VLKN | Verband der leitenden Krankenhausärztinnen und -ärzte in der Nephrologie

Deutsche Gesellschaft für Nephrologie

ENGLISH VERSION

Dialysis Standard for Hospitals by the German Society of Nephrology (DGfN)

S1-Guideline

Structural quality requirements for intermittent and continuous renal replacement therapy in hospitals (Version 1.0)

German Society of Nephrology (DGfN)

Association of senior hospital physicians in Nephrology (VLKN)

Association of German Renal Centres (DN)

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Information on the preparation of this guideline

Process of reaching consensus

A guideline group consisting of 11 experts and the guideline coordinator drafted, discussed and revised the content of the guideline in several videoconferences in 2021 and 2022 and in the meantime by email circulation. The present version was edited and unanimously agreed upon.

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Disclosure of conflicts of interest

Potential conflicts of interest of the guideline group members were submitted using the currently valid AWMF form. The declarations were assessed by the guideline coordinator, Prof. Dr. Martin Kuhlmann, with regard to the existence of a thematic relationship to the guideline. The potential conflicts of interest of the guideline coordinator, Prof. Martin Kuhlmann, were assessed by Prof. Jan C. Galle. For all those involved in the development of the guideline, the review showed that there were no commercial or otherwise justified conflicts of interest for the guideline group that required a consequence, such as abstention, for individual experts.

External review and approval

The consensus version prepared by the guideline group was approved by the executive board of the DGfN on 25.01.2022, by the board of the VLKN on 16.02.2022 and by the board of the DN e.V. on 11.02.2022.

Period of validity and updating procedure

The validity period of the guideline is 5 years. It is thus valid until February 2027.

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Rationale of the guideline

Renal Replacement Therapy (RRT) for acute or chronic renal failure has developed considerably in recent years and is now used in very different technical ways in German hospitals. Apart from kidney transplantation, a distinction is made between intermittent and prolonged intermittent and continuous procedures, in which blood is purified either extracorporeally using synthetic filters (haemodialysis, HD) or intracorporeally using the peritoneum as a biological filter (Peritoneal Dialysis, PD). All RRT procedures, including peritoneal dialysis, can be performed in the hospital for both acute and chronic kidney failure, either as inpatient or day-care dialysis or in intensive care units. HD and PD can be regarded as equivalent in terms of effectiveness, outcome and complication rates.

While intermittent extracorporeal RRT, like classical haemodialysis, was primarily used for the inpatient and day-care treatment of patients with chronic renal insufficiency, continuous blood purification procedures are the most frequently used form of RRT for acutely ill patients in intensive care. In recent years, technical developments have increasingly blurred the boundaries between these procedures, and continuous and intermittent procedures now include characteristic aspects of each other. Moreover, both chronic and acute PD can be adequately used in critically ill patients with renal failure in intensive care units. The multitude of available dialysis modalities opens up the possibility of using RRT in the hospital individually and indication-specific. It is therefore rightly demanded that both intermittent and continuous dialysis procedures be fully available in intensive care units at all times of the day and night and that they be carried out professionally with high quality standards.

In the intensive care units of German hospitals, there is an inhomogeneous situation with regard to staff and professional responsibilities and qualifications in the implementation of intermittent and continuous RRT. Often, there is a lack of important structural facilities, personnel and professional prerequisites to make the broad spectrum of RRT fully available to severely ill patients on an individual basis and in accordance with guidelines. Although continuous RRT is used almost universally in the larger hospitals, indication and treatment management are often in the hands of specialist disciplines that have no specific nephrological training in the field of RRT and in the management of patients with chronic kidney disease [1].

Acute and chronic kidney diseases lead to complex metabolic changes that require nephrological multimodal management. Renal replacement procedures interfere directly and indirectly with metabolism, water, electrolyte and acid-base balance, haemodynamics and the pharmacokinetics of drugs and are associated with a specific risk of complications. Today, renal replacement procedures are no longer a "one-size-fits-all" procedure, but must be individually adapted to the situation of patients in outpatient as well as in inpatient and intensive care settings with regard to modality, vascular access, therapy duration, therapy frequency, dose, anticoagulation and monitoring.

