

Remote Patient Monitoring – now or never

Unlocking the full potential of remote patient care



APRIL 2022

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Executive Summary

During the COVID-19 pandemic, health systems urgently adopted digital health technologies to enable remote care to provide continuity of and access to care for patients, while protecting patients and medical staff from unnecessary risks.

While the pandemic is receding, these central issues of health system resilience remain as relevant as ever. The focus of this paper is the digital technologies and services that enable remote care, including remote patient monitoring solutions, which we refer to here as Remote Patient Monitoring (RPM). RPM solutions allow health providers to monitor the onset of disease and symptom progression remotely, engage with patients virtually to modify care plans and provide education on self-care based on changes in the patient's condition.¹ RPM solutions can predict, prevent, and manage events through continuous remote monitoring and treatment of health conditions while facilitating remote and face-to-face consultations and interventions with healthcare professionals (HCPs).

RPM solutions have the potential to^{2,3,4,5,6}:

- Ensure timely intervention, enabling better patient outcomes
- Improve adherence to treatment and self-management of health conditions
- Improve access to healthcare and reduce inequalities
- Reduce costs of healthcare services, hospitalisation rate and hospital stays

The academic literature has begun to demonstrate the benefit of RPM solutions for specific conditions. While the evidence base needs to mature, digital solutions have an established track record, including in the six disease areas covered in this paper: (1) heart failure; (2) sleep apnoea; (3) musculoskeletal disorders; (4) chronic respiratory diseases; (5) chronic kidney disease; and (6) diabetes. This paper provides case studies of RPM for each of these disease areas.

Some health systems have made progress in widening access and uptake of these solutions. However, there remain numerous barriers in place, including resistance to integration of RPM solutions into the treatment pathway; limited access to early RPM funding; specific RPM value assessment frameworks not broadly adopted across Europe; interoperability challenges as well as data privacy and security aspects at the European level; and gaps of health and digital literacy in healthcare professionals and patients. Furthermore, while the momentum for digital health solutions overall has been significant during the pandemic, there is a risk that the sense of urgency fades and progress stalls. It is important that this momentum is maintained for the benefit of patients, healthcare professionals, health systems and society.

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- 1) HIMSS. Remote Patient Monitoring: COVID-19 Applications and Policy Challenges. Accessed November 28, 2021. <https://www.himss.org/news/remote-patient-monitoring-covid-19>
 - 2) Haute Autorité de Santé. Suivi par télésurveillance des patients porteurs d'un moniteur cardiaque implantable. Published March 11, 2021. Accessed November 26, 2021. https://www.has-sante.fr/upload/docs/application/pdf/2021-03/rapport_ts_mci_vd.pdf
 - 3) Dinesen B, Haesum LKE, Soerensen N, et al. Using preventive home monitoring to reduce hospital admission rates and reduce costs: a case study of telehealth among chronic obstructive pulmonary disease patients. *Journal of Telemedicine and Telecare*. 2012;18 (4). doi:10.1258/jtt.2012.110704
 - 4) Centers for Disease Control and Prevention. Using Telehealth to Expand Access to Essential Health Services during the COVID-19 Pandemic.; 2020. Accessed November 26, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/telehealth.html>
 - 5) O'Connor M, Asdornwised U, Dempsey ML, et al. Using Telehealth to Reduce All-Cause 30-Day Hospital Readmissions among Heart Failure Patients Receiving Skilled Home Health Services. *Appl Clin Inform*. 2016;7(2):238-47. doi: 10.4338/ACI-2015-11-SOA-0157. PMID: 27437037; PMCID: PMC4941836
 - 6) Bond CS, Worswick L. Self Management and Telehealth: Lessons Learnt from the Evaluation of a Dorset Telehealth Program. *Patient*. 2015;8(4):311-6. doi:10.1007/s40271-014-0091-y. PMID: 25315192

This background document is intended to provide EU and national policymakers and payers with a briefing on the potential of RPM. The paper provides some examples of potential benefits that RPM solutions may bring, followed by the barriers that prevent their wider use. Finally, eight considerations are set out to ensure the potential of RPM is deployed for the benefit of European patients, healthcare professionals, health systems and society.

Introduction & Background

RPM solutions “allow health providers to monitor disease and symptom progression remotely and then engage with patients virtually to modify care plans and to provide education on self-care, based on changes in the patient’s condition”⁷ They can thus play a key role in ensuring continued patient access to care. For the purpose of this paper, both teleconsultations and telemonitoring will be considered within the RPM terminology. These solutions can contribute significantly to the future of care delivery and access within sustainable and resilient healthcare systems if supported by adequate reimbursement and funding, combined with adequate value assessment frameworks.

The impact of COVID-19 on health systems has given new impetus to the wider use of RPM solutions. Since early 2020, the demand for teleconsultations has risen significantly in response to the restrictions facing in-person and on-site delivery of healthcare. To cope with the pandemic and the corresponding risk of leaving patients untreated, some health systems and providers have temporarily adapted some of their rules and regulations to enable the broader implementation of RPM solutions.^{8,9} Such measures are designed to limit the unnecessary risk of COVID-19 exposure for both patients and healthcare professionals. Beyond COVID-19, studies have shown that a comprehensive implementation of telemedicine, including RPM solutions, has the potential to significantly reduce healthcare costs.^{10,11}

However, while the momentum for RPM solutions, as well as teleconsultations, has grown during the pandemic, there is a risk that this sense of urgency fades and progress on widespread adoption stalls.



Considerations

- 1: Raise awareness by encouraging broader use of RPM solutions
- 2: Enable sustainable, adequate, and timely funding reimbursement of RPM solutions and related medical activities that have demonstrated benefits
- 3: Support investment and accelerated coverage of RPM innovation through early funding
- 4: Strengthen transparency in decision-making on availability and funding
- 5: Use appropriate and proportional evidence to assess the value of RPM solutions
- 6: Reshape health system treatment pathways to integrate RPM solutions that have demonstrated their value
- 7: Ensure adoption by the Member States of the recommended standard of care
- 8: Introduce training programmes on digital health to improve the level of digital literacy in Europe

7) HIMSS. Remote Patient Monitoring: COVID-19 Applications and Policy Challenges. Accessed November 28, 2021. <https://www.himss.org/news/remote-patient-monitoring-covid-19>

8) Deutsches Ärzteblatt. Videosprechstunden haben sich etabliert. Accessed November 26, 2021. <https://www.aerzteblatt.de/nachrichten/120885/Videosprechstunden-haben-sich-etabliert>

9) Health Advances. The Changing Fortunes of Telemedicine in Europe – Past, Present, and Future beyond COVID-19. Published May 6, 2022. Accessed February 15, 2022. <https://healthadvancesblog.com/2020/05/06/the-changing-fortunes-of-telemedicine-in-europe/>

10) Dinesen B, Haesum LKE, Soerensen N, et al. Using preventive home monitoring to reduce hospital admission rates and reduce costs: a case study of telehealth among chronic obstructive pulmonary disease patients. *Journal of Telemedicine and Telecare*. 2012;18 (4). doi:10.1258/jtt.2012.110704

11) Computer Weekly. Telemedicine to save healthcare industry tens of billions globally by 2025.; 2021. Accessed November 26, 2021. <https://www.computerweekly.com/news/252500459/Telemedicine-to-save-healthcare-industry-tens-of-billions-globally-by-2025>

In addition, despite the need to promote prevention and optimal management of chronic diseases to reduce the burden of these conditions on ageing populations, as well as on healthcare systems¹², there remain many barriers to the adoption of RPM solutions.

