



# Financial and infrastructural resources for new technology implementation

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**Abstract:** Promotion of surgical technology relies on the availability of financial and infrastructural resources, particularly as traditional sources of funding, such as National Institutes of Health (NIH) grants, have waned in recent decades. Resources for financial support depend on the stage of development and the context in which the idea is being studied. For technologies being evaluated by clinical trials, insurance reimbursement may assist with support as the Affordable Care Act (ACA) has mandated that routine costs of enrollment in clinical trials be covered by health insurance. However, there are exceptions to this, as not all insurance providers are required to adhere to the ACA. Additional sources of funding when a clinical trial is not feasible or practical include stimulation grants from institutions, surgical societies, and the NIH. Industry partnership also remains a critical resource in the development of new technology; in addition to industry grants, corporate partnership for development, implementation, and eventual marketing of surgical technologies may assist with innovation. Although a risk of conflict of interest exists in this setting, a properly structured collaboration may allow for swifter development of new technology while maintaining strict ethical standards. Finally, organizations may assist with promoting innovation by critical infrastructure. This includes establishing a culture of collaboration, facilitating access to mentorship, and providing material support for such research. In conclusion, existing barriers to development of new technology may be circumnavigated by utilization of available financial and organizational resources.

**Keywords:** Surgical innovation; surgical grant; Affordable Care Act (ACA); surgical technology

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## Introduction

Continuous innovation is critical to the field of surgery, both for the advancement of surgically treated diseases as well as the professional development of surgeons themselves (1). However, numerous barriers exist to such innovation, particularly financial and structural barriers (2). In the United States, it has been well established that National Institutes of Health (NIH) funding to surgical departments has been on the decline, with a 27% decline in total NIH funding from 2007 to 2014 (3). Additionally,

there was a 39% decrease in R01 awards (Research Project Awards) between 2003 and 2013, which are the original NIH awards for health research and have historically been used to encourage investigation by individual surgeon-scientists (4). In 2019, surgeons received just 2.2% of NIH grant awards (5). Young surgical faculty have also faced a lower success rate for K award (Mentored Research Scientist Career Development Award) proposals relative to their peers in other clinical departments (6). A number of reasons for these changes have been proposed, including a decreased belief among surgeons that participating in basic

**Table 1** Common sources of funding for research, innovation, and trials

Funding category	Sources of funding
Insurance	Medicare
	Medicaid in specific states
	Private insurance
Grants	NIH
	Clinical Trials Cooperative Groups
	Other governmental agencies
	VA
	DOD
	PCORI
	NCCN
Foundations	–
Institution	Pilot
	Technology development and transfer grants
Industry	IST
	Industrial trials
Philanthropy	–

NIH, National Institutes of Health; VA, Veteran's Administration; DOD, Department of Defense; PCORI, Patient-Centered Outcomes Research Institute; NCCN, National Comprehensive Cancer Network; IST, Investigator Sponsored Trials.

research is realistic as well as increasing administrative and clinical duties (1). Of a survey conducted among academic surgeons in 2000, the majority of respondents felt that they lacked the funding and institutional support to participate in basic research (1). This article is aimed at reviewing the medical and business literature for resources available within the United States for implementation of new surgical technology, both in the context of conducting clinical trials and in the adaptation of promising technologies that have already been approved for use. A comprehensive summary of these resources is provided in *Table 1*.

### Insurance reimbursement

Reimbursement for care under a clinical trial may be one mechanism for funding the use of experimental surgical technology. Starting in 2014, the Affordable Care Act (ACA) mandated reimbursement for the routine costs

associated with enrollment in all phases of clinical trials. Public Health Service (PHS) Act Section 2709(a) states that group health plans and health insurance issuers offering insurance to a qualified individual “(I) may not deny the qualified individual participation in an approved clinical trial with respect to the treatment of cancer or another life-threatening disease or condition; (II) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and (III) may not discriminate against the individual on the basis of the individual’s participation in the trial” (7). Of note, this wording specifically stipulates that the treatment must be for cancer or another life-threatening disease. Nevertheless, all insurance providers that must adhere to the ACA are required to reimburse such costs, including standard Medicare.