The German Society of Nephrology (DGfN), the Association of Senior Hospital Physicians in Nephrology (VLKN) as well as the Association of German Renal Centres (DN) aim at a significant improvement of structural quality as well as quality assurance in the application of intermittent and continuous RRT in hospitals. This guideline describes the requirements for the personnel, technical and organisational structure for a high-quality and safe implementation of the different modalities of RRT in hospitals. This guideline extends the existing "Dialysis Standard" of the German Society of Nephrology [2] to the sensitive areas of RRT in hospitals.

2. Structural quality requirements for intermittent extracorporeal renal replacement therapy in hospitals

2.1 Spectrum and characteristics of intermittent extracorporeal RRT

The spectrum of intermittent extracorporeal RRT in hospitals includes intermittent and prolonged intermittent haemodialysis, intermittent haemofiltration and intermittent haemodiafiltration, the most important characteristics of which are outlined below.

2.1.1 Intermittent haemodialysis, haemofiltration and haemodiafiltration

- Intermittent haemodialysis (iHD), haemofiltration (iHF) and haemodiafiltration (iHDF) are defined in the OPS catalogue as dialysis treatments designed to last no more than 6 hours.

- HD, HF and HDF differ in principle in the way they eliminate uraemic toxins. While >95% of toxin elimination in iHD occurs by diffusion into the dialysate, this occurs exclusively by convection in iHF, which is performed without dialysate flow. The iHDF represents the combination of iHD and iHF with the aim of optimally combining diffusive and convective toxin elimination. The plasma water filtered in iHF and iHDF is substituted by sterile electrolyte solution in parallel.

- The extracorporeal blood flow rate is usually set to ≥ 250 ml/min for iHD, iHF and iHDF.

- The dialysate flow rate is always set higher than or at least equal to the extracorporeal blood flow rate for iHD and iHDF; no dialysate solution is used for iHF.

- With iHF and iHDF, the substitution solution is administered either upstream or downstream of the dialysis filter or combined. Accordingly, one speaks of predilution, post-dilution or mixed-dilution mode.

- In the case of iHDF in post-dilution mode, the convective filtration volume is at least 2.5 l/h, but ideally significantly higher; an intermittent 'high-volume HDF' is characterised by an administered convective filtration volume of >23 l/1.73 m² body surface area (BSA).

- The substitute solution (haemofiltration solution) can be provided from pre-prepared bags or prepared directly by the dialysis machine 'online' continuously during the treatment procedure.

- In 'online iHDF', the intravenously administered substitute solution is prepared online by the dialysis machine from the dialysis water provided by an osmosis unit in a sterile and pyrogen-free manner.

- The effectiveness of an iHD or iHDF is assessed by the elimination of urea, a surrogate marker for water-soluble small-molecule uraemic toxins; an adequate dialysis dose is considered to be a urea clearance > 200 ml/min with a dialysis time of at least 4h, corresponding to a treatment index Kt/V >1.2 per dialysis treatment.

- The effectiveness of exclusively or mainly convective dialysis procedures, such as iHF and iHDF, is assessed by convective filtration volume.

- The treatment frequency for iHD, iHF or iHDF performed in hospital depends on clinical necessity (volume status, circulatory stability, diuresis, electrolyte disturbances, etc.); for chronic dialysis patients

treated as day patients, the treatment time of each individual session should generally not be less than 4 hours.

2.1.2 Prolonged intermittent haemodialysis, haemofiltration and haemodiafiltration

- Prolonged iHD and iHDF are defined in the OPS catalogue as dialysis treatments that are designed for a treatment time > 6 hours, but not for a continuous treatment of 24h or longer.

- As these procedures share characteristics of intermittent and continuous RRT in terms of duration and frequency, they are also referred to as hybrid procedures or Prolonged Intermittend Renal Replacement Therapy (PIRRT). Typical applications include Extended Daily Dialysis (EDD), Extended Daily Dialysis with Filtration (EDD-f), Slow Low-Efficiency Dialysis (SLED), Sustained Low-Efficiency Daily Dialysis (SLEDD), Sustained Low-Efficiency Daily Diafiltration (SLEDD-f) and Accelerated Venovenous Hemofiltration (AVVH).

