Physician – Engineering Collaboration

Kevin E. Bennet

The collaboration between physician and engineer is critical for the effective development of new devices and systems for the medical environment. There are a number of methods of collaborative practice in industry, and most physician/engineering collaboration is between structurally different organizations in which there are a variety of economic, social, and behavioral barriers to effective communication. Mayo Clinic has embedded engineers in patient care, research, medicine, and surgery, in order to create new devices and systems which are tailored directly to the needs of medical care and patients. The organization has electrical, mechanical, biomedical, software and chemical engineers as well as technologists, machinists and a glassblower combined in a Division of Engineering that concentrates on novel developments. The Mayo engineering staff collaborates with over sixty departments and divisions and hundreds of physicians, creating devices and instrumentation sometimes with additional collaboration with companies and research institutions around the world. Protecting intellectual property is critical so that the innovations can be brought to market for the ultimate benefit of the patient.

Background

The Division of Engineering at Mayo Clinic has been an embedded engineering organization whose roots can be traced to 1915, where engineers and technologists have been collaborating with physicians, surgeons, and scientist to create and deploy devices and instrumentation for the benefit of patients [1].

Mayo Clinic is originally located in Rochester, Minnesota with other major locations in Scottsdale, Arizona and Jacksonville, Florida. The Clinic is celebrating its 150th anniversary this year. It has revenues of over $8 billion and has 4,100 physicians and scientists and over 61 000 employees. The organization is developed around a model of committee governance and salaried staff and is designed to be collaborative in nature.

The division of engineering was created from an instrument shop founded in 1915, and during the 1940s added engineers to the staff for collaboration in development of devices and systems. To ensure the Division of Engineering can concentrate on novel devices and systems, the Clinic has an additional staff of 200 individuals responsible for equipment maintenance. Further, while the division does create software primarily for embedded systems, the Clinic does have 600 other programmers for development and maintenance of the clinical and business systems.

Collaboration with the division is open to any staff member, and many more ideas and problems are brought to engineering than can possibly be completed based upon the staffing and budget of the group. Much of the organization is maintained by a budget allocated from the Clinic, and additional funds are available from direct grants to the organization or grants to collaborators. A prioritization process was developed to help the organization and collaborators decide what projects should move forward. The challenge is not to discover areas in need of engineering innovation but to select the highly valuable projects and collaborators to set the stage for clinical success. Fig. 1 is an example of an engineering innovation that converts the open-heart surgical procedure to replace cordae, to minimally invasive surgery. Cordae are the tendons that ensure mitral valve operation.

Collaboration

The division has found that close collaboration from the initiation of the project to the use and/or commercialization of the

1094-6969/14/$25.00©2014IEEE

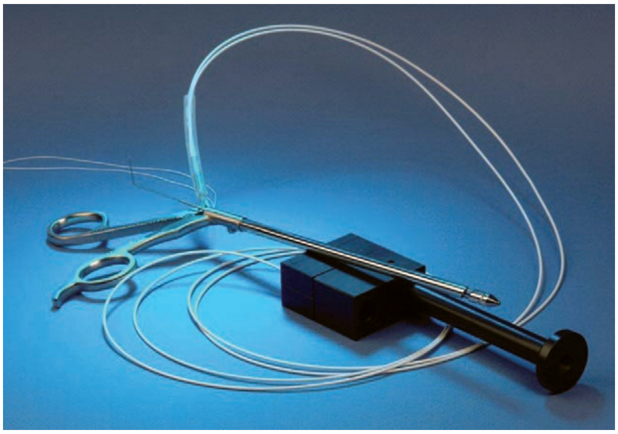

Fig. 1. This device is an engineering innovation that was developed to use in a minimally invasive surgical procedure versus an open-heart surgical procedure to replace cordae tendons. Cordae are tendons that control the mitral valve

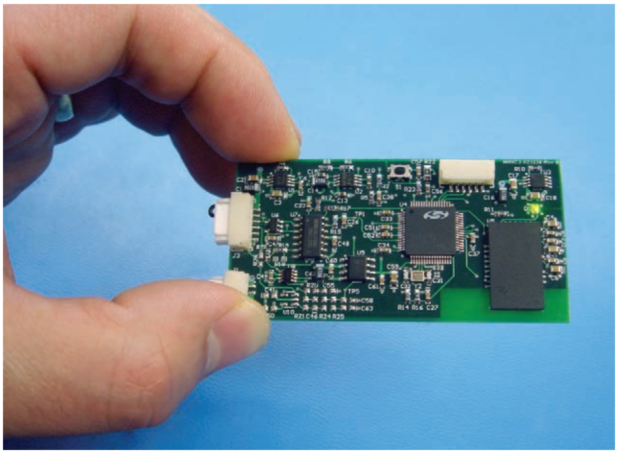

Fig. 2. A rack of electronic instruments that measured brain neurotransmitters was condensed to this small circuit board with multiple protection circuits.

resulting device or system is critical for the success of the project. The dynamic range of collaboration can be a few hours of consultation or many projects over many years.