This background paper presents the medical technology industry's perspective on this issue. It argues that it is crucial that we build upon the momentum created by the use of RPM during the pandemic and that all stakeholders work collaboratively to overcome barriers to further access. In order to give a comprehensive overview, this paper is divided into four sections (A-D):

- Section A defines RPM solutions and provides concrete examples of their benefits and challenges
- Section B elaborates on the potential value of RPM across six major chronic diseases
- Section C identifies the barriers preventing the deployment of RPM solutions
- Section D includes considerations for tackling barriers and promoting the use of RPM solutions for the benefits of patients, health systems, healthcare professionals and wider society.

Section A

What are RPM solutions?

RPM is a concept which “allows health providers to monitor disease and symptom progression remotely and then engage with patients virtually to modify care plans and to provide education on self-care, based on changes in the patient’s condition”.¹³ It is a concept that straddles both telehealth and telemedicine¹⁴, all of which comprise the wider category of e-Health (figure 1).¹⁵ Traditionally, RPM would exclusively refer to telemonitoring, but due to their increased and crucial role during the COVID-19 pandemic, teleconsultations have also been included in the scope of this paper. This expanded definition of RPM refers to any telecommunications and electronic information processing technologies used to monitor a patient’s status at a distance, measure certain medical parameters remotely (e.g., blood pressure, heart rate, weight, or oxygen saturation) and facilitate remote communication (telecare) between patients and healthcare professionals.

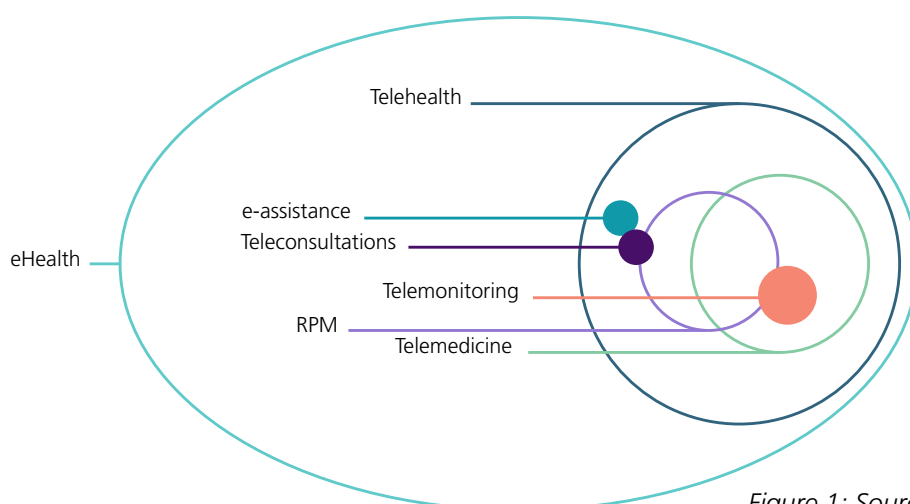


Figure 1: Source MedTech Europe 2022

12) European Commission, DG Health and Food Safety. Scoping study on communication to address and prevent chronic diseases: Final Report, 2015, ICF International. https://ec.europa.eu/health/system/files/2018-10/2015_chronic_scopingstudy_en_0.pdf

13) HIMSS. Remote Patient Monitoring: COVID-19 Applications and Policy Challenges. Accessed November 28, 2021. <https://www.himss.org/news/remote-patient-monitoring-covid-19>

14) Please see glossary for further definitions

15) HIMSS. Remote Patient Monitoring: COVID-19 Applications and Policy Challenges. Accessed November 28, 2021. <https://www.himss.org/news/remote-patient-monitoring-covid-19>

RPM solutions offer innovative technologies that support healthcare management, including:

- **Stand-alone medical measuring devices** (e.g., patches, watches or textiles that can monitor, for instance, sleep disorders, ECG, body temperature, blood glucose concentration and body posture; external monitors, including heart rate monitor, pulse oximeter, etc.)
- **Implantable devices** (e.g., Cardiac Implantable Electronic Devices (CIEDs) providing useful physiological data to support arrhythmia therapy and heart failure management or diabetes sensors to monitor glucose)
- **Digital platforms** to facilitate structured support consultations for patients 24/7, including teleconsultations (e.g. Health Apps).

RPM solutions often connect to the cloud, delivering data for remote monitoring of, and improving care for, patients with chronic diseases (e.g., sleep-disordered breathing, respiratory disorders, chronic obstructive pulmonary disease, or asthma), as well as for enabling early detection of complications.

The benefits of RPM solutions

RPM solutions promise to play a crucial role in facilitating the management of chronic conditions, which are rising in Europe and placing health systems under strain. Moreover, RPM solutions can be potentially used to support diagnosis and screening. As such, these solutions should be an integrated part of healthcare. This has been shown specifically for remote monitoring during the COVID-19 pandemic, which became essential for supplementing traditional face-to-face interaction between healthcare professionals and patients.

For instance, since spring 2020 in Germany, physicians and psychotherapists have taken advantage of existing RPM solutions by offering unrestricted teleconsultation hours, enabling healthcare professionals to deal with a greater number of patients. France too has seen an important rise in teleconsultation services. Before COVID-19, the national insurance fund recorded and reimbursed about 40,000 teleconsultations per month, a figure multiplied ten-fold in one week during the pandemic.¹⁶

Among others, RPM solutions can bring the following benefits to patients, health systems, healthcare professionals and wider society:

- **Ensuring timely intervention:** Remote monitoring establishes a more fluid exchange of information between patients and healthcare professionals, resulting in a closer follow-up of patients' conditions, as well as more accurate and timelier clinical and technical interventions. By speeding up interventions, RPM solutions can thus contribute to better patient outcomes including quality of life by preventing the worsening of their health conditions.
- **This is particularly relevant to chronic conditions:**¹⁷ By measuring specific health parameters and permanently monitoring health conditions, RPM solutions can play a key role in preventing the worsening of those conditions or even fatal episodes.¹⁸

16) Health Advances. The Changing Fortunes of Telemedicine in Europe – Past, Present, and Future beyond COVID-19. Published May 6, 2022. Accessed February 15, 2022. <https://healthadvancesblog.com/2020/05/06/the-changing-fortunes-of-telemedicine-in-europe/>

17) Dinesen B, Haesum LKE, Soerensen N, et al. Using preventive home monitoring to reduce hospital admission rates and reduce costs: a case study of telehealth among chronic obstructive pulmonary disease patients. *Journal of Telemedicine and Telecare*. 2012;18 (4). doi:10.1258/jtt.2012.110704

18) Hindricks G, Taborsky M, Glikson M, et al. Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. *Lancet*. 2014;384(9943):583-590. Doi: 10.1016/S0140-6736(14)61176-4. PMID: 25131977

For example, patients with diabetes, particularly Type 2, who make use of RPM solutions have shown a more significant HbA1c reduction than those who do not.^{19,20,21}

- **Improve adherence to treatment and self-management of health conditions**²²: As a result of data from continuous monitoring, patients can live more autonomously and with improved life quality.
- **Improve access to healthcare and reducing inequalities**²³: RPM solutions proved to be an effective and often convenient alternative to face-to-face consultations or minor treatments in healthcare centres during the pandemic, particularly for groups of people who face restrictions in accessing healthcare centres due to geographical distance, age, physical conditions, or time limitations. Beyond the pandemic, a 2014 study found that activating an RPM protocol, which enabled remote consultations and follow-ups with healthcare professionals, reduced ambulance transport by 44%.²⁴
- **Reduce costs of healthcare services, hospitalisation rate and hospital stays**²⁵: The widespread use of RPM solutions could contribute to reducing the frequency of hospital admissions and lower healthcare costs, although large-scale studies of prolonged home monitoring with more extended follow-up are required. Driven by teleconsultation services, RPM and chatbots, telemedicine is projected to be able to save the global healthcare industry \$21bn in costs by 2025, rising from \$11bn in 2021.²⁶ Moreover, based on a study in France and Germany, healthcare digitalisation could result in efficiency gains of about €55 billion, which could come to €120 billion if extrapolated for the entire EU-27, out of which 40% could be realised by supporting teleconsultation, remote monitoring of chronic diseases and unified electronic health records (EHR).²⁷ RPM solutions would reduce administrative costs through more data-driven and collaborative decision-making processes including physicians and patients.²⁸

Section B

Case Studies: RPM in six chronic disease areas

Several common chronic diseases were selected to illustrate the everyday benefits of RPM solutions and how they contribute to positive change for patients, health systems, healthcare professionals, and broader society. These cases include (1) heart failure; (2) sleep apnoea; (3) musculoskeletal disorders; (4) chronic respiratory diseases; (5) chronic kidney disease; and (6) diabetes.

