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## **Recommendation to implementation of remote patient monitoring in rheumatology: lessons learned and barriers to take**

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## VIEWPOINT

# Recommendation to implementation of remote patient monitoring in rheumatology: lessons learned and barriers to take

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## ABSTRACT

Remote patient monitoring (RPM) leverages advanced technology to monitor and manage patients' health remotely and continuously. In 2022 European Alliance of Associations for Rheumatology (EULAR) points-to-consider for remote care were published to foster adoption of RPM, providing guidelines on where to position RPM in our practices. Sample papers and studies describe the value of RPM. But for many rheumatologists, the unanswered question remains the 'how to?' implement RPM.

Using the successful, though not frictionless example of the Southmead rheumatology department, we address three types of barriers for the implementation of RPM: service, clinician and patients, with subsequent learning points that could be helpful for new teams planning to implement RPM. These address, but are not limited to, data governance, selecting high quality cost-effective solutions and ensuring compliance with data protection regulations. In addition, we describe five lacunas that could further improve RPM when addressed: establishing quality standards, creating a comprehensive database of available RPM tools, integrating data with electronic patient records, addressing reimbursement uncertainties and improving digital literacy among patients and healthcare professionals.

## INTRODUCTION

Remote patient monitoring (RPM) leverages advanced technology to monitor and manage patients' health remotely and continuously. It can prevent unnecessary clinical visits in patients in disease remission. Through RPM healthcare, providers can collect more granular information and more dimensions of diseases including PROMs. Thereby, care could become more targeted, more individualised and more effective. For instance, RPM combined with a treatment escalation protocol enabled significantly more patients with rheumatoid arthritis (RA) to reach remission and to reach remission earlier.<sup>1</sup>

The results of a recent systematic review by Arumalla *et al* highlighted the safety

## KEY MESSAGES

- ⇒ Remote patient monitoring (RPM) is increasingly being implemented as it saves resources and improves both healthcare efficiency and quality.
- ⇒ Successful RPM implementation requires addressing barriers at the service, clinician and patient levels, including data governance, technical quality, reimbursement and digital literacy.
- ⇒ To optimise RPM implementation, there is a need for quality standards, a comprehensive overview of available tools, interoperability, reimbursement guidelines and efforts to improve digital literacy for both patients and healthcare professionals.

of different ePROM-based monitoring approaches of patients with inflammatory arthritis. None of the 8 studies with a total of 4473 demonstrated worsening of disease activity and face to face (F2F) could be safely reduced.<sup>2</sup> Most studies included patients with RA and used the RAPID-3 as the main ePROM instrument. Seppen *et al* proved in a recent randomised controlled trial (RCT) that remote care based on weekly e-PROMs in patients with RA with stable low disease activity was non-inferior to usual care in terms of the  $\Delta$ DAS28-ESR and led to a 38% reduction in rheumatologist consultations.<sup>3</sup> In another landmark RCT, de Thurah *et al* demonstrated that less frequent monitoring, 3-month intervals with CRP and FLARE-RA Questionnaire, enabled cost-savings and reduction of F2F visits.<sup>4</sup> Another RCT failed to demonstrate a significant improvement in patient satisfaction and disease activity.<sup>5</sup> Findings from the Remote Monitoring of Rheumatoid Arthritis study indicated a very high app adherence with patients valuing the patient-centred approach.<sup>6</sup>

Though increasing numbers of rheumatology clinics have overcome common barriers in RPM implementation, many clinics

are still identifying the needed actions and searching for solutions. Ample papers exist about the value of RPM.<sup>2-9</sup> In 2022 EULAR points-to-consider for remote care were published to foster adoption of RPM, providing guidelines on where to position RPM in our practices.<sup>10</sup> But for many rheumatologists, the unanswered question remains the ‘how to?’ implement RPM.

The Southmead rheumatology department rolled out an RPM care pathway for patients with RA on b/tsDMARDs in mid-2020. Over the course of the next year, over 140 hours of clinic time were saved, along with ~€80 000 in unnecessary appointment costs. Patient surveys indicated that patients were satisfied and the >90% were happy to have repeated non-F2F appointments. The department is now working to roll-out this flexible follow-up model across other parts of their rheumatology service. By mid-2023, they had over 1100 patients enrolled with over 40 000 completed ePROMs. This success story was

preceded by many barriers since the app first launched in 2018. The experience of Southmead and others led to several learning points that could be helpful for new teams planning to implement RPM.

