ESC European Society of Cardiology

European Heart Journal - Digital Health (2022) **3**, 121–122
https://doi.org/10.1093/ehjdh/ztac017

LETTER TO THE EDITOR

Telemonitoring of heart failure patients is reimbursed in Germany: challenges of real-world implementation remain

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Online publish-ahead-of-print 19 April 2022

Since January 2022, remote patient monitoring of patients with heart failure (RPM-HF) is reimbursed by the statutory health insurance (SHI) funds in Germany.[1] The SHI-insured population accounts for ∼88% of Germany's population, i.e. ∼73.3 mio. subjects, whereas 12% are insured by private health insurances. Remote patient monitoring of patients with heart failure is the first digital care management programme that will be implemented in the German health care system.

This fundamental decision by the Federal Joint Committee (G-BA), the central authority defining the catalogue of benefits that have to be reimbursed by all SHI funds, was based on a carefully balanced assessment by the Institute for Quality and Efficiency in Health Care (IQWiG).[2] The IQWiG reviewed the results of four randomized controlled trials (RCT) with at least 6 months of follow-up[2]—that is, two with non-invasive RPM (TIM-HF[3] and TIM-HF2[4]) and two with invasive RPM (IN-TIME[5] and TELECART[6]).

Remote patient monitoring of patients with heart failure was defined by the G-BA as a HF management based on sensor-derived data that carefully observes time-sensitive corridors, provided cooperatively by a residential SHI-accredited physician [primary care physician (PCP); in particular cardiologists or internal medicine specialists] and a physician-led telemedical centre.[1]

Remote patient monitoring of patients with heart failure may only be provided for patients meeting all of the following conditions[1]:

- NYHA functional Class II or III, with left ventricular ejection fraction <40%;
- Implanted device (ICD, CRT-P/-D) or being hospitalized for decompensated HF in the past 12 months;
- Heart failure treated according to guidelines;
- No factors identified preventing or jeopardizing the transmission of the monitoring data or impeding self-management of the patient.

In Germany, the number of patients suffering from HF in 2018 was nearly 2.5 mio. according to a data review of the SHI funds.[7] It is estimated that ∼200 000 patients per year may be eligible for RPM-HF.[1,8]

The decision to reimburse RPM also serves to create a relevant telemedicine market in Europe, which may stimulate further technological innovations in the field. However, the implementation and upscaling process of RPM in a larger real-world setting decisively differs from the implementation of other interventions, e.g. a new approved drug, which will be produced, prescribed, and dispensed by pharmacies as soon as reimbursement issues have been solved. In contrast, RPM requires equipment (e.g. invasive or non-invasive sensors, telemedical health records) as well as standard operating procedures and care pathways for the involved medical staff and the treated patient (e.g. for patient education or management of alerts). Moreover, enormous efforts are necessary to qualify medical staff running the RPM.

Hence, beyond reimbursement, the upscaling of RPM-HF in the real world represents the key issue of the now starting implementation process. For several reasons, in particular, the lack of specific resources, it is not feasible to simply copy the settings of the respective clinical trial into real world. For example, a 24/7 RPM-HF service was provided during the TIM-HF[3] and TIM-HF2[4] studies. Both studies identified an almost identical profile of high-risk patients, but observed that only one-third of the study population initiated alerts to the telemedical centre outside business hours.[9]

As a consequence, the G-BA decided, that cardiologists may offer RPM-HF for their patients during office hours, and are free to decide, whether a high-risk patient should receive intensified RPM 7 days a week thus also involving a telemedical centre (see *Figure 1*).[1]

Another issue is the duration of RPM-HF. In the RCTs, the follow-up period was fixed according to the study protocol.[3–6] Follow-up

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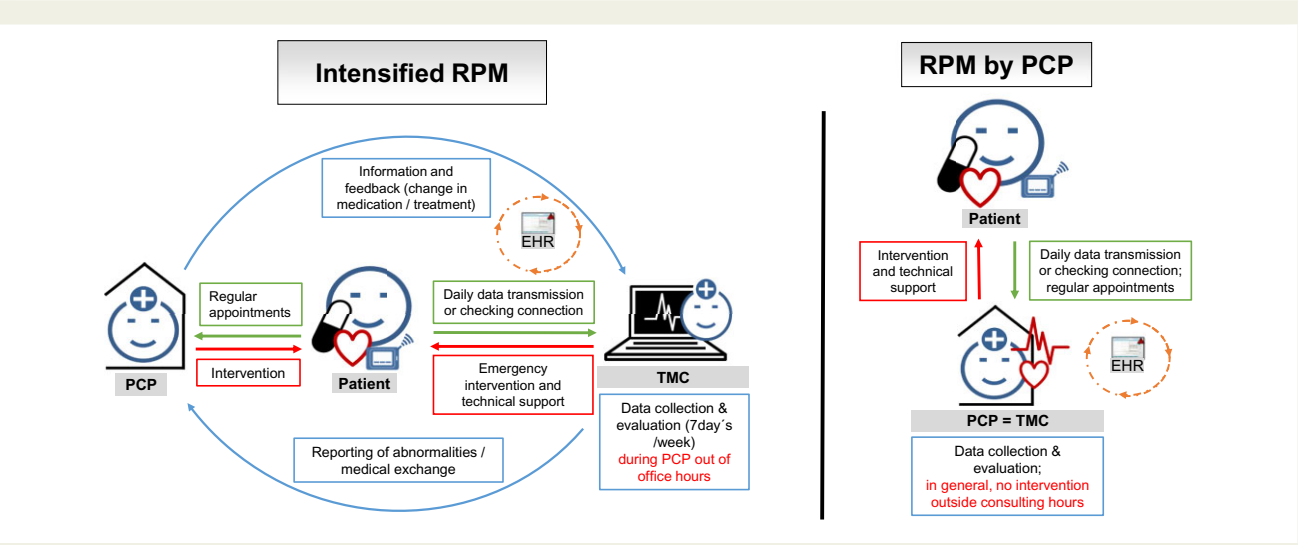

Figure 1 Remote patient monitoring of patients with heart failure: two scenarios. EHR, electronic health record (patient file); PCP, primary care physician/cardiologist; RPM, remote patient monitoring; TMC, telemedical centre.

studies did not show a differential benefit (in terms of clinical endpoints) when stopping RPM after 6 or 12 months.[10] However, the G-BA decided that RPM-HF eventually should be offered life-long. After RPM has been started, PCP and patient jointly have to re-check after 3 months and every 12 months thereafter, whether the prerequisites for a continuation of RPM are still being met.[1]

Finally from the viewpoint of research, the structural differences between RPM settings applied in RCTs vs. the upcoming structure in real world mandate to investigate the effectiveness of the new standard RPM-HF care pathway, e.g. by initiating a registry.

In summary, the implementation of RPM-HF in Germany will provide important information for the further development of digital care programmes and their implementation in other health care systems.

Conflict of interest: F.K. has received research grants from the German Federal Ministry of Education and Research (BMBF) and from the German Federal Ministry of Economic Affairs and Climate Action (BMWK); F.K. was and is member of advisory boards of Abbott, Sanofi and Biotronik. S.S. has received research grant from the German Federal Ministry of Education and Research (BMBF), and the European Union; S.S. is member of advisory boards of Sanofi, Boehringer, Bayer, Novartis and Biotronik. M.S. has no conflicts of interest with regard to the content of this letter to disclose.

Data availability

The data underlying this article are available in the article.

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