

The Current Home Hemodialysis Practices and Patients' Safety Related Factors: A Case Study from Germany

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Abstract—The increasing costs of healthcare on one hand, and the rise in aging population and associated chronic disease, on the other hand, are putting increasing burden on the current health care system in many Western countries. For instance, chronic kidney disease (CKD) is a common disease and in Europe, the cost of renal replacement therapy (RRT) is very significant to the total health care cost. However, the recent advancement in healthcare technology, provide the opportunity to treat patients at home in their own comfort. It is evident that home healthcare offers numerous advantages apparently, low costs and high patients' quality of life. Despite these advantages, the intake of home hemodialysis (HHD) therapy is still low in particular in Germany. Many factors are accounted for the low number of HHD intake. However, this paper is focusing on patients' safety-related factors of current HHD practices in Germany. The aim of this paper is to analyze the current HHD practices in Germany and to identify risks related factors if any exist. A case study has been conducted in a dialysis center which consists of four dialysis centers in the south of Germany. In total, these dialysis centers have 350 chronic dialysis patients, of which, four patients are on HHD. The centers have 126 staff which includes six nephrologists and 120 other staff i.e. nurses and administration. The results of the study revealed several risk-related factors. Most importantly, these centers do not offer allied health services at the pre-dialysis stage, the HHD training did not have an established curriculum; however, they have just recently developed the first version. Only a soft copy of the machine manual is offered to patients. Surprisingly, the management was not aware of any standard available for home assessment and installation. The home assessment is done by a third party (i.e. the machines and equipment provider) and they may not consider the hygienic quality of the patient's home. The type of machine provided to patients at home is similar to the one in the center. The model may not be suitable at home because of its size and complexity. Even though portable hemodialysis machines, which are specially designed for home use, are available in the market such as the NxStage series. Besides the type of machine, no assistance is offered for space management at home in particular for placing the machine. Moreover, the centers do not offer remote assistance to patients and their carer at home. However, telephonic assistance is available. Furthermore, no alternative is offered if a carer is not available. In addition, the centers are lacking medical staff including nephrologists and renal

nurses.

Keywords—Home hemodialysis, home hemodialysis practices, patients' related risks in the current home hemodialysis practices, patient safety in home hemodialysis.

I. INTRODUCTION

CHRONIC kidney disease is not a rare disease and its prevalence is on the rise globally. For example, in Germany, there are minimum two million renal patients [1], and from the treatment perspective, in 2017, there were 94,072 patients performing dialysis therapy, of which 93.14% were on HD, 6.07% on PD, and 0.78% on HHD [2]. To get a closer picture of the dialysis patients and their treatment modalities, reports from large dialysis centers can be analyzed. In Germany, RRT is provided in four different ways: Non-profit chains PHV (*Patienten Heimversorgung*), KfH (*Kuratorium für Heimdialyse*), private dialysis centers, and dialysis units in hospitals. The share of KfH is about 30% and comprises of 16 dialysis centers [3]. In 2017, in total, KfH had 19,080 patients on dialysis of which 15,507 were on ICHD (In-Center Hemodialysis), 1,678 on ZHD (Zentrierte heimdialyse/limited care), 1,615 on PD (Peritoneal Dialysis) and 280 on HHD [4]. Moreover, this report shows a decrease in HHD and an increase in other dialysis modalities between 2007 and 2017. Similarly, the number of transplantation has been decreased, respectively. For example, the total number of HHD patients has been decreased from 305 in 2009 to 280 in 2017. On the other hand, renal transplantation has been decreased from 2,907 in 2007 to 1,921 in 2017 [4]. These numbers indicate that HHD has been decreasing since 2007, while other dialysis modalities have been increasing in Germany, despite the numerous advantages associated with HHD.

