



## Institutional Innovation

## Surgical innovation as the driver of change in academic surgery

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## Introduction

For centuries, academic departments of surgery have been charged with the management of surgical knowledge. This has been accomplished through the following: application, providing the highest quality surgical care; training, educating medical students, residents, fellows, and faculty; discovery, advancing the practice of surgery; and dissemination, improving the health of the community. To fulfill this responsibility, leaders of academic departments of surgery have leveraged a wide range of human, structural, and relational knowledge and skills—their intellectual capital.

This process has been stressed by today's economic environment. Academic surgeons are increasingly pressured to generate greater financial returns through clinical activities to support medical center activities. On the positive side, this has spurred a subtle but real cultural change within the field of academic surgery, including an increased focus on developing additional revenue streams via surgical innovation and entrepreneurship.

In short, most modern academic departments of surgery now realize that they must take advantage of their intellectual capital to explore, develop, and capitalize on leading-edge ideas. This mandates outreach to and collaboration with multiple components of universities and the community, such as departments of engineering, design institutes, industry, and entrepreneurs. It is our fervent belief that these important alliances will continue to drive change in academic surgery.

*Benefits of innovative intellectual capital to departments of surgery*

To foster a culture of innovation in an academic surgery department is advantageous. Entrepreneurial activity can enhance

student, resident, fellow, and faculty scholarship and prestige. Contrary to common wisdom, entrepreneurial activity and industry partnerships do not promote a movement away from careers in academia and do not emphasize commercial outcomes to the detriment of more fundamental research. A recent study of 6,840 science and engineering doctoral students at 39 US universities demonstrated that basic science research activity, the number of publications, and interest in an academic career were not significantly different between labs that encouraged entrepreneurship and labs that did not.<sup>1</sup> In addition, labs that encouraged entrepreneurship were more likely to report invention disclosures.<sup>1</sup> Seen this way, it can be argued that a focus on innovation nurtures discovery and development at all levels.

Undoubtedly, the opportunities for revenue generation are immense. The passing of the Bayh-Dole Act in 1980 allowed universities, nonprofit institutions, and small businesses to maintain ownership of their federally funded intellectual property. The ensuing financial returns with licensing income and royalties have been remarkable. Although federal, industrial, and other research funding remained effectively stable between 2012 and 2016, licensing income increased by 13% to almost \$3 billion in 2016, according to the annual Association of University Technology Managers (AUTM) Licensing Activity Survey.<sup>2</sup> Running royalties, cashed-in equity, lump sums and fees, and other gross income have also risen exponentially. Overall, research institutions received equity from almost half of all of the startups formed in 2016 alone.<sup>2</sup> At a time of declining reimbursement per unit for clinical activities, these activities can provide much needed unrestricted funds for departmental academic support and reinvestment.

Academic surgical innovation also exposes numerous other avenues for research funding. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are additional federal sources of funding for academic surgery departments. Under these programs, small businesses may apply for grants dedicated to technology commercialization. Although universities and other research institutions may not apply

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for these grants directly, they may be subcontractors to either homegrown or external small businesses who are funded by these grants. Other options for research funding include the numerous federal and private agencies that back technology transfer activities and translational research. The opportunities for departmental partnerships with industry for research financing are also extensive. Finally, innovation can also help attract alumni and philanthropic funds to the department.

As noted, the success of an academic department of surgery lies not only in its high-quality care, education, and research activity, but also in how the department impacts its community. The commercialization of inventions is critical to the dissemination of knowledge, communicating the impact of surgical research on society. The community also profits through job creation, economic growth, retention of local talent, and the provision of entrepreneurial training and local startup funding.<sup>3</sup> From Michael E. DeBakey, a pioneer in cardiovascular surgery, to John H. Gibbon, Jr, the inventor of the revolutionary heart-lung machine, to Dr. Thomas J. Fogarty, inventor of the embolectomy catheter, surgeon innovators have been the primary drivers of progress in the last century. Surgical innovations from these visionaries and their like have tremendously enhanced the quality-of-life around the world.