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- 19) H. Tchero, P. Kangambega, C. Briatte, S. Brunet-Houdard, G.-R. Retali y E. Rusch. Clinical Effectiveness of Telemedicine in Diabetes Mellitus: A Meta-Analysis of 42 Randomized Controlled Trials. *Telemedicine Journal and e-Health*, 2019; 25(7), 569-583. <https://www.liebertpub.com/doi/10.1089/tmj.2018.0128>
- 20) S. W. H. Lee, C. K. Y. Chan, S. S. Chua y N. Chaiyakunapruk. Comparative Effectiveness of Telemedicine Strategies on Type 2 Diabetes Management: A Systematic Review and Network Meta-Analysis. *Scientific Reports*, 2017; 7(1), 12680, 1-11. <https://www.nature.com/articles/s41598-017-12987-z>
- 21) T. L. Michaud, J. Ern, D. Scoggins y D. Su. Assessing the Impact of Telemonitoring-Facilitated Lifestyle Modifications on Diabetes Outcomes: A Systematic Review and Meta-Analysis. *Telemedicine and e-Health*, 2021; 27(2), 124-136. <https://www.liebertpub.com/doi/10.1089/tmj.2019.0319>
- 22) Bond CS, Worswick L. Self Management and Telehealth: Lessons Learnt from the Evaluation of a Dorset Telehealth Program. *Patient*. 2015;8(4):311-6. doi:10.1007/s40271-014-0091-y. PMID: 25315192
- 23) Centers for Disease Control and Prevention. Using Telehealth to Expand Access to Essential Health Services during the COVID-19 Pandemic.; 2020. Accessed November 26, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/telehealth.html>
- 24) Langabeer JR 2nd, Gonzalez M, Alqusairi D, et al. Telehealth-Enabled Emergency Medical Services Program Reduces Ambulance Transport to Urban Emergency Departments. *West J Emerg Med*. 2016;17(6):713-720. doi:10.5811/westjem.2016.8.30660. PMID: 27833678; PMCID: PMC5102597
- 25) Dinesen B, Haesum LKE, Soerensen N, et al. Using preventive home monitoring to reduce hospital admission rates and reduce costs: a case study of telehealth among chronic obstructive pulmonary disease patients. *Journal of Telemedicine and Telecare*. 2012;18 (4). doi:10.1258/jtt.2012.110704
- 26) Computer Weekly. Telemedicine to save healthcare industry tens of billions globally by 2025.; 2021. Accessed November 26, 2021. <https://www.computerweekly.com/news/252500459/Telemedicine-to-save-healthcare-industry-tens-of-billions-globally-by-2025>
- 27) European Commission. Shaping the Digital Transformation in Europe.; 2020. Accessed February 15, 2021. https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=69479.
- 28) Langabeer JR 2nd, Champagne-Langabeer T, Alqusairi D, et al. Cost-benefit analysis of telehealth in pre-hospital care. *Journal of Telemedicine and Telecare*. 2017;23(8):747-751. doi: 10.1177/1357633X16680541

Heart failure

Heart failure is a prevalent health condition today, causing an enormous burden on individuals and societies.

- One in five people are expected to suffer from heart failure once in their lifetime²⁹
- In Europe, mortality rates in patients with heart failure are 11% and 41% at one year and five years of follow-up, respectively.³⁰
- Heart failure also has a severely negative impact on patient quality of life and their mental well-being – for many patients performing physical and social activities or engaging in fulfilling relationships is no longer a prospect³¹
- The disease challenges the sustainability of health systems. Direct healthcare-related expenditure is already high and is projected to increase, in part due to an overall ageing population.³² Heart failure is responsible, in most westernised economies, for about 2% of all healthcare expenditure. In one year, the costs related to heart failure in the European Union (24 Member States) were estimated to be around €29 billion.³³

Timely diagnosis, treatment and effective monitoring are crucial.³⁴ However, missed, or late diagnosis, re-hospitalisation, inefficient use of healthcare resources and poor patient involvement currently represent a significant barrier to optimal and high-quality heart failure care. RPM solutions in support of heart failure could provide a more personalised approach, with the potential to bring about better health outcomes for patients at lower healthcare costs,³⁵ by ensuring by ensuring timely diagnosis and treatment, therefore enabling the prevention of complications and potential hospitalisations.³⁶

29) World Heart Federation. Epidemiology and risk profile of heart failure. Accessed November 26, 2021. <https://world-heart-federation.org/resource/heart-failure-infographic-2/>

30) Mosterd A, Cost B, Hoes AW, de Bruijne MC, Deckers JW, Hofman A, Grobbee DE. The prognosis of heart failure in the general population. The Rotterdam Study. *Eur Heart J*. 2001 Aug;22(15):1318-27. doi: 10.1053/euhj.2000.2533.

31) Faller, H et.al. Der Kansas City Cardiomyopathy Questionnaire (KCCQ) – ein neues krankheitsspezifisches Messinstrument zur Erfassung der Lebensqualität bei chronischer Herzinsuffizienz. Psychometrische Prüfung der deutschen Version. In: Psychotherapie, Psychosomatik, Medizinische Psychologie. 2005 (55), p. 200–208

32) de Meijer, C., Wouterse, B., Polder, J., & Koopmanschap, M. The effect of population aging on health expenditure growth: a critical review. *European journal of ageing*. 2005; 10(4), 353–361. <https://doi.org/10.1007/s10433-013-0280-x>

33) European Heart Network. Heart Failure and Cardiovascular Diseases – A European Heart Network Paper. Published April 22, 2019. Accessed February 25, 2022. <https://ehnhart.org/publications-and-papers/publications/1202:heart-failure-and-cardiovascular-diseases.html>

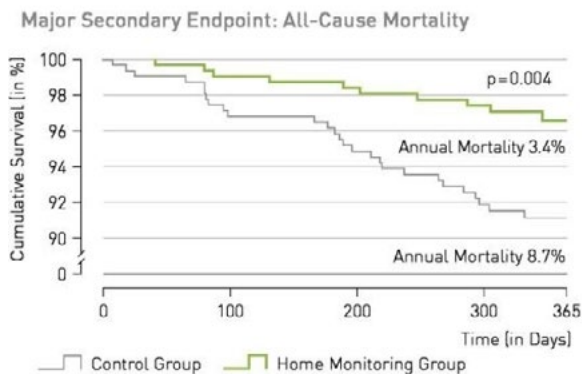
34) Cowie MR, O'Connor CM. The Digital Future Is Now. *JACC Heart Fail*. 2022 Jan;10(1):67-69. doi: 10.1016/j.jchf.2021.11.003. PMID: 34969500; PMCID: PMC8711689.

35) Cowie MR, Lam CSP. Remote monitoring and digital health tools in CVD management. *Nat Rev Cardiol*. 2021;18(7):457-458. doi:10.1038/s41569-021-00548-x

36) Treskes RW, Beles M, Caputo ML, et al. Clinical and economic impact of HeartLogic™ compared with standard care in heart failure patients. *ESC Heart Fail*. 2021;8(2):1541-1551. doi:10.1002/ehf2.13252

How do RPM solutions contribute to positive change in heart failure?