The current literature revealed that home healthcare offers promising benefits i.e. low cost, improved quality of life and flexibility for patients. For instance, the cost of HHD is lower than ICHD [5], [6] and offers better quality of life [7]-[9], [10]. In addition, the survival rate of HHD is higher than ICHD in particular with frequent and nocturnal HHD [11]-[13]. Interestingly, the intake of HHD is not only low but had decreased over time, at least in KfH dialysis centers. There is a lack of research work to study the current HHD practices and identify and explore the reasons behind the low HHD rate in Germany. Some attempts have already been made, for example, a survey was conducted in 137 dialysis centers in

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Germany regarding the behavior of nephrologists towards assisted HD (AHD). The study revealed that the main barriers to AHD in Germany are; the lack of funding, lack of staff, lack of expertise or experience, and the lack of team motivation [14]. Furthermore, the pay-per-performance system was introduced in Germany and approved in 2007. Based on this system, it is necessary for all centers to send quality treatment parameters (related to guidelines e.g. KDOQI, KDIGO, and EBPG) to a central system in order to receive the payment for the provided treatment. Each center is evaluated based on four parameters (spKt/V1.2, frequency per week 3, duration per session 4 hours, and Hgb 10g/dL) and the number of patients allowed to fail the requirements are 15%. In addition, it is mandatory for each center to comply with the internal benchmark system which includes parameters like albumin, phosphate, calcium, etc. However, the internal benchmarking was anonymous and therefore, centers were not identified because there is no obligatory cut-off values. State-wise quality assurance committees have been founded and centers are anonymously evaluated by the committees. It was revealed that, from the total 742 dialysis centers, 556 centers got informative letters, 125 centers had random evaluation, 182 did not reach the 15% range and were notified to present written medical reasons, 64 centers got notification to change their approach, and 35 centers have to appear in front of the committee. However, the benchmark system has shown improvements [3]. Therefore, it creates further motivation to study the current practices of the hemodialysis centers in Germany and to find out significant reasons especially risk-related factors in their HHD procedures and practices. To the authors' knowledge there is the absence of studies to explore the challenges and obstacles in HHD especially factors related to risks in the HHD process in Germany.

II. METHODOLOGY

A case study was conducted in a group of dialysis centers in the south of Germany. The center comprises of four dialysis centers, one center is only offering limited care and another one is situated in the regional hospital and does not provide HHD. However, the two centers offer HHD and are located at about 8 km proximity from each other. In total, there are 350 chronic dialysis patients, of which, four are on HHD and one was transplanted. The total staff is 126 which include six nephrologists. Two in-depth interviews were conducted, one with the head nephrologist and one with the head nurse. One interview took place at the nephrologist home and the second interview was carried out in one of the centers. Seven steps of the interview i.e. thematizing, designing, interviewing, transcribing, analyzing, verifying and reporting were followed [15]. The interview was recorded and transcribed.

III. RESULTS AND DISCUSSION

The results revealed the following risk-related factors in the HHD practices: 1. The lack of curriculum in the HHD training 2. Lack of awareness about the HHD standards for home assessment and installation 3. The complexity of HD machine

4. The absence of proper remote monitoring 5. The absence of alternative for a lay carer at home 6. The absence of allied health care services 7. The lack of assistance to solve a conflict between patient and carer 8. Shortage of medical staff 9. Others risk-related factors.

A. HHD Training

In both nephrologists' [16]-[18] and patients' [19] views training is one of the key factors in successful HHD. It is apparent that a well-established training curriculum is required in order to avoid any procedure related failure in the HHD treatment process. For instance, the risk of HHD failure technique was studied in Canada and it was found that the risk of HHD techniques was higher between 2008 and 2012 compared to previous years [20]. Importantly, a case from New Zealand has reported where a 67-year HHD patient was exsanguinated due to the error in the washback procedure. The saline bag was connected "to the venous end of the extracorporeal blood circuit instead of the arterial end" [21, p.1]. However, the authors have recommended reviewing the HHD training protocols and manuals, among others [21]. This could be the reason that the Canadian Standards (Z364.5-10(R2015)) for safe installation and operation of hemodialysis and peritoneal dialysis in a home setting also cover patient and caregiver training, documentation, and records, etc. [22]. Furthermore, *generally accepted practices* (GAPs) are developed as guidelines which also include patients training. However, a study revealed that HHD training is not always adhering to the GAPs. For example, 90% of the trainings are not consistent with the GAP (skin antisepsis before cannulation), the use of alcohol in accordance with IFU for application motion, time, dry time, and use of sterile pad [23]. On the other hand, studies such as [24], [25], shows that the risk of infection is higher in HHD than in ICHD, especially the access related infections. Non-adherence to the GAPs in training could increase the risk of infections in HHD patients. However, in the studied dialysis centers, there is no proper mechanism to check the usage of skin antisepsis before cannulation at home. Only the volume of the liquid has been observed by analyzing the bottle. However, this is not a reliable methodology.