- EDD and EDD-f are classical iHD or iHDF procedures in which the dialysis time is extended to >6 hours.

- SLED, SLEDD and SLEDD-f correspond to iHD or iHDF usually extended to 12h with a significantly reduced dialysate flow or ultrafiltration/substitution rate.

- AVVH is characterised by the use of higher ultrafiltration rates of 4-5 L/h in a shorter period of 8-10 h, accelerating substance and fluid elimination, which in CVVH would otherwise extend over a 24 h period.

- Prolonged iHD/iHDF is usually performed with a blood flow ≥ 200 ml/min.

- Prolonged iHD/iHDF is usually performed with a dialysate flow ≥ 100 ml/min.

2.2 Technical structures for intermittent extracorporeal RRT in hospitals

- At least 2 dialysis machines are available that are approved for intermittent extracorporeal RRT and meet the requirements specified in chapters B.5 and B.13 of the DGfN Dialysis Standard.[2]

- For prolonged intermittent extracorporeal RRT, only single-batch or multifunctional dialysis machines approved for intermittent HD/HF/HDF procedures may be used.

- The haemodialysis machines used must be state of the art and should largely protect patients from risks during treatment. The devices must be certified in accordance with the Medical Devices Act (MPG) and must be maintained and operated in accordance with the manufacturer's instructions (instructions for use, technical manual). This applies in particular with regard to the disinfection of the devices.

- All haemodialysis machines must be equipped with volume balancing (controlled ultrafiltration) and sterile filters in the dialysate circuit to enable dialysis with high-flux dialysers.

- The dialysis and haemofiltration solutions used for iHD, iHF and iHDF must strictly comply with all the requirements mentioned in chapter B.9 of the DGfN Dialysis Standard.[2] For the performance of on-line HF and on-line HDF, machines with double sterile filtration of the dialysate/substitution solution are required.

- Dialysis machines used in the hospital for intermittent extracorporeal RRT must ensure a blood flow of at least 250 ml/min and a dialysate flow of at least 250 ml/min.

- Only tubing systems approved for use with the particular dialysis machine may be used for dialysis treatments.

- Dialysis filters used in dialysis treatment must meet the requirements specified in chapter B.6. of the DGfN Dialysis Standard.[2]

- The ultrapure water required for the preparation of the dialysis solution is provided either by a mobile stand-alone osmosis unit or by a central osmosis unit.

2.2.1 Requirements for the facilities for providing ultrapure water and dialysis fluid in hospitals

In order to largely exclude the risk of infection from the equipment for the preparation, distribution and disposal of ultrapure water, concentrate and dialysis solution, the following criteria must be taken into account in the design of the water treatment plant:

- The water required for the production of dialysis solution must be softened and treated with reverse osmosis.

- The reverse osmosis system used for the production of ultrapure water, the ring line and all parts in contact with the media must comply with the Medical Devices Act.

- Permeate lines must be laid as a ring line with a small cross-sectional diameter and avoiding dead spaces.

- You must be able to disinfect the permeate ring line.

- If heat disinfection is used, the permeate ring line must be able to withstand temperatures of 90°C.

- A maximum ring line length of 250 m must not be exceeded.

- Intermediate tanks for storing permeate are not permitted.

- For the disposal of the dialysate, a pipe separation must be provided to prevent retrograde contamination.

- With regard to the quality requirements and the monitoring of ultrapure water and dialysis fluid, the specifications of the European Pharmacopoeia and the ISO Standard 23500-2019 [3] regarding the monitoring of numerous chemical contaminants must be observed.

- In the ultrapure water system, the bacterial count must not exceed 100 CFU/ml at any sampling point. Coliform bacteria or Pseudomonas aeruginosa should not be detectable at all. The upper limit for the endotoxin content of water and dialysis solution samples is 0.25 IU/ml.

