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Assisted peritoneal dialysis in Europe: a strategy to increase and maintain home dialysis

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ABSTRACT

Peritoneal dialysis (PD) is a form of kidney replacement therapy with the major advantage that it can be performed at home. This has a positive impact on patients' autonomy and quality of life. However, the dialysis population is ageing and physical and/or cognitive impairments are common. These limitations often form a barrier to PD and contribute to the low incidence and prevalence of PD in Europe. Assisted PD can be a solution to this problem. Assisted PD refers to a patient being assisted by a person or device in performing all or part of their dialysis-related tasks, thereby making PD more accessible to elderly but also younger frail patients. In this way, offering an assisted PD program can help lower the threshold for initiating PD. In this review, we provide an overview of the epidemiology of assisted PD in Europe, we discuss the different categories and clinical outcomes of assisted PD, and we present how assisted PD can be implemented in clinical practice as a possible strategy to increase and maintain home dialysis in Europe.

Keywords: assisted peritoneal dialysis, device-assisted, home dialysis, informal caregiver, kidney replacement therapy

INTRODUCTION

Peritoneal dialysis (PD) is a kidney replacement therapy (KRT) performed in the patient's living environment, thereby contributing to more autonomy and flexibility, and better quality of life. PD also offers several medical advantages, such as better preservation of residual kidney function, greater hemodynamic stability and vein preservation, while the survival of patients treated with PD is comparable to those treated with hemodialysis (HD) [1, 2]. However, only a minority of dialysis patients in Europe are treated with PD [3].

Patients can have physical and/or cognitive impairments that make it even more challenging or impossible to start or continue PD independent of the care by others or support by aids [4].

Assisted PD can overcome these barriers by aiding patients performing PD [5, 6]. Assisted PD can be offered by a person or a device to both incident and prevalent PD patients. In this review, we provide an overview of the epidemiology of assisted PD in Europe, the different categories and the clinical outcomes of assisted PD. Finally, we discuss how assisted PD can be applied in clinical practice as a possible strategy to increase and maintain home dialysis.

EPIDEMIOLOGY OF ASSISTED PD IN EUROPE

In Europe, the yearly incidence of KRT (i.e. HD, PD or kidney transplantation) is about 128 persons per million population

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Figure 1: Availability and reimbursement of assisted PD in Europe. (A) Availability of assisted PD. Red = no availability; orange = moderate availability: assisted PD is done, however not structurally organized and not available nationwide; green = high availability: established assisted PD programs are available in (almost) all dialysis centers within the country; white = unknown. References: Brown et al. [11]; Belgium/The Netherlands: "Authors information".

(p.m.p.), while the prevalence is 931 p.m.p., equivalent to about 1 in 7800 Europeans. Only 13% of incident dialysis patients start with PD, and only 5% of prevalent dialysis patients are treated with PD. Currently, 55% of the incident and 47% of the prevalent dialysis population is older than 65 years [3]. Moreover, the prevalence of functional and/or cognitive impairments in patients with kidney failure in this age group is high [7], limiting their ability to perform PD themselves (i.e. self-care PD). Offering assisted PD to these patients might enable them to initiate or to continue PD despite their limitations. Recent studies show that the uptake of PD is indeed higher in countries where assisted PD is more readily available [8, 9]. This beneficial effect is seen both when assistance is provided by a healthcare professional and when provided by a close relative [8, 10]. Data on the epidemiology of assisted PD in Europe are limited and the reported numbers are probably underestimated since there is generally no systematic registration. Moreover, this underestimation is even more pronounced in cases where informal caregivers provide assistance, as there is limited awareness of how often this actually happens. Brown *et al.* conducted a survey on the availability and reimbursement of assisted PD across 13 European countries [11]. The results are illustrated in Fig. 1. Increased awareness of the advantages of PD, patient education, and engagement of policymakers and healthcare professionals to develop and support assisted PD programs have been identified as the top priorities to increase availability of assisted PD.

