SUPPORTING CKD PATIENTS AT HOME

Summary of presentations from the Baxter Satellite Symposium held at the 52nd European Renal Association — European Dialysis and Transplant Association (ERA-EDTA) Congress, London, UK, on 31st May 2015

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MEETING SUMMARY

Dr Heaf opened the symposium by welcoming the attendees and introducing the speakers. Prof Cowie explained the concept of remote monitoring and outlined some of the tools available in cardiology, which include telephone monitoring, standalone equipment, and implanted devices. The challenges and usage of remote monitoring throughout 15 years of use in cardiology were explained, and emphasis was placed on the ability of remote monitoring devices to enable shared decision-making between the patient and healthcare professionals (HCPs) and their ability to align management strategies with patient needs. Prof Pestana then described the advantages and limitations of home-based peritoneal dialysis (PD). PD is an existing therapy that may benefit from additional patient and clinical support through telemonitoring and remote monitoring devices. Studies that assessed telemonitoring as a support for home-based PD versus centre-based haemodialysis were evaluated and the importance of shared decision-making was emphasised. The requirement for personalised decision-making tools in order to enhance medical supervision and provide more data for clinical decisions was discussed.

Learning From Others: The Benefits of Remote Monitoring in Cardiac Care

Professor Martin R. Cowie

The remote monitoring of patients with cardiac disease has been studied and used for around 15 years. Remote monitoring has received support from policymakers in order to move care from hospitals to the home environment, and the technology of remote monitoring is seen by politicians as a solution for sustainable healthcare. Remote monitoring has also been supported by patients; however, most patients who are involved in remote monitoring require reassurance through some face-to-face contact with HCPs. Remote monitoring is unlikely to be required by every patient throughout the entire duration of their condition, but some technologies have demonstrated usefulness in detecting periods of sudden worsening and decompensation, which has resulted in earlier and more appropriate care and, in general, such technologies help to support self care and shared decision-making.

The current standard of care for patient management in cardiac disease is through a 10-minute physician appointment, with data collected during the appointment determining the management of the patient for the following 3 months. If the condition of a patient worsens then a long hospital admission may ensue, followed by discharge to the same follow-up methodologies of physician appointments. The simplest method of remote monitoring that builds upon patient—physician appointments is telephone communication, while standalone equipment can also be used to monitor clinical measures, patient activity, and symptoms. Implanted devices such as cardiac resynchronisation therapy (CRT) and implantable cardioverter defibrillators can provide an additional layer of information to healthcare providers, but also bring new challenges of how to manage the data provided, which data protection measures are required, and what legal protocols should be implemented.

Benefits of the remote monitoring devices include improvement in self-monitoring by patients and the earlier detection of deterioration. Patients adept in managing their own information can adjust their own therapy and become decision-makers. Furthermore, implementation of remote monitoring technologies requires the determination of responses and responsibilities by the patient for given situations. Depending on the requirements, remote monitoring devices can provide reminders about medication and lifestyle, and can help inform more focussed face-to-face follow-up, including the frequency, location, and content of such follow-up. For example, a remote monitoring device may allow patients to look at their data, set limits, enter symptoms, and access educational videos, as well as enable HCPs to monitor the data periodically. Implanted devices can provide detailed information of a patient's medical condition, including heart rhythm, fluid retention, pulmonary artery pressure, and also about their activity levels. Such information may aid decision-making by the patient and/or their healthcare team.

Publications describing the different types of remote monitoring devices have reported mixed results. A meta-analysis of small studies that evaluated the effect of telephone contact and standalone systems on patients with heart failure (HF) found that all-cause mortality was significantly reduced with telephone contact,[1] while reductions in hospitalisation related to chronic HF were reported for both the telephone and standalone system interventions. However, the large USA TELE-HF study that assessed the effect of an automated telephone service found that 15% of patients who were randomised never contacted the service, 50% of patients stopped using the service within 6 months, and there were no differences in measured clinical outcomes.[2] A German study of 710 randomised patients with a median follow-up of 26 months assessed the effect of telemonitoring and found no differences between groups regarding hospitalisation due to HF, cardiovascular (CV)-related death, and all-cause mortality.[3] However, it should be noted that the patients were relatively young and stable, with half exhibiting minimal symptoms and New York Heart Association (NYHA) Class II. Comparatively, the UK project 'Whole System Demonstrator' evaluated the effect of telehealth and telecare in 6,191 patients across 283 general practices, and found reductions of over 10% in emergency room visits, emergency admissions, elective admissions, bed days, and also an 8% reduction in tariff costs.[4] However, this initiative has not yet been rolled out at a national level, which could be due to the low value for money, with a reported quality-adjusted life year (QALY) cost of £92,000.[5]

