The import climate for U.S. medical equipment market in Kenya is good. There are no import barriers, and the customs duty range from 0 percent to 15 percent. The following documentation is required to facilitate importation of medical equipment: Import declaration form (IDF) Commercial invoice Airway bill (airfreight) or bill of lading (sea freight) Pre-shipment inspection Clean Report of Findings (CRF).Imports with a free on board (FOB) value over US$5,000 are subject to a pre-shipment inspection, at the port of shipment. Pre-shipment inspection can be done by one of the two appointed supervision services companies, namely Cotecna Inspection SA and Intertek Testing Services (ITS) International. The cost of pre-shipment inspection is 2.75 percent of the cumulative cost, insurance and freight (C.I.F) value, payable as an import declaration form (IDF) processing fee. If not indicated, freight is calculated at 18.5percent of the consignment cost, and insur-

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ance 1.5 percent of the sum of the consignment cost and freight. Medical equipment is generally exempt from both import duties and value added tax (VAT). Exceptions include microscopes and dental chairs, which attract 5 percent duty and liquid-filled clinical thermometers that attract 15 percent import duty and 18 percent VAT.No approval is required to import any kind of irradiating device. However, prior to installation of any irradiating device the Radiation Protection Board must conduct an inspection and thereafter grant a license. There is no ban on the import of any type of pre-owned (used and refurbished) medical equipment to Kenya so long as the performance characteristics conform to the existing national standards and where none exist, reference is made to the International Organization Standards (ISO)[13].
The trademark name and country of origin must be displayed in English and/or Kiswahili for all categories of medical equipment. In addition, an expiry date must be shown for all medical consumables [12].

1.4.4 Brazil

Brazil approved a law that regulates the import of refurbished medical equipment. Companies that are interested in this niche have to comply with a rigid set of guidelines, including, date of refurbishment, accurate adjustment and calibration. The refurbished equipment must meet the exact same performance ofnew equipment. Also, the manufacturer must provide technical assistance in Brazil or designate a local representative to provide the service. Trade Barriers, including tariffs, non-tariff barriers and import taxes—Import Licenses: Automatic License As a general rule, Brazilian imports are subject to the 'automatic import license' process. This procedure requires that the Brazilian importer submits information concerning each import, including description of the product as well as the harmonized tariff classification number, quantity, value of the shipment, shipping costs, etc. This information will be used for purposes of preparing the 'Import Declaration' (locally known as the DI). Subsequently, all information is fed into Brazil's customs computer system known as the SISCOMEX. The Brazilian Foreign Trade Secretariat (SECEX) is the government agency responsible for granting import licenses [12]. Non-Automatic License (LI) whenever imports are subject to the Non-Automatic License (LI) regime, the importer must provide information concerning each shipment to Brazilian customs authority either prior to shipment or prior to customs clearance. The required information includes a description of the product as well as the harmonized tariff classification number, quantity, value of the shipment, shipping costs, etc. Prior to Customs Clearance: Products imported under the drawback regime, as well as imports destined to the free trade zones and the National Council for Scientific and Technological Development. Prior to Shipment Clearance: Products subject to special controls from SECEX or which require approvals from other Brazilian government agencies. Such products may include: used products in general, products that enjoy import tariff reductions, imports that do not involve payment from importer to the exporter—e.g., samples, donations, temporary admission, psychotherapeutic drugs, products for human or veterinary research; weapons and related products, radioactive products and rare earth metal compounds, crude oil, oil derivatives or other petroleum derivatives, anti-hemophilic serum, medications with plasma and human blood, products that may be harmful to the environment—e.g., CFC, mailing machines, stamp selling machines, airplanes, etc [13].
Shortly after feeding the SISCOMEX system information concerning a specific shipment, the SISCOMEX system will indicate whether or not a 'non-automatic import license' is required. On February 15th 2001, ANVISA (National Health Administration Agency) published resolution RDC nº 25, which regulates imports of used medical equipment. The resolution imposes strict requirements that used equipment must meet before it can be imported into the country. Some of the requirements include: Registration with Brazil's Vigilancia Sanitaria agency. If the product does not require such registration, submit evidence to support your claim;

- Obtain an import license. The license must state the country of origin, detailed information of product, name of manufacturer, model and technical specifications;
- The equipment must be thoroughly cleaned and refurbished;
- All parts and pieces subject to wear and tear must be replaced;
- The equipment must be professionally calibrated to meet original specifications which must be certified by the original manufacturer;
- New labels must be affixed and an instruction manual must be provided;
- Submit the year the equipment was refurbished;
- The equipment must pass thorough quality control tests; and
- Make spare parts and components available in Brazil during the useful life of the equipment.