Further, we have differentiated research from engineering in that research would be the discovery or elucidation of natural phenomenon and is highly open ended, while engineering would be the creation of a device or system that satisfies specific use cases and project need. While collaboration with certain clinicians or laboratories may continue for decades, engineering involvement is project-oriented with specific deliverables, budgets, and timelines. Fig. 2 is an example of an engineering project that condensed a rack of electronic instruments that measure brain neurotransmitters to a small circuit board with multiple protection circuits, and that will ultimately be converted to an integrated-circuit implantable device. Once completed, the projects are turned over to the laboratory or used in clinical practice, and at a later point in time, the devices or systems can be refined to better supply a more optimum solution to the problem and issues.

By being a part of the Clinic, engineering staff are available to participate in research meetings, surgical procedures, hallway discussions and other focused and ad hoc meetings. Further, other groups with varied skills such as finance can be brought into the mix to examine how a new treatment could be reimbursed or the commercialization group can evaluate patent positions, freedom to operate, as well as licensing and commercialization issues at the end of the projects.

The engineering staff brings a multi-disciplinary team to bear on the project. This includes project managers to provide direction and continuity, an engineering staff (electrical, mechanical, biomedical, chemical engineers) that brings many different perspectives and skills from engineering experiences, software engineers (GUI vs embedded skills), technicians, designers, machinists, glassblowers, as well as a host of students and post-docs.

In addition to good engineering practice, the needs of healthcare include a variety of safety regulations and standards such as the Health Insurance Portability and Accountability Act (HIPAA), ASTM Medical Device Standards and Implant Standards [2], the Federal Food and Drug Administration (FDA) [3], AAMI and ANSI standards, and harmonized IEC standards including UL 60601-1. The staff needs a working knowledge of these standards to ensure patient safety and prevent redesigning a product if commercialization is appropriate.

Engineering within Medical Care

The value that engineering can provide to medicine is substantial. It has been estimated that health care systems failures result in 100 000 deaths and one million injuries each year [4]. First and foremost is the value in the ability to provide devices and systems to improve the outcomes of medicine and surgery. Since much of healthcare is management of information and creation of knowledge, the combination of disparate pieces of information allows determination of problem and identification of solution. Improvements in communication and speed with which procedures and tests are performed and correlated lead to a reduction in hospital stays, which results in lower costs and less risk of nosocomial (hospital derived) infections. For example, processes that ease transition and communication of information allow the use of reflexive testing, resulting in improved outcomes, reduced hospital stays, and result in lower costs. We have found that the identification of problems in medical care is rather straightforward. The challenge is to sort through the vast number of problems and define the issues such that discovery, innovation, and invention can occur, while allowing the planning of testing and demonstration to prepare for clinical trials and FDA approval.

Medicine is a different market than most, since the consumers of the medical care are in most cases not the purchaser of the services. Cost and waste reduction are paramount in this industry. A system or device that can replace a currently used product will typically not be successful unless it can reduce the overall cost of service. New commercial offerings that improve outcomes without reducing cost are difficult to introduce into the market. Management of the hundreds of thousands of medical and laboratory specimens that are generated has been

Fig. 3. An image-based tracking system that automatically catalogue physical specimens in trays for later accurate retrieval.

a chronic problem. A solution is an image-based tracking system that was designed to automatically catalogue physical specimens in trays for accurate later retrieval (Fig. 3).

Collaborative Plan

As an integral part of the technology development, there are very important aspects of the plan that are uniquely provided by the engineering talent. The engineering staff owns the overall project management, in that many engineers have experience and education to plan the work effort and calculate resource requirements of the project to ensure that the timeline and budget are reasonable and are determined before the project is initiated so that resource constraints can be accommodated. The key to success is the requirements analysis and functional specifications which can only be developed adequately by involving the end users from the start of the planning process, ensuring that the conditions under which the device or system is used are understood and the outcome fits the operations environment.

The testing, safety analysis and validation of the device or system is critical for success, since the safety of the patient when the device or system is used is paramount. This is not to say that all of the devices or systems are inherently safe since in many cases the implantable or surgical device must be introduced in the body in a way that cannot be safe, but it is incumbent upon the engineering staff to make the device as safe as possible while delivering the treatment. For example, the minimally invasive heart valve repair device must penetrate the heart and operate in a very electrically sensitive area of the body.

The engineering staff uses its skills and knowledge to mitigate the safety issues and must enlist medical professionals to determine whether the remaining risk is worth the expected outcome. An education plan must be developed to train the users of the device or system. A plan to roll out the device in medical or surgical practice must be developed, as well as the conditions of use. The device is then evaluated by protocol and revised appropriately. The key to success is to ensure that the device meets the requirements and control is maintained upon revisions, such that the devices and systems are actually trialed rather than be in a continued state of requirements creep. The following outline reviews the steps necessary to promote smooth and successful production of a new device:

- Overall project management
- Requirements analysis and functional specifications, involving end users from the start
- Design and fabrication of prototype devices
- Testing, safety analysis and validation
- Education
- Roll out
- Use
- Revision (as a new project)

Neurosurgery Example

In 2006, Kendall Lee, MD, PhD joined the neurosurgical staff of the Mayo Clinic and devoted half of his time to research. His interest was the possibility of improving the science and technology of deep brain stimulation (DBS). Since its development in the 1980s, DBS had been effectively deployed in tremor disorders but without full understanding of the mechanism of action. Further, Dr. Lee was interested in measuring feedback such that DBS stimulation would be controlled by measuring the neurochemical output of the stimulation. While these concepts have a long and successful history in a variety of technological areas, they had not been employed within medicine for the measurement and control of DBS.