However, there are some insurance providers that are not required to adhere to this mandate. Medicaid is regulated by the states rather than the federal government, so adoption of clinical trial enrollment reimbursement is determined on a state-by-state basis. Currently, only ten states and the District of Columbia have provisions for coverage in such cases. These include Alaska, California, Indiana, Iowa, Maryland, Montana, North Carolina, Texas, Vermont, and West Virginia (8). Additional exceptions to this rule include so-called grandfathered private insurance plans, which are insurance plans that were in existence on March 23, 2010 and have not made any significant changes in coverage since that time. Although there are ACA regulations to which grandfathered plans must comply, the mandate regarding reimbursement for clinical trial costs is not among them (9). This may affect a significant proportion of patients with private health insurance. The 2017 Employer Health Benefits Survey by the Kaiser Foundation found that 23% of firms offering benefits offered a grandfathered health plan, and 17% of employees were enrolled in one such plan (10). Additionally, health insurance plans regulated by the Employee Retirement Income Security Act of 1974 may qualify for the same exemptions given to grandfathered plans (11). Finally, Medicare Advantage plans have been noted on a prior study of insurance denials for clinical trial reimbursement to have a particularly high rate of denial, accounting for 34.2% of denials reported by respondents (11). These stipulations on insurance coverage represent a barrier to reimbursement that would need to be taken into account.

Thus, although barriers remain for timely reimbursement

of the routine costs associated with clinical trial enrollment, this may be an option for many patients with Medicare, private insurance coverage, or other any insurance that is required to adhere to the ACA mandate, including Medicaid in select states.

### Grant funding

Although randomized, controlled trials are considered the gold-standard for evaluating efficacy of new treatment options, such a design may not be as effective for evaluating new surgical devices or technologies. It has been suggested that large prospective cohort series or registries that document outcomes and adverse events may be more practical (12). However, this trial design may preclude mandated insurance coverage for the costs of enrollment, and additional sources of funding would be required.

### NIH funding

The traditional source of financial support for such research is grant funding. NIH grant funding awarded to surgeons has been in decline in recent years (3), which is thought to be due to a combination of financial strain, competing clinical duties, and lack of protected time for surgeon-scientists (13). However, grants from a variety of sources still exist for surgical innovation, including NIH grants. The well-known Research Project Grants (R01) have been the traditional vehicle for funding such research, with a total budget of \$20,757,000,000 for 11,035 funded grant applications from all medical specialties in 2018 (14). In addition, other grants including the R43 Phase I Small Business Innovation Research (SBIR) and R41 and R42 Small Business Technology Transfer (STTR) grants are also available. In a study of NIH grant funding for development of smartphone intervention apps between 2014 and 2018, SBIR and STTR grants accounted for 40.8% of those used to fund such investigation, with an average grant of \$345,058 in 2018 (15). Training grants and career development awards (K awards) are also available for trainees and young surgical faculty, with an average grant size of \$187,967 in 2020 (16).

Consideration for NIH grants require an application from an individual researcher and his or her collaborators, which is available through the NIH website (17). Grant applications then undergo dual peer review by a Scientific Review Group (also referred to as a study section) composed of non-federal scientists with appropriate

expertise and then an Institute and Center National Advisory Council with members composed of scientific and public representatives (18). Although NIH grants may not be the right fit for all technology development projects, investigation into grant options remains worthwhile in many cases.

### *Clinical trials cooperative groups funding*

Many clinical trials run by cooperative groups are funded and supported by the National Cancer Institute (NCI). These trials involve large numbers of patients, take part in many locations, and allow for large trials to be accomplished in a short time (19). The ideas and leadership for trials can come from any member of a cooperative group. The current U.S. cooperative groups are the Alliance for Clinical Trials in Oncology, ECOG-ACRIN Cancer Research Group, NRG Oncology, Southwest Oncology Group (SWOG), and Children's Oncology Group (COG). The NCI clinical trials cooperative groups are part of the National Clinical Trials Network (NCTN). Whereas phase 1 and 2 trials may be conducted in single centers, most innovation programs that progress to phase three trials have to be tested in a multicenter fashion (19). For cancer or radiologic innovations, the cooperative groups are a great resource for funding trials of late-stage development of innovations.

