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Who approves/pays for additional monitoring?

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Major considerations in the provision of healthcare are availability, affordability, accessibility, and appropriateness, especially in the setting of heart failure where disease burden is growing, developments have been rapid and newer biomarkers, diagnostic and imaging techniques, monitoring systems, devices, procedures, and drugs have all been developed in a relatively short period of time. Many monitoring and diagnostic systems have been developed but the disproportionate cost of conducting trials of their effectiveness has limited their uptake. There are added complexities, in that the utilization of doctors for the supervision of the monitoring results may be optimal in one setting and not in another because of differences in the characteristics of organization of healthcare provision, making even interpretation of the trials we have had, still difficult to interpret. New technologies are continuously changing the approach to healthcare and will reshape the structure of the healthcare systems in the future. Mobile technologies can empower patients and carers by giving them more control over their health and social care needs and reducing their dependence on healthcare professionals for monitoring their health, but a significant problem is the integration of the multitude of monitored parameters with clinical data and the recognition of intervention thresholds. Digital technology can help, but we need to prove its cost/efficacy and how it will be paid for. Governments in many European countries and worldwide are trying to establish frameworks that promote the convergence of standards and regulations for telemedicine solutions and yet simultaneously health authorities are closely scrutinizing healthcare spending, with the objective of reducing and optimizing expenditure in the provision of health services. There are multiple factors to be considered for the reimbursement models associated with the implementation of physiological monitoring yet it remains a challenge in cash-strapped health systems.

Introduction

Access to healthcare is central to wellbeing, life expectancy, and social protection. However, there is not an agreed definition or standard approach to its availability across the world and even across the more developed EU systems. Key dimensions of access to healthcare are availability, affordability, accessibility, and appropriateness. These concepts are crucial to understand how the healthcare system can approve and pay for new monitoring systems for physiological parameters and drug efficacy in chronic disease states. This is especially relevant in heart failure (HF) where disease burden is growing, developments have been rapid and newer biomarkers, diagnostic and imaging[1] techniques, monitoring systems, devices, procedures, and drugs[2–4] have all been developed in a relatively short period of time. Many monitoring and diagnostic systems, for example, have been proven to be efficacious in one healthcare system[5] or setting,[6–9] but not in others,[10] where the background risk,[11] the level[12] and type of patient care,[13] and follow-up arrangements may be quite varied,[14] carrying with it a differing ability to respond to the

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new information monitoring can provide. Some are highly specific to the settings in which they potentially add clinical value[15–17] and expecting large-scale outcome trials for every aspect of improved clinical care may be an unrealistic expectation. Even the type of patient[18] that eventually gets into trials may, for many reasons, be different from real-world HF patients.[19,20] The trials themselves need to be monitored[21–23] adding cost and complexity[24] and potentially acting as a brake on health system care delivery improvement as a result. Simple aspects of healthcare[25–27] cannot be tested in large-scale trials, we simply cannot afford so to do.

Access to healthcare is integral part of the European Pillar of Social Rights. However, the type of quality, effectiveness of healthcare vary greatly amongst European Countries. This is dependent of how the health system developed prior to the European integration in the individual Countries and the funds available/allocated in each Country for healthcare. Low effectiveness of healthcare has a negative impact on access to new technologies. However, the use of ineffective technologies leads to a waste of healthcare resources.[28] On the other hand, inexpensive treatments may be very difficult to introduce because of the disproportionate cost of conducting trials of their effectiveness.[29,30]

Inappropriate monitoring or ineffective technologies may cause an overuse of procedures rather than at unproblematic accessibility. Also, the utilization of human resources is an integral part of the provision of new technologies and depends on the characteristics and organization of the specific healthcare system. The utilization of doctors for the supervision of the monitoring results may be optimal in one setting and not in another because of differences in the characteristics of organization of healthcare provision, making even overviews of multiple trials hard to interpret.[31,32]

New technologies are continuously changing the approach to healthcare and will reshape the structure of the healthcare systems in the future. Some systems such as the UK's NHS are more responsive to these innovations while others are slower in embracing them, although in each the cost-benefit relationship may be very different.[33–35]

Mobile technologies can empower patients and carers by giving them more control over their healthcare and social care needs and reducing their dependence on healthcare professionals (HCPs) for monitoring their health.[36] They can improve not only self-management through education, remote monitoring, and treatment adherence but also support development of online healthcare provision. The main problem is the integration of the multitude of monitored parameters with clinical data and the recognition of intervention thresholds.