Using the successful case of RPM implementation in Bristol as a starting point, we will outline the barriers of RPM implementation, provide available solutions and highlight current lacunas in rheumatology to enable the promises of RPM in our clinics.

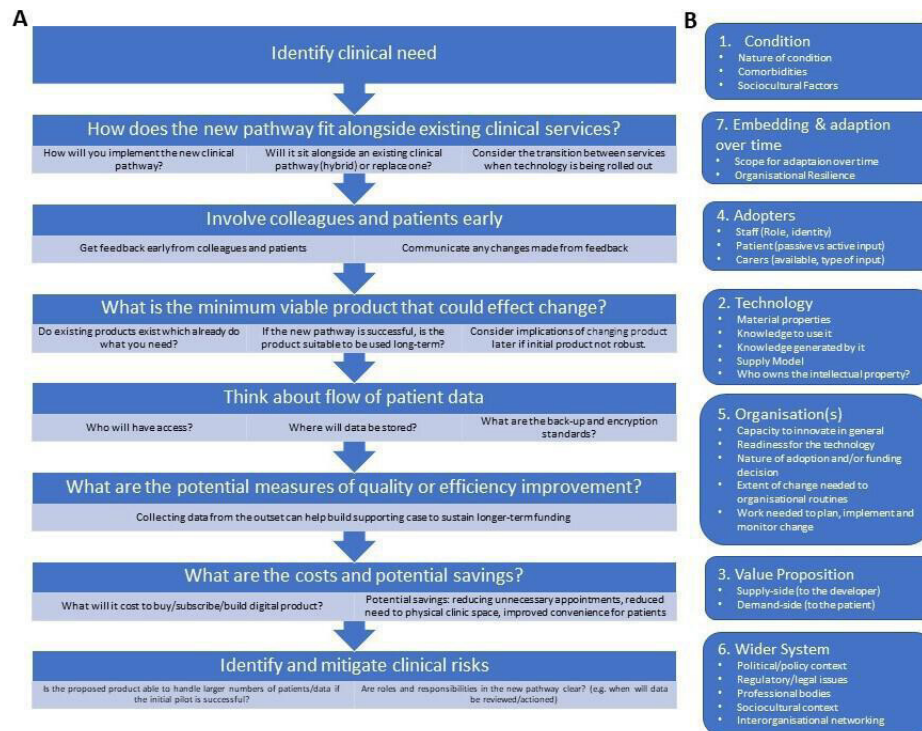
### Empowering patients, enhancing efficiency: a clinical example of smartphone app-based remote monitoring in rheumatology

In line with many other rheumatology departments, the department at Southmead Hospital, Bristol, UK has faced a number of challenges. Increasing demand for rheumatology services and a constrained staffing levels meant alternative ways of working were needed. In 2018,

**Table 1** Description of the barriers for RPM implementation with additional recommendations

	Barrier	Recommendation
Service level	Regulatory	Most digital solutions have to be in accordance with the Medical Device Regulation and be CE marked. Involve experts for advice if unsure.
	Data governance	Keep care pathway simple. Be aware of regulations (eg, GDPR/HIPAA). Data warehousing (including cloud) must be within the EU jurisdiction for GDPR purposes.
	Data access	Ensure patient data is accessible and copies of data files available on request.
	Economical	Consider using existing digital products where appropriate rather than building bespoke solutions.
	Maintenance	Ensure any product provided includes ongoing regular service support and security patch updates to avoid development of ‘bugs/glitches’ over time.
	Reimbursement	Work with managers to understand how reimbursement may be affected by proposed care pathway changes. Successful use cases can offer suggestions (see text for online resources).
	Purchasing	In addition to cost, think about the long-term sustainability of the product including opportunities to improve/iterate the digital product within the clinical service.
Clinician	Clinical governance	Follow local clinical governance processes. Think about safety netting and ensure that any RPM data used to influence clinical decisions are documented in the notes. Check data and cybersecurity procedures are in place with the RPM solution provider.
	Awareness of available digital products and their quality	Use healthcare app directories where available to find suitable apps or review existing use cases to identify existing solutions and care pathways that could be adapted for local use.
	Enthusiasm	‘Start small to grow tall’—Win over unsure colleagues/organisations by starting with small cohorts of patients with simple tweaks to a clinical pathway to demonstrate potential.
	Data overload	Clear communication with patients about data monitoring in the pathway is essential. Include safety nets such as advice lines, monitored email addresses or on-call physicians.
Patient	Being seen	Communication and engagement with patient groups is essential. Consider codesigning the care pathway with patients to understand concerns and opportunities.
	Accessibility	Consider using a hybrid model of care that allows for both users and non-users of the technology. Try to ensure service benefits (eg, expedited reviews) benefit both those who are digitally engaged and not.
	Engagement and drop-off	Highlight the utility of the data when interacting with patients who have submitted information. Remind and encourage patients who stopped or not engaged with the digital solution