Above all, in the words of management guru Peter Drucker,<sup>4</sup> “Innovation is change that creates a new dimension of performance.” Academic departments of surgery are in the ideal position to drive such transformative change in healthcare. They are best able to recognize their own inefficiencies and unmet needs and identify innovative ideas to amend these deficits. With a strong infrastructure and access to diverse patient populations, academic departments of surgery can test innovative ideas within their intended environment, thus easing the identification of issues with new technologies, influencing product development, and facilitating the implementation of these innovations. By spurring change themselves, they are able to weather distracting industrywide pressures and determine their own future. Finally, by focusing on areas that are meaningful to all surgeons, academic departments of surgery can align the departmental vision and activate the innovative spirit within.

#### *Recognizing and supporting innovative intellectual capital*

Academic departments of surgery are distinguished first and foremost by the quality of their faculty. Hence, the leverage of human intellectual capital is crucial to their success. However, because surgeon innovators have different mindsets than straightforward science researchers and may produce nontraditional outputs, a novel approach is required for the recognition and academic advancement of these faculty members.

Numerous studies have demonstrated support for the inclusion of innovative activities in academic promotions. As early as 1994, a national survey of 115 universities demonstrated support for faculty engagement in “use-oriented research,” specifically treating patentable inventions as “refereed articles.”<sup>5</sup> The desirability of such attribution has been confirmed by a number of more recent surveys of university faculty members.<sup>3</sup> One caveat of these surveys is that the majority did not focus on the medical school, per se, but rather the entire institution. We still await a focused study evaluating the attitudes of medical school deans and promotions committees about the proper valuation of commercialization and meaningful innovation in the promotions process.

To understand the current climate, we performed focused interviews of ten prominent academic physicians from across the United States. Informed consent was obtained from all interviewed subjects to participate in interviews for research purposes and anonymous use of their interview responses. We offered anonymity

to help extract the most candor. Based on their wide-ranging responses, it is clear that perspectives regarding the recognition of physician entrepreneurship are mixed. Of the academic physicians, six noted a negative institutional stance toward innovation, with innovative activity actually adversely affecting applications for professorship. One academic physician even remarked that innovation is viewed as a “dirty business,” because of the ensuing issues with conflict of interest. Two other academic physicians believed that the physicians sought out by industry are generally already successful by traditional means (ie, they already have published extensively in recognized journals) and therefore there is no benefit to evaluating industry relationships as additional criteria for career advancement. Only two academic physicians considered innovative activity to be highly valued in applications for professorship or tenure. Despite these attitudes, most of the interviewees acknowledged that academic medicine is currently undergoing much cultural change, with a new “broadened notion of success,” especially focused on innovation.

Based on the principle “you get what you incentivize,” we argue that medical schools need to expand promotions criteria to include the recognition of patents, commercialization, physician entrepreneurship, and physician relationships with industry. Sanberg et al<sup>3</sup> provide a comprehensive list of public and private universities that incorporate entrepreneurial activities into tenure and promotion documents and include the actual language used in these documents. They discovered that some institutions’ tenure and promotion documents simply state that patents could be included as scholarly activities; whereas other institutions explicitly list a variety of innovative activities that are recognized as scholarly activities.<sup>3</sup> The authors support the use of strong language in promotions documents that specifically includes patents, patents pending, invention disclosures, licensed products, other technology transfer or commercialization activities, other intellectual property, startup companies, SBIR and STTR awards, other business-related grants or contracts, collaborations with industry, and the guidance of students in entrepreneurial activities as scholarly activities.<sup>3</sup> Important to note, the promotions process must include an independent assessment of the merit, value, or impact of all activities. For example, simple invention disclosures should be given less weight than approved patents or successful technology transfer activities.