There are severe penalties for companies that do not follow the requirements listed above, including assessment of stiff fines and even confiscation of the equipment. Therefore, it is critical that U.S. exporters of used medical equipment coordinate closely the transaction with the Brazilian importer. We also strongly advise that U.S. companies obtain the services of a reputable Brazilian customs brokerage firm with significant experience related to imports of medical equipment [12].

1.4.5 United Arab Emirates

(Standard Operating Procedures for Permitting of Chemicals and Hazardous Materials in Abu Dhabi): The Environment Agency–Abu Dhabi's (EAD's) establishes standards of conduct for all public and private entities for the promotion of environmentally sound management practices for chemicals and hazardous materials in Abu Dhabi Emirate. The code is developed in line with the Federal Law No. 24 and its bylaws regarding the management of chemicals and hazardous materials [13]. These standard operating procedures (SOPs) clearly define the roles of the proponent and EAD in order to put in place practices that will minimize potential health and envi-

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ronmental risks associated with the handling of chemicals and hazardous materials. These SOPs are intended to support the requirements of Abu Dhabi Emirate Environment, Health and Safety Management System (EHSMS) Regulatory Framework (Decree 42 of 2009). The proponent must comply with any additional requirements for the import, export, handling, storage, and use of chemicals or hazardous materials within the EHSMS Regulatory Framework (without exception).
Failure to comply with these conditions will result in the environmental permit being revoked. Furthermore, EAD is developing an integrated system for hazardous materials management that contains a distribution module that will allow hazardous materials storage and industrial facilities to record and track quantities of materials they store, distribute, and use, and to maintain an inventory of their stocks [13].

3 METHODOLOGY

The proposed system steps for the SOPs are: the technical specification, the operation requirement, the electrical safety, decontamination and the environmental procedures (Fig. 1).

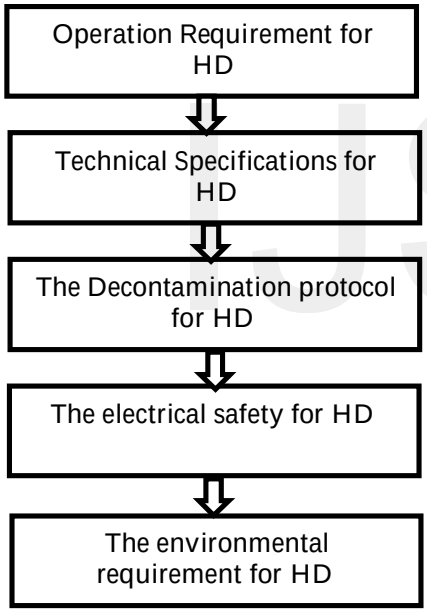

Fig.1: SOPs Block diagram

3.1 Operational requirement

Operational requirements are those statements that "identify the essential capabilities, associated requirements, performance measures, and the process or series of actions to be taken in effecting the results that are desired in order to address mission area deficiencies, evolving applications or threats, emerging technologies, or system cost improvements [16]. The operational requirements assessment starts with the Concept of Operations (CONOPS) and goes to a greater level of detail in identifying mission performance assumptions and constraints and current deficiencies of or enhancements needed for operations and mission success. Operational requirements are the basis for system requirements. Machine should have facility for variable Sodium, Acetate, Bicarbonate, Regulated Ultra Filtration, Sequential Dialysis (Isolated UF). Upgradable to future software developments and can be linked with patient Data Management System. The blood pump should be able to run at least from 50 to 600ml/min and adaptable to standard A-V blood lines and should run even in the absence of water or dialysis flow.