Figure 2: Mortality rate of heart failure patients with and without the usage of an RPM device³⁷



RPM technology can enable better patient outcomes by **sending alarm signals in the event of heart rate deviations that would otherwise go unnoticed**. The healthcare professional can intervene immediately, counteracting a fatal development of the disease (Figure 2).

RPM of heart failure patients could contribute to reduced healthcare expenditures.^{38,39,40} Sending alerts to the patient and health professional on worsening the condition, RPM allows for timely treatment.

It can thereby contribute to the **reduction of hospitalisation rates, or the overall length of potential hospital stays**.^{41,42} As a result, hospital per day costs can be reduced.

Sleep Apnoea

Sleep Disordered Breathing (SDB) is a widespread disease whose treatment poses new challenges for healthcare professionals and patients across Europe. Obstructive Sleep Apnoea (OSA), a condition in which breathing stops involuntarily for brief periods during sleep, affects 20% of the adult population worldwide. In Europe, around 175 million people suffer from OSA.⁴³ Standard treatment is PAP therapy (“positive airway pressure therapy”).

Studies reveal that untreated forms of SDB can lead to obesity, strokes, atrial fibrillation, diabetes, hypertension, and coronary artery disease (CAD), severely affecting patients’ lives. In its untreated state, SDB contributes to an increased demand for healthcare services and associated costs.⁴⁶ Depression is also a common side effect of SDB, with women being particularly at risk. OSA patients often suffer from daytime fatigue in daily life, causing a lack of productivity, social functioning, and vitality. As a result, untreated SDB can contribute to a significant increase in unemployment and socioeconomic costs.⁴⁴ The daily burden moreover results in a reduction of patients’ overall quality of life.

As the disease affects the patient during an unconscious state, it requires a special form of treatment.

37) IN-TIME (biotronik)

38) IN-TIME (biotronik.com)

39) Hindricks G, Taborsky M, Glikson M, et al; IN-TIME study group*. Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. *Lancet*. 2014 Aug 16;384(9943):583-590. doi: 10.1016/S0140-6736(14)61176-4. PMID: 25131977.

40) Peter L. Kolominsky-Rabas, Christine Kriza, Anatoli Djanatliev, Florian Meier, Steffen Uffenorde, Jannis Radeleff, Philipp Baumgärtel, Ines Leb, Martin Sedlmayr, Sebastian Gaiser, Philip B. Adamson, and on behalf of the National Leading-Edge Cluster Medical Technologies ‘Medical Valley EMN’. *Telemedicine and e-Health*. 2016 Oct.798-808. <http://doi.org/10.1089/tmj.2015.0226>

41) Abraham WT, Adamson PB, Bourge RC, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial [published correction appears in *Lancet*. 2012 Feb 4;379(9814):412]. *Lancet*. 2011;377(9766):658-666. doi:10.1016/S0140-6736(11)60101-3

42) European Society of Cardiology (ESC). Remote monitoring keeps heart failure patients out of hospital. Accessed November 29, 2021. <https://www.escardio.org/The-ESC/Press-Office/Press-releases/Remote-monitoring-keeps-heart-failure-patients-out-of-hospital>

43) Malhotra A, Heinzer R, Morrell MJ, et al. Late breaking abstract - European prevalence of OSA in adults: Estimation using currently available data. *Sleep and control of breathing*. 2018. doi:10.1183/13993003.congress-2018.0a4961

44) Jennum, P. and J. Kjellberg, Health, social and economical consequences of sleep-disordered breathing: a controlled national study. *Thorax*, 2011. 66(7): p. 560-6.

Patients receive a medical device connected to a facial mask, which administers positive airway pressure in algorithmic intervals. However, these medical devices are not connected to health professionals, who are thus unable to intervene if needed. As such, the management of the treatment for sleep apnoea must be performed in a sleep lab, which is frequently difficult for patients. These types of treatments were particularly difficult during the COVID-19 pandemic when face-to-face contact between healthcare professionals and patients was no longer possible. RPM solutions would contribute to a positive change in the treatment of sleep apnoea, as patients would no longer need to attend to a sleep lab and treatment could be fully monitored remotely.

How do RPM solutions contribute to positive change in sleep apnoea?



Remote monitoring or self monitoring

RPM solutions such as telemonitoring software offer a way to view sleep patterns from a distance. The software continuously collects data, making it easier for healthcare professionals to diagnose and decide on further therapy. If changes in the patient's condition occur, the healthcare professional can **adjust remotely**. Decisions about further therapy and care can be made based on the monitored data, supporting healthcare professionals in providing high-quality care to patients, including complex cases, which require clinic visits.



Patients using telemonitoring devices have **better sleep quality**, leading to **improved daytime functioning** and a reduction in daytime fatigue.⁴⁵ Patients also report that they gain a better understanding of their disease. Proactive intervention by the physician means that individualised support can be offered at all stages of the therapy, contributing to the mental health of patients and their partners.⁴⁶

Musculoskeletal disorders

Musculoskeletal Diseases (MSD) are characterised by a painful reduction in the function of the musculoskeletal system.⁴⁷ The disease is especially prevalent in the EU among the working population. Three out of every five workers in the EU suffer from MSD symptoms, such as backache and muscular pain.⁴⁸

- Patients in MSD care often report anxiety about their consultation appointment. Due to the specifications of their illness, patients face logistical difficulties in visiting their health professional, and waiting times for appointments remain high.
- Healthcare professionals on the other hand notice that patients sometimes consider it as difficult to remember and report on all the developments and symptoms of their disease. As such, many healthcare professionals do not receive an accurate depiction of their patients' health status, jeopardising the treatment pathway.

45) Sjösten N, Vahtera J, Salo P, et al. Increased risk of lost workdays prior to the diagnosis of sleep apnea. *Chest*. 2009;136(1):130-136. doi:10.1378/chest.08-2201

46) Chen C, Wang J, Pang L, Wang Y, Ma G, Liao W. Telemonitor care helps CPAP compliance in patients with obstructive sleep apnea: a systematic review and meta-analysis of randomized controlled trials. *Ther Adv Chronic Dis*. 2020;11:2040622320901625. Published 2020 Mar 6. doi:10.1177/2040622320901625

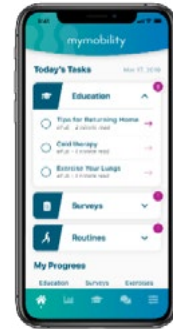
47) World Health Organization. Musculoskeletal conditions. <https://www.who.int/news-room/fact-sheets/detail/musculoskeletal-conditions>. Published 2021. Accessed February 15, 2022.

48) European Agency for Safety and Health at Work. Work-related MSDs: prevalence, costs and demographics in the EU. Accessed February 15, 2022. <https://osha.europa.eu/en/publications/summary-msds-facts-and-figures-overview-prevalence-costs-and-demographics-msds-europe>.

How do RPM solutions contribute to positive change in MSD?

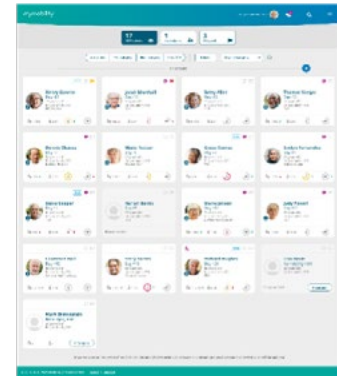
MSD patients can receive engaging educational content pre- or post-surgery through RPM digital platforms, helping them to **better understand the treatment process, as well as manage the post-procedural phase.**

Digital platforms can support physicians in the interaction with patients. When appropriate, some consultations can happen remotely, and patients expect to spend less time waiting in a physician's office – a preference likely to grow following the COVID-19 pandemic.