### *Other peer reviewed funding*

Other government grants are also available for research and innovation. The most prominent sources are Veteran's Administration (VA), Department of Defense (DOD) (20), Patient-Centered Outcomes Research Institute (PCORI) (21), and National Comprehensive Cancer Network (NCCN) (22). Foundations are another source of funding for innovations. Some of the most prominent United States foundations include American Kidney Fund, Amicares Foundation, American Cancer Society, American Heart Association, Sickle Cell Disease Association of America, Muscular Dystrophy Association, American Lung Association, American Diabetes Association, and National Brain Tumor Society (23).

### *Institutional small pilot grants, technology transfer grants*

Additional grant funding for innovation may also be available from academic institutions and/or departments (24). One study from the Perioperative

Services group at the Hospital for Sick Children found that offering small grants of approximately \$10,000 to stimulate innovation resulted in many applications with novel ideas, and the authors concluded that small grants were an excellent option for stimulating innovation within institutional departments (24). Although only select departments may have the funds available to provide such grants, identification of opportunities from a researcher's own department or institution may provide a more accessible source of financial support to promote development of a novel idea. Similarly, some national and international surgical societies also have grant funding available to stimulate innovation, including seed grants and supplemental funding for investigators who have already received a K award (25).

### ***Barriers to utilization of grant funding***

One key barrier to the utilization of grant funding is the competitive nature of research grants due to the limited overall funding available. The NIH Data Book Report published in 2021 reports that success rates for R01 applications from 2016–2020 have ranged from 19–21% (14). Success rates for phase II SBIR grants were slightly higher over the same years, ranging from 25–42% (26). However, the comparative success of surgical applications versus those of other medical specialties are not available in those reports, and it is unknown how grant applications for development of surgical technologies fare specifically in this funding environment. Additional barriers that have been identified include the financial strain of protected time for grant-funded research as well as the significant resources necessary to produce preliminary research that may allow for successful grant applications (13).

### **Industrial grants**

Finally, industry grants may be another possible source of funding. Many investigators are reluctant to partner with industry due to the risk of bias, and this risk should not be understated. One retrospective review of studies reporting on efficacy of the da Vinci robot found that studies that had received more than \$9,557.31 were more likely to report positive robotic surgery results (27), and a 2016 meta-analysis of 165 surgical randomized controlled trials found that those with industry funding were more likely to report a positive outcome without statistical justification (28). Given this risk, there has been a call for surgical societies

to establish strict policies regarding conflict of interest, particularly for researchers seeking to present their data (29). Additionally, strict journal requirements are in place which require the disclosure of industry relationships prior to publication (30). However, it has been proposed that properly structured partnerships between academic institutions/teams and industry may accelerate and enhance development of new technologies (31). Thus, industry grants remain a resource that should be considered when seeking financial support for new technological innovation.

### **Industry partnership**

Partnership from industry remains a critical resource in the development of new surgical technologies, particularly as grant funding has waned (32,33). Establishing such a partnership for new product innovation primarily occurs in one of two pathways; either a surgeon-initiated corporate partnership (34) or an industry-initiated approach of an academic institution or researcher (31). In the former, the idea and intellectual property (patent) originate with the surgeon, who typically licenses the rights to a manufacturer. The corporate partner then takes over responsibility for development, regulatory approval, sales, marketing, and all other necessary business functions, and the innovator is compensated using a royalty system (34). Similarly, another option for an inventor who wishes to commercialize their product without licensing their rights is the entrepreneurial model, in which the surgeon forms a legal partnership or corporation and is then directly involved in business management (34). This can be extremely time consuming and may not allow the surgeon to continue in practice. Starting a company also requires business and fundraising skills that are not usually not in the armamentarium of a surgeon. Thus, starting a company is a much less common pathway for inventors of surgical technology (34).

More likely, a medical technology company may approach a researcher or academic institution with a request to partner on a project in order to cocreate a new technology based on a perceived need (31), or to test a product already vetted in human trials. There are two main types of trials performed in this context: Investigator Sponsored Trials (IST) and industrial trials (35). IST are unsolicited clinical trials proposed and originated by an investigator at a hospital, medical center, or medical school. These are unique, novel, and scientifically valid research evaluating unmet medical needs and are designed by academic investigators. They can be partly or completely funded

by industry but are seen as academic investigations (35). One example of this design is the MERIT-UC trial, which investigated the efficacy of Methotrexate in induction and maintenance of remission in ulcerative colitis (35). On the other hand, true industrial trials are those originating from industry and intended on garnering approval for a device or drug for human use, or for a new indication for a device or drug already approved for human use (33,35). The budgets for the two types of trials are very different owing to the rigor for data capture necessary in industrial trials because of intent for Food and Drug Administration (FDA) regulatory submission (36,37). Even though the budgets for IST are smaller, they are given much more academic credit because they originate and are designed to address academic questions, which are typically closely aligned with the priorities of providers. Regardless of which trial design is used, such investigation is an opportunity for collaboration on the part of the academic investigators as well as their industry partners that can result in significant patient benefit.