3.2 Technical Specification

Specification (often abbreviated as spec) may refer to an explicit set of requirements to be satisfied by a material, design, product, or service [17]. Should a material, product, or service fail to meet one or more of the applicable specifications [18], it may be referred to as being out of specification; the abbreviation OOS may also be used [19]. In casual usage, under spec or over spec are used when something is worse or better than specified (compare over engineering), though in general (such as for sizes) there is only a notion of "in spec" or "out of spec", not "better" or "worse". A specification is a type of technical standard. A technical specification may be developed by any of various kinds of organizations, both public and private. Example organization types include a corporation, a consortium (a small group of corporations), a trade association (an industry-wide group of corporations), a national government (including its military, regulatory agencies, and national laboratories and institutes), a professional association (society), a purpose-made standards organization such as ISO, or vendor-neutral developed generic requirements. It is common for one organization to refer to (reference, call out, cite) the standards of another. Voluntary standards may become mandatory if adopted by a government or business contract. A design or product specification describes the features of the solutions for the requirement specification. Sometimes the term specification is here used in connection with a data sheet (or spec sheet). This may be confusing. A data sheet describes the technical characteristics of an item or product as designed and/or produced. It can be published by a manufacturer to help people choose products or to help use the products. The proposed technical specifications for HD machine are shown in table 1,2,3,4 and 5 according to the famous companies (Fresenius and Gambro). Also the most HD machines in Sudan are from those companies.

TABLE 1
TECHNICAL SPECIFICATIONS FOR HD MACHINE (BLOOD CIRCUIT)

Blood circuit	Fresenius	Gambro
Arterial pressure, mm hg	-300 to +280	-400 to 150.
Venous pressure, mm hg	-60 to +520	0 to 450
Blood pump range, ml/mi	15-600	10-500
Heparin pump range, ml/h	0.1-10 (20, 30, 50 mL syringe	0.5-9.9

TABLE 2
TECHNICAL SPECIFICATIONS FOR HD MACHINE (DIMENSION)

Dimension	Fresenius	Gambro
Dimensions (h×w×d) cm	133 x 50 x 34 (52.4 x 19.3 x 13.4); base 63	144 x 61 x 71 (56.6 x 24 x

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	(24.8) deep	27.9)
FLOOR SPACE, m2 (ft2)	Approx .0.3 (3.2)	0.43 (4.6)
WEIGHT, kg (lb)	80 (176.4)	120 (264)

TABLE 3
TECHNICAL SPECIFICATIONS FOR HD MACHINE (ALERTS(CONFIGURATION))

Alerts(Configuration)	Fresenius	Gambro
Detection of blood leak(ALERTS)	Stops blood pump, clamps line, UF turned off 3	Stops blood pump, clamps line, reduces UF rate to minimum
Detection of air / foam	Stops blood pump, clamps line, UF turned off 3 Also visual and audible alarm, alarm stored	Stops blood pump, clamps line, reduces UF rate to zero
Conductivity	Bypass, visual and audible alarm, alarm stored Also visual and audible alarm, alarm stored	Bypass
Arterial / venous pressure	Stops blood pump, clamps line, UF turned off3	Stops blood pump, clamps venous line, UF rate to zero
Temperature, high / low	Bypass, visual and audible alarm, alarm stored Also visual and audible alarm, alarm stored	Bypass

TABLE 4
TECHNICAL SPECIFICATIONS FOR HD MACHINE (DIALYSATE DELIVERY)

Dialysate Delivery	Fresenius	Gambro
Proportioning system	Volumetric	Servo-controlled
Comfort control, °c	35-39	34-39.5
Temperature alerts °c	33.5-40	32-41
Conductivity range, ms / cm	12.8-15.7 1	13-17, 0.1 increment
FLOW, mL / min	300, 500, 800	350increments of 50
Transmembrane pressure, mm hg	-60 to +520	0 to 450
Bicarbonate	24 to 40 mmol / L	Yes
Sodium therapy	Yes . 125-150 mmol / L	Yes
Ultrafiltration pace, l / hr	0-4, profiled UF	0.1-4
Ph monitor	Not needed	Yes
Microprocessor (Calibration)	Intel embedded micro processor system	PENTIUM Geode GX-1, 233 MHz, 128 Mb
Storage options	Treatment, failure data	Procedure in operator's manual
Interface Protocol	Bidirectional RS232	LCD video, touchscreen
Display type	LED, color LCD	LCD
Water Loss Alert	Visual, audible, cyclic integrity test	YES

TABLE 5
TECHNICAL SPECIFICATIONS FOR HD MACHINE (DISPLAYS (STAINING POSTS))

Displays (Staining Posts)	Fresenius	Gambro
Dialysate pressure	Not displayed	Yes
Transmembrane pressure	Yes	Yes
Conductivity	Yes	Yes
Flow rate	Yes	Yes
Elapsed time	Yes	Yes
Time left	Yes	Yes
Prescribed time	Yes	Yes
Bypass signal	Flow indicator, LED	Yes

3.3 Microbial testing of haemodialysis machine disinfection

The Biomedical Technologist, Renal Dialysis Technician, or Renal Nurse who is trained and has demonstrated competency in dialysis water practices will use the procedure outlined in this document to collect dialysis water samples for microbial testing, and to perform the necessary actions should test results for microbial counts exceed the acceptable limits [20]. Table 6,7,8 and 9 show the proposed protocol microbial testing of HD machine disinfection system.