Dr. Lee met with the author to discuss potential collaborative projects, and the potential value to the patient of the feedback loop became very apparent. Utilizing a variety of techniques, a plan for the future development and joint development was derived. With the foundation of the Neural Engineering Laboratory jointly directed by Lee (neurosurgeon) and Kevin E. Bennet (engineer), the staff has grown to 23 research scientists and engineers. In collaboration, over 20 members of the Division of Engineering have worked on discovery, design, and fabrication of a variety of projects. These include specialized head frames (Fig. 4) for electrode implantation, wireless neurotransmitter detectors, custom integrated circuits, algorithms to separate the neurotransmitter signals from the other brain activity and diamond based

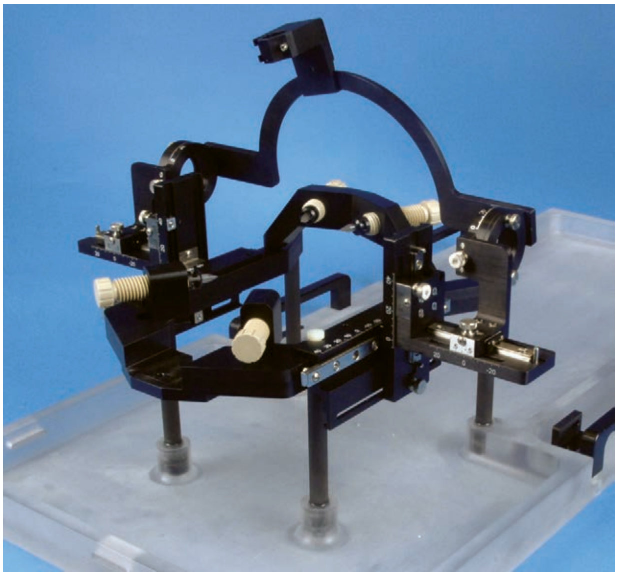

Fig. 4. A specialized head frame.

neurotransmitter detectors. Engineers have participated in many neurosurgeries to better understand the operating room environment as well as the biological and human needs of the patient.

Conclusion

The close collaboration of physicians and engineers provides many opportunities for innovation and improvement in devices and systems for medical care. Physicians typically utilize a teaching mode of communications when they speak with their patients and tailor their explanation to the experience and educational level of their patients. We find that this communication technique works well in engineering collaborations even though most physicians do not have an engineering background and most engineers do not have medical experience. The selection of the collaborators is critical for success, not unlike collaboration across differing engineering or science disciplines. We embed our engineering group within the medical practice for long-term relationships. Definition of the project and working from first principals are keys to success, such that the problems are explored rather than working on solutions based upon known or unknown biases of the proponents.

We hope to see many more collaborations between those involved in medical care and engineering, leading to novel solutions to the real problems of the patients. There is an urgency to complete devices and systems and get them into clinical practice since *the patients are waiting*.

References

[1] "60 Years of Engineering Innovation Teamwork among Physicians, Researchers & Engineers," MC2066-14, Mayo Clinic, Rochester, MN, USA, 2008.

[2] *ASTM Medical Device Standards and Implant Standards*, 2014. [Online]. Available: http://www.astm.org/Standards/medical-device-and-implant-standards.html.

[3] *FDA Medical Devices,* 2014. [Online]. Available: http://www.fda.gov/MedicalDevices/default.htm.

[4] Committee on Quality of Health Care in America, Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century*. National Academies Press: Washington DC, USA, 2001.

Kevin E. Bennet (kbennet@mayo.edu) received a B.S. degree in Chemical Engineering from MIT and an MBA from Harvard University. He is Chair of the Division of Engineering of the Mayo Clinic of Rochester, MN, Assistant Professor of Neurosurgery and co-Director of the Neural Engineering Laboratory of Neurologic Surgery. His division collaboratively develops and applies new technology for clinical practice and research and efforts include deep brain stimulation, wireless physiological monitoring and minimally invasive surgery. Mr. Bennet joined the Mayo Clinic in 1990 with current and past appointments as Chair of Strategic Alliances, Vice Chair of Information Technology Standards & Architecture Subcommittee, Clinical Practice Committee Equipment Subcommittee, Information Technology Coordinating Executive Committee, Pharmacy and Therapeutics Committee, and Medical/Industry Relations Committee as well as chair and membership in various workgroups and taskforces. He has also served as a reviewer of *Mayo Clinic Proceedings* and the National Institutes of Health (NIH) Small Business Innovation Research program. He has over 30 years of experience in technology development, holds patents concerning semiconductor and optical technology, and has founded several technology-based companies.