The total income from grants, contracts, royalties, and other activities may also be used to assess the value of the innovative activities. This evaluation will require faculty who are well versed in entrepreneurship, innovation, or industry relationships to act as independent assessors in the promotions process. The expected culture change will allow the recognition of surgeon innovators and accelerate academic surgical innovation.

#### *Building a culture of innovation*

If modern departments of surgery desire to stimulate entrepreneurship across the department, a culture of innovation must be nurtured. It is unlikely that it would flourish without support.

First and foremost, proper supervision must be in place so that surgeon innovators can be involved in the research and development of their own inventions. Within the same interviews discussed earlier in this report, the prominent academic physicians were surveyed about their beliefs regarding any adverse influences of entrepreneurship or industry relationships. Seven out of the ten academic physicians interviewed disputed the idea that entrepreneurial efforts or consulting relationships with industry create bias in research results, affect the publication of research, inhibit collaboration, or lead to patient harm. Undoubtedly these opinions reflect the belief that the majority of innovators are motivated by a

desire to help patients and advance medicine and that, in reality, only a few “bad seeds” have prompted the negative views of physician involvement in industry. However, these relatively few incidents drove the development of very constraining conflict-of-interest policies that led to the estrangement of innovative physicians from academia.

Academic departments of surgery have the opportunity to change these perceptions. Thoughtful modifications in conflict-of-interest policies will be crucial to this goal. Because the inventors are the “subject matter experts” for their inventions, they are optimally suited to guide the evolution and application of their ideas. With proper transparency and oversight, surgeon innovators should be allowed to influence the licensing decisions regarding their inventions or hold management positions in their own startups. Reasonable equity distributions to surgeon innovators should also be encouraged. With more control over their inventions and no incentive to leave to profit from their innovative spirit, surgeon innovators would be more likely to stay in academia, serving as role models for the next generations.

To accomplish this, it is essential that appropriate conflict management plans are enacted. Such management plans involve guidelines regarding the frequent review of all consulting commitments, restrictions on the use of institutional resources for innovative efforts, limits on the direct involvement of inventors in late stage research and clinical trials, and other related considerations. With this system of checks and balances, an arrangement that is mutually beneficial to academic departments of surgery and surgeon innovators can be put into place.

Once surgeon innovators are hired and retained, academic departments of surgery must boost the social or relational intellectual capital, which promotes partnerships, knowledge sharing, and patient-centered care. This has been found to play the strongest and most direct role in fostering innovative practices.<sup>6,7</sup> It is important for the department leadership to demonstrate that innovative activity is valued at the same level as traditional research.

New entrepreneurial sabbatical programs across the country have been established to encourage faculty to develop their research into products and services. For example, the University of Minnesota (Minneapolis) has an established 1-year Entrepreneurial Leave Program that facilitates translational research while allowing faculty to maintain their university benefits.<sup>8</sup> These programs help overcome conflicts of interest and other barriers to faculty entrepreneurship while increasing faculty expertise and engagement with industry.

Academic departments of surgery must also develop the framework for faculty members to communicate, disseminate their research, and share their expertise, all with the goal of enhancing the organization's innovative capabilities. In this regard, a monthly “innovation board” in which faculty, fellows, residents, students, nurses, and other staff members participate in a multidisciplinary innovation meeting would truly embody the innovative spirit.

To sustain a culture of innovation for generations to come, academic departments of surgery must also expand their focus on training to the development of future innovative intellectual capital. The University of Michigan Department of Surgery (Ann Arbor) has been actively engaged in teaching the entrepreneurship and innovation process to medical students, residents, and surgeons.<sup>9,10</sup> They have learned that it is essential that the organization overall see the value in such activities:<sup>9</sup> specifically, whether the return on investment is increased revenues; increased donor or industry contributions; increased grants or extramural funding; or contributions to the missions of education, research, or patient care; the rationale must be clearly articulated and frequently evaluated. This has the best opportunity of

maintaining critical buyin from other key stakeholders, including institutional leadership, investors, and experienced mentors. When done properly, programs like Michigan's can change departmental culture such that innovation and commercialization is a natural and expected academic behavior.