Digital technology can connect patients and providers, leading to a more convenient and tailored service. However, this service has to prove its cost/efficacy before being implemented and paid for.[37]

Remote monitoring uses technology to monitor changes in patients' health status outside of the clinical settings. These systems have initially been developed by conveying information through fixed-line technology now they use mobile/Wifi/Bluetooth infrastructures. They allow HF patients to use a device to perform a measurement of a physiological parameter[38] and to send the data to a healthcare professional or to a system that uses artificial intelligence to trigger signals when needed. The use of integrated physiological monitoring should be prompted by an HCP. However, digital technology has increased the potential for remote monitoring and, with the advent of apps and wearables, patients are increasingly bringing the innovation to HCPs.

Recent advances in the development of bio-sensing wearables are extending their capability to move beyond simply tracking activity. New technologies allow a continuous monitoring of a broad range of physiological parameters. Development in bio-sensing wearables allow automated monitoring and detecting real-time changes in patients with HF. Data gathered from physiological monitoring can be used to update medical history and real-time information to support early detection in worsening of health status.[39]

Despite the general excitement for the new technologies and their supposed potentials, if they have to be integrated in the healthcare provisions they will have, individually of globally when integrated in a detection system, to prove their efficacy in reducing hospitalizations and deaths and their cost/effectiveness.

Governments in many European countries and worldwide are trying to establish frameworks that promote the convergence of standards and regulations for telemedicine solutions. The Global Harmonization Task Force has been commenced by a group of countries (the EU, USA, Canada, Japan, and Australia), with the objective of streamlining and harmonizing all regulatory requirements regarding medical technologies. This process may enable a better economic assessment of the cost/efficacy of the technologies and, therefore, enable decisions on reimbursements.

Different forms of delivery and use of remote monitoring solutions for patients with HF can define the supply and demand structure for the provision of services. The cost of providing remote physiological monitoring solutions and services can be managed by a service model operated by service providers, and a technology platform model operated by medical personnel. Factors influencing investments in monitoring physiological parameters in HF patients depend on the access to mobile technology, on the safety of information technology security, and on the need for chronic care. Healthcare systems are mainly focused on hospital-centric care models that absorb more than 90% of the cost of care for HF patients and are not usually well equipped to meet the challenges of physiological monitoring.

Health authorities are closely scrutinizing healthcare spending, with the objective of reducing and optimizing expenditure in the provision of health services, and of replacing older established therapies with newer perhaps less risk-prone therapies.[40] Because of the constant increase in demands for health services driven by demographics and epidemiology, and lower relative funding for health systems, diffusion and access to physiological monitoring services will become a major concern in the short term.

There are several factors to be considered for the reimbursement models associated with the implementation of physiological monitoring services across the EU. The escalating costs associated with healthcare provision (infrastructure and operational expenditure) and the dynamics of the workforce in the medical field play a major role in defining the costs. The needs of service improvement require we look regularly at the effectiveness of routine practice[41,42] and ways to incrementally improve outcomes.[43–45]

The availability of additional financial resources to be allocated to healthcare is also problematic in some countries and this has an impact on the decision making about the reimbursability.

However, healthcare systems continue to struggle with unsustainable conditions due to demographic dynamics in the EU and elsewhere, the decreasing share of the active population, and the increasing need for treatment for chronic diseases.

The financing of healthcare provisions for physiological monitoring will require complementing healthcare funds with private expenditure (e.g. out-of-pocket payments and patient co-payments). However, this may prove extremely difficult, as most of the healthcare systems have traditionally been mainly funded by public sources. Of course, should individual physiological monitoring prove to be cost-effective, they can be immediately be embraced and reimbursed by the healthcare system providing that they will lead to savings on hospital expenditure in the long term.

