# Remote Patient Monitoring in Peritoneal Dialysis

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# Introduction

Maintenance peritoneal dialysis (PD) is a costeffective therapy which confers major psychosocial advantages as compared to in-center HD with a greater degree of freedom and infrequent hospital visits. It can be realized in any age group with permanent PD catheters being used even in newborns and young infants. On the other hand, home PD requires significant medical and technical knowledge and encumbers families with major responsibility, preventing PD treatment in some families and resulting in early PD technique failures in others [1]. About half of pediatric patients on maintenance PD have inadequately controlled salt and water homeostasis and increased left ventricular mass index [2]; CKD MBD disease is insufficiently controlled [3]. Nonadherence with the prescribed regime is common. In a cohort in Kansas City, 45% of 51 children exhibited some nonadherence to prescribed PD regimen [4]. One important strategy

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to improve the quality of care in PD is increasing surveillance and support of the families at home.

For many decades patients and their carers have been keeping paper-based records of their PD treatments at home to be reviewed at the next outpatient appointment and were in contact with their clinical teams mainly via phone. At the beginning of the twenty-first century, PD cyclers with integrated digital card systems were introduced. These give retrospective insight into PD performance, complications, and adherence. The rapidly evolving digital technology now opens the doors to numerous opportunities, altering the face of medicine as we currently practice it. Remote patient monitoring (RPM) through telemedicine offers heightened treatment surveillance and has the potential to reduce the burden felt by families delivering care at home, to improve treatment adherence, and through realtime feedback loops to improve knowledge through individualized education. The latest generations of PD cycler have been or are being equipped with online monitoring technology that allows for automated, online transfer of the PD regime, ultrafiltration volumes, and triggered alarms, together with manually entered data sets such as body weight and blood pressure to the dialysis center and respective data-based communication with the families. This should improve PD patient care and the families' confidence by sharing medical responsibility and in turn promote the use of PD. The large data sets



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created by RPM have to be processed, respective communication with the families has to be established, and the impact on present and future therapeutic standards requires careful consideration.

#### Definitions

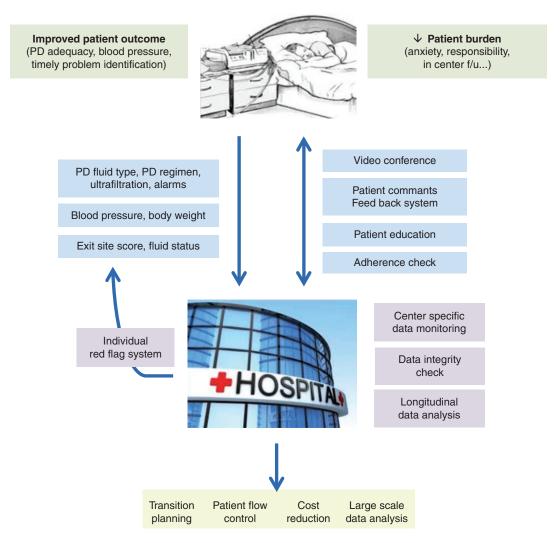
Telemedicine comprises the use of information and (electronic) communication technologies between patient caregivers and healthcare providers to exchange information for diagnosis, treatment, and prevention of diseases and injuries (i.e., remote monitoring of patients) regardless of the physical location of the participants in order to advance the health of individuals. The broader term, telehealth, encompasses nonclinical services, i.e., education, and is often used interchangeably with telemedicine [5].

#### **Remote Monitoring Techniques**

At present remote patient monitoring of pediatric PD patients is mostly limited to phone calls, e-mails, fax, and regular mails. This type of communication limits data transfer and, except for phone calls, may be associated with a significant time lag. More recent cycler generations are equipped with card systems and reduce the burden of data collection and allow for retrospective but comprehensive analysis of the PD performance at follow-up visits, namely, UF rates per dwell, flow rate alarms, and adherence to the prescribed regimen. The card system requires regular use at home and must be brought along to the follow-up visits in the dialysis center.