In Europe, France and Denmark have the largest experience with assisted PD. A large retrospective study based on data from



Figure 1: Continued. (B) Reimbursement of assisted PD. Red = no reimbursement; green = reimbursement available: reimbursement of PD assistance is provided by the government; white = unknown. References: Brown et al. [11]; Pommer et al. [41]; Belgium/The Netherlands: "Authors information".

the French Language Peritoneal Dialysis Registry looked at incident PD patients between 1 January 2006 and 31 December 2015. Among 11 987 patients, 6149 (51%) started with assisted PD, of whom 5052 (82%) were assisted by a home care nurse and 1097 (18%) by a family member. The median age of patients starting assisted PD was 79.6 and 74.3 years for nurse-assisted and caregiver-assisted PD, respectively. This was considerably older than patients on self-care PD (median age 56.5 years) [12]. Yet another retrospective cohort study, based on data from the same registry between 2008 and 2012, found that only 17% of patients between the ages of 18 and 65 years who started PD required assistance. An important finding was the significant association between the initiation of assisted PD and patient characteristics such as age, gender, underlying kidney disease and comorbidities, as well as a center effect not explained by center characteristics [13]. Compared with France, where assisted continuous ambulatory PD (CAPD) is the preferred assisted PD modality, Danish patients who are assisted during PD most frequently receive assisted automated PD (APD) [14].

Limited data are available on the costs of assisted PD. The additional cost of providing professional assistance for PD differs between countries. In France, for example, the annual price for assistance per patient is around ϵ 23 400 for CAPD and ϵ 18 200 for APD [15]. In both France and Denmark, the operational cost of assisted PD is equal or inferior to the cost of in-center HD [14, 16]. A study from the Netherlands among elderly patients with kidney failure also concluded that providing assisted PD is costeffective [17].

Table 1: Categories of assisted PD.

Category of assisted PD	Definition
Person-assisted	Patient is assisted by another individual
Caregiver-assisted	Assistance is provided by an informal caregiver (i.e. partner, family member, friend or neighbor)
Nurse-assisted	Assistance is provided by a healthcare professional, usually a nurse
Partially assisted	PD is performed by both patient and assistant with a well-defined assignment of tasks
Fully assisted	PD is completely performed by the assistant
Device-assisted	PD involving the use of a device that supports the patient and/or informal caregiver and/or healthcare professional

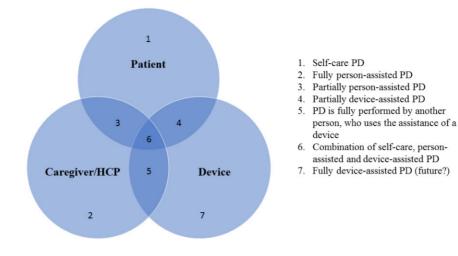


Figure 2: Devices for assisted PD. This figure shows some examples of devices (both developed by industry and local hospitals) and is not a complete representation of all currently existing devices. (A) EZ-OpenerTM with hook and pincer (Baxter Healthcare). (B) EZ-AssistTM (Baxter Healthcare). (C) UC connection device. Top picture: connection of the transfer set and the tubing of the PD fluid set. Bottom picture: connection of the transfer set and a new sterile cap (Pak *et al.* [21]; Supplemental video: https://journals.sagepub.com/doi/10.1177/08968608221085430?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed). (D) Connection device. Developed in Deventer Hospital in the Netherlands. (E) StaySafe connection deviceTM (Fresenius Medical Care; https://fmcna.com/products/ home-dialysis-equipment/stay-safe-overview/). (F) Tool to remove mini cap from transfer set. Developed in University Hospital Brussels. (G and H) Tools to break the frangible seal of the dialysate bag. Developed in Deventer Hospital in the Netherlands (G) and by Baxter Healthcare (H). (I) Tool to poke a hole in the dialysate bag to hang it. Developed in Deventer Hospital in the Netherlands. (J) Tool to remove the pull ring on the tubing of the dialysate bag. Developed in Deventer Hospital in the Netherlands. (K) Tool to help inject antibiotics into the dialysate bag. Developed in Deventer Hospital in the Netherlands. (L) Amia APD SystemTM (Baxter Healthcare; https://renalcareus.baxter.com/pd-patient/amia; Sharma *et al.* [23]). (M) SignoluxTM. Left: vibrating pad. Right: flash module (www.humantechnik.com). (N) StaySafe MyTraining VRTM (Fresenius Medical Care; https://www.freseniusmedicalcare.com/en/virtual-reality-training-pd). (O) LiberDi portable PD system (PPDSTM) (Tanasiychuk *et al.* [24]; https://www.liberdi.com/liberdi-receives-fda-regulatory-clearance/).