It is generally stated that the adoption of physiological monitoring increases benefits, reduces costs (consultation costs, travel costs, and time spend) and increases patient survival and quality of life. However, more scientific evidence is needed to demonstrate the cost/efficiency of physiological monitoring and large-scale trials are needed to demonstrate the impact of a wider deployment.

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References

1. Čelutkienė J, Plymen CM, Flachskampf FA, de Boer RA, Grapsa J, Manka R, Anderson L, Garbi M, Barberis V, Filardi PP, Gargiulo P, Zamorano JL, Lainscak M, Seferovic P, Ruschitzka F, Rosano GMC, Nihoyannopoulos P. Innovative imaging methods in heart failure: a shifting paradigm in cardiac assessment. Position statement on behalf of the Heart Failure Association of the European Society of Cardiology. *Eur J Heart Fail* 2018;**20**:1615–1633.
2. Rosano G. Medical treatment of heart failure with reduced ejection fraction—prognostic indication. *Int Cardiovasc Forum J* 2017;**10**:16–21.
3. Vitale C, Rosano G, Rosano G. Medical treatment of heart failure with reduced ejection fraction improving clinical status and functional capacity. *Int Cardiovasc Forum J* 2017;**10**:22–28.
4. Rosano G. Medical treatment of heart failure with reduced ejection fraction—aimed at reducing rehospitalisations. *Int Cardiovasc Forum J* 2017;**10**:29–33.
5. Koehler F, Koehler K, Deckwart O, Prescher S, Wegscheider K, Winkler S, Vettorazzi E, Polze A, Stangl K, Hartmann O, Marx A, Neuhaus P, Scherf M, Kirwan BA, Anker SD. Telemedical Interventional Management in Heart Failure II (TIM-HF2), a randomised, controlled trial investigating the impact of telemedicine on unplanned cardiovascular hospitalisations and mortality in heart failure patients: study design and description of the intervention. *Eur J Heart Fail* 2018;**20**:1485–1493.
6. Harjola VP, Parissis J, Brunner-La Rocca HP, Čelutkienė J, Chioncel O, Collins SP, De Backer D, Filippatos GS, Gayat E, Hill L, Lainscak M, Lassus J, Masip J, Mebazaa A, Miró Ò, Mortara A, Mueller C, Mullens W, Nieminen MS, Rudiger A, Ruschitzka F, Seferovic PM, Sionis A, Vieillard-Baron A, Weinstein JM, de Boer RA, Crespo-Leiro MG, Piepoli M, Riley JP. Comprehensive in-hospital monitoring in acute heart failure: applications for clinical practice and future directions for research. A statement from the Acute Heart Failure Committee of the Heart Failure Association (HFA) of the European Society of Cardiology (ESC). *Eur J Heart Fail* 2018;**20**:1081–1099.
7. Masson S, Latini R. HOME HF: an honest report of an (apparently) doable study. *Eur J Heart Fail* 2018;**20**:481–482.
8. Biering-Sørensen T, Santos M, Rivero J, McCullough SD, West E, Opotowsky AR, Waxman AB, Systrom DM, Shah AM. Left ventricular deformation at rest predicts exercise-induced elevation in pulmonary artery wedge pressure in patients with unexplained dyspnoea. *Eur J Heart Fail* 2017;**19**:101–110.
9. McDonald K, Troughton R, Dahlström U, Dargie H, Krum H, van der Meer P, McDonagh T, Atherton JJ, Kupfer K, San George RC, Richards M, Doughty R. Daily home BNP monitoring in heart failure for prediction of impending clinical deterioration: results from the HOME HF study. *Eur J Heart Fail* 2018;**20**:474–480.