Latest cyclers now provide integrated automated online data transfer technology. This system includes a home cycler which transfers the data to a secure storage place, i.e., cloud storage. The storage space has to be highly protected but

accessible to various partners. The patient and the care takers should have access to the individual personal data, including the ability to scrutinize longitudinal data for optimal use. Authorized persons of the medical team in the dialysis center should have full access to all their patients. Healthcare authorities and administration may have access as appropriate according to national legislation, to help design and improve PD services for their local community and population wide [6]. Ideally, data collected online should automatically be integrated in existing electronic health records, to prevent data loss and needless duplication of data entry. Additional online functions that may be established are individual online communication portals between families and their clinical teams, remote reprograming of the cycler at home, and the ability to monitor and re-order dialysis consumables online. In parallel to analyzing longitudinal data from individuals, the wealth of knowledge and information contained within the collective dataset could form the basis of additional functions such as informing research and benchmarking. In the future we anticipate several digital devices being connected together to provide several parallel functions in unison for one patient clinical pathway. For example, we could see PD machines being used together with blood pressure monitors, scales, video systems, and oximetric devices to gain a comprehensive view on a patient's dialysis treatment (Fig. 18.1). This together with technologies such as voice recognition and Bluetooth connectivity should minimize or even eliminate the need of manual data entry and improve data quality, density, and reliability. Patients could be prompted to report on outcomes at regular intervals, e.g., by providing semi-quantitative assessments of well-being and individual patient symptoms over time. Finally, there is an opportunity to expedite and redesign education and training programs, combining face-to-face training with virtual and simulated learning modules. A virtual training program has recently been implemented in pediatric PD with success [7].



**Fig. 18.1** Schematic presentation of advanced remote patient management with data transfer between the patient and his family at home and the dialysis center (blue

squares), respective actions required at the dialysis center (purple squares), and expected patient benefits (green squares)

## **Benefits of RPM**

The potential benefits of RPM depend on the technology implemented and the readiness of the operator. RPM allows real-time transfer of relevant treatment data between patient's homes and their clinical teams. Issues or emerging trends prompt conversations through different communication portals such as text messaging and audio and video conferencing and allow redefining or refining treatment parameters, including reprogramming of the cycler. This should provide an array of advantages, including the timely recognition of PD-associated problems, such as catheter dysfunction and peritonitis; inadequate treatment performance, e.g., with regard to PD fluid turnover and ultrafiltration; and monitoring of treatment adherence. Nonadherence has been shown to associate with peritonitis and PD technique failure rate. A single home visit can improve adherence and outcome [8]; thus similar effects may be achieved by means of RPM. With increased awareness, insight into trends and deviations, and earlier interventions, RPM should 318

significantly improve patient outcomes. The patient and families' treatment-related medical responsibility and perceived burden should decline with the online connection with the clinical teams. This should increase the recruitment of patients and their families into home PD and improve the experiences of managing PD at home and thus quality of life. Continuous training, counseling, and educational features should further improve treatment efficacy and safety and reduce the need for planned and unscheduled incenter assessments. The latter may counterbalance and potentially even exceed the costs of the technology. On a larger scale, the accumulating treatment data should provide significant information on technical shortcomings, PD efficacy, and complications and allow for targeting of future developments (Fig. 18.1).

To date, automated online data transfer of PD treatment data has only been realized in a few dialysis centers [6]. The burden of collecting and communicating treatment related data is reduced, but data such as blood pressure and body weight measurements still require manual data entry. Video conferencing in PD thus far has been reported from a single dialysis center only [9]. In this center 25 adult PD patients were remotely monitored for blood pressure, blood glucose, exit site and dialysate state, and medication for a total of 200 RPM months with 172 teleconsultations. These were compared to 32 non-remote-managed patients, of whom several had refused RPM. The number of emergency room visits and of hospitalizations and their duration declined with RPM; the associated costs were lower. The observed decline in patient contacts for technical and medical issues during the mean follow-up of 1 year may reflect RPM-related training effects and improved reassurance of both sides due to the higher degree of surveillance.

Published RPM experience in pediatric PD is thus far limited to few children. In these patients RPM appeared useful in detecting and solving clinical and technical problems of automated PD, reduced the number of shortened PD treatments [10], and improved fluid status [11]. In a pilot trial in Heidelberg, automated online transfer of body weight and blood pressure readings was established in 2005 [12]. Fourteen APD, five incenter HD, and one home-HD patients were followed for 2-5 weeks. This allowed for early detection of hypotensive and hypertensive blood pressure episodes and successful counteractions. Confidence increased in both the families and the medical team. At Great Ormond Street Hospital London, UK, 17 children switched from standard care to RPM using the web-based platform Sharesource<sup>TM</sup>. Uptake was excellent, and prearranged patient appointments and number of dialysis-related hospital-based consultations decreased. The number of PD prescription changes increased substantially, mainly related to PD delivery alarms, indicating a more personalized dialysis prescription to patients with more timely adjustments. There was a shift toward greater virtual and remote care.