TABLE 6
STANDARD DIALYSATE

total viable microbial count	<100 CFU / ml
Action level	50 CFU / ml
After disinfection	0 CFU / ml

TABLE 7
THE LABORATORY ASSAYING TECHNIQUE USED FOR TESTING MICROBIAL GROWTH

Test method	Spread plate
Sample volume	1.0 ml
Assaying time	Within 4 hr of collection or 24 hr if immedialety refrigerated
Culture media	Tryptone Soya Agar
Incubation temperature	35 °c
Incubation time	48 r

TABLE 8
SPECIMENS

▪ Equipment	20 ml syringes Alcohol swabs Gloves
▪ Produce	
Select the dialysis machine to be tested.	• Record the machine: IDs,data time and initials of the designated tester on the microbial testing of dialysate

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		sheet • Get a syring, two alcohol swabs • Label the sterile container the machine ID, data and time • Put on a pair of gloves • Open the alcohol swab and use it to clean the sample port at the inlet to the dialyzer. Make sure the alcohol swab is fully swabbed over the injection site. • Discard the alcohol swab after use &give the alcohol time to evaporate. • Using a new alcohol swab , fold the swab into a triangular shape & use the pointed end to clean the inside of the sample port. • Discard the swab & let the alcohol evaporate • Using a syring, aspirate dialysate out of& into the port before filling the syring. • Use another new & sterile syringe to collect a fresh sample of dialysate .collect 50 ml of fluid. • Firmly seal the container .discard the syringe. • The second dialysate sample is drawn frame the outlent of the dialyzer.
▪ Send the samples to the microbiology laboratory for testing.		

TABLE 9
ANALYTICAL CONSIDERATIONS

▪ Supplies	▪ Tryptone Soya A gar
▪	▪ Disposable sterile Petri dish ▪ Glass rod spreader ▪ Incubator ▪ Sterile 1 ml pipettes
▪ Procedure	▪ Mix water samples by vortexing the sample container. Plates 1 ml onto the center of agar plate.Spread inocula with glass spreader. ▪ Incubate plates at 35 °c ▪ Calculate the total colony count ▪ Identification of the organism is not required ▪ Report total CFU per milliliter

3.4 Safety

3.4.1 HD machine chassis current

The HD machine chassis current in normal operation could be 100μA and up to 500μA if the earth conductor breaks. The allowable current for equipment connected to the heart is 50μA in a single fault condition. Even this may be enough to cause VF as Laks et al (1996) commented that the minimum current shown to cause VF in a human was 15μA. Deller (1979) commented "(HD) Equipment that has been constructed to BS 5724 should not, by its design, give rise to primary electrical hazards".

3.4.2 HD Machine Leakage Current

Jonsson & Stegmayr (2000) measured patient leakage currents of four machines (Gambro AK10, AK100 & Fresenius 2008 (C&E) & 4008E with values from 1 to 20μA in normal condition and 60 to 140μA with a broken earth conductor; measure at dialyser connectors. Main on applied part produced 3,500μA leakage current. Jonsson et al, (2005) then measure in vitro patient leakage current in single fault condition at the tip of a vascular catheter primed with blood; median 68μA (range 35-118μA). When mains was applied to the catheter tip a dangerous leakage current was measured; median 610μA (range 441-662μA).

3.4.3 Environmental requirements

Environmental is abstracted in cleanness.It is necessary of using friction, cleaning and disinfection 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 [21].

4 RESULTS AND DISCUSSIONS

The assessment of the efficiency and safety of the HD machines was done in two groups: Group one: six centers of haemodialysis in Khartoum state were selected to test the efficiency and safety of the HD machines (Used machines) as shown in table 10. Group two: twenty Fresenius and twenty Gambro donated machines were selected to test the efficiency and safety of the HD machines (donated machines) as shown in table 12.