CE, Conformité Européene; EU, European Union; GDPR, General Data Protection Regulation; HIPAA, Health Insurance Portability and Accountability Act; RPM, remote patient monitoring.



**Figure 1** Summary of (A) the practical steps to implementing remote patient monitoring and how these map to (B) The non-adoption, abandonment, scale-up, spread, sustainability (NASSS) framework for ex post-theorisation of technology-supported change in healthcare.<sup>30</sup>

clinicians at Southmead hospital started offering rheumatology patients a smartphone app (Living With) to enable them to report their symptoms remotely, using ePROMs (including RAPID-3, HAQ-DI, self-reported DAS28-CRP), flare reporting and fatigue diaries.<sup>8</sup> The app was a commercial product with a monthly subscription fee which included all support, set-up, delivery and data management in line with UK General Data Protection Regulation (GDPR) legislation. In addition, patients were able to set their own symptom trackers and the app included patient information and contact information for the rheumatology team. Data entered by the patient was viewed by clinicians via a web-based portal.

Initially, a number of patients recruited to use the app were small (4–10 patients per month), and data was used mainly to add information to the clinical consultation. To avoid creating additional work streams for the clinical team that would need to be included in clinical job planning, patients were told at enrolment that their clinical scores were not being routinely checked outside of clinical reviews and that if they needed clinical assistance they should contact the department using existing telephone and email advice line channels. By adopting this approach, no additional clinical time was required to monitor and run the service. Prior to the COVID-19 pandemic, while remote consultations were undertaken within the team, the number was limited to a few patients, usually in long-term remission. However, the team had planned to integrate remotely collected ePROMs into parts of the service to improve efficiency.

One particular area that was identified was the b/tsDMARD service. The UK guidelines recommend 6-monthly review to monitor safety and efficacy to justify continued prescription of these high-cost drugs. This cohort of patients represented a significant proportion of the department’s outpatient follow-up activity, and due to the efficacy of these treatments, many of these patients were in remission and would not otherwise require 6-monthly reviews.

Initial scoping work commenced in 2018/2019—this included questionnaires given to patients in waiting rooms which explored patient’s access to the required technology needed to use the patient app. This showed that 87% of surveyed patients had a smartphone and email, and only 13% and 6% reported not having access to a smartphone or email, respectively, (mean age 54 years (range 17–86), 70% female). Only in 20% of the clinical visits, the treatment was changed.

With the arrival of the COVID-19 pandemic, the necessity of RPM was rapidly escalated and further influenced the clinical pathway redesign. The rheumatology team worked together (including pharmacists, specialist nurses and doctors and the wider rheumatology team and patient representative group) to incorporate hybrid clinics. This involved integrating non-F2F modalities (telephone/video/virtual) with traditional F2F clinic appointments. The team used the ePROMs collected via smartphone app to obtain an accurate clinical picture for the reviewing clinician. This longitudinal data improved (non-)F2F consultations. For patients who regularly