A number of barriers to partnership with industry have been identified. One of the most prominent is fear on the part of the surgeon of either loss of academic reputation, business failure/failure of the partnership, or deviating from typical practice to engage in a system that is foreign to physicians (34). However, prior to approaching industry with a new innovation, it is helpful to screen the project for funding; this can be done with the simple, powerful R-W-W screen (real, win, worth it) that has been used by the company 3M to evaluate thousands of business projects (38). Furthermore, the ethical considerations of development and adoption should also be considered carefully, as the first responsibility of the surgeon is to do no harm (39). Indeed, a cross-sectional survey of the American public found that while industry involvement in the development of new medical technologies was felt to be a necessity, the public trusted the physician to take the lead in maintaining ethical principles and had little trust in government or industry to regulate conflict of interest (32). Thus, the natural inclination of surgeons to generate creative solutions to clinical problems while upholding ethical standards may complement the need of corporations to identify opportunities for innovation (40), and such relationships may be beneficial to all parties including patients (34).

### **Institutional resources/investment**

Adoption of emerging surgical technologies that are already

supported by evidence may present an additional set of challenges. Hospital budget management has become more and more tenuous in recent years, and in such times any new innovation must not only be beneficial to surgeons and patients but also to hospital financial stakeholders (41). Consequently, the perspective of chief financial officers, procurement specialists, business managers for perioperative services, and members of value analysis committees has become increasingly critical in the successful implementation of surgical innovation. According to Egeland *et al.* in 2017, adoption of a new technology or device must produce “short term” savings by replacing an expensive product with a cheaper option (that is, within a quarter budget or at longest a fiscal year). If it cannot, these stakeholders would need to confirm that the innovation either boosts efficiency or prevents high cost events (41). Value analysis committees would also look favorably on new technologies if there is clear improvement in patient safety. If a new technology costs more, there would need to be clear documentation through business plans that it would increase revenue either through surgical volume or reimbursement.

One example of how the financial perspective has influenced the adoption of new surgical technology is the da Vinci robotic surgery system. Although many surgeons have come to prefer using robotic technology due to the enhanced ergonomics, three dimensional visualization, and shorter learning curve when compared with laparoscopy (42), the additional costs associated with adoption of a robotic program have been found to be nearly prohibitive in some settings (43). However, multiple studies have investigated methods by which such technology may become cost effective. One cost analysis of introducing robotic-assisted surgery in the Bambino Gesù Children’s Hospital found that the financial implications became less of a burden with a higher number of robotic cases, with a break-even point at 349 interventions or more per year (44). Another study comparing the cost-effectiveness of robotic colectomy to laparoscopic and open colectomy found on one-way sensitivity analysis that achieving a shorter robotic case time (172 minutes from a baseline mean of 210 minutes per case) would allow robotic cases to overcome laparoscopy in cost-effectiveness (45). Finally, a cohort study of patients who had undergone five urologic or gynecologic procedures found that those who had their operation in a hospital in a competitive regional market were more likely to have undergone a robotic-assisted procedure, raising the question of how marketability may influence the financial



ramifications of adopting a robotics program (46). Thus, the financial considerations in the adoption of new surgical technology may be complex. However, incorporating the perspective of hospital finance professionals as well as health economists who specialize in cost-effectiveness analysis when advocating for such innovation can contribute to more successful implementation.

