

Exchange

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Really Getting to the Heart of the Matter

In the University of Minnesota's Visible Heart® Laboratory (supported by the University and Medtronic), the unseen becomes the seen. By becoming accessible, though, the functional anatomy of the human heart is visibly astonishing. The technology developed here on campus has illuminated mysteries, educated medical practitioners, informed product development, and very likely saved lives—still, it seems no one remains more awed by the experience than Dr. Paul Iaizzo, the Visible Heart® Lab and Lillehei Heart Institute's director. In his new technical review paper with Dr. Michael G. Bateman, Iaizzo's passion and knowledge come pulsing through as he explores the applications of Visible Heart® imaging to date and their consequences for researchers and patients.

Inside the labs at the Medical School's Department of Surgery, Iaizzo and his team have worked to reanimate mammalian hearts—often pig but also human hearts, those deemed non-viable for transplant but certainly viable for scientific advancement—and to capture video and still images. Together, the resulting visualizations make up an invaluable free access website or medical library of imagery that is available to surgeons, student, teachers, and biomedical engineers or anyone who goes online (<http://www.vhlab.umn.edu/atlas/>) courtesy of the Lab and another of its partners, LifeSource. To summarize that breadth of experience and data would seem an insurmountable task, even for researchers who spend their days (and nights) navigating vital organs. But Iaizzo and Bateman accomplish this with brevity and clarity in the journal *Cardiovascular Diagnosis and Therapy*.

"The study of reanimated large mammalian hearts... has enhanced the design, development, and testing of novel cardiac therapies," Iaizzo and Bateman write—an understatement, but an important point. "Pivotal to these advances has been significant improvements in cardiac imaging." That is, when it comes to creating better outcomes for patients, getting a good view through photos, video, and

even 3-D printer models of thousands of hearts has been key to assessing prototypes for new technologies and surgical approaches to different types and stages of heart disease. The work Iaizzo, his colleagues, and his students are doing right here in the Twin Cities is driving this knowledge.

The resulting visual catalog, presented online at "The Atlas of Human Cardiac Anatomy," "is an open resource, which continues to provide researchers with important insights," and, the authors assert, "The Visible Heart® model has provided our scientists, engineers, and clinical collaborators with an innovative heart model to better understand how the dynamic forces and complex anatomic structures of the heart interact with a broad range of cardiac devices... We are continually in the process of enhancing the overall utility of our system and methodologies."

The Lab has also created a physical library of over 300 human heart specimens, most of which have been perfusion-fixed so to preserve their end-diastolic shape (as if they were full of blood). As the Lab moves forward in developing and improving imaging of these specimens employing MRI and CT imaging modalities as well as static endoscopic images, so to optimize the creation of 3-D models, they believe their work "may also provide a 'glimpse into the future'" of hybrid operating rooms and support the ongoing creation of cutting-edge cardiac technologies. As Iaizzo told the University of Minnesota's *Medical Bulletin* last year, "We get thank-you letters from anatomists all over the world." Further, he says "it's a huge privilege" to be able to glean as much information as possible from each specimen and, in turn, use those insights to inform work around the globe. We are highly motivated by the generous gifts of these specimens from the organ donors and their families: we try to maximize the knowledge we gleam and share from each specimen.

In a BBC spot titled "How to Mend a Broken Heart," available on YouTube, an astonished reporter looks on as Iaizzo demonstrates how to reanimate a pig's heart, then dims the lights to

About

Exchange, a publication from the Medical Industry Leadership Institute, features dialogue on medical industry research and application. The content is a summary of research from both academia and the medical industry, followed by commentary on the importance of the research and its application. Topics highlighted in the *Exchange* span all sectors of the medical industry and include commentary from leaders in the field, as well as researchers from the University of Minnesota and other academic institutions.

better see the live images coming from inside the beating organ. "It is like a 'Fantastic Voyage' every time," Iaizzo enthuses, "and it's a different voyage in every heart." The reporter says excitedly, "Seeing the heart like this makes me appreciate what it is we're trying to mend. These inner workings are like no piece of engineering I've ever seen." These days, the sentiment still rings true. But the view? That's available, courtesy the Visible Heart® Lab.