Moreover, no written curriculum for HHD training was found in the studied centers during the first interview. The reason given behind the lack of training curriculum is the low number of new HHD recruitments, which restrict the centers from investing resources in developing an HHD training curriculum. The absence of HHD training curriculum will make the training unstandardized which means every trainer (i.e. renal nurse) will deliver the training in their own way with their own contents. There exists a probability of something to be missed during the training. However, recently they have just developed the first version of the HHD training curriculum. Only a soft copy of the machine manual had been provided to the HHD patients and they are aiming for a proper training curriculum in the near future. The manual might not be appropriate in case of complications. For instance, in a study from the Netherland, in which technical documentation

of three devices (dialysis system, infusion pumps, and ventilators) were studied to analyze risk-related factors, among others. The study found that in 43% technical documents, risk analysis of warnings, precautions and contraindications were missing [26]. On the other hand, complaints are received from the lay carers at the beginning of the HHD concerning the emergency situations, in particular managing different machine's alarms. In some cases, carers got help from the HHD machine manual [19].

Besides the curriculum, the delivery method of the training is also important and can play a significant role in the HHD process. Studies have already been proved that innovative methods of training have a positive influence on patients' learning skills [27] and consequently it will reduce the HHD procedure-related risks to certain extent. For example, Toronto General Hospital, Canada [27] and Hull & East Yorkshire Hospital Trust, Hull, UK [28]. At Toronto General Hospitals, an innovative room has been developed where training is delivered in a simulated form. In the second example, a shared care concept has been introduced which means patients collaborate with each other's in the center in the presence of renal nursing support, in order to increase the learning efficiency of the patients. However, in the studied dialysis centers, they are not aware of such innovative techniques in HHD training and the same reason was mentioned i.e. the low number of new HHD recruitments. Another important aspect of training is the content of training. A study has highlighted the following training content: Information about dialysis procedures, fistula care, catheter care, as well as about chronic renal failure, nutrition, control of weight, hygiene, and exercises and traveling [29]. The content of the current HHD training in the studied centers include only HHD procedures related contents but does not provide information on topics such as chronic renal failure, nutrition, exercise, and traveling, etc.

B. Standards for Home Assessment

In several countries, standards are developed for home assessment and HHD system installation. For example, in the UK, London Health Sciences Center (LHSC) analyze patients' house, installation planning, renovation and installation of equipment against certain parameters, to ensure that patients' home met an acceptable level of infrastructure services. In addition, treated water should comply with the standard set by AAMI (Association for the Advancement of Medical Instrumentation) [30]. Similar standards exist in Canada i.e., Z364.5-10(R2015)) for the installation and operation of HHD and PD. This standard covers home assessment, physical space requirements, plumbing, electricity and water, supply storage and waste, etc. [22]. In the studied centers, such standards are not known due to the fact that a third party i.e., the machine and equipment provider is responsible for the home assessment and installation. In the studied case, the dialysis technicians are carrying out the home assessment and installation and the supplier of the machine and equipment is responsible for the installation process. So far, it is not clear to the management of the dialysis centers, if the service provider

has developed a standard or following a specific standard for home assessment and installation. The dialysis technician might not consider some hygienic issues at patients' homes and the patients might be exploited to infections. However, the centers test the quality of water against certain standards. In addition, the water supplier is informed about the HHD patient. In case of any disruption in the water supply, the water supplier will immediately inform the HHD patients.