- In on-line haemofiltration or on-line haemodiafiltration, where the substitute is prepared by sterile filtration of dialysate, the exclusive use of ultrapure water is required. According to the European Pharmacopoeia, stricter limits apply to the ultrapure water used in this process, with a maximum bacterial count of 0.1 CFU/ml and an endotoxin content < 0.03 IU/ml.

- The microbiological quality of the ultrapure water in ring lines must be checked and documented at least twice a year.

2.3 Spatial structures for intermittent extracorporeal RRT in hospitals

2.3.1 Requirements for dialysis-specific space in hospitals

Intermittent dialysis treatments can only be performed in hospitals outside intensive care units at specially equipped treatment stations. The requirements for space in the hospital go beyond the requirements set out in chapter A.5. of the DGfN Dialysis Standard [2] for outpatient dialysis centres.

- Dialysis treatment stations must be accessible without obstruction from three sides. A minimum distance of 130 cm between two dialysis treatment places is required.

- The treatment stations must be easily visible to the dialysis staff at all times.

- Additional hospital-specific requirements are:

- Oxygen and compressed air supply at each dialysis station

- Possibility of haemodynamic monitoring at each dialysis station

- Possibility of spatial isolation of individual dialysis stations

- Equipment for resuscitation measures, including provision of a hospital-internal resuscitation team

- X-ray diagnostics available on site

- In the treatment rooms assigned for inpatient or day-care haemodialysis, a point-of-care blood gas analyser (BGA) device and an ultrasound device equipped with standard ultrasonic transducers must be available

In addition to the treatment rooms, the following other facilities must be provided:

- Separate examination and dressing room

- Separate procedure room with equipment (see above) for the insertion of central venous dialysis catheters

- Clean working room/working area for preparation of medicines and infusions

- Unclean working room/working zone with sink, bedpan cleaning and disinfection unit

- Storage area for dialysis consumables

- Storage area with refrigerator for thermosensitive medications

- Rooms for water treatment and storage of concentrate

- Room with water connections for maintenance of dialysis machines and, if necessary, mobile osmosis units

2.3.2 Requirements for the room equipment of a dialysis unit in a hospital

- The medically used rooms of a dialysis unit are working areas of protection level 2 according to the Biological Agents Ordinance and the Technical Rules for Biological Agents (TRBA 250) and must be equipped accordingly. Wall surfaces and floors of the medically used rooms must be smooth, waterproof, washable and disinfectable with disinfectants.

- For dialysis-specific installations, the DIN standard ISO 11197 must be observed; the lines must be conveyed in closed ducts whose outer surfaces can be disinfected. Radiators and air diffusers must be easy to clean. Floor coverings should be antistatic.

2.4 Organisational structures for intermittent extracorporeal RRT in hospitals

- The responsible care of intermittent extracorporeal RRT in the hospital is always provided by a medical and nursing team of a nephrology focus clinic or focus department or a focus practice with a physician with the focus designation nephrology (specialist nephrologist).

- A 24/7 specialist nephrology on-call service with readiness for action within 30 minutes is provided. The medical expertise must comply with the quality assurance agreement on blood purification procedures §135 Para. 2 SGB V.

- A 24/7 on-call nursing service is provided with an operational readiness within 30 minutes. Nursing staff participating in the on-call service must be able to demonstrate safe handling of intermittent dialysis and the use of vascular accesses (catheter connection, shunt puncture) for dialysis treatment.

- Medical and nursing staff must demonstrate sufficient knowledge and practical experience in the use of heparin, citrate and alternative substances for anticoagulation during dialysis treatment.

- Each dialysis treatment must be documented in a standardised dialysis protocol.

- For day-care dialysis services, participation in the intersectoral quality assurance renal replacement therapy (QS-RRT) is obligatory.

- Dialysis facilities must have trained staff to ensure hygiene. This may require staff with the following qualifications: hospital hygienists, doctors responsible for hygiene, hygiene specialists, staff responsible for hygiene in nephrological care. The binding qualification requirements are specified differently in the hygiene ordinances of the federal states.