10. Cotter G, Metra M, Davison BA, Jondeau G, Cleland JGF, Bourge RC, Milo O, O'Connor CM, Parker JD, Torre-Amione G, van Veldhuisen DJ, Kobrin I, Rainisio M, Senger S, Edwards C, McMurray JJV, Teerlink JR; VERITAS Investigators. Systolic blood pressure reduction during the first 24 h in acute heart failure admission: friend or foe? *Eur J Heart Fail* 2018;**20**:317–322.
11. Tamargo J, Rosano G, Walther T, Duarte J, Niessner A, Kaski JC, Ceconi C, Drexel H, Kjeldsen K, Savarese G, Torp-Pedersen C, Atar D, Lewis BS, Agewall S. Gender differences in the effects of cardiovascular drugs. *Eur Heart J Cardiovasc Pharmacother* 2017;**3**:163–182.
12. Pellicori P, Clark AL, Kallvikbacka-Bennett A, Zhang J, Urbinati A, Monzo L, Dierckx R, Anker SD, Cleland J. Non-invasive measurement of right atrial pressure by near-infrared spectroscopy: preliminary experience. A report from the SICA-HF study. *Eur J Heart Fail* 2017;**19**:883–892.
13. McDonald K, O'Hanlon R, Savage HO, Khushaba RN, Colefax M, Farrugia S, Javed F, Schindhelm K, Wilcox I, Cowie MR. Sleep-disordered breathing in chronic heart failure is highly variable when measured remotely using a novel non-contact biomotion sensor. *Eur J Heart Fail* 2017;**19**:688–690.
14. Di Nardo M, Stoppa F, David P, Lorusso R, Ranieri VM, Mascia L. Reversed differential cyanosis during veno-arterial extracorporeal membrane oxygenation in infants: the reevaluation of an old phenomenon. *Eur J Heart Fail* 2017;**19**:117–119.
15. Magnussen H, Canepa M, Zambito PE, Brusasco V, Meinertz T, Rosenkranz S. What can we learn from pulmonary function testing in heart failure? *Eur J Heart Fail* 2017;**19**:1222–1229.
16. Lopatin Y, Rosano G. Treatment of patients in the vulnerable phase (at discharge or early after discharge). *Int Cardiovasc Forum J* 2017;**10**:37–40.
17. Consolo F, Sferrazza G, Motolone G, Contri R, Valerio L, Lembo R, Pozzi L, Della Valle P, De Bonis M, Zangrillo A, Fiore GB, Redaelli A, Slepian MJ, Pappalardo F. Platelet activation is a preoperative risk factor for the development of thromboembolic complications in patients with continuous-flow left ventricular assist device. *Eur J Heart Fail* 2018;**20**:792–800.
18. Olivier A, Pitt B, Girerd N, Lamiral Z, Machu JL, McMurray JJV, Swedberg K, van Veldhuisen DJ, Collier TJ, Pocock SJ, Rossignol P, Zannad F, Pizard A. Effect of eplerenone in patients with heart failure and reduced ejection fraction: potential effect modification by abdominal obesity. Insight from the EMPHASIS-HF trial. *Eur J Heart Fail* 2017;**19**:1186–1197.
19. Vonbank A, Drexel H, Agewall S, Lewis BS, Dopheide JF, Kjeldsen K, Ceconi C, Savarese G, Rosano G, Wassmann S, Niessner A, Schmidt TA, Saely CH, Baumgartner I, Tamargo J. Reasons for disparity in statin adherence rates between clinical trials and real-world observations: a review. *Eur Heart J Cardiovasc Pharmacother* 2018;**4**:230–236. Review. Erratum in: *Eur Heart J Cardiovasc Pharmacother* 2019;**5**:36. *Eur Heart J Cardiovasc Pharmacother* 2019;**5**:36.