C. The Hemodialysis Machine

Five different models of HHD machines were studied in the UK, and it was revealed that the size of the machine which lacks portability and the time around dialysis procedure was disliked by patients [31]. The authors have suggested several areas of improvement in the studied models. Further studies such as [21], [32]-[34] have emphasized that simple dialysis procedure and setup are important for dialysis patients, which indicates that, specially designed machines for HHD is important. The study in which a 67-year old HHD patient from New Zealand was reported also suggested customized machines for home use [21]. However, portable machines for home use are currently available in the market such as NxStage System One. In the case study, it was found that they are using Fresenius F5008 for HHD which is similar to the one in the dialysis centers. The reason was given that it is easy to replace the machine immediately in case of any technical failure. However, Fresenius F5008 is still big in size and lacking portability. In addition, the set-up and procedures might be complicated compared to the new portable machines such as Nxstage series. The complexity of the machine could pose some risk to patients. Furthermore, the model is capable to send dialysis data to the center on a regular basis. However, the center does not have a data receiving or recording system and they do not check the machine on regular basis, unless a problem arises. However, the machine has been checked on a yearly basis in order to comply with *STK* (Sicherheitstechnische Kontrolle). The dialysis data are only stored in the black-box of the machine and only checked in case of complications by a dialysis technician. Studies have shown that sometimes a patient or a carer is not complying with the prescribed treatment regimen or they are simply careless. As quoted from one study, "my husband is not the most honest person, so if I wasn't right there listening to what he was saying. He could be very misleading in what he was saying to the doctor and the picture painted was entirely different than what it was" [19, p. 654]. In this case, it is difficult to monitor if a patient or a carer is really complying with the treatment regimen and if the carer is honest or not. This situation could be very risky and can influence patient treatment negatively.

D. Remote Monitoring

Studies such as [35], [36] show that remote monitoring is important for patients and particularly correlated with patients' interest in NHHD (Nocturnal Home Hemodialysis) [37]. Furthermore, a study indicated that video-as-a-service for HHD patients could increase the confidence in HHD patients

[38]. Remote monitoring will not only provide support to HHD patients but to carers as well [37]. At early stages of HHD, it is difficult to handle emergency situations such as dealing with different machine's alarms, etc. and therefore carers have often complained [19]. In this case, remote monitoring would be very helpful especially video-as-a-service. However, the studied centers do not offer remote monitoring; only a call service is available. In some situations, it might be difficult to explain complications appropriately on the phone. As well, these centers offer only personal assistance at the beginning of HHD for a few days, where a dialysis technician and a renal nurse are present at the patient's home. After that, if any problem arises and which cannot be easily solvable on the phone or in an emergency situation, the patient must visit one of the dialysis centers for the continuation of the hemodialysis therapy. For HHD patients it might not be convenient to visit the centers in the case of complications or emergency. This could further demotivate patients to continue HHD. Furthermore, there may also be some reluctance by patients to contact the centers for perceived small issues; however, patients can underestimate the risks posed their health.

E. Alternatives for Lay Carer

In the case a carer is not available due to any reason; a replacement or alternative should then be provided. Studies have shown such cases where carers were not available due to emergency situations; for example, once a carer had leg injuries and was not able to provide care to the HHD patient [37]. Sometimes carers need a break, and in that case, an alternative should be provided, since independent HHD therapy is not allowed. In the studied dialysis centers, the only alternative is to visit the dialysis center for the HD therapy. Visiting the dialysis center for an HHD patient might be difficult, especially when a patient is an employee, and it might have some disadvantages such as infection risk at the center, reduced motivation for the continuation of the HHD therapy, and psychological effects of routine disruptions in the HHD therapy, etc. The reason behind the absence of this service is the lack of renal nursing staff available for home visits. Besides carers' alternative, assisted HHD could also be offered to HHD patients. This would also enable the older patients to carry out HD therapy at home. However, the studied centers do not have such an option; even though in many dialysis centers in Germany it is a common practice to assist old patients on HHD. According to a survey conducted in 137 dialysis centers in Germany, 51% of the dialysis centers are offering assisted hemodialysis (AHD), of which, 47% offer both PD and HD, 47% PD only and 7% home HD only. In addition, 96% nephrologists have suggested that AHD is meaningful in different ways [14]. However, AHD is offered to elderly patients only. It could also be offered to patients who do not have a carer or need an alternative for short period of time.

