

## Between Prevention and Treatment

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The significance of early detection is almost universally recognized. As technology becomes increasingly more sophisticated, the ability to detect disease earlier in its progression is rapidly becoming a reality for many of the diseases where early detection is considered to be essential to good outcomes. Even for diseases where no treatment is available, emphasis is being placed on early detection as a promising route to the development of effective treatment [1]. New technologies for early detection are being developed that raise similar challenges as well as new ones. For example, possible uses of synthetic biology in the realization of the capability to detect and intervene on the basis of biochemical markers indicative of pathology will signal a shift in the boundaries of therapy. In essence, as a theranostic technology (therapy and diagnosis), synthetic biology integrated with converging technologies could operate as an internal “biophysician”, performing both diagnostic and therapeutic functions. However, this development comes with multiple complexities, not the least of which is for the concept of disease and illness [2]. If an internal mechanism effects cure upon manifestation of emerging pathology, the “disease” never actually materializes since the biochemical markers trigger cure, thus arresting the development to frank onset of disease. So we either must regard this as treating pre-disease or we must expand the scope of what we regard as disease.

While the development of synthetic chemical structures that are effective in preventing onset and/or recurrence may signal a major development in the promotion and maintenance of health and well-being, it fundamentally alters the concept of therapy, which traditionally has required the onset of disease before the administration of treatment. Unlike treating high blood pressure, which itself is a malfunction, some biochemical markers are less clearly pathological although they may be indicative of pathology. The potential shift that this technology could facilitate is significant and as research proceeds, critical questions must be asked about both the underlying research process (e.g. selection of appropriate participants) and integration into the healthcare system if the technology proves successful.

One of the greatest challenges for this earliest detection technology emerges from the nature of disease, or at least what we know and do not know about it. More complex applications of theranostic technology could attempt to address multi-factorial disease, only part of which may be targeted, albeit effectively, by internally acting detect-and-treat technologies. Thus, the ultimate success of the theranostic technology will also rest on the extent to which it can accommodate the complexity of disease onset and progression that does not follow the cascade model [3].

Of course, some applications do not necessarily invoke this ambiguity in classification. For example, in the case of recurrent disease e.g. prostate cancer, early detection of recurrence plays a pivotal role in prognoses. Thus, internal biochemical detection and treatment, e.g. for specific types of tumors presents different types of complexity [4]. One of the greatest challenges for this type of technology is specificity, which, again, forces questions about selection of appropriate clinical trial participants to the forefront.

Theranostics, as one of the technologies that is likely to incorporate synthetic biology, could very well affect the concept of disease and

illness, and thus potentially many of our institutional practices and procedures. Consequently, theranostics, a biomedical approach standing between prevention and treatment, could forebode significant changes in health care and its underlying concepts. Yet, several hurdles currently stand between research (fundamental and translational) and optimal integration and uptake should the technology prove successful.

Would current general approaches to selection of trial participants (e.g. “last hope” or healthy) provide appropriate frameworks for theranostic technologies and, if so, for which diseases? Who will prove appropriate candidates for theranostic interventions that presumably will come at considerable cost? The promise of theranostic technology is a complex one that will present major challenges for clinical research and the practice of medicine. Indeed, while the pressing ethical dilemmas of current biomedical technology surround us, those on the horizon also call for attention, perhaps also providing opportunities for adjustments and modifications while still in development.

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