Paul Iaizzo is a Professor of Surgery, Integrative Biology & Physiology, and also instructs courses at the Carlson School of Management at the University of

Minnesota. He is also the Associate Director of the Institute for Engineering in Medicine (IEM), the Medtronic Professor of Visible Heart® Research, the Director for Education of the Lillehei Institute, and the Director of the Malignant Hyperthermia Muscle Biopsy Center at the University. He earned his degrees in biology and physiology at the University of Minnesota and held post-doc positions with the Mayo Clinic (funded by the National Institutes of Health) and the Technical University of Munich. A global educator, Iaizzo's service is nowhere more prominent than at the University of Minnesota, where he was recently honored by being inducted into IEM's "Academy of Medical Device Innovators" (<http://www.iem.umn.edu/innovators/index.html>). ■

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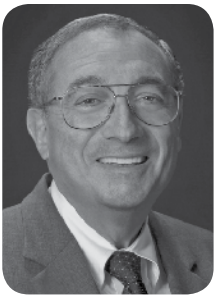
Exchange—A dialogue on medical industry research and application

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Commentary

by *Richard A. Justman, MD, National Medical Director for Medical Policy Development, UnitedHealthcare*



In *Really Getting to the Heart of the Matter*, a glimpse into Dr. Paul Iaizzo's Visible Heart® Lab demonstrates some of the possibilities of advanced cardiac imaging in improving treatment of persons with heart disease. However, to level set, all medical technologies, including those that identify and treat heart disease,

must achieve the Triple Aim of better health, better care (including a better patient experience), and lower cost. How well does advanced cardiac imaging achieve the Triple Aim?

Coronary CT angiography (CCTA) was introduced several years ago with the promise that it might replace more invasive procedures, obviate the need for additional testing, make it easier to discern cardiac chest pain from non-cardiac pain, make the management of chest pain in Emergency Departments more efficient, and reduce the cost of managing acute coronary syndrome (ACS). Device manufacturers marketing the technology enthusiastically embraced these assumptions.

The Rule Out Myocardial Infarction Using Computer Assisted Tomography II (ROMICAT-II) study was published in the *New England Journal of Medicine* on July 26, 2012 (N Engl J Med, 367:4, July 26, 2012). This well-designed, randomized controlled trial (RCT) studied the use of CCTA in the Emergency Department as part of a triage strategy to evaluate chest pain. Some of the results were expected, but some were surprising. As expected, CCTA made the triage of chest pain more efficient. However, participants in the CCTA group had more downstream testing, increased radiation exposure, and saw no decrease in the overall cost of care. The study may not be the final word on the efficacy of CCTA, but

at this point, its use in emergency care does not appear to achieve better health, better care, or lower cost (let alone all three)

The lesson I take from this study is that *all* new medical technologies must be subjected to rigorous, evidence-based review. We must learn not only whether and how they work, but also how they compare to available services used to manage important health conditions like heart disease. Cardiac imaging, illuminating as it is, will still have to pass the Triple Aim test before earning its spot among other approaches to cardiac care.

Dick Justman is national medical director of UnitedHealthcare, a national health service delivery company. Dick is accountable for medical technology assessment, clinical support of pharmacy programs and clinical support of benefit administration. He has been with UnitedHealthcare since 1993. Dick received his bachelor's degree from Cornell University and his MD degree from the State University of New York at Buffalo. He is board-certified in pediatrics, and received his postgraduate training at The University of Chicago Hospitals and Clinics and the Johns Hopkins Hospital. Dick practiced pediatrics in Minneapolis, Minnesota for fifteen years before joining UnitedHealthcare.

He has served on the Institute of Medicine Forum on Drug Discovery, Development and Translation; the Institute of Medicine Committee to Identify Highly Effective Clinical Services; the American Medical Association CPT-5 Project; the American Medical Association Initiative to Transform Medical Education (ITME); and an expert panel developing an Evidence Report on diabetes education for children with type I diabetes, commissioned by the Agency for Healthcare Research and Quality (AHRQ). Dick served two terms on the AHRQ Stakeholders' Panel for its Effective Health Care program. ■