Why PM1.0 Will Not Create Radical Health Care Change Prompting the Need for PM2.0

By Peter Keeling

Peter Keeling is an expert in personalized medicine and the CEO of Diaceutics, a company that specializes in the identification and validation of genetic tests for therapeutic targeting. As Diaceutics' CEO, Keeling has been a vocal proponent of the need for a move from PM1.0 to PM2.0, arguing that the current approach to personalized medicine is insufficient to drive the kind of transformative change that the healthcare industry needs.

The introduction of the concept of personalized medicine has been accompanied by a proliferation of terms like theranostics, pharmacogenetics, personalized healthcare, precision medicine and stratified medicine. However, Keeling argues, the concept of personalized medicine was often overhyped and constantly reshaped in favor of someone else's preferred definition. He believes that the current approach to personalized medicine, referred to as PM1.0, is not moving the field forward at the pace needed to address the health challenges of the 21st century.

Keeling points out that personalized medicine has been seen as a niche activity, only for those experimenting in oncology, or confused as an ersatz alternative to the standard drug development process. He argues that to drive up the cost of melanoma treatment, we need to focus on better early diagnostics, prognostic testing, and responder testing alongside supercomputers and social media and smartphone applications. This will empower patients and lead to a smarter future perspective of where the technology can go even if it is not there yet.

Keeling also highlights that in the majority of cases where a therapy will be commercialized with a test, it is the FDA or EMEA that are arbitrating on the choice of test, implying that the patient's best interest is often not the most important consideration. He argues that the incentives for PM1.0 have been unclear, and the financial uncertainties have disconnected building sites and stakeholders.

Keeling concludes that the concept of PM2.0 is needed to move personalized medicine beyond PM1.0 and create the conditions for a step past a "1.0" approach. The core of PM2.0 is the introduction of the concept of a total system in a disease. Specifically, to replicate a PM2.0 world, we have modeled the combined impact of better diagnostics, prognostics, responder testing, and the use of supercomputers and social media.

The key to PM2.0 is the integration of previously disparate stakeholders around that new trajectory. Keeling argues that the political returns to winning the cold war against the USSR were deemed enormous, and that the same approach is needed for personalized medicine. PM2.0 is not just about investing in new technologies; it is about investing in the systems that can enable the technology to be used effectively.

Keeling concludes by saying that personalized medicine is benefiting from an ever higher profile among professional investors and industry leaders as relating to a niche (read minor fringe activity), only for those experimenting in oncology, or confused as an ersatz alternative to the standard drug development process. He argues that the time is now for a full systems approach to personalized medicine, not just a partial system, if we are to deliver the called-for health care step change and provide the industrial rewards commensurate with the investment.

References:

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**Figure 1:** Melanoma PM2.0 clinical impact analysis.

**Figure 2:** Figure 1 illustrates marginal and transformative clinical impact of a systems integration model applied in one disease area (melanoma). We have replicated these models in infectious and metabolic disease and see similar profound impact.

**Figure 3:** Figure 2 describes the increases and decreases in costs in our Melanoma 2.0 model. What these models point to is that a systems integration in melanoma derived from better early diagnostics, prognostic testing and responder testing alongside supercomputers and social media and smartphone applications in patients' personalized health care empowerment is a significant force for change and is in line with the need for a move toward PM2.0.

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