CATEGORIES OF ASSISTED PD

Depending on the patient's limitations and needs, PD can be partially or fully performed by different types of assistance. Assisted PD can thus be divided into several categories (Table 1). The most common form of assisted PD is when assistance is provided by another individual (i.e. person-assisted PD), who may be an informal caregiver (i.e. caregiver-assisted PD) or a nurse (i.e. nurse-assisted PD). With caregiver-assisted PD, dialysis can be performed by the partner of the patient, another family member, a friend or a neighbor. In case of nurse-assisted PD, dialysis is performed by a healthcare professional (usually a nurse). In both cases, the assistant is first trained by experienced PD nurses in the dialysis center [18]. A combination of caregiver-assisted and nurse-assisted PD is also possible. For example, a nurse can set up the cycler during the day, and the partner can connect the patient to the cycler in the evening. During partially assisted PD, the patient and assistant perform PD together. An example of a patient that could benefit from partially assisted PD is someone with reduced strength, who may not be able to lift the dialysis bags but may be capable of making a sterile connection and/or manage to launch the cycler treatment. In the case of partially assisted PD, it is essential to assess which tasks to be performed by the patient and which by the assistant. It is important to encourage the patient to be involved in his/her PD treatment as much as possible [19].

Another form of assisted PD is device-assisted PD, where the patient and/or informal caregiver and/or healthcare professional receives support from an aid to perform PD. Different devices developed to aid in performing PD are shown in Fig. 2. Most of the devices developed to date are connection devices. The EZ-OpenerTM is a device that can assist patients with



PD=peritoneal dialysis

Figure 3: Possible combinations of (assisted) PD.

unstable hand function and/or reduced hand strength. It contains a holder for the fluid bag connector to facilitate sterile connection to the patient line (Fig. 2A). The EZ-Assist[™] device is another relatively simple tool that can be used to make a sterile connection by patients with reduced hand strength or unilateral paralysis (Fig. 2B) [20]. Both EZ-Opener[™] and EZ-Assist[™] come with a hook that can be used to remove the pull ring and a pincer that can be used to break the seal on the tubing connected to the dialysate bag [20]. The dialysis unit of the United Christian Hospital in Hong Kong developed its own connection device for connecting the transfer set and the tubing of the PD fluid set, as well as a device to put a new sterile cap on the transfer set (Fig. 2C). This connection device-assisted PD showed similar outcomes in terms of peritonitis, PD technique survival and patient survival compared to caregiver-assisted PD [21]. The nephrology department at Deventer Hospital in the Netherlands has also developed a connection device for patients who can perform PD with only one hand (Fig. 2D). Another connection device is the StaySafe[™]. The different steps (drain, flush, fill and close) are written on the device and should be followed sequentially by turning the blue disk. In this way, the system is designed to guide the patient in an intuitive manner. The rotating system eliminates the need to clamp and unclamp the lines. At the end of the dialysis exchange, a pin is automatically inserted into the patient's line, so that when the line is disconnected, the contact with the outside world is already sealed, thus attempting to reduce the risk of peritonitis due to touch contamination (Fig. 2E).

Although the focus of device-assisted PD to date has been primarily on creating a sterile connection, the potential application of device-assisted PD could be much broader. For example, device-assisted PD could also be a technical help to hang the dialysate bag on the drip stand, to remove the cap from the catheter or to break the frangible seal. In specific cases, it might be valuable to collaborate with an occupational therapist to develop helpful tools [22]. For example, at the University Hospital of Brussels, the occupational therapist helped to develop a tool to remove the mini-cap from the transfer set (Fig. 2F). The Deventer Hospital in the Netherlands developed devices to break the frangible seal (Fig. 2G), poke a hole in the dialysate bag to hang it (Fig. 2I) and remove the pull ring (Fig. 2J), and a tool to help inject antibiotics into the dialysate bag (Fig. 2K). Baxter Healthcare also developed a device to break the frangible seal (Fig. 2H).

For patients with mild cognitive or visual impairment, the Amia APD System[™] could be helpful via its voice system to guide the patient through the various steps of APD (Fig. 2L) [23]. Unfortunately, this device is not available in Europe. Devices that can convert a cycler's alarm into a vibration or light, for example the Lisa[™] and Signolux[™] systems, could be of help to patients suffering from hearing loss (Fig. 2M).