2.5 Staffing structures for intermittent extracorporeal RRT in hospitals

2.5.1 Medical staff

The staffing requirements for performing intermittent RRT outside and inside intensive care units correspond to the minimum requirements for certification as a nephrology speciality department (DGfN) based on the requirements for an inpatient nephrology speciality department according to § 11a, Section 3, Appendix 9.1, Annex 9.1.4 BMV-Ä. These include:

- The provision of at least 2 specialists in nephrology, whereby one of these specialists must have been assigned the medical and organisational responsibility for the performance of intermittent dialysis treatments,

- The staffing requirements for the partial inpatient performance of intermittent dialysis treatments including the obligation to participate in QS-RRT in accordance with the existing quality assurance agreement on blood purification procedures pursuant to § 135 Para. 2 SGB V.

2.5.2 Nursing staff

Dialysis treatment is a medical treatment and is carried out with the assistance of registered nurses, nephrology specialists and medical assistants. For all forms of treatment, specially trained, qualified staff must be employed for direct patient care. This includes nephrology specialists, registered nurses, medical assistants and medical assistants after appropriate training. A nurse providing intermittent dialysis treatment in hospital outside and inside intensive care units must demonstrate the following qualifications:

- Safe and regular handling of the dialysis procedure to be used*.

- Safe and regular handling of temporary and permanent dialysis catheters (according to the hospital's internal SOP)*.

- Safe and regular puncture and care of arteriovenous dialysis accesses*.

- Justification: Malpuncture of dialysis accesses when improperly handled is the main cause of destruction of arteriovenous fistulas with subsequent surgery and prolongation of hospital stays.

- In-depth knowledge and skills in dressing dialysis access lines*.

- Confident management of dialysis complications*.

- Safe and regular performance of dialysis treatments using heparin and citrate as well as alternative anticoagulation procedures*.

- Safety and sufficient experience in monitoring patients during dialysis treatments, including dialysis-specific features.

- Proof of familiarisation with all dialysis machines used and kept on hand.

* Regularity is defined in this context as the independent care of >100 treatments with the respective intermittent dialysis procedure per year. The sufficient qualification of the nurse must be confirmed by a specialist in nephrology who is authorised to provide further training or by a certified dialysis nurse.

3. Structural quality requirements for continuous extracorporeal RRT in hospitals

The spectrum of continuous extracorporeal RRT in hospitals includes continuous venovenous haemodialysis (CVVHD), continuous venovenous haemofiltration (CVVHF), continuous venovenous haemodiafiltration (CVVHDF) and slow continuous ultrafiltration (SCUF). These procedures require special medical and nursing expertise in their implementation and monitoring and are associated with increased medical expenditure, e.g. with regard to anticoagulation. The choice of procedure is primarily dependent on individual patient needs as well as local availability, medical and nursing expertise and also has medical-economic aspects.

3.1 Spectrum and characteristics of continuous extracorporeal RRT

- Continuous extracorporeal RRT is defined in the OPS catalogue as dialysis treatments that are planned and prescribed over at least 24 hours.

- SCUF is based on the slow filtration of plasma water without the use of dialysis or substitution solution and is mainly used in patients with fluid overload.

- CVVHF is based on the continuous filtration of plasma water in which the ultrafiltrate is completely or largely replaced by a sterile substitution solution which is infused before (predilution) or after (post-dilution) the haemofilter. Substance elimination is purely by convection.

- CVVHD corresponds to continuous haemodialysis treatment with a slow, countercurrent dialysate flow in a low-flux dialysis filter. In this case, substance elimination takes place almost exclusively by diffusion. By using a high-flux filter, an additional convective component of substance elimination can be added to CVVHD.

- CVVHDF is a combination of CVVHD and CVVHF in which the ultrafiltrate is completely or largely replaced by sterile substitution solution in pre- or post-dilution mode. The combination of diffusive and convective substance elimination results in increased removal of higher molecular weight substances.

- Continuous extracorporeal RRT is usually performed with a blood flow of 100 - 150 ml/min.

- In CVVHD/CVVHDF, the dialysate flow rate is usually 20-35 ml/min.

- In CVVHF/CVVHDF, a filtration/substitution rate of 25 ml/kg/h is aimed for.