F. Allied Healthcare Services

Literature have already highlighted that HHD patients need

dietary [39], [40], emotional & psychological [41], [42] and spiritual support [42]. A study from 71 dialysis units in Australia showed that to a certain extent they are offering allied health services (i.e. social work, psychology/psychiatry, dietary, home visits and respite care). However, only 61% of respondents said they are receiving adequate social work services, 34% psychology/psychiatry, 59% dietary, 45% home visits and 27% respite care, respectively. In the case study, the dialysis centers do not provide any allied health services at a pre-dialysis stage or during the dialysis particularly, an emotional & psychological, and dietary services are not offered. For example, some studies have indicated that hemodialysis therapy at home has some psychological effects on patients. A narrative study in Sweden has identified some changes in the peaceful home environment. For instance, the noises generated by the hemodialysis machine were found to be disturbing for the HHD patient [43]. Furthermore, some patients perceive the hemodialysis machine at home negatively, as one patient referred to it as "bastard" [44].

G.No Assistance in Case of Conflict between Patient and Carer

Some research has shown that interpersonal conflicts arise between the patients and carers. Different reasons could be accounted for interpersonal conflicts, for example, negative behavior, dishonesty, manipulation, and non-compliance with the treatment regimen [19]. For instance, a patient was quoted previously, "my husband is not the most honest person; so, if I wasn't right there listening to what he was saying, he could be very misleading in what he was saying to the doctor and the picture painted was entirely different than what it was." [19, p. 654]. Dishonesty, manipulation and non-adherence to the treatment regimen could be very dangerous for the HHD patients. The centers in the case study do not offer any assistance for solving conflicts among patients and carers and the only available solution was ICHD.

H.The Lack of Medical Staff

Studies have shown that the lack of skilled medical staff is one of the significant barriers to HHD [17], [45]-[47]. Similar findings were also revealed by this study. These centers are lacking medical staff including nephrologists and renal nurses. On the other hand, there is a shortage of skilled medical staff in the country. HHD recruitments require skilled staff to manage different HHD activities such as training, remote monitoring, home visits, and handling emergency situations, etc. In these circumstances, the HHD patients will not be properly managed and that could pose risks to the patients. On the other hand, recruiting more independent HHD patients could solve this issue to a certain extent. Since the dialysis centers do not allow HHD without a carer, the shortage of medical staff has an influence to limit the HHD services, for instance, remote assistance, home visits for emergency situations, replacing lay carers for short time, etc. It might expose the current HHD patients to some risky situations.

I. Others

Some other issues have been identified such as the removal

of a dialysis system in the case the patient has quit HHD. In one case, the patient received a transplant and no longer had a need for HHD; however the supplier of the equipment failed to remove it from the patient's home even though they were informed. This situation might also have some negative psychological effects on the patient.

IV. LIMITATION AND FUTURE RESEARCH

These results are based on four dialysis centers operating in the south of Germany and may not represent all dialysis centers and HHD practices in Germany. In addition, the studied dialysis centers do not have a large number of HHD patients and therefore, they may not give that much attention to improving their current HHD practices. However, there is a need for further research with a bigger sample size which should include dialysis centers from different parts of Germany, especially large and well-established dialysis centers with more HHD patients. In addition, in the case study, other stakeholders such as HD machine manufacturer, equipment supplier, dialysis technician, etc. should be included to understand the whole system.

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