Finally, it is worth mentioning that devices can also be used to assist patients with PD training. The Stay Safe MyTraining VR^{TM} is a virtual reality-based training tool. There is a "learning mode" in which each step is demonstrated by a virtual nurse, and a "test mode" in which the patient performs the steps independently and is corrected for errors (Fig. 2N).

New, promising devices are currently being investigated. One of these, LiberDi portable PD system (PPDSTM), also transfers information about the effluent directly to the dialysis center, thus helping to detect possible peritonitis or catheter dysfunction (Fig. 2O) [24].

Unfortunately, few devices are currently available for clinical use, even though their use could be a good strategy to reduce the burden on the healthcare system and informal caregivers. Therefore, investing in the development of new devices could be a possible way to make PD more accessible. 3D printing technology may have interesting potential for both the development of new devices as well as for making established devices more readily available across centers by sharing 3D printing designs.

The use of devices could also have disadvantages. Hightechnology devices may be too complex for patients to use. Furthermore, the risk of making technical errors remains. For example, with the use of the StaySafeTM connection device, pneumoperitoneum was observed in two patients. In both

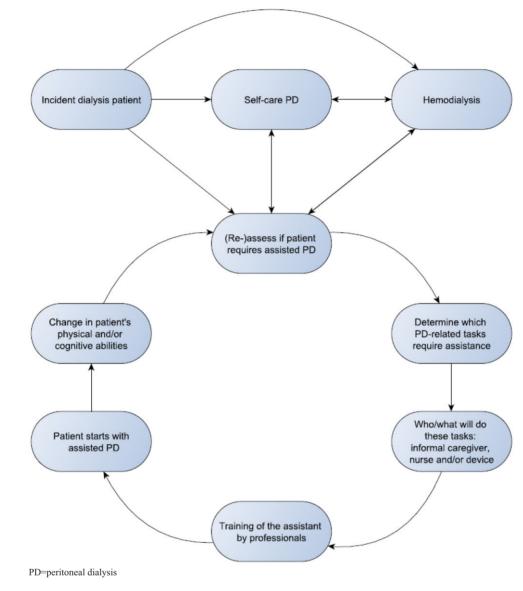


Figure 4: Assisted PD pathway.

cases, the cause was not a malfunction of the device itself, but rather improper use by the patient [25]. This illustrates that these devices are only a support tool, and that proper training and adequate cognitive functioning of the patient or assistant remain extremely important.

Figure 3 shows the possible combinations to offer assistance in PD. What works best for the patient needs to be evaluated on an individual basis. Over time, it is also possible to switch between different categories of assisted PD or even to allow the patient to perform self-care PD.

OUTCOMES

Most studies investigating assisted PD show great variability in outcomes, depending on the patient groups being compared [26]. In older studies, assisted PD patients were compared with self-care PD patients. However, patients currently treated with assisted PD are typically older and more frail compared with self-care PD patients [12, 13]. Although earlier studies found higher peritonitis rates in assisted PD compared with self-care PD, more recent studies showed no differences in incidence of PD-related peritonitis and technique failure rate [14, 27]. In addition, two observational studies showed lower risk of transfer to HD with nurse-assisted PD compared with self-care PD [28, 29]. Other observational studies showed lower peritonitis rates with nurse-assisted PD compared with self-care PD in specific patient groups, such as the elderly and those with diabetes mellitus [30– 32]. Therefore, assisted PD can be considered a safe alternative to self-care PD. In addition, peritonitis rates are similar between nurse-assisted PD, caregiver-assisted PD and device-assisted PD [21, 27, 33].