Due to the cost, resource, and organisational implications of remote monitoring devices for all patients with chronic CV disease, the technology may be most effective if targeted at more unstable patients. Remote monitoring devices would enable closer surveillance of high-risk patients by the healthcare team for any deterioration in the patient's condition and facilitate earlier intervention with the aim of avoiding the need for hospitalisation. However, pattern recognition is required to monitor these patients and such skills take time to develop. Separating 'noise' from 'signal' is not always straightforward, and more data can sometimes result in more decision-making rather than a better outcome. In theory, indicators of worsening symptoms in HF can present around 2-3 weeks prior to HF decompensation.[6] A study that retrospectively analysed data from tens of thousands of patients with HF and an implanted pacing device reported an algorithm that could stratify high and low-risk patients: patients who were at high risk were ten-times more likely to be admitted to hospital within the next 30 days due to HF compared with the low-risk patients, but even in the high-risk group the absolute risk of hospitalisation was still only 4% over 30 days.[7] Such a lack of a positive predictive value is off-putting to many clinicians.

One of the challenges of remote monitoring is to manage a potentially enormous data stream appropriately and make the correct decision with the large amount of data available, ensuring that support staff are trained in how to deal with any alerts. The controlled DOT-HF study assessed the effect of an audible alert when patients crossed preset thresholds of transthoracic impedance determined by an implanted cardiac device. It reported an increase of 79% in hospitalisations compared with devices without the preset thresholds (p=0.02). The increase in hospitalisations seen in association with preset thresholds may have been due to the pacemaker alarm that may have made patients anxious, and this anxiety was then transmitted to the HCPs who erred on the side of caution and admitted such patients to hospital for observation. This highlights the need for appropriate training and support for HCPs involved in remote monitoring programmes.[8] A more positive outcome was recently reported from the IN-TIME study,[9] conducted in Australia, Europe, and Israel, that compared the daily remote monitoring of cardiac implanted devices versus usual care. The study reported a >60% reduction in mortality in a total of 664 patients, as well as an 8.3% reduction in the composite all-cause score including all-cause death, overnight hospital admission for HF, change in NYHA class, and change in patient global assessment (p=0.013).[9] The ALTITUDE study also demonstrated improved survival of patients who were given heart monitoring devices that were networked to transmit remote data versus non-networked devices, albeit in an observational setting. Further results are imminent as one of the world's largest remote monitoring studies, REM-HF, is near completion. The REM-HF study has randomised 1,650 patients with implanted cardiac devices from 9 English hospitals, and has a follow-up of at least 2 years.[10]

Another aspect of remote monitoring is the allowance of greater involvement of the patient in managing their own care. Patients with diabetes can now monitor their blood glucose levels and adjust the insulin accordingly, while a mid-level team member can monitor the data and determine if and when input from the physician is required.[11] This provides the patient with greater confidence, an improved ability to self care, and a deeper understanding of their signs and symptoms. It also better utilises the time of the physician.[12]

In conclusion, the technology of remote monitoring lends itself towards shared decision making between the patient, mid-level team members, and physicians. Remote monitoring supports self care and involvement of the patient and a more tailored approach towards their needs.[11]

Remote Monitoring to Support CKD Patients: What Are the Needs?