TABLE 10
ASSESSMENT THE EFFICIENCY AND SAFETY OF THE HD MACHINES IN GROUP ONE

Test	Yes	No
Is the machine able to organize the sodium bicarbonate amount's whereas doesn't harm the patient?	6	0
Is it allowed to update the machine mean while connecting the patient's data with data base receivers?	6	0
Is the blood pump able to work at least between 50-600ml / min?	3	3
Is the machine conductivity range between 12-16 m s?	6	0
Is the machine able to discover the solution's negativity and positivity?	5	1
Dose the device have screen to explain the while terminologies within 15-20 min?	6	0
Does the machine have sensitive to discover the blood clotting?	5	1
Dose the machine have the bicarbonate holder?	6	0

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Does the machine have a schedule for periods of sterilization in the long term?	6	0
Is there a control in the process of filtration through the flow and control the volume through the technique of measurement?	5	1
Is the calibration do for the Machine periodically?	2	4
Is there a system to protect the variables of electricity coming into the machine?	5	1
Is there an audible alert when you get a problem in filtration?	6	0
Is there a possibility to connect the machine with a computer when you get a problem?	0	6
Is there a possibility to measure blood pressure in the servo?	6	0
Is there a battery in the servo?	6	0
machine conform to the specification and international standards	6	0
the issuer of the machine has a certification ISO	6	0
agent's commitment to maintenance	6	0
commitment to the training of engineers and physician	5	1
equipment preventive maintenance recommended by the manufacturer	4	2
alert audio visual change when the value of conductivity temperature or leaking blood or air	4	2
Is there an audio visual alert when stopped pump blood?	6	0
Is there an audible alert when the pressure change visible vein and artery?	6	0
Can electricity input device for me is 220 to 240v.50Hz?	6	0
Did you place qualified storage solutions for the laundry?	4	2
Did unit continuous operating temperature of 10-40 and 15-90 moisture?	6	0
Is there disposable included in the kidney industrial transmission line?	6	0
Is the machine system open system?	4	2
is there a leak detector for blood ?	6	0
Is there a leak detector for air?	6	0

From group one the total numbers of YES was 160 and total numbers of NO was 26. Fig. 2 shows the percentage of YES and NO. As can be shown the percentage are 86.02% and 13.98% for YES and NO respectively. According to the numbers of YES and No, the efficiency and safety of group one divided into six samples as shown in table 11. From the table the efficiency and safety for group one is 61.29%.

Table 12 is shown the efficiency and safely of group two. If the microbial count exceeds 1 CFU/ml (outlet), retest the offending machine after disinfection with peracetic acid. If after retesting the offending machine after disinfection shows the same result, the machine will be reject. For water used for for haemodialysis applications (inlet), there will be action limit of 50 CFU/ml. As can be shown in table 12 all the machines were pass the efficiency test expect one machine G20 (2.5%). Also M6, M12, M15, G6, G12 and G18 were not pass the safely test (15% from the total HD machines). The efficiency and safely of group two were 85%.

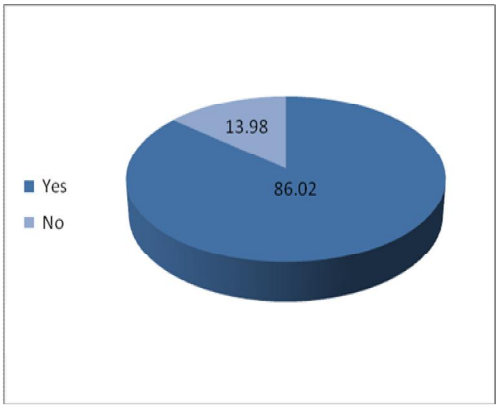

Fig. 2: The percentage of YES and NO of group one.

TABLE 11
THE EFFICIENCY AND SAFETY OF GROUP ONE

Samples	Yes	No	Total	Percent %
Sample #1	114	0	114	61.29
Sample #2	25	5	30	16.13
Sample #3	16	8	24	12.9
Sample #4	3	3	6	3.23
Sample #5	2	4	6	3.23
Sample #6	0	6	6	3.23
Total	160	26	186	100

5 CONCLUSION

According to the absence or specialized authorities that control and regulate operation of haemodialysis may cause many serious problems. This work is a case study for small sample space which contains two event (group one and group 2) to test the efficiency and safety of the HD machines. The result shows that from group one 38.71% is the absence of the efficiency and safety so these centers need to apply The SOPs for HD machine. From group two 15% of the HD machines were rejected and that are important for safely healthcare and this work is the beginning step to improve the use of the HD machine to give a better work.