**Table 2** Recommendations for optimisation of RPM implementation in rheumatology practices based on identified lacunas

Lacuna	Recommendation	Whom it concerns
I. The quality of RPM is not easily assessed due to lack of knowledge and/or unclarity on the technology, legal aspects and scientific validity of the tools. The role of RPM in clinical rheumatology practice is addressed in the 2022 EULAR PTC. <sup>10</sup>	Develop quality standards regarding the legal, technical, medical and ethical requirements for RPM tools (in rheumatology). These should entail requirements and recommendations about certification, documentation, maintenance, interoperability and scientific validation.	For example, EULAR task force European Commission.
II. There is no clear overview of the available digital medical devices.	Build a central database of existing (MDR certified) RPM (rheumatology) tools that are available and a central library of successful use cases. Integrate and interaction with the emerging EUDAMED database should be ensured.	EULAR European commission.
III. Reimbursement is uncertain.	Actively advocate proper reimbursement for RPM tools and the associated physician work. Support validation studies to show economical benefit.	EULAR advocacy group Politics and Regulation.
IV. EPD systems provide no or limited integration of external RPM tools.	Negotiate and collaborate with EPD software companies to support integration of RPM tools from different software companies. Make interoperability a relevant aspect of certification and the reimbursement process.	EULAR advocacy group Politics and Regulation.
V. Digital literacy limits optimal RPM usage by patients and healthcare professionals.	Provide courses to improve digital literacy of patients and healthcare providers to prevent health disparities.	Patient and health professional organisations Medical Schools and CME providers Politics and Regulation.
EPR, Electronic Patient Record; EUDAMED, European database on medical devices; EULAR, European Alliance of Associations for Rheumatology; MDR, Medical Device Regulation; PTC, Point to Consider; RPM, remote patient monitoring.		

reported being in remission and had up-to-date satisfactory blood monitoring, the team were able to complete a b/tsDMARD review without needing to call or see the patient (a ‘virtual’ review). The patients received a letter summarising the outcome of their biologics review and could call the rheumatology advice line whenever needed. Reviewing could take place following the default 6-month modality or earlier on clinician’s or patient’s request (expedited review) or F2F appointment (escalated review) at any point and an F2F review was mandatory every 3 years.<sup>11</sup>

### Lessons learned

Like the team in Bristol, those considering implementing RPM will face several challenges that can be broadly categorised into service, clinician and patient level barriers, which are outlined below and in [table 1](#). [Figure 1](#) provides a practical flow of all issues to address. In addition, we formulate five recommendations that require further attention from the rheumatology community and policy-makers to maximise the accessibility and quality of RPM within rheumatology ([table 2](#)).

### Service level Regulatory

Telemonitoring systems in healthcare can be classified into two categories: those classified as medical devices and those that are not. According to the Medical Device Regulation (MDR) a medical device is defined as “any instrument, apparatus, appliance, software (...) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease (...)”.<sup>12</sup> In the past, basic RPM systems which solely store, communicate, or display information and did not include interpretative results or decision support have typically not been classified as a medical device. They fall under general consumer technology regulation and do not undergo the same rigorous evaluation as medical devices. However, data privacy and security regulations, like the GDPR in the EU apply to both, medical devices and non-medical devices used for telemonitoring.

Many apps or computer software used in medical applications will require a Conformité Européene

(CE) certification or similar for use within the EU.<sup>13</sup> By affixing the CE marking, the manufacturer declares that the medical device complies with all relevant safety and performance requirements within the scope of the European MDR, respectively, the former Medical Device Directive. Outside the EU, there are often equivalent regulations (United Kingdom Conformity Assessment (UKCA)/Medicines and Healthcare products Regulatory Agency (MHRA) in the UK,<sup>14</sup> Policy for Device Software Functions and Mobile Medical Applications in the US<sup>15</sup>). These regulations can be complex and are often specific to the intended use of the product rather than generic to the product in isolation. To minimise barriers, use an existing digital product that is already CE Certified (or equivalent). When purchasing a digital product, enquire if it is CE Certified and if not, it is worth seeking advice if CE Certification is required. Bear in mind that subsequent iterations of a product or care pathway where the digital product is used may mean that CE Certification is needed where it was not before.

### Data governance

Strict data governance rules (GDPR in the EU/UK, HIPAA in the USA) provide the framework for how patient sensitive information is shared and managed. Keep your care pathway simple and minimise the number of organisations and people involved that will have access to sensitive data. Because data governance rules vary between countries, there is no 'one-size-fits-all' approach. However, key points to consider for all data protection regulations will include: who holds the data and where is it stored (see below 'Cloud storage'). What parties will have access to the data and will the data be anonymised/linked-anonymised/encrypted. How long will the data be stored for. Creating a flow-diagram of the data flow can be a helpful way to visualise parties involved and ensure appropriate data regulations are followed at each point. Due to regional variations in data protection regulations, involve local institutional expertise with data governance processes early in care pathway design. GDPR regulation requires at a minimum that this data is stored within the EU and has minimum encryption standards. Some EU countries have more stringent rules, so local legal and governance advice is needed before patient data is shared with servers outside of institutions. Understand where the data is warehoused—'cloud' data is always physically stored somewhere. For the purposes of GDPR, this data warehouse must be located within the EU's jurisdiction.