Professor Manuel Pestana

Dialysis currently represents the most expensive chronic therapy available: the treatment is 6-7 times more expensive than treating a patient with acquired immune deficiency syndrome, and 30-40 times more costly than the management of chronic obstructive pulmonary disease. Within the dialysis modalities, studies into home-based PD have shown various benefits compared with haemodialysis, with a cost saving of >€25,000 per year and >€45,000 per QALY reported in Spain,[13] and economic benefits reported globally.[14] A breakdown of the main areas where home-based PD cost savings have been reported compared with haemodialysis is provided in Table 1.[15] Furthermore, home-based PD has certain clinical and psychological advantages over haemodialysis. These include improved short-term patient survival, similar long-term survival, and greater independence due to flexibility around how, when, and where the dialysis is performed. It also allows for a more liberal diet.

Requirements of home-based PD include a medical support system as there is greater patient responsibility to manage their therapy and clinical characteristics including weight, blood pressure, and fluid balance, as well as how to handle complications and any difficulties. In this respect, a well-structured home visit programme may be beneficial in areas such as improved knowledge coupled with continuous training and better compliance. Studies have reported an increase in patients who choose PD upon availability of the home-visit programme[16] and also improved technique survival (p=0.018) over 60 weeks.[17,18] Retrospective cumulative survival was also significantly improved over 400 days in incident patients managed with home-based PD (p<0.001) versus patients given haemodialysis with an arteriovenous fistula or central venous catheter.[17] However, the majority of patients worldwide are still treated with in-centre haemodialysis due to structural and social factors, poor training, and a lack of interest from nephrologists.[19] As the sustainability of healthcare systems requires reflection upon the costs and efficiencies of the services, PD represents an under-used modality.

Although PD offers many benefits, there are still some challenges in optimising the modality. As well as support provided to the patient for any difficulties or complications, improved communication between the patient and centre is required so that clinical decisions are not delayed and the patient does not require a visit to the emergency department or nephrology centre. If these challenges are not addressed, the patient may perceive the nephrology centre as being remote. Therefore, there is a need to improve the prediction and detection of any complications that may occur. Additionally, supportive tools to empower the self-management of the patient, shared decision-making with the physician, and improved feedback and evaluation of actions taken by the patient to HCPs at the treatment centre, may improve home-based PD.

Remote monitoring, or telemedicine, is a tool that may help improve the communication between patients and HCPs and reduce the perceived remoteness of PD.[20] As most patients own the necessary equipment and internet connection for telemedicine,[21] the technique may serve to improve the detection of complications, thereby reducing the need for unscheduled visits to the nephrology centre or emergency department. A study evaluated the efficacy of telemedicine through websites for PD in urban and rural areas of India and found that rural patients had significantly improved survival compared with urban patients.[22] Gallar et al.[23] also found a reduction in hospitalisation rates from 5.7 days to 2.2 days per year through the use of videoconferences and teleconferences where patients were at home, with cost savings also reported.

Table 1: Cost analysis of HD and PD access in incident dialysis patients.[14]

	Mean cost in euros (€ [95% CI])			
Intervention	With AVF (n=65)	With TCC (n=45)	PD (n=42)	p value
Access surgery	401.7 [343.8-459.6]	252.9 [190.5-315.4]	540.7 [526.8-584.7]	<0.001
HD catheter interventions	141.2 [57.7-234.6]	718.7 [576.0-861.5]	72.8 [26.9-118.8]	<0.001
Diagnostic imaging	344.7 [187.8-501.7]	151.3 [52.9-249.8]	0	<0.001
Hospitalisation	469.2 [57.9-996.3]	2746.2 [494.8-4997.5]	516.7 [67.5-965.9]	0.010
Transportation	193.4 [128.3-258.5]	339.1 [236.0-442.2]	41.4 [28.1-54.6]	<0.001
Total	1555.2 [974.0-2136.2]	4208.2 [2050.7-6365.9]	1171.6 [737.6-1526.0]	<0.001

From Manuel Pestana, presentation at the 52nd European Renal Association — European Dialysis and Transplant Association (ERA-EDTA), London, UK, on 31st May 2015.
AVF: arteriovenous fistula; CI: confidence interval; HD: haemodialysis; PD: peritoneal dialysis; TCC: tunnelled cuffed catheter.

