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Commentary: The swing of the pendulum between innovation and regulation

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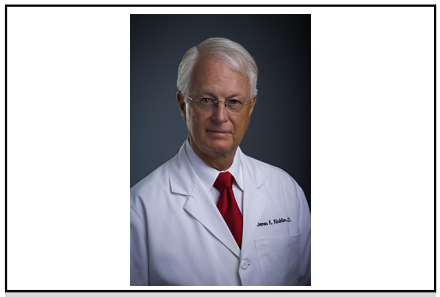

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CENTRAL MESSAGE

The balance between emphasis on quality assessment for patient protection and encouragement of innovation must be thoughtfully considered for the field of MCS to flourish.

Hanke and colleagues[1] have provided an excellent overview and commentary on innovations, including alternative surgical strategies, in the field of continuous flow left ventricular assist devices (LVADs). Some areas of their review are worthy of additional comment. In a very informative section, they refer to the 4 subtypes of innovation. These are timely comments in the current environment of quality assurance, ranking of hospitals, and the focus on observed deaths to expected deaths. Throughout the brief history of cardiac surgery, we have always struggled with the proper balance between innovation and quality assurance. Many would argue that the pendulum has currently moved a bit too far in the direction of regulation. In the word of congenital heart surgery, for example, the obsession with *US News and World Report* program rankings, based in part on publically reported outcomes, has perhaps led some programs to become risk averse and focus away from surgical innovation (with the potential for adverse outcomes). On the other hand, demand for quality is paramount in protecting patients. The interest in alternative surgical strategies for LVAD implantation is an excellent example. As the authors state, "…the regulatory oversight for the application of new surgical techniques is rather nonexistent." It is well established that the sine qua non of a quality implant technique is optimal positioning of the inflow cannula such that there is minimal flow disturbance from mitral valve inflow into the device. When alternative anatomic approaches are employed, we must not lose sight of the fact that a powerful source of morbidity is an inflow cannula which is partially obstructive to inflow. Thorough assessment for cannula position and flow characteristics should be mandatory for all LVAD operations.

The authors also underscore the need for continued innovation in device technology. It could be argued that Medtronic's (Minneapolis, Minn) decision to discontinue production of the HVAD device has dealt an important blow to the pediatrics community. The larger size of the HM3 LVAD (Medtronic) has left an important group of pediatric patients (those younger than about age 10 years) without a suitable device that is size appropriate. This is particularly disheartening given the good results achieved with the HVAD in pediatric patients.[2] The need for an effective device smaller than the HM3 is clearly present, but has this decision by Medtronic, a device company giant, dampened the enthusiasm of young innovative engineers who may perceive the current environment to be less tolerant for any missteps while engaging in disruptive innovation?

Finally, perhaps among the most challenging and needed innovations relates to prevention of adverse events (the primary drivers of mortality and quality of life during support), which often seem immutable with current continuous flow

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LVADs.[3] Certainly the lack of physiologic pulsatility has created a milieu that is favorable for gastrointestinal bleeding and intracerebral hemorrhage, with potentially profound consequences.[4] The ability to predict these serious adverse events by examining a patient's substrate complexities (perhaps identified through innovative analytics) and impose preventive strategies through management of these physiologic perturbations would have a major influence on the overall acceptance and application of these life-saving devices.

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