Digital platforms may also **provide older adults with the opportunity to stay connected,** as many elderly people face social isolation.⁴⁹

The use of RPM solutions in MSD can significantly improve quality of life, enhance patient independence, and assist clinicians to proactively manage a person's care, while requiring less post-operative physiotherapy and fewer emergency department visits. Overall, this may lead to cost reduction and less pressure on health systems.⁵⁰



Chronic respiratory diseases

Chronic Respiratory Diseases (CRDs) target the airways and lung structures. These typically include Chronic Obstructive Pulmonary Disease (COPD), asthma, pulmonary hypertension, and occupational lung diseases. CRDs are caused by tobacco, air pollution and other chemicals and dust. Although there are various palliative treatments available to dilate airways and reduce shortness of breath to improve patients' quality of life, these diseases are incurable.

Unnoticed exacerbations of COPD are associated with higher morbidity and mortality rates and reduce patients' overall quality of life. An increasing number of patients in Europe require mechanical ventilation and this can be provided in outpatient settings. RPM supports the management of ventilated patients outside the hospital. In current treatment pathways, however, conventional Non-Invasive Ventilation (NIV) requires in-hospital therapy initiation, as well as regular in-patient follow-up visits. This brings increasing costs to health systems and has become increasingly difficult in the context of current COVID-19 restrictions.⁵¹

49) Derynda et al. Adoption Among Seniors During COVID-19 Pandemic Impacts Mental Health and Feelings of Companionship, *Innovation in Aging*, 2020; 4 (1). p. Available at: https://academic.oup.com/innovateage/article/4/Supplement_1/965/6036980965, (Accessed on: 22/07/21)

50) Tack C. A model of integrated remote monitoring and behaviour change for osteoarthritis. *BMC Musculoskeletal Disorders*. 2021;22(1). doi:10.1186/s12891-021-04555-4

51) Schöbel C, Waletzko C, Werther S, Franke C, Rehorn W, Taube C. Telemedizin in der Außerklinischen Beatmung. *Der Pneumologe*. 2020;18(1):27-33. doi:10.1007/s10405-020-00364-z

How do RPM solutions contribute to positive change in chronic respiratory disease?

An RPM monitoring device can be used preventively to detect and avoid life-threatening situations at an early stage. The device further simplifies the management of treatments by alerting healthcare professionals and patients if vital signs fall below or exceed the limits defined in the treatment plan.

Access to up-to-date monitoring data makes quick identification of problems and immediate intervention possible. Monitoring simple home ventilation device data like breathing rate or breathing volume can already show trends gathered by the device. This also simplifies interprofessional consultations by interpreting the development of the disease and making decisions on treatment adaptations. If the patient's healthcare team can access the same data at the same time, a more holistic analysis can be made.



Remote monitoring device



For the management of patients with COPD, telemonitoring has been shown to have a positive impact on the patient, offering a more rapid clinical response to ensure that those at higher risk of exacerbation receive the care they need.⁵² Moreover, telemonitoring can improve the quality of care through enhanced access to patient data, disease management and patient engagement.⁵³ Patients may also experience improved satisfaction by avoiding burdensome in-person clinic visits and/or decreased anxiety while being monitored.⁵⁴

Chronic kidney disease

In 2019, Chronic Kidney Disease (CKD) affected more than 55 million people living in the EU and caused almost 130,000 deaths.⁵⁵ It is projected to become the fifth leading cause of death by 2040, above all cancer types, Alzheimer's, diabetes, HIV and tuberculosis.⁵⁶ While kidney transplantation provides the best clinical outcomes for patients⁵⁷, this may not be available or suitable for every End-Stage Renal Disease (ESRD) patient. Therefore, many patients depend on dialysis, which can be delivered in hospitals or in patients' homes.

52) World Health Organization. Global diffusion of ehealth: Making universal health coverage achievable: Report of the third global survey on eHealth. Published December 15, 2016. Accessed February 15, 2022. <https://www.who.int/publications-detail-redirect/9789241511780>.

53) Kruse C, Pesek B, Anderson M, Brennan K, Comfort H. Telemonitoring to manage chronic obstructive pulmonary disease: Systematic literature review. JMIR Medical Informatics. 2019;7(1). doi:10.2196/11496

54) Ibid.

55) Vanholder R, Annemans L, Bello AK, et al. Fighting the unbearable lightness of neglecting kidney health: The decade of the kidney. Clinical Kidney Journal. 2021;14(7):1719-1730. doi:10.1093/ckj/sfab070

56) Foreman KJ, Marquez N, Dolgert A et al. Forecasting life expectancy, years of life lost, and all-cause and cause-specific mortality for 250 causes of death: reference and alternative scenarios for 2016-40 for 195 countries and territories. Lancet. 2018; 392: 2052-2090

57) The Renal Association. Clinical Practice Guidelines. Assessment of the potential kidney transplant recipient. Accessed February 15, 2021. https://bts.org.uk/wp-content/uploads/2016/09/10_RA_KidneyRecipient-1.pdf.

Disproportionately, patients are being dialysed in the hospital.⁵⁸ Among other factors, this may be because organising dialysis at home and transport to and from the place of dialysis can be challenging for health systems and patients^{59,60}. Moreover, patients may feel not equipped to perform the treatment alone at home.⁶¹ With hospital capacity and staffing pressure increasing⁶², a problem exacerbated by COVID-19⁶³, patients are calling for increased choice in treatment options and for improved access to home therapies.⁶⁴ Therefore, there is a compelling case to rethink dialysis care organisation and delivery.

How do RPM solutions contribute to positive change in chronic kidney disease?

Digital health solutions, such as RPM can support and enable home dialysis therapies. Through RPM, physicians can interact with patients, providing them with instant feedback on their technique, and directly monitor patient-specific data and treatment-specific parameters which can, in turn, avoid further complications.⁶⁵ Patients can be included in their treatment decision-making, enhancing autonomy and confidence.

Healthcare professionals might be more confident that patients will receive appropriate oversight at home, allowing for early preventive interventions and increased treatment adherence.⁶⁶

Patients are likely to be more autonomous and see reductions in time spent travelling or in waiting rooms. This can increase patients' quality of life and help offset societal costs of care (for example, increased job retention).⁶⁷

Finally, RPM can create more **sustainable health systems** by enabling more dialysis patients to be treated in their homes and freeing up hospital resources for more acute cases.⁶⁸ For example, remote-monitoring-enabled home dialysis treatments were associated with lower hospitalisation rates and fewer hospitalisation days.⁶⁹

58) ERA-EDTA Registry Annual Report 2016. Accessed February 15, 2022. <https://www.era-edta-reg.org/files/annualreports/AnnRep2016.pdf>.

59) Vanholder R, Annemans L, Brown E, et al. Reducing the costs of chronic kidney disease while delivering quality health care: A call to action. *Nature Reviews Nephrology*. 2017;13(7):393-409. doi:10.1038/nrneph.2017.63

60) Haute Autorité de Santé, Évaluation économique de la télésurveillance pour éclairer la décision publique: Quels sont les choix efficaces au regard de l'analyse de la littérature? Published December 2020. Accessed February 15, 2021. https://www.has-sante.fr/upload/docs/application/pdf/2020-12/rapport_evaluation_telesurveillance.pdf

61) Magnus, M., Sikka, N., Cherian, T., & Lew, S. Q. (2017). Satisfaction and improvements in peritoneal dialysis outcomes associated with telehealth. *Applied clinical informatics*, 26(01), 214-225

62) Osman MA, Alrukhaimi M, Ashuntantang GE, et al. Global nephrology workforce: gaps and opportunities toward a sustainable kidney care system. *Kidney Int Suppl* (2011). 2018;8(2):52-63. doi:10.1016/j.kisu.2017.10.009

63) Kliger AS, Silberzweig J. Mitigating risk of COVID-19 in dialysis facilities. *Clinical Journal of the American Society of Nephrology*, p.707-709, 2020;15(5):707-709. doi:10.2215/cjn.03340320.