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TABLE 12
ASSESSMENT THE EFFICIENCY AND SAFETY OF THE HD MACHINES IN GROUP TWO

No	Model	serial Number	operation house	Efficiency	Safety (Decontamination process) microbiological testing	
					Inlet	outlet
M1	Fresenius	4XCAE881	29.750	Pass	Zero CFU / ml	Zero CFU / ml
M2	Fresenius	4XCAE882	22.406	Pass	Zero CFU / ml	Zero CFU / ml
M3	Fresenius	4XCAE883	31.161	Pass	Zero CFU / ml	Zero CFU / ml
M4	Fresenius	4XCAE884	22.429	Pass	<30 CFU / ml	Zero CFU / ml
M5	Fresenius	4XCAE885	30.902	Pass	>200 CFU / ml	Zero CFU / ml
M6	Fresenius	4XCAE886	20.406	Pass	<30 CFU / ml	>300 CFU / ml
M7	Fresenius	4XCAE881	29.750	Pass	Zero CFU / ml	Zero CFU / ml
M8	Fresenius	4XCAE882	22.406	Pass	Zero CFU / ml	Zero CFU / ml
M9	Fresenius	4XCAE883	31.161	Pass	Zero CFU / ml	Zero CFU / ml
M10	Fresenius	4XCAE884	22.429	Pass	<30 CFU / ml	Zero CFU / ml
M11	Fresenius	4XCAE885	30.902	Pass	>200 CFU / ml	Zero CFU / ml
M12	Fresenius	4XCAE886	20.406	Pass	<30 CFU / ml	>300 CFU / ml
M13	Fresenius	4XCAE884	22.429	Pass	<30 CFU / ml	Zero CFU / ml
M14	Fresenius	4XCAE885	30.902	Pass	>200 CFU / ml	Zero CFU / ml
M15	Fresenius	4XCAE886	20.406	Pass	<30 CFU / ml	>300 CFU / ml
M16	Fresenius	4XCAE881	29.750	Pass	Zero CFU / ml	Zero CFU / ml
M17	Fresenius	4XCAE882	22.406	Pass	Zero CFU / ml	Zero CFU / ml
M18	Fresenius	4XCAE883	31.161	Pass	Zero CFU / ml	Zero CFU / ml
M19	Fresenius	4XCAE884	22.429	Pass	<30 CFU / ml	Zero CFU / ml
M20	Fresenius	4XCAE885	30.902	Pass	>200 CFU / ml	Zero CFU / ml
G1	Gambro	S / N 17 / 37	24.594	Pass	Zero CFU / ml	Zero CFU / ml
G2	Gambro	S / N 200 86	14.946	Pass	Zero CFU / ml	Zero CFU / ml
G3	Gambro	S / K 14 351	19.277	Pass	Zero CFU / ml	Zero CFU / ml
G4	Gambro	21422	22.429	Pass	<30 CFU / ml	Zero CFU / ml
G5	Gambro	24567	8.351	Pass	>200 CFU / ml	Zero CFU / ml
G6	Gambro	21420	13.440	Pass	<30 CFU / ml	>300 CFU / ml
G7	Gambro	16351	8.351	Pass	Zero CFU / ml	Zero CFU / ml
G8	Gambro	17930	15.148	Pass	Zero CFU / ml	Zero CFU / ml
G9	Gambro	17649	15.348	Pass	Zero CFU / ml	Zero CFU / ml
G10	Gambro	21411	15.148	Pass	<30 CFU / ml	Zero CFU / ml
G11	Gambro	17137	22.429	Pass	>200 CFU / ml	Zero CFU / ml
G12	Gambro	3504	9.252	Pass	<30 CFU / ml	>300 CFU / ml
G13	Gambro	16351	10.223	Pass	Zero CFU / ml	Zero CFU / ml
G14	Gambro	7159	5.654	Pass	Zero CFU / ml	Zero CFU / ml
G15	Gambro	6973	5.254	Pass	Zero CFU / ml	Zero CFU / ml
G16	Gambro	17651	8.251	Pass	<30 CFU / ml	Zero CFU / ml
G17	Gambro	16269	18890	Pass	>200 CFU / ml	Zero CFU / ml
G18	Gambro	21418	14057	Pass	55 CFU / ml	>300 CFU / ml
G19	Gambro	21421	16670	Pass	<30 CFU / ml	Zero CFU / ml
G20	Gambro	17148	18918	Not pass	No need	Not Working

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