Designing Medical Devices for the Developing World: Best Practices and Hands-on Approaches in D-Lab Health

Amit Srivastava
Children's Hospital, Boston

Priyanka Jain, Shichao Liang, Allen Lin, Deepali Ravel, Yi Wang, and Jose Gomez-Marquez
Massachusetts Institute of Technology

The design of medical technologies for developing countries is a multidisciplinary process. We describe a model process for an appropriate medical device design. D-Lab Health combines real world projects and partners with a diverse student team to provide experiential educational opportunities in a developing country health care setting; in turn, the partners benefit from student medical device designs. In order to effectively communicate practical design strategies toward an appropriate design for medical technology, a series of accelerated technology learning modules was developed using commercially available and customized medical devices. Each module included a formal framework for the students to think about the competing priorities of the user, chooser, payer, and approver of such global health technologies, christened the "global health innovation compass." These modules provided a hands-on laboratory experience that demystified the design process. This was particularly useful for nonengineering students who were able to add value to the project through their life-sciences background. An essential component of the course was a weeklong visit to our field partners in Nicaragua to enable the students to get first hand experience and to identify a health need they could address with a technology solution. Subsequently, the students utilized their hands-on training to develop medical device prototypes within an abbreviated production schedule of 3 weeks. We describe the design process for one such prototype "a low cost glucometer."

A Device and Methodology for Continuous Hypothermic Perfusion of Explanted Large Mammalian Hearts, Followed by In Vitro Langendorff Reanimation: Pilot Studies

Robin M. Brusen, Christopher D. Rolfes, Stephen A. Howard, Michael G. Bateman, and Paul A. Iaizzo
University of Minnesota

The current methodologies of clinical heart transplantation limit the ischemic window to 4–6 h. Periods longer than this can induce dysfunction in the organ and can lead to increased patient morbidity and mortality. An alternative to the current methods of static cold storage (CS) is continuous hypothermic perfusion (CHP), where a hypothermic oxygenated crystalloid solution is mechanically perfused through the coronary arteries. This has been shown to preserve the function for up to 72 h, but the techniques have yet to be optimized. We have developed an apparatus and methodology for performing CHP on large mammalian hearts, followed by reanimation in our in vitro Langendorff apparatus (The Visible Heart™). We are also investigating the utility of the cardioprotective agents docosahexaenoic acid and [D-Ala2, D-Leu5] enkephalin, both of which have shown cardioprotective effects in our laboratory, and we believe that their addition to the preservation solution can further extend the transplant window. A series of pilot studies has been performed to date, with modestly successful results. Hearts preserved with CHP seem to show better functionality than CS hearts but far worse functionality than hearts reanimated immediately after explant. We hope to use this system to optimize CHP methodology and eventually develop a system for prolonging the window for heart transplantation.