Koneksa's Playbook Digest: Focus on Oncology

Background

Remote monitoring for medical conditions has existed for decades. The old versions of remote monitoring usually included single modalities: blood-pressure monitors, Holter cardiac ECG monitors, or actigraphy devices.

Remote monitoring jumped onto the radar of both the general population, as well as clinical researchers, when a new version of monitoring technologies emerged: fitness trackers powered by smartphone apps, which allowed real-time data synchronization and data summary visualizations for end users (Godfrey et al., 2020).

Despite not being cleared as medical devices by regulators, many of these monitoring technologies provided valuable health information. Their potential was quickly recognized by both life science and academic researchers (Izmailova et al., 2018). The promise was alluring, but this technology, coupled with a lack of experience, rapidly inflated the hype bubble to a point where it became difficult to distinguish between futuristic dreams and statements supported by real data.

The result of this ambiguous situation, in relation to medical research, was a patchwork of efforts: a variety of pilot studies, often underpowered and suboptimally designed and deployed without frameworks or guidance materials on how to design and perform remote monitoring clinical experiments. This challenge was recognized by the group who created the Digital Medicine Society (DiMe), which began bringing together professionals with diverse expertise to harmonize the field and establish guiding principles.

The Playbook

Recently, DiMe published *The Playbook*, a digital medicine manual touching on multiple aspects of digital measures in the clinic. This is a comprehensive resource for anyone looking to learn what a validated clinical measure means, how to select appropriate measures, how to utilize the right technology for study participants, and how to make it work in practice.

Koneksa and *The Playbook*

Koneksa has been an active participant in the creation of *The Playbook* as part of our commitment to advancing digital medicine and enabling the early adoption of digital tools.

Even the best manuals remain manuals until the content is applied to real life and yields a meaningful impact and results. Our goal with this digest is to provide exactly that, relating real-world experience demonstrating *The Playbook* in practice.

Koneksa provides a scientific research and technology platform that allows our customers and collaborators to deploy digital biomarkers and measures in clinical trials. One of our earliest productive collaborations was with Montefiore Medical Center. This partnership enabled the deployment of fitness trackers in oncology research, providing opportunities for enhancing clinical care delivery.

Clinical research and care delivery in cancer faces unique challenges. While treatment outcomes and disease management are well supported by imaging and lab tests, these measures provide little information about the patient experience of anticancer therapy. Understanding the patient journey becomes increasingly important as novel therapies are approved, putting oncologists and their patients in the position to have to choose among treatment options.

Case Study: Digital Biomarkers in Oncology

Dr. Nitin Ohri, Associate Professor in Radiation Oncology at Montefiore, developed the concept of measuring the physical activity level of patients using commercial fitness trackers and comparing that data to treatment outcomes. Monitoring activity is not new; oncologists have known for some time that less active patients do fare worse during anticancer treatments, which

often have serious side effects. This idea is also at the core of the performance status (PS), a physician rating scale assessing a patient's functional status to determine their eligibility for a clinical trial or to guide a choice of therapy.

As with any rating scale, PS carries a degree of subjectivity and represents a snapshot in time. To address these inherent shortcomings, Dr. Ohri wanted to monitor physical activity remotely, objectively, and systematically.

The selection of technology for the study was particularly important. Montefiore's local patient community is notably multiethnic and multilingual, with varying levels of proficiency in English. The majority of cancer patients are older. Therefore, this study required a device that could collect data as passively as possible and would not require advanced technology literacy.

Dr. Ohri offered his patients the option to wear a fitness tracker before, during, and after radio- or chemoradiotherapy. The technology was acceptable to users: patient compliance was 95%. Moreover, the results demonstrated that daily step count was a strong dynamic predictor of near-term hospitalizations (Ohri et al., 2017). These results were extremely well reproduced in a much larger cohort (Izmailova et al., 2019). Study data also showed inactive subjects with significantly shorter progression-free survival: 5.3 versus 18.3 months (Ohri et al., 2019). Notably, traditional instruments such as PS and a quality of life questionnaire were not predictive of hospitalizations.

In all, these studies indicated that daily step count was not only inexpensive, noninvasive, and easy to deploy, but offered a prognostic value, the potential to enhance care, and the opportunity to provide a more objective assessment of patients' functional status. In a follow-up to the Montefiore studies, the NRG Foundation will lead an upcoming multi-institutional randomized trial funded by PA CURE.

Conclusion

The results generated by our collaboration with Montefiore Medical Center provide an example of the meaningful aspects of health that digital medicine can enable; the risk of hospitalization

and the ability to be active are meaningful to patients and can have wide-ranging effects on their prognosis and overall physical and mental wellness.

The concept of interest (COI) demonstrated here is the continuous monitoring of physical activity, and the digital measure is daily step count (*The Playbook* slide 61). This is a combination of a new concept and a novel measure (Goldsack et al., 2020), which were carefully tailored to the context of use: capturing patient experiences and enhancing care delivery during anticancer treatments.

Koneksa plans to provide regular updates to our customers and the digital medicine community about Playbook-related research findings and real-life examples to support the continued growth of digital medicine.

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