No randomized trial comparing standard care to RPM in PD has thus far been accomplished. An RCT in high-risk, nurse-supported HD patients yielded significant advantages with remote monitoring of blood pressure, blood glucose, heart rate, and O2 saturation and including video conferencing [13]. The number and duration of hospital admissions decreased in the 19 patients on RPM, and emergency room visits and costs were reduced as compared to standard of care.

Strong evidence in favor of RPM has been obtained in other disease conditions. RPM of patients with type 2 diabetes mellitus improved adherence [14]. A recent overview on systematic reviews on RPM in patients with heart failure provided grade 1A evidence for a reduction in hospitalizations and mortality. The impact of mobile phone-based monitoring and videoconferencing remains uncertain [15].

# RPM Implementation and Data Handling

When implementing RPM in PD, benefits have to be carefully balanced against the limitations and potential drawbacks associated with data transfer. In contrast to conventional patient care with monthly in-center follow-up and communication by phone calls or fax, large-scale, continuous online data flow requires standardized procedures within the center and careful communication with the families, taking into account linguistic and intellectual barriers. The benefits of monitoring numerous parameters must be balanced against the risks of data overflow. Country-specific legal aspects regarding informed consent, storage, and access to the data need to be followed. Data governance and assurance processes need to be designed and implemented. Families need to be informed on what data is being collected and how the clinical teams monitor the data, how often by whom on which days of the week. The data surveillance procedures established should maximize the benefits such as reduced phone calls and timely (online) interventions and still be feasible within clinical routine, e.g., should be in line with clinicians' working hours. Families need assurance on how the personal information will be protected and confidentiality maintained and on how it may be used for present and future analyses. All this requires thorough information of patient and caregivers and also training of the clinical teams (Table 18.1). During the beginning phase of rolling out RPM, two parallel systems will be working together, the established clinical pathways and the digitally enhanced pathways. This may at least transiently increase the complexity and costs and thus resource pressure for the organization.

**Table 18.1** Remote patient monitoring (RPM), step-by-step implementation and adaptation process

Choose technique and parameters to monitor; define data monitoring and action process
Verify alignment with law and regulations
Train staff (doctors and nurses)
Approach and train patients and carers
Set individual flags and alerts
Start RPM
Repeatedly review data sets and alerts, the analysis, and decisions taken based on RPM
Assess patient adherence to RPM
Refine individual and center RPM settings
Evaluate learning process
Reconsider standards of clinical practice established before RPM has been amended

Families and clinicians need to be trained using the RPM systems correctly and develop a solid understanding of the limitations of the system. Over-reliance in automated systems may result in adverse events and reduce situational awareness. In the PD treatment setting, there are acute and chronic communication needs. Availability of online communication does not necessarily provide adequate communication. Families have to be clear that they are still responsible for contacting the clinical team in case of acute problems. Real-time data assessment is not feasible 24/7 and unlikely to improve outcome [16]. Despite the online data transfer, a time lag still has to be considered, and urgent support will still need to be accessed through a phone call, even though communication platforms may allow the two-way exchange of information and immediate decision-making during office hours. RPM cannot delay or even replace emergency visits in case of urgent medical problems.

The monitoring functions require individual, patient-specific margin settings and respective alarm signals. UF range and blood pressure targets have to be defined, and potential technical pitfalls such as false readings must be considered. Regular readjustment, e.g., of target body weight, will be required. Thus, critical review of the pursued versus actual therapeutic success is essential at regular intervals during conventional face-to-face interactions between family and the clinical team. Setting rigorous alarm systems in RPM may result in unnecessary, frequent perturbations of domestic ambiance and possibly in mental and cognitive disconnection with the alarms. Conversely, liberalizing alarm limits may not sufficiently alert families and clinicians to a critical scenario and thus result in avoidable patient harm, e.g., regarding ultrafiltration and blood pressure control. The ambition to standardize and automate treatment practice with RPM needs to be balanced with the requirements for personalized care. RPM should be considered an adjunct in providing safe and effective clinical care but cannot replace human interactions and direct, face-to-face communication and training. Over-reliance on technology may result in failure

to seek help. In the limited publications to date, this, however, has not been reported to be a critical issue.