20. Cotter G, Davison BA. Unmodifiable events, heart failure research, and 'risk-based monitoring' in large studies-the unholy triumvirate. *Eur J Heart Fail* 2018;**20**:1639–1644.
21. Zannad F. Monitoring renal safety in mineralocorticoid receptor antagonist trials. *Eur J Heart Fail* 2017;**19**:466–468.
22. Filippatos GS, de Graeff P, Bax JJ, Borg JJ, Cleland JG, Dargie HJ, Flather M, Ford I, Friede T, Greenberg B, Henon-Goburdhun C, Holcomb R, Horst B, Lekakis J, Mueller-Velten G, Papavassiliou AG, Prasad K, Rosano GM, Severin T, Sherman W, Stough WG, Swedberg K, Tavazzi L, Tousoulis D, Vardas P, Ruschitzka F, Anker SD. Independent academic data monitoring committees for clinical trials in cardiovascular and cardiometabolic diseases. *Eur J Heart Fail* 2017;**19**:449–456.
23. Swedberg K. Lessons for the monitoring of safety in clinical trials. *Eur J Heart Fail* 2018;**20**:148.
24. Bristow MR, Sharma K, Assmann SF, Linas S, Gersh BJ, Grady C, Rice MM, Singh S, Boineau R, McKinlay SM, Greenberg BH. Data and safety monitoring board evaluation and management of a renal adverse event signal in TOPCAT. *Eur J Heart Fail* 2017;**19**:457–465.
25. Dovancescu S, Pellicori P, Mabote T, Torabi A, Clark AL, Cleland J. The effects of short-term omission of daily medication on the pathophysiology of heart failure. *Eur J Heart Fail* 2017;**19**:643–649.
26. Atherton JJ, Hickey A. Expert comment: is medication titration in heart failure too complex? *Card Fail Rev* 2017;**3**:25–32.
27. Mollace V, Rosano G, Malara N, Di Fabrizio E, Vitale C, Coluccio M, Maiuolo J, Ali Wasti A, Muscoli C, Gliozzi M, Mollace R, Musolino V, Carresi C, Fini M, Silvestrini B. Aspirin wears smart. *Eur Heart J Cardiovasc Pharmacother* 2017;**3**:185–188.
28. Albert C, Estep JD. Economic impact of chronic heart failure management in today's cost-conscious environment. *Card Electrophysiol Clin* 2019;**11**:1–9.
29. Gruson D, Pouleur AC, Makris K, Chrysohoou C. Systematic vitamin D supplementation and monitoring: improving outcomes in heart failure? *Eur J Heart Fail* 2017;**19**:686–687.
30. Rosano GMC, Tamargo J, Kjeldsen KP, Lainscak M, Agewall S, Anker SD, Ceconi C, Coats A, Drexel H, Filippatos G, Kaski JC, Lund L, Niessner A, Ponikowski P, Savarese G, Schmidt TA, Seferovic P, Wassmann S, Walther T, Lewis BS. Expert consensus document on the management of hyperkalaemia in patients with cardiovascular disease treated with renin angiotensin aldosterone system inhibitors: coordinated by the Working Group on Cardiovascular Pharmacotherapy of the European Society of Cardiology. *Eur Heart J Cardiovasc Pharmacother* 2018;**4**:180–188.
31. Dierckx R, Inglis SC, Clark RA, Prieto-Merino D, Cleland JG. Telemedicine in heart failure: new insights from the Cochrane meta-analyses. *Eur J Heart Fail* 2017;**19**:304–306.
32. Adamson PB, Ginn G, Anker SD, Bourge RC, Abraham WT. Remote haemodynamic-guided care for patients with chronic heart failure: a meta-analysis of completed trials. *Eur J Heart Fail* 2017;**19**:426–433.
33. Martinson M, Bharmi R, Dalal N, Abraham WT, Adamson PB. Pulmonary artery pressure-guided heart failure management: US cost-effectiveness analyses using the results of the CHAMPION clinical trial. *Eur J Heart Fail* 2017;**19**:652–660.
34. Boriani G, Da Costa A, Quesada A, Ricci RP, Favale S, Boscolo G, Clementy N, Amori V, Mangoni di S Stefano L, Burri H; MORE-CARE Study Investigators. Effects of remote monitoring on clinical outcomes and use of healthcare resources in heart failure patients with biventricular defibrillators: results of the MORE-CARE multicentre randomized controlled trial. *Eur J Heart Fail* 2017;**19**:416–425.