64) European Kidney Patients' Federation. European Kidney Patient Federation Manifesto 2020. Published October 2, 2020. Accessed February 15, 2022. <https://ekpf.eu/wp-content/uploads/2020/10/EKPF-Manifesto-2020.pdf>

65) Osman MA, Alrukhaimi M, Ashuntantang GE, et al. Global nephrology workforce: gaps and opportunities toward a sustainable kidney care system. *Kidney Int Suppl* (2011). 2018;8(2):52-63. doi:10.1016/j.kisu.2017.10.009

66) Wallace EL, Rosner MH, Alscher MD, et al. Remote Patient Management for Home Dialysis Patients. *Kidney Int Rep*. 2017;2(6):1009-1017. Published 2017 Jul 29. doi:10.1016/j.ekir.2017.07.010

67) Ibid.

68) Sanabria M, Buitrago G, Lindholm B, et al. Remote Patient Monitoring Program in Automated Peritoneal Dialysis: Impact on Hospitalizations. *Perit Dial Int*. 2019;39(5):472-478. doi:10.3747/pdi.2018.00287

69) Ibid.

Diabetes

Diabetes is a ‘silent pandemic’ and one of the major health challenges of our generation. 60 million people are living with diabetes in Europe – equivalent to the population of Italy⁷⁰ – and the number is set to rise to 66 million people by 2030⁷¹, with profound human and economic costs. A life-long and chronic condition, diabetes requires 24/7 management and hundreds of decisions per day to keep glucose levels safely within range and avoid acute health emergencies (like low blood sugar) as well as chronic complications.

If not effectively controlled, diabetes leads to serious life-threatening health complications, including cardiovascular events, blindness, amputations, and kidney failure.⁷² Managing diabetes and its comorbidities places enormous demands on individuals, families, healthcare professionals and health services, as well as the wider economy and social structures.⁷³

How do RPM solutions contribute to positive change in diabetes?

Digitally enabled tools and services, such as glucose monitoring and insulin delivery systems, could have the potential to strengthen diabetes self-care while enabling better remote care by healthcare professionals, therefore improving outcomes and quality of life, and reducing the burden of diabetes management on individuals and their care teams in a cost-effective manner.⁷⁴

Digitally enabled tools and services not only empower patients with diabetes to better manage the complexity of their condition through self-care, but better connect them to healthcare professionals who can provide more precise and personalised remote care and services based on the significant amount of health information produced.⁷⁵ The COVID-19 pandemic emphasised the contribution of digitally enabled services, including teleconsultations, to the treatment of diabetes⁷⁶. According to a recent survey, more than 76% of healthcare professionals members of the Spanish Society of Diabetes had started using or had increased their use, of remote consultations. In this study more than 87% believed remote consultation played a more important role in the management of diabetes patients than before the pandemic.⁷⁷

Connected glucose monitoring systems can track and predict glucose levels, alerting patients with diabetes, their families and loved ones and care teams to urgent situations like hypoglycaemia (low blood glucose) and helping reduce the need for hospitalisations or emergency services.⁷⁸

70) Istituto Nazionale di Statistica. Population and Households. Accessed February 15, 2022. <https://www.istat.it/en/population-and-households>

71) International Diabetes Federation. IDF Diabetes Atlas. Accessed February 15, 2022. <https://www.diabetesatlas.org/data/en/region/3/eur.html>

72) World Health Organization. Diabetes. Accessed February 15, 2022. <https://www.who.int/news-room/fact-sheets/detail/diabetes>

73) Kebede MM, Pischke CR. Popular Diabetes Apps and the Impact of Diabetes App Use on Self-Care Behaviour: A Survey Among the Digital Community of Persons With Diabetes on Social Media [published correction appears in *Front Endocrinol (Lausanne)*. 2019 Apr 05;10:220]. *Front Endocrinol (Lausanne)*. 2019;10:135. Published 2019 Mar 1. doi:10.3389/fendo.2019.00135

74) Fleming, G.A., Petrie, J.R., Bergenstal, R.M. et al. Diabetes digital app technology: benefits, challenges, and recommendations. A consensus report by the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) Diabetes Technology Working Group. *Diabetologia* 63, 229–241 (2020). <https://doi.org/10.1007/s00125-019-05034-1>

75) The Global Diabetes Community. Emotional Impact on Families. Updated January 7, 2022. Accessed February 15, 2022. <https://www.diabetes.co.uk/emotional-impact-on-families.html>

76) Choudhary P, Bellido V, Graner M, Altpeter B, Cicchetti A, Durand-Zaleski I, Kristensen FB. The Challenge of Sustainable Access to Telemonitoring Tools for People with Diabetes in Europe: Lessons from COVID-19 and Beyond. *Diabetes Ther*. 2021 Sep;12(9):2311-2327. doi: 10.1007/s13300-021-01132-9.

77) Sociedad Española de Diabetes. Encuesta sobre la atención a las personas con diabetes durante la pandemia Covid19. Accessed February 15, 2022. <https://www.sediabetes.org/institucional/encuesta-atencion-personas-con-diabetes-pandemia-covid19/>

78) Rosella LC, Lebenbaum M, Fitzpatrick T, et al. Impact of diabetes on healthcare costs in a population-based cohort: a cost analysis. *Diabet Med*. 2016;33(3):395-403. doi:10.1111/dme.12858

Smart insulin delivery systems like pumps and pens calculate and track insulin dosage data, delivering insulin either automatically or by sending reminders and alerts that strengthen adherence. Medical applications, whether integrated or stand-alone, can track and display health trends, and provide education and coaching to improve diabetes management. These digital devices and services are underpinned by algorithms (either stand-alone or within the devices) that turn significant amounts of health data into meaningful information to inform better decision-making by people with diabetes and their care teams.

Section C

Challenges to the wide use of RPM solutions

The pandemic has highlighted how heterogeneous the European landscape is regarding the wide use of e-Health in general, and RPM solutions specifically. In its 2021 report 'Secondary use of health data in Europe', the Open Data Institute (ODI) provides data on the current quality and progress in the use of digital technologies within healthcare across Europe. Its findings indicate that, while European health data ecosystems are beginning to mature, the development and employment of digital technology for healthcare data remains highly uneven across Europe. It underscores that one significant barrier to further integration and systemic interoperability is the fragmentation of health-data infrastructure and the absence of common open standards for data sharing.⁷⁹ RPM solutions are critical for facilitating the management of chronic conditions, which are rising in Europe and placing health systems under growing strain. Widespread use of telemedicine innovation could improve patient outcomes and reduce costs for health systems. However, limited investment in building the infrastructures as well as the lack of appropriate funding and reimbursement mechanisms in Europe prevent patients' access to these technologies. More specifically, five main challenges for the adoption and use of RPM solutions stand out:

- **Resistance to integration of RPM solutions into the treatment pathway:** Pathways are complex and often span across many siloed parts of the health service. The lack of a patient-centric approach (rather than disease-centered) across pathways – where multidisciplinary teams are interacting - limits integration within health systems. Within the RPM field, it is evident that siloed settings hinder the integration of RPM solutions into treatment pathways⁸⁰
- **Limited access to early funding mechanisms:** Some European countries have implemented mechanisms to fund promising medical technology innovations at market entry, such as Accelerated Coverage Pathways for Innovations.⁸¹ Some of these mechanisms allow patients to access clinically promising treatments while further evidence is being collected to bridge evidence gaps (and to enable future traditional reimbursement or funding).⁸² However, only few of these mechanisms extend to RPM solutions and services.
- **Adequate value assessment frameworks adapted to the specificities of RPM solutions are not broadly adopted in EU27 health systems, nor exist at EU level:** This prevents a more clinical and economic value generated by RPM solutions as part of the treatment pathway, presenting a barrier to transforming and innovating healthcare.

