

The Translation of Tissue Engineering Strategies to Clinical Practice

Michael J Yaszemski, M.D., Ph.D

The introduction of novel treatments to clinical practice begins with a clear description of either a gap in the current treatment for a condition, or a treatment that is not yet optimal for the condition that it addresses. This clinical need is studied in the research lab and is then translated back to clinical practice. The process by which this bedside to bench and back cycle occurs is one of continuous improvement that has well defined components. These include preclinical basic and animal studies, the development of standards where none currently exist, funding from governmental or private sources, protection of intellectual property, good laboratory practices, medical-industry interactions, good manufacturing practices, clinical trials, regulatory approval and oversight, coverage determination by the Centers for Medicare and Medicaid Services as well as by private payers, disclosure and management of conflicts of interest in research and clinical practice, and, ultimately, adoption by physicians in the treatment of their patients. The combination of scaffolds, cells, and bioactive molecules that are present in many tissue engineering applications frequently present new challenges in many of the steps mentioned above.