Preface

Special Issue on Development, Evaluation and Management of Innovative Digital Medical Devices

As society ages and more innovative, highly effective diagnostics and treatments are available, the prevalence of chronic diseases is increasing. People live longer and more individuals spend decades in chronic conditions with the expectations of maintaining their quality of life, ability to work and independence. Therapeutic efficiency, sustainability of the healthcare system and their impact on society's labor capacity are key issues in all countries. Treatment goals have evolved in the past years placing greater emphasis on disease characteristics of the individual (e.g. their personal genetic predisposition, disease progression, lifestyle and other factors affecting treatment efficiency). On the other hand, treatment goals have expanded to outcomes that reflect personal needs, perceptions and preferences. Health-related quality of life, well-being, social roles, and work capacity have become core elements of treatment outcome assessments. Precision medicine aims to provide solutions to these challenges by shifting from a standardized approach to personalized treatments that consider individual uniqueness and prioritize real world data.

Digital medical devices (DMDs) are playing an increasingly important role in meeting the growing demand for healthcare. New innovative DMDs, using artificial intelligence (AI) and machine learning (ML) solutions, can make treatments more efficient, safer, individualized and more cost-effective by offering personalized and automated therapies based on mathematical modelling and monitoring real-world data. With the development and spread of DMDs, there has been an increased demand for stricter regulations. In May 2021, the new European medical device regulation (2017/745 Medical Device Regulation, MDR) opened a new era in medical device authorization and marketing. The MDR mandates that the efficacy and safety of medical devices be supported by clinical evidence, necessitating data collection throughout the device's life cycle. Therefore, compliance with MDR rules is essential from the development phase through implementation and follow-up of new DMDs.

Addressing these demands requires intensive research and the development of novel scientific methods. Designing personalized DMDs to optimize individual-level treatment – drug doses, regimens, and timing – needs advanced computational methods, mathematical modeling, data engineering and more sophisticated input data.

Clinical trials providing evidence for medical decision-making about DMDs have brought new methodological challenges. For instance, computer generated models (virtual patients) are gaining increasing importance in clinical trials. These can simulate the characteristics of real patients so that parts of trials can be conducted within a computer environment. Sophisticated tumor models, that are based on the deep understanding of tumor growth, may enable optimizing therapeutic strategies (maximizing efficacy, minimizing adverse events) adjusted to the specific tumor's characteristics. AI-based chatbots may enable patients with health information and be used as health advisors. Training programs using virtual reality solutions may help to simulate situations in the rehabilitation process of patients that would be hard (or impossible, costly) to perform in the real world. Despite the immense potential and advantages of AI-based medical advancements, their usability for medical decision-making requires guarantees regarding their clinical benefits and risks, based on transparent, repeatable and explainable trials that allow comparability with treatment alternatives.

Systematic literature review and meta-analysis of clinical trials are potential sources of clinical evidence. However, these are only feasible if trial design, outcome measurement and transparent reporting follow well-established standardized methods formulated in guidelines and checklists. Clinical trials involving AI-based DMDs present new complexities and potential source of bias (e.g., characteristics of the training and testing samples, AI algorithm version used, etc.) that need to be addressed in the clinical trial design and reporting standards. Consensus guidelines (checklists) should be followed by researchers and scientific journal editors have the responsibility in applying them consistently in the evaluation of manuscripts.

One of the major advances of DMDs is that they can monitor the patient and provide 24/7 data recording. Utilizing digital data from DMDs as a source for clinical evidence mandates comprehensive understanding of their relationship with clinically relevant outcomes (e.g., continuous glucose monitor data in diabetes to predict the risk of diabetes complications; body motion data considering the antropometric characteristics of the individual to predict, prevent or detect falls in the elderly). Although a vast amount of data is being generated by DMDs in every second worldwide, their relationship to survival, functional capacity, health-related quality of life and well-being outcomes is an underexplored area.

Successful implementation and sustainable financing of complex and costly DMDs, such as therapeutic and social robots or virtual reality-assisted surgeries, require not only strong clinical evidence (safety, effectiveness), but also health economic evidence (health technology assessment) and management strategies. However, outcome measurement and cost-effectiveness analysis methods developed for the assessment of drugs in the past decades may not be suitable for DMDs, novel methodological improvements are needed.

Implementation and management of DMDs may be hampered by subjective factors like users' digital literacy, internet skills, acceptance difficulties, fears from automated treatment systems or remote control, negative attitudes towards DMDs and cybersecurity concerns. Family members providing care for their loved ones in need (they are called as 'informal caregivers' in literature) play vital role in supporting not only the patient, but also the healthcare system and the society. Their attitudes and capabilities to use AI-based health technologies can be deterministic in the acceptance and proper use of DMDs. These subjective factors of the patients and their caregivers need to be explored and measured in a scientifically sound way. These measures can be used to adjust the design of the technologies according to the users' needs, may help to identify subgroups at risks (e.g., lower digital literacy or self-efficacy), develop targeted educational programs and assess their effects.

In this special issue, we aimed to address these methodological challenges of the development, clinical and economic evaluation, and management of DMDs. We believe that the studies presented in this issue are valuable contributions to the development and efficient use of digital medical devices, thereby supporting the ultimate goal, the improvement of the health of patients and society.

Guest Editors:

Márta Péntek

Health Economics Research Center, University Research and Innovation Center; Doctoral School of Innovation Management, Obuda University, Bécsi út 96/b, H-1034 Budapest, Hungary, pentek.marta@uni-obuda.hu

Levente Kovács

Physiological Controls Research Center, University Research and Innovation Center, Obuda University, Bécsi út 96/b, H-1034 Budapest, Hungary, kovacs@uni-obuda.hu