To assess outcomes such as hospitalization, mortality and health-related quality of life (HRQoL), it is preferable to compare assisted PD with in-center HD to limit selection bias. However, only few studies compared assisted PD with in-center HD. Oliver *et al.* found no difference in hospitalization rates between

PD-related task	Physical and/or cognitive limitations that are barriers	Solutions to overcome these barriers
General Performing the steps of PD with proper technique and in the correct order	- Cognitive problems	 Poster with images of different steps Person-assisted PD Self-care PD under supervision of a caregiver or nurse APD machine with voice guidance^a
Hearing the alarms of the APD machine	- Hearing disability	- Partner of the patient - Device that converts sound into vibration or light ^a
Reading the instructions on the APD machine	- Visual impairment	- Person-assisted PD - APD machine with voice guidance ^a
Preparation Hygiene: wearing a mouth mask, washing and desinfecting hands, desinfecting the table	- Cognitive problems	- Poster with images of different steps - Person-assisted PD
Checking the materials: - concentration and volume of the PD solution - expiry date of the PD solution, mini cap, APD cassette and clamps - expering whether the PD solution is clear - squeezing the bag to check for leaks - integrity of the frangible seals and the pull rings of the dialysate bags	- Cognitive problems - Visual impairment	- Poster with images of different steps - Person-assisted PD
Tear off the packaging around the dialysate bag and the drain bag	- Reduced strength in the arms	- Person-assisted PD (for example 2 times a week) - Potential solution: development of packaging that is easier to open
Hanging the dialysate bag on the drip stand	- Reduced strength in the arms and/or legs - Inability to stand up independently	 Person-assisted PD Potential solution: development of a drip stand that can ascend and descend automatically
Placing the dialysate bags on top of the APD machine	- Reduced strength in the arms	- Person-assisted PD - Replacement of 5 L dialysate bag by two 2.5 L bags; eventually adjust to 8-prone cassette
Connection Remove the pull rings from the dialysate bag and from the lines, removing the mini cap from the transfer set	- Reduced strength in the arms and/or hands - Difficulties with fine motor skills	 Person-assisted PD Device-assisted PD: hook to remove the pull ring^a Device-assisted PD: tool to remove the mini cap^a
Making a sterile connection between dialysate bags and the different lines; and between transfer set and patient line or patient connector	 Reduced strength in the hands Difficulties with fine motor skills Tremor Visual impairment 	- Person-assisted PD - Connection devices ^a
Breaking the frangible seal of the dialysate bag	- Reduced strength in the hands	- Person-assisted PD - Device-assisted PD: pincer ^a

Table 2: Tasks, limitations and solutions.

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PD-related task	Physical and/or cognitive limitations that are barriers	Solutions to overcome these barriers
Draining Opening and closing the twist clamp or clamp on the line of - Reduced strength in the hands the transfer set	- Reduced strength in the hands	 Person-assisted PD Placement of a rubber band on the twist clamp to improve grip Using a plastic atraumatic kocher instead of a clamp on the line of the transfer set
Weighing the amount of drainage	- Visual impairment - Inability to read and write	- Person-assisted PD - Weighing scale with larger digits or one that generates audible numbers
Flushing Breaking the frangible seal of the dialysate bag	- Reduced strength in the hands	- Person-assisted PD - Device-assisted PD: pincer ^a
Disconnect Disconnect the patient line and placing a new mini cap on the transfer set	 Reduced strength in the arms Difficulties with fine motor skills Tremor Visual immainment 	- Person-assisted PD - Connection devices ^a
Emptying the drain bag	- Reduced strength in the arms and/or legs	- Person-assisted PD - Emptying in smaller fractions using a jerry can or direct connection to the drain
Green = continuous ambulatory PD· orange = APD· blue = both		

assisted PD and in-center HD patients (11.1 vs 12.9 days/year, P = .19) [34]. Assisted PD patients were more likely to be hospitalized for dialysis-associated reasons, with peritonitis and technique failure being the most common causes. Also, the mortality rate was comparable in both groups (0.11 per patient-year, P = .94).

HRQoL is particularly important for patients who wish to have their treatment at home. The Frail Elderly Patient Outcomes on Dialysis (FEPOD) study found comparable HRQoL between elderly patients on assisted PD and matched patients receiving in-center HD, except for treatment satisfaction, which was higher in patients on PD [35, 36]. In summary, assisted PD can be considered a safe dialysis modality for the intended population with similar outcomes in terms of hospitalization, mortality and HRQoL.

ASSISTED PD IN CLINICAL PRACTICE

In this section, we first describe the patient's journey prior to starting assisted PD. This fictional example applies to incident dialysis patients. For prevalent patients on self-care PD or HD who need or want to transition to assisted PD, a similar approach can be used. Afterwards we will discuss the steps at which assistance can be applied.