### Data access

Patient data stored by the service provider in off-site servers or in the cloud can be difficult to access. Patient data captured via remote platforms is an important part of the clinical record as well as providing useful future data for audits and research—ensure that digital providers have clear and robust mechanisms to allow data downloads in a secure and usable format so that they can be backed up in institution data storage facilities if required.

### Economical barriers

Bespoke creation of software is costly, time-consuming and complex due to regulations surrounding software used in healthcare. Navigating these regulatory barriers can be difficult, so consider using existing digital products where appropriate rather than building bespoke solutions. Even building in-house products using open source platforms (such as RedCAP) may still be classed as a medical device depending on how the data are used. Often adjusting existing products can be adapted to local needs at a fraction of the cost of developing from scratch. Most companies with pre-existing experience will also be able to provide products that have acquired appropriate CE/UKCA marking. They may also have prepopulated documents and data management policies that are required for data governance purposes and will understand data regulations in healthcare applications. Be cautious if working with service providers that have little or no experience of operating in the healthcare environment and seek advice from an expert if necessary.

### Maintenance

App/software developing 'bugs' over time or becoming non-functional with major service and security updates (iOS/Android/Windows, etc) can be an issue. Ensure any product provided includes ongoing regular service support and security patch updates. Without this, most apps and many webpages will be non-functional after 6–9 months, even if nothing is changed from the user side.

### Reimbursement

Existing reimbursement/tariff/charging structures might not apply to the RPM tool (lacuna III). This can lead to institutional pushback. In the USA, remote monitoring is covered by Medicare.<sup>16</sup> In Europe, the reimbursement is highly fragmented by different healthcare systems and insurers. In some countries, healthcare providers or hospitals can get an agreement on optional provision for RPM tools with health insurers. Some tools will have a subscription model that customers or insurers pay for if there is sufficient evidence that the tool reduces costs.

If changing the care pathway from F2F to non-F2F methods, discuss the care pathway with managers. In most cases, more efficient care can provide benefits to patients, providers and payers. Examples from organisations where RPM has been successful can be helpful to evidence potential savings or quality improvements. Special interest networks such as the Digital Rheumatology Network<sup>17</sup> can be an ideal network to link in to others who have had experience implementing these solutions in different healthcare settings. In the UK, the National Health Service (NHS) Digital Playbook can be a helpful resource.<sup>18</sup> If it is difficult to quantify potential financial and time savings, a pilot implementation to demonstrate proof of concept can help highlight benefits to all stakeholders as well as offering the ability to identify and fix any problems at an early, small-scale stage.

### Purchasing

Models of purchasing can include subscription, free/freemium and licence purchase. Think about the long-term sustainability of the product within the clinical service. If the digital product will be central to the service, it is important to use a product that is likely to be viable for many years. Changing over service providers for an app is challenging if hundreds of patients need to download a new app. Free products are attractive, but can have drawbacks including limited development/improvement opportunities, and the service may be more likely to be withdrawn if not financially viable for the developer. Licence purchase options offer a more fixed cost, but may not include development/improvement of the product in the price. Subscription models have an ongoing running cost, but often include technical support and development/improvement of the product in the price.

### Clinical governance

When implementing RPM, as with any clinical pathway update or change, follow local institutional clinical governance recommendations. Important considerations are; having a clear pathway of how the data collected through RPM will be used, who it will be checked by, when, and how often. What safety nets are in place if there is a problem with the RPM system? In Bristol, patients were informed that their data were not monitored outside of clinic appointments, and they knew to contact the department if they needed additional clinical input. Furthermore, the RPM solution was introduced in parallel with the previous F2F clinical model (a hybrid clinic model), meaning that F2F reviews remained an option for any patient when it was needed, or if the patient did not wish to/was unable to use the RPM. If clinical decisions are made using data from the RPM solution, these should be documented in the medical record. If the RPM solution is not integrated in the electronic patient record (EPR), then documentation of the important ePROM or data that is informing the clinical decision in the notes is the most straightforward. If data is not integrated in the EPR, then data can be stored as a datafile in the organisation's data warehouse (see section on integration and interoperability). Ensure that the provider of the RPM solution has appropriate protection and solutions in place to mitigate cyber threats.