Notably, innovative activity will not be generated solely from the academic department. The value of potential collaborations between academic departments and departments of engineering and business, independent entrepreneurs or healthcare startup companies, design institutes, or industry is widely appreciated. In the belief that transdisciplinary research is essential to advance scientific discovery, the American Academy of Arts and Sciences commissioned their Advancing Research in Science and Engineering 2 (ARISE 2) report. It delineates a new model for transdisciplinary research that promotes integration across scientific disciplines and cooperation among academia, government, and the private sector throughout the discovery and development process.<sup>11</sup> Model programs include the University of Michigan Fast Forward Medical Innovation program, which brings together people from the university and from industry to fund biomedical researchers and accelerate the innovation and commercialization processes.<sup>12</sup> The Mayo Clinic Center for Innovation (Rochester, MN) acts in a similar capacity, collaborating with numerous universities across the country and multiple industry partners to employ “design thinking” principles to address patients' needs.<sup>13</sup> The University of California system sponsors the California Institutes for Science and Innovation, in which multiple programs across the state of California drive innovation. One such institute, QB3 in the Bay Area, empowers University of California life science researchers and entrepreneurs through five incubators, two seed-stage venture capital firms, and a medical device initiative.<sup>14</sup>

In 2015, our own institution, Cedars-Sinai Medical Center (Los Angeles, CA), partnered with Techstars (Boulder, CO), a US-based venture firm that hosts mentorship-driven business development programs. Every 6 months, a competitive call for interested startup companies attracts about 500 applications from all over the world. We select 10–12 companies and host them for 90 days on our campus, providing \$40,000 per month of support for each. During this intense period, Cedars-Sinai clinical and academic personnel mentor the companies, helping to further develop the innovative technologies and integrate them into established care delivery systems.<sup>15</sup> All companies in the first two cohorts signed research or commercial contracts with Cedars-Sinai or other academic medical centers. In collaboration with Cedars-Sinai physicians, multiple startups performed and published studies of their products. Most important, the engagement of more than 250 physicians, residents, nurses, executives, and other staff in more than 1,000 hours of meetings with the startups demonstrates the innovative spirit stimulated by this program. Numerous other programs, including Stanford Byers Center for Biodesign (Stanford, CA), Cleveland Clinic Innovations (Cleveland, OH), and the Johns Hopkins Sibley Innovation Hub (Washington, DC), have similar highly successful multidisciplinary medical innovation programs.<sup>16</sup> The expansion of these programs is just one more indicator of the importance of such development to drive greater efficacy and efficiency in healthcare.

In conclusion, the mission of academic departments of surgery is to enhance the practice of surgery and simultaneously educate and serve the needs of their faculty, residents/fellows, medical students, patients, and community. To accomplish this charge, academic surgeons are increasing their involvement in innovation and entrepreneurship. All current data suggest that innovative activity promotes discovery and advancement without detriment to traditional scholarship and academic achievement. Entrepreneurship

also generates funds that can be reinvested into departmental research, growth, and alignment. In sum, leveraging innovative intellectual capital and building a culture of innovation has the potential to allow modern academic departments of surgery to better fulfill their multiple missions.

To be sure, establishing a culture of innovation compatible with academic values will require significant work and expertise to navigate. A philosophy shift across the board is necessary. The hiring and promotions processes must endorse patents, commercialization, physician entrepreneurship, and physician-industry relationships as scholarly activities. Conflict-of-interest policies must incorporate surgeon innovators into the research and development process, with proper oversight in place. Innovative intellectual capital must be nurtured through training and multidisciplinary interactions. Finally, stable innovative collaborations must be forged across healthcare systems, academia, government, and industry.

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