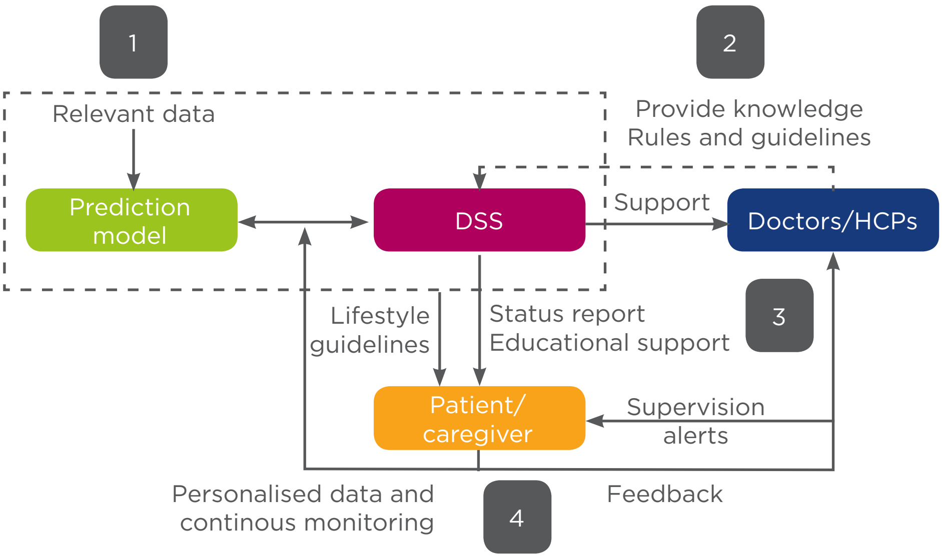

Figure 1: Illustration of a personalised decision-support system, which is based upon predictive models, established clinical guidelines, and the health and lifestyle monitoring strategies of the patient.
From Manuel Pestana, presentation at the 52nd European Renal Association — European Dialysis and Transplant Association (ERA-EDTA), London, UK, on 31st May 2015.
DSS: decision-support system; HCP: healthcare professional.

