FEATURE

# Eight Steps to Medical Innovation in Pediatric CHD

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In presenting the Mullins Lecture, James E. Lock, MD, Boston Children's Hospital and Harvard Medical School, Boston, Massachusetts, USA, addressed the need for innovations in pediatric congenital heart disease (CHD) therapy and considered the key rules that are associated with achieving this.

Drawing on his own clinical experiences, Dr. Lock discussed medical innovation, in pediatric CHD or any specialty, as a multistage process, defining 8 important steps required to allow breakthroughs to deliver improved clinical capabilities.

## REVIEW THE LITERATURE

An initial, thorough review of the medical literature—at least 50 papers—is a vital step for any researcher embarking on an innovative project. Dr. Lock emphasized the need to avoid focusing excessively on the recent literature, because often the most important information can be found in the oldest publications. Because innovation commonly links unrelated topics, he stressed the significance of not limiting a literature review to directly related subject matter. For instance, when they performed their first transcatheter ventricular septal defect closure, Dr. Lock and colleagues were able to avoid using blade pulmonary valvotomy after reviewing data from a 1953 paper by Rubio-Alvarez and colleagues. The technique appeared successful in 1 case described in the paper, but there was an overall lack of evidence for improved patient outcomes using this procedure due to a lack of success in 3 additional patients.

## DEVELOP ANIMAL MODELS

Animal models remain a vital component of innovation, and wherever possible, they should be used to evaluate a new procedure. Dr. Lock referred to a neonatal lamb model of branch pulmonary artery stenosis as one of the most important models with which he has been involved. It demonstrated that balloon angioplasty works in the absence of atherosclerosis by means of a controlled tear of the vessel's tunica intima and part of the media, and it formed the basis of efforts to perform a successful angioplasty.

However, animal models have limitations and often fail to work as planned. They must sufficiently mimic the human disease to be relevant, so it is important to take into account key differences in anatomy and physiology between humans and the animal species under consideration. For example, thrombophilia occurs more readily in sheep than humans.

## CONSULT WITH COLLEAGUES

Establishing and maintaining an extensive consultation network with colleagues is an essential aspect of innovating success. Cooperation and collaboration with experts in different medical specialties—such as surgeons for hybrid procedures, electrophysiologists for ablation, and anesthesiologists for high-risk interventions—are important, not only in propelling an innovative idea but also in building political consensus for it.

## MAKE A LIST

Dr. Lock stressed the need to avoid focusing narrowly on one particular approach to the problem. Instead, he advised that innovators must formulate as long a list as possible of potential approaches to the problem and evaluate them thoroughly before choosing one. When starting to perform fetal aortic valve interventions, for instance, Dr. Lock and his team selected their preferred imaging technique, approach to fetal rotation, catheter access route, and cannula type after careful consideration of all available options.

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### SELECT YOUR FIRST CASE CAREFULLY

To maximize the chance of procedural success, Dr. Lock also highlighted the importance of picking the first patient very carefully, stating that many people fail to consider this. Wherever possible, a new procedure should first be performed on a patient with a serious medical problem for which there are few, if any, treatment options available. The patient's family must also be strongly supportive of using the innovative procedure, which should itself be a technically straightforward one. It should also be performed with existing tools that can be subsequently modified as necessary, because any protocol will need to be refined after its first use.

### USE PEER REVIEW FOR REGULATORY APPROVAL

Protocols for first-in-human procedures should be submitted for peer review to determine whether the risk/benefit ratio favors performing a technique that has not been done before. Instead of an institutional review board–generated protocol, this should be a patient-specific—not patient-generic—and procedure-specific review. Uninvolved peers should be used to determine whether it is in the patient's best interest to undergo the new procedure. This type of regulatory approval is well accepted by regulatory agencies and institutional leadership.

### PERFORM A MOCK DRILL

It is also essential to perform a thorough mock drill of the technique in advance of performing it in the first patient. Although it is impossible to anticipate all problems in advance, this exercise will enable you to see some of the issues that can potentially arise, and determine how you should respond to them, thereby improving the likelihood of procedural success in the patient.

### BE SURE TO SUCCEED

It is imperative to have a successful first case involving a new procedure. Although failure is more bearable in end-stage patients, in whom comorbid diseases greatly reduce the chances of success, it is devastating in cases in which patients have other treatment options. Also, if the procedure fails in the first patient, it becomes increasingly difficult to obtain permission to perform the procedure in future cases, and this sets back progress in the field significantly.

In addition to the need to be honest and self-critical to maintain credibility and reduce the risk for making a mistake more than once, Dr. Lock stressed the importance of sharing the credit for success with all colleagues involved. Concluding that nothing succeeds like success, he also advised against publishing single case reports of first-in-human procedures, because of the steep learning curve between the first and subsequent cases.

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