79) Open Data Institute. Secondary use of health data in Europe. Published September, 2021. Accessed February 15, 2022. <http://theodi.org/wp-content/uploads/2021/09/Secondary-use-of-Health-Data-In-Europe-ODI-Roche-Report-2021-5.pdf>

80) Mairesse GH, Braunschweig F, Klersy K, Cowie MR, Leyva F. Implementation and reimbursement of remote monitoring for cardiac implantable electronic devices in Europe: a survey from the health economics committee of the European Heart Rhythm Association. *Europace*. 2015;17(5):814-818. doi:10.1093/europace/euu390

81) MedTech Europe. Taxonomy of Value-Based Access Programmes – Funding for Innovation (Guidance). Published June 17, 2019. Accessed February 15, 2022. <https://www.medtecheurope.org/resource-library/taxonomy-of-value-based-access-programmes-funding-for-innovation/>

82) PWC. The Early Access to Medicines Scheme: An independent review. Accessed February 15, 2022. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/509612/eams-review.pdf

- **Interoperability challenges as well as data privacy and security concerns at the European level:** In light of competing competencies among the EU and the Member States regarding the rules on data protection, data security and interoperability, fragmentation in Europe persists which inhibits the wider use of RPM systems.
- **Gaps of digital literacy among healthcare professionals and patients:**⁸³ Several healthcare professionals and patients are still not familiar with digital technologies. Although healthcare professionals receive training and continuous professional development (CPD) schemes, the digital skills gap may still occur due to the growing development of new digital technologies to address the most significant healthcare challenges. Patients with low health literacy who are predisposed to poor health outcomes are particularly poised to benefit from the use of digital technologies.⁸⁴ However, this population may lack the ability to engage with technology effectively.⁸⁵ Implementing RPM solutions imply changes in the organisation of healthcare and hence in the competence healthcare professionals require, as well as in the role patients play in their care pathway.

Section D

Considerations

COVID-19 has significantly increased the use of RPM solutions and services to provide care under the restrictions caused by the pandemic. Many health actors today acknowledge the value of digital solutions such as RPM and call for existing hurdles that prevent their widespread deployment and use beyond the pandemic to be reduced⁸⁶. Such a development may not only benefit patient outcomes, but also healthcare systems, both in terms of improving capacity and workflow.

The considerations below highlight relevant principles and areas for action that would allow healthcare systems, healthcare professionals and patients to reap the benefits of RPM solutions and services. As the organisation of healthcare delivery, including funding and reimbursement, is a Member State competence, action needs to be taken by healthcare authorities and payers at a national level. However, the considerations can be carried out and facilitated by all healthcare stakeholders, such as European and national policymakers, healthcare professionals, patient organisations and industry to support the shared goal of improving healthcare outcomes for all citizens across Europe.

Consideration 1: Raise awareness by encouraging broader use of RPM solutions

The positive impact of RPM solutions on patients and health systems is increasingly recognised through a growing set of case studies and databases⁸⁷. They can improve the safety and health status of patients⁸⁸ by supporting an efficient, integrated care delivery across settings and medical disciplines; they can empower patients and encourage patient-physician interaction thus preventing a worsening of chronic conditions; and could help to achieve savings in public healthcare spending.

Considering the possible benefits and the dynamic evolution of RPM solutions, broader use of these solutions in chronic care pathways should be encouraged.

83) Ibid.

84) Vollbrecht H, Arora V, Otero S, Carey K, Meltzer D, Press VG. Evaluating the Need to Address Digital Literacy Among Hospitalized Patients: Cross-Sectional Observational Study. *J Med Internet Res*. 2020;22(6):e17519. Published 2020 Jun 4. doi:10.2196/17519

85) Ibid.

86) Task Force for the management of COVID-19 of the European Society of Cardiology . ESC guidance for the diagnosis and management of cardiovascular disease during the COVID-19 pandemic: part 2-care pathways, treatment, and follow-up [published online ahead of print, 2021 Nov 16] [published correction appears in *Eur Heart J*. 2021 Dec 20;:]. *Eur Heart J*. 2021;ehab697. doi:10.1093/eurheartj/ehab697

87) For further evidence, please refer to the paragraph 'The benefit of RPM solutions'

88) For further references, please refer to the evidence reported in the previous paragraphs.

Policymakers at the EU and national level, as well as health authorities, payers and healthcare providers can play a significant role in further promoting and incentivising the use of RPM solutions in care delivery.

Consideration 2: Enable sustainable, adequate and timely funding/reimbursement of RPM solutions, and related medical activities for those that have demonstrated benefits

COVID-19 has highlighted the value of RPM solutions and services in many disease areas. Yet only a very limited number of them are adequately reimbursed in traditional (non-emergency) funding schemes. National and regional policymakers and payers⁸⁹ should set up clear and adequate funding/reimbursement frameworks to incentivise the adoption of those RPM solutions which have demonstrated benefits for patients or the healthcare system. Moreover, even if in Europe, funding/reimbursement of health technologies is a national competency (leading to mechanisms not being uniform across the Member States), the European Union could incentivise the Member States and regions to capture and analyse the value of RPM solutions in order to learn and share good practices, such as the right conditions that enable faster and widespread uptake and use.

Healthcare professionals (physicians, nurses, etc.) play a crucial role in ensuring the correct use of RPMs and in protecting, processing and analysing the health data received from RPM solutions. The data received can support healthcare professionals in their decision-making. Those responsibilities should be reflected appropriately in the funding/reimbursement frameworks for healthcare professionals. A first step in this direction could be to compensate virtual consultations at a similar level as in-person consultations.

Some steps in this direction are being made. A few Member States have implemented specific funding/reimbursement for some RPM solutions and services (e.g., transmitters for cardiac implanted devices are reimbursed in France and RPM devices for sleep apnea and ventilation are reimbursed in Germany. While this is of course a positive evolution, further improvements are needed.

Consideration 3: Support investment and accelerated coverage of RPM innovation through early funding

In several countries and regions in Europe, health systems experiment with temporary innovative ways of funding medical technology innovations at initial market access. Successful experiences include a broad range of mechanisms such as those described in Accelerated Coverage Pathways for Innovation⁹⁰ or dedicated innovation procurement programmes (e.g. Public Procurement of Innovative Solutions). Some of these new funding mechanisms, such as 'ETAPES' (Expérimentation de Télémedecine pour l'Amélioration des Parcours en Santé^{91,92}) in France, already apply to RPM solutions. National and regional policymakers and payers in all Member States should aim to scale up these funding mechanisms for RPM solutions and services and make them a structural part of national and regional reimbursement systems.

Next to national/regional reimbursements, the European institutions should ensure that a sufficient part of their financial instruments (Horizon Europe, including the EIC, Digital Europe, Next Generation EU, ESIF) is made available to finance new RPM solutions and to scale up promising and innovative approaches in this area. The 2021-2027 EU4Health programme should be used to support innovative approaches to the organisation of health systems and the integration of digital tools and services in all prevention and treatment pathways.