- Central venous, large lumen double or multi-lumen catheters are used for dialysis access

3.2 Technical structural requirements for continuous extracorporeal RRT in the hospital.

- At least 2 machines for the performance of continuous renal replacement procedures are available, which can be used at the designated treatment site and are approved for continuous treatment procedures.

- The requirements for dialysis machines specified in chapter B.5. of the DGfN dialysis standard must be observed.

- The blood flow on the dialysis machine must be continuously adjustable between 50 and at least 300 ml/min.

- The dialysate flow must be continuously adjustable on the dialysis machine between 50 and at least 300 ml/min.

- The dialysers used for continuous extracorporeal RRT meet the requirements specified in chapter B.6. of the DGfN dialysis standard.

- For continuous dialysis treatments, only tubing systems approved for use with the respective dialysis machine are used.

- Dialysate/substitute solutions approved for continuous dialysis procedures are provided in bags.

3.3 Spatial structural requirements for continuous extracorporeal RRT in hospitals

- Continuous extracorporeal RRT may only be performed in hospital wards equipped for continuous haemodynamic monitoring.

- In a hospital where continuous extracorporeal RRT is performed, the possibility to perform intermittent extracorporeal RRT must always be available.

- Storage room for dialysis consumables.

- Rooms for storage of dialysate/substitute solutions.

- Room for maintenance of dialysis machines.

- In wards where continuous RRT is performed, a POC BGA machine and a sonography machine equipped with a convex, linear and sector transducer must be kept available.

3.4 Organisational structural requirements for continuous extracorporeal RRT in the hospital.

- These procedures may only be performed by trained staff; a nephrologist must be available at all times.

- Provision of a specialist nephrologist on call 24/7 with readiness for action within 30 minutes. The specialist competence must comply with the quality assurance agreement on blood purification procedures §135 Para. 2 SGB.

- 24/7 on-call availability/presence of a nurse who can demonstrate safe handling of the performance of continuous dialysis and meets the criteria mentioned in 2.5.2.

- Both doctors and nurses must demonstrate sufficient knowledge and regular practical experience in the use of heparin, citrate and alternative substances for anticoagulation during dialysis treatment.

- Continuous dialysis treatments must be documented in a standardised dialysis protocol.

- Coordinated indication- and procedure-specific standard protocols (SOP) are available.

- Topic-specific continuing medical education (CME) is offered regularly for all professional groups involved.

3.5 Personnel structure requirements for continuous extracorporeal RRT in hospitals

3.5.1 Medical staff

3.5.1.1 Physician responsible for continuous RRT

The physician responsible for the indication and performance of continuous extracorporeal RRT is a physician with a specialisation in nephrology or a specialist in internal medicine with a KV licence for the provision of renal replacement procedures. The latter establishes the indication for treatment and determines the treatment procedure as well as the dialysis prescription. Alternatively, a specialist with an additional qualification in intensive care medicine can assume responsibility for performing RRT if evidence of the following expertise is available:

- Experience in performing continuous extracorporeal RRT (evidence of >500 treatment cases) *

- Experience in placing central venous double lumen dialysis catheters (evidence of >100 catheter implantations) *

- Confident and regular experience in performing continuous RRT using heparin and alternative anticoagulants (including citrate) *

- Proof of familiarisation with all dialysis machines used and maintained.

*Confirmed by a specialist in nephrology authorised for the inpatient part of the further training in the focus of nephrology.

It is the responsibility of the physicians responsible for performing RRT to ensure that the medical and nursing staff involved in the treatment are sufficiently qualified to perform continuous RRT.

3.5.1.2 Physician supervising continuous RRT

The doctors supervising the treatment do not have to be internists with a specialisation in nephrology, but they must have sufficient qualifications and understanding of the continuous RRT applied so that they can intervene in the treatment at any time if necessary. The following qualifications must be demonstrated:

- Performance of at least 150 intermittent or prolonged intermittent haemodialysis procedures or evidence of structured induction (e.g. shadowing in a dialysis unit of a nephrology focal hospital or department or in an outpatient dialysis facility) *

- Experience in the performance of continuous haemodialysis and haemofiltration treatments (>50 treatment days) or proof of structured training*

- Experience in the placement, handling and care of central venous dialysis catheters*

- Confident in performing RRT using heparin and citrate as well as alternative anticoagulation procedures*

- Safe handling of complications of RRT*

- Proof of familiarisation with all devices used and maintained for RRT.