Obviously, there is much more to be said regarding legal and ethical implementations. A helpful, more detailed description on this can be found elsewhere.<sup>19</sup>

### Clinician barriers

#### Awareness of available digital products and solutions and their quality

Thinking through care pathway changes to incorporate digital solutions can be time-consuming. In a busy clinical practice, there may not be time to build a new care pathway from scratch. At this point, no complete registry exists (lacuna II); however, there are several resources

where existing clinical apps and existing digital care pathways can be located. In the EU, the EUDAMED database is currently being established, which aims to provide a living picture of the lifecycle of medical devices.<sup>20</sup> It will integrate different electronic systems and resources to collate and process information. In the UK, the NHS Digital Playbook<sup>18</sup> and the Organisation for the Review of Care and Health Apps<sup>21</sup> offer valuable, however, not complete orientation. In the USA, the university of Arizona provides an extensive, though incomplete, overview of available providers.<sup>22</sup> A registry that contains an overview of all viable products should ideally also address the quality of the product legal, technical, medical and ethical requirements for RPM tools. The standards of the quality are still an omission (lacuna I) that be an interesting follow-up work for the EULAR task force that created the EULAR RPM guidelines

Attending conferences or events which showcase existing successful digital care pathways (eg, Digital Rheumatology Day) can be a good way of finding inspiration as well as useful contacts from clinicians who have already begun implementing solutions.

### Enthusiasm

Clinical colleagues may not share the enthusiasm for change, being too busy for change. A useful mantra is '*Start small to grow tall*'—starting with small cohorts of patients with simple tweaks to a clinical pathway are easier to implement individually and can prove a useful demonstration of potential to colleagues and managers.

### Data overload

Concern about 'data overload' or missed clinical signs that were reported remotely is often cited as a concern by clinicians. Clear communication with patients as to what they can expect at the outset is essential. For instance, the data will not be monitored between clinical reviews. Signpost patients to safety nets such as advice lines, monitored email addresses or on-call physicians.

### Integration and interoperability

Concern that remote monitoring data will not be integrated into the hospital EPR is a frequently reported issue. Think carefully what data integration is actually needed. The most straightforward integration involves an interoperable data download to institution data warehousing on a regular basis. This can work well if the digital solution being used has its own portal for data viewing (eg, graphs/trends etc) and all that is required is a data backup for governance purposes. A simple way to achieve this is to agree a table format and data file (eg, .csv) that you need your data in with the supplier of your RPM provider and arrange a regular data download from the provider to the institutional data warehouse. Make sure file transfers are secure—for most purposes, a secure file transfer protocol is adequate. Check with your local IT team about the level of encryption required and if patient data needs to be delinked from patient

identifiers in the transfer process. For most organisations, regular data downloads from external software solutions is routine and they will have standard operating procedures for such transfer of data. More complex integration requirements are those that involve building data viewers in an existing hospital EPR using data drawn from the remote monitoring solution. This can be difficult as it often requires the EPR and the remote monitoring software to have compatible data sharing interfaces and will require both the hospital EPR and remote monitoring companies to invest in development work. A push towards a universal international standard for health data sharing is underway (HL7-FHIR) but not yet universally present.<sup>23</sup> Integrating fully with the hospital EPR will also require the EPR software provider to dedicate resources to developing and maintaining data viewers appropriate for the clinical requirement (lacuna IV).

### Patient barriers

Similar to the importance of including legal experts in the team, it is very helpful to have patient representatives in your team.

### Being seen

Concern that their clinician will not see them because ‘everything will be online’. Communication and engagement with patient groups is essential. Ideally use a co-design process and involve patient representatives/groups from the beginning and through the development of the new care pathway and maybe even with the digital product selection. Patients are often more open to change than clinical teams think, but may have concerns which could be opportunities to further improve the new care pathway, or highlight areas where clearer communication is needed.