Most of the patients presenting kidney failure have no medical contraindication to PD [37]. When a patient progresses to kidney failure, information and KRT modality education should be offered. After careful consideration by both patient and physician during a shared decision-making process, PD may be chosen. Then, an assessment must be made to determine whether the patient is able to perform PD independently or if there is a need for (some degree of) assistance. This evaluation should be done in both older and younger patients, as the latter might also benefit from assisted PD. Based on the initial assessment, it can be decided whether there is an indication for additional testing to objectify the physical and cognitive limitations and associated functional dependency. Many of these tests were developed for the elderly, but they can also be used in younger patients [7, 38]. A home visit by a dialysis nurse and/or a social worker may be useful to determine whether the home is suitable for PD [39]. Based on this comprehensive multifactorial assessment, the healthcare professionals can determine whether the patient is capable of self-care PD or requires partial or full assistance. If the patient is a suitable candidate for assisted PD, it is also important to schedule the PD catheter insertion in a timely manner.

Based on the identified physical and cognitive limitations, it should be determined for which PD-related tasks the patient requires assistance, and who can carry out these tasks. A patient's informal caregiver may be considered to initiate caregiver-assisted PD. If no one is available, the possibility of nurse-assisted PD should be explored. In specific cases, deviceassisted PD can be offered.

In all cases of person-assisted PD, the assistant should be properly trained; in the case of partially assisted PD, the patient is also involved in training. Even in the case of fully assisted PD, it remains important to involve the patient as much as possible. This education is provided by professionals, usually the hospital's PD nurses. Training can take place in the hospital or in the patient's home.

¹Examples of these devices are depicted in Fig. 2.

It is important to regularly reassess whether the level of assistance matches the patient's needs and whether the informal caregiver is still physically and mentally able to continue providing PD assistance. In this way, it can be decided to switch between partially assisted, fully assisted PD and HD over time. If the patient's physical and/or cognitive condition improves, a transition to self-care PD can still be made. The process by which patients enter and exit the assisted PD pathway is illustrated in Fig. 4.

As discussed earlier, some patients will require fully assisted PD, while for others partially assisted PD is sufficient. Table 2 shows the different tasks of PD, physical and/or cognitive limitations that pose a barrier to performing these tasks, and the possible solutions that assisted PD can provide to overcome these barriers. It is important to determine very precisely which steps patients find difficult to provide the most appropriate type of assisted PD. It is also important to emphasize that device-assisted PD can provide solutions and can reduce the workload of informal caregivers and nurses.

CONCLUSIONS

In this review, we discussed how assisted PD can be a strategy to increase the uptake of PD in Europe. The current incidence and prevalence of PD in the European dialysis population is low. The dialysis population ages, and dialysis patients often experience physical and/or cognitive impairments. It is thus important to acknowledge that assisted PD might overcome these barriers for self-care PD. Offering a subsidized assisted PD program at a national level may lower the barrier to initiate PD. However, the availability of assisted PD programs is currently limited in many European countries and there is a paucity of epidemiologic data. A more systematic registration of assisted PD, for example through a national registry, is eagerly awaited. In addition, little is known about the experiences and quality of life of informal caregivers providing assisted PD. The caregiver study of the "Dutch nocturnal and home dialysis study to improve clinical outcomes" (DOMESTICO) is an ongoing study that will examine this [40]. A better global picture of the current situation of assisted PD in Europe may help to expand availability of assisted PD.

It is important to consider person-assisted PD and deviceassisted PD. The latter can reduce the workload of healthcare professionals and informal caregivers. New technologies such as 3D printing may support development and availability of new devices for the execution of PD. In addition, device-assisted PD is an interesting solution from an economic point of view; a simple device that does the work instead of a nurse results in a lower financial burden for the healthcare system. In conclusion, both person-assisted PD and device-assisted PD are promising strategies to increase and maintain PD with favorable clinical outcomes.

DATA AVAILABILITY STATEMENT

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AUTHORS' CONTRIBUTIONS

A first draft of the article was written by M.R. and subsequently edited by the other authors. The manuscript has been

read and approved by all authors, the requirements for authorship (as stated by the International Committee of Medical Journal Editors) have been met, and each author believes that the manuscript represents honest work.

CONFLICT OF INTEREST STATEMENT

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