In the early phases of RPM, RPM provides support to established standards of care. As experience builds up, RPM may result in modifications of what is considered "good practice." For example, RPM may reduce the number of scheduled visits, e.g., reduce the face-to-face contacts. Optimized data presentation to easily visualize and track daily changes, e.g., of body weight, ultrafiltration, and blood pressure, against targets should facilitate data handling and optimize timely intervention. Interventional algorithms may evolve and improve the efficacy of decisions. Noteworthy, continuous comprehensive online data assessment may be perceived by some families as inappropriate surveillance and violation of privacy. Thus, the patient and families should have the right to opt out and discontinue online data transfer at all times. Centers performing RPM in PD thus far reported good overall acceptance with only occasional requests to discontinue RPM. The benefits of being supported at home obviously predominate over perceived disadvantages in the majority of families.

## Regulatory Issues and Reimbursement

Local practices are legally obliged to establish and provide assurance on adequate risk management around the technical aspects of RPM and data protection, aligned with local/national laws and regulations. Protection of personal data is a critical issue and requires careful consideration by respective professionals. Adequate reimbursement essential sustainability is for of RPM. Telemedicine and RPM are increasingly acknowledged as part of medical care together with a comprehensive and online accessible electronic patient file. Reimbursement, however, varies between countries. Applying RPM in pediatric dialysis may shift patient care from a primarily center-based treatment with close follow-ups to a more virtual care. Virtual care without direct patient contact is associated with medical risk and requires time and careful consideration; adequate reimbursement of these activities needs to be achieved with insurance providers. Implementation of RPM should optimize patient care and not be considered a tool to reduce costs without significant improvements in patient outcome.

## Conclusion

Telemedicine is a megatrend, with 29,000 publications in PubMed, of which 20,000 have been published the last 10 years. This interest is likely to continue and to multiply. In view of the widespread Internet access and greater adoption of digital devices in every aspect of our lives, the demand for telemedicine is rising. The expanding technical specification profiles, the growing functionality, and the user-friendly interfaces with ease of application of RPM place it at the heart of our promise to improve patient care. Within this context it is surprising that RPM has not yet been broadly established in (pediatric) PD and evaluated. At present, personal communications and small observational reports are positive; solid scientific evidence on the best mode of RPM, costeffectiveness, the impact on family burden, quality of life, PD performance, and patient outcome, however, is scant. Vigorous research is required to understand the true impact of telehealth. An ongoing randomized PD trial in Canada (CONNECT trial) will provide significant information in adult patients. Large-scale prospective observational data from the International Pediatric Peritoneal Dialysis Network, IPPN, will provide pediatric evidence on the impact of RPM on PD and patient care modalities, biochemical and cardiovascular outcome, infectious and non-infectious complications, technique failure, modality switch, and death.

Next to scientific evidence, usage and success of RPM will depend on the feasibility of implementation in clinical routine and daily family life and on the interoperability with other data systems. A continued local and international surveillance of the RPM process regarding technical aspects and the impact on clinical decisionmaking and targeted outcomes is required to provide the best outcome. In numerous countries with major limitations of healthcare budgets and inadequate or even missing dialysis options, in countries with shortage of medical staff, and in those where patients face very long distances to the dialysis centers, RPM should be an important mean to increase PD implementation.

Particular attention has to be paid on how virtual communication and RPM will transform patient care. Effective communication relies on the two-way exchange of information, verbal and non-verbal clues, and the ability to connect with people and gain their trust. Non-verbal clues apparent when communicating face to face may be missed; subtle signs of families not coping may be only detectable during personal communication. The human element, the "care" element of medicine, may be altered or even lost in digitally enhanced care pathways. This unintended consequence needs to be investigated and addressed. Until then RPM practices need to be adopted within clear boundaries interspersed with frequent opportunities of face-to-face interaction for scrutiny and reassurance. Up to now, RPM has mainly been used as an adjunct to established care. At present, the positive and sometimes even enthusiastic communications of the pediatric centers applying RPM in children on chronic PD are encouraging.

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