**Confirmed by a specialist authorised to provide further training with a specialisation in nephrology from a nephrology specialisation clinic or department or an outpatient dialysis facility.

3.5.2 Nursing staff

Nurses who supervise intermittent extracorporeal RRT in intensive care units must demonstrate the following qualifications:

- Proof of familiarisation with all dialysis machines* to be used

- Safe and regular handling of the RRT* to be used

- Safe handling of temporary and permanent dialysis catheters (according to hospital-internal SOP)*

- Thorough knowledge and skills in dressing dialysis accesses*

- Confident handling of complications of RRT*

- Knowledge and confidence in handling the alarm systems of the dialysis machine

- Safe and regular handling of dialysis procedures using heparin and citrate as well as alternative anticoagulation procedures*

- Safety and sufficient experience in monitoring patients during dialysis treatments, including dialysis-specific features.

*Confirmed by a specialist with specialisation in nephrology who is authorised to provide further training or a certified nephrology specialist nurse.

4. Structural quality requirements for intermittent and continuous Peritoneal Dialysis (PD) in hospitals

In principle, peritoneal dialysis is designed as a home dialysis procedure for independent performance by the patient or trained persons. Since PD is performed by only about 7% of all people requiring dialysis in Germany, the exposure and correspondingly the detailed knowledge of this procedure is lower than for continuous and intermittent RRT procedures on a broad scale outside the main subject of nephrology. In the case of acute hospitalisation, the continuation of independent handling of the PD by those affected is usually no longer given. Improper management of the PD procedure or unnecessary changes to

extracorporeal RRT during hospitalisation pose a significant risk to PD patients in terms of complications, morbidity and ultimately mortality.

Peritoneal Dialysis (PD) can be performed under hospital inpatient conditions in patients with acute or chronic diseases, either as a manual or machine-assisted renal replacement procedure, both outside and inside intensive care units. In every hospital where PD patients are treated, medical and nursing expertise as well as appropriate structures for the proper implementation of the procedure must be available.

4.1 Definition and characteristics of continuous and intermittent peritoneal dialysis procedures

Peritoneal dialysis was originally designed as a continuous procedure with several daily manual changes of dialysate, so that there is always dialysate intraperitoneally (continuous ambulatory PD, CAPD). By using machine cyclers, the retention time of the dialysate can be reduced while at the same time increasing the change frequency. Depending on whether dialysate is also present in the abdominal cavity outside the time spent on the cycler, a distinction is made between continuous (continuous cycler-assisted PD, CCPD) and intermittent PD procedures (automated PD, APD; nocturnal intermittent PD, NIPD). This is distinguished from intermittent centre PD (IPD), in which PD is performed on only 3 - 4 days of the week, but for 8 - 12 hours each time, as an outpatient in a dialysis centre or as an inpatient/partial inpatient in a hospital, and no dialysate remains in the abdominal cavity outside this treatment period.

A PD prescription includes the determination of the dialysate volume instilled into the abdominal cavity and the dialysate concentration, as well as the number, timing and frequency of dialysate changes. Cycler-supported PD procedures usually use chip cards on which the individual PD prescription is programmed by the treatment team on the one hand and the actual treatment data are stored by the cycler on the other hand. Chip cards can only be programmed and read via special computer programmes. Alternatively, there are possibilities for cloud-based remote programming of PD cyclers.

In Germany, two PD systems are available that differ in terms of materials and dialysis solutions and are not compatible with each other (Baxter and Fresenius). Dialysis solutions of the two PD systems differ in composition with regard to type (glucose, amino acids, icodextrin) and concentration of the osmotic agent used. The connectors between the PD catheter and the dialysate bag are also manufacturer-specific and not compatible between the PD systems. The dialysis access used in PD is a subcutaneously tunneled 1-lumen PD catheter running from extra- to intraperitoneal. After implantation, the catheter is equipped with a PD system-specific transfer piece, which is later used for connections with the tubing systems of the PD dialysate bags under aseptic conditions.