### **Institutional infrastructural resources**

It has been well established in the business literature that the infrastructure of an organization can be optimized to encourage innovation, and this requires a purposeful and strategic effort on the part of the organization. The researchers DeGraff and Quinn of the University of Michigan Ross School of Business have proposed an “innovation genome”, in which aspects of four competing values (collaboration, creation, control, and competition) are combined to establish a culture that promotes innovation according to the goals of the organization and the level of risk it is willing to accept (39). The organization can then work backwards through three levels, first establishing a purpose, then practices, and finally people, particularly leadership behaviors (39). Purposeful development of leadership behaviors that encourage and prioritize innovation then facilitates the development of specific infrastructural aspects.

Multiple organizational characteristics have been identified as helpful, even necessary, for promoting surgical research. One national, qualitative survey of academic surgeons, specifically K Awardees and surgical department chairs, identified aspects that were considered critical to the success of young surgical faculty who have received K Awards. These included material support from the institution in the form of protected time for research, financial support for purchasing of needed equipment and hiring necessary research personnel, and physical space (13). As such, it was postulated that large surgical departments may be better poised to support such activity, as there may be more funds readily available and additional partners who can share the burden of clinical coverage. However, K Awardees require significant investment on the part of the institution that is not necessary for all surgical research, and the end goal of such investment in this context was to secure external funding (13). Thus, although this study provides a framework of ways in which surgical research can be materially supported, the exact manner in which this should be implemented will vary by institution and researcher.

An additional institutional resource that has been identified as critical to the success of surgical research is mentorship, and this may be even more important than material support (47). The study of K Awardees identified that these young surgeon-scientists typically had networks of mentors, brought together by loosely aligned interests (13). This need not be a formal system. However, surgical innovators would benefit from additional guidance, particularly with regards to federal regulations (39). For example, a survey of 665 surgeons of the ethical considerations of surgical research and innovation in the operating room revealed that most surgeons are not familiar with governmental bodies regulating such research outside of the FDA and local Institutional Review Boards (IRBs) (48). Thus, mentorship may assist not only with idea development but also with navigation of regulatory requirements. In addition, collaboration with other surgical specialties and/or other innovation-driven researchers can allow researchers to adapt existing knowledge to one's own specialty or invention. This may be achieved by developing an open-source community within an organization, in which new ideas can be refined or improved, and strengthening human connections by encouraging frequent and open communication (39). In summary, establishing a culture of multidisciplinary collaboration with facilitated access to mentorship may be one of the most critical aspects of promoting surgical innovation within an organization.

Many of the institutions with a commitment to innovation also have a robust infrastructure for device and drug production and for rigorous clinical trials (*Table 2*). One example of such infrastructure is machine shops for prototyping and production facilities for Good Medical Practice (GMP) preproduction of drugs. Having an office for filing Investigational New Drugs (INDs), Investigational Device Exemptions (IDEs), and other FDA related documents as well as having a project manager/trials specialist infrastructure all greatly facilitate translation of novel discoveries to human use. Most institutions that have such a robust infrastructure for innovation have successful intellectual property protection/technology transfer offices. Examples of such infrastructure include the Office of Technology Management at the University of California San Francisco (49) and the Office of Technology Transfer at the University of Michigan (50). Within the infrastructure of such institutions are usually also pilot and trials grants programs that fund use of the core facilities and early trials that increase the value of technologies before formal licensing.

**Table 2** Institutional infrastructure for successful programs in innovation

Infrastructure type	Examples
Physical	Core labs
	Genomic and molecular analysis facilities
	Computational core
	Correlative analytics core
	Production facilities
	Prototyping machine shop
	Device manufacturing
Clinical trials	GMP drug production facility
	IND/IDE office
	Trials office
Personnel	Institutional DSMB
	Mentors
	Trials writers
Financial	Project managers
	Pilot grants
	Technology and development and transfer grants
	Trials direct costs
	Salary support for investigators

GMP, Good Medical Practice; IND, Investigational New Drugs; IDE, Investigational Device Exemption; DSMB, Data and Safety Monitoring Board.

## Conclusions

Although financial and infrastructural barriers exist to surgical innovation, these can be circumnavigated by utilization of funding from a variety of sources including reimbursement, grants, and partnership with industry. Further dedicated study of funding mechanisms will be necessary to promote successful utilization as few studies currently exist. However, purposeful establishment by organizations of a collaborative environment with access to material and production support will assist in encouraging surgical innovation. This review provides a comprehensive summary of the financial resources available for surgical innovation and development of new technologies in order to inform surgeons and surgical trainees of available options.

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