### Accessibility

Difficulty understanding or using the app/digital software may be a problem. There will always be different levels of uptake between patients. This may be influenced by factors such as access to technology, digital literacy, physical or cognitive impairment etc (lacuna V). When designing the care pathway to include remote monitoring, consider using a hybrid approach which includes a pathway for patients who are not using RPM and allows for both users and non-users of the technology. This makes the new care pathway more resilient, even if initial uptake is slower than hoped. Try to overcome barriers to inclusion, for example, different language versions, clear colour contrast for visually impaired and easy usability for impaired motor function. Many smartphones have accessibility features that can assist use of the device. It is likely that whatever solution is implemented, there will be areas for improvement in accessibility and inclusion. However, by considering the barriers at the outset, mitigations can be sought early on. By adopting a hybrid multimodal follow-up model, people who may have limited access to the RPM will still have access to more

traditional models of care (eg, F2F reviews) and may even have quicker access to these reviews if efficiencies have been made through the adoption of RPM which may free up F2F clinical reviews. Accordingly, ensure that any service design equitably benefits those with and without the technology (eg, a reduced waiting list/quicker time to review benefits all patients). Enquire if the proposed digital solution has been co-designed with patients.

### Engagement and drop-off

Patients may stop using the app/digital software.<sup>9</sup> Variable usage of any remote monitoring tool is inevitable. However, use of any new technology such as an app can be encouraged by clinicians demonstrating to patients that they are using the data submitted by the patient and that it is useful. Encouraging patients to keep entering data at clinical interactions if they have stopped submitting information. On screen, email and SMS reminders can be helpful, although overuse of reminders can lead to ‘reminder fatigue’ and may cause a patient to disengage completely. ePRO preference largely varies from patient to patient and enabling patients to individually choose ePROs may increase adherence.<sup>24</sup>

### Selecting the right tool: quality criteria for RPM tools

It can be challenging for non-RPM specialists to be aware of relevant quality aspects for RPM tools and it can be unclear to what extent the tools fulfil all necessary requirements (lacuna I). Quality criteria for telemonitoring are essential to ensure the safe and effective use of digital technologies in healthcare. These criteria often align with established regulatory frameworks such as the UK’s NHS Digital Technology Assessment Criteria or various regulations within the EU (eg, German DiGA process).<sup>25 26</sup> Key quality criteria encompass various aspects, including data security and privacy, clinical efficacy, usability and interoperability.

The US government does provide valuable information on RPM (and teleHealth) but this is mostly informative instead of setting standards.<sup>27 28</sup> As outlined in the barrier section, there are many tools to select from and choosing an appropriate one is a crucial step towards successful RMP implementation. To assess the benefits and potential risks of apps, a robust assessment is essential and must consider the entire lifecycle of mobile medical apps, including design, development, deployment and postmarket surveillance.<sup>29</sup> While the exact assessment and criteria differ between the jurisdictions (USA, EU, UK) and specific process (primary regulatory approval, medical guidelines, reimbursement), key dimensions of assessment are universally present and include:

- Clinical validity and efficacy: digital health apps must be evaluated for their clinical validity (whether the app’s measurements and outcomes are reliable) and efficacy, supported by scientific evidence and adherence to relevant clinical guidelines. Clinical trials and real-world data analysis are crucial in establishing the effectiveness of these apps.



- ▶ Technical quality: the assessment includes an evaluation of the technical performance and reliability of mobile medical apps, including interoperability and possible integration into existing health IT systems.
- ▶ Data privacy and security: assessment processes do prescribe strict adherence to data protection regulation systems (eg, GDPR) and information security standards.
- ▶ Usability and user experience: assessing the accessibility, usability, usefulness and user experience of mobile medical apps is crucial for their adoption and adherence.
- ▶ Safety and risk management: mobile medical apps must undergo rigorous risk assessment to identify potential hazards and establish risk mitigation strategies. Aspects include potential and actual adverse events, data breaches, and ensure that the benefits outweigh the risks.