4.2 Technical structures for peritoneal dialysis in hospitals

In hospitals where PD patients are regularly treated, complete equipment with materials and dialysis solutions for both PD systems must always be kept available.

- PD treatments must only be performed with PD solutions and PD cyclers approved for the intermittent or continuous PD procedure and PD system used

- Transfer pieces, adapters and tubing systems for the PD system used must be kept on hand

- Bags with dialysis solution in at least 3 different glucose concentrations must be available

- An IT structure with computer, software and card reader must be available for at least one PD system in use

- At least 2 sterile packed peritoneal dialysis catheters must be kept in stock at all times.

4.3 Spatial structures for peritoneal dialysis in hospitals

In hospitals where PD patients are regularly treated, specific premises must be provided:

- Separate, designated treatment room (area of at least 8 m²).

- Room with PD-specific IT equipment including card reader

- Designated storage room for PD materials and dialysate bags

- Secure and hygienically controlled storage space for PD cyclers

- When performing inpatient/partial inpatient IPD, a dialysis treatment room with at least 2 parking spaces must be provided.

4.4 Organisational structures for peritoneal dialysis in hospitals

In hospitals where PD patients are regularly treated, specific organisational structures must be established:

- Presence of a treatment team consisting of nephrology-trained nursing staff and specialist nephrology expertise

- Provision of a competent medical team with expertise in implantation and explantation of PD catheters

- Interdisciplinary agreed and adhered to Standard Operating Procedures (SOP)

- Regular continuing education events for medical and nursing staff (CME)

- Surgical and radiological competence with experience in dealing with PD patients is available

- Established cooperation with a laboratory for the laboratory-chemical examination of dialysate samples

- Contractually regulated technical support for the maintenance of PD cyclers.

4.5 Staffing structures for peritoneal dialysis in hospitals

In hospitals where PD patients are regularly treated, both medical and nursing nephrological expertise must be available 24/7 at short notice.

4.5.1 Medical staff

The physician who indicates and prescribes the PD must have a specialist qualification in nephrology or be a physician in further training in nephrology*.

*As proof of continuous competence, the independent treatment of >10 PD patients per year and the independent prescription of > 20 PD treatments per year is required.

4.5.2 Nursing staff

The following requirements must be met for the qualification of nursing staff entrusted with intermittent or continuous PD treatment:

- Specialist nephrology nurses who have been referred to PD treatment

- Proof of familiarisation with all devices and cyclers* used in PD

- Safe handling of the PD procedure to be used and the PD system* provided

- Safe handling of the use, connection and dressing of PD catheters

- Comprehensive knowledge of dialysis solutions, intra-abdominal application of drugs and in therapy management and documentation*

- Confident handling of a change of the crossover piece in case of a change of the PD system

- Safety in recognising and dealing with complications of peritoneal dialysis*

- Safety and sufficient experience in monitoring patients during dialysis treatments, including dialysis-specific peculiarities.

*Confirmed by a specialist with specialisation in nephrology who is authorised to provide further training or by a certified nephrology specialist nurse.

5. Literature

1. Willam C, Meersch M, Herbst L, Heering P, Schmitz M, Oppert M, John S, Jörres A, Zarbock A, Janssens U, Kindgen-Milles D. Current status of renal replacement therapy implementation in German intensive care units. Med Klin Intensivmed Notfmed 2021 https://doi.org/10.1007/s00063-021-00835-y

2. Dialysis standard of the German Society of Nephrology 2016 in the updated version of 25.02.2020 (https://www.dgfn.eu/dialyse-standard.html?file=files/content/downloads/20201120_Dialysestandard_Version_25-02-2020.pdf&cid=2212)

3. ISO 23500-1:2019 Preparation and quality management of fluids for haemodialysis and related therapies (https://www.iso.org/obp/ui/#iso:std:iso:23500:-1:ed:-1:v1:en)