35. Cowie MR, Simon M, Klein L, Thokala P. The cost-effectiveness of real-time pulmonary artery pressure monitoring in heart failure patients: a European perspective. *Eur J Heart Fail* 2017;**19**:661–669.
36. Gensini GF, Alderighi C, Rasoini R, Mazzanti M, Casolo G. Value of telemonitoring and telemedicine in heart failure management. *Card Fail Rev* 2017;**3**:1–121.
37. SUPPORT-HF 2 Investigators and Committees. Home monitoring with IT-supported specialist management versus home monitoring alone in patients with heart failure: design and baseline results of the SUPPORT-HF 2 randomized trial. *Am Heart J* 2019;**208**:55–64.
38. Lefler LL, Rhoads SJ, Harris M, Funderburg AE, Lubin SA, Martel ID, Faulkner JL, Rooker JL, Bell DK, Marshall H, Beverly CJ. Evaluating the use of mobile health technology in older adults with heart failure: mixed-methods study. *JMIR Aging* 2018;**1**:e12178.
39. Raj LM, Saxon LA. Haemodynamic monitoring devices in heart failure: maximising benefit with digitally enabled patient centric care. *Arrhythm Electrophysiol Rev* 2018;**7**:1–298.
40. Niessner A, Tamargo J, Koller L, Saely CH, Schmidt TA, Savarese G, Wassmann S, Rosano G, Ceconi C, Torp-Pedersen C, Kaski JC, Kjeldsen KP, Agewall S, Walther T, Drexel H, Lewis BS. Non-insulin antidiabetic pharmacotherapy in patients with established cardiovascular disease: a position paper of the European Society of Cardiology Working Group on Cardiovascular Pharmacotherapy. *Eur Heart J* 2018;**39**:2274–2281.
41. Raatikainen MJP, Penttilä T, Korhonen P, Mehtälä J, Lassila R, Lehto M. The quality of warfarin therapy and CHA_2DS_2-VASc score associate with the incidence of myocardial infarction and cardiovascular outcome in patients with atrial fibrillation: data from the nationwide FinWAF Registry. *Eur Heart J Cardiovasc Pharmacother* 2018;**4**:211–219.
42. Dan GA, Martinez-Rubio A, Agewall S, Boriani G, Borggrefe M, Gaita F, van Gelder I, Gorenek B, Kaski JC, Kjeldsen K, Lip GYH, Merkely B, Okumura K, Piccini JP, Potpara T, Poulsen BK, Saba M, Savelieva I, Tamargo JL, Wolpert C, ESC Scientific Document Group. Antiarrhythmic drugs-clinical use and clinical decision making: a consensus document from the European Heart Rhythm Association (EHRA) and European Society of Cardiology (ESC) Working Group on Cardiovascular Pharmacology, endorsed by the Heart Rhythm Society (HRS), Asia-Pacific Heart Rhythm Society (APHRS) and International Society of Cardiovascular Pharmacotherapy (ISCP). *Europace* 2018;**20**:731–732. Erratum in: *Europace* 2018;**20**:738.
43. Salmonson T, Dogné JM, Janssen H, Garcia Burgos J, Blake P. Non-vitamin-K oral anticoagulants and laboratory testing: now and in the future: views from a workshop at the European Medicines Agency (EMA). *Eur Heart J Cardiovasc Pharmacother* 2017;**3**:42–47.
44. Rosano GMC, Seferovic P. 2017 ESC guidelines focus on dual antiplatelet therapy. *Eur Heart J Cardiovasc Pharmacother* 2018;**4**:131–132.
45. Kubica J, Adamski P, Buszko K, Kubica A, Kuliczkowski W, Fabiszak T, Jilma B, Alexopoulos D, Paciorek P, Navarese EP. Rationale and Design of the Effectiveness of LowEr maintenanCe dose of TicagRelor early After myocardial infarction (ELECTRA) pilot study. *Eur Heart J Cardiovasc Pharmacother* 2018;**4**:152–157.