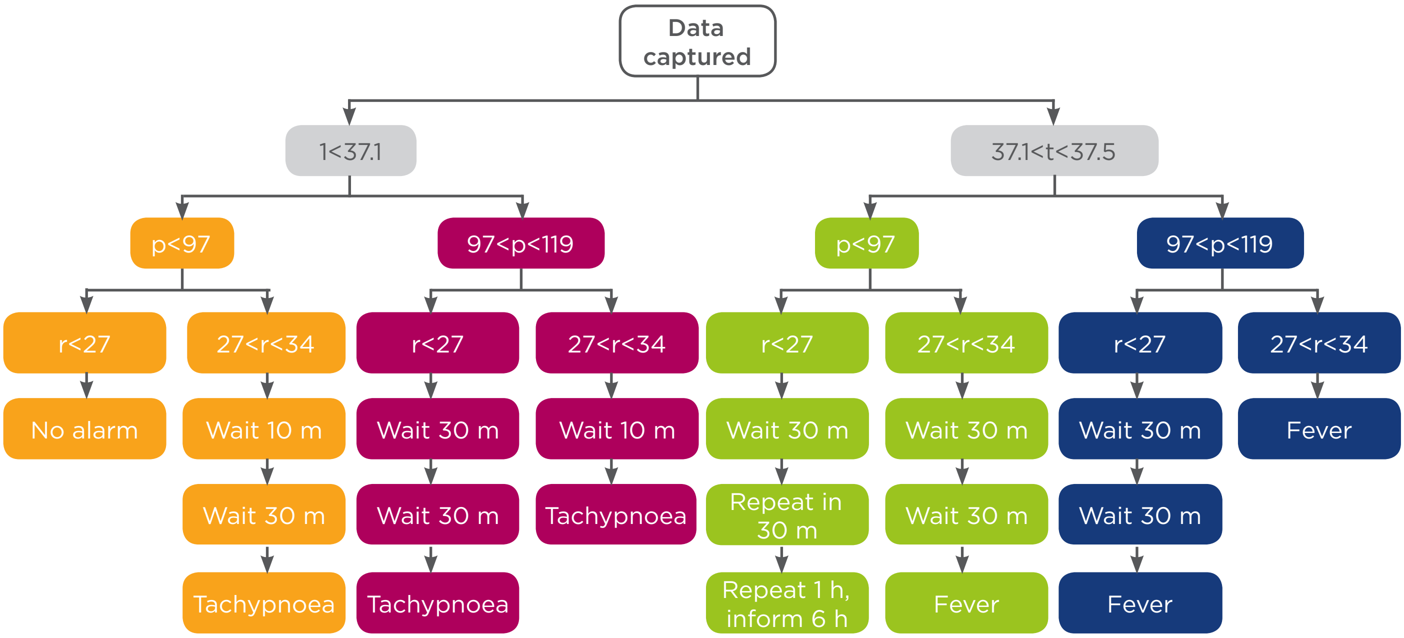

Figure 2: Flowchart of a medical decision protocol using temperature, pulse, and respiratory rate.
From Manuel Pestana, presentation at the 52nd European Renal Association — European Dialysis and Transplant Association (ERA-EDTA), London, UK, on 31st May 2015.
p: pulse; r: respiratory rate; t: temperature; h: hour; m: minute.

Although studies of remote monitoring have shown some positive results, unmet needs include the improvement of shared decision-making between patients and HCPs through personalised decision support tools, clinical guidelines, health and lifestyle monitoring, and improved risk prediction. Shared decision-making between the patient and HCPs involves the exchange of information, deliberation of options, deciding on the priority for taking action, and then making a decision.[24] Shared decision-making can be facilitated by the requirement for explicit decisions to be made within the remote monitoring tool by the patient and HCP. Through the provision of balanced information on the benefits and risks of certain options to the patient as well as knowledge and understanding of their needs and goals to provide context, support from the remote monitoring tool as well as complementary information from an HCP can provide context to decisions that are required of the patient.[25] Barriers to shared decision-making include time constraints and a lack of applicability to certain patients or clinical situations.[26] Within the field of diabetes, a power imbalance between the patient and provider, lack of health literacy, and denial of the situation by a patient were also found to be obstacles in shared decision-making. Facilitators of the shared decision-making process were improved HCP motivation and training of the patient as well as patient-mediated interventions.[26]

Data collection regarding the lifestyle of the patient by the remote monitoring tool can be helpful to make more informed clinical decisions. The accumulation of demographic, clinical, and social data from the patient may influence certain clinical outcomes and support the development of personalised decision-support systems (DSS), as shown in Figure 1. The development of an effective DSS tool involves the development of a prototype and then increasing the fidelity of the prototype through the observation of prospective users' interactions with the prototype. Through understanding the needs, goals, strengths, limitations, and context of the user, more intuitive processes can be put in place and the prototype refined through facillitating the tool towards the user.[25] Patient decisions and certain system alerts can also be tailored and supported through a greater knowledge of the patient's clinical situation, enabling patient empowerment, remote monitoring of the parameters of the patient, and improved compliance.

Accumulation of patients' clinical and demographic data can also allow for more accurate prediction and detection of risks, as well as the earlier identification and knowledge-based handling of complications. Alert messages can include the probability of the complication occurring, with a warning message and explanation of the factors underlying the decision, again enabling a co-decision by the patient and allowing for communication between the patient and HCP on a more timely basis. A medical decision protocol, as shown in Figure 2, provides an example of a decision flow chart of the remote monitoring tool, with certain observations requiring confirmation through repeated measurements prior to the issue of an alert, explanation, and plan of action to the patient and HCP. As an example, the diagnosis of volume overload or depletion will be determined from certain clinical, patient-related, and prescription-related parameters that include blood pressure, weight, impedance, ultrafiltration volume, PD modality, dwell time, residual renal function, and body mass index.

In summary, improved integration of home and personalised healthcare monitoring systems with secure and effective communication between patients and HCPs, as well as appropriate tools for shared decision-making with HCPs, may result in enhanced medical supervision and improved clinical outcomes. The use of predictive systems based on computer modelling will provide a sound rationale for clinical decisions. Personalised decision-making tools will also refine the communication between patients and HCPs, and ameliorate clinical supervision through better monitoring and management of the care process.

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