89) For further information on reimbursement of digital health technologies, please refer to MedTech Europe's publication 'Recognising the value of digital health apps: An assessment of five European healthcare systems' available at the following link: <https://www.medtecheurope.org/resource-library/recognising-the-value-of-digital-health-apps-an-assessment-of-five-european-healthcare-systems/>

90) MedTech Europe. Taxonomy of Accelerated Coverage Pathways for Innovations (ACPIs). Published October 26, 2021. Accessed February 15, 2022. <https://www.medtecheurope.org/resource-library/taxonomy-of-value-based-access-programmes-funding-for-innovation>

91) Ministère des solidarités et de la santé. La télésurveillance : ETAPES. <https://solidarites-sante.gouv.fr/soins-et-maladies/prises-en-charge-specialisees/telesante-pour-l-acces-de-tous-a-des-soins-a-distance/article/la-telesurveillance-etapes>

92) Started in 2018, ETAPES will come to an end mid-2022 and should be replaced by a sustainable funding mechanism for RPM solutions demonstrating their value.

Consideration 4: Strengthen transparency in decision-making on availability and funding

Citizens have high expectations regarding transparency and accountability of decisions by public or semi-public bodies on funding. There should always be clear and public criteria on how decisions on access for patients to RPM and other digital health technologies are made. Funding and reimbursement decisions should be predictable and follow guidelines⁹³ set at the regional and local levels. An example of clear and transparent implementation of access decisions could be the evidence standards for digital health by [NICE](#).

Consideration 5: Use appropriate and proportional evidence to assess the value of RPM solutions

The scattered decision-making landscape in Europe for value assessments of digital health technologies represents a high additional cost for manufacturers. The challenge lies in ensuring that the solutions offered respond to health system-specific needs, without slowing down the introduction of new digital technologies on the continent.

When performing value assessments, national authorities should make use of appropriate and proportional evidence to assess the intrinsic value of digital solutions whilst considering their specific nature. Furthermore, technology assessments need to be closely linked to reimbursement and funding decisions to facilitate the use of technology and the transformation of health systems. Finally, representatives of all stakeholders concerned (e.g. consumers, healthcare professionals, manufacturers) should be involved in defining an adequate value assessment framework for RPM and other digital health solutions.

Consideration 6: Reshape health systems' treatment pathways to integrate RPM solutions that have demonstrated their value

Treatment pathways should be updated on a regular basis to reflect the latest medical, scientific and technological developments, and be implemented in a harmonised manner across the EU. RPM solutions and services should be considered as an integral part of patient-centred care pathways. The uptake of digital solutions such as RPM should become a reality in the entire healthcare ecosystem once solutions have demonstrated their value for the patient and/or the healthcare systems. In this way, care pathways can be designed and applied in a more integrated way across different health settings and medical disciplines.

Consideration 7: Ensure adoption by the Member States of the recommended standard of care

While the EU has no responsibility in setting guidelines for adopting RPM, it can have a role in facilitating the harmonisation of standards of care. Today, more and more guidelines and standards of care are developed at the European level by European medical societies. Medical societies should be encouraged to make sure new digital technologies, such as RPM solutions and services, and the opportunities they offer to patients and healthcare professionals, are recognised and integrated in EU guidelines defining the standard of care.

Consideration 8: Introduce training programmes on digital health to improve the level of digital literacy in Europe

Given the increased demand for basic and advanced digital skills by 2030, the healthcare professionals receive training via their continuous professional development (CPD) schemes. Closing the digital skills gap of the healthcare professional is an identified need. Significant efforts are made at the EU and national levels to establish efficient and effective up-and reskilling opportunities⁹⁴.

93) MedTech Europe. Six Key Principles for the Efficient and Sustainable Funding & Reimbursement of Medical Technologies. Published July 25, 2017. <https://www.medtecheurope.org/resource-library/six-key-principles-for-the-efficient-and-sustainable-funding-reimbursement-of-medical-technologies/>

94) European Commission. Digital Skills For Digital Transformation of Health and Care System. Accessed February 15, 2022. https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=69479.

These initiatives and programmes provide opportunities to make healthcare professionals more familiar with RPM solutions and services as well as their positive value for clinical decision-making and patient outcomes. This can thus incentivise the integration of these solutions in the care pathways of patients with chronic conditions.

Professional medical societies play a pivotal role in promoting digital literacy and strengthening the digital competence of the healthcare professional and should receive support at the EU and national levels.

The COVID-19 pandemic prompted a significant increase in the interaction of healthcare professional with patients through RPM solutions, which allowed for continued access to timely and needed care. Moreover, digital health solutions such as RPM have empowered patients to gain more control over managing their health conditions. Patient empowerment through greater digital health literacy thus should be part of 'digital training' programmes at the EU and national levels, with the aim of making patients an informed and active partner in their health and care pathway.

Glossary

Digital Health: Digital health and care refer to tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of health and lifestyle. Digital health and care have the potential to innovate and improve access to care, quality of care, and to increase the overall efficiency of the health sector (Source: MedTech Europe, 2020)

eHealth: Refers to ICT tools and services that can improve prevention, diagnosis, treatment, monitoring and management. It can benefit the entire community by improving access and quality of care and by making the health sector more efficient. eHealth also includes: - information and data sharing between patients and health service providers, hospitals, health professionals and health information networks; - electronic health records; telemedicine services; - portable patient-monitoring devices, operating room scheduling software, robotised surgery and blue-sky research on the virtual physiological human (Source: MedTech Europe, 2020)

Funding: it reflects a willingness to pay for procedure/treatment or device by payers (source: MTRC)
Patient Clinical Outcome: Patient Clinical outcomes are measurable changes in health, function or quality of life of patients that result from delivered care. Clinical outcomes can be measured by activity data such as hospital re-admission rates, or by agreed scales and other forms of measurement. (Great Ormond Street Hospital for Children – NHS Foundation Trust)

Reimbursement: A system for providing payment for a procedure or technology (source: MTRC)

Remote Patient Monitoring: Remote patient monitoring allows health providers to monitor disease and symptom progression remotely and then engage with patients virtually to modify care plans and to provide education on self-care, based on changes in the patient's condition. (Source: HIMSS)

Telehealth: Telehealth involves the use of telecommunications and virtual technology to deliver health care outside of traditional healthcare facilities. Telehealth, which requires access only to telecommunications, is the most basic element of "eHealth," which uses a wider range of information and communication technologies (ICTs). Telehealth examples include virtual home health care, where patients such as the chronically ill or the elderly may receive guidance in certain procedures while remaining at home. Telehealth has also made it easier for health care workers in remote field settings to obtain guidance from professionals elsewhere in diagnosis, care and referral of patients... Well-designed telehealth schemes can improve health care access and outcomes, particularly for chronic disease treatment and for vulnerable groups. Not only do they reduce demands on crowded facilities, but they also create cost savings and make the health sector more resilient (Source: MedTech Europe, 2020)

Telemedicine: The use of electronic communication and information technologies to provide or support clinical care at a distance. Included in this definition are patient counselling, case management (e.g. telemonitoring), and supervision of medical patients by health professionals (Source: MedTech Europe, 2020)

Telemonitoring: Telemonitoring designs systems and services using devices to remotely collect/send vital signs to a monitoring station for interpretation. Telemonitoring is the remote exchange of physiological data between a patient at home and medical staff at the hospital to assist in diagnosis and monitoring (this could include support for people with lung function problems, diabetes etc). It includes (amongst other things) a home unit to measure and monitor temperature, blood pressure and other vital signs for clinical review at a remote location (for example, a hospital site) using phone lines or wireless technology (Source: COCIR)

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- For further information on reimbursement of digital health technologies, please refer to MedTech Europe’s publication ‘Recognising the value of digital health apps: An assessment of five European healthcare systems’ available at the following link: <https://www.medtecheurope.org/resource-library/recognising-the-value-of-digital-health-apps-an-assessment-of-five-european-healthcare-systems/>
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