## DISCUSSION

Numerous studies have confirmed the validity and safety of RPM in the context of rheumatology clinics. The 2022 EULAR PTC has clearly outlined the role and significance of RPM in these clinics.<sup>10</sup> In this viewpoint, we addressed the service, clinician and patient barriers faced when implementing RPM in rheumatology practice. Our goal was to empower all rheumatology teams that are considering integrating RPM into their care practices by offering valuable tips and providing links to available resources and tools. For those who want to read further into the subject of theorising and evaluating health and care technologies, we advise you to read the papers on the NASSS framework, focusing.<sup>30</sup> These papers discuss both preimplementation and postimplementation theoretical assessment.

Next, we highlighted five lacunas for the optimal implementation of RPM: quality standards, comprehensive overview of the available tools, EPD integration, reimbursement and digital literacy. We hope future initiatives will address these lacunas and we will contribute to that where possible.

When integrating RPM into your care, it is essential to consider not only the present possibilities but also to understand the perspective for the future. Current clinically implemented RPM approaches are largely based on questionnaires and partially blood collection by other healthcare professionals. For diagnosis, remote patient assessment is more accurate the more information is made available to the practitioner and this is likely also the case for RPM.<sup>31</sup> Wearable digital technology, including smartwatches, has gained attention as a potential tool for monitoring and managing rheumatic diseases. One of the primary motivations behind their use is the ability to passively collect biometric and activity data, enabling regular and continuous tracking of patients' functional health status. These digital biomarkers encompass various physiological, motion

and behavioural measurements that hold promise in providing objective proxies or complementary information to subjective patient-reported outcome (PRO) measures.<sup>32</sup> By correlating digital biomarkers of activity with PROs related to pain, fatigue, functional impairment and disease activity, a better understanding of the relationship between physical activity and RA could be achieved. This information could automatically tailor personalised exercise interventions and continuously support patients at home to promote an active lifestyle.<sup>33</sup> Artificial intelligence (AI) techniques are increasingly being employed to harness the vast amount of data collected through these wearables. Machine learning can train AI algorithms to identify patterns, correlations and predictive insights based on digital biomarkers associated with pain, sleep and activity in patients with rheumatic diseases.<sup>34</sup> Combined with capillary self-sampling that enables convenient and reliable measurement of inflammatory markers and autoantibodies at home, these AI models could provide personalised predictions and recommendations for disease diagnosis, management and symptom monitoring.<sup>35 36</sup>

In addition to wearable sensors, images and videos captured through smartphone cameras can play a relevant role in assessing motion patterns and conducting functional tests. Cameras integrated into smartphones allow for detailed visual documentation of joint swelling, deformities and movements, particularly in the hands.<sup>37</sup> These images and videos can be analysed using machine learning techniques, leveraging AI algorithms to detect and quantify specific motion patterns or fluctuations in joint swelling. By objectively assessing hand motion and other functional tests through visual data, doctors and researchers could gain valuable insights into the disease progression and the effectiveness of treatment interventions, which could potentially broaden the scope of monitoring and evaluating remotely. Further research and clinical validation is necessary to establish the utility and accuracy of these digital biomarkers and AI algorithms in the context of rheumatic disease and to integrate them into clinical practice effectively.

RPM is increasingly applied to other diseases that have clearly defined treatment targets such as gout and axial spondyloarthritis.<sup>38 39</sup> Besides simple electronic questionnaires, chatbots are increasingly being used for hybrid approaches with ePROs being complemented by synchronous video consultations.<sup>40</sup> Holistic digital platforms, that is, luscii.com enable a combination of communication channels and adaptability within a single application. Large citizen science projects enable us to answer beliefs such as whether the weather actually affects disease activity of rheumatic diseases.<sup>41</sup>

## CONCLUSION

There is no one-size-fits all RPM approach. The individual approach is influenced by multiple factors including disease type, activity, duration, eHealth literacy as well as

possibilities and restrictions of the environment. Crucial aspects of success is to ensure all relevant expertise is on board, make use of the solutions of others, ‘*Start small to grow tall*’ and take into account adaptiveness to ensure sustainability, scalability and optimal usage of new developments. Finally, let us communicate well and work together to prevent repetitive problems and to create the necessary power to make relevant legal, infrastructure and healthcare changes.

Finally, let us strive to communicate effectively and collaborate to proactively prevent repetitive problems. As well as to harness the necessary force and power to bring about meaningful legal, infrastructure and healthcare changes to